CF
PPS please.

PRIME MINISTER

ACARD REPORT ON MEDICAL EQUIPMENT

OR
PL typing PS letter for my sig.
(copy draft up here) The letter to Sir F can be digitised.

Sir Francis Tombs has submitted to you a report on medical equipment drawn up by a working group, and endorsed by the Council.

The report and his covering letter are at Flag A. A summary of the report's recommendations is at Flag B.

The report grew out of a concern that the UK medical equipment industry was showing signs of failing to keep up with its international competitors. It concludes among other things that the industry does need to adopt a more international perspective, that Government support for R & D needs to be increased, and that NHS decision makers need strong support to encourage them to support the UK industry wherever possible.

Sir Francis seeks your agreement to publication, which you normally give for the ACARD reports of this kind. John Fairclough agrees that you should give it in this case. DHSS are content.

DHSS would then need to coordinate a draft response. John Fairclough notes that the Government will need to consider particularly carefully the recommendations dealing with public expenditure (eg an increase on capital equipment budgets for Health Authorities), providing additional manpower to the DHSS Procurement Directorate, expanding the evaluation programme for new medical equipment and increasing Government support for R & D in the industry. But he thinks the general tenor of the report is reasonable and consistent with the general direction of Government policy.

Agree to publication? Agree that DHSS should be asked to coordinate a Government response? Yes MEA

A letter of acknowledgement for your signature to Sir Francis Tombs is attached at Flag C.

MEA

MARK ADDISON
30 May 1986

CJ2AAX

JCBG

Peter Casey
Fisheries Group DTI.

WO39

MR ADDISON - No. 10

27 May 1986

ACARD REPORT ON MEDICAL EQUIPMENT

The Advisory Council for Applied Research and Development (ACARD) has recently considered a report on the medical equipment industry prepared by a Working Group set up by the Council. ACARD approved the report and invited Sir Francis Tombs to submit it to Government. He will shortly be sending a copy to the Prime Minister. For your information a copy is attached. A summary of recommendations follows the foreword. I attach a draft reply for the Prime Minister to send to the ACARD Chairman.

ACARD would like the report to be published and have invited Sir Francis Tombs to seek the approval of the Prime Minister. It has been customary for such approval to be given, and I see no reason why approval should not be given in this case. Although the Government will wish to consider the recommendations carefully, particularly those which involve public expenditure (paras 68, 100, 144 and 154), the general tenor of the report is reasonable and consistent with the broad directions of Government policy.

The Council will expect the Government to provide a written response. The subject is of interest to several Departments and two Research Councils, but the natural lead Department is DHSS and I recommend that they be invited to co-ordinate the Government response. It would be helpful if the Prime Minister could draw the attention of her colleagues to the report and indicate to them how the report will be handled by means of a Private Secretary's letter. A draft is attached. We shall supply you with the required number of copies.

JOHN W FAIRCLOUGH
Chief Scientific Adviser

DRAFT LETTER FOR THE PRIME MINISTER'S PRIVATE SECRETARY TO SEND TO PS/SECRETARY OF STATE FOR HEALTH AND SOCIAL SECURITY

ACARD REPORT ON MEDICAL EQUIPMENT

The Prime Minister has received a report from the Advisory Council for Applied Research and Development (ACARD) on the medical equipment industry, together with a covering letter from the Chairman of ACARD. A copy of the report is attached.

The Prime Minister has agreed that the report should be published.

As is customary, a written response will be provided by Government and the Prime Minister has asked that the Secretary of State for Health and Social Security should take the lead in co-ordinating the Government response.

I am copying this letter and the report to the Private Secretaries of other Cabinet Ministers and to Sir Robert Armstrong and the Chief Scientific Adviser, Cabinet Office.

DRAFT LETTER FOR THE PRIME MINISTER TO SEND TO SIR FRANCIS TOMBS

Thank you for your letter of [22 May] and the Council's report on medical equipment. The medical equipment industry is an important one for this country, and the Council's recommendations will need to be considered carefully.

I agree to publication of the report. I have asked for arrangements to be made for the Government's written response and this will be communicated to ACARD in due course.

R23/45

ADVISORY COUNCIL FOR APPLIED RESEARCH AND DEVELOPMENT

70 Whitehall, London SW1A 2AS Telephone: 01-233

The Rt. Hon. Margaret Thatcher, MP.,
The Prime Minister,
10 Downing Street,
London, SW1.

sgk DHSS

22 May 1986

Dear Prime Minister,

ACARD REPORT ON MEDICAL EQUIPMENT

The Advisory Council for Applied Research and Development (ACARD) has recently completed a study of the medical equipment industry. I have pleasure in enclosing a copy of the report on the study. The report, and its recommendations, have been endorsed by the Council who have invited me to submit it to the Government, and seek your approval for publication.

The UK medical equipment industry has a turnover of around £1 billion a year. The industry world-wide has seen substantial growth in recent years, and is expected to continue to grow for the foreseeable future. It is a high technology industry in which Britain has been very successful, but where there are signs that our industry is beginning to fall behind in important areas of the business. It is also an industry which is strongly influenced by the public sector which, in addition to its normal activities towards industry, is, through the NHS, its dominant home customer.

In the view of the report, the long term health of the industry will depend on an adequate level of research and development, with strong links with academic research and clinical practice. It will also depend on being able to attack overseas markets successfully, which will require better marketing and design, and the removal of the unnecessary regulatory barriers which exist, particularly in Europe. It will also require a home market which not only provides a base of demand for products which can be sold profitably overseas, but also allows growth opportunities for the many small companies in this business. Many of the difficulties which the industry faces are by no means unique to medical equipment, but we have tried to concentrate on those which are, or which at least apply to this industry with particular force.

The report makes a considerable number of recommendations, which are summarised at the end of the report. They cover a wide area, including the encouragement of R&D links between firms and health service staff, Government R&D support, and the regulatory and information activities of DHSS. The most important group of recommendations, however, is aimed at the character of the home market, which is determined by the actions of NHS buyers. We believe that this market needs to be a free one, but also well-informed and responsible, which implies considerable improvements in NHS systems, attitudes and practices. ACARD believes that if its recommendations are accepted, they will provide an environment in which this important and growing industry has every chance to prosper, provided that those within it take the opportunities offered to them.

Yours sincerely,

Francis Tombs

Sir Francis Tombs

Enclosure

ADVISORY COUNCIL FOR APPLIED RESEARCH AND DEVELOPMENT

REPORT ON MEDICAL EQUIPMENT

Cabinet Office
May 1986

FOREWORD

The UK medical equipment industry has a turnover of around £1 billion a year, and has in the past been one of Britain's successes. It is a business much of which can expect to see major technical changes over the next few years, and which is becoming increasingly international. Indeed, with the UK representing only a very small proportion of the world market, it is essential for the industry to take an international view if it is to be able to afford the commitment to R&D which will be necessary to keep up with the competition in many areas of the business. Although many indicators of its performance remain strong, there are worrying signs that the industry may be failing to keep up, both technically and commercially.

The industry is also strongly influenced by the actions of the public sector. In addition to the usual background of Government economic policy and industrial sponsorship, it operates both nationally and internationally in a complex regulatory environment. Above all, its home market, which is important for any industry, is dominated by the actions of buyers within the National Health Service.

Against this background, ACARD set up a Working Group in December 1985, with the following terms of reference:

i. to examine the UK medical equipment industry, with particular reference to its technological capability, its international opportunities, and its prospects in the face of international competition;

ii. to review the effects of the activities of Government and other public bodies on the ability of the industry to compete world-wide, including where relevant their effects on the character of the domestic market;

iii. to make recommendations.

The members of the Working Group were:

*Sir Rex Richards FRS — Director, Leverhulme Trust
(Chairman)

*Mr M Bullock	Corporate Finance Director, Barclays Bank plc
Mr P F Burden	Director of Manufacturing Operations, Rolls-Royce Ltd.
Mr. R.F.O. Burlinson	Managing Director, Orbec Ltd.
Mr. J. Hutton	Senior Research Fellow, Centre for Health Economics, University of York
Mr B D Muddell	Director, Business Planning, Smiths Industries Medical Systems
Professor D K Peters	Professor of Medicine, Royal Postgraduate Medical School
Mr C J Spry	District General Manager, Newcastle Health Authority
Mr P R D Styles MBE	Director-General, British Health Care Trade and Industry Council

*ACARD member

The Group also had assessors from the Department of Health and Social Security, the Department of Industry, and the Science and Engineering Research Council, who made valuable contributions to its work.

The report of the Working Group was considered by ACARD in May 1986, and has been submitted to the Government for their consideration. It is now published to draw attention to the Group's recommendations, and as a stimulus to discussion.

The Council is grateful to the members of the Working Group for their contribution to ACARD's work, and to the many companies, organisations and individuals who helped in their work, including the ACARD Secretariat in the Cabinet Office.

SUMMARY OF RECOMMENDATIONS

A. Our central recommendation is in para 73, in which we emphasise that NHS decision makers should be kept constantly aware that NHS purchasing is by far the dominant domestic influence on the shape of the UK medical equipment industry, and that the NHS benefits both directly and indirectly from a healthy UK industry. We recommend that the Health Departments should issue guidance emphasising the need for a full option appraisal, including full consideration of British equipment and making use of the available expert advice, for all major NHS purchases whether or not they are financed from public funds. (para 73)

B. NHS decision makers need stronger support in terms of systems, information, and expertise. The new NHS Director of Procurement and Distribution should continue the process of improving NHS information, financial, and purchasing systems as rapidly as possible. DHSS should take steps to provide for increased research and information on the health economics of new techniques and equipment. Health Authorities should be encouraged to invest in new equipment where this can be shown to offer increased efficiency, and the economic appraisal expertise available to Health Authorities should be strengthened. The DHSS/SHHD evaluation programme should be continued and expanded, and the modest expenditure devoted to it should be materially increased. The pump-priming funds available to the DHSS should be used primarily to introduce new medical technologies of British manufacture to the NHS and to promote their rapid assessment. (paras 64, 66, 67, 77 and 144)

C. The capital equipment provision in both Regional and District Health Authority budgets should be increased, and steps should be taken to ensure that this provision is used for the purpose for which it was allocated. (para 68)

D. The market for equipment in the primary health care sector is growing rapidly outside this country. In considering policy on the funding of primary health care services, the Government should take into account the interest of the medical equipment industry in a GP market parallel to that existing elsewhere. Trial practices should be established in which GP's would be

encouraged to provide a greater range of services, and UK industry should be linked with this experiment and encouraged to use these practices as a test ground for new products aimed at the GP market. (paras 92 and 93)

E. Government support for R & D on medical equipment should be substantially increased. A mechanism should be set up to coordinate the programmes of DHSS, DTI and SERC in the medical equipment field. This mechanism should involve participation by MRC and industry. (paras 154 and 155)

F. The industry needs to address international markets, and there are several steps the Government could take to help it to do so. The regulatory environment is particularly important. Additional manpower should be provided to STB for the operation and expansion of the Manufacturer Registration Scheme. The Government should take a stronger political initiative within the European Community to create a freer internal market in medical equipment by eliminating the barriers currently created by differing national standards and regulatory regimes. (paras 100 and 102) The Government should recognise the value to UK industry of overseas students studying medicine and its supporting disciplines here, and in particular should give positive encouragement to postgraduate study in the UK in these areas. (para 75) DTI should give wider publicity to market reports from British Posts overseas and to the other help to exporters which Posts can provide. (para 54)

G. A single Branch within DTI should be given coordinating responsibility for all those sponsorship and support activities towards the medical equipment industry that fall to DTI, including responsibility for liaison with DHSS and SERC on matters relating to the industry. (para 126)

H. We found perceived barriers to the essential close collaboration between the industry and members of the health care professions, and make recommendations to overcome them. The Health Departments should issue new guidance to Health Authorities which, whilst reiterating the need to prevent corruption in purchasing activities, gives positive encouragement to the creation of R & D links with UK-based firms. They should also issue guidance on the terms of relationships with firms, and should encourage Health Authorities

to employ staff on contracts which permit them, if they wish, to spend part of their time in industry. (paras 117, 118 and 119) The Health Departments, the main trade associations and those professional associations which are active in this field should take steps to improve understanding between people in industry and those in the health service. (para 120)

I. The industry could also derive greater benefit from the education and training system. SERC should give high priority to medical engineering in their support of postgraduate training. Medical engineering, industrial design, and management engineering should be priority areas for future university appointments. (paras 158 and 159)

J. There are problems in obtaining good and relevant statistical and market data on the industry. A joint group from industry, Customs and Excise and DTI should be set up to produce a more helpful classification scheme for the Government statistics relating to the industry. (para 163) The NHS should begin now to plan how its equipment purchasing data could be made available to industry. (para 164)

INTRODUCTION

1. The medical equipment industry is a major one, with a turnover in the UK of around £1 billion a year. It has seen substantial growth world-wide in recent years, growth which is expected to continue in the foreseeable future, and which in some areas has been quite spectacular. It is an industry in which Britain has been very successful, and which contains important high technology sectors. It is also an industry strongly influenced by the actions of the public sector which, in addition to its normal activities towards industry, is in this case, through the NHS, its dominant home customer. But there are signs that the UK is falling behind the game in important areas of the business. It was these circumstances which led ACARD to set up this Working Group.

2. There is no universally accepted definition of what the medical equipment industry is, and almost every writer on the subject adopts a slightly different view. For our study, we have taken a pragmatic view based on industrial considerations as well as what is actually produced and traded. We have concentrated on those sectors which produce hardware specifically designed for medical use. Following DHSS practice, we have included in this definition both capital and consumable items. The wide range of this definition can be seen by listing just a few of the items which come within it: artificial hip joints, autoclaves, catheters, electrocardiographs, forceps, hospital beds, massage apparatus, MRI scanners, spectacles, syringes, wheelchairs. However, whilst directing our attention primarily to this area, we have also looked at a penumbra of other activities surrounding it, which some would include in the definition of medical equipment. Various kinds of laboratory equipment, diagnostic kits, and surgical dressings come within this latter area, as do some major components of medical equipment (eg magnets for MRI). As suggested above, our reasons for regarding a given area as within, or not within, our "core" are in some cases partly industrial. Thus, for example, surgical dressings are produced mainly by the pharmaceutical industry, which is very different in character from the medical equipment industry as we have defined it. In addition, we have tried to take note of developments in other areas where these seem likely to impinge on the business of our "core" industry. An example is the development of intravenous anaesthetics, which will affect the market for the traditional inhalation equipment.

3. We have found in the United Kingdom an industry which seems to us to be at

the crossroads. It has many strengths, but also a number of weaknesses. It is being exposed to fiercer competition than ever before, both at home and abroad, in a rapidly changing technological environment. The potential for success is there, but so is the potential for a failure which would leave our successors wondering how another major British industry was lost.

4. In what follows, we have inevitably concentrated more on the weaknesses than on the strengths, because it is in these areas that we see the greatest scope for action. We have also produced many more recommendations addressed to the public sector than to industry. This partly reflects the position of ACARD as an advisory body to Government. It also partly reflects our preference for recommendations to specific recipients to take specific actions over more general recommendations aimed at "the industry". It does not, as we hope the text makes clear, reflect a belief that all fault, or all merit, lies with Government rather than industry. Indeed it is, and must remain, those in industry who will carry the main burden of responsibility for success or failure.

THE WORLD MARKET AND THE UK's PLACE IN IT

5. There are no reliable and up to date figures for the world market in medical equipment. This stems partly from the familiar delays in producing international statistics, but much more from the fact that, as we have already indicated, "medical equipment" is not an area in which statistics have been collected on a well-defined and accepted basis. We have had to use such figures as we could find, from a variety of sources. One set of industry analysts, applying a rather wide definition of medical equipment, estimates the world market in 1985 as $30 billion, broken down as follows:

Table 1

	Sales ($ billion)			
Product Group	US	Europe	Rest of World	Total
Laboratory diagnostics	2.50	1.25	1.25	5.00
Imaging	2.75	1.25	1.00	5.00
Other electromedical	2.75	1.25	1.00	5.00
Single-use	6.50	3.00	2.50	12.00
Specialties	1.50	0.75	0.75	3.00
Total	16.00	7.50	6.50	30.00

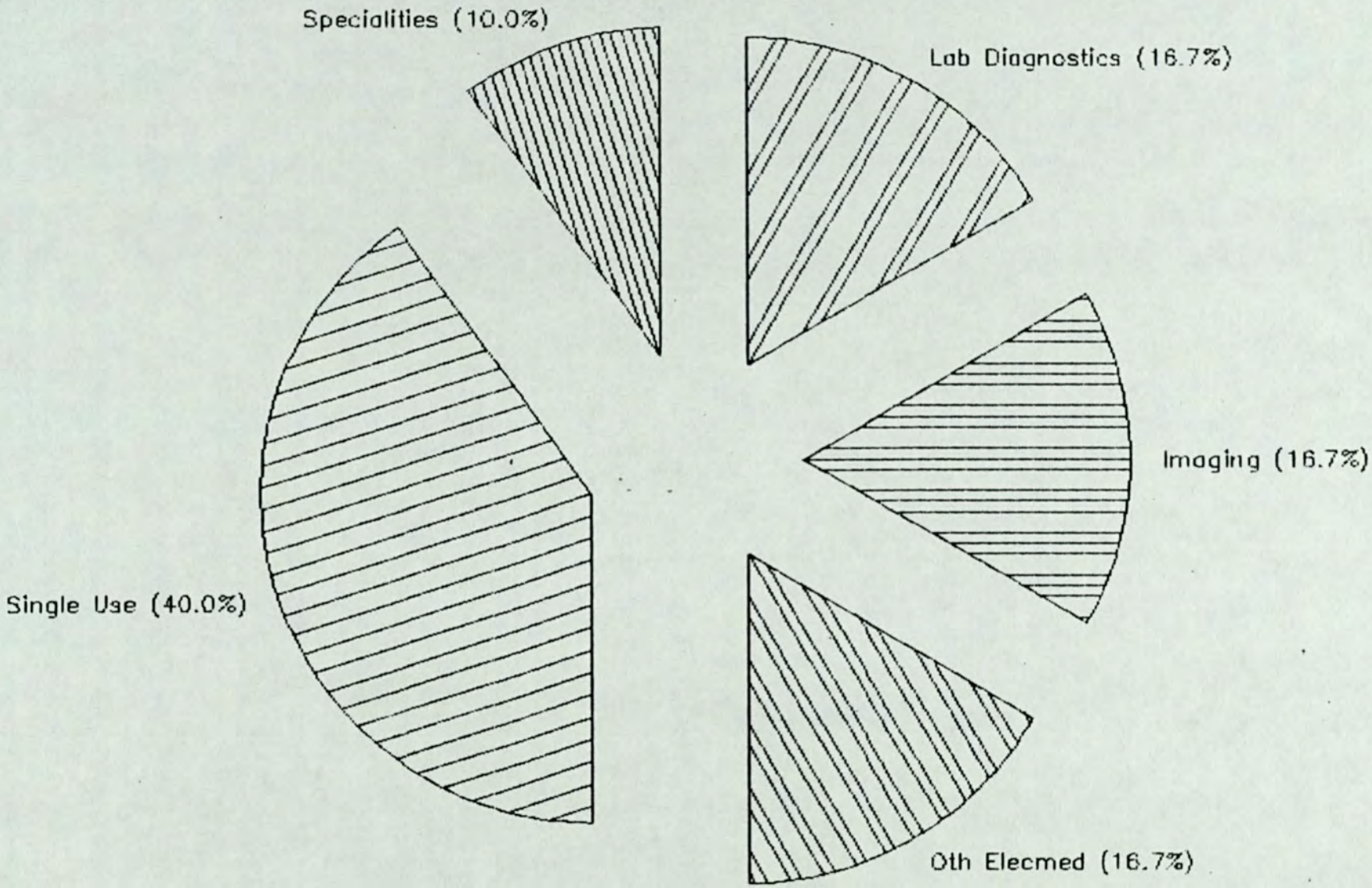
(Source: E.B. Savory Milln & Co.)

6. A more detailed breakdown by equipment type is given in Appendix 1. Those of us with knowledge of the market regard these figures as plausible, but we must emphasise that we have not been able to check them, and their authority is simply that of their source. It will be seen immediately that the market is dominated by the USA, which on all estimates amounts to about half the world market (strictly, the free world market). The UK market is generally reckoned to amount to around 4% of the total. This is consistent with the picture derived from DHSS statistics and estimates, which show a UK market, on their definition (wider in some respects and narrower in others) of around £1 billion a year.

7. We have not found it possible to obtain figures for market growth which are both consistent and credible. The DHSS figures appear to show UK market growth of around a third (in cash terms) between 1982 and 1984, equivalent to

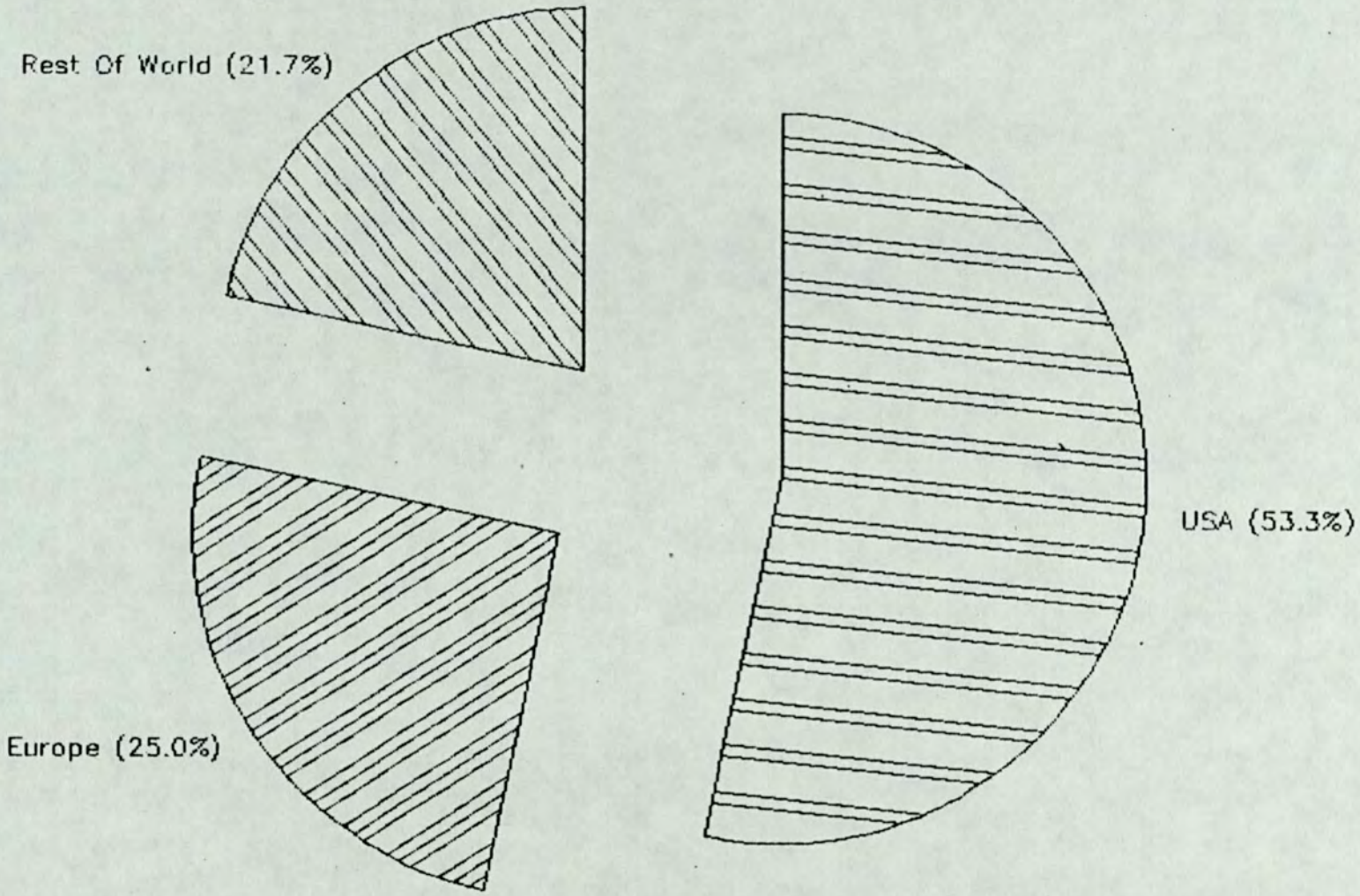
Estimated World Market by Product

1985



Estimated World Market by Area

1985



growth in real terms of some 9% a year, but it must be said that this does not accord with the perception of many in the industry about their principal market. The most reliable figures available are for US production which, according to the US Department of Commerce, grew by 6.9% a year in real terms between 1977 and 1983, and is forecast to grow at 4.9% a year from 1986 to 1990. These figures, however, mask a very wide variation between different types of equipment, some of which industry analysts forecast to show annual increases of 25% or more. These are mainly to be found amongst the areas of new technological opportunity, which we discuss later in this report (para 105 et seq.)

8. International trade in identifiable medical equipment in 1983 amounted to somewhat over $3bn, on the OECD's rather restrictive definition. The principal exporter was, not surprisingly, the US, followed by Germany, Japan and the UK. Some way behind came Ireland, France, Switzerland, Italy, Sweden and Yugoslavia.

9. The UK has for many years maintained a positive trade balance in medical equipment. But between 1980 and 1984 the position deteriorated quite markedly (Table 2). Imports grew faster than exports in every year from 1981 onwards, so that although the trade balance did not change greatly in cash terms, it came to represent a much smaller proportion of the total volume of trade (imports plus exports). 1985 showed a reversal of this general trend, with a sharp increase in the trade balance. Exports retained the growth levels they had shown in the previous few years, whilst the growth of imports slowed very markedly. This may reflect a slowdown of home demand resulting from the shortage of money perceived within the health service.

Table 2

UK TRADE IN MEDICAL EQUIPMENT 1980-1985

	Exports		Imports			
	Value £m	% change over previous	Value £m	% change over previous	Trade balance £m	Trade balance / Total trade %
1980	266.0	11.7	196.0	10.0	70.0	15.2
1981	287.9	8.2	244.7	24.9	43.2	8.1
1982	348.3	21.0	306.2	25.1	42.1	6.4
1983	411.5	18.1	371.3	21.2	40.2	5.1
1984	476.6	15.8	433.9	16.7	42.7	4.7
1985	560.5	17.6	470.4	8.4	90.1	8.7

Source: DHSS analysis of Customs and Excise statistics

10. Table 3 shows the UK's performance in particular markets. The figures demonstrate that the UK industry is showing encouraging growth in the US, albeit from a low base, and with much lower growth in 1985. But our trading performance in Europe has been very disappointing, given that this market is on our doorstep, and that the main parts of it are fellow members with us of the European Community. Our performance vis-a-vis the rest of the world is more satisfactory in trade balance terms, though we see a rapid growth in import penetration, from a low base. Our principal export markets in this category are Japan, the Middle East and the countries of the former Empire. We may therefore be seeing the effects of erosion of our position in former colonies, coupled with the recent decline in the position of the OPEC countries. Increasing import penetration probably reflects mainly the rise of Japan in this business, but there are also imports of relatively low technology items from emerging countries like Malaysia.

Table 3

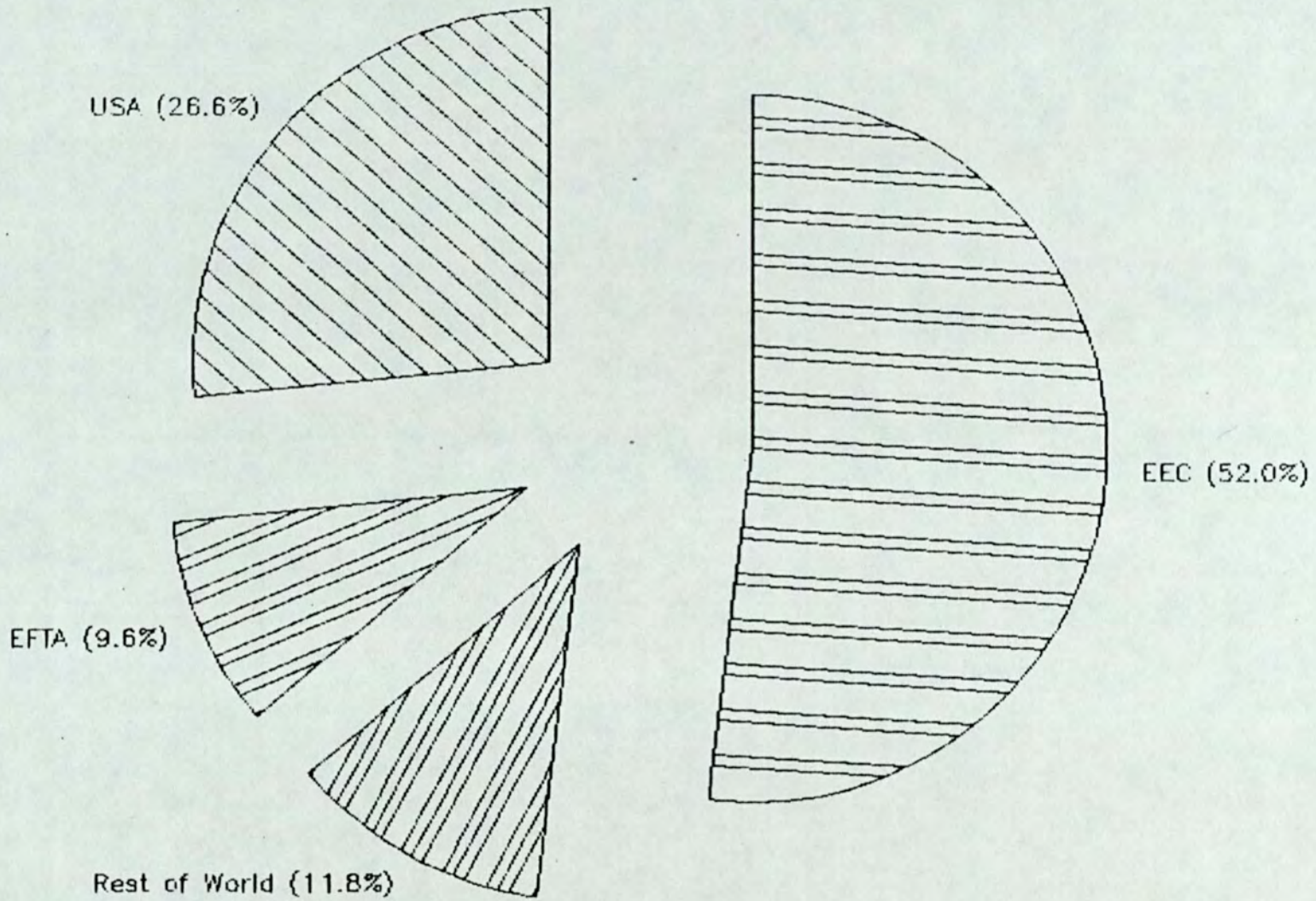
UK TRADE IN MEDICAL EQUIPMENT 1980-1985 BY AREA

	Exports		Imports		
	Value £m	% change over previous	Value £m	% change over previous	Trade balance £m
USA					
1980	25.9	n/a	40.4	n/a	- 14.5
1981	30.9	19.6	66.2	63.9	- 35.3
1982	41.8	35.0	93.5	41.2	- 51.7
1983	71.6	71.5	121.3	29.7	- 49.7
1984	92.2	28.8	131.8	8.6	- 39.6
1985	98.8	7.2	125.2	-5.0	- 26.4
EEC					
1980	101.5	n/a	116.7	n/a	- 15.2
1981	97.0	- 4.4	129.7	11.1	- 32.7
1982	113.3	16.8	156.9	21.0	- 43.6
1983	139.7	23.4	176.5	12.5	- 36.8
1984	163.9	17.3	214.8	21.7	- 50.9
1985	196.5	19.9	244.5	13.8	- 48.1
EFTA					
1980	23.5	n/a	17.3	n/a	+ 6.2
1981	23.3	- 0.8	21.8	25.8	+ 1.5
1982	27.2	16.9	25.8	18.1	+ 1.4
1983	29.2	7.3	34.3	32.9	- 5.1
1984	34.0	16.4	40.9	19.4	- 6.9
1985	41.9	23.1	45.0	10.1	- 3.2
REST OF WORLD					
1980	115.1	n/a	21.6	n/a	93.5
1981	136.7	18.8	27.0	25.2	109.7
1982	166.1	21.5	30.0	11.2	136.1
1983	170.9	2.9	39.2	30.7	131.7
1984	186.5	9.1	46.4	18.4	140.1
1985	223.3	19.7	55.6	19.9	167.6

Source: DHSS analysis of Customs and Excise statistics

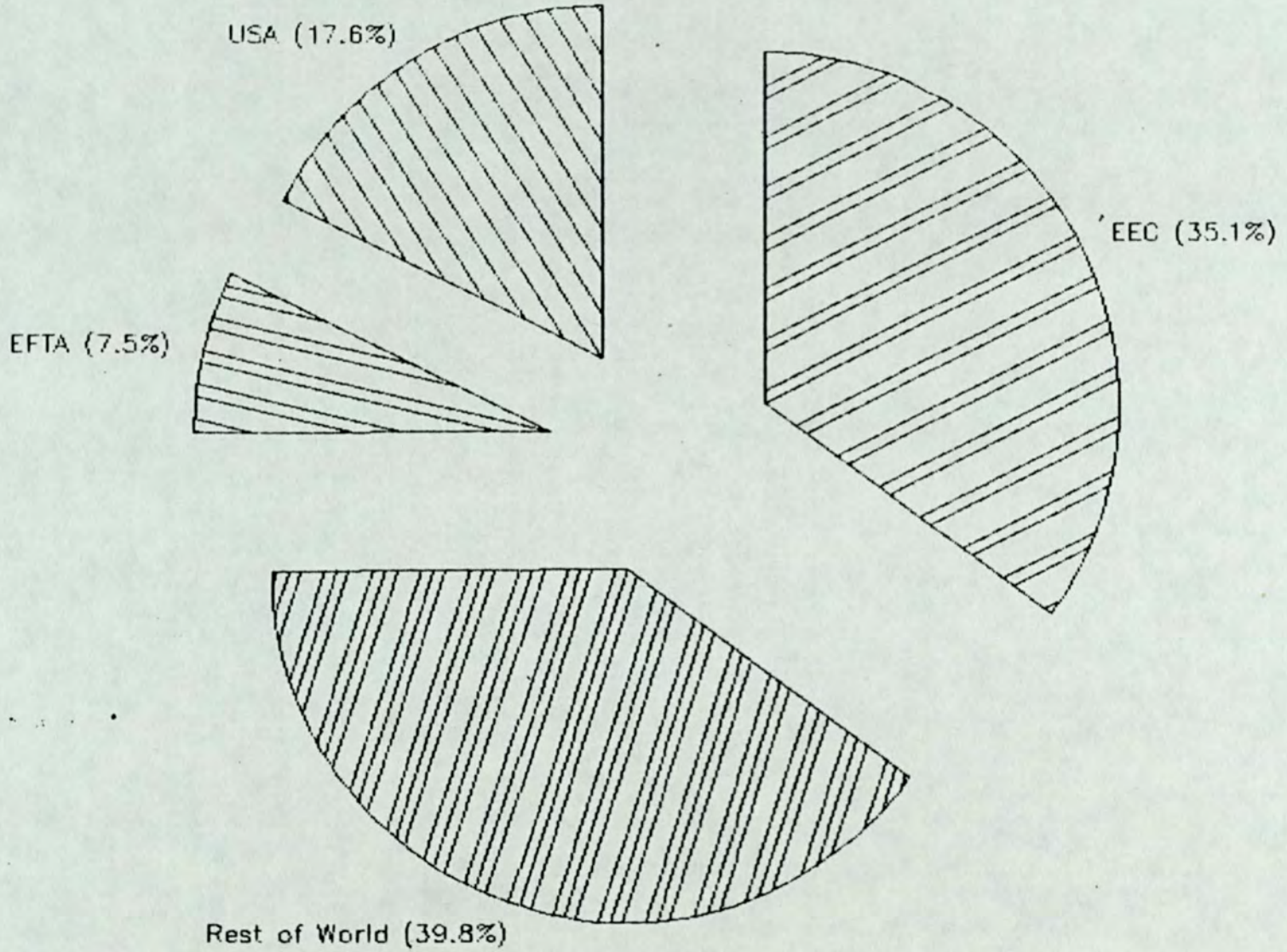
UK Imports of Medical Equipment

1985



UK Exports of Medical Equipment

1985



11. At the level of individual countries, the UK's top ten export markets in 1985 were (in order), the USA, Germany, France, Saudi Arabia, Ireland, Italy, Japan, the Netherlands, Australia and Denmark. This list has changed very little over the previous few years. Thus our principal competitors are also among our principal overseas markets. One implication of this is that any obviously protectionist strategy towards the industry could be highly counterproductive, and most industrialists to whom we have spoken would oppose any such strategy.

12. Appendix 2 shows the UK's trade performance for particular sectors of the business. This information is, however, difficult to interpret, mainly because some of the categories themselves are not very usefully defined. This reflects fundamental limitations in the original data gathering.

13. The statistics do not, we must admit, present a clear picture. They can be interpreted in support of the hypothesis that the UK is falling behind internationally, but they can equally well be interpreted as showing a highly successful performance interrupted by a brief dip in the early years of this decade. The picture we have gained from our industrial, medical, and NHS contacts is, however, much clearer. It tells of an industry which is falling behind in the areas of high technology, and surrendering the leading edge of clinical practice increasingly to foreign competition. At the same time, it is under threat in lower technology, commodity, areas from low-cost competitors in the developing countries. We do not believe that this evidence, anecdotal though it is, can be set aside. On the contrary, we think it likely that it is giving warning of major problems before these are reflected in the statistics. The picture is not, however, one of unrelieved gloom. There are British firms in many areas who are performing successfully in demanding areas of the international market. Britain also has a strong position in medical science, which, as we shall see, should be a considerable industrial asset. But the situation overall nevertheless gives us considerable concern.

THE BRITISH INDUSTRY

14. Data on the UK medical equipment industry are very incomplete. Indeed, in some ways it is misleading to refer to a medical equipment industry at all. For many firms medical equipment is only a part of their overall business. More important, the term embraces, as we have seen, a wide variety of products, within which individual enterprises are often very specialised. For any given product, there are likely to be only four or five real competitors in the market place, and the market can therefore be regarded as broken into a large number of subsectors. Nevertheless, the term is not meaningless. There clearly exist firms a substantial part of whose business consists in selling goods, other than pharmaceuticals, which are specifically designed for medical use. And these firms operate in an environment which is distinctive and which has a large number of common features between the various subsectors. We look first at the statistical data on the sector, and in particular at its financial performance.

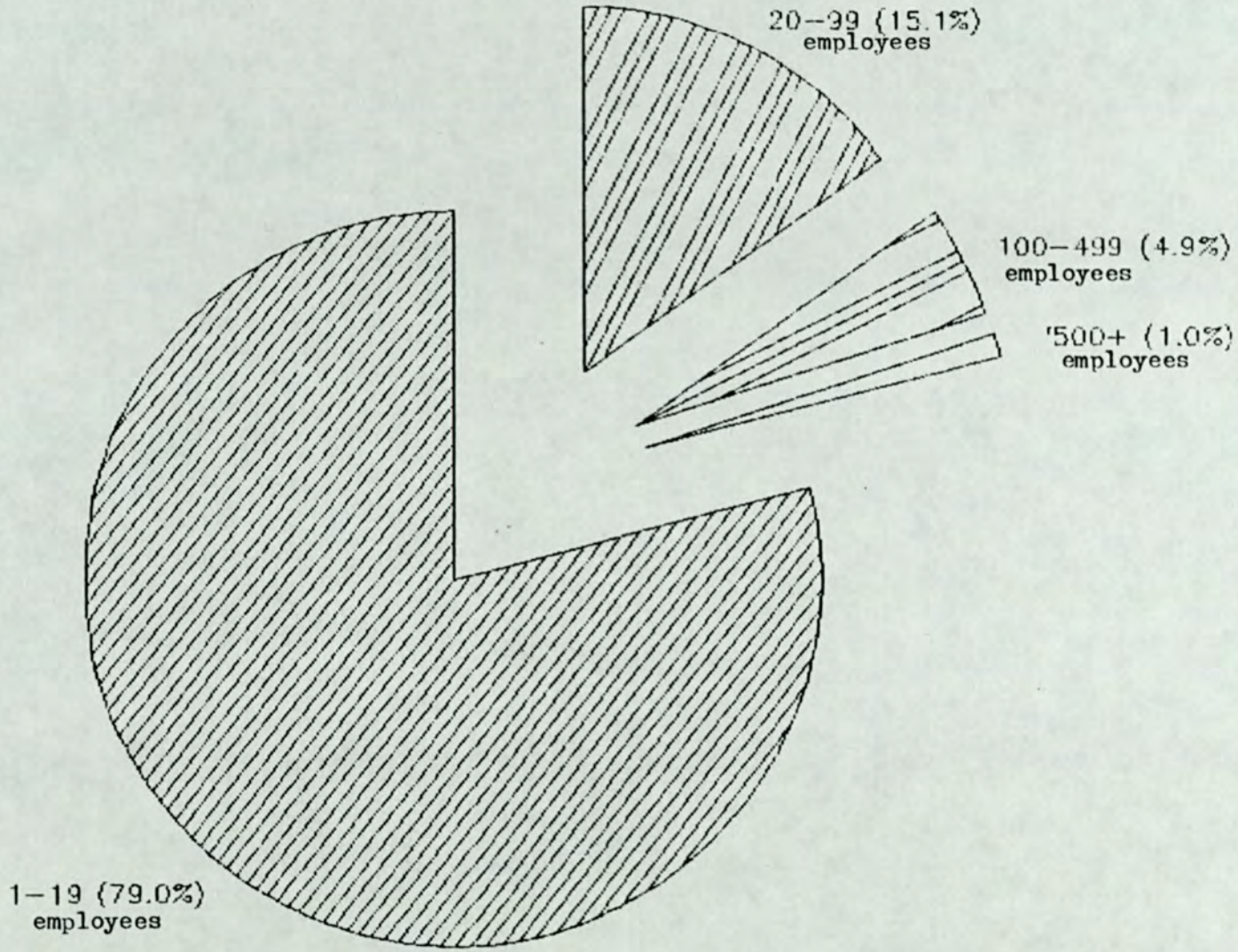
15. DTI performed a special analysis for us of the 1980 and 1983 Census of Production data covering a large majority of firms in the industry. This provides us with a statistical picture of the sector. It is based on "establishments" (typically single manufacturing sites) rather than companies. The evidence suggests that the total number of companies involved will be about 10% less than the number of establishments.

16. This analysis shows us a sector which is relatively small, comprising approximately 0.5% of the manufacturing sector. Average sales of the largest establishments are only some £22m. On the other hand the average sales of the smaller companies are quite high at a little over £200K and there are a number of attractive aspects to the sector's performance: output growth is faster than the rest of manufacturing, gross value added as a proportion of sales is reasonably high and, with improving labour productivity, net margin on sales is also improving. In the light of this, it is noteworthy that the population of the sector has not increased; in fact we find a broadly stable population of just over 1,000 establishments, the great majority of which are very small (78%) employing below 20 employees.

17. The 230 establishments comprising the small (20-99 employees) to large (over 500 employees) segment compares broadly with the 300 core medical equipment companies identified by commercial analysts, with a further 100

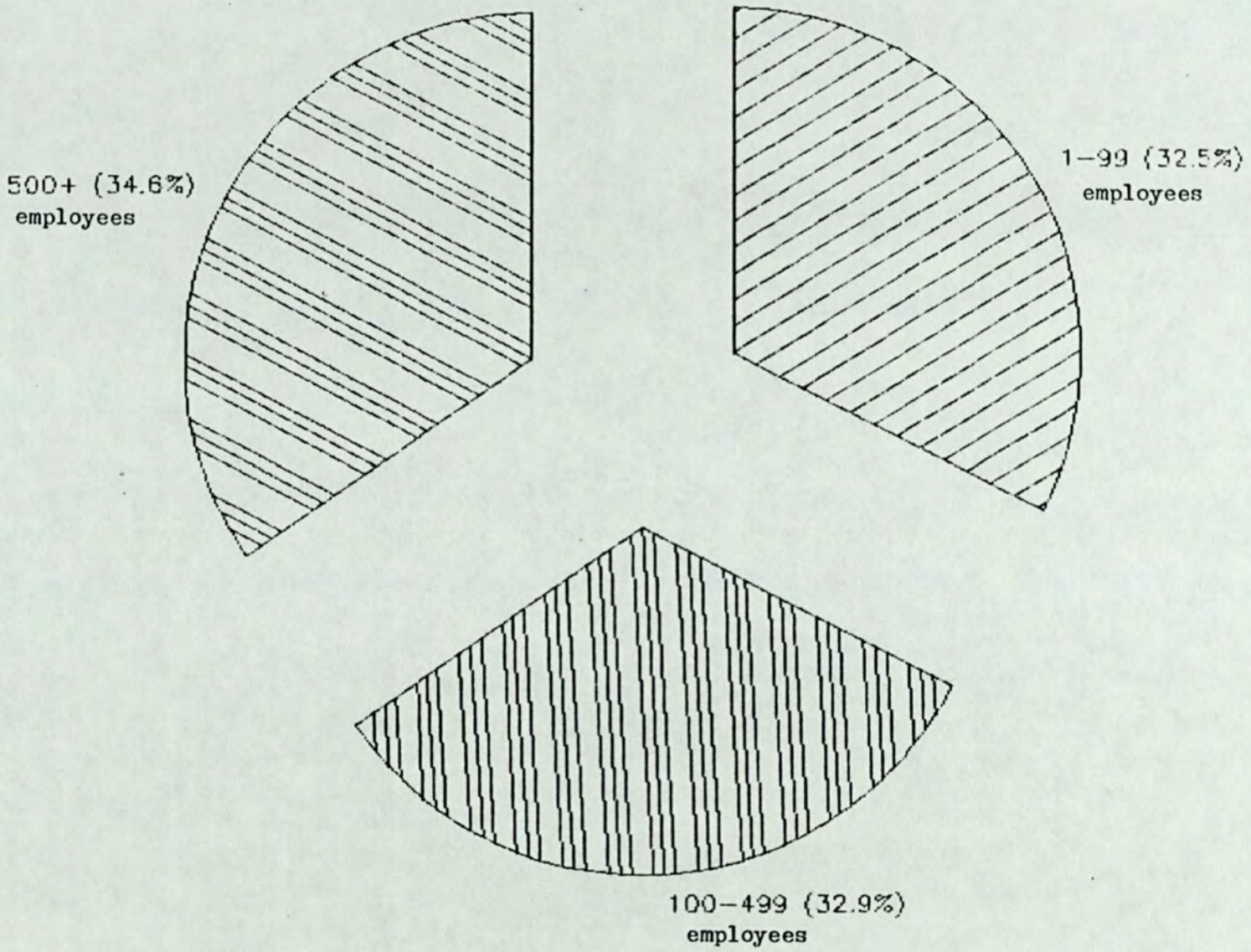
Medical Equipment Industry

Number of Establishments
by number of employees



Medical Equipment Industry

Gross Output by size of establishment



engaged peripherally in the sector alongside other light engineering or electronics activities.

18. Total output is shared roughly equally between the large, medium and small segments, but output per establishment naturally varies with size:

Establishment size	Average Turnover £K
Very small/small	200
Medium	4,500
Large	22,300

(Source: 1983 Census of Production)

19. In 1983 gross output of the sample was £731m, nearly 50% higher in cash terms than in 1980, suggesting a lively compound growth rate of approximately 15%. This compares with manufacturing output as a whole which fell by 6% over the same period. £116m of this gross output was accounted for by factored goods. These thus constitute a significant part of the business even for manufacturing companies.

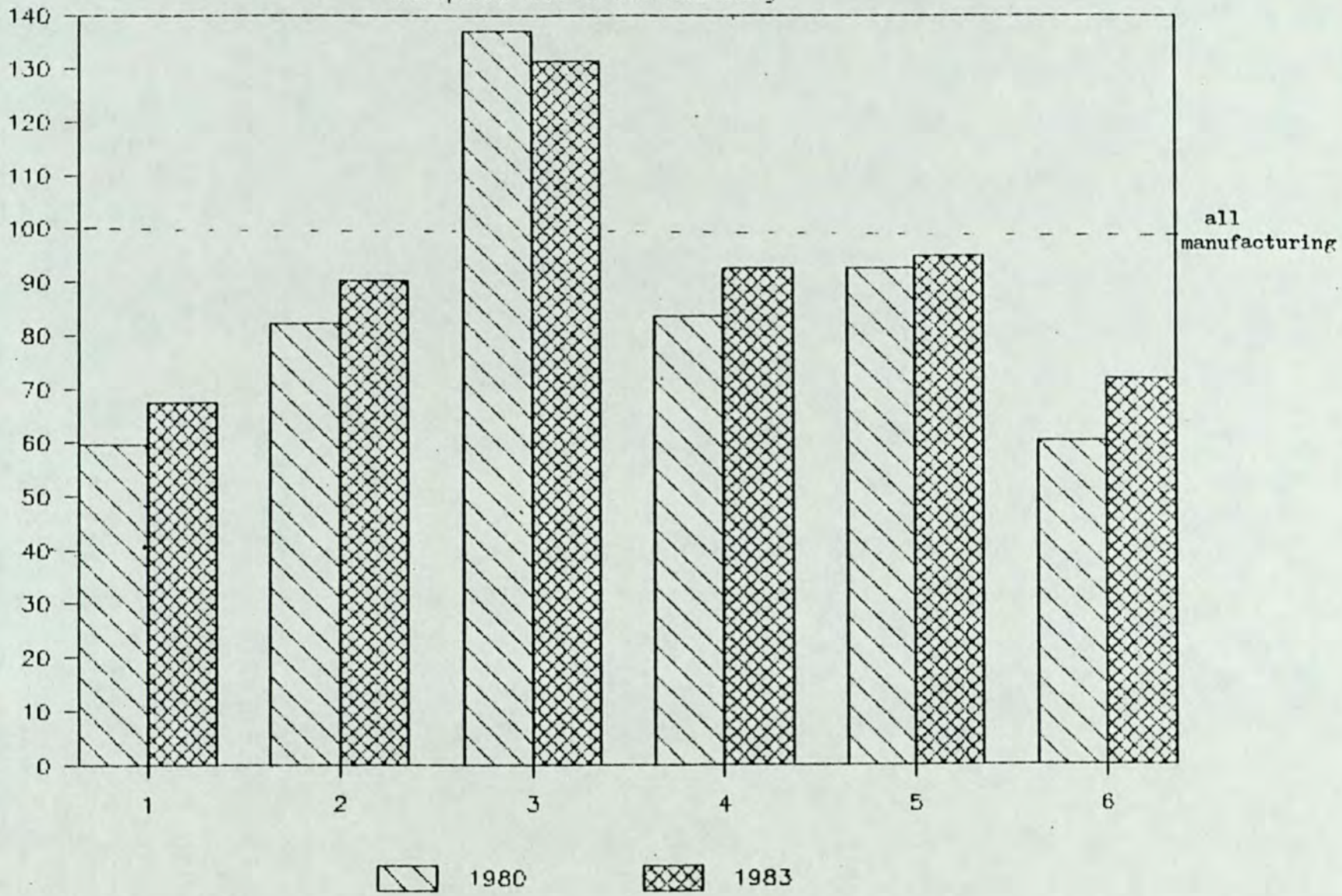
20. Total employment in 1983 was 29,000, a fall of 10% from 1980 despite the increase in output. This fall was concentrated in the operatives section of the workforce; the number of technical and administrative staff in fact rose slightly over the period. There does not appear to be any correlation with capital expenditure trends, which appeared to be weaker proportionally to sales in 1983 than 1980 (3.4% of sales as against 4.1%).

21. Compared to manufacturing as a whole, the industry appears to have lower wage and salary costs for both operatives and technical and administrative staff, and lower capital intensity; however the gap narrowed somewhat between 1980 and 1983. The lower capital intensity is not surprising given the assembly nature of most companies' operations, and the low pay levels may be explained by a large population in unskilled or semi-skilled operatives in the disposables sector in particular.

22. The sector has a reasonably high ratio of gross value added to gross output of approximately 47%, and an improving margin on sales with which to

Medical Equipment Industry

Compared with All Manufacturing



1. Gross output per head
2. Gross value added per head
3. Gross value added/gross output
4. Wages and salaries per operative
5. Wages and salaries per admin, tech and clerical employee
6. Net capital expenditure per head

service depreciation and capital - 12.7% to 15.8%. This reflects the higher labour productivity. The ratio of gross value added to gross output is noticeably higher than manufacturing as a whole (47% as against 35%).

23. There are some signs of rationalisation within the sector in the three years spanned by the censuses, with the number of medium sized establishments falling by 6% and their share of gross output also falling. Sales by the larger establishments rose considerably faster than the rest of the sector (by 99% as against 50%). However, the large establishments' gross value added as a proportion of sales appears to have fared worse than the overall sector performance with their margin falling from 49.2% to 40.7% as compared with 48.5% falling to 46.9%. The share of output taken by smaller companies also increased, as did their gross value added margin.

24. A published analysis of medical equipment manufacturers' accounts by Inter- Company Comparisons covers 60 medium and large companies, based on 1983/84 data. Not all principal UK manufacturers are included, and because of the usual differences in definitions, data cannot be compared directly with those from the Census of Production.

25. The ownership of the 60 companies is divided between:

Foreign Groups	12
UK Industrial Group Companies	15
UK Independents	33
	60

26. The picture that emerges is again of a fairly attractive financial performance and position: reasonably rapid growth, high profitability and good liquidity. These features are also well spread between the different types of companies and there are signs that the UK owned companies are performing more strongly, on the face of it, than the foreign owned businesses. This may, however, reflect the impact of intra-group charges or pricing by the foreign groups. Even so, both the portfolio of medical equipment companies being assembled by the UK industrial groups and the UK independent segment show good

signs of financial health.

27. US owned companies comprised four out of the top five companies in the industry (Travenol, Abbott, Sherwood and Dentsply), but thereafter the UK industrial group members occupied a strong position, with the independents comprising the bulk of the rest of the market. The UK industrial groups appear to have assembled portfolios of companies by acquisition of mid-sized companies, rather than to have developed their interests "organically". There is little evidence of venture capital affecting the industry strongly to date.

28. The largest turnovers (for their UK operations in each case) amounted to £64.1m for Travenol, £46.9m for Abbott and £28.2m for Picker. Thereafter there were only a further eight companies with turnover above £10m. Although there are large individual variations, sales had grown more slowly over the previous three years among the foreign companies and particularly rapidly for the UK independents - 4.6% per annum v 24.8%, with UK industrial companies growing at 6.5% per annum. Export sales data are patchy, but for these companies exports appear to average 37% of turnover, higher amongst the top ten, but broadly similar between the different types of company. Given that total turnover will include some imports, this figure is broadly consistent with Government statistics.

29. The ratio of profit before tax to sales averaged 7% across all the companies. Apart from a sharp jump in 1981/2 in profitability after a previous gradual decline, there are no particular trends discernable. The average return on capital employed over the past three years for companies included in this sample was 17.8%. This is noticeably higher than many other manufacturing sectors during this period and is higher than several related sectors.

30. We now turn to the small company segment. For this segment, fewer statistical data are available, and we have had to rely to a greater extent on our own experience. Within the industry, small companies broadly play three roles: first they act as distributors for other people's products, either produced by other small UK manufacturers or imported from abroad. Second, there are the small component or sub-assembly manufacturers who either supply other larger companies on a subcontractor basis, or who attempt to supply end users, usually relying on distributors to market their products. Finally, there are those small companies that manufacture or assemble their own discrete, stand-alone products. Again, many rely on distributors or possibly

larger companies acting on an OEM basis to sell their products to the end user. Some, however, do employ their own direct sales forces.

31. There are several factors which appear to contribute to making the medical equipment sector a difficult one for small companies to enter and in which to grow rapidly.

32. Most product development in the industry has to be undertaken on a speculative basis, in the hopes that a market for the product can be found at the end of the development process. Although the NHS is a large buyer relative to its sector, the NHS does not procure any large amount of equipment R & D on its own account. The course of the development process is frequently dependent on a close personal relationship between medical staff in a hospital and the technical staff of a small company. The products are frequently very highly customised to meet a particular hospital's requirements and may not be produced with an eye to the larger market opportunities.

33. Small companies naturally enough tend to cover very narrow parts of the market, both in terms of products and geographic areas. It seems that companies are constrained by the costs of broader market penetration rather than by lack of technological resources or lack of initial profitability. Typically new companies will sell a narrow range of products into a limited number of Regional Health Authorities, relying on a gradually developed contact within the Authority or an important local hospital to produce highly customised, high margin, products to suit particular local markets. They find it difficult to extend their marketing to other Authorities or other countries. These companies are thus frequently high value but low volume producers with little chance to develop a sustained and efficient level of production. For these reasons there appears to be a reasonably high birth and death rate in this lower segment of the industry: entrepreneurs are attracted initally by the charm of an apparently secure high margin sale, but thereafter are unable to develop a sustainable scale of operations.

34. Similarly, the inhibiting cost of large scale marketing also appears to block a development path noticeable in many other technological markets whereby companies start generating cash flow from distribution and then use their cash flow to lever themselves into the development of their own discrete products - an attractive market pull model of development.

35. A further important hindrance to the stronger development of this segment of the industry, and indeed of medium sized companies too, is the erratic and highly seasonal nature of the procurement process by Health Authorities. This ties up higher than usual amounts of working capital and is an important contributory factor to erratic profitability and eventually company failure in the small company end of the industry. We discuss this further below (para 68).

36. To some extent these problems of high market entry and penetration costs and uncertain sales levels can be overcome by startup companies being created with sufficient capital mass. Attracted by the overall healthy returns of the sector, a number of new companies have been started, financed by a combination of venture capital and institutional funds. While this is an encouraging trend, two factors appear to be holding back a higher flow of such capital. First, a number of the companies formed decided to tackle the emerging large systems end of the electromedical market. Although the returns in the early stages were attractive, they have increasingly had to compete directly against the larger electronics majors that have entered the market and the smaller companies' returns have progressively suffered. Those companies, such as the Oxford Instruments Group, which chose to enter intermediate or component markets, have done noticeably better. Second, it seems that the high costs of marketing can be "fought through" but not leapfrogged with greater capital. Hence, despite the strong performance of the established companies, new companies in the medical equipment sector have difficulty in offering the rapid initial growth which venture capitalists seek.

37. In summary, the sector's overall financial health appears to be reasonably good. Sales growth, productivity growth, profitability and liquidity are well above average; although there are some signs of "thinning" in the middle of the industry, this may have been due to the demise of weaker companies, and there are indications of fresh domestic capital coming into the industry at the top end. The bottom end also continues to be active and there are some smaller companies based on strong technological positions that have managed to grow into well found medium sized operations with strong international sales.

38. On the other hand, there are some features of the present position which are not as healthy as they should be. First, the diseconomies of marketing and budgeting described earlier are inhibiting the full development of what is, in most areas, a technologically effervescent small company sector. It appears

difficult for well managed small companies to grow rapidly. At the upper end there is still strong evidence that, despite the involvement of larger capital from the UK industrial groups, British companies are losing market share in domestic and overseas markets where technologically and even financially there appear to be no barriers to their competing effectively.

39. These disquieting features are reinforced for us both by the evidence we have heard from practising clinicians, which is virtually unanimous in telling us that the UK industry is missing out both in larger equipment and at the leading edge of technology, and also by some sample data on NHS purchasing which we have been able to obtain.

40. We have been supplied with an analysis of the annual issues of 1310 stock lines held in a medical and surgical store serving Hammersmith Special Health Authority and Paddington DHA. This shows the following picture:

	% by number	% by value
Produced by British firms	64	53
Produced in the UK by foreign firms	31	29
Supplied from abroad by foreign firms	5	18

41. It is supported by an analysis of the inventory of electromedical equipment held at the Hammersmith Hospital. Only 4.5% of the British-made items have a replacement cost above £10,000, as opposed to 20% of the foreign-made. This differential is still greater if only items bought in the last 5 years are considered, the corresponding figures being 3% for British-made and 25% for foreign-made items. These figures clearly suggest that the UK industry is tending to lose out at the upper end of the market in price terms, though any sample of this kind is naturally dominated by X-ray and pathology laboratory equipment.

42. This picture is borne out by a sample of purchases by Newcastle DHA over the period 1980-1985. This sample, covering items in selected categories, accounted for 19% of the DHA's total inventory value, and was skewed in favour of large, expensive items, the average value being £65K. 32% of this sample, by value, was made in Britain, again supporting the impression that high-cost

equipment is predominantly of overseas origin.

43. It is more difficult to get objective data on technology levels, but as we have said, the evidence from clinicians (borne out by a tour which some members of the Group made of a major "leading edge" hospital) is unanimous that the UK's position is being eroded. There are undoubtedly British firms that are amongst the world leaders in their particular sectors, but they are spread thinly; in those leading edge areas where the UK is represented at all, it tends to be represented by a single firm. This makes the industry very vulnerable to any failure by that firm, or sometimes to deliberate predation by competitors seeking to eliminate a rival.

44. One factor contributing to the health of the industry will be the ability of companies to choose appropriate manufacturing strategies. The manufacturing strategy of a firm will be strongly influenced by the market which it is serving. In the commodity end of the business companies need to offer goods from stock which implies a stock holding of finished goods and possibly also holding stock at lower levels of added value, such as raw material, forgings or castings. At the other end of the medical equipment sector, capital goods, often of high technology, it is usually essential to provide a very rapid service support organisation which in its turn requires the company to hold stocks of replacement parts. It is likely that the problem of inventory management will be common throughout the medical equipment industry. Holding inventories can impose a significant financial burden on the enterprise, and a clear management manufacturing strategy is necessary to minimise inventories.

45. All companies, with the exception of those simply factoring other people's goods, will need an assembly and product assurance organisation, in many cases involving sterilisation, and will need to conform with the DHSS registration scheme. Whether to make the individual piece parts which comprise the saleable product is a discretionary decision. The parts which should be selected for domestic manufacture should be those which have the greatest effect on the performance of the saleable item, are preferably unique to that business, and command a high margin. These parts should be made with the highest level of manufacturing technology and automation consistent with the volumes involved. Other parts should be purchased from organisations who have built up an expertise in serving other industries.

46. In the high technology capital goods areas of the medical equipment

industry, this strategy appears to be followed in that most detailed parts are purchased from specialist suppliers and, as seen above, the companies are doing quite well with an adequate return on capital employed. These companies appear, rightly, to be concentrating their managerial and financial resources on the technology of the product rather than on manufacturing. At the commodity end of the business there are some well planned manufacturing operations with a strong emphasis on production engineering. However, there is also a number of companies, a possibly dwindling number, who attempt to make a large proportion of what they sell using traditional semi-craft methods. These companies are very vulnerable to low cost imports, and our observations of several of these companies indicate declining market share and retrenchment into highly differentiated specialised sectors of the market to enable them to survive. Our view is that only by making changes to their manufacturing practices will they succeed, probably by further retrenchment into a range of products in which they can become significant in world terms, and hence achieve sufficient throughput to justify a high level of automation.

ADDRESSING THE WORLD MARKET

47. As we have seen (para 6 above) the UK market constitutes a relatively small percentage of the world total, which is dominated by the USA, and as a result, exporting is essential for those firms whose activities are capital intensive or whose products involve high R&D costs. Only thus can they hope to attain sales levels comparable with their foreign, and particularly American, rivals and hence to sustain the investment and/or R&D required to remain competitive. The experience of the Swedish industry suggests that the task of competing successfully in the world market from a relatively small home base is not a hopeless one.

48. The emerging interest of major UK industrial groups such as GEC, BTR, BOC, Unilever, and Smiths Industries opens up the possibility of a British multinational sector. In this regard, the example of Picker International is instructive. In this case GEC created a multinational by acquisition, and this led to its UK products having a better presence in the USA and elsewhere, which in turn has led to an expansion of manufacturing in the UK.

49. The creation of true multinational companies is likely to remain a rare circumstance, though a very important one when it occurs. For most companies, world markets will be addressed by exporting. However, the need to export is not one which has always been recognised throughout the industry; there is evidence that many firms who had previously depended almost wholly on the home market were driven to export only when hit by limitations on NHS growth. There is also evidence that firms remained for too long dependent on traditional markets and were reluctant to enter the US and European markets.

50. The world market is fiercely competitive. Besides high performance standards in the product, firms have to satisfy a variety of technical standards and regulatory regimes. We discuss the regulatory picture in more detail below (para 94 et seq.). In most countries, products are chosen (as in the UK) by individual doctors and hospitals, so it is vital that exporters have marketing organisations which can reach down to this level. If they are selling capital equipment, they must often maintain a servicing capability to respond within hours to a failure in any one of the hospitals supplied. They may also have to defend themselves against potentially expensive challenges by their rivals, for example to their patent rights.

51. In general, it is only major companies that can enter a new market by setting up their own marketing organisations there from scratch. Most companies have to find local distributors, and finding the right distributor is of critical importance. The exporter obviously wants a distributor with good market access and servicing coverage, but he also wants a firm small enough for his product to be a significant part of his business. Once he has found a distributor, he will need to maintain good contact with him, train his staff as appropriate, and respond to his signals about what the local market requires. All this requires a positive commitment to, and involvement with, the market. Sometimes a small company may "piggy-back" on the marketing organisation of a larger one. This can be very successful if there is a good match between product ranges, but in this situation the smaller company's worries about the priority given to its products, and the fear of being bought out, tend to be still greater.

52. There have been attempts, notably by the British Health-care Export Council, to organise co-operative distribution and/or servicing arrangements in specific overseas markets. This appears a sensible approach, but none of these attempts has succeeded in practice. Companies have been doubtful whether their products would receive their fair share of the co-operative company's attention and unwilling to commit the necessary up-front costs to an unproven scheme.

53. The support which Government provides to exporters is particularly important for an industry of this character. We welcome the moves by the British Overseas Trade Board to direct its support for overseas missions towards tightly focussed missions aimed at specific countries and specific product areas. But we regret the cut-backs in fairs and exhibition support, which is now insufficient to support all the activities which are considered worthwhile. This form of support is very necessary for small exporters, and fairs and exhibitions are an acknowledged way of making contact with potential distributors.

54. A further form of support to exporters is provided by the commercial staff in British Posts (Embassies, Consulates, etc.) overseas. These can be of particular value in helping companies to establish contact with potential distributors. The comments on the quality of this service which we have received from industry range from glowing to highly critical. We ourselves have received some very useful information from Posts, and it is our impression that the quality of commercial staff has improved markedly in recent years. It is

clear that first class help can be given both by staff who have in some way specialised in commercial work and also by non-specialists who are able to bring their full ability and commitment to bear on a commercial post. We hope that the Foreign and Commonwealth Office will continue its efforts to upgrade the status of commercial work and the quality of those performing it, and to eliminate any remaining vestiges of the attitude which saw commercial posts as second class and a distraction from the mainstream of diplomacy. We are also concerned that the availability of market reports produced by our overseas Posts is not sufficiently well-known; we recommend that DTI should give wider publicity to them and to the other help to exporters which Posts can provide.

55. We stress once again that exporting can no longer be a discretionary activity for an industry which has no protected home market. The UK market is in many cases too small to provide the turnover which companies need if they are to match the R & D capabilities at the high technology end, or the manufacturing capabilities at the low cost end, of major international competitors. Our industry cannot avoid this competition, even in its home market, and it must therefore meet it head-on by becoming international itself.

NHS PURCHASING

56. The NHS is by far the dominant buyer of medical equipment in the UK, and its practices determine the character of the national market. It does not operate for profit, and this is an important difference from the health services of many other developed countries. The vast bulk of medical equipment currently is used in hospitals, and this section therefore concentrates on the NHS hospital service. We deal subsequently with the general practitioner (GP) market. Where procedures are described, they are those relevant to equipment purchase for existing hospitals. The fitting out of new hospitals follows slightly different rules, but the same underlying principles.

57. The NHS does not function as a single entity. In England, the service is organised into 14 Regional Health Authorities (RHAs), which are in turn divided into a total of some 200 District Health Authorities (DHAs). Both RHAs and DHAs enjoy very considerable autonomy, and in particular RHAs have virtually total purchasing autonomy. In other parts of the UK, different organisational structures apply. For example, in Scotland the 15 Area Health Boards have some aspects of medical equipment advice, evaluation and supply undertaken by the Common Services Agency. In England, although there may be similarities in organisational structures, management styles and detailed working practices of both RHAs and DHAs can vary very considerably from one to another. Nevertheless, for equipment procurement there are typical patterns which do not vary greatly in substance.

58. The second important feature which must be noted is that the management and purchasing practices of the NHS are at present in a state of very considerable flux. Changes are being introduced which, in general, we welcome, but at present their application is very incomplete and very patchy. Thus we cannot describe a settled and uniform situation. We have therefore chosen to describe the practices which prevailed in England before the recent changes, and which still largely prevail in many places, and to indicate the important ways in which they are changing.

59. Decisions to purchase capital equipment are made by committees subject to budgetary constraints. The process is initiated by a user, normally a doctor but sometimes a scientist, putting forward a bid. After discussion with colleagues within his own department, the bid will be put forward to the DHA. The DHA usually has a capital committee which decides the relative priorities

of the different bids, and ranks them in a number of categories according to cost. For items below some level, the DHA will have authority to purchase. For larger items, the DHA will submit a list of ranked bids to the RHA, which will in turn combine these into a regional ranking. Purchasing takes place from the head of each list until the available budget is exhausted.

60. As a result, equipment choices in the past were primarily determined by users, whose main motivation was, naturally enough, to obtain what they saw as the best possible equipment for their patients and staff. Users did not have capital budgets of their own, and their financial interest was therefore primarily in whether the running costs were sustainable within the departmental budget. The eventual outcome was determined by bargaining between medical and scientific colleagues both within and outside the committee structure. A study by York University researchers found that: "For individual equipment bids the comparison of alternative models is done by the bidder, and the information on which he makes his choice is not generally available to the final decision-making committee. In only 15% of cases did divisional colleagues challenge users' bids and in only 7% of cases did they suggest alternative suppliers or equipment. Regional Scientific Officers frequently question bids on the grounds that the equipment is not the most appropriate for the purpose. This is done on the basis of past experience and knowledge of the market rather than detailed appraisal of the alternatives." There was little joint purchasing of capital equipment by departments in the same hospital, and still less between Health Authorities.

61. Regional Supplies Officers in practice tended to come into the process after the decision to purchase had been made, and their job was then to buy the selected equipment as efficiently as possible. They were frequently constrained to use single tender action, often in circumstances where the manufacturer knew that his equipment had been selected and accepted by the relevant committee. He therefore had little incentive to reduce the price previously quoted. Even where the tendering process was nominally competitive, users frequently wrote specifications such that only one manufacturer could meet them.

62. In the view of the York researchers, the fact that equipment choices were made by a large number of users, and that cost was a minor factor in choice, encouraged firms to differentiate their products in order to establish brand loyalty in the form of clinical preference. This prevented their achieving long production runs, but allowed them to charge prices high enough to remain

viable. Other reasons, including the past performance record of the company and its equipment, and a desire for local standardisation, can also be adduced to explain the considerable brand loyalty which exists in this field. But the York analysis is certainly consistent with the pattern we have discerned of a large number of small "national niche producers" unable, and perhaps to some extent unwilling, to break out of their niches and achieve growth and an international presence.

63. As we have noted above, there are developments in NHS management which are changing the practices of the past. They include:

(a) the increasing authority of Regional Scientific Officers, which has led to more frequent challenge to users' recommendations at Regional level;

(b) the introduction of option appraisal for larger capital purchases;

(c) an increasing concern with value for money in the field of medical equipment maintenance;

(d) the designation of Departmental Equipment Officers in clinical departments with responsibility for a range of aspects of equipment use and budgetting;

(e) the introduction of management budgetting, which brings the consultant face to face with the financial consequences of his clinical activities;

(f) the development of more disciplined and questioning approaches to the allocation of funds for medical equipment purchase;

(g) the introduction of general managers to whom consultants are accountable for their use of resources;

(h) the gradual emergence of centres of expertise, arising from the designation of Regions as centres of contracting responsibility for particular classes of equipment.

64. All these developments are tending inexorably to constrain the freedom of

doctors and scientists to determine equipment selection free from the critical scrutiny of others, and without responsibility for the financial consequences of their actions. As such, they tend in the direction of the free, but responsible and informed, market that we should like to see in the UK. But, as we have said, their impact so far is patchy. There are many reasons for this, but two important ones are the low level of awareness among NHS purchasing staff of the appraisal techniques which they will now be expected to use, and the generally poor state of information on equipment holdings and recurrent costs, which means that the data base for proper whole-life costing is largely absent. There is much action to improve NHS information systems, but clearly the lack of information now constrains the speed at which the purchasing environment can change. We urge the new NHS Director of Procurement and Distribution to continue the process of improving NHS information, financial, and purchasing systems along the lines set out above, as rapidly as possible.

65. Where the new information systems have been introduced, they have revealed budgets for capital equipment which appear wholly inadequate in the light of replacement needs for existing equipment, let alone the new opportunities now being offered. Global figures are not available, but one DHA which has responsibility for equipment to the value of some £25 million has an annual budget for its replacement of £825,000. This must be compared with assessed replacement needs averaging around £2 million a year, and a backlog of equipment already being used past its optimum replacement date worth £6.2 million. An RHA in another area with direct responsibility for a £70 million inventory has an annual budget for its replacement of £3.5 million. Although the actual numbers quoted will vary considerably from one Authority to another (depending partly on how responsibility is split in different Regions), we have no reason to believe that the ratios these figures imply are at all atypical. They suggest that something like a doubling in equipment replacement budgets would be necessary to achieve reasonable equipment lifetimes.

66. In fact, there is some evidence that the NHS should, on a pure efficiency basis, be doing more than simply replace existing equipment as it becomes worn out. We believe that there are areas in which capital can and should replace labour, with a saving in the cost of health care. Routine analyses of body fluids are amongst the more obvious examples. We are also aware that manufacturers' claims of savings often need to be treated with considerable scepticism. There is therefore a need for evaluation of the economics of new

techniques and new equipment. Often this will need to be based on practical trials, which it would obviously be inefficient for every Health Authority to conduct independently. This might be done by DHSS itself, but there are alternative possibilities, for example MRC through its new Health Service Research Committee or an independent institute for health economics. We believe that the availability of such information is particularly important within a system like the NHS, where cash-limited funding may in some circumstances prove a disincentive to efficiency, in contrast to profit-oriented systems elsewhere. (See para 78 below.) We therefore recommend that DHSS take steps to provide for increased research and information on the economics of introducing new techniques and equipment, and that Health Authorities should be encouraged to invest in new equipment, where this can be shown to offer increased efficiency. This too is likely to require an increase in capital equipment budgets.

67. National assessments of efficiency will always need to be interpreted locally, and supplemented by local assessments for smaller-scale innovations. As we have already suggested we are not convinced that Health Authorities generally have the necessary expertise to do this. We recommend that the economic appraisal expertise available to Health Authorities should be strengthened.

68. If the recommendation in para 66 is accepted, it will immediately come up against the difficulty, in a system geared to cash accounting, of finding the funds for the initial equipment purchases. Closely related to this is the problem of annuality. There is certainly a large bunching of orders at the end of the financial year, which imposes on manufacturers serious problems of production planning and cash flow, and which almost certainly produces inefficient purchasing decisions. We are not convinced that this is an inevitable consequence of the present system of annual budgets. The flexibility which Health Authorities now have, both within and between financial years, should be sufficient in a well-managed system to avoid this bunching. The real problem seems to be that many Health Authorities use their capital budget as a financial regulator, and in particular delay commitments until after NHS pay has been settled, typically half-way through the financial year. Pay accounts for a large fraction of total NHS expenditure, and settlements sometimes exceed the provision made for them. Typically a 1% variance on pay above the provision in the cash limit will equate to around 50% of an Authority's annual target for cost improvements. To maintain the service development targets which those

improvements were intended to finance, the Authority may well sacrifice part of its equipment budget. Thus even a fairly small variance in the costs of pay awards can translate into a quite large change in the much smaller capital equipment budget. Since we are not in a position to recommend reforms of the NHS pay system, we can see no practical way of avoiding this situation without restricting the freedom of Health Authorities to use their capital budgets in this way. We are aware that this runs counter to the desirable aim of giving greater responsibility to Health Authorities, but given the present financial pressures in the health service, we see no alternative if the necessary levels of capital expenditure are to be achieved. We recommend that the capital equipment provision in both Regional and District Health Authority budgets should be increased and that steps should be taken to ensure that this provision is used for the purpose for which it was allocated. We recognise that this involves substantial sums of money, but the situation exemplified by the figures above has convinced us that it is necessary.

69. For smaller equipment and disposables, the procurement picture is very different. These are sold at the level of the DHA or the individual hospital. Doctors, nurses and sometimes service departments (eg sterile supplies departments) may all play important roles, but the greatest single influence is that of Supplies Officers. Price is the dominant influence on choice. The main difference between these two types of sales is that once an enabling contract for disposables has been let, a steady level of business is more or less assured until a new tendering round, whereas small equipment is subject to a less severe version of the"regulator" effect referred to above. Here too, recent initiatives are leading to a more disciplined model, including a rather greater degree of centralisation, with more binding commitments to national, inter-Regional and Regional contracts.

70. Our concerns in this area are rather different from those in the area of capital equipment, though one which is common to both is the level of cost accounting expertise in the NHS. This is particularly relevant to sterile items, where Health Authorities have to choose between single use and resterilisation. Closely related is our concern that choices between competing products may be based too strongly on initial costs, with too little attention given to overall value for money. This is particularly relevant to items with a limited lifetime (eg surgical instruments), where durability needs to be a factor in the evaluation.

71. In some cases, particularly at the commodity end of the market, there is a

conflict between quality and price in circumstances in which it may not be clear to the purchaser what is being foregone by opting for the cheaper item. For example inadequate control of sterilisation by a manufacturer may become apparent only from a large statistical sample of his products. Even in cases where the trade-off will eventually become apparent to the user, this may happen only after long-term contracts have been let, to the detriment of better quality manufacturers, and with a distorting effect on the price structure of the market. The problems identified in this paragraph are ones of lack of information, rather than competence and practice in evaluating available information. In our view, they need to be addressed in the context of attempts to create a better informed market, and particularly the DHSS Manufacturer Registration Scheme, which we discuss below (para 99 et seq).

72. We have considered whether we should recommend an extension of bulk purchasing, particularly at the Regional level, both for capital and for non-capital equipment. The arguments for doing so are the savings which would accrue to the NHS and, from the industrial point of view, a reduction in the very fragmented market, allowing opportunities for companies to achieve faster growth. It would also allow the available expertise within the NHS to be deployed on a smaller number of key decisions. The disadvantages are that large-scale co-ordination can move too slowly to respond adequately to changes in clinical demands and in the products on offer, the risks of monopoly, and the vulnerability of firms to decisions on individual large contracts. There have been considerable moves in the direction of co-ordinated purchasing and of the creation of centres of expertise within the NHS, and the dynamic continues to be in this direction. We welcome these moves, in particular those towards greater co-ordination (aided by the increased influence of Regional Scientific Officers) and the use of nationally-agreed specifications. We do not feel it necessary to recommend any new initiatives in addition to those already under way.

73. We consider that it should be kept constantly before NHS decision makers that NHS purchasing is by far the dominant domestic influence on the shape of the UK medical equipment industry, and that the NHS benefits from a healthy UK industry both directly, in having a competent source of supply close at hand, and in the important indirect sense that the funding available for the NHS is a direct function of the health of the economy. We welcome the group set up under the chairmanship of a DHSS Minister, Mr Whitney, to study what further action the NHS might take to improve the competitiveness of its supplying

industry more widely. In the medical equipment field, as we have already indicated, we have no wish to see protectionist measures introduced to sustain uncompetitive firms, but we do believe it important that NHS purchasers should ensure that British options are fully considered, drawing on the centres of expertise existing within the NHS and academe and the advice available from DHSS Procurement Directorate. Where a proper option appraisal is carried out, we should expect this to be done as a matter of course. But we are concerned that major purchases are still sometimes made without a full option appraisal, particularly where they are funded from charitable sources. We recommend that DHSS and the other UK Health Departments should issue guidance emphasising the need for a full option appraisal, including full consideration of British equipment and making use of the available expert advice, for all major NHS purchases whether or not they are financed from public funds.

THE RELATIONSHIP BETWEEN HOME AND OVERSEAS MARKETS

74. Given the importance of export markets, it is legitimate to ask how important is the relatively small domestic market to the prosperity of the industry. We believe that it is very important. Some of the reasons why this should be so are common to many industries; they include the intrinsic value of domestic sales, which still provide a very large part of the industry's demand and are the base from which a small company will normally hope to grow. They also include the confidence given to overseas buyers by home sales, and the availability of demonstration installations. In the case of medical equipment, the "demonstration" function assumes particular importance within the medical education system.

75. We have become very aware of the importance of the medical education system in influencing buyers' choice of equipment. It appears quite common for a doctor to buy a particular make of equipment simply on the basis that it is what he has used during training, or that he has encountered it at an important centre he has visited. It is still more common for training to have a more subtle, but still very important, influence in establishing brand names in the trainee's mind, accustoming him to particular conventions (eg in the layout of controls), or establishing clinical practices (eg nursing premature infants in enclosed incubators rather than open cribs). For all these reasons, it is important to industry that overseas medical students should continue to seek training here rather than in the countries of our industrial competitors. It is still more important at the postgraduate stage, because those who study at this level are likely to be the opinion leaders, and important influences on purchasing, in their own countries. <u>We recommend that the Government should recognise the value to UK industry of overseas students studying medicine and its supporting disciplines here, and in particular should give positive encouragement to postgraduate study in the UK in these areas.</u>

76. The home market also offers the possibility of close interactions with users. This is not only a means of obtaining market feedback, important though that is; users are important in the innovation process as a source of new ideas, and even when the idea originates in industry, they have an important role in evaluating its usefulness and shaping its application to clinical practice. The UK's strength in advanced medical practice and research should be of great value to our industry, but there is evidence of considerable scope for improvement in the interactions between industry and health service

professionals. We discuss this below (para 110 et seq.).

77. The relationship between home and overseas markets will clearly depend in part on how far their requirements, in terms of hardware, are similar. From our investigations, we believe that in general there is great similarity between the underlying requirements of countries in the developed world, though there will from time to time be national "fashions" for or against particular new techniques. However, the NHS is inherently conservative in respect of genuinely new medical technologies, expecting their efficacy to be clearly demonstrated before it will buy equipment in significant quantities. This can hardly be faulted on medical grounds, but it does stand in contrast to the US, which is, if anything, over-receptive to innovation. Recent changes in charging systems in the US resulting from Government pressure to reduce the cost of the Medicare programme (the so-called Diagnosis Related Groups) have led to a greater concern for value for money, but it is likely that the US will remain a more receptive climate for innovation than the UK. It will need a deliberate effort to create market openings in the NHS for new technologies. We recommend that the pump-priming funds available to the DHSS (para 145 below) should be used primarily to introduce new medical technologies of British manufacture to the NHS and to promote their rapid assessment.

78. Although underlying requirements may be similar, the way in which equipment is sold may differ substantially between markets. In most of the important developed-country markets, profitability is the driving motivation, and a major consideration in purchasing decisions. Cost-based systems such as the NHS require a different sales approach, and show different priorities in their purchasing. In the NHS, net annual expenditure tends to be the driving financial motivation, rather than profit, overall economic impact, or even efficiency. For example, an instrument which allowed a hospital to increase its throughput for some diagnostic test at the same total annual cost might in the US be welcomed as offering the possibility of generating more income, and hence profits. In the UK, the impact could be that more patients, having been diagnosed, would have to be treated, thus increasing net annual expenditure. Of course, by no means all cases will be of this type, and we believe that the divergence between the two purchasing approaches is in fact greater than it needs to be, because the factors that contribute to efficiency in a cost-based system are very similar (though not identical) to those which contribute to profitability. We have already (paras 66 and 67 above) made recommendations to improve the efficiency orientation of the NHS in its equipment buying. We

believe that this will have the incidental effect of aligning the UK market more closely with export markets, and that the information provided by efficiency assessments will prove valuable when selling to profit-based systems.

79. One particular manifestation of different health-care funding systems, which leads to a clearly visible difference in equipment markets, concerns general practitioner services. In the US, and to a lesser extent in Europe, there is a significant market, which many commentators expect to grow rapidly, for relatively small equipment aimed at GPs. In the UK this market is very weak, for reasons which we discuss below (para 83 et seq.).

80. So far, our discussion has been of developed country markets. Markets in the underdeveloped countries are in principle different. It has been suggested to us that there is a potentially large market for "appropriate technology" equipment - simple, cheap, and rugged. Certainly many observers believe that such a market ought to exist, and that equipment of this kind would meet a real need. But to say that a market ought to exist is not to say that it does. Developing countries often perceive their own needs differently from Western observers, and it appears that many doctors and hospitals in such countries are reluctant to buy what they see as second class equipment. The World Health Organisation has certainly had very limited success in trying to achieve agreement on specifications for "appropriate technology" hardware. In addition, the countries involved are, by definition, relatively poor, and much of what they can afford to spend on health care must be devoted to providing the most basic services. We have already seen that the equipment market outside the US and Europe is estimated to account for less than a quarter of the total, and this includes a number of fully developed countries (eg Japan, Australia, Canada). We remain to be convinced that "appropriate technology" equipment specifically designed for developing countries is at present, in hard commercial reality, a major ungrasped opportunity for British industry. This is not to say, however, that there will not be market opportunities for less sophisticated versions of some currently expensive items, directed <u>both</u> at cost-conscious institutions in the developed world and at underdeveloped countries. It is also very possible that an "appropriate technology" market will emerge in the future, and this area will merit re-evaluation from time to time.

81. Although inherent needs are similar over much of the world, there are

major non-tariff barriers to trade imposed by differing standards and regulatory regimes. These force firms to create and maintain variants of their basic products for specific markets, and to submit them to several essentially similar national tests. They can impose very considerable costs and delays in penetrating new markets. This is a major issue which we consider below (para 94 et seq.).

82. This section has considered the relationship between home and overseas markets. It has argued that the home market can and should provide an important springboard for the penetration of world markets. In identifying ways in which the link between home and overseas markets could be improved, to the benefit of industry, it has identified three areas which merit substantial coverage in their own right. These are the GP market, regulatory regimes, and interactions with users. We discuss the first two of these in the succeeding sections, and the third as part of our discussion of research and development.

THE GENERAL PRACTITIONER MARKET

83. In most developed countries there are signs that more and more treatment and diagnostic tests will be given by GPs, thereby generating a rapidly increasing market for medical equipment designed specifically for the GP, but for reasons to be discussed below this trend is making little progress in the UK.

84. The GP market world-wide is growing rapidly, and this trend is expected to increase in the future, largely due to developments in technology. Biotechnology and other improvements in analytical techniques are making it possible for routine analyses (eg blood glucose) to be carried out cheaply and quickly without specialist staff. Developments in electronics make it possible to reduce the cost of other diagnostic instruments (eg electrocardiographs) to the point where they can reasonably be considered for use in surgeries. Information technology now offers the prospect not only of automating "office" functions, but also of allowing data (eg diagnostic images) to be transmitted between hospitals and surgeries.

85. At the same time, the high costs of the "hotel" services in hospitals are leading to pressure for as many patients as possible to be treated in the community, and for hospital stays to be minimised where they cannot be avoided altogether. This will increase the equipment market outside the hospital service (though in the UK one would expect local authorities and community health services to be involved as well as GPs). The implications for testing are less clear, partly because the out-patient clinic is a very valid option, and will probably vary between different types of test. A hospital referral for a test can confidently be expected to involve more administration and more medical time than the same test conducted in the GP's surgery, but the overall economics will depend on the efficiencies to be gained from high throughput, and the extent to which wider availability of facilities results in unnecessary testing. We are not aware that the comparative economics of delivering particular types of health care through the hospital system or through GPs have been well studied for the UK. We believe there is a case for such study, preferably by the practical route of establishing trial practices in which GPs would be encouraged to provide care and testing of types normally performed in hospitals.

86. In the UK, the way in which GPs are funded militates strongly against

their taking on additional responsibilities which require them to acquire equipment. Hence it denies UK manufacturers a home market sector corresponding to that which exists, and which will become increasingly important, overseas.

87. British GPs are formally independent contractors to the NHS. They are contracted to provide "general medical services", but these are nowhere precisely defined. Nor are there accepted professional norms defining at all closely what should be done by GPs rather than in the hospital service. Some norms clearly exist, but the boundary area is wide and very fuzzy.

88. The structure of GPs' fees and allowances is complex, but two features stand out: direct reimbursement of expenses applies to only a few types of expense (albeit important ones), none of them related to equipment; and only in a very few cases is a doctor paid a fee for services of a particular kind. Cervical cytology testing provides an example of such a case. The levels of fees and charges are set annually such that the average GP should earn, after expenses, a sum determined by the Review Body. For those expenses not reimbursed direct, including the purchase of equipment, historic data are used to calculate what the average GP can be expected to spend.

89. There is a financial incentive for a doctor to provide a better service only in so far as by doing so he can obtain additional fees for the services provided or can attract more patients. The scope for either is limited. There are few fees for providing particular services. Nor is it easy to attract patients - patients are remarkably loyal and in rural areas there may be no other practice nearby. There is no financial incentive for him to raise the level of care offered, nor to take on himself something for which he could reasonably refer the patient to hospital. Spending on equipment effectively comes directly out of his own pocket, and can only be recovered if it enables him to support more patients, or to provide one of the specific services for which a special fee is payable.

90. This system encourages GPs to run their practices economically, but it also tends to push any sophisticated health care towards the hospitals, whether or not this is the most cost-effective way to provide it. It is difficult for funds to flow between these two parts of the health care system should a shift in responsibilities be regarded, now or in the future, as offering greater efficiency.

91. There are other possible ways of funding GPs which would create an equipment market more akin to that in other developed countries. However, some of these, such as direct reimbursement for spending on equipment, or a greatly extended system of fees for services provided, might go to the other extreme by encouraging GPs to take on unnecessary work. This is not our intention. We consider that what is needed is a system of financing which links GP and hospital spending, and encourages the most cost-effective distribution of the total resource, without the artificial constraints of the present system. The Health Maintenance Organisations which exist in the US provide one model of such a system, but we have not studied this model in detail. We note that at least one RHA is also considering ways of making a financial link between hospital and primary health care; we are encouraged that they see valid arguments for such a link on health care grounds alone.

92. We do not claim that a major change in health service financing can be considered on the basis of the industrial interest alone. It is possible that this interest might be consistent with the more efficient delivery of health care, but it would have taken us well beyond our remit to consider this area in detail. However Ministers are considering policy on the funding of primary health care services, including GPs, and believe that the points we have made should be taken into account in that consideration. We recommend that, in considering policy on the funding of primary health care services, the Government should take into account the interest of the medical equipment industry in a GP market parallel to that existing elsewhere.

93. If there were to be a rapid emergence of a GP market in the UK, there is a serious risk that British industry would be unprepared and that much of the benefit would go overseas. However, if trial practices of the kind referred to in para 85 were established, this would allow industry to prepare itself for larger scale change. More positively, it could, and in our view should, be linked with active encouragement to British industry to develop and test in practice products aimed at a future UK GP market. We recommend that trial practices be established in which GP's would be encouraged to provide a greater range of services, and that UK industry should be linked with this experiment and encouraged to use these practices as a test ground for new products aimed at the GP market.

REGULATORY REGIMES

94. As we have noted above, differing national regulatory and standards regimes fragment the world market, and can impose substantial delays and costs on exporters. (Typical figures for the certification of a piece of clinical analysis equipment might be 2-4 months, and £10,000-25,000, for a single European market.) They thus constitute major barriers to trade. This is true whether or not they are discriminatory in intent or in the way they are applied. The UK has a reputation as one of the most free and open markets for medical equipment, and industry is not seeking any form of protectionism. Rather, it is seeking equally free access to other markets.

95. The most obvious means of regulation of the market is by means of standards, and in the UK the NHS is advised to require conformity with relevant British Standards where these exist. Most important markets have their own national standards. The differences between them sometimes, of course, reflect real underlying differences (for example in mains voltages). In a few cases, they seem to be deliberate attempts to protect a domestic industry. The majority, however, are simply the result of individual countries creating their own standards independently, before any international standards exist. Once this has happened, the process of reconciling these standards can be very slow. Even when international standards have been set by the international standards organisations, their translation into national standards may be equally slow. Britain has a good record in this respect. The US has one of the worst, because it lacks any strong national standards body. As a result, individual states and cities tend to create their own standards or rely on those of the Underwriters' Laboratories, which as the name suggests is a private testing organisation created by the insurance industry. There are domestic pressures for greater harmonisation, but so far they have made relatively little progress.

96. There is little that can be done directly to improve the position in the US. Harmonisation of European standards would, however, be very beneficial in itself, and might well increase the pressures towards harmonisation in the US. This is an obvious area for action within the European Community, but so far the Commission has produced only one Directive in this area, on the harmonisation of safety requirements for medical electrical equipment. Despite having been over 10 years in gestation, this is limited in its effect, and some Governments (notably Germany) have in the interim established national legislation which conflicts with it. We believe that there is scope for much

greater action by the Community in this area.

97. In the UK, the main force for action on standards for medical equipment is the Scientific and Technical Branch (STB) of DHSS's Procurement Directorate, operating through the machinery of the British Standards Institute as appropriate. STB are fully aware of the need for greater harmonisation of standards, and are heavily involved in the relevant international bodies. Their work is well regarded by the industry.But we are not convinced that the problem is sufficiently appreciated, or given sufficient priority at the political level. We consider that if progress is to be made at anything like the speed which is desirable a strong political impetus is necessary. The obvious vehicle for this is the European Community, where it would fit well with the UK's general emphasis on removing the remaining obstacles to free internal trade.

98. Product standards do not, by themselves,constitute an adequate system of regulation. They can cover some important areas, such as electrical safety, but in a rapidly-moving field with a wide diversity of products it is not possible to have comprehensive standards for each. Nor can product standards adequately cover manufacturing practice, which is important when (for example) poor sterility control or an occasional defective item can have potentially disastrous effects for the individual patient. There are two broad approaches to this problem. One is product approval, in which every new product has to be approved, normally after testing, by the national authority. The "homologation" scheme operated by France is of this type. There are three objections to this approach: it requires a great deal of effort to operate; it does not address the question of manufacturing standards; and it may act as an undesirable brake on innovation. The UK has therefore favoured the alternative approach of manufacturer registration.

99. The Manufacturer Registration Scheme was set up by DHSS in 1982 and is gradually being expanded until eventually it will include all medical equipment. The aims of the scheme are to:

control manufacturing quality by monitoring companies' manufacturing standards and practices;

provide information for the NHS which will be of assistance in purchasing;

give the NHS confidence in manufacturers' claims of compliance with

product standards.

100. Manufacturers are inspected by DHSS, and are required to satisfy it that their manufacturing facilities and processes comply with Guides to Good Manufacturing Practice issued by DHSS and based on British Standards. Once approved, the company is included in a register which is issued to the NHS and updated regularly. The NHS is recommended to buy products covered by the Guides only from registered manufacturers. The scheme is open to overseas manufacturers, whose premises DHSS also inspects. We consider that this is a good system, but we are concerned that STB, who are responsible for the Scheme, do not have the resources to operate it in the way we should wish to see. First, the scheme is not being expanded as fast as we should wish. Second, there is some feeling in industry that the Scheme is in fact operating to the disadvantage of British manufacturers, because the limited resources available do not allow overseas manufacturers to be inspected as frequently and as thoroughly as British ones. We recommend that additional manpower be provided to STB for the operation and expansion of the Manufacturer Registration Scheme.

101. DHSS are negotiating with the US FDA an agreement whereby each would accept the other's inspections, but no other nation yet has in full operation a scheme similar enough to permit further such agreements. There is however currently considerable activity in various countries to set up new manufacturer registration or type approval schemes, but there is no generally accepted form for such schemes. This is causing some alarm among manufacturers (not only UK ones) because of the differing requirements they will have to meet and inspections to which they will have to submit. Here as in the case of standards, the EC has failed to set a European pattern which would prevent a proliferation of incompatible national schemes among its members, some of which (eg the French scheme) operate in a highly protectionist way. Here, too, only a political initiative has any chance of giving a real impetus to harmonisation.

102. We recommend that the Government should take a stronger political initiative within the European Community to create a freer internal market in medical equipment by eliminating the barriers currently created by differing national standards and regulatory regimes.

RESEARCH AND DEVELOPMENT

103. There is no good quantitative information on the sector's expenditure on R & D. Research at the beginning of the decade by a York University group found R & D expenditures in the region of 7-8% of turnover amongst a sample of medical capital equipment manufacturers. This is a high figure by the standards of manufacturing industry generally. But the sample was drawn from the medical electronics sector, and may have been biased towards larger firms, both factors which one might expect to lead to higher R & D expenditures than for the medical equipment industry as a whole.

104. Outside the medical electronics sector, we believe that R & D levels are much lower. Even amongst successful companies in the disposables sector, for example, figures of around 2% would be more typical. The anecdotal evidence suggests that some companies have very low levels of R & D, and that this is primarily devoted to fairly small product improvements rather than to preparing the company's technology base for major changes. We are very concerned at this picture, which suggests R & D levels wholly inadequate to maintain and develop the UK's position in a rapidly moving industry.

105. We have identified a number of areas in which major technological developments are going on or can be foreseen in the near future. These technological developments are likely to change appreciably the performance and/or cost of medical products in these areas and thus represent commercial opportunities also. They can be expected to provide high growth areas for the business over the medium term.

106. There is overlap between some of the categories chosen for this list so that the same technological development may appear under more than one heading. We nevertheless felt that this grouping provided the clearest presentation of the main areas of opportunity.

1. <u>Materials</u>

New and improved materials, particularly non-metallic, for use in replacing body tissues, fluids and structural components, particularly blood vessels; entry ports to the body.

2. <u>Implantable devices</u>

Orthopaedic replacements; replacement organs eg heart valves, intra-ocular lenses; active devices - cardiac pacemakers and other stimulators for organ control, pain relief, muscle activation. Devices (which may not be entirely implanted) for controlled release or infusion of drugs or other therapies. Monitoring devices, particularly biochemical sensors.

3. Laboratory Diagnostics

Equipment and reagents for use in the laboratory; biosensors. Automation of more processes - microbiology, bacteriology, microscopy.

4. Diagnostic kits

Simple kits which allow diagnostic testing of body fluids to be done away from the laboratory; biosensors.

5. Medical Imaging

Magnetic resonance imaging (possibly associated with spectroscopy); ultrasonic imaging; other forms of tomography. Function studies using radioisotopes. Digital radiology - detectors; image storage and transmission; display units, associated software.

6. Other diagnostic methods

Magnetic resonance spectroscopy; magneto-encephalography; magneto cardiography; endoscopy; expert systems.

7. Patient monitoring

Improved sensors; computerised signal analysis; displays and warnings.

8. Surgery

Surgical endoscopy; laser surgery; variable-wavelength lasers; improved transmission fibres. Micro-surgery.

9. Anaesthetics

Respiratory gas analysers; blood gas sensors; injectable non-local anaesthetics.

10. Therapeutic devices

Infusion pumps (which may be associated with sensors in closed-loop systems); other forms of controlled drug release; laser-stimulated drug breakdown. Stimulators for muscle control, pain relief, restoration of function.

11. Wound healing

Materials for covering and filling wounds; artificial skin; replacement body fluids.

12. Support for the Elderly/disabled

Prosthetic and orthotic devices with improved function; appearance and control. Improved actuators for use by handicapped people. Incontinence control and management devices.

13. Screening

Simple, cheap, accurate (possibly home-use) devices/techniques for screening for major diseases: e.g. cancer, heart, stroke.

107. We have not attempted to give an exhaustive list, nor to provide detailed accounts of any of these developments, nor to rank them in any order of importance. They are given as examples of potentially important developments in a rapidly expanding area. Our main concern has been to demonstrate that this is a business much of which will see major technical changes over the next few years. Those companies that hope to remain in the parts of the business that will be affected will need to make a large commitment to research and development.

108. We do not believe that Britain can afford to ignore these areas. They cover a large part of the sector, and a substantial part of the remainder is vulnerable to low-cost competition from the less developed countries. These areas of technological change represent opportunities for a nation with a

strong technological base and a leading position in medical research, provided that the links can be made between that research and the development of saleable products.

109. Some of the areas we have identified, for example in imaging, involve levels of cost which are likely to make them the prerogative of at least moderately large companies. But for many of the others this is not so and we see nothing in the technology which is inherently inconsistent with a flourishing small and medium sized company sector. But these "leading edge" areas will in general be characterised by high R & D costs <u>in relation to market size.</u> This implies that a successful operator in one of these areas will need to capture a significant proportion of the world market for his product.

RELATIONS BETWEEN INDUSTRY AND USERS IN R & D

110. Academic studies of the medical equipment industry have demonstrated the importance of strong interaction with users if innovation is to be successful. Indeed, ideas for new products often come from users themselves. Successful innovatory firms therefore need convenient access to prospective users, and develop close relationships with such groups, most frequently (but by no means exclusively) in the teaching hospitals. Besides the access which they give to the leading edge of medicine, and the practical user experience which they bring to bear on development, such links also connect the firm and its product to influential points on the medical grapevine which, as we discuss elsewhere, is an important influence on marketing. A successful firm of even moderate size will seek such links internationally, but a small firm is likely to depend strongly on domestic links, often with a more or less local hospital. For any firm, its domestic links are likely to be of particular importance, because it is obviously easier to sustain a close relationship with someone close at hand.

111. For UK industry, such links assume particular importance. First, the UK is, as we have already mentioned, amongst the leaders in medical science. This offers the industry the opportunity to get close to the leading edge of medicine, and access to the ideas emanating from its practitioners. Second, the NHS has, by the standards of other health services, a very high level of scientific support. This forms a huge resource which could be a great asset to an industry whose own stock of qualified people is relatively small.

112. The evidence we have received on this topic has been conflicting. There have been some conspicuously successful examples of co-operation between industry and the health service. But we have also been told by both doctors and industrialists that such links are more difficult to forge in the UK than in the countries of our major competitors. The reasons given for this have varied widely. Our own view is of a very patchy situation in which some firms and some health service staff, find no difficulty in linking together whilst others either see no need for such links or have an exaggerated perception of difficulties. We have no doubt, however, that there is room for improvement.

113. Part of this improvement needs to come from industry. There are too many UK firms who pay insufficient attention to R & D, or who do not devote the necessary effort, particularly high-quality technical staff, to creating and maintaining relations with the medical community. There is also sometimes a

failure to understand the imperatives and constraints motivating doctors, researchers, and scientific staff. As a result, those who are able and willing to collaborate often find it easier to form relationships with foreign companies.

114. But we also have no doubt that there is room for improvement within the health-care system, and particularly the NHS. Hospitals rightly see their primary role as treating patients, and some researchers are fiercely jealous of their academic freedom and hence will not accept any constraints of commercial confidentiality. But there are many examples world-wide, and in other fields within the UK, of successful relationships between academic researchers and industry in which both sides accept that their legitimate interests have been met. And there is no reason why hospitals cannot accept collaboration with industry as an important subsidiary objective, which can bring them positive benefits.

115. There are some hospitals in which collaboration with industry is indeed viewed as an entirely normal practice for many staff. In others however, the prevailing culture seems to regard any collaboration as exceptionally difficult. In particular, a close link between a doctor and a particular firm tends to be viewed with suspicion as liable to give rise to conflict of interest, if not outright corruption. As a result, some of those who do wish to co-operate with industry feel obliged to maintain relations with several competing companies; this in turn makes those companies reticent about discussing commercial secrets which they fear may leak to their competitors. One influence adduced here is the Prevention of Corruption Acts, and the guidance on them issued by the Health Departments. This guidance has been interpreted by some as strongly discouraging the development of any close contacts with firms. This has led many senior managers and consultants in the NHS to be profoundly cautious about entering into relationships with industry.

116. As we have already seen, this caution is largely unnecessary; other institutions have demonstrated that such relationships pose no insuperable problems, are entirely consistent with a high standard of probity in public purchasing, and can be accepted as a normal and desirable way of working. Nevertheless, we consider it important to remove this perceived barrier where it exists.

117. We recommend that the Health Departments should issue new guidance to

Health Authorities which, whilst reiterating the need to prevent corruption in purchasing activities, gives positive encouragement to the creation of R & D links with UK-based firms.

118. In our view, collaborative arrangements between health service staff and firms should normally involve some tangible benefit to the individual and/or his department. Where hospital facilities are used, it is also right that the hospital should benefit, and the terms should take full account of any associated costs. Many health service professionals have little knowledge of how to structure their relationships with firms, and how to deal with such matters as intellectual property rights. We believe that it would be right for the Health Departments to issue guidance in these areas. Once the guidance is issued, doctors and scientists should generally be allowed to negotiate their own arrangements, subject to their declaring these to their Health Authority administration, and to some mechanism based on peer review to prevent gross violations of the norms.

119. A further positive step would be arrangements under which people could work part-time for the health service and part-time for industry, including forming their own companies. Such arrangements are rare in the UK, but much more common overseas. In the US, for example, it is common for small medical companies to have practising clinicians and hospital scientists on their boards of directors and thus both involved in and benefitting directly from the exploitation of their research. We recommend that the Health Departments should encourage Health Authorities to employ staff on contracts which permit them, if they wish, to spend part of their time in industry.

120. Underlying many of the problems, perceived and real, which we have identified is a large measure of mutual incomprehension between industry and the health service. There are many on both sides who need to be more aware of the concerns and priorities of the other, and the ways in which they can interact. Therefore, in addition to the more specific measures above, we recommend that the Health Departments, the main trade associations and those professional associations which are active in this field should take steps to improve understanding between people in industry and those in the health service.

GOVERNMENT INDUSTRIAL SPONSORSHIP AND SUPPORT

121. Sponsorship and support responsibility for the medical equipment sector is divided between DHSS and DTI. MRC and SERC also have relevant research and development activities. BTG is involved in its normal role of commercialising inventions.

122. DTI makes available its normal means of financial support to industry, including support for investment (eg regional assistance, or assistance for inward investment). So far as R & D support is concerned, responsibility is split, the historical basis of division being that equipment used with the patient present fell to DHSS and equipment used with the patient absent to DTI. This division is no longer regarded as well-founded, and is not observed in practice. The growing use of electronics in instrumentation has drawn DTI into direct involvement with "patient present" products. This has been facilitated by the support mechanisms available to DTI such as the former Microprocessor Applications Project and Support for Innovation (including the support administered by the Biotechnology Support Unit). It has also been influenced by the shortage of funds in DHSS to support major projects in industry, so that it is increasingly DHSS practice to pass expensive industrial support projects on to DTI for consideration. DTI however maintains its own close contacts with firms in the electromedical and biotechnology sectors, many of whom seek support direct from DTI.

123. In early 1986, DTI had outstanding R&D support for medical equipment projects totalling £8.2 million, which might be expected to lead to annual expenditure of around £2.5 million. This figure for grants outstanding had declined sharply over the previous two years, mainly as a result of the moratorium introduced by DTI in 1984 and the subsequent changes in the Support for Innovation scheme announced in April 1985. The largest proportion of the outstanding grants was towards the instrumentation/electronics sector (46%) followed by biotechnology (43%). In addition, there were extant pre-production orders in the electronics sector totalling £3.2million. Following the review already referred to, this form of support is currently available only under very limited circumstances.

124. The instrumentation branch of DTI's Electronics Applications Division, which is responsible for the instrumentation/electronics part of the industry, has a technical committee on which sit representatives of DHSS and the MRC Clinical Research Centre, and hold 6 monthly meetings with DHSS at Under

Secretary level. When a medical project comes to the Division, whether for R & D support or other selective assistance, advice is sought from STB, who contribute to the technical appraisal. Other parts of DTI draw on DHSS advice as required, on a less formal basis.

125. Of the industrial opinions of DTI that we have received, the majority are favourable; its officials (including those involved with export promotion) are characterised as helpful, and understanding business. But it has been suggested that the industry suffers from not having a sponsorship section within DTI able to represent its views on matters of general industrial policy. We suspect also that large parts of the industry, outside the electronics and biotechnology areas, may not have regarded DTI as having any great relevance to their business.

126. We believe the fragmentation of sponsorship responsibility within DTI is a weakness. It deprives the industry of a clear voice within DTI, and it creates problems for those other organisations (such as SERC) who want to co-ordinate their activities with those of DTI . It may also lead to a lack of awareness of the industry amongst those in DTI for whom responsibility for some part of it is a small part of a more diverse workload. We recommend that a single Branch within DTI should be given coordinating responsibility for all those sponsorship and support activities towards the medical equipment industry that fall to DTI, including responsibility for liaison with DHSS and SERC on matters relating to the industry. This would not preclude some DTI support being given through special units, such as the Biotechnology Unit, provided there was liaison with the designated Branch.

127. Within DHSS, the primary responsibility for sponsorship falls to the Procurement Directorate and in particular the Scientific and Technical Branch. This has a number of relevant responsibilities, of which the most important are described below.

128. One section of STB is responsible for the normal non-financial sponsorship of the industry, including such things as links with trade associations, competition policy, commercial intelligence, representation of the industry's interests within Whitehall etc. This section also administers the Manufacturer Registration Scheme.

129. There are various specialist groups within STB which are responsible for

liaising with BSI and others on national and international standards for their products. In practice, they are the leading UK participants in standards-making in this area. This area has been dealt with above (para 94 et seq.).

130. The DHSS programme of support for equipment research and development and evaluation has been in existence for about 20 years. The funds reached their highest level in 1980/81. Since that date, they had declined in real terms by about 30% until 1985/86, when a special additional allocation of £0.5 million was made to help cope with an increasing number of requests for support of nuclear magnetic resonance applications. The total allocation for 1985/86 was £5.2 million. This can be split into three broad areas. About £2 million is spent on the evaluation of new medical products (para 140 et seq.). £1.2 million is spent in support of the Bioengineering Centre at Roehampton. This Centre is operated by University College, London, with whom DHSS have a long-term contract for the development of new methods of manufacturing and fitting artificial limbs. The remaining £2 million is spent in support and development across the board.

131. The distribution of this £2 million can be analysed in several ways. One is in terms of where it is spent:

universities	- 40%
hospitals	- 34%
industry	- 26%

132. The numbers of projects (total of 68) are distributed in almost the same proportion. This is rather unusual. The typical pattern in the past has been for there to be a smaller number of more costly projects with industry, and the change may reflect the increasing practice of passing on major industrial support projects to DTI for consideration.

133. One can also analyse the areas in which this £2M R & D money is spent:

aids for disabled (including incontinence)	- 25%
path lab equipment and reagents	- 24%
medical imaging	- 18%
surgical implants	- 6%
dental materials	- 5%

sterilisation methods and monitoring	- 5%
medical optics (incl lasers)	- 4%
others	- 13%

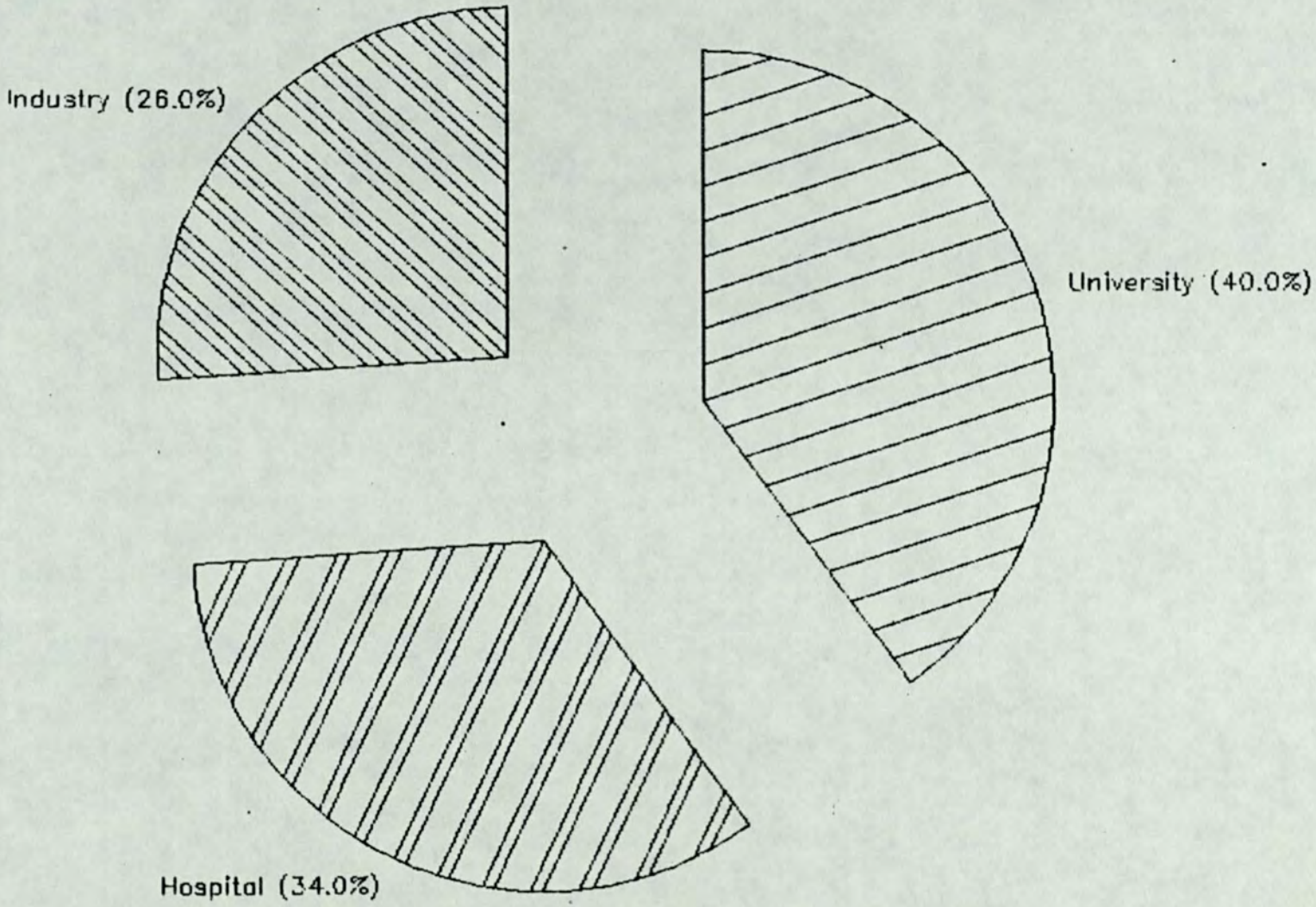
134. This distribution reflects the special priority which DHSS gives to equipment for the elderly and the disabled as well as the two dominant technology areas of imaging and pathology. This special priority in turn reflects partly the Department's direct responsibility for services for the disabled and partly the lack of strong market pull for innovation in these areas.

135. Apart from the Bioengineering Centre, DHSS support only two centres on a long-term basis, both in the area of aids for the disabled. All other support is given to individual projects. Few of these are actually invited by the Department, but STB staff are very active in stimulating outside bodies to make proposals, and in reshaping proposals received. The programme is under the control of a Research Liaison Group which, besides the research management from the Procurement Directorate, includes members from the Customer Divisions in DHSS and 5 external advisers appointed by the Chief Scientist. This Group is involved particularly in the strategic balance of the programme, identification of new areas of interest, and decisions on high-spend or long-running projects. Individual projects may be authorised by the Director of STB if they receive medical and customer support as well as the approval of at least two external referees. A number of small advisory groups exist to help in the oversight of particularly important areas (eg magnetic resonance imaging).

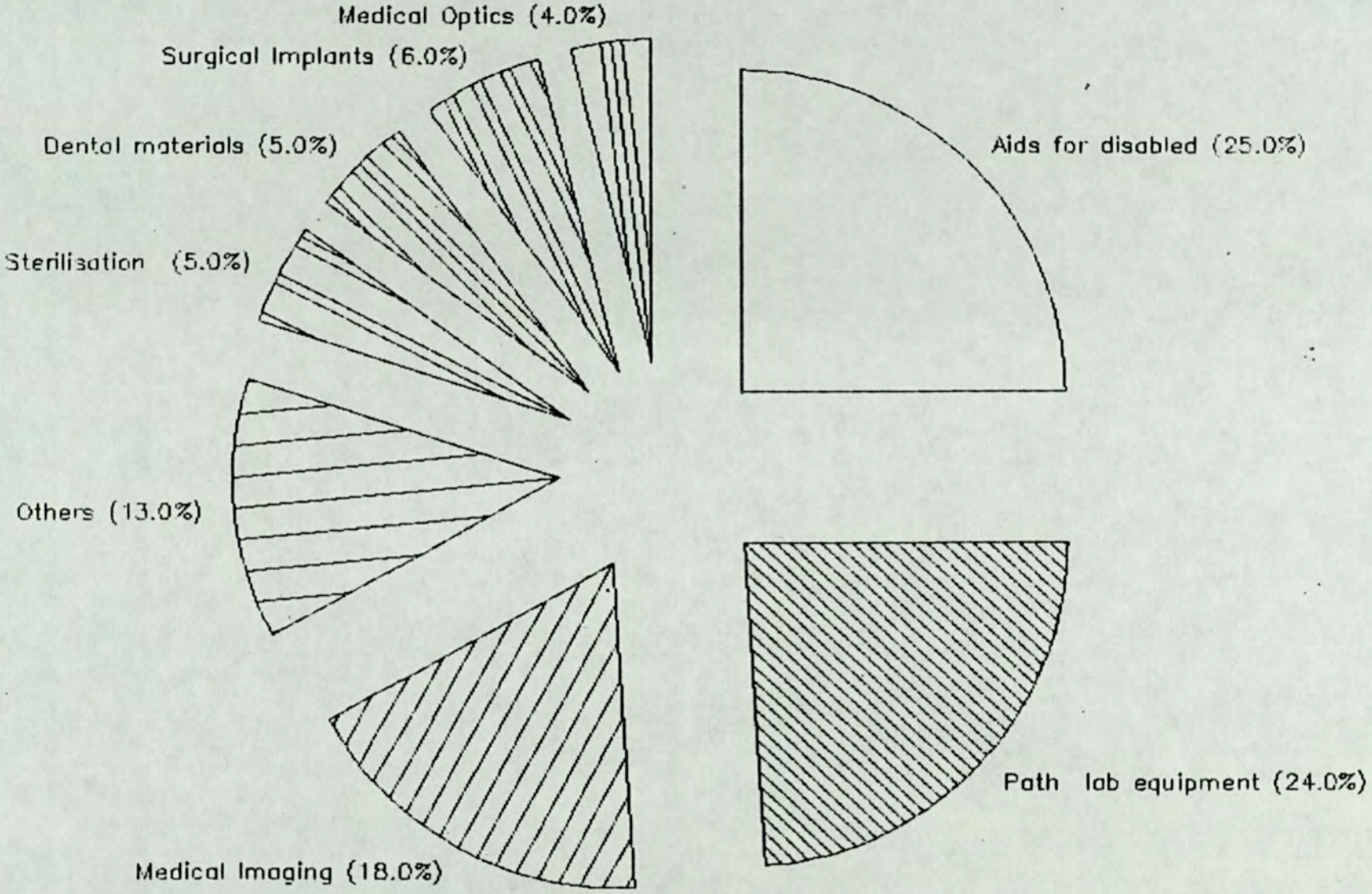
136. DHSS normally receive between 40 and 60 R & D proposals each year of which about three-quarters are accepted. However, a good deal of informal filtering goes on before proposals are submitted. There is also a good deal of re-direction - particularly to DTI - and liaison with SERC and BTG, though DHSS acknowledge that liaison arrangements still require some improvement. With the exception of one very costly project, we are not aware of good proposals being turned down for lack of money. But the number of submissions is small, and to a large extent controlled by DHSS itself with knowledge of the money available. In addition, we have already seen that major industrial proposals tend to be redirected to DTI.

137. The outcome of projects is monitored by the Research Liaison Group. DHSS have assessed the outcome of the 50 projects which have come to completion

DHSS Supported R&D by Sector



DHSS Supported R&D by Area



during the last two years as follows:

3 produced patents
9 produced new assay or test methods
5 produced new products now in manufacture
5 produced prototype requiring further testing
10 produced reports for publication which appeared to represent the end of the project
8 produced reports indicating further work is needed
6 were unsuccessful

138. The first three categories represent a fairly reasonable assurance of success while the next three are somewhat uncertain.

139. When developments are funded in industry, DHSS seeks a levy payment on sales, the levy being set "at a level which would not affect sales". Receipts are low. In the case of developments in universities and research establishments, the industrial property is transferred to BTG for exploitation.

140. Evaluations of new medical equipment are recommended by DHSS technical officers. Equipment is bought by DHSS and handed over to the evaluating body, normally a Health Authority which can expect to retain it once the evaluation is complete. (In the special case of X-ray equipment, it is sold to an authority at 50% of its cost price.) For some types of equipment, DHSS has designated evaluation centres to embark on a continuous programme of comparative evaluation, and at some of these DHSS has funded staff. In other cases, it arranges ad hoc evaluations of batches of equipment. The Scottish Home and Health Department (SHHD) also arranges comparative evaluations. The main emphasis has been on electromedical equipment, in view of the implications for safety, accuracy of diagnosis and reliability of operation. The programme is still limited in its scope, and has tended to concentrate on more expensive and sophisticated types of equipment.

141. In most cases, each item of equipment is subjected to:

i. a technical assessment against current safety and performance standards;

ii. a subjective assessment of the quality of construction, the serviceability and the likely reliability;

iii. a period of "user" experience, to establish its clinical acceptability in operational and ergonomic terms.

142. Findings and results are discussed with the manufacturer or supplier, who is given an opportunity to comment in writing. Reports on all the models in a batch are then published, complete with manufacturers' comments, in special "Evaluation Issues" of "Health Equipment Information". Each issue is intended to be a "buyer's guide", covering all models which have been evaluated and which are still on the market in the UK, as well as carrying full reports on any recent models. Any which stand out as particularly good or bad value are highlighted. Although there is no firm quantitative evidence there is reckoned to be a good correlation between DHSS evaluation reports and the subsequent sales of the equipment in question.

143. Several European countries have broadly similar evaluation programmes and there is a European "club" which acts as an information exchange, and tries to harmonise the form of reports. Other countries' reports are said to be generally no less objective than DHSS's own, but are not sufficiently similar in form and coverage to be published in the UK as they stand. Rather, they are used as pointers for DHSS's own evaluations. This largely reflects the fragmentation of the market by standards and regulation, so that the models on sale in one country are unlikely to be precisely similar, and tested against precisely the same standards, as those in another. We should like to see more harmonisation of report formats, but recognise the obstacles so long as this regulatory picture persists.

144. Although it is aimed at the NHS, the DHSS/SHHD evaluation procedure is welcomed by industry, as providing a basis for informed decision taking, without imposing choice. It is contrasted favourably with more dirigiste regimes which have been followed elsewhere, and which, by delay in responding to technical developments, have tended to fossilise the market. We ourselves strongly support the concept, as aiding the creation of the open but informed and responsible market which we wish to see. We have also been impressed by the form and content of the evaluation reports which we have seen. <u>We recommend that the evaluation programme be continued and expanded, and that the modest expenditure devoted to it should be materially increased.</u> We have in mind an increase of the order of 50% in real terms.

145. STB also has pump priming funds, about £0.5 million a year, to support the purchase of new equipment normally at the early production stage. As in the case of evaluation studies, the purchase is made by DHSS and the equipment becomes the property of a Health Authority which is expected to produce a short assessment report. For pump priming, however, the initiative comes formally from the manufacturer, normally after discussion with DHSS technical officers. Cases are assessed within STB, in consultation with DHSS medical staff and the relevant Regional Scientific Officer (for all but very small projects), and decisions are made by the Branch Director. DTI are not normally involved.

146. The criteria include encouraging British industry by initiating a market, providing a shop window, providing a base for the development of exports, encouraging technological and medical advance, etc. During 1984/85 contracts to the value of £412K were placed in respect of 17 product types, which were distributed to 53 locations. The programme is well-regarded by industry. It is close in character to the evaluation programme, and can be seen in some ways as a variant of it.

147. In general, those parts of the industry that have regular contact with STB have a high opinion of its technical competence and its work in standards, quality assurance, and evaluation. They are concerned that staff reductions have now left the Branch overstretched. Its R&D programme is much less well known in industry, and does not seem to be regarded as an important source of industrial benefit. We believe that it should be more widely publicised, though we recognise that at the present low level of funding this might well lead to demands well in excess of resources.

148. The Chief Scientist of DHSS spends relatively small sums of money on evaluating the economics, in health service terms, of new equipment developments. We have recommended above (para 67) an increased activity in this area, without commitment as to the route.

149. Local Health Authorities also spend some money on R & D; it is not known how much of this is on equipment, but the figure is believed to be small.

150. SERC has a "specially promoted programme" in medical engineering. This was initiated in 1977 as a programme in biomaterials, but in 1981 its remit was broadened to cover all aspects of medical engineering. Between 1978 and the end of 1985 156 grants were awarded to a total value of approximately £5 million.

Grants outstanding currently amount to £2.4 million, which can be expected to give rise to an annual expenditure of some £1 million with an industrial contribution of some £160,000. In addition, there are 38 current training awards, giving rise to an annual expenditure of a little over £200,000. Research activities under this programme include the development and evaluation of new materials for implantation, the design of new prostheses, the characterisation of diseased tissue that has to be replaced, the production of external aids for the disabled, investigation into new methods for the care of the incontinent and developments in advanced imaging techniques. Not surprisingly, in view of the origins of the programme, there remains a strong emphasis on biocompatible materials and applications for materials in medicine, this topic accounting for 30-40% of current support. Diagnostic aids are also important, at 20-30% of support. DHSS are represented on the committee which is responsible for the programme, and their advice is influential.

151. The SERC programme is, in keeping with the role of SERC, in the area of basic/strategic research, and SERC funding is restricted to academic institutions and hospitals, though co-operative programmes with industry are encouraged. In fact, 71% of grants under the programme have active industrial collaboration, and about a third of projects completed to date have led to patents. There are two main limitations on the programme. One is finance, which at present allows SERC to support only 25% by value of the proposals received, which is a lower figure than SERC would regard as normal. The committee responsible for this area is very aware of budgetary limitations and hence tends to discourage high value applications and to reduce significantly the value of those approved. Interest in medical engineering is increasing rapidly, and is leading to increased demands on finance. The second limitation is the lack of mobility within the university system, which inhibits the formation of the interdisciplinary teams which are necessary in much of this work.

152. There is some relevant SERC support outside the specially promoted programme. In particular, the Biotechnology Directorate is spending about £0.5 million a year on biosensors, and the Chemistry Committee a similar sum on molecular sensors. In neither case, however, is the programme exclusively, or even dominantly, medical in its aims.

153. MRC does not have a programme in medical engineering or medical equipment per se, though new ideas of potential commercial value frequently emerge from

the work which it supports. MRC is keen to improve the translation of such ideas into commercial products and has recently set up a large centre for collaboration with industry at the National Institute for Medical Research. MRC is also strongly involved in the support of research groups, either in its own units, in hospitals, or in universities who may be the first users of new equipment, and actively promotes studies of the usefulness of new techniques (such as MRI) in order to establish their clinical value. The MRC also supports from time to time research into novel medical techniques and equipment as part of its role in the advancement of basic medical science and medical practice, though it would not regard this as a major part of its activities. Thus, although there is close liaison between officials of the MRC and those of the DHSS and SERC, research and development on medical equipment forms a relatively minor part of the discussions.

154. In summary, the total Government support for R&D on medical equipment, excluding the Bioengineering Centre, SERC training awards and DTI pre-production orders, is of the order of £6 million a year, or rather less than 1% of the industry's turnover. This figure is low by the standards of many other high technology industries, especially those benefitting from defence R & D expenditure, and very low by the standards of agriculture, fisheries and food (for which the figure is around 3%). It is more surprising given the direct benefit which the public sector, in the shape of the NHS, might hope to derive from the results of R & D. It also needs to be seen against the background of the widespread belief that over much of the industry private investment in R&D is too low to remain competitive in the long term (para 104 above). We recommend that Government support should be substantially increased. We believe that a rough doubling in real expenditure over a 4-year period would be both realistic and attainable.

155. Even at this increased level (around 1.5% of the industry's turnover), Government support will not be large. It must therefore be well-spent, and in this connection we are concerned at the fragmentation of responsibility for programmes. We have already made proposals to unify responsibility in DTI, and we understand that SERC have established internal coordination arrangements. But we believe there is still a need to improve coordination between Departments. These links should involve MRC, as a body which should be well-attuned to the future prospects for medical science and practice. We recommend that a mechanism should be set up to coordinate the programmes of DHSS, DTI and SERC in the medical equipment field. This mechanism should

involve participation by MRC and industry.

156. Although in general we believe that funds will be best spent by responding to specific proposals, we consider that the Departments involved should take deliberate steps to ensure that support is available in those areas in which the UK has a fledgling high technology medical industry with reasonable prospects of success. They should also ensure that support is available for key underlying technologies, and for leading-edge medical technologies which have not yet reached the stage of industrial development. It is possible to encourage proposals in these areas, whilst retaining a basically responsive system, as all three Departments have demonstrated in this field or elsewhere. One particular priority for the new coordination arrangements will be to encourage joint proposals linking industry with health service staff and academics.

THE INDUSTRY AND THE EDUCATION SYSTEM

157. As we have seen, the medical equipment industry will be highly dependent on technology for its future, and hence on attracting the right R&D manpower, in terms of both quality and skills. It is dependent on marketing to a large population of prospective users, most of them of high technical competence themselves, and it suffers from weakness in its industrial design. We are concerned that in all three of these areas the industry is not managing to recruit the people it needs.

158. So far as R&D is concerned, the growing electronic content of medical equipment means that the industry requires electronic engineers and software engineers. Both these skills are acknowledged to be in short supply, and to be a problem in the economy more generally. We support the efforts being made to increase the supply of these skills, recognising that an important part of doing so will be to increase the numbers in schools taking mathematics and physics at A level. Some parts of the industry also perceive a shortage of molecular biologists and medical engineers. These are skills whose shortage is felt less generally in the economy, and which are also more specific than is appropriate as the subject of an undergraduate course (though some coverage of these areas at the undergraduate level is entirely right and appropriate). Specialists in these areas must be produced very largely by postgraduate training. Ideally, industry would itself play a large part in developing, or sponsoring the development of, the people it needs. But this is much easier for large firms than for small ones, and in an industry with few large firms, this route cannot be relied upon. We recommend that SERC should give high priority to medical engineering* in their support of postgraduate training. We include in this taught courses, research training, and mid-career updating schemes. We note, and support, the priority already given by MRC to molecular biology. In medical engineering (which is of course an interdisciplinary subject), we are aware that the rate at which training can be expanded may well be limited by the number of academic staff available to teach. For this reason, and also in the interests of research, we recommend that the development of medical engineering groups be a priority area for future university appointments.

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*Medical engineering is the term we have chosen to use here to mean the application of all forms of physical science and engineering to the design, development, and production of equipment for use in the diagnosis of illness or

the treatment or care of patients. It includes the fields of biomaterials and biosensors, and the application of engineering methodology to the investigation and treatment of patients. It embraces the activities which others have called biomedical engineering, bioengineering, or clinical engineering.

159. We have heard, and in some cases seen for ourselves, that too much British medical equipment is badly designed. This is not primarily a matter of aesthetics, though these too may influence user choices. From the user's point of view it is primarily concerned with reliability and ease of use. From the manufacturer's point of view design for manufacture is of great importance to the efficiency and cost of production. Enlightened manufacturers involve a good industrial designer at a very early stage in the development of a new product. But there are too few such manufacturers and, probably as a result, few industrial designers specialising in this area. We support the efforts of SERC, DTI and others to increase the industry's awareness of the importance of design and the supply of skills in this area and the related one of management engineering. We recommend that these areas too should be given priority for future university appointments.

160. We are also concerned at the quality of the marketing staff deployed by the industry. We have heard too many times that representatives of overseas companies are both more professional in their marketing technique, and also better able to discuss their products as technical equals with prospective buyers. To a large extent the fault here must be laid at the door of an industry which sets too small store by the quality of its representatives in the field, and hence does not recruit (and pay for) the standard of representation it needs. But we believe it also has something to do with a national attitude to selling which holds it in low esteem, and with a general low level of business education nationally. Although we do not offer any formal recommendations in this area, we nevertheless believe it essential for the industry to ensure that its sales and marketing staff are adequately trained, particularly in respect of their ability to discuss the technical aspects of products with prospective users.

STATISTICS

161. This report has commented at various points on the inadequacy of the statistics, both national and international, relating to medical equipment. People in Government, trade associations and industry have said that they are hampered in their work by lack of knowledge of UK production, domestic market, and overseas trade broken down on a basis which is consistent between different sources, and which is sensible medically and industrially. Whilst the problem of international statistics is only to a limited extent within the power of the UK to solve, improvements could and should be made to the availability of UK data.

162. The two most relevant sources of Government statistics are the overseas trade statistics collected by Customs and Excise, and the quarterly and annual Census of Production data collected by the Business Statistics Office, which is part of DTI. The types of information collected for these two statistical series are in principle capable of giving a good picture of the industry. But there are problems with the way the information is classified:-

a) The structure of the trade statistics at the most basic level (the tariff heading, identified by an 8-digit code number) is unhelpful. Many items of interest cannot be identified, and too high a proportion of the trade flows fall into ill-assorted residual categories.

b) This structure cannot be aligned closely with that of the quarterly production statistics.

c) In the Annual Census of Production, the industry as we have identified it is scattered through a number of Activity Headings. This problem was largely solved for us by a special analysis performed by the Business Statistics Office, but this is not a facility which industry can generally use.

163. If these problems could be solved, we think the UK statistics would provide as much as could reasonably be expected of them. We know that there are problems in changing Government statistical classifications. In particular, there are various international requirements to be met. But the information we

have seen from other countries operating under the same constraints leads us to believe that the problems of collecting and presenting the statistics more helpfully are not insuperable given the will to do so. To achieve this improvement will, however, require a great deal of detailed work. We therefore recommend that a joint group from industry, Customs and Excise and DTI should be set up to produce a more helpful classification scheme for the Government statistics relating to the industry.

164. Industry also needs more detailed information on such matters as sales of particular equipment types, and market shares of firms. This kind of information is appropriately obtained from commercial, rather than Government, sources, but the supply of such information in the UK is slender. In the US, it is more freely available, largely from commercial firms who buy and analyse basic purchasing information from hospitals. Similar information from the NHS would be valuable to industry (and also to researchers and administrators) and if sold to commercial analysts could provide a modest financial benefit to the health service. In the past, NHS information systems on equipment have not been sufficiently good for this to be a realistic possibility. Although some authorities are still moving much too slowly the position is now improving sufficiently for it to be considered. We recommend that the NHS begin now to plan how its equipment purchasing data could be made available to industry.

CONCLUSION

165. The main responsibility for the future of the medical equipment industry will rightly rest with those in that industry. But because of the many points at which Government interacts with the industry, there is much that Government can do to help. Our hope is to see a financially healthy industry with a strong presence at the leading edges of technology, where the UK should be able to hold its own in the longer term. This presence will require an adequate level of R & D, and strong links with both academic research and clinical practice. In our view, the long-term financial health of the industry will depend on its being able to attack overseas markets successfully. In addition to technical competence, this will require good marketing and design and the removal of the unnecessary regulatory barriers which fragment the European market in particular. It will also require a home market which not only provides a base of demand for products of a kind which can be sold profitably overseas, but which also allows companies to grow from being highly specialised and local niche producers to medium-sized companies with coherent, well-designed and well-marketed product ranges.

166. The character of the home market is determined by the behaviour of the NHS, which must recognise the impact which its practices, and especially its procurement, have on the UK industry, and must accept some responsibility for the health of that industry. This implies not only changes in the attitudes of individual buyers, but also changes in systems and in the availability of information. Buyers need better information, and they need to take more account of efficiency in their buying decisions. The home market needs to be rather less fragmented, particularly in using nationally agreed specifications and procedures but not to the extent of massive centralisation of purchasing. Our aim is a free, but well-informed and responsible market, which we believe is the main need of the industry.

THE WORLD MARKET FOR LABORATORY DIAGNOSTICS DEVICES - 1985

Product type	Sales value ($ million)
Clinical Chemistry	2,000
Immunology	1,750
Microbiology	750
Other	500
Total	5,000

THE WORLD MARKET FOR IMAGING DEVICES - 1985

Product type	Sales value ($ million)
X-ray	3,000
CT X-ray	800
MRI	300
Ultrasound	600
Nuclear medicine	300
Other	negligible
Total	5,000

THE WORLD MARKET FOR OTHER ELECTROMEDICAL DEVICES - 1985

Product type	Sales value ($ million)
Patient monitoring	1,100
Anaesthetics	750
Dialysis and Heart-lung	450
Laser surgery	200
Infusion pumps	500
Endoscopes	250
Pacemakers	900

Other	850
Total	5,000

THE WORLD MARKET FOR SINGLE-USE DEVICES - 1985

Product type	Sales value ($ million)
Dressings, bandages	1,500
Infusion supplies	1,100
Needles, syringes	750
Sutures, needles and ligatures	700
Drapes, clothing	700
Catheters, tubes	500
Gloves	450
Dialysis supplies	400
Anaesthesia and respiratory supplies	300
Ostomy products	300
Nursing care products	250
Electrodes and gels	250
Incontinence products	250
Staplers	200
Oxygenation supplies	100
Medical gases	300
X-ray films and supplies	3,000
Other	950
Total	12,000

(Source: E.B. Savory Milln & Co.)

Mechano - Therapy Appliances, Massage Apparatus etc	1980	17.0	9.1	+ 7.9
	1981	24.7	10.9	+ 13.8
	1982	24.9	14.9	+ 10.1
	1983	27.5	17.3	+ 10.2
	1984	28.9	20.8	+ 8.1
	1985	32.2	20.8	+ 11.4
Hygiene Articles of Rubber	1980	10.3	3.0	+ 7.3
	1981	10.8	2.4	+ 8.4
	1982	8.5	3.0	+ 5.6
	1983	8.6	3.9	+ 4.6
	1984	5.2	2.4	+ 2.8
	1985	10.8	5.4	+ 5.4
Medical Sterlising Apparatus	1980	3.6	0.8	+ 2.8
	1981	2.7	0.9	+ 1.8
	1982	4.7	1.3	+ 3.4
	1983	2.7	1.3	+ 1.3
	1984	2.6	1.9	+ 0.7
	1985	4.5	2.3	+ 2.2
Invalid Carriages	1980	4.8	0.5	+ 4.3
	1981	4.1	0.7	+ 3.4
	1982	4.7	0.6	+ 3.1
	1983	4.5	2.1	+ 2.4
	1984	5.4	1.8	+ 3.6
	1985	6.4	1.4	+ 5.0

Appendix 2

UK TRADE IN MEDICAL EQUIPMENT BY SECTOR
£m

	Year	Exports	Imports	Balance
Spectacle Glass, Frames - Parts	1980	20.6	29.0	- 8.3
	1981	21.8	26.6	- 4.8
	1982	30.8	36.6	- 5.9
	1983	34.5	37.8	- 3.4
	1984	41.8	47.4	- 5.7
	1985	45.2	61.1	- 15.8
Instrumental - Ophthalmic, Medical, Surgical, Dental, Veterinary and Dissecting, also Medical Appliances including Dental	1980	115.8	68.9	+ 46.9
	1981	129.5	87.3	+ 42.2
	1982	154.0	107.7	+ 46.2
	1983	185.2	136.8	+ 48.4
	1984	216.6	171.6	+ 45.1
	1985	262.6	188.8	+ 73.8
Orthopaedic Appliances including Limbs, Eyes, Teeth, Deaf Aids and Parts	1980	18.2	18.2	+ 0.1
	1981	20.1	22.3	- 2.2
	1982	21.1	30.9	- 9.8
	1983	26.1	42.5	- 16.4
	1984	42.7	52.3	- 9.6
	1985	47.7	55.4	- 7.6
Electro-Medical Apparatus excluding X-Rays	1980	20.3	17.3	+ 3.0
	1981	25.5	18.8	+ 6.7
	1982	31.7	20.5	+ 11.2
	1983	37.9	29.4	+ 10.5
	1984	50.8	34.8	+ 15.9
	1985	70.2	35.1	+ 35.2
Apparatus based on use of X-Rays or Radiations from Radio-Active Substances	1980	26.7	27.2	- 0.5
	1981	31.6	46.1	- 14.5
	1982	48.0	62.4	- 14.3
	1983	62.1	67.4	- 4.3
	1984	55.6	65.4	- 9.8
	1985	48.3	63.2	- 14.9
X-Ray Films (including Dental Film)	1980	17.1	18.7	- 1.7
	1981	7.1	24.1	- 17.0
	1982	6.5	22.7	- 16.3
	1983	10.6	27.1	- 16.6
	1984	11.7	28.9	- 17.2
	1985	14.4	29.9	- 15.5
Furniture - Medical, Dental, Surgical and Veterinary	1980	11.6	3.3	+ 8.2
	1981	10.0	4.6	+ 5.4
	1982	13.4	5.6	+ 8.8
	1983	11.9	5.6	+ 6.2
	1984	15.3	6.6	+ 8.7
	1985	18.1	7.2	+ 10.9

GLOSSARY OF ABBREVIATIONS

ACARD	Advisory Council for Applied Research and Development
BSI	British Standards Institution
BTG	British Technology Group
CT	Computer tomography
DHA	District Health Authority
DHSS	Department of Health and Social Security
DTI	Department of Trade and Industry
FDA	Food and Drugs Administration
GP	General Practitioner
MRC	Medical Research Council
MRI	Magnetic resonance imaging
NHS	National Health Service
OECD	Organisation for Economic Cooperation and Development
OPEC	Organisation of Petroleum Exporting Countries
RHA	Regional Health Authority
SERC	Science and Engineering Research Council
SHHD	Scottish Home and Health Department
STB	Scientific and Technical Branch (a part of DHSS)