4
Research and Development; Policies Related to Medical Devices

Columbus may have been impelled by a desire for spices, but it was the supply **of corn which was increased**

—Kenneth J. Arrow

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4. Research and Development Policies Related to Medical Devices

INTRODUCTION

New medical devices arise from a process of research and development (R&D)—purposeful activities requiring the investment of time and other economic resources in the investigation of scientific or technical problems. R&D is frequently classified into three phases:

- *Basic* research—original investigation whose objective is to gain fuller knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications in mind (421).
- *Applied* research—investigation whose objective is to gain knowledge or understanding necessary for determining the means by which a recognized and specific need may be met (421).
- *Development*— systematic use of the knowledge or understanding gained from research in the design and development of prototypes and processes (413).

Investment in R&D, particularly in development, is a necessary, but not sufficient, condition for technological progress' in medical devices. Some new devices may result from sudden insights, with little developmental work needed; others may require a laborious and slow development phase with high levels of investment. All new devices (or device improvements) need some level of development and possibly research. Yet there are no guarantees that greater investment in R&D will lead to higher levels of technological progress in a field. The productivity of R&D depends to a 1arge extent on the present state of scientific knowledge (413) and to some extent on the existence of a "product champion" (413), but it may also depend on how the R&D is organized: who performs it, who funds it, how funding decisions are made, and the social and economic structure in which it occurs.

The purpose of this chapter is to examine Federd R&D policy as it relates to medical devices.[2] As in other areas of Federal policy, questions of R&D policy transcend the medical devices field. Federal stimulation of industrial R&D through direct subsidies or indirect policies (e. g., tax policy) has been a national concern **(67,70).** Similarly, Federal support for basic research and training as a long-term national investment in technological change and R&D capacity has been discussed widely in general terms **(280)** and in terms of biomedical research as a whole (413).

This discussion will concern itself neither with the broad issues of R&D policy nor with public policy instruments that cannot be readily targeted to specific fields such as medical devices (e.g., the use of income and corporate tax incentives to stimulate R&D). It is important to note, however, that global R&D strategies may have an impact on the level, directions, and settings of R&D on medical devices that is as great or greater than the impact of R&D strategies directed specifically at medical devices. (App. G contains an analysis of the impact of recent changes in Federal tax policy on medical devices R& D.)

To address the specific issues pertaining to R&D for medical devices, the chapter first presents data on expenditures for and performance of medical-device-related R&D. The chapter also analyzes sources of support for medical-device-related R&D. The concluding section of the chapter discusses problems that have been identified and policy options to address them.

'Technological progress is defined here as the continual introduction to practice of new and more useful ways of serving human purposes (262).

[2] R&D in the Veterans Administration is discussed in ch. 7.

TRENDS IN MEDICAL DEVICES R&D

For two reasons, it is difficult to identify and quantify R&D activities specifically related to medical devices. First, most basic and some applied research lays the scientific foundation for a wide range of future products and processes, including medical devices, without being specifically attributable to a device or even to a class of devices. Second, the R&D data that are published are either aggregated or classified in a manner that is inconsistent with the definition of medical devices used in this report. The picture of device-related R&D must be sketched from disparate and only partially relevant data sources.

Annual estimates of the level of health-related R&D expenditures in the United States are available from the National Institutes of Health (NIH), but these estimates are not broken down by phase of R&D and are not specific to medical devices. In 1980, health R&D totaled an estimated $7.89 billion, of which 28 percent was performed, and 31 percent was funded, by industry (404).[3]

Annual estimates of R&D conducted by medical device companies are available from the National Science Foundation (NSF) survey of R&D in industrial firms, but their validity as estimates of industrial R&D on medical devices is somewhat limited. The NSF's estimates of company-wide R&D for firms whose primary line of business is one of the five medical device Standard Industrial Classification (SIC) codes[4] overestimate industrial R&D on medical devices to the extent that the medical device companies conduct R&D in other product categories and underestimate it to the extent that R&D for medical devices is conducted by firms classified in other SIC codes. Because many medical devices firms are owned by large multiproduct firms, [5] the balance is likely to be toward underestimation of industrial R&D on medical devices.

NSF's estimates of company-wide expenditures for applied research and development are broken down into general product categories such as professional and scientific instruments" and "other electrical machinery equipment and supplies. " These categories are too broad to allow the extraction of applied research and development expenditures that pertain specifically to medical devices. Basic research expenditures are collected for the company as a whole and are not broken down by product class.

These caveats must be recognized in interpreting table **23,** which presents estimates of industrial R&D expenditures aggregated over the five medical devices SIC codes. In the 1974-80 period, industrial R&D expenditures, which include both company and Federal funding, grew at an average annual rate of 16.1 percent in the five medical devices SIC codes, as compared with an annual growth rate of 11.7 percent in industry as a whole **(422,424).** It is also interesting to note that although R&D expenditures for medical devices are probably underestimated, in 1980, industrial R&D expenditures for firms in the five medical devices SIC codes were equal to 3 percent of the value of such firms' shipments (see table 23); in industry as a whole, R&D expenditures were equal to 2.4 percent of the value of shipments (422,424).

The data suggest that the medical devices industry is relatively R&D-intensive. In 1980, for firms in the five medical devices SIC codes, company-sponsored R&D was equal to 2.9 percent of the value of such firms' shipments; for industry as a whole, company-sponsored R&D expenditures amounted to only 1.6 percent of the value of shipments (422,424). For the rate of company Investment in basic research, there is little difference between medical devices firms and industry as a whole. In 1979, firms in the five medical devices SIC codes reported that 3.7 percent of their company-sponsored R&D was basic research, while the figure for industrial firms as a whole was 4.1 percent (422,424).

[3]The NIH estimates of industrial R&D for health are imprecise and probably underestimated due to limitations of the data on which the estimates were based (449).

[4]The five medical devices SIC codes are: 3693 (X-ray and electromedical equipment), 3841 (surgical and medical instruments), 3842 (surgical appliances and supplies), 3843 (dental equipment and supplies), and 3851 (ophthalmic goods) See ch. 2 for further information on the SIC codes.

[5]Three obvious examples are the General Electric Co., with extensive R&D in medical imaging; E. I. du Pont, with R&D in health-related products; and Johnson & Johnson, Inc. , a drug company with several device subsidiaries. (Because Census Bureau data are confidential, it is impossible to state with certainty the severity of the classification problem.)

Table 23.—industrial R&D in Five SIC Medical Devices Codes[a], 1974-80 (dollars in thousands)

Year	Basic research	Percentage of total	Applied research	Percentage of total	Development	Percentage of total	Not identified	Percentage of total	Total	Percentage of shipments
1974		2 '0/0		25 1°/o		70.60/o		1.7%		2.8%
1975:::	NA	NA	NA	NA	NA	NA	NA	NA	168,884	2:9
1976 . . .	6,234	3.1	33,046	16.6	90,957	45.8	68,637	34.5	198,874	3.0
1977 . . .	8,406	3.7	65,994	28.8	154,277	67.5	NA	NA	228,677	2.8
1978 . . .	NA	NA		NA	NA	NA	NA	NA	273,794	3.0
1979. . .	11,272	3.8	67,968	23.3	188,690	647	23,821	8.2	291,751	2.8
1980 . . .	NA	NA	NA	NA	NA	NA	NA	NA	348,707	3.0

NA indicates information not available because of issues of confidentiality
aThe five Standard Industrial Classification (SIC) code medical devices categories are
SIC 3693: X-ray and electromedical equipment
SIC 3841: Surgical and medical instruments
SIC 3642: Surgical appliances and supplies
SIC 3843: Dental equipment and supplies
SIC 3851: Ophthalmic goods

SOURCES U S Department of Commerce, Bureau of Industrial Economics, 1983 *U.S Industrial Outlook*, Washington, DC, January 1983; US. National Science Foundation "Survey of Industrial Research and Development, " conducted by the U S Bureau of the Census, 1982

SOURCES OF SUPPORT FOR MEDICAL-DEVICE-RELATED R&D

R&D for medical devices takes place in numerous settings—private companies, hospitals, and university and government laboratories. The sources of support for these activities are highly varied. It is impossible to isolate the sources of funding of medical-device-related R&D performed in academic or government laboratories from those for other health or general R&D, but data are available on the sources of funding of medical devices R&D conducted in industry. [b]

Table 24 shows the sources of support for industrial R&D in the five SIC medical devices codes. The level of support from NIH and other Federal agencies is substantially lower for industrial R&D in these SIC codes than it is for industrial R&D as a whole. In 1980, the Federal Government funded less than 3 percent of the R&D conducted by firms in these SIC codes, compared with 29 percent of R&D conducted by industry as a whole (422).

Federal Support for R&D on Medical Devices

The Federal Government supports over 52 percent of total health R&D, most of it (70 percent) through grants and contracts from NIH (404). Table 25 shows the distribution of R&D grants and contracts awarded by NIH in fiscal year 1982.

[b]The limitations of the NSF industrial R&D survey apply in interpreting these data, however.

Table 24.—Sources of Support for Industrial R&D in Five SIC Medical Devices Codes[a], 1974-80

Year	Total industrial R&D	Federal	Company	Percent change in company-sponsored R&D
	(thousands of dollars)			
1974. .	$142,080	$3,635	$138,445	—
1975. .	168,884		164,006	18.5%
1976. .	198,874	5,464	193,410	17.9
1977. .	228,677	5,727	222,950	15.3
1978. .	273,794	5,623	269,171	20.7
1979. .	291,751	4,788	286,963	6.6
1980. .	348,707	7,125	341,582	19.0

[a]The five SIC codes are the same as those listed in table 23.

SOURCES U S Department of Commerce, Bureau of Industrial Economics, 1983 U S *Industrial Outlook*, Washington, DC, January 1983; U.S. National Science Foundation, "Survey of Industrial Research and Development, " conducted by the U.S. Bureau of the Census, 1982.

Industry received approximately 6 percent of total NIH grants and contracts for that year. (Of course, these grants and contracts encompass much more than the development of medical devices, including some basic research, drug and biotechnology development, and procurement of items such as research laboratory equipment.)

Despite the small proportion of NIH funds that goes to industry, NIH and other agencies' support for R&D in specific medical device areas is probably sizable in absolute terms. The National Institute for Handicapped Research's Rehabilitation Technology program, for example, administers a $9 million annual program of grants and con-

Table 25.—R&D Grants and Contracts Awarded by the National Institutes of Health (NIH), Fiscal Year 1982

Performing institution	'Total amount (thousands of dollars)	Percentage of total
Domestic institutions	$2,709,248	99%
Nonprofit	2,558,010	94
Higher education	2,025,822	74
Medical schools	1,412,540	52
Government	40,656	1
Federal	2,083	0
Research institutes	470	0
Hospitals	404	0
Other	1,209	0
State and local	38,574	
Research institutes	1,774	1
Hospitals	26,362	1
Other	10,438	0
Other nonprofit	491,531	18
Research institutes	275,575	10
Hospitals	163,188	6
Other	52,768	2
Profit	151,238	6
Foreign institutions	22,820	1
Total	$2,732,068	100%[a]

[a]Percentage may not sum to 100 because of rounding errors

SOURCE: U.S. Department of Health and Human Services, National institute of Health, Office of Program Planning and Evaluation and the Division of Research Grants, *NIH Data Bock* 1983 Washington, DC, June 1983, table 17

tracts to 18 centers engaged in applied research and development of rehabilitative-devices (299). NIH's critical role in supporting the development of renal dialysis technology is described in box G.

A recent analysis of NIH, NSF, and Department of Energy grants and contracts active as of May 1983 revealed that almost $50 million was related to diagnostic imaging (460). This medical imaging R&D was scattered throughout the institutes and agencies and covered a wide assortment of subjects including not only development or refinement of new imaging devices, but the use of imaging techniques to enhance understanding of disease processes. A high proportion of these grants went to academic and other nonprofit institutions, and therefore supplemented the R&D on medical imaging conducted by industry. NIH funding in the medical imaging area has, in retrospect, had important impacts on the later development of commercial imaging devices. Box H presents the history of Federal funding for research on nuclear magnetic resonance (NMR) imaging.

Private Sources of Funds for R&D on Medical Devices

How do medical device firms go about financing the R&D that is not supported by direct grants and contracts? Firms have two potential sources of financing: retained earnings and the financial capital markets. If funds are sought from external sources, they may be generated either through debt or equity instruments. Tables 26, 27, and 28 present data on the sources of financial capital to firms in three Internal Revenue Service (IRS) industry categories:

- optical, medical, and ophthalmic goods (IRS **3845);**
- other electrical (including but not limited to X-ray and electromedical devices) (IRS 3698); and
- all manufacturing (IRS 40).

These industry classifications include a substantial number of firms not engaged in the production of medical devices, and the data pertain to

Box G.—Federal Support for Renal Dialysis R&D[1]

The research activities of the Federal Government have played an important part in the development of knowledge on the causes and treatment of end-stage renal disease (ESRD). The National Institutes of Health (NIH) funded early work on maintenance dialysis and supported research on transplantation as well. In 1982, the total amount spent by NIH on kidney-related research was estimated at about $90 million (269). This might be compared with the approximately $73 million spent by NIH on kidney and urinary tract diseases in 1979 and the $47 million spent in the area in 1976 (396). The Veterans Administration and the Public Health Service have also provided resources for the demonstration of maintenance dialysis therapy. The research support continues today, but some difficult policy issues are evident.

The contribution to dialysis treatment of this Federal investment is significant. NIH has contributed to the development of a number of innovations, including the following (269):

- development of hollow fiber dialyzers,
- enhancement of efficiency of flat-plate dialyzers,
- introduction of "single-needle" dialyzers,
- determination of protein levels for diets for dialysis patients,
- establishment of national registry of patients on dialysis (responsibility later assumed by the Health Care Financing Administration),
- development of specific absorbents for uremic wastes,
- development of wearable artificial kidney for self-treatment,
- improvement in prevention and treatment of chronic bone pain and bone fractures in patients,
- development of treatment measures for chronic anemia in patients, and
- development of concept of hemofiltration.

An examination of trends in funding, however, suggests that these direct contributions are likely to decline. Overall spending for the Chronic Renal Disease Program, a subdivision within the National Institute of Arthritis, Diabetes, and Kidney Diseases' Kidney and Urologic Diseases Program fell roughly 31 percent between 1979 and 1981, after adjustment for inflation. Research in the area of maintenance therapies, which included applied research on hemodialysis, peritoneal dialysis, hemofiltration, and other aspects of therapy, fell by 68 percent over the period. Furthermore, within NIH as a whole, maintenance therapies took up only about 6 percent of the ESRD-related research (461).

[1]Based on a case study prepared for OTA by Romeo (260).

the financing of all activities in these fields, not just the financing of R&D and innovation. Consequently, the interpretation must proceed with caution.

Table 26 shows that in 1980, external equity became a very important source of financing for small firms in the optical, medical, and ophthalmic goods category. Retained earnings have consistently been less important to firms in this category than they are to manufacturing firms as a whole. The shift by small firms in the optical, medical, and ophthalmic goods category toward external equity may be the result of the infusion of large amounts of venture capital into new companies in this area in 1979. Notice also that small optical, medical, and ophthalmic goods companies depend to a greater extent on all forms of external financing than do large firms in the same Industry.

The role of venture capital in financing innovation i n general and new medical devices in particular has increased dramatically since 1978. Venture capitalists are investors who specialize in providing financial capital to small and, sometimes, new firms. From 1969 to 1977, the total venture capital pool in the United States remained virtually unchanged, at the level of about $2.5 billion to $3 billion (190). Since then, however, the total venture capital pool has increased sharply, reaching between $3.5 billion and $4 billion in 1979 (441), $5.8 billion in 1981 (442), and an estimated $7.5 billion as of December 1982 (440).

Box H.—Federal Funding of Research on Nuclear Magnetic Resonance Imaging[1]

Government policies related to medical device research and development (R&D) by universities and manufacturers can have impacts on the evolution of technology and the shape of particular device industries. The history of Government funding of NMR imaging research in the United States reflects these impacts.

NMR imaging is an exciting new diagnostic imaging modality that has captured the interest of the medical profession. It has many desirable attributes, including the use of radiowaves and powerful magnetic fields rather than ionizing radiation. It also offers excellent tissue contrast without the need for injection of potentially toxic contrast agents and allows visualization of areas such as the posterior fossa, brain stem, and spinal cord, which are not well seen with other imaging techniques. Finally, the technique offers the *possibility* of detecting diseases at earlier stages than is currently possible and of permitting accurate pathologic diagnoses to be made noninvasively.

NMR also has disadvantages. NMR imagers are expensive and logistically difficult to install. They may also require more physician time in performance of patient examinations than do computed tomography (CT) or other imaging techniques. Moreover, at this time, the exact role of NMR imaging in clinical medicine, particularly its efficacy compared to other imaging modalities, has yet to be defined.

Over the past decade, the National Institutes of Health (NIH) has supported research relating to NMR imaging, biomedical applications of NMR parameters, and biomedical applications of NMR spectroscopy. Although NIH has provided some funds for development and use of software and ancillary hardware, it has not provided, and does not plan to provide, support to clinical or research institutions to be used either to develop or purchase NMR imaging machines for use in human imaging.

NIH has had an active intramural program of research involving applications of NMR for many years. Over the past 6 years, Dr. David Hoult, a physicist and electronics engineer, has conducted research focusing on NMR imaging instrumentation techniques. Dr. Robert Balaban has been studying physiological applications of phosphorus, sodium, and nitrogen specNMR for the past 3½ years. Also, a research group has been formed by Dr. Charles Meyers of the National Cancer Institute (NCI) to explore the use of NMR in the study of the metabolism of both normal and cancer cells as well as the effect of various drugs on cellular metabolism. The group will also be exploring possible applications of NMR to the study of tumors (62).

Using funds contributed by several institutes, NIH has purchased a whole-body NMR imaging system on which it will perform clinical studies including investigations of the development of disease, the effects of chemotherapy and radiation therapy on NMR parameters, and whether NMR can be used to predict patients' responses to chemotherapy and radiation therapy.

NIH has also engaged in active extramural support of NMR imaging. A few of the NMR-related extramural grants have been funded by the National Heart, Lung, and Blood Institute (NHLBI) and other institutes, most of them have been funded by NCI. The first extramural NCI grant related to NMR imaging was awarded to Paul Lauterbur at the State University of New York-Stony Brook in 1973 after publication of a landmark article on NMR (191). The award was made to help Lauterbur further develop his techniques of NMR imaging and investigate application to cancer research. His initial funding of approximately $200,000 per year for 3 years has been renewed at an approximately constant level, without interruption, since 1973. Lauterbur also received a grant from NHLBI in 1975 related to the use of NMR imaging to study blood flow and an additional $100,000 per year from that institute since 1978. NIH also supported early work monitoring NMR of surgically excised human tumors (76,77) and tumors in mice and rats (144,152), as well as on the imaging of tumors in live animals (75).

NIH is currently funding approximately $2 million of research to NMR imaging or in vivo spectroscopy in at least 10 different (460). The Department of Energy has awarded an additional $1.8 million for NMR-related research (460). In October 1982, the Diagnostic Imaging Research

Branch of NCI announced a solicitation of proposals for the performance of studies: 1) to explore and define the current and potential usefulness of present-day NMR imaging systems in clinical applications; 2) to establish optimal imaging conditions for NMR use in specific clinical problems; and 3) to carry out comparative performance and evaluation studies to determine the capabilities and limitations of NMR imaging systems in comparison with other modalities. Announcement of awards, which originally was to take place in June 1983, occurred in spring 1984 (250).

NIH is also planning to issue a Request for Applications for grants to study the physical, chemical, and biological bases for the measurements used in NMR imaging. Although a 3-year program with up to $1 million in grants in the first year is being considered, to date funds have not been approved (250). NIH is also considering the possibility of funding a small number of training fellowships in NMR (250).

The National Science Foundation (NSF) supported a $309,000 pioneering research project in NMR imaging at the University of California, Berkeley, through its Research Applications Directorate (Instrumentation Technology Program) during 1977 through 1979, but currently has no programs that support research in NMR imaging per se. In the most recent Small Business Innovation Research program solicitation of NSF, research proposals pertaining to the application of superconductivity to electronically oriented industries, improved NMR probes, and new procedures for NMR data display have been particularly encouraged.

[1]Based on a case study prepared for OTA by Steinberg and Cohen (291).

Table 26.—Sources of Financial Capital to Firms in IRS Category 3845: Optical, Medical, and Ophthalmic Goods, 1976-80

Ratio	Asset size class (000s) $1-$5,000	$5,000+
External equity to assets		
1980	0.38	0.18
1979	0.16	0.19
1978	0.23	0.18
1977	0.24	0.20
1976	0.26	0.23
Retained earnings to assets		
1980	0.08	0.35
1979	0.16	0.37
1978	0.14	0.39
1977	0.21	0.40
1976	026	0.40
Long-term debt to assets		
1980	0.14	0.13
1979	0.27	0,17
1978	0.20	0.16
1977	0.20	0.14
1976	0.12	0.13
Short-term debt to assets		
1980	0,20	0.17
1979	0.24	0.13
1978	0.22	0.16
1977	0.17	0.17
1976	0.20	0.15
Trade debt to assets		
1980	0.18	0.17
1979	0.13	0.15
1978	0.17	0.12
1977	0.13	0.09
1976	0.18	0.09

SOURCE: U.S. Department of the Treasury, internal Revenue Service, Sourcebook *of Statistics of Income*, for years 1976-80, as cited in (26).

Variability in the amount of venture capital in the United States is influenced by many factors, including sensitivity to general variables in the overall economy (e.g., interest rates and inflation), changes in capital gains tax laws, and changes in pension fund investment rules.

Recent changes have led to a resurgence in the United States in the supply of venture capital. Especially important to the supply of venture capital have been decreases in the rate at which long-term capital gains are taxed. In 1978, the rate of taxation was reduced substantially; more recently,

Table 27.—Sources of Financial Capital to Firms in IRS Category 3698: Other Electrical, 1976-80

	Asset size class (000s)			
Ratio	$1-$5,000	$5,000-$25,000	$25,000-$100,000	$100,000+
External equity to assets				
1980	0.16	0.18	0.14	0.09
1979	0.12	0.14	0.15	0.10
1978	0.20	0.17	0.15	0.12
1977	0.22	0.18	0.14	0.13
1976	0.16	0.23	0.19	0.13
Retained earnings to assets				
1980	0.16	0.33	0.48	0.22
1979	0.27	0.39	0.42	0.23
1978	0.22	0.37	0.48	0.25
1977	0.19	0.40	0.47	0.25
1976	0.29	0.35	0.45	0.25
Long-term debt to assets				
1980	0.18	0.14	0.13	0.27
1979	0.13	0.13	0.17	0.28
1978	0.14	0.14	0.13	0.27
1977	0.14	0.12	0.13	0.24
1976	0.11	0.13	0.15	0.28
Short-term debt to assets				
1980	0.32	0.21	0.15	0.30
1979	0.25	0.18	0.16	0.27
1978	0.22	0.19	0.16	0.25
1977	0.22	0.18	0.16	0.26
1976	0.22	0.18	0.13	0.23
Trade debt to assets				
1980	0.19	0.16	0.10	0.12
1979	0.19	0.14	0.10	0.12
1978	0.20	0.13	0.10	0.13
1977	0.21	0.12	0.10	0.12
1976	0.20	0.11	0.09	0.11

SOURCE: U.S. Department of the Treasury, internal Revenue Service, *Sourcebook of Statistics of Income*, for years 1976-80, as cited in (26)

the Economic Recovery Act of 1981 established the long-term capital gains tax rate at 20 percent for individuals and 28 percent for corporations, making venture investments more attractive than they hereunder the pre-1978 rate of 49 percent. Also, in 1979, pension fund regulations of the Employee Retirement Income Security Act were interpreted as allowing some pension fund money to flow into venture capital investments.

The results of these changes are evident in data presented in table 29, which shows capital cornmitments to private venture capital funds for the years 1978 to 1982. Not only have the total annual outlays of venture capital funds increased as a whole, but also the amount available from pension funds has grown dramatically since 1979: in 1982, pension funds represented one-third of the new capital commitments to private venture capital firms (443).

In 1981, venture capital investments in medical and health-related products and services constituted about 6 percent of investments made in organized venture capital markets (26). Table 30 shows the 1982 distribution of venture capital investments by stage of investment in four product categories: medical imaging, other medical products, industrial products, and electronics.

The two medical devices categories—medical imaging and other medical products—show a relatively high proportion of investments in early stages, although in medical devices, as in other fields, the organized venture capital market appears to invest negligible amounts at the earliest (seed money) stage of development. The relatively important role of venture capital firms in financing the startup of new medical device firms suggests that investors have been more likely to take greater risks in this field than they have in other

Table 28.–Sources of Financial Capital to Firms in IRS Category 40: All Manufacturing, 1976.80

Ratio	Asset size class (000s)			
	$1-$500	$5,000-$25,000	$25,000-$100,000	$100,000+
External equity to assets				
1980	0.13	0.13	0.16	0.16
1979	0.13	0.12	0.16	0.16
1978	0.14	0.13	0.17	0.17
1977	0.18	0.15	0.18	0.17
1976	0.16	0.16	0.19	0.18
Retained earnings to assets				
1980	0.29	0.33	0.33	*0.28*
1979	0,30	0.34	0.33	*0.29*
1978	0.28	0.35	0.34	0.30
1977	0.28	0.36	0.34	0.30
1976	0.29	0,35	0.34	0.28
Long-term debt to assets				
1980	0.18	0.18	*0.28*	*0.25*
1979	0.18	0.18	0.20	*0.24*
1978	0.17	0.16	0.20	*0.24*
1977	0.17	0.17	0.21	*0.25*
1976	0.16	0.17	0.20	*0.26*
Short-term debt to assets				
1980	0.21	0.21	0.19	0.19
1979	0.21	0.21	0.19	0.18
1978	0.21	0.21	0.18	0.17
1977	0.21	0.19	0.17	0.16
1976	0.20	0.19	0.17	0.15
Trade debt to assets				
1980	0.18	0.15	0.12	0.12
1979	0.19	0.15	0.12	0.13
1978	0.19	0.15	0.12	0.12
1977	0.18	0.14	0.11	0.12
1976	0.19	0.13	0.10	0.12

SOURCE: US. Department of the Treasury, internal Revenue Service, *Sourcebook of Statistics of Income,* for years 1976-80, as cited in (26)

Table 29.—Capital Commitments to Independent Private Venture Capital Funds, 1979-82

	1978	1979	1980	1981	1982
Total capital committed (dollars in millions):					
Corporations	$22	$28	$127	$142	$ 175
Endowments and foundations	19	17	92	102	96
Foreign investors	38	26	55	90	188
Individuals and families	70	39	102	201	290
Insurance companies	35	7	88	132	200
Pension funds	32	53	197	200	474
Total	$216	$170	$661	$867	$1,423
Percentage of total capital committed:					
Corporations	10%	170/0	19%	170/0	120/0
Endowments and foundations	9	10	14	12	7
Foreign investors	18	15	8	10	13
Individuals and families	32	23	16	23	21
Insurance companies	16	4	13	15	14
Pension funds	15	31	30	23	33
Total	100%	100%	100%	100%	100%

SOURCE Venture Economics, Wellesley Hills, MA, "Venture Capital Investment in the Medical Health Care Field; contract report prepared for the Office of Technology Assessment, August 1983. See app F for a description of the Venture Economics database from which these data were derived.

Table 30.—Percentage of Types of Venture Capital Financing in Medical Devices and Other Fields, 1982[a]

Type of financing	Medical imaging	Other medical products	Industrial products	Electronics
Seed money	0%	1%	1%	1%
Startup and first stage	57	56	29	35
Expansion	43	38	37	58
Leveraged buyouts and acquisitions	0	1	27	1
Other	0	4	6	5

[a]See app. F for a description of the Venture Economics database from which this table is derived

SOURCE: Venture Economics, Wellesley Hills. MA, "Venture Capital Investment in the Medical Health Care Field; contract report prepared for the Office of Technology Assessment, August 1983.

fields, even in a traditionally high-technology product category such as electronics. Yet, these data also suggest that small and new firms seeking seed money must frequently look to their owners' and friends' contributions of both time and money. See box I for an example.

THE SMALL BUSINESS INNOVATION RESEARCH PROGRAM

The Small Business Innovation Development Act (Public Law 97-219), enacted into law in 1982, requires each Federal agency whose extramural R&D obligations exceed $100 million to set aside a small percentage for R&D grants or contracts with small businesses. NIH's Small Business Innovation Research (SBIR) budget amounted to $5.6 million in fiscal year 1983 and $8.2 million in fiscal year 1984.[8] The awards are made in three phases: Phase I involves small awards of 6 months' duration for proving the scientific and technical feasibility of new ideas; Phase II involves further development of these ideas with the addition of a plan to acquire non-Federal venture capital in the subsequent phase; and Phase III involves only non-Federal capital committed to pursuit of commercial applications (but Federal involvement may be in the form of agreements to purchase products).

Each agency may determine the categories of projects within its SBIR program and has control over the size of the maximum award in each phase, the amount of sharing of R&D expenses required of awardees, and the methods and procedures used to solicit and select among proposals. Because the SBIR program is specifically targeted to ideas with commercial promise, the grant awards are generally skewed toward applied research and development and away from-basic research.

The NIH SBIR program made its first Phase I awards in October 1983 in the form of grants of $50,000 in total costs or less. NIH required grantees to commit to sharing in the costs of the research and will pay no profit or fee in addition to costs. An analysis by OTA of NIH SBIR grant applications and awards revealed that an estimated 42 percent of the SBIR applications responding to the first solicitation were for medical devices (see table 31). No significant differences were found in the ratio of awards to proposals between medical devices and other types of research.

It is premature to evaluate the effectiveness of the SBIR program on small business innovation in medical devices. Although it is clear that there has been a reallocation of research dollars from other R&D programs within NIH to the SBIR initiative, it is unknown to what extent the dollars have been shifted from research funds that would have gone to academic and nonprofit institutions or from research funds that would have gone to industry anyway. Furthermore, if the shift occurred within industry, it is unknown at this time to what extent it represents a net transfer of R&D funds from large firms to small firms or simply a net redistribution of Federal funds among small firms.

'The percentage increases from 0.2 in fiscaI year 1983 to 1.25 within 4 years.

[8]NIH actually expended $7.3 million in fiscal year 1983 (425).

Box I.—Financing New Devices: Metatech Corp.[1]

After having spent 35 years with major companies in the pharmaceutical industry in jobs ranging from bench chemist to executive vice-president, I decided in 1978, as so many others had decided before me, that it was now time to become my own boss and to do only those things that I wanted to do. Accordingly, I established Metatech Corp. with the not too modest or restrictive mission "to develop products based on high technology." Because of my background, it was probably inevitable that most of my interests would be in the medically related field, although we do have several products not related to medicine. . . .

I decided that during the initial phase of company development I would not build up an internal research staff. The first dollars spent by a company for research are usually devoted entirely to new and creative projects. However, as a company grows, more and more money is spent protecting what has already been developed. In addition, a research staff that must be kept busy has been built. It sometimes happens that when a project is finished by a group of researchers, the next problem is not the one that the staff is best qualified to solve. Since research staffs are never terminated, the alternative is to allow the existing staff to continue work along lines of their own interests, and other specialists are hired to enter new areas. . . .

In my own experiences, I had had contacts with research and development groups throughout the world, so I thought I knew where the best talent existed to solve any problem. To meet my own requirements, then, without building up a staff I decided to do all my work through outside contracts. Thus, when a problem was solved, the research group no longer existed as an overhead for the company. This procedure has worked very well. Projects have been worked on in England, Israel, Japan, West Germany, and Belgium, as well as here at home. . . .

I had set a time limit of 5 years during which to develop a line of products that could then be sold through any of the channels mentioned previously. How successful has this effort been? We now have 21 products available for promotion and sale. All of them meet the criteria that I established originally. Eleven patents have already issued, and we have 16 applications pending. A long list of potential products awaits future funding. . . .

I have not mentioned the first hurdle that an inventor or entrepreneur must overcome, namely financial support. Partly from choice, partly from necessity I financed Metatech with my own money. At the beginning, I made a few half-hearted attempts to interest outside investors in my company. However, I soon found out that venture capitalists were really not interested in venturing. I had no sales or profits, so there was a risk connected with the operation. I therefore decided to finance my own work, to make my own mistakes in private, but also to have the total freedom to do anything I wanted to do. After having developed some 20 products, I tried again. In March of 1983, I received the investment capital to establish the organization necessary to market the products. . . .

Occasionally, I think back to the days when I could work a normal 12-hour day and depend on someone else to do important things like making coffee. These occasions occur only rarely, and do not last long. Two major hurdles have been overcome—financing and development of products—and preliminary sales contacts and some sales have been made. I might even start to build an internal research organization.

[1]Excerpted from a paper prepared for OTA by Carney (54).

Table 31.–Analysis of Applications for Small Business Innovation Research (SBIR) Grants, National Institutes of Health, 1983[a]

	Biotechnology applications[b]	Medical devices applications[c]	All other applications[d]
Percentage of total grant applications	6%	42%	52%
Percentage of applications receiving awards . . .	21%	23%	18%

[a]See app. E for estimation methods.
[b]Proposals for R&D on medical devices and other technologies using biotechnology.
[c]Proposals for R&D on medical devices not using biotechnology.
[d]Proposals for R&D on technologies that neither involve the use of biotechnology nor are medical devices

SOURCE: Office of Technology Assessment

Implementation of the SBIR program may also affect the productivity of the SBIR program in stimulating development of new medical devices. One issue is whether or not the program stimulates those with the best ideas from a commercial perspective to submit grants. It is interesting to note that in fiscal year 1983, the Department of Health and Human Services (DHHS) (mainly NIH) had the lowest ratio of proposals to awards—six to one—of all Federal agencies. The average ratio of proposals to awards for Government as a whole was 11 to 1 (425). Implementation strategies, including the choice of topics included in the Public Health Service solicitation, the methods used to distribute information on the SBIR program to small businesses, and policies regarding cost-sharing are likely to have influenced the proposal rates.

FEDERAL SUPPORT FOR ORPHAN DEVICES

The Federal Government has recently been charged with the responsibility of identifying and promoting "orphan products," including both drugs and medical devices. The Orphan Drug Act (1983, Public Law 97-414) defines orphan products as drugs and devices for rare diseases or conditions. A rare disease or condition is further defined in the act as one that occurs so infrequently that there is no reasonable expectation that the cost of developing or making the product for such a condition can be recovered from sales of the device.

In the case of drugs, the 1983 act authorizes the Secretary of Health and Human Services to provide four kinds of support for those that have been found to be orphans:

- a 50-percent tax credit on all clinical testing expenses associated with the drug,
- award of an exclusive 7-year right to market a drug that is unpatentable (through the new drug approval authority of the Food and Drug Administration (FDA)),
- technical assistance in the development of clinical testing protocols, and
- award of grants and contracts for clinical testing expenses associated with an orphan drug. (FDA budgeted $500,000 for this function in fiscal year 1983 and $1 million in 1984 (116).)

These benefits are not available to devices.

The 1983 law also established an Orphan Products Board, with responsibility to "promote the development of drugs and devices for rare diseases or conditions . . .," but its specific functions relate to drugs alone. Thus, the support of orphan devices under the new law is largely a conception rather than a reality. Recently, however, NIH has become active in supporting R&D on orphan devices. For example, the National Institute of Neurological and Communicative Disorders and Stroke issued a request early in 1984 for proposals to develop orphan products including drugs, biological, and devices (403).

The definition of an orphan device as stated in the 1983 law and in most discussions of the issue

(115,405) is inadequate because it fails to differentiate between products that are prohibitively costly but not particularly valuable from those that are both costly and valuable. Ideally, a device should be considered an orphan when it can be shown to be:

- very valuable to potential users, particularly in relation to the cost of development, production, and distribution: and
- so costly to develop, produce, and distribute that it would be impossible or inequitable to expect potential users to pay a price that would allow producers to recover these costs.

To take an extreme example, a lifesaving device whose cost per patient is $100,000 would be likely to meet the ideal criteria for an orphan device, whereas a $100,000 per-patient device that improves the quality of life a bit for only a fraction of those who use it probably would not.

Products for rare diseases or conditions frequently (but not ***always)*** meet the aforementioned criteria for an orphan device, because a large part of the cost of R&D and marketing is fixed regardless of the number of units actually sold. With fewer potential users over which these costs can be spread, the price at which the device would have to be sold is likely to be prohibitive. However, a product for a rare disease that is not particularly valuable to users in relation to its costs would not meet the two criteria above, though it would fall into the definition in the act.

There may also be products for relatively common diseases whose costs are still high relative to patients' abilities to pay for them. See box J for a discussion of wheelchairs.

Health insurance, developed as a response to the disparity between the cost of services and patients' abilities to pay for them, complicates matters even further. Third-party payment, which spreads the burden of payment across a broad pool of individuals, is a mechanism for rendering previously orphaned services and products affordable. Indeed, because health insurance generally reduces patients' out-of-pocket costs for health care services, a device whose cost would normally be prohibitive may have an effective price well below that level. For example, coronary artery bypass graft surgery and its related care were estimated to cost approximately $15, 000 to $20,000 in 1981 (454). Third parties have paid for a very large share of these costs, and in 1982, approximately 170,000 bypass operations were performed (401).

Health insurance also forces a redefinition of the market, because insurers' decisions about the coverage of a device and, if covered, the appropriate level of payment become major determinants of patients' and providers' abilities to pay for it. If a service is not covered by health insurance, it may be orphaned; covered and paid for generously, it is not.

Thus, the definition of an orphan device is inextricably linked to the policies of third-party payers. Whereas drugs, particularly those prescribed for use outside of hospitals and other institutions, are poorly covered by health insurance plans (insurance paid only 26 percent of total U.S. expenditures for outpatient prescribed medicines in 1977 (180)), and may therefore occasionally be prohibitively costly to potential users, expensive devices are, with exceptions, in a more favorable position. Devices used for diagnosis or therapy in hospitals, physicians offices, and the home are generally covered by public and private health insurers.

Coinsurance requirements usually follow those for other services provided in the same setting. For example, diagnostic laboratory tests provided as part of the physician's office visit typically have the same coinsurance rate (say, 20 percent) as is applied to the physician's own service.

An example of the difference that insurance payment can make in the definition of an orphan is the recent characterization of an immunoassay test for testicular cancer as an orphan by FDA (205). The test is considered an orphan device because the prevalence of testicular cancer in the United States is less than 200,000 (116). Yet this test will probably be covered by third-party payers as a diagnostic service; so it is questionable whether it actually requires special development assistance.[9]

[9]FDA has not provided substantial assistance to the developers of the test (116).

Box J.—The Wheelchair: An Orphan Device?[1]

Wheelchairs fall into four broad categories: general-purpose manual wheelchairs, power wheelchairs, manual sports wheelchairs, and power alternatives (other motorized vehicles not shaped like a chair). The term "wheelchair" refers here to all four types of equipment.

OTA reported in 1982 that there were about 9 million Americans with lower extremities missing, paralyzed, or impaired (352). Of those people, approximately 1,168,000 (1 American in 200) used wheelchairs. Users in 1977 included 650,000 noninstitutionalized persons (367) and an additional 518,000 residents of nursing homes. The number of nursing home users is expected to grow to 584,000 by 1985, an annual growth rate of 1.5 percent (251).

Although the total size of the wheelchair market is large, the needs of potential users in terms of function and design are highly varied. A 1983 market study by Invacare estimated that the home-care market accounts for 30 percent of the $125.7 million total wheelchair market. (Home-care chairs tend to be manual, fairly standard models for people with limited mobility.) Another 30 percent of the market was attributed to institutions, including hospitals, nursing homes, and rehabilitation centers. (Institutional wheelchairs are also standard, manual chairs used almost exclusively for transport within the institution.) The remaining 40 percent was attributed to rehabilitative care, for active and acute users who are neither home-bound nor institutionalized. (Rehabilitative chairs may be from any of the four basic categories and cover a wide range of customization and cost.)

Over half of all wheelchair purchases are at least partially paid for by government sources. In 1976, 11 percent of purchases were reportedly paid for by the Veterans Administration (213). An estimated 90 to 95 percent of all wheelchair purchases are at least partially funded by third parties (Government or private insurer); only 5 percent are paid totally by the user (214).

Blue Cross of Massachusetts, the largest private insurer in that State, illustrates the impact of insurance payment decisions on the market for wheelchairs. Insurance coverage of wheelchairs depends first on whether the patient's policy covers durable medical equipment. If it does, reimbursement is usually for 80 percent of the reasonable charge. However, Blue Cross will pay only for the least costly wheelchair that meets the user's physical needs. For a new, more costly wheelchair to be covered, it must have a unique feature of *medical* benefit not available on a less costly model. Depending on the policy, purchase of an electric wheelchair is covered up to $2,711; power alternatives are covered up to $2,700. New products are reviewed for coverage by the Medical Review Board. A Physician Advisory Panel may be consulted in cases where the medical benefits of a new product to an expensive new wheelchair with potential usefulness to a small fraction of the market will actually be reimbursed at a level sufficient to make it affordable to those who would benefit from it.

Thus, it appears that although the overall market for wheelchairs is large, the disparate needs of users and the limitations on payment rates may substantially reduce the effective market for new, more expensive designs. More research would be needed to determine whether wheelchairs constitute a class of orphan devices.

[1]Based on a case study prepared for OTA by Shepard and Karon (282).

Thus, while insurance coverage for the use of diagnostic and therapeutic devices is not complete, it is generally much higher than for outpatient drugs. Exceptions to this general rule are:

- preventive devices (e. g., screening tests, home self-testing kits) which are less frequently covered under health insurance plans;
- rehabilitative devices, which are often poorly covered under private and public third-party payment plans (352); and
- devices subject to restrictive third-party payment limits (e. g., some hospital devices under 'Medicare's per-case pricing for inpatient hospital care).

Even in these categories, however, most devices will not meet the ideal definition of an orphan. If they can be developed and distributed at a sufficiently low price, a large enough market may still exist despite poor coverage by third parties.

STATE AND LOCAL INITIATIVES RELATED TO R&D FOR MEDICAL DEVICES

States have increasingly looked to R&D-intensive industries such as medical devices for economic development opportunities. A recent census of State government initiative for high-technology development conducted by OTA identified 38 programs in 22 States with dedicated" programs of high-technology development (3.53). In addition, OTA identified 15 "high-technology education" initiatives, undertaken in conjunction with State universities and dedicated to providing to inventors and entrepreneurs skills they need to create firms that will develop or commercialize emerging technologies. Only a few of these programs actually provided product development assistance or laboratory or office space for new and growing businesses.

Perhaps the program most directly relevant to medical devices is the Health-Care Instrument and Device Institute (HIDI) at the State University of New York at Buffalo, which has been designated by the State of New York as a State-supported center to facilitate direct interface between academic institutions and the needs of industry (see box K). Although the HIDI program has several missions, an important one is to put into practice ideas generated by inventors in the university community (113).

Another popular initiative is the establishment of a research or science park on or adjacent to a university campus. These parks are often encouraged by State or local tax incentives, but many universities have also seen the advantage of encouraging this type of development. In general, these and other universitv-based initiatives are seen as a way of providing consulting opportunities for faculty, employment opportunities for students, and enhanced research funding for the university. Rensselaer Polytechnic Institute, for example, has provided incubator space for entrepreneurs who need assistance to start a busi-

Box K.—The Health-Care Instrument and Device Institute (HIDI)[1]

As part of its advanced technology program, the State of New York has recently designated and funded the School of Medicine, State University of New York (SUNY) at Buffalo as a center for health care technology. HIDI at SUNY-Buffalo was officially designated in January 1984 as a center to facilitate the direct interface between academic institutes and the needs of industry. The State of New York will provide dollar-for-dollar matching funds with other sources up to a maximum of $1 million per year.

HIDI has a core staff of seven at present and is further supported by the scientists and physicians at SUNY-Buffalo and the Roswell Park Memorial Institute.

One of HIDI's missions is to put into practice ideas generated by inventors in health care technology. Most of the inventions, though not all, are expected to be drawn from the university community. Special incentives are used to encourage faculty to submit their ideas to HIDI for potential development. In return, faculty members may receive increased compensation.

HIDI is generally involved in development only to the point of demonstrating technical feasibility and clinical applicability. Then, the patents and technical know-how are sold to firms on an exclusive basis. HIDI will also undertake proprietary R&D for industry on projects that are initiated by sponsors and will generally receive royalties for any inventions that arise.

The ultimate goal of HIDI is to be self-sustaining, with subsidies from New York State gradually tapering off and being replaced by self-sustained income from sales to and contracts with industry.

[1]Based on an article by Anbar (13).

ness (354). Several other universities also provide incubator space for students, including Georgia Tech, Carnegie-Mellon University, Massachusetts Institute of Technology, and the University of Missouri (which also provides commercialization assistance to students.) While some of these centers also assist qualifying small businesses, their major emphasis is on the enterprising student (354).

University-based programs such as these have been criticized for drawing faculty away from the conduct of more basic research in favor of applied research and development. There is also the related issue of maintaining free and open communication within the research community. Successful commercialization requires shielding a potential product from a firm's competitors, as well as obtaining proprietary rights to the invention. To some extent, these requirements conflict with the ideal of freedom of expression in academic environments. Nor has it been documented that the resources provided by university-based centers are addressing the specific barriers to commercialization faced by small or new firms. Since most of these projects are relatively new, it is not possible at this time to evaluate their effects either on innovation or on the quality and quantity of basic research.

DISCUSSION AND POLICY OPTIONS

Is the current level of Federal and industry support for R&D related to medical devices adequate? Federal support for industrial R&D can be viewed as supplementing private firms' activities in ways that advance the public good. Federal support is justified when private firms are not likely to engage in as much R&D as is socially desirable.

Basic research has long been recognized as being particularly subject to underfunding by private firms (56,228,230). To be efficient, basic research should embody as few constraints as possible on research directions and be subject to wide disclosure of research results. These conditions conflict with the ability of private firms to reap the full benefits of their investment in basic research (230). Hence, private firms are likely to underinvest in basic research, and Federal support may be necessary.

As R&D projects are more closely targeted to products or processes with commercial potential, however, the argument in favor of Federal support becomes weaker. The private medical device firm is likely to be able to appropriate more fully the benefits of its investment in R&D the closer the project is to a commercializable device. And as research becomes more targeted and specific to a device, the societal gains from full disclosure of research findings decline.

Two conditions suggest that the present level of private R&D for medical devices is generally adequate. First, if industrial R&D responds to the demands of the market, as has been suggested by several observers (273,276), then the high level of demand for medical devices resulting from health insurance and other third-party payment for health care would argue that medical devices R&D has been adequately, perhaps more than adequately, stimulated. Second, the $5.4 billion Federal investment in health R&D (404) provides a rich and continuing source of new scientific knowledge that creates opportunities for development of new medical devices.

Against this positive picture for R&D on medical devices is the potentially deleterious effect of premarket regulation on the cost and uncertainty of investment in R&D for new medical devices. A Louis Harris survey reported that because of FDA regulations, 27 percent of responding firms stated that they would not consider developing a new Class III device[10] and another 11 percent stated that they would be unlikely to consider any device development (197).

[10] A new Class 111 device must be approved by FDA as safe and effective prior to marketing (see ch. .s).

However, the available evidence seems to suggest that, except perhaps for small firms and manufacturers of Class III devices, the medical devices regulations as they have been implemented have not added substantially to the cost of development, because the vast majority of devices introduced since the passage of medical device regulations in 1976 have not been required to undergo rigorous premarket testing (see ch. 5 for details). However, firms have been subject to some uncertainty about how the regulations would be applied.

The Federal Government has recently embarked on a new strategy—the SBIR program—that does not increase overall R&D budgets but instead shifts the allocation of health R&D funds from other uses to the program's recipients (small firms). The NIH SBIR budget is likely to come at least partially from funds that would otherwise be used for basic research and would go to nonprofit institutions. Therefore, the program probably results in a small net shift of health R&D funds toward the development of medical devices. It is impossible to know whether this shift is in the best interest of society. Given that the SBIR program will consume an increasing proportion of NIH grant and contract funds in the future, continuing scrutiny of the program's grant solicitation and selection methods is advisable.

There are specific areas where increased targeted Federal support of R&D on medical devices may be justified. True orphan devices—those meeting the dual criteria of high per-unit cost of development and distribution relative to potential users' ability to pay and high value in relation to cost—are by definition worthy of support. However, it is difficult to differentiate between devices that lack a sufficient market because those who value them highly cannot afford them and devices that lack a market because their extra benefits to society do not outweigh the costs of bringing them to market. Sound criteria for identifying devices meeting the ideal definition of orphan have not been developed either in the law or in regulations.

The problem of orphan devices may grow as pressures to contain health care costs lead third-party payers to develop increasingly restrictive payment policies. Because the definition of a true orphan device is inextricably linked to the policies of major third-party payers regarding coverage and levels of payment, criteria for identifying orphan devices will have to take these payment policies into account.

There appear to be sound theoretical reasons for supporting development of devices meeting the ideal definitions of orphan: high value in relation to cost and high per-unit cost of development and distribution relative to potential users' ability to pay. Whether in practice there are many devices that meet this definition, however, has not been investigated.

One way to assist the development of orphan devices, apart from providing direct Federal grants and contracts for R&D, would be to amend the Orphan Drug Act (Public Law 97-414) to make orphan devices eligible for the tax credits and grants offered under that act. The act currently provides a 50-percent tax credit for all clinical testing expenses associated with an orphan drug and authorizes the Secretary of Health and Human Services to make grants for clinical testing. It is important to recognize, however, that the currently inadequate definition of orphan products in the law, which depends on the "rare disease" criterion to identify orphan drugs, may encourage devices that are not worth their costs to society to be designated as orphans. Thus, it would probably be premature to change the law until criteria and methods of analysis are developed that will allow for adequate differentiation between devices that lack a market because they are truly orphaned and those that are simply not worth their costs to society.

Option 1: Mandate that DHHS develop criteria and methods for *identifying* ***true orphan*** *devices.*

This option would be particularly useful now, when Medicare is implementing restrictive new payment policies in hospitals and changes in physician payment are being contemplated. Without adequate methods for assessing the extent to which a given device meets criteria for orphanhood, decisions about R&D subsidies (either

through direct grants or tax subsidies) for orphan device development are unlikely to be appropriate.

Because the criteria for orphanhood go well beyond issues of safety, effectiveness, and disease incidence to payment issues, the development of such criteria and methods would probably require participation of a number of constituent agencies of DHHS, including FDA, NIH, and the Health Care Financing Administration.