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Annual Review of Law and Ethics

Band 4 (1996)

Herausgegeben von
B. Sharon Byrd
Joachim Hruschka
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Vorwort

Die meisten Beiträge zu diesem Band des *Jahrbuchs für Recht und Ethik* sind aus einem interdisziplinären und internationalen Symposion zum Thema „Biotechnological Challenges for Law and Ethics“ hervorgegangen, das die Herausgeber des Jahrbuchs in der Zeit vom 5. bis 11. August 1995 im Study and Conference Center der Rockefeller Foundation in Bellagio, Italien, veranstaltet haben. An diesem Symposion haben Mediziner, Philosophen, Juristen und Wirtschaftswissenschaftler teilgenommen, und zwar: *Arno Baltes* (Erlangen), *B. Sharon Byrd* (Jena), *Ellen Wright Clayton* (Nashville), *Lloyd R. Cohen* (Arlington), *Raphael Cohen-Almagor* (Haifa), *Thomas Crofts* (Frankfurt an der Oder), *Angelika Drescher* (Erlangen), *Roger B. Dworkin* (Bloomington), *Gonzalo Herranz* (Pamplona), *David Heyd* (Jerusalem), *Joachim Hruschka* (Erlangen), *Lawrence Hunsicker* (Iowa City), *Jan C. Joerden* (Frankfurt an der Oder), *Frances Myrna Kamm* (New York), *Matthias Kaufmann* (Halle), *Matthias Kettner* (Essen), *Kamiar Khajavi* (London), *Rita Kielstein* (Magdeburg), *Hans-Martin Sass* (Bochum), *Albrecht E. Sippel* (Freiburg), *Deborah Spitz* (Boston), *Peter Stanglow* (Frankfurt an der Oder). Für die Finanzierung dieses Symposions danken wir der Rockefeller Foundation, dem Land Brandenburg, dem Stifterverband für die Deutsche Wissenschaft und der Dr. Alfred Vinzl-Stiftung.

Neben der Ergänzung der Symposions-Ergebnisse durch weitere Beiträge namhafter Wissenschaftler und Wissenschaftlerinnen sind im Abschnitt „Advance Directives in Multicultural Perspective“ die Ergebnisse eines gleichnamigen Forschungsprojekts aufgenommen, das an der Georgetown University, Washington, unter der Leitung von Prof. Dr. Hans-Martin Sass durchgeführt und von der Volkswagen-Stiftung finanziert wurde.

Für die Unterstützung bei der Drucklegung dieses Bandes des Jahrbuchs danken die Herausgeber insbesondere Frau *Ayke Darius* am Institut für Strafrecht und Rechtsphilosophie in Erlangen, Frau *Susen Pönitzsch* am Lehrstuhl für Strafrecht und Rechtsphilosophie in Frankfurt an der Oder und Frau *Heike Frank* im Verlag Duncker & Humblot in Berlin.

Der fünfte Band (1997) des *Jahrbuchs für Recht und Ethik* wird sich vorwiegend dem Thema „Kants *Metaphysik der Sitten:* 200 Jahre Tradition in der Unterscheidung von Recht und Moral“ widmen.

Die Herausgeber

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Problems Posed by Genetics for Law and Ethics: American Policies

Ellen Wright Clayton

We live in an age of intense interest in genetics. It is now possible to detect many diseases that for some time have been thought of as genetic, disorders such as chromosome anomalies and metabolic diseases that are inherited as simple Mendelian traits. The more dramatic development has been the recognition that many people have mutations that place them at much higher risk than the general population of developing relatively common diseases such as cancer and cardiovascular disease that previously had not generally been thought of as "genetic." The ability to treat these disorders and to avert the effects of predisposing alleles has also grown, although not nearly so quickly. The purpose of this paper is to explore the forces in the United States that govern the development and dispersion of these tests and to ask what role personal choice will have in how these tests are made available and used.

The focus of this paper will be on the use of genetic tests to provide information about the present and particularly the future health of the individual who is being tested. These tests range from metabolic assays that have been used for years to diagnose genetic diseases such as phenylketonuria to newer techniques, such as linkage and direct mutation analysis, that can be used both to diagnose current illness as well as to detect mutations in genes that predispose the individual to develop diseases such as cancer. The use of genetic tests for reproductive decision making raises some different issues that will be discussed in a separate section of this paper.

I. Characteristics of Scientific Research and Health Care in the United States that May Affect Development and Use of Genetic Tests

In order to understand the specific issues posed by genetics, it is necessary first to examine the complex system of health care in which this information will be used. A number of forces exist, many of which work in opposition to each other.

1. Factors Favoring the Spread of New Technology

There is tremendous interest in expanding knowledge and in bringing new tests and technology to market. The directions taken in research depend on a complex set of interactions between public and private funding entities and investigators. Turning first to the relationships between public funding agencies and researchers, for many years, billions of dollars of public funds have been devoted to basic and applied research. Of this money, the three billion dollars currently being spent over 15 years under the auspices of the National Center for Human Genome Research to sequence the genomes of humans as well as of other organisms represent only a fraction of the publicly funded research that seeks to determine the role that inheritance plays in the development of disease. Which projects are funded depends on initiatives taken by the agencies and on the evaluation of proposals by peer reviewers who bring their own sense of what constitute worthwhile questions to the table. Thus, the current emphasis placed on genetics is shaped by and shapes the questions pursued by investigators, whose own careers in turn depend on their ability to obtain funding and to demonstrate the relevance of their research.

The public's primary interest in promoting research has always been the expectation that increased knowledge will improve health. To this end, the results of research undertaken with public funds have been used by the private sector to bring technologies to market. This public-private partnership has received increasing emphasis in recent years and is now an explicit part of many projects.[1] Private entities have also conducted or funded a great deal of research themselves. These private efforts are driven by the need to achieve profits and so must seek to serve the needs and demands of patients and health care providers. These demands in turn can be affected by numerous factors, including marketing by private companies, the general enthusiasm of the media for reporting new discoveries in genetics, and the desires of physicians to provide and patients to receive the latest technologies, many of which enter the market with relatively little regulation. The resulting demand appears to be virtually insatiable.

2. Factors that Tend to Limit Patients' Options Regarding These Technologies

a) The Limited Role of Informed Consent – A Vision of Patient Choice Largely Unfulfilled

In the wonderland of this technology, the naive observer might look at the requirements of informed consent in medicine and non-directive counselling in genetics and conclude that patients are truly free to decide which technologies to use.

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[1] This sort of collaboration is exemplified by the National Action Plan for Breast Cancer, a public-private collaboration to promote the development of optimal approaches to cure breast cancer.

The true impact of the doctrines of informed consent and non-directive counselling on medical practice, however, is much more limited than might appear on superficial inspection. Honest assessment reveals that thoroughgoing conversation and shared decision making between patients and physicians occurs infrequently.[2] The possibility, and even the desirability, of non-directive counselling is increasingly called into question.[3]

The commitment by physicians to patient choice was always fragile at best. Informed consent and non-directiveness are true newcomers in the field of medical ethics, arising only in the latter half of this century. Notions that patients should follow doctors' orders are far more deeply ingrained in medical practice. The language of medicine is full of terms such as "compliance" that convey this picture of unequal authority within the physician-patient relationship. In reality, physicians generally play an important and even dispositive role in determining what options patients consider and elect.

b) The Roles of Efficacy and Third Party Payment

Factors external to the physician-patient relationship also limit patient choice. One of these forces is the process by which the impact of health care is assessed, which often ignores the role of patients' desires. Outcomes research, for example, measures such endpoints as death, morbidity, and health care costs. Psychosocial consequences of medical interventions typically are not included in the calculus. In such analyses, a patient's choice to pursue something other than the least costly or most life-prolonging intervention would be viewed as an adverse outcome even if the patient's choice of care were more concordant with his or her wishes and values.

Another factor is the growing role that third party payment and, to a lesser extent, the government as provider plays in limiting patients' options. As noted previously, clinicians have a large role in deciding what interventions to pursue. For much of this half of the century, clinicians' decisions were relatively unrestrained and generally were rather insensitive to cost because payers reimbursed for what the doctor ordered, a factor that may have made patients happy but that many cite as contributing to the dramatic increase in health care costs in the United States.

This has begun to change. Third party payers in the United States increasingly exclude some tests and treatments from coverage or limit the percentage of the charges covered. Similarly, national and state governments offer some interventions and not others. It is here that the emphasis on efficacy has its main effect.

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[2] *Jay Katz*, The Silent World of Doctor and Patient, New York: Free Press, 1984.

[3] *Angus Clarke*, "Is Non-Directive Genetic Counselling Possible?", 338 Lancet 998 (1991).