

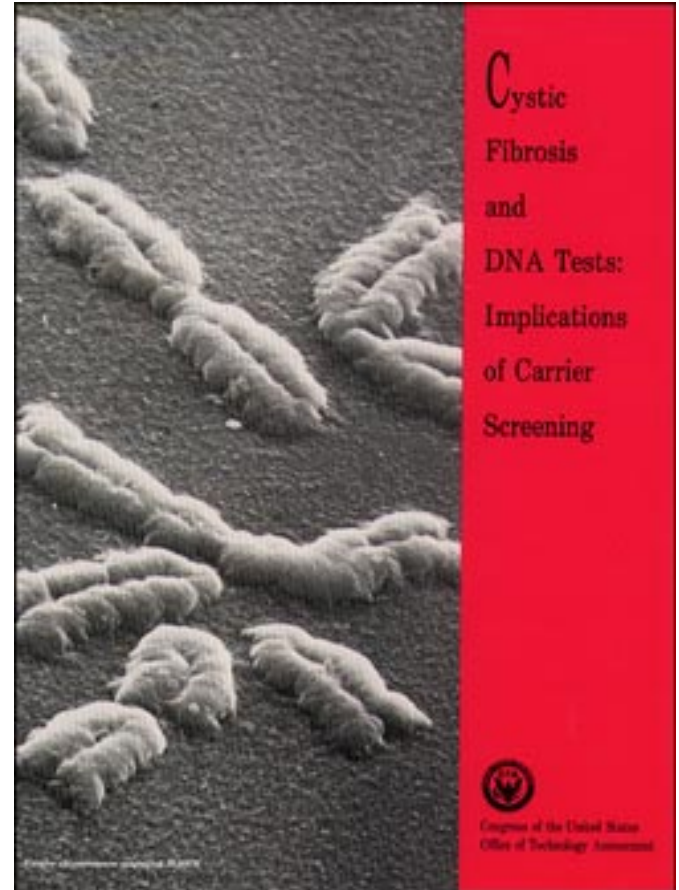
*Cystic Fibrosis and DNA Tests:
Implications of Carrier Screening*

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Foreword

Nearly 10 years ago, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research speculated about the potential ethical, legal, and social consequences that might occur if a test were available to identify carriers for cystic fibrosis (CF)¹, the most common, life-shortening, recessive genetic disease in American Caucasians. Time and technology have moved forward. The mysteries of biological inheritance—first explored by Austrian monk Gregor Mendel over a century ago—are yielding to modern science. A CF carrier test is no longer a prospect; it is now reality. The test's existence raises broad societal questions about the use of genetic information. And beyond CF tests, expectations of scores of additional genetic tests loom on the horizon as scientists in the United States and abroad pursue an ambitious mission to map and sequence the entire human genetic blueprint, or genome.

Ongoing interest in the Human Genome Project, as well as concern about the potential magnitude and effects of routine CF carrier screening, led the House Committee on Science, Space, and Technology and the House Committee on Energy and Commerce to request an evaluation of the scientific, clinical, legal, economic, and social considerations of widespread carrier screening for CF. The study was also endorsed by Representative David R. Obey. *Cystic Fibrosis and DNA Tests: Implications of Carrier Screening* presents a range of options for action by the U.S. Congress in six broad policy areas:

- genetics education and the public,
- genetics training and education of health care professionals,
- discrimination,
- clinical laboratory and medical device regulation,
- instrumentation to automate DNA diagnostics, and
- integration of DNA assays into routine clinical practice.

OTA prepared this report with the assistance of a panel of advisors and reviewers selected for their expertise and diverse points of view. Additionally, hundreds of individuals cooperated with OTA staff through interviews or by providing written material. These authorities were drawn from academia, industry, and professional societies, as well as Federal and State agencies. OTA gratefully acknowledges the contribution of each of these individuals. As with all OTA reports, however, responsibility for the content is OTA's alone.

In publishing this report, OTA concludes that the value of the CF carrier test is the information it provides. No one can estimate in common terms what it means to an individual to possess information about his or her genetic status, especially when the value concerns reproductive decisionmaking. As our knowledge of the human genome increases, what we do with information such as CF carrier status will depend on the perceptions and beliefs of all Americans. We believe that public understanding of this new knowledge and its implications is necessary for its wise and thoughtful application.



| JOHN H.-GIBBONS
Director

¹President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Screening and Counseling for Genetic Conditions: The Ethical, Social, and Legal Implications of Genetic Screening, Counseling, and Education Programs* (Washington DC: U.S. Government Printing Office, 1983).

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NOTE: OTA is grateful for the valuable assistance and thoughtful critiques provided by the advisory panel members. The panel does not, however, necessarily approve, disapprove, or endorse this report. OTA assumes full responsibility for the report and the accuracy of its contents.

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