chapter 7
Economic Considerations

"Every time we obtain a sample . . . we make sure there is a piece of paper . . . I take all the risks and put $25 million of investment into the research. I don't want the patient then saying, 'Yeah, but it came from me.' "

—Michael S. Ostrach
Vice President, Cetus Corp.
The Baltimore Sun, Apr. 6, 1986

"In nearly every case, the cells will never yield anything of commercial value. But lotteries do have winners. In exceptional circumstances, one person's cells will have a special property that makes them uniquely valuable."

—Edward Dolnick
The New Republic **195(3739):16, 1986**

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Economic Considerations

The fundamental economic question that arises when considering the use of human tissues and cells in biotechnological research and commerce is that of payments to sources. And if sources are to be paid, what factors will enter into the price calculation? This chapter summarizes economic arguments for and against payments for provision of human tissues and cells, analyzes the organization of provision of human biological materials along market and nonmarket lines, and describes the potential role of nonprofit institutions in brokering human biological materials.

PAYMENTS TO SOURCES

On economic grounds, it is possible to argue both for and against paying the sources of human biological materials. Arguments over payments for human biological materials used in biotechnological research and commerce echo the debate that has gone on for many years over donations of kidneys for transplantation and donations of blood for transfusion and therapeutic products. Five principal issues are essential in the debate:

- the equity of production and distribution,
- the added costs of payments to sources and costs associated with that process,
- social goals (the merits of an altruistic system of donations versus a market system),
- safety and quality (both of the source and the biological materials), and
- potential shortages or inefficiencies resulting from a nonmarket system or from changing from a nonmarket system to a market system,

Of these issues, two appear to be central. Issues of equity argue in favor of a system of payments to sources. On the other hand, the added costs of payments to sources and associated costs argue against such a payment system. The factors related to social goals, safety and quality, and shortages do not now offer compelling support either for or against paying sources.

Equity

The equity of a system can be considered from both the production and distribution sides. On the production side, one issue is whether any of the participants are receiving an inequitable return for their services or products. On the distribution side, issues arise regarding access to the services or products by parties who seek them.

Production of Human Biological Materials

It can be argued that some sources are not entitled to the value of the tissues and cells they provide because they do nothing to develop the materials into a valuable product. Diseased tissue, for example, is actually a threat and sources are willing to pay a physician to excise it. By this reasoning, sources perceive such human biological materials as less than worthless, and it is only the intervention of the researcher that gives the tissue value. It is the researcher, therefore, who should legitimately realize the economic value of the tissue.

On the other hand, it could be argued that the sources of tissues and cells are entitled to the value of any resources ultimately derived from them. This view holds that human beings have the right to treat certain physical parts of their own bodies, particularly regenerative parts, as objects for possession, gift, and trade (I). As the commercial potential of biotechnology emerges, this viewpoint could become increasingly relevant. If it is possible to determine or estimate the potential value of biological materials, then as information is distributed, patients, or their agents, will come to know the values of tissues and cells they may possess and they will expect adequate recompense.

Distribution of Human Biological Materials

Researchers desiring human tissues and cells from other researchers, especially at other institutions, must rely on the willingness of other researchers and institutions to cooperate. By custom and ideology, the main incentive to this cooperation is the scientific commitment to the free flow of ideas and materials. To date, the system has operated fairly efficiently. However, as biotechnological products and processes are being commercialized this free flow of information and materials occasionally is being curtailed and in many cases is becoming more formal. There may also be shortages of human tissues and cells for basic research if the incentives to cooperate prove insufficient to motivate researchers to go to the trouble of supplying fellow researchers.

When access to a good is not based on market values, other nonmarket forms of distribution can arise, One unfortunate feature of many nonmarket systems is corruption, sometimes expressed in side payments. The kidney procurement system provides an example. In principle, access to kidneys is determined on the basis of criteria such as length of time on the waiting list, tissue type, need, and age. At least one medical center, however, placed wealthy patients needing kidneys ahead of other patients, with equal needs, on its waiting list (9).

Added Costs

Two types of additional costs would be incurred if sources were compensated for their specimens: the actual compensation to the sources and the cost of administering the program (also called "transaction costs"). These costs could add significant burdens to the process of developing biotechnological products and processes from human tissues and cells.

payments to sources could range from large sums that might be awarded to a handful of sources who have rare tissues to small sums given to the many sources of more common tissues. In either case, because tissues and cells generally are obtained as byproducts of needed medical treatment, most sources are unlikely to refuse access to their tissues and cells on grounds of insufficient payment. Thus, payments will likely easily exceed the amount required to draw forth the services of an adequate number of sources. For this reason, the actual compensation to sources is unlikely to have a large economic impact on the biotechnological uses of human biological materials.

The transaction costs associated with paying sources, however, are likely to dwarf the costs of actual payments to the sources. Studies employing human cell lines, for example, may take years to complete and the final commercial application may be the result of accumulated research based, in part, on a number of different cell lines. The transaction costs incurred by a researcher to maintain records of the origin of all the cell lines leading to the development of a particular cell line with commercial applications could be sizable (6). Furthermore, transaction costs will be incurred for the many uses of cell lines and cells that do not have direct commercial applications (see ch. 2) or even have no value. For instance, it is possible that cells from a specific patient will not successfully become established in culture for technical reasons. Or cells might become contaminated with bacteria. Thus, some tissue samples—probably the overwhelming majority—will never be developed into cell lines and yet would incur significant transaction costs (6).

In addition, because many preliminary experiments must be carried out before a commercial application is discovered or developed, it would be difficult to negotiate a value for a particular human tissue at the time it is obtained. Scientists also would have considerable difficulty establishing the relative value of individual cell lines that lead to commercial application. Some experiments with cell lines will contribute more to commercial application than others, and it would be difficult to assess their value a priori or even after the fact (6).

Many of the cell lines used in research are used for purposes other than developing commercial products. Cell lines are used to test whether particular substances are required for cells to grow or to test the response of cells to exogenous agents. The physiology or the morphology of the cell might be explored, or the cells might be used as a means to propagate viruses. Cells are also used

as model systems for screening carcinogens or teratogens. In addition, cell lines can be used in research from which negative findings contribute to knowledge, but do not result in a commercial product. Finally, many cell lines are used as untreated controls in research as the cell line in question is manipulated. Even if any of these applications resulted in commercialization, it is likely that many cell lines from many patients would have been used in the research. The transaction costs borne by the researcher in tracking the patient origin of the cells used for research collateral to actual commercialization and negotiating their value would be high (6).

Another potential problem associated with a payment system is the harm it could have on information exchange among scientists. As the informal distribution system operates today, cell lines are shared among researchers to confirm research results or to begin new research projects, Negotiations over the transfer and value of property rights for cell lines could reduce the exchange of information among scientists (6).

Another area of transaction costs might also occur—the cost of negotiating between the researcher or physician and patient over transferring property rights. These negotiations would create sizable costs for all parties even if the debated cell line never has a commercial application. For instance, because the patient and the researcher or commercial firm have different degrees of knowledge regarding commercial applications of cell lines, the patient may have to retain knowledgeable third parties or consultants. The principle is the same as hiring a knowledgeable broker to aid the purchase and sale of stocks and bonds (6), An additional factor is that conflicts over the distribution and value of rights may impose additional stress on sick patients.

Social Goals

Social goals also enter into the debate over the merits of a market system versus a nonmarket, or altruistic, system. Arguments in favor of payments for human tissues and cells are based on three lines of reasoning. First, the primary issue can be viewed as a need to save lives; in the case of organs, this need is not met by free donations because too few donations are made so payment is necessary (2). Second, requiring altruism where substances of great value are concerned leads to black market activity and, in fact, the opposite of the desired behavior. Third, altruism alone may not be sufficient motivation to provide enough materials to meet demand. Altruism is not necessarily the primary factor in the decision to donate, for example, when pressure is placed on a sibling or parent to provide a kidney to a relative in need (3,5).

Inherent in most arguments against paying sources for bodily materials is the widespread moral repugnance at the notion of a market in human body parts. This repugnance is most strongly felt in the case of organ sales, where, for example, permanent physical damage to the organ vendor may result. An additional argument relates to the relationship between patient and physician (or researcher). Introducing monetary motives on either part could affect the bond of trust between patient and doctor. On the other hand, the altruistic provision of human biological materials by one person to another in order to save a life may contribute to the bonds that hold communities together (11).

Safety and Quality

The issues of safety and quality probably are not major concerns for most biotechnological uses of human biological materials, Most such tissues and cells are removed in the course of needed surgery for the patient's benefit, so the motives of the source (or payment to him) is not likely to affect either the source's safety or the quality of the biological materials obtained.

In those few instances where provision of human tissues and cells may be discretionary, payment could influence the safety of both the source and the recipient of human biological materials. When the procurement activity itself poses risks to the source, the potential for harm would likely be exacerbated by the promise of payment. Motivated by the promise of payment, for example, individuals might accept a measure of medical risk to provide their kidneys for transplantation, in effect becoming organ mines for wealthier people in need of kidneys. Similarly, when commer-

cial whole blood collectors were in business in the United States there were numerous reported cases of excessive bleeding of donors and lower quality blood.

The quality of human specimens can affect the safety of the recipient. There has been a dramatic increase in scientists' awareness of the potential for viral contamination of human derived biological in recent years. Blood products have transmitted hepatitis and acquired immune deficiency syndrome, and pituitary hormone preparations have transmitted Creutzfeld-Jakob disease to previously healthy recipients. Similar problems can be expected to arise with any tissues and cells of human origin. Viewed from one perspective, commercial pressures could aggravate quality problems, while altruistic systems could help ensure good quality (11). On the other hand, quality may be problematic precisely because there is insufficient commercialization and because of the protection from liability that voluntarism might afford to those people responsible for procuring and dispensing human tissues and cells (8).

Shortages

At present, there is no apparent shortage in the availability of human tissues and cells for biotechnological use. Shortages that may develop in the current nonmarket system are likely to be a function of inherent shortages of a particular type of tissue in the population, or a problem of access and transportation. As the techniques of biotechnology and the biotechnology industry mature, however, this situation may change. In a time of shortages, two mechanisms to draw forth an adequate supply of human tissues and cells for research purposes are: 1) the motivation of sources by altruism (e.g., the possibility that the research will lead to a cure for a serious illness); and 2) payment to sources.

Opponents of payments to sources argue that a market system could exacerbate shortages of needed human samples. They fear that any hint of monetary concerns would discourage donations by eliminating the altruistic motivation and potential sources would hold out for the highest bidder.

Proponents of paying sources, in contrast, argue that if altruism is not the primary motive in providing human tissues and cells, payments to sources might draw forth a larger supply. One example of this was seen in the early years of the whole blood market, when insufficient supply by altruistic donors was supplemented by supplies from paid donors. Nonprofit blood collectors have succeeded in the last 20 years in nurturing the motive of altruism in donors, so now blood shortages, while still occurring seasonally, no longer are a major problem.

Those in favor of payments to sources argue the case for a market system most strongly in the context of cadaver organ donations. Patients are indeed dying because of the shortages of certain cadaver organs, such as livers and hearts. Proponents of payments for cadaver organs argue that such payments would be virtually certain to increase the number of cadaver organ donations. Although there might be some decrease in organ donations from people whose primary motivation was humanitarian, there would likely be a net gain in the number of organs available (2,3).

A market system can be the most efficient method of handling shortages because a free market tends to equate demand and supply at some equilibrium price level. Systems in which prices are regulated at below market values generally suffer shortages, often relying on the altruism of providers or direct coercion to obtain the socially desired result. Nevertheless, where an economic activity is already organized along nonmarket lines and the primary motivation of participants is altruism, and where the demand for the item is fixed, any introduction of market activities may not elicit an increased supply of donations—it may even have the undesired effect of reducing the level of donations. The precise effect that introducing a market system would have on supply of human biological remains a matter of speculation.

MARKET V. NONMARKET SYSTEMS

The present system for developing human-derived commercial biotechnology products contains both market and nonmarket activities, although there are few instances of actual payment among researchers for human tissues and cells. Some researchers and physicians, however, do have consulting relationships with biotechnology or pharmaceutical companies which provide access to tissues and cells derived from humans or products of research involving human materials.

At university research centers, scientists are generally required to share the fruits of their research with the university. Where university researchers and biotechnology companies have a defined research relationship, the potential value of the human biological materials maybe shared. In many cases, however, biotechnology firms do not themselves purchase undeveloped human tissue. Instead, they may negotiate with a researcher who has already developed a cell line, gene probe, or something else of potential value. The structure of these deals can either be direct purchase, royalty agreements, or any of a number of other possibilities.

By the time a biotechnology company enters the picture and begins to negotiate with a researcher, there is generally already reason to believe that the product is of potential value. Since the researcher is an informed negotiator, he is likely to recognize the potential value of the undeveloped tissue. In this situation, the researcher—rather than the biotechnoloy company or human source—may reap the value of the undeveloped tissue. Should a market arise where undeveloped tissue could be bought and sold, any added value that is currently being realized by the researcher, physician, university, or biotechnology company might be recaptured by the source of the human tissues and cells.

At present, there is no widespread movement toward a change in the existing system of free provision of human tissues and cells for use in research and commerce in biotechnology. Stimulus for such a change may come from: 1) judicial decisions resulting from current litigation and any additional cases that might arise in the future, and 2) a greater interest in the uses of human tissues and cells in biotechnology as the commercial profitability of the industry begins to be realized (10).

There are several ways to organize a market system in human biological materials to minimize the problems that might arise. For instance, payments to sources could be made prospectively, before commercialization is a likely outcome of the research. At that time, neither physician/researcher nor patient/subject will have reason to believe that the cells are especially valuable. People who believe that individual specimen sources should share more fully in commercial successes may object to this approach, however, particularly if they are patients (to whom a fiduciary duty is owed). They might prefer to make a large payment to the one fortunate source whose tissues or cells are ultimately incorporated into an invention, but give **no** payment to the majority whose specimens were used and discarded. In a way, this is a form of lottery, raising the possibility that participants would be unduly influenced by the lure of a prize. Payment to one fortunate source also fails to recognize the contributions of those sources whose specimens were also essential components of the research leading to the final invention, even though not a part of the invention itself.

If a prospective payment approach were used, payments could be made **on** the basis of a flat fee to patients and research participants for sale of their specimens. (While many research subjects are now paid for their participation, they are not explicitly paid for their tissue. Patients generally are not paid for their specimens, either.) This prospective payment approach would result in uniform payments to all specimen sources who do not waive payment and would require only minimal paperwork and recordkeeping. The amount of research money needed to make these payments could be calculated from the projected number of patient/subject specimens stated in the research proposal.

Alternatively, payments that vary among sources could be negotiated by the physician/researcher and each patient/subject early in a re-

search project. If negotiated before either party knows whether the specimen has valuable characteristics or whether a commercial product will result, the fee is likely to be low. In cases involving common types of cells, no negotiation at all would be necessary: the researcher would budget a fixed amount per specimen and would refuse to pay more since there are numerous sources of appropriate tissue. However, the researcher would also have the flexibility to pay a higher fee to individuals whose tissues and cells have unusual characteristics. This approach lets market forces affect the transactions between researchers and sources and gives researchers significant discretion in determining an appropriate payment, but it may result in increased time resolving negotiations and perhaps even bidding among competing researchers,

When tissues or cells are purchased from a source at the time of surgical excision, rather than later when a commercial product has been developed, neither the patient nor the researcher knows whether the tissue has value and the tissue's value is its expected value. This expected value depends on the probability that a commercially viable product can be developed. In principle, then, this value could be estimated at the time of excision and the amount, probably nominal, could be paid to the source. The cost would be similar to the costs pharmaceutical companies have incurred in conducting worldwide searches for chemical samples. An alternative form of agreement could provide an initial, nominal amount to the source with the promise of a percentage of any future profits if commercial gain is realized,

If the patient objects to the payment offered and if the researcher does not value the tissue more highly, then no deal would be struck. Since there is no reason to believe a priori that the tissue is unusual, neither researcher nor subject would have concern that something of value was being lost. If the patient has some reason to think his tissue is rare, or if he is a risk taker and unwilling to accept the researcher's statistically fair offer, he would have every right to go to the expense of having the tissue examined himself.

Prospective payment to sources conceivably could be used by researchers engaged in applied research where the objective is to develop a commercially viable product. Much research, however, is not directed toward developing a product. How would researchers engaged in such basic research obtain their tissue? It would clearly be desirable for these researchers to be given tissue by patients at no cost and undoubtedly some sources will be motivated by altruism. The problem for these sources will be whether to trust the researcher when he tells them that the goals of the research are noncommercial. Further complicating the matter is the fact that the researcher may not be able to anticipate where the research will lead and may end up with an unanticipated commercial product after all.

Other approaches could be used to encourage the researcher to reveal his true intentions regarding his research objectives. For instance, a researcher might have two informed consent forms. If he thinks there is commercial potential, then he buys the right from the patient with a commercial consent form. If he thinks that his research has no commercial potential, then he and the patient sign a free-donation consent form. However, the noncommercial consent agreement would contain clauses with penalties for the researcher should his research lead to a commercial product. The beneficiary of the penalty might be the nonprofit university where the research is performed. This structure could provide incentive to encourage the researcher to reveal his best guess as to where the research is likely to lead.

A market system might also operate on the basis of retrospective payment to sources—that is, payment after prospects for commercialization are recognized or realized. Inherent in a system of retrospective payment is the possibility that a source could have unrealistic expectations about the likelihood of commercial success, the degree of profitability, or the relative importance (and value) of the raw material as compared to other aspects of the research and development effort. Retrospective payments could encourage sources to engage in a form of extortion, demanding unreasonable prices for consent to use their specimens, confident that companies have already invested years of research and development (and millions of dollars) in the product. A retrospec-

tive **negotiation** process would require the assistance of attorneys representing both parties.

Neither prospective nor retrospective payment appears to be prohibited by the physician's fiduciary duty to his patient. What is more likely to bean unacceptable breach of that duty would be a failure to disclose information about commercial potential or provide for some fair system of compensation.

Any design of a feasible system of payments to sources would require further information and analysis. A useful and relevant model to consider where unpaid and paid **donations** exist side-by-side is the blood and plasma donation system currently operating in the United States. For most of their activities, the whole blood and plasma sectors operate in rather different spheres. However, the largely nonprofit whole blood sector (which relies on unpaid donations) and the largely commercial plasma sector (which pays its sources) do compete in the sale of finished plasma products. This example of a hybrid nonprofit/commercial organization of economic activity **may** prove instructive in considering payments to sources of human tissues and cells for biotechnology uses.

THE ROLE OF NONPROFIT ORGANIZATIONS

Nonprofit organizations may play an important role in the marketing of human tissues and cells, just as they have in the procurement and distribution of blood and organs. A clear and unequivocal nonprofit organization for procuring and distributing human biological materials may be necessary to preserve the trust between sources and recipients and ensure the continued provision of human specimens for research. Providing tissue to an assuredly nonprofit organization may allay the suspicions of sources who want to support basic research but who do not want any one person to benefit financially from their contribution.

Nonprofit institutions often step in to fill the need when markets fail to deliver a sufficient quantity of certain goods that are clearly in demand. In many instances, it is a public nonprofit institution—the government—that provides the service. The government also can intervene less directly to regulate markets by controlling prices, requiring that providers be licensed, or declaring certain goods to be nonmarketable.

Private nonprofit enterprises* are the form of organization most relevant to the provision and receipt of human tissues and cells. There are two general ways to finance nonprofit organizations. Some nonprofits, such as CARE or the American Red Cross, receive their income primarily in the form of grants or donations. These organizations are called donative nonprofits. In contrast, commercial nonprofit) such as many hospitals and daycare centers, receive their income primarily from the sale of services. In the case of donative nonprofit) the patrons are the donors. The patrons of commercial nonprofits are the customers receiving the services (i').

What characteristics of an activity make it more suitable to nonprofit than for-profit organization? Why, for example, do people wishing to provide food assistance to impoverished persons overseas donate money to an organization such as CARE when they could engage the services of an experienced commercial grocery distributor? The main reason appears to be that with certain products consumers are unable to evaluate accurately whether the promised good or service has been delivered. In such circumstances the market may provide insufficient discipline for a profit-seeking producer. The key element seems to be trust. In the preceding example, the source does not know and is not in contact with the party receiving the food. Consequently, the source would have great difficulty verifying that the grocery distributor had fulfilled its part of the agreement. The source therefore needs a trusted organization to fulfill the agreement. Because of the legal constraints under which it must operate, a nonprofit is likely to serve in that role better than its for-profit coun-

[1]It is important to note that if profits are defined as the excess of revenues *over* costs, then private nonprofit enterprises also earn profits. The difference between profit and nonprofit institutions lies in whether the earnings are distributed to those who have control over them.

terpart. Nonprofit enterprises therefore can be seen as a response to a particular kind of market failure.

Commercial nonprofits, such as hospitals, differ from donative nonprofits in that the bulk of their income is in the form of payments made by patrons in direct exchange for services. Since the recipient of the service is also the source, the type of market failure described in the food aid example (resulting from the distance between the source and the recipient) does not occur, The consumer, however, may still prefer to deal with a commercial nonprofit firm rather than a for-profit firm because the services sought are of such a nature, or provided under such circumstances, that the consumer must necessarily entrust a great deal of discretion to the producer—a discretion that the consumer may be in a poor position to police.

It can be expected that when the profit motive is eliminated, a price is paid in terms of incentives. Nonprofit firms are often slower in meeting increased demand and less efficient in their use of inputs than for-profit firms. Furthermore, despite the limitations placed on them, some nonprofit probably do distribute some of their net earnings through inflated salaries and perquisites. Nonetheless, where the consumer is in a poor position to judge the services he is receiving, any for-profit organization of production and distribution is likely to rate second best to a nonprofit enterprise despite the expected efficiency losses.

Alternatives to Nonprofit Institutions

Many goods and services are not easily evaluated by consumers and yet are commonly provided by for-profit firms. Medicinal drugs are one example, as are the services of doctors, lawyers, automobile mechanics, and television repairmen. But these services are generally small and discrete and consumers can switch suppliers relatively easily if they become dissatisfied. Furthermore, special institutions have arisen to provide additional protection for consumers. Doctors and lawyers, for example, must be licensed and are subject to some supervision and discipline from their respective professional organizations. Drugs prescribed by doctors are subject to Federal regulation for safety and efficacy, Nonprofit distributors are likely to arise where such protective mechanisms have not developed or are inadequate.

Regulation of for-profit organizations can help maintain the strengths of for-profit organizations while limiting their flaws. This regulation can either be imposed by the government or can be imposed contractually through free negotiation directly between the parties. Limits on rates of return, for example, are often imposed on natural monopolies such as public utilities. Under such regulation, prices are restricted to a level that permits the firm's shareholders to earn a specified rate of return on their investment while protecting the public good. Firms subject to regulation of their rates of return can be viewed as special cases of nonprofit organizations.

Nonprofit Institutions and the Government

Nonprofit organizations have four principal inherent weaknesses:

- Nonprofit institutions may be severely limited in their ability to raise capital since they are unable to sell equity shares. They must rely instead on donations, retained earnings, and debt for capital financing.
- While commercial nonprofit entities must legally use the entire sum paid by the consumer to produce services, the consumer has no assurance that the services he pays for will be provided to him. Patients in private hospital rooms, for example, often subsidize ward patients through their high room and board charges.
- Profits are an important motivator of management efficiency, and nonprofit institutions might be expected to be somewhat less vigilant in eliminating unnecessary expenses than their for-profit counterparts.
- The profit motive is a powerful incentive for ensuring that firms enter an industry and expand when the demand for the industry's product increases. Stripped of this motive, nonprofit organizations might be more sluggish in responding to changed demand.

In response to these problems, a number of services commonly provided by nonprofit organizations are frequently also undertaken by government, such as education and hospital care. The taxing power of the government gives it a strong advantage over nonprofits. Government organizations also have access to capital and a degree of accountability not necessarily found in all types of nonprofits.

At least one nonprofit corporation that procures and distributes human biological materials is supported by the Federal Government. The National Disease Research Interchange (NDRI); Philadelphia, PA) is a nonprofit corporation founded in 1980 to advance the procurement, preservation, and distribution of tissues and organs for research (figure 7-l). It was established by the National Institutes of Health and the Pew Memorial Trust in response to requests from the biomedical community for regular access to human tissues in order to corroborate animal studies. Since 1981, NDRI has distributed more than 20,000 tissue samples to research laboratories in the United States. Researchers are asked to reimburse NDRI for tissues. Typical charges range from $10 for eye tissue (e.g., iris) and $200 for pancreatic tissue to variable amounts for intestinal tissue (4).

Interaction of For-Profit and Nonprofit Institutions

Different types of human tissues and cells are now used for a variety of nonprofit and profit purposes. Human samples are used by the pharmaceutical industry to produce drugs, by transplant surgeons to transplant vital and nonvital organs, and by hospitals to transfuse blood. In each instance, the human material can be considered a factor in a production process.

Four key features of these markets, however, distinguish human biological materials from many other goods and services. First, there is no necessary connection between the value of the human biological material and the price of the material. By law, certain types of human materials, such as organs for transplantation, are not permitted

Figure 14.— Promotional Material, National Disease Research Interchange

SOURCE: National Disease Research Interchange, Philadelphia, PA.

to be sold; by fiat, therefore, the price of these resources is zero. Diseased human tissues and cells used in research have also, by custom, been free to investigators. For healthy tissue that researchers recruit from sources, compensation varies, but usually covers only time and inconvenience. Second, there may be nonprice regulation of who may provide human biological materials, how the transaction is to occur (e.g., through informed consent), and who receives the final product. Third, even when the price of human specimens is zero, there are a significant number of persons with altruistic motives who willingly offer their tissue. Fourth, many of the organizations involved in producing the final product are nonprofit organizations.

This distribution scheme is a direct consequence of the extraordinarily high symbolic value placed on human tissues and cells that often requires suppliers of these materials to be motivated by altruism alone. However, while altruism is required to be the motivator of supply for many types of human biological materials, no such requirement is made of other participants in the production process, which may at times include for-profit actors. To control this production process, some regulation of prices, rates of return, and distribution may be imposed. The regulation can take several forms and involve public and private nonprofit organizations.

As described in chapter 5, the law is unclear in defining the rights relating to human biological materials. In the case of organs for transplant, the law only specifies that the source does not have the right to sell it. The law does not specify who may in fact reap the economic value of the organ. Legislating that the source does not have the right to sell an organ and that it can only be transferred at a price of zero does not, however, reduce the value of the organ to zero. What it does, instead, is transfer the value of the organ from the source to other parties.[2] These could be the owners of the other factors of production, the entity that produces the final product, the purchasers or recipients of the final product, or all of these parties. How the parties share in the value of the zero-priced factor depends on the supply and demand conditions prevailing in the market and on the degree of control the producer has over the market.

[2] Suppose, for example, that a market for transplantable kidneys existed. There are three parties to the transaction—the donor, the surgical/hospital team, and the recipient—and they are able to accomplish the transaction at prices agreeable to all. The amount required by the family of the kidney donor to proffer the kidney is $50,000, the amount required by the surgical/hospital team to bring forth its services is $100,000, and the kidney recipient is willing to pay $150,000. Suppose further that a law is passed requiring all transactions in kidneys to be gifts, thereby prohibiting the kidney donor's family from selling the kidney and reaping its economic value of $50,000. Who will now realize this value? The intent of the legislation was that the value of the kidney be transferred as a gift from the kidney donor to the recipient, with the transplant ultimately costing the recipient only $100,000. Yet, because nothing is done to ensure this outcome, a different outcome is possible. Depending on the conditions of the transplantable kidney market, it may be possible for the surgical/hospital team to realize the value entirely by charging the recipient $150,000. Of course, this transfer of the value of the kidney from the donor to the surgical/hospital team would be subject to a broad ethical debate.

SUMMARY AND CONCLUSIONS

The traditional relationships between sources and researchers, and among researchers at different institutions, have been informal and involved free exchange or transfers. Today, however, the techniques of biotechnology and the potential for profits and scientific recognition have introduced issues of commercialization into various uses of human tissues and cells.

At present, there is no widespread sentiment favoring a move toward a market system for human tissues and cells. Two principal factors will likely determine whether a change occurs in the current system of free donation of human tissues and cells for use in biotechnological research and commerce. A change could arise from: 1) judicial decisions in present or future cases under litigation, or 2) a greater public interest in the uses of human biological materials in biotechnology as the commercial profitability of the biotechnology industry begins to be realized.

From the point of view of equity, a market structure has a strong appeal because it eliminates the

potential windfall realized by parties receiving the free donation. On the other hand, the magnitude of the transaction costs associated with payment to sources may be sufficient to deter any forays into a market structure. perhaps the most likely development is that there will be little practical difference between a market and nonmarket structure for handling human tissues and cells: because of the great uncertainty about the value of any one sample of human tissues or cells and the small percentage of useful tissues and cells, the market price for untested tissue will be nominal.

For the present nonmarket system to continue to operate successfully, a clear and unequivocal nonprofit organization of procurement and distribution of human tissues and cells may be necessary to preserve the trust between sources and takers and to ensure the continued supply of donations of human biological materials for research purposes.

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