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THE ETHICS *of* GENETIC COMMERCE

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Preface

The human species is rapidly acquiring vast new knowledge about itself that is different in kind, potential, and peril, than any that has gone before. I refer, of course, to genetic knowledge about the human body that goes to the very foundation of our physical, emotional, and mental existence. This development is not merely one of knowledge, but also one of technology. For we are now extending our grasp to the very levers that control our constitution as individuals and as a species. This accession of knowledge and enhancement in technological power represent opportunities and dangers unlike any ever encountered in human history.

Perhaps the closest analogy to these sweeping changes in knowledge and power occurred in the early modern era with the "Copernican Revolution." Suddenly an entirely new understanding of the cosmos gained sway that challenged the fundamental understanding of man's place in the universe. No longer was man near the center of the universe, no longer did he occupy a position near the pinnacle of the great chain of being. Instead, we came to see ourselves as being located at the periphery in a world with no inherent order, lodged merely on the "third rock from the sun" in a minor solar system comprising a fragment of one galaxy among many.

Current developments in genetic knowledge will require, I believe, a similar re-ordering of our understanding. But the present condition is more dramatic and challenging that the Copernican Revolution in three important respects. First, the new genetic knowledge strikes much more directly to the core of human existence than did the new cosmological understanding. While the greater physical knowledge of the early modern period did require a new grasp of man's place in the cosmos, today's new genetic knowledge demands a new understanding of the very core of what it is to be human. While the Copernican Revolution eventually led to a new view of man as a moral animal, today's Genetic Revolution raises the question of whether man is a moral animal at all. If, for example, human disposition to behave in certain ways is reliably traceable to genetic factors that largely determine how a particular organism acts in the world, what role is left for moral categories or normative appraisal of human conduct?

Second, the scientific advances of the early modern period only required a revision in the understanding of man as a static being. The place of man in the order of things may have been reappraised, but it was only the understanding of the human that changed, not the nature of the human being itself.

Today, genetic engineering not only gives us the ability, and perhaps necessity, to understand ourselves in a new way, but also it promises or threatens to give us the means to actively control and direct our very genetic makeup as we go into the future. For the first time in human history, man now has the power to direct his evolutionary future. This raises a vision of eugenics on a scale never imagined before.

Third, there is a great difference between the early scientific revolution and today's Genetic Revolution in the immediacy and significance of the commercial potential of this new knowledge. While the new physical understanding led to the Industrial Revolution and eventually carried us to today's globalization, it did so relatively slowly over four or five centuries. By contrast, today new genetic knowledge is acquired and commercialized almost simultaneously, with every incremental advance leading almost immediately to new products and services. A further difference in the process of commercialization ties in with our first point – today's commercialization strikes to the very heart of what it is to be human, in contrast to the earlier commercialization of physical processes. Our rapidly expanding genetic knowledge today points toward a near future in which the elements of humanity closest to our moral core may themselves be produced, manipulated, commodified, and exchanged.

As such, I believe that the challenges of genetic commerce, both as a topic of understanding and as a process requiring direction, will be at the core of debate for decades to come. This volume attempts to contribute to an emerging understanding of the crucial questions raised by our new Promethean challenge by tackling three key topic areas. Part I focuses on "genetic screening," the analysis and use of genetic information about individuals, an issue that arises most saliently in the employer–employee relationship. The most intensely commercialized aspect of genetic commerce today is in agriculture and foodstuffs with the rise of genetically modified foods, the topic of Part II. Of all the dimensions of genetic commerce, the issue of the genetic modification of food seems to be at the forefront of public attention and has entered the public arena most prominently in controversies about labeling such modified foods. The third part of this book addresses specific business topics tied to genetic commerce, such as patenting genetic knowledge, pharmaceutical mergers and the potential monopolization of genetic knowledge, and the implications of genetic testing on non-human mammals.

Contributors to this volume come from diverse backgrounds, both within academics and from the corporate sector, from the United States and abroad. They also represent a diversity of backgrounds in business, social science, and philosophy. Both the papers and the discussions surrounding the symposium at which these papers were presented were enriched by these diverse perspectives. I hope that you will find the exchange of ideas included in this book as enriching as did we who participated in the symposium.

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Part I

Genetic Screening

One of the most likely areas for the application or misapplication of genetic information is in the genetic screening of individuals. In the business context, employees and potential employees are perhaps most likely to face screening. Any employer who considers hiring, training, and providing health insurance to an individual might well want to know the genetic vulnerabilities of that prospective employee. But non-employees are also not immune to genetic screening. For example, health insurers would love to be able to exclude high-risk clients from the pool of their policyholders. Of course, genetic screening can have substantial benefits for the person screened. For example, an individual might well want to know whether he possesses certain genetic characteristics that might affect his future or the life prospects of an offspring. Similarly, businesses also might reasonably want to avoid placing employees with risky genetic profiles in environments that are likely to harm them particularly.

In his essay, "Is a Genetics Screening Program for Job Applicants Ethical? An Analysis of the Conditions Necessary for Required Genetic Screenings in the Hiring Process," Thomas Harter analyzes the conditions under which employment screening can be ethically acceptable. Harter clearly believes that genetic screening of employees can be justified in certain situations, and he specified the condition under which employers can justifiably engage in genetic screening.

Duane Windsor focuses on the business ethics and public policy implication of genetic screening in his chapter, "The Business of Genetic Screening." Thus Windsor also addresses genetic screening of employees and health insurance applicants. In the course of his analysis, Windsor considers whether markets fail to promote social welfare in matters such as genetic screening, and he analyzes the contexts in which public policy initiatives might ameliorate such presumed market failures. For Windsor issues of human rights play a considerable role in the analysis, and he ultimately concludes that, with very few exceptions, the "... weight of considerations favors a complete ban on business use of individual genetic information."

In their chapter, "Genetic Commerce: The Challenges for Human Resource Management," Karen Markel and Lizabeth Barclay focus on what they see as the likely consequences of completing the Human Genome Project for issues of genetic screening, particularly in the context of human resource management.

While acknowledging that issues of genetic screening may not be of paramount importance right now for human resource managers, Markel and Barclay clearly believe that these issues will become of central importance to the human resource function.

Ronald Munson focuses on individual rights in his discussion of genetic screening in "Geneticize Me! The Case for Direct-to-Consumer Genetic Testing." He begins by noticing that those who posture as protectors of individual rights often want to restrict the autonomy of individuals. Munson finds such efforts to be well intentioned, but ultimately paternalistic. This analysis leads Munson to believe that a successful case can be made for the right of individuals to purchase genetic information about themselves directly and without regulation. Thus Munson ultimately concludes, "Given that our society is committed to the autonomy of the individual, we should endorse policies that make it possible for people, if they choose, to acquire personal, reliable genetic data without going past a gatekeeper."

In "Proscription, Prescription, or Market Process? Comments on Genetic Screening," Eugene Heath surveys the question of genetic screening with reference to the other chapters discussed above. In doing so, Heath takes a critical stance that focuses on maintaining the principle of individual autonomy and choice within a market context, arguing that these conditions of choice are crucial to innovation and experiment. As Heath puts it: "The freedom to choose and select, to enter and exit, are essential to a good society and good lives and these freedoms should not be disregarded in favor of proscriptions and prescriptions that are not fully justified." Thus, Heath generally rejects the strictures others are willing to impose on genetic screening in favor of a view of rational actors able to make independent and uncoerced choices.

1

Is a Genetics Screening Program for Job Applicants Ethical? An Analysis of the Conditions Necessary for Requiring Genetic Screenings in the Hiring Process

Thomas Harter

Introduction

Genetic screening in the workplace is a two-headed problem. On one hand, all things being equal, some job applicants and employees who are qualified for certain jobs, may pose occupational risks to themselves and others because they have genetic predispositions or hypersusceptibilities that increase their risk of developing a genetic disease. On the other hand, not hiring job applicants or firing employees only because they may develop a genetic disease is a form of genetic discrimination.

Assuming employers want to minimize occupational risks without unjustly discriminating against current or potential employees, this chapter takes up the question of when, if ever, it is permissible for employers to require genetic screenings as part of the hiring process. Specifically I argue that, despite standard concerns and reasons for disallowing genetic screenings in the workplace, those concerns can be ameliorated by requiring employers to meet the conditions of justification, consent, accuracy, and confidentiality, thereby allowing employers who meet these conditions to require pre-employment genetic screenings, and disallowing pre-employment genetic screenings when these conditions are not met.

There are several key issues to address. First, I summarize the scope of the problem. Second, I look at the purpose, reasons, and benefits of genetic screenings in the workplace. Third, I discuss the reasons for disallowing genetic screenings as part of the hiring process, focusing on genetic discrimination and loss of privacy. Fourth, I show how these concerns can be resolved by requiring

employers to (1) provide adequate justification(s) for using genetic screenings as part of the hiring process, (2) receive consent from job applicants before having the genetic screening(s), (3) ensure that the genetic screenings are accurate, and (4) treat the information received from the genetic screening as highly confidential. Then having set out my main arguments, I consider two objections to my thesis: that requiring genetic screenings provides an alternative to employers cleaning up workplaces, and that enforcing these conditions for required genetic screenings may be too difficult.

Summarizing the Scope of the Problem

Before the 1990s and the Human Genome Project, few major companies genetically screened their employees.[1] Since then the prospect of using genetic screenings in the workplace, although still ethically debated, has become more common. One reason for this, as already stated, is employers wanting to minimize occupational risks while increasing employee safety. Other reasons for using genetic screenings, which I explore more fully in the next section, include employers wanting to efficiently manage the costs of treating employees with genetic diseases, and employers also wanting to minimize potential risks to the general public. In order to successfully argue that employers may permissibly require genetic screenings for applicants, there must be empirical evidence showing correlations between genetic hypersusceptibilities, genetic diseases, and certain workplace exposures.

Elaine Draper, in her book *Risky Business*,[2] gives the following examples of these kinds of correlations:

> People with SAT enzyme deficiency may have increased susceptibility to emphysema and chronic bronchitis under conditions of exposure to pulmonary irritants. Exposure to certain hemolytic chemicals may trigger sickling crises among individuals with sickle cell trait. Individuals with G-6-PD deficiency may be at greater risk of anemia or hemolytic crisis when exposed to oxidizing chemicals such as nitroamino and nitroaromatic compounds. Aryl hydrocarbon hydroxylase

[1] In one of the most famous publications on genetic screening in the workplace, the Office of Technology Assessment (OTA) report "Genetic Monitoring and Screening in the Workplace" (October 1990) included a 1982 survey of several hundred Fortune 500 companies to determine how many of them genetically screened their employees; 366 of the 500 companies responded (a 65% response rate). Of those 366 companies, 17 (4.6%) claimed to use genetic testing of some form over the previous 12 years, 4 (1.1%) anticipated using genetic screenings in the next 5 years, and 55 (15%) said they would possibly use genetic screenings in the next 5 years. While there were slight changes in the survey when it was given again in 1989, the results were nearly the same. Twenty companies in the 1989 survey, as opposed to the 17 in the 1982, claimed to have genetically screened employees. For more information about the report and survey see Office of Technology Assessment (1990).

[2] See Draper (1991).

> deficiency appears to increase susceptibility to lung cancer among those encountering specific industrial pollutants. Over fifty diseases have been associated with human leukocyte antigens.
>
> Draper (1991, p. 25)

Although there may be other types of genetic diseases with links to hypersusceptibilities and workplace exposures, Draper nicely illustrates this aspect of the problem. Namely, companies with employees who may be at risk for developing a genetic disease because they are hypersusceptible to certain workplace exposures, and believe they have a right to genetically screen employees and applicants for those hypersusceptibilities because doing so helps minimize occupational risks. However the other aspect of this problem is whether genetically screening employees and applicants is ethical because doing so identifies those individuals with hypersusceptibilities, presumably with the intention of removing them from whatever workplace exposures are putting them at risk for developing a genetic disease.

Draper also successfully illustrates this aspect of problem by discussing DuPont's highly publicized genetic screening program. From 1972 until the early 1980s, DuPont screened all of its African American employees and applicants for the sickle cell trait and sickle cell disease.[3] However, "the extent to which the company's program was truly beneficial or in fact coercive and discriminatory was hotly debated in government hearings, professional conferences, and major news stories and editorials across the United States" (Draper, 1991, p. 130). Yet without proof that the program was beneficial in some way, it seems DuPont was not justified in screening its African American applicants and employees, and thus likely they were engaging in genetic and racial discrimination. From this the full scope of the problem is clear, while companies may cite an obligation to identify, and consequently remove, hypersusceptible employees or applicants from workplace exposures that may put them at risk for developing a genetic disease, doing so may lead to various forms of unjustifiable discrimination. Before showing how it is possible to ethically require genetic screenings for applicants without unjustly discriminating against them, it is necessary to show the purpose, reasons, and benefits of genetic screenings in the hiring process.

Purpose, Reasons, and Benefits for Genetic Screenings in the Hiring Process

In his article, "Warning: Screening Workers for Genetic Risk," Thomas Murray gives four general purposes of genetic testing in the workplace.[4] These include

[3] See Draper (1991, p. 130).

[4] See Murray (1983).

diagnosis, research, information, and exclusion:

> First, the tests could be used in the clinical diagnosis of an individual ill worker. Second, tests could be used in research to establish links between genetic predispositions and reactions to workplace hazards. Third, information gained from the tests, along with any established or reasonably suspected link with work-related illness, could be presented to workers for their consideration. Fourth, the tests could be used to exclude workers from jobs where they had a genetic condition believed to result in a heightened susceptibility to the hazards normally encountered in that job.
>
> Murray (1983, p. 6)

By using genetic screening in the workplace, employers can determine which applicants are "hypersusceptible" to certain genetic diseases. That is, genetic screenings help determine which applicants are more likely to fully develop a genetic disease if they come in contact with certain workplace exposures that increase their risk. Consider Draper's example of an employee with the trait for sickle cell anemia. Assuming that the employee is not exposed to hemolytic chemicals there is a chance that the sickling gene may remain dormant. However, if that employee happens to work in an area exposing her to hemolytic chemicals, she is then considered hypersusceptible to have a sickling crisis.

Both Murray and the Council on Ethical and Judicial Affairs for the American Medical Association (CEJA) discuss the justifications employers give for implementing a genetic screening program for the purpose of detecting these hypersusceptibilities. Murray states,

> First, they can point to their moral duty to protect workers. Paternalism originally meant taking care of those with less power – the parent and child is the paradigm. Second, companies can cite their financial obligation to use the company's resources in the most efficient way possible, including preventing the loss of employee time due to illness, or money through the workman's compensation system. Third, they can emphasize their desire to avoid lawsuits alleging a *failure* to adequately protect genetically susceptible workers from harm.[5]
>
> Murray (1983, p. 6)

Likewise, CEJA claims in their report "Use of Genetic Testing by Employers,"

> Employers will have a number of potential justifications for genetic testing in the workplace. In some cases, there may be an argument in favor of testing for

[5] Emphasis added. I believe that Murray's third justification fits better under both the first and second arguments. The *failure* to adequately protect workers is an extension of their moral duty to protect them, while the obligation a company has to use its financial resources efficiently precludes its desire to avoid a lawsuit.

> public health reasons. Companies have expressed concern about the possibility of an employee's genetic susceptibility to illness from exposure to a chemical or other substance in the workplace. In addition, employers may not want to hire individuals with certain genetic risks for jobs that bear on the public's safety. Other justifications are based not on concerns about health but on concerns about costs, specifically the costs to the *company* of hiring workers with a genetic risk of disease. Individuals who have a heightened risk for certain illnesses may be less attractive as employees; on average, they may be able to spend fewer years in the work force, and they may impose greater health care costs on the employer.[6]
>
> CEJA (1991, p. 1827)

Detecting which applicants are hypersusceptible hinges on three primary benefits that apply across multiple industries: benefits to applicants, benefits to the general public, and benefits to the company. First, determining which applicants are hypersusceptible allows employers to prevent those applicants from being placed in jobs that increase their risk of either developing or manifesting a genetic disease. Second, determining which applicants are hypersusceptible may help prevent current employees, as well as the general public, from being placed in harm's way. For example, consider a bus driver applicant who suffers seizures caused by a genetic form of epilepsy. These seizures can be brought on in numerous ways, including exposure to certain light patterns. Although most forms of epilepsy can be controlled with medication, an employer would presumably still want to know if an applicant were epileptic because of the possibility that the applicant may have a seizure driving a bus full of people. Lastly, the ability to determine which applicants are hypersusceptible may help companies (1) avoid costly lawsuits stemming from a failure to protect those applicants, current employees, or the general public from possible harms, (2) avoid paying higher insurance premiums,[7] or (3) avoid having to cover the cost of applicants needing time off from work to treat their illnesses. Yet despite the potential benefits, there are many arguments for why employers should not use genetic screenings in the hiring process.

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[6] See Council on Ethical and Judicial Affairs, American Medical Association (1991). It is possible that the justifications of using genetic screenings to determine hypersusceptibilities cited by Murray and CEJA could extend in their scope to include screening workers who already have burgeoning genetic diseases.

[7] While the 1996 Health Insurance Portability Accountability Act (HIPPA) "prohibits group health plans from using any health status-related factor, including genetic information, as a basis for denying or limiting eligibility for coverage or for charging an individual more for coverage," it is unclear whether or not this prohibits insurance companies from legally charging higher premiums to companies with workers who have genetic diseases or hypersusceptibilities. National Human Genome Research Institute, National Institutes of Health, January 2004. See National Institutes of Health (2005).

Reasons against Using Genetic Screening in the Hiring Process

On May 6, 2002, Burlington Northern Santa Fe Railway Co. paid $2.2 million to thirty-six employees in a settlement with the Equal Employment Opportunity Commission (EEOC).[8] The settlement was reached after Burlington Northern "admitted to conducting undisclosed genetic testing after the workers complained of carpal tunnel syndrome stemming from work related activities" (French, 2002, p. 1). In their defense, Burlington Northern claimed they were screening employees to confirm the existence of carpal tunnel syndrome, but that this was done in conjunction with "a comprehensive medical examination" (French, 2002, p. 1). On September 12, 2002, there was a Congressional hearing before the Subcommittee on the Constitution, questioning the "Privacy Concerns Raised by the Collection and Use of Genetic Information by Employers and Insurers."[9] Both the Burlington Northern case and the Congressional hearing highlight what many articles on genetic screening in the workplace quickly point out: two dangers of requiring genetic screenings in the hiring process are genetic discrimination and invasion of privacy.

Genetic Discrimination

Larry Gostin[10] states the problem with genetic discrimination is that it "violates basic tenets of individual justice and is detrimental to public health" (1991, p. 112). He continues,

> Discrimination based upon actual or perceived genetic characteristics denies an individual equal opportunity because of a status over which she has no control. Discrimination based on genetic factors can be as unjust as that based on race, gender, or disability. In each case, people are treated inequitably, not because of their inherent abilities, but solely because of pre-determined characteristics. The right to be treated equally and according to one's abilities in all the diverse aspects of human endeavor is a core social value.[11]
>
> Gostin (1991, p. 112)

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[8] See *EEOC v* (2002). See French (2002).

[9] See House of Representatives Subcommittee on the Constitution of the Committee on the Judiciary (2002).

[10] See Gostin (1991).

[11] While I agree with Gostin that some forms of genetic discrimination are unjust, I do not believe it is the case that all forms of genetic discrimination are unjust. Although I do not specifically argue for this point in the article, my project is guided by the belief that not only are some forms of genetic discrimination just, but also that genetic discrimination is required in certain cases when jobs bear on public safety.

Genetic discrimination can manifest in several ways. First is future unemployability. Because genetic screenings determine which applicants have hypersusceptibilities, "Employers may be reluctant to hire individuals who have a genetic predisposition for developing a disabling illness . . . because these individuals may become prematurely unable to work" (CEJA, 1991, p. 1827). Thus, applicants with specific career training or job skills may be unable to find work if they have a noted genetic hypersusceptibility. Requiring genetic screenings may also lead to hiring practices that would be in violation of the EEOC and the Americans with Disabilities Act of 1990 (ADA), as employers may be tempted to hire applicants without hypersusceptibilities who do not appear in danger of developing a genetic disease.[12]

Genetic discrimination can also manifest through over-reliance on the results of genetic screenings. In both their 1991 articles, CEJA and Gostin note that the results of genetic screening are not as accurate as the public may believe. CEJA reports,

> Genetic tests are poor predictors of diseases and even poorer predictors of disabling diseases. Genes are often characterized by incomplete penetrance; that is, many individuals who carry the gene will never show manifestations of the gene. When the gene manifests itself, it will be characterized by variable expression – the extent of the gene's effects may differ widely from person to person. Among individuals with sickle cell anemia, some die within the first years of life, while others survive into their 50s. In many cases, behavioral modification can limit gene expression . . . Even in cases in which the gene will ultimately cause disabling disease, the effects of the gene may not appear for some time. For example, the onset of Huntington's disease does not occur until the patient is between the ages of 30 and 50 years. Consequently, the use of genetic tests would result in individual's being denied employment well before they became unable to work. In sum, genetic tests would have a high false-positive rate and, therefore, would result in many individuals being denied employment unfairly.
>
> CEJA (1991, p. 1827)

[12] William Murry, James Wimbrush, and Dan Dalton state that, "Genetic markers that would indicate proclivity towards future illness or disease in individuals may or may not constitute a disability. The ADA defines a disability as, '(A) A physical or mental impairment that substantially limits one or more of the major life activities of such individual, (B) a record of such impairment, or (C) being regarded as having such an impairment (Americans with Disabilities Act of 1990).'" They further claim, the "Equal Employment Opportunity Commission (EEOC) interpretative guidelines in 1995 expanded on this definition specifically to include genetic testing when they indicated that in order to make a claim under the ADA '. . . an employee must show he or she has a genetic defect, the employer knew about the defect, and the employer took discriminatory action based on that knowledge' (Workplace Visions, 1998, p. 5)" (pp. 366–367). For further information, see Murry and Dalton (2001).

Echoing these claims, Gostin states, "For most genetic diseases the onset date, severity of symptoms, and efficacy of treatment and management are highly variable" (1991, p. 114). He concludes,

> The reliability and predictive value of genetic tests are limited by the extent to which mutations are known and prevalent in the target population. Variability exists in the onset, presentation and outcome of disease, and predictions are confounded by a multiplicity of genetic, biomedical, and environmental factors. For all these reasons, significant scientific uncertainty surrounds much genetic testing.
> Gostin (1991, p. 114)

However, because both CEJA's and Gostin's articles were published in 1991, it is important to examine the current accuracy of genetic tests. This is an issue I take up in the next section discussing the conditions for required genetic screenings.

Another possible manifestation of genetic discrimination is through ethnic or racial discrimination. This is because certain ethnic groups have been linked to particular genetic diseases. For example, people of African descent have been linked to sickle cell anemia,[13] and Ashkenazi Jews to Tay-Sachs.[14] One concern is that "screening could stigmatize and negatively impact historically disadvantaged groups (cf. Task Force on Genetic Information and Insurance)" (MacDonald and Williams-Jones, 2002, p. 237). Thus, genetic testing could lead to increased racial discrimination. However, it is also possible that racial discrimination could lead to genetic discrimination. Imagine an employer who requires only African American applicants to be screened for the sickle cell trait and then removes from the candidate pool any applicant with a positive test.[15]

Invasion of Privacy

Genetic screenings are also considered inappropriate in the hiring process because they unduly invade the applicant's privacy. As Joseph Kupfer[16] explains,

> Many different sorts of information can be obtained, most of it valuable to the company. Some information concerns such things as credit ratings or religious

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[13] Sickle cell anemia is also commonly linked to people in "Spanish-speaking regions (South America, Cuba, Central America), Saudi Arabia, India, and Mediterranean countries, such as Turkey, Greece, and Italy." See Sickle cell anemia. *Webster's New World Medical Dictionary* (2nd edition, 2003).

[14] See MacDonald and Williams-Jones (2002).

[15] While racial discrimination is illegal in the hiring process, current debates about the legality of genetic discrimination in the hiring process are ongoing. For further information, see Gostin (1991), Murry et al. (2001), and Strudler (1994).

[16] See Kupfer (1993).

> affiliations, other involves ascertaining physical facts by monitoring drug use. Is genetic screening any different in principle from drug screening, polygraph tests, or surveillance? In at least one regard it seems to be. Although in most cases we have some control over whether a gene is expressed as a disorder, we cannot control whether we *have* the gene in the first place. Whether we have the disposition, the vulnerability to the disorder, is out of our hands. We have some say over our work, religion, credit rating, and most of us can choose to use drugs or not. But not so with genes. They are in us and of us, forever. This lack of control is especially compounded in the workplace because of related lack of power in this context.
>
> Kupfer (1993, p. 21)

Hence genetic screenings are different from other types of personal information applicants may be required to give employers because they reveal information individuals have no control over and cannot change. But how exactly is revealing genetic information about oneself is an undue invasion of privacy? Kupfer makes two presumptions here. One, individuals tend to guard information about themselves they believe make a part of their personhood. Two, part of what dictates personhood are our genes. So because individuals cannot control or change their genetic make-up, being required to reveal this information for the sake of employment seems in some regard an undue invasion of privacy. However if individuals did have some control over their genetic make-up, or at least have some control over how their genetic information is used by employers, Kupfer might be reduced to saying that although genetic screenings do invade privacy to some degree, genetic screenings are not an *undue* invasion of privacy.

In addition to the fear that genetic screenings unduly invade privacy, other concerns include the psychological burdens genetic screenings place on applicants, the nature and scope of the information revealed, and confidentiality of that information. For instance, genetic screenings may force applicants to learn information about themselves they might not otherwise want to know. One reason for this might be a fear of social stigmatization associated with certain genetic diseases, like Alzheimer's. Another reason might be the shame and embarrassment some applicants may feel about themselves; applicants who learn they are hypersusceptible to a genetic disease may somehow feel inferior to those who are not. Applicants may also feel embarrassed by special requests their families or employers may have regarding their hypersusceptibilities, perhaps by having those applicants fill out special insurance forms, or visit with a genetic counselor. MacDonald and Williams-Jones discuss these and other psychological burdens in "Ethics and Genetics: Susceptibility Testing in the Workplace":

> Genetic information can be a significant psychological and social burden, especially if one is told one has "a defective gene," or is "at risk." Such news might

> affect a person's conception of health and identity, lead to stigmatization, or even make a person unemployable or uninsurable . . . Forcing employees to undergo genetic screening also forces the employee to deal with the resulting information, and studies on the psychological impact of genetic testing have shown that it may sometimes be better "not to know".
>
> MacDonald and Williams-Jones (2002, p. 237)

Murry et al. add in "Genetic Screening in the Workplace: Legislative and Ethical Implications,"

> It has been shown that individuals who have found out they are carriers of a genetic mutation have negative feelings and react with varying levels of distress. The negative connotations that are associated with genetic testing, particularly with respect to potential employment opportunities, create for an employee the inevitable perception of inadequacy.
>
> Murry et al. (2001, p. 373)

These psychological burdens may be perpetuated in part by the nature and scope of the information revealed. Genetic screenings are primarily used to determine whether individuals have a genetic disease or hypersusceptibility. While employers may use that information, for the reasons cited by Murray and CEJA, a yet unanswered question is, how much personal information should applicants be required to disclose for the sake of employment? Assuming employers want to hire those whom they feel are the best applicants, they should have a right to know information about those applicants relevant to the job for which they are applying. Yet genetic screenings offer detailed information about applicants that they may wish to keep private and are not necessarily relevant to the job. Consider a young applicant whose screening reveals the trait for Alzheimer's. Although this is a debilitating disease, its onset is not until late in life, and presumably has little relevancy during the time the applicant is actually employed. However, because there is a social stigma associated with Alzheimer's, the applicant may wish to keep the information private. So there is reason to believe there are limits to an employer's access of an applicant's genetic information. But what are these limits and why is the privacy of an applicant something that ought to be valued?

Kupfer grants that employers do have rights and interests to prevent potential occupational risks resulting from hypersusceptibilities. However he also believes that,

> Such interests are not overriding, not in a society which claims to value the individual's autonomy and privacy. The employer has no more right to a total genetic profile than he has to information about one's sexual habits, recreational activities, or religious and political beliefs – even though knowledge of these and other details of our lives might well be of use to him.
>
> Kupfer (1993, p. 22)

Thus the limits of employer privileges to genetic information hinge on two points. One is the relevancy of the information; if there is no association between the genetic information revealed and the specific job being applied for, then employers should not have privileges to that information. The other point is the value placed on privacy; because privacy is something that society values, applicants have a right not to disclose genetic information about themselves to employers, especially when that information is deemed irrelevant. Yet why is it that privacy is something society values and employers ought to respect? Privacy is something that ought to be valued and respected by employers because it allows applicants and employees to build the kind of trusting relationships necessary for a company to flourish. Conversely, employers who do not value the privacy of their applicants and employees create an atmosphere of distrust that would seem to undermine a company's ability to achieve any kind of long-term flourishing.

There is also a fear that an applicant's genetic information will be shared by any number of interested third parties. Depending on the hypersusceptibility, genetic counselors may want the applicant to disclose the information to other potentially affected family members. Insurance companies will want applicant results for the sake of determining the employer's premiums. Genetic discrimination is also a problem here because of the possibility that employers, wishing to keep their premiums low, will not hire applicants with certain hypersusceptibilities. Additionally, applicants with known hypersusceptibilities may find it too difficult and expensive to purchase insurance independently. Other employees may claim a right to be informed of any newly hired applicants with hypersusceptibilities.

The case against requiring genetic screenings in the hiring process is strong. However, the prima facie obligation to refrain from requiring these screenings can be overridden in certain circumstances. The result will be the permissibility of employers requiring genetic screenings for applicants as part of the hiring process.

Conditions for Using Genetic Screening in the Hiring Process[17]

Justification

To require the genetic screenings of applicants, employers must ensure that (1) the screenings are to check for hypersusceptibilities with known correlations

[17] Wicks et al. in their essay "Screening Workers for Genetic Hypersusceptibility: Potential Ethical, Legal, and Social Implications from the Human Genome Project," provide similar conditions to

to certain workplace exposures, (2) the risks associated with those hypersusceptibilities and workplace exposures are applicable to all applicants, and (3) the information from those screenings is assessed and used appropriately. Only by meeting all three of these conditions, will an employer meet the condition of justification. This is because while each of these provisions provides a partial justification for required genetic screenings, they are by themselves too weak to withstand the aforementioned reasons for why required screenings should not be allowed in the workplace. For instance, while provision (1) states that screenings are only done for the sake of checking hypersusceptibilities with known correlations to workplace exposures, it is possible that if this were the only requirement for justification, some employers may use this provision as a way to eliminate an entire ethnic group from the candidate pool. Yet when coupling provision (1) with (2) or (3), it becomes much more difficult to justify such a racist practice, as provision (2) requires the screenings be applicable to all applicants, and provision (3) requires the information from genetic screenings be used appropriately by employers. To see how each of these provisions might work in practice, consider again Draper's example of people with sickle cell trait potentially developing a sickling crisis from exposure to hemolytic chemicals.

Under provision (1), a plant that exposes employees to hemolytic chemicals is at least partially justified in screening applicants for the sickle cell trait because of the demonstrated correlation between the two. Again, the reason for this is that employers want to minimize the occupational risks present in the workplace. Screening applicants for genetic traits that are shown to correlate with certain workplace exposures is acting in the best interests of the company, their employees, and the applicants by trying to minimize both safety risks and the costs incurred when workplace injuries occur. However, screening applicants for the sickle cell trait is unjustified in cases when there are no correlations between the trait and any type of workplace exposure, as doing so has no demonstrable impact on the overall safety and health of the organization and its employees.

Under provision (2), a plant that exposes employees to hemolytic chemicals is, again, partially justified in screening applicants for the sickle cell trait. The reason here is that anyone with the trait, working with hemolytic chemicals, is at risk for developing a sickling crisis. However, employers cannot know which applicants are hypersusceptible unless those applicants test positive for the trait. This is why I claim the associated risks between hypersusceptibilities and workplace exposures must be applicable to all applicants. When there is a

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the ones listed here for permissible required genetic screenings in the workplace. However, while they discuss these conditions in a broad context, I specifically focus on how employers must meet these conditions to require genetic screenings in the hiring process. For the Wicks essay, see Wicks et al. (2004).

correlation between hypersusceptibilities and workplace exposures, employers must treat all applicants as though they have the hypersusceptibility until the results of the screenings are revealed. Again the reason for this is because the occupational risks applicants with the trait may face, if they come in contact with the correlating exposure, applies to all applicants with that trait, but it is indeterminate who actually has the trait until all applicants have a genetic screening, whereby those with the trait are identified.

Finally, under provision (3), screening applicants for the sickle cell trait is justifiable only when the information is assessed and used appropriately by employers. Appropriately using this information means, it is only used to determine which applicants are at risk for developing a genetic disease. When employers use this information for anything other than determining an applicant's hypersusceptibility, it is unjust genetic discrimination and an undue invasion of privacy because applicants would then be revealing information about themselves that has little or no bearing on the jobs for which they are applying.

It may also be the case that appropriately using an applicant's genetic information requires employers to weigh an applicant's results depending on how strong the correlations actually are between hypersusceptibilities, workplace exposures, and the likelihood those hypersusceptibilities will develop into full-blown genetic diseases. Thus, weighing an applicant's genetic information may also require employers to consider other non-genetic factors, such as the quality and level of the applicant's education, as well as the amount and quality of the applicant's experience. If an employer at a plant that exposes employees to hemolytic chemicals highly values an applicant's experience, it is likely the applicant with most experience will be hired over others. But, if that applicant were to test positive for the sickle cell trait, the employer may need to evaluate the likelihood that the applicant will develop a sickling crisis during his employment. If the likelihood is strong, the employer may consider hiring an applicant with less experience, but who does not have the sickle cell trait. If the likelihood is small, the employer may still choose to hire the applicant with the sickle cell trait. The primary reason for this is that, "Small increases in relative risk do not justify exclusion. Even with large increases in relative risk, if the absolute risk remains low, exclusion is hard to justify" (Murray, 1983, p. 8). So as the strength of correlations between hypersusceptibilities, genetic diseases, and workplace exposures varies, so too will the weight given to the results of the genetic screenings.[18]

[18] The fluctuation of weight given to the results of genetic screenings may also help neutralize the problem of unemployability. This is because, in some cases, employers will value non-genetic factors (such as education) more highly than the results of genetic screenings, even if those results show an applicant is hypersusceptible. Thus, applicants are not, and will not, necessarily be evaluated solely on the basis of their genetic screenings.

Although the condition of justification rests on employers meeting these three provisions, Congress has begun taking steps making it illegal to use the results of genetic screenings as part of the hiring process. On February 17, 2005, the Senate passed the Genetic Information Nondiscrimination Act of 2005 (GINA).[19] *Section 202* of *Title II: Prohibiting Employment Discrimination on the Basis of Genetic Information*,

> Prohibits, as an unlawful employment practice, an employer, employment agency, labor organization, or joint labor-management committee from discriminating against an employee, individual, or member on the basis of genetic information, including by: (1) for an employer, failing to hire or discharging an employee or otherwise discriminating against an employee with respect to the compensation, terms, conditions, or privileges of employment; (2) for an employment agency, failing or refusing to refer an individual for employment; (3) for a labor organization, excluding or expelling a member from the organization; (4) for an employment agency, labor organization, or joint labor-management committee, causing or attempting to cause an employer to discriminate against a member in violation of this Act; or (5) for an employer, labor organization, or joint labor-management committee, discriminating against an individual in admission to, or employment in, any program established to provide apprenticeships or other training or retraining.[20]

While this act is meant to protect employees and applicants from genetic discrimination by disallowing employment decisions being made on the basis of genetic information, it does not specify whether or not genetic information may be considered at all in the hiring process. This is important because if employers are not to consider *any* genetic information when making hiring decisions, it becomes difficult to legally justify any sort of pre-employment genetic screening program. However, if employers are allowed to consider some types of genetic information in the hiring process, then it may still be possible to legally justify required screenings when the correlations between hypersusceptibilities, workplace exposures, and genetic disease are evident. For example, in situations where applicants are applying for jobs that will expose them to hemolytic chemicals, an employer, having met the conditions of provisions of justification, may find it necessary for the sake of occupational safety to determine which applicants have the sickle cell trait. However, this does not mean that the employer would or should make his hiring decision based solely on this information, as doing so would violate the provisions I give for justification. So while I agree that hiring decisions made only on the basis of genetic screenings are genetic discrimination, I also believe if the

[19] The bill unanimously passed 98–0.

[20] See National Human Genome Research Institute, National Institutes of Health (2005).

reasons for those genetic screenings meet the condition of justification they should be legally permissible.

One may also question whether it is ethical to impose legal constraints on the use of genetic information in the hiring process. Is it, or should it be, the case that it is always wrong to discriminate against applicants based, at least partially, on their genetic information? Prima facie it appears that the legal requirements of GINA could conflict with employers wanting to minimize occupational risks in the workplace. Consider again the bus driver applicant who suffers epileptic seizures. If the employer knows this information and hires the applicant regardless because he is the most qualified, the employer is unjustly putting the applicant and the general public in danger if the applicant were to have a seizure while driving a bus. However according to GINA, knowing this information and not hiring the applicant may be illegal genetic discrimination. Here again marks the importance of justification. The question of whether it is wrong to discriminate against this applicant because he has a genetic form of epilepsy depends on different contextual factors. If on one hand, the correlations between the applicant's seizures and workplace exposures are weak, and the applicant is taking medications to mitigate the effects of the epilepsy, then the likelihood increases that not hiring the applicant because of his genetic information is both illegal and unethical. If on the other hand, the correlations between the applicant's seizures and workplace exposures are strong, and the applicant is not doing all he could to mitigate the effects of the epilepsy, then while the chances are still high that not hiring the applicant is illegal, it also seems the case that not hiring the applicant based on this genetic information is ethical, as the employer is thereby helping to protect both the applicant and the general public from what seems to be foreseeable harm. The next condition of required genetic screenings in the hiring process is consent.

Consent

The CEJA report states that, "Testing must not be performed without the informed consent of the employee or applicant for employment" (1991, p. 1830). This is fairly uncontroversial when genetic screenings are voluntary. Yet, how is it possible to uphold the need for consent if employers require pre-employment screenings? One possibility, similar to other forms of pre-employment testing, is for employers to inform applicants that they will be required to have a genetic screening before they will be considered for employment. The advantage of this is that it gives applicants the ability to choose whether or not they want to continue as applicants for that employer. However in certain situations, it is also possible that when there are limited jobs available, jobs that require a particular set of skills or educational level, or jobs that are too good

to refuse, requiring applicants to have genetic screenings may be coercive.[21] This is due to the limited options applicants have regarding their employment, such as working with employers to set the terms of their contracts. If applicants test positive for hypersusceptibilities, employers may not hire them, or if an employer does hire an applicant with a hypersusceptibility, the contract may be for less money than expected, or the employer may want the applicant to pay a higher insurance rate.[22]

One solution to this problem is for employers to request, rather than require, pre-employment genetic screenings. While this may work for jobs with minimal health risks, it may be inappropriate for jobs whose risks have stronger associations. Again this depends on the correlations between certain hypersusceptibilities, genetic diseases, and workplace exposures. When there are stronger correlations, it becomes necessary for employers to move beyond requesting, into requiring genetic screenings.

The question is, assuming required genetic screenings are coercive in certain situations, is the coercive practice justified? The answer depends on both the strength of the correlations and the overall strength of the justifications employers give. If hypersusceptible applicants can be hired without jeopardizing the safety of themselves or others, and without causing undue financial burdens to employers, the requirement is unjustifiable and illegitimately coercive because the information from the screenings will have little or no effect on the overall safety of the workplace. When the screenings are unjustifiable and illegitimately coercive, applicants may refuse the screenings while remaining candidates for those jobs. However, if hiring hypersusceptible applicants would jeopardize the safety of themselves and others, or cause undue financial burdens for employers, then the requirement, while possibly still being coercive, is justifiable because employers do have obligations to ensure workplace safety while minimizing occupational risks.[23] In such cases, applicants refusing

[21] It is necessary here to make a distinction between a coercive practice and coercion. A coercive practice is the attempt to get a person to do something they otherwise might not want to do using threats, either directly or indirectly. Parents who expect their children to meet a curfew and threaten them with being grounded if they do not are employing a coercive practice. However, coercion is making someone do something they might not otherwise want to do using force. Prisoners beaten until they sign confessions of wrong-doing are coerced, regardless of their guilt or innocence. Required genetic screenings may be coercive, although not coercion, if the applicant might not otherwise want to have a genetic screening, but feels that have to because they only have training correlating to the specific job being applied for, or because they do not want to lose a rare job opportunity. For more information about the distinction between coercive practices and coercion, see Arnold (2001).

[22] All three of which, as previously stated, are illegal practices.

[23] While it is also necessary to give arguments showing what exactly these obligations may be, doing so here is beyond the scope of this chapter.

screenings may be legitimately removed from the candidate pool. The next condition of required pre-employment genetic screenings is accuracy.

Accuracy of the Genetic Screenings

Both CEJA and Gostin warn against employers being over-reliant on the results of genetic screenings because of their false-positive and false-negative rates, and their inability to predict whether or not genetic diseases will manifest and to what degree. In the 1997 report "Promoting Safe and Effective Genetic Testing in the United States," the National Institutes of Health Task Force on Genetic Testing (NIH-TFGT) also warns against relying on inaccurate screenings:

> Although extensive use has eventually proved most tests to be of benefit, a few have not proved helpful and were discarded or modified. In the meantime, people were wrongly classified as at-risk and subjected to treatments that, in their case, proved unnecessary or sometimes harmful. Others, who could have benefited from treatment were classified as "normal" and not treated.[24]

So one fear in requiring genetic screenings is that they may have questionable accuracy such that some applicants may be incorrectly identified as being hypersusceptible, which may cause employers to remove them from candidacy, while some applicants may be hired having undetected hypersusceptibilities, which then places the safety of themselves and others at risk. However the literature on the accuracy of genetic screenings in identifying hypersusceptibilities is deficient. Despite this, there are criteria genetic screenings must meet to be considered accurate.

When developing genetic tests the NIH-TFGT holds that, "the clinical use of a genetic test must be based on evidence that the gene being examined is associated with the disease in question, that the test itself has analytical and clinical validity, and that the test results will be useful to the people being tested."[25] Thus one requirement of accurate genetic screenings is that they must demonstrate a correlation between the genetic diseases in question and the DNA strands under investigation. One must also be able to predict whether a particular screening will yield a positive or negative result, and then establish measures to make the tests as accurate as possible. This means that when there is a correlation between a particular DNA strand and a genetic disease, the screening should return a positive result, and when there is no correlation between the DNA strand and a genetic disease, the result should be negative. However,

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[24] See National Institutes of Health Task Force on Genetic Testing (1997).

[25] "Promoting Safe and Effective Genetic Testing in the United States, Chapter 2." April 28, 2005, available from http://www.genome.gov/10001733.

the criterion that these screenings benefit those being tested deals more with the psychological impact of the screenings than with the accuracy of the actual tests. So while this may be a necessary condition in developing genetic tests, it is not necessarily important when requiring those tests to be accurate. As more information becomes known about the links between particular DNA strands, genetic diseases, and hypersusceptibilities, and is incorporated in the development of genetic tests, the accuracy of these tests, and consequently genetic screenings, will become better, thus strengthening this condition of required screenings in the hiring process. The last condition of required pre-employment screenings is confidentiality.

Confidentiality

Requiring genetic screenings for applicants raises many fears about the loss of their privacy. Who has privileges to their genetic information and how will that information be used? Will applicants be able to remain anonymous? Will applicants be given the results of their screenings, perhaps against their wishes? To require genetic screenings of applicants, employers must also ensure a high level of confidentiality regarding the privacy of the applicants and their genetic information.

One criterion listed by MacDonald and Williams-Jones is that, "Testing should be carried out by an independent lab, and results of genetic tests should be given to workers directly, either by a geneticist or genetic counselor; test results should be held confidential, and revealed to the employer only at the employee's request" (2002, p. 238). This criterion may also apply to applicants. Employers requiring genetic screenings for applicants should provide them through independent testing facilities. Applicants must also then be able to meet with a geneticist or genetic counselor to discuss their results, and decide whether or not to disclose that information to employers. Employers should also take creative measures to ensure the privacy of applicants.

An example of how this might work in practice would be to require the genetic screenings early in the hiring process – before any face-to-face interviews. Applicants would be required to not attach any personal identifications to their applications or resumes, with employers assigning applicants random identification numbers. This allows employers to maintain the privacy of applicants prior to their screenings. Employers would also need to ensure that the testing facilities test only for those hypersusceptibilities correlating with known workplace exposures. Only after applicants have been screened and allowed to view their results would that specific information be accessible by employers. In addition to having legal standards for the use of genetic information, employers should have separate codes of ethical behavior that all applicants have access

to concerning how their genetic information is used and who has access to it. Applicants wishing to remain anonymous or wishing to not receive their results should have those wishes respected by the testing facilities and employers. One way for applicants to remain anonymous is for the testing facilities and employers to continue referring to them by their identification numbers until employers make a hiring decision. Another possibility would be for applicants to choose pseudo-names that they would be referred to throughout the hiring process.[26]

This, however, is a difficult criterion to uphold if an applicant does not get the job applied for and wants to know why. When determining how the genetic information of applicants is used, or trying to answer why an applicant did not get certain job, employers must inform applicants that the results of genetic screenings provide only one set of considerations in the hiring process, with other factors being given various weight depending on their relevancy. If applicants indicate concern of their results, employers should continue referring them to genetic counselors.

While this does not solve all the problems of confidentiality, it establishes both the need of employers and those conducting the screenings to treat the information with the same respect and privacy as other medical records, and to understand that the applicants ultimately decide whether or not to share that information.

Objections and Replies

There are two main objections to this view. The first objection is that requiring pre-employment genetic screenings provides employers an alternative to cleaning up workplaces. So, for example, rather than trying to minimize employee exposure to hemolytic chemicals, employers using genetic screenings can eliminate the risk of employees developing sickle cell disease by not hiring applicants with the sickle cell trait. However, this objection is wrong in two ways. First, according to the National Institutes of Health there are approximately 900 different genetic tests offered through various laboratories,[27] ranging in price from $100 to $2000.[28] The discrepancies are due to the uniqueness of the disease being tested for and complexity of the screening for that disease.

[26] While this does seem somewhat extreme, it may be the only way to ensure that applicants who do not wish to be directly associated with their results are able to do so.

[27] National Human Genome Research Institute, National Institutes of Health (September 2004). National Institutes of Health, Washington, DC. April 29, 2005, available from http://www.genome.gov/10506784.

[28] United States National Library of Medicine: National Institutes of Health. April 22, 2005. National Institutes of Health, Washington, DC. April 29, 2005, available from http://ghr.nlm.nih.gov/info=genetic_testing/show/cost_results.

Depending on the number of applicants being screened and for which diseases, the costs employers incur for these screenings may, in some cases, be more than if employers attempted to eliminate hazardous workplace exposures.

Second, even if requiring pre-employment genetic screenings is more effective than cleaning up workplaces, employers still have an obligation to maintain a level of cleanliness and safety that aims at protecting all employees from foreseeable harms. So while being exposed to hemolytic chemicals may cause individuals with the sickle cell trait to develop a sickling crisis, the health of those without the trait who are also exposed to the chemicals may also be negatively affected. Employers who would use genetic screenings as a way to avoid cleaning up workplaces neglect to consider the importance of maintaining a clean work environment for the sake of all their employees, not just the ones with hypersusceptibilities.

The second objection is that it is too difficult to enforce the conditions of justification, consent, accuracy, and confidentiality. Here again the law is an ally. Although legal measures cannot predict the multiple varieties of pos sible violations, laws can set sanctions that penalize employers who fail to meet these conditions. Laws that forbid the discrimination of employees based on their genetic information already exist. Yet, in addition to a company's codes of ethical behavior, new laws are necessary to enforce the conditions of required pre-employment genetic screenings. These new laws should be designed to apply across multiple industries, with fines varying based on the nature and degree of the violation. For instance, an employer will face a heavier fine for discriminating against an applicant if the required genetic screening was unjustified and illegitimately coercive, as opposed to the genetic screening being unjustified, yet non-coercive.

In addition to the law, employers should have an ethics policy specifically addressing pre-employment genetic screenings that outlines the conditions for requiring these screenings, as well as examples of what does not count as permissible under those conditions. Employers should explicitly state their justifications for requiring genetic screenings, citing the evidence of correlations between certain hypersusceptibilities, genetic diseases, and workplace exposures, while also listing any conditional exceptions for applicants refusing to be screened; and why, if the screenings are coercive in certain situations, they believe the screening is still justified. Employers should also provide information concerning the accuracy and confidentiality of the screenings, addressing how the information is obtained and used. Lastly, a copy of the policy should be given to all applicants for review *before* consenting to have a genetic screening.

While it may be difficult to enforce the conditions of required genetic screenings for applicants, it is possible. The conditions are enforced through laws penalizing violations, as well as through company ethics policies that applicants must agree to, outlining the justifications for the screenings. If the ethics

policies fail to avoid genetic discrimination, the applicants are able to appeal to the law. If, however, the ethics policies and the law both fail to avoid genetic discrimination, enforcing these conditions may need to occur through other means, such as protests against employers or appeals to the media. Enforcing these conditions may also require having internal or independent task forces whose job is to ensure industry-wide compliance. This may also help curb any possible "free-rider" problems by making all employers meet these conditions rather than just a few.

Those who believe required genetic screenings in the hiring process provide an alternative to cleaning up workplaces or that the conditions of justification, consent, accuracy, and confidentiality are too difficult to enforce, may be correct that without proper regulations this fairly new form of applicant screening will be abused by employers. However, requiring genetic screenings as part of the hiring process should not be viewed as anything other than what it is – a managerial tool helping in the decision-making process.

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2

The Business Ethics of Genetic Screening

Duane Windsor

Introduction

Business ethics and public policy face a complex "brave new world" (Curley & Caperna, 2003) of biotechnology innovations affecting both humans and other organisms. The constellation of business ethics issues arising in biotechnology innovations includes the health care and employment implications of human genome sequencing, as well as genetically modified organisms (GMOs), DNA sampling of human populations (Baird, 1995), human DNA banking and biobanking (Blatt, 2000; Tavani, 2004; Van Orden, 2005), cloning of organisms including humans and organs including human, stem cell research, ownership of embryos or fetuses or genetic information (Suter, 1993; Berg, 2005), and genetic information patenting. This constellation generates ample scope for ethical concerns and public policy debates (de Carvalho, 2005). A new field of "genethics" is in the offing (Knoppers, 2000). The recent scandal concerning alleged human cloning fabrications by a South Korean researcher illustrates misconduct possibilities.

This chapter focuses narrowly on the business ethics and public policy of genetic screening. Business ethics concerns voluntary or expected moral standards for the conduct of a business or a businessperson. Material gain is a powerful motivator of behavior; it may or may not be consistent with moral conduct. There are situations in which business profit must be sacrificed to public interest; the legal basis for such situations is well established (Elhauge, 2005). The justification for pursuit of material gain must be that markets promote social welfare in some respect; the limit on pursuit of material gain is where markets degrade social welfare in some respect. Public policy in this context addresses circumstances in which voluntary business self-regulation proves insufficient.

On June 26, 2000, Prime Minister Tony Blair (United Kingdom) and President William J. Clinton (United States) announced jointly at the White House that the International Human Genome Project and the Celera Genomics

Corporation had both completed initial sequencing of the human genome. On February 12, 2001, the Human Genome Project sequencing centers and the Celera Genomics Corporation jointly announced initial analysis of the human genome sequence and publications in *Nature* (Lander et al., 2001) and *Science* (Venter et al., 2001), respectively. The history of the two projects was reviewed at the time by the staff of *Science* (Staff, 2001).

Ojha and Thertulien (2005) conclude that this genetic revolution generates four key issues for public health: genetic privacy, regulation and standardization of genetic tests, gene patenting, and education of society and health care professionals. Genetic and molecular assessments are likely to become routine components of health care in the future. The Centers for Disease Control (CDC) estimated in 2003 that about 600 of some 1,000 genetic tests for health conditions were already available for clinical testing (Ojha & Thertulien, 2005). Presumably, an individual will be able eventually to obtain a full genetic scan at relatively low cost. This fact alone raises the issue of whether insurers should be obliged to pay for such scanning; and if so, excluded from access to the genetic test information.

The present chapter is concerned with genetic privacy and the implications of nonprivacy for inappropriate discrimination against individuals and groups. New biotechnology has raised considerable medical, popular, and political concern over the possibility of discriminatory practices (Weiss, 2004). "Recent scientific breakthroughs have opened new doors for medical researchers analyzing DNA, RNA, and chromosomal changes. While the advancements yield promising hope for individuals diagnosed with rare genetic diseases, they also can lead to discriminatory practices in the health insurance market and in the workplace" (U.S. Senate, 2005, p. 3).

The two likely practices of immediate concern are business screening of insurance applicants and of employees. One concern deals with consumer rights (specifically insurance access and pricing); the other concern deals with employee rights (specifically job standards and health costs). Three issues are immediately indicated.

One issue is whether these rights are fundamental human rights, rights universal for all individuals everywhere, and as such necessary and inherent attributes of being human. The weight of considerations is that the rights involved are fundamental and universal. In the United States, the rights should be viewed as fundamental liberties protected by extension of the Bill of Rights.

A second issue is whether reliance should be placed on business voluntary self-regulation and by implication the proposed "Iron Law of Responsibility" (Davis, 1973). This approach favors deference to business ethics relative to public policy action. The latter should occur when and only if business ethics fail – assuming that a failure of social legitimacy of a business or an industry is sufficient to provoke an effective public policy response. Dodd (1932) was

explicit that he did not favor reliance on discretionary corporate social responsibility by managers but rather favored strengthening legal protections for consumers and employees (Weiner, 1964). The weight of considerations favors immediate public policy action as a safeguard. The article argues that in this particular instance – genetic screening of individuals – the weight of considerations falls on the side of a variant of the so-called "precautionary principle."

A third issue is the content of public policy, whether addressed immediately or delayed in deference to business voluntary self-regulation. Nothing prevents consideration now of what to do if the "Iron Law of Responsibility" (Davis, 1973) becomes a necessity. The weight of considerations favors a complete ban on business use of individual genetic information. Exceptions may be required, especially in employment as distinct from insurance. But the burden of proof for such exceptions must rest on business rather than on society or individuals. The burden of proof is always an important matter. Clear and enforceable rights also affect the burden of transaction costs in a market economy. The basic argument for business access is profitability: to have weight of consideration, that access must lead to social welfare.

The presumption properly must be in favor of individuals' rights to privacy and nondiscrimination as against business needs or business opportunities. No business is morally free to require, acquire, or use individual genetic information for insurance or employment purposes. The property rights to genetic information (Spinello, 2004) rest inherently (and organically) in the individual human being and cannot shift to whoever manages to capture that information in some manner. Genetic information cannot be regarded as discarded private information or property that becomes subject to business capture (Van Orden, 2005).

Legislative action should be undertaken to prohibit business, under civil and criminal penalties, from doing anything with individuals' genetic information. Action should proceed now and on a variant of the precautionary principle. That principle has defects; but the defects seem least relevant in relationship to rights of privacy and nondiscrimination with respect to personal genetic information. Some genomic information may be individual property; some may prove to be a commons (Rifkin, 2000). Some groups of people presently may be protected under some statutes in the United States or elsewhere (e.g., civil rights, disabilities, etc.). But such protection is very uneven. There may be legitimate exceptions to a general ban, but burden of proof rests on business to demonstrate social utility (not business profitability) of exceptions. The immediate bases for a general ban are individuals' rights to privacy and nondiscrimination, and a precautionary principle with respect to genetic information control. Broader bases rest on consumer and employee protection rights – still very poorly developed. The social case for restriction is that genetic predisposition is a random lottery within the population.

The remainder of this chapter is structured as follows. The next (second) section examines the three basic elements of the policy issue: the social role of business, consumer rights in insurance matters, and employee rights in job matters. The third section examines the Genetic Information Nondiscrimination Act of 2005 (S. 306), which was passed by the U.S. Senate (98 to 0, with two present but not voting) in February 2005, with Bush Administration and strong bipartisan support, and which as of December 2006 was awaiting U.S. House action as H.R. 1227 (according to a search of the Library of Congress THOMAS information system). The proposed law appears to be generally satisfactory for addressing employment and insurance matters. The proposed law should be evaluated closely according to the strict standards proposed in this chapter. The section also looks briefly at the employment posture of the European Union (EU). The fourth section discusses a proposed precautionary principle for employment and insurance protection. A precautionary principle in this context urges full protection of individual rights to privacy and nondiscrimination. The concluding section summarizes the key arguments of the chapter.

Basic Elements of Insurance and Employment Issues

Nondiscrimination in insurance and employment is closely linked to privacy or confidentiality of genetic information. Nondiscrimination policy implies privacy policy as a strong corollary. The latter is necessary, if not automatically sufficient, to the former. The United States presently prohibits discrimination on the basis of a number of observable attributes such as race or gender, and on the basis of information that would have to be discovered from an individual such as religion or national origin (of naturalized citizens or permanent residents). Privacy, while arguably not a perfect constitutional or legal right, is a strongly held and customary value in American society.

There is a strong presumption in favor of privacy. The Fourth Amendment to the U.S. Constitution reads: "The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no warrants shall issue but upon probable cause, supported by oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized." The amendment addresses state action only and not private (i.e., business) activities. But the extension to a person's genetic information is hardly a conceptual stretch: nothing more personal can be imagined. The meaning of the amendment points to reasonableness and probable cause as standards for state action. Vague genetic tests, the current state of science, hardly meet those standards. Perfect genetic tests may generate future difficulties for discussion, but even so reasonableness and probable cause for access to such tests and resulting test

information would seem strong guides signaling privacy and nondiscrimination policies even in private action.

The Bill of Rights does not directly and explicitly protect privacy as a listed right. Nevertheless, privacy is a fundamental liberty. How much more private can genetic information be? The key judicial opinion on privacy, a well-established law, is *Griswold v. Connecticut* (381 U.S. 479, 1965). The opinion held that the Bill of Rights is not flatly restricted to its specific language. Rather the Bill of Rights creates "penumbras" (i.e., zones) around the First, Third, Fourth, and Ninth Amendments (*Griswold*, pp. 481–486). This set of "penumbras" creates a "new" constitutional right to (technically this author would urge recognition rather than creation of) privacy in marital relations. The state of Connecticut had criminalized anti-contraceptive counseling and treatment for married persons. The state convicted Griswold (Executive Director, Planned Parenthood League of Connecticut) and Dr. Buxton (Medical Director and a Yale Medical School professor), as accessories, and fined each $100. The finding of *Griswold* is that privacy, albeit violated under certain conditions, is a fundamental liberty. The finding deals with interpersonal relations, and not even with intraperson gene information.

The three basic elements of the policy issue are the social role of business, consumer rights in insurance matters, and employee rights in job matters. Each element is examined below in a separate sub-section.

Social Role of Business

Currently, genetic screening amounts to use of blood samples to determine what may be predispositions (risks) for certain diseases and traits – without respect to actual occurrence or severity. Genetic tests are presently vague. Public health cases for genetic screening of individuals, or groups, such as risk for sickle cell anemia, must be weighed against the unfortunate history of eugenics. The presumption must be that even mandatory genetic information is the property of the individual and subject to strict medical confidentiality. A business operates to maximize the wealth of investors and their agents. Any firm ideally wishes to practice perfect price discrimination under conditions of coercive monopoly and asymmetric information. Actuarial insurance illustrates this principle: firms understandably prefer to sell insurance to low risk customers (and at high margin). It must be presumed businesses disregard ethics and laws other than as externally enforced constraints obeyed only to the limits of cost-benefit calculations concerning the firm's bottom line. Upon this analysis, no firm can be trusted with individuals' genetic information or expected to operate as a social agent. This comment is an application of the precautionary principle rather than an empirical assertion.

Consumer Rights in Insurance Matters

Adam Smith was clear that demand is superior to supply. The latter responds to the former. Consumers are not automatically entitled to insurance except by public policy requirement. Investors must decide on the supply side of insurance markets whether to meet consumer demand for coverage of various types. In some instances, governmental action to provide insurance protection may be necessary. There is however a reasonable basis for arguing that there should not be discrimination in insurance coverage, where extended, on suspect grounds (e.g., race, gender, religion, etc.). A developing economics literature seeks to demonstrate a basis for insurance pricing discrimination using genetic information (Hoy & Lambert, 2000). This literature argues efficiency effects of insurance markets. One can divide situations between compulsory health insurance (e.g., Canada) and voluntary health insurance (e.g., United States). The former situation must address pricing variations. The latter situation must address in addition access. In the U.S. setting, health insurance is voluntary: no insurer is obliged to extend coverage. Insurers will deny access or practice price discrimination by compulsorily required genetic information. Privacy and nondiscrimination argue against such practice. Insurers may have to be restricted to pricing insurance pools. The proposed Genetic Information Nondiscrimination Act addresses underwriting practices.

Employee Rights in Job Matters

In the United States, in the absence of constitutional considerations, employment is effectively at will: at the discretion of the employer. Otherwise, an employee or applicant would possess a strong right to specific employment. As with insurance coverage, there is a reasonable basis for arguing that there should not be discrimination by suspect categories or attributes. There are arguably legitimate exceptions for job-related risks such as susceptibility to toxic environments and so forth. Genetic tests are presently vague. Exceptions should be subjected to special scrutiny. Businesses have motives for advancing arguments to self-interest without respect to effects on others or on society. Burden of proof falls squarely on business. Generally privacy and nondiscrimination should be the prevailing principles for business ethics and laws. Where the effects are health related (affecting business insurance costs), then an alternative to business use of genetic information is reform of insurance coverage and pricing. U.S. policy is committed to full employment (implying potentially governmental employment if necessary); such policy is vitiated by widespread use of screening practices that would effectively deny any employment to a particular individual, unable to find any job. Public policy would have to provide employment or compensation.

The Genetic Information Nondiscrimination Act

"Current law already protects the use and disclosure of all individually-identifiable health information, including genetic information. These protections are included under the Department of Health and Human Services (HHS) Standards for Privacy of Individually Identifiable Health Information . . ." (U.S. Senate, 2005, p. 4). The Health Insurance Portability and Accountability Act of 1996 (HIPAA) provides some protection for some individuals against genetic discrimination. It bars use of individual genetic information in denying or limiting health insurance coverage for members of a group plan. The law does not provide, however, any protection for individuals outside of group plans. The law does not prohibit rating based on genetic information. The law does not prohibit health insurers from disclosing or demanding access to genetic information.

There is bipartisan support for increasing protections for individuals. On February 8, 2000, President Clinton issued Executive Order 13145 prohibiting discrimination in U.S. government employment based on predictive genetic information. Clinton stated: "Today, powerful ways of technological change threaten to erode our sacred walls of privacy in ways we could not have envisioned a generation ago" (McQuillan, 2000). On June 23, 2001, President George W. Bush asked Congress to pass a law regulating this area.

The Genetic Information Nondiscrimination Act of 2005 (S. 306), introduced February 7, 2005, 109th Congress, by Senator Olympia Snowe (R-ME) with cosponsors, would prohibit discrimination on the basis of predictive genetic information with respect to health insurance and employment. The bill, amended, was reported out favorably by the Senate Committee on Health, Education, Labor, and Pensions (HELP) on February 9. The Enzi Amendment, a substitute, made technical corrections to the bill. The Senate, 98-0 and two present but not voting, passed the amended act – supported by the Bush Administration – on February 17. On March 10, Representative Judy Biggert (R-IL) with over 240 cosponsors introduced H.R. 1227, the Genetic Information Nondiscrimination Act of 2005. The bill was referred to appropriate House committees. House action had not occurred as of December 2006. Senator Snowe had introduced the bill previously in the 108th Congress (S. 1053) on May 13, 2003, with cosponsors. Reported out favorably by HELP, with the Gregg Amendment, a technical substitute, the bill passed the Senate 95-0, but was not acted on in the House during the 108th Congress.

The proposed law defines genetic information as information (other than age or sex) about the genetic tests of an individual or family member or the occurrence of a disease or disorder in family members of an individual. The proposed law defines a genetic test as an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or

chromosomal changes. The bill specifically excludes any analysis of proteins or metabolites that does not detect such attributes or any analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by an appropriately trained and expert health care professional. In the area of insurance, the proposed law prohibits: (1) using genetic information for enrollment restrictions or premium/contribution adjustments; (2) requesting genetic testing or test results except as necessary for treatment, payment, or health care operations; or (3) requesting or requiring use of genetic information for underwriting. In the area of employment, the proposed law prohibits: (1) discrimination against individuals by employers, employment agencies, labor organizations, or training programs on the basis of genetic information; or (2) collection of genetic information, unless required by law, except as necessary to monitor workplace toxic substances or when requested by the employee. The proposed law safeguards confidentiality of genetic information in the workplace.

The proposed law would require the Secretaries of HHS, Labor, and Treasury to issue implementing regulations and would require enforcement activities by the Secretaries of HHS and Labor and the Equal Employment Opportunity Commission (EEOC). The proposed law would establish a commission to review the science of genetics and to make recommendations concerning whether to establish a disparate impact standard for genetic discrimination. (The issue concerns situations in which there is no intentional adverse action, but nevertheless there is disparate impact on some category of persons.) The proposed law would preempt some state laws and restrict state and local government use of genetic information in employment and employee health care practices. The proposed law would operate in effect through Title VII of the Civil Rights Act, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and the Employment Retirement and Income Security Act (ERISA).

Concerns about impacts so far may be considerably overblown. It has been reported that there is no evidence of use of genetic information by health insurers, and that considerable state and federal consumer protections are in place (Desmarais, 2002). The Congressional Budget Office (CBO) estimated (February 14, 2005) that the proposed law would increase the number of individuals obtaining insurance by only about 1,000 annually. Those individuals have rights to be protected. A small number does not invalidate acting on the basis of a precautionary principle: the issue is rather whether there is any harm to business and society from public policy protection in this area. Many employees have concerns that discrimination may occur (Armour, 1999), and reassurance may have a functionally useful role. The National Partnership for Women and Families (2004, p. 3) reports instances of inappropriate use of genetic information for employment and insurance discrimination. Surveys by the Johns Hopkins University Genetics and Public Policy Center, "Public

Awareness and Attitudes about Genetic Technologies," suggest that the proportion of respondents opposed to business access to genetic information is high and rose from 85% in 2002 to 92% in 2004 concerning employers and from 68% in 2002 to 80% in 2004 concerning insurers. Among college-educated respondents, about 97% oppose business access in both employment and insurance. These data suggest also that there is greater average concern about employment discrimination than about insurance discrimination. However, it should be noted that any systematic employment discrimination would link on to exclusion from company-sponsored group insurance plans. The difference between the general population and college-educated population might be explained by greater awareness or greater concern, or simply as a calculation concerning reservation of rights.

The European Group on Ethics in Science and New Technologies (EGE, 2003) issued an opinion on workplace genetic testing that is generally supportive of the positions taken in the Genetic Information Nondiscrimination Act.

There may be unavoidable obligations to carry out workplace genetic testing for the safety of the workforce and others. "Employers have a duty to protect members of their workforce and other parties that might possibly be harmed as a result of either sudden or progressive sickness of an employee. It is possible that in some cases, genetic testing of an employee might be the only way of ensuring that this duty is carried out. Employers also have a primary duty to ensure that employees are provided with a safe working environment and are not exposed to harmful occupational hazards" (EGE, 2003, p. 13, 1.11.2. Duties of Employers to Employees and Other Parties).

There is little scientific basis for thinking presently that genetic tests have much predictive value. "... An applicant's ability to carry out the work is sometimes also assessed during a medical examination. Working contracts are often subject to a probationary period – an additional safeguard for the employer. A genetic test of limited predictive value would add nothing to knowledge of an applicant's ability to carry out the work at the outset and would give very little information on how this might change in the future" (EGE, 2003, p. 13, 1.11.3. Employee's Ability to Carry Out Work).

The weight of considerations favors individual rights over business applications. "Another ethical issue is the validity of a test, its relevance, reliability and predictive value. At the present time very few tests would achieve a high score in all of these categories. It would be manifestly unfair to base important decisions regarding employment or promotion on the results of tests either of dubious relevance or with low reliability or predictive value. Any benefits emerging from such tests in terms of protection of employees or third parties could be greatly offset by suffering resulting from false negatives and false positives" (EGE, 2003, pp. 13–14, 1.11.4. Validity of Genetic Tests).

A Precautionary Principle for Privacy and Nondiscrimination

There may prove to be health reasons or employment reasons for mandatory genetic testing in particular instances. S. 306 recognizes some of these reasons, such as unusual sensitivity to toxic substances. It is an open issue perhaps as to whether addictive behaviors such as smoking or drinking might have a genetic basis that would be useful information in treating a patient (Cutler & Glaeser, 2005). These possibilities make an absolute ban approach difficult.

This section argues that a precautionary principle is valid for justifying a policy of explicit protection of privacy and nondiscrimination rights. The principle places burden of proof on anyone seeking access to individuals' genetic information. The application of the principle in this context is that under no circumstances should violation of personal privacy, or individual or group discrimination occur on the basis of genetic information – unless there is a persuasive demonstration that the precautionary principle should be abandoned in specific instances. Even in that circumstance, specific instances do not invalidate the precautionary principle as a general approach. This expression of position suggests that a rule of privacy or nondiscrimination is not automatically an absolute ban regardless of circumstances: there may be exceptions to the precautionary principle that must or ought to be accepted – after careful investigation. Exceptions must reflect a careful cost-benefit analysis (Masood, 1996) weighing individual interests against community (i.e., commonwealth) interests. There may be circumstances (hypothetically) in which the latter could be superior to the former. The following stricture is therefore highly pertinent: "Privacy erodes first at the margins, but once eliminated, its protections are lost for good, and the resultant damage cannot be undone" (Bunce, 2005, p. 747).

Dworkin (1978, pp. 22–28) distinguishes among rules, principles, and policies as types of standards. A "policy" is a community goal (i.e., an economic, political, or social situation) to be reached or maintained. A "principle" is "a requirement of justice or fairness or some other dimension of morality" (Dworkin, 1978, p. 22). "Thus the standard that automobile accidents are to be decreased is a policy, and the standard that no man may profit by his own wrong a principle" (Dworkin, 1978, p. 22). "Rules are applicable in an all-or-nothing fashion" (Dworkin, 1978, p. 24): the facts of a situation determine whether the rule is applicable. Any exception to a rule compels a redefinition of the rule (Dworkin, 1978, p. 25). "If two rules conflict, one of them cannot be a valid rule" (Dworkin, 1978, p. 27). A rule is functionally important only – i.e., useful, and rule conflict must resolved by "considerations beyond the rules themselves" (Dworkin, 1978, p. 27). "Principles have a dimension that rules do not – the dimension of weight or importance" (Dworkin, 1978, p. 26). A

principle inclines a decision one direction or another (Dworkin, 1978, p. 26). Where principles conflict, the relative weight of the principles must be considered (Dworkin, 1978, p. 26).

A precautionary principle is grounded in a realistic problem: ". . . decision-makers are constantly faced with the dilemma of balancing the freedom and rights of individuals, industry and organisations with the need to reduce the risk of adverse effects to the environment, human, animal or plant health. Therefore, finding the correct balance so that the proportionate, non-discriminatory, transparent and coherent actions can be taken, requires a structured decision-making process with detailed scientific and other objective information" (Commission, 2000, p. 3).

The "precautionary approach" appears in the Agenda 21 declaration, the Rio Declaration on Environment and Development (Commission, 2000, p. 11), adopted along with the Statement of Principles for the Sustainable Management of Forests, by more than 178 governments at the UN Conference on Environment and Development (UNCED) at Rio de Janeiro (June 1992). Chapter 35 of Agenda 21 on "Science for Sustainable Development" states the approach as follows at the end of Paragraph 3 (35.3): "In the face of threats of irreversible environmental damage, lack of full scientific understanding should not be an excuse for postponing actions which are justified in their own right. The precautionary approach could provide a basis for policies relating to complex systems that are not yet fully understood and whose consequences of disturbances cannot yet be predicted." The precautionary principle basically states that the possibility of irreversible damage should ban activity or compel action despite lack of "full" scientific understanding. The key word in the statement of the principle is "full" – a word left undefined.

The UN General Assembly's World Charter on Nature (October 1982) (Commission, 2000, p. 11) hints at the principle, without invoking the specific term. In Paragraph 11, concerning control of activities "which might have an impact on nature" and use of "the best available technologies" to "minimize significant risks to nature": "(a) Activities which are likely to cause irreversible damage to nature shall be avoided; (b) Activities which are likely to pose a significant risk to nature shall be preceded by an exhaustive examination; their proponents shall demonstrate that expected benefits outweigh potential damage to nature, and where potential adverse effects are not fully understood, the activities should not proceed . . ." The key word is "fully" – a word left undefined. The Charter does suggest at Paragraph 12 (b) that: "Special precautions shall be taken to prevent discharge of radioactive or toxic wastes."

The EU addressed potential risks from GMOs by adopting the precautionary principle. This principle essentially would restrict use of GMOs until scientific evidence of absolute safety is firmly established. Evaluation of the principle is complicated by the concrete circumstances that the EU was

(1) directly restricting entry of food products derived from essentially U.S. and U.S.-derived GMOs, and (2) responding to strong European "green" consumer objections to such food (and by extension other) products. It may be the case that the policy is in reality un-principled and a masquerade for a politically and economically motivated posture.

The EU placed a five-year freeze on new biotechnology products as a practical application of the precautionary principle. In June 2003, the United States, Canada, and Australia – major food crop exporters – filed a complaint with the World Trade Organization (WTO) that the EU ban violated the WTO trading system. In July 2003, the EU Parliament approved legislation to permit sale of biotech foods that were clearly labeled as GMO, so that consumers would have the choice to avoid (and boycott) such foods. The step signaled effective abandonment of the precautionary principle in favor of labeling, which may have its own difficulties (Galant, 2005).

Objections have been raised that the proposed "principle" is ambiguous (Feintuck, 2005). Something approaching absolute certainty of scientific evidence appears unattainable. And any risks of GMO usage might not be encountered for decades. The "principle" is not a cost-benefit approach, a weighing of risks against benefits. The "principle" is simply an absolute ban until absolute certainty of safety is established. "It should however be noted that the precautionary principle can under no circumstances be used to justify the adoption of arbitrary decisions" (Commission, 2000, p. 13).

A global application of this "principle" itself creates hazards because all options in social situations involve risks (Sunstein, 2004). The "principle" looks sound in some situations only because some hazards are perceived to be more salient than other hazards (Sunstein, 2004). From this viewpoint, the European approach to the GMO looks like a politically and economically motivated posture (Sunstein, 2004), rather than an application of scientific methodology to evaluation of risks. Accepting the imprecision of the term, Feintuck (2005) argues that the notion may still serve to assert public domain values – a collective orientation – against powerful private interests (e.g., economic interests and technological imperatives) in this particular instance.

GMO crops can have benefits. The first generation of such crops focused on farmer profitability through production-cost reductions or higher yields (Anderson, 2004). GMO crops may reduce chemical pesticide use. The second generation of GMO crops focuses on attributes of interest to consumers (Anderson, 2004). For example, "golden rice" features a higher level of vitamin A that could improve the health of unskilled labor in developing countries (Anderson, 2004). There is also documented risk of open spread of GMO seeds and cross-contamination of products (Swiss company, 2005). In September 2000, DNA fragments from "StarLink" GMO corn approved only as animal feed were found in taco shells being sold in stores for human consumption.

In November 2000, the FDA recalled some 300 types of adulterated corn foods. Voluntary business self-policing had failed in some manner.

Goeschl et al. (2005) suggest that the current arrangements for global exchange of biological information may incentivize ecological destruction. They argue that the existing stock of natural genetic resources is largely in the countries of the South. Biotechnological innovation occurs largely in the North. A result is potentially increased threat to the biodiversity stock and increased stress on conservation efforts. They conclude that there ought to be a careful examination of the global costs and benefits of the current arrangements. Their line of reasoning hints at a variant of the precautionary principle: the global biodiversity stock is more important in the long run than more immediate biotechnology innovation.

Originating in environmental protection, the precautionary principle has acquired wide legal applications (Sunstein, 2003; Feintuck, 2005). "Hence this principle has been progressively consolidated in international environmental law, and so it has since become a full-fledged and general principle of international law" (Commission, 2000, p. 11). "The precautionary principle is not defined in the [EC] Treaty, which prescribes it only once – to protect the environment [environment title, specifically Article 174]. But *in practice*, its scope is much wider, and specifically where preliminary objective scientific evaluation, indicates that there are reasonable grounds for concern that the potentially dangerous effects on the *environment, human, animal or plant health* may be inconsistent with the high level of protection chosen for the Community" (Commission, 2000, p. 3).

Most generally, the principle places the burden of proof on the creator of a potential risk (e.g., GMO manufacturer). Additionally, the principle requires regulation of activities (e.g., GMO food crops) even though there is no showing of likely significant harms. In this broad form, the precautionary principle is simply a paralyzing ban on change (Sunstein, 2003). As Sunstein points out, the principle assumes for example that nature is always benign. Sunstein invokes various examples, some controversial, concerning global warming, nuclear power, pharmaceuticals, pesticides, cloning, and GMOs (see also Hahn & Sunstein, 2005). Sunstein suggests that such decisions should be tackled in ways other than the precautionary principle. Sunstein (2005) points to what he labels "laws of fear" impeding progress. The proposed alternative is cost-benefit analysis (Hahn & Sunstein, 2005). This proposal can be reconciled with Feintuck (2005) if what Feintuck means by public domain values or a collective orientation is the objective interest of the majority, as distinct from the subjective belief (if "fear") of the majority.

This section has reviewed briefly the history of the precautionary principle in order to establish that a principle rather than a rule (i.e., an absolute ban) should be at work in regulation of genetic information. The precautionary

principle arose in environmental protection and has spread to other areas of application. It has the appeal of caution against potentially irreversible effects of scientifically uncertain changes. It has the potential defect of halting any progress unreasonably. The EU, in the GMO question, arguably distorted the "principle" into a rule functioning as an absolute ban. A principle must weigh considerations. "The precautionary principle, which is essentially used by decision-makers in the management of risk, should not be confused with the element of caution that scientists apply in their assessment of scientific data" (Commission, 2000, p. 3). "The precautionary principle is relevant only in the event of a potential risk, even if this risk cannot be fully demonstrated or quantified or its effects determined because of the insufficiency or inclusive nature of the scientific data" (Commission, 2000, p. 13). In certain circumstances, division of qualified opinion can invoke a precautionary principle. The European Commission makes this linkage, drawing on the WTO Appellate Body report on hormones, Paragraph 194: "In some cases, the very existence of divergent views presented by qualified scientists who have investigated the particular issue at hand, may indicate a state of scientific uncertainty" (Commission, 2000, p. 17, note 2).

Conclusion

This chapter narrowly focuses on human rights of consumers and employees to privacy and nondiscrimination with respect to personal genetic information. These human rights are universal, although they may not be strictly absolute. The human rights position asserted here does not depend on any argument regarding human exceptionalism. Humans obviously have these rights if other organisms do; and they have these rights in this particular instance without regard for other organisms – one way or the other.

The weight of considerations is that the U.S. House should join the U.S. Senate, supported by the Bush Administration, in passage of the proposed Genetic Information Nondiscrimination Act. The states similarly should protections, as should the EU. The consumer and employee rights addressed in the proposed law should be regarded as universal human rights. The rights are grounded in strong privacy and nondiscrimination principles. A precautionary principle should be applied: exceptions to these privacy and nondiscrimination rights should have a strong public interest foundation; and the burden of proof should be on the proposer and beneficiary of exceptions. The precautionary principle, arising in environmental protection, has become more broadly applied. It arguably has various defects. These defects do not appear to affect its use for protection of privacy and nondiscrimination rights. A precautionary principle links such rights, solidly grounded and universal if not absolute, to public policy action. The precautionary principle suggests public policy

protections in preference to reliance on business voluntary self-regulation. The forces for material gain are powerful enough that there should be strong public policy constraints on business access to individual genetic information for any employment or insurance purposes. There may be appropriate exceptions, but the burden of proof is on business. In some instances, governmental action – to support employment or insurance – may prove necessary and desirable in order to preserve the precautionary principle concerning genetic information protection.

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3

Genetic Commerce: The Challenges for Human Resource Management

Karen S. Markel and Lizabeth A. Barclay

Purpose of this Chapter

The American Civil Liberties Union reports that genetic testing in the workplace is on the rise. Genetic testing is the ability to determine the presence of a genetic marker for a specific disease or condition. In 1982, a federal government survey reported that 1.6% of responding companies were using genetic testing. In a survey conducted by the American Management Association in 1997, 6–10% of employers were found to be conducting genetic testing (American Civil Liberties Union, 2000). With the completion of the Human Genome Project (HGP), scientists have the ability to define individual genetic composition. In turn, other scientists are now working on new ways to test for genetic conditions that may indicate individual predisposition to known diseases such as cancer. While this research is noble in its cause, it could have a negative impact on society in terms of how this information is (mis)used. Organizations, in particular, must be cautious in their use of genetic testing for current or potential employees.

There are two main uses of genetic testing for organizations: screening and monitoring. Genetic screening is used in the selection process to determine if a potential employee is genetically fit for employment. Diamond (1983) described this as the "ascertainment of susceptibility to future harm" (p. 232). Genetic monitoring is used to examine if the organization's current workforce may have a certain genetic predisposition that may inhibit their ability to perform a specific job (e.g., hazardous work environment). Monitoring is designed to find actual harm (Diamond, 1983). These applications of genetic testing will be discussed throughout this chapter. In particular, we will examine the ethical, political, strategic, and practical concerns for human resource management (HRM) responsibilities within organizations as they pertain to the various forms of genetic testing. A prescription for how HR professionals will need to address these concerns is also proposed.

The Challenges for Human Resource Management

Ethical

HR managers may become the boundary spanners between society and the organization in terms of the ethical treatment of employees with regards to genetic testing. Organizations will no doubt consider using the information collected through genetic testing for the purposes of employee recruitment, promotion, and retention. Organizations generally use testing of many types to protect their human capital and their investment in that capital. Potential employees may be tested as part of the screening process, or even for internal promotions or retention if specific job environments change. Therefore, it is natural to assume that organizations might consider genetic test as a new protocol as genetic tests validity increases.

As previously mentioned, organizations have two primary uses for genetic testing: screening and monitoring. However, unlike many currently used personnel tests, individuals may argue as to the timeliness of genetic testing for organizational purposes. For example, if the testing results merely indicate the presence of a genetic marker for a disease, but the disease itself has not occurred, there is an issue as to how the organization might use this information. The case of Huntington's disease (Huntington's) illustrates our point. Huntington's is a degenerative condition of the central nervous system that usually develops at around age 30 or 40. Affected individuals become severely debilitated and require extensive assistance until an often premature death. Should an organization make an employment decision based on this knowledge? There is no guarantee that any employee will remain employed or healthy over time. In addition, through genetic testing, an individual may be identified as a carrier for a particular condition. Just because an individual might be a carrier for the disease (only has one of the necessary two genes), does not indicate that the affected individual will develop the disease. Therefore, if a current or potential employee tests positively as a carrier, the organization might now consider the new increased insurance liability they may take on; however, while this individual will not develop the disease, his or her children might. The ethical issue arises because this could be an area where these individuals may be discriminated against. Is the risk of future cost (e.g., an employee's child manifesting the disease) warranting the exclusion of a healthy individual? In such a case it is not unreasonable to suggest that some organizations would exclude the individual for other "stated" reasons. In fact, a recent article in the *Wall Street Journal* (Lublin, 2004) indicated that job applicants were not disclosing chronic illnesses because they believed that they would be screened out of a job because the employer would perceive higher costs associated with such a hire. These

applicants believed that the employer would find other "reasons" to not hire them.

Of additional concern here, is whether an organization's practice of genetic testing may be subject to tests of adverse impact. Human resource professionals will have to determine whether a program of genetic testing (un)intentionally discriminates against individuals of protected groups with certain genetic imperfections. Genetic markers may have ethnic group links.

HR managers will also have to determine if the genetic testing is truly job related; a very subjective area. It may be relatively clear cut if an organization is trying to determine whether an individual may have a predisposition to developing a problem in a potentially hazardous environment. For example, in *Echazabal v. Chevron* (reported in Little & Makee, 2002–2003), Echazabal was denied employment because he had hepatitis C. The job he wanted could have worsened his condition. The Supreme Court in a 9-0 ruling said, "by hiring employees whom they know will be injured by the job, employers could be complicit in injury" (p. 302). Although this case was not related to genetic makeup per se, it suggests that employers may increasingly avail themselves of genetic (medical testing) technology to reduce risk exposure.

However, this issue becomes less clear when genetic testing may be used to screen for psychological or behavioral traits. For example, Brock (1994) states, "the Human Genome Project [this has mapped the human genome structure] will eventually enable us to understand human motivational and character traits as having important genetic determinants" (p. 26). Such identification of genes or disease locations could lead to a reductionism approach. If society believes that inappropriate employee behavior can be reduced to genetic causes, the ways individuals are selected, trained, or evaluated could radically change without input from those in our field.

Based on the above discussion, do employees have a right to refuse to provide genetic information or submit to this testing? As discussed in the next section of this chapter, it is still unclear where the legal environment stands on this issue, but many potential or current employees are likely to refuse to provide this information unless a clear connection to their jobs and possibly a rationale for its intended use and protection are provided. There seems to be a trend on the part of employees to be cautious in sharing health information with their employers either due to fear of future opportunities or possible rising employer health care costs. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) addresses some issues of privacy regarding health care information, the details are discussed in the next section. However, employers can still require genetic testing; the dilemma surrounds both how to use that information and who should have access to it. For example, if employers request employees' genetic information does the employer have the appropriate means to correctly interpret the findings? Genetic test results are likely to be relatively complex in their findings, and organizations

will need to ensure that their human resource staff has the capabilities to draw the appropriate conclusions as they are relevant to that organization. Also, not all individuals may want to know whether they may be genetically predisposed for a disease. Therefore, HR professionals will have to develop protocols for both disseminating this information within the organization and to the individual employee tested. At some point in time legislation may also detail the appropriate use of such information within the workplace.

Does the level of privacy of genetic test results depend on the impact this individual has on the organization? For example, if an organization is negotiating a large executive compensation package for a new member of top management, is knowledge of their genetic information more critical than for a lower-level employee? While organizational policies are supposed to be equally applied throughout the organization, there is some evidence that one's organizational level can impact policy application. Stone and Colella (1996) suggest that when employees suffer from disabilities beyond their control, supervisors may act leniently toward them (p. 363); however, would a person in an executive position receive such deferential treatment? Human Resource practitioners will need to address this issue to mitigate any potentially discriminatory practices in relation to which employees are tested and how the information is used across the organization.

The issue of whether employer insurance will bear the costs of genetic testing for individual use is likely to be the responsibility of employee benefits managers. If employers use these tests as part of an occupational safety (e.g., monitoring) or recruitment (e.g., screening) program, the organization must bear all costs. However, individuals may want to have their own genetic tests conducted for their own use as part of their own health care coverage. Gibons (2004) indicates that health plan managers need more information about genetic services. Similarly, Human Resource Managers also need such information in order to consider negotiating such benefits. This already is an issue with regard to whether insurance policies cover genetic testing of unborn children. Therefore, human resource professionals will have to assess not only whether to provide coverage for these tests, but also at what cost to employees. Also, can organization mandate genetic counseling or genetic testing of (unborn) children or spouses in an effort to minimize health care costs? Although this seems somewhat farfetched, one should recall that in the 1950s and 1960s candidates for high-level executive positions often had their wives subjected to "screening" for appropriateness.

Political

Asch (1996) states , "people who carry genes for disabilities or illnesses, and people who themselves are affected by those conditions, are likely to experience employment problems that the civil-rights laws are not designed to solve"

(p. 159). Other authors (Hubbard & Henifin, 1985; Gostin, 1991; Natowicz et al., 1992; Nelkin & Tancredi, 1994; Nelkin & Lindee, 1995) have also become increasingly concerned that advances in genetic testing techniques will lead to discriminatory employment practices despite legislation such as the Americans with Disabilities Act of 1990 (ADA) and state-specific legislation. Human Resource professionals need to be concerned with the relevant legislation and case law surrounding genetic testing to know what recourse their (potential) employees may have if they feel discriminated against based on the test results and develop employment practices to minimize this risk. There is likely to be new legislation to address how genetic testing information can be used and how to disseminate, however, neither legislation nor case law has yet to address these problems. Below is a discussion of the existing legislation and case law that illustrate the issues of concern for Human Resource professionals in this area.

The Legislation

Executive Order 13145, signed by President Clinton on February 8, 2000, prohibits discrimination in federal employment based on genetic information. This order defines such discrimination as well as defines how genetic information shall be treated (e.g., confidentiality and disclosure standards) in the federal government. At least 24 states have adopted similar legislation for state government employees (Miller, 2000). The Genetic Non-Discrimination bill passed in the Senate and under review by the House of Representatives is the first attempt to clarify these issues and provide protection in this area in the private sector. These laws are clearly meant to protect individuals against discrimination based on their genetic information, however, much of the case law argues protection under the ADA.

The ADA was established to prohibit discrimination against qualified individuals with a disability, those with a record of a disability and those perceived as having a disability. For example, employers must provide reasonable accommodation of the workplace to make their ability to work a smooth process (e.g., a magnifying glass on a computer monitor, accessibility to the building). Employers must also offer benefits to disabled workers on the same basis as those offered to able-bodied employees. Because this law is relatively new, it has been subject to much interpretation in the court system. Its use to support an individual's discrimination claim (based on genetic information) has begun to be tested and is discussed in more detail below. Although individuals have sued their employers with claims of discrimination based on a genetic disability using the ADA, the courts have not granted these individuals protection under this law. The existing case law is discussed in the next section.

Organizations are also responsible for adhering to both the federal Occupational Safety and Health Administration (OSHA) and comparable state

agency guidelines that require organizations to provide a safe working environment. This may mean through genetic screening or monitoring as the situation dictates. As new genetic tests are developed, HR managers will need to monitor the development of protocols for using these tests in their industries.

The last relevant piece of legislation that HR managers need to understand is that HIPAA prohibits group health insurance plans from using genetic information to establish rules for eligibility or continued eligibility. HIPAA also states that genetic information shall not be treated as a pre-existing condition in the absence of a diagnosis of the disease (Greengard, 1997). However, HIPAA does nothing to prohibit an insurer from raising rates or excluding all coverage for a particular condition. It is interesting to note that both OSHA and HIPAA may drive the future of how genetic testing may be used and its results disseminated, unless new legislation is passed specifically for genetic testing. Currently OSHA (and its state counterparts) has protocols in place for when genetic testing (most often monitoring) is conducted for certain jobs that may expose affected individuals to higher predispositions to various conditions. HIPAA also handles confidentiality of medical information, which genetic test results are likely to be considered.

Case Law

There are several examples of how individuals are beginning to file discrimination claims on the basis of genetic makeup. Although individuals with genetic defects are not a protected class under the Title VII of the Civil Rights Act of 1964, they may receive protection through legal action. The following examples illustrate how cases involving genetic screening have been argued and decided.

In a case examining the use of genetic testing for employee screening, the Burlington Northern Santa Fe Corporation (Porter, 2001) was found to have illegally tested employees for genetic problems. In an interim settlement reached with the Equal Employment Opportunity Commission through mediation, the company agreed to pay $2.2 million to 36 workers. The company, which was found in violation of the ADA (United States Equal Employment Opportunity Commission, 1999), took blood samples from employees to ascertain whether they were genetically predisposed to carpal tunnel syndrome. The company did not use the information to move workers to different jobs. However, the violation was related to gathering of DNA information because the employees had not given consent.

The National Sickle Cell Anemia (SCA) Control Act of 1972 provides another example of genetic screening misuse. SCA is a genetically transmitted disease. It primarily affects those of African descent; however, there are other groups that can also be affected, for example Arabs, Greeks, Italians, Latin Americans, and those from India (Sickle Cell Information Center, 2003). An

individual possessing two sickle cell genes has SCA. A person with SCA experiences episodes of severe pain, develops organ damage related to circulation problems, and generally has a shorter life span. An individual who has one sickle cell gene is labeled as having Sickle Cell Trait (SCT). These individuals do not have the disease and do not exhibit clinical symptoms (Hubbard & Henifin, 1985). The original intent of the National SCA Control Act of 1972 was to both authorize funding for genetic services to assist individuals in making childbearing decisions (rather than to provide treatment) and to provide guidelines to specifically reduce stigmatization (Reilly, 1978). However, despite this, a number of negative outcomes occurred, some related to employment. The U.S. Air Force Academy prevented blacks with SCT from attending flight school for more than 10 years (Suzuki & Knudtson, 1989). The belief was that the presence of even one copy of the gene could lead to problems with low-oxygen conditions such as those experienced at high altitudes. In 1981, after legal action and no evidence that supported the Academy's concerns, the policy was changed (Suzuki & Knudtson, 1989).

More recently, black employees at the Lawrence Berkeley Laboratory had pre-employment sickle cell testing. The United States Court of Appeals, Ninth Circuit decided on February 3, 1998 that the Laboratory had violated these employees rights under Title VII of the Civil Rights Act by singling them out for non-consensual testing on which their employment was contingent (Washington State Department of Health, 2003). Originally, the employees claimed violation under the ADA. However, their claim was denied on those grounds.

Public policy is vague in determining whether genetic discrimination should be treated under current laws that address discrimination. Some court rulings have stated that individuals with genetic imperfections are not protected under the ADA, the most likely legal option. It appears that genetic discrimination differs from other forms of disability discrimination. This is challenging because the genetic problem may not be readily visible or immediate. Therefore, human resource professionals need to be proactive in handling this information in an impartial and professional manner.

Strategic

These cases and existing legislation illustrate the conundrum organizations face in deciding whether to determine the genetic risks of their employees as well as what potential actions to take based on this information. There are no clear legal guidelines for either gathering genetic information or what human resource actions are appropriate. Diamond (1983) states, "caution must be taken that genetic testing does not become a form of discrimination disguised as science" (p. 242). While it is clear that all organizations must adopt an approach toward genetic testing, the extent and nature of this protocol is likely

to vary by the industry, role of human capital, and accompanying approach to risk management.

The need for genetic testing is going to vary between organizations both within and among industries. For example, organizations in a more clearly hazardous work environment (e.g., handling toxic substances) are going to have to employ genetic testing as part of their overall approach to employee safety and as mandated by governmental safety organizations. However, as many organizations are increasing their reliance on human capital, this role of genetic testing becomes less clear. Some organizations may choose to employ genetic screening to not only test for genetic disease but also personality "defects." Human resource professionals will have to determine the role of genetic testing in their overall screening procedures.

Conventionally, corporate risk management has centered on conducting a financial assessment of some type of organizational change that may expose a company to increased liability or loss. Examples of such assessment would be a bank assessing the profit/loss probabilities associated with a new service, a manufacturing organization determining if a change in the pricing structure of a product would reduce market share, or an organization considering the costs associated with the closing or relocation of a plant. In spite of this focus, Pyne and McDonald (2001) state that [financial] organizations' "people risk" is the top risk facing enterprises. Erven (2004) further suggests that risk management has not paid sufficient attention to HRM risks. Pyne and McDonald's (2001) report identifies risk areas related to people such as poor decisions, poor leadership, outdated reward strategies, and untrained staff. The issues surrounding genetic testing for organizations touch upon several of these "people" areas. Organizations will have to develop specific protocols for their human resource managers to handle the issues with genetic testing. There will have to be a clear connection between what genetic tests to administer and specific job duties. There will have to be a rationale for using these tests and also specific measure to ensure that all organizational members who may be privy to this information are trained in handling the communication issues that accompany such personal employee information.

There has been some research about the use of genetic information in risk assessment or insurance underwriting (Pokorski, 1997; Peters, 1998; Steinberg, 2000). Pokorski (1997) has made cogent arguments for the use of genetic information in insurance underwriting. Stone (1996) indicates that from the health insurance perspective, adverse selection (people with identified genetic aberrations who know of them will be more likely to seek insurance than those who do not have genetic problems) will occur unless the company itself has access to this medical information. Human resource managers will need to address the use of genetic screening with the employer's insurers. Although the insurance industry has begun thinking about how to use genetic information,

human resource managers have yet to address the potentially increased exposure to higher insurance costs related to genetic conditions that could necessitate expensive medical treatment. Also, if employers' risks of genetic mutations are because of workplace conditions (e.g., chemical handling), organizations will have to determine the impact on both the employees and the organization's rate of worker's compensation claims, which in turn may influence rates for this type of insurance.

Recommendations

Human resource responsibilities typically include all activities that pertain to the recruitment, development, administration, and retention of human capital for organizations. Increasingly these responsibilities are often tied to each organization's strategic position that will likely guide the development of goals within each HR activity. The organizational strategy will drive the HR strategy both with respect to the industry and competitive direction. For example, if an organization needs to recruit individuals that are resilient to certain hazardous work conditions, they will need to make goals to that effect; genetic screening will likely support that goal. Table 3.1 details the specific HR responsibilities and the accompanying genetic testing considerations that these professionals must address. We outline recommendations for organizations in how their HR professionals might address these considerations. Together these recommendations provide a starting point for HR to establish its own protocol of action for the inclusion or exclusion of genetic testing.

In order for HR to establish a both legally defensible and effective program for incorporating genetic testing into its activities, the following considerations should be taken into account. Effective recruitment and selection

Table 3.1 Genetic Testing Considerations for HRM

Human resource responsibility	Considerations
Recruitment	Genetic screening Hazardous work environment
Selection	Genetic screening and monitoring
Training and development	Confidentiality Dissemination of test results
Compensation and benefits	Job relatedness Adverse impact Insurance
Labor relations	Treatment specified within collective bargaining agreement

procedures should be both reliable and valid. If genetic testing works toward this effectiveness, the program will likely be legally defensible as well. For example, if genetic testing is used to confirm a condition that could harm a job candidate if they work in a hazardous environment, and that individual is then screened out of employment, the organization will be able to argue that the genetic test was used both to protect the individual from harm as well as the organization from liability. Caution must be made that the test must be used for all workers applying for these jobs, not just those in certain groups (e.g., Lawrence Berkeley Laboratory case).

To this effect, the protocol for handling any inclusion of genetic testing will need to address how this information will be disseminated as well as communicated to any individuals tested. Individuals within organizations will need to be trained with appropriate procedures for handling this very personal and confidential information. Organizations may even want a third party provider to handle this type of testing to both reduce corporate liability and leave the matter in expert hands. Also, this may help individuals feel that the information will be handled in a more confidential manner; similar to Employee Assistance Plans.

Any program of genetic testing needs to be able to be justified as job related. Therefore, organizations must be able to argue effectively that any employees or job applicants tested are being screened uniformly and for current job specific capabilities. An interesting example that illustrates this importance is the case involving Target Stores. In an effort to improve hiring procedures, Target identified emotional characteristics that are problematic in security guards. On the recommendation of psychological consultants, Target began to administer pre-employment psychological screening tests. Applicants (who were denied employment) sued Target (*Soroka v. Dayton Hudson Corp.*, dba Target Stores) on the basis that some questions that dealt with religion and sexual orientation violated their rights to privacy. Although the plaintiffs lost on the grounds of rights to privacy (a third party vendor was used to score the examinations), the court held that questions that violate privacy must be directly and narrowly related to the nature of the employees duties (American Psychological Association, 2005). Also, the program must be tested to ensure that the program of genetic testing does not inadvertently create adverse impact. The program must not systematically screen certain groups while not screening others, a discriminatory environment.

Insurance is a relatively complicated organizational issue with regards to genetic testing. Organizations must consider how legislation affects their ability to limit coverage for pre-existing genetic conditions as well as their own approach to minimizing their overall insurance liability. This must all be assessed in relation to the various insurance packages offered. For example, does the company not only provide coverage for the employee but also for the employee's family? The issue then arises as to the appropriateness of testing

these insured individuals, although they do not directly work for the organization but may increase its insurance costs.

Unions are likely going to drive how genetic testing can be used by organizations, aside from legal constraints. In most unionized workplaces, seniority is used as the means whereby job promotions and rewards are allocated, so testing is not likely to be used for these human resource decisions, however, organizations may want to start screening new employees with these tests as they become available. Just as unions are now increasingly accepted a two-tier wage structure, they may be forced to accept a two-tier benefit/screening structure, especially if the organization can argue for its use to limit insurance liability and overall benefit costs. The use of genetic testing is likely to become a new bargaining issue.

Conclusion

While genetic testing may not impact many Human Resource Managers in the immediate future, as the technology develops, individuals not trained in the sciences will be confronted with complicated technical data. The ethical code of the Society for Human Resource management (SHRM, 2005) states that we are socially responsible. This suggests that we, as HR professionals, consider genetic testing in a larger social framework. The ethical, political, strategic, and practical issues discussed in this chapter and the accompanying recommendations proposed provide a clear rationale that the issues surrounding genetic testing will become something all HR professionals must address.

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4

Geneticize Me! The Case for Direct-to-Consumer Genetic Testing

Ronald Munson

Let me begin with a bit of science fiction.

It is September 1, 2020 – Tom Henson's 25th birthday. Tom is in enviable good health, but he's beginning to sense that he isn't going to be immortal. He realizes that hidden among the arcane codes of his DNA may be the trigger of a genetic time bomb. Perhaps, given timely medical intervention, he may be able to delay indefinitely a life-threatening explosion. If delay is impossible, then he can at least take that into account as he plans how to live his life.

Yet Tom is not sure exactly what genes he should be worried about. His parents were Caucasian immigrants from an English academic town who were killed in a plane crash when he was 12, and he never knew either set of grandparents. Does heart disease run in his family? Cancer? Alzheimer's?

Sitting by the pool at his apartment complex and watching the sunlight shimmer off the water, Tom decides in a flash of resolution that he will find out more about himself. He uses his wireless notebook to search the Web for genetic testing laboratories. After checking with Medical Consumer, he decides on Gentrue, because of the quality of their educational components, the reliability of their results, and their support services. Tom flips through the list of tests and potential diseases, but he's immediately stumped. He's an English literature scholar and knows more about the meter of *Beowulf* than point mutations. What test should he choose?

The disease descriptions beside the associated tests are helpful. He is not of African descent, so a test for sickle cell seems unnecessary. Cystic fibrosis looks possible, because it is the most common genetic disorder among Caucasians, but as he reads the description, he realizes he couldn't have the disease without knowing it. Apparently, though, he could be carrying a copy of the gene. Probably he ought to get the test. Maybe Corrine should also be tested before they have kids. He should ask her about her family.

Tom reads about Huntington's disease and decides he definitely needs to be tested. He doesn't know his family history, so maybe one of his parents

transmitted the gene to him. Knowing he would eventually develop a fatal disease anytime from his early 40s onward could make a huge difference to him. He would want Corrine to know that if she married him, she could be a widow in 15 years. And there would be kids to think about. If necessary, they could do in vitro fertilization and embryo selection to avoid passing on the gene to a child.

But what about the family-related forms of colon cancer or heart disease? Colon cancer might not get him until his 50s, but a heart attack might kill him right now. Reading about heart disease, he thinks that maybe he should see if he has inherited the gene for familial hypercholesterolemia. His coronary arteries might be plugged with plaque already.

Surfing through the screens, Tom catches sight of an option he had not noticed earlier – the Gentrue Multitest. If he Fed-Exes a sample of blood to Gentrue, using a company supplied kit, the lab can put his cells through an automated process involving biochip arrays of genetic probes to test simultaneously for the presence of 600 of the genes most commonly involved in genetic disease. The Multitest seems worth the thousand dollars, if for no other reason than it will spare him the task of having to decide which of the 2000 tests offered by Gentrue he should have.

Tom is relieved to see that as part of its basic package Gentrue offers up to an hour of private education and as much as 2 hours of advising with a licensed genetic counselor. The guaranteed privacy of the testing is also appealing. Some things are so private only he should know them, not his employer, insurer, friends, and maybe not even Corrine. He likes not having to go through the hassle of making an appointment with some doctor he barely knows, then trying to explain why he wants the tests. The doctor may push him to justify his choices, or even laugh at them. And then the results would become part of his record, and who knows what that might lead to?

Gentrue's notification system also appeals to him. He can order the tests online, and a physician will review the results. But to get the results Tom will have to go to a clinic. A nurse-practitioner with special training in genetics will explain them to him and, if necessary, refer him to a specialist. If the results are likely to be upsetting, Tom will see a clinical psychologist or social worker who will provide him with immediate support and arrange for him to receive further care.

Tom waves a hand and opens up the Gentrue client data page.

No Universal Agreement

A present-day Tom Henson could turn to the genetic testing services offered on over a hundred web sites (Gollust et al., 2003). Most sites sell services connected with determining paternity, registering personal identity, and banking DNA for later use in disease or genealogical testing. Fewer than 20 sites offer

health-related genetic tests, and some of these are for services involving scientifically suspect advice about optimal nutrition or delayed aging. Yet several sites provide direct access to genetic tests for cystic fibrosis, sickle cell disease, and hemochromatosis. The same tests can be obtained at walk-in centers, and both web sites and bricks-and-mortar laboratories provide women the opportunity to be tested for the mutations BRCA1 and BRCA2, which predispose them to breast and ovarian cancer. Both women and men have the chance to be tested for a genetic predisposition to cardiovascular disease.

The sparse array of test offerings could easily be expanded to something like the roughly 500 common genetic tests now available only through physicians. Biotech companies defend the genetic tests they offer directly to the public, and at any moment a company like Tom Henson's Gentrue may start up, ready to sell to consumers almost any genetic test they choose.

The evidence indicates that the public generally favors genetic testing and may be waiting for more to be offered directly to them. A 2002 Harris Poll showed that by eight-to-one American adults thought genetic testing was a good thing, and the more those surveyed were familiar with genetic testing, the more they favored it. They also indicated a willingness to pay for it. A full 81% said they would be likely to have a genetic test for a major disease that could be treated, yet almost half (49%) said they would have a test for such a disease, even if there were no treatment or any way to reduce their risk. Fully 69% indicated they would be "somewhat likely" to get a comprehensive genetic test like Tom's Multitest. While 90% were willing for their regular doctor to have their test results, only a small percentage, all minorities, thought that employers or insurers should get them (Harris Poll, 2002). Similar figures characterize the population surveyed in a British study (Levit, 2001; for a Canadian view, see Williams-Jones, 2003). Williams-Jones calls attention to several practical and regulatory problems facing any country.

It is reasonable to assume that, like Tom, a large number of people want health-related information about themselves, yet want to keep it private. The success and continued popularity of home pregnancy tests illustrates this. When women could find out if they were pregnant only by consulting a physician, some hesitated to be tested. Their physician would know the test results (a significant consideration in a small town), and even having had the test would become part of their medical record and thus known to others. Thus, many women had to live with unnecessary anxiety, put off making health-related decisions, and failed to get early prenatal care. The privacy permitted by self-administered pregnancy testing has brought undoubted benefit to a considerable number of women (Shew et al., 2000; Sadler et al., 2004).

The surveys I cited earlier show that a high percentage of our population want to have genetic information about themselves, yet also want to keep it under their control. Like home pregnancy testing, direct-to-consumer (DTC)

genetic testing preserves privacy and permits people to decide whom, if anyone, to inform about the results.

While potential consumers express a positive attitude toward genetic testing, physicians and scientists, focusing on BRCA1/2 testing offered directly to women, have made DTC genetic testing in general a flashpoint of controversy. The possibility that the range and number of tests might increase and the alleged harms of public access to them have prompted critics to demand that DTC testing be discouraged or prohibited in favor of testing mediated by a physician or other health care professional.

Germany and Norway have banned DTC genetic testing outright, but so far the United States and Britain have left it unregulated (Human Genetics Commission, 2003). Even so, some advisory boards and medical organizations have rejected the idea of DTC testing. The National Human Genome Research Institute Task Force report on genetic testing discourages consumer-directed testing (Holtzman & Watson, 2005), and the American College of Medicine (ACM) announced its opposition in a formal statement. "Genetic testing of individuals or families for the presence of or susceptibility to disease are medical tests," the ACM asserted (American College of Medicine Genetics Board of Directors, 2004). Furthermore, "genetic testing should be provided to the public only through the services of an appropriate qualified health care professional" who should "be responsible for both ordering and interpreting the tests."

The Positive Argument: Autonomy

Contrary to the position of the critics, I claim that our commitment to recognizing the autonomy of individuals supports a policy of permitting people to gather their own genetic information. Granting the presupposition favoring autonomy accepted by our society, to justify prohibiting DTC genetic testing, critics must show that it causes harm to people other than its consumers or violates some significant state interest. Even if critics were right in claiming that DTC testing confuses some consumers, encourages them to waste money, causes them unnecessary worry, or gives them a false sense of security, it does not follow that DTC genetic testing should be proscribed.

Nevertheless, in agreement with the critics, it may be reasonable to impose regulations requiring that test purveyors provide consumers with the information and the support they need to make informed choices about tests and to understand and deal with test results. I eventually will address the arguments of the critics, but I want to begin by explaining why individual autonomy favors a policy of allowing DTC genetic testing.

We act autonomously when our actions are the result of our decisions, when they are self-determined. Autonomy is thus infringed when our behavior is

coerced or manipulated. Our society is committed to recognizing the determining power of the individual in making self-regarding decisions. We allow people to decide how to live their lives, including deciding how they want to spend their money and what risks they want to take. Some people, knowing the risks associated with being positive for (say) a gene associated with Alzheimer's disease, may choose to be tested for it, but other people, for a variety of reasons or no reason at all, may decide they do not want to be tested.

Autonomy, if it is to be exercised, must be protected, and that is the purpose of informed consent. Informed consent is a way to minimize the chance that, when it comes to decision making, people will be deceived, exploited, tricked, misled, duped, manipulated, or pressured so that their autonomy is violated. If a significant violation of autonomy occurs, the resulting decision is not, in a real sense, the individual's. Informed consent is thus a means of making sure that the agent of an action is also its true author.

For informed consent to be legitimate (valid, genuine, etc.), we require that the people consenting be adults who are competent to make decisions. We additionally demand that they be provided with information relevant to the decision at hand and that the information be understandable and sufficient to allow competent people to weigh the character and consequences of the actions open to them. We require, finally, that the decision makers be protected from coercive forces, deception, or other factors that infringe on their autonomy and thus take away some of their power to decide. To emphasize this last requirement, we typically speak redundantly of consent that is "free and informed."

With respect to DTC genetic testing, drawing on the above observations, the requirements of autonomy as protected by the conditions of informed consent support the following practices:

1. We should limit contracting for genetic testing to competent adults. We can assume, in absence of evidence to the contrary, that adults are prima facie competent. Someone seeking a genetic test must affirm that he or she is an adult, and anyone violating this requirement would be subject to a legal penalty.
2. We should permit people to contract for genetic tests only for themselves. Protecting the privacy of others (a breach of privacy is a violation of autonomy) requires that we prohibit people from securing genetic information by sending in cell samples (e.g., hair, skin, chewed gum, blood, etc.) from somebody else. (The problem of testing one's child is a special one I shall not address.) Thus, someone contracting for a genetic test must affirm that he or she is the source of the genetic material supplied. This should be a legal requirement, and anyone violating it should be subject to a penalty.
3. We should require that laboratories offering DTC tests communicate the results only to the consumer, unless the consumer dictates otherwise. The

results of genetic tests count as health information of a sort that is already protected by state and federal laws.

4. Biotech companies soliciting consumers for testing services must not provide information that is false or misleading. Critics of advertising for genetic tests currently available point out various ways ads often promise more than can be delivered. Some ads, for example, suggest that women who find they are negative for familial breast cancer genes (BRCA1 and BRCA2) can feel secure, but this is to ignore the risk of sporadic breast cancer. (See below for additional discussion.)

   Deception undercuts autonomy. The conditions for informed consent are not satisfied when what is offered as information is wrong or deceptive. Exercising autonomy requires that people be allowed to deliberate, and meaningful deliberation is not possible when relevant facts are missing or obscured. Thus, to preserve autonomy, we must prohibit vendors of genetic tests from making false or misleading promises to potential consumers. (We already prohibit such practices by sellers of cars and dishwashers and so need only extend the laws to DTC genetic testing.)
5. What makes genetic tests unique products is that their results can have a predictive power unmatched by any other kind of health information. An unwary consumer may learn she carries a lethal gene and be so devastated that she commits suicide. The special character of genetic tests thus imposes on laboratories offering them a special obligation to educate potential consumers. Test vendors must see to it that the conditions of informed consent are satisfied and that consumers understand both the tests they agree to take and the meaning of the results.

The function of informed consent is not to protect people from the consequences of their actions. Rather, it is to make sure that they can know (so far as anyone does) the nature and results (the potential risks and benefits) of each course of action open to them. A test provider must warn consumers not to look through the keyhole of genetic testing if they do not want to see what is on the other side of the door.

Warning alone is not enough, however. The laboratory must also be prepared to provide those who get bad news with the initial support and counseling they need. That this is a moral obligation (and should become a legal duty) stems from the uniquely predictive character of genetic testing. Telling someone he has high blood pressure is to give him bad news, for it predicts that problems like heart disease and stroke may be in his future. But telling someone he has the gene for Huntington's disease is to offer a stronger and more certainly lethal prediction. Any laboratory offering genetic testing has to assume the burden of supporting people who get such news, in much the same way that a cruise ship must have lifeboats.

Although different models of notification and support may be possible, an acceptable one must meet the following requirements: (a) a licensed physician must supervise and review the testing procedures and results; (b) the test results must be delivered to a client in a face-to-face setting by someone like a genetically-trained nurse-practitioner who can interpret them and refer the client for any necessary follow-up to a physician or a medical specialist; (c) the client must have access to immediate psychological support by a clinical psychologist or social worker who can also arrange for longer-term care.

My argument here favors a social policy of making genetic tests directly available to those who want them and who meet the conditions for informed consent. The presupposition favoring autonomy also favors allowing DTC genetic testing, and it is this implication that critics must rebut. If they are successful in demonstrating that DTC genetic testing substantially threatens the welfare of the public or certain classes of individuals, the ACM position is the proper policy and should be adopted nationally.

Challenge and Response

Critics have offered a variety of reasons for restricting genetic testing and making it available only to the patients of "health care professionals," but I will consider only the three strongest ones.

Consumers Will Get No Practical Value

The most forceful objection to DTC testing is Hubbard and Lewontin's argument that genetic testing itself has little practical value and attendant hazards. They point out that, in the great majority of cases, correlation between DNA patterns (genes) and diseases are only statistical, and most likely as-yet unknown social, economic, psychological, or other biological factors play a role in determining exactly which people carrying the same genes will develop a disease (Hubbard & Lewontin, 1996).

Thus, to use their central example, although BRCA1/2 have been linked to increased susceptibility to breast or ovarian cancer, BRCA1 has over a hundred known variants and BRCA2 has many forms. Yet only a few variants have been associated with breast or ovarian tumors. If a woman tests positive for BRCA1 and is from a "cancer prone" family, she is much more likely than others to develop cancer. "Yet about 90 percent of women with breast or ovarian cancer do not fall into these categories" (Hubbard & Lewontin, 1996, p. 1193). Even a woman who does is not certain to develop cancer. Her lifetime risk may be high, but she may escape both forms of the disease, given the unknown factors. On the grounds of these "biological uncertainties," Hubbard and Lewontin reject

the legitimacy of the susceptibility testing for BRCA and colon cancer offered by several commercial laboratories. If these tests are of no use, then selling them to the consumer cannot be justified.

The argument that genetic testing is without practical value is unpersuasive, however. Hubbard and Lewontin admit that when it comes to autosomal diseases like sickle cell and x-linked ones like Huntington's, genetic testing has value, presumably because the pattern of heritability of these diseases is sufficiently well understood to make genetic testing accurate and reliable. These at least are tests that legitimately could be offered to consumers.

So what about the Hubbard–Lewontin argument against testing for BRCA mutations, ovarian cancer, and familial colon cancer? It amounts to nothing more than the fact that we can test only for predispositions to these diseases. That is, we have established no more than a statistical association between the presence of the gene and the occurrence of the disease. Hubbard and Lewontin admit that the chance of a woman from a cancer prone family who tests positive for BRCA1/2 has a lifetime risk of 85% for developing breast cancer and an additional risk (now thought to be 60%) for developing ovarian cancer. Yet, they suggest, this knowledge has no practical worth, so why should people pay to be tested?

But consider an analogy. We do not know all the factors that are responsible for car accidents that result in deaths. Some people walk away from accidents of a sort that kill many others, and we are ignorant about the factors that make a difference. Yet if I knew that my lifetime risk of dying in a car accident was 85%, I might plan my life differently. (I might buy a bicycle, fly, walk, or take the train.) I would not assume that because unknown factors exist in causing fatal accidents, I might as well ignore such a high statistical risk.

Knowing your risk for breast cancer does not allow you the same sort of options as when a car accident threatens your life, but that does not mean you cannot alter your behavior. It would make sense to ignore the BRCA1/2 statistics only if knowing them could not make any difference. Hubbard and Lewontin, like other critics, assume that the only reason to know if you are predisposed to a disease is so that you can prevent it or treat it effectively. This ignores the fact that (as the surveys I cited indicate) most people want to know what they are up against. If they know they are positive for a cancer-causing gene, they can take this into account in the decisions they make about marriage, children, career, or other aspects of planning their lives. Hubbard and Lewontin appear to think that when it comes to risks posed by a genetic predisposition, ignorance is bliss. But they forget the rest of the saying – ignorance is bliss only "when 'tis folly to be wise."

Hubbard and Lewontin mention the possibility that a woman testing positive for BRCA1/2 may try to prevent the developing cancer by having a prophylactic double mastectomy or having her ovaries removed. Even if she does this, they point out, she cannot be sure that cancer will not develop in

the tissues remaining. While this is true, the decision is not one Hubbard and Lewontin ought to be making for the entire class of women with the mutation. Certainly the surgery is severe, and not all women would elect to have it. Yet some would choose even a desperate option, if it meant having a chance at preserving their lives. (Recent studies indicate that women who have the double mastectomy survive longer.)

By the reasoning of Hubbard and Lewontin, it is also pointless for anyone to be tested for the Apo E gene. A positive test predicts with 90% accuracy that someone with two copies of the e4 form (e4/e4) will develop Alzheimer's disease before age 80. Unlike breast cancer and colon cancer, however, only treatments of modest value are available; thus Apo E testing is pointless. Yet, once again, the mistaken assumption here is that information that is of no value to the physician in treating the patient, is also of no value to the patient. As Wachbroit (1996) reminds us, "Over the past few decades there has been an intense effort to articulate and defend a person's right to be informed of his or her medical condition". People now want to take responsibility for the medical part of their lives, and this requires reliable information.

The medical paternalism of the past embodied the view that the physician alone decided what the patient should know about his health. If the physician thought the patient might be frightened by a diagnosis, he might decide to keep quiet about it. Why worry the patient needlessly? Many people died fully expecting to recover in a few weeks. We are well past this point in medical practice. Studies done decades ago showed that the great majority of patients want to know the truth about their condition, and by now informing patients and getting their consent before treating them has acquired an entrenched ethical and legal status (Bok, 1978). Despite this move favoring autonomy, critics of genetic testing and DTC testing, in particular, remain unwilling to allow people to discover facts about themselves if a laboratory procedure is required.

The justification for this reluctance is not warranted. We place no restriction on those who go to web sites or libraries to research their family background to learn what it suggests about their disease risks. Why then should we restrict them in getting their DNA tested? Some people will choose not to learn genetic facts about themselves. Even now, when a physician must order the test for a patient's Epo E status to determine if she is at risk for heart disease, some patients ask not to be told the results. Similarly, some people who have a parent with Huntington's disease know the chance is fifty–fifty that they have inherited the gene, but they decide not to be tested. Other people decide the opposite, and this is exactly as it should be.

Although the Hubbard–Lewontin objection to genetic testing is flawed, their overall criticism points to a condition for testing that ought to be met. No genetic test should be offered to the public until there is expert agreement that the test is both accurate and reliable. No one's interest is served by a test that has a high level of false positives or false negatives or cannot be relied on

to yield the same results on retesting. As Gollust and her collaborators (2002) put the point, "The availability of commercial genetic tests should be based on professional recommendations founded on empirical evidence, not merely on the technical feasibility of a test or its commercial potential". No one, neither a physician nor a DTC laboratory, ought to offer tests that may be worthless.

DTC Testing Will Increase the Costs of Health Care

Critics claim that people like Tom Henson may drive up the costs of health care by seeking genetic information (McCabe & McCabe, 2004). First, most people know little about genetics or medicine, and so the tests they order may be inappropriate. Tom may not realize that, given his age, it is pointless for him to get tested for muscular dystrophy, and given his ethnicity, he should not bother to be tested for beta thalassemia. Similarly, women without a family history of breast cancer may decide to be tested for BRCA1/2, but the results are not likely to tell them anything useful. Hence, the money people would spend on irrelevant tests would drive up the costs of health care in our society.

Furthermore, if a range of genetic tests were available directly to consumers, people would start demanding that their insurer pay for them. Consumers would think of the tests as a legitimate health-related expense, and insurers would be under considerable pressure to include coverage for them in their policies. Thus, self-prescribed genetic testing would increase the cost of health care without getting much useful health information in return.

The answers to these objections are straightforward. First, the way to curb spending on irrelevant genetic tests is for commercial enterprises offering the tests to provide educational information about the nature of the diseases and the value of the tests. People may not always spend their money rationally, but they rarely set out to buy goods of no value to them. Tom, properly informed, is not likely to pay for BRCA testing.

Providing such information, as I argued earlier, is a condition a test provider must meet to satisfy the requirements of informed consent. The provider has an obligation to supply the information consumers need to make considered choices. (This means supplying the positive and negative predictive value of the tests: McCabe & McCabe, 2004, p. 59.) Thus, they must be given facts relevant to tests and diseases that will allow them to deliberate about whether to get the test. This makes buying a genetic test more like buying a computer than a coffee mug. Some technical information about the product has to be supplied before it can be used properly. (The converse of this is that if consumers do not make use of the information, they have no one to blame but themselves. The exercise of autonomy is not a guarantee of satisfaction.)

Will people purchase genetic tests that their physicians might judge they do not need? Very likely. People spend several million dollars a year on vitamins

and dietary supplements that most researchers consider of little or no value. Yet our society is committed to the notion that people should be allowed to spend their money on whatever pleases them, so long as others are not directly harmed or an important public interest is not violated.

When criticizing DTC testing as a potential waste of money, it is easy to forget that it will allow people to learn facts about themselves that may bring them benefit. For example, they may gain immense relief by discovering that the worry that they are carrying a particular gene (e.g., for cystic fibrosis) is groundless. Or they may find that they are at risk for a disease that can be anticipated so that early intervention may extend their lives. Someone knowing she carries a gene predisposing her to colon cancer can, at the least, get regular colonoscopies and thus increase the chance that cancerous changes are discovered in time for surgery to be effective.

It is possible that the overall costs of early intervention on the basis of genetic knowledge may not only save lives, but may reduce overall medical costs. As with other forms of preventive medicine, significant savings might be made on hospital stays, physician time, and loss of productivity. Whether widespread use of DTC genetic testing will have this result is an empirical matter that remains unknown at present.

What about the objection that consumers would soon start pressing their insurers to pay for genetic tests? This may be true, but it is not necessarily bad. First, direct access to genetic testing is only another factor insurers would need to consider in the complex process of setting and negotiating rates. Some insurers now consider it to their benefit to offer coverage that encourages policyholders to participate in "wellness" programs, calculating that the expenditure will be recouped by reducing the costs of treating "lifestyle" diseases. If data show that genetic testing will not bring similar benefits, insurers may disallow reimbursement, the way they now do not pay out for unproven but supposedly therapeutic practices like replacing silver–amalgam dental fillings with composite ones.

Furthermore, if DTC testing does not lower the net costs of health care, the costs ultimately will be borne by the consumer. Genetic testing is, at the least, another product for which people may opt to spend their money. It could be said, in this respect, to resemble the work of fortunetellers. Some may wish people did not spend their money having their palm read, but choosing to "waste" one's money in that fashion is an exercise of autonomy in the special form of discretionary spending.

Test Results Might Cause Harm

Critics of DTC genetic testing point to the potential harms it poses to consumers (Hildt, 1999). Thus, someone learning that he is positive for Apo E e4/e4

may see himself doomed by Alzheimer's, decide his life no longer has meaning, and become severely depressed or even kill himself. Someone discovering she is positive for a BRCA mutation may then live in constant anxiety, waiting for breast cancer or ovarian cancer to flare up and threaten her life.

Also, although the news itself may not be devastating, what the consumer makes of it may be. Most people lack much of an understanding of genetics and disease, so they may misinterpret the results of a test. A sickle cell carrier may believe he has the disease. He may suffer in silence, his mistaken belief draining the joy from his life and crushing his ambitions – and all for nothing.

For critics, threats like these are sufficiently great that DTC genetic testing should not be available. Only a health care professional should order a genetic test, interpret the results, and, if necessary, provide the patient with support and guidance.

Survey data show that people are likely to react in negative ways when they test positive for a genetic disorder. Bonadona et al. (2002) studied 23 post-treatment cancer patients who were told that they also tested positive for genetic susceptibility to breast, ovarian, or colon cancer and found that 8 were distressed by news, 14 had various negative feelings, and 16 were worried about a recurrence of cancer. The findings of studies like these confirm the critics' claim that people can be threatened by genetic information, but they do not support the additional claim that the potential harm requires rejecting DTC testing in favor of physician-mediated testing. There is surely another way.

I argued earlier that the predictive nature of genetic information imposes on DTC test providers a special obligation to educate and protect consumers. Getting bad or unintelligible genetic test results is difficult for anybody, and what is crucially important is that someone be available to provide interpretation and psychological support. Physicians have traditionally played this role, but nothing in principle stands in the way of passing on the responsibilities to specially trained nurse-practitioners and to clinical psychologists and social workers employed by DTC laboratories.

We have had experience with self-initiated, direct, and anonymous testing for HIV (Bindman et al., 1998). We know it is possible for commercial laboratories to devise systems that require those who are going to receive bad news to get it in a setting in which they also receive expert advice and psychological counseling. A system modeled on HIV testing could be put into place for genetic testing (Mehlman et al., 1996). The cost to test providers would be greater than sending results to the consumer by e-mail, and it might turn out that commercial genetic testing is not sufficiently profitable when such requirements are met. This seems unlikely, though, given the public's hunger for genetic information.

The same accuracy we demand of information supplied to potential consumers about genetic tests we should also demand for advertisements for

genetic tests. Ads that are misleading in the ways Hull and Prasad (2001) complain about are unjustifiable, but that ads can be misleading does not support the conclusion that DTC genetic tests ought not be allowed. To think otherwise would be as mistaken as believing we should not allow people to buy land because some sellers perpetrate fraud.

Conclusion

Beckman (cross-referred in Hull & Prasad, 2001) has pointed out that, when it comes to genetic testing, those who claim to be protecting the autonomy of individuals do so, paradoxically, by arguing that we must limit it. That is, the critics of DTC genetic testing claim that, for one reason or another, people should be kept from finding out genetic facts about themselves. They will either not understand them, misunderstand them, or be devastated by them. Those who discover the facts are no longer as free to act as they would be if they were ignorant of them. Thus, restricting freedom actually preserves freedom.

This way of thinking is well intentioned, but it puts adults in the same category as children whose parents protect them from the facts so that they may preserve their illusions about the Tooth Fairy. But when it comes to gathering information about their health status and making health-related decisions, people have rejected repeatedly and forcefully this sort of paternalism in favor of exercising their autonomy.

Although Bonadona et al. (2002) reported that most of her 23 subjects experienced distress upon learning they had tested positive for a gene predisposing them to cancer, she also found that 22 of the 23 did not regret having had the genetic test (p. 97). Her study is consistent with others showing that people want to have direct access to genetic tests (Harris Poll, 2002, p. 1). This is not surprising. To shape their lives, people need to make decisions, and making reasoned decisions requires information. Given that our society is committed to the autonomy of the individual, we should endorse policies that make it possible for people, if they choose, to acquire personal, reliable genetic data without going past a gatekeeper. Yet it is also crucial that we take the steps necessary to satisfy the conditions of informed consent, because we must also protect autonomy. This means educating people about genetic diseases and dispositions and warning them that the information they may receive may itself pose a danger to them. The strongly predictive character of genetic information places on test providers an obligation to meet the immediate needs of people who may receive crushing test results.

I said at the beginning that as a consequence of our presupposition favoring autonomy, the case for DTC genetic testing is prima facie. I have shown, I

believe, that the strongest reasons critics urge against direct access to genetic testing are not persuasive. Autonomy, in this case, is not trumped by a compelling state interest or the likelihood that others will be harmed. Thus, autonomy should prevail and DTC genetic testing should be permitted.

Life is an earnest affair, and most adults know they will be better equipped to cope with it when they know the facts. Even if the facts should turn out to be hard and bitter, people want to be free to learn them.

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5

Proscription, Prescription, or Market Process? Comments on Genetic Screening

Eugene Heath

A competitive market – established by a legal framework that allows for buying and selling, producing and manufacturing, servicing and advising – encourages competition, experimentation, and innovation. This is not a new insight,[1] even if it is sometimes ignored. Markets are innovative, and one of the more recent and unsettling innovations is the commercial use of genetic testing or screening. For a business firm, such tests provide the sort of knowledge that points to several benefits: a diminished risk that employees will succumb to job-related illnesses, an overall decline in employee medical liabilities, and a lessened probability that third parties will suffer injuries caused by an employee. Yet the use of genetic screening, in hiring and in insurance, raises concerns about rights, autonomy, and privacy. These issues are broached quite forcefully in the four essays focusing on genetic testing.[2] In offering critical commentary on the salient points of these papers, I maintain that the principle of autonomy and

[1] F. A. Hayek explains this idea in "Competition as a Discovery Procedure," in *New Studies in Philosophy, Politics, Economics and the History of Ideas* (Chicago: University of Chicago Press, 1978) (pp. 179–190). In a similar vein, Jane Jacobs suggests that the values that underlie commerce are the same as those that underlie science: "[S]cientific investigation proliferates and scientific knowledge ramifies and accumulates as a sequel to flourishing commercial life." *Systems of Survival: A Dialogue on the Moral Foundations of Commerce and Politics* (New York: Random House, 1992) (p. 44).

[2] Duane Windsor, "The Business Ethics of Genetic Screening" (in this volume, pp. 25–29), Thomas Harter, "Is a Genetics Screening Program for Job Applicants Ethical? An Analysis of the Conditions Necessary for Requiring Genetic Screenings in the Hiring Process" (in this volume, pp. 3–23), Karen S. Markel and Lizabeth A. Barclay, "Genetic Commerce: The Challenges for Human Resource Management" (in this volume, pp. 42–52), and Ronald Munson, "Geneticize Me! The Case for Direct-to-Consumer Genetic Testing" (in this volume, pp. 55–68). Citations from these essays will be noted within parentheses.

choice, as exercised within the varying conditions of commercial interaction, is crucial to innovation and experiment. The freedom to choose and select, to enter and exit, are essential to a good society and good lives, and these freedoms should not be disregarded in favor of proscriptions and prescriptions that are not fully justified.

Rights, Contracts, and the Precautionary Principle

In his provocative chapter, "The Business Ethics of Genetic Screening" (in this volume, pp. 25–39) Duane Windsor argues that there should be a complete ban on genetic screening, whether for employment or insurance. Motivated by the understandable and laudable desire to forestall negative consequences of the new technology, Windsor reaches a conclusion that pivots on two claims, that the individual has certain fundamental and universal rights and that the precautionary principle has relevance to the commercial use of genetic screening. However, he does not delineate his argument in a concise way, so the following is offered as a reconstruction:

(i) The right to privacy and the right against discrimination are "fundamental and universal" (p. 26) rights.[3]
(ii) Because a business "operates to maximize the wealth of investors and their agents" (p. 29), one cannot reasonably expect any business to use the results of genetic tests in ways that do *not* risk violating a right to privacy.[4]
(iii) Because insurance companies also operate "to maximize the wealth of investors and their agents" (p. 29), one cannot reasonably expect such companies to use the results of genetic tests in a non-discriminatory manner.[5]
(iv) Since it follows, from (ii) and (iii), that one cannot expect businesses to use the results of genetic tests in ways that do not risk violating rights to privacy or non-discrimination, then a public policy is needed to ensure that the use of genetic tests does not risk violating these rights.
(v) The precautionary principle ought to be applied to protect rights of privacy and non-discrimination.

[3] "The weight of considerations is that the rights involved are fundamental and universal. In the United States the rights should be viewed as fundamental liberties protected by extension of the Bill of Rights" (Windsor, p. 26).

[4] "It must be presumed businesses disregard ethics and laws other than as externally enforced constraints obeyed only to the limits of cost–benefit calculations concerning the firm's bottom line. Upon this analysis, no firm can be trusted with individuals' genetic information or expected to operate as a social agent" (Windsor, p. 30).

[5] "Insurers will deny access or practice price discrimination by compulsorily required genetic information. Privacy and nondiscrimination argue against such practice" (Windsor, p. 30).

(vi) The application of the precautionary principle, in this context, "favors a complete ban on business use of individual genetic information" (p. 27).
(vii) Therefore, the government ought to institute a complete ban on the use of genetic testing for businesses or insurance.[6]

There is much that one might comment on in this argument, but most of my remarks will focus on the right of privacy and the precautionary principle.

Let us turn to the first premise, which invokes rights to privacy and non-discrimination. It is not entirely clear how Windsor understands these rights. He states that these are rights of consumers and of employees, but he does not delineate their content or point out the claims that could be generated on behalf of the rights-holders. He does, however, maintain that such rights are "fundamental and universal" (p. 26), but he offers no explanation for this contention, only the proclamation, "The weight of considerations is that the rights involved are fundamental and universal" (p. 26).

Each of the rights specified in premise (i) have varying interpretations, but Windsor does not elaborate on these. An (alleged) right to privacy is woefully vague, if not altogether dubious.[7] Windsor's appeal to the U.S. Constitution, as the particular American application of this more universal right, is of little help in sorting out either the content of the right or its justification. Those who accept his interpretation, that there is some constitutional right of privacy, will have their opinions reinforced; those who do not will find this invocation presumptuous and question begging, if not altogether irrelevant.

Windsor proceeds to suggest – apparently in defense of his appeal to this right – that there is "a strong presumption in favor of privacy" (p. 28). The evidence for this presumption he takes from the Fourth Amendment to the U.S. Constitution. He states that it is not a "conceptual stretch" (p. 28) to move from the prohibition against "unreasonable searches and seizures" (p. 28) to what I suppose is a presumption against securing genetic information about persons other than oneself. It is worth recalling, however, that the Fourth Amendment focuses on what may or may not be done by a *public* official against a person's will. However, genetic screening concerns private (commercial) exchanges. If Windsor wants to argue that any contractually arranged genetic screening is coerced and non-voluntary, then he should do so. If he wants to argue that the Fourth Amendment has created a set of expectations about the nature of privacy that entails certain presumptions about genetic screening, then he ought to do this, too. But he does neither of these. Nor does he show why an amendment

[6] Windsor also advocates the passage of the Genetic Information Nondiscrimination Act. Since his arguments are directed less towards the specifics of this piece of legislation than towards the broader moral claim, I address only the latter.

[7] Such a right does not appear in the classic literature on rights and it is unclear how one can make sense of the right without first positing some other rights such as a right to property.

regarding *public* officials has force over that to which *private* individuals might agree or contract.

Indeed, the very appeal to the Fourth Amendment ignores altogether the fact that this amendment concerns "unreasonable" searches and seizures. Presumably what is reasonable and unreasonable, permissible and impermissible, is precisely what is at issue. If so, then on a quite plausible formulation of the right to privacy, the bearer of the right may allow others to view, hold, consider, or transmit that which would otherwise be deemed private (or out of bounds). After all, even if one has a right to privacy, such a right may include the power to grant permissions to peek! My diary is my own, but if someone says, "I will give you $100 if you let me look at the hot bits," then since the very offer of money is but a manner of respecting my right to privacy, it does me no good to harrumph: "I have a right of privacy!" But it might do me some real good to ask, "Cash or charge?"

As he develops his case, Windsor invokes another right of individuals, a property right in their own genetic information: "The property rights to genetic information ... rest inherently (and organically) in the individual human being, and cannot shift to whoever manages to capture that information in some manner" (p. 27). One must hesitate at this formulation. For example, I do not have a property right to genetic *information*, not even my own. I may have a property right to my genes, but the right to information is distinct. (Consider an analogy: If I own the topsoil on my lawn, that fact does not entail that I have a property right to information about the nutrient levels of the soil.) Perhaps I may acquire a right to genetic information about myself, but I must, presumably, either generate this information on my own (requiring years of education and a fair amount of laboratory equipment) or I must hire someone to generate it for me, stipulating to that person the proviso that I retain control over the information generated. That information is mine; it is my property. On this account, the property right to genetic information is not some basic right but a right subsidiary to a more general right to contract with others to use elements of one's body to generate information about oneself. Thus, any sort of right to genetic information is, in fact, the sort of right that is analogous to that right that we have to our medical information: personal medical information (at least of a certain sort) exists because of someone's relation to us (viz., the investigating physician with whom we have voluntarily contracted); the information appropriately gleaned from that relation is to be used or transmitted only with our permission.

If this formulation is preferable to the claim that one has some bare property right to genetic information, then it would also seem to follow that this right would allow one to voluntarily relinquish, by gift or contract, one's genetic information. For example, if a person or firm offers me a job on the condition that I provide (or otherwise relinquish) genetic information about

myself, then why should I, the owner of the genes, be forbidden from taking that job and surrendering that information? If I have a property right to that information, or a right to allow another party to generate that information, then it is no longer so obvious why a firm should be forbidden from making me a job offer on the condition that I surrender genetic information. And if this right to my genetic information is a property right, then surely the burden of proof is, *pace* Windsor's counsel, on those who would prohibit my use of this property, including those who would ban the use of genetic screening.

Windsor's appeals to rights might be more perspicuously drawn, and this would strengthen his interesting case. Nonetheless, it is important to point out that he is not contending that any choice or contract to relinquish genetic information to an employer is *ipso facto* a violation of one's right to privacy. In other words, a right of privacy is compatible with the right to relinquish to other one's genetic information. (If Windsor were to argue the converse, that a right to privacy is violated by relinquishing one's genetic information, then it is not at all clear how he could contend that one's genetic information is a property right.) Thus, as I have reconstructed Windsor's argument, premise (ii) is compatible with accepting employment on condition of providing the firm with genetic information; however, the premise explicitly maintains that relinquishing this information, though not itself violating a right to privacy, sets in train the *risk* of having one's privacy violated (e.g., through the firm's use or transmission of that information). Unless one construes premise (ii) in this manner, then it would be unclear as to why Windsor would even need to invoke the precautionary principle: if a surrender of one's genetic information violates a fundamental and universal human right, that alone should be sufficient for prohibiting such transactions. Thus, since Windsor does not maintain this claim, it seems clear that the transaction to surrender one's genetic information is not, in itself, a violation of rights.

Premises (ii) and (iii) suggest that the surrendered information might be used in ways which violate either the right to privacy or to non-discrimination. But why might this occur? Windsor does not delineate specific examples, but he does allude to a motive for such misuse: "It must be presumed [that] businesses disregard ethics and laws other than as externally enforced constraints obeyed only to the limits of cost–benefit calculations concerning the firm's bottom line" (p. 29). Let us grant this melancholy view of business,[8] along with Windsor's right to privacy. We may also grant, without argument, Windsor's contention, in premise (p. 27) that a public policy is required.

[8] If we assume some such motivations to hold for businesspeople, then by what reason do we refrain from attaching a similar type of motive to others, including academics, journalists, politicians, and public administrators? Why ought we to assume that these individuals act for the public weal rather than the private?

We arrive, then, at the precautionary principle, premises (v) and (vi). Windsor recognizes some of the deficiencies of this principle, but he does not state exactly how he understands the principle. He contends that it is a *principle* rather than a rule (p. 34), and that it has been endorsed by a variety of distinct organizations or commissions (p. 35),[9] but he does not articulate the principle so that one can discern its strength or its implications. And yet, he concludes, "The 'principle' is simply an absolute ban until absolute certainty of safety is established" (p. 36). This statement suggests that the principle, which has varying degrees of strength, is invoked with maximum force: an "absolute ban until absolute certainty."

One may first question why the precautionary principle is essential to this discussion, especially since the idea of "irreversible harm" does not seem as relevant to a violation of a right to privacy or to non-discrimination as it does, say, to environmental destruction or genetic engineering. Of course, any such violation is irreversible in that it cannot be taken back, but such violations may be compensated nonetheless. Along with penalties for misuse of such data, the requirement of compensation may prove sufficient for eliminating and redressing many such violations. In fact, these legal penalties may be preferable to a general ban on all genetic screening.

Of course, there is no guarantee that there will be *no* such violation. This takes us to the legitimacy of the principle itself. Despite his admissions – following the work of Cass Sunstein[10] – that the principle so understood "itself creates hazards" (p. 36) and may set in place "a paralyzing ban on change" (p.37), Windsor concludes that the principle requires a ban on all genetic screening. I need not rehearse the critical points so ably noted by Sunstein, for Windsor is aware of these. However, it is not clear how Windsor's appeal avoids these criticisms. Sunstein notes how a weak version of the precautionary principle need not seem unreasonable.[11] However, even apart from the vagueness of the principle, Sunstein's conceptual point remains: the principle may forbid any action – including that of a ban! – precisely because such action may run its own risk![12] For example, if the precautionary principle

[9] It is not surprising that the principle has been endorsed by bureaucratic organizations such as those noted by Windsor (p. 35). For the administrators of these bodies know that if some terrible event arises, then they may be blamed; on the other hand, if other positive events never come into being then they will not be blamed at all. Thus, an assumption of self-interested action on the part of the administrators of bureaucracies may be at least as plausible as the assumption that these administrators act for the public good.

[10] *Laws of Fear: Beyond the Precautionary Principle* (Cambridge: Cambridge University Press, 2005).

[11] "The most cautious and weak versions suggest, quite sensibly, that a lack of decisive evidence of harm should not be ground for refusing to regulate." Sunstein, 18.

[12] "In some of these cases, it should be easy to see that in its own way, stringent regulation would actually run afoul of the Precautionary Principle. The simplest reason is that such regulation might well deprive society of significant benefits, and hence produce serious harms that would otherwise not occur." Sunstein, 29.

counsels a "complete ban," then one must take into account that such a ban may risk other goods (including products that are crucial to a variety of industries and manufacturers) that could be profitably produced only by the use of genetic screening. Windsor may rightfully protest that his ban would include a proviso that the burden of proof is placed on the employer to demonstrate that in some particular case the ban should be lifted. However, he does not explain what the burden of proof must demonstrate or to whom. This ban, and its imposition of a burden of proof, may well raise the cost of production to such an extent that firms will exit the field or opt not to engage in certain types of manufacture. A complete ban on genetic screening in the workplace might raise the cost of manufacturing to a level that would either decrease competitiveness in that industry or eliminate the industry altogether. This, too, is a risk that must be weighed in the balance.

The Costs of Doing Business

Unlike Duane Windsor, Thomas Harter[13] holds that there are instances in which genetic testing should be permissible. He delineates, in a thorough and careful manner, how such screening must be justified, consensual, accurate, and confidential. Yet there is a significant and unintended consequence of imposing these conditions: they may so raise the cost of doing business that firms decide to cease manufacturing needed goods, or businesses simply disappear, unable to generate revenues sufficient to cover costs.

Harter carefully summarizes the reasons that firms might want to institute genetic screenings. Like Windsor, he too notes "two dangers" (p. 8) that may arise from such screenings, discrimination, and invasion of privacy. In his discussion of privacy, Harter draws on the work of Joseph Kupfer.[14] However, Harter does not make clear how relinquishing (or making available) genetic information, as a condition of employment, would constitute an "undue invasion of privacy" (p. 10). Setting aside any quibble between an "invasion" and an "undue invasion," it is worth pointing out that the phrase "invasion of privacy" has at least two senses: in one sense, the phrase may be used to refer to an impertinent question (e.g., "Are you seeing a psychiatrist?"), but in another, and stronger, sense the phrase may be employed to refer to a violation of some right. For example an impertinent question may probe for private information, but however rude or irrelevant that question may be, it need not violate a right.

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[13] "Is a Genetics Screening Program for Job Applicants Ethical? An Analysis of the Conditions Necessary for Requiring Genetic Screenings in the Hiring Process," (in this volume, pp. 3–23).

[14] Kupfer (1993), The Ethics of Genetic Screening in the Workplace. *Business Ethics Quarterly*, 3, 17–25.

The second stronger sense of the phrase could be asserted when, say, a stranger peers through the window of one's home or someone plants a camera in one's house and surreptitiously films one's daily activities. It is not altogether clear that genetic screening for employment rises to the stronger sense of "invasion of privacy." One may grant that genetic information is part of what individuals understand to "make-up part of their personhood" (p. 11); moreover, one's genetic configuration is not subject to one's control.

However, it is not clear that either condition, as noted by Harter, is necessary to establish the stronger thesis of invasion, nor is it obvious that the two conditions are together sufficient for that thesis. One's ancestors also make up one's personhood and who these ancestors are is not up to one's control. But having to reveal these ancestors, as a condition of contract, does not seem to constitute an undue invasion of privacy, though it may seem impertinent. Perhaps what is required is some additional condition of vulnerability: that the (genetic) information not only makes up part of one's personhood but may plausibly contain information about particular vulnerabilities or weaknesses.[15] Even if these conditions, suitably clarified, establish that genetic information is private, they do not obviously suffice to show that the *request* for genetic information, as a condition of employment, is an "invasion of privacy," at least in the strong sense (even if it is an impertinence).

Harter notes that an employee's rights to privacy are not absolute, for an employer has an interest in forestalling workplace risks (p. 12). Thus, Harter suggests, there are conditions under which an employer could require genetic screening. What he does not consider is whether his own words belie his suggestion that regulations are needed. In pointing out the value of privacy he describes how,

> Privacy is something that ought to be valued and respected by employers because it allows applicants and employees to build the kind of trusting relationships necessary for a company to flourish. Conversely, employers who do not value the privacy of their applicants and employees create an atmosphere of distrust that would seem to undermine a company's ability to achieve any kind of long term flourishing (p. 13).

In this passage Harter reveals how there exist market incentives for respecting privacy. One firm's recognition of the importance of privacy provides a competitive advantage relative to the firms that do not. If these incentives function as Harter suggests, then is it even necessary to specify conditions for the use of genetic screening? The processes of market competition should ensure that

[15] Harter notes that "the nature and scope of the information revealed" would constitute another "concern" but he seems to treat this as a concern distinct from that of privacy (p. 11).

firms come to adhere to some baseline protocols that honor the importance of privacy. That such norms may emerge will not guarantee that all firms will put in place the same policies; however, via a process of experimentation firms will seek to set in place the necessary genetic screens consonant with the conditions requisite to maintaining trust.

That processes internal to the market might generate outcomes that serve both to encourage efficiency and to respect the values of employees is not an outlandish notion, especially if the concern for privacy is as deep and widespread as Harter and others have described. Nonetheless, it is important to consider Harter's proposal, namely, that genetic screenings must be justified, consensual, accurate, and confidential. My general criticism is that these four conditions, if enforced, would raise the cost of doing business and might risk, as noted above in Section I, reducing competition or eliminating an industry altogether. Why might that be? Harter elaborates three elements of an adequate justification: that the screenings must be correlated with workplace exposures, that the risks are "applicable to all applicants" and that the information that is gleaned "is assessed and used appropriately" (pp. 13–14). These are costly requirements. In fact, their vagueness provides an open invitation to litigation. The second requirement, that the risks be applicable to all applicants, is a difficult, if not confusing, stipulation – unless, of course, one knows a priori that all applicants are subject to the same risks.[16] However, in a company that employs males and females this clause would disallow screening for risks that apply, say, only to males. If, as Harter states, a firm is to apply the screening to all, regardless of a known risk (p. 14), then he raises the cost of doing business in an irrational manner. Suppose that a company has one hundred employees and ninety are female, ten are male. Imagine, further, that only males have a hypersusceptibility to a disease that may be linked to the firm's manufacturing process. Is this company to test all ninety females in addition to the ten male employees who are susceptible? Harter seems to suggest that the answer is "yes," and that would seem to make a fetish out of a policy of non-discrimination.

The third requirement of an acceptable justification holds that the information must be "assessed and used appropriately." This clause is woefully vague: it demands a judgment about the correlation between the test and the workplace exposures, and it requires "appropriately weighing an applicant's

[16] It is unclear how Harter wants us to understand this clause. For example, he writes, "[E]mployers cannot know which applicants are hypersusceptible unless those applicants test positive for that trait. This is why I claim the associated risks between hypersusceptibilities and workplace exposures must be applicable to all applicants. When there is a correlation between hypersusceptibilities and workplace exposures, employers must treat all applicants as though they have the hypersusceptibility until the results of the screenings are revealed" (pp. 14–15).

genetic information" (p. 15) in relation to other factors.[17] Unless this clause could be rendered more precise, then it would stymie new entrants into the field, discourage the use of processes for which genetic screening might be helpful, and open up a web of possibilities for litigation.[18] (Further costs would arise in order to meet the fourth condition, confidentiality. This condition is met only if there are independent testing facilities and counselors who are available to discuss the results with employees (p. 20).)

Here is the endgame. A company has a choice: it can either do without genetic screening and subject itself to the risk of employee litigation (if, say, an employee gets ill) or it can genetically screen and subject itself to the risk of litigation if an employee does not get a job, has a grievance, falls ill, or otherwise claims "inappropriate testing." What will this company do? It may cease manufacturing the good and disappear.[19]

Market Processes

Profs Markel and Barclay[20] describe some of the practical implications of the issues taken up in the previous essays. In so doing they clearly demonstrate, in a broad and nuanced manner, the host of responsibilities (ethical, political, and strategic) that genetic screening would demand of Human Resource Managers. A significant value of their essay is its recognition, even if implicit,

[17] The essay by Markel and Barclay points out how difficult it is to determine if genetic screens are job related. See p. 44 of "Genetic Commerce: The Challenges for Human Resource Management."

[18] Consider Harter's striking description of the difficulties involved in weighing whether it would be discriminatory to refuse to hire an individual with epilepsy: "The question of whether it is wrong to discriminate against this applicant because he has a genetic form of Epilepsy depends on different contextual factors. If on one hand, the correlations between the applicant's seizures and workplace exposures are weak, and the applicant is taking medications to mitigate the effects of the Epilepsy, then the likelihood increases that not hiring the applicant because of his genetic information is both illegal and unethical. If on the other hand, the correlations between the applicant's seizures and workplace exposures are strong, and the applicant is not doing all he could to mitigate the effects of the Epilepsy, then while the chances are still high that not hiring the applicant is illegal, it also seems the case that not hiring the applicant based on this genetic information is ethical, as the employer is thereby helping to protect both the applicant and the general public from what seems to be foreseeable harm" (p. 17).

[19] As an example, the number of firms manufacturing vaccines has declined tremendously over the past 35 years. The explanation for this decline has much to do with the costs of manufacture, including the cost of liability suits. See the special issue of *Health Affairs* 24 (May/June 2005), in particular the essay by Paul A. Offit, "Why are Pharmaceutical Companies Gradually Abandoning Vaccines?" (pp. 622–630).

[20] "Genetic Commerce: The Challenges for Human Resource Management" (in this volume, pp. 42–52).

of the importance of permitting markets to experiment with genetic tests as a means of determining what is both efficient and acceptable. Throughout the essay they note some of the variables that might influence a firm's decision to require a particular sort of genetic screening. As the authors conclude, the "need for genetic testing is going to vary" (p. 49) among firms within and across industries. They summarize in a table (p. 51) the types of considerations that human resource managers must consider. They point out, for example, that regardless of the legal environment, "many potential or current employees are likely to refuse to provide this [genetic] information unless a clear connection to their jobs and possibly a rationale for its intended use and protection are provided" (p. 44). They describe how human resource professionals will "develop protocols" (p. 45) for genetic screening. Such protocols will specify when screening is required, how information is processed, and how the results are communicated to employees (p. 49). As Markel and Barclay observe, "the extent and nature of this protocol [of genetic testing] is likely to vary by the industry, role of human capital, and accompanying approach to risk management" (p. 49).

Whether or not employees or potential employees will agree to these tests, the types of protocols that may be put in place, the types or kinds of counseling, and so on are matters that might be left for market participants to determine via their own negotiations and interactions and in light of scientific developments and changes in products and production techniques. Barclay and Markel do not assume, for example, that organizations *must* hire an independent firm to perform genetic screens; rather they suggest that "Organizations may . . . want a third party provider" (p. 51) as a means of diminishing liability and ensuring expertise. All in all, the essay of Markel and Barclay reveals how the laws that frame and undergird the market ought to permit, even in the case of genetic screening, variation and experimentation. Laws that do not permit such can offer little more than flat prohibitions or complicated rules honed to each industry (or, more realistically, perhaps, honed to each industry's preferences as communicated to legislators and regulators by industry lobbyists).

In the course of describing the responsibilities of human resource professions, Markel and Barclay also raise an interesting question: What to do about the executives? When we consider a topic such as genetic screening we tend to think of employees on the factory floor or technicians working in the lab. We hardly give a thought to the relatively fewer individuals in the paneled executive suites. However, Markel and Barclay wonder whether genetic screening might be more justified in the case of the high-level executive. We might push this consideration further: Is such screening justified because the executive is a person less easily replaced than other employees? Or are these tests justified because of the critical functions of the executive? These are, perhaps, two sides of the same coin, but each points to another possibility, that such screening is justified because the compensation allotted to an executive provides a Board

of Trustees with the "moral leeway" to demand more of that individual than might be demanded of others.

Autonomy

Prof. Munson has contributed a valuable and thoughtful defense of direct-to-consumer (DTC) genetic testing.[21] He defends this practice by appealing to the idea of autonomy: that our actions ought to flow from our own decisions. Taking such a principle as a prima facie assumption, he argues that, in cases where there is informed consent, competent adults should be permitted to contract for their own genetic tests.[22] This is a very straightforward and clear thesis and it is one that should be welcomed. (He contends similarly that deceptive trade practices, on the part of genetic test vendors, would serve to undermine autonomy.) Too few business ethicists uphold an ideal of genuine autonomy, and Munson is readily aware of the organizations and forces that might seek to regulate or forbid its exercise. His appeal to autonomy can be defeated by establishing that DTC testing "substantially threatens the welfare of the public or certain classes of individuals" (p. 61). Munson ably responds to the arguments launched against his appeal, showing that even on consequentialist grounds the reasons given are, in fact, rather weak. None demonstrate any threat to public welfare.

Autonomy is an important principle. If it bears the significance that Munson attributes to it, then it may have implications not fully recognized in the papers under discussion. In particular, if my actions should reflect my free choices, then perhaps we need not mandate all sorts of laws specifying conditions on when or whether a firm might request (as a condition of hiring) that an employee undergo a genetic screen. Prof. Munson recognizes that individuals may purchase, on their own, genetic tests that are not necessary and he underscores how this fact is one consequence of permitting autonomous choice. However, why not allow firms to stipulate, as a condition of employment, genetic tests that are not fully justified? Or why not permit companies to request genetic screens of some but not all applicants? It is not clear to me that

[21] "Geneticize Me! The Case for Direct-to-Consumer Genetic Testing" (in this volume, pp. 55–68).

[22] At one point, Munson declares that his argument "favors a social policy of making genetic tests directly available to those who want them and who meet the conditions for informed consent. The presupposition favoring autonomy also favors allowing DTC genetic testing, and it is this implication that critics must rebut" (p. 61). I take Munson's real conclusion to be one concerning DTC testing. I set aside whether or not his argument also "favors" a "social policy . . . making genetic tests directly available."

such requests would violate autonomy, even if such tests might be, for other reasons, less than fully desirable.

Having advocated the permissibility of a market in DTC tests, Prof. Munson nonetheless maintains that these should include the option of "support and counseling" (p. 60): "someone [must] be available to provide interpretation and psychological support" (p. 66). He contends (a) that it is a "moral obligation (and should become a legal duty)" for firms to institute such counseling (p. 60) and (b) that certain minimal standards should be required to render effective this obligation. Taking the latter point (b) first, Munson admits that the imposition of these minimal standards might have the effect that "commercial genetic testing is not sufficiently profitable when such requirements are met" (p. 66). He states that this consequence "seems unlikely," but it is not clear on what basis he can make this claim. The particular provisos that he requires – review of each test result by a licensed physician, delivery of test results in a face-to-face setting by a genetically trained nurse practitioner, and the guarantee to each client of "access to immediate psychological support by a clinical psychologist or social worker" (p. 61) – seem quite agreeable, but it is not clear why such agreeability must be prescribed for others. Even if such arrangements have their appeal (e.g., "That is the sort of testing regimen that I would choose"), what seems agreeable to some persons – with their incomes, preferences, and habits – might not be agreeable to others.

This leads back to point (a). Presumably, as Munson attests, there is a moral requirement that the testing firm provide some post-screening counseling. Munson states that the moral obligation derives "from the uniquely predictive character of genetic testing" (p. 60), in particular, that fact that genetic testing may reveal predictions of terrible disease or death. He concludes, "Any laboratory offering genetic testing has to assume the burden of supporting people who get such [bad] news, in much the same way that a cruise ship must have lifeboats" (p. 60). With regard to the moral obligation, our intuitions might be less rigid than we realize. Let us recall consider Munson's own example of Tom Henson. Tom selects a genetic testing company, "Gentrue," from his wireless notebook. He then opts for the "Gentrue Multitest" (p. 56) and, using the special kit supplied to him by this firm, he collects a blood sample and sends it, via Fed Ex, to Gentrue. According to Munson, Tom will receive "up to an hour of private education and as much as 2 hours of advising with a licensed genetic counselor" (p. 56). As Munson elaborates,

> He can order the tests online, and a physician will review the results. But to get the results Tom will have to go to a clinic. A nurse–practitioner with special training in genetics will explain them to him and, if necessary, refer him to a specialist. If the results are likely to be upsetting, Tom will see a clinical psychologist or social worker who will provide him with immediate support and arrange for him to receive further care (p. 56).

For these services, Tom will pay $1,000 (p. 56). But let us consider a slight alteration of Munson's original example.

Suppose that Tom were to discover another company on his wireless, a firm whose name is "Gencheap". Gencheap offers a multitest that checks for the same susceptibilities and dispositions as the "Gentrue Multitest." And according to Medical Consumer, Gencheap has a rating for reliability of results that rivals that of Gentrue. However, Gencheap, unlike Gentrue, offers no post-screening counseling or psychological services. In fact, Gencheap makes it very clear that it does not offer these services and requires its clients to sign a statement that attests to their knowledge of this fact. The second difference between the two companies is that whereas Gentrue charges $1,000 for its multitest package with support services, Gencheap offers the same multitest, without support, for only $625. Tom elects to purchase the Gencheap multitest for $625, deciding that he has better things to do with the remainder of his $1,000.

What is the moral of this tale? If Gencheap may compete with Gentrue, then not only is the overall state of affairs more preferable (than if Gencheap were legally prohibited from competing), but Tom Henson's autonomy is enhanced. However, if Munson's requirement of counseling were put into law, then firms such as Gencheap would not be allowed entry into the market. The original intuition that would justify this prohibition now seems less persuasive. In fact, it is hard to escape the thought that an enforceable requirement to maintain counseling services is, in fact, paternalistic, a conclusion that Munson might want to avoid. Just as we do not require libraries[23] to have counselors on hand if someone reads or learns something that is devastating, neither should we require this of firms.

That is not to say that the general idea of counseling is not appealing. It is. But why must this be mandated? The great lesson of markets, as governed by a genuine rule of law, is that they allow innovations and they work to adapt to consumer interests. Why not allow them to function, encouraging the owners and managers of firms to exercise virtue and good judgment as they respond to the preferences of both customers and employees? This question is not to suggest that anything goes, only that before the business ethicist begins proscribing and prescribing, we might first permit the market process to evolve.

[23] Indeed, we may recall what Munson states about research in the library: "We place no restriction on those who go to web sites or libraries to research their family background to learn what it suggests about their disease risks. Why then should we restrict them in getting their DNA tested?" (p. 63)

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Part II

Genetically Modified Foods

Perhaps the most economically significant area of genetic commerce today is in the arena of genetically modified foods (GMFs). The altering of plant genes, the market for modified seeds, and the growth and distribution of harvested modified foodstuffs comprise a market worth many billions of dollars. GMFs also touch the individual in more visible ways than other aspects of genetic commerce today. On the positive side, modified foods promise greater harvests, higher agricultural productivity, and perhaps cheaper food with the potential to alleviate hunger. By contrast, many object to the non-natural character of GMFs, some on grounds that might be characterized as esthetic, and some due to a fear that GMFs will lead to seriously adverse consequences, such as loss of genetic diversity, extinction of plants that humans have relied on for millennia for food, unanticipated health problems, and even a genetic catastrophe in which GMFs infect natural plant species with hugely disastrous consequences.

Johann Klaassen accepts the direct challenge to "Frankenfoods" and ultimately argues in their favor in his essay, "Commercialization of the Agrarian Ideal and Arguments against the New 'Green Revolution': Feeding the World with 'Frankenfoods'?" In doing so, he considers a further objection to GMFs – the view that their development by large chemical concerns such as Monsanto will place third-world farmers in thrall to first-world corporate interests. However Klaassen believes that proper supervision of these firms can prevent exploitation of small farmers, and he concludes that the advantages of GMFs ultimately outweigh their potential risks. Chris MacDonald and Melissa Whellams address the question of mandatory labeling of GMF products in "Corporate Decisions About GM Food Labeling." MacDonald and Whellams acknowledge that consumers have expressed a preference for such labeling, but that firms have largely not responded to this clear desire. They ultimately conclude that: "Given the lack of solid evidence for any risk to human health, and the serious market disadvantage almost surely associated with costly unilateral action, no individual company has an ethical obligation to label its GM foods."

In "Transgenic Organisms, the European Union, and the World Trade Organization," Dennis Cooley also considers the role of trade agreements in regulating the production and labeling of GMFs and transgenic organisms. In Cooley's view, public opinion and scientific evidence conflict in the guidance they give regarding the production and labeling of GMFs. One way to resolve

this impasse is to look at a third source of guidance – agreements and commitments that nations have already made. Cooley argues that, in many cases, nations have already committed to trade agreements and these trade agreements specify much of the proper practice regarding food labeling. This is a specific problem for the EU which, according to Cooley, imposes strict regulations on GMFs that conflict with WTO agreements.

In contrast to the other chapters in this part, Denis Arnold essentially defends voluntary labeling of GMFs in his essay "Moral Imagination, Stakeholder Engagement, and Genetically Modified Organisms." Arnold's argument turns on the idea of moral imagination: "the ability to reexamine conventional practices and to imagine novel courses of action that have the capacity to improve outcomes from a moral perspective." The morally imaginative firm might engage in stakeholder dialogue with the ultimate result of voluntarily labeling the GMFs that the firm produces. According to Arnold, such a result can improve the firm's standing with its public and may lead to improved financial results for the firm. While agreeing that firms may not have an ethical obligation to label GMFs, morally imaginative firms may find compelling reasons to provide such labeling nonetheless.

6

Transgenic Organisms, the European Union, and the World Trade Organization

Dennis Cooley

Introduction

The European Union's (EU) regulatory framework for transgenic organisms (TOs) replaced the former de facto moratorium, in effect since 1998 (Regulation (EC) 258/97). Among the rules are strict safety testing and authorization provisions, as well as requirements for all products containing transgenic ingredients to be traceable from "farm to fork," and those exceeding 0.9% authorized TOs or 0.5% unauthorized TOs be labeled as such (EC (1), pp. 1–9). Furthermore, animal feed will now be governed by the same principles as food (Pew Initiative on Food and Biotechnology (1), p. 8).[1]

The framework clearly incorporates the Precautionary Principle and the right of consumers to know what is in their food as two of the document's primary guiding rules (EC (1), pp. 5 & 9; EC (2), p. 1).[2] In part, based upon Article 1 of the Cartagena Protocol on Biosafety, the EU claims the right to implement a new framework which "establishes a regulatory regime for [TOS] after a careful assessment of risks, appropriate control and monitoring measures, and proper information to consumers" (EC (1), pp. 1 & 9).[3] Of course, this standard is stricter than those employed in the United States and many other countries.[4]

[1] If it can be shown that EU regulations are unjustified for products consumed by humans, then it will follow that they are unjustified for products consumed by animals.

[2] The Cartegena Protocol on Biosafety seems to be the international standard adopted by the EU.

[3] The meaning of ambiguous terms, such as careful assessment of risk, is a matter of interpretation. Each of the individual parties involved in the issue will use the definition that best suits its conceptual framework.

[4] Even before the framework was finalized, the United States, Canada, Egypt, and Argentina filed a complaint with the WTO against the EU's moratorium on authorizing new transgenics for the market (EuropaBio, 2003, p. 1). Third party support for the complaint comes from Australia, Chile, Colombia, El Salvador, Honduras, Mexico, New Zealand, Peru, and Uruguay.

Given the still restrictive nature of the EU's framework, the complainants are likely to continue to press their claims and file new cases due to what they will see as unnecessarily difficult trade requirements. The United States, for instance, has already called the new rules costly, unworkable, unenforceable, unnecessary, and illicitly discriminatory (Pew Initiative on Food and Biotechnology (1), p. 12).

The EU's regulations on testing, authorization, labeling, and tracing are unethical. First, the framework causes unnecessary harm to the degree it should be prevented. Second, the WTO's goal of improving lives through its agreements' linkage of free trade, equalitarianism, and "[increased] living standards, full employment ... expansion of demand, production and trade in goods and services with the optimal use of the world's resources, in accordance with the objective of sustainable development" cannot be achieved (United Nations, 2003, p. 196). By using scientifically unsupported assumptions to make decisions, the framework violates the WTO's Agreement on the Application of Sanitary and Phytosanitary Measures (SPS). The result is the market becomes more inefficient and unfair. Furthermore, although the labeling and traceability rules do not as clearly violate the WTO's Agreement on Technical Barriers to Trade (TBT) as it does the SPS, implementing the EU regulations sets a dangerous precedence, based on irrelevant and illicit biases, such as cultural prejudices, for unjustifiable restrictions of all trade. Finally, I will suggest a course of action the EU can take to satisfy the WTO agreements and accomplish the Union's long-term objective of providing consumer information and promoting safety.

Two Moral Arguments

In order to validate ethically the framework of regulations, the EU must satisfy two conditions. First, the rules cannot cause what John Stuart Mill calls unjustifiable harm to others. That is, the regulations may permissibly produce only necessary harm. Second, the EU cannot violate any morally legitimate trade agreement regulating the market, such as the WTO's SPS or TBT. Conjoined together, the two conditions comprise a plausible ethical principle to evaluate actions and trade regulations. Avoiding undue harm to others and honoring legitimate contracts are at least prima facie conditions for ethical duties.

In *On Liberty*, John Stuart Mill argues for minimal government intervention in free trade. "Restrictions on trade, or on production for the purposes of trade, are indeed restraints; and all restraint, *qua* restraint, is an evil" (Mill, 1988, p. 164). In order for utility to be maximized, buyers and sellers will freely move capital so that fair priced and quality goods are distributed efficaciously (Ibid., pp. 163–164). In general,

> there is no one so fit to conduct any business, or to determine how or by whom it shall be conducted, as those who are personally interested in it. This principle condemns the interferences ... of the legislature, or the officers of government, with the ordinary processes of industry.
>
> Mill (1988, p. 178)

The only time individuals or governments may interfere with another individual's trade liberties is if there is a "strong case from utility" (Hollander, 1985, p. 686).[5] In other words, the restriction must maximize utility.

For Mill, no action should be prevented unless it causes unwarranted harm to others. "Acts, of whatever kind, which, without justifiable cause, do harm to others, may be, and in the more important cases absolutely require to be, controlled by the unfavorable sentiments, and when needful, by the active interference of mankind" (Mill, 1988, p. 123). In other words, if unfavorable sentiments cannot control an illicit action, then, in some cases, active interference in another agent's freedom to perform actions is validated. Of course, the criterion to evaluate the legitimacy of this type of interference is whether or not such actions tend to maximize utility. If it can be shown elements of the EU's regulatory framework cause unjustifiable harm, then, according to Mill, they should not be adopted, and it is morally permissible for others to actively prevent them from being implemented.

In addition to the requirement not to cause undue harm, individuals and "civilized societies" or nations have a duty to honor their morally legitimate contracts/trade agreements (Pound, 1959, pp. 133–136 & 151).[6,7] The reason why this capitalistic obligation exists is obvious. First, markets require utility maximization, justice, and freedom of choice in order to operate ethically (Velasquez, 1998, pp. 408–410). If investors and companies could not have some sort of knowledge and guarantee about what will happen in the future and at what time, then it would be irrational for them to enter the market. No buyer or seller would risk his capital in such a chaotic system. Furthermore, it would be impossible for businesses and governments to plan for even short-term goals if contracts and agreements did not exist (Mill, 1988, p. 173). International codes such as those of the WTO agreements "provide [transnational corporations] with better defined environmental and public interest objectives and standards with which to formulate policies and procedures in pursuit of their corporate purposes" (Allison & Prentice, 1990, p. 714). Such planning can "incorporate moral thinking into multinational decision making

[5] For an excellent analysis of Mill's view on the proper role of government in free markets, see Samuel Hollander's ninth chapter in *The Economics of John Stuart Mill, Volume Two: Political Economy*.

[6] Some might argue that capitalism is unethical; hence, what is a necessary condition for capitalism to exist is prima facie unethical as well. However, for the purposes of this chapter, I will stipulate that capitalism is ethical.

[7] Of course, some contracts do not need to be honored, especially if they contract for illegal services. Furthermore, if the contract does not offer consideration to one or more parties, fraud has been committed, or one or more of the parties is/are not competent to give consent, as well as other reasons, then the contract can be voided.

on the grounds of its long-term competitive payoffs" (Donaldson, 1989, p. 39). In return, countries obtain benefits from corporate activities and increased trade to allow for the best type of competition according to market forces in the country, while transnationals fulfill their duties by adhering to national standards and policies protecting the welfare of the country's populace and environment (Allison & Prentice, 1990, p. 714). Hence, it is vital for capitalism that contracts and agreements be internally and externally enforced.

The Two Relevant WTO Agreements

The WTO's Agreement on the Application of Sanitary and Phytosanitary Measures is designed, in part, so that member states can protect, with certain limitations, the health of residents, animals, and plants, which in turn protects the health of the member state itself (SPS, 2.1).[8] Limitations on trade must be justified on scientific principles and "sufficient scientific evidence," and cannot "arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail" (SPS, 2.2 & 2.3). In other words, in order to limit trade, there must be objective – not subjective – justification for the restriction. Speculations about possible risks are insufficient grounds to support trade decisions, especially if there is scientific evidence to the contrary. Moreover, the evidence must support a claim that the restriction is necessary to protect the life or health of humans, animals, or plants.

The only instance in which scientific evidence need not be used immediately to justify a restriction of trade is laid out in Paragraph 7 of Article 5.[9] "In cases where relevant scientific evidence is insufficient, a Member may

[8] 2.1 Members have the right to take SPS measures necessary for the protection of human, animal, or plant life or health, provided such measures are not inconsistent with the provisions of this Agreement.

2.2 Members shall ensure that any SPS is applied only to the extent necessary to protect human, animal, or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in Paragraph 7 of Article 5.

2.3 Members shall ensure that their SPS do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. SPS shall not be applied in a manner which would constitute a disguised restriction on international trade (SPS, Article 2).

[9] Unlike Article XX of the General Agreement on Tariffs and Trade 1994 (GATT), in which member states must show that it is necessary to violate GATT rules in order to protect health or the environment, SPS rules do not allow for exceptions.

provisionally adopt sanitary and phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary and phytosanitary measures applied by other Members" (SPS, 5.7).[10] However, the exception to the science rule does not entail, in the face of opposing scientific evidence, that restrictions can be applied based on theoretical risk. Rather, limitations on trade can be justified if and only if there is inadequate evidence to evaluate potential danger to health and life. Furthermore, the member state desiring to restrict trade has the burden of justifying the limitation in a timely manner, which entails open-ended restrictions are impermissible.[11]

The WTO's Agreement on Technical Barriers to Trade is another avenue by which EU members can attempt to justify its regulatory framework. The TBT allows member states "to adopt technical regulations and conformity assessment procedures if these have a legitimate objective, such as protecting health or the environment" (Wolff, 2001, pp. 2–3). Once again, like products must be treated alike regardless of where they originated (TBT, 2.1 & 2.2). As did the SPS, the TBT allows limitations on trade. However, the limitations must use available scientific and technical information and may not be more restrictive than is required to fulfill legitimate objectives such as "national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment" (TBT, 2.2).[12] One of the two legitimate objectives which might permit labeling and the traceability ensuring accurate labeling is consumers' right to know what is in the products they are buying. The additional information allows consumers

[10] The rest of the rule reads, "In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the SPS accordingly within a reasonable period of time" (SPS, 5.7).

[11] In their cases the pro-transgenic side will use SPS 2.1–2.3 to argue that the EU is imposing illicit restrictions on trade, while the EU will use 5.7 to justify their actions.

[12] The parts relevant to the regulation of TOs are:

2.1. Members shall ensure that in respect to technical regulations, products imported from the territory of any Member shall be accorded treatment no less favorable than that accorded to like products of national origin and to like products originating in any other country.

2.2. Members shall ensure that technical regulations are not prepared, adopted, or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade restrictive than necessary to fulfill a legitimate objective, taking account of the risks non-fulfillment would create. Such legitimate objectives are, inter alia: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are inter alia: available scientific and technical information, related processing technology or intended end uses of products (TBT, 2.1 & 2.2).

to make informed decisions about one of the most important areas of their lives, viz., what they eat. The second objective is the protection of the health, safety, or lives of humans, animals, plants, or the environment. Labeling, traceability, and maintenance of low levels of transgenic presence in products might be warranted to achieve the latter goal.

The Regulatory Framework

In order to legitimatize a moratorium or restriction on trade using TBT or SPS, the EU must present sufficient scientific evidence transgenics and their processes are dangerous to health, life, or the environment to outweigh current data that transgenics are no more dangerous than conventional or organic products and processes. Moreover, if SPS' sufficient evidence criterion is taken seriously, then it is necessary to use only those sources providing objective evidence. If the EU merely re-numerates the theoretical risks, then in the absence of other legitimate scientific information, it is rational to believe the existence of a risk has not been established. Until satisfactory justification is found to call into question the conclusions based upon adequate evidence, it would be irrational to think the theoretical risks are actual risks. Furthermore, we should not take up the impossible to satisfy standard that TOs have to be shown to be "unequivocally safe" (Stilwell & van Dyke, 1999, p. 11), because no product can be guaranteed not to harm someone in some way. If the unequivocally safe standard is adopted, the absurd conclusion follows that all products should cease to be traded; none is unequivocally safe. The best we can do is to adopt a more reasonable criterion banning products with unreasonable risks caused by their normal use.

There are many pieces of evidence supporting the claim TOs are not unreasonably dangerous or they pose no more risk than conventional products. First, a number of scientific societies and studies have shown claims about transgenic dangers to be exaggerated. The Royal Society found allergenic risks of transgenics to be no greater than conventional crops, the use of specific viral DNA sequences in transgenic plants is negligible, and eating transgenic DNA has no effect on those who eat it (The Royal Society, pp. 1–4). The United Kingdom's GM Science Review Panel, made up of 25 experts, concluded "novel plants are unlikely to lead to the creation of superweeds [and] 'there have been no verifiable untoward toxic or nutritionally deleterious effects' on human health" (*BBC News*, p. 1). Furthermore, the U.S. National Academy of Sciences, in a report requested by the Food and Drug Administration (FDA), found there was little health risk from TOs (Powledge, 2003, p. 1). Finally, the Royal Society and the U.S. FDA determined many TOs are substantially equivalent to conventional crops (Royal Society, p. 5; Monsanto, p. 8; FDA,

1992, pp. 22984–22985).[13] What this classification entails is TOs are not fundamentally different from conventional organisms as a product although they have very different origins. Hence, the risks for one are virtually identical to the risks for the other.

The U.S. regulatory framework for conventional products already addresses many of the EU's concerns about the safety of transgenics. Although the standards employed by the United States do not rise to the level of the Precautionary Principle, they still can prevent dangerous transgenic products from reaching the market. In the United States, there are three agencies regulating transgenics or products containing TOs. First, the U.S. Department of Agriculture (USDA) oversees meat and poultry products. Its mandate states the agency has authority over:

> Any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in 340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions (USDA, 7CFR340.1).

The USDA requires producers obtain permits for most regulated articles from the agency, and formal notification for every TO within the borders of the United States. Those that can be introduced without a permit must meet six strict requirements, which exclude all but the most innocuous of TOs. For example, the regulated article cannot be a weed, the genetic material introduced must be stably integrated, the function of the introduced genetic material is known and its expression in the regulated article does not result in plant disease, the expression cannot cause infection, toxic, or pharmaceutical results, and the genetic material cannot possess a viral or disease danger to plants, animals, or humans (USDA, 7CFR340.4). Overall, the USDA addresses each of the concerns the EU has about dangers to the lives and health of humans, animals, plants, and the environment.

[13] The EU has explicitly rejected the substantial equivalence standard in favor of the Precautionary Principle (EC (2), p. 3). However, it is unclear what scientific evidence the EU used to show that the Principle is better or at least as good as the substantial equivalence standard favored by scientific societies.

The second U.S. agency regulating transgenics is the FDA. The FDA's authority is over all food or food additive transgenics, with the exception of meat and poultry products. Any new TO is considered to be generally recognized as safe (GRAS) if and only if "the objective characteristics of the substance [do not] raise questions of safety sufficient to warrant formal premarket review and approval by the FDA" (FDA, 1992, p. 22985). In order to be considered as GRAS, each new TO must be evaluated using a stringent decision tree. Of the 11 possible pathways in the tree, 7 lead to required consolation with the FDA or outright rejection of the proposed organism. Clearly the stringent approval criteria demonstrate the FDA is meaningfully concerned about allergens, toxicity, and other possible problems caused by TOs (FDA, 1992, p. 22993).

Finally, the Environmental Protection Agency (EPA) has authority over pesticides and pesticide residues in food (FDA, 1992, p. 22985). The EPA's mandate was given to it by two federal acts. First, the Federal Insecticide, Fungicide, and Rodenticide Act requires pesticides used in the United States to be registered and "prescribes labeling and other regulatory requirements to prevent unreasonable adverse effects on health or the environment" (EPA (2), 1). Second, the EPA controls maximum permissible pesticide residue in food as authorized in the Federal Food, Drug, and Cosmetic Act. The standard for evaluating risk used for both types of EPA oversight is that there is a reasonable certainty no harm will result from the aggregate exposure to the pesticide or pesticide residue, rather than the more restrictive Precautionary Principle which requires there be absolute certainty no harm will occur (EPA (1), 110 STAT. 1516).

Given the standards of the three federal agencies overseeing the introduction of new TOs, there is excellent reason to believe the approved TOs do not pose unreasonable risks to the health of consumers. After all, in order to be authorized or left unregulated, each new TO must undergo a rigorous decision process in which the TO is examined for its potential impact on the health of not only human beings, but plants and animals as well. In addition, the organism is evaluated for its possible effects on the environment. If the TO poses an unreasonable danger or harm to members of any one of the four categories, then it is not allowed into the market.

The positive evidence for transgenics not posing unreasonable harms makes it more difficult to support the claim transgenics might be harmful. If the standard by which claims are evaluated is based upon rationality, then those who contend TOs pose serious risks must now not only provide sufficient evidence to refute the claim of those who do not think there are unreasonable problems, but the former must also give adequate justification their claim is true (Durbin, 1968, p. 55). In the face of evidence to the contrary, the mere possibility harmful consequences can occur from transgenics is insufficient to validate banning them.

Legal precedence is also useful for moral decision-making. People are able to make choices about the future based on legal precedence, especially if the ruling shows how the WTO is likely to decide a similar restriction of trade. In the Beef Hormone case, for instance, the United States filed a complaint against the EU over the latter's moratorium on beef raised with growth hormones. The WTO's Appellate Body found against the EU, in part, due to its scientific evidence not establishing the claim there was a cancer risk from ingestion of the beef (USTR, p. 113). Furthermore, the Precautionary Principle was rejected in the case because caution without scientific support is insufficient to support a sanitary measure (Fredland, p. 9). Since scientific evidence is lacking in regard to legitimize treating transgenic differently from conventional crops, it follows the EU must provide scientific evidence to justify its moratorium and new framework.

The ruling in the Beef Hormone case has two further moral implications. First, the precedence is an indication to businesses on how the WTO agreements are to be interpreted. They become the international standards by which to evaluate future claims. Furthermore, precedence allows for businesses to plan for their future. If it is clear scientific evidence is needed in addition to the Precautionary Principle, then those companies with scientific evidence backing the safety of their products are justified in believing markets will be open to them when their products are ready. They should not expect to be excluded from the market based on the Precautionary Principle alone. Hence, the Beef Hormone case precedence is useful evidence in this moral debate.

The uniformity of transgenic and conventional organisms serves as the basis for the final argument why the EU's regulatory framework is unethical. Given TOs and conventional crops are virtually identical, if the framework does not single out a conventional organism for regulation based upon safety concerns, then on the grounds of SPS and TBT, TOs should receive the same treatment. Aristotle's definition of justice – likes must be treated as like, while unlikes can be treated differently – shows us it would be an injustice to treat the two types of organisms differently (Aristotle, 1941, Bk. V, Chapters 1–3).

The EU is fully aware conventional crops and breeding techniques are not without their own risks. It is known some crops created through conventional methods resulted in very dangerous plants; for example, an insect-resistant celery caused skin burns because of its accumulations of psoralen and a potato line, which in cool weather, accumulated toxic levels of solanine (The Royal Society, p. 6). Furthermore, researchers have used chemical or radiation induced mutagenesis or cross-species hybridization to develop conventional organisms used in products that do not face the type of restriction imposed or about to be imposed by the EU's frameworks (The Royal Society, p. 6). These are merely a small number of the known dangers.

Given the actual risks to the health and lives of humans, animals, plants, and the environment have been shown from conventional organisms developed through conventional methods, it is unwarranted to not regulate these in the same manner as transgenics. If there is a danger a TO will harm humans or others, then it is necessary to recognize conventional organisms can do the same things to equal or possibly greater extents.[14] Hence, if the EU does not require conventional organisms to pass the same conditions as transgenics, then ceteris paribus, the EU is acting unjustly.[15]

In addition to the evidence transgenics pose no more danger overall than do their conventional counterparts, there are scientific data available showing TOs might be better. In certain studies, it has been proven TOs reduce the amount of pesticide use. This result has many benefits. First, the environment does not have to bear the brunt of additional pesticides and the dangers to health associated with them. In the case of Spanish transgenic cotton, the number of sprayings in a growing season has been reduced from 10–12 for conventional cotton to 1–2 for transgenic cotton (Roberts, 2003, p. 1). In addition, a large study of insecticide use and yield conducted on Indian cotton by Qaim et al. showed the pesticide use for conventional cotton was 3.2 times greater than that of Bt cotton. At the same time, the yield for Bt cotton was 80% greater than for conventional cotton (Qaim & Zilberman, 2003, p. 900). A second advantage is the reduction in pesticide costs for producers. The National Center for Food and Agricultural Policy states California could achieve $207 million in annual benefits from the savings from the 66 million pound reduction of pesticides used in agriculture provided the widespread adoption of transgenic crops (Lee, 2003, p. 3). A third advantage is producers become less reliant on chemicals because they use less of them. Finally, the health benefits from the reduction of pesticide use are enormous. Without having to handle the chemicals, for example, producers reduce their exposure risks (African Biotechnology Stakeholders Forum, ABSF (1), pp. 2–3).

Other positives have already been cited in the section on who has been harmed by the moratorium, but bear repeating at this juncture. The combination of biotech crops and Roundup herbicide has been shown to pose fewer risks than herbicides used with conventional crops (Stein, 2003, p. 1). Moreover, biotech crops, in addition to pesticides and no-till, reduce erosion, save large amounts of money in prevented sedimentation costs, improve the

[14] This recognizes the National Academy of Science's concern that it is very difficult to identify actual risks to the environment at the early stages of a new technology.

[15] The Royal Society argues that if transgenic organisms are to be evaluated scientifically, then it is necessary to establish standards. In order to have standards, it is necessary to come to some agreement as to what are normal non-transgenic organisms, objective human health goals for the product, and evaluation methods to determine how well the target TO achieves those goals (The Royal Society, pp. 1 & 6).

habitats of ground, air, or aquatic dwellers, and reduce flooding, greenhouse gases, and fuel consumption (CTIC, pp. 4–11).

Given the proven benefits and lack of undue risk from transgenics, the EU cannot legitimately claim either the SPS or TBT supports a TO moratorium. Since there is no reasonable threat to the health or life of humans, animals, plants, or the environment, then neither the SPS' nor TBT's exemption clause to the restriction of trade is satisfied. Hence, the EU has been inflicting unjustifiable harm on transgenic producers by breaching their international trade agreements.

Traceability and Labeling

The traceability and labeling requirements in the EU's regulatory framework violate both Mill's prohibition on unnecessary harm and interference, and the SPS and TBT of the WTO. In order to understand why the two requirements have these features, it is important to know what they are and why the EU adopted them.

The EU argues a traceability condition is legitimate to include in its framework for three reasons. First, traceability allows for the control and verification of the labeling process. Since some end products, such as refined soy oil, do not contain any proteins, whether transgenic or not, it is necessary to be able to trace their ingredients back to verify if transgenics were used. Second, traceability allows for the targeted monitoring of potential environmental effects. If harm occurs, then the EU can quickly act to minimize damages and hold those responsible liable for damages. Third, if a TO causes unforeseeable risk to human health or the environment, then the product can be withdrawn efficiently. In order to achieve the three goals, the EU requires:

1. Operators shall have systems and procedures in place to identify to whom and from whom products are made available.
2. For [TOs] intended for the deliberative release into the environment, operators must transmit specified information on the identity of the individual [TO(s)] a product contains.
3. For [TOs] intended for food, feed, or for processing, business operators may either transmit the specified information mentioned above or transmit a declaration that the product shall only be used as food, feed, or for processing, together with the identity of the [TO(s)] that the product may contain.
4. For food and feed produced by [TO(s)] operators shall inform the next operator in the chain that the products are produced from [TO(s)].
5. Operators shall retain the information for a period of 5 years and make it available to competent authorities on demand (EC (1), pp. 6–7).

However, since it has already been shown two of the three justifications – monitoring potential environmental effects and unforeseeable risks – are not scientifically, rationally, or ethically justified, the five requirements will be interpreted in light for the need to ensure the accuracy of labels and the labeling system. Although treated as separate in the EU's new regulatory framework, the traceability and labeling requirements do overlap. In order to ensure labeling is accurate, it is necessary to have farm to fork traceability.

The EU's labeling requirements are very strict. Any product containing more than 0.9% of approved TOs and 0.5% of unapproved TOs from unintentional mixing must be labeled as containing TOs (EC (2), p. 3). In fact, the EU requires "All foods produced from [TOs] irrespective of whether there is DNA or protein present of [TO] origin in the final product," which entails even the highly refined soy or corn oils having no transgenic proteins in them must be labeled as containing transgenics (EC (2), p. 2).[16] The producers are the ones who have to do the labeling because they control the process of growing and transportation, and they can best incorporate labeling costs into product pricing. A result of the latter is transgenic producers and companies can internalize expenditures by pricing products with TOs at a value reflecting the actual cost of production.

Labeling can be a legitimate exercise of control if it is not a de facto trade barrier proscribed by either SPS or TBT. The EU believes it has the duty to many of its citizens to inform them of something they clearly do not want, but unless the SPS or TBT legitimizes it, the EU cannot prevent the goods from coming into the Union (EC (1), p. 5). Since the available scientific evidence and case law have already been shown not to support the restriction of trade under SPS, the focus will shift to the Agreement on Technical Barriers to Trade. Perhaps TBT can justify labeling and traceability where SPS cannot.

The TBT is a better trade agreement than SPS for arguments to label products for several reasons. First, there are no legal precedents under the TBT to guide decisions. Unlike the SPS which has the Beef Hormone case in which the EU restrictions on meat from cattle raised with hormone injections were found to be illegal, there has never been a case brought under TBT (Friedland, p. 11). The benefit is negative precedent will not automatically make it harder to win a defense based on the TBT.

[16] There has already been a disagreement over soy oil. In September 2000, Thailand informed the WTO committee that Egypt restricted tuna canned with transgenic soy oil, and was barring importation of tuna from Thailand based upon the assumption that Thailand used such oil in its canning, which it does not (Wolff, 2001, p. 2). The oddest part of the complaint was the failure to recognize that refined soy oil does not contain any of the genetic material about which Egypt was concerned.

Second, the TBT is a more natural agreement to use for labeling than the SPS. Since the TBT agreement covers "packaging, marketing, or labeling requirements as they apply to a product, process, or production method," it explicitly covers TOs and products containing them (Stilwell & van Dyke, 1999, p. 9). The TBT is on point in the labeling issue, unlike the SPS which deals more with the products themselves.

In order to use TBT, the EU would have to show the labeling and traceability measures have a legitimate objective, are not more trade restrictive than necessary, and TOs and products containing them are not substantially the same as conventional organisms and products containing them (Wolff, 2001, p. 3). Of the three requirements, the first generally receives the most attention. The legitimate objectives offered for justifying traceability and labeling rules are:

1. Education and raising awareness.
2. Environmental protection and the Precautionary Principle approach.
3. Food safety and health considerations.
4. Consumers' right to know what they are eating.
5. The ability to influence foreign and domestic precaution practices.
6. Assorted ethical and religious concerns (Appleton, 2000, pp. 567–578).[17]

Of the justifications, the strongest is the fourth: consumers' right to know what they are eating. Labeling the products allows consumers to make informed choices about one of the most fundamental activities people do, viz., eating. People eat to survive. Since this is such a vital and personal issue for individuals, the argument is they should have the information they require to make informed decisions.

Moreover, it already is the case products similar to TOs have to be labeled for consumers. Pharmaceuticals, for example, have to be described in great detail on their packaging, including but not limited to possible side effects that might occur from normal use of the product. Since food is usually more important to human survival than pharmaceuticals, it is claimed food should be labeled as well. If people have the right to make decisions about headache medicine, then ceteris paribus, they have the same right to make decisions about what they eat.

The third condition needed to show TOs are insufficiently similar to their non-transgenic counterparts, which will justify different treatment, has three requirements (Stilwell & van Dyke, 1999, p. 10). First, the EU must establish its consumers' tastes and habits differ sufficiently between the two products.

[17] Stilwell and van Dyke's reasons for labeling are the same as the first four of Appelton's six reasons.

Second, there must be sufficient differences between the physical characteristics and end uses of TOs and their products, and non-transgenics and their products. Third, the product's nature, properties, and qualities must be shown to be sufficiently different from those of conventional or organic products.

Although some, such as Stilwell and van Dyke, point to studies indicating the majority of people desire labeling for products containing transgenics, it is not clear such evidence is sufficient to establish the first condition has been met. After all, the condition refers to their tastes and habits, not to what they desire in regard to labeling, which is not as hard to prove as either a taste or habit of entire societies.

Regardless of whether or not the condition is satisfied, the other two are not. Stilwell and van Dyke argue that TOs containing genetic information and proteins not existing in their conventional counterparts are sufficient to prove the second condition has been met (1999, p. 11). According to them, the physical characteristics and end uses of transgenics are sufficiently different from conventional products. Transgenics contain more or different genes from the conventional products of the same species; hence, they need not be treated the same.

However, there are a number of problems with the sufficient difference claim, including but not limited to the fact, that without some of the drawbacks of non-TOs, TOs are intended to serve purposes identical to their non-transgenic counterparts. Transgenic soybeans, as well as other crops, are generally recognized as the same as non-transgenics, which is why they are being developed. In fact, one of the problems often cited against the market introduction of transgenics is there is no way, short of testing, to determine if mixing has occurred. The products generally have the same appearance and other characteristics.

Furthermore, Stilwell and van Dykes' extremely low standard will misclassify conventional and organic crops. If a non-transgenic species had merely one beneficial mutation, then it too would not satisfy this condition, even though the new organisms are virtually genetically identical to the old. One genetic variation is sufficient to treat old and new differently.

The third condition has also not been met. The best evidence given to prove transgenics and their products are sufficiently different in properties, nature, and qualities from their non-transgenic counterparts, is the assertion "the full extent to which [TOs] and [non-TOs] . . . differ has not yet been established" (Stilwell & van Dyke, 1999, p. 11). However, when there is no evidence to support the claim of difference, then it is irrational to assume there is a difference between the two types of organisms, in the same way it is irrational to say there is ***not*** a difference, when there are no data to that effect. Hence, without evidence, it is impossible to know if the third condition has been met or not. Since the TBT does not state that, when lacking evidence of any kind, it

is permissible to assume the third condition has been met, it is illegitimate, according to the TBT, to discriminate between TOs and their products and their non-transgenic counterparts.

Moreover, making consumers' right to know about theoretical risks an adequate justification to impose trade restrictions based upon TBT leads to unethical results. If the right to labeling is based on safety concerns, then objective scientific evidence would be required to validate labeling.[18] If the consumer wanted to know the information, such as for safety concerns as in the case of transgenics, then there must be some scientific proof to show the consumer's concern is warranted. Otherwise, there are unjustified limitations on trade based on irrational fears. Products would not be able to enter the market, not because something was actually wrong with them, but merely because a nation's citizens were ignorant of their true characteristics.

Second, if consumers' right to know is based on reasons other than safety, then no matter how unjustified the clamor is, labeling can be required for any product causing public outcry. Policy decisions about trade could be based primarily upon morally irrelevant prejudices. For example, if people did not want to eat products containing French ingredients because they think the French unhygienic, which might have an impact on the sanitariness of their production processes, then it would be permissible to require labeling of all products containing ingredients imported from France. Of course, many decisions about labeling would be the result of illicit bias, but that would be irrelevant to invoking TBT's exemption clause. Without requirements for objective evidence and the exclusion of irrational prejudices, the result would be that any theoretical risk, no matter how unlikely, could be sufficient grounds to justify expensive trade frameworks.

Furthermore, with the precedence such as the one for labeling transgenics in hand, it will be virtually impossible to prevent any country from furthering its own wrongful ends through restrictive trade barriers. If one country wanted to harm another by preventing the latter's products from entering the market, then the former could invoke the precedent to justify costly labeling and traceability requirements. The leaders of developed nations, for example, might prevent developing nations from becoming competitive by inciting public outcry over some non-existent or irrelevant feature of a product. The result is undue harm to the developing nation's producers and the market as a whole.

Even without the dangerous precedent being set, the traceability and labeling regulations are unnecessarily costly. The EU framework imposes the burden of paying for "the system of traceability to identify to whom and from whom [transgenic] products are made available" (EC (2), p. 2). The Friends

[18] If there are actual safety concerns, then labeling would probably fall under SPS.

of the Earth, an environmental group opposing TOs, believes the regulations will keep the EU's market closed to transgenics and products containing them (Pomeroy, 2003, p. 1). The overall framework's labeling and traceability requirements may be too onerous and expensive because of expensive, difficult testing, ensuring and enforcing compliance, and costly separation maintenance (USTR, p. 112; Pew Initiative on Food and Biotechnology (1), p. 12; Wolff, 2001, p. 3). Labeling will be restrictive because it creates unfair burdens for the producers, especially for farmers in the developing world. In order to be able to know what to label and how, as required by EU regulations, producers must have systems in place allowing them to trace their products from farm to fork. In very poor areas of the world, establishing and maintaining the system is cost prohibitive. In one study, identity preservation has been shown to add 6–17% to farm costs (Anderson & Nielson, 2000, pp. 3–4). That in turn will cause poor farmers in developing nations to pay higher prices for seeds than they do now, since seed companies will have to pass the costs of creating and maintaining such a complex system onto the producers.

Moreover, the farm to fork requirement of traceability is virtually physically impossible for the developing world to maintain. According to the ABSF, farmers comprise 80% of the total population in Africa, which makes it virtually impossible to trace the origin of any TO or product containing more than 0.9% of approve transgenic ingredients (ABSF (1), p. 4). There are too many opportunities for the mixing of transgenics and non-transgenics. Farmers in the developed world, on the other hand, make up only 2% of the population. It is much easier, as a result, to trace TOs from farm to fork in the developed world than it is in the developing world. Hence, contrary to the WTO's Agreement on Agriculture which states differential treatment should be to the benefit of the least developed countries, the rules the EU has adopted are biased against the developing world (WTO (1), Part IX, Article 15 and Part X, Article 16). Given the WTO agreements' mandate to "encourage preferential treatment in favour of developing countries and less developed countries in the form of special assistance," the EU's framework violates not only the letter but also the spirit of the agreements (United Nations, 2003, p. 196).

Furthermore, although the right or freedom of consumers to choose what they eat is emphasized repeatedly in the EU's regulations,[19] those documents say nothing about the reduction of choices for producers (ABSF (1), p. 1). Transgenics have proven benefits for African producers and citizens, such as avoiding up to 70% of crop loss, reducing dependency on expensive chemicals, and preserving sensitive wild life habitats from being converted to crop

[19] See the European Commission's "Wallstrom and Byrne welcome EP acceptance of a trustworthy and safe approach to GMOs and GM food and feed."

production (ABSF (1), p. 2). If TOs are not used, African producers will have to return to a system in which there is a 40% crop loss to diseases and pests (ABSF (1), p. 1). The result is more exposure to dangerous chemicals for reduced yield. Indian cotton farmers have also been shown to have benefited enormously from transgenics. Their crop yield increased dramatically, while their pesticide use was cut into less than a third of that used on conventional cotton.

Finally, labeling a product as containing TOs has been shown to reduce consumer demand for the good. In a study conducted by Tegene et al., it was proved the information on the packets of three items – potatoes, vegetable oil, and corn tortilla chips – had an effect on the prices human subjects were willing to pay for the goods. If the information was anti-TOs, then the bid value decreased by 35%. If there was a combination of pro- and anti-transgenic information, the bids were 16%, 24%, and 29% lower than before the information was given to the human participants. Finally, if scientific information was added to the pro- and anti-transgenic information, the bid reduction ranged from 0% to 11%. These results are consistent with the conclusion that consumers place the greatest weight on negative information (Huffman, 2004, pp. 9–10; Tegene et al., 2003, pp. 1–3). Given these facts, it is clear labeling products containing TOs as such makes consumers less likely to buy them. The U.S. State Department believes labeling will cost the United States alone $4 billion in lost sales per year (Pew Initiative on Food and Biotechnology (1), p. 12). If the loss is so great for a wealthy country such as the United States, it will be worse for countries unable to absorb such costs. Hence, even though there is insufficient scientific evidence to establish the claims of the anti-transgenic groups, the marketability of transgenic products is reduced. This will, of course, negatively affect the ability to make profits from the technology regardless of the form in which it appears.

The unfairness of requiring producers and others in the transgenic market to pay for the EU's labeling and traceability system is clear. First, the system is expensive to implement and maintain. Second, labeling a product as containing transgenics reduces many consumers' desire for the product. The result is those who are legally obligated to maintain the system and label their products, even though there is nothing meriting such requirements, have to pay the costs for the very system that is treating them unjustly. At the same time, conventional producers receive the unfair benefits of not having to go through the same stringent approval process, not having to pay for the traceability system, not having to label products, and having their products preferred over transgenics merely because of uninformed consumers. The EU's discrimination, on these grounds alone, violates the SPS, TBT, and Mill's prohibition on unnecessary harm.

Labeling could create a trade barrier due to its negative effect on consumers. Recall negative information has greater impact on consumers than does

positive, and scientific information can only, at best, eliminate the effect such information has on consumers (Tegene et al., 2003, p. 2). Given that the risks are merely theoretical rather than actual as shown by the contrary scientific evidence, it follows labeling transgenics or the products containing them unfairly favors non-transgenics. As Friedland states, non-EU businesses will be forced to label products in a way that will repulse EU consumers (Friedland, pp. 4 & 12). Arthur Appleton argues labeling actually violates the consumers' right to know because the negative information, not supported by scientific data, deceives the consumer into thinking there is something wrong with the product when there is objective evidence to think otherwise (Appleton, 2000, p. 577). Hence, the labeling requirements actually defeat the goal the EU has set for itself; consumers are worse off than they otherwise would have been. The new requirements to label and trace TOs from farm to fork not only cannot be justified on the grounds of SPS or TBT, but those trade agreements and Mill's prohibition on unnecessary harm forbid the rules from being implemented. The scientific evidence available and the requirements of rationality make it impossible to justify restrictions based on mere theoretical risk. Furthermore, the ends which labeling and traceability are supposed to achieve are not as well served as they would be if transgenic products and their conventional counterparts were treated identically. The end result is if the EU intends to proceed with the implementation of the new framework, it will have to find other justifications for their actions.

A Suggestion

Although EU regulations for the authorization and labeling of TOs and products containing TOs cannot be validated on the grounds of SPS, TBT, or Mill, the EU could achieve its stated goals in a legal and ethical way. Under WTO agreements, member states have no restrictions on regulating their own producers (Appleton, 2000, p. 570). That is, without violating either SPS or TBT, states can impose stiffer burdens upon domestic producers than they can on foreign producers. If EU member states are concerned about labeling, traceability, and authorization, then they could make the regulatory framework under discussion mandatory for domestic producers and voluntary for foreign producers. The result would be domestic products would have the labels the EU desires for its consumers, while imported products would have them only if the producers and companies chose to supply them. If the consumer wanted to have non-transgenic products, then he or she could buy the domestic products guaranteed not to contain them. If the consumer does not care, then he or she can buy labeled or unlabeled products.

There are many benefits to this suggestion. First, the EU can satisfy consumers' demands while honoring their trade agreements and avoiding unnecessary harm to others. Second, consumers have the freedom to vote with their wallets. Third, businesses and nations can have access to markets that would have been closed. Fourth, the freedom of producers and companies is not limited by required labeling and traceability. Monsanto, for one, has endorsed the voluntary labeling of products containing TOs (Monsanto, p. 9). Finally, one of the greatest benefits of this approach is nations will not be involved in long and costly legal battles, which cause strained international relations.

Making the EU framework mandatory for domestic producers and voluntary for foreign producers is a good capitalistic way of handling the problem of transgenics and consumer choices. If a country's market is not willing to support transgenics, then transgenic products will not sell. Producers will see they do not sell, and then shift resources to products that will. However, if there is no great demand for non-transgenics or information, then the market will show that as well. Regardless of which path the market actually follows, it is clear there will only be fair competition for all. The market will work the way it should, which no entity can say treated them unfairly, regardless of whether or not it managed to fulfill its goals in the process.

Conclusion

The spirit behind the Royal Society's statement "scientific assessment must inform policy decisions but cannot pre-empt them, and that public opinion must be taken into account throughout" is useful in helping to decide what to do about TOs in the marketplace (The Royal Society, p. 1). Neither science nor public opinion is by itself sufficient justification for the creation, adoption, or implementation of public policy, but consulting each is necessary for making moral policy. When the two are in conflict, then a third condition, that of trade agreements, can be useful in resolving the dispute. If a trade agreement has committed a nation to a standard to be used by all, then, regardless of short-term desires, the nation must follow the standard for the market's good, and ultimately, for the good of the nation and its citizens as well.

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7

Commercialization of the Agrarian Ideal and Arguments against the New "Green Revolution": Feeding the World with "Frankenfoods"?*

Johann A. Klaassen

> Those who labour in the earth are the chosen people of God, if ever he had a chosen people . . . – Thomas Jefferson, *Notes on the State of Virginia.*

According to the World Hunger Education Service, approximately 850 million people around the world are seriously malnourished, and malnutrition will play a role in the deaths of more than 5 million children in 2005 (World Hunger Education Service, 2005). From my privileged position in one of the wealthiest nations in the world, it seems that providing food to the hungry – or, better, helping the hungry to feed themselves – should not be particularly difficult. Admittedly, though, this is a project that the nations of the "First World" have been working on since the end of World War II: at first through the crop hybridization projects of the "Green Revolution", and more recently through the introduction of genetically engineered (GE) food crops (also known, more colorfully, as "Frankenfoods"). But both the Green Revolution and GE foods have come under persistent attack by social philosophers, environmentalists, and other commentators, who argue that these technologies should be banned.

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- The views expressed are my own, and not those of First Affirmative Financial Network, LLC, or of anyone else associated with First Affirmative.

Should we be concerned that, despite all our technology and wealth, we will not be able to feed the hungry?

While some of the arguments brought forward against GE foods have been directed at the biotechnology and its products – arguments I have addressed at length in another place (Klaassen, 2005) – other arguments are directed at the corporations involved with GE crops. In this chapter, I will address the three most prevalent of these business ethics arguments, and show how each falls short of demonstrating that these companies must stop their projects. While we may well need to regulate these corporations carefully, we should allow them to continue to do the research necessary to develop and commercialize their GE seeds. And thus, in absence of other arguments, we *can* feed the world with Frankenfoods.

The "True Foods Network" (TFN) has identified nine major transnational biotechnology corporations as the primary purveyors of this "radical new technology" (TFN, n.d.).[1] Monsanto is the largest and most often discussed of these – "about 70 percent of all GE crops grown worldwide derive from Monsanto technology", according to TFN. Recent industry consolidation has moved that mark up to about 88%, according to the ETC Group, and has made Monsanto the world's largest seed company (ETC Group, 2005).[2] In what follows, I will focus my discussion primarily on the practices and business of Monsanto, as a proxy for the remainder of the industry.

Changing Forms of Life: Arguments from the Dependence of Small Farmers upon Large Corporations

The first of the arguments against the purveyors of GE crops is that they are forcing small farmers, particularly in the Third World, into a dependent relationship to large corporations. This argument is not new, having appeared in criticisms of the original "Green Revolution" technologies of the preceding generation. Deane Curtin summarizes the point this way:

> Green revolution hybrid seeds are not self-pollinating, so they must be repurchased each year from a seed company. The biotechnology revolution now occurring in agriculture carries plant monoculture further, to the level of individual

[1] The nine corporations, in order of the volume of material available, are: (1) Monsanto, (2) Bayer Crop Science, (3) Syngenta, (4) Dupont/Pioneer Seeds, (5) Dow/Mycogen (Dow AgroSciences), (6) BASF, (7) Exelixis Plant Sciences, (8) Groupe Limagrain, and (9) Takii & Company.

[2] Note that the ETC Group, "the Action Group on Erosion, Technology, and Concentration", was formerly known as "RAFI", for "Rural Advancement Foundation International"; their work under that name was well known in anti-GE activist circles.

> brand names. Agrochemical companies are now engineering seeds to respond (or not respond) only to their particular commercial brand of fertilizer, herbicide, or pesticide.
>
> Curtin (1998, p. 251)

Relatively recent technological developments have created strains of GE plants which are not only "not self-pollinating" in the sense that the heavily hybridized plants were, but which actually (and intentionally) produce sterile seed – a set of developments collectively known as "Terminator Technology (TT)". And as Curtin notes, many of the agrochemical companies under consideration here have created plant strains that resist their own proprietary herbicides, but the whole movement toward such propriety systems has come to be known as "Roundup Ready®" seed, after Monsanto's remarkably successful – patented and trademarked – line of crops. The TT and Roundup Ready (RR) are slightly but significantly different, and I think they create slightly but significantly different sorts of dependency. Moreover, it is not entirely clear what might be morally objectionable about these dependencies of small farmers on large corporations. In this section, I will sketch an account of the types of dependency each creates, and then briefly examine the moral status of each of these, in order to show that Monsanto has not (in this respect, at least) created a morally problematic relationship with the farmers using its products.

Let's look first at "TT".[3] Known within the industry as "genetic use restriction technologies", or "GURTs", these technologies come in two main forms. *Trait-specific restrictors*, or "T-GURTs", "turn off" or prevent the expression of particular (usually implanted) genes – for example, insect-resistance genes, or herbicide-resistance genes. Crops engineered with T-GURTs would produce seeds in which the special traits specific to the variety would no longer appear; any seeds saved for replanting in subsequent years would most likely not be superior to ordinary crops. In contrast, *variety-specific restrictors*, or "V-GURTs", turn on a gene that prevents the plant from producing viable seeds. Crops engineered with V-GURTs, in other words, produce sterile seeds; any seeds saved for replanting simply would not germinate. Normally, when critics speak of "TT", they mean V-GURTs.[4] For the moment, the corporations that hold GURT patents have pledged not to use them in their seed products – though they do continue to develop the technology, seeking new patents and testing new potential applications – so the discussions to follow are almost purely theoretical.

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[3] Much of what follows depends on work done by Keith Bustos of the University of Tennessee, see Bustos (2005).

[4] For more detail on GURT technologies, see Visser et al. (2001), FAO (2001), and Eaton et al. (2002). And for more on the distinction between T-GURTs and V-GURTs, see the ETC Group (2003).

The implications of this technology for farmers are clear: if I were to plant a field of TT wheat, for example, the wheat grains I harvested would be useless as seed, and fit only for consumption or sale. But farmers have traditionally saved the very best of their crop for the next year's planting, thus improving the seed stock while fostering independence. Those farmers who plant TT crops must buy new seed stock for every planting, which fosters a very non-traditional dependence of small farmers on large seed companies.

> With the advent of genetic engineering, the farmer is becoming a renter of proprietary seeds and livestock – and he or she is losing the right to make farm-level decisions. Companies like Monsanto are attempting to dictate how farmers will farm and under what conditions. This is popularly known as "bioserfdom." The result is that food production is being taken out of the hands of independent farmers.
>
> Shand (n.d.)

In short, those farmers who might choose to try TT crops once might thereby lock themselves into an apparently vicious cycle of dependence upon Monsanto: no longer able to depend on this year's harvest for next year's seed, they will be forced to buy new seed or stop farming.

Let's look next at "RR" technologies. Monsanto pioneered the use of GE techniques to engineer resistance to broad-spectrum herbicides, with remarkable results. Various RR crops have been available for "more than a decade", according to Monsanto's own promotional materials, and while other GE biotech firms have pursued similar approaches, none has yet approached Monsanto's success.

Roundup® is Monsanto's line of glyphosate-based herbicides. While glyphosate[5] is extremely toxic to plants, in laboratory testing it appears to be very nearly non-toxic to animals and insects. It also breaks down relatively quickly, having a "half-life" of 45–60 days in soil and significantly less in water. Some recent studies have cast doubt on the safety of glyphosate-based herbicides, but Pesticide Action Network U.K. reports that while some field workers have reported health problems after working in recently sprayed fields most of these effects have been minor and can be traced to other chemicals in the commercial herbicide (Relyea, 2005; Richard, et al., 2005; PAN-UK, n.d.). In short, it appears to be remarkably powerful yet fundamentally benign – and Roundup has become the best-selling herbicide of its type in the world. Roundup can be used as a "pre-emergent" herbicide, applied to fields after crops are planted but before they begin to grow, in order to prevent fast-growing weeds from

[5] This information is drawn from Extension Toxicology Network (n.d.) and Spectrum Laboratory (n.d.).

crowding out crop plants. But "RR" crops contain special genes that make the plants resistant to Roundup, allowing farmers to spray their fields at any time – which allows them to destroy the weeds that appear later in the growing season as well, and thus presumably to increase crop yields.

Monsanto has aggressively defended their patents on RR crops, sometimes to the apparently ridiculous extreme of suing farmers for the presence of "volunteer" (i.e., unplanted and usually unwanted) RR plants in their fields.[6] But part of their defense of their patents has been to use contractual language to prohibit farmers from saving RR seeds from year to year, suing violators (Yancy, 2003). Use of RR seeds therefore creates dependence on Monsanto in two ways. On the one hand, without Roundup, RR seeds are no better (and may well be worse) than conventional seed varieties,[7] which creates a need for the farmer to purchase not just the seed but the "package" of herbicides, insecticides, and fertilizers specially designed to accompany it, increasing initial crop costs substantially – and tying the farmer to the use of Monsanto's products. On the other hand, as with TT seeds, farmers cannot save RR seeds from this year's crop to plant next year, but must buy new seeds every year.

To summarize: TT and RR seeds both make small farmers dependent upon large biotechnology companies such as Monsanto by forcing them to stop saving seeds from this year's crop for next year's planting – via biological necessity, in the case of TT, and via contracts and lawsuits, in the case of RR. In addition, RR seeds make farmers dependent on the companies that sold them the seeds in the sense of forcing them to purchase a full package of "agricultural inputs", the pesticides, and other chemical enhancements specifically designed to maximize yields on the particular company's brand of seeds. But is Monsanto doing anything unethical by promoting RR seeds and considering the feasibility of TT?

The first question to ask is this: Who are the farmers being targeted by Monsanto for TT and RR seed sales? The ETC Group, in their work, makes it sound like Monsanto's targets are "resource poor farmers" and "small holder farmers", particularly in the Third World: "Over 1.4 billion people – primarily poor people in the developing world – depend on farm-saved seed as their primary seed source. Terminator technology seeks to create dependency on external inputs and it will undermine local seed and plant breeding technology" (ETC Group, 2003). But this underestimates one key fact about the state of

[6] For a startling example, see the case of Percy Schmeiser, a Canadian farmer sued by Monsanto for patent infringement because of the presence of volunteer Monsanto canola in his non-Monsanto-seeded fields. An online archive of stories and statements is available at http://www.biotech-info.net/percy_schmeiser.html (accessed August 2005).

[7] For a summary of several studies performed in the late 1990s, see "Roundup Ready soybeans have yield trade-off" (2000).

agriculture in the world today: there are two fundamentally different types of farmer, each of which relies on a different seed supply system. The "formal" seed supply system "is composed of public and private organizations with specialized roles in supplying new varieties"; the "informal" system, on the other hand, "is composed of individual farm households, each carrying out most seed systems functions on its own, with little or no specialization" (Maredia & Howard, 1998, p. 2). The formal seed system, represented by Monsanto and other transnational biotechnology corporations, supply seeds and the "agricultural inputs" – fertilizers, pesticides, and so on – that are necessary to grow GE and other specialized high-yield crops. Their main clients are "large- and medium-scale farmers", who "use markets to purchase uniform genetic materials that are highly responsive to chemical inputs and embody specific characteristics (e.g., color, uniformity of grain size) that are rewarded by the market". The informal seed system, represented by individual farmers' stores of saved seed and the informal trading and improvement mechanisms that grow up in small agricultural communities, supply seed to the lower end of the medium-scale farmers as well as to small, "more subsistence-oriented smallholders" (Maredia & Howard, 1998, p. 4). Among African small farms, for example, remarkably little seed is purchased from corporate sources: "About 60–70% of seed used by African smallholders is saved on-farm, and . . . 20–30% is borrowed or purchased locally" (Maredia & Howard, 1998, p. 1). In other words, approximately 10% of the seed planted by small farmers in Africa is purchased from corporate suppliers.

GE seeds are, generally speaking, "neither affordable nor relevant to the needs of resource-poor farmers" (ETC Group, 2003, p. 3), who instead

> value characteristics such as drought tolerance, early maturity or good storage characteristics more than fertilizer responsiveness. Because of the small size of their landholdings, mixed cropping practices, and strategy of minimizing production risks by diversifying the variety base, small holders also demand relatively small quantities of seed, but for a number of varieties of the same crop, and recycle seed over more seasons than larger commercial farmers.
>
> Maredia & Howard (1998, p. 4)

So it is highly unlikely that smallholders will ever become dependent on Monsanto: the company cannot profitably market seeds and chemicals to smallholders, whose needs differ radically from the "factory farmers" who form Monsanto's target market. It's difficult to see how TT or RR seeds could cause any particular ethical problem for the relationship between smallholders and transnational corporations, if there is no significant such relationship.[8]

[8] This is the main point of the argument in Bustos (2005); see especially pp. 12–13.

Moreover, if a farmer were to try the TT or RR seeds for one planting season, and discover that they were not a good fit for her farming techniques, technology, and culture, it is difficult to see how Monsanto could prevent her from returning to traditional seed stocks in subsequent seasons.

It seems to me that the only way that Monsanto could put itself into an ethically problematic position would be if it did in fact pursue an aggressive marketing tactic with Third World smallholders, as some groups worry they will (Christian Aid, 1999), deceptively or coercively convincing those farmers to plant the GE crops that they don't want or need, and then similarly coercing them to continue using those same GE seeds. This unlikely seeming scenario surely cannot support the conclusion that GE crops must be banned, though; a strict set of controls on marketing materials and sales techniques at play in the apparently endangered communities should suffice. To be sure, Monsanto and other transnational biotechnology firms are trying to enhance their profitability by commercializing RR seeds, and exploring the possibilities of TT seeds, but they are not doing this at the expense of the already-impoverished Third World farmers.

Sowing the Seeds of Debt: Arguments from the Dependence of the Poor upon the Rich

Now, a certain skepticism is bound to arise in those who have read more than a bit in the work of Vandana Shiva, among others – as she points out, there has been a veritable epidemic of suicide among the small farmers of India over the last 8 years or so, which Shiva and others have tied to Monsanto and other biotech corporations:

> As debts increase and become unpayable, farmers are compelled to sell kidneys or even commit suicide. More than 25,000 peasants in India have taken their lives since 1997 when the practice of seed saving was transformed under globalisation pressures and multinational seed corporations started to take control of the seed supply. Seed saving gives farmers life. Seed monopolies rob farmers of life.
>
> Shiva (n.d.)

Others tie these suicides more directly to the farmers' mounting debts, which are then blamed on the policies of "liberalisation and privatisation" forced on Indian regional governments by the World Bank and the International Monetary Fund (IMF) (McGhie, 2005). Deane Curtin ties the success of the Green Revolution and its GE-crop successors to debt, too, saying that it "depends on loans – and the ability to repay loans – from Western dominated international agencies, such as the World Bank" (Curtin, 1998, p. 251).

The impression these sorts of statements leave is that (a) First World multinational corporations such as Monsanto are, in fact, aggressively marketing their GE products to the very small Third World farmers who need them least; (b) First World financial institutions such as the World Bank and the IMF are making loans to farmers who can't afford to repay them, catching them in a "debt trap" from which they can't escape; and (c) poor harvests and outright droughts in the most heavily affected regions force the debts to mount beyond hope of recovery, until finally (d) the heavily indebted farmers are committing suicide as a way of escaping from the mounting pressure of their debts, and in an attempt to secure some relief for their survivors, some of whom receive 100,000 Rupees (about $2,200) in special bereavement payments from the regional government.

But sociological and economic studies of the affected regions do not support this picture, and certainly do not support blaming Monsanto and the IMF.[9] The farmers who commit suicide are predominantly younger men with substantial family-related financial obligations. As the opportunities for non-agricultural employment are minimal at best in the affected regions, these farmers are forced to look to agricultural means to obtain an income. Traditional forms of subsistence farming may feed the family, but do not create an income, so they feel forced to attempt industrial-style monocropping. These farmers are too small, and too poor, to qualify for loans from traditional banks, and so must turn to "non-institutional sources of credit", usually "dealer/lenders" who come from other parts of India. These dealer/lenders are willing to lend the farmers money at "usurious" rates, if the farmers will also (a) buy the seeds, pesticides, and fertilizers from them, at their inflated prices, and then (b) sell their crops to them at a pre-agreed price, sometimes as much as 25% below the market price. To make matters worse, the crops sometimes fail because the seed these farmers plant is "spurious" – not the high-quality, name-brand seed that was promised, but an inferior seed fraudulently repackaged.

It is undeniably true that Indian farmers are committing suicide because of their debts,[10] and that this is due in part to a shift from traditional, biologically diverse, subsistence agriculture to a profit-driven, monoculture-based, industrial-style agriculture. Some part of that shift from subsistence to industry

[9] The following is drawn from these three excellent sources: Vidyasagar and Chandra (2004), Aiyar (2004), and Stone (2002).

[10] It should be noted, though, that not everyone is concerned by the suicide rate among Indian farmers, since it doesn't appear to exceed suicide rates in general. For comparison, Swaminathan Aiyar notes that the suicide rate in Andhra Pradesh, one of the epicenters of the recent rash of farm suicides, has an overall suicide rate of about 13.6 per 100,000; the rate is about 28.8 in Kerala, a more prosperous region of India, about 13.9 in the United States, and about 14.5 worldwide. See Aiyar (2004a).

is itself due to governmental and international policies designed to foster "liberalization and privatization" in India's agricultural regions – which I will discuss more fully in a moment – but a substantial part of that shift is due to the social pressures of everyday family life in modern India. Swaminathan Aiyar, one of India's foremost economists, claims that today, "spending on pesticides and fertilisers is a minor cause of debt, much smaller than debt incurred for marriages, death feasts, and other social obligations" (Aiyar, 2004). When we add to this financial strain the difficulties imposed by multi-year droughts and dried-out wells, commodity price compression causing substantially reduced profit margins on the few successful harvests, and the predatory practices of India's dealer/lenders, we can see the crushing weight of the "debt trap". But the debts that are crippling local economies in India, and causing farmers to commit suicide, are not the result of Monsanto's marketing efforts, and are not owed to the World Bank. The only real profits being made in this vicious cycle are ending up in the pockets of India's predatory "non-institutional lenders".

Walmartization of a Way of Life: Arguments from the Nature of a Fundamental Human Endeavor

On the other hand, it has been argued, surely the farm troubles throughout the Third World are in large part due to the increasingly industrialized and commercialized nature of agriculture. For the last 12,000 years or so, farming has been the main occupation of human beings, with small farms providing a livelihood to Jefferson's "chosen people of God"; but today farming has become the domain of big business. The commercialization of agriculture, it is argued, is ethically wrong in two respects. First, it represents a unique and fundamental change in the relationships between human beings and our food, between human beings and the land, and between farmers and non-farmers, and must count as a degradation of human well-being in these respects. Second, the commercialization of agriculture has made possible – if not required – the commoditization of genetic information by way of claims of intellectual property rights (IPRs). This has in turn brought about "biopiracy", the "theft" (from Third World nations, generally) of knowledge about and genetic material of traditional crops and pharmaceutical plants, perpetrated by governments, research universities, and especially multi-national corporations based in the First World. In this section, I will address each of these arguments in turn.

Farms that once provided work and sustenance for large numbers of people are instead now being run with the profit motive in mind – with workers producing commodity crops for sale instead of farmers producing food crops

for consumption. HRH Charles, the Prince of Wales, recently made the point this way:

> I have always believed that agriculture is not only the oldest, but also the most important of humanity's productive activities. It is the engine of rural employment and the foundation stone of culture, even of civilization itself. And this is not just some romantic vision of the past: today some 60 per cent of the four billion people living in developing countries are still working on the land.
>
> So when I read "visions", such as that for the Indian state of Andhra Pradesh, for instance, which are based around monoculture, artificial fertilizers, pesticides and GM, my heart sinks. The missing ingredient in these great plans is always sustainable livelihoods and its absence increases the existing, awful drift towards degraded, dysfunctional and unmanageable cities.
>
> HRH Charles, Prince of Wales (2004)

Prince Charles owns vast swaths of Cornwall farmland, and some of his tenants experiment with various organic farming methods.[11] But I believe that for all the Prince's high ideals, and protestations to the contrary, there is a sense in which the idealization of the indigenous farming methods of the Third World does constitute a "romantic vision of the past".

In 1830, the human population of the world was approximately 1 billion and of the United States nearly 13 million. For all the bustle of the cities of the eastern seaboard, it is estimated that 90% of all Americans were directly involved with the management of a farm. Even at that late date, relatively few American grain farmers used long-handled metal scythes to harvest their crops – most used short-handled sickles to cut the stalks, in much the same time-consuming and back-breaking fashion that the first farmers did 12,000 years earlier. But in 1831, 22-year-old farmer Cyrus McCormick invented the "Virginia Reaper", a simple machine which did nothing more than cut the stalks of the grain quickly and efficiently. Subsequent refinements in the 1850s allowed the machines to bundle the grain, ready for laborers to bind – and by the 1880s, reapers also automatically bound the sheaves with twine, and deposited them in the field, ready to be gathered and taken to the mill for processing.

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[11] The Prince of Wales is also the 24th Duke of Cornwall, and owns nearly 212 square miles of farmland. His tenants are prohibited from planting any GE crops. In addition, "The Duchy actively encourages its tenants to practice conservation alongside commercial farming. It does this by spreading information on best practice and responsibilities under environmental legislation, encouraging high levels of biodiversity, and raising awareness of the principles of organic farming, and the potential of other agri-environment schemes." See the Prince's web site with information about the Duchy of Cornwall, available online at http://www.princeofwales.gov.uk/about/duc_index.html; accessed August 2005.

The reaper represents the first major step in the direction of an astonishing mechanization of agricultural labor:

> The reaper and other farm machines ... allowed fewer and fewer people to produce more and more food and fiber. In the process, our society was transformed. Instead of 90 percent of the population farming to meet the nation's needs, as was the case in 1831, today fewer than 2 percent of the U.S. population are directly involved in farming.
>
> SVAREC (n.d.)

Without reaping machines, a bushel of wheat took approximately 3 hours to harvest; with the machines, the same bushel took less than 10 minutes, a 94% improvement in efficiency. The reaper allowed a single farmer to harvest far more grain by himself than he could have dreamed without it; it made large farms physically possible. McCormick himself, though, made them economically viable: "He also was a pioneer in business techniques: easy credit to enable farmers to pay for machines from increased harvests; written performance guarantees; and advertising to convince farmers to buy his reaper" (SVAREC, n.d.). But the increased costs of maintaining the machinery, and purchasing the newest, most efficient machines, drove farmers to borrow more money – and to expand their farms by borrowing yet more money to buy out neighbors and buy up previously unused, marginal land. A major drought hit the upper Midwest in the late 1880s, landing many farmers in desperate straits and playing a significant role in the economic depression of 1893.

McCormick's mechanical reaper brought about a tremendous change in the way we relate to the world. Before McCormick, the vast bulk of Americans worked the land; afterward, we had a bloody Civil War and the economic predations of the "Gilded Age". Long before the Green Revolution, the first rumblings of the industrialization of agriculture divorced the vast bulk of Americans from their food in a manner that would have been unthinkable in 1830. Separated from the farms, Americans moved to the cities, and lost touch with the land as well – and now see farmers only as the producers of their food, not as their neighbors, their friends, their relatives. Admittedly, something is lost when human beings are completely divorced from the land we inhabit. "There are two spiritual dangers in not living on a farm;" Aldo Leopold writes: "One is the danger of supposing that breakfast comes from the grocery, and the other that heat comes from the furnace" (Leopold, 1970, p. 6).[12] On the

[12] Leopold himself did not shrink from modern "technological agriculture", as he saw in it a kind of salvation from the unsustainable practices which had conspired with drought to create the Dust Bowl, but he clearly did wish for a true science of conservation, on which to found a sustainable agriculture. See, for example, "The Round River" (1970, pp. 188–202).

other hand, we must look back at the "simpler, better way of life" to which so many people appeal, and ask if it's really what we want. Channapatna Prakash, in testimony before a Congressional panel on biotechnology, said this:

> There's also this imperialistic attitude, that somehow we need to keep Third World farmers away from the clutches of this new knowledge, the Western knowledge . . . I'm frankly sick and tired of hearing those kinds of arguments, because I grew up seeing what "local knowledge" is. It's losing one-third of your children before they hit the age of three. Is that the local knowledge that you want to keep reinforcing and perpetuating?
>
> Prakash (2000)

Others ask if "brutal folkways" such as African practices of female circumcision or the Indian practice of "sati" are not "just as authentic and indigenous as native eating habits" (Mooney, 2001). These are not subtle arguments, to be sure. It may well be the case that not all technological improvements should count as "progress", but I think that some can – and technologies that can help provide food to the starving must count among them.

Then again, it might well be the case that "things are different this time": where the mechanical inventions of the Industrial Revolution enabled the commoditization of agriculture in general, modern biotechnology has enabled the commoditization of agricultural genetic information. While Cyrus McCormick was clearly within his rights to patent his reaping machine, and then to defend his patent aggressively, it's not nearly as clear that Monsanto should have the right to patent the genomes of their GE corn or soybeans, and then to aggressively defend those patents. There are two fundamental issues at stake here, both of which have fallen under the rubric of "biopiracy". First, it's not clear that living things or their genomes should be the sort of thing one should be able to patent. Our current patent law and regulatory schemes are set up to grant "IPRs" over plants and animals (as long as certain conditions are met), but why think that living organisms can or should be held as private property? Second, even if IPRs do make sense with respect to living things, the corporations that acquire them are not necessarily doing so in an entirely above-board way. If Monsanto "discovers" an organism which has a long history of certain uses in a Third World country's traditions and culture, and uses their R&D team's expertise to make IPR-based patent claims, which in turn allow them to commercialize that organism, does Monsanto bear any obligation to the residents of the country where the "discovery" was made? The vastly improved farming machines of the 19th and 20th centuries made efficient commercial farming possible, but the biotechnological advances of the 21st century seem to be commercializing life itself. Is that legitimate?

Property rights in general have never been entirely non-controversial, and IPRs lack the concreteness that other forms of property rights appear to have.

That is, while we might not agree how it is that someone can come to own a square mile of prime Kansas farmland, we can at least touch that dirt, and the controversy has an obvious practical consequence; questions about who owns an idea, though, have the air of metaphysical nonsense (even though the consequences may be just as real, at least in the monetary sense). For the purposes of this essay, though, let us assume that in general IPRs make sense, and that a patent system is a reasonable way to enforce those rights. But does it make sense to apply IPRs to, and so to allow patents on, living organisms or genes?

In most systems, patents are awarded on the basis of three criteria: inventiveness, novelty, and usefulness. But, as agronomist Paul Gepts notes, biotechnology has progressed to the point that GE organisms are not particularly novel, do not require particular inventiveness, and are frequently of marginal usefulness – in other words, patents on living creatures or their genomes "challenge these three main criteria, yet they have become increasingly frequent. For example, in 1980, 16 patents were awarded for gene sequences. In 1990, the number was more than 6000, and in 2000, more than 355,000" (Gepts, 2004, p. 1300). While the justification for particular patents on organisms and genes may be shaky, there is still a larger-scale justification on offer: it would not be fair to refuse patents to the corporations that have developed GE food crops, because of the work put into that development process. Richard DeGeorge puts the point this way:

> Within the economic system of free enterprise, those who spend time and/or money in developing a product or the expression of an idea deserve a chance to receive recompense if the result they achieve is useful and beneficial to others who are willing to pay for it. It would be unfair or unjust for others to take that result, market it as their own, and profit from it without having expended comparable time or money in development, before the original developer has a chance to recoup his investment and possibly make a profit.
>
> DeGeorge (2005, pp. 549–550).

Monsanto's genetic engineers have certainly spent considerable time and money developing the products their company sells, true enough. But that doesn't answer the larger question: does it matter that those products are alive? My intuition – and it is nothing more than that – is that while it is important to recognize that the patented items are living organisms, such considerations provide limits to the scope of but do not invalidate such claims. It matters, yes, but not enough to make them unpatentable.[13]

[13] There is a large literature that has developed around this very issue; one of the very best articles is Resnick (2001).

But I also believe that much depends on how the corporation comes to make its patent claims. Where do the original seed stocks come from, and how were they obtained? Paul Gepts puts it this way:

> A highly unfortunate side effect of the commoditization of biodiversity is that it has led to the active pursuit of IP protection in developed countries of specific crop germ plasm originating in developing countries without appropriate authorization or compensation (called by some "biopiracy").
>
> Gepts (2004, p. 1304)

Vandana Shiva is more direct: biopiracy is "the patenting of indigenous biodiversity related knowledge" (Shiva, 1999; see also Shiva, 1997). A recent decision of the European Patent Office (EPO) has brought an exemplary case to a close. "In 1995, [US-based chemical corporation] W.R. Grace patented neem-based biopesticides, including Neemix, for use on food crops. Neemix suppresses insect feeding behaviour and growth in more than 200 species of insects" ("India wins . . . ", 2005). Vandana Shiva and her NGO, the Research Foundation for Science, Technology, and Ecology, joined the government of India and several other NGOs to challenge the patent based on "prior existing knowledge" – extracts from the neem tree have been used as an anti-biotic in India for more than 2,000 years. The patent was challenged immediately after it was granted, and was rescinded in 2000; W.R. Grace appealed that decision, though, because normally "prior existing knowledge" has meant scientific research published in peer-reviewed journals, not the traditional knowledge of indigenous cultures. After another 5 years of deliberation, the EPO rendered a final decision rescinding the patent in March of 2005, much to the joy of the opponents of biopiracy. This is a first for such "traditional knowledge", and could set a precedent to prevent future biopiracy; it is still unclear whether the U.S. and Japanese Patent Offices will follow suit, and what impact such decisions will have on the industry.

Patent decisions like this might well make biopiracy impossible, but I doubt that it will slow the pace of the "Walmartization" of agriculture in general. Some have argued that this industrialization and commercialization of agriculture is entirely new, perhaps 50 years old or less, that GE crop technologies will only increase its pace, and that this represents a significant loss of human well-being (Spitzer, 2003). But 19th and 20th century farm machines greatly accelerated monocropping in the American heartland, and provided the first real push toward the industrialization of agriculture. As a result of this technological development, the American population shifted from 90% agricultural employment in the 1830s to 2% or less today – a shift which in turn has enabled the United States to boast one of the highest standards of living in the world, and to become a global economic powerhouse. This industrialization of agriculture also accelerated the commoditization of food, which has in turn created

an opening for the patenting of living organisms and their genomes, another development that many find objectionable. While I agree that these patents rest on conceptually shaky ground, I believe that this is cause for caution, but not for banning such patents outright. And while I think that corporations have a much greater responsibility to the original sources of their "enhanced" products, I also believe that the neem case cited here shows that the political and legal tide is turning in the direction of social and political equity. About 12,000 years ago, human beings made a remarkably quick transition from the wandering life of the hunter–gatherer to the settled life of the agricultural society; perhaps we are in the midst of a similar transition now.

Conclusions

I quote Thomas Jefferson at the outset of this essay very deliberately. Jefferson believed very strongly in the dignity of the agricultural way of life, and held up the small family farmer as a moral and political ideal – the perfect citizen for an American republic, because of his self-sufficient life. Jefferson himself invented a special mould-board for plowing on hillsides, enabling farming in previously difficult to farm areas like the Piedmont. But while he lived through the very early stages of the Industrial Revolution, he died in 1826, 5 years before McCormick invented his reaper. What might he have thought about our modern agriculture? Clay Jenkinson suggests that thoroughly modern Jeffersonians "are not afraid of science and technology . . . they realize that the careful use of science and technology is infinitely preferable to any form of nostalgia or Ludditism" (Jenkinson, 2004, p. 90). Jefferson was a progressive, I think, who saw great potential for scientific farming; to my mind, he would have seen biotechnology as a step forward.

Some have argued that GE crops will place small farmers, especially in the Third World, in thrall to large multi-national corporations such as Monsanto. I have shown that as long as Monsanto's marketing efforts are monitored to prevent them from abusive, deceptive, and coercive tactics, we do not need to worry that they will exploit relatively powerless Third World farmers. Some have argued that the use of GE seeds forces poor farmers, again especially in the Third World, to go deeply into debt to Monsanto and First World lending institutions. There is good evidence, though, that farm debts in the Third World are not being caused by Monsanto or exploited by Western financial institutions, but instead by local predatory "dealer/lenders". And some have argued that the commercialization of agriculture has degraded our relationship to each other, to our food, and to the planet. But I have argued that the commercialization of agriculture is neither a new phenomenon nor something that must necessarily be feared, and so not necessarily an evil. These are the three

most common types of arguments raised against Monsanto and the other corporations that create and commercialize GE crops, especially "Frankenfoods" – but they all fail to establish that these corporations must cease operations. In absence of other strong arguments, I believe that we should continue to heavily regulate and closely monitor these corporations – but that we must not prevent them from engaging in their business.

Death and disease caused by starvation are not brought about only by a simple lack of food – in too many places where sufficient food is hypothetically available, people starve to death because of political corruption, poor transportation systems, and the simple inability to afford what food might be available. GE foods can't possibly overcome all these hurdles, but they can make it possible to deliver healthier foods to those in need, at a lower cost than ever before. And I believe that we can, therefore, use Frankenfoods to help feed the world.

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8

Corporate Decisions About Labeling Genetically Modified Foods

Chris MacDonald and Melissa Whellams

Does a company producing genetically modified (GM, a.k.a., "novel" or "engineered") foods (or foods with GM *ingredients*) have an obligation to label its foods as GM? Many consumers and advocacy groups are frustrated by the lack of corporate responsiveness in this regard. Public opinion polls suggest that the public (both in North America and in Europe) strongly favors positive labeling[1] of GM foods. Industry in North America, however, has failed to respond, potentially leading to the conclusion that – despite rhetoric about consumer choice and consumer sovereignty – the corporate world has once again demonstrated its indifference to consumer values. This chapter looks in particular at the GM food labeling issue as it is faced by Canadian companies, though we hope that the conclusions reached here will be readily extended to the situation faced by companies in other relevantly similar jurisdictions.

Because of the role that we feel is played by the history of government and industry reactions to this issue, we first must survey recent history of the debate over GM food labeling in some detail.

Background: The GM Food Labeling Debate

There has been considerable discussion, over the last few years, of whether and how agri-food companies should convey to consumers information regarding various characteristics of their products. Not surprisingly (given the special attention paid these days to all things bearing the word "genetic") one topic that has been a particular focus of attention by the public, the media, and academics has been the issue of labeling GM foods.

[1] "Positive labeling" is labeling that indicates that a product does indeed contain GM ingredients. By contrast, "negative labeling" is labeling that indicates that a product is "GM free." Throughout this chapter, when we refer to labeling, we will be referring to positive labeling unless otherwise specified.

Genetic modification in principle refers to "any change to the heritable traits of an organism achieved by intentional manipulation" (Health Canada, 2003). By definition this includes traditional crossbreeding techniques, although the recent frenzy over GM foods pertains primarily to transgenic modification achieved through micromanipulation of genetic material in laboratories.

Since 1994, Health Canada (the federal agency responsible for food safety) has approved the sale of over 60 "novel foods" in Canada, including GM corn, soybeans, potatoes, canola, and squash (Health Canada, 2004). As soy and corn derivatives such as soy flour, soy protein, corn meal, corn syrup, and soy and corn oil are common ingredients in packaged foods, it is safe to say that – whether they know it or not – most Canadians have consumed GM foods or products containing GM ingredients. According to Food and Consumer Products Manufacturers of Canada (FCPMC), 60–70% of food products on grocery shelves contain GM ingredients (National Institute of Nutrition, 2001).

By the late 1990s, there was relatively high consumer awareness about GM foods in Canada. An Angus Reid Poll conducted in the fall 1999 reported that 78% of Canadians surveyed had seen, read, or heard something about GM foods. Thirty-two percent of those surveyed identified "food safety/health concerns/allergies" as a risk associated with GM foods (Ag-West Biotech Inc., 2000). According to an Ipsos-Reid/Globe and Mail Poll conducted in August 2001, 63% of Canadians stated that they would be less likely to buy food that had been modified genetically or contained GM ingredients (Foss, 2001). In a (mostly) free market where consumers can voice their opinions with their dollars, one might wonder how GM products have managed to stay on the shelves. However, GM foods fall into the category of "credence goods," products that have certain characteristics that are not apparent to consumers before or even after consumption. Thus consumers so far have had no way of identifying whether particular foods were a product of genetic modification, a fact that substantially limits their power to "cast their votes."

Consumer groups, NGOs, and activist organizations have attempted to convince specific corporations – including most notably Kraft and Starbucks – to label their GM products. Thus far, these attempts have been unsuccessful. Despite survey results suggesting a consumer preference for labeling of GM foods, and despite the pleadings of activists, industry has failed to respond. Some might say that this constitutes an instance of "market failure." That term is itself contentious, but the failure of a market to produce a good for which there is (apparent) demand is at least very close to what economists have traditionally termed "market failure." More technically, the apparent market failure here lies in the fact that, due to an information asymmetry (producers have a better chance of knowing whether their products contain GM material than do consumers), there is an oversupply of (based upon misleadingly high demand for) GM foods. That is, consumers currently buy a lot of GM foods, not because

they want them, but because they are unable to tell GM foods from the non-GM foods that many, at least, claim to prefer. It is worth noting that precisely this sort of refusal to comply with public values is responsible for considerable disenchantment with the corporate world, and for driving a wide range of activist-driven approaches to business ethics and corporate social responsibility.

Government "Response"

When markets fail to provide what the public wants, this is often seen as justifying government intervention. Indeed, in this case the Canadian government did respond, after a fashion, to the industry's inaction and the public's expressed concern. In particular, it responded by empowering a broadly representative committee to draft a policy. The story of the Canadian government's response to this issue begins in April 2001, when Private Members Bill C-287, which proposed mandatory labeling of GM food, was introduced into the House of Commons. The bill was narrowly defeated in October 2001 despite consumer support.

In October 2003, a poll sponsored by the Consumers Association of Canada and conducted by Decima Research revealed that 88% of 2000 Canadians surveyed supported mandatory labeling of GM foods (Chase, 2003). Yet the Canadian government continued to ignore consumer demand for mandatory labeling of GM foods and officially adopted a standard for *voluntary* labeling in April 2004. The standard, under the verbose title *Standard for Voluntary Labeling and Advertising of Foods That Are and Are Not Products of Genetic Engineering*, was developed by a Canadian General Standards Board (CGSB) committee comprised of representatives of food producers, manufacturers, distributors, consumers, general interest groups, and government. The *Standard* aims to assist consumers in making informed food choices by allowing companies to signal whether their foods are or are not products of genetic engineering.

The voluntary nature of the *Standard* essentially puts the onus of labeling back onto food producers and manufacturers. Current legislation under the *Canadian Food and Drugs Act* requires that all foods, including GM products, be labeled where potential health and safety risks (e.g., allergens) have been identified, or where foods have undergone significant nutritional or compositional changes. Since Health Canada has deemed GM foods to be safe, companies are not required to label products as GM, but under the new *Standard*, companies may voluntarily label their foods as products of genetic engineering.

Prior to the release of the *Standard*, Donald Boulanger, Spokesman for Agriculture Minister Lyle Vanclief, was confident that companies would voluntarily label GM food products in response to consumer demand, "They will

make sure to label their products as GMO-free if this is what consumers want" (quoted in Chase, 2003). Arguably Mr. Boulanger's statement was slightly optimistic, as few, if any, labels pertaining to genetic modification have appeared on food products since the adoption of the *Standard* in the spring of 2004. This is not surprising considering the task of labeling products according to the *Standard* is seemingly onerous and presently offers little benefit to the obliging food companies.

The questionable utility of labeling GM foods is likely one of the factors that led to a voluntary rather than mandatory labeling standard. Arguably, a label that states "Product of Genetic Engineering" does not provide enough meaningful information to consumers, and could mistakenly be perceived as a warning. Jeanne Cruikshank of the Canadian Council of Grocery Distributors (CCGD) and Member of the CGSB Committee explains that "people have suspicions when they don't have access to information" (quoted in National Institute of Nutrition, 2001, p. 3).

The CCGD's Cruikshank argues that since GM foods do not pose a risk to human health, labeling is a "like to know" issue and therefore should not be mandatory. On the other hand, many would argue that consumers have the *right* to know what is in their food and the *right* to choose what they eat, and that labels at least begin to help consumers make that choice. Although the label itself may not contain information about the technology used in genetic engineering, the *Standard for Voluntary Labeling* explicitly states that claims must contain a reference to an external, readily accessible source of further information – such as a toll-free telephone number or a web site – if the process used to engineer the food has not been described on the label (CGSB, 2004). The extra information obtainable through web sites or toll-free numbers could provide consumers with enough knowledge to make informed purchasing decisions. That being the case, it seems that labels *would* allow consumers to cast their votes and the market would have to respond accordingly.

Now note that in fostering the creation of and adopting a standard, the government did in a sense "respond" to the will of the public. However, its adoption of a *voluntary* labeling standard – that is, a standard that provides a framework for voluntary, non-mandatory labeling by individual companies – failed to give the voting public what they seem to want, viz., that GM foods be *required* to be labeled.

Dilemma for the Individual Company

The situation faced by individual agri-food companies, then, is one in which they know that the public has – whether for good or bad reasons – considerable misgivings about GM foods, but in which neither the market nor the

government has responded to those misgivings. We thus have the makings of a "hard problem" of ethics. That is, companies are faced with a situation in which they are arguably being dishonest with their customers (viz., committing a lie of omission), but in which a unilateral change in strategy (positive labeling of their GM products, when no one else is doing so) would almost certainly have a significant deleterious effect on market share. Many public advocacy groups, and at least some scholars, have advocated for labeling as an ethical requirement. Jackson (2000), for example, argues that labeling "fosters consumer autonomy and moves toward more participatory decision-making."

Given this characterization of the issue, What's a well-intentioned company to do? Should it voluntarily label its GM products or not? Do individual corporations have an ethical obligation to act, in the face of a failure of key democratic institutions to give the public what it wants?

At least some companies have taken this on as an ethical obligation. The web site for an American company called AquaBounty – producer of a fast-growing, GM strain of salmon – states that the company "has made a company decision to require that all licensees growing AquAdvantage fish agree to a labeling requirement."[2] So apparently at least some companies seem to agree with activist organizations in feeling that it is ethically incumbent upon agri-food companies to engage in positive labeling of their GM products.

We argue, however, that although unilateral action in this regard might be admirable, an agri-food company has no ethical obligation to label its GM foods, given the current social, legal, scientific, and economic context. While neither government complacency nor market failure constitutes a general excuse for inaction on the part of individual corporations, we argue that the particular characteristics of this case make it unreasonable to expect unilateral action.

Our argument for this conclusion is based, in a sense, on the characteristics that this situation *lacks*. In point of fact, it lacks pretty much all of the characteristics that would make unilateral, self-sacrificing action morally obligatory. Note that by "self-sacrificing," we only mean to describe behavior that implies for the agent a net loss in well-being, not necessarily a fatal sacrifice. On at least some moral theories (notably Hobbesian Social Contract Theory) an agent can never be required to sacrifice his or her life. But most ethical theories do hold that it is at least sometimes ethically mandatory for agents to take unilateral action, to their own detriment. (Indeed, on some views this is the essence of ethics.)

So what characteristics are *lacking* in the GM food labeling issue, such that the presence of those factors would provide at least a prima facie case for an ethical obligation to undertake unilateral labeling? We believe the following four factors to be particularly salient.

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[2] Available on-line at http://www.aquabounty.com/label.htm, accessed February 14, 2005.

No Legal Standard and No Expression of Concern by Government

To date, North American governments have declined to require labeling of GM foods. There is thus no legal requirement for companies to indicate, through labeling or any other means, that their food products are either modified genetically or contain GM ingredients. Of course, those of us who teach ethics are often at pains to point out that law and ethics are two distinct domains. Thus the fact that companies that fail to label their GM foods are breaking no laws does not immediately imply that they are doing nothing unethical. Yet here we argue that in highly regulated industries such as food, agriculture, and biotechnology, the absence of specific regulation does provide an important piece of evidence to be used in the determination of the ethical status of a given piece of corporate behavior.

And clearly, if things were different – if government had taken legislative or regulatory action – then companies would have a pretty clear ethical obligation to act. After all, in a free democratic society, corporations (and individuals) have a strong prima facie obligation to obey the law. So, a legal requirement is generally sufficient to generate an ethical requirement, even in cases in which the law is generally disregarded. So, were there a law in place, it would be ethically incumbent upon any given company to label its GM foods, even if other companies were not doing so. But that, of course, is not the case here.

Further, note that far from there being any legal requirement regarding GM food labeling, there has not even been any official expressions of concern by North American regulatory agencies. If there were such expressions of concern – for example, by Health Canada or the U.S. Food and Drug Administration (FDA) – this might signal that regulatory action was in the offing. In such circumstances, we might think it ethically appropriate for companies to be proactive, rather than waiting to be legally forced to act. But far from expressing concern, Health Canada has declared GM foods to be just as safe as non-GM foods.[3] And a spokesman for the FDA has declared: "we have seen no evidence that the bioengineered foods now on the market pose any human health concerns or that they are in any way less safe than crops produced through traditional breeding."[4]

No Well-Documented Danger to Human Health

Even in the absence of legal or regulatory action by government, agri-food companies might well be ethically required to take action if there were credible,

[3] http://www.cbc.ca/news/background/genetics_modification.

[4] FDA Commissioner Jane E. Henney, quoted at http://www.fda.gov/fdac/features/2000/100_bio.html.

non-speculative evidence that the products they were selling posed a threat to human health. Companies have a positive obligation to act when the health of consumers is at stake. So, for example, we generally see it as ethically mandatory for pharmaceutical or medical devices companies who become aware of dangers posed by their products to recall those products, even in advance of action by regulators. The Dow Corning breast implant debacle is a well-known example of a company's failure in this regard. And Johnson & Johnson's handling of the Tylenol crisis is a classic example of a company acting admirably in this regard. The general principle, here, is that if a company's product is hurting people, and if it is possible to eliminate or mitigate that harm, then a company is ethically required to do so.

A review of the extensive literature debating the safety of GM foods is beyond the scope of this chapter. But our reading of the meta-analyses offered by various blue-ribbon panels suggests that to date no substantive risk has been detected. According to the World Health Organization, "GM foods currently available on the international market have passed risk assessments and are not likely to present risks for human health."[5] The most *critical* meta-analysis seen so far by Canadian companies has been the Royal Society of Canada's Expert Panel Report, "Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada." Yet that report focuses on what the Expert Panel felt to be the inadequacy of current Canadian regulatory mechanisms. That is, rather than declaring GM foods risky, the Expert Panel declared that the current policies of the Canadian government are not adequate to ensure that future GM food products may reliably be declared safe. Despite its detailed, 265-page analysis of existing evidence, the Expert Panel stopped short of actually stating that GM foods pose any real risk to human health.

Thus it seems easy to arrive at the conclusion that no evidence yet exists that GM foods pose a risk to consumers. Some have argued, of course, for the adoption of the "Precautionary Principle" with regard to poorly understood technologies such as biotechnology. The Precautionary Principle received its most high-profile enunciation as part of the 1992 *Rio Declaration on Environment and Development*. Principle 15 of the Rio Declaration states that, "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[6] This Principle has been formulated as a response to our understanding that given our current state of technological development, and given what we now know about the latent and cumulative effects of various technological developments upon our environment (and resultant

[5] 20 Questions on genetically modified (GM) foods, available on-line at http://www.who.int/foodsafety/publications/biotech/20questions/en.

[6] Available on-line at http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm.

deleterious effects upon human health and well-being), at least some technological developments hold the worrying potential to have far-reaching, long-lasting, and nearly unforeseeable disastrous consequences. The idea thus is that caution is warranted, in the absence of definitive knowledge that a given technology is either safe or unsafe.

Yet if arguments for the adoption of the Precautionary Principle are indeed well founded (something we neither affirm nor deny), the Principle is clearly best suited to application to public policy, rather than corporate decision-making. To the best of our knowledge, no one has proposed the Principle as a standard for business conduct. In particular, the adoption of the Precautionary Principle is *most* defensible in situations in which the technology in question is going to be prohibited across the board: that is, it is a principle that, if applied at all, seems to warrant banning altogether the technology in question. If the fear truly is that a given technology will result in "serious or irreversible damage," then the decision whether to adopt or forego that technology ought not be left to individual choice. Thus the application of the Precautionary Principle only makes sense as a social choice; it cannot be a principle for guiding the behavior of individual corporations.

No Consensus in the Industry

As noted above, the agri-foods industry has, with a few notable exceptions, declined to engage in positive labeling of GM foods in jurisdictions where such labeling is not legally required. Of course, the fact that industry in general has not adopted labeling as a standard practice does not, by itself, imply that no individual company ought to do so. If consumers' lives were at risk, for example, then it very likely *would* be ethically mandatory for individual companies to take action. But, as noted above, this is not the case here. To ask an individual company to take action would be to ask them to do serious (perhaps even fatal) harm to their market share, with a resultant decrease in shareholder value, all in the name of honesty about a product characteristic that, to the best of our knowledge, just does not matter to the health of consumers.

Is There a Right to Know?

Among the most persuasive arguments in favor of labeling GM foods has been the claim that, independent of concrete evidence about risk, consumers have a *right* to know what they are eating. For many consumers, labeling is not about risk, but about freedom, autonomy, and informed control. The key moral claim, here, is that "I have a right to know what I'm eating."

While rights-talk is clearly forceful, and often persuasive, we need to think clearly about whether the rights-claim alluded to here actually stands. A full

examination of the notion of consumer rights, and the theoretical foundations upon which such rights might stand, is beyond the scope of this chapter. Instead, we merely offer the following three observations.

First, we note that an interest alone does not generate a right. What consumers (some consumers) most *clearly* have with regard to GM foods is an interest. There are two ways of reading the word "interest," and both may well apply here. First, one may have an interest in X merely by being *interested in*, or concerned about, or wanting to know more about X. In this sense, we can say that, for example, I have an "interest in" French cuisine, or an "interest in" knowing what long-lost classmates have been up to. Clearly, survey evidence supports the claim that consumers have, in this sense, an interest in – that is, they are interested to know about – the issue of labeling, and many of them have an interest in knowing whether their foods are in fact genetically modified. Secondly, one may be said to have an "interest in" X if one's well-being is somehow tied to X. So, for example, I may say that I have an interest in municipal politics, given that the decisions made by local government affect my well-being, and that of my family, in a large number of ways.

But in neither of these cases – neither uses of the word "interest" – does having an interest automatically imply having a right. Clearly, merely being interested in something does not give you a right to information about it: I may be interested in knowing about my neighbor's finances – to know more about them might be entertaining, or satisfy my curiosity – but in no sense do I have a *right* to know about them. Indeed, my neighbor's finances are (in most cases) none of my business. We can only plausibly claim a right when the interests being served are somehow central to our well-being. In general, we reserve talk of rights for those matters in which the absence of a certain thing (the thing to which we claim a right) would make life bad. But even having an interest in this second, stronger sense, does not automatically generate a right. For example, if I am a store owner I have an interest in (i.e., my welfare is directly affected by) having large numbers of people patronize my store; but in no sense does that give me a right to their patronage.

Second, if we are to consider attributing to consumers a right to know, we must recall that for every right I claim, there is a correlative obligation to be borne by someone else. Thus, if consumers are to have a right to certain information, on whom does the obligation to provide that information fall? The obvious answer seems, in this case, to be the companies involved in producing, packaging, and selling GM foods. But before attributing such an obligation, we would first need to establish both that imposing such an obligation would not infringe some other important right, and that fulfilling the requirements of such an obligation would not be unduly burdensome. In regards to the former, we should ask whether the companies involved have a right to manufacture and sell a legal product for which no significant scientific evidence of

danger exists. In regards to the latter, we need to ask whether the costs to be borne by companies in fulfilling such an obligation would be larger than the purported benefits to consumers. And even if, having considered these issues, we are still convinced that there is a right, on the part of consumers, to know that their food is genetically modified, we still need to ask whether the companies involved are indeed the most appropriate bearers of the correlative obligation, or whether such an obligation might more suitably fall upon (for example) government or consumer advocacy groups.

Third, before we get too serious about attributing a right, on the part of consumers, to know whether their food is genetically modified, we ought to ask whether unilateral labeling by individual companies is an effective means of fulfilling the interests that such a right would seek to protect. That is, even if we agree that (at least some) consumers have a serious interest in knowing whether their foods are genetically modified, such that having that knowledge would contribute significantly to their well-being, it is not at all clear that unilateral action by individual companies (the topic of this chapter) would be the best way to satisfy that interest. For one thing, there are serious concerns about whether consumers in general will know what a particular label ("GM free," or "may contain some genetically engineered ingredients") actually means. Further, if some, but not all companies engage in labeling (some in positive labeling, some in negative labeling), will consumers really have enough information about the range of products available to them to make informed, effective choices about the things that matter to them?

Thus many significant challenges remain, many obstacles to taking seriously the idea that consumers have a right to know whether their food is genetically modified, a right that would impose upon various companies a correlative obligation to label their foods. For the time being, then, it is impossible to take such a rights-claim seriously.

Conclusion

We conclude, then, that at the current time the issue of labeling GM foods has none of the key characteristics that, if present, might well make such labeling ethically mandatory for individual agri-food companies. The argument presented here does not necessarily imply that governments ought not to require labeling, or that the agri-food industry ought not be more responsive to consumers' concerns. We simply argue that given the lack of government intervention, the lack of collective action on the part of the industry, and the lack of clear evidence of risk to human health, individual companies cannot reasonably be expected to take unilateral action.

We have essentially argued, then, that companies should not feel obligated to take unilateral action, so long as they are marketing, in good faith, a legal product that they feel poses no threat to the public – in other words, so long as they play by the established rules of the game. Nevertheless, we acknowledge that there remain legitimate worries about GM foods that need to be addressed by the food and regulatory industries. For example, we share the worry, voiced by other authors, that the current regulatory framework needs to be strengthened in order to ensure that regulatory agencies have the capacity to accurately assess the safety of foods created through modern biotechnology. We are also apprehensive about potential conflicts of interest that can arise in partnerships between regulatory agencies and private corporations, and the resulting potential for regulatory capture. However, we believe these issues to be ones of social policy, not corporate ethics. And corporate responsibility for social policy is minimal. In this regard, we should urge companies to promote informed discussion and debate, to avoid hollow public consultations that could erode democratic values, and to refrain from abusing their power to manipulate the rules of the game.

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9

Moral Imagination, Stakeholder Engagement, and Genetically Modified Organisms

Denis G. Arnold

An important feature of contemporary debates regarding economic globalization concerns the development and deployment of genetically modified organisms (GMOs) by agribusinesses. Protagonists in this debate explicitly identify the primary issues of contention as ethical issues. Nonetheless, ethicists have largely ignored the many questions raised by recent advances in the genetic engineering of food and this neglect is evident in the paucity of published work on the ethical obligations of agribusinesses regarding GMOs. It is, therefore, a pleasure to comment on the work of Johann Klaassen, Chris MacDonald and Melissa Whellams, and Dennis Cooley. Each of the chapters these authors have contributed to this volume provides a nuanced ethical analysis of the obligations of distinct actors in the global debate over GMOs. Johann Klaassen argues that Monsanto and the other agribusiness corporations that have brought to market genetically modified seeds neither exploit nor harm poor farmers and do not undermine the integrity of traditional relationships between humans, food, and the planet. Chris MacDonald and Melissa Whellams argue that, despite the concerns of many Canadian citizens regarding the presence of GMOs in their food, corporations have no ethical obligation to label their genetically modified food as genetically modified. Finally, Dennis Cooley argues that the European Union's new regulations on the testing, labeling, and tracing of GMOs are unethical in that they cause illegitimate harm to the producers of GMOs and, presumably, to consumers through higher prices. A common and provocative theme among these chapters is that the nongovernmental organizations (NGOs), such as Greenpeace and the Research Foundation for Science, Technology and Ecology, that condemn the use of GMOs are, by and large, ill informed with regard to the scientific issues and – at best – unpersuasive with respect to their ethical analyses regarding the implications of GMOs. These criticisms of NGOs are, in my judgment, largely correct. One may wish to quibble with elements of the philosophical foundations that one or more of our authors use to support their

conclusions. However, each of the papers relies on a careful attention to the facts regarding the real or potential harm of GMOs. Given these facts, it is difficult to dispute the claim that most of the objections to GMOs made by NGOs are without merit. And given the paucity of ethical arguments brought to bear in support of the anti-GMO positions, it seems reasonable to conclude that philosophical burden of proof lies with these critics of GMOs.

In these brief comments I want to defend three claims. First, I argue that some prominent NGOs are themselves engaged in unethical behavior regarding GMOs. Second, I argue that morally imaginative agribusinesses ought to proactively engage in stakeholder dialogue with their NGO critics and others. Third, I argue that while it may be true that corporations do not have an ethical obligation to label GM products, morally imaginative corporations that want to demonstrate ethical leadership have good reasons for doing so. Before I do this, however, I want to qualify my remarks. It is not my position, nor it is that of Klaassen, MacDonald and Whellams, and Cooley as I understand them, that agribusinesses have exhibited no unethical behavior regarding GMOs. For example, Klaassen points out that some companies, such as W.R. Grace, have engaged in "biopiracy" by patenting, or attempting to patent, "crop germ plasm originating in developing countries,"[1] with little or no genetic modification, as well as "indigenous biodiversity related knowledge."[2] Naturally occurring crop germ plasm and indigenous knowledge (typically developed over generations) regarding the varied uses of local organisms are properly understood as knowledge held in common by indigenous communities. The shared feature of such "commons" is that no one has the exclusive right to choose whether and how others use the resource. No one, in other words, has the ability to exercise a property right regarding these common resources. When a corporation simply asserts ownership over such commons, it is reasonable to characterize these actions as morally equivalent to theft. So to, when large agribusinesses are too aggressive in the protection of their legitimate patent rights, as when Monsanto takes legal actions against farmers whose fields include "unplanted and usually unwanted"[3] Roundup Ready plants in their field, they are rightly criticized for causing undeserved and unwarranted harm.

As Klaassen, MacDonald and Whellams, and Cooley point out, NGOs such a Greenpeace and the Research Foundation for Science, Technology and Ecology do not merely criticize the objectively unreasonable and unethical practices of agribusinesses, they condemn nearly all GMO related commercial activity. To the extent that they are successful in convincing average citizens that GMOs

[1] Johann A. Klaassen, Commercialization of the Agrarian Ideal and Arguments against the New "Green Revolution": Feeding the World with "Frankenfoods"?, p. 122.

[2] Ibid.

[3] Ibid., p. 5.

should be restricted or banned, they may cause genuine harm not only to agribusinesses, but also to vulnerable human populations. For example, Cooley points out that pesticide use for conventional cotton is 3.2 greater than that for Bt cotton, while the yield for Bt cotton is 80% greater than conventional cotton.[4] Genetically modified crops that reduce the need for pesticides while enhancing yield are of great benefit to the laborers who work in the fields, to those who need the crops, to the businesses that run the farms, to communities that are home to the farms, and to the local and regional governments that must cope with run-off pollution and other negative effects of heavy pesticide usage. When NGOs lobby against the use of GMOs such at Bt cotton on unwarranted grounds, they themselves ought to be condemned as unethical given the substantial harm to others the success of their lobbying efforts may have. The motives of NGOs in such cases are unclear, but may be driven by mere ideology or by a desire to tap into public fears as a way of garnering additional financial support. However, if NGOs are genuinely interested in having a positive impact on the practices of agribusinesses such as Monsanto, they ought to begin to take seriously the scientific evidence related to GMOs while at the same time taking better account of the substantial benefits GMOs can have for humanity.

The chapters by Klaassen, MacDonald and Whellams, and Cooley discussed here each defend some version of the thesis that agribusinesses have no ethical obligation to stop the research, development, and deployment of GMOs so long as current standards of safety are maintained and their target markets continue to be industrial farmers. One strategy for such companies would be to simply ignore or attempt to discredit NGO critics. However, I want to recommend an alternative strategy for corporations that are interested in demonstrating moral imagination and leadership. Let me explain what I mean by moral imagination. A capacity for moral imagination may be characterized as the ability to reexamine conventional practices and to imagine novel courses of action that have the capacity to improve outcomes from a moral perspective.[5] The morally imaginative manager is one who envisions innovative practices that address compelling moral problems while gaining strategic advantages. Given the adversarial stances toward agribusinesses of most NGOs concerned with GMOs, and given the genuine fear that appears to pervade the thinking of NGO leaders, one suspects that genuine efforts at stakeholder dialog on the part of agribusinesses might help to diffuse the adversarial climate, allow for misinformation to be dispelled, and encourage all parties to focus

[4] Dennis Cooley, "Transgenic Organisms, the European Union, and the World Trade Organization," p. 96.

[5] For a more expansive discussion of the concept see Denis G. Arnold and Laura P. Hartman, "Moral Imagination and the Future of Sweatshops," *Business and Society Review* 108: 4 (Winter 2003): 425–461.

their attention on the much more narrow range of ethical issues – such as the legitimate boundaries of intellectual property rights and food labeling – where conversations, rather than references to sound data, are needed to resolve disputes. In recent years a similar process has occurred with leading companies in the apparel and footwear sector such as adidas-Salomon and the Gap. This has resulted in significantly improved working conditions for workers in the supply chains of these companies.

My final point is that agribusiness companies that wish to exhibit morally imaginative leadership should voluntarily label their genetically modified products as such. I am persuaded by the argument of MacDonald and Whellams that agribusiness companies have no ethical obligation to label their foods.[6] However, I am not persuaded by their argument that labeling will have a "deleterious effect" on individual agribusinesses. Cooley points out that consumers place significant weight on negative information.[7] But agribusinesses do not need to portray GMOs as negative. Instead they can and should advertise genetic modifications as "enhancements" that improve product quality, reduce costs, improve environmental protection, and contribute to famine prevention. A British study found that in 2000 only 29% of respondents approved of GM foods, whereas in 2002 41% approved.[8] The change has been attributed to increased knowledge on the part of consumers regarding GMOs. The more consumers know, it would appear, the less fearful they are of GMOs. In 2002 agribusiness interests spent $5 million to help defeat an Oregon ballot initiative requiring that GM foods be labeled. Similar expenditures devoted to stakeholder engagement and the voluntary labeling of GM foods as beneficially enhanced products may have a positive influence on public attitudes toward GMOs while helping to advance the cause of products beneficial to humanity.

It is worth noting that agribusinesses that demonstrate morally imaginative leadership via stakeholder engagement and voluntary labeling may reap substantial strategic benefits. In particular, helping to disarm irrational public concerns may help prevent burdensome, mandatory regulations concerning GMOs such as those enacted by the European Union. We may therefore conclude that stakeholder engagement by agribusinesses regarding GMOs is both morally praiseworthy and strategically advantageous.

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[6] "Corporate Decisions About Labeling Genetically Modified Foods," Chris MacDonald and Melissa Whellams, p. 136.

[7] Cooley, "Transgenic Organisms, the European Union, and the World Trade Organization," p. 103.

[8] *Frankenfoods v. Luddites, The Economist*, June 5, 2003.

Part III

Corporate Governance and Genetic Commerce

Chris MacDonald and Melissa Whellams address the question of mandatory labeling of GMF products in "Corporate Decisions About GM Food Labeling." MacDonald and Whellams acknowledge that consumers have expressed a preference for such labeling, but that firms have largely not responded to this clear desire. They ultimately conclude that: "Given the lack of solid evidence for any risk to human health, and the serious market disadvantage almost surely associated with costly unilateral action, no individual company has an ethical obligation to label its GM foods."

This part considers some of the key issues that arise in operating firms and establishing control over industry in our new world of genetic commerce. In many ways, scientific knowledge continues to outstrip human moral wisdom. As it has since the dawn of the modern era, technological advancement raises new sets of problems that challenge our traditional modes of moral thought. While this has certainly happened in physics over the last centuries, issues of genetic commerce go even more directly to the heart of human concerns: "What is it to be human?" "Who can gain, control, use, and own information about DNA that may be unique to my body?" "To what degree can aspects of humans be justly commodified?" These and related issues pose serious and continuing challenges to human self-understanding for the 21st century. The chapters in this part each focus on particular aspects of the giant conceptual problems that lie before us.

Asher Meir explores the role of patenting of genetic information about humans in his essay "Who Owns My Ideas About Your Body?" Meir argues that ". . . current patent law is well equipped to encourage productive research, as long as the law is carefully applied and patents are given only to truly patentable inventions whose extent is clearly defined." Meir acknowledges that patenting human stem cells does tend to portray them as "mere objects of commerce," but such a regime can encourage research that is truly useful to humans and can even have an altruistic dimension. Meir ultimately concludes that "An ethical patent regime should encourage research which fulfills the promise of relieving suffering, discourage irresponsible treatment of research

subjects, and also make a positive and humane statement about the place of medical research in our society."

In his chapter, "Pharmaceutical Mergers and Genetic Technology: A Problematic Combination," Michael Potts tackles the problem of increasing concentration in the pharmaceutical industry – a concentration that may be exacerbated as a result of the Human Genome Project. Potts considers the possibility that just a few large pharmaceutical companies may gain effective control over DNA products and that such concentration may make physicians dependent on one or on a few companies for certain classes of drugs that are derived from genetic research. Potts discusses four ways to alleviate these potential problems including antitrust enforcement, adjustments in patent law, the free availability of genetic information, and resistance to the current merger trend.

Jamie Hendry focuses on the treatment of animals in genetic engineering in her chapter, "Stakeholder Care Theory: The Case of Genetic Engineering." Hendry argues that the dominant approaches to business ethics do not provide adequate guidance about the treatment of non-human subjects, and she emphasizes the advantages of a stakeholder care theory that she believes provides a superior framework for thinking about the treatment of non-human mammals in genetic engineering.

In "Unresolved Issues and Further Questions: Meir, Potts, and Hendry," Laura Hartman considers each of the three previous chapters in this part. While generally agreeing with Meir's analysis, Hartman considers some more innovative challenges to his views and asks whether the arguments he addresses are really the strongest that opponents of the current patent regime can raise. While accepting the wisdom of Pott's attempts to find a balance between economic freedom and the pursuit of corporate interests, on the one hand, and better social outcomes, on the other, Hartman raises serious doubts about the practicality and ultimate success of some of Potts's proposed solutions. In Hartman's views, the pharmaceutical industry faces contingencies and opportunities that militate in favor of continuing concentration. While Hartman generally agrees with Hendry's criticisms of other ethical traditions in their application to non-human test subjects, she finds that Hendry cannot satisfactorily establish the proper priorities for ordering the interests of mammals and humans in genetic engineering.

10

Who Owns My Ideas About Your Body?

Steps toward a humane intellectual property regime for human stem cells and other human tissues

Asher Meir

General Introduction

The scientific study of human stem cells, as well as other human tissue, bears great promise to benefit mankind, yet it also bears a great potential for irresponsible use of our unique human inventive gift. The challenge for our race is to effectively exploit the ability of this technology to alleviate human suffering and to advance understanding, while ensuring that scientific and commercial enthusiasm do not trample human rights and human dignity.

A surprisingly important focus of the ethical debate over stem cell research (SCR) is the granting of patents for inventions in this area. The seemingly arcane and mundane topic of patents has played a central role in the ethical debate for two reasons: the influence of patents on the direction of research and development and the powerful statement patents make about the extent of human mastery over their subject matter.

Patent law critically influences what kinds of research and development can attract private funding. In effect, patents are the fulcrum which transmits market forces to the research establishment. Without them, scientific innovation cannot be effectively translated into commercial success. It follows that subtle changes in patent policy can have an important impact on research agenda and research practices.

The direction of research has ethical importance both in terms of commission and omission. The patent regime should encourage the development and dissemination of treatments that improve the quality of life, without encouraging destructive research practices.

In addition, the entire concept of "intellectual property (IP)" is ethically charged, because intellect signifies transcendence, while property signifies limitation and exploitation. Intellectual creations, even more than material ones,

are never created ex nihilo by the inventor; rather they are necessarily rooted in a general cultural inheritance. Furthermore, their abstract nature means that they can be enjoyed by all without detracting from the enjoyment of any. Giving an individual the right to appropriate the fruits of such creations certainly requires ethical scrutiny.

The ethical paradox of "IP" is augmented when the subject of the patent is not a novel invention of the human mind but rather is based on human physiology, which is the common heritage of all mankind. Patents on stem cells could be interpreted as ownership and economic exploitation of mankind.

These considerations will guide us in envisioning what kinds of patent policy will best serve the ethical nature of mankind.

From a practical point of view, a patent regime should encourage the development of novel therapies to benefit the greatest number of patients, without inducing undesirable research practices that violate the rights and dignity of subjects.

From a cultural point of view, the patent regime should convey the impression that society is granting the inventor a limited economic right as an incentive for his effort, not lordship over a vital aspect of human knowledge and technology.

This chapter will attempt to assess the extent to which ethical problems are present in current patent regimes, and to suggest practical ways of raising ethical standards in this area.

The first section of the chapter is a general overview of what patents are and what kinds of ethical issues they raise. The second section discusses concerns arising from the way the patent regime impacts the conduct of research. The third section discusses inherent problems in granting property rights, including patents, in stem cells.

Patents and Their Ethical Dimension

For hundreds of years, governments have granted special legal rights to inventors to enable them to profit from their ideas. This process began in an ad hoc fashion as isolated inventors were granted special "letters patent" from the sovereign; later on the process was rationalized with the establishment of government patent offices with equitable criteria.

It is only natural that a variety of perspectives have developed around this venerable institution. The legal practitioner views the patent system somewhat differently from the more abstract jurist, while the economist also has a unique point of view. Each approach has its own explanation as to what patents are, why we grant them, and how they are obtained. Each approach, when carefully examined, displays unique ethical insights as well.

The Legal Approach to Patents

Patent legislation typically formulates a kind of contract between the sovereign and the inventor, in which the patent right is viewed as a reward for and thus a stimulus to innovation. Legislation and relevant treaties combine with the tradition of case law to create the patent regime in a particular jurisdiction.

A typical example is the U.S. Constitution, which gives the Congress the power to "promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."[1]

From here we see that a patent is an "exclusive right," and it is granted for the instrumental goal "to promote the progress of science and useful arts."

Patent protection is not meant only to encourage the production of new inventions, but it is also designed to encourage their disclosure. By giving protection which is broader than that granted to trade secrets, inventors are encouraged to publicize their innovations by publishing a patent. Keeping an invention secret stifles innovation by preventing others from using it or from learning from it, and wastes resources because keeping a secret can be very costly.

The exact criteria which are considered to successfully attain this goal have evolved through a centuries-long process of trial and error, and today patentability of an invention depends on the nature of the invention, its subject matter, and its intended use.

Nature of Invention

In order to be patentable an innovation must have three qualities: it must be novel, useful, and non-obvious.

The novelty criterion is evaluated by verifying that no such invention is recorded in "prior art," that is the body of existing record of innovation.

Despite its name, the usefulness criterion is not meant to exclude inventions which are "useless," which do not need any protection. Rather, it is meant to withhold protection from innovations which are general or theoretical in character, and which do not clearly enunciate what specific use and practical benefit they are expected to produce.

The non-obviousness criterion is evaluated by asking if the average skilled person in the relevant field of knowledge could have been expected to conceive the same idea.

These criteria are directly related to the purpose of the statute. Giving protection to inventions which are not new or not innovative does not promote innovation, it stifles it. Such protection would take inventions which already

[1] U.S. Constitution, Section 7, Paragraph 8.

exist or which could easily be conceived and remove them from the public domain, so that anyone who wanted to use them would have to secure the permission of the patent holder.

Likewise, giving protection to inventions which are not "useful" gives much more protection than is necessary, because a general idea will typically encompass a vast ambit of potential inventions. Furthermore, the inventor will have less incentive to perfect the invention because such refinements are not needed to obtain a patent.

Subject Matter

Patents are granted on products and processes; many useful innovations are considered neither products nor processes and are not eligible for patents. For example, in the United States new plant varieties which are sexually reproduced are not patentable, but rather are protected by the Plant Variety Protection Act of 1970.

This limitation is very significant for the biotechnology industry, since the novel nature of biotechnology inventions repeatedly raises the question of whether they fall into the category of patent statutes which speak of "manufactures," "compositions of matter," and the like. Indeed, a recent Canadian Supreme Court decision ruled that the Harvard oncomouse, which is a mouse with certain genetic anomalies bred in by a sophisticated process, is not patentable. The court did not deny that the oncomouse is novel, useful, and non-obvious; rather, the majority concluded that a higher life form such as a mouse is not a "composition of matter" according to the intent of the statute. Therefore, a process patent on the procedure for producing the mouse was allowed, but a patent on the mouse itself invalid. It is now up to the legislature in Canada to clarify this issue.[2]

The subject matter restriction has a salient ethical aspect. An invention which is not a "product or process" is considered to lack the required degree of artificiality which would justify giving a property right. The seemingly technical conclusion of the Canadian court concluding that mice are not "products" actually bases itself on many considerations which are clearly ethical in nature. For example, the majority opinion points out that a higher life form is "generally regarded as possessing qualities and characteristics that transcend the particular genetic material of which it is composed."[3]

The Canadian Supreme Court also considers that allowing such patents, while prohibiting patents on human beings, would require the court to pass

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[2] Harvard College vs. Canada (Commissioner of Patents). 2002 SCC 76 File no. 28155. Available from URL: http://www.lexum.umontreal.ca/csc-scc/en/rec/html/harvard.en.html.

[3] Ibid., Section B (1).

judgment on where to draw the line – hardly a simple matter in the world of biotechnology where transgenic species are the rule rather than the exception! The court ruled, "It is not an appropriate judicial function of the courts to create an exception from patentability for human life given that such an exception requires one to consider both what is human and which aspects of human life should be excluded." This is not a function for the court but rather "presumably will require Parliament to engage in public debate, a balancing of competing social interests, and intricate legislative drafting."[4]

Intended Use

Another important requirement is that the exploitation of the invention should not contradict public order or public morality. For example, the European Patent convention states that "European patents shall not be granted in respect of inventions the publication or exploitation of which would be contrary to 'ordre public' or morality."[5] Traditionally this stipulation was used to withhold protection from dangerous inventions such as weapons, but at least one country has broadened this concept to include patents on human organs, which are considered contrary to human dignity.[6]

This condition has an evident ethical basis. Since patents are meant to promote the "useful arts," there is an obvious public interest in promoting only those arts whose use is beneficial to humanity.

Natural Law Approach to Patents

The law of IP, like that of tangible property, is often conceived as resting not on the basis of legislative fiat but rather on basic moral principles. Most people feel that stealing objects constitutes a fundamental moral outrage which is not dependent on a precise statutory definition of property; this approach can be extended to stealing ideas.

In this approach the inventor's ownership of his or her idea is a natural outgrowth of the intimate personal connection the innovator has with the fruit of his or her unique creative capacity. This unique connection is formalized in a legal right of exclusivity. A report from the U.S. Office of Technology Assessment states that some arguments "justify property rights as entitlements

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[4] Ibid., Section B (2).

[5] European Patent Convention, Part II, Chapter I, Article 53(b) cited May 8, 2003. Available from URL: http://www.european-patent-office.org/legal/epc/e/ar53.html (accessed May 8, 2003).

[6] Code de la propriete intellectuelle. Legislative section, Book VI, Chapter 1, Article L 611–617. Available from URL: http://www3.ccip.fr/irpi/code-propriete (accessed May 8, 2003).

to the fruits of one's labor and draw upon themes derived from John Locke's seminal discussion of property rights."[7]

This approach would give us a somewhat different understanding of the various criteria.

Nature of Invention

An idea that is not novel is not the fruit of the inventor at all, but rather of someone else. And if the idea is not obvious, the connection with the inventor is rather tenuous: the invention is not the fruit of his or her unique creativity but rather of his or her professional training, which is shared with an entire community of similarly skilled individuals.

The usefulness criterion could be understood according to this approach by suggesting that natural law ownership cannot extend to anything which is beyond the owner's ability to encompass and exploit. Locke states: "As much as any one can make use of to any advantage of life before it spoils, so much he may be labour fix a Property in. Whatever is beyond this, is more than his share, and belongs to others."[8] In a natural law framework, a person can acquire a field but not a continent. Extending this idea to IP, we would not be willing to acknowledge ownership over a law of nature with its vast potential for new products and processes.[9]

Subject Matter

The restrictions on subject matter have a particularly intuitive interpretation according to a natural law approach. Certain physical entities have such a salient public character that no one would think of providing property rights in them, and the same applies to intellectual entities.

For example, it is hard to imagine that the citizens of the United States would ever consent to granting private ownership of the Statue of Liberty,

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[7] U.S. Congress, Office of Technology Assessment. *New Developments in Biotechnology: Patenting Life – Special Report*, OTA-BA-370. Washington, DC: US Government Printing Office (p. 130). April 1989, Available from URL: http://www.wws.princeton.edu/cgi-bin/byteserv.prl/~ota/disk1/1989/8924/892410.PDF (accessed May 8, 2003).

[8] Locke, J. (2003). *Second Treatise on Government*. Swansea: University of Wales Swansea, Chapter 5, Paragraph 30. Available from URL: http://www.swan.ac.uk/poli/texts/locke/lockcont.htm (accessed May 22, 2003).

[9] This approach to IP has use in explaining patents, but is particularly valuable in understanding copyrights. Copyrights are granted even when the artistic works have little economic value and even when the investment required to produce them is small; they also last for a much longer time than patents. The creative input in producing a work of art is greater than that in producing an industrial invention, so the greater applicability of the natural law approach is understandable.

even if there were iron-clad assurances that access and upkeep were safeguarded and even improved. The Statue is such a most prominent symbol of American freedom and international friendship that the very fact of private ownership would demean its importance.

By the same token, certain ideas have a salient public character which in itself has immense public worth. One example might be the earth's biological inheritance. The general consciousness that this inheritance belongs to all mankind might be of greater value than any economic benefit that would be obtained by allowing private ownership of plant varieties which are obtainable by ordinary cross-breeding.

Economic Approach to Patents

The economist has no difficulty identifying a patent as an instance of legal monopoly. The economic justification of this monopoly has its roots in the fact that ideas are a "public good": one individual can use them without depriving another, and furthermore it is technically impossible for one individual to exclude others from using the good.

Ideas are free to use, but they are expensive to produce. And since ideas are a public good, the innovator of the idea is unable to recoup his investment in producing them. After the inventor pours a thousand, a million, or a billion dollars into his idea, others can benefit from it without any payment. In order to maintain an incentive to create and disclose innovative ideas, some kind of reward is necessary; and for a variety of reasons giving a legal monopoly has been considered one of the most effective types of reward.

In a seminal economic analysis of patents, William Nordhaus wrote that "information is expensive to produce, cheap to reproduce, and difficult to profit from." One solution is patents, which are "licenses for a monopoly on information for a specified period of time."[10]

According to this point of view, the three patentability criteria are meant to maintain an appropriate balance between the extent of the investment and the extent of the reward. We do not want to make the reward to innovation so small that inventors will not find it worth their while, yet we also do not want to make the reward so large that the social cost is excessive. As Nordhaus remarks in regard to patent lifetime, "First, a longer life increases invention. This is a positive effect. Second, a longer life means that the monopoly on information lasts longer and thus there are more losses from inefficiencies associated with monopoly."[11]

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[10] Nordhaus, W. D. (1969). *Invention, Growth and Welfare: A Theoretical Treatment of Technological Change* (p. 70). Cambridge, MA: MIT Press.

[11] Nordhaus (1969, p. 76).

It follows that novelty and non-obviousness are requirements because pre-existing or obvious inventions can be produced at little cost. Therefore, it is unjustified to offer a large reward for coming up with them. Richard Posner writes, "The functional meaning of obviousness is discoverable at low cost. The lower the cost of discovery, the less necessary patent protection is to induce the discovery to be made."[12]

Conversely, usefulness is required for patentability because a patent on an invention that is too general will have immense economic value. Even if the idea does require a large investment, granting a patent will give a reward incommensurate with the effort required to produce the idea.

How SCR Patents Can Best Stimulate Productive Research

Patents are designed to encourage productive investment in beneficial ideas, but no guarantee exists that they will achieve this aim. A patent system which is poorly designed can overly restrict access to inventions; can induce too little investment or too much; and can also encourage undesirable activities. All of these concerns have been raised with regard to biomedical research; one influential paper summarizes this view by stating that "Commercial incentives are widely assumed to contribute to human health, but this is not necessarily the case. There is growing concern that market principles have been improperly applied."[13]

The Problem with Patents

Once a product has already been invented, patents are problematic because they are monopolies, implying the problems of increased price and reduced availability. Since monopolists are shielded from competition they have less incentive to offer competitive prices. This loss is supposed to be the tradeoff necessary to induce invention in the first place. However, while the patent system does work well on the whole there is no guarantee that in any particular area of concern it will succeed in encouraging research and development.

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[12] Posner, R. A. (1992). *Economic Analysis of Law* (4th edition, p. 39). Boston, MA: Little Brown and Co.

[13] Nelkin, D., & Andrews, L. (1998). Homo economicus: commercialization of body tissue in the age of biotechnology. *Hastings Center Report*, September to October, *28*(5), 30–39.

Following is a partial list of ways in which a patent regime may fail to induce the appropriate, economically efficient benefit from research and development:

1. If patent protection is inadequate, there will be inadequate incentives to create and publicize new inventions. Inventors will find that new ideas are not worth the investment because others will steal them, or they will make new inventions but keep them secret.
2. Conversely, the monopoly power of a patent holder may, ironically, provide less incentive to further innovation. Innovation is one way of obtaining a competitive advantage; if the monopoly rights are too extensive the patent holder may be able to "rest on his laurels" and refrain from further innovation.
3. If patent protection is too extensive, then too much may be invested in innovation. Wasteful patent races may develop where a number of firms invest large sums in substantially identical research, each one hoping to be the first to obtain a patent and enjoy excessive monopoly revenues.
4. When the scope of patent protection is not clearly defined, the result may be very expensive litigation.[14] A related cost is that of "defensive patenting" where patents are not needed to protect innovations from competition but are taken out to defend against infringement suits and conversely to threaten competitors with these suits.[15]
5. When commercial application of a patent requires combining ideas from a number of patent holders, negotiations among the various rights holders may be so complicated as to preclude effective exploitation of the various rights. This effect has been called the "anticommons" in an influential article.[16]
6. Sometimes the research necessary for innovation may itself be socially undesirable. For example, some research has involved denying treatment to patients or engaging in intrusive or dangerous treatments that would not be indicated on therapeutic grounds. While this is not exactly a failure of the patent regime, it can be one result of the incentives created by such a regime.

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[14] Of course this litigation is not completely without social benefit. Some litigation is necessary precisely to help clarify the exact extent of patent protection on the basis of judicial precedent. But careful attention at the stage of legislation or of patent writing can often provide the same degree of clarity at far less expense.

[15] Bronwyn, H., & Ziedonis, R. H. (2001). The patent paradox revisited. *RAND Journal of Economics*, *32*(1), Spring, 101–128.

[16] Heller, M. A., & Eisenberg, R. S. (1998). Can patents deter innovation? The anticommons in biomedical research. *Science*, *280*, May, 698–701.

We will devote a short section to the ways in which the economic theory of patent answers these concerns in general and, where appropriate, to specific concerns relating to SCR. A more detailed discussion is beyond the scope of this chapter, belonging more properly to a survey of patent law in general.

How Do SCR Patents Measure Up?

Let us examine the consequences for patent policy of each of these considerations in the context of SCR. The main source of information in the analysis of the SCR business is the biweekly newsletter *Stem Cell Business News*:[17]

1. *Monopoly profits*: Various schemes exist which spur innovation, yet avoid the problem of monopoly profits. Two examples are direct government sponsorship of innovation or awarding a money prize to an inventor. (Mandatory licensing is one version of this.) Research suggests that these alternatives are generally inferior solutions for patentable innovations, because only the innovator has a clear idea of the value of the invention. The government has much less knowledge and is unable to adequately assess the true value. Thus they are likely to provide inadequate compensation for some ideas while spending excessively on others. Monopoly rights ensure that the inventor recoups an amount, that is roughly proportional to the social value of the invention.
2. *Complacency*: The patent system strives to avoid this problem mainly through limitations on a patent's scope. Such limitations are meant to ensure that a patent provides adequate incentive to innovate but does not excessively deter other inventions. A patent, which is of appropriate breadth, can be invented around at an expense which is significant but not prohibitive. In this way, the competitor has an incentive to take out a license rather than engage in wasteful duplicative invention, but the patent holder has an incentive to offer a license at a reasonable price knowing that an excessive demand will make it worthwhile for the competitor to invent around the patent.

   Complacency does not seem to be a feature of the SCR industry, which is characterized by dozens of relatively small companies, none of which has a dominant position in any broad technology, and all of whom are fiercely competing for financing and market share.[18]
3. *Inadequate protection*: Inadequate patent protection is a deterrent to investment if inventions cannot be kept secret. There is no evidence that

[17] *Stem Cell Business News*. Leesburg, VA: DataTrends Publications.

[18] In an examination of about 9 months of the newsletter during 2002 and 2003, dozens of companies were significant enough to be considered newsworthy. No company dominated the news.

inadequate protection is an obstacle in SCR. While 2002 was a very hard year for the industry, none of the various analyses we found in the press attributed this problem to inadequate IP protection, and companies freely entered into many licensing agreements indicating that they feel their proprietary techniques and cell lines are adequately protected. One publication claimed that in Canada, "99% of companies rely on patents (rather than products) as their sole source of value."[19] Another, exhaustively researched paper concludes that "virtually all biotechnology discoveries are patented."[20]

4. *Patent races*: SCR is advancing on so many different fronts, there does not seem to be any single "mega-invention" out there which companies are working on simultaneously. The business seems to be characterized by a huge number of niche technologies, which enable each of the large number of small firms to develop its own particular IP portfolio.
5. *Uncertain scope*: Another way in which patents can deter innovation is if they are of uncertain scope. Such uncertainty invites expensive and wasteful litigation. Sometimes patents are taken out with the sole intent of bullying competitors in court.[21] The remedy is to strive to have transparent rules establishing when a patent is infringed.

   Practically speaking, the stem cell business seems to be characterized by little litigation – perhaps due to the staking out of niches as previously described. Over a period of over 9 months, the newsletter *Stem Cell Business News* reported on dozens of companies whose success depends on proprietary products and on nearly the same number of IP rights (IPR) transfers through licenses, sales, acquisitions, or MTAs, but only a handful reported patent disputes!
6. *Anticommons*: A prominent recent article suggests that special problems may arise from patents on "upstream" technologies. If many different "upstream" inventions are required to produce any particular "downstream" application, then negotiations may be prohibitively difficult.[22]

   However, experience shows that the profit motive provides significant motivation for these upstream patent holders to find ways to overcome

[19] Patenting pieces of people. *Nature Biotechnology*, *21*(4), April 2003, 341.

[20] Lerner, J. (1995). Patenting in the shadow of competitors. *Journal of Law and Economics*, *38*, October, 463–495.

[21] This phenomenon is documented in Hall and Ziedonis, above. Their research suggests that this problem may be particularly troublesome in technologies with a short product lifetime and with relative ease of keeping trade secrets. These traits do not seem to characterize SCR, which so far has displayed very long product cycles and in which trade secrets are relatively unimportant as a means of protecting IP.

[22] Heller and Eisenberg.

obstacles to negotiation. In the case of SCR, we see a pattern of patent holders trying at first to maintain very restrictive arrangements with licensees, but after a year or two conceding that a more accommodative policy is necessary. This suggests that the anticommons problem is real but temporary.

For example, a number of firms made high-profile licensing agreements in the summer 2001. *The Scientist* cited Q. Todd Dickinson, a former Commissioner of the U.S. Patent and Trademark office, as saying "In reality, all these licensing issues are fairly straightforward. I don't think there's anything here that's unusual, aside from the visibility and the fact that it's gotten to the presidential level as a matter of public policy. I've seen much more complex licensing schemes than this. It can look kind of complex, but this is pretty simple stuff. It's a pretty garden-variety kind of licensing program."[23]

In addition, the structure of the SCR business seems to be rather flat – more like a geyser field than a stream. Many companies have parallel but slightly varying versions of basic technology, with no single technology critical to a large swathe of research. So the basic presumption of the anticommons model, a situation where many technologies are needed for a useful product, does not seem to be applicable in this market. When licensing agreements are called for, there do not appear to be daunting obstacles to arranging them.

7. *Undesirable research protocols*: Even when the innovations encouraged by patent law are desirable, the research that leads to these innovations may have undesirable elements. Sometimes research activities are inherently unethical, as when vital medical treatment is withheld or when experimentation is damaging to subjects. In other cases, the profit motive may create conflicts of interest, which will create an incentive for unethical activities.

These collateral effects of a patent system will be discussed in the next section of this chapter.

Summary: Effects of Patents on Research

From an economic point of view, there does not seem to be anything special about SCR that would recommend a unique, sui generis IP regime. On the contrary, the current patent regime seems to be working remarkably well.

A survey of the business literature reveals that there are a large number of small companies each developing a specific niche of the market for SCR applications, where the value of each company is largely dependent on its proprietary

[23] Agres, T. (2001). Stem cells: steady momentum towards funding. *The Scientist*, *15*(18), September 17, 8. Available from URL: http://www.the-scientist.com/yr2001/sep/agres_p8_010917.html (accessed May 22, 2003).

knowledge or biological materials. A large fraction of companies' revenue is reported to be derived from sales or licensing agreements or material transfer agreements. In addition, there are a large number of acquisitions in which IP portfolios are listed as a significant consideration in the target firm's value. We cited above an industry report claiming that for virtually all firms, revenue is derived exclusively from patents. Over a period of almost a year, only a handful of patent infringement disputes were mentioned.

One prominent researcher did mention that material transfer agreements were an important obstacle in obtaining high-quality cells.[24] However, patents were not mentioned. Furthermore, joint testimony of the United States stem cell industry before a Senate panel decried the many obstacles in obtaining cells, but IP considerations were not mentioned at all.[25]

Various explanations for the poor performance of biotech stocks over the year 2002 tended to focus on the poor performance of the market as a whole, loss of investor confidence to a prominent scandal, and concerns over possible political obstacles to continued research. No analysis mentioned legal IP problems such as inadequate protection, blocking patents, or dissipation of resources in infringement battles.

The lack of problems due to IP difficulties in the past does not mean that such problems cannot arise in the future. Experience suggests that in rapidly developing technologies there can be a danger that the same type of innovation, which is non-obvious at one stage, may become routine and hence non-patentable at a more advanced stage of development. Therefore, the following guidelines will be appropriate:

- Patents should be given only for innovations that are truly new and non-obvious, not for the accreted discoveries, which are a routine part of laboratory research. This distinction is a dynamic one, and the same type of innovation that is new today may become routine in a few years time.
- Patents should be given only for innovations which have a concrete promise of useful application, not those for which any potential use is only speculative.
- Examiners and courts should ensure that the exact boundaries of patent protection are as clear as possible. Such a "bright line" will help eliminate costly court battles. These battles are a setback to research in themselves, and their prospect can deter inventors from entering the fray in the first place.

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[24] Dalton, A. (2002). US firms blocking stem cell research. *The Scotsman*, October 17. Available from news.scotsman.com (accessed October 24, 2002).

[25] Stem cell researchers voice their frustration over Bush policy. *Stem Cell Business News*, *1*(11), October 4, 2002, 1.

Impact of IP Regime on Ethical Problems in SCR

Introduction

In the previous section, we asked how a patent system can be designed to induce enough effective research; in this section we discuss how it can avoid creating destructive research practices. In this way we address the ethical problems of commission and not only those of omission.

One troubling ethical problem of embryonic SCR is the practice of destroying in vitro embryos to extract stem cells. This issue is beyond the scope of the IP section of this chapter, because this question is equally present no matter what IP regimen is guiding the research. Whatever IP system is adopted will be required to take steps to discourage any research which is improper from the point of view of bioethics. If there are no specific laws against a specific practice, then the IP system can be used as a tool; for example, some practices may be considered as unpatentable due to a conflict with public order and morals; or if the main source of innovation is government funding this funding can be withheld from problematic types of research. However, this evaluation has no area of overlap with the study of IP regimens per se.

Another possible difficulty is that the economic advantages of SCR patents may create new conflicts of interest between patients and treatment providers. The ability of the physician to obtain lucrative property rights based on biological material from patients creates an incentive to extract these materials with inadequate consent or lacking consent altogether. This problem exists with respect to all types of cells or tissues: individuals who are donating their own cells (adult stem cells); new mothers donating placental or umbilical cords; abortion patients donating the aborted fetus; IVF clients donating unused embryos; or women donating their eggs for SCR.

This problem can take many forms:

- A pure "donor" relationship may be influenced by duress, as when a fertility clinic exerts subtle pressure on clients to donate unused embryos as a tacit condition for continued treatment, or when the economic incentives for egg donation are so great as to impair the judgment of indigent young women.[26]

[26] Healy, B. (2003). Donors at risk: the high cost of eggs. *U.S. News and World Report* (online newspaper), January 13. Health section. Available from www.usnews.com/usnews/issue/030113/health/13donor.b.htm (accessed January 7, 2003). A similar phenomenon is documented in a *BBC* report claiming that residents of Moldovia have donated kidneys for as little as $3,000 because of financial distress. Bell Bethany. Moldovia's desperate organ donors. *BBC News*, May 21, 2003. Available from URL: http://news.bbc.co.uk/1/hi/world/europe/3046217.stm (accessed May 22, 2003).

- When required medical procedures yield economically valuable biological materials, the patient may be inadequately informed of the value of these materials so his or her waiver of rights to these materials may lack full informed consent from an economic point of view.
- The choice of medical procedure may be consciously or unconsciously biased by the desire to obtain such biological material. The patient's consent to the procedure itself may not be fully informed if the treatment provider gives a skewed explanation for the desirability of a particular course of treatment or diagnostics.

We can identify a variety of ethical questions related to this aspect of medical research:

- Is the allocation of profit between physician and patient equitable?
- Is there true informed consent on the part of the patient?
- Does the research regimen prevent the patient from obtaining adequate care? Such care could be withheld either because the treatment provider has an incentive to deprive the patient or because the lack of trust between patient and physician keeps the former from undergoing tests and procedures, which are truly necessary.

Informed Consent

At least since Kant enunciated his "practical imperative," ethicists have acknowledged the importance of treating others as ends in themselves by respecting their autonomy, and not only as a means to an end. This autonomy can be violated by outright coercion or by more subtle forms of guile.

Since patients are a means for medical researchers to obtain valuable scientific knowledge, such researchers have to take particular care to respect the wishes of patients and research subjects by obtaining adequate consent. While national legislation as well as international agreements such as the Helsinki Declaration provides guidelines for informed consent, experience teaches that declarations are not enough and there is also a need to structure the treatment environment in a way that does not encourage bypassing true informed consent.

These concerns are magnified when the medical knowledge obtained from research serves not only as a means to obtaining knowledge and recognition, but also as a direct means of enrichment. The ethical complication introduced by the profit motive is both quantitative and qualitative.

Quantitatively, the profit motive provides one additional incentive to obtain medically valuable biological material. But the profit motive is also qualitatively different from the other motives. The main difficulty is that this motive is not in itself ethically grounded. We will now elaborate on these two elements.

The Profit Motive As an Obstacle to Informed Consent

The desire to obtain knowledge can be part of a selfish, acquisitive urge, as it was in the case of *Dr. Faustus*. But more often this desire is itself part of a desire to benefit humanity. To a lesser extent, the same is true of fame: a person seeks fame, not notoriety; he or she wants to be acknowledged as someone who did something extraordinary to benefit others.

Since these inducements to medical research are themselves ethically grounded, the concern for patients' rights is likely to be an effective, if partial, counterbalance. This concern will constitute part of the encompassing ethical calculus.

However, the desire for monetary gain has a much less salient ethical aspect. While we do observe that people desire to obtain wealth in order to spend it on socially worthwhile ends, such ethical motivations are usually a much smaller part of this kind of acquisitiveness. The result is that the "ethical counterbalance" of patients' rights will have less impact. Indeed, this consideration can even outweigh the desire for knowledge and fame, and lead individuals to engage in research which is lucrative yet not particularly informative.

The conclusion seems to be that from a psychic point of view, a profit system carries a greater risk that the practitioner will fail to view ethically correct treatment of the patient as an integral part of his medical practice. We can identify a number of ways of dealing with the problem created by the profit motive:

- One way is just to eliminate the profit motive altogether. In our case, if we were to disallow patents on SCR then the practitioner would not stand to make substantial sums from any innovations based on biological material from patients. This alternative can be attractive if other motives are sufficient to induce intensive research.
- We could rely on the market itself to remedy the problem. Perhaps we could rely on competition to incentivize practitioners to act in an ethical way, thus enhancing their reputations and their clientele.
- We could promulgate regulations which create economic incentives to informed consent. For example, an "eminent domain" approach can solve some of the negative incentive problems, as we explain below.
- Finally, we could seek to structure research protocols in a way that encourages ethical rather than market approaches to decision-making. The idea is not to create economic incentives to obtain informed consent but rather to induce the researcher to apply ethical criteria to this issue, instead of economic criteria.

Let us analyze each of these directions.

Eliminating the Profit Motive

While the profit motive is undoubtedly one powerful way of unlocking human energy and creativity, it is not the only way. It is worth examining whether other motivations such as love of knowledge and the desire for recognition and academic advancement might not be equally effective without creating the same problems of informed consent.

It is true that the dash to recognition, no less than the dash to profit, may trample patients' rights. Indeed, some of the worst examples of ethically repugnant treatment of research subjects were in government-sponsored studies.[27]

However, there are two reasons to believe that in general public sponsorship could achieve better treatment of patients. One is the culture of public service which we expect from the public sector; this is related to the point we made above that the entire organizational orientation is basically an ethical one. The other factor is the openness and transparency, which characterizes the public sector and the academic environment, as compared with the culture of secrecy that is such an essential part of competitive industry.

Working against this consideration is the fact that competition is a critical and highly effective stimulus to positive treatment of clients. When the public sector tramples the rights of subjects they may have no alternative but to suffer.

It seems that public-sector research should be viewed as an essential adjunct to the private sector. In this way public-sector involvement increases competition rather than decreasing it. Government-financed studies will bring a public-service mentality and public-service transparency, yet will both face and provide competition for ethical behavior vis-a-vis the private sector.

Creating Market Incentives for Informed Consent

When faced with a patient whose tissues may have monetary value, a treatment provider might want to withhold this knowledge from the patient for one of three economic reasons:

1. The physician might want to appropriate this monetary value for himself and not share it with the patient.
2. The physician might fear that revealing the value to the patient would lead to an intractable bargaining situation.
3. The physician might feel that even if offered an appropriate monetary inducement the patient would withhold consent.

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[27] One notorious example is the Tuskegee syphilis study in the United States, where researches deprived syphilis sufferers of treatment for decades in order to study the course of their disease. In the meantime the patients' health deteriorated and they continued to infect others with this dangerous disorder. No one got rich or famous from this study, and even the scientific value of the results is not particularly impressive. It seems that bureaucraticsm can be at least as heartless as avarice.

In economic terms, the first scenario presents an "equity" problem, the second and third an "efficiency" problem: The first scenario assumes that the social value of the biopsy will be realized; the question is who will appropriate it. In the second case, seeking informed consent may introduce a market failure (bilateral monopoly), which leads to a socially desirable test not being performed. In the third scenario, not seeking informed consent introduces a market failure, which leads to a socially undesirable test being performed: the patient endures excessive discomfort, which is not justified by the economic value of the test.[28]

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[28] These concepts can be clarified through a simplified abstract example. This is an economic, cost–benefit model in which we will assume that all benefits and costs can be quantified. While in an actual situation we will want to know the relative weight of economic incentives as against medical or ethical considerations, the purpose of this model is to isolate and examine the specifically economic dimension of this problem.

Let us suppose a certain biopsy is likely to have some economic value due to its use in medical research. In addition, the biopsy will make a certain contribution to the patient's own well-being. On the cost side, the patient evaluates the discomfort of the biopsy as "costing" him a certain sum. (In addition, the biopsy may have some economic cost to perform; we will ignore this consideration since it is not relevant to the phenomenon we are trying to understand.)

To be precise, suppose that the research value of the tissue is one thousand dollars, the medical contribution of the test to the patient is also one thousand dollars, and the discomfort of the test is also one thousand dollars. Then the social value of the test is one thousand dollars, and the economically efficient outcome is that the patient accepts an inducement of between zero and one thousand dollars to consent to the test and grant economic rights to the treatment provider. From an equity point of view, the "fair" division of the economic surplus is dependent on a variety of considerations, but elementary fairness suggests that half and half is equitable: the patient gets a $500 royalty and the treatment provider will earn the same sum from use or sale of the tissue sample.

In the context of this example, we might depart from this ideal for any one of the three reasons mentioned above. These considerations would be expressed as follows.

In the first case, the physician believes that the informed patient would accept a five hundred dollar inducement to carry out the procedure, but prefers to keep this sum for himself.

In the second case, the physician is worried that even though the fair allocation is to split equally the thousand dollars added value, the patient will demand the full thousand dollars or even more, an excessive amount, and the result will be that no test will be performed and no one will benefit.

In the third case, the physician is worried that the patient is so afraid of the biopsy that even one thousand dollars would not induce agreement.

In each of these cases, the treatment provider has an economic incentive to violate professional ethics and exaggerate the true medical necessity of the test, convincing the patient that even without an inducement it is in his interest to have the test done. Alternatively, the physician may fairly state the medical value of the test, allowing the patient to consider that the test is worthwhile since the medical value to him is equal to the discomfort. Yet the physician may withhold knowledge of the research value so as not to be faced with a demand for an inducement.

While the issue of informed consent is framed in terms of a physician ordering "unnecessary" diagnostic tests, we see from these examples that tests may be unnecessary from an individual point of view but necessary from a social point of view. In the first two scenarios the tests should be done; only in the third is the procedure truly unwarranted.

The second case should be particularly worrisome, because it demonstrates that from a cost–benefit perspective, the demand for informed consent can actually be counterproductive. The sense of unfairness is greatest in those high-profile cases where the physician makes a fortune from the patient's suffering, yet it is exactly in these cases where informed consent may be an obstacle to equity!

Let us take the well-known case of John Moore, whose treatment providers made millions of dollars off a patent based on his biological materials, which were taken from him under false pretenses. There can be little doubt that if they had offered Moore a share of this money that he would have consented to the additional tests, which were intrusive but not in any way dangerous.

Yet full disclosure could well have resulted in a disastrous market failure. Had Moore known of the value of his tissues, we would have a situation of "bilateral monopoly" which could easily have ended in stalemate. The patient would have had a monetary incentive to threaten to hold out for a large sum, which might not have been forthcoming. This would have resulted in the loss of millions of dollars of social value, as measured by the market value of the patents.

In many cases, law resolves problems of bilateral monopoly by establishing a fixed statutory standard of recompense. For example, in the case of salvage of a ship in distress the salvor is entitled only to reasonable recompense. This keeps the salvor from demanding an exorbitant price, which could lead to an inequitable outcome or even to a breakdown in negotiations. If the amount is insufficient, the salvor can decline.[29] Another example is unjust enrichment, where a person who performs a service is entitled to fair recompense although no negotiations took place.[30]

The parallel in our case is to establish an equitable statutory recompense for biological materials, and presenting both patient and physician with a take-it-or-leave-it choice.[31] The physician will not benefit from hiding his material benefit, because the "unjust enrichment" aspect of the payment will compel him to pay even without negotiation. He will not need to fear patient holdout, because the patient is faced with a take-it-or-leave-it offer. And if the patient

[29] See for example Posner (1992, pp. 116–117).

[30] See Posner (1992, pp. 133–134).

[31] In the above example, we might establish a statutory recompense of five hundred dollars for this particular test as long as the physician makes at least this amount.

In the first case, the physician has no incentive to mislead the patient, because even without patient consent recompense is mandatory.

In the second case, the patient has no incentive to hold out for a larger sum because the law requires him to accept five hundred dollars or nothing.

In the third case, the patient will refuse to undergo the procedure because the recompense is insufficient, and this is the efficient outcome.

truly believes that the compensation is inadequate for his troubles, he can always refuse to take part.

Of course in an actual treatment setting there would be many additional considerations, including the difficulty of quantifying medical value and patient discomfort, and the existence of ethical norms and rules. However, it is important to understand the cost–benefit dimension of the issue in isolation before we combine this perspective with other considerations. A fixed payment schedule established by regulatory policy could encourage informed consent in tissue donations.

Encouraging Ethical Decision-Making

The careful cost–benefit analysis we just performed suffers from a significant ethical lacuna: it assumes that costs and benefits can be calculated independently of their ethical context. The approach presented above assumes there are quantitative measures of how much the biopsy hurts and how much the research is worth to patients.

Yet introspection and research both confirm that the "utility" of acts is intimately dependent on their meaning. The same procedure that may be considered unbearably painful in one context, may be cheerfully borne in another.

This claim was forcefully made by Richard Titmuss in his highly influential book on donating blood, a topic which can serve as a paradigm for other types of tissue donation. After an exhaustive examination of blood donation procedures in a number of countries, Titmuss concludes: "The evidence in preceding chapters shows the extent to which commercialization and profit in blood has been driving out the voluntary donor. Once man begins to say, as he sees that dollars exchange for blood supplies from Skid Row and a poor and often coloured population of sellers 'I need not longer experience (or suffer from) a sense of responsibility (or sin) in not giving to my neighbour' then the consequences are likely to be socially pervasive."[32]

Utilitarian analysis would encourage us to compare the value of blood to the inconvenience and discomfort of donation, and settle on an appropriate recompense. However, Titmuss concluded that while donating blood is considered bothersome and painful when done for profit, it is considered inspiring and uplifting when done as an act of altruism. His study was highly influential in leading to a change in donation policy in the United States that almost completely eliminated paid donations.

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[32] Titmuss, R. M. (1972). *The Gift Relationship – from Human Blood to Social Policy* (pp. 198–199). New York: Vintage Books, Random House.

The general applicability of Titmuss's conclusion is still a subject of controversy. One subsequent study opined, "One difficulty of Titmuss's argument is that he never proves it."[33] It is still possible that on the whole the extent of donations would be greater under a system of paid donors. However, the presence of such an attitude to some extent is certainly borne out by Titmuss's interviews. As he writes, "Practically all the voluntary donors whose answers we set down in their own words employed a moral vocabulary to explain their reasons for giving blood."[34]

This in turn suggests that the market solution suggested in the previous section is actually quite deficient. While the statutory payment regimen is the ideal solution given the costs and benefits, it will not be optimal if the costs are themselves endogenous to the regimen. In other words, the very fact that this solution is enunciated in market terms vitiates the ethical motivation for donation and thus deprives the patient of an important source of satisfaction from his or her contribution to medical advancement.

Let us examine a variety of possible solutions.

Inducement Limited Only at Locus of Donation

One obvious solution would be to eliminate all kinds of inducements for tissue donation. This would be parallel to the existing situation in blood donation, where the blood banks obtain blood free from donors and afterwards sell it as an ordinary commodity to hospitals or other blood banks. A problem with this approach is that it may violate equity.

In the case of James Moore, his physicians obtained a commercially valuable patent on a cell line derived from his excised spleen, though the consent he gave was limited to non-commercial research use. When Moore sued the physicians for conversion (improper use of his property), the defendants maintained that these cells were not property at all. The Court of Appeal pointed out the paradox in this position, stating: "Defendants' position that plaintiff cannot own his tissue, but that they can, is fraught with irony."[35]

Payment to a Third Party

One way of dealing with the equity problem would be to provide for payment to some third party. For example, some fraction of the commercial value

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[33] Hough, D. (1978). *The Market for Human Blood* (p. 29). Lexington, MA: Lexington Books.

[34] Titmuss (1972, p. 237).

[35] *Moore v. Regents of the University of California*, 793 P.2d 479 (Cal. 1990). Available from URL: http://www.richmond.edu/~wolf/moore.htm (accessed May 22, 2003).

of donated tissue could be donated to some kind of fund, which would help patients. We could imagine that some proceeds from blood sales by blood banks would help finance transfusions for needy recipients, and so on.

In this way the economic value of the donation is realized in an equitable way without granting a salient commercial character to the act of donation.

Non-demeaning Form of Payment

A desirable goal would be to provide some kind of monetary payment to provide a sense of equity yet still maintain the mentality that the main reason for the donation is to help others. Attaining this ideal requires careful thought.

While it is true that monetary payment generally goes together with market approaches to valuation, the exchange of money does not automatically erase the deeper aspects of human interaction. As we will demonstrate in more detail in section "Intrinsic Objections to Property Rights in SCR," money payment can be consistent with ethical motivation if the payment is not excessive, not the object of bargaining, and if it is appropriately designated.

In light of this insight, we might want to try and preserve the desirable economic incentives of the fixed payment scheme while still trying to emphasize the inherent human element of donation. Following are some possible suggestions how this could be achieved:

- The payment should not be designated as "payment for valuable tissue" but rather as "recompense for trouble".
- Ideally, the payment should not be an actual transfer but rather a credit. The work of Kahneman and Twersky and others shows that there is a significant difference in the way individuals view gains versus foregone losses.[36] (Of course this may not be practicable in countries where there is little or no deductible on medical insurance, whether private or public.)
- Establishing a standard price, which we pointed out above can help solve some holdout problems, could have an additional virtue: excessive payments could have the effect of stamping the donation process as a market exchange and eliminating the altruistic motive.

Conclusion

Medical research runs a constant danger of violating the rights of research subjects by viewing them as merely means to obtaining medical knowledge,

[36] See for example Kahneman, D., & Tversky, A. (1979). Prospect theory: an analysis of decision under risk. *Econometrica*, *47*, 263–291.

and this danger is augmented by the presence of a profit motive. These rights need to be safeguarded by obtaining informed consent for all procedures.

Yet physicians may be reluctant to solicit full and adequate informed consent, particularly with respect to the economic and financial aspects, either because of a desire to obtain personal benefit or out of a fear that excessive disclosure could result in frustrating and fruitless negotiations.

One solution to this problem is to impose a mandatory payment schedule for tissue donations that are used for commercial purposes. Obtaining informed consent does not cost the treatment provider anything, because even without it he would have to make a payment and even with it the patient is not given excessive leverage.

However, it is desirable that this payment not be perceived as defining the donation as a commercial transaction. Such a perception could have the effect of neutralizing the altruistic motivation for tissue donation. The desire to help others is a powerful and inspiring motivator, which is not necessarily effective than the profit motive.

Of course there may still be valid reasons to require some kind of payment, to increase motivation and to maintain equity. Even so, it is desirable that the altruistic dimension of the donation be maintained. Any payment should be reasonable in extent and carefully denoted. Another desideratum would be to provide it as a credit and not as a cash payment, or to pay it to a charitable fund and not to the donor.

Intrinsic Objections to Property Rights in SCR

Introduction

There are two distinct dimensions to the ethical impediments that apply to granting property rights in living organisms: utilitarian and intrinsic. Granting patents may lead to undesirable consequences, or it may be ethically objectionable in and of itself.

In the previous sections we discussed the utilitarian considerations, which stem from the fact that granting property rights creates a particular set of behavioral incentives. We have to consider if these incentives are motivating people to act in an ethical way, which benefits society.

However, this debate also has an intrinsic dimension: perhaps it is inherently unethical, even absurd, to speak of granting IPR in living organisms. The very name "creatures" suggests that these beings are the products of the Creator; there is an obvious element of hubris in calling ourselves their "inventors." Furthermore, we are used to relating to living creatures, our figurative cousins, with a certain degree of empathy; the question arises if the

reductionist attitude encouraged by a one-dimensional property relation may not constitute a tragic impoverishment of our spiritual world and our relationship with our environment.

This intrinsic impediment is obviously augmented when the living organism under discussion is man himself. Our most prominent value systems place man at the center of our ethical world. The Biblical perspective views man as created not only by, but actually in the very image of the Almighty. The profoundly influential perspective of Kantian ethics views man alone as worthy of intrinsic ethical consideration, due to our unique level of rationality.[37] Arrogating to ourselves ownership of an aspect of mankind involves a far more serious aspect of hubris than appropriation of another aspect of creation. Likewise, the reduction of man to a mere object of trade is obviously more serious than the parallel reduction as regards animals or inanimate goods.

The Commodification Controversy

One term, which repeatedly arises in the debate over IPR in bioethics, is "commodification." The concern is that a cognitive relationship between man and some object that was formerly deep and nuanced becomes reduced to a merely utilitarian relationship which is shallow and barren.

Commodification is one way of relating to someone as a means rather than as an independent end. In particular, a commodity is viewed as a means to making profit.

The commodification of human beings would constitute an obvious violation of Kant's "practical imperative," his second formulation of the categorical imperative, which forbids treating other rational beings as mere means to an end.[38] From a Kantian point of view, it is not necessary that any degrading use be made of an individual for an ethical violation to take place; the problem is the point of view of the user. For example, if an adoption broker views the infant as a commodity only, then the relationship to the child has a dimension of exploitation even if both the natural and adoptive parents are concerned primarily with the child's well-being. Kant himself stated that sale of human organs for purely commercial purposes violates the categorical imperative.[39]

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[37] Schneewind, J. B. (Ed.) (1997). Lectures on ethics. In H. Peter, & J. B. Schneewind (Eds.), *The Cambridge Edition of the Works of Immanuel Kant* (No. 27, 460 pp.). New York: Cambridge University Press.

[38] Kant, I. (1952). Fundamental principles of the metaphysic of morals. In Mortimer, J. A. (Ed.), & Hutchins R. M. (editor in chief), *Great Books of the Western World* (p. 271). Chicago, IL: Encyclopedia Brittanica Inc.

[39] "Man cannot dispose over himself, because he is not a thing. Hence a man cannot dispose over himself; he is not entitled to sell a tooth, or any of his members". Cited in (29) (No. 27, 460).

Philosophers since Kant have identified ethical problems with commodification of non-human property as well. Carlyle and Marx retained Kant's humanistic focus but pointed out that excessive commodification of objects can impoverish the human element otherwise present in exchange;[40] while Heschel goes farther and states that our relationship to our entire environment should be one of appreciation, and not merely manipulation.[41]

In the case of stem cells, the danger of commodification presents itself on all of these levels. Instrumental use is made of the nascent human being, of human tissue, and of human research subjects; the specifically human element of the patient–practitioner relationship is de-emphasized in favor of the commercial element; and natural phenomena are declared human property in an avowed attempt to facilitate their manipulation.

Of course the presence of danger often dictates merely caution, rather than avoidance. The specter of commodification does not necessarily invalidate the use of IP in SCR; it may merely obligate us to seek ways to minimize the hazards.

In order to study the problem of commodification in patenting, it will be necessary to examine this topic in greater detail.

The Roots of the Commodification Debate

Commercial relationships have been viewed suspiciously throughout history. Commerce relates to objects solely on the basis of their value in trade, and this method of valuation may lead to a diminished appreciation of other, more profound measures of value, whether inherent or utilitarian.

The concern for the social impoverishment incumbent on commodification became particularly acute in the early 19th century, as commerce became the dominant mode of human interaction in an increasing number of areas. This concern came from varying places on the political spectrum.

It is in this period that we find the conservative thinker Thomas Carlyle bewailed that the dominance of a system of market valuation overturned traditional relationships of duty, in a period when "cash payment had not then grown to be the universal sole nexus of man to man."[42]

During the same era, Carlyle's radical contemporary Karl Marx was expounding his theory of alienation and reification, in which relating to

[40] In his essay "Chartism," Carlyle repeatedly bemoans the fact that the market culture reduces all human relationships to the "cash nexus." Marx in Section 4 of Volume I of Capital outlines his theory of the "fetishism of commodities," whereby market valuation of production alienates us from the production and the producers alike.

[41] Heschel, A. Y. (1965). *Who Is Man.* Stanford: Stanford University Press.

[42] Carlyle, T. Chartism.

economic goods as commodities regrettably obscures the relationships between the worker on the one hand and the employer, the customer, and the product of labor itself on the other.[43]

We see that the "commodification" of commodities themselves involves two main problems: one is the impoverishment of the relationship between man and object, and the other is the impoverishment of the relationship between man and man. In the ideal situation, I both appreciate the unique character of a particular object as well as its relationship to the individual who created it; when it is reduced to a commodity I relate to its monetary value and form no lasting bond with the producer.

As we apply these concepts to the commercialization of products of the human organism, the two dimensions become conflated: ownership of a particular human organ or human gene may inculcate a reductionist view of humanity in which a human being is little more than the sum of his or her marketable anatomic parts, causing us to lose sight of the unique, transcendental human value of the person created in the Divine image.

Is Commodification Truly the Ogre We Fear?

While the obligation to relate to others as independent ends is an ethical axiom, the assertion that commercial society violates this remains a conjecture. We have to ask exactly what aspects of this commerce are objectionable, and under what circumstances they may be appropriate.

What we seek is some concrete evidence that relating to something as a commodity indeed tends to degrade or cheapen our awe and respect for it. Certainly we cannot blame the spread of the market system for all human ills! There can be no doubt that despite Carlyle's nostalgia and Marx's triumphalism, decadence and exploitation both predate the market's rise and survived its demise.[44]

One could easily claim that the exact opposite holds: that it is precisely the commodification of a man's biological endowment, which enables us to esteem his spiritual essence in the purest fashion! In this scenario, the true villain is the holistic, pre-capitalistic mode of apprehension, which fails to separate a person's utilitarian, economic worth from his inherent spiritual worth. When the artisan was selling his labor, his trade was his identity and the aristocrat was his master 24 hours a day. But the proletarian selling his

[43] Marx, K. Capital, Vol. I, Section 4.

[44] That is, in those countries which adopted non-market alternatives to capitalism.

labor power becomes the equal of the plutocrat the moment he punches out of work at the end of the day.

The analog to SCR might state that permitting property rights in human cells is a positive way of emphasizing that human worth is not a function of our mere biological constituents but rather of substantive participation in human consciousness and human society.[45]

If we were to examine this hypothesis, however, we would find ample evidence that commercial connections do indeed have a tendency to crowd out other types of interaction and esteem.

One demonstration that commodification can be demeaning is linguistic. Our vocabulary is replete with pejorative terms whose demeaning connotation stems solely from the commodification of some normally esteemed value. A soldier is the symbol of honor, a mercenary the symbol of contempt. And even a libertine who might admire a "ladies' man" disdains the "gigolo."

We can also find concrete behavioral evidence that commodification is considered degrading. We mentioned previously evidence brought by Richard Titmuss that at least some individuals are more willing to donate blood than are willing to sell it for small amounts. When people donate blood they feel they are serving an exalted human purpose, yet the identical act, which indeed serves the identical purpose, is debased in their eyes when it bears a salient commercial character.

Even so, we should acknowledge the theoretical distinction between commodification and degradation. And we can also point to those instances where commodification can constitute an elevation in status for a relationship that would otherwise be even more debased. A hired worker who sells his labor enjoys more status than a chattel slave who is bought for money but forced to work without recompense, and even this latter can look down on a prisoner in a press gang.

This theoretical distinction should persuade us that the focus of our ethical attention should not be toward the extent of commodification per se, but rather the extent to which some kind of market relationship demeans or effaces some more exalted non-market relationship which would otherwise be present. One precedent for this kind of approach is the work of Margaret Jane Radin. Radin does not speak of a sharp demarcation between commodification and other kinds of valuation, but rather of "indicia of commodification." Furthermore, she points out that "Literal commodification and

[45] We find a fascinating parallel to this conundrum in the debate over the humanistic significance of the theory of evolution. It has often been averred that the belief that man is descended from the apes degrades man's unique spiritual status; yet the opposite claim has also been heard: it is precisely the theory of evolution which emphasizes man's ascent over his descent.

commodification in conceptualization need not be coextensive in practice, but they are loosely interdependent."[46]

Indeed, we can find an expression of this idea in Kant. In his Lectures on Ethics, Kant discusses the ethical prohibition on treating the human body as an object of commerce; in particularly he is objection to prostitution. Kant asserted: "Man cannot dispose over himself, because he is not a thing. He is not his own property – that would be a contradiction." Therefore, Kant reasons, "a man cannot dispose over himself; he is not entitled to sell a tooth, or any of his members."

Kant's lecture continues: "But now if a person allows himself to be used, for profit, as an object to satisfy the sexual impulse of another, if he makes himself the object of another's desire, then he is disposing over himself, as if over a thing, and thereby makes himself into a thing by which the other satisfies his appetite, just as his hunger is satisfied on a roast of pork. Now since the other's impulse is directed to sex and not to humanity, it is obvious that the person is in part surrendering his humanity, and is thereby at risk in regard to the ends of morality."[47]

Note that while in the first paragraph Kant opines that selling of organs is unethical, in the following paragraph he is focusing not on the money exchange per se but rather at the fact that the person is being used merely to satisfy the appetite of the other person. This seems to allow for the possibility of some kind of money exchange as long as the essence of the exchange is not purely exploitative.

Compensation and Transformation of Commodification

After we evaluate the potentially damaging ethical impact of commodification, we need some way of weighing this damage against the economic benefit which market relations can provide, which involve their own ethical value in reducing human suffering. After all, we have pointed out that even ordinary commercial relations involve some degree of instrumentalization in human relations, yet we consider that the ethical benefits of free markets in advancing human freedom and providing for basic wants outweigh this blemish.

Ethically questionable exchange relationships can be validated in two distinct ways: compensation or transformation. In other words, the benefits from allowing such exchange may outweigh the conceded detrimental effect of

[46] Radin M. J. (1996). *Contested Commodities: The Trouble with Trade in Sex, Children, Body Parts and Other Things* (p. 118). Cambridge, MA: Harvard University Press.

[47] Heath, P., & Schneewind, J. B. (Eds.) (1997). *Lectures on Ethics* in *The Cambridge Edition of the Works of Immanuel Kant* (No. 27, 386 pp.). New York: Cambridge University Press.

commodification, or these benefits may actually vitiate these detrimental elements through a transformation of the nature of the ethical act.

An example of validation through compensation would be commercial sponsorship of cultural activities. Dependence on commercial advertising can adversely affect both the content and the context of popular entertainment, yet this tradeoff has been considered worthwhile because of the immense resources commercial enterprises are willing to devote to popular culture in return for the ability to advertise, and because of the concrete benefits to sellers and consumers from the advertising itself.

An example of validation through transformation is military service. The unique social constraints on hostile acts by soldiers generally guarantee that they are viewed gratefully as servants of their country, not regretfully as unavoidable "hired killers."

Since avoiding a problem is better than overcoming it, we should strive to create a property regime in medical research in which the ethical benefits transform and elevate the commercial aspects to the greatest possible extent. This requires a careful examination of what properties successfully effect such a transformation.

While exchange relations can be transformed so as to co-exist with an essentially ethical act, this transformation requires certain restrictions on the scope of the market relationship. Indeed, the very fact that the public imposes restrictions because of its values automatically signals a non-market kind of valuation and diminishes the extent of commodification. Radin writes, "[L]aissez-faire markets represent complete commodification, and regulated markets represent incomplete commodification. Regulated markets represents incomplete commodification in a stronger sense in situations where they reflect internally plural meaning."[48]

In general, we discover that such transformation is facilitated when market relations are restricted in duration and scope.

Taking the example of military service, servicemen and women are required to make a long-term commitment unlike any found in civilian life; even the most dangerous tasks are not paid commensurately with what civilians are paid to assume such hazards; their hostile actions are subject to strict discipline and to the most rigorous limitations in order to maintain purity of arms.

We can find a precedent for these principles in the Hebrew Bible, which limits commodification by placing careful economic restrictions on certain kinds of trade. In the 25th chapter of Leviticus, we learn that neither land nor men should be viewed as mere commodities. Land, because "the land is Mine; for your are strangers and settlers with Me" (Lev. 25:23); men, because "they are My servants" (Lev. 25:55). Yet trade in land and labor is not forbidden outright,

[48] Radin (1996, p. 116).

rather it is limited in scope and duration. Land ownership is restricted through the Jubilee release and the Sabbatical year; slave ownership is limited through limiting servitude to 6 years and by forbidding demeaning service.

Extrapolating to the instance of medical research, the ethical difficulties in granting property rights in materials, techniques or devices could be partially overcome by practical and symbolic limitations on these property rights. Here is a list of limitations that could maintain the essential ethical character of the research while sustaining a place for market incentives to advance it:

1. Limitations on the duration of patent protection are already a feature of these rights. Patents provide protection for a period of 20 years.
2. Certain restrictions on the kinds of inventions also exist already, including the restrictions on subject matter and the requirement for novel, non-obvious, and useful inventions. Likewise, patent law already makes the crucial stipulation that patent protection is granted only when complete details of the invention are disclosed. Process patents are clearly less commodifying than product patents and so the ruling of the Canadian Supreme Court allowing only process patents on higher life forms has the salutary effect of vitiating commodification.[49]
3. Current patent law does not restrict limited, non-commercial research use of a patented technique; this loophole could be expanded to some kind of "fair use" criterion. Already many laboratories are willing to provide availability of proprietary materials to researchers as long as a material transfer agreement is signed.
4. Conducting medical research can be defined as a per se ethical act only if the principle objective of the research is for vital therapeutic goals. Regulations limiting the possible uses of patents could have the effect of guaranteeing that this objective remains foremost.
5. Since the objective of research is public benefit from any therapies or diagnostics developed, the ethical dimension of the research could be augmented by a provision for compulsory licensing of the invention when appropriate. Many countries already have such provisions; in other countries some degree of public research subsidy could be viewed as a kind of "quid pro quo" for the power to compel availability when necessary.

Note that not all of these goals need to be achieved by the patent law itself. For example, if the use of embryonic stem cells were limited by regulation to vital medical purposes, this would have the effect of transforming the character of IPR in these cells even if the patent per se was not limited to such uses.

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[49] The dissenting opinion in the judgment acknowledged this fact, but implied that commodification is objectionable only with respect to human beings, and that the current wording of the patent act is sufficient to avoid giving property rights in human beings. See footnote 2, Section E of the dissent.

Importance of Public Debate

Appropriate regulation and legislation can make a critical contribution to creating a humane IP system with regard to stem cells and other human tissues. Although we do not envision in this chapter altering the fundamental rules relating to patenting these materials, the overall regulatory environment has a profound impact on the public perception of IP rights in this area. We can identify a number of distinct loci of this impact:

1. IP may have the effect of encouraging research, which is ethically problematic from the point of view of bioethics or medical ethics. For example, it may encourage unwarranted use of embryos or encourage a lack of adequate informed consent. This implies the necessity of implementing specific regulations, which will effectively prevent unethical procedures.
2. As Margaret Radin points out, the very fact that the public authority intervenes to limit the uses of a particular good makes a statement that this good is subject to public interests and is not purely a commodity. We added that the particular character of the limitations, such as limitations in duration, scope, and subject matter, can portray an image of a technology and an industry devoted primarily to human well-being, and this image may help counter any reductionist impression given by the marketplace activity.
3. Continuing in this vein, even if ultimately no legislation or regulation is adopted, there is critical importance in creating public debate on these topics. The very fact that IPR in human biology are candidates for regulation or legislation creates a healthy opportunity for public discussion and values clarification. This creates a clear mandate for policy involvement in order to shape not only any regulation, but also in order to take maximum advantage of any public attention given to these vital ethical issues.

Conclusion

Patent policy is a fairly arcane area of legal research, yet it has surprising importance in the ethical debate over SCR. Since only patents enable private investments in this technology to be profitable, patent policy is critical in shaping the nature of this research.

Because scientists acknowledge that SCR has great potential to relieve human suffering, the role of patents in encouraging productive research has a prominent ethical dimension. In addition to a scientific analysis we need an ethical analysis as well as an economic one to see if this research fulfills our expectations.

Beyond the specific details of patent protection, the very fact of patent protection makes an important and authoritative public statement about the public standing of this research. It tends to place such research squarely in the sector of

market activity. After all, patents are not granted for new methods of relieving poverty or, for that matter, for novel approaches to problems in bioethics.

Standard economic analysis can greatly help in studying the effectiveness of patent policy, but even in this area we need to take account of the important ethical motivations that act within the research framework. Research subjects need to be reminded that their participation is not only a means to increased economic profit, but also to improve human well-being.

Our conclusions in this area are that current patent law is well equipped to encourage productive research, as long as the law is carefully applied and patents are given only to truly patentable inventions whose extent is clearly defined.

Market forces can encourage not only productive activities, but also destructive ones, such as the trampling of patients' rights. Carefully designed regulations can do much to align economic incentives with ethical ones, helping ensure that informed consent is obtained from all research subjects including donors. It would be helpful if these regulations were framed in a way, which continues to give expression to the altruistic dimension of such participation.

Patents on human stem cells do tend to depict them as mere objects of commerce, but this tendency can be partially counteracted by careful attention to the details of protection. Regulatory limitations on the extent and subject matter of patents, as well as on the use of the resulting technologies, can help prevent unethical practices, and also makes an important statement about the continuing public interest in this field – a statement which gainsays the view that human tissues are commodities only and which invites public debate and interest in this topic. Such regulation can encourage a more holistic view of the value of this research without vitiating the role of private investment in moving research forward.

An ethical patent regime should encourage research which fulfills the promise of relieving suffering, discourage irresponsible treatment of research subjects, and also make a positive and humane statement about the place of medical research in our society.

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11

Pharmaceutical Mergers and Genetic Technology: A Problematic Combination

Michael Potts

Recent mergers in the pharmaceutical industry have resulted in the creation of mega-corporations that control an increasing percentage of the pharmaceutical market, especially particular classes of drugs. In recent years, due to the biotechnological revolution in the field of genetics, large pharmaceuticals have gained access to a number of genetic patents and products through licensing agreements with biotech firms. With the mapping of the human genome opening the possibility of discovering more targets for drugs to attack disease, some pharmaceutical firms have begun to buy smaller biotechnology companies, including those involved in genetic research. The biotechnology industry itself has become more concentrated, with smaller firms merging into large firms and biotech companies expanding into pharmaceutical development. Since both traditional pharmaceuticals and biotechnology firms have patented or applied for patents on a number of genes and gene sequences, this raises the possibility of a small number of companies holding a monopoly over particular genes, gene sequences, and/or genetic technology, and over the drugs developed through research on such technology.

This chapter will focus on the difficulties created by the combination of pharmaceutical mergers and the rise of genetic technology and the genomics revolution. After a discussion of the background of recent pharmaceutical mergers and the current interest of these companies in expanding into the genetics realm, I will argue that two major sets of problems arise from this combination. My focus will be limited to research on the human genetic code that leads to the development of new drugs. First, a significant amount of genetic information, particularly involving intellectual property rights, could be held by a relatively small group of mega-corporations created through mergers. In this context I will discuss the possibility that patents on DNA products, including genes and gene sequences, could become concentrated in the hands of a few large pharmaceutical companies.

The second set of problems clusters around physicians becoming dependent on one or on a few companies for certain classes of drugs that are derived from genetic research (e.g., cardiovascular drugs or drugs to treat acid reflux). This not only limits physician choice, but also drives up the price of drugs, because it is easier for companies holding a monopoly to set the price of their choice without competition to drive costs down.

Finally, I will discuss four ways to avoid the problem of over-concentration in the market for products developed on the basis of genetics research: (1) aggressive enforcement of existing antitrust laws, (2) revising patent law to close loopholes which allow companies to patent gene products from the same gene almost indefinitely, (3) continuing to emphasize the free availability of genetic information, following the example of the public databases from the Human Genome Project (HGP), and (4) resistance by pharmaceutical firms of the current trend toward mega-mergers.

The Background

The last 15 years have witnessed a spate of pharmaceutical mergers, which have led to greater concentration in the industry. Some of the most important mergers are summarized in Table 11.1.

Pharmaceutical mergers are fueled by the advantages of increased size, summarized by Jung (2005, p. 3).

Increased size enables pharmaceutical companies to:

- fill pipeline gaps,
- expand or deepen therapeutic areas,
- spread risk by placing bets on more projects and technologies,
- achieve cost savings by eliminating duplicate resources,
- become a more attractive research partner,
- negotiate better deals with suppliers.

Another factor that has encouraged pharmaceutical firms to merge is managed care. Since payments for drugs are determined by agencies attempting to cut health care costs, the incentive is for pharmaceutical firms to operate with less expense. Mergers help to eliminate duplicate resources. A larger company also has a superior bargaining position for negotiating better deals with suppliers.

But probably the most important factor fueling the drive for pharmaceutical mergers is the increased cost of research and development (R&D). In the United States, the "pharmaceutical industry invests 16% of its revenues into R&D" (Schwetizer, 1997, p. 21). In 1990, it took "10 years from the time a scientist

Table 11.1 Important Pharmaceutical Mergers

Date	Pharmaceutical 1	Pharmaceutical 2	Transaction value (billion)
2005	Novartis	Struengmann	$8.4
2004	Sanofi-Synt	Aventis	$65.5
2003	Pfizer	Pharmacia	$60.7
2002	Amgen	Immunex	$16.7
2000	Pfizer	Warner-Lambert	$88.8
2000	Glaxo Wellcome PLC	SmithKline Beecham	$172
2000	Pharmacia and Upjohn	Monsanto	$52
1999	Hoechst AG	Rhone-Poulenc Rorer (new company called Aventis)	$21.9
1997	Hoffmann-La Roche	Boehringer Mannheim	$11
1996	Ciba-Geigy (Novartis)	Sandoz	$63
1995	Glaxo	Burroughs Wellcome	$14.1
1995	Pharmacia	Upjohn	$13
1995	Hoescht-Roussel	Marion Merrell Dow	$7
1995	Rhone-Poulenc Forer	Fisons	$2.9
1994	American Home Products	American Cyanamid	$9.7
1994	Hoffmann-La Roche	Syntex	$5.3

Compiled from Levy (1999), BBC News (2000), Global Policy Forum (2000), Crooks et al. (2000), Bureau of Competition (2005), DrugResearcher.com (2005), drugintel.com (2005), usdoj.gov (2005), Wikipedia (2005).

first has a research idea until a product is marketed, at a cost of $259 million." In addition, "only one in 60,000 compounds synthesized by pharmaceutical laboratories could be regarded as "highly successful" (Schwetizer, 1997, p. 21). A 2003 report estimated that the average cost to successfully launch a new drug has risen to $1.7 billion (Gilbert et al., 2003).

Another factor that increases the cost of putting a new drug on the market in the United States is the FDA approval process. Although necessary to protect the public from drugs which have harmful side effects or lack efficacy, the process takes a great deal of time, an average of 9 years (Levy, 1999, p. 8). The approval process not only adds expenses related to setting up clinical trials, but also eats up time during which the drug could be on the market making a profit for the company. It also lessens the time a product on the market is under patent protection. In the United States, "Patents are good for 20 years from filing date" (doegenomics.org, 2005). Some biotech firms file for provisional patents, which allows the individual or company "up to 1 year to file their actual patent claim" (doegenomics.org, 2005). This increases the effective

length of the patent by 1 year while further research is done on the product. Subtracting the time for the FDA approval process to be completed, the effective patent life of a drug once it is on the market is about 10–12 years. For "blockbuster drugs" which make over $1 billion in sales annually (Gassmann et al., 2004, p. 5), losing that many years of patent protection potentially costs a company billions of dollars a year in lost sales and millions in profits. When patent protection runs out for blockbuster drugs and generic companies step in, this is also costly, because generics are significantly cheaper than name-brand drugs. Although the company initially manufacturing the drug retains its brand name and some customers will remain loyal to the brand, most customers will purchase the lower priced product, and managed care companies will prefer to pay for the lower priced product.

These factors, along with "dwindling pipelines of promising new products" (Slud, 2000), have resulted in fewer blockbuster drugs which help fuel huge R&D and marketing budgets, as well as increasing profit margins. The desire for profitable new products fuels the focus on innovation that is behind "this frenzy of mergers perhaps more than any other factor" (Marcotullio, 2001, p. 455).

The need to innovate not only encourages mergers, but also the expansion of traditional pharmaceutical firms into the biotech industry. Many traditional pharmaceutical firms have roots in the chemical industry. Before the biotechnological revolution of the latter 20th century, most pharmaceutical R&D was based on organic chemistry. Traditional pharmaceutical firms were thus ill equipped to face rapid advances in biochemistry and genetics with the attendant explosion in genetic information and technology (Bogner & Thomas, 1996, pp. 108–109). In response, from the 1980s on, they piped into biotechnology through product licensing agreements and strategic alliances. Small biotech firms are happy to form such alliances, since many lack the "minimum effective size" to sustain "their research programs" even when they have an "established product" (Bogner & Thomas, 1996, p. 19). In 2000, only "24 of the 3,000 biotechnological companies worldwide were profitable" (Gassmann et al., 2004, p. 53). Some biotech firms themselves are becoming larger through mergers and have developed their own extensive R&D and marketing programs; they are, in effect, large pharmaceutical firms with a biotech foundation.

The most significant developments in biotechnology involve genetics. Genetic technology, including gene splicing and other techniques of genetic engineering, was well established in the 1980s, and has been used in agriculture, resulting in controversy over the use of genetically engineered crops. But it is the potential of genetic research to revolutionize human medicine that has peaked the interest of both traditional pharmaceutical and biotech firms. The HGP, designed to map the genes making up the sum total of the genetic instructions for a human cell (Biotechnology Industry Organization, 2005),

was completed in 2000 (although detail work will continue indefinitely). "Genomics describes the process of identifying genes involved in diseases through the comparison of individuals with and without disease" (Gassmann et al., 2004, p. 63). Mapping the genome has resulted in the discovery of genes linked to particular diseases (e.g., the $BRCA_1$ and $BRCA_2$ genes are linked to a tendency for breast cancer). Because genes make the proteins that govern cells, disease is now being explored at the molecular level to target specific diseases at that level. In "pharmacogenomics," researchers match patients to drugs based on the patient's genetic profile and use such information to develop new drugs (Spice, 2000). What makes the HGP so attractive for pharmaceutical firms is that while only about "500 biological targets for drugs have been identified so far, it is estimated that the HGP will produce another 3,000 to 10,000 new targets" (Gassmann et al., 2004, p. 57). In the pharmaceutical industry, genomics came into its own "in 1993 when Human Genome Sciences formed its partnership with SmithKline Beecham. . . . No major pharmaceutical company is now without genomics capabilities, whether in-house or accessed through licensing agreements" (Gassmann et al., 2004, pp. 64–65).

For big pharma to exploit the HGP in R&D, it must gain access to information, technology, and patents. To be eligible for patenting, DNA products, like all products for which patents are sought, must meet the criteria of practical usefulness, novelty, and nonobviousness, as well as being describable so that someone "skilled in the field" could "use it for the stated purpose" (doegenomics.org, 2005). In the United States, "DNA products usually become patentable when they have been isolated, purified, or modified to produce a unique form not found in nature" (doegenomics.org, 2005). Patents have been issued for genes, gene fragments, single-nucleotide polymorphisms (SNPs, which alter the sequence of amino acids in DNA and which may be associated with particular diseases), gene tests, proteins, and animal stem cells (doegenomics.org, 2005). At the end of 1999, the major holders of gene patents were as shown in Table 11.2 (from Feldbaum, 2001).

Although in the recent past major pharmaceutical firms have relied on strategic alliances and licensing to gain access to genetic technology, they are increasingly turning to mergers. James Pierce notes that the mergers of "Glaxo Wellcome with SmithKline Beecham, Pfizer with Warner-Lambert, Pharmacia and Upjohn with Monsanto – were driven in large part by their hope of cashing in on pharmacogenomics" (quoted in Spice, 2000). While strategic alliances and licensing agreements will continue, "such licensing is becoming increasingly expensive" (Whalen, 2005, p. C4). According to Anne Marieke, "it is starting to make more sense to buy small biotech companies outright and gain extensive access to their technology" (quoted in Whalen, 2005, p. C4). Another possibility is a large pharma merging with a large biotech firm, modeled on the merger of Rosche and Genentech. Although smaller biotech firms exist and

Table 11.2 Major Holders of Gene Patents

Organization	Number of gene-based patents
U.S. Government	388
Incyte Pharmaceuticals	356
University of California	265
SmithKline Beecham	197
Genentech	175
Eli Lilly	145
Novo Nordisk	142
Chiron	129
American Home Products	117
Isis Pharmaceuticals	108
Massachusetts General Hospital	108
Human Genome Sciences	104
University of Texas	103
Institut Pasteur	101

more are founded every year, and these mitigate market concentration, they usually do not survive as independent firms, since the minimum effective size ("the size necessary to maintain a strong presence over time as early patents expire or as competitive substitutes enter the market" (Bogner & Thomas, 1996, p. 18)) is much larger than entry-level size. The current trend toward mergers between biotechs and between traditional pharmas and biotechs of all sizes will most likely continue.

Problems and Limitations

The problems arising from pharmaceutical mergers and genetic technology result from a combination of: (1) rapidly increasing concentration in the pharmaceutical industry resulting from the merger of mega-corporations, many of which are products of previous mergers; (2) increasing expansion of traditional pharmaceuticals into genetics due to alliances and mergers with biotech firms; and (3) increasing concentration of genetic technology and gene patents into fewer firms.

One may question whether there really is a problem. In order to survive and remain competitive, large pharmaceutical firms must expand into biotechnology, especially into genetics research and genomics. If larger firms have the resources to develop, manufacture, and market helpful drugs more effectively than smaller firms, this will benefit society. Greater financial resources, better equipment, lowered transportation and administrative costs, and the

unification of genomic sequencing, bioinformatics, and pharmaceutical development under the same umbrella could create an ideal environment for developing effective drugs based on genetics research. Genetic information is exploding at an exponential rate, and it may take the resources of a few huge corporations, as well as the federal government and universities, to successfully exploit genetics in medicine, in agriculture, and in other fields. Since pharmacogenomic drugs tend to focus on small populations, only large firms may be able to afford the higher R&D budgets required when there will likely be a smaller profit margin per product.

Granted that large company size is necessary for a company to adequately exploit the revolution in genetics, over-concentration in the market is morally problematic for two major reasons: (1) monopoly power over genetic technology and intellectual property and (2) limiting the choices of physicians and patients, leading to higher health care costs.

The Problem of Monopoly Over Genetic Resources

If a relatively small number of mega-pharmaceuticals created by mergers gain too much control over genetic resources, this can result in a monopoly. If this occurs, the ability of a few companies to control the use of genetic information will be enhanced. The problem is not with the privacy of genetic information, since such information used in pharmaceutical research will not typically be from identifiable individuals; nor does the moral problem concern access to data from the HGP, which is freely available to all. The difficulty does not involve access to raw information, but control over the exploitation of such information. This is seen most clearly when considering patents on genes and gene products. As major pharmaceutical firms continue to merge and buy up small (and some large) biotech firms, the number of gene patents will become more and more concentrated in the hands of a few mega-pharmaceutical companies. These companies will have increased bargaining power with the federal government and with universities to buy licensing rights to government and university patents. As these companies attain the technology for synthesizing genes, gene fragments, and SNPs, they will be able to patent more DNA products over time. Although intellectual property rights are essential for effective R&D, too much concentration of control over genetic products implies the power to use or refrain from using those products in R&D, licensing rights to their use, and making profits on products based on genetic research. With less competition between firms, royalty fees on patented gene products could become exorbitant. Drugs developed from such research would then become more expensive, and fewer people who need them would have access to them, either because they would be unable to afford them due to lack of insurance

or inadequate insurance, and because managed care firms, which focus on cost-control, are less likely to pay for them. The new federal drug prescription program could be put under more financial strain as well.

One might reply that patents on an invention are only good for 20 years. With the R&D and regulatory process eating up patent protection time, "the effective period of patent protection is rarely more than 8 years in the pharmaceutical industry" (Gassmann et al., 2004, p. 128). However, patent rights can be extended for a considerable time. Laura Glasgow argues that pharmaceutical companies have pushed "intellectual property rights . . . to their limits in an attempt to maximize profits on popular name brand drugs" (Glasgow, 2001, p. 227). Once a product goes off patent, generic manufacturers can produce the same product for a much lower price, cutting deeply into profits, especially when "blockbuster drugs" go off patent. Glasgow states that pharmaceutical firms have tried to hold onto valuable patents beyond the 20-year limit with the following tactics:

> (1) using legislative provisions and loopholes to apply for a patent extension; (2) suing generic manufacturers for patent infringement; (3) merging with direct competitors as patent rights expire in effort to continue the monopoly; (4) recombining drugs in slightly different ways to secure new patents and layering several patents on different aspects of the drug to secure perennial property rights; and (5) using advertising and brand name development to increase the barrier to entry for generic drug manufacturers (Glasgow, 2001, pp. 227–228).

If pharmaceutical firms have engaged in such practices to extend patents on popular drugs, it is a small jump for them to apply similar tactics to extend patents on DNA products such as genes and gene fragments. The fourth tactic Glasgow mentions, recombining drugs, is significant for gene patents. A company could synthesize several strands of the same gene (or develop a new method of synthesizing the same gene), effectively extending intellectual property rights over the gene. What makes this process easier is the difficulty of defining a gene in contemporary biology. As Evelyn Fox Keller puts it, "today, the gene can no longer be said to be an identifiable sequence of DNA, a mappable locus on the chromosome, a clear-cut functional unit, or even a stable entity transmitted through time" (Keller, 2000, p. 274). With such doubt about defining a gene, a company could try to justify any number of patents on variations of the same "gene." More confusion arises if two companies patent different sequences of the same gene (especially if another company has already synthesized and patented the whole gene). Not only it is difficult to delineate intellectual property rights, such confusion can also increase the costs of licensing fees if a company has to pay several other companies for rights to use the same gene. And if a company develops new methods to synthesize the same gene, gene fragment, or SNP, these methods can also be patented.

Limitation of Choice

Finally, an overly concentrated market in gene-based pharmaceuticals limits a physician's choice of drugs to prescribe to patients. In part, this is a version of an existing problem in the pharmaceutical industry: even when the market as a whole was less concentrated than today, there often *was* concentration within therapeutic classes of drugs. Since there is no substitutability between different classes of drugs (e.g., antibiotics are one class, cardiological drugs another) (Bogner & Thomas, 1996, p. 24), it is easy for a small number of companies to dominate one class of drugs. These monopolies are sometimes mitigated by other companies developing "me-too drugs," drugs similar in chemical structure and efficacy to the original drug. For example, there are several versions on the market of the cholesterol-lowering statin drugs made by different companies. But this may not be as viable an option for gene-based drugs given the increasing number of pharmaceutical mergers and buyouts of biotech firms as well as control of a biotech firm's products through licensing and alliances. If mega-pharmaceuticals patent a large number of sequences on the same gene (and they could do this even on genes patented by the U.S. government and universities), they would effectively control R&D based on those products. For example, suppose a pharmaceutical company gained control of patents on several genes and gene sequences correlated with hypercholesterolemia (extremely high cholesterol). On the basis of R&D on these gene sequences, the company develops and markets an effective drug to treat gene-linked hypercholesterolemia. The company not only owns the patent on the drug itself but also on the gene sequences, the basis on which the drug was developed. As a result, the company dominates the market on the product and can charge what it wishes as well as control supply. "Me-too drugs" would not be possible unless the company controlling the gene patents licenses the right to use the relevant gene or gene sequences in research – and even then, there would be no incentive for the company to control licensing fees.

Although more products does not necessarily translate into better products, if different companies do research on the cardiovascular system, for example, competition encourages more R&D, and more R&D is good for the development of better products. In addition, competition drives down costs. Without adequate competition among pharmaceutical firms, physicians are more limited in their options for prescribing to patients. Rising costs also put financial pressure on the patient and on managed care organizations, including both private firms and Medicare and Medicaid.

Practical Steps

There are practical steps that can be taken to prevent over-concentration in the market for products derived from genetic research. First, the Federal

Trade Commission should aggressively enforce existing antitrust laws. In the past, the Commission has been hesitant to stop a merger outright. But recent mergers of mega-pharmaceutical companies which themselves were created from earlier mergers of large firms can lead to over-concentration in the pharmaceutical market as a whole. Before the most recent spate of pharmaceutical mergers, in 1998, "the 100 U.S. companies with the greatest dollar volume of sales made up approximately 96 percent of the U.S. market" (Crooks et al., 2000, p. 3). Turning to the world market, the "top twenty-five companies in the world account for 44 percent of the world market. Fourteen of these companies are based in the United States" (Agrawal, 1999, p. 36). This data is also pre-2000. Since a number of large mergers have occurred since then, it is probable that the market is even more concentrated today. This can lead to the typical problems stemming from monopolies: lack of competition (especially on particular classes of drugs), higher prices, price collusion among a few large firms, and weak innovation. These are not morally neutral problems, for they can result in patients not receiving the drugs they need and can slow research which can help people with serious diseases. If the FTC determines that a major merger would lead to general over-concentration in the pharmaceutical industry, it should consider the ultimate option of denying the merger.

Short of outright denial of a merger, the FTC has other options to remedy potential monopolies resulting from mergers. Since some pharmaceutical mergers result in monopolies over particular classes of drugs, the FTC may require a company to divest itself of a product – that is, "the competing assets can be sold to a third party or spun-off into a viable competitor" (Balto & Mongoven, 1999, p. 271). Care must be taken, however, to ensure that the competitor will be able to effectively manufacture and market the spun-off or sold product. For example, when Pfizer and Pharmacia merged in 2003, the FTC required Pfizer to divest darifenacin (a treatment for overactive bladder) to Novartis AG; femhrt (a hormone replacement therapy) to Galen Holdings plc; and Pharmacia to divest its rights to sexual dysfunction drugs in development. The FTC also required other divestitures (Bureau of Competition, 2005, pp. 15–16).

Similar remedies could be applied after a merger that creates a monopoly on a product developed through genetic research. If a merger leads the resulting company to control a large percentage of the market for a drug developed from genetic research, for example a drug to treat genetic-linked hypercholesterolemia, the FTC could require the company to divest itself of the drug before the merger could take place.

Another remedy the FTC uses is to require that the company resulting from a merger license a product to another company. This is often done "when the majority of a firm's value lies in its intellectual property and the ability to innovate ... In addition, intellectual property often is embodied in patents, and the patent system has its own complex system of legal protections"

(Balto & Mongoven, 1999, p. 274). An example relating to genetics involves the 1997 merger of Ciba-Geigy and Sandoz to form Novartis.

> [The FTC] complaint alleged that the merger of CIBA-Geigy and Sandoz would result in an anticompetitive impact on the innovation of gene therapies. The firms' combined position in gene therapy research was so dominant that other firms doing research in this area needed to enter into joint ventures or contracts with either Ciba-Geigy or Sandoz in order to have any hope of commercializing their own research efforts. Without competition, the combined entity could appropriate much of the value of other firms' research, leading to a substantial decrease in such research (Bureau of Competition, 2005, p. 30).

The FTC required Novartis "to grant to all requesters a non-exclusive license to certain patented technologies essential for development and commercialization of gene therapy products" (Bureau of Competition, 2005, pp. 30–31). If the FTC were to use its enforcement option in similar cases, problems with merged pharmaceutical firms gaining monopolies over gene-based products could be mitigated.

In addition to FTC regulation, patent laws should be revised to close loopholes in patenting genetic material. The current system fails because of the ability to patent not only a gene, but also numerous sequences on the same gene. A company could take advantage of this to maintain control over R&D based on a particular gene far beyond the normal 20-year patent limit. This is in addition to the problem of multiple companies patenting different sequences on the same gene, creating confusion over proper ownership. Both problems are compounded by the difficulty of defining a "gene."

The U.S. Patent and Trademark Office should bring order to the patenting of gene products. The Nuffield Council on Bioethics has questioned whether patents should continue to be allowed on DNA sequences, given the current ease (and thus lack of inventiveness and nonobviousness) involved in isolating them (Nuffield Council on Bioethics, 2002, p. xi). If most gene sequences are determined not to be patentable, this would go a long way toward solving the problem of conflicting patents. The process of reform should also involve a dialogue with geneticists, companies making use of genetic resources, universities, and government. In addition, as an editorial in *The Lancet* suggests, there could be a "system of formal review by independent advisors, including lay people, ethicists, religious leaders, and scientists." (The Lancet, 2002, p. 349) The focus should be on delineating the scope of patent rights on the same gene when its sequences are patented, as well as closing loopholes that could allow a company to maintain patent rights on a gene almost indefinitely.

Third, the emphasis on the free flow of genetic information, exemplified by the public databases from the HGP, should continue. The pharmaceutical industry should receive credit for the "establishment of a non-profit

foundation to find and map 300,000 common SNPs (they found 1.8 million)" (doegenomics.org, 2005). "[T]en large pharmaceutical companies and the U.K. Wellcome Trust philanthropy" were involved, and "the consortium planned to patent all the SNPs found but to enforce the patents only to prevent others from patenting the same information. Information found by the consortium is freely available" (doegenomics.org, 2005). The more information is freely available, the more companies can use it in their own R&D, stimulating creativity in R&D and increasing competition.

Finally, the pharmaceutical industry should show some self-restraint on mergers, which are fueled in part by investors' expectations of double-digit returns. Such growth may not be realistic in the long-term, and exaggerated expectations only serve to fuel bigger mergers with the risk of over-concentrated control of particular markets. Pharmaceuticals should continue to cooperate with other firms through licensing agreements and alliances rather than jump on the bandwagon of mergers and buyouts. With effective regulation, control over patent rights, and voluntary cooperation between firms, the danger of over-concentration over resources in the age of genomics can be averted.

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12

Stakeholder Care Theory: The Case of Genetic Engineering and Non-human Mammals*

Jamie R. Hendry

Introduction

As scholars in the field of business ethics continue their search to identify constructive and practical ways to guide managerial decision-making, biotechnology, a dominant force in business and scientific research activities, has emerged as a new challenge to ethical theory at the nexus of business ethics, scientific ethics, and public policy. Commercial pressure to move forward quickly with products based on the technology has been met by concerns about potential long-term impacts, with much of the ethical scholarship focused on plants used in food production or the genetic engineering (GE) of humans. In order to bridge the gap between the ethics of GE in crops and that associated with humans, this chapter addresses the question of how business managers should consider non-human mammals used in GE. Further, focusing on GE can demonstrate the need a world of rapidly advancing technology has for a more holistic business ethic than those commonly discussed by scholars and practitioners.

While concerns about Frankenfoods, labeling of food products containing genetically manipulated organisms (GMOs), designer babies, and human clones has dominated much of the worldwide public debate on GE, scholarly work has covered much broader ground. Scholars have challenged patenting organisms; raised questions about the ethics of developed country scientists' confiscating potentially valuable organisms from developing countries; written about non-food plants used for clothing or cultivated for pharmaceuticals; and charged that the recent ascendancy of private sources in the funding of

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scientific research, even in public institutions, has slanted research toward commercially oriented questions. Although many scientists want to push ahead with the technology, those questioning the ethics of GE emphasize the need to slow down. The Precautionary Principle (PP) is invoked time and again, with advocates for greater patience noting that, given our level of ignorance about long-term effects, we risk a great deal by releasing GMOs or cloned organisms into the environment.

Uncertainty about the future impacts of widespread use of biotechnology is a key reason why the most predominant theories of business ethics – utilitarianism, integrative social contract theory, and stakeholder theory – do not provide adequate guidance regarding GE. Applying a utilitarian calculus requires that we have some idea of the potential outcomes of our action, their likelihood, and the value of their costs and benefits, but we do not. The failure of ISCT to address concerns about non-human animals, plants, and ecosystems except inasmuch as they affect humans separates ISCT even further from being able to adequately address concerns regarding biotechnology. And stakeholder theory comes up against perhaps its biggest challenge in biotechnology: when considering the potential ramifications of GE, "who and what really counts" reveals significant difficulties with the theory in its present form.

This chapter proposes a managerial ethic that not only can guide managers in their behavior toward non-human animals as subjects of GE, but can also guide us in determining appropriate business behavior in the broadest sense. In the course of developing this ethic, this chapter discusses some of the existing and potential dangers from proceeding to pursue biotechnology without an adequate ethic in place; draws on theories from the natural and social sciences to suggest why a more holistic ethic is needed for a biotech world; and discusses the relevance of traditional ethics to the construction of ethical theory suitable for the challenges associated with GE. Ultimately, this chapter proposes a stakeholder care theory that is not only broadly applicable, but also well suited to helping managers think about the moral ramifications of making non-human mammals the subjects of GE.

Complex Systems and GE

The biosphere is a complex system comprised of an enormous number of interconnected components and displaying a high degree of dynamism. In an open, self-organizing system of this type, meteorologist Edward Lorenz (1963) noted that the initial conditions are so important and the interactions among the components are so unpredictable that the flap of a butterfly's wings in Brazil could lead to a tornado in Texas. In the case of the biosphere, humankind's activities affect other system components and the system as a whole; while we may be able to predict the outcomes of particular human activities in the short

term with some accuracy, the complexity of the system is such that long-term predictions are highly uncertain (Lissack, 1999).

Today, one of the human technological activities affecting the biosphere and offering both the most promise and the most peril is biotechnology. According to the UN Convention on Biological Diversity, "Biotechnology is any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use." This includes such early and seemingly benign practices as the brewing of beer or the making of yogurt, as well as such recent and concerning practices as GE (a.k.a., genetic modification, gene splicing), the process of altering the genetic makeup of an organism not attendant with the organism's usual reproductive process. Cloning – the reproduction of an exact genetic copy of an organism – can be considered a GE activity and has been successfully achieved for an array of mammals including mice, sheep, cattle, pigs, cats, dogs, and horses. More commonly, the term GE denotes the manipulation or replacement of particular genes of an organism in order to assure particular characteristics in the organism thereby created.

Benefits of GE

Proponents suggest a range of reasons why GE should be pursued with vigor. GE bacteria have been created to remediate of contaminated sites in the environment, such as from chemical spills. GE is being used for the production of vaccines and medications; given the rate at which ease of production is increasing and production costs are falling, the promise for more and cheaper medical products seems tremendous. Microorganisms have been developed that produce pharmaceutical products such as human insulin quickly and inexpensively, providing real hope for those with diabetes. Specially engineered research animals are being developed to assist scientists in the study of particular diseases, such as the oncomouse used in cancer research. Scientists have suggested that humans could be genetically tested for predisposition to diseases and treated accordingly; for example, a child could be tested for a gene predisposing her to breast cancer; that gene could be replaced so that she would no longer be threatened by the disease.

GE crops with built-in pesticides (e.g., Bt corn) allow farmers to reduce their use of commercial pesticides, which not only will lead to a cleaner environment, but will also help restore the profitability of farming and thus encourage more people to farm. Those with resistance to particular herbicides (e.g., Roundup Ready soybeans) increase yield per acre, again improving farming's profitability and land use efficiency. GE can also be used to address particular dietary issues prevalent in certain areas of the world; for example, Golden Rice

was developed to treat vitamin A deficiency in developing countries, a leading cause of blindness. Crops and farm animals that will thrive in poor soil and climate conditions can be developed using GE, thereby offering great promise for feeding the world's hungry. In fact, GE farm animals can be developed whose production levels are higher than those of their non-GE cousins.

Proponents of GE suggest that this technology can be used to bring pigs to market weight faster as well as to enable elephants to live on vegetation ubiquitous in areas of Africa less desirable for human habitation, thereby helping them adapt to relocation habitats more quickly than they would naturally. Similarly, scientists might be able to develop such things as sea birds and seals in Alaska whose hair would naturally repel oil, so that they would be better suited to survive oil spills than their naturally bred cousins.

Dangers of GE

On the other hand, opponents have a long list of reasons why GE is dangerous. Uncertainty about the long-term effects of GE seems to be the primary basis for opposing commercial use of the techniques (Bruce, 2003; Myhr & Traavik, 2003; Pascalev, 2003; Scott, 2003). Scientists still are not sure what impact genetic manipulation will have on the individual plants or animals that carry the genes, on the humans who may consume them, or on other individuals that come in contact with them. Further, they do not know the sorts of changes the release of GMOs might create in entire species or ecosystems. Scientists who oppose field testing during these early stages of our experience with GE have noted that it is virtually impossible to contain reproductive activity when individuals – whether plant or animal – are placed into an even marginally open environment (Bruce, 2003; Scott, 2003). Assuming that the individuals carrying particular transgenic DNA and their offspring are reproductively successful, which they are likely to be for myriad reasons, the number of individuals within a given species carrying that transgenic DNA will grow over time. This will likely lead to a narrowing of the gene pool and a lessening of the species' adaptability to changing environmental conditions (Johnson, 2003).

GE development practices, testing, and patenting have all proven problematic. Developed world scientists often remove potentially useful organisms from countries in the developing world without compensating those countries for them (Tsioumanis et al., 2003). Although the FDA has rigorous testing requirements for drug products, no similarly rigorous testing requirements have been developed for GE non-drug products, meaning that companies under tremendous pressure to profit quickly may place dangerous products on the market prematurely (Johnson, 2003). Patents have been granted for entire organisms developed using GE even when the scientists involved only modified specific

parts of the organisms, which seem to violate previous patent practices. Patents have also been granted for all or part of an individual person's genetic code or for cell lines derived from an individual's cells without that individual's knowledge (Tsioumanis et al., 2003).

Serious concerns have been raised about the level of power that accrues to companies in the GE field. For example, farmers using Roundup Ready soybeans must not only purchase Monsanto's seed every year, but also its Roundup herbicide. And since the vast majority of GE research is financed by profit-seeking companies, some worry that the only research questions being asked are those likely to lead to profits (e.g., Myhr & Traavik, 2003).

Finally, the potential for genetically engineering or cloning humans has dominated media discussion on the topic. Several companies have cloned human embryonic cells (Regalado et al., 2001; Chase & Regalado, 2002; Birchard, 2004; Regalado, 2004), which some believe may open the door for deeply troubling methods of human reproduction and possibly a world of "designer babies."

Applying Common Theories of Business Ethics to GE

Common ethical theories applied to business situations run into a range of difficulties when faced with questions regarding GE, most notably the facts that non-human living things are at the heart of this technology and that the potential future impacts of GE are tremendously uncertain.

Utilitarianism

Business ethics tend to address only human behaviors toward other humans, leaving non-human animals, other living things, ecosystems, and the environment out of the picture altogether. Utilitarian ethical theorists (e.g., Singer, 1975) commonly allow for the consideration of sentient non-human animals, so there would seem to be some hope for a utilitarian business ethic to handle issues of GE. Unfortunately, the common way for utilitarian theories of *business* ethics to address economic activity is manifest in cost–benefit analysis (CBA). CBA requires that we first develop a number of alternative behaviors we could choose to enact; determine the potential consequences of each alternative; establish probabilities for each set of consequences; assign dollar figures to the benefits and costs associated with each set of consequences; and finally compare the economic outcomes as a means of choose from among the alternatives. CBA as a utilitarian tool for decision-making in an economic system can be tremendously helpful; unfortunately, the greater the uncertainty about the potential consequences, the less effective is CBA. In the case of GE, CBA is virtually worthless, because the level of uncertainty is so high: complexity

studies have made us aware that, in a complex system – such as the planetary ecosystem – prediction about long-term outcomes associated with a particular action today is essentially impossible. Further, the failure of scientists to study GE organisms carefully and completely before releasing them into the biosphere means that we have little or no data upon which to base our predictions about even short-term future states, their likelihoods, or costs and benefits expected to be associated with them. Thus even if we subscribe to a utilitarian business ethic that allows for the consideration of sentient non-human animals, no justifiable inputs can be determined that would make a utilitarian calculus meaningful in the case of the commerce associated with GE.

Integrative Social Contract Theory (ISCT)

ISCT is no more effective at handling questions of GE than utilitarian ethics are. Although one *could* imagine ISCT with a triple-bottom-line focus, its most common conceptualization focuses "upon *economic* ethics, ... where 'economic ethics' refers to the principles establishing the boundaries of proper behavior in the context of the production and exchange of goods and services" (Donaldson & Dunfee, 1999, pp. 27–28). ISCT comprises the implicit contracts to which a group of rational, human members of a global economic community would agree when reasoning from behind a partial "veil of ignorance" – they are aware of their economic and political preferences, although not of their particular economic community or status. One problem with ISCT is thus that the natural environment and its non-human components are a matter of concern only to the extent that humans can agree that they are of concern; likely, this would only occur if harms to the natural environment or components thereof could evidently harm human beings as well. Further, Donaldson and Dunfee claim that the "efficiency hypernorm" included in ISCT protects the environment because scarce ecological resources will be valued highly; yet many environmentalists would argue that the value of the natural environment goes far beyond what can be quantified into dollars. Even though ISCT contractors come to the table with a set of moral principles to apply to their economic situations (Donaldson & Dunfee, 1999, p. 27), in a world of growing human population and thus growing focus on economics, other values are likely to be given short shrift in a consensus-seeking ethic. Finally, the economic press focuses on GE's potential for tremendous economic benefit (as well as social benefit, which is undoubtedly discussed to ease concerns about unbridled greed); far less attention is paid the tremendous uncertainty regarding the long-run effects on species, ecosystems, or even humans. Without forcing the parties to the contract to take a very long-term view (in which case they *might* see that the social risks for humans would be considerable), ISCT's contracts would probably not address the potential negative effects of GE.

Stakeholder Theory

At first blush, stakeholder theory would also seem to be fairly inept at handling questions involving GE. When we consider the debates between opponents and proponents of GE, we begin to recognize that Freeman's definition of stakeholders – "individuals or groups that can affect or are affected by the organization's achievement of its objectives" (1984, p. 46) – is more problematic in this case than in perhaps any other. It appears that *everyone and everything* could be considered a stakeholder of GE: because of the interactions among all living things, not only are the individual genetically engineered organisms affected, other individuals in their species with which they interact are also likely to be affected, as are organisms in other species with which they interact, the ecosystems in which they live, humans in contact with them, and so on. And yet stakeholder theory may be enhanced in ways that enable it to more effectively handle questions about GE.

Stakeholder theory has proven to be one of the most influential notions in business ethics over the last 20 years. Freeman suggested that managers should consider stakeholders when making decisions for the firm not only because it was "the right thing to do," but also because doing so would likely enable the firm to garner greater success than if managers were simply to focus on stockholders. Business and society scholars seized the notion of stakeholders enthusiastically, employing it in sharp contrast to Friedman's (1962, 1970) model of economic activity which pronounced profit maximization for the benefit of stockholders to be the only proper goal for a publicly traded company. So many views of stakeholder theory were advanced during the ensuing decade that Donaldson and Preston (1995) observed that stakeholder theory had morphed into normative, descriptive, and instrumental forms; but they noted that the normative core was really the heart of the theory and the way in which it could make its most important contributions to managerial thought.

Freeman (2000) has consistently maintained that stakeholder theory should not be viewed as either instrumental or normative, but rather should be characterized as managerial, comprising both. He rejects what he calls the Separation Thesis, which suggests, "The discourse of business and the discourse of ethics can be separated so that sentences like 'x is a business decision' have no moral content, and 'x is a moral decision' have no business content" (1994, p. 412). Instead, Freeman envisions a world of stakeholder capitalism in which "value is created because stakeholders can jointly satisfy their needs and desires" (2000, p. 176), "there are many different ways to engage in value creation and trade," and "businesspeople continuously create new sources of value" (2000, p. 177). In decision-making, managers consider their impacts on stakeholders because the firm itself depends upon cooperative relationships with those stakeholders – it is both "the right thing to do"

and "good business" to attend to stakeholders, because the two realms are not separated.

In one of the more complete and recent treatments of stakeholder theory, Phillips (2003) developed a fairness principle associated with the theory and explicitly asserted that stakeholder cooperation is at the center of stakeholder theory. According to Phillips, " [S]takeholders should have a slice of the organizational outputs and a voice in how value is added by the organization that is consistent with their contributions to the organization" (2003, p. 162).

That said, however, Phillips insisted that the natural environment was not a stakeholder, regardless of its contributions to the organization. He devoted most of the chapter to describing his rationale; the crux of his argument is, "Only humans are capable of the necessary volitionality in the acceptance of benefits of a mutually beneficial cooperative scheme. Stakeholder theory is anthropocentric" (2003, p. 143). Nevertheless, Phillips suggests that the natural environment can be morally considerable without being a stakeholder and notes, "[S]takeholder theory does not claim to be a comprehensive moral theory. . . . [S]takeholder theory is not exhaustive of ethics even within organizational contexts" (2003, p. 144).

Although Phillips surely offers a very thoughtful, diligent treatment of stakeholder theory, it is not without weaknesses. To begin with, stakeholder theory need not be anthropocentric, and it need not require that individuals or groups freely choose to participate in order for them to be considered stakeholders. Further, stakeholder theory or any other business ethic should be designed so that it is *useful* to businesspersons; an ethic is managerially ineffectual if it requires that managers look elsewhere for guidance in handling an enormous range of decisions, as Phillips suggests managers would have to do with his form of stakeholder theory (2003, pp. 144–145). This chapter thus proposes a version of stakeholder theory that is non-anthropocentric, recognizes non-human stakeholders, and is (hopefully) as holistic as a theory of business ethics can be. First, however, we will explore care theory, a central component of the enhanced stakeholder theory that will be applied to the question of GE and non-human mammals.

Care Theory: Origin, Current Conception, and Expansion

When Lawrence Kohlberg's (1958, 1981) empirical studies indicated that women's levels of moral development were not as high as those of men, his Harvard colleague Carol Gilligan (1982) decided to look into the issue more closely. Kohlberg's model had been developed based upon studies of male subjects, whose descriptions of moral situations seemed to imply that the decision-maker

and those affected by his decision were autonomous individuals and that decision-making at more advanced levels of moral development was about seeking justice. On the other hand, Gilligan found that women portrayed their experiences of facing moral situations differently than men: women's descriptions of similar circumstances seemed to imply that they viewed these situations as being all about relationships and caring for others. Gilligan concluded that women and men were both able to reach high levels of moral development but that they simply approached moral situations differently, with men focusing on justice and women focusing on care.

Care theory,[1] which grew out of Gilligan's work (Hekman, 1995), emphasizes the importance of connections among people and nurturing in relationships. It is an active ethic not focused solely on "caring about," but also on "caring for." Noddings says:

> [I]t is well known that many women – perhaps most women – do not approach moral problems as problems of principle, reasoning, and judgment. . . . If a substantial segment of humankind approaches moral problems through a consideration of the concrete elements of situations and a regard for themselves as caring, then perhaps an attempt should be made to enlighten the study of morality in this alternative mode.
>
> Noddings (1995/1984, p. 8)

Although care theory has been contrasted with justice theory (Rawls, 1971), in fact the problems of acting in a just manner and caring at the same time are not as major as they might first appear. By its very nature, care theory is partial, not impartial: partiality is a central feature of caring, of interconnectedness, of the recognition that we may be more closely connected with one individual than we are with another. Yet the fact that caring admits partiality does not mean that caring is without reason or justice. Caring means doing your best to determine the right way to behave toward those for whom you care. A key component of caring for Person A is that you converse with Person A and with others in order that you can better grasp Person A's position, feelings, and outlook (Koehn, 1998). To the extent that you must decide how to act regarding

[1] Care theory is also often referred to as feminist theory. This chapter does not incorporate this terminology for two primary reasons. First, the term "feminist" is sometimes construed as meaning that all women use one voice and all men use another; that is patently false, nor is it appropriate to suggest that there *should* be separate voices. Groenhout (2004) has done a nice job of demonstrating the "feminine" voice in the writings of two ancient male philosophers, Augustine and Levinas, as a means of demonstrating that care theory is not solely for women nor is it solely based on women's viewpoints. Tronto (1993) has made similar observations about Francis Hutcheson and Adam Smith. Second, in the American culture, as soon as the term "feminist" is used, many listeners or readers will close their minds to whatever follows; because this would be a disservice to those listeners/readers, this chapter avoids the term "feminist." Instead, the terminology of "care" rather than "feminism" seems to put the emphasis where it belongs.

issues having to do with Person A, you need to consider all of your alternatives and find the one that enables you to care for Person A the best, while still caring for others in your web of relationships. Through dialogs and reasoning, a caring person is able to act justly while still admitting his partiality.

As an example, we can consider the renowned Heinz dilemma used by Kohlberg (1981) to test subjects' level of moral development. Simply because Heinz may care more for his wife than he does for the pharmacist does not preclude him from acting justly toward the pharmacist. A caring Heinz would first consult with his wife to determine what her views of the situation are so that he could ascertain ways to care for her appropriately. Assuming she wants him to get the medicine for her, a just but caring Heinz would still not kill the pharmacist to get it, nor would he steal the medicine outright. Instead, he might negotiate with the pharmacist to repay him over time or he might seek a loan from the banker or from a relative. If neither of those appears to be an option, Heinz might seek another pharmacist with whom to negotiate for the drug. Or he might steal the medicine with the intention of paying the pharmacist back at a later time. In other words, a caring Heinz would seek solutions that would privilege his wife but that also preserve the integrity of his whole web of relationships.

The web of relationships of many humans undoubtedly includes non-human living things and the natural environment as a whole, but little has been said in the care theory literature about those relationships. Many of us have close emotional ties to our pets and can imagine circumstances in which we would privilege our pets over at least some humans. This could be a situation as simple as choosing to share an ice cream cone with our pet rather than with a homeless person; or it might be a situation as heart-wrenching as saving our pet's life in a flood instead of the life of a human stranger. Similarly, many of us feel moved to care about and for aspects of the natural environment, whether it be an eight-point buck we spotted in a neighbor's field, a 300-year-old tree in the state forest, or the Arctic National Wildlife Refuge. As is true with humans and inter-human relationships, we appreciate these aspects of the natural environment and our relationships with them for their uniqueness; that is part of what fosters caring.

In this expanded version of care theory, our moral behavior toward non-human living things and other components of the natural environment is influenced by our level of connectedness to them, just as is true for our moral behavior toward humans. The degree to which we care about and for a particular buck, a particular tree, or a particular ecosystem is influenced by many of the same factors that influence our caring for other humans: our physical proximity to them, our having a personal relationship with them, our ability to empathize with them, our sense of their importance to others, and so forth. To emphasize, caring is based upon relationships and connectedness; it is both an attitude and an action: a person cares *about* something and he puts that emotion into practice by caring *for* it as well.

Stakeholder Care Theory and Its Application to Non-human Nature

Managing profit-seeking organizations does not preclude caring both about and for others, although caring has rarely been addressed in management research. In fact, most business ethics explicitly seek to remove the notion of emotions such as caring from consideration, preferring to focus on objectivity and impartiality. However a blend of care theory and stakeholder theory would seem an appropriate way of handling a whole host of questions in business ethics. The notion here would be to go beyond stakeholder theories such as that of Phillips (2003) to develop a theory of business ethics that recognizes the uniqueness of each situation and each relationship among firms and stakeholders. Several authors pursued this track in the 1990s (Freeman & Gilbert Jr., 1992; Wicks et al., 1994; Burton & Dunn, 1996; Wicks, 1996; Dobson, 1997; Rabouin, 1997; White, 1999; Crittenden, 2000), but the effort seems to have stumbled for no apparent reason, and little has been written about it since. Stakeholder care theory holds great promise for addressing complex ethical issues in management, not the least of which would be those related to commercial pursuits incorporating GE.

Before discussing the blending of stakeholder theory and care theory, we should address Phillips' (2003) suggestion that those accorded "stakeholder" status must have *voluntarily* contributed to the organization, nor should such status be granted to *humans only*. Although Phillips' discussion of stakeholder theory focuses on the firm's obligations to stakeholders, he makes explicit his belief that the obligations derived from his theory are reciprocal (2003, p. 93); and because non-humans and the natural environment are not able to act volitionally and are thus also not able to act reciprocally, Phillips deems that they are not stakeholders and that stakeholder theory is anthropocentric (2003, p. 143). But if the contribution to the business is the key criterion for prioritization of stakeholder interests, as Phillips suggests (2003, p. 162), surely most companies reap a tremendous contribution from the natural environment; the fact that the environment does not voluntarily consent to be exploited seems beside the point. Why should a stakeholder theory not address the means through which managers should consider this contribution and endeavor to distribute voice and value accordingly?

Stakeholder care theory recognizes the contributions of humans, non-humans, and the natural environment to business firms and thereby yields a vision of a world where economic, social, and environmental interests are intertwined. Reciprocity is not a feature of the theory: managers following stakeholder care theory recognize that non-humans and the natural environment may not act in caring ways toward companies; yet managers behave ethically toward these stakeholders because it is the right thing to do, the caring thing

to do for those about whom you care. As a result, the kind of world that could arise out of stakeholder care theory is a world similar to but beyond Freeman's (2000) world of stakeholder capitalism: a world where business means cooperating as well as enjoying spirited – but not mean-spirited – competition; a world where all of us – individuals, organizations, species, and ecosystems – are able to flourish; a world where we value the contributions made and outcomes achieved by each individual and collective, human and non-human alike; a world where we care *about* future generations even as we care *for* present ones.

In order to enact that world, we must first be explicit that business firms exist in a web of relationships comprising other firms, individual consumers, governmental bodies, activist organizations, individual employees, ecosystems, community organizations, species, media representatives, and so forth. Company relationships with some of those in their web will naturally be closer and more caring than those with others. In order for managers to assure that they are caring in appropriate ways for each stakeholder, they will engage in regular dialogs with representatives of those stakeholders. During this process, managers must diligently pursue perspectives from multiple representatives, as a balanced view of that stakeholder's situation requires that the manager not place too much emphasis on a limited number of views.

On occasion, managers may not be able to find a stakeholder representative from within the membership of that particular stakeholder. For example, if a company is considering locating a plant in an area where many families are below the poverty line, the manager may want to speak with some of those families. None may be willing to come forward, however. At that point, the manager may choose to approach people who have worked with the poor in that community and thereby have specialized knowledge of that group. As was true for stakeholder representatives who are actually members of a stakeholder group, though, in order to obtain a balanced and objective perspective and thereby enable truly caring decisions, the manager should seek the views of multiple specialists.

Non-humans and the natural environment – whom stakeholder care theory considers to be stakeholders by virtue of the fact that they "are affected by the organization's achievement of its objectives" (Freeman, 1984, p. 43) as well as by the contribution they make to a business – cannot speak for themselves. Clearly, however, we as managers can assume that, just like humans, these non-human stakeholders desire not only to survive, but also to flourish. Although they cannot speak to us in the language humans use to speak to one another, we can attempt to become more sensitive to non-humans and the natural environment – their needs, desires, and preferences – and we can ask specialists such as ecologists and animal behaviorists to represent their interests to us as we seek ways to appropriately care for them.

Obviously, many managers will have great difficulty with the suggestion that they should seek to understand the perspective of and thereby to care for a corn plant – one of the species that has been at the center of the GE controversy; they see the corn plant as being completely different from themselves and are unable to empathize with its position. On the other hand, most managers will have little difficulty understanding the perspective of a human who is the potential subject of GE; they can rather easily imagine being in that position, can think more clearly about what it would mean to care for such a person, and can imagine how GE could affect the entire species *homo sapiens*. Toward the end of explicating how stakeholder care theory can help managers behave ethically toward those aspects of nature that are non-human, this chapter will now focus on the question of genetically engineering non-human mammals: as fellow mammals, humans can more easily empathize with non-human mammals than with plants, insects, or even birds and therefore may be more easily able to care for them as stakeholders of commercial enterprises.

The Case of GE and Non-human Mammals

Non-human mammals stand to benefit perhaps as much from GE as do humans. They too are likely to reap the rewards of medical therapies, genetic testing, vaccine and hormone production, reduced usage of pesticides and herbicides in farming, increased availability of food in formerly unsuitable climates, and so on. Nevertheless, individual GE research subjects may not benefit directly. The risk faced by non-human subjects of GE research emphasizes their relative powerlessness: truly, they are the quintessential example of the "is affected by" portion of Freeman's (1984) initial definition of stakeholder. As such, they would seem to be particularly in need and deserving of managerial moral consideration. And while this is always the case for the subjects of scientific research, the level of uncertainty and thus risk is higher here, because this field of research is still so new. For example, although not enough individuals have been cloned from any one species of mammal for us to have statistically significant results, there is some indication that cloned mammals have short life expectancies compared to other individuals in their species. Further, we are unsure about how interactions among genes will manifest themselves when new genes are "spliced" into the DNA of an individual: it is possible that a replaced gene could have acted to prevent the expression of another gene such that, without the replaced gene's presence, the previously unexpressed gene could have significantly deleterious effects.

Clearly, business firms are determined to pursue GE; therefore, development and some level of controlled testing are going to proceed. From a stakeholder care manager's perspective, the non-human mammals used in such

testing should be cared for as important stakeholders, not treated with disdain or callousness. They are, after all, making a tremendous contribution to the firm's future and are being placed at tremendous risk in the process. Managers should seek to understand the point of view of these mammals through observation and through dialog with knowledgeable specialists having multiple perspectives on the situation. Managers should assure that company employees care for these mammals beyond the level of minimal survival while still caring about those individuals and species that may benefit from the research.

Similarly, managers should care about and for the species from which GE research subjects are gathered. Beyond their own intrinsic value, those species interact with others in their ecosystems, contributing to the health of the Earth and ultimately of humankind as well. Once a GE mammal is released into a population of its species, the potential for harmful effects becomes possible; and the more GE individuals are released, the greater and swifter the harm. Genes that have evolved over millions of years as the species has adapted to its environment may be supplanted by genes from completely different animals – or even plants or microbes. Unlike nuclear waste, which decays over time and exhibits half-lives, genes spread through a species over time; in other words, the longer the gene is out in the population, the more impossible stopping its expression becomes. So by virtue of a company's choosing to focus on individuals from a particular species in its research, it may jeopardize the future of that entire species, should unanticipated consequences result once GE individuals are reintroduced into the species population at large. Thus, the species as a whole and all of its members become relevant stakeholders concurrent with company releases. Managers will recognize that similar unanticipated consequences could befall mankind if we were ever to begin replacing human genes with those of other species; and the manager's ability to empathize (or at least sympathize) with a species finding itself in this situation will enable her to act in a caring manner toward that species, sheltering it from harm by preventing the release of individuals into the population until overwhelming evidence indicates that the genetic changes will not harm the species as a whole. As is true of caring for individual members of the species, managers should seek the counsel of those with specialized knowledge of the species and seek alternative ways of testing the GE individuals on a larger scale but still prior to their release into the general population.

Going further, the manager must also recognize that the GE target species is not the only one affected when GE individuals are released: other species that interact with the target species can also be affected. For example, suppose a species depends on the target species as food. If the GE change causes the numbers of individuals in the target species population to decline, the dependent species population may also decline, or the members of the dependent species may begin to feed on some other food source, which could increase the

population of the dependent species or cause the population of the new food source species to decline. In any case, it should become apparent to the stakeholder care manager that at least a chance exists that the release of GE mammals into the population at large could have unintended consequences that could affect non-targeted species. Again, the manager will tap into her own ability to imagine what would happen if key human food sources, such as soy or chicken, suddenly became far less available. To the extent that the company should care for not only those individuals or species that it affects directly, but also those affected unintentionally, managers need to seek information about non-targeted species as well.

In all of this, the potential magnitude of unforeseen consequences is tremendous; releasing GE individuals into the population at large can have cascading and unpredictable impacts. Those who study the interaction among individuals and species as well as ecosystems know that adaptation occurs slowly and that an ecosystem can be destroyed by or can take decades to recover from shocks. Companies working in GE should adopt a stakeholder care theory aimed at caring for the individuals, species, and ecosystems they stand to affect if they release GE organisms into the population at large. Information gathering about the non-human GE research subjects should extend much further than among their own researchers; managers should seek a whole range of views and look for alternative ways to pursue the research. A caring attitude toward their stakeholders will undoubtedly lead them to find new means of testing the technology thoroughly, modeling cultural, ecological and evolutionary factors (Scott, 2005) prior to any releases. Further, managers adopting stakeholder care theory will take ongoing responsibility for caring for those affected by unintended consequences.

Conclusion

When we begin to contemplate the morality of a corporation's acting in ways that potentially jeopardize the future of a population of organisms or even an entire species, and when we then recognize the tidal wave of impacts the future of that particular species could have on ecosystems or even the entire planet, we begin to see just how inadequate our current theories of business ethics are for addressing biotechnology. Anyone conversant in the natural sciences will likely understand the suggestion that everyone and everything is a stakeholder in GE. Ecological studies demonstrate that the Earth is a complex system, its myriad interconnected components affecting one another in often unpredictable ways. If we are to cultivate a world where all living things prosper, we must begin now to recognize the importance of caring for one another, human, and non-human alike.

As stewards of the dominant institutions of society today and responsible members of the planetary community, managers should adopt stakeholder care theory as a means for guiding their conduct not only toward other humans and their organizations, but also toward non-humans, species, and ecosystems that have a stake in business activities. In order to care appropriately for their stakeholders, managers need to ascertain the concerns and needs of those stakeholders and to embrace stakeholders in an emotional and active way. In the case of non-humans and the natural environment, studying the natural and social sciences can be beneficial in this process. Learning about ecology is bound to yield an appreciation of the complexity and interconnectedness of the planet and perhaps even a reverence for creation as a whole. Building our own knowledge and fostering knowledge in others should include having an ongoing dialog among ourselves, particularly including those with specialized knowledge that provides them with insight into the physical and affective-psychological interconnectedness among individuals, species, and ecosystems.

Is it possible for a manager to uphold stakeholder care theory and yet move ahead with GE? Of course. Continually seeking information about stakeholders, the manager would consider how best to care for each stakeholder, including those who have closer relationships with his company and those who will pay the price if GE outcomes are not as planned. He would pursue alternative means for demonstrating care that yield different results. Ultimately, the manager would continue GE research if he concluded that caring for the various stakeholders was best manifested by those activities and that such research would lead to a world in which humans and non-humans, individuals and species, ecosystems and the Earth as a whole will cooperate and flourish.

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13

Unresolved Issues and Further Questions: Meir, Potts, and Hendry

Laura Hartman

The following comments relate to three chapters that present evidence of the broad challenges that face us as ethicists when confronted with developments in areas of human understanding and conception. Though we are at times the ones to have inspired and advanced these developments, the human capacity for understanding and integration is not always as expansive as our capacity for creativity. Thus, we are often perplexed or challenged (and at times astonished at the challenge) by the ultimate ethical and other consequences of our creativity. And these challenges are not simplistic or basic in their implications; "our lives are likely to be more fundamentally transformed in the next few decades than in the past 1,000 years," says author Jeremy Rivkin of genetic engineering (GE) and its commerce. The three chapters that comprise this panel demonstrate the evolution from an idea's fruition to the analysis of its impact and eventual resolution of the dilemmas it may pose. At conceptualization, the creator may not anticipate the implications – or the breadth of the implications – that may reside in application. By evaluating these analyses, perhaps we may be more sensitive to the consequences at the origin or inception of the idea, rather than once the consequences occur.

Since this is an emerging arena for ethical evaluation, perhaps the most effective perspective from which to begin is the free market, or European individualism. Where no regulation currently exists – or where we are evaluating the evolving regulatory environment in a developing arena – the free market approach offers a starting point from which to then build a scheme that serves the needs of relevant stakeholders. One can thereby evaluate the potential gains and losses to stakeholders as a result of increased or decreased regulatory constraints.

It should also be noted that, in areas that present novel ethical challenges, that which is considered most provocative and vexing by one colleague may be accepted as rote by another who is far more confounded by an alternate query. Such is the case with the analyses presented by these three chapters. For instance, though one examination focuses on whether certain biotechnological

processes may be patentable (Meir), another presumes patentability via precedent and proceeds to evaluate the corporate environment in which the patents are held (Potts). Similarly, Meir is satisfied with the concept of a 20-year (actually 21 years, as explained in his chapter) limitation on patents, while Potts summarily explains that patent rights "can be extended for a considerable time." Finally, in comparison to Meir's support for current levels and extents of patent regulation, Potts instead suggests revisions in order to close "loopholes which allow companies to patent gene products from the same gene almost indefinitely."

"Who Owns My Ideas About Your Body," by Asher Meir

In exploring Meir's analysis of the intellectual property regime for human stem cells, one cannot help but ask whether anything is wrong with our current regime, and whether anything can be gained in terms of more effective incentives or implications under a more or less constraining environment. Meir contends that current patent law application to issues involving stem cell research is sufficient "as long as the law is carefully applied and patents are given only to truly patentable inventions whose extent is clearly defined." Since that is what the law itself requires, Meir seems to be supporting the current system and is simply advocating strong and consistent application of that system to this new area of patentable product.

However, Meir's chapter goes beyond this mere support for the legal regime and also addresses the key areas of possible contention. Though he still suggests that the law adequately responds to these ethical challenges, the contentions themselves form the internal debate of the discussion that ensues. Meir suggests a key balance for analyzing the challenges to patenting what is essentially something generated by the human body is "to effectively exploit the ability of this technology to alleviate human suffering and to advance understanding, while ensuring that scientific and commercial enthusiasm do not trample human rights and human dignity." This balance appropriately forms the essential and central point of Meir's judgment in connection with stem cells as intellectual property.

In Meir's evaluation of the problems with patents however, he evidences the appropriateness of the extant balance by suggesting the problems inherent in extremely faulty systems. For instance, he suggests the implications of an inadequate or, conversely, excessively expansive regime. I would suggest that the arguments against the current environment remain more subtle and instead the sufficiency of the existing regulatory response could be more strongly supported by refuting these *subtle* challenges than by addressing only the most extreme. As an example, Meir mentions that "if the patent protection is too

extensive, then too much may be invested in innovation." Undoubtedly, Meir's argument is irrefutable in its breadth. However, the more complicated and prickly question is exactly where the line is drawn between protection that is appropriate and that which is "too extensive." Meir also applies the same general analysis to the concern about inadequate protections and concludes that the current period of protection is acceptable. Without some discussion of the gray areas lingering between the two extremes, one is left in a bit of fairy tale limbo as Goldilocks' *only* remaining choice is the one in the middle, which is of course "just right." It is curious to me that somehow the patent duration of 20 years is coincidentally "just right" without further analysis, informed by free market considerations such as those Meir mentions in this section.

Later in his analysis, Meir leaves the question of the propriety of the current regime to evaluate its application with specific regard to the financial incentives involved in the system. The issue of compensating someone for the value of their tissues or the procedure required to access those tissues can be evaluated using a strictly economic or free market perspective. Yes, the individual may hold a unique and novel property right, however the same holds true for the seller of a particular piece of real estate. No two pieces of real property are exactly the same, yet the free market seems to work under those circumstances. This is not the situation of eminent domain as discussed in the chapter but instead more appropriately compared to a basic house sale. If someone wants that unique piece of property and is willing to pay enough to encourage the owner to sell, a sale takes place. If not, then the sale does not ensue. Similarly, if someone wants biological materials and is willing to pay a sufficient price, the individual may be willing to sell. If not, then the sale does not ensue. The free market is sufficient under these circumstances since individuals may place different values and premiums on the use of their body parts for various purposes, among other personal distinctions. Relating this application to another of Meir's arguments, a free market approach will determine whether there are any implications to calling the payment "recompense for risk and discomfort" versus "payment for valuable tissue." There is no need for additional regulatory response in any of these areas since the market will respond with appropriate incentives and implications.

One comparison not originally raised by Meir during the panel discussion but which seems intuitively applicable to the current analysis is the concept of slavery in America. Especially when addressing the evolution of a regulatory regime, the arena of greatest consternation is often the dystopic gray area where the law actually permits actions which promulgate unethical outcomes, such as the slave trade in U.S. past. Meir also discusses the intrinsic objections to property rights in stem cell research. The question of property rights in living organisms is addressed but only passing reference is made to one of the most startling issues of property ownership in U.S. history. Moreover, in

discussing commodification, it would seem a natural extension to remind readers that it was the resulting degradation of the African-Americans that arguably led in part to the abhorrent treatment to which they were subjected as slaves. A national moral climate thereafter resolved that people could not hold a property interest in another person, thus perhaps resolving some of the ethical issues raised by Meir in one fell swoop.

I find myself convinced by Meir's conclusion that, notwithstanding challenges to the contrary, patent law does in fact satisfactorily respond to what many believe to be vexing questions. However, I cannot help but feel that the detractors of the current regime may have stronger arguments than those offered by Meir.

"Pharmaceutical Mergers and Genetic Technology: A Problematic Combination," by Michael Potts

Potts contends that perhaps the free market is allowing the over-concentration of firms involved in genetic research and technology and expresses concern over a number of ethical and legal implications. Again, however, Potts presumes we seek the middle position of "just right," where perhaps market and stakeholder interests are best served by allowing extant incentives to prevail. For instance, though Potts is concerned about the current trend toward what he calls "mega-mergers," there seem to be some compelling reasons to allow these mergers to take place. Potts' own charts explain that mergers allow pharmaceutical firms to reap a number of benefits, many of which would provide value to varied stakeholders. Mergers allow the larger resulting firm to expand or deepen therapeutic areas, to achieve costs savings (which may be passed on to other stakeholders), to become a more attractive research partner (which may fuel research opportunities that might not otherwise exist), and so on.

Moreover, Potts' own analysis highlights the increasing costs of research and development, and of marching a new drug through the FDA approval process. These costs and the pressures associated with them promote both innovation as well as expansion deeper into the biotechnology industry. By allowing mergers, if not outright encouraging them, the market is ensuring that research and innovation by the "mega-mergers" continue rather than allow the small biotech start-ups to be stymied by these increased costs and risks. Potts warns, "although smaller biotech firms exist and more are founded each year, and these mitigate market concentration, they usually do not survive as independent firms . . ." In the alternative, if we regulate to prohibit or restrict the mergers that form the basis of Potts analysis, we are likely to find a market replete with large pharmaceuticals having no experience in biotech,

and small firms with an expertise in biotech but insufficient funding and other resources with which to take their innovations to the market. "It is starting to make more sense to buy small biotech companies outright and gain extensive access to their technology."

Potts is persuasive in his admonitions against accepting the market processes as manageable or adequate. He stresses the impact on control over the exploitation of raw information if the mega-firms exert too much control over genetic resources. Potts contends that excessive concentration of control in this arena would lead to the extraction of exorbitant royalty fees in exchange for licenses to utilize the genetic product. However, if the fees become inappropriately high and firms designed to exploit these resources either cannot or choose not to engage in their use, then market forces will command a reduction in fees. Admittedly, one possible result is simply for these firms to pay the high fees and pass the costs to pharmaceutical consumers, resulting in a reduction in access to drugs for those who cannot afford the prices.

A balance must be struck, and in fact that is the foundation of Potts' essentially rational argument. Perhaps the challenge to Potts then is the definition of his term, "over-concentration," and a recommendation as to where to draw the line between that concept and "just right." Though he sufficiently argues for his suggested practical steps to prevent over-concentration, I would suggest that he does not define the term such that the urgency that he evidently senses is transmitted to his readers. Finally, Potts concludes with a proposition that pharmaceuticals "show some self-restraint on mergers," but he was more than persuasive earlier in his argument with regard to the value of the merger to both the large pharmaceutical and the small biotech merger partner, so it is not easy to see how this possibility might come to a realistic fruition.

"Stakeholder Care Theory: The Case of Genetic Engineering," by Jamie Hendry

Hendry's analysis represents an extension of stakeholder theory in order to address an area previously considered by some scholars to be outside of the scope of this concept. Whilst I agree with both the value of Hendry's proposal to broaden the application of stakeholder theory, and with her ultimate conclusions, I find myself at odds with the process by which she arrives at these conclusions.

The first segment of Hendry's analysis discusses the application of two ethical theories to issues involving GE with regard to non-human subjects and the environment. The first theory she considers is utilitarianism. The author dismisses the applicability of utilitarianism to the ethical challenges posed by GE primarily because prediction about long-term outcomes associated with a particular action today is essentially impossible. However, later in her discussion

Hendry quite specifically outlines a number of potential risks from GE. Since outcomes are almost always predictable only to a particular margin of error, utilitarianism is based in part on the decision-maker's proclivity toward risk. Hendry is contending therefore, not that the outcomes are not at all known but instead that the risks involved of any specific outcome are not calculable. As such, utilitarianism can in fact be applied; it is simply that the risks might be so uncertain as to greatly outweigh the benefits. One might imagine, however, a situation where a life-saving pharmaceutical poses enormous risks, but those whose lives are at risk opt to submit to the drug nonetheless.

Hendry asserts that Integrative Social Contract Theory (ISCT) is also insufficient to respond to the ethical challenges of GE. My first dispute is with the implementation of the theory. Hendry contends that the hypernorms of a group are those determined by the application of a veil of ignorance. Rather, I would suggest this concept would be better validated in terms of the application of distributive justice than in ISCT. This would, I submit, direct that hypernorms are determined by seeking the convergence of a number of sources that create a consensus around specific values and their application. In addition, notwithstanding either interpretation, I would dispute Hendry's conclusion that agreement is unlikely among decision-makers with regard to non-humans, species or ecosystems. I do not suggest that such agreement is clear or easy, simply that it may be possible.

After dismissing the application of these two theories, Hendry then focuses her discussion on stakeholder theory. She suggests extension of the theory beyond Phillips' 2003 conclusion that stakeholder theory does not adequately provide for non-human or environmental subjects, raising the important consideration that humans may certainly speak on behalf of these subjects since many issues that surround them impact many if not all human stakeholders. Her discussion brought to mind the eventuality of a child as a stakeholder. The child may not be capable of consciously and deliberately accepting the benefits of a mutually beneficial cooperative scheme; yet one may not assert that a child is therefore incapable of being a stakeholder. Hendry explains furthermore that it is Phillips' contention that the environment cannot act reciprocally. This argument, too, seems somewhat foreclosed. If we act upon the environment, the environment responds.

In the end, I conclude similarly to Hendry, although perhaps for different reasons. The single remaining issue left open by Hendry, and for which I have no suggestions either at this point, is how to determine or resolve conflicts among stakeholders or priorities when extending stakeholder theory. Is this a presumption in favor of humans over non-humans in light of conflicts, of non-humans over the environment? In considering the extremely pressing and conflicting issues raised by GE, I fear that a resolution of these challenges will be critical and, I expect, not prone to unanimity.

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