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Genetic fix: should we dare, who will decide?

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As we begin to face the issues raised by the new biomedical technologies—genetic manipulation, prolongation of life, organ transplantation, drug control of behavior—professionals from many disciplines are seeking ways to manage such problems. In Congress, Sen. Walter Mondale (D, Minnesota) has championed a bill that calls for establishing a two year commission to study such complex ethical questions. The group would be composed of 15 professionals in fields ranging from law to medicine, from theology to technology, and would be financed to the tune of about $1 million a year. Although the bill was endorsed unanimously by the ninety-second Congress in December 1971, it was not acted upon by the time the session ended. It was recently resurrected, however, as Senate Resolution 71, and is again pending. Following are several fine examples of the good that such a commission could do. These further reinforce my view that the tools of more effective and responsive societal guidance are sorely needed. The "commission forerunners" are limited in scope, support, funds and staff, but their contributions illustrate the need for a full-fledged, representative, adequately endowed and staffed commission.

The Hastings report on mass screening

The Institute of Society, Ethics and Life Sciences, often referred to as the Hastings Institute (it is located in Hastings, New York), has issued a report on the ethical and social issues raised by screening large numbers of people for genetic disease.[1] Daniel Callahan, the director of the institute, explained, "The group that formulated the guidelines for mass screening was mostly opposed to the whole idea but favored a cautious and careful approach."

The report provides a set of criteria for assesssing the merits of a particular screening program, criteria that seem very sensible and self-evident, but nevertheless were often ignored by those who set up mass screening programs before the report was available, and even now, continue to be overlooked.

The report's basic criterion is that no program be set up before adequate testing procedures are available, "to avoid the problems that occurred initially in phenylketonuria (PKU) screening." Mandatory screening for PKU was required as of 1971 in 43 states, although the test is not 100 percent reliable. Many children were identified wrongly as having the disease, and quite a few who did have it passed the test as healthy.

The sickle cell testing program, recently introduced in great hurry without a thorough review by any authoritative, representative board, also fails by the Hastings criteria. The program tests schoolchildren at a time when the disease very often has already struck, or newborns, a stage when detection is difficult. Testing couples who are considering having a child would make more sense, although such programs are difficult to administer.

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Besides asking for safe tests, the Hastings group also called attention to a *risk of possible psychologic or social injury*. The question is: How harmful will the "labeling" of affected persons be? As the result of mass screening tests, people will be labeled as carriers of sick genes, which may harm their social standing and their view of themselves. Social scientists vary on the degree of importance they attach to the ways people come to view themselves and to be viewed by others. (For instance, who is branded a "criminal" and who is "law abiding"?) However, social science data leave no doubt that in some areas labeling has serious consequences.

Regarding the issue at hand, if young children are told that they have an XYY chromosome structure, which occurs in about one of every 1000 males born and which has been repeatedly reported as being associated with a predisposition toward seriously deviant behavior,[2] they could easily begin to view themselves as having a criminal destiny. Moreover, if parents are told that their child carries the XYY gene, many may suspect that normal assertive moves of the child are manifestations of criminal potential; consequently, they may push their youngster—whatever the influence of genes—into an aggressive and ultimately criminal personality and way of life.

Beyond parents, teachers and self-image, such labeling is likely to affect the attitudes of practically everyone who knows about a person's genetic test scores. This is no longer a hypothetic consideration. The undesirable consequences of which the Hastings group warned have already made themselves felt. In 1971 the state of Massachusetts, responding to the demands of black community leaders and their white supporters, passed a law requiring that all school age children be tested for the sickle cell trait, which is relatively common among black children (it hits one out of every 500)[3] and very rare among other groups. The trait is harmless by itself, but when both parents have it there is a 1 in 4 chance that their child will have the disease.[3] Before long, a dozen states had followed Massachusetts.

The results of the tests, presumably kept only on school records, have increasingly been used to brand carriers of the disease as poor employment risks[3,4] and poor risks for life insurance.[4] Recently, many black people started wondering whether or not the undesirable consequences of the test outweighed its benefits, especially as there is yet no known cure for the illness.

Related questions must be asked about other genetic tests that are being increasingly used, promoted or sought. Screening programs for carriers of the gene for Tay-Sachs disease was started among Jewish people in Baltimore in 1971. A screening test for Cooley's anemia, relatively more common among people of Mediterranean descent, is being developed. A new genetic test will soon predict susceptibility to emphysema,[5] while tests for dysautonomia (that hits one of every 1500 Caucasian babies),[6] are being actively sought.

Dozens of other tests are likely to follow. If they are to do more good than harm, there must be a mechanism for reviewing the programs before they are enacted. The Hastings criteria, formulated by a private group, do not command the support and power of criteria formulated by a public authority.

The Hastings report also declares that it is necessary to accompany a new program with *carefully designed and executed public information programs*. Experience shows that the public—even some doctors—confuse the sickle cell trait with the disease of sickle cell *anemia,* which occurs only when *both* parents have the trait and then only in approximately one out of four of their offspring.

Various developments have made the hospital structure obsolescent

This particular Hastings report (other ones are being formulated) is not comprehensive. For instance, it does not deal with the question, how safe is safe?—an essential issue for new tests—or how can safety be tested before screening is done en masse? Second, because the report is based chiefly on deliberations and dialogue, it shows little benefit from empirical input to back up its points. Nevertheless, it is of immense value, if only because it provides all those who will listen with a detailed list of what must be taken into account before screening programs are initiated.

The main source of the weakness in the Hastings Institute's efforts is not in the group itself, but in the absence of an authority in Washington. No private group can possibly have the necessary national visibility and clout. If similar efforts were undertaken by a national commission, composed of leading authorities in their respective fields, and representative members of the community backed up by congressional status and staff, the results would command a much greater following. Even if such a national body were formed, of course, private groups

would still have to continue their deliberations. These issues must be as widely discussed as possible. A continuous dialogue of many divergent viewpoints is essential.

Another development illustrates how, without the benefit of a review mechanism, the nation tries to cope with its need to review and form health care policy. The American Hospital Association issued a "bill of rights for patients," first in November 1972 and again in January 1973, to its 7000 member hospitals.[8] The 12 point bill was formulated by a committee appointed by the trustees of the AHA and discussed by its regional advisory boards, composed of hospital administrators. Consumer representatives also were involved.

Several hospitals adopted the bill, and at least two institutions (Boston's Beth Israel Hospital and New York's Martin Luther King Jr. Health Center) now provide their own version of it to patients. But most hospitals did not embrace it. And yet, the charter is of great value. Both technologic and social developments have rendered the existing hospital structure virtually obsolescent and in need of a new definition of the relationship between patient and institution.

If the patient must be unconscious, the right to refuse service is not his

The fact that those who administer hospitals took the initiative in preparing the bill is hardly surprising, since no community-based body exists to assume such duties. However, it must also be noted that the charter, lacking public hearings of the kind a congressional committee would have generated, was not subject to wide discussion or publicity. It is no wonder, then, that the charter is easy to ignore. Moreover, the fact that it was formulated by a board composed chiefly of those in power will hardly reassure the more activist "consumer" groups. (Actually, Dr. Willard Gaylin went so far as to state that the document "perpetuates the very paternalism that precipitated the abuses."[9])

Like most documents formulated chiefly to express a sentiment and to affirm a position the AHA bill is long on general statements and short on attention to specifics, and the latter are essential if it is to be widely applied. For example, the bill's statement, "The patient has the right to refuse treatment . . ." is qualified by the phrase "to the extent permitted by law," as though the law provided a clear guideline. Actually, if the patients themselves have the right to insist, for instance, that life-extending machines be turned off, they must be conscious when they so choose. But then their action would be tantamount to suicide. On the other hand, if the patient must be unconscious beyond recall before the machines can be turned off, the right to refuse service is not his. Who then exercises the right? One doctor? Two? Three? With, or without, consultation of the next of kin? Under what medical conditions?

The Medical Society of the State of New York suggested adding the clause "irrefutable evidence that biological death is inevitable,"[10] but such evidence may come long before a person loses consciousness. The society also suggested adding the phrase "[the choice] is the decision of the patient and/or the immediate family with the approval of the family physician."[11] But what if there is no family physician? And should not at least one other doctor, not so deeply involved, be consulted? Clearly the patient's bill of rights leaves these and many other issues unresolved.

If the authors of the bill had expressed greater concern with procedure they would have been more aware of the need for local ethics boards to review decisions made to "turn off" lives; the need for national and international boards to formulate guidelines; and a research staff to study the actual results of various steps undertaken in order to apply them in future deliberations. (There are review committees inside hospitals but these, with few exceptions, are limited to physicians only and only to those in that hospital.)

This example will have to stand for scores of others, all of which resemble the bill of rights as a document that, although well-intentioned and encouraging, has not been sufficiently "processed" or provided with the mechanisms, e.g., local review boards, for thorough implementation.

The abortion ruling

Another example of the need for ethical clarification of national decisions emerged on January 22, 1973, when the U.S. Supreme Court overruled all state laws that prohibit or restrict a woman's right to obtain an abortion during her first three months of pregnancy.

This act turned a matter that was previously controlled by the government over to individual choice. It also left it up to agencies other than the government to inform patients of the risks involved

in abortions, which are now estimated to be undergone by 1.6 million American women each year.[12] The risks are not trivial. While an abortion performed by a well-trained physician during the first 12 weeks of pregnancy is said to be safer than a tonsillectomy or an actual birth (the death rate for abortion is 2 per 100,000 patients; for tonsillectomy, 17; for pregnancy, delivery and postnatal period, 20),[11] in an abortion done in the second trimester[12] complications are three to four times more likely to arise.[11]

It is not the Supreme Court's business to follow up such a ruling as its one on abortion, to arrange the necessary public education campaign, to advise those who either use no contraceptives or unreliable means not to rely on abortion for birth control, or to caution those who want an abortion not to put it off. This, it might be said, is the job of another department. But a public authority could insure that matters the court leaves undone will indeed be looked after by the appropriate agencies.

Next the ruling involves an empirical matter. By getting the state out of the business of regulating abortions in the first 12 weeks of pregnancy, the Supreme Court, also, in effect, allows *any* M.D., not just a gynecologist, to perform an abortion. Several physicians, including Drs. Morton A. Schiffer and Bernard Nathanson,[13] suggested that it would have been better to limit the abortion practice to qualified doctors and hospitals and clinics appropriately equipped and staffed.

The issue here is not whether they or the justices are right, but that no systematic procedure is available to bring pertinent medical data before the court before it rules. The court will hear experts as "friends of the court," but this procedure is occasional rather than systematic; further, it tends to attract individuals, voluntary associations or civic groups, and only rarely institutionalized "think tanks" with their data banks and research staffs. The court, in these matters, is simply obsolescent; like Congress, it follows the same procedures used a half century ago before the knowledge explosion (when one or a few experts knew more than you needed to know about a particular area) and before computers existed.

Medical review boards

Another important development came from a different direction. In October 1972, the Congress enacted a bill widely referred to as H.R. 1, a large package of amendments to the Social Security Act. The numerous clauses of the bill run to 940 pages, and among these is Section 249F, barely known to the general public. The amendment calls for creation of Professional Standards Review Organizations (PSROs). The basic idea is to subject hospitals and other health units to outside review, not only of use of funds—the typical accountability expected and required of anyone who uses public money—but also of professional, that is, medical, matters. The main motive seems to be to reduce the number of the poor and the aged who are sent to hospitals by doctors, and whose care is charged to the taxpayers. (The amendment calls for checking nonemergency cases with the PSROs before admission.) At the same time, the provision opens the door, in principle, to outside, or perhaps even public, scrutiny of what doctors are doing.

The law is rather vague as to who is to provide these outside review boards, but the basic assumption is that physicians will oversee physicians. Even this is quite innovative because many doctors feel they need no overview and that if review is to take place, it should be by their peers, that is, by people who are equal to them in status. These are usually members of the same hospital staff or local medical society who are often beholden to each other. Actually, peer reviews are often surprisingly strict. But don't we need more?

> Casting a vote is no longer enough to secure a responsive government

The PSROs that are to be established throughout the United States by January 1, 1976, go one step farther by calling for "outsiders" to review insiders and act as a kind of medical audit. But, if these outsiders are chosen by the local medical societies, they may not be as independent as they should be of those they are to review.

Above all, it seems desirable that the PSROs should include not only doctors but also community representatives and "specialists" in societal and ethical matters to make sure that consumer, social and moral issues be taken into account and to counteract any self-serving tendencies of doctors.

The PSROs represent an important spot at which to enter the closed professional system, because, unlike community advisory boards set up around hospitals or comprehensive health planning agencies, PSROs will be able to control the flow of taxpayers' funds and hence carry much more weight.

As the ninety-third session of Congress started in early 1973, Senator Mondale reintroduced his bill. The Senate might approve it again, but no one can make any predictions about the House.

Also, early in 1973, Sen. Edward Kennedy (D, Massachusetts) held extensive hearings on an issue that a health ethics commission, had it existed, would have examined: the conditions under which experimentations with human subjects can be permitted. The press was again filled with gory reports about this or that ethical violation, but paid little attention to the more general questions concerning how any such regulations could be implemented. But progress was made during the hearings as two colleagues called for the establishment of a more advanced, more potent health-ethic commission than the Mondale bill outlines.

A proposal for independence

Dr. Jay Katz, adjunct professor of law and psychiatry at Yale University, suggested that a permanent body be established to regulate all federally supported research involving human subjects. Such a board, Katz said, should be independent from the government, since much experimentation that requires supervision is carried out in government owned laboratories. He wanted the President to appoint the board, and suggested that "its members should come from many disciplines, including representatives from the public at large," and that the board should have "regulatory authority," that is, it should formulate policy and set up the needed regulations and mechanisms to promote them.[14]

Note that the concern in the Kennedy hearings focused on those relatively few persons who are subjects in experiments. My feeling is that we are all "subjects"—the millions of women who take the pill, the millions of people who do not receive genetic counseling, the millions exposed to food additives that may well be carcinogenic, and so on. We need to develop a more effective review mechanism of all illness-producing and illness-preventing forces.

It is up to us all to see that the reforms will not stop here. The efforts to form effective and responsive overview mechanisms cannot be advanced by a few senators and professors. Their future depends on citizens being informed and alerted to the regulatory functions—beyond the popular "human interest" stories—and on the general public, led by active groups of citizens taking on this issue as they took on those for peace in Vietnam, civil rights and pollution control.

Action is needed on several fronts. On the national level, Congress must be urged to set up a permanent National Health Ethics Commission that includes members of various disciplines, not just medicine, and representatives of the public backed up by a research staff.

Locally, each state, city and town needs a health ethics board to oversee its hospitals and clinics, its medical healers and researchers.

Individually, citizens and their leaders need to inform themselves about new medical and genetic developments and the issues raised by their effects on matters of illness and health, life and death. The people must be the guards of the guards. Professionals cannot be left to be guided only by their own lights and those of their peers.

Only when the citizens learn more about the ways that society may be directed to respond to their needs, and only when they act armed with this new knowledge rather than following the interest or preconceptions of the few, will the country be managed for their well-being. Casting a vote once every few years is simply no longer enough to secure a government that is responsive to the people and truly concerned with their future. An informed and active citizenry, dealing with national and local governments, as well as with administrative boards of health institutions, has become a prerequisite not just for a sound democracy but for a healthy body, a normal child, and indeed, for life itself.

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