HEALTH AND LIFE SCIENCES AT THE OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS

Roger C. Herdman, M.D.

Clyde J. Behney, M.B.A.

Just over 10 years after the U. S. Congress added the Office of Technology Assessment (OTA) and the Congressional Budget Office (CBO) to its existing support agencies—the General Accounting Office (GAO) and the Congressional Research Service (CRS)—few appreciate the scope and magnitude of their research, assessment, and auditing activities. Their annual combined budgets in FY 1984 of about $350 million involved a staff of over 6,000. Their activities, both analytic and informational, range across the entire spectrum of national interests, from the economic and social to the scientific and political. The resources devoted to these efforts indicate congressional awareness of the increasing complexity of matters before it.

An important contributor to this complexity is technology. During any session, Congress may make decisions regarding environmental health hazards, ballistic missile defense, organ transplantation, nuclear power, or recombinant agricultural research, to mention a small sample from recent agendas. No legislator could be familiar with or have time to research the scientific and technological aspects of these major national issues. Yet thoughtful approaches to policy require understanding the influences of existing and emerging technology.

How can representatives of the public, mostly without advanced scientific and technical training, adequately consider technological complexities? One solution was to establish an Office of Technology Assessment. As Congress declared in 1972, when this occurred:

> Technology continues to change and expand rapidly . . . it is essential that (its) . . . consequences . . . be anticipated, understood and considered. . . . The Federal agencies presently responsible to the Congress are not designed to provide the Legislative Branch with adequate and timely information, independently developed. . . .

Each congressional agency is set up differently. OTA, for example, is supervised by a 12-member Congressional Board, structured to evenly balance the two major parties and houses of Congress. Board approval of OTA's work agenda insures that projects, which must be requested by Congressional committees or Board members, are carefully considered and meaningful to Congress before being undertaken. The budget given OTA to support these activities in fiscal year 1985 is $15.5 million.

OTA has from the outset given attention to health issues. Indeed, its first report was on the subject of bioequivalence of drugs. In time, what began as attentiveness to health as a subject became formalized, first to a stand-alone Health Program, and then, in 1978, to a Division of Health and Life Sciences that included the Health Program, along with ones in Food and Renewable Resources, and the Biological Applications (Figure 1).

https://doi.org/10.1017/S0266462300003810 Published online by Cambridge University Press

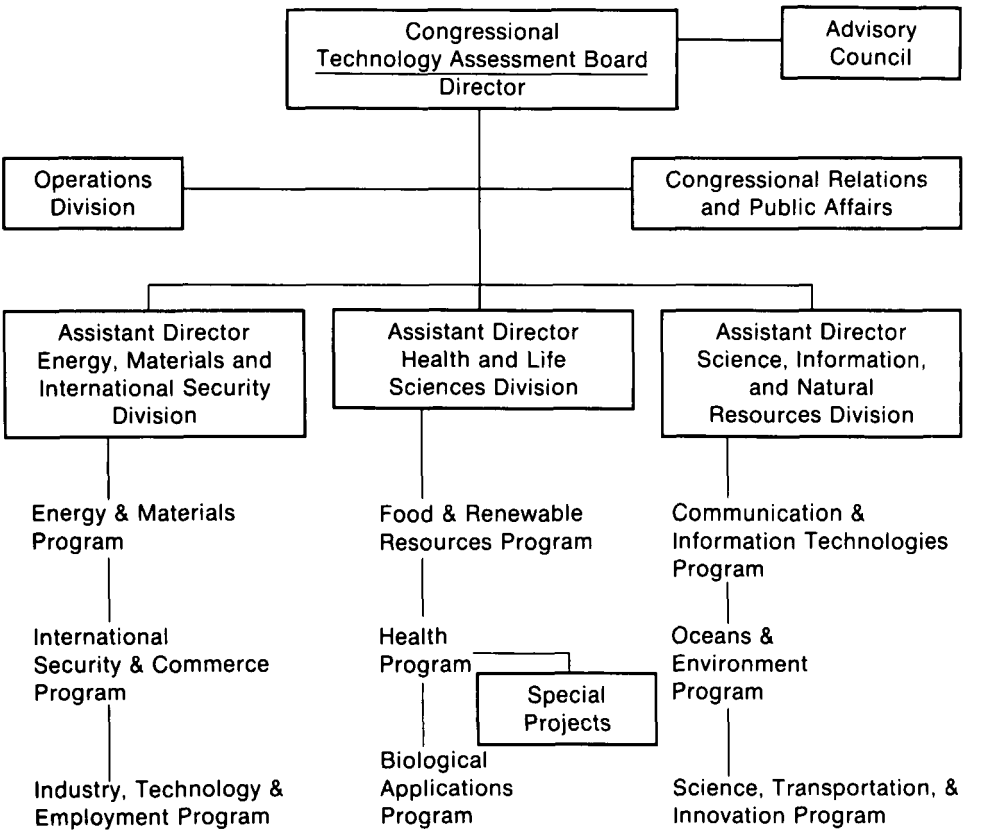

Figure 1. OTA organization chart.

We have pondered whether the Health and Life Sciences Division as an operational entity within OTA has been responsive to critiques by the National Academy of Engineering and National Academy of Sciences in the late 1960s that technology assessment was "critically deficient," ignored externalities, failed to provide early warning, and even if properly pursued whether it could be useful in congressional decision making. We have asked ourselves if we are fulfilling the congressional statutory requirements. Are the agenda setting, the production and dissemination of output of OTA consistent with a long-range plan, and day-to-day objectives relevant to that plan?

The statutory language is clear: "The basic function of the Office shall be to provide early indications of the probably beneficial and adverse impacts of the application of technology and to develop other coordinate information which may assist the Congress." OTA's basic mission was intended to be technology assessment at its best, not only reactive, but proactive. Thus the Health and Life Sciences Program not only reaches out to project-specific advisory panels representing national expertise and constituencies but also, because it is possible in a clearly defined area such as health, it takes the step, unusual for OTA, of having a standing Health Program advisory committee (Table 1). Its definition of tech-

https://doi.org/10.1017/S0266462300003810 Published online by Cambridge University Press

Table 1. Health Program Advisory Committee

Sidney S. Lee, M.D., Chair
President, Milbank Memorial Fund

H. David Banta, M.D.
Consultant
World Health Organization

Robert Evans, Ph.D.
Professor
Department of Economics
University of British Columbia

Rashi Fein, Ph.D.
Professor, Department of Social Medicine and Health Policy
Harvard Medical School

Harvey Fineberg, M.D., Ph.D.
Dean
School of Public Health
Harvard University

Patricia King, J.D.
Professor
Georgetown Law Center

Joyce C. Lashof, M.D.
Dean
School of Public Health
University of California, Berkeley

Alexander Leaf, M.D.
Professor of Medicine
Harvard Medical School
Massachusetts General Hospital

Frederick Mosteller, Ph.D.
Professor and Chair
Department of Health Policy and Management
School of Public Health
Harvard University

Norton Nelson, Ph.D.
Professor
Department of Environmental Health and Management
School of Public Health
New York University Medical School

Robert Oseasohn, M.D.
Associate Dean
University of Texas

Nora Piore
Senior Advisor
The Commonwealth Fund
New York, NY

Dorothy Rice
Regents Lecturer
Department of Social and Behavioral Sciences
School of Nursing
University of California, San Francisco

Richard Riegelman, M.D., Ph.D.
Associate Professor
George Washington University
School of Medicine

Walter Robb, Ph.D.
Vice President & General Manager
Medical Systems Operations
General Electric
Milwaukee, WI

Frederick C. Robbins, M.D.
President
Institute of Medicine

Rosemary Stevens, Ph.D.
Professor
Department of History and Sociology of Science
University of Pennsylvania

nology—the practical application of knowledge—provides sufficient breadth and flexibility to allow the widest reasonable exploration of subject matter.

While an array of projects dealing with impacts of biology deserve attention, Congress and the Health and Life Sciences Division emphasize major applications of science, in particular to food and health. The emphasis flows from reasons Congress has for requesting studies. Public concerns often turn into congressional interests. For example, public anxiety over the use of animals in biologic testing

and experimentation leads relevant committees to ask how necessary the LD 50 (a test for toxicity) is, what effect banning animal use in cancer research would have on its progress or cost or would products be safe without animal testing. The Division can provide scientific evidence and policy options on the issue to committees, based on advice from animal welfare groups, industry, and the scientific community. At other times, Congress wants to know how well its programs are working or what could be done to move a program toward certain objectives, as when OTA (and the Division) was asked to consider rationales to restructure Medicare physician compensation. Sometimes Congress wants future projections, as in the Division's study of emerging technologies to detect mutational change and their potential application in evaluating or regulating toxic hazards, and the Agent Oranges and occupational exposures of the future.

The recent output of the Biological Applications Program exemplifies the broad scope of our work on the impacts of biology. It includes studies on neuroscience, commercial biotechnology, genetic testing in occupational disease, world population and fertility planning technology, impacts of applied genetics, technology and aging, alternatives to animal use in testing and experimentation, and reproductive hazards in the workplace. The list exemplifies OTA's attempt to respond to current issues, look at emerging ones, focus itself on individual technologies, and evaluate groups of them with widespread influences.

The health program, the largest and one of the oldest in OTA (in existence for nine years), will now be discussed in greater depth and used as an example of the way OTA engages in setting agendas, performing assessments, and disseminating results. The program's internal strategy is based on such practical matters as financial resources, staff expertise, and relevance of work to OTA's mandate. OTA does not conduct or contract for new investigational research in the field. (In a single exception, OTA did contract for some new work on mutagenicity of saccharin.) It seeks to discover, aggregate, and analyze information, viewpoints, and constituent positions from published work and from participants and observers of the technologies being assessed.

Early on, the Health Program decided that in view of the state of the art of technology assessment, work should focus on defining and extending methods and systems for performance of this function. At that time, as the NAS study noted, technology assessment tended to ignore externalities, such as social costs and benefits, and failed to provide early warning of deleterious effects. The result of this original strategy was a series of studies on: opportunities for assessing medical technology, efficacy and safety of medical technologies, the implications of cost-effectiveness analysis, strategies for medical technology assessment, postmarketing surveillance of prescription drugs, and randomized clinical trials. These studies expanded the scientific understanding of technology assessment, pointed out remedies to deficiencies, and made contributions to specific technical areas of interest to Congress. In retrospect, this strategy has been a good one; surely one of OTA's responsibilities was to insure that methods and systems had been properly developed and defined.

In the meantime, although individual technological issues, coverage decisions, and safety and efficacy evaluations have been, and still are, more the province of executive and other noncongressional institutions, the program has undertaken studies of particularly interesting technologies that exemplify general issues of

national import or are themselves of significance. Such studies have often been offshoots of, and associated with, major assessment projects. Examples include an array of technologies from pneumococcal vaccine, CT scanners, and joint prostheses to cyclosporine A. This work forms a background to a continuing emphasis on reports devoted to larger analyses of research development and diffusion of health-related technology.

This work on individual technology can be compared with the work of the Office of Health Technology Assessment (OHTA), a part of the executive branch's National Center for Health Services Research, and exemplifies the difference between the executive and congressional approach. OHTA assessments will focus on safety, efficacy, maturity, reasonableness and the like, and result in a recommendation that will most likely mean actual reimbursement or not by the federal government. In short, its work is specific and oriented to regulatory policy. OTA's assessments deal more with broad policy implications as well as safety and efficacy. Thus its work leads to information and advice for general policy initiatives more than specific decisions on individual technologies.

Lastly, the program has developed a series of efforts in three major areas: computers and information, environmental and occupational health, and financing and structural issues in health care. This has resulted in reports on medical information systems, MEDLARS, computers and medical information, on saccharin, environmental cancer risks, EPA premanufacture notice policies, occupational health and safety controls, and on Medicare and technology, DRG evaluation methods, physician compensation and supply, Indian health, and so on.

The relative intensity of work on the various subjects has fluctuated over time. The subject of information and science and computers has been of continued interest, but not very active recently. On the other hand, continuing consumption by the health care system of increasing fractions of gross national product, and mounting federal deficits, have stimulated a great deal of thought and activity on the part of Congress and thus of OTA. In the case of environmental and occupational health, and associated science and high technology, continuing emphasis has led to the creation of a separate Special Projects staff administratively supported by the Health Program. This has served to recognize OTA's commitment to the importance of this subject, and the need for an identified institutional focus. The nature of this work often involves this staff in coordination and cooperation with other programs and divisions working on specific environmental issues within the agency.

As already noted, external factors have had a major influence on the strategy, tactics, and resulting agenda. Among these factors have been: an increase in client congressional committees and thus in diversity and number of requests, a greater propensity for Congress to ask for short response work and thus studies of smaller size and greater immediacy, and finally, congressional use of the program (and OTA) to perform oversight functions and to respond to new statutory imperatives. Clearly, Congressional mandates to select and oversee the Prospective Payment Assessment Commission, or to review and monitor Veterans Administration studies on veterans exposed to Agent Orange, or nuclear weapons directly impose tasks and tactics; also in some cases legislative language has actually specified study content, as in the 1984 Deficit Reduction Act section regarding physician payment systems.

The net result is that the Health Program (and OTA in general) contributes its advice to Congress and receives back sometimes agreement and sometimes expressions of other needs. Since statutorily mandated studies are expressions of confidence in OTA work and rarely come without some advance notice and opportunities for discussion, they should not be viewed as impositions even though they may circumvent the normal control mechanisms of the OTA Board.

The work of the Health Program, as of all OTA programs, falls into major assessments requiring 1 to 2 years to complete and obligating $500,000 or more of budget, and lesser projects such as workshops, background studies, technical memoranda, and other special responses. OTA's congressional board approves initiation, monitors budget, and authorizes release (but does not approve content) of work costing over $30,000. Projects are also differentiated in that assessments provide policy alternatives and other options while smaller efforts are primarily informative. In no case are actual courses of action recommended.

How are assessments, once approved by one or another of the ways described, carried out? There are a number of important steps. A preliminary review of literature and information from knowledgeable experts defines the operational resources likely to be available and allows a framing of the questions and scope of work more precisely. Consultations with congressional committees, and in particular CBO, CRS, and GAO staff, insure that congressional concerns will be accurately addressed and without duplication of effort from other congressional agencies. It is also often advisable to coordinate with nongovernmental bodies, such as the Institute of Medicine. The outcome is a careful initial definition of work to be done; time, staff, and budget to do it; and an initial sense of human resources available nationally for the work.

Considerable effort is expended in assembling a panel of advisers for an assessment. These panels are not expected to reach a consensus or approve results. They are expected to represent relevant constituencies and areas of expertise, to insure that assessments are complete, accurate, and fairly representational of viewpoints, and include reasonable options for Congress. Panels generally include 10–20 individuals and meet three to four times over the course of preparation of any assessment. Panel members and (at least as many and often considerably more) other experts or interested parties review assessments before release. For these reasons, considerable effort and thought go into constituting each panel. Supplementing panels further (since federal employees may not serve on panels) are liaison staff from congressional committees, the three sister Congressional offices, and executive branch agencies. This group, in particular the executive agency staff, can often provide major informational input. OTA studies benefit substantially from the willingness of the executive, almost without exception, to devote considerable time advising and providing such data as may be available. The NIH is perhaps the best example of such cooperation.

The last key step, outside of the actual performance by program staff of the work of discovering, gathering, organizing and analyzing the information and producing the assessment report, involves decisions with the advice of the panel and other advisers on segments of work to be performed by non-OTA consultants and contractors and the identification of the best available experts to perform these tasks. As a general rule, over half of each assessment budget is devoted to such activities. The vast bulk of the actual report, however, is written by OTA staff.

Table 2. Health and Life Sciences Division Selected Publications

1985 (Projected)

Assessments
Technology and Indian Health
Physicians and Medical Technology
Techniques for Determining Human Mutation Rates
Designing an Evaluation of HCFA's Prospective Payment System
The Changing Structure of American Agriculture
Alternatives to Animal Use in Testing and Experimentation
Reproductive Hazards in the Workplace

Case Studies/Background Papers
Costs of Nurse Practitioners
Mental Health Services for Children
Africa Tomorrow: Technological Alternatives to Food Aid
Technologies to Benefit Agriculture and Wildlife
Artificial Intelligence

1984

Assessments
Health and Safety Controls in the Workplace
Blood Policy and Technology
Federal Policies and the Medical Device Industry
Status of Biomedical Research for Tropical Diseases
Medical Technology and the Costs of the Medicare Program
Technologies to Sustain Tropical Forest Resources
Commercial Biotechnology: An International Analysis
Technology and Aging in America

Case Studies/Background Papers
Medical Technology and DRGs
Human Gene Therapy
Technology, Renewable Resources and American Crafts
Sustaining Tropical Forest Resources: Reforestation of Degraded Lands and U.S. and International Institutions
Innovative Biological Technologies for Lesser Developed Countries
Impacts of Neuroscience
Studies of: NMR, Dialysis Equipment, Urinary Incontinence, the Boston Elbow, the Contact Lens Industry, Wheelchairs, Alcoholism Treatment, Digital Subtraction, Angiography, Continuous Peritoneal Dialysis, ICUs, Implications of Lengths of Stay in Hospitals, Therapeutic Apheresis, and Hearing Impairment

1983

Assessments
Water Related Technologies for Sustaining Agriculture in U.S. Arid/Semiarid Lands
World Population and Fertility Planning Technologies: The Next 20 Years
Genetic Testing and the Prevention of Occupational Disease

Case Studies/Background Papers
Scientific Validity of Polygraph Testing
Impact of Randomized Clinical Trials
EPA's Pre-Manufacture Notices
Water Related Technologies: Selected Foreign Experiences
Plants: The Potentials for Extracting Protein, Medicines and Other Useful Chemicals
Agricultural Post-Harvest Technology

Table 2. (*cont.*)

1982
Assessments
Medical Technology Under Proposals to Increase Competition in Health Care
Strategies for Medical Technology Assessment
Technology and Handicapped People
Post Marketing Surveillance of Prescription Drugs
U.S. Cropland and Rangeland Productivity
Case Studies/Background Papers
MEDLARS and Health Information Policy
Technology Transfer at NIH

Space is not available for detailed descriptions of the performance of assessments here. These methods are reviewed in depth in the Health Program publications referred to earlier. In general, though, it is not sufficient to describe what a technology is and how it works. An assessment means, and Congress needs to know, how a technology fits into society; all the "costs" and all the positive and adverse impacts need exploration. This means immediate and long-term impacts, and it certainly includes a technology's legal, social, political, and ethical impacts. Technologies are not conceived, developed and applied in isolation; they are a part of a civilization of great complexity and can have an array of effects, large and small, immediate and far reaching, seen and unforeseen. An assessment is, as a necessary result, a complex, uncertain, and difficult undertaking requiring considerable thought and planning.

For the Health and Life Science Division's programs (and OTA) to fulfill their mission, their products must reach an audience. The immediate audience must be the relevant committees of Congress. But Congress is a public body, and these products need to be available to the general public and interested parties in academia, industry, and other organized groups. Availability through the Government Printing Office, which publishes all OTA reports, does not insure wide distribution. Dissemination of information is enhanced by a number of other activities. Among these are availability through the National Technical Information Service (NTIS). Also, as reports are issued either OTA or requesting members or committees of Congress hold press briefings or issue press advisories. Program staff write derivative articles for the general and scientific literature. Staff frequently provide testimony at congressional hearings based on assessment results, give interviews for the various media, or speak at scientific meetings or in other forums. Finally, continually updated lists of publications and work in progress are provided to all Members of Congress, as well as a network of interested citizens across the nation. In this way the work of the Division and OTA is made widely known.

And, in this way the work can make a difference in national affairs. Sometimes the result of OTA's work is that Congress does not act; perhaps a study on genetic screening in the workplace shows that the science is not yet up to useful application. Sometimes the result is a discrete action, as when OTA's work on tropical diseases helped to continue funding for the Gorgas Memorial Laboratory or work on Agent Orange improved management of major studies. And sometimes the result is harder to discern when the information and options form a knowledge

base which, with other information, lays the groundwork and gives a sense of confidence to address legislation dealing with health and agricultural programs.

Although this discussion has focussed on health and the Health and Life Sciences Division, the conclusions are germane to OTA as a whole. The objective has been to describe the activities of a unit of one of the four congressional offices, to familiarize the reader with the kind of work that is done and how it is carried out (see Table 2 for recent and projected output). Although OTA's immediate task is to serve the Congress, implicit and appropriate in the enabling Technology Assessment Act of 1972 was the intention that the products would be generally known and useful to the public.