Appendixes

Appendix A
Method of the Study

History of the Project

The origins of this study lie in the passage of the Medicare Catastrophic Coverage Act of 1988 and its subsequent repeal in 1989. That act included a broad measure that would have extended Medicare coverage to outpatient prescription drugs. In doing so, it would have resulted in greater coverage of outpatient immunosuppressive drugs (now limited to coverage for only 1 year), and it also would have established a home intravenous drug therapy benefit. With the repeal of that act, these two specific coverage expansions once again became issues before Congress.

In April of 1990, the Senate Committee on Finance asked the Office of Technology Assessment (OTA) to revisit these two topics and the relevant coverage and payment issues they involve. The proposed assessment was approved by OTA's congressional Technology Assessment Board on June 2, 1990, and it began the following month. The assessment was conducted in two parts leading to two separate reports, one on immunosuppressive drugs and one on home intravenous drugs.

Conduct of the Immunosuppressive Drug Study

The preliminary draft of the study of immunosuppressive drugs was prepared under contract to OTA by Diane Burnside Murdock of Falls Church, Virginia.[1] During her preparation of the draft, the contractor consulted with consumer and professional organizations, Federal and State agency personnel, health services researchers, independent health professionals, and other interested individuals in order to identify critical issues and relevant sources of data. The contractor also consulted **frequently** with OTA staff regarding the scope and directions of the study.

In addition, the contractor conducted literature reviews and received a substantial amount of data from a variety of individuals and organizations. Some of these data were previously unpublished, and OTA is indebted to these individuals and organizations for their cooperation and assistance.

Most major OTA studies have a panel of outside experts chosen to advise OTA staff on the study and ensure that all significant points of view are represented. This study was originally intended to be performed in coordination with an ongoing study of drug research and development, with the same advisory panel. It transpired, however, that the two studies had little directly in common, and the advisory panel for the earlier study proved inappropriate for the existing study. Because of the short time me for this study, it also proved infeasible to appoint a separate advisory panel at the point for the current study.

To ensure that sufficient expert advise was obtained and that all viewpoints were represented, OTA staff took especially great care to involve a variety of outside persons in the review of the draft material. Some preliminary findings from the report were presented in organized informal discussions with staff of the U.S. Health Care Financing Administration, the Urban Institute, and OTA. A revised draft was then sent to over 40 experts in the field, including medical providers, patient organizations, health care payers, researchers, and others with interest and knowledge in the area of organ transplantation and immunosuppressive therapy for their review and comment. The final draft, incorporating revisions based on reviewers' comments, was transmitted to the Technology Assessment Board in May 1991.

[1] Diane Burnside Murdock is a consultant in health policy and planning in the Washington DC area. Before turning to consulting she held a number of positions in the health policy field, including senior policy analyst at the Prospective Payment Assessment Commission and senior budget analyst at the Congressional Budget Office.