Appendix E.— Legal Status of CEA/CBA

Most of the existing statutory authorities that guide Federal health-care-related agencies allow the agencies to use or support CEA/CBA. Recently, however, two legislative initiatives—Public Law 95-623 establishing the National Center for Health Care Technology (NCHCT) and the National Health Planning and Resources Development Amendments to Public Law 93-641—placed special emphasis on the use and support of CEA by NCHCT and by health systems agencies (HSAS). Although these laws are not mandates, they are explicit suggestions to do CEA or CBA studies. The language of Public Law 95-623 calls for NCHCT to "give appropriate emphasis" to cost effectiveness (among a number of other criteria) while conducting and supporting research on health care technology. Similarly, the health planning amendments state that cost effectiveness should be one of the criteria that HSAS use while carrying out their mandate to review the appropriateness of existing facilities (see ch. 7 for a detailed discussion). These two laws are as close as Congress has come to requiring a health-care-related agency to perform or support CEA or CBA studies as part of its mission.

At the other end of the legislative spectrum from these two laws are the statutes that authorize and guide the efforts of the Food and Drug Administration (FDA). FDA has traditionally interpreted its mandate as excluding or strongly discouraging the formal evaluation and incorporation of economic costs and social benefits in its regulatory proceedings (127a). Although, FDA has done a small number of costs and benefits type comparisons of proposed initiatives, those analyses were conducted in response to executive orders calling for: Inflationary Impact Statements (E.O. 11821, 1974), Economic Impact Statements (E.O. 11949, 1977), and Improving Government Regulations (E.O. 12044, 1978). Those orders applied to executive agencies that proposed major regulations, i.e., regulations having an annual impact on the economy of $100 million or more or causing a major increase in costs or prices for individual industries, levels of government, or geographic regions. Any agency that proposed a regulation falling into one of these categories was required to examine the costs and benefits of the proposed action.

One section of the food additive amendments to FDA's mandate, usually referred to as the "Delaney clause," (The Food, Drug, and Cosmetic Act, 21 U. S. C., sec. 409c3a, 1976) explicitly prohibits the balancing of risks and benefits in a proposed regulation of a food additive that has been shown to be carcinogenic (127a). The inflexible language of this amendment has stimulated a number of legislative proposals to repeal or alter the "Delaney clause," and/or alter FDA's authorizing legislation to allow or require the balancing of risks and benefits in proposed regulatory or rulemaking initiatives. [1] The most prominent of the initiatives is the bill introduced in the 96th Congress as the "Drug Regulation Reform Act of 1979."

The legal status of CEA and CBA in the decisionmaking processes of other agencies of the Federal Government is in a much greater state of conflict, confusion, and flux. In the past 10 years, numerous court rulings have attempted to define and clarify the role of CEA and CBA in the decisionmaking processes of regulatory agencies. Increasing congressional attention is being focused on the potential usefulness of CEA and CBA techniques, especially as they pertain to the decisionmaking efforts of several regulatory agencies. Over 65 bills were introduced in the last two Congresses that would require various agencies to incorporate CEA, CBA, or risk-benefit techniques into their formal decisionmaking procedures (600). For many agencies, the legislation would simply formalize a CEA/CBA process that is now informal. In a number of other agencies, a formal or informal process of using CEA/CBA does not exist. In any case, many of the proposed changes would make explicit that which past legislation has left vague and open to judicial and agency interpretation.

In the past decade, a number of health, safety, and environmental laws have added to the Federal Government's involvement in the regulation of highly controversial areas of society and business. [2] In many instances, the specific purpose and intended outcomes of the legislation were inadequately defined after the general goals were established. In addition, the types of procedures allowed or required to initiate agency action, or the level of "evidence" required to support a given initiative, were left vague in the authorizing legislation. In many cases, these things were left vague with good reason. The uncertainties

[1] Most of the reaction was stimulated by the use of the "Delaney clause" to initiate a ban of saccharin, an artificial sweetener used extensively in this country. For a detailed analysis of the technical issues involved in the proposed saccharin regulation, see *Cancer Testing Technology and Saccharin* (466), prepared by OTA.

[2] Included among these laws are (127a): 1) Safety and Health Act (Public Law 91-596); 2) Consumer Product Safety Act (Public Law 92-573); 3) Amendments to the Pesticide Act (Public Law 92-516, Public Law 94-140, Public Law 95-396); 4) Solid Waste Disposal Act (Public Law 94-580); 5) Toxic Control Act (Public Law 94-469); 6) Medical Device Amendments (Public Law 94-295); 7) Safe Drinking Water Act of 1977 (Public Law 95-190); 8) Clean Air Act Amendments of 197? (Public Law 91-604, Public Law 95-95). Perhaps the most well known is the National Environmental Policy Act of 1969— NEPA (U.S.C. sec. 4321 et seq., 1970). It has been responsible for a significant number of legal challenges regarding the decisionmaking methods of a host of Federal agencies.

involved in the issues, the imprecise nature of the best available data, and many other factors required that the authorizing statutes remain flexible.

The broadly worded statutory language, however, has left the door open for procedural challenges, differing interpretations of the laws, and litigation. The practical result of this problem is that the courts have been repeatedly forced to clarify and define what is required of the agencies in establishing a rule or regulation. Numerous court cases have challenged the decisionmaking procedures of the Environmental Protection Agency, the Consumer Product Safety Commission (CPSC), the Nuclear Regulatory Commission, the Occupational Safety and Health Administration (OSHA), and others.[3] One of the results of this litigation is an increasing pressure on the agencies to include more formal and explicit costs v. benefits comparisons in their decisionmaking and evidence-gathering procedures.

Neither the courts nor Congress are totally unfamiliar with CEA or CBA techniques. The Federal courts have been concerned with agency actions using costs and benefits since the early 1940's (526). Congress has required the Corps of Engineers to justify water resource projects with cost-benefit calculations since the late 1930's. Recent years, especially the last 10, however, have witnessed an increasing awareness of the use of CEA/CBA in the regulatory decisionmaking process. Enactment of the National Environmental Policy Act (NEPA) in 1969 and the issuance of the executive orders mentioned above marked the beginning of significant judicial involvement in the area of procedural and substantive review of CEA/CBA use in the regulatory process.

Despite a decade of litigation, conflict, and debate, the role of formal CEA/CBA in the regulatory process still remains ill-defined and unclear in many, if not most, decisionmaking situations. The courts have had, and continue to have, a difficult time in producing a coherent body of law that establishes uniform standards of judicial review in this area (this is especially true for NEPA-related issues). They have not been able to reconcile the conflicting standards that have been placed into various statutes that indirectly require many agencies to balance the social costs and benefits of their regulatory initiatives (526). The courts review agency initiatives with three basic criteria in mind: 1) Did the agency conform to the procedures set out in the law? (the procedural test); 2) Was the cost-benefit comparison arbitrary or capricious~ (a substantive and due process test); and 3) What is the "substantial evidence on the record as a whole?" (also a substantive test). Putting these criteria into practice has not always been easy or successful. The limitations of the methods of CEA/CBA, the vagueness of the legislative language and intent, the differing interpretations of the level of sophistication or rigor required in the cost-benefit comparisons, and the reluctance of the courts to substitute their judgments for agency expertise have contributed to the continuing confusion that surrounds the use of formal CEA/CBA techniques in the decisionmaking process.

A number of recent and pending Federal District Court rulings may be able to give further indications of the direction in which the courts are moving with respect to requiring CEA or CBA techniques in the decisionmaking process. One should keep in mind, however, that the courts' opinions may be specific to an agency, may be subject to later reinterpretation by a higher court, or may be applicable only to the specific statutory wording on which the rulings turn. OTA is not suggesting that these opinions will have significant impact on the health-related agencies examined in this assessment. As judicial signals that may very well broadcast to a number of executive agencies the extent to which formal CEA/CBA techniques might be used or required in their decisionmaking procedures, however, these opinions are worthy of note.

The litigation many observers may be watching most closely is the "benzene case" now before the Supreme Court.[4] That case involves a number of issues, but the primary focus is on two questions: 1) Is OSHA required to use a costs v. benefits comparison to support its proposed standards? and, 2) If so, is the analysis OSHA claims to have performed adequate to support its decision? A lower court answered yes to the first and no to the second, and overturned OSHA'S proposed benzene standards for the workplace (20). The lower court held, in part, that OSHA had failed to properly or adequately compare the benefits expected from the proposed regulation to the anticipated costs of compliance to determine if a "reasonable relationship" existed.[5]

[3] This appendix does not attempt to provide a comprehensive discussion of the development and interpretation of the case law that guides this area of regulatory behavior. At best, an attempt is made to touch on the recent judicial highlights that have built upon earlier rulings. For a more complete analysis of the courts' involvement in this area, see references **41, 42,** and **526.**

[4] *1ndustria/ Union Department, AFL-C1O v. American Petroleum, et al. No. 78-911)* and *Marshall u American Petroleum Institute, et al. (No. 78-1036).*

[5] The language in OSHA'S mandate (Occupational Safety and Health Act, 29 U .S.C. sec. 652 et seq. (1975)) requires that OSHA has the obligation to enact only standards that are "reasonably necessary" or appropriate to provide safe or healthful workplaces and that standards dealing with toxic materials be "feasible, " OSHA must determine whether benefits expected from a standard bear a reasonable relationship to costs imposed by the standard. The Circuit Court rulings in the CPSC and OSHA cases hinge on these phrases; "reasonably necessary, " "feasible," and whether benefits expected bear a "reasonable relationship" to the costs expected.

Circuit Court rulings involving CPSC were cited by the court in the benzene case to illustrate the evidence requirements that the court felt are necessary to determine if a proposed initiative is "reasonably necessary" when the proposed standard's benefits are balanced against the costs, or burden, of compliance with the standard. [b]The Supreme Court will determine if OSHA'S statutory language requires it to go beyond the data it has used in the past and follow the guidelines established by the CPSC rulings for the use of costs v. benefits comparisons in its decisionmaking procedures.

The available evidence strongly indicates that there is mounting legislative and judicial pressure to formalize the use of CEA/CBA in many decisionmaking areas in the Federal Government. To date, most of this pressure has been focused on the regulatory agencies. It is uncertain at this time if these pressures will expand into the health care system.

[b]The rulings cited in the OSHA opinion as guiding the determinations were:

1. *Aqua Slide 'N' Dive* v. *Consumer Product Safety Commission*, 569 F. 2d. 832 (5th Cir. 1978). and
2. *D. D. Bean & Sons* v. *Consumer Product Safety Commission*. 574 F. 2d 643 (1st Cir. 1978).

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