STATEMENT
OF
THE AMERICAN COLLEGE OF PHYSICIANS
BEFORE THE
SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES
June 7, 1984

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

The American College of Physicians (ACP) is pleased to have this opportunity to appear before you today to outline our views on technology assessment and the roles of the public and private sectors in its performance. My name is Edwin P. Maynard, III, MD, FACP, the Chairman of the College's Health and Public Policy Committee. I am an internist in active practice at the Massachusetts General Hospital and Assistant Clinical Professor of Medicine at Harvard Medical School. With me today is John R. Ball, MD, JD, the Associate Executive Vice President for Health and Public Policy of the ACP.

The College was founded in 1915 to uphold high standards in medical education, medical practice, and medical research. Today the College represents over 60,000 doctors of internal medicine, specialists in related non-surgical fields, and physicians-in-training. Approximately one-third of our members are Fellows of the College (FACP), a designation based upon their having met standards of scholarship and contribution to the science and practice of medicine beyond their eligibility for specialty board certification in internal medicine. The ACP membership includes private practitioners providing primary health care; medical specialists in such fields as gastroenterology, endocrinology, oncology, and cardiology; medical educators; and researchers. It is the largest organization of general internists and allied subspecialists in the world.
The statement we present today outlines the views of the American College of Physicians on the roles of the federal government and the private sector in medical technology assessment and reflects the College's own long history and extensive activity in assessing the procedures and technologies used in internal medicine.

Our statement focuses on four questions we see as central to the technology assessment debate:

1. What is the role of the federal government in medical technology assessment?
2. What is the role of the private sector in medical technology assessment?
3. Are there appropriate activities in technology assessment that are not now adequately carried out?
4. How may the functions of the public and private sectors best be structured to be most productive?

Let me begin by outlining the kind of activities in technology assessment that it would seem, from a professional medical society's perspective, to constitute an appropriate federal role.

Role of the Federal Government in Technology Assessment

On a conceptual level, government has several responsibilities to the public that it serves, among which are the protection of the public purse and the assurance of the free flow of information on which people can make more informed choices. From this conceptual base, it seems valid that the federal government have a role in medical technology assessment. Functions within that role would appropriately be three: (1) determining, to the extent
possible, the safety and effectiveness of the technologies for which government pays, directly and indirectly, so that the federal government -- the largest single payer for health services -- may itself be a prudent purchaser; (2) supporting the production of information, most specifically the basic science of technology assessment methodologies; and (3) disseminating information on the safety and effectiveness of medical technologies.

The issue of the federal government's role as prudent purchaser of health services, particularly of technologies, is one of which this subcommittee is well aware, but it is worth a moment to review certain historical points in the evolution of that role. From 1965, marking the enactment of Medicare, until about 1977, the federal government had no structured process for deciding what technologies, new or old, it paid for under the Medicare program. Medicare reimbursement, for the first dozen years of that program, was based on a rather pragmatic, albeit unwritten, interpretation of the law: that is, that if sufficient billings were received by the program for a technology, that technology became, in essence, "reasonable and necessary," and thus eligible for reimbursement. There was no internal process to assure that the technologies themselves were of value, and no working process to determine the appropriateness of their application.

Beginning early in 1977, and culminating later that year in the formation of the Office of Health Practice Assessment in the Office of the Assistant Secretary for Health, and in the development of written procedures for giving medical advice to the Medicare program, at that point newly in the Health Care Financing Administration (HCFA), the Public Health Service
began to structure the first step of a two-step process. That process, consisting of first, a medical decision as to the value of a technology, and second, a financing decision as to its reimbursement, began to rationalize the system of reimbursement decision-making for Medicare, thus potentially starting Medicare on the difficult road to becoming a prudent purchaser.

The passage, in 1978, of legislation establishing the National Center for Health Care Technology (NCHCT) set in statute the medical advisory relationship of the Public Health Service to the Health Care Financing Administration, thus enhancing the "prudent purchaser" function. It also established two other important functions: the financial support, albeit small, of the basic science of technology assessment, and the dissemination of technology assessment information. Three years ago, at Congressional hearings on the reauthorization of the National Center, the American College of Physicians supported the Center's reauthorization on the twin bases that its functions fostered an appropriate governmental role and that its structure was appropriate to its functions.

As you know, the Center failed to gain budget support, and met its organizational demise in late 1981. Since that time, its functions have been assigned to the Office of Health Technology Assessment and to the research grant authority of the National Center for Health Services Research.

Although in a moment I will address the organizational structure of the activities in technology assessment, I would like to return to the
functions that constitute an appropriate federal role. The first, evaluating technologies in order to better inform reimbursement decisions, is critical if federal health programs are to restrain their own costs. We should all agree that the reimbursement system should be concerned with paying for that which is appropriate in health care and not paying for that which is inappropriate. The most reasonable way in which decisions of this sort can be made is by utilizing information from valid technology assessment. Without such information, reimbursement decisions would be based at best on the same tenuous foundation they were based on in the first dozen years of the Medicare program: the pressure generated by provider billings. With good information, federal reimbursement programs can operate with at least minimal assurance that what is being paid for is valid medically. In addition to the information itself, the federal government needs to continue to have a defensible and open structure and process for technology assessment -- one that ensures that all legitimate interests are heard and that all relevant data are considered.

The second appropriate federal function is support for technology assessment. This function flows from a central federal responsibility having to do with information production. There are two kinds of support that the American College of Physicians views as valid: support for the "basic science" of technology assessment, and support for assessments themselves. In the first instance, the science of technology assessment is young, needing support for growth and for the development of additional and more refined mechanisms by which to evaluate medical technologies. In the second instance, present federal activity in performing assessments is limited -- limited in scope,
in that it relies almost solely on the data and opinion provided without
cost to the government by the private sector, such as that provided by the
American College of Physicians' Clinical Efficacy Assessment Project;
and limited in subject matter, in that it addresses almost solely those
issues presented by Medicare reimbursement needs. Such limitations are
too narrow. Further, present activity in federal funding outside technology
assessment is severely constrained. As we understand it, grant support
for technology assessment flows from the available extramural research
funds of the National Center for Health Services Research, an institution
whose extramural research budget has historically been severely limited.
In a time in which the kind of information that health services research can
produce is critically needed to form a rational basis for health services
expenditures, it seems unwise to add another competitor -- technology
assessment -- to the funding pie, without enlarging the pie.

A third federal function in technology assessment is the dissemination of
information necessary for making good clinical decisions. If technology
assessment information is valid enough for making reimbursement decisions,
it should be sufficiently medically valid to inform clinical decision-making.
More extensive efforts deserve to be made to inform clinicians of the
results -- both data and recommendations -- of federal technology
assessments. Such information would be most helpful in enhancing the
appropriate application of technology by clinicians as it would be in
enhancing the appropriateness of reimbursement decisions.
Role of the Private Sector in Technology Assessment

Technology assessment is not solely a federal role. The private sector -- clinicians, professional societies, hospitals, and technology producers -- all have roles, and all perform some of a range of functions. For example, since 1976, the American College of Physicians has participated extensively with the Blue Cross and Blue Shield Associations in the Medical Necessity Project, a project originally designed to weed out medically outmoded procedures that no longer were appropriate, either for application or for reimbursement. The Medical Necessity Project represents both the kind of cooperation and clear delineation of responsibility in the private sector that can be mirrored by the public sector. Through the project, reimbursement decisions are based on what is medically valid information. But it is the medical profession -- professional societies such as the College -- that produce the medical data and determine its validity; and the reimbursers -- the Blue Cross and Blue Shield Associations -- that decide coverage (reimbursement) policy. By analogy, parenthetically, it would seem appropriate for the Public Health Service to continue to provide the medical advice on which the Health Care Financing Administration would then make coverage decisions.

The Medical Necessity Project, in which the American College of Physicians has continued active participation, has had other effects. In 1978, it recommended policy, based on medical input, primarily from the College, that "routine" hospital admission laboratory tests not be considered routine -- that is, not applied to every hospitalized patient unless clinically valid in each individual case. Since 1978, the project has
expanded its scope to the examination of the appropriate clinical indications for valuable technologies -- diagnostic imaging, cardiovascular techniques, and common laboratory tests, for example.

For the last three and one-half years, the College, through its own Clinical Efficacy Assessment Project (CEAP), utilizing a highly structured process of literature review, subspecialty society and expert opinion polling, and committee critique, has examined intensively over fifty technologies used in the practice of internal medicine. The final products of these assessments, publications two to ten printed pages in length, present the current state of knowledge of the technology's safety, efficacy, and effectiveness, and in many cases also present the clinical indications for its use, its cost, and its relative value against alternative technologies. CEAP recommendations are widely disseminated to a variety of users -- our own membership through the College's news magazine, the Observer; the membership and other physicians through the College-published Annals of Internal Medicine, with a circulation of 100,000; Blue Cross/Blue Shield; the federal government; and other reimbursers.

The central purpose of the Clinical Efficacy Assessment Project is to enhance appropriate use of technologies by the practicing internist through providing the best available information on their medical value. Working closely with Blue Cross/Blue Shield, the College has been able to help rational reimbursement decisions be based also on good medical information. Such a partnership facilitates what we believe is a basic purpose of the reimbursement system: to pay for medical procedures that are medically
appropriate, and to refuse to pay for those that are not medically appropriate.

In this statement we have focused on only two of the many private sector institutions having a valid interest in medical technology assessment -- the medical professional society, carrying out a responsibility we owe to our membership and to other segments of society by assessing the medical value of what we physicians do with our patients; and the reimburser, attempting to be responsible to its beneficiaries by paying for appropriate medical procedures, and importantly, by maintaining its resources by refusing to pay for that which is without medical value. There are, of course, many others who are interested in, and perform, technology assessment: individual physicians, constantly re-evaluating the value of different technologies in their application to greatly varying individual clinical situations; researchers, performing detailed analyses of single procedures, thus providing the basic information on which clinical decisions can be made; hospitals, analyzing the cost-effectiveness of hardware to determine if its purchase will be prudent; manufacturers, evaluating both the technology and the potential market, to determine if a new technology represents significant additional benefit clinically to be marketable; and several others. Thus, there are in the private sector a host of activities being performed by a wide range of institutions, often for differing purposes. How these may appropriately interact and how they may interface with the public sector is the subject of the next two sections of this statement.
Technology Assessment Issues Not Now Adequately Addressed

There are several issues related to technology assessment that are not now adequately addressed. Among those are: methodology, priorities, coordination, information dissemination, and funding.

1. **Methodology.** Most present technology assessment activity relies on a combination of user opinion and research studies. Although already available data could benefit from collection and analysis, and although available techniques -- including epidemiologic studies, randomized controlled clinical trials, cost-effectiveness and cost-benefit analyses -- could benefit by more rigorous application, the state-of-the-art of technology assessment is still young, and additional methodologies of assessment may profitably be discovered and developed.

2. **Priorities.** Assessments today are, by and large, being driven by the reimbursers, although in some cases -- the Clinical Efficacy Assessment Project of the American College of Physicians and assessment activity in some other professional societies -- there is internal priority setting in response to membership need. Federal activity, with the valuable exception of the consensus development exercises at the National Institutes of Health, is carried out largely in response to the needs of the Medicare program. There is a need to examine to a greater degree the needs of the practicing physician in making clinical decisions and to be more responsive to those needs. After all, what technology assessment should enable is more informed, and likely more productive and more prudent, clinical decisions.
3. **Coordination.** Technology assessment presently is a set of separate bilateral transactions: the Health Care Financing Administration and the Public Health Service, the American College of Physicians and its membership, researchers and the scientific community, and so forth. Better coordination of the activity would provide less of a duplication of effort, and would help the producers of assessments be more responsive to the users of assessments.

4. **Information Dissemination.** For the most appropriate clinical decisions to be made, there are at least two prerequisites: valid information, and appropriate incentives. For the reimbursers to make coverage decisions without the dissemination of the medical bases for those decisions misses the most productive opportunity for enabling future clinical decisions to be better informed scientifically and medically. In fact, what the College has found in its working with Blue Cross/Blue Shield is that often the dissemination of credible medical information is sufficient to cause significant positive changes in practice patterns. All of the producers of technology assessments need to do a better job in disseminating the results of assessments to the ultimate users -- physicians and patients. The federal government should not shirk its responsibility as a producer of relevant information to ensure that information is widely shared. It is essential that information on safety, effectiveness, and efficacy, as well as valuable data on cost-effectiveness and indications for appropriate utilization of the technology be disseminated broadly. Although others may argue that information dissemination by the federal government represents an unwarranted intrusion into the practice of medicine, we would strongly disagree. The practice of medicine is enhanced, not harmed, by valid information, from whatever
source. To preclude the sharing of information that could potentially better inform medical decision-making borders, in our view, on the reprehensible.

5. **Funding.** Although the priorities for technology assessment have to a large extent been determined by reimbursers, both public and private, those same reimbursers have been strangely loath to pay a share of the cost of the assessments. That the Medicare program pays essentially nothing to determine whether what it reimburses for is worthwhile is, on its face, irrational. It would seem, on the other hand, altogether rational for the federal government, and other reimbursers, to invest some amount in order to be a prudent purchaser of health technologies. As it stands today, many of the producers of technology assessment fund the activity -- for example the American College of Physicians, using this year over $150,000 of membership dues for the purpose -- while the users sustain the benefit.

Assessing the value of new technologies would seem to be in the interest of both those who apply the technology and those who may ultimately pay for it. Yet, although physicians clearly recognize an evolution in the application of a technology -- from its use in experimental protocols, through its use in highly sophisticated settings, to its general use by the practicing physician -- reimbursers typically recognize only two stages: experimental and therefore not reimbursable; and generally applied and therefore reimbursable. What is needed is recognition of the grey zone: that significant and sometimes long period in which a technology is neither experimental nor ready for wide application, but during which
when performed in certain appropriate settings the technology may clearly benefit patients. While providing some funding of the procedure under these limited applications, the reimburser could accumulate quite valuable data that would make a later reimburse/not reimburse decision better informed.

Structuring Technology Assessment

The public sector -- the federal government -- should continue technology assessment for its own purposes (to be a prudent purchaser) and for other public purposes, principally to produce information on which, in part, clinical decisions can be made. The American College of Physicians strongly supports the continuation and the strengthening of the federal government's activities in technology assessment. Specifically, the College supports the assessment of safety, efficacy, and effectiveness, and emphasizes the validity of the federal government -- principally, the Public Health Service -- performing assessments that relate to cost-effectiveness and appropriate use of technology.

The private sector -- physicians, hospitals, insurers, manufacturers, patients, and others -- should continue the host of activities in technology assessment that are necessary for appropriate clinical decision-making as well as for appropriate economic decisions. The Institute for Health Care Technology Assessment, as proposed by S. 2504, would be an important step in enhancing both coordination of private and public sector activities and dissemination of the results of assessments. The College, therefore, supports the intent of S. 2504, as well as the specific provisions having to do with the functions of the Institute. This Committee is well
aware of the general support of the medical community for the proposed functions, as they reflect the consensus of an Institute of Medicine Committee that last year proposed a public-private sector consortium having many of the same functions. The American College of Physicians was privileged to have several of its Fellows sit on the IOM Committee, and a former president of the College chaired it.

The College believes, however, that the legislation could be strengthened in two important ways. First, the line of credit of $2,000,000 through the Department of Health and Human Services, available over a seven-year period, is most probably insufficient to support the Institute until it is able to become self-sustaining. It was the estimate of the IOM Committee that a minimal first year budget would be approximately $1,000,000. We support the concept that the Institute eventually be self-sustaining. However, seed funding should be sufficient so that the Institute take root and grow, rather than being allowed to wither.

Second, the Board of Directors should be revised to call for individuals within categories of expertise, not individuals who represent organizations. Such a change in the proposed legislation would enhance the probability that the Institute would benefit from the best substantive advice and strengthen its chances to be a vigorous enterprise. Although we recognize that such a change would raise the problem by whom the initial appointments to the Board would be made, we believe on balance it more appropriate that categories of expertise, rather than organizations, be named. Other
mechanisms of appointment are available, as by the Secretary, Department of Health and Human Services, through the Institute of Medicine, or through a combined process in which the Congress, the Department, and the private sector participate.

Conclusion

The American College of Physicians supports enhancing the roles of both the private and public sectors in technology assessment. The federal government should continue its own activities directed toward becoming a prudent purchaser of health care goods and services and toward disseminating valuable assessment information. Likewise, the private sector must continue its own necessary activities in technology assessment. Where there are gaps in those activities, the provisions of S. 2504 are likely to be quite helpful, and the College supports the functions of the Institute for Health Care Technology Assessment provided for by the proposed legislation.

Thank you for the opportunity to appear before you today. We would be pleased to respond to any questions you may have.