

MODULE 1

Tradition, Profession, and Values in Public Health

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Issue Essay

This module asks the difficult questions—what is public health? and what is public health ethics? The module also recognizes that even though public health and biomedical ethics overlap, they have distinct aspects. The module examines the unique population-based perspective of public health and how it can be distinguished from patient-centered biomedical ethics. Additionally, scholars and practitioners often use ethical analyses with other forms of reasoning, particularly law and human rights. The module, therefore, explores the relationship among public health ethics, public health law (notably the exercise of the state's police power), and human rights. The various meanings of each form of reasoning are discussed, as well as the similarities and differences among them.

What Is Public Health?

In thinking about the application of ethical thought to problems in public health, it is important first to understand what we mean by public health. How is the field defined and what is its content—mission, functions, and services? Who engages in the practice of public health—government, the private sector, charities, community-based organizations? What are the principal methods or techniques of public health practitioners? In truth, finding answers to these fundamental questions is not easy because the field of public health is highly eclectic and conflicted.

Definitions of public health vary widely, ranging from the utopian conception of the World Health Organization of an ideal state of physical and mental health to a more concrete listing of public health practices. The Institute of Medicine, in its seminal report on the *Future of Public Health* in 1988, proposed one of the most influential contemporary definitions: “Public health is what we, as a society, do collectively to assure the conditions for people to be healthy.” The IOM’s definition emphasizes the cooperative and mutually shared obligation (“we, as a society”). It reinforces the fact that collective entities such as governments and communities take responsibility for health. The goal of public health is the health of populations—rather than the health of individuals—and this goal is reached by a generally high level of health throughout society, rather than the best possible health for a few. The field of public health is concerned with health promotion and disease prevention throughout society. Consequently, public health is less interested in clinical interactions between health care professionals and patients, and more interested in devising broad strategies to prevent, or ameliorate, injury and disease.

The State of Debate. Scholars and practitioners are conflicted about the “reach” or domain of public health. Some prefer a narrow focus on the proximal risk factors for injury and disease. The role of public health agencies, according to this perspective, is to identify risks or harms and intervene to prevent or ameliorate them. Others prefer a broad focus on the socio-cultural-economic foundations of health. Those

favoring this position see public health as interested in a more equitable distribution of social and economic resources because social status, race, and wealth are important influences on the health of populations.

What are Public Health Ethics?

If public health is what society does collectively to assure the conditions for healthy people, then what are public health ethics? Public health ethics may be defined as the principles and values that help guide actions designed to promote health and prevent injury and disease in the population. In thinking about this problem it will be helpful to distinguish public health ethics from biomedical ethics.

The field of biomedical ethics has richly informed practice and policy in medicine and health care. Biomedical ethics has often stressed the importance of individual interests of patients, notably the right to autonomy, privacy, and liberty. Ethicists, however, at least until recently, have given insufficient attention to the equally strong values of partnership, citizenship, and community. As members of a society in which we all share a common bond, we also have an obligation to protect and defend the community against threats to health, safety, and security. There remains much work to do in public health ethics. Is the population-based perspective of public health different from the patient-centered perspective of medicine? Is a public health ethic merely the aggregation of individual interests in a population? What is the moral standing that should be attached to the common good? Under what circumstances should individual interests yield to achieve a collective benefit for the population?

Some scholars have thought about public health ethics in three overlapping ways: professional ethics (the values that help public health professionals to act in virtuous ways); applied ethics (the values that help to illuminate hard problems in public health policy and practice); and advocacy ethics (the overarching value of population health and social justice).

Professional ethics are concerned with the ethical dimensions of professionalism and the moral trust that society bestows on public health professionals to act for the common welfare. This form of ethical discourse stresses the distinct history and traditions of the profession, seeking to create a culture of professionalism among public health students and practitioners. It instills in professionals a sense of public duty and trust. Professional ethics are role oriented, helping practitioners to act in virtuous ways as they undertake their functions. Currently, the Public Health Leadership Society is developing a Code of Public Health Ethics (available at www.publichealthlaw.net/reader).

Applied public health ethics are concerned not so much with the character of professionals as with the ethical dimensions of the public health enterprise itself. Here, scholars study the philosophical knowledge and analytic reasoning necessary for careful thinking and decision making in creating and implementing public health policy. This kind of applied ethics is situation or case-oriented, seeking to understand morally appropriate decisions in concrete cases. Scholars can helpfully apply general ethical theory and detached analytical reasoning to the societal debates common in public health.

In addition to “professional” and “applied” ethics, it is possible to think of an “advocacy” ethic informed by the single overriding value of a healthy community. Under this rationale, public health authorities think they know what is ethically appropriate, and their function is to advocate for that social goal. This populist ethic serves the interests of populations, particularly the powerless and oppressed, and its methods are principally pragmatic and political. Public health professionals strive to convince the public and its

representative political bodies that healthy populations, reduced inequalities, and social justice are the preferred societal responses.

The State of Debate. Scholars and practitioners disagree on each of the three forms of public health ethics. First, many believe that a code of ethics, or at least a well-articulated values statement, could increase the status of the field and help clarify the distinctive ethical dilemmas faced by public health professionals. Others, however, point to the fact that no single public health profession exists, but rather a variety of different disciplines—e.g., epidemiologists, nurses, sanitary engineers, and public health educators. It would be difficult to find a single set of values that is relevant to each of these distinct groups. Second, many believe that the value of population health and safety should be salient. However, others criticize the public health model because it assumes that the appropriate mode of evaluating options is some form of cost-benefit calculation that appears to permit, or even require, that the most fundamental interests of individuals be sacrificed in order to produce the best overall outcome. Applied public health ethics draws from the traditions of utilitarianism, which is not always favored in modern philosophical scholarship. Third, many believe that the central role of public health is to advocate for community health and social justice. Public health advocates are supported by a body of literature demonstrating a relationship between socio-economic status and healthy populations. However, others believe that it is not self-evident that health and justice should always be the prevailing value. They also point to the fact that the redistributive agenda of public health is best reserved to the political branches of government.

What is Public Health Law?

Public health law differs from ethics in that it is concerned with a body of rules of action prescribed by controlling authority and having binding legal force. Law is found in constitutions, which empower governments to act and set limits on their power; statutes, which are enacted by legislative bodies and control the actions of individuals and businesses; regulations, which have similar effects as statutes but are usually promulgated by the executive branch; and court cases, which interpret the constitution, statutes and regulations, often setting binding precedent.

Law is a primary means with which government creates the conditions for people to lead healthier and safer lives. Law creates a mission for public health authorities, assigns their functions, and specifies the manner in which they may exercise their authority. Law is a tool in public health work which is used to influence norms for healthy behavior, identify and respond to health threats, and set and enforce health and safety standards. The most important social debates about public health take place in legal fora—legislatures, courts, and administrative agencies—and in the law's language of rights, duties, and justice.

The police power is the most famous expression of the natural authority of sovereign governments to regulate private interests for the public good. The police power is the inherent authority of a state to protect, preserve and promote the health, safety, morals, and general welfare of the people. To achieve these communal benefits, the state retains the power to restrict, within constitutional limits, private interests—personal interests in autonomy, privacy, association, and liberty as well as economic interests in freedom to contract and use property.

Law can be an effective tool to achieve the goal of improved health for the population. Statutes, regulations, and litigation, like other public health prevention strategies, intervene at a variety of levels, each designed to secure safer and healthier populations. First, government interventions are aimed at *individual* behavior

through education (e.g., health communication campaigns), incentives (e.g., taxing and spending powers), or deterrence (e.g., civil and criminal penalties for risky behaviors). Second, law regulates the *agents of behavioral change* by requiring safer product design (e.g., safety standards and indirect regulation through the tort system). Finally, law alters the informational (e.g., advertising restraints), physical (e.g., city planning and housing codes), or business (e.g., inspections and licenses) *environment*.

The State of Debate. Not everyone believes that law is an appropriate way to protect and promote the community's health, and when law is used in any of its manifestations it is bound to create controversy. Coercive interventions aimed at changing individual behavior are perhaps most contentious, such as infectious disease powers. Many people believe that government should rarely exercise coercive powers either because they are ineffective (e.g., it will "drive the epidemic underground") or overly intrusive (e.g., it will undermine autonomy, privacy, or liberty). Regulation of products through the tort system is also controversial. Here, people argue that tort law often offers the wrong kind of incentives (e.g., deterring innovation for vaccines or pharmaceuticals) and is inefficient (e.g., devoting too many resources to lawyers). Finally, regulation of the informational or economic environment is controversial. Think about the disputes that arise from regulation of advertising of cigarettes (public health versus free speech) or the regulation of businesses through licenses and inspections (public health versus property rights).

What is the Role of Human Rights in Public Health?

The language of human rights is used in different, but overlapping, ways. Some use human rights language to mean a set of entitlements under international law, while others use human rights for its aspirational, or rhetorical, qualities. Depending on the way in which human rights is used, the field can have features that are quite similar to law or ethics.

Legal scholars use human rights to refer to a body of international law that originated in response to the egregious affronts to peace and human dignity committed during World War II. The main source of human rights law within the United Nations system is the International Bill of Human Rights comprising the United Nations Charter, the Universal Declaration of Human Rights, and two International Covenants of Human Rights. Human rights are also protected under regional systems, including those in American, European, and African countries.

Human rights are often divided between those that protect civil and political rights on the one hand and economic, social, and cultural rights on the other. Civil and political entitlements include the right to life, liberty, and security of person; the prohibition of slavery, torture, and cruel, inhuman, or degrading treatment; freedom from arbitrary interference with privacy, family, or home; and freedom of conscience, religion, expression, and association. Economic, social and cultural rights include the right to social security, education, and work, as well as the right to share in scientific advancement and its benefits. Notably, human rights instruments recognize the right of everyone to the highest attainable standard of physical and mental health, "including the right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing and medical care and necessary social services." (Universal Declaration of Human Rights, Art. 25).

The language of human rights is often used for its aspirational, or rhetorical, qualities. When "rights" language is invoked, it is intended to convey the fundamental importance of the claim. It expresses the idea that government should adhere to certain standards, or provide certain services, because it is right and just

to do so. Human rights as a symbol commands reverence and respect. Used in this aspirational sense, human rights need not be supported by text, precedent, or reasoning; they are self-evident and government's responsibility simply is to conform.

The State of Debate. Although human rights are supported by a body of international law and express an inspiring idea about personal dignity, they are often criticized for imprecision and lack of enforceability. Civil and political rights are perhaps the most precisely defined and carefully studied, but international agencies often fail to rigorously defend these rights in the real world. Economic, social and cultural rights are thought to be vague and unenforceable. For example, the conceptualization of health as a human right, and not simply a moral claim, suggests that states possess binding obligations to respect, defend, and promote that entitlement. Considerable disagreement, however, exists as to whether "health" is a meaningful, identifiable, operational, and enforceable right, or whether it is merely aspirational or rhetorical. To achieve the goal of greater clarity and enforceability, the United Nations Committee on Economic, Social, and Cultural Rights issued *General Comment No. 14: The Right to the Highest Attainable Standard of Health* (2000). This General Comment seeks to define the right to health and suggest ways in which it can be enforced.

Tradeoffs Between the Collective Good and Individual Rights

Public health law and ethics often require careful balancing between individual interests in personal (e.g., autonomy, privacy, and liberty) and economic (e.g., contracts and property) freedoms on the one hand and collective interests in health safety and security on the other. Certainly, freedom and security can be mutually reinforcing. Affording individuals their rights can result in greater overall wellbeing by empowering people to safeguard their own health and safety. For example, if people do not fear loss of privacy or liberty, they are more likely to seek medical and public health services. Coercive powers can literally "drive epidemics underground."

Sometimes policy makers must make hard tradeoffs between individual and collective interests and, in these circumstances, they need to be guided by ethical values and attentive to legal procedures and norms. Public health laws and our courts have traditionally balanced the common good with individual civil liberties. As Justice John Marshall Harlan wrote in the seminal United States Supreme Court case of *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), "the whole people covenants with each citizen, and each citizen with the whole people, that all shall be governed by certain laws for the 'common good.'" *Jacobson* was a case that concerned compulsory vaccination, but the difficult tradeoffs between public and private interests can extend to many areas of public health concern ranging from infectious disease control powers (e.g., testing and screening, partner notification, and quarantine) to control of businesses (e.g., inspections and nuisance abatements) and the professions (e.g., licensing).

How should society determine whether to intervene to protect the public's health and safety when doing so will diminish a personal or economic interest? There is no sure way to know when interventions are necessary and appropriate, but here are some of the factors that need to be taken into consideration:

Step One: Demonstrate Risk. Risk is a complex idea that involves several dimensions. First, what is the nature of the risk? Risks arise from numerous sources including physical, chemical, organic, environmental, and behavioral. Second, what is the duration of the risk? Risks may be imminent, distant, acute or chronic. Third, what is the probability that the risk will actually occur? Risks may be either highly likely or remote.

Finally, what is the severity of harm should the risk materialize? Harms can be catastrophic or relatively trivial if they do occur. They may affect individuals or populations, current or future generations, or people or the things that people value (e.g., plants, animals, or the environment).

Step Two: Demonstrate the Intervention's Effectiveness. The intervention should be reasonable likely to reduce the risk. Public health is primarily about prevention so one important measure is whether the intervention is reasonably like to work. This is a “means-ends” inquiry, which seeks to understand if the public health intervention will lead to effective risk reduction.

Step Three: Assess the Economic Cost. The intervention should not only be capable of reducing the risk, but it should do so at a reasonable cost. Policy makers, therefore, should discover the costs to the regulatory agency and the subject of the regulation. Wherever possible, policy makers should prefer strategies that are least expensive and most effective. The reason is that government only has limited resources. If it spends money wastefully on an intervention, it will not have those resources available for another, potentially more effective, intervention. Thus, cost-ineffective measures have “lost opportunity” costs.

The criterion to prefer cost-effective measures does not mean that society must wait until there is unassailable scientific evidence before it can intervene. Some advocates have argued for the adoption of a “precautionary principle.” The precautionary principle is not consistently defined but it means that public health authorities may act to prevent future harms to people and the environment even in the absence of conclusive proof that the harm is real or that the intervention will be effective.

Step Four: Assess the Burdens on Human Rights. Sometimes even cost-effective policies should not be undertaken if they disproportionately burden human rights. Policy makers, therefore, should think about the invasiveness of the intervention, the frequency and scope of the infringement, and the duration of the infringement. Human rights do not always trump public health, but they certainly need to be weighed carefully.

Step Five: Assess the Fairness of the Intervention. Policies should be formed and implemented in just ways. Thus, there should be a fair distribution of benefits and burdens. Ethicists examine fairness in a variety of different ways, but they often focus on need and risk. Benefits or public health services should often be distributed based on need. That is, those who have the greatest need should have some claim to the benefit or service. On the other hand, regulatory burdens should often be distributed on the basis of risks posed. That is, those who pose the greatest risks to the public or the environment should bear the costs and burdens of regulation. There are certainly other ways to evaluate the just allocation of benefits and burdens (e.g., principles of the most efficient distribution), but need and risk are two likely criteria.

In summary, a public health intervention can be evaluated using several criteria: (i) the nature, probability, and severity of the risk; (ii) the likelihood that it will be effective in meeting its objectives; (iii) the economic costs entailed, including opportunity costs; (iv) the burdens on human rights, and (v) the fairness, including a just allocation of benefits and burdens.

Conclusion

The field of public health is highly complex. What is the meaning of pivotally important abstract concepts that are common in public health: population, community, risk, harm, and benefit? How should society decide when it is necessary and appropriate to intervene to protect the public's health? Are factors such as risk, effectiveness, cost, burdens, and fairness the best ways to evaluate public health interventions? How does the population perspective differ from the individual perspective? To what extent should social justice be an animating value in public health? Scholars and practitioners use various forms of reasoning in analyzing these problems, notably ethics, law, and human rights. Each form of reasoning has its own benefits and disadvantages. While each form of reasoning is distinct, all the forms overlap in important ways. One thing is certainly clear, there are no "correct" answers in public health. However, careful examination of principles and values taken from each of these fields can clarify thinking and, ultimately, lead to more effective and just policies and practices in public health.

Further Readings in Public Health Law and Ethics

Books

Beauchamp DE, Steinbock B (eds.), *New Ethics for the Public's Health*, New York: Oxford University Press, 1999.

Gostin LO (ed.), *Public Health Law and Ethics: A Reader*, Berkeley and New York: University of California Press and Milbank Memorial Fund, 2002.

Gostin LO, *Public Health Law: Power, Duty, Restraint*, Berkeley and New York: University of California Press and Milbank Memorial Fund, 2000.

Articles

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Gostin LO, Sapsin JW, Teret SP, *et al.*, The Model State Emergency Health Powers Act: Planning and Response to Bioterrorism and Naturally Occurring Infectious Diseases, *JAMA* (2002) 288:622-628.

Gostin LO, Public Health, Ethics, and Human Rights: A Tribute to the Late Jonathan Mann, *J Law, Med & Ethics* (2001) 29: 121-130.

Kass NE, An Ethics Framework for Public Health, *Am J Pub Health* (2001): 91:1776-1782.

Roberts MJ, Reich MR, Ethical Analysis in Public Health, *Lancet* (2002) 359:1055-1059.

Thomas JC, Sage M, Dillenberg J, Guillory VJ, A Code of Ethics for Public Health, *Am J Pub Health* (2002): 92:1057-59.

Internet Resources

Web site of the Center for Law and the Public's Health at Georgetown and Johns Hopkins University (CDC Collaborating Center Promoting Health Through Law): <http://www.publichealthlaw.net>

Web site accompanying the book, Gostin LO (ed.), *Public Health Law and Ethics: A Reader*, Berkeley and New York: University of California Press and Milbank Memorial Fund, 2002:
<http://www.publichealthlaw.net/reader>

Fact Sheet: Tradition, Profession, and Values in Public Health

This module explores the relationship between public health ethics, public health law (notably the exercise of the state's police power), and human rights. The various meanings of each form of reasoning are discussed, as well as the similarities and differences among them.

I. What Is Public Health?

- Definitions of public health vary widely; however, a unifying theme is that public health is a mutually-shared, societal obligation. Collective entities such as governments and communities must take responsibility for promoting the health of the public.
- The Institute of Medicine defines public health as “what we, as a society, do collectively to assure the conditions for people to be healthy.” (*Future of Public Health, 1988*)
- The focus of public health is the health of populations, rather than the health of individuals.
- Public health is more concerned with broad strategies to prevent or ameliorate injury and disease than with clinical interactions between professionals and patients.
- Scholars and practitioners are conflicted about the “reach” or domain of public health between 2 major foci:
 - Narrow focus on the proximal risk factors for injury and disease; or
 - Broad focus on the socio-cultural-economic foundations of health.

II. What are Public Health Ethics?

- Public health ethics are principles and values that guide actions to promote health and prevent injury and disease among the population.
- Public health ethics should be distinguished from biomedical ethics.
 - Biomedical ethics often stress the importance of individual interests of patients.
 - Public health ethics emphasize partnership, citizenship, and community.
- Some scholars have structured public health ethics in three overlapping ways:
 - Professional ethics are concerned with ethical dimensions of professionalism.
 - Applied ethics relate to dynamics of the public health enterprise itself.
 - Advocacy ethics are informed by the single overriding value of a healthy community.
- Scholars and practitioners disagree on each of the three forms of public health ethics.
 - A code of ethics could clarify the field and provide guidance regarding ethical dilemmas.
 - Some suggest that no single public health profession exists. It is difficult to find a single set of values that relates to all public health professionals.

III. What is Public Health Law?

- Public health law refers to rules of action prescribed by controlling authority and having binding legal force. Law is found in constitutions, statutes, regulations, and court cases.
- Law creates a mission for public health authorities, assigns their functions, and specifies the manner in which they may exercise their authority.
- The most important public health debates occur in legal fora—legislatures, courts, and administrative agencies—and in the law’s language of rights, duties, and justice.
- Police power is the inherent authority of a state to protect, preserve and promote the health, safety, morals, and general welfare of the people. The state may restrict individual interests within limits to achieve these communal benefits.
- Law regulates behavior and alters the informational, physical, and business environment. However, the appropriate role of law in public health is controversial (e.g., coercive interventions aimed at changing individual behavior may unduly restrict liberty and foster resentment).

IV. What is the Role of Human Rights in Public Health?

- The language of human rights is used in different, but overlapping, ways in public health.
- Human rights may refer to a set of entitlements under international law, or may be invoked for aspirational, or rhetorical, purposes.
- Considerable disagreement exists as to whether “health” is a meaningful, identifiable, operational, and enforceable right, or whether it is merely aspirational or rhetorical.
- Although human rights are supported by international law and express an inspiring idea about personal dignity, they are often criticized for imprecision and lack of enforceability.

V. How to Evaluate Public Health Interventions

- Policy makers should subject public health interventions to systematic evaluation.
 - Demonstrate risk.
 - Demonstrate effectiveness.
 - Assess economic cost.
 - Assess human rights burdens.
 - Assess fairness.

Case Study 1: Legal and Ethical Implications of a Public Health Approach to Disability¹

Malik Johnson has been the Human Resources Manager of MedCentre, a hospital in West Virginia, for two years. Monday morning, Juanita Carlson, the Benefits Coordinator at MedCentre, informed Malik of the hospital's plan to implement screening procedures to detect hepatitis B among prospective and incumbent employees.

Viral hepatitis B can be transmitted when blood or bodily fluids from an infected individual enter the body of an individual who is not immune to the virus; e.g., from mother to unborn child or from partner to partner via unprotected sexual intercourse, blood transfusion, or sharing needles. Symptoms of hepatitis B include jaundice, fatigue, abdominal and/or joint pain, loss of appetite, and nausea. These symptoms are more common in adults than in children, yet approximately 30% of infected individuals will not experience any symptoms. In the absence of vaccination or treatment, death from chronic liver disease occurs among 15-25% of hepatitis B infected individuals. The hepatitis B vaccine, available since 1982, is the best protection against contracting the virus; however, other precautions are also advisable, such as condom use and/or refraining from injection drug use.

Juanita stated that screening MedCentre employees for hepatitis B was necessary to (1) alert MedCentre's HMO to potential elevated costs in its medical coverage, (2) notify the hospital's administration that special accommodations may be needed (e.g., infection control and/or leaves of absence for seropositive individuals), and (3) protect the hospital's patients and employees from the transmission of this contagious disease. Malik suspected that the screening plan was also influenced by the recent hepatitis B diagnosis of MedCentre's chief cardiac surgeon, Michele Kim.

MedCentre provided notification of the screening plan in a brief memorandum to current employees and to individuals who received an offer of employment from the hospital as of Monday afternoon. The plan was to become effective the following Friday, at which point all prospective and current employees were instructed to report to the hospital's laboratory for screening.

Malik is responsible for responding to employees' questions about MedCentre's screening plan. Juanita also assigned Malik the task of evaluating the plan in light of employees' concerns in a confidential memorandum to MedCentre's Board of Directors.

Prospective Employees

Paula Smith, a prospective employee in MedCentre's maintenance department, called Malik on the telephone immediately after she read MedCentre's notification memo on Tuesday morning. Ms. Smith was concerned that MedCentre would rescind its recent offer of employment once her seropositive status was discovered.

Ms. Smith questioned why MedCentre needs to screen maintenance staff members at all. Ms. Smith does not understand how screening for hepatitis B status relates to the responsibilities or performance of her job.

¹ I thank James G. Hodge, Jr., and research students at the Georgetown University Law Center, for help in researching and drafting these case studies.

Because maintenance staff members have limited contact with patients and/or other MedCentre employees, Ms. Smith argued that the threat posed by infected maintenance staff members at the hospital is minimal. Although Ms. Smith agrees that the effects of hepatitis B may be debilitating and the costs of treatment may be considerable, she does not see why hepatitis B should be singled out from other diseases that impose a similar burden, such as syphilis.

Malik thanked Ms. Smith for expressing her concerns, promised to research the answers to her questions, and told her he would return her telephone call in a couple of days.

Current Employees

After Malik ended his conversation with Ms. Smith, he received a second urgent telephone call. This time, the voice on the other side of the line belonged to Robert Jones, a loyal employee and respected orthopedic surgeon at MedCentre for fifteen years. Dr. Jones suspected that he contracted hepatitis B from a recent, unprotected homosexual encounter. Dr. Jones told Malik that he was keenly aware of the case of Dr. Kim, whose hepatitis B diagnosis last month prompted her leave of absence, contributed to the temporary rescission of her surgical privileges, and generated relentless gossip around the hospital.

The prospect of sharing Dr. Kim's fate terrified Dr. Jones. He is troubled that his homosexual orientation and his seropositive status could both be exposed to the detriment of his career at the conservative hospital. Dr. Jones is afraid that a hepatitis B diagnosis will quickly become a stigma, and that people will perceive him as incapable of performing his responsibilities as a surgeon. Dr. Jones needs assurance that he will not be discriminated against by MedCentre staff or patients on the basis of his serological status.

Malik sympathized with Dr. Jones' predicament and promised to address his concerns in a confidential meeting with him on Thursday morning.

Disability Discrimination

Tonya Perez, MedCentre's general legal counsel, outlined the relevant disability law pertaining to the hospital's screening plan. Ms. Perez told Malik that the Americans with Disabilities Act of 1990 (ADA) places certain limitations on employer-mandated medical examinations, including the screening of employees. Under the ADA, an employer can require the screening of prospective employees *after* an offer of employment has been made but before a prospective employee commences work. All prospective employees must be subjected to the same examination and the information collected must be maintained in a separate, confidential medical record. Furthermore, an employer can require the screening of current employees if such medical examinations are shown to be "job-related" or "consistent with business necessity." Again, the results must be kept in a separate, confidential medical record. Prospective or current employees may not be discriminated against on the basis of their disabilities. Thus, qualified persons with a disability may not be terminated or adversely treated because of their disabilities. A "qualified" person with a disability must meet all the essential criteria for performing the job and must not pose a significant risk to himself or others.

Ms. Perez noted that even if MedCentre's screening plan is otherwise legally permissible, MedCentre must also avoid unlawful discrimination in violation of the ADA. Modern jurisprudence indicates that hepatitis B meets the criteria for a "disability" under the ADA since its taxing physiological manifestations may "substantially limit" the "major life activity" of working. For example, symptoms such as extreme nausea or

fatigue may constrain Paula Smith's ability to perform the physical tasks associated with her position as a hospital maintenance staff member. Furthermore, the ADA protects individuals such as Robert Jones who are "regarded as" disabled, or who have a record of disability. However, the courts have been divided as to whether a person infected, but not yet symptomatic, is covered under the ADA as a person with a disability. Therefore, the question arises, from a perspective of law and ethics, can MedCentre use the information acquired from the screening to discriminate against seropositive individuals on the basis of their serological status? If we assume that seropositive individuals do have a disability, then MedCentre must neither manifest nor tolerate adverse treatment of an individual diagnosed with hepatitis B who is "otherwise qualified" for a hospital position, if "reasonable accommodations" or "modifications" can be made on his or her behalf (e.g., leaves of absence).

A Public Health Approach

You are Malik's first choice for consultation regarding his assignment from MedCentre's Board of Directors. Malik wants to adopt a public health perspective that addresses the human rights and ethical issues implicated in MedCentre's screening plan. Malik's memorandum must offer recommendations that are legally and ethically sound. Due to Malik's time constraints, he has asked that you e-mail him responses to the following questions by tomorrow evening:

- Should MedCentre screen all employees, or should it "target" or limit screening to employees whose jobs involve regular contact with hospital patients and employees, as Paula Smith suggested? Assuming that certain jobs are less likely to transmit infection via interpersonal contact, will general screening be perceived as paternalistic?
- Should MedCentre obtain employees' consent to the screening? If so, how can MedCentre ensure that the employees are sufficiently informed?
- How should MedCentre document and store the records of screening results?
- How should MedCentre notify employees of their serological status? Should or must MedCentre provide counseling?
- What "reasonable accommodations" can or should MedCentre make for seropositive individuals? Is vaccination legally, ethically, or economically feasible?
- What preventative procedures and/or programs can MedCentre implement to ensure that seropositive individuals are not discriminated against on the basis of their serological status?

Case Study 1: Discussion

Ethical Problems

This case study presents two sets of ethical dilemmas.

Paula Smith, a prospective employee at MedCentre, raises concerns regarding the ethical implications of general versus targeted screening procedures. Assuming that certain jobs at MedCentre are less conducive to transmission of hepatitis B than others, is general screening of all employees unnecessary, inefficient, and/or paternalistic? Conversely, would targeted screening exclude seropositive individuals and/or alienate already marginalized individuals or groups? Also, how should MedCentre decide which employees to “target” for screening; e.g., by the level of risk associated with their employment positions (e.g., extent of interpersonal contact) or by the level of risk associated with their personal habits (e.g., intravenous drug use or promiscuous sexual behavior)? As Human Resources Manager of MedCentre, Malik Johnson must evaluate the costs and benefits, both economic and philosophical, of these two screening alternatives before writing his memorandum of recommendations to the Board of Directors.

Second, Malik must address the concerns of Robert Jones, a current employee at MedCentre, regarding discrimination. What safeguards (e.g., educational or training programs) should MedCentre implement to ensure that seropositive individuals will not be discriminated against on the basis of their serological status? Malik must be attentive to the privacy and bodily integrity concerns of individuals who will be screened, yet he must also ensure effective screening procedures that will protect MedCentre’s patients and staff from transmission of hepatitis B.

Relevant Values

As the liaison between MedCentre’s staff and administration, Malik is aware that different values are motivating the perspectives of each “side.” For example, MedCentre employees subject to screening, such as Paula Smith and Robert Jones, have prioritized the values of bodily integrity, autonomy, liberty, and privacy; whereas MedCentre’s Board of Directors will likely prioritize the values of efficacy and efficiency, and MedCentre’s investors/patrons may prioritize the value of conservatism. Malik’s recommendations must be informed by each of these values, yet Malik must also acknowledge the value of compromise.

Necessary Information

An integral step in resolving these ethical dilemmas is for Malik to gather all information pertaining to MedCentre’s screening plan and to the individuals whom it will involve. For example, Malik should consult with other MedCentre officials to determine the source and extent of funding allocated for the screening procedure. This information may determine which type of screening is more feasible and/or appropriate (e.g., are sufficient funds available for general screening of all employees?) as well as which preventative measures or safeguards can be implemented to prevent discrimination subsequent to the screening (e.g., are sufficient funds available for educational/training programs and/or for counseling?).

Malik should also have several informal discussions with MedCentre’s administrators and employees about the screening plan. These talks will help Malik identify where sensitivities may lie and where compromises

may be made. They will also reinforce the values mentioned above and ensure that Malik's recommendations to the Board of Directors are ethically sound.

Finally, Malik should schedule another meeting with Tonya Perez, MedCentre's general legal counsel, to ensure that his recommendations are legally valid. Malik will want to discover and avoid legal issues that surfaced in comparable screening programs in other medical centers. He will also want to ensure that Tonya is prepared to defend MedCentre's screening plan against potential lawsuits.

Stakeholders to the Decision

Throughout the decision-making process, Malik must be respectful of and attentive to the many stakeholders to this decision. Malik's recommendations to the Board of Directors must be informed by the interests, concerns, and values of MedCentre's prospective employees, current employees, patients, administrators, and investors/patrons. As was noted in the above sections, each of these parties and entities has values and needs that may conflict with those of the others.

Available Options

Malik must carefully assess the values that each recommendation serves, as well as its financial, political, and organizational feasibility. A sample of the many potential recommendations that Malik can offer in his memorandum to MedCentre's Board of Directors includes the following:

- General screening of all employees to minimize stigma and/or alienation associated with targeted screening and to convey the message that everyone should be cognizant of the risks associated with hepatitis B
- Confidential and professional screening procedures conducted by authorized medical personnel who are respectful and discreet
- Notification of serological status via contact information provided directly by the employee who was subject to the screening, with provision of referrals and a free counseling session for seropositive individuals
- Access to and disclosure of medical records limited to those with a legitimate need to know; e.g., to medically treat the employee
- Implementation of educational and training initiatives to prevent discrimination

Decision Process

Although the foregoing analysis is essential for Malik's own decision process regarding recommendations to MedCentre's Board of Directors, the "official" decision process that determines the fate of the screening plan will begin (or will recommence) when the Board receives Malik's memorandum. It is hoped that the Board's final decision on the plan will be influenced by the input of each of the stakeholders discussed above. However, to ensure that the plan continues to be responsive to the interests, needs, and values of these diverse stakeholders, perhaps Malik can suggest the formation of an Oversight Committee that contains a representative from each "side."

Case Study 2: Protecting Health Information Privacy

Dr. Sharon Smart is a senior genetics researcher for Genomatic, Inc., an emerging pharmaceutical company that researches and develops pharmacogenomic products. Dr. Smart was the lead researcher in a recent large-scale clinical study designed to test the efficacy of *Alive*, a new pharmaceutical. *Alive* is designed to successfully treat a terminal form of ovarian cancer that has common genetic links in a sizable portion of the general public. The study amassed considerable, longitudinal health data on thousands of research subjects. Genomatic's shares recently soared on the NASDAQ stock exchange in expectation of potential approval of *Alive* through the Food and Drug Administration (FDA). Genomatic had sought final FDA approval after completing its clinical drug trials.

Seeking FDA Approval

As part of the approval process, the FDA requested copies of relevant medical records of individuals involved in the clinical drug trials for *Alive*. In its correspondence, the FDA said that it needed the data for review and examination pursuant to the approval process for *Alive*. In her laboratory in Rockville, Maryland, Dr. Smart assembled the personally identifiable data, including research subjects' informed consent forms. Each of the research subjects had previously executed a general waiver for the release of his or her medical records to "federal authorities, including the FDA, for the purposes of conveying study results."

In the same letter, the FDA also asked for additional medical data about whether the research subjects involved in the *Alive* clinical trials had participated in other clinical trials at Genomatic. The FDA suggested that it wanted this data to confirm that Genomatic had not improperly recruited its research subjects for multiple trials, or provided incentives for their long-term participation in the company's clinical trials programs. Another pharmaceutical company had recently engaged in a practice of soliciting clinical trial research subjects from community homeless shelters. These individuals became "career" research subjects, participating in dozens of trials and reaping sizeable financial incentives.

Dr. Smart contacted an FDA official about the second request for information. She inquired as to whether the approval process for *Alive* was contingent upon forwarding the research subjects' additional medical data. The official suggested that "while the approval process is independent of the request for the additional data, companies that fail to comply with all FDA information requests may see their products' approval delayed."

Responding to Public Health Authorities

That same afternoon, Dr. Smart received a telephone call from Dr. Needy at the state cancer registry. Operated as part of the state department of health, the cancer registry tracks a variety of cancer cases pursuant to state statutory authorization. Dr. Needy had recently learned about Genomatic's drug trials for ovarian cancer. He asked Dr. Smart to provide the names of all of Genomatic's clinical research subjects who had been diagnosed with ovarian cancer. Dr. Smart suggested that the names of these individuals would have already been provided by the subjects' treating physicians or private laboratories that had tested tissue samples for cancer cells. Dr. Needy agreed, but responded that his office had recently uncovered a new type of ovarian cancer that did not typify existing forms of the disease. Specifically, he wanted Dr. Smart to provide the requested information so that the state cancer registry might confirm this potential new form of ovarian cancer tied to the genetic link.

Sharing with Academic Researchers

Before Dr. Smart could respond to the state cancer registry's request for her research subjects' data, she opened an e-mail from her colleague at Genomatic, Dr. Duit, who worked in the company's headquarters in Seattle. Dr. Duit was the chief information officer for Genomatic. He had recently received a request from the dean of the medical school at a major university that sought access to some of the company's clinical trials databases. Researchers at the medical school thought that some of Genomatic's information might further research on a joint pharmaceutical project between the university and Genomatic.

Dr. Smart called Dr. Duit to question whether she could share the data without the specific informed consent of the subjects. Dr. Duit assured her, "I've spoken with our legal counsel, and he told me that there is no state law against sharing this data (at least in Washington state). We need this data, Sharon. Our CEO recently pledged monetary support to the university to broaden our information-sharing network. The university has some data we can use, and we have some data they can use." Dr. Smart further questioned the use of the data, to which Dr. Duit responded, "Sharon, this is a mutually beneficial practice. Genomatic and the university may both benefit, but the public will benefit as well through improvements in medical science. There's a strong need to collaborate to bring these medical advancements to the public. I'm as sensitive to the privacy issues as you are, but no one debates the value of using this data. Now, send me the data tomorrow."

Toward A Resolution of these Information Requests

Dr. Smart is uncertain what to do regarding each of these requests for data. Each entity requesting the data seems to have a legitimate claim to the identifiable information. Yet, to share the data with each of these entities may compromise the research subjects' interests in maintaining the privacy of their health information. Dr. Smart seeks your help in answering the following questions:

- Should Dr. Smart provide the identifiable health data about her clinical research subjects to the FDA as part of the drug approval process for *Alive*?
- Must Dr. Smart provide additional identifiable health data to the FDA for its review of Genomatic's recruitment of clinical research subjects?
- Must Genomatic meet the state cancer registry's request for data on those research subjects enrolled in the *Alive* trials?
- Should Dr. Smart forward the requested data to the chief information officer at Genomatic if she knows the officer will share the data with outside researchers at the university medical school?

Case Study 2: Discussion

Ethical Problems

The four contexts in which Dr. Smart is asked to share identifiable health data about Genomatic research subjects enrolled in clinical trials for the cancer drug, *Alive*, implicate significant ethical issues.

First, Dr. Smart must decide whether she can provide the information to the FDA for drug approval purposes. Federal health information privacy law clearly permits disclosure of health information where the FDA needs the data for approving or rejecting new or existing drugs. Although individuals may prefer to keep their health information private, there is strong public health support for the FDA's role in approving pharmaceuticals to serve the public's interests in safe and efficacious drugs.

Second, Dr. Smart must consider whether she can share the information with the FDA for purposes of broadly monitoring enrollees in clinical drug trials. This issue raises the implied question of whether the research subjects have any claim to prevent Dr. Smart from disclosing their data to the FDA. If the FDA's second request is not justified by existing informed consent, and assuming that obtaining further consent is impractical, Dr. Smart must determine whether a communal need to protect potential or actual human research subjects from exploitation or abuse may warrant the otherwise prohibited disclosure of information.

Third, Dr. Smart must determine if the state cancer registry is entitled to the subjects' health information for the purposes of identifying new cancer cases, or at least for verifying existing cases. State laws generally authorize state cancer registries to collect information on cancer prevalence through mandatory reporting requirements. These reporting requirements allow public health authorities to more accurately gauge the prevalence of cancer in the population, identify cancer trends, and take preventative measures to address avoidable incidences of cancer. Therefore, Dr. Smart's response to this data request is contingent upon whether or not individual privacy rights to highly-sensitive cancer data outweigh communal goals of cancer reporting.

Finally, Dr. Smart must decide if she can offer the information to Genomatic's chief information officer, who plans to share the data with medical researchers at a university supported by the company. Federal privacy law and human subject research provisions may permit the sharing of identifiable health data for research purposes in some contexts. However, Dr. Smart must acknowledge that the monetary incentive underlying Genomatic's corporate interests in sharing the data may complicate her ethical decision-making.

Relevant Values

The information requests above invoke a series of legal, ethical, and human rights values that center on the balance between respecting an individual's right to health information privacy and promoting the use of identifiable data where needed to protect the public health or accomplish other communal goods.

Individuals, such as the subjects in Genomatic's clinical research trials, may put a premium on the value of privacy regarding their health information. Normative values of autonomy and justice strongly support the rights of persons to control the circumstances in which their identifiable health data are acquired, used, disclosed, or stored. Legal, ethical, and human rights principles also support some levels of individual control over identifiable health data, including limiting the access, use, or disclosure of this information.

Storage access prohibitions, use restrictions, and informed consent requirements are protections that derive from these privacy concerns.

However, the value of individual privacy regarding health information is not absolute. Sharing identifiable health data may be justified where needed to promote various communal goods and values (e.g., public health, human research), or where necessary to prevent harms to others (e.g., duty to warn requirements). Particularly in the public health setting, the access, use, and disclosure of individual health data is needed to survey the population's health and protect against actual or potential threats to community health. The ability to share data to accomplish the communal values or goals of public health is justified under the ethical theory of utilitarianism and the moral principle of paternalism.

Necessary Information

Dr. Smart must obtain more information before she can respond appropriately to each of the data requests.

First, Dr. Smart must determine the scope of Genomatic subjects' informed consent. The original informed consent language suggests that the release of a subject's research record shall be made to "federal authorities, including the FDA, for the purposes of conveying study results." This language seems to authorize the FDA's initial request for such data pursuant to the approval process for *Alive*. However, even if each subject did provide informed consent, Dr. Smart must assess whether his or her consent is sufficiently broad to release data to the FDA for purposes of confirming that Genomatic did not improperly recruit the research subjects for multiple trials, or provide incentives for their long-term participation.

It may also be necessary to determine whether the subjects' informed consent was obtained under duress. For example, many of the Genomatic subjects enrolled in the study may suffer from a terminal form of ovarian cancer. If *Alive* represents the only available treatment option, the agreement of the subjects to enroll in the study and release their data to the FDA may not be truly informed consent. It will therefore be important for Dr. Smart to examine exactly what the subjects understood from the language and context of the consent. Alternatively, Dr. Smart may want to determine if it is feasible to obtain further consent from the subjects.

Second, Dr. Smart will want to carefully review the state reporting requirements and privacy laws, perhaps with the guidance of an attorney. These laws may set the parameters of Dr. Smart's responses to the data requests.

Finally, Dr. Smart should ensure that Genomatic officials support her decisions before she offers them to the individuals who requested the data. Perhaps company policy and the input of company officials will facilitate Dr. Smart's decision-making.

Stakeholders to the Decision

In this scenario, there are several stakeholders to Dr. Smart's decisions regarding the release of Genomatic subjects' health information. For example, individuals and/or entities with a vested interest in the outcome of Dr. Smart's deliberations include: Genomatic, Genomatic's research subjects, the FDA, the state cancer registry, the university, and perhaps all past, present, and future subjects in clinical research trials (assuming that Dr. Smart's decisions may set a standard or precedent for Genomatic, if not for other pharmaceutical companies).

Available Options

Dr. Smart may choose to explore the following options, assuming they are compatible with the further investigations that were recommended above:

- Obtain further informed consent from Genomatic subjects
- Release all health information requested by each individual/entity
- Limit disclosure to that which is clearly authorized by state privacy and reporting laws
- Defer to Genomatic company policy and/or input from company officials

Decision Process

Dr. Smart's decision process will be influenced by each of the steps, individuals, and entities outlined above. To ensure that Dr. Smart's responses to the data requests are responsible as well as legally and ethically sound, she will want to involve as many knowledgeable people as possible in her decision-making process. Perhaps Dr. Smart should summarize her planned responses to the data requests in a memorandum to Genomatic officials. Dr. Smart can then schedule a meeting with the Genomatic officials to discuss the legal, ethical, and human rights issues implicated in this scenario, and reach a consensus regarding the extent of permissible disclosure.

Case Study 3: Legal and Ethical Implications of a Public Health Approach to Funding Cancer Research and Treatment

Barry Fine is the Chief Financial Officer of BioTech, a Fortune 500 company that makes generous annual contributions to promote biomedical research in national laboratories and medical centers. Barry is responsible for ensuring that BioTech's resources and reputation are well-served by its charitable contribution. He has carefully evaluated the funding requests of dozens of worthwhile organizations. After weeks of indecision, Barry has determined two potential recipients for this year's gift.

Center for Lung Cancer Research

The appeal from the director of the Center for Lung Cancer Research (CLCR), a governmental public health agency in Washington, D.C., resonated with Barry. The letter explained that CLCR desperately needed BioTech's funds to develop new methods of screening for lung cancer. For nearly two decades, CLCR had advocated chest X-Rays for screening purposes. CLCR now sought alternative screening methodologies after findings from the Mayo Lung Project indicated that chest X-Rays were not necessarily efficient means of tracking the cancer. (National Institute of Health, Press Release, Aug. 15, 2000). To date, no alternative screening method for lung cancer has been shown to significantly improve survival rates.

CLCR hoped to reduce the "false positive" problems associated with chest X-Ray screenings (e.g., exposure of non-malignant tumors) by refining its spiral computed tomography (CT) technology. CLCR scientists were on the brink of developing a modified CT scan that was better able to locate abnormal, malignant growths on the lungs, but additional financial support was needed to continue their work.

The CLCR letter characterized lung cancer as the most common and fatal, yet least well-funded, form of cancer, with approximately 170,000 new cases diagnosed each year. The American Cancer Society reported in 2001 that lung cancer kills more Americans than breast, prostate, and colorectal cancers combined, with dramatic increases in the number of new diagnoses of lung cancer among women. Although most causes of lung cancer are related to the use of tobacco, lung cancer can also be caused by radon or asbestos exposure and lung diseases, including tuberculosis. Early detection of lung cancer when it is localized (e.g., before the cancer spreads to other organs in the body) greatly increases the five-year survival rate. By helping to improve measures of early detection of lung cancer, CLCR's proposal concluded that BioTech can prolong, if not save, countless lives.

BioLogics

Next to CLCR's letter on Barry's desk was a fax from the chief executive officer of BioLogics, a small medical research center in Florida. BioLogics' plea for BioTech's funds was also compelling. The CEO confided that based on blood and urine tests and a bone marrow biopsy, he had recently been diagnosed with Waldenström's Macroglobulinemia (WM), a rare, chronic form of cancer classified as a low-grade lymphoma. This disease causes abnormal plasma cells to multiply out of control, invading bone marrow, lymph nodes, and the spleen and producing excessive amounts of IgM, an antibody that causes thickening of the blood. In extreme cases, the increased concentration of IgM in the blood can lead to heart failure, typically within five to seven years.

BioLogics' fax stated that approximately five out of 1,000,000 people are diagnosed with WM each year. The disease usually affects people who are over the age of sixty-five; however, it can also be found in

younger people. Cancer registries in the United States indicate that this cancer is more common among men than women and among Caucasians than African-Americans. Some patients do not report any symptoms prior to diagnosis. Other patients experience enlarged lymph nodes or spleen, as well as fatigue, headaches, weight loss, a tendency to bleed easily, visual problems, confusion, dizziness, and loss of coordination. The CEO of BioLogics was told that these symptoms are due to the thickening of his blood from the IgM. Unfortunately, WM has an unknown cause and no known cure. Many hematologists have never seen a single case of this form of cancer, hence its nickname as an “orphan” disease.

A lack of satisfactory treatment of WM inspired the CEO of BioLogics to send BioTech the request for funds. Because WM is such a rare disease, there is no government-approved course of treatment. Current treatment methodologies are determined by the thickness of the patient's blood, and may include chemotherapy, plasmapheresis, and/or biological therapy. The main goal of treatment is to reduce the amount of abnormal blood cells, bone marrow cells, and protein in the blood.

Consistent with its reputation as an “innovative” or “cutting-edge” research center- and with its compassion for its CEO- BioLogics has prioritized research of new treatment methodologies for WM, and seeks BioTech’s financial backing for this endeavor.

A Public Health Approach to Funding Decisions

After reviewing the proposals extensively, Barry concluded that both projects would be worthwhile investments for BioTech, yet each had distinct benefits and disadvantages. Funding for lung cancer research was clearly needed and could lead to significant improvements in early detection and treatment for this common, fatal disease. Alternatively, funding for WM could directly benefit the CEO of BioLogics and could bring much needed attention and resources to this rare disease.

Barry needs guidance on the legal, ethical, and human rights implications of this important decision. Specifically, Barry requests your professional opinion on the following issues:

- What criteria should Barry use to make the funding decision; e.g., how will legal, ethical, practical, and financial issues contribute to BioTech’s decision-making process?
- Should Barry, and BioTech by extension, adopt a public health perspective or a clinical approach regarding the implications of this decision?
- What influence should the demographics of the two diseases have on the decision?

Case Study 3: Discussion

Ethical Problems

This case study presents Barry Fine, the Chief Financial Officer of BioTech, with the ethical dilemma of choosing between the Center for Lung Cancer Research (CLCR), a governmental public health agency in Washington, D.C., and BioLogics, a private medical research center in Florida, as potential recipients of BioTech's annual contribution to promote biomedical research.

Barry must consider the ethical implications of this important decision. The framework for Barry's ethical analysis will be shaped by his conception of cancer as either a clinical matter or as a public health issue. The demographics of the two diseases may influence BioTech's funding decision. For example, should the tendency of WM to disproportionately affect older, Caucasian men disincline Barry to support its funding, in favor of a more "equal opportunity" disease, such as lung cancer? The answer to that question will depend on whether Barry wants to use the BioTech funds to directly address clinical cases (e.g., helping the CEO of BioLogics treat his WM) or to convey a more general, population-oriented message (e.g., highlighting the public health problem of tobacco use by exposing lung cancer as one of its long-term consequences).

Relevant Values

Barry's decision will be influenced by several important values. First, Barry must consider the values of BioTech, a conservative, prestigious organization that will want to preserve its reputation as such. Second, Barry must consider BioTech's like-minded investors, who want to ensure that BioTech retains its status as a Fortune 500 company. Third, Barry will be influenced by his own values, such as integrity and psychological and/or financial security. Finally, Barry must carefully weigh the values of CLCR and BioLogics, and determine if their values are compatible with those of the other people and entities involved in this decision.

Necessary Information

Before selecting the recipient organization, Barry must gather more information.

First, Barry should consult with other executives at BioTech regarding whether the funds can be split between CLCR and BioLogics. If dividing the funds is not an option, Barry should inquire as to which organization is preferable- and why. Perhaps Barry can schedule a meeting with BioTech's Board of Directors to discuss the benefits and disadvantages associated with each organization.

Second, Barry must obtain more detailed information regarding exactly how CLCR and BioLogics plan to use the BioTech funds. For example, it may be important to discover whether these organizations anticipate short-term or long-term results; e.g., whether they will use the funds to support further academic research, clinical trials, and/or technological development and innovation. Barry may request that CLCR and BioLogics send him proposals that elaborate on their specific intentions. This additional information would also enhance Barry's presentation to BioTech's Board of Directors, enabling a more thoughtful and informed decision.

Finally, Barry should review past funding decisions and reevaluate the criteria that BioTech used to make those decisions. Perhaps certain patterns or organizational profiles will emerge that would simplify Barry's decision process.

Stakeholders to the Decision

There are various stakeholders to BioTech's funding decision, including: BioTech, BioTech's investors, Barry Fine (in his capacity as Chief Financial Officer of BioTech), CLCR, BioLogics, and all current and future patients diagnosed with lung cancer or WM.

Available Options

Depending on the outcome of the above investigations, Barry may have the following options regarding the BioTech funding decision:

- Divide the BioTech funds equally (or as otherwise needed) between CLCR and BioLogics
- Choose CLCR since BioTech's funds will likely reach more people due to the prevalence of lung cancer in the general population
- Choose BioLogics since WM is arguably more in need of attention and resources
- Choose another worthy recipient from among the dozens of funding requests that BioTech received
- Defer to BioTech's Board of Directors to make the final decision

Decision Process

Barry's decision process will be influenced and informed by each of the stakeholders listed above. The final funding decision will also reflect the considerations and values that have been mentioned. Perhaps a formal meeting involving Barry Fine, BioTech's Board of Directors, the director of CLCR, and the CEO of BioLogics is the most appropriate forum for the final decision process. Attention to each of these factors, individuals, and entities is essential to making an ethical decision that will promote the public health and serve the private interests involved.