

# *Homo Economicus*

## Commercialization of Body Tissue in the Age of Biotechnology

by DOROTHY NELKIN and LORI ANDREWS

The human body is becoming hot property, a resource to be "mined," "harvested," patented, and traded commercially for profit as well as scientific and therapeutic advances. Under the new entrepreneurial approach to the body old tensions take on new dimensions—about consent, the fair distribution of tissues and products developed from them, the individual and cultural values represented by the body, and public policy governing the use of organs and tissues.

**I**n recent years, biotechnology techniques have transformed a variety of human body tissue into valuable and marketable research materials and clinical products.

Blood can serve as the basis for immortalized cell lines for biological studies and the development of pharmaceutical products; the catalogue from the American Tissue Culture Catalogue lists thousands of people's cell lines that are available for sale. Snippets of foreskin are used for the development of artificial skin. Biopsied tissue is used to manufacture therapeutic quantities of genetic material.

Body tissue also has commercial value beyond the medical and research contexts. Placenta is used to enrich shampoos, cosmetics, and skin care products. Kary Mullis, a Nobel Prize-winning geneticist, founded a company called Star Gene that uses

gene amplification techniques to make and market jewelry containing DNA cloned from famous rock stars and athletes. The idea, says Mullis, is that "teenagers might pay a little money to get a piece of jewelry containing the actual piece of amplified DNA of somebody like a rock star."<sup>1</sup>

There is also a market for services to collect and store one's tissue outside the body. People can pay to store blood prior to surgery or embryos in the course of in vitro fertilization. A Massachusetts company, BioBank, stores excess tissue removed during cosmetic or other surgical procedures for the patient's future use. New companies such as Safe-T-Child and Child Trail have formed to collect and store tissue samples to identify children who have been kidnapped. And a company called Identigene advertises on taxicabs and billboards (call 1-800-DNA-TYPE) for a service to collect tissue for DNA identification that would establish paternity in child support disputes. There are about fifty private DNA testing centers in the United States, hundreds of university laboratories undertaking DNA research, and over 1,000 bio-

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technology companies developing commercial products from bodily materials.

These expanding markets have increased the value of human tissue, and institutions with ready access to tissue find they possess a capital resource. Access to stored tissue samples is sometimes included in collaborative agreements between hospitals and biotechnology firms. In a joint venture agreement, Sequana Therapeutics, Inc., a California biotechnology firm, credited the New York City cancer hospital, Memorial-Sloan Kettering, with \$5 million in order to obtain access to its bank of cancer tissue biopsies that could be useful as a source of genetic information.<sup>2</sup>

Physicians who treat families with genetic disease are approaching geneticists and offering to “sell you my families”<sup>3</sup>—meaning that they will, for a fee, give the researcher their patients’ blood samples. Scientists who isolate certain genes are then patenting them and profiting from their use in genetic tests. Hospitals in Great Britain and Russia sell tissue in order to augment their limited budgets. Between 1976 and 1993 Merieux UK collected 360 tons of placental tissue each year from 282 British hospitals and sent them to France for use in manufacturing drugs.<sup>4</sup> Human tissue has become so valuable that it is sometimes a target for corporate espionage and theft.

In the United States the potential for commercial gain from the body grew as a consequence of legislative measures that were enacted in the 1980s to encourage the commercial development of government-funded research.<sup>5</sup> Legislation allowed universities and nonprofit institutions to apply for patents on federally funded projects and also provided tax incentives to companies investing in academic research. At the same time, changes in patent law turned commercial attention toward research in genetics. A landmark U.S. Supreme Court case in 1980 granted a patent on a life form—a bacterium—setting the stage for the patenting of human genes.<sup>6</sup> In the mid-1980s the U.S. Patent Office began granting patent rights for human genes.<sup>7</sup> It has since received over 5,000 patent applications and has granted more than 1,500, including patents for bone and brain tissue and DNA coding for human proteins.

Today, joint ventures between industry and universities are thriving, and research scientists are increasingly tied to commercial goals. Industry has become a significant source of funding for genetics research. As Francis Collins observed, companies have resources for gene hunting that the academies cannot match: “It’s important not to ignore the way things have changed in the last 3 years in human genetics [because of industry]. Gene hunting used to be a purely academic exercise.”<sup>8</sup> Nearly

every major geneticist is associated with a biotechnology firm; some as directors, others as consultants. And scientists, hospitals, and universities are patenting genes.

The body, of course, has long been exploited as a commercial and marketable entity, as athletes, models, prostitutes, surrogate mothers, and beauty queens are well aware. Yet there is something strange and troubling about the traffic in body tissue, the banking of human cells, the patenting of genes. In the 1984 public hearings concerning anatomical gifts, Albert Gore, then a U.S. Congressman, was troubled by a growing tendency to treat the body as a commodity in a market economy: “It is against our system of values to buy and sell parts of human beings. . . . The notion has perhaps superficial attraction to some because we have learned that the market system will solve lots of problems if we just stand out of the way and let it work. It is very true. This ought to be an exception because you don’t want to invest property rights in human beings. . . . It is wrong.”<sup>9</sup>

But what *is* troubling about the commodification of the body? What is the problem with the growing interest in human tissue for the manufacturing of pharmaceutical or bioengineered products? Clearly the interest in the body is driven by instrumental and commercial values; but so too, as Gore suggested, are most technological endeavors. Moreover, much of the body tissue useful for biotechnology innovation—hair, blood, sperm—is replenishable. And we normally regard body materials such as umbilical cord blood, foreskin, the tissue discarded after surgery—and, in some cases, even the excess embryos created for in vitro fertilization—as simply refuse, like bloodied bandages and other medical wastes. Why not, then, view the body as a useful and exploitable resource if this can advance scientific research, contribute to progress, or provide lifesaving benefits to others? Why are there demonstrations against the privatization of cordblood, lawsuits against the commercialization of cell lines, protests against the patenting of genes? Why are commercial developments in the removal, storage, and transformation of human tissue controversial?

To answer these questions, we undertook a study of several prominent disputes over the ownership of the body, the collection of human tissue, and its distribution as a resource. These disputes reflect the collision between commercial claims for body tissue and individual interests or cultural values. They reflect a conviction that turning tissue, cell lines, and DNA into commodities violates body integrity, exploits powerless people, intrudes on community values, distorts research agendas, and weakens public trust in scientists and clinicians.

## Historical Controversies

Research and clinical uses of body parts have been controversial since the early days of anatomical dissection. The process of cutting and fragmenting the body once evoked images of evil, and Dante-esque visions of Hell.<sup>10</sup> As the Renaissance brought growing interest in anatomy, the use of bodies in medical schools was gradually accepted. Yet dissection remained controversial well into the nineteenth century, mainly due to the exploitative manner of obtaining anatomical specimens and the commercial interests involved. Bodies, in short supply, became, as historian Michael Sappol described them, valuable commodities, "objects of exchange whose value fluctuated according to the law of supply and demand."<sup>11</sup> Anatomy departments paid between \$10 and \$35 for a body, more than the weekly wage of a skilled worker at that time. Body snatching became a lucrative business as dead bodies were obtained in devious ways—through grave robbing, the bribing of hospital attendants, and even the murder of beggars. Historian Ruth Richardson describes how corpses were "quarried": "Parts extracted were sold to those who could use them, such as dentists and wigmakers, and to those who assisted medical research and study, such as articulators of bones for medical skeletons and medical specimen makers. Profits were to be made at every stage."<sup>12</sup>

Despite riots and demonstrations,<sup>13</sup> the practice of body snatching continued in America until anatomy laws, passed in various states throughout the nineteenth century, eased the shortage by allowing medical schools to use the bodies of executed murderers and the unclaimed dead.<sup>14</sup> These laws regularized the practice of dissection, but throughout the nineteenth century, writes Sappol, people remained sensitive to the dangers of commercialization, insisting that the body remain "outside the capital nexus, outside the exchange of goods, . . . sequestered from the market economy."<sup>15</sup>

Later experiments in organ transplantation were welcomed as "medical milestones," but still evoked worries about market exploitation. As organs became valuable commodities, would physicians hasten deaths? Would valuable organs be harvested for a fee from needy people or from citizens of the Third World?<sup>16</sup>

The historical disputes over dissection and organ transplants reflected several concerns about the effect of commercial interest in the body: the violation of body integrity as corpses were "snatched" for profit and cut into parts; the devaluation of personal characteristics as the body was viewed as an object with replaceable and collectible parts; and conflict between the interests of

doctors and scientists and those of patients and their families. These concerns were ultimately assuaged by the passage of the Uniform Anatomical Gift Act (1968) and the National Organ Transplantation Act (1984), which assure the noncommercial, voluntary donation of bodies and their parts for research and transplantation.

Today, old tensions have taken on new dimensions as the commercial potential of human tissue has caught the entrepreneurial imagination. Few laws are in place to address the proper uses of cells, tissues, and genes. Instead, disputes over the ownership, collection, and distribution of human tissue have ended up in the media and in the courts.

## The Ownership of Body Tissue

John Moore, a patient with hairy cell leukemia, had his spleen removed at the University of California, Los Angeles School of Medicine in 1976. His physician, Dr. David W. Golde, patented certain chemicals in Moore's blood purportedly without his knowledge or consent and set up contracts with a Boston company, negotiating shares worth \$3 million. Sandoz, the Swiss pharmaceutical company, paid a reported \$15 million for the right to develop the Mo cell line.

Moore began to suspect that his tissue was being used for purposes beyond his personal care when UCLA cancer specialists kept taking samples of blood, bone marrow, skin, and sperm for seven years. When Moore discovered in 1984 that he had become patent number 4,438,032, he sued the doctors for malpractice and property theft.<sup>17</sup> His physicians claimed that Moore had waived his interest in his body parts when he signed a general consent form giving the UCLA pathology department the right to dispose of his removed tissue. But Moore felt that his integrity was violated, his body exploited, and his tissue turned into a product: "My doctors are claiming that my humanity, my genetic essence, is their invention and their property. They view me as a mine from which to extract biological material. I was harvested."<sup>18</sup>

The court held that clinicians must inform patients in advance of surgical procedures that their tissue could be used for research, but it denied Moore's claim that he owned his tissue. Who then should reap the *profits* from parts taken from an individual's body? The court decided that the doctor and biotechnology company rather than the patient should profit. The decision rested on the promise of biotechnology innovation. The court did not want to slow down research by "threaten[ing] with disabling civil liability innocent parties who are engaged in

socially useful activities, such as researchers who have no reason to believe that their use of a particular cell sample is against a donor's wishes." The court was concerned that giving Moore a property right to his tissue would "destroy the economic incentive to conduct important medical research."<sup>19</sup>

Justice Stanley Mosk, dissenting, objected to the notion that the body—"the physical and temporal expression of the unique human persona"—could be regarded as a product for commercial exploitation. For, he argued, the spectre of direct abuse, of torture, of involuntary servitude haunts the laboratories and boardrooms of today's biotechnological research industrial complex (p. 515).

The privileging of biotechnology companies encouraged a genetics gold rush. In 1992 Craig Venter, a molecular biologist, left the National Institutes of Health to form The Institute for Genomic Research (TIGR), where he compiled the world's largest human gene data bank containing at least 150,000 fragments of DNA sequences. The Institute for Genomic Research was initially funded by a \$70 million grant from a firm, Human Genome Services (HGS). Two months after the agreement, HGS contracted with SmithKline Beecham, which gained an exclusive stake in the database with first rights on patentable discoveries. Geneticist David King described the situation: "You have a corporation trying to monopolize control of a large part of the whole human genome, literally the human heritage. Should this become private property?"<sup>20</sup>

The concerns about commercial exploitation of the body expressed in *Moore* have assumed more complex dimensions in disputes over the collection of human tissue in a global context. Scientists and biotechnology companies are searching the world for disease genes. But critics have viewed the collection of tissue from indigenous populations as a violation of cultural values, and associate these efforts with past forms of exploitation.

### Collecting Tissue from Indigenous Populations

Because people from isolated populations may have unique body tissue, western geneticists, biotechnology companies, and researchers from the Human Genome Diversity Project (HGDP) are seeking blood and hair samples from indigenous groups throughout the world. Their goals are to find disease genes by identifying families with a high rate of genetically linked conditions; to develop genetic tests and therapeutic products; and to "immortalize" the DNA from "vanishing populations."<sup>21</sup>

In March 1995 researchers from the National Institutes of Health obtained a virus-infected cell line from a man from the Hagahai tribe in Papua, New Guinea. The cell line, which could be used to develop a diagnostic test, became patent number 5,397,696. Accused of exploitation, the NIH withdrew the patent claim in December 1996. Meanwhile, Sequana Therapeutics, collaborating with the University of Toronto, collected DNA

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samples from the island of Tristan de Cunha for research on asthma and then sold the rights to develop therapeutic technologies for \$70 million to a German company, Boehringer Ingelheim.<sup>22</sup> Western scientists are also negotiating contracts to collect DNA samples from Chinese families with genetic diseases. But China's eugenics policies include efforts to identify families with genetic abnormalities so as to prevent them from reproducing. Thus the DNA samples may also be a valuable resource for Chinese authorities seeking to implement oppressive eugenics laws.

The HGDP has confronted angry opposition. Indigenous groups view the taking of their tissue as exploitation. They have accused the program of violating community values, "biopiracy" or "biocolonialism," one more effort to divide their social world. A representative of an indigenous group opined, "You've taken our land, our language, our culture, and even our children. Are you now saying you want to take part of our bodies as well?"<sup>23</sup> Some objections reflect beliefs, expressed in collective rituals involving blood or body parts, about the social meaning of body tissue—its role in maintaining the integrity of the community and the relationship of the individual to the collective.<sup>24</sup> Others believe that their future might be compromised by the collection of their DNA. Once scientists have what they need from them, there would be no reason to help them stay alive. This pessimistic view was fueled by researchers who promoted the project as a way to "immortalize" the cell lines of groups that will become extinct.

Indigenous groups also question the relevance of the scientific work to their own health needs, which have less to do with genetic disease than with common disorders such as diarrhea. They argue that DNA is collected, often without adequate knowledge or consent, and then used for products relevant only in wealthy nations. And Native Americans suspect that genetic data will be used against them: just as criteria of blood quanta were used to define political entitlements to land and social services, so DNA could be used to override long-standing social relationships. Thus in 1993 the World Council of Indigenous Peoples unanimously voted to "categorically reject and condemn the Human Genome Diversity Project as it applies to our rights, lives, and dignity."<sup>25</sup>

In response to concerns about exploitation of indigenous resources, the United Nations Convention on Biodiversity (1992) had sought to assure that national governments receive just compensation for commercial use of both human and agricultural resources. But the interest in genetic resources suggests that this approach may lead to further exploitation of indigenous groups as they become profit centers for their governments. Moreover, some groups do not want compensation—the very idea of commercializing the body offends them and contradicts their world view. For them, the body has a social meaning tied to colonial history, traditional communal rituals, and concerns about continued exploitation.

### **The Distribution of Body Tissue**

Commercial interests are also involved in the distribution of products derived from the body. The market involvement in the distribution of umbilical cord blood has become controversial as a resource considered communal became privatized. In 1988 a French research team headed by Dr. Eliane Gluckmann developed a way to process umbilical cord blood so that it could be used as an alternative for bone marrow in treating life-threatening diseases. Blood from the umbilical cord is rich in stem cells that produce mature red and white blood cells and platelets. Its use for transplantation has several advantages: it is readily available—at least 10,000 umbilical cords are routinely clamped, cut, and discarded each day in the United States. Cord blood is also less immunoreactive than bone marrow. The researchers envisioned a system of nonprofit cord blood banks where the frozen blood would be stored and available for distribution with minimal delay to those in need of transplantation. It was to be a communal resource.

The likelihood that a newborn infant will ever need his or her umbilical cord blood is less than one in 10,000.

However, attracted by potential markets, cord blood companies created private banks and urged prospective parents to store their infant's cord blood privately as "insurance" against future medical needs. In effect, these companies are creating a market and generating a need.<sup>26</sup>

The commercialization of the product led to the use of strong-arm marketing tactics. Cord blood companies employ a direct marketing approach obtaining mailing lists from diaper services and magazine subscriptions to sell the promise of innovation and future progress to vulnerable prospective parents. Cord blood, they say, is a "low cost edge on an uncertain future."<sup>27</sup> In case of emergency it is "immediately available off the shelf." This marketing strategy plays on the risk-averse sentiments of those who prefer to rely on their own resources rather than on the state, and it exploits parental guilt—the desire to "do right" by one's children.

In 1991 an American company, Biocyte Corporation, sought a patent for its method for cryopreserving newborn blood stem cells to secure rights to its storage and distribution. Biocyte obtained European and U.S. patents covering "hemopoietic stem and placenta cells of neonatal and fetal blood, that are cryopreserved, and the therapeutic uses of such cells."<sup>28</sup> These patents gave the company rights over storage of stem cells from cord blood and also over therapeutic services. The European Group on Blood and Marrow Transplantation protested, claiming that patenting would impede further research and discourage the formation of nonprofit banks. The idea of patenting also evoked moral outrage against commodifying a "natural" substance and turning a product of childbirth into a commercial object.<sup>29</sup> Cord blood, once a body substance discarded as useless, became a hot clinical property, and a focus of tension over commercialization of the body and the equitable distribution of body tissue for therapeutic purposes.

### **Theft—The Ultimate Symbol of Commodification**

Products that attain commercial value are inevitably subject to theft, a not uncommon form of redistribution. The traffic in body parts has persisted, spurred as in the nineteenth century, by a shortage of organs and tissue. Body parts have been bought from coroners, stolen from the site of accidents, and sold to meet the demands of industry and medicine.<sup>30</sup> Today, cell lines are a target for international espionage.<sup>31</sup> In a sting operation, agents of the Food and Drug Administration posed as representatives of a tissue bank and ordered tissue from a California dentist who tried to sell them body parts at a dis-

count.<sup>32</sup> In France, a government investigation exposed an embezzlement scheme in which private companies billed local hospitals for synthetic ligament tissue that, it turned out, came from human tissue, which in France cannot legally be bought and sold.<sup>33</sup>

Funeral home personnel and coroners have also engaged in tissue theft. In one case, a morgue employee allegedly stole body parts and sold them nationally—a situation uncovered unexpectedly when the body of a twenty-one-day-old infant was exhumed for other purposes and found to be missing his heart, lungs, eyes, pituitary gland, aorta, kidneys, spleen, and key brain parts.<sup>34</sup> In Britain seventeen people who contracted Creutzfeldt Jacob disease from human growth hormone accused the Medical Research Council and the Department of Health of unlawfully buying, from mortuaries, the pituitary glands from 900,000 bodies to extract the growth hormone. The tissue was taken without the consent of the individuals before death or their families, in violation of British law.<sup>35</sup>

Demands for spare embryos have also led to undercover redistribution in the in vitro fertilization business. At the University of California at Irvine, over 75 couples were affected by theft of eggs and embryos at the university clinic where Dr. Ricardo Asch had apparently been secretly selling some of the eggs extracted from his infertility patients to other patients who were duped into thinking they were from legitimate donors. More than forty civil lawsuits were filed. In July 1997 the university agreed to pay \$14 million to seventy-five couples; two dozen lawsuits still remain. Embryo theft was “predictable, almost inevitable,” says Boston University health law professor George Annas. “The field [of in vitro fertilization] is so lucrative and so unregulated that someone was just bound to do it.”<sup>36</sup>

### Problems with the Business of Bodies

References to body parts in the medical and scientific literature increasingly employ a language of commerce—of banking, investment, insurance, compensation, and patenting. Gene sequences are patented; cord blood is a “hot property,” the body is a “medical factory.” Companies “target” appropriate markets for their products. Pathology organizations lobby the government to allow them to use stored tissue samples without consent, for they view such samples as “treasure troves” or “national resources” for research. Geneticists talk of “prospecting” for genes. The body is a “project”—a system that can be divided and dissected down to the molecular level. In a

striking statement in the *Moore* case, the defendant, UCLA, claimed that even if Moore’s cells were his property, as a state university it had a right to take the cells under “eminent domain.”

The body tissue disputes we have described—over the ownership, collection, and distribution of body tissue—raise questions about the assumptions underlying this language of commerce. Who will profit? Who will lose?

### **Market incentives to treat body tissue as a valuable and collectible commodity may also have troubling psychological effects.**

How will exploitation be avoided? They reflect conflicting beliefs about the body. Is body tissue to be defined as waste, like the material in a hospital bed pan? Is it refuse that is freely available as raw material for commercial products? Or does body tissue have inherent value as part of a person? Are genes the essence of an individual and a sacred part of the human inheritance? Or are they, as a director of SmithKline Beecham purportedly claimed, “the currency of the future.”<sup>37</sup>

Disputes suggest that commodifying human tissue, usually without the person’s knowledge or consent, is troubling because it threatens the well-being of individuals and violates social assumptions about the body.<sup>38</sup> And they suggest that commercialization can also have serious implications for science and medical practice.

*Individual Concerns.* Commercial interests continue to evoke fears of patient exploitation. John Moore’s experience suggested that the commercial interests of doctors can encourage them to take more tissue than is needed for the benefit of their patients. Physicians or institutions with economic interests can also easily influence the decisions of individuals in vulnerable situations. Patients who are hospitalized may be reluctant to withhold consent. New parents, at an uncertain time in their lives, are vulnerable to the pitch of cord blood company salesmen.

The market incentives to treat body tissue as a valuable and collectible commodity may also have troubling psychological effects. Psychologists have found that a sense of coherence and body integrity is essential to individual development and a person’s sense of self, and that control over what is done to the body or its parts is important to psychological well-being.<sup>39</sup> Some people try to place limits on how their body is used. In light of past research exploitation, some African-American

women refuse to allow amniotic tissue to be collected for prenatal diagnosis out of concern about the uses that could be made of this tissue.<sup>40</sup> And some families with genetic diseases who provided tissue to trusted researchers for investigations related to their disease object when they learn their tissue was to be sold to commercial enterprises for unrelated research.<sup>41</sup> Using individuals' tissue in ways that violate their beliefs can disturb their sense of self-agency.

### **Patenting in biomedicine hardly enhances trust. Nor does it necessarily encourage the best research.**

The potential for commercialization creates incentives for researchers and physicians to ignore patients' wishes and their beliefs about the body. Jewish tradition maintains that as man was created in the image of God, in death the body should retain the unity of that image.<sup>42</sup> Consequently, in the Orthodox Jewish community, the body must be buried whole. Unauthorized taking of tissue for commercial use would violate these religious beliefs about the body.

Popular repugnance to the commodification of the body is suggested by a recurrent image of the bar code on the body. A pregnant woman in London painted a bar code on her belly to protest patenting of cord blood.<sup>43</sup> A television technician mumbled to one of us while cleaning up his gear: "I used to be a human, then I became a social security number; now I am just a bar code, a commodity like the cloned sheep."

The business of bodies may also intrude on the privacy of individuals. Body tissue in the age of biotechnology is a source of valued information. The cord blood banked and the tissue collected from indigenous groups can yield not only research materials, but also information about biological relationships and future genetic conditions. Body tissue can be used to identify the genetic predispositions of individuals (of interest to insurers), to redefine political entitlements (as Native Americans fear), or to reinforce social stereotypes (for example, through research on race and genes for aggression).<sup>44</sup>

**Social Concerns.** The body is not just a neutral object. We have, says historian Anthony Synnott, "imposed layers of ideas, images, meanings and associations on these biological systems which together operate and maintain our physical bodies. Our bodies and body parts are loaded with cultural symbolism."<sup>45</sup> The norms

that guide the disposition of body tissue reflect community ideals and social priorities. The history of blood donation, for example, suggests the importance of beliefs about the relationship of blood to communal values.<sup>46</sup> Giving blood and body tissue is a way to affirm social connectedness by linking donors to strangers and donations to the public good. "Donations" based on economic self-interest rather than altruism tend to be devalued.

In the cord blood disputes, critics viewed commercialization as violating the social values involved in free and anonymous donation. They questioned the legitimacy of treating human tissue as private property and worried about fairness and equity in its distribution. So too in the patent disputes. A European environmental group called the Biocyte patent totally inappropriate: "It is as if the first anatomist who described the human heart and the connected blood circulation would have wanted the patent on the human heart, the blood circulation and all the drugs, heart surgery methods . . . that sometime in the future might be developed."<sup>47</sup>

Commercial interests in the body also evoke more general moral and religious reservations. The Boston-based Council for Responsible Genetics declared that "[t]he commercialization and expropriation of these life materials is a violation of the sanctity of human, animal, and plant life."<sup>48</sup> If secular groups are vaguely uncomfortable about patenting the body, religious groups are more explicit: they believe that patenting turns the body into a product, violating the sovereignty of God and the "inherent sanctity of life." The issue, said a representative from the Southern Baptist Convention, "is going to dwarf the pro-life debate within a few years."<sup>49</sup>

### **Implications for Science and Medicine**

The business of bodies affects the fiduciary relationship between doctors and patients. Medical research and clinical practice are ideally considered distinct from the motives of the market. We are leery of scientists who have profit motives in the outcomes of their research or clinicians who have economic interests in particular procedures. Yet a 1996 study of 789 biomedical papers published by academic scientists in Massachusetts found that in 34 percent, one or more authors stood to make money from the results they were reporting.<sup>50</sup> This was because they either held a patent or were an officer or advisor of a biotech firm exploiting the research. In *none* of the articles was this financial interest disclosed.

Patenting in biomedicine hardly enhances trust. Nor does it necessarily encourage the best research. Though considered essential to protect discoveries and provide incentives for investment in research, patenting may actually impede research. Surveys find that patenting has led to reductions in openness and data sharing, delays in publication, and tendencies to select research projects of short-term commercial interest.<sup>51</sup> In several cases, corporations with vested interests have tried to suppress the publication of research findings that were not in their interests. Strains over conflicting commitments have caused some researchers to sever their commercial ties. In June 1997 genetics researcher Craig Venter separated from Human Genome Sciences, giving up a promised \$38 million in order to obtain his intellectual freedom.<sup>52</sup> He said the move was prompted by company pressure to delay publication of his results and to influence his scientific findings. He has since joined another commercial venture.

Commercial incentives are widely assumed to contribute to human health, but this is not necessarily the case. Research in gene therapy, for example, has failed so far to meet expectations. Although 567 people have undergone gene therapy in over 100 protocols, it has not been demonstrated that any of them benefited clinically.<sup>53</sup> An NIH review panel found that the economic incentives to develop gene therapies were so strong that virtually every institute at NIH created a gene therapy program, whether or not the institute had strength in the field.<sup>54</sup> And the panel noted that in the rush to undertake gene therapy, the development of other easier-to-achieve conventional treatments for the same diseases is likely to be ignored (pp. 9, 32). As Richard Gold points out in his book *Body Parts*, property interests have skewed research toward biotechnological cures (because that is where the money is) rather than more conventional therapies or efforts to determine the underlying social and environmental causes of disease.<sup>55</sup>

Moreover, commercialization of body parts may prevent patients from obtaining appropriate health care services by obstructing the distribution of research benefits. Patent rights allow the researcher who identifies a gene to earn royalties on any test or therapy created with that gene. A British hospital that tested a patient for cystic fibrosis was asked to pay royalties because a private company held the patent on the gene.<sup>56</sup> Some laboratories are giving up a useful hormone test to determine whether a fetus has Down syndrome because the royalty fees exceed Medicaid reimbursement.<sup>57</sup> A patent monopoly on cord blood storage would hamper the development of community cord blood banks, leaving patients who do not

have the money to store their infant's blood without a remedy if their child develops a disorder requiring a cord blood transplantation. The real costs in such cases are borne by patients denied appropriate treatment.

There is growing concern that market principles have been improperly applied. People have obtained commercial rights without making an inventive contribution or without determining the purpose of their discovery. Dr. Mark Bogart merely noted the correspondence between a particular hormone level and the chance that a fetus has Down syndrome, yet he was granted a patent and is trying to collect a fee for each diagnostic test relying on measurement of that hormone. Protesting health care providers have filed suit to challenge the patent.<sup>58</sup>

Similarly, numerous patents have been issued on partial gene sequences, even though the patent seekers did not know what the sequences did. In July 1991 Human Genome Sciences received a patent on the DNA sequence for the CCR5 receptor on immune system cells. Now it has been found the receptor opens cells to HIV infection, providing a basis for the development of treatments for HIV infection. But every researcher developing such a treatment will have to pay a licensing fee to Human Genome Sciences.<sup>59</sup>

Incidents like these trouble even venture capitalists. Michael Heller and Rebecca Eisenberg of the University of Michigan School of Law point out a paradoxical consequence of the grant of biotechnology patents: "A proliferation of intellectual property rights upstream may be stifling life-saving innovations further downstream in the course of research and development."<sup>60</sup>

### The Policy Response

The law has not yet settled with respect to controlling commercial interests in body tissue and resolving questions of consent and compensation for the use of cells and genes. However, we are beginning to see some efforts to extend to this area the principles of consent and noncommodification that were developed to regulate organ donation. Certain professional organizations are emphasizing the need to obtain patient consent even if the tissue used has already been removed from the patient's body. When researchers sought to analyze previously collected tissue samples at the Centers for Disease Control, an advisory group pointed out that "retaining tissue samples or immortalizing cell lines may violate cultural or religious beliefs."<sup>61</sup> Guidelines issued by the American College of Medical Genetics require that patients be asked for consent before research is done on their tissue samples and that patients have an option to



have their samples withdrawn or destroyed at any time.<sup>62</sup>

But the policy world is going further, questioning whether commercialization of the body should be allowed even with patient consent. Some scientists as well as activists have challenged the patenting of human genes. And at least one government has stepped in to challenge the transformation of a research tissue bank into a private company resource: when a French foundation holding the DNA fragments of 5,000 diabetics tried to sell this database to an American biotechnology company, the French government intervened; the ownership of this resource remains in dispute.<sup>63</sup>

Robert Bellah has observed that “[a]ll the primary relationships in our society, those between employers and employees, between lawyers and clients, between doctors and patients . . . are being stripped of any moral understanding other than that of market exchange.”<sup>64</sup> In this climate, developments in biotechnology are increasingly linking the biomedical sciences with the aggressive commercialization that is invading nearly every sector of human life. But as biomedical research becomes more closely tied to commercial goals, the encroachment of the market is triggering a growing sense of disillusionment and mistrust. For the encroachment of commercial practices on the human body is increasingly challenging individual and cultural values, encouraging exploitation through the collection and use of tissue, and turning tissue (and potentially people) into marketable products.

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#### References

1. “Kary Mullis,” *Omni Magazine*, April 1992, p. 69.
2. “Cancer Genetics Joint Venture,” *Business Wire*, 20 August 1996.
3. David Cox, Stanford University, personal communication.
4. Heather Kirby, “Something Nasty in the Night Cream,” *The Times* (London), 3 April 1992.
5. See, for example, Andrew Kimbrell, *The Human Body Shop: The Engineering and Marketing of Life* (San Francisco: Harper San Francisco, 1993); Sheldon Krimsky, *Biotechnics and Society* (New York: Praeger, 1991); and Paul Rabinow, *Making PCR* (Chicago: University of Chicago Press, 1996).
6. *Diamond v. Chakabarty*, 447 U.S. 303 (1980). Initially, researchers assumed that genes were not patentable since patent law covers “inventions” and prohibits patenting the “products of nature.”
7. See, for example, Rebecca S. Eisenberg, “Patenting the Human Genome,” *Emory Law Journal* 39 (1990): 721-45.
8. Quoted in Jon Cohen, “The Genomics Gamble,” *Science* 275 (1997): 767-72, at 767.
9. House Hearing on H.R. 4080, “National Organ Transplant Act”: Hearing Before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, 98th Cong., 1984, p. 128.
10. Caroline Bynum, *The Resurrection of the Body* (New York: Columbia University Press, 1995).
11. Michael Sappol, “The Cultural Politics of Anatomy in 19th Century America: Death, Dissection, and Embodied Social Identity.” Unpublished doctoral thesis, Columbia University, 1997, pp. 526-28. Forthcoming, Princeton University Press, 1998.
12. Ruth Richardson, “Fearful Symmetry, Corpses for Anatomy: Organs for Transplantation,” in *Organ Transplantation: Meanings and Realities*, ed. Stuart J. Youngner, Renée C. Fox, and Lawrence O’Connell (Madison: University of Wisconsin Press, 1997), ch. 5 at 82.
13. Sappol, “Cultural Politics of Anatomy,” documents and describes these riots and their goals.
14. The first anatomy law was passed in Massachusetts in 1831.
15. Sappol, “Cultural Politics of Anatomy,” p. 196.
16. Kimbrell, *The Human Body Shop*.
17. *Moore v. Regents of the University of California*, 793 P.2d 479 (Cal. 1990).
18. Quoted in John Vidal and Hohn Carvel, “Lambs to the Gene Market,” *The Guardian* (London), 12 November 1994.
19. *Moore v. Regents of the University of California*, p. 495.
20. Quoted in “Staking Their Claims to Parts of Your Body,” *The Independent*, 6 December 1994.
21. The distribution of genes across populations can also help answer intriguing questions about human origins and patterns of migration. L. L. Cavalli-Sforza, A. C. Wilson, C. R. Cantor et al., “Survey of Human Genetic Diversity: A Vanishing Opportunity for the Human Genome Project,” *Genomics* 11 (1991): 490-91.
22. Global Information Network, 8 December 1995 (Westlaw Data Base); “\$2 Million Received for Gene Discovery Program,” *Gene Therapy Weekly*, 6 November 1995.
23. Zef Productions Ltd., “The Gene Hunters,” documentary film, aired by British Broadcasting, Channel 4, 1995.
24. See, for example, Michael O’Hanlon, *Reading the Skin: Adornment, Display and Society Among the Wahgi* (London: British Museum, 1989).
25. World Council of Indigenous People, “Resolution on the HGDP,” Native Net Archive Page <http://broc09.uthsa.edu/natnet/archive/nl/hgdp.html>.
26. Sugarman et al., “Ethical Issues in Umbilical Cord Blood Banking,” *JAMA* 278 (1997): 938-43.
27. Frank Molloy, “Banking Fetal Cells,” *Hartford Courant*, 19 August 1995.
28. Declan Butler, “U.S. Company Comes Under Fire on Patent on Umbilical Cord Cells,” *Nature* 382 (1996): 99; Susan Kelleher and Kim Christensen, “Fertility Patients Fight over Twins,” *Orange County Register*, 18 February 1996.
29. Interview with Helena Paul, Gaia Foundation, 11 April 1997, London.
30. “The Human Body Parts Trade,” *World Press Review* 1, no. 4 (1994): 38.
31. Charles M. Sennott, “New Cold War: Spies Target Corporation,” *Boston Globe*, 19 January 1997.

32. CBS Evening News, 21 May 1996.
33. Catherine Tastemain, "Oversight for Tissue Transplants," *Nature-Medicine* 1, no. 5 (1995): 397.
34. Frank J. Murray, "Survivors May Sue Over Theft of Body Parts," *Washington Times*, 6 November 1995.
35. Dominic Kennedy, "Families Challenge Legality of Trade in Pituitary Glands," *The Times* (London), 4 September 1995.
36. Karen Brandon, "Emerging Fertility Scandal Has Californians Rapt," *Chicago Tribune*, 24 March 1996.
37. Global 2000, Communiqué, 1997.
38. Lori Andrews and Dorothy Nelkin, "Whose Body Is It Anyway?" *The Lancet* 351 (1997): 53-57.
39. Daniel Stern, *The Interpersonal World of the Infant* (New York: Basic Books, 1985).
40. Rayna Rapp, "Refusing Pre-Natal Diagnosis: The Uneven Meanings of Bioscience in a Multicultural World," *Science, Technology and Human Values* 23 (1998): 45-70.
41. Declan Butler, "French Geneticists Split Over Terms of Commercial Use of DNA Bank," *Nature* 368 (1994): 175.
42. Maurice Lamm, *The Jewish Way in Death and Mourning* (New York: Jonathan David Publishers, 1969), p. 10.
43. Interview with Helena Paul.
44. Barbara Bernier, "Class, Race and Poverty" Medical Technologies and Socio-Political Choices." *Harvard BlackLetter* 11 (1994): 115
45. Anthony Synnott, *The Body Social* (London: Routledge, 1993), p. 1. There is a rich literature on the social meaning of the body. Classic works include Mary Douglas, *Purity and Danger* (London: Routledge, 1996 [1966]); Mary Douglas, *Natural Symbols* (Middlesex, England: Penguin, 1973); Renée Fox and Judith Swazey, *Spare Parts* (New York: Oxford University Press, 1992); Piero Camporesi, *Juice of Life: The Symbolic and Magic Significance of Blood* (New York: Continuum, 1995); Mike Featherstone, Mike Hepworth, and Bryan S. Turner, eds., *The Body: Social Process and Cultural Theory* (London: Sage Publications, 1991); Peter Freund, "Bringing Society into the Body," *Theory and Society* 17 (1988): 839-64. The difference between scientific and social constructions of the female body is explained in Mary Jacobus, Evelyn Fox Keller, and Sally Shuttleworth, eds., *Body/Politics: Women and the Discourses of Science* (New York: Routledge, 1990) and Emily Martin, *The Woman in the Body* (Boston: Beacon Press, 1987). See also Susan Lindee, "The Repatriation of Atomic Bomb Victim Body Parts to Japan." *Osiris*, forthcoming 1999. In addition, Sander Gilman has explored how stereotypes about the body and body meaning are used to impose identity. Sander Gilman, *The Jew's Body* (New York: Routledge, 1991).
46. Richard M. Titmuss, *The Gift Relationship* (New York: Pantheon, 1971).
47. Global 2000, Communiqué, 1997.
48. "Resisting Commercialization of Our Genes," Conference organized by the Council for Responsible Genetics, Cambridge, Mass., 26 October 1996.
49. Richard Stone, "Religious Leaders Oppose Patenting Genes," *Science* 268 (1995): 1126; Mark J. Hanson, "Religious Voices in Biotechnology: The Case of Gene Patenting," Special Supplement, *Hastings Center Report* 27, no. 6 (1997).
50. Sheldon Krimsky et al., "Financial Interests of Authors on Scientific Journals," *Science and Energy Ethics* 2 (1996): 395-410.
51. David Blumenthal et al., "Participation of Life Science Faculty in Research Relations with Industry," *NEJM* 335 (1996): 1734-39; and Sheldon Krimsky et al., "Financial Interests."
52. Tim Friend, "Gene Trailblazers Past Warp." *USA Today*, 24 June 1997.
53. Nicholas Wade, "Team That Put Gene Sequencing on the Map Splits," *New York Times*, 24 June 1997.
54. Stuart H. Orkin and Arno G. Motulsky, co-chairs, "Report and Recommendations of the Panel to Assess the NIH Investment and Research on Gene Therapy," 7 December 1995.
55. E. Richard Gold, *Body Parts: Property Rights and the Ownership of Human Biological Materials* (Washington, D.C.: Georgetown University Press, 1996), p. 37.
56. U.K. Clinical Molecular Genetics Society, Statement, Opposing Gene Patenting, 1996.
57. Kurt Eichenwald, "Push For Royalties Threatens Use of Down Syndrome Test," *New York Times*, 23 May 1997.
58. Paul Elias, "Prenatal Test Sparks Intriguing Patent Dispute," *The Recorder*, 29 August 1997.
59. Eliot Marshall, "HIV Experts vs. Sequencers in the Patent Race," *Science* 275 (1997): 1263.
60. Michael A. Heller and Rebecca S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research," *Science* 280 (1998): 698-701.
61. Ellen Wright Clayton, Karen K. Steinberg, Muin J. Khoury et al., "Informed Consent for Genetic Research on Stored Tissue Samples," *JAMA* 274 (1995): 1786, 1788.
62. "American College of Medical Genetics Statement, "Storage and Use of Genetic Materials," *American Journal of Human Genetics* 57 (1995): 1499-1500.
63. Butler, "French Geneticists Split."
64. Robert Bellah, "Class Wars and Culture Wars in the University Today," *Academe* (July 1997): 22-26, at 24.