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Quality Assurance Systems and Global Markets

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The Honorable Henry A. Waxman
Chairman, Subcommittee on Health and the Environment
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

This report compares and contrasts the regulatory policies and procedures and quality assurance requirements for marketing medical devices in the United States, Japan, and Canada with those that are proposed for the European Economic Community. It also examines the preparedness of U.S. device manufacturers to compete in a global market that is based on adherence to international standards.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from its date of issuance. We will then make copies available to interested organizations, as appropriate, and to others upon request.

If you have any questions or would like additional information, please call me at (202) 512-2900 or Kwai Cheung-Chan, Director of Program Evaluation in Physical Systems Areas, at (202) 512-3092. Other major contributors to this report are listed in appendix VI.

Sincerely yours,

Eleanor Chelimsky
Assistant Comptroller General

Executive Summary

Purpose

The economic integration of the European Free Trade Association member countries into the European Economic Community (EEC) has created the world's largest single market. The basis for participation is adherence to internationally based technical standards and the principles of total quality assurance. For the U.S. medical device industry to compete successfully in either the EEC or other sectors of the global market, such adherence will be required. The Chairman of the House Subcommittee on Health and the Environment of the Committee on Energy and Commerce asked GAO to compare U.S. policies and procedures for the marketing and quality assurance of medical devices to those currently in existence in Japan and Canada and to those being developed by the EEC.

For this evaluation, GAO posed five study questions: (1) What are the similarities and differences among the U.S., Japanese, and Canadian policies and procedures for the premarketing regulation and quality assurance of medical devices? (2) What are the major components of the proposed EEC system for the premarketing regulation and quality assurance of medical devices? (3) To what extent are U.S., Japanese, and Canadian policies and procedures compatible with those that are proposed for the EEC? (4) How prepared is the U.S. medical device industry for competing in a global market? (5) How have U.S. device manufacturers responded to the EEC single market?

Background

The U.S. medical device industry has been the international leader in the development and sale of devices. In 1992, the United States accounted for nearly half ($39 billion of $81 billion) of the world's production of devices. Two thirds of the U.S. device exports ($6.1 billion of $9.1 billion) are purchased in Japan, Canada, and the EEC. With regard to the safety context in which medical devices are developed, produced, and sold, the U.S. regulatory system has been an international model.

There is, however, a growing consensus that to maintain a leadership position, or even to remain competitive in the global market, the quality of U.S.-manufactured devices must be improved and impediments to a free market removed. One way to improve product quality is to enhance quality assurance, and one impediment to market access is differential standards.

The results and findings of GAO's review are primarily based on a comprehensive examination of relevant policies and procedures, along with current literature in the field; structured interviews with government officials and others; and the responses from a survey of a random sample

of U.S. medical device manufacturers drawn from the U.S. Food and Drug Administration's listing of domestic medical device manufacturers. GAO obtained a 79-percent response rate from the survey, and the results of its analyses can be generalized to the entire population of U.S. medical device manufacturers.

Results in Brief

GAO's analyses show that current systems (that is, policies and procedures) for premarketing regulation in the United States, Japan, and Canada function in a similar manner, although structures and operations are different in some areas. In addition, all three countries are undergoing convergent changes to increase the safety and effectiveness of devices, improve product quality and international competitiveness, and achieve international harmonization of regulatory requirements.

Although the proposed EEC and U.S. regulatory systems are far from incompatible, their emphases appear to be different. GAO found that, in contrast to the proposed U.S. regulatory requirements that tend to stress the assurance of device safety and effectiveness, the primary aim of the proposed EEC regulatory system is the enhanced production and exchange of goods throughout the EEC. Therefore, it seems possible that despite their similarity of functions and parallel efforts to move toward harmonization, the proposed regulatory systems of the United States and the EEC may turn out to be sufficiently different from each other to result in continued impediments to market access and failure to eliminate the current system of duplicate inspections and approvals for U.S. and foreign device manufacturers.

GAO's survey results show that a sizable proportion (39 percent) of U.S. device manufacturers report unawareness of the nature, scope, or immediacy of the potential challenges to their industry from the global market or the EEC. Further, the majority of U.S. device manufacturers are focusing more on improving product quality and increasing their share of the domestic market than on enhancing their competitiveness in foreign markets.

Principal Findings

Similarities and Differences Among Systems

The overwhelming majority (90 to 95 percent) of all devices in the United States, Japan, and Canada enter the market through a similar process: they need not demonstrate safety and effectiveness because they have been declared substantially equivalent to a previously marketed device. With regard to quality assurance, statutes or regulations in both the United States and Japan require periodic inspections of a manufacturer's system for building in quality. In the United States, these requirements are contained in the provisions of the good manufacturing practices regulation. Canada does not have a quality assurance regulation.

Some existing differences between the proposed EEC regulatory system for medical devices and those of the U.S., Japan, and Canada have to do with (1) the use of a Europe-wide classification scheme based on determining how a device is used in relationship to the human body and (2) systematic referral to international standards for product quality and market approval. Compliance with the EEC requirements will be mandatory for participation in the single market.

Although the EEC's proposed regulatory approach for medical devices is similar to that of the United States insofar as the degree of regulatory control is directly proportional to the perceived risk associated with a given product class, the EEC's device classification system dealing with how a particular device is used on or in the body could result in dual classification for some devices. More importantly, there is no EEC provision for market approval based on a device's "substantial equivalence" to some previously marketed device. Further, in contrast to the existing requirements in the United States, Japan, and Canada, the EEC's market approval and quality assurance requirements are directed toward a total quality system that focuses on quality throughout the life cycle of a device rather than on the manufacturing process alone.

U.S. Device Manufacturers' Preparedness for the Global Market

The majority (54 percent) of U.S. device manufacturers responding to GAO's survey perceived that during the next 5 years their greatest competitive challenge would be coming from other U.S. manufacturers, and about half (45 percent) did not identify any comparative trends in the quality of U.S.-made devices versus that of foreign competitors. Among the manufacturers who reported concern about the relative competitiveness

of U.S.-manufactured devices in the global market, GAO found that their most frequent response was to increase their investment in research and development for improving the quality of current products. Overall, 50 percent of manufacturers said they have put a quality program in place. However, in some cases, they plan to move their manufacturing offshore to lower labor or regulatory costs.

GAO found that the greatest level of manufacturer preparation for international competition is shown by a minority of companies—the large and medium multinational manufacturers—rather than the overwhelming majority of small U.S.-based companies that make up the U.S. device industry. Overall, about 43 percent of GAO's respondents said they had not acted to prepare for the advent of the single market.

Recommendations

In light of the increasing trend toward global markets and considering also the differing aims and emphases (especially those related to "substantial equivalence" and product design focus) driving U.S. and EEC regulatory requirements, certain activities assume critical importance. In this regard, GAO endorses current efforts to revise the U.S. good manufacturing practices regulation and other premarketing requirements in a manner that advances international harmonization without compromising the protection of the public health from unsafe or ineffective medical devices. GAO recommends that the Secretary of Health and Human Services direct the Commissioner of the Food and Drug Administration to increase the internal coordination, outreach, and focus on small manufacturers of its educational and guidance programs for exporting.

GAO further supports the efforts of the U.S. Task Force on the EEC Internal Market and the Secretary of Commerce to monitor developments and coordinate their activities. GAO recommends that the Task Force Chair, in cooperation with the Secretary of Commerce, make a targeted effort to inform U.S. medical device manufacturers on progress toward the single market and changes related to harmonization that may affect their competitiveness.

Agency Comments

The Department of Health and Human Services generally agreed with the report. The agency's comments appear in appendix V. Suggested technical changes have been made where appropriate.

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Bibliography

Glossary

Related GAO Products

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Abbreviations

CDRH	Center for Devices and Radiological Health
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
DSMA	Division of Small Manufacturers Assistance
EEC	European Economic Community
EFTA	European Free Trade Association
FDA	U.S. Food and Drug Administration
GAO	U.S. General Accounting Office
GATT	General Agreement on Tariffs and Trade
GMP	Good manufacturing practice
HIMA	Health Industry Manufacturers Association
HHS	U.S. Department of Health and Human Services
ISO	International Organization for Standards
JIS	Japanese industrial standards
PMS	Postmarketing surveillance
PQA	Preproduction quality assurance
QA	Quality assurance

Introduction

Background

The globalization of our daily lives is evident everywhere—from the vast array of products in our markets to the attention paid to exchange rates in the morning news. Globalization is not simply a matter of increased trade; it can be seen in the worldwide market for currencies and credit, in the patterns of production, and in the flow of information. Driven by significant advances in science and technology, the world economy is characterized by increasing international integration and the emergence of new economic power centers.

Within Western Europe, trade and regulatory barriers are rapidly being dismantled as the European Economic Community (EEC) moves toward an integrated economy. Economic integration is displacing ancient rivalries, and prosperity has become a joint pursuit. The EEC is in the process of creating the world's largest single market. The single-market concept seeks to eliminate three principal types of barriers to all kinds of intra-European trade and commerce: (1) physical, (2) technical, and (3) fiscal.[1] Member countries will open their borders to people, companies, investments, transportation, and all other aspects of commercial life.

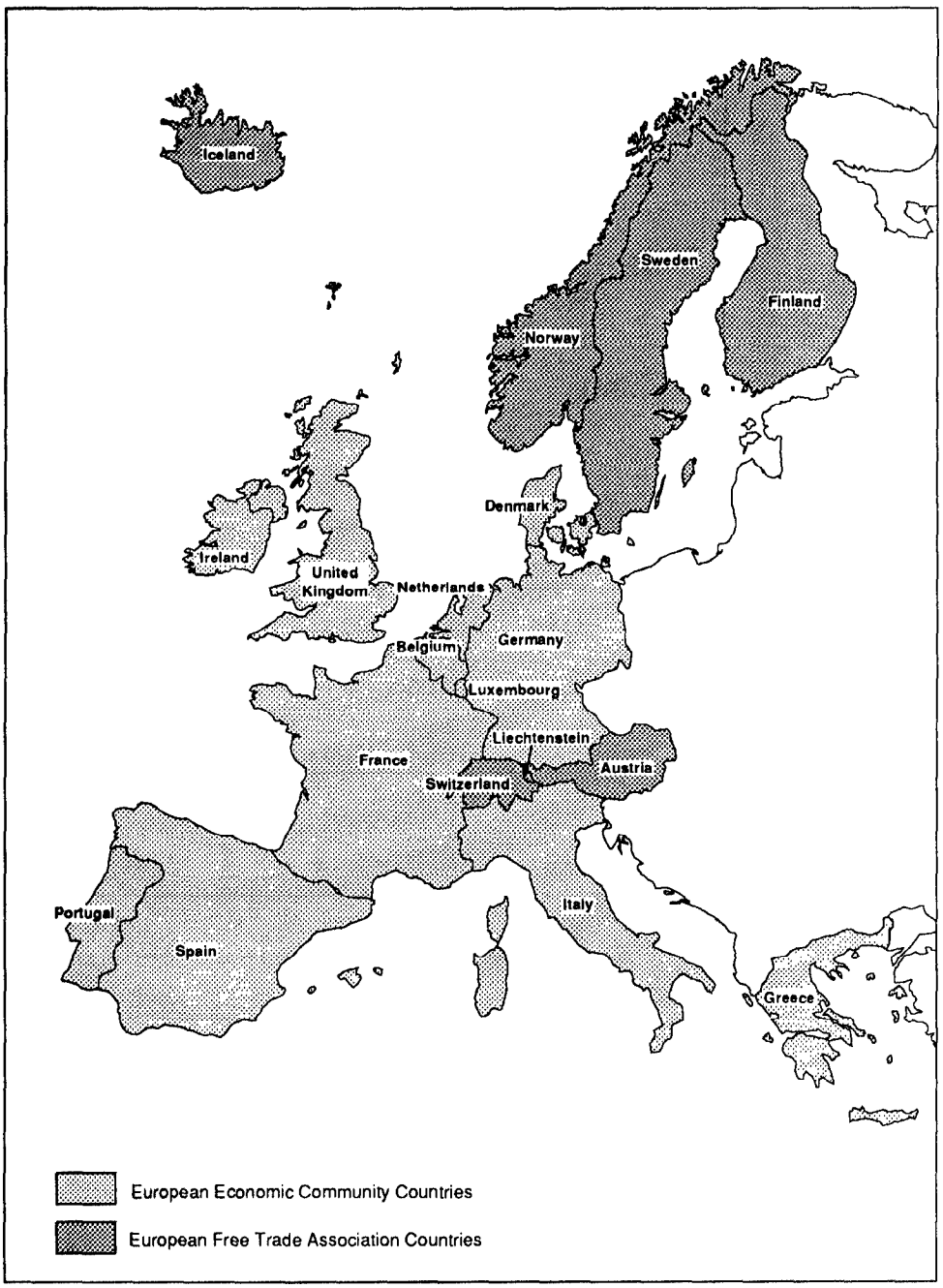
Recently, the foreign ministers of the EEC and the European Free Trade Association reached agreement to join together and create a free trade zone known as the European Economic Area.[2] It will contain some 380 million consumers and reach from the Arctic Circle to the Mediterranean Sea and from the Atlantic Ocean to the western border of the former Soviet Union. This agreement creates the world's largest and wealthiest single market, accounting for 43 percent of world trade—a trading bloc larger than the United States and Japan combined. (See figure 1.1.) Further, a record number of countries, some newly independent, are expressing interest in membership simultaneously in the European community.[3] Turkey, Cyprus, and Malta have formally applied, and others have indicated their interest in doing so. If the EEC does open its doors to all potential applicants, it could grow to over 30 members.

[1]See U.S. General Accounting Office, European Single Market: Issues of Concern to U.S. Exporters, GAO/NSIAD-90-60 (Washington, D.C.: February 1990), for further information on the single market.

[2]European Free Trade Association countries include Austria, Finland, Iceland, Liechtenstein, Norway, Sweden, and Switzerland. The European Economic Community is composed of the following nations: Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, and United Kingdom.

[3]See Congressional Research Service, European Community Enlargement: Background and Issues for the United States, CRS/92-264F (Washington, D.C.: March 4, 1992.)

Figure 1.1: The New European Economic Area



The EEC plans to adopt unified horizontal and vertical standards and requires certification of compliance with these standards for products

with health, safety, or environmental implications, known as regulated products.[4] These standards are guidelines and technical specifications that are approved by an EEC-designated standards-setting body. Certification is a process by which the producer or certifier attests that a product, service, or person satisfies the requirements of the referenced standard. In the EEC, medical devices are designated as regulated products. Consequently, the U.S. medical device industry must be prepared for its products to meet the EEC standards, testing, and certification requirements if they are to be marketed in the EEC.

Medical Device Industry

Like virtually every other industry in the United States, the $39 billion medical device industry has encountered the trends toward global markets and increased competition. Unlike other major industries in the United States, it has increased its positive trade balance throughout the last decade, despite the nation's recent overall trade deficits.

Over the past decade, this industry's average annual growth rate has exceeded 11 percent. It is important to note that, over the past 5 years, more than a third (37 percent) of this industry's production growth has gone to serve overseas markets. The industry produced $9.1 billion in exports and a $4.1 billion trade surplus in 1992, while increasing employment at an average annual rate of about 4 percent, currently providing jobs for over a quarter of a million Americans. Over two thirds of the medical devices exported from the United States are purchased by Europe, Japan, and Canada. In 1992, U.S. manufacturers accounted for about half (49 percent) of the world's $81 billion production of medical devices and diagnostics and exported one out of every five medical devices and diagnostics produced in this country.

Domestic and International Challenges

Recent domestic and international developments suggest that the U.S. medical device industry's future and the benefits that have accrued to the nation's competitiveness may be more tenuous than its strong historical performance suggests. Several other developed countries have reached the same level of technological sophistication as the United States in many health-care technology areas. For example, Germany has a particularly strong and broad-based health-care technology industry while Japan is extremely competitive in several product areas, such as electromedical

[4]Horizontal standards are those that apply to whole industries or across a broad sector of industry, such as quality systems standards or standards for sterilization. Vertical standards are those that are relevant only to particular types of products, such as standards for infusion equipment or particular catheters.

imaging equipment. These two countries alone account for nearly half of U.S. medical imports. A recent U.S. Department of Commerce study warns that "trends emerging overseas in product introduction and government support to industry are making foreign companies more vital global competitors than ever before."[5] Many foreign firms have already demonstrated their ability to develop, commercialize, and sell their products in international markets and have gained a more secure presence within the large, open U.S. market by establishing strong distribution networks and subsidiaries.

Given the increasingly favorable climate some foreign health-care technologies are enjoying at home and in the United States, U.S. companies may begin to lose market share—especially if they do not have the same access to foreign markets as their competitors have to the vast U.S. market, if they cannot adapt as quickly and freely as local companies to the major changes taking place in foreign regulatory environments, and if they are generally not ready and able to compete successfully in an increasingly competitive global marketplace.

Objective, Scope, and Methodology

Objective

The Chairman of the House Subcommittee on Health and the Environment asked us to provide the Subcommittee with a comparative analysis of the U.S. policies and procedures for marketing and quality assurance (QA) of medical devices and the counterpart controls in place or being developed by its major trading partners—Japan, Canada, and the EEC.

To meet our objective, we developed the following evaluation questions:

1. What are the similarities and differences among the U.S., Japanese, and Canadian policies and procedures for premarketing regulation and QA of medical devices?

2. What are the major components of the proposed EEC system for the premarketing regulation and QA of medical devices?

[5]U.S. Department of Commerce, Technology Administration, Emerging Technologies: A Survey of Technical and Economic Opportunities (Washington, D.C.: U.S. Government Printing Office, Spring 1990).

3. To what extent are the policies and procedures in the United States, Japan, and Canada compatible with those that are proposed for the EEC?

4. What are the nature and extent of preparedness of the U.S. medical device industry for competing in a global market?

5. How have U.S. device manufacturers responded to the EEC single market?

Scope

Our review concentrates on the aspects of the medical device regulatory systems of the United States, Japan, Canada, and the EEC that are related to market access: premarketing review and approval, as well as quality assurance.[6]

Our preliminary efforts had indicated that each national system we reviewed recognizes the importance of monitoring the performance of devices after they have been approved for public use—postmarketing surveillance (PMS). Further, the U.S., Japanese, and Canadian systems all include similar PMS programs, and the design for the EEC's PMS program is similar to these existing systems. However, many of the specific elements of the EEC's PMS program have not been approved for adoption and others that have been proposed are subject to modification. Similarly, the implementation of the provisions of the recently enacted Safe Medical Devices Act of 1990 that are related to device tracking and other PMS activities may significantly alter the U.S. PMS requirements. We concluded that a comparison of PMS systems would be premature and did not include them in this review. Instead, in accordance with the Subcommittee's needs, we restricted our review to selected generic elements of each nation's regulatory system and conducted an analytical comparison among the system elements and regulations. Our fieldwork was conducted from December 1990 to March 1992.

Methodology

Answering our evaluation questions required that we collect different kinds of information from many sources. To understand the regulatory structures, policies, and procedures for reviewing and approving the quality assurance requirements for medical devices of the selected countries, we began by performing a comprehensive review of the available literature. This literature included published and unpublished

[6]By medical device regulatory system we mean the laws, regulations, and government practices concerning the life cycle of medical products: development, testing, production, distribution, and use.

government reports, legislative histories, enabling legislation, health agency regulations, and a variety of technical documents.

We conducted structured interviews with government officials, program managers, and staff responsible for reviewing and approving devices for market to clarify, confirm, and supplement documentary evidence and findings.[7] Each of the selected nation's regulatory systems was in constant flux because of attempts to respond to both domestic influences and international developments. We obtained updates on national and international developments through attendance at international conferences and by reviewing weekly industry newsletters and monthly EEC publications.

The data we collected about standards, testing, certification, and total quality assurance systems were obtained from private-sector foreign and domestic standards development organizations and government officials who work closely with these organizations. We obtained trade statistics and trends from industry association and official government documents.

We surveyed a stratified random sample of 357 U.S. medical device manufacturers to measure their level of knowledge, preparation, and concerns about the impending regulatory changes in the EEC and the increasing competitiveness of the international market. Our sample was drawn from the U.S. Food and Drug Administration's (FDA's) list of all U.S. medical device manufacturers. We subdivided the population of U.S. device manufacturers into mutually exclusive and exhaustive strata based on device class. Within these strata, we selected a separate and independent sample using GAO's random number generator. The universe of 4,138 cases was made up of the following: class I, 1,242; class II, 2,499; and class III, 397. We used data collected for each stratum to develop separate within-stratum estimates. We combined (weighted) these separate stratum estimates to form an overall estimate for the population. We obtained responses from 284 (actual number, unweighted), or 80 percent of the manufacturers who received a questionnaire.

The characteristics of our sample generally reflect the characteristics of the U.S. medical device industry—the overwhelming majority (92 percent) of firms employ fewer than 500 people; about half (51 percent) produce medium-risk (class II) devices, and a quarter produce the highest risk (class III) devices; and 62 percent of our sample export their product, with

[7]A list of the government agencies and private organizations from which we obtained documents and other information related to this study is presented in appendix I.

Canada and the EEC being by far the most frequent destination. Our survey results can be generalized to the universe of U.S. medical device manufacturers.[8] (See appendix II for a reproduction of the questionnaire.)

Our industry perspective was supplemented by structured interviews with officials of three U.S. medical device manufacturing firms whose quality assurance systems were at various stages of implementation and with trade and industry association representatives in each country.

The nature of the data we collected required both qualitative and quantitative analysis. We systematically reviewed and synthesized the qualitative data describing the various regulatory systems to develop and confirm analytical flow charts of their content and operations for comparison. Our statistical procedures for the analysis of the survey data used the statistical package for the social sciences (SPSS-X). We edited, coded, keypunched, and verified the data we collected. Our analysis included frequencies, cross-tabulations, and associated statistical tests. We performed chi square and other tests of significance using appropriate statistical techniques. The results of these analyses are presented where appropriate throughout the report.

We obtained formal written comments from the U.S. Department of Health and Human Services (HHS) on a draft of this report and revised our draft to take account of the comments as appropriate. The draft report also benefited from reviews and comments provided by representatives from the U.S. medical devices industry. (See appendix III for the names of the industry reviewers.)

Report Organization

The remainder of the report is organized as follows: chapter 2 describes and compares the premarketing regulations and QA programs for devices in the selected countries, with a focus on the proposed EEC regulatory system and the harmonization efforts of U.S., Japanese, and Canadian regulatory agencies. Chapter 3 presents the findings of our survey of U.S. medical device manufacturers that are related to their attitudes and behaviors about competing in a global market. Chapter 4 presents the findings of our survey of U.S. medical device manufacturers and their activities and level of preparation for the EEC single market. And chapter 5 contains our conclusions and recommendations.

[8]One of our analysis variables was company size. FDA distinguishes three firm sizes based on their sales volume: (1) small ($0-$499,999), (2) medium ($500,000-$9,999,999), and (3) large ($10,000,000 and above). Another variable we used was exporter-nonexporter status. We use U.S. Food and Drug Administration categories throughout this report.

Premarketing Regulatory Requirement and Quality Assurance Systems

Introduction

Historically, the U.S. premarketing regulatory requirements and quality assurance procedures for regulating medical devices have been used as a model for the requirements and procedures of other nations.[1] This chapter addresses the first three evaluation questions listed in chapter 1. We focus on the U.S. requirements and procedures and use them as the principal framework for comparison with the proposed EEC system of premarketing regulations and quality assurance procedures for medical devices. References to specific elements of the Japanese and Canadian systems are included where significant differences are present and where they add clarity to the analysis. This chapter also includes our analysis and interpretation of the potential effect of the similarities and differences among the models for the international harmonization of regulations and procedures.

Premarketing Regulations—United States, Japan, and Canada

U.S. Device Classes

In the United States, the basic principle underlying the regulatory structure for medical devices is regulation in accordance to two criteria: (1) the degree of potential risk and (2) the types of regulatory control needed to reasonably ensure their safety and effectiveness. Medical devices are grouped into three classes according to these criteria—class I devices (such as bedpans and tongue depressors) are those for which general controls provide reasonable assurances of safety and effectiveness, class II devices (for example, syringes and hearing aids) require special controls in addition to general controls, and class III devices (for example heart valves and pacemakers) must undergo scientific review and approval by FDA and are subject to general controls

[1]In the United States, medical device regulation is the responsibility of the Department of Health and Human Services' Food and Drug Administration; in Japan, the Ministry of Health and Welfare's Pharmaceutical Affairs Bureau, Medical Devices Division; and in Canada, the Department of Health and Welfare, Health Protection Branch.

as well.[2] The majority of all devices on the U.S. market are designated as class II.

Principal Routes to Market for Devices in the United States

Contingent upon a device's classification, there are two primary routes to market—premarketing review and premarketing approval.[3] (Figure IV.1 in appendix IV shows FDA's premarketing review and approval processes.) The major difference between the review and approval processes is that the latter requires governmental review of scientific evidence of a device's safety and effectiveness prior to market approval.[4] These regulatory requirements are equally applicable to domestic manufacturers and importers.

FDA has only recently begun to require manufacturers to submit premarketing approval applications for devices that were on the market before the 1976 device amendments; the agency has not developed any performance standards for class II devices. Both of these provisions were included in the 1976 amendments. As a result of the manner of implementation of the basic medical device law and regulations, most devices (90 to 95 percent), regardless of classification, have reached the U.S. market without demonstrating their individual safety and effectiveness.[5]

The premarketing review process generally consists of evaluating a manufacturer's written assertion that the product to be marketed is "substantially equivalent" to a product already on the market. Generally, a

[2]General controls includes company registration, product listing and application with FDA, adherence to good manufacturing practices, and prohibition against adulteration and misbranding. The Safe Medical Devices Act of 1990 modified the statutory language for the development of performance standards to that of special controls. Special controls may include promulgation of standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions. See our report, U.S. General Accounting Office, Medical Devices: Early Warning of Problems Is Hampered by Severe Underreporting, GAO/PEMD-87-1 (Washington, D.C.: December 1986), for a more detailed discussion of the U.S. device classification structure.

[3]The statutory name for premarketing review is premarket notification (510(k)). We use the term premarketing review to indicate that this process includes not only the manufacturer's notification requirement but also FDA's review of the submitted application to verify the manufacturer's claim and, in some cases, a manufacturing practices inspection.

[4]Among the evidence that may be included are controlled studies and investigations, objective trials without matched controls, documented case histories conducted by qualified experts, reports of significant experience (such as the results of research conducted in foreign countries), or any combination of these.

[5]A small proportion (between 5 and 10 percent) of devices reach the market in the United States, Japan, and Canada through a premarketing approval application, reclassification petition, or product development protocol.

finding of substantial equivalence does not represent and should not be construed as a government certification of the safety and effectiveness of a device. It means only that the device is "substantially" (in itself, an imprecise term) equivalent to a precedent device that itself may not have been shown to be safe or effective either.[6] Such products are "grandfathered" into commercial distribution.[7]

FDA performs manufacturing practices inspections of buildings and facilities when manufacturers notify FDA of their intent to go into production at a new site or when manufacturers submit a premarketing approval application. More recently, FDA carried out a pilot program of conducting QA inspection on selected substantially equivalent submissions.

Japan's Device Classes

In Japan, devices are classified by their purpose of use and are divided into five types: (1) instruments and apparatus (such as anesthesia machines and scalpels), (2) medical supplies (for instance, x-ray film and sutures), (3) dental materials (for example, dental metals and root canal filling material), (4) sanitary supplies (for example, condoms and sanitary tampons), and (5) medical devices for animal use only. The five types of devices are subdivided into 103 categories, each of which includes specific products.[8]

Principal Routes to Market for Devices in Japan

There are three separate but related routes to market for medical devices in Japan: (1) direct application from foreign manufacturers to the Minister of Health and Welfare, (2) original application from domestic manufacturers and importers to local government, and (3) application to local government for permission to add or modify a formerly licensed product.[9] These routes to market include one that equates with the U.S. substantial equivalence review and account for about 90 percent of medical devices that enter the Japanese market. (Figure IV.2 in appendix IV shows the Japanese premarketing review and approval processes.)

[6]The United States, Japan, and Canada require that manufacturers have available and present upon request information to support their claim of safety and effectiveness.

[7]The purpose of the substantial equivalence provision was to enable FDA to ensure that "new" devices distributed after May 28, 1976, were not marketed until they complied with premarketing approval requirements or were reclassified into class I or II.

[8]Medical devices for use on animals only are omitted from these categories. These devices are within the jurisdiction of the Ministry of Agriculture, Forestry, and Fisheries.

[9]See Japan Ministry of Health and Welfare, Pharmaceutical Affairs Bureau, Medical Devices Division, Guide to Medical Device Registration in Japan, 3rd ed. (Tokyo, Japan: Yakuji Nippo, Ltd., November 1990), for a detailed discussion of the Japanese review and approval processes for medical devices.

Within the basic Japanese regulatory framework, a proportion of medical devices do not require review or approval. Devices listed under 33 of the 103 categories are exempt from approval product by product because of their exclusive use by specialists, demonstrated effectiveness and safety, and reliable operating technique. Similarly, devices that conform to Japanese industrial standards (JIS) specifications are also exempt from approval on the grounds that they are widely used and that their quality and description, as publicly well recognized products, have been established on the basis of comprehensive knowledge of current medical science and engineering practices.

Importers and foreign device manufacturers must apply through the national or local government for a license and approval for each manufacturing site. The license and approval-granting authority, local or national, depends on the route to market selected. The granting of a license is based principally on an examination of QA procedures in the manufacturing facility, whereas the granting of a device approval is given after an examination of the structure, quality, efficiency, standards, and other conditions of safety and effectiveness of the product to be manufactured or imported. The examinations vary depending on the characteristics of the device to be manufactured. Quality assurance inspections of manufacturing equipment and facilities are required for new device and substantial equivalent applications.

Canada's Device Classes and Principal Route to Market

There is no Canadian system for device classification. Between 75 and 85 percent of the devices that are available in Canada are imported, primarily from the United States. Therefore, device regulation in Canada depends upon the regulations in the exporting countries. Canada's medical device regulations under its Food and Drug Act generally require that devices be safe and effective.

Canadian regulations require that a "Part II" or premarketing notification be submitted to the Health Protection Branch within 10 days of marketing a device. This notification includes the required company identification and registration information as well as identification of the device that is currently or was previously marketed in Canada to which the device is similar or that it modifies.[10] (Figure IV.3 in appendix IV shows the Canadian premarketing review and approval processes.)

[10]See Ministry of Health and Welfare, Environmental Health Directorate, Health Protection Branch, "Food and Drugs Act, Excerpts Applicable to Medical Devices," Medical Devices Regulations (Ottawa, Ontario, Canada: September 1990), for a detailed discussion of the Canadian review and approval processes for medical devices.

Similarities and Differences Among Premarketing Regulations

The U.S. and Japanese regulatory requirements are based on a device classification scheme in which the degree of regulation depends upon the potential risk associated with the device. Canada does not have a similar framework. The overwhelming majority of devices, in each of the three countries, reach the market more because of their equivalence to (or modification of) a device that is already legally marketed than because of their class or a demonstration of their safety and effectiveness. The minimum requirement in each country is that manufacturers must submit some form of notification to the appropriate national authority, indicating their intention to market a device, and must have available or submit summaries of related safety and effectiveness data.

The principal differences among the countries are in their implementation of their respective regulations. For example, regulatory implementation and enforcement are centralized at the federal level in the United States and diffused to local government bodies in Japan. In Japan, many devices may be marketed by conforming to JIS performance standards, which are generally based on international standards. The U.S. and Canadian regulatory structures do not provide such a route for market approval. The Japanese system requires premarketing QA inspections to a greater extent than does the United States, although Japanese QA requirements and inspections have been characterized as less rigorous than U.S. inspections. For example, Japanese licensing procedure requires that all manufacturers or importers have their QA procedures examined and approved prior to marketing a medical device. Canada does not currently have a premarketing QA inspection program but is in the process of developing quality systems requirements for medical devices.

Each of the three countries has indicated that its regulations are currently being reviewed and revised with the intent of harmonization and establishing mutual recognition agreements of regulations and international acceptance of results.

Quality Assurance Requirements—United States

In the United States, the principal QA requirements are contained in the provisions of the good manufacturing practices (GMP) regulation.[11] GMPs are quality assurance practices and standards in manufacturing, including packing, storage, and installation, intended to prevent the production and distribution of defective devices. The regulation is divided into 10 subparts and defines GMP requirements in terms of over 50 broad QA objectives. (See

[11]See U.S. General Accounting Office, Medical Technology: Quality Assurance Needs Stronger Management Emphasis and Higher Priority, GAO/PEMD-92-10 (Washington, D.C.: February 1992), for a detailed discussion of the U.S. GMP program.

table 2.1.) These objectives apply to all medical devices and to a number of activities necessary to prevent the manufacture of defective medical devices. FDA monitors compliance with the GMP regulation through a program of biennial inspections of manufacturers' facilities.[12]

Table 2.1: U.S. GMP Regulation, 21 C.F.R. Part 820 (1992)

Subpart	Requirement
A. General provisions	
B. Organization and personnel	Adequate organization and personnel to ensure compliance with the regulation; adequate quality assurance program
C. Buildings	Adequate design and space to facilitate cleaning, maintenance, and necessary operations
D. Equipment	Adequate equipment designed, constructed, placed, and installed to facilitate maintenance, adjustment, and cleaning. Adequate equipment for intended use in manufacturing process[a]
E. Control of components	Adherence to written procedures for acceptance of components. Testing to be based on accepted statistical rationale[a]
F. Production and process controls	Adherence to written procedures to control production processes. Adequate process validation and change control[a]
G. Packaging and labeling control	Adequate controls to maintain label integrity
H. Holding, distribution, and installation	Adherence to written procedures for warehouse control, distribution, inspection, or instructions for installation
I. Device evaluation	Adherence to written inspection and test procedures to ensure specifications are met. Adequate failure investigation, including corrective actions[a]
J. Records	Maintenance of all required records; adequate device master and history record; adherence to complaint review procedures. Adequate complaint analysis procedures[a]

[a]Provisions of the proposed revised regulation.

Following the principles of flexibility and regulation in proportion to perceived risk, the GMP regulation is designed to serve as a framework within which manufacturers can incorporate their individual QA programs. The required QA activities are proportional to the potential for error in manufacturing and to the resulting risk of injury or death to patients or users.

[12]The addition of design controls to the GMP regulation was authorized by a provision of the Safe Medical Devices Act of 1990.

Recently, FDA has, in advance of proposed rulemaking, solicited comments on several major revisions to the GMP regulation.[13] The most significant revisions involve QA requirements for preproduction (PQA), subcontractors of device components, and servicing of used devices. The proposed requirement for PQA specifies that device manufacturers should adhere to formal controls for planning the design effort, formal output of the design effort (for example, drawings), formal approval of the output, documented design changes, and simulated end-use testing. These design controls should also ensure that design requirements and design outputs are adequate for their intended use.[14]

One reason for FDA's new emphasis on QA in the preproduction stage of device manufacturing is the information it obtained from its analysis of medical device recalls from fiscal years 1983 through 1988.[15] GMP problems caused 47 percent of these recalls, while 44 percent were caused by design defects.[16] FDA concluded that most of the design-related problems could have been avoided had manufacturers implemented proper PQA practices. This suggests that the current GMP regulation, with its focus on manufacturing, although necessary, is not sufficient to ensure the production of safe and effective medical devices. Under current GMP requirements, a superior production QA process can, at best, ensure production of the medical devices as designed. However, if there is an inherent flaw in a device design and its component parts, the current GMP program can also ensure the production of a defective device.

The proposed requirements regarding suppliers involve documentation of a supplier's ability to provide high-quality components. In making this proposal, FDA asserts that each supplier should have demonstrated QA capability because quality cannot be inspected "into" components as they are delivered to manufacturers who finish the devices.

[13]U.S. Food and Drug Administration, Center for Devices and Radiological Health, Suggested Changes to the Medical Devices Good Manufacturing Practices Regulation: Information Document (Rockville, Md.: November 1990). FDA estimates that the revised GMP will be proposed in the Federal Register in early 1993 and a final rule issued 12 to 18 months later. At the earliest, new GMP requirements will not be in place before 1994.

[14]FDA, Center for Devices and Radiological Health, Division of Compliance Programs, Preproduction Quality Assurance Planning: Recommendations for Medical Device Manufacturers (Rockville, Md.: September 1989).

[15]FDA, Center for Devices and Radiological Health, Device Recalls: A Study of Quality Problems (Rockville, Md.: September 1989).

[16]The remainder were for miscellaneous causes such as failure to control radiation from sunlamps, misbranding, and other problems that could not be attributed to manufacturing or design problems.

The proposed review requirement is to have devices returned for servicing and repair reviewed and evaluated by a formally designated unit in accordance with written procedures.[17] Among other things, the evaluation should include a trend analysis of malfunctions, and when trends are detected, they should be treated as complaints and processed accordingly.

FDA's revision of the GMP regulation reflects dual concerns—increasing the safety and effectiveness of medical devices through a quality assurance approach and recognizing the increasing importance of regulatory development in the global market for devices. FDA has stated that the proposed changes in the GMP regulation would improve the quality of medical devices manufactured and distributed in the United States by ensuring that all manufacturers design and manufacture devices under a more comprehensive quality assurance system.

The revised GMP regulation is being developed in harmony with the growing international movement toward having a quality system and generally accepted international standards as the basis for medical device regulations.[18] According to an FDA official, the revised rule will, as much as possible, reflect the provisions of and use language and presentation format similar to the relevant international standard. Because the GMP regulation requires mandatory adherence by manufacturers, as opposed to the voluntary nature of international standards, some differences will remain. Where the wording is different between the GMP regulation and international standards, FDA proposes to add supplements to the rule. The supplements will be the parts of the current GMP that are not now in the relevant international standards.

FDA decided against a verbatim adoption of the existing international standards principally because of the changes being proposed for those international standards in 1996. A revision of the existing international standards for quality systems, scheduled to take effect in 2000, would be closer to a total quality management program standard. Many of the proposed additions would not be appropriate for a regulation. Moreover, there is now under way a movement to develop an international quality standard specific to medical devices. An FDA official believes that once the

[17]This new review requirement applies only to manufacturers of finished devices. Servicing done by hospitals and other providers, as well as by third parties, would remain unregulated.

[18]The quality system documents and guidance sponsored by the International Organization for Standards (ISO)—ISO 9000 series of quality system standards—have been adopted in 46 countries. A more detailed discussion of the applicability of the ISO 9000 series to medical devices is contained in the EEC section of this chapter.

revised U.S. GMP regulation is adopted it will be a good model for an international quality standard for medical devices.

Quality Assurance Requirements—Japan

In Japan, QA requirements for medical devices are contained in that nation's GMP regulation.[19] The Japanese GMP regulation is of relatively recent origin, having been made final in 1988, and it is very similar to the existing U.S. GMP regulation. The implementation of the regulation and compliance monitoring is decentralized. The responsibility for inspecting manufacturing facilities and certifying compliance is often delegated to local government authorities, with supervision and guidance from the central authority.

It has been reported that in an effort to harmonize QA systems around the world, the Japanese Ministry of Health and Welfare intends to modify the existing GMP regulation. One of the principal bases for changes in the regulation will be accepted international standards for QA systems.

Quality Assurance Requirements—Canada

Canada does not have a formal GMP regulation or other separate QA requirement. It relies principally on informal inspections of manufacturers' facilities to monitor QA.

Similarities and Differences Among Quality Assurance Requirements

The United States and Japan, with some notable differences, have similar QA requirements for medical devices. Both are focused primarily on the manufacturing process rather than on the complete life cycle of a device. Canada has no such requirements. The United States conducts its own GMP inspection of both domestic and foreign device factories.

The principal differences between the U.S. and Japanese QA requirements are in implementation and compliance monitoring. In the United States, GMP requirements are implemented and monitored by a central federal authority—FDA. Japanese GMP requirements for inspections and enforcement are largely delegated to local government authorities. According to an FDA official, this type of implementation may result in inconsistencies of application of the regulation and nontransferability of inspection results. The current Japanese medical device QA system has been characterized by FDA officials as being at the same state of development and implementation as the U.S. system was 14 years ago.

[19]See Japan Ministry of Health and Welfare, Pharmaceutical Affairs Bureau, Medical Devices Division, Guide to Medical Device Registration in Japan, 3rd ed. (Tokyo, Japan: Yakuji Nippo, Ltd., November 1990), for a more detailed discussion of the Japanese GMP program.

The United States, Japan, and Canada have each begun a process to modify their existing QA systems. Each has indicated that the basis of its modification will be international quality system standards and harmonization of device regulations.

Premarketing Regulation—EEC

European Economic Community—Device Classes

The EEC has established a three-tiered device classification scheme with the degree of regulatory control directly proportional to the perceived risk associated with a given product class. Further, the EEC's device classification system is overlaid with a criterion of how a particular device is used on or in the body.

Class I has the lowest level of requirements and covers products that present relatively little risk to patients. Classes IIa and IIb are the next regulatory level. Class IIa covers invasive and noninvasive products generally for short-term use; class IIb is for active products therapeutically delivering energy or substances at potentially hazardous levels. Class III represents the most stringent level of regulation and controls on products that are used to diagnose or monitor or come in contact with the circulatory or central nervous system. It also covers long-term implants that undergo chemical change in the body or those that are absorbed. This classification scheme results in the majority of devices being designated class I.

The EEC has adopted a system of directives as the principal method of regulatory control and for achieving harmonization across all sectors of the community. Three out of a total of 282 directives are specifically related to medical devices.[20] Each medical device directive specifies the "essential requirements" as the uniform conditions for placing on the market and using a specific type of device with the aim of protecting the health and safety of patients, users, and third parties. After the specific directives are adopted and the transition period is completed, only medical

[20]The proposed device directives are for (1) active implantable (for example, pacemakers), (2) any device not an active implantable or in-vitro diagnostic (for example, electromedical equipment such as apnea monitors), and (3) in-vitro diagnostics (for example, blood sugar testing kits).

devices that meet the essential requirements of the applicable directive and are marked with a "CE" insignia can be sold in the EEC.[21]

The essential requirements are the EEC version of U.S. and Japanese GMP (or QA) and safety requirements. They have the force of law and are intended to set out criteria that can be objectively assessed and that, if satisfied, will properly safeguard the public health. However, in contrast to the United States and Japan, the EEC's QA requirements are entwined with and specified for device design, manufacturing, and packaging throughout the essential requirements contained in each device directive rather than being segregated into separate documents. For example, the first part of the essential requirements includes (1) provisions for safe design and construction, (2) safety and performance provisions throughout the intended shelf life and in ordinary conditions of use, and (3) the risk-benefit concept. The second part of the essential requirements includes provisions concerning chemical, physical, and mechanical properties; sterilization; and labeling and instruction for use.

Standards

The essential requirements in each directive reference horizontal and vertical standards that are being issued by European standards bodies: the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC). The horizontal standards will govern activities common to a variety of industries such as sterilization processes, biocompatibility, electromagnetic compatibility, symbols, and electrical safety. The vertical standards will address the requirements related to given product families. One of the most pervasive horizontal standards adopted by the EEC is the International Standards Organization's ISO 9000 series quality documents for quality systems.[22]

The ISO series consists of five standards documents. ISO 9000, entitled "Quality Management and Quality Assurance Standards—Guidelines for Selection and Use," describes fundamental quality concepts and provides guidance on how the other standards in the series are to be used. ISO 9001, entitled "Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation, and Servicing," is the most

[21]EEC officials refer to EEC-92 as the concept of a single market rather than a deadline date. It is estimated that EEC-92 will be a long-term process with complete implementation and enforcement several years in the future. The medical device directive for active implantable devices was adopted in June 1990, with a transition period until January 1995. The remaining two directives are currently at various stages of development and, following adoption, will have a transition period that may reach 2000.

[22]Within the EEC, this series is identified as EN 29000-29004 and is a verbatim adoption of the ISO series.

comprehensive standard of the series and is particularly relevant for companies that design, manufacture, and service their products. ISO 9002, entitled "Quality Systems—Model for Quality Assurance in Production and Installation," addresses quality assurance programs in manufacturing and servicing processes—this scope of activities is similar to those addressed by the current U.S. GMP regulation. ISO 9003, entitled "Quality Systems—Model for Quality Assurance in Final Inspection and Test," is the least comprehensive standard in the series and is particularly relevant to distributors and other service organizations. ISO 9004, entitled "Quality Management and Quality System Elements—Guidelines," is a standard that provides quality management planning and guidance on implementation. Additionally, CEN is at work on an EEC quality system standard (EN 46001) specific to the different categories of medical devices. The vertical standards, sometimes referred to as product-specific standards, will be particularly useful in preventing deceptive practices and ensuring adequacy and consistency in the quality of specific products and product families.

According to the EEC's officials, the primary goal of the development and adoption of specific product standards under CEN and CENELEC is to harmonize the member states' existing technical regulations regarding product form and function, as well as their compatibility and interchangeability with other products. One of the primary objectives of these standards is to promote economy in human effort, materials, and energy in the production and exchange of goods throughout the EEC.

These standards will become the primary means by which medical device manufacturers demonstrate that their quality systems conform with the related portions of the essential requirements of the EEC medical device directives that will regulate medical devices in the latter part of the 1990's and beyond. For this reason, standards such as those in EN 29000 and the forthcoming EN 46000 series, while technically voluntary and developed in the private sector, are probably tantamount to mandatory requirements in Europe.

Routes to Market for Medical Devices—EEC

In general there are two main routes to obtaining clearance to sell medical devices in Europe—quality assurance systems certification and product-type examination. Certification is the process of obtaining approval from an organization that has been accredited to assess companies according to the ISO 9000 series and other relevant quality standards and receipt of the certificate of registration issued by the

assessing organization. After the initial certificate of registration is issued, most registrars typically also conduct two or three "surveillance visits" per year.

The objective of product-type examinations is to prove by visual checks and laboratory testing that the equipment complies with safety standards under test conditions. Examinations of medical devices include electrical and mechanical safety, functional safety of hardware and software, biochemical compatibility of disposable devices and implants, radiation and noise emissions, and electromagnetic compatibility.

Product-type testing may be more costly and time-consuming than quality systems registrations for companies that market more than a few products. A manufacturer, under this conformity assessment procedure, must submit each product-type for examination followed by production verification, production quality assurance, or product quality assurance.

Conformity Assessment

The European Commission's resolution entitled "The Global Approach to Conformity Assessment" covers what is known in the United States as the product approval process and embraces several fundamental concepts.[23] First, it is modular in design and includes alternative approaches for product approval by the conformity-assessment process. Second, products are assessed within the modules for conformity against European QA standards. Third, it establishes a European system for third-party testing and certification of conformity by a "notified body."[24] Fourth, it acknowledges that bilateral agreements between the EEC and non-European governments are essential to and must be negotiated to attain a proper functioning of the global approach.

The alternative conformity assessment modules range from simple self-certification of product quality to the establishment, operation, and certification of a total quality assurance system for device manufacturers.

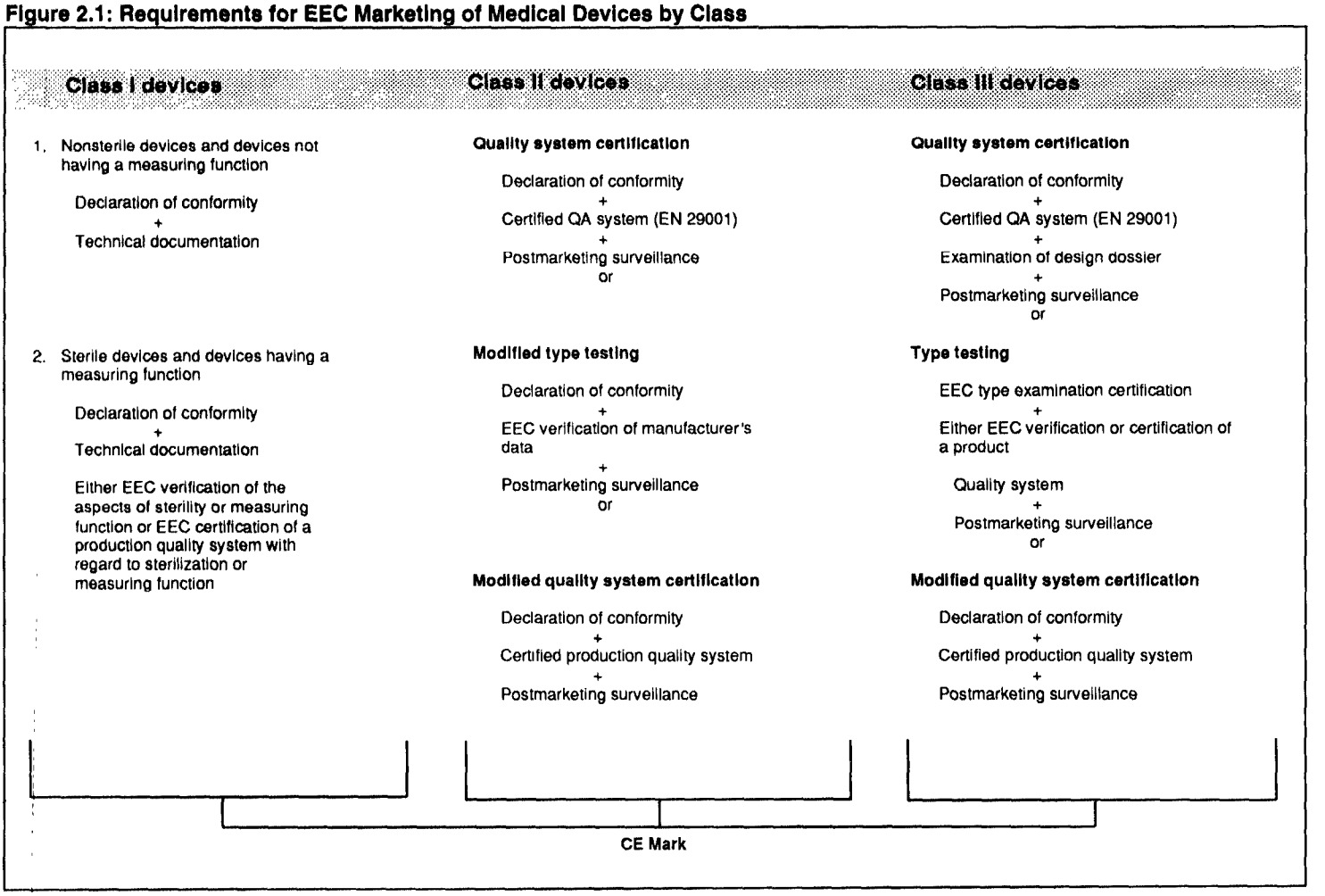
Figure 2.1 shows that manufacturers may combine the modules for assessment in various ways, depending on a device's classification, which

[23]The global approach covers all products, whether medical devices, toys, or plumbing equipment. See Commission of European Communities, A Global Approach to Certification and Testing: Quality Measures for Industrial Products (Brussels, Belgium: July 1989).

[24]Notified bodies are organizations and laboratories appointed by each member state that demonstrate that they have the organizational structure, technical capacity, and necessary processes to pass judgment that the essential requirements in the applicable directives have been met. At present, all notified bodies must be located within the EEC.

(as noted above) is based on the perceived risks associated with the device. The greater the potential risk involved with the product, the greater the requirements to ensure safety and third-party verification of compliance.

Figure 2.1: Requirements for EEC Marketing of Medical Devices by Class



Similarities and Differences Between EEC and U.S. Premarketing Regulations and QA Procedures

Device Classes

The regulatory requirements for the various classes of medical devices are very similar in the United States and the EEC. There are, however, critical differences in their basis for determining the appropriate classification. Devices are classified under the U.S. system primarily by what is thought to be needed to reasonably ensure safety and effectiveness; under the EEC system, they are classified by how devices are used in relation to the human body.

In many cases, a device would receive the same classification from both systems. However, FDA officials have said that the proposed EEC classification scheme could place a substantial number of existing devices in a lower class than they currently have under the U.S. system. The majority of all existing devices under the EEC criteria are assigned to class I. The majority of devices are now designated class II under the U.S. system.

There are no provisions for "substantial equivalence" type of route to market for devices within the EEC system as we noted are available in the United States, Japan, and Canada. This means that all manufacturers who wish to sell a product in the EEC, regardless of its class and current market status, must conform to the essential requirements established for that device. This requirement means that devices legally marketed through the U.S., Japanese, and Canadian "substantial equivalence" type of route to market will still be required to meet EEC regulations if they are to be sold in the EEC single market.

Quality Systems and GMPs

ISO 9000 will become the basis for the revision of the U.S. and Japanese GMP regulations and the development of a new one for Canada and the EEC. The most relevant comparison is between the anticipated changes in the GMP regulation and ISO 9001, "Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation, and Servicing."

The lack of design controls in the current U.S. GMP regulation represents an important difference from the ISO 9000 series standards. However, a provision of the Safe Medical Devices Act of 1990 (Public Law 101-629) mandates the addition of design controls to the forthcoming revision of the U.S. GMP regulation.

The GMP regulation and ISO 9001 also differ in controls governing subcontracting and servicing. ISO 9001 is generally more stringent in these areas. The only provision not contained in the revised U.S. GMP regulation will be contract review. FDA considers this outside its area of responsibility, because it involves the relationship between a firm and its customer. U.S. manufacturers may have to increase the level of documentation maintained about the product servicing component of their quality systems to meet the EEC's requirements.

According to FDA, in some areas, the current GMP regulation is more stringent than ISO 9001. The proposed additions to the U.S. GMP regulation will make these two quality systems more similar. One of the most important areas is complaint handling, which FDA views as an increasingly important part of postmarketing assurance of device safety and efficacy.

Inspections

Statutes in both the United States and the EEC have been interpreted by their respective officials as to what is an appropriate or allowable delegation of authority to inspect and approve QA procedures. According to the EEC directives, the member states may designate organizations as notified bodies with the authority to approve device manufacturers' quality systems and issue a CE mark, which will permit the product to be marketed. Although these notified bodies may subcontract a non-European company to inspect a manufacturer's quality system and perform product testing, the notified body itself must be located in the EEC and retain the final responsibility for the inspections and examinations.[25]

FDA officials have generally interpreted their mandate to protect the public from unsafe and ineffective devices as a responsibility that could not be delegated to others, including other national governments, individual state governments, and private-sector organizations.[26] The exceptions are cases in which reciprocity is established through a negotiated mutual

[25]Several U.S.-based companies are preparing to meet the criteria established by the EEC to be designated as a subcontractor for European notified bodies.

[26]FDA's Center for Devices and Radiological Health (CDRH) is considering contracting out some of its work as a way of dealing with the demands imposed by the 1990 device act. The work would entail analyzing summaries of safety and effectiveness that will be required of manufacturers of pre-1976 class III devices. However, CDRH is not considering contracting out product review functions.

recognition agreement. Therefore, FDA will not accept the findings of a foreign device inspection organization without the benefit of such an agreement. A similar situation exists with regard to the frequency of GMP inspections. U.S. statutes mandate that U.S. device manufacturers' facilities be subject to biennial GMP inspections, and EEC policies may require that manufacturers be inspected at least biannually.

International Harmonization of Medical Device Regulation

Ideally, international harmonization should result in a situation in which national regulations will be similar enough to allow the countries to accept one another's market approval and GMP inspections. Reciprocity would decrease the regulatory burden and expense on both government and industry in the cooperating nations. For example, it could mean that government resources that are presently allocated to conducting foreign GMP inspections and premarketing reviews and approvals could be reallocated to other responsibilities. It could also mean that device firms doing business across national borders would need to be inspected only by their own country's health agency staff or designated organization rather than by both countries, as is necessary now. In this section, we discuss some of the implications of the similarities and differences between the U.S. and EEC premarketing regulation and QA requirements for achieving harmonization.

Device Classes

The existing procedures for determining the appropriate class for a given device in the U.S. and EEC systems could lead to different classification and regulatory controls for the same device. This could mean, for example, that the same device could be designated as class I in the EEC system and as class II in the U.S. system. This device could then be approved for market in the EEC after meeting the requirements for class I devices rather than the more stringent requirements under both systems for class II devices. Such differences in classification would perpetuate the present situation in which market approval has to be obtained from each jurisdiction.

GMP and Quality Systems

The United States and the EEC are revising and developing their respective regulations for QA requirements associated with the manufacture of devices. The U.S. GMP and the EEC regulations will be very similar, although one is a regulation and one is a voluntary standard, as they will both be based on ISO 9001. In both systems, some regulatory requirements will be satisfied by good manufacturing practices and their additions, some by standards, and some by quality systems. Conformity to either set of these

requirements, although necessary, may not be sufficient to obtain market approval in both systems.

The difference between the revised GMP regulation and the standards will be in the supplements. According to FDA officials, these differences could be resolved in the guidance that the EEC is now developing for the application of the EEC quality system standard—EN 46001 to the different categories of medical devices. The proposed GMP revision will incorporate all of ISO 9001 and EN 46001. Therefore, any U.S. manufacturer who was in compliance with the revised GMP regulation would be in compliance with the EEC's QA requirements.

The principal task for both system developers is to ensure that the additions being added to the U.S. GMP regulation are included in the guidance being developed by the EEC and vice versa as the acceptable methods for producing devices. It will allow manufacturers to develop one quality system that would be acceptable in their primary markets.[27]

As with differential device classification among the countries, lack of agreement and compromise on the QA requirements, and on the frequency of QA inspections, means continued duplicate processes and inefficient use of resources for both systems. Additionally, differential premarketing regulations and QA requirements may exacerbate the trend toward regulatory shopping for offshore manufacturing and the concomitant loss of U.S. jobs.

Summary and Implications

The defining characteristic of the U.S. and Japanese premarketing regulatory structure is device classification and regulation in proportion to perceived risk associated with the device. The majority of devices in the United States, Japan, and Canada reach the market as substantially equivalent to previously marketed devices rather than following the more stringent approval process that requires empirical evidence of safety and effectiveness.

In the United States and Japan, QA requirements for devices are generally contained in their respective GMP regulations. These regulations are almost exclusively focused on the manufacturing process. Canada does not have a

[27]The United States currently has GMP reciprocity with the United Kingdom and on April 15, 1992, reached an agreement with Canada that calls for the two countries to adopt a common GMP, with similar requirements, although with possible differences in format. FDA has also been negotiating with Japan for several years in an effort to establish GMP reciprocity. Meanwhile, the Japanese health officials have announced their intention to adopt a version of the ISO 9000 quality documents.

similar device classification or GMP regulation; instead, it relies heavily on the regulations and procedures of exporting countries.

The EEC has a basis of regulatory controls similar to that of the United States and Japan—regulation in proportion to perceived risk associated with the device, with the added dimension of how a device is to be used on the human body. The EEC has proposed three directives for achieving harmonization of device regulations throughout the Community. The essential requirements in each directive specifies criteria to safeguard the public health. Internationally based harmonized standards will become the primary means by which manufacturers demonstrate that their quality systems conform with the directives and their products will be approved for marketing through a modular conformity-assessment process.

The revised U.S. GMP regulation, if adopted, will cover the entire life cycle of a device and prescribe the nature and contents of a required quality system. It is proposed to be similarly organized, use equivalent terminology, and be similar in scope to the quality system referenced in applicable EEC directives. However, a comparative analysis between the proposed GMP regulation requirements and the EN 29001/ISO 9001 standard shows that in several critical areas related to device safety and effectiveness such as managing complaint files, coverage in the standard is not sufficient for compliance with the revised U.S. GMP regulation.

Consistent with one of the underlying principles of the global approach—the need for bilateral agreements between nations—all countries in our study are increasing their regulations for health-care technology. Moreover, all systems are becoming more similar, which should help harmonization. However, all have a long way to go. The regulatory authorities in each nation we examined plan to implement a version of quality assurance systems and increase the role of vertical standards in the manufacture of devices.

Each of the representatives of the national health-care systems we talked with indicated that this is a period of unprecedented change in the international regulation of medical devices and opportunity for unprecedented cooperation and harmonization among nations. According to these officials, these changes should provide greater worldwide confidence in the safety and effectiveness of medical devices.

Although each nation has indicated an interest in pursuing mutual recognition agreements, our findings are that systematic structural

differences present some major barriers to overcome in certain areas. There remain several formidable obstacles to this harmonization, and comprehensive mutual recognition agreements could still be many years away.

U.S. Medical Devices Industry in the Global Market

Introduction

The rapidly changing national and international regulatory environment along with increasing competitiveness in world markets will have a profound effect upon U.S. medical device manufacturers. Recent statistics indicate that international markets are becoming increasingly important to the industry. Some factors accounting for this include increasing competition and slower growth in the domestic market along with an increasing rate of imported products. In 1980, U.S. consumption accounted for approximately 60 percent of the global market for devices and diagnostics. In 1992, the U.S. market as a percentage of the global market had actually dropped to approximately 44 percent. The U.S. medical device industry's level of preparedness for these changes may well determine their individual future success, as well as the future competitive position of the industry in the world market.

This chapter addresses the fourth evaluation question: What are the nature and extent of preparedness of the U.S. medical device industry for competing in a global market? We were interested in manufacturers' attitudes and perceptions about the status of the U.S. device industry and its products; their responses to the perceived status of their industry and products, including the role of quality assurance systems; and their assessments of selected incentives and nontariff barriers to participation in the global market. Chapter 4 focuses specifically on U.S. device manufacturers and the EEC.

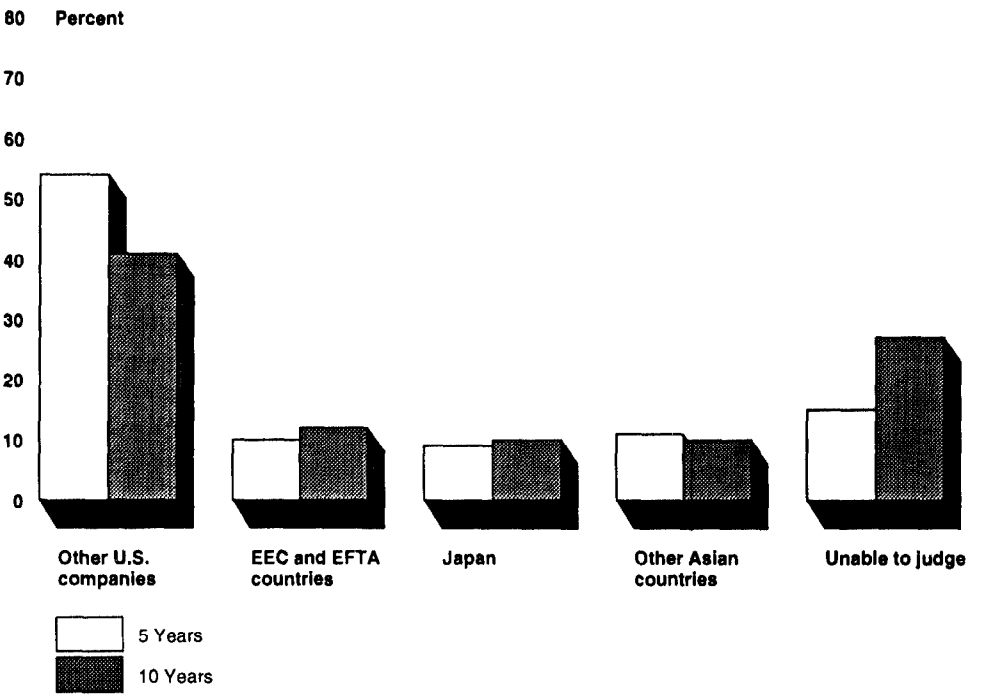
Industry and Products Status

International Competitors

We were interested in what our respondents perceived to be the short- and long-term competitive position of the U.S. device industry in the world market. When we asked them from whom their firms will receive the greatest competitive challenge within the next 5 years, the majority (54 percent) of all manufacturers said it would be coming from other U.S. device manufacturers. (See figure 3.1.) We found that, regardless of firm size or export status, the perception of the importance of the domestic market did not change. Thirty percent of the manufacturers were about evenly divided in their opinions that the EEC and EFTA, Japan, and other Asian countries would be the source of their greatest competitive challenge within 5 years. Not surprisingly, exporters were more likely to

see foreign manufacturers as potential challenges to their competitive position than were nonexporters.

Figure 3.1: Manufacturers' Rating of Their Greatest Competitive Challenge



Our respondents indicated that they thought the relative importance of their potential challengers would be the same in the long term—10 years. These findings are consistent with our findings that at least 80 percent of the industry's products are consumed in the domestic market and that slightly more than one third (38 percent) of the manufacturers were nonexporters.

Product Quality

We asked our industry respondents several questions related to how devices that are manufactured in the United States compare in quality and cost to devices manufactured in other countries. Slightly more than half (55 percent) of our respondents said that they could come to some general conclusion about how U.S. medical devices compare with similar foreign devices. Of those that responded, the majority (55 percent) said they

thought that U.S. products are of higher quality than foreign-made products, slightly more than one third (34 percent) said they are comparable, and only 9 percent said that U.S.-made products were of lower quality than similar foreign-made devices. We found that exporters were much more likely to believe that U.S. medical devices are of higher quality. (See table 3.1.)

Table 3.1: Manufacturers' Perceptions About the Quality of U.S. Medical Devices Compared With Similar Foreign Products

Rating	All manufacturers	Nonexporters	Exporters[a]
Higher quality	21%	14%	23%
Somewhat higher quality	34	15	42
Comparable quality	34	52	27
Somewhat lower quality	9	11	8
Don't know	2	8	0
Total	**100%**	**100%**	**100%**

[a]Association between nonexporters and exporters = chi square (4df) = 21.4; $p < .0003$. The probability value reported is an estimate of the likelihood of finding a chi-square value of this size or larger from a sample of this size when in fact there is no association in the population. In an interpretation of the size of the chi-square value, the probability stated gives a rough estimate of the chi-square value for a random sample.

We also asked U.S. manufacturers if they could identify any general trend in the quality of medical devices compared with their foreign competition; the majority (54 percent) said they could not. Among the manufacturers who did note a trend in the quality of U.S. devices, most said U.S. devices are gaining (43 percent) or at least maintaining (40 percent) their level of quality in comparison to their foreign competition. We found that small firms were almost twice as likely as medium or large firms to believe that U.S. firms are gaining on their foreign competition; medium and large firms were more than twice as likely as small firms to believe that the United States is maintaining the current status, as can be seen in table 3.2.

Table 3.2: Trend in the Quality of U.S. Medical Devices Compared With Foreign Products

Rating	Manufacturers	Small firms	Midsize firms	Large firms[a]
Gaining	43%	64%	38%	31%
Maintaining current status	40	18	41	57
Falling behind	13	12	18	6
Don't know	4	6	3	6
Total	**100%**	**100%**	**100%**	**100%**

[a]Association between firm size = chi square (6df) = 12.6; $p < .05$.

Thirteen percent of all respondents thought that the quality of U.S.-manufactured devices is falling behind that of foreign competitors. The manufacturers who were exporters were much more likely than nonexporters to express this belief.

The responses we obtained from firms of different size may be explained by the fact that it is the medium and large firms that are more likely to be involved in the export market and, probably therefore, most familiar with the quality of foreign-made products.

Product Cost

The last competitive product characteristic we inquired about was comparative pricing. When we asked our survey respondents how their products compare with foreign products with respect to price, their responses were almost equally distributed among the four choices: cost more, 22 percent; cost about the same, 22 percent; cost less, 28 percent. The relative distribution of the responses was the same when export status and the size of the company were included in the analysis. We found that 25 percent of the exporters said their devices cost more, while 28 percent said their devices are comparably priced, and almost one third (32 percent) said that their devices cost less. As for large firms, more than half said their prices are higher than prices of foreign devices, and only 6 percent said their prices are lower. And almost half (44 percent) of small firms did not know how their prices compared to similar foreign-made devices. (See table 3.3.)

Table 3.3: Price of Foreign Medical Devices Compared With Similar U.S. Products[a]

Pricing	Small firms	Midsize firms	Large firms
Foreign priced higher	21%	27%	6%
Comparably priced	17	21	31
Foreign priced lower	18	27	54
Don't know	44	25	9
Total	**100%**	**100%**	**100%**

[a]Chi square (6df) = 37.3; p < .000.

Manufacturers' Responses to Perceived Global Competitive Status

Quality and Cost of Products

We were interested in what, if any, actions the manufacturers who had indicated a concern about their competitive positions had undertaken or were planning to take. We found that the most frequent response of manufacturers who thought that the quality of foreign devices is increasing was to increase their investment in research and development for improving the quality of their current product or introducing the next generation of products. This was especially the case for exporters. Most manufacturers who thought their products are priced higher than or comparably with foreign-made products indicated that they are taking action to improve their competitive position. Some manufacturers reported that they are planning to move their manufacturing offshore in order to compete more favorably with foreign-made goods.

Quality Assurance Systems

"Quality" has moved to the forefront of corporate strategy in recent years as companies face increasing international competition for revenues and profits. The literature provides numerous examples of the successes and failures that have been associated with the "total quality" movement. Although the jury may still be out, the notions of service and product quality have begun to rise from the fad status of the 1980's to a strategic imperative of the 1990's for U.S. companies. In the medical devices industry, an overwhelming majority (84 percent of all manufacturers and 93 percent of exporters) believe that if a firm is recognized as a quality leader, it will hold a favorable market position in terms of competition.

We asked our survey respondents what the level of their firms' activity was in relation to the adoption of a quality improvement program as a strategic business activity. Table 3.4 shows our results. Overall, we found that 50 percent of firms have put a quality program in place (57 percent of exporters and 37 percent of nonexporters) and that quality program implementation cuts across all sizes of firms, with 39 percent of small, 49 percent of medium, and 72 percent of large firms having instituted such a program.

Table 3.4: Company Action in Relation to Implementation of a Quality Assurance System

Level of activity	All manufacturers	Nonexporters	Exporters[a]
No interest in quality improvement as a business strategy	10%	18%	5%
Recently acquired knowledge, no action taken	34	35	34
Acquired knowledge, too costly to implement	5	10	2
Program in place, no results yet	11	13	10
Program in place, encouraged with results	38	24	47
Program in place, discouraged with results	1	0	2
Total[b]	**99%**	**100%**	**100%**

[a]Association between nonexporters and exporters = chi square (5df) = 26.6; $p < .001$.

[b]Do not total 100 percent because of rounding.

Although manufacturers recognize the importance of adopting international quality standards to compete for business abroad and in the domestic market, adherence can be costly and time-consuming. Estimates for a small company to conform to these standards range from $2,000 to $25,000 and above. Moreover, compliance requires other expenditures, such as employee training costs as well as those associated with periodic surveillance visits and complete reviews by the quality registrar.

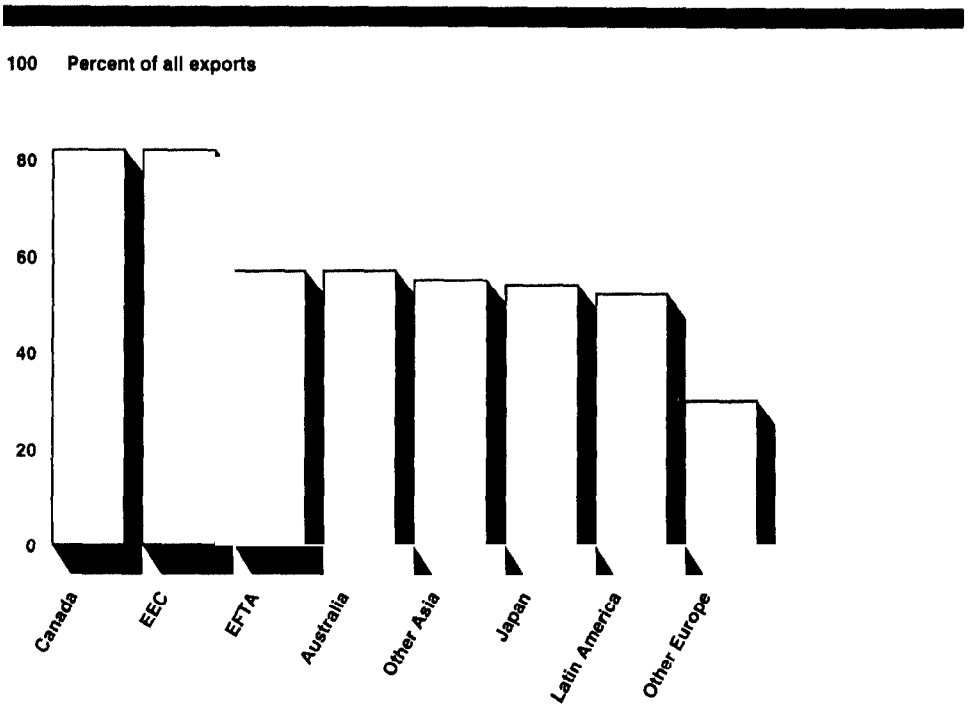
As in the wider global market, a clear determination of the cost-benefit ratios for the medical device companies that have implemented a quality program may be premature. However, the early results look promising. Of all firms that have implemented a quality program, three fourths (75 percent) said they were encouraged with the results, and an even larger proportion (79 percent) of exporters indicated that they too were encouraged with the results. Slightly more than 10 percent of the companies said that they had not seen any results yet, and only 1 percent were discouraged with the results.

Incentives for Exporting

The majority (62 percent) of the firms responding to our survey participated in the export market for medical devices. They exported all classes of devices to destinations in virtually every country in the world. (See figure 3.2.) About 82 percent of our respondents exported their

products to Canada while the same percentage exported to the EEC, and more than half (57 percent) exported to one or more of the EFTA nations.

Figure 3.2: Destination for U.S. Medical Device Exports



When we asked the exporters why they decided to export their products, the most frequent answer (85 percent) was to gain a wider market, followed by a more favorable regulatory environment (20 percent), slower growth for their products in the domestic market (17 percent), and fewer bureaucratic barriers (16 percent). No other reason accounted for more than 13 percent of the responses.

It seems clear that specific factors influence manufacturers to export their products, including the desire to increase market share and to minimize the effect of regulatory controls. What are the factors that manufacturers believe facilitate the export of medical devices? To find out, we asked all manufacturers about nine factors that might be thought to make participating in the export market easier. We asked them to rate these factors on a five-point scale ranging from very great importance to little or no importance. The factors likely to facilitate exports that were rated as

having great and very great importance are shown in table 3.5. Of most significance to our survey respondents were information of various kinds and tax credits.

Table 3.5: Factors Rated as "Great or Very Great Importance" for Facilitating Exports of Medical Devices

Factor	Great or very great importance	Number of respondents
a. Information on export markets	61%	166
b. Information on foreign agents or distributors	53	144
c. Tax credits or other tax incentives	58	156
d. Federal grants for exporters	45	122
e. Greater coordination among government agencies for information regarding export requirements	52	142
f. Strategies for exporting (seminar, etc.)	32	86
g. Greater government cooperation and coordination with the private sector on exporting information	48	130
h. National testing and certification program for devices	28	76
i. Government registration of quality systems	19	52

Information

The majority of respondents tended to rate as of great or of very great importance all the factors that we presented that were associated with access and availability of various kinds of export-related information. The factors that elicited the highest level of these responses were information on markets for medical devices, 61 percent; tax credits or other tax incentives, 58 percent; information about foreign agents and distributors, 53 percent; and greater coordination among government agencies for information regarding export requirements, 52 percent. We found the value of export market information to be similarly high across all sizes of firms.

Some of our respondents took advantage of the opportunity to elaborate on their opinions about how important they thought export-related information was to them. For example, one manufacturer said, "the small manufacturer needs knowledge and understanding more than anything . . . training materials, step-by-step procedures, instructions on how to export, a number to call for free counsel when a question arises, all would help the small manufacturer in making the commitment to export." A second manufacturer said, "we need one government source to obtain information; now we get different information, depending on the source."

Another wrote, "with limited personnel and resources, it is difficult to wade through extensive regulations and to find the right person or agency to deal with."

This finding was not consistent with much of the other data we collected. Generally, we found that there was a great deal of export information and assistance available from government sources. And the government agency that is most closely associated with the medical device industry, FDA, does provide a central source of information and referral for manufacturers.

FDA's Division of Small Manufacturers Assistance (DSMA) is a principal contact point for device manufacturers seeking information about participation in the global market. DSMA was initiated after congressional recognition of the unique vulnerability of small device manufacturing firms to regulatory action. The 1976 Medical Device Amendments mandated the establishment of an office to provide technical assistance and other nonfinancial assistance to small manufacturers. The primary responsibility of DSMA is to respond to telephone and written inquiries. DSMA generally provides informal and individualized assistance. Its operating policy is to respond within 72 hours of any request. The DSMA staff characterized their work as advisory, providing quick responses to questions that might take weeks or months if a formal response were expected from either FDA's regulatory staff or a company lawyer. DSMA staff frequently contact FDA's Office of Compliance and Surveillance and the Office of Device Evaluation, as well as the other U.S. agencies for manufacturers who seem unable to obtain the information they need.

Among its other activities, DSMA is primarily responsible for the contents and publication of FDA's Export Manual and the distribution of export information packages to those who are interested.[1] DSMA's plans include the establishment of a centralized export information library for the industry, to include technical and standards-related information for manufacturers from other government and private sector sources. However, DSMA representatives report that resource constraints have forced them to curtail some activities and delay implementation of others.

A principal source of information for device manufacturers is trade and professional organizations. Nevertheless, we found that more than half (60 percent) do not belong to any organization; only 47 percent of

[1]U.S. Department of Health and Human Services, Export of Medical Devices: A Workshop Manual (Rockville, Md.: August 1990).

exporters and 30 percent of nonexporters hold memberships in such organizations. Large companies are almost five times more likely to belong to an organization than a small company; medium companies, two times more likely.

Our interpretation of the data does not support manufacturers' contention that there is an absence of export information and assistance. However, it may be that those who are most in need and might derive the greatest benefit—small manufacturers—may not be aware of how and where to obtain the available information and assistance. Additionally, the uncharted mass of information and the resources necessary to navigate that mass may be prohibitive.

Tax-Related Incentives

The relatively high ranking given to tax credits or other tax incentives appeared to be particularly important for medium and large exporting firms. One of our respondents said, "I believe if the government can provide tax credit or incentives for exporting it would be doing the most effective thing to encourage exporting." Another said, "I would like to see investment tax credits reinstated for American-made production equipment. This would help expand our manufacturing base and capacity while increasing gross national product and domestic employment." Statements like these were supported by others.

Government and Industry Cooperation

The general sentiments our respondents expressed about the factors of government-industry cooperation and coordination were for a more supportive, less adversarial relationship with government in general and FDA specifically. We noted that their comments compared what they perceive as the supportive and facilitating government activities in other countries with what they believe is their relationship with the U.S. agencies. The tenor of these comments seemed to be exemplified in the statement of one of the respondents: "We need a positive attitude from government, not control and more requirements. The government must become a partner, not an adversary. Help us improve our quality and procedures so that we can compete better." Another small manufacturer expressed similar concerns in the following statement:

"FDA's export approval time is too burdensome, slow, and often includes vague requests for information. Many manufacturers, including all of our company's U.S. competitors, have established manufacturing facilities outside the United States, primarily in Canada, for the sole purpose of avoiding many FDA requirements for exportation of medical devices."

The Congress and device industry association representatives have expressed some serious concerns about the increasing average FDA review time for premarketing review and approval applications. A Health Industry Manufacturers Association (HIMA) executive stated that

"It takes less time to gain approval of new devices in other countries—sometimes years less—than in the U.S. In most cases, a firm decides to move (off-shore) because officials feel they cannot afford to wait for FDA approval before starting to get a return on investment in a new device product."

FDA officials said that the quality of premarketing reviews takes priority over speed. Specifically, it would be difficult to achieve a speed-up of device approval while ensuring the quality of scientific review the U.S. public wants. And, in the case of applications based on "substantial equivalence" to marketed devices, they are getting more and more complicated and less resemble those devices they claim equivalence with, further complicating the process and delaying final agency decisions. Additionally, FDA officials cite the escalating demands on the agency's resources required by recent legislation and specific public health crises such as the silicon breast implant review, as contributing to decreased production in device reviews and approvals.

National Testing and Certification and QA System Registration

National testing and certification programs and government registration of quality systems were the factors that manufacturers indicated as the least important for facilitating the export of medical devices. They did not influence manufacturers' ranking of the factors, whether or not they were exporters. Exporters and nonexporters ranked the incentives in approximately the same order.

These findings suggest that while manufacturers do want increased government assistance and support—ranging from information, through tax credits, to federal grants—they do not want increased government monitoring of their activities such as would be involved in national testing and certification, registration of quality systems, and other regulatory requirements. Indeed, they may be willing to locate facilities and jobs offshore to avoid them.

Nontariff Barriers

Nontariff barriers to international trade generally refer to practices, excluding a variety of tax-related factors, that inhibit the free flow of goods and services across national borders and that may result in

restricted market access and an unfair trade advantage for one or more of the trading partners. Our review of the literature and discussions with knowledgeable persons in the field pointed to four specific nontariff barriers that may be particularly important to medical device manufacturers: (1) public procurement policies, (2) rules of origin, (3) intellectual property rights, and (4) product liability.[2] All these have historically been governed by the principles of the General Agreement on Tariffs and Trade (GATT).[3]

We asked our respondents who were exporters how important these nontariff barriers were to them. We asked them to rate all the barriers on a five-point scale ranging from very great importance to little or no importance. The proportions of respondents who rated each barrier as being of great importance and very great importance are shown in table 3.6.

Table 3.6: Exporters' Rating on Importance of Nontariff Barriers

Issue	Great or very great importance	Number of respondents
Public procurement policies	30%	50
Rules of origin	33	54
Intellectual property rights	37	62
Product liability	53	89

Product liability was the most frequently selected nontariff barrier (53 percent) as being of great or very great importance. Nearly 40 percent of our respondents said that intellectual property rights were of highest importance to them as exporters; 32 percent, rules of origin; and 30 percent, public procurement policies. The size of the firm did not affect this ranking.

Summary and Implications

Generally, U.S. device manufacturers are focused on the domestic market. Although this is the market for the majority of their products, a substantial proportion of U.S. device manufacturers also export their products and

[2]See entries for public procurement, rules of origin, intellectual property rights, and product liability in the glossary. These nontariff barriers are discussed with specific reference to the EEC single market in chapter 4 of this report.

[3]The basic principles that underlie GATT are (1) the most-favored-nation concept, which states that the contracting parties will conduct their commercial relations with each other on the basis of nondiscrimination; (2) national treatment, which provides that imported products should receive the same treatment as domestically produced products with respect to internal taxation and regulation; and (3) the concept that any protection of domestic industries should cause the least distortion to trade possible and the belief that tariffs are the preferred form of protection. Both the United States and the EEC are signatories of GATT.

will be affected by the globalization of the medical device market. Yet, a substantial proportion of manufacturers were unable to address several critical issues (such as where the greatest competitive challenge will arise in the coming years, how U.S. devices compare with foreign-made devices, and trends in the comparative quality of U.S.-made devices).

The importance for U.S. medical device manufacturers of developing a more global perspective is underscored in the market statistics compiled by HIMA. HIMA statistics show that although the U.S. market represented around 60 percent of the world market in the 1980's, it accounts for only 44 percent today. While the U.S. market is nearly twice as large as that of the EEC, the EEC market tops the list as the world's most attractive market. This view is based on the existence in the EEC of solid market growth trends, an open climate for business opportunities, relatively strong per capita consumption growth prospects, and a move toward regulatory harmonization. The future competitiveness of companies in the industry will depend on their ability to position themselves in rapidly expanding non-U.S. markets.

Manufacturers indicated that the kinds of things that would make it easier for them to become more involved in the global market were various forms of government assistance, such as providing information, implementing tax credits, and representing their interests in international trade negotiations, rather than increasing regulatory oversight.

Partially in response to what some manufacturers view as a burdensome and adversarial regulatory system, a number of U.S. device companies are shifting operations overseas, driven by an interest in getting products on the market more rapidly and inexpensively. FDA's product approval slowdown in 1991 and 1992 is cited as a factor that has accelerated the shift greatly. These moves offshore generally mean the export of production jobs as well as key personnel—regulatory, management, engineering, and research and development.

The overwhelming majority (84 percent) of U.S. device manufacturers believe that if a company is recognized as a quality leader, it will hold a favorable position as a market leader. In response to this market imperative, most manufacturers support the development and adoption of international standards. The costs associated with adherence to these standards may partially explain why small firms (the majority of U.S. medical device manufacturers) lag behind medium and large size companies in their implementation.

U.S. Medical Device Manufacturers and the EEC

Introduction

The EEC should clearly be important in U.S. thinking about the future shape and contents of the global medical devices market because of the large quantity of its imports from the United States, its single-market regulatory requirements, its emphasis on quality assurances, and the international competition it invites. It is a major player in world and U.S. markets for medical devices, consuming approximately 20 percent of the world production of devices and 41 percent of the medical devices exported by U.S. manufacturers in 1992. The EEC is the second largest medical device market in the world, but in terms of per capita consumption, it is the third largest.

This chapter addresses the fifth evaluation question: How have U.S. device manufacturers responded to the EEC single market? We asked all our survey respondents about their attitudes and perceptions about the development of the EEC system. Specifically, we asked them if they were interested in the developments that were taking place in the EEC, what they believed would be the effect of the EEC and the CE mark on their market share, and the effect of the EEC's technical requirements on device quality and worldwide standards. Device manufacturers who are already producing and selling products in Europe will be the first to be affected by the completion of the single market. Therefore, to that proportion of our sample that were currently participating in the European market, we also directed a series of questions about the nature and scope of activities they had undertaken in response to the developing EEC system.

These survey results and our analysis are presented in the sections that follow. This chapter also includes our analysis and interpretation of concerns the U.S. device manufacturers and government agencies have about nontariff barriers and how they relate specifically to the EEC.

Interest in EEC Developments

When we asked the U.S. medical device manufacturers how interested they were in information on the EEC's proposals for the single-market plan for medical devices, less than half (46 percent) indicated that they were very interested or had a great interest. (See table 4.1.) However, the proportion of exporting manufacturers that responded in this category (66 percent) was significantly larger. These manufacturers said that they either seek general information on topics that are related to market issues or make a concerted effort to obtain detailed information on the same issues. However, a considerable proportion of manufacturers overall (36 percent) said that they only occasionally seek information related to market issues or had no interest in EEC developments.

Table 4.1: Manufacturers' Interest in EEC Information

Rating	All manufacturers	Nonexporters	Exporters[a]
Little or some interest in EEC developments	36%	74%	12%
Moderate interest: generally seek information on topics directly related to market issues	18	11	22
Great interest: seek information on all or nearly all topics directly or indirectly related to market issues	46	15	66
Total	**100%**	**100%**	**100%**

[a]Association between nonexporters and exporters = chi square (2df) = 110.9; p < .000.

These findings seem to contradict the manufacturers' responses to our question about what factors they thought would make exporting easier. Four out of five of the top factors they named were related to the availability of various types of export-related information. To try to explain this apparent discrepancy, we examined the relationship between manufacturers and interest in EEC market information, controlling for the size of the company and exporter status. We found that the medium and large firms that export their products are the firms that are actively seeking market information and are interested in EEC developments. This seems to suggest that the small U.S. device manufacturers are concentrating on the domestic market, to the exclusion of the market potential inherent in the EEC.

Market Share

We asked our respondents how much of a challenge they believed EEC-produced devices would present to their market shares domestically, in the EEC, and globally. Fifty-three percent of all manufacturers thought that medical devices that will be produced in the EEC will be a great challenge to them within the EEC itself, and 30 percent thought that European-made products would be a great challenge to them in the global marketplace. However, only 15 percent saw them as a challenge in the U.S. market. Exporters and nonexporters did not differ in their predictions of the level of the challenge that European medical devices will pose for U.S. manufacturers. (See table 4.2.)

Table 4.2: Manufacturers' Estimation of EEC Medical Devices as a Challenge to U.S. Market Shares

Challenge	In the U.S. domestic market	In the EEC market	In the global market
Little or some extent	42%	12%	16%
Moderate extent	26	14	31
Great or very great extent	15	53	30
No basis to judge	18	21	23
Total[a]	**101%**	**100%**	**100%**

[a]Do not total 100 percent because of rounding.

These findings may be interpreted to mean that U.S. device manufacturers believe themselves to be secure in the domestic market, believing that if they are challenged by foreign manufacturers, that challenge is most likely to be in the international and especially the EEC market. However, there may be objective reasons to be less sanguine than our respondents appear to be with regard to the domestic market. As already noted, the slower growth for products in the U.S. market along with increasing imports, such as the $27 million medical device trade deficit with Germany in 1991, will increase domestic competition. The decreased U.S. consumption of 60 percent of the global market for devices and diagnostics in 1980 to 44 percent in 1992 cannot be wholly accounted for by growing foreign markets. The lessons learned in other industrial sectors—for example, consumer electronics and automobiles—show that the United States can lose its preeminence to foreign competitors.

Quality Marks

The CE mark will be used to identify all products that have met the applicable EEC regulation and have been approved for marketing throughout the EEC and affiliated nations. The mark may be interpreted by some consumers as an official, and perhaps an international, designation of a high-quality product. Marked products may also be considered qualitatively different from products that do not display a similar "quality mark" and therefore may be preferred by consumers.

We asked U.S. device manufacturers how they thought their customers would interpret such a mark. Half of all manufacturers and 58 percent of exporters believed their customers will be more likely to buy a product with an approval mark or seal from a testing agency or authorizing body. However, only one third of all manufacturers and 39 percent of the

exporters thought that their customers would be willing to pay a higher price for the product with the mark. (See table 4.3.)

Table 4.3: Effect of a Medical Device With an Approved Mark or Seal

Customers will be more apt to buy a product with an approved mark or seal	All manufacturers	Nonexporters	Exporters[a]
Yes	51%	40%	58%
Uncertain	33	43	26
No	17	17	16
Total[b]	**101%**	**100%**	**100%**

[a]Association between nonexporters and exporters = chi square (2df) = 9.8; $p < .01$.

[b]Do not total 100 percent because of rounding.

When we include the size of the firm in our analysis, the results are more diverse. Over three fourths (77 percent) of the large firms thought their customers would be more likely to buy a product with a mark or seal, although only 58 percent thought customers would be willing to pay more for it. Medium-sized firms reported 51 percent and 27 percent, respectively. Small firms indicated that 35 percent would buy the marked product and 30 percent would be willing to pay more for it.

These responses suggest that most device manufacturers think that if a customer has a choice between two comparably priced devices, one with a mark or seal and one without, the customer will purchase the device bearing the approval. However, a significant proportion (33 percent) of all manufacturers were uncertain of the effect of a mark or seal.

Technical Standards

The harmonized standards to be adopted by the EEC will give technical expression to the essential requirements that manufacturers must meet to market a device within the European community. The EEC's position is that these technical standards will facilitate the free flow of goods and services throughout the EEC and provide buyers with reliable measures of quality and product standardization.

We asked our respondents what their perceptions were with respect to the effect of the EEC's use of technical standards within its device regulatory system. Almost half (48 percent) of all manufacturers said that the EEC's technical requirements will ensure products of better quality. However, when added together, a larger proportion of them said that either they

were uncertain (20 percent) or had no basis to judge (23 percent) whether the EEC's technical requirements will result in greater assurances of product quality. These data are shown in table 4.4.

Table 4.4: Effect of European Harmonized Technical Standards on Product Quality

European standards as greater assurance of quality	All manufacturers	Nonexporters	Exporters
Yes	48%	46%	49%
Uncertain	25	37	20
No	27	17	31
Total	**100%**	**100%**	**100%**

These responses were somewhat consistent with manufacturers' responses regarding whether they thought their customers would be willing to pay more for a certification-of-quality mark. That is, slightly over one third (37 percent) of them believed that the EEC's technical requirements will result in better-quality devices, and about a third of the manufacturers believed that their customers would be willing to pay more for a device that conforms to those requirements.

In spite of a majority of manufacturers' either being unsure or thinking that the EEC's technical requirements would not ensure greater product quality, more than half (54 percent) of them said that these requirements will influence global standards. Slightly more than a third (36 percent) of the manufacturers said that they were unsure of or had no basis to judge the influence of the requirements on global standards.

Our data show that nonexporters and small firms were less engaged in the EEC's developments and their potential effect on the medical devices market. Nonexporters are less certain than exporters; 59 percent said they were not sure if technical requirements ensure better quality, and 55 percent said they did not know if global standards will be affected. This is compared to 32 percent and 25 percent, respectively, for exporters. The size of the firm also had a significant influence on whether a better-quality product was believed to be a certain outcome of technical requirements. Specifically, 29 percent of large firms, 39 percent of medium firms, and 56 percent of small firms could not determine if quality would be improved. (See tables 4.5 and 4.6.)

Table 4.5: Influence of European Harmonized Technical Standards by Export Status

European technical standards for medical devices will affect worldwide standards	All manufacturers	Nonexporters	Exporters[a]
Yes	54%	40%	62%
Uncertain	22	31	17
No	10	6	12
No basis to judge	14	24	8
Total[b]	**100%**	**101%**	**99%**

[a]Association between nonexporters and exporters = chi square (3df) = 25.2; $p < .000$.

[b]Do not total 100 percent because of rounding.

Table 4.6: Influence of European Harmonized Technical Standards by Firm Size[a]

European technical standards for medical devices will affect worldwide standards	Small firms	Midsized firms	Large firms
Yes	40%	57%	68%
Uncertain	30	19	16
No	10	11	7
No basis to judge	21	13	9
Total[b]	**101%**	**100%**	**100%**

[a]Chi square (6df) = 13.2; $p < .04$

[b]Do not total 100 percent because of rounding.

We asked our respondents whether they thought the United States should have medical device standards that coincide with international standards. Almost two thirds (64 percent) of device manufacturers thought the United States should harmonize domestic standards with international standards. This was especially true for exporters and large and medium-sized firms, with approximately three fourths of each of those categories favoring harmonization. Forty-four percent of nonexporters and 48 percent of small firms favored harmonizing standards as well.

Typical of the comments we received were "We need to have international standards by which all products can be universally accepted" and "It is very important to have an identical product regulatory system for the United States and the EEC countries. This will enable us to produce higher quality and more cost effective devices." Another manufacturer told us that "currently a manufacturer can't make one product for world-wide distribution. The process of meeting the requirements for a variety of

countries is much more complex and costly than simply manufacturing to the most stringent standard." (See table 4.7.)

Table 4.7: Manufacturers' Opinion Regarding Harmonization of Medical Device Standards

Domestic standards should be harmonized to coincide with international standards	All manufacturers	Nonexporters	Exporters[a]
Yes	64%	44%	76%
Uncertain	25	41	14
No	12	15	10
Total[b]	**101%**	**100%**	**100%**

[a]Association between nonexporters and exporters = chi square (2df) = 31.6; p = < .000.

[b]Do not total 100 percent because of rounding.

One small manufacturer said:

"One major obstacle to exporting for a small company is the expense of acquiring the necessary agency approvals for marketing a product in different countries. Acquiring any agency approval can easily run $10,000. The manufacturer often simply has to decide if the expense should be made for the domestic market. Since the European market is generally of greater risk, the investment is typically placed in the domestic market. If EC 92 standards were accepted in the U.S. marketplace then at least medical products designed to these standards for domestic sale would at least qualify for exporting."

Our data generally show that it is the medium and large exporting firms that are most interested in the EEC's regulatory developments and their potential market effect. The small, nonexporting firms, which make up a significant proportion of the U.S. device industry, see the EEC as only a potential challenge in the export market. And although a majority of firms are uncertain or could not decide whether the EEC's requirements will ensure greater product quality, the majority of them do believe that they will influence global standards and that the U.S. industry should make an effort to harmonize its standards with international standards.

U.S. Device Manufacturers in Europe

We were particularly interested in the kind of adjustments that the manufacturers that were currently producing in (18 percent) or exporting to (82 percent) the EEC have made or plan to make as a result of the developing EEC single market.

Business Activities

We asked a subsection of our respondents how they thought the single-market regulation would affect their businesses.[1] Almost half (45 percent) of them said that the new European regulations will make no appreciable difference in their business activities. The majority of manufacturers were about evenly divided in their thinking about the potential effect of the single market on their exporting to the EEC. Slightly more than one quarter (27 percent) of them thought that exporting to the EEC would be easier, while the new market requirements will make exporting more difficult for the remaining 28 percent.

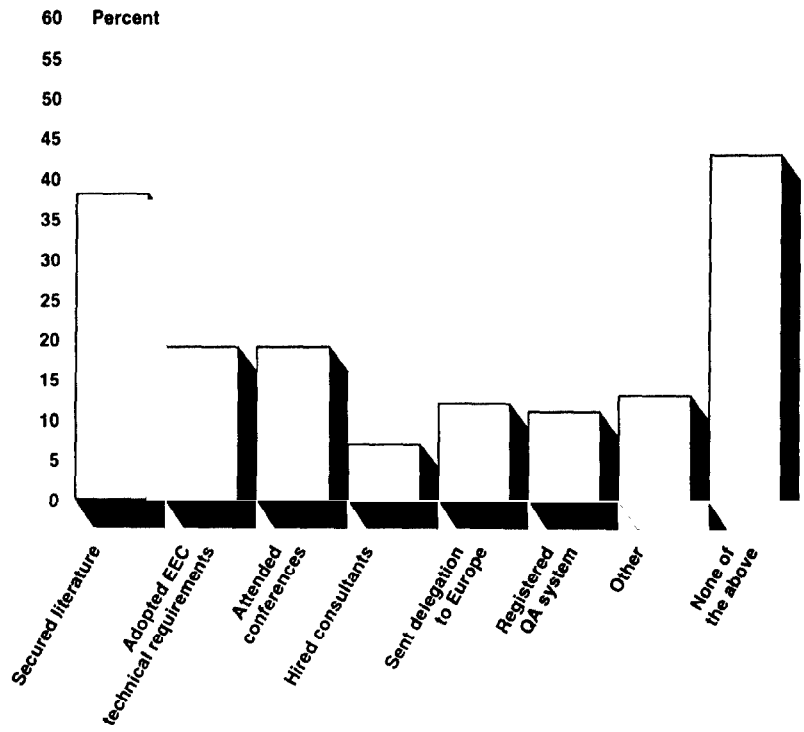
Additionally, in a measure of self-assessment, we asked the respondents how they would rate their own company's preparations for the requirements for marketing in the EEC. The majority (63 percent) of the manufacturers described themselves as fairly or moderately well prepared, and 10 percent said they were well or extremely well prepared. However, over one quarter (27 percent) indicated that they thought their companies were poorly prepared.

Actions Planned or Implemented

The logic of our expectations was that exporters' actions would reflect their perceptions of the effects of the single market on their ability to continue to do business in Europe after the single-market regulations become law and their self-assessment of their preparedness. To find out, we asked exporters about the actions they had taken over the previous 12 months. We asked them to identify which of eight specific actions their firms had taken in preparation for the new EEC single market. These data are shown in figure 4.1.

[1]Of the firms that currently produce devices in Europe, 72 percent are large firms and the remaining 28 percent are medium-sized firms; no small firms produce devices in Europe. Of the firms in our sample that currently export to the EEC, 94 percent plan to continue exporting after the single market has been established.

Figure 4.1: Exporters' Preparations in the Past 12 Months



The most frequently reported action (43 percent) was "none of the above." Thirty-eight percent said that they had secured literature on the EEC's single market. However, less than 20 percent of the manufacturers indicated that they had taken any type of action that might be considered "proactive," such as modifying their business plans to meet the technical requirements of the EEC or sending a delegation to Europe to explore business opportunities.

When we asked the manufacturers about action and plans for producing and distributing devices in Europe, a different picture emerged. Sixty-eight percent of the manufacturers who currently produce devices in Europe said they had expanded European production within the last 2 years; and of the manufacturers who had not already done so, the majority said they plan to within the next 2 years. Our data suggest that the growth of U.S. production of devices in Europe will occur through the expansion of U.S. companies. Only 11 percent of European-based, U.S.-owned companies

have merged, acquired, or formed a joint venture with a European partner, and only 19 percent report that they will probably do so within the next 2 years. (See table 4.8.)

Table 4.8: Exporters' Actions and Plans for Marketing in the EEC Single Market

Preparation	Yes: within past 2 years	Yes: within the next 2 years
Expanded production in Europe	68%	65%
Expanded or changed distribution of products	60	34
Merged, acquired, or formed a joint venture with a European partner	11	19

Similarly, the majority (60 percent) of manufacturers who distribute devices in Europe had expanded or changed those distribution arrangements within the past 2 years. Of the manufacturers who had not, about one third (34 percent) said they would change their distribution arrangements within the next 2 years, and 20 percent were undecided.

Additionally, the findings from another recent survey of industry opinions about competitiveness issues indicates that some manufacturers' preparation for the EEC are the same as we found for their preparation for the wider global market—offshore manufacturing.[2] About 16 percent of the respondents reported that their company had moved production facilities out of the United States for competitive reasons. Places mentioned included England, Italy, Mexico, and Puerto Rico. Easier access to the EEC, lower taxes, "more control over the bottom line," and getting devices to the market more rapidly were mentioned as advantages of the move. One respondent reported that his firm could market products 4 to 6 years faster in the EEC than in the United States.

Our analysis and interpretation of the available data reveal a somewhat more diverse picture of the activities and preparedness of the manufacturers who are currently involved in doing business in Europe than the self-assessments would suggest. On one hand, it appears that manufacturers have largely been passive actors or mere observers in the regulatory revolution that is taking place in Europe. On the other hand, manufacturers have been quite active in planning for new or changed production and distribution arrangements for the new Europe.

It is important to note that in our survey and elsewhere, some manufacturers have consistently pointed to FDA's regulatory processes as

[2]Washington Business Information, Inc., "FDA Approval Process Seen Hurting Competitiveness," Devices and Diagnostic Letter (Arlington, Va.: April 24, 1992), p. 5.

one of the most serious threats to their competitiveness. The approval processes and the device tracking provision of the Safe Medical Devices Act of 1990 are cited most often. The trend of moving facilities offshore may be a response to competitive challenges but it may also be viewed as "regulatory shopping." These types of responses to competition and the global market may serve as temporary solutions but they may also act as barriers to international harmonization and may have a greater cost for all stakeholders in the long run. As international device regulatory requirements become more alike, there will be fewer opportunities for manufacturers to engage in regulatory shopping. A more efficient strategy may be to be proactive, make the required adjustments in their policies and processes, and get ahead of their competition for the new regulatory era.

One proactive measure is contained in the provisions of the Regulatory Flexibility Act of 1980 (Public Law 96-354) that requires federal agencies, upon determination that their regulations will have a significant economic effect on a substantial number of small entities, to perform an analysis that examines alternative, less onerous ways for small businesses to comply with intrusive regulations. If FDA abides by the provisions of this act, then small manufacturers will be afforded some measure of protection against the disproportionate effect of regulatory burden that may adversely affect competition in the marketplace, impede innovation, and discourage improvements in quality and productivity.

Nontariff Barriers—EEC

Our review of the literature and interviews with U.S. device manufacturers and U.S. and EEC officials all pointed to the potential importance of any differences between the "theory" of the EEC and the "practice" of the EEC. The "theory" refers to a unified set of regulations that facilitate cross-border trading, economies of scale, high-quality products, and a level playing field for international trade. The "practice" of EEC refers to how the single market might actually operate as a "United States of Europe" and how the individual member states might implement the various community directives. Many of the fears of U.S. manufacturers regarding the potential practice of the EEC were summed up in the phrase "fortress Europe," which generally referred to the imposition of nontariff barriers by the EEC or its member states to obtain a competitive edge for European-based firms. This section discusses some issues and concerns related to four important nontariff barriers—public procurement, rules of origin, intellectual property rights, and product liability.

Public Procurement

The development of a common public procurement policy is one of the more important issues facing U.S. manufacturers doing business in the new Europe. More than any other issue, it will serve as a measure of the EEC in theory and practice. In discussing medical device marketing in Europe, it is important to understand that national health authorities can most usefully be seen as purchasers of health-care services on behalf of their citizens. They may not themselves be suppliers of service. In some countries, health care is provided through a three-layered hierarchy of general practitioners or family doctors, local hospitals or private clinics, and large regional hospitals. While financing for these entities may come from the state, each is likely to be relatively autonomous in making decisions on purchasing. Similarly, individual departments in hospitals may have autonomy within agreed budgets. This means that decisions to purchase many medical devices may be made by individual doctors, nurses, technicians, and hospital administrators, and selling efforts must be directed toward these individuals and not toward the national health authorities.

This is a broad generalization with some important exceptions. There are many medical device categories for which regional or national authorities establish policies and that have important effects on sales. For example, in the United Kingdom, efforts to reduce costs have resulted in contracts for supplying some very commonly used items such as dressing being negotiated regionally or even nationally. In Germany and France, approval for the purchase of capital equipment costing more than a fixed price requires approval at regional or even national levels.

The single market will in the long term create pressures for change in purchasing medical devices. However, it is important to note that while the EEC is working to harmonize its regulatory requirements, reimbursements will still be the sole responsibility of member states. In the short to medium term, the effects of the single market are likely to be small in the public procurement and reimbursement areas; this period is also likely to be the most vulnerable for U.S. manufacturers. Individual countries will retain their different national markets, and diversity will continue to be common.

One concern facing U.S. trade officials centers on how some individual member states might circumvent the theory of the single market. For example, the EEC will publish a list of notified bodies, including their nationality and identification number. Since the CE mark will be accompanied by a number identifying the notified body that affixed it, it

may be expected that hospitals and doctors will ask for certain CE marks. This would in effect result in product discrimination.

A related concern of U.S. trade officials and manufacturers is the timely premarketing review of non-European-manufactured devices. When notified bodies are established, there may be a rush for quality system certification and product type testing. It is often the company that is first on the market with new products that captures a large part of the market. Discriminatory practices in the form of preferential treatment for European manufacturers from the notified bodies could result in a competitive disadvantage for U.S. manufacturers.

Furthermore, some critical procurement issues are not addressed in the directives, such as pricing, reimbursement, and distribution. Therefore, member states may institute their own procedures, and manufacturers will have to continue to meet a variety of requirements across nations. For example, some member states have already chosen to institute certain distribution practices that are not required in other countries.

Rules of Origin

"Rules of origin" generally refers to laws, regulations, and administrative practices that are applied to ascribe a country of origin to goods in international trade. They are used for such purposes as implementing preferential trade programs and granting most-favored-nation trade status. They are also used to determine eligibility to sell to a government entity that has "buy national" procurement policies. Local contents requirements specify the level of investment necessary to market a product in a particular country. U.S. trade officials and manufacturers have expressed their concern about the possible trend of "forced investment," or favoring European products and technologies over others through local contents provisions in the directives and through the application of different rules of origin.

In the emerging global economy, it is almost impossible to determine a product's origin. Previously, products had distinct national identities. Regardless of how many international borders they crossed, their country of origin—the name of which was usually imprinted right on them—was seldom in doubt. Products were manufactured in one location because economies of scale necessitated a central site.

But in the emerging global economy, quantities can be produced efficiently in a variety of locations and combined in different ways to serve customer

needs in many places. What is now traded between nations is not so much finished goods as specialized research, design, fabrication, management, marketing, advertising, consulting, and financial and legal services.

Under current EEC policy, member nations may refuse a bid from a foreign nation for products with less than 50 percent EEC contents. Moreover, if the procuring agency does consider a bid, it must grant a 3-percent price preference to equivalent offers from national firms as an incentive to buy a local product. This kind of development points to the European intention to develop European industries rather than creating a truly open market.

This policy could influence U.S. firms to invest in the European community in order to avoid EEC penalties and, in the case of multinational firms, to transfer manufacturing operations to the EEC at a cost to U.S. employment. U.S. firms need to be free to determine where they will establish manufacturing facilities and to base their determinations on commercial considerations. Investment decisions should not be forced by restrictive regulations.

Intellectual Property Rights

Intellectual property results from the physical manifestation of original thought. National governments provide the protection of rights to individuals and organizations for intellectual property primarily through copyrights, patents, and trademarks. Alternatively, a business can protect technology by treating it as a proprietary trade secret.

The EEC is expected to increase and enforce intellectual property protection at a common level throughout the single market. U.S. trade officials have said that a single community patent and trademark system would substantially reduce costs and marketing delays for U.S.-made products in the EEC. The EEC Commission acknowledges that companies will not invest in high-risk, long-term projects unless they are guaranteed adequate protection for the results of their efforts and have convened an intergovernmental task force to resolve these types of issues.

Product Liability

The foundation for product liability within the EEC is the interaction between the domestic laws of member states, the EEC product liability

directive, and the Convention on Jurisdiction and the Enforcement of Judgments in Civil and Commercial Matters.[3]

The rationale of the product liability directive is as follows:

1. To remove the need for claimants to prove fault; this operates as an alternative remedy to normal remedies in contract and tort. The directive creates a system of no-fault liability, not a system of strict liability. Liability is imposed for damage by defective products.

2. Liability is extended so that every consumer in the EEC has at least one party within the EEC against whom an action can be brought.

3. The effect of any exemption clauses in respect of damages to consumers is nullified. The directive does impose certain limitations on a manufacturer's liability in that it removes the consumer's right to sue the manufacturer over a defective device where the damage emerges only after a latent period of 10 years or more. Once the damage is discovered, there is a limitation period of 3 years.

The directive also gives member states a number of alternatives to limit its scope. Two important options to U.S. manufacturers are a developmental risk defense and a financial liability limit for death or personal injury caused identically by products with the same defect. The developmental defense is similar to what is referred to in the United States as the "state-of-the-art" defense. The defense consists of a producer's proving that the state of scientific and technical knowledge when a product was put into circulation did not allow the existence of a defect to be discovered.

In the United States, the importance of knowing which state to select for product liability litigation has been recognized for a number of years, considering such factors as jurisdictions that award punitive damages and those that impose a doctrine of industrywide liability without actual and specific proof of causation, joint and several liability, and maximum damage limits.

The adoption of the directive together with the Brussels Convention has similarly created a number of options, and the decision of a plaintiff of the

[3]Our discussion of product liability is adapted from a presentation given by Stephen Kon at the international conference, Europe 1992: Impact on the U.S. Medical Device, Diagnostic and Equipment Industries, Washington, D.C., July 12, 1990. Mr. Kon is a partner in the firm of S. J. Berwin, United Kingdom, where he heads the EEC law team.

location to initiate a suit may be influenced by the substantive laws of product liability as implemented by individual member states and the enactment of various options in the directive in the different EEC jurisdictions.

The basic rule of the Convention concerning jurisdiction is that a plaintiff must sue a defendant in a country where the defendant is domiciled, the issue of domicile being determined by the internal law of the court judging the matter. A corporation is deemed to be domiciled where it has its "seat," which can include its registered office or other official address. However, an alternative to the principle of domicile is that a defendant can be sued in the state where the harmful event occurred, and when this is different from the domicile, the European Court of Justice has established that the plaintiff has a choice between suing in the state where the harm took place and the state where the actual damage occurred. Consequently, a multinational device firm can be sued in a number of potential jurisdictions at the choice of the plaintiff. Regulations of individual nations are often different and, in some cases, more strict than those being proposed by the EEC, and this lack of uniformity is not expected to be resolved for some time.

As a result of the EEC directive, all firms exporting products to the EEC can be held liable for damages resulting from defects in their products for up to 10 years after the products were made available. Consequently, all manufacturers may have to increase their expenditures for quality control and quality assurance throughout the life of the device—design through postmarketing. Good documentation of the quality assurance measures and production and control processes might permit or facilitate supplying evidence for a defense. Manufacturers will have to be in a position to prove that each of their products has been free from defects for up to 10 years after the product has been circulated in the market. This period could extend beyond the life cycle of the product—design through obsolescence and removal from the market.

This suggests that if manufacturers succeed in proving by means of their internal quality assurance or other quality management systems that a product has been made without any defects and, on delivery, was in conformity with the essential requirements, the EEC directives, and the applicable EN standard, they significantly improve their ability to prevail in an EEC court.

Summary and Implications

U.S. manufacturers' perceptions and beliefs about the potential effect of the EEC on their industry was similar to their perception about the globalization of the industry. About one third reported little interest in developments in the EEC, and a relatively small proportion thought that the EEC-produced devices would be a serious challenge to them in the domestic market.

Although many manufacturers thought that their customers would prefer a quality-marked device, such as EEC-approved devices, not as many thought their customers would be willing to pay more for the device. However, since about a quarter of U.S. manufacturers believe that their devices are already priced higher than foreign devices, they may still lose some of their market share. And although U.S. manufacturers are not convinced that the type of standards that are being proposed for the EEC will guarantee better-quality devices, they seem to believe that international harmonization of standards will ensure equity.

Generally, the larger U.S. firms, particularly those that are currently doing business in the EEC, have taken the greatest actions in preparation for the single market. However, it is the small firms that make up the bulk of the U.S. device industry and that have the most to gain from active participation in the EEC market, yet they seem to be the firms that are the least engaged. The trends toward offshore manufacturing and regulatory shopping may be creating greater problems than they are solving as a response to regulatory controls and the EEC.

At the present time, U.S. trade officials and manufacturers are optimistic that the completion of the single market will result in an open market, making a real contribution to the world economy and to the international trading system. It is also true, however, that some developing EEC policies with protectionist tendencies are reason for concern within the U.S. government and in the private sector.

Conclusions and Recommendations

The objective of our review was a comparative analysis of the U.S. policies and procedures for marketing and QA for medical devices with their counterpart controls in Japan, Canada, and the EEC. We pursued our objective with a set of evaluation questions to obtain information on the similarities and differences among the various national regulatory policies and procedures for premarketing review and approval of medical devices and the nature and extent of preparedness of the U.S. medical device industry for competing in a global market.

Conclusions

Similarities and Differences Among Systems

The structure of regulatory policies and procedures for premarketing review and approval in the United States is differentiated from its counterparts in Japan and Canada primarily by its classification of devices according to what is needed to reasonably ensure safety and effectiveness. However, the actual functioning of these three systems is very similar.

Our review of the various national regulatory policies and procedures for premarketing review and approval of medical devices revealed that they were all, including the proposed EEC system, in a state of flux. The principal objectives of these changes were to develop national systems that more closely approximate a total quality assurance system; incorporate international-based technical standards and other types of controls to improve product quality, increase the safety and effectiveness of devices, and harmonize international regulatory requirements; and promote international competitiveness.

The changes that are being proposed for the EEC device regulatory structure are primarily directed at the development of the single market and the concomitant benefits that may occur to the EEC's domestic device industry and its international market share. The EEC system is exerting a substantial influence on the contents and requirements of other national systems because of the size of the potential market represented by the EEC and its affiliated states, the requirement for compliance with the EEC to participate in the single market, international agreement on the potential commercial and governmental efficiency benefits of harmonization, and the belief that elements of the EEC system may contribute to improved device quality.

The components of the proposed EEC system for marketing a device are similar to the components of the U.S. system and are significantly different from those present in the Japanese and Canadian systems. The principal differences between the U.S. system and the EEC system are operational, including the basis of device classification, the use of international standards as references for product quality and approval to market, and third-party certification of compliance with the essential requirements.

In revising the U.S. device regulatory requirements, FDA must balance its principal mandate to protect the public health with the recent addition to its mandate under the Safe Medical Devices Act of 1990 to promote agreements with foreign countries and to facilitate commerce.

The U.S. system as revised will not be identical to the system proposed for the EEC, which may result in the continued necessity for duplicate inspections and approvals for U.S. and foreign device manufacturers by their respective national health authorities. The ideal would be mutual certification and approval to market a medical device between the United States and the EEC, assuming equivalent requirements of product safety and effectiveness. Over the medium term, however, given the fundamental differences in an institutional constraints approach, both industry and regulators may benefit from harmonization of key regulatory requirements, such as in the area of quality systems.

U.S. Device Manufacturers' Preparedness for the Global Market

The present standing of the medical device industry in the U.S. economy and global markets and manufacturers' perceptions of the high quality of U.S. health-care products are factors that may have led to complacency on the part of U.S. manufacturers. We found that the majority of U.S. device manufacturers are focused on the domestic market. And a significant proportion of them are not cognizant of the nature, scope, or immediacy of the potential competitive challenges to the industry from the global market or the EEC. The greatest level of preparation is shown by the minority of firms—the large and medium multinational firms—rather than the overwhelming majority of small U.S.-based firms that make up the U.S. device industry. A significant proportion (58 percent) of U.S. manufacturers said they had not taken potential preparatory actions for the EEC over the last 12 months. Small manufacturers were the least likely to have taken any action in response to the EEC.

It is not clear that U.S. device manufacturers have learned some important lessons from the relatively recent experience of other U.S. industries. That

is, in many product areas, U.S. companies have lost market shares, both at home and overseas, to foreign competitors. These competitors have the advantage of dealing in a world marketplace that allows them to amortize research and development expenditures, reduce costs, and develop higher-quality products and services. Therefore, even if they do not export, domestic companies, whether large or small, are still faced with global competitiveness.

Our survey results indicate that U.S. device manufacturers would like to have government export assistance, principally in the forms of information and financial support. The least desirable assistance is government oversight, such as national testing and certification of quality systems. Some manufacturers' response to what they perceive as U.S. regulatory hurdles is to move manufacturing facilities offshore in search of less burdensome regulatory processes.

While we found that there is no lack of information sources or information about exporting to the EEC or the global market, our respondents reported a deficiency of information directly relevant to their needs. It may be that manufacturers will have to be more proactive in seeking information and assistance. However, the providers of information may also need to focus their assistance more on guidance and implementation of requirements, as well as greater coordination and publicity as to their location and availability.

The major impediment to an evaluation of the EEC single market and its implications for the medical devices industry is its evolutionary nature. Some components of the system are still at the planning and design stage. Implementation and coordination of the system by individual member states may be years away. While the specifics in different product and service sectors can be debated, the bottom line is that there is going to be a single European market that U.S. manufacturers should prepare for. At the outset at least, this market is going to be a very complicated business environment. There will be overlapping and conflicting regulations and jurisdictional issues that the Commission and the member states will have to negotiate.

There is an important interrelationship between the single market program and the ongoing Uruguay Round of multilateral trade negotiations under the auspices of GATT. The two exercises overlap in many key areas where international efforts at trade liberalization parallel ongoing efforts within the EEC. While for the most part these efforts have been generally

complementary, decisions made by the European community in the single market may constrain the degree of liberalization achievable.

While there is a measure of transparency for the single market program as it is being formulated in the Commission, there is no roadmap or experience in implementing a program of this type. New agencies, policies, and dispute settlement mechanisms may have to be invented to cope with the enormous task of delivering on the 1992 program as legislated.

There was a considerable amount of concern about the part of manufacturers and governmental officials on whether the implementation of the single market will result in an open market or impose nontariff barriers and other protectionist regulations. Exporters and government officials have followed the development of the single market program with great interest.

On numerous occasions, the U.S. government has expressed its strong support for the EEC single-market program. This support is based on the premise that the single market program will be implemented in a trade liberalizing, nondiscriminatory manner that provides U.S. and European firms an equal opportunity to take advantage of its benefits. Within the U.S. government, multiagency and single agency organizations have been established to monitor EEC developments and their potential effect on U.S. trade interests and to coordinate U.S. responses.

Recommendations

In light of the increasing trend toward global markets and considering also the differing institutional constraints and approaches (especially those relating to "substantial equivalence" and product design focus) driving EEC and U.S. regulatory requirements, certain activities assume critical importance. In this regard, we endorse current efforts to revise the U.S. good manufacturing practices regulation and other premarketing requirements in a manner that advances international harmonization without compromising the primary objective of protecting the public health from unsafe or ineffective medical devices. Furthermore, we recommend that the Secretary of Health and Human Services direct the Commissioner of the Food and Drug Administration to increase the internal coordination, outreach, and focus on small manufacturers of its educational and guidance programs for exporting.

We further support the efforts of the U.S. Task Force on the EEC Internal Market and the Secretary of Commerce to monitor developments and

coordinate activities. We recommend that the Task Force Chair in cooperation with the Secretary of Commerce make a targeted effort to inform U.S. medical device manufacturers on progress toward the single market and changes related to harmonization that may affect their competitiveness.

Selected Information Sources

In the United States

Government Agencies

Embassy of Japan, U.S. Attache for Health and Welfare

National Institute of Standards and Technology

Office of the U.S. Trade Representative

U.S. Department of Commerce, International Trade Administration

U.S. Department of Health and Human Services, Food and Drug Administration

U.S. Department of State

U.S. Small Business Administration

Private Sector

American National Standards Institute

Baxter Healthcare Corporation

Baxter World Trade

Health Industry Manufacturers Association

Johnson and Johnson Medical, Inc.

Interpharm, Inc.

National Electrical Manufacturers Association

Underwriters Laboratories, Inc.

ZMI Corporation

In Japan

Government Agencies

Ministry of Health and Welfare, Pharmaceutical Affairs Bureau

Ministry of International Trade and Industry

U.S. Embassy, Japan, Commercial Section

Private Sector

American Chamber of Commerce, Japan

Japan Federation of Medical Devices Association

In Canada

Government Agencies

Department of National Health and Welfare Canada, Health Protection Branch

External Affairs and International Trade Canada

- Industrial Trade Policy Division
- International Trade Policy Division

Industry, Science, and Technology Canada: Resource Processing and Industries Branch, Health Care Products Division

National Research Council Canada

- Biomedical Technology Program
- Canadian Medical Biotech Equipment

U.S. Embassy, Canada, Bureau of European and Canadian Affairs

Private Sector

Technology Institute for Medical Devices for Canada

In the European Economic Community

Government Agencies

Commission of the European Communities

- Internal Market and Industrial Affairs
- Testing and Certification
- Trade and International Relations

Intercantonal Control for Medicine, Switzerland

Ministry of Health, France

U.S. Embassy, France

U.S. Mission to the European Communities

Private Sector

European Committee for Standardization

European Committee for Electrotechnical Standardization

Swiss Association for Certification

International Organization

Organization for Economic Cooperation and Development, France

Survey of Medical Device Manufacturers

United States General Accounting Office

Survey of Medical Device Manufacturers

Instructions

The U.S. General Accounting Office has been asked by the Congress to evaluate the competitive position of the U.S. medical device industry, especially in consideration of the forthcoming European Community's Single Market (EC 1992) regulations. As part of our evaluation, we are soliciting U.S. medical device manufacturers' perspectives on issues concerning the long-term competitiveness of the American medical device industry.

This survey includes the following topics: information about your business, attitudes, and behaviors related to the international commerce of medical devices, perceptions and actions related to product quality, and incentives designed to increase the competitiveness of U.S. medical devices.

Your answers can be reported by checking the appropriate response or by filling in the blanks. The questionnaire should take about 20 minutes to complete. We are asking you to return the questionnaire to us within 10 days, using the enclosed business reply envelope.

If you have any questions, please feel free to call Nancy Briggs or Edward Logsdon at (202) 275-3575. In the event that the business reply envelope is misplaced, our return address is:

U.S. General Accounting Office
Nancy A. Briggs
Room 5844
441 G St., N.W.
Washington, D.C. 20548

1. For how many years has your company been manufacturing medical devices?

   _____(number of years)

2. How many full-time workers do you employ?

   _____(number of workers)

3. What was the dollar volume of your sales for the past full year? (Answer for either calender or fiscal year.) *(Check one.)*

   1(6)

   1. ☐ 0 - 499,999
   2. ☐ 500,000 - 9,999,999
   3. ☐ 10,000,000 - Up

4. What class(es) of device(s) do you manufacture? *(Check all that apply.)*

   (6-8)

   1. ☐ Class I
   2. ☐ Class II
   3. ☐ Class III

5. Is your company a member of a standards, trade, or professional organization?

   1. ☐ Yes (If yes, please list memberships below.)
   2. ☐ No

6. To what extent, if at all, do you think that medical devices produced in the European Community will challenge the market share of U.S. medical products?

(European Community includes the following countries: Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, and the United Kingdom.) *(Answer for each of the markets specified below.)*

	Little or no extent (1)	Some extent (2)	Moderate extent (3)	Great extent (4)	Very great extent (5)	No basis to judge (6)
1. In the U.S. domestic market						
2. In the European Community market						
3. In the global marketplace						

7. In general, how interested, if at all, is your company in information on the European Community's proposals for their Single Market Plan for medical devices? *(Check one.)* (9)

   1. ☐ Little or no interest in European Community developments
   2. ☐ Somewhat interested (occasionally seek information related to market issues)
   3. ☐ Moderately interested (usually seek general information on topics directly related to market issues)
   4. ☐ Very interested (seek general information on all or nearly all topics that are directly or indirectly related to market issues)
   5. ☐ Have a great interest (make a concerted effort to obtain detailed information on all, or nearly all, topics that are directly or indirectly related to market issues)

8. Do you now export a medical device? *(Check one.)* (10)

   1. ☐ Yes (continue)
   2. ☐ No (go to question 27)

9. What class(es) of device(s) do you export? *(Check all that apply.)* (11-13)

   1. ☐ Class I
   2. ☐ Class II
   3. ☐ Class III

10. What proportion of all your domestically manufactured medical devices do you export?
    _____(percent of sales)

11. To which country (or countries) do you now export? *(Check all that apply.)* (14-22)

   1. ☐ One or more countries that make up the European Community (Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, or the United Kingdom)
   2. ☐ One or more of the countries that make up the European Free Trade Association (Austria, Finland, Iceland, Norway, Sweden, or Switzerland)
   3. ☐ Other European country (or countries)
   4. ☐ Canada
   5. ☐ Australia
   6. ☐ Japan
   7. ☐ Other Asian country (or countries)
   8. ☐ Latin American country (or countries)
   9. ☐ Other (Please specify.)

   _____

   _____

12. Why did your company decide to export? *(Check all that apply.)*

(23-29)

1. ☐ Wider market
2. ☐ More favorable pricing for your product abroad
3. ☐ More favorable regulatory environment abroad
4. ☐ Demand higher abroad
5. ☐ Fewer bureaucratic barriers
6. ☐ Slower growth for your product in the U.S.
7. ☐ Other (Please specify.)

_____

_____

_____

_____

13. If you now export to a country that is a member of the European Community, do you plan to continue to export after the new Single Market regulations for medical devices become effective? (Check "Not applicable" if you do not export to a country that is a member of the EC and go to question 24.) *(Check one.)*

(30)

1. ☐ Yes
2. ☐ Probably yes
3. ☐ Undecided
4. ☐ Probably no
5. ☐ No
6. ☐ Not applicable

14. If you answered no, probably no, or undecided to question 13, what are your reasons for planning not to export?

_____

_____

_____

_____

_____

15. How will the Single Market regulations affect your business? *(Check one.)*

(31)

1. ☐ Will make exporting easier
2. ☐ Will make no appreciable difference
3. ☐ Will make exporting more difficult

16. Within the past 2 years, have you expanded or changed your distribution arrangements in Europe? *(Check one.)*

(32)

1. ☐ Yes (go to question 18)
2. ☐ No (continue)

17. Within the next 2 years, do you plan to expand or change your distribution arrangements in Europe? *(Check one.)*

(33)

1. ☐ Yes
2. ☐ Probably yes
3. ☐ Undecided
4. ☐ Probably no
5. ☐ No

18. Do you produce medical devices in Europe? *(Check one.)*

(34)

1. ☐ Yes
2. ☐ No (go to question 21)

19. Within the past 2 years, have you expanded production in Europe? *(Check one.)*

(35)

1. ☐ Yes (go to question 21)
2. ☐ No

20. Within the next 2 years, do you plan to expand production in Europe? *(Check one.)*

(36)

1. ☐ Yes
2. ☐ Probably yes
3. ☐ Undecided
4. ☐ Probably no
5. ☐ No

21. Within the past 2 years, have you merged, acquired, or formed a joint venture with a European partner? *(Check one.)*

(37)

1. ☐ Yes (go to question 23)
2. ☐ No

22. Within the next 2 years, do you plan to merge, acquire, or form a joint venture with a European company? *(Check one.)*

(38)

1. ☐ Yes
2. ☐ Probably yes
3. ☐ Undecided
4. ☐ Probably no
5. ☐ No

23. In general, how would you evaluate your own company's preparation for the requirements for marketing in the European Community? (In answering, consider the available information.) *(Check one.)*

(39)

1. ☐ Poorly prepared
2. ☐ Fairly well prepared
3. ☐ Moderately well prepared
4. ☐ Very well prepared
5. ☐ Extremely well prepared

24. Over the last 12 months, which, if any, of the following actions has your company taken in preparation for the new EC market? *(Check all that apply.)*

(40-47)

1. ☐ Secured literature on the European Community's Single Market Plan
2. ☐ Modified business plans to meet the technical requirements of EC 1992
3. ☐ Sent a delegation to a medical device conference for information on EC 1992
4. ☐ Hired consultants to help meet EC requirements
5. ☐ Sent a delegation to Europe to explore business opportunities
6. ☐ Registered your firm with an organization that will certify your quality assurance system
7. ☐ Other
8. ☐ None of the above

25. As an exporter of medical devices, rate the importance of the following issues? *(Check one column for each row).*

	Little or no importance (1)	Some importance (2)	Moderate importance (3)	Great importance (4)	Very great importance (5)	No basis to judge (6)
1. Public procurement policies						
2. Rules of origin						
3. Product liability						
4. Intellectual property rights						

26. In your opinion, what are the three largest obstacles to exporting your product? (Please rank your responses, with 1 being the greatest obstacle.)

1. _____

2. _____

3. _____

27. Within the next 5 years, from whom will your company find its greatest competitive challenge? *(Check one.)*

(48)

1. ☐ Other American companies
2. ☐ European Community and European Free Trade Association countries
3. ☐ Japan
4. ☐ Other Asian countries
5. ☐ Other
6. ☐ Don't know; no basis to judge

28. Within the next 10 years, from whom will your company find its greatest competitive challenge? *(Check one.)*

(49)

1. ☐ Other American companies
2. ☐ European Community and European Free Trade Association countries
3. ☐ Japan
4. ☐ Other Asian countries
5. ☐ Other
6. ☐ Don't know; no basis to judge

29. Do you think it's possible to make a general conclusion about how U.S. medical devices compare with similar foreign products? *(Check one.)*

(50)

1. ☐ Yes
2. ☐ No (go to question 31)

30. If you do, are they of *(Check one.)*

(51)

1. ☐ Higher quality
2. ☐ Somewhat higher quality
3. ☐ Comparable quality
4. ☐ Somewhat lower quality
5. ☐ Poorer quality
6. ☐ Don't know; no basis to judge

31. Compared with foreign competition, do you note any general trend in the quality of U.S. medical devices? *(Check one.)*

(52)

1. ☐ Yes
2. ☐ No (go to question 33)

32. If so, are they *(Check one.)*

(53)

1. ☐ Gaining
2. ☐ Maintaining current status
3. ☐ Falling behind
4. ☐ Don't know; no basis to judge

33. If the quality of foreign medical devices is improving, how is your company responding? (Check "Not applicable" if you disagree with the above premise.) *(Check all that apply.)*

(54-59)

1. ☐ Not applicable
2. ☐ Increasing research and development expenditures
3. ☐ Conducting joint ventures with other U.S. firms
4. ☐ Conducting joint ventures with foreign firms
5. ☐ Other (Please specify.)

_____

_____

_____

_____

34. How are foreign medical devices priced compared to your product? *(Check one.)*

(60)

1. ☐ Higher
2. ☐ Comparably priced
3. ☐ Lower
4. ☐ Don't know

35. If foreign medical devices are comparably or lower priced, what actions has your firm taken? *(Check one.)*

(60)

1. ☐ Not applicable
2. ☐ Actions taken by your firm (Please specify.)

_____

_____

_____

_____

_____

36. In relation to quality improvement as a strategic business activity, which of the following statements best describes your company's level of activity? *(Check one.)*

(61)

1. ☐ No interest in pursuing quality improvement as a business strategy
2. ☐ Recently acquired knowledge; exploring programs
3. ☐ Acquired knowledge; too costly to implement
4. ☐ Program in place; no results yet
5. ☐ Program in place; encouraged with results
6. ☐ Program in place; discouraged with results

37. In your opinion, is a medical device manufacturer who is a quality leader in a particular area in a more favorable market position in terms of competition? *(Check one.)*

(62)

1. ☐ Yes
2. ☐ Generally yes
3. ☐ Uncertain
4. ☐ Generally no
5. ☐ No
6. ☐ No basis to judge

38. In your opinion, will your customers be more apt to buy a product with an approved mark or seal from a testing agency or authorizing body? *(Check one.)*

(63)

1. ☐ Yes, customers would prefer
2. ☐ Uncertain
3. ☐ No, wouldn't make any difference

39. In your opinion, will your customers be willing to pay more for a product with a such a mark or seal? *(Check one.)*

(64)

1. ☐ Yes
2. ☐ Probably yes
3. ☐ Uncertain
4. ☐ Probably no
5. ☐ No

40. In your opinion, will the technical requirements for medical devices being proposed by the European Community result in greater assurances of product quality? *(Check one.)*

(65)

1. ☐ Yes
2. ☐ Probably yes
3. ☐ Uncertain
4. ☐ Probably no
5. ☐ No
6. ☐ No basis to judge

41. In your opinion, will the technical requirements being proposed by the European Community for marketing medical devices influence worldwide standards for devices? *(Check one.)*

(66)

1. ☐ Yes
2. ☐ Probably yes
3. ☐ Uncertain
4. ☐ Probably no
5. ☐ No
6. ☐ No basis to judge

42. If you do not export your product now, to what extent, if at all, would you consider exporting your product if the U.S. government allowed tax credits or other tax incentives for exporters of medical devices? (Check "Not applicable" if you export now.) *(Check one.)*

(67)

1. ☐ Not applicable
2. ☐ To little or no extent
3. ☐ To some extent
4. ☐ To a moderate extent
5. ☐ To a great extent
6. ☐ To a very great extent

43. In your opinion, should the U.S. harmonize domestic standards to coincide with international standards for medical devices? *(Check one.)*

(68)

1. ☐ Yes
2. ☐ Probably yes
3. ☐ Uncertain
4. ☐ Probably no
5. ☐ No

44. In your opinion, how important are each of the following incentives for facilitating the export of medical devices? *(Check one column for each row.)*

	Little or no importance (1)	Some importance (2)	Moderate importance (3)	Great importance (4)	Very great importance (5)	No basis to judge (6)
1. Information on export markets for medical devices						
2. Information on foreign agents/distributors						
3. Tax credits or other tax incentives for exporters of medical devices						
4. Federal grants for exporters						
5. Greater coordination among government agencies for information regarding export requirements						
6. Strategies for exporting (i.e., seminars and conferences)						
7. Greater government cooperation and coordination with the private sector on exporting information						
8. National testing and certification program for devices						
9. Government registration of quality systems						

45. We would be interested in your thoughts on ways, to improve the future economic climate for the medical device industry in international trade. Please feel free to make additional comments in the space below.

Thank you.

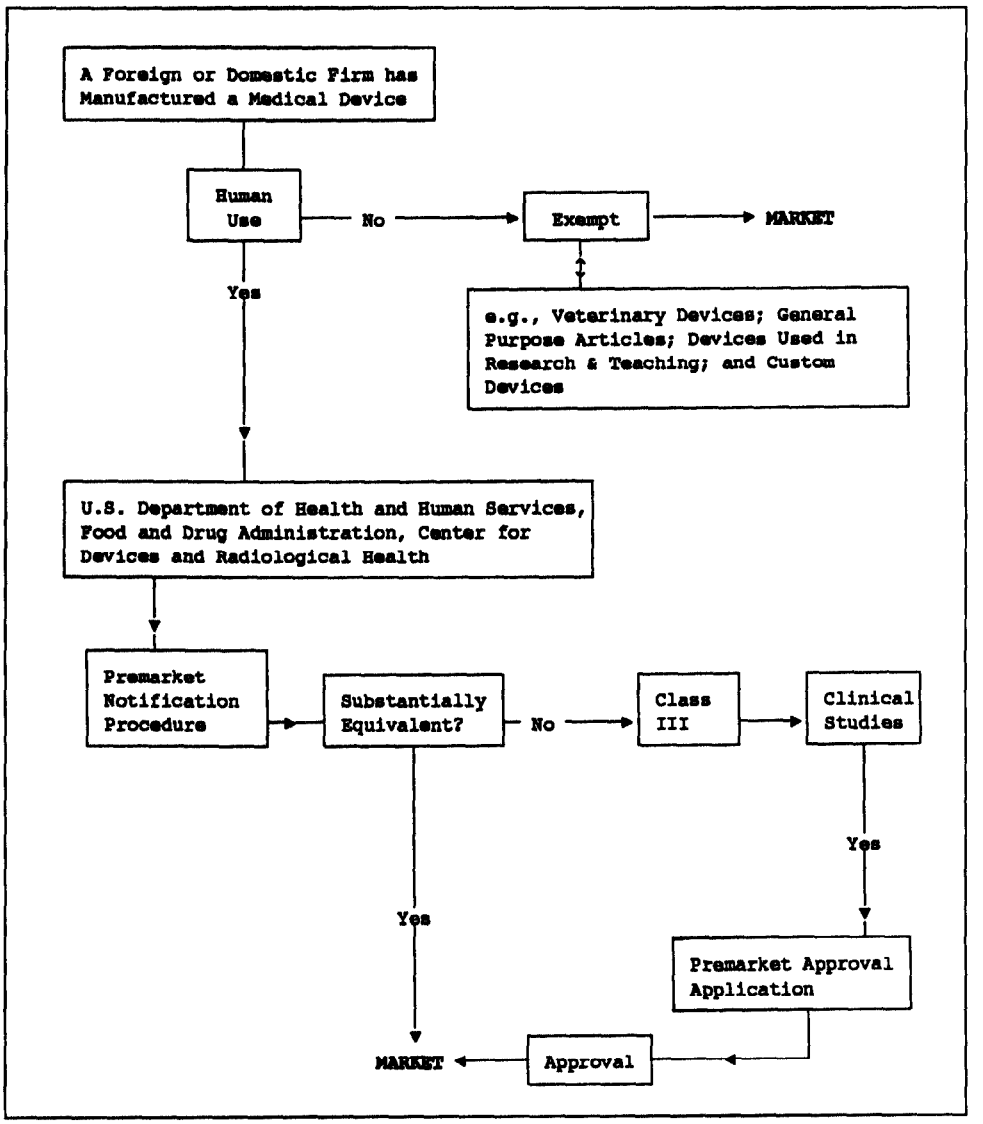
Technical Advisory Review Board

Philip B. Jarvis
Manager, Quality Assurance and Regulatory Affairs
Medrac Inc.
Indianola, Penna.

Edward M. Rozynski
Vice President, International Health Industry Manufacturers Association
Washington, D.C.

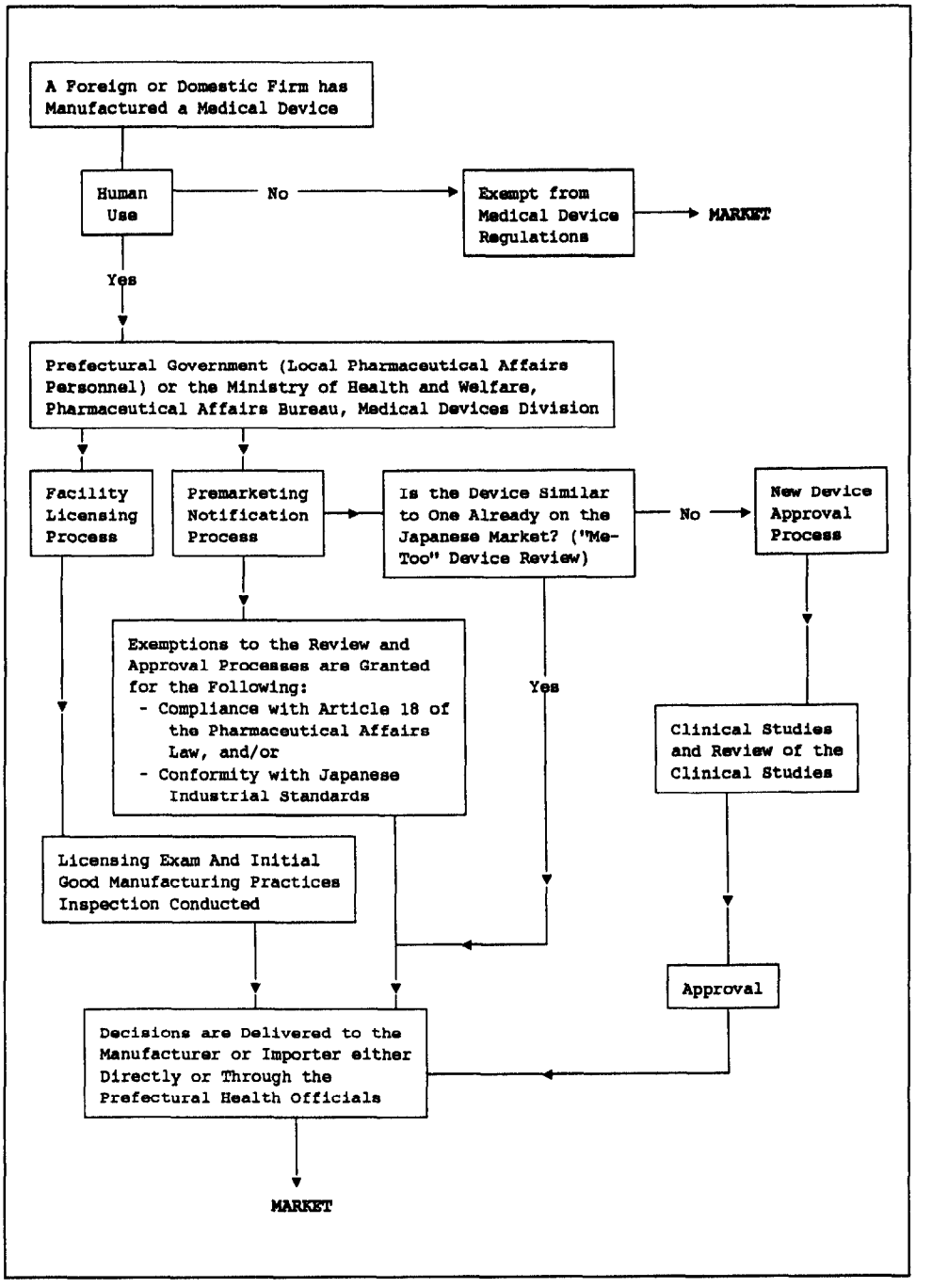
Premarketing Review and Approval Process for Medical Devices in the United States, Japan, and Canada

Figure IV.1: U.S. Premarketing Review and Approval Process for Medical Devices



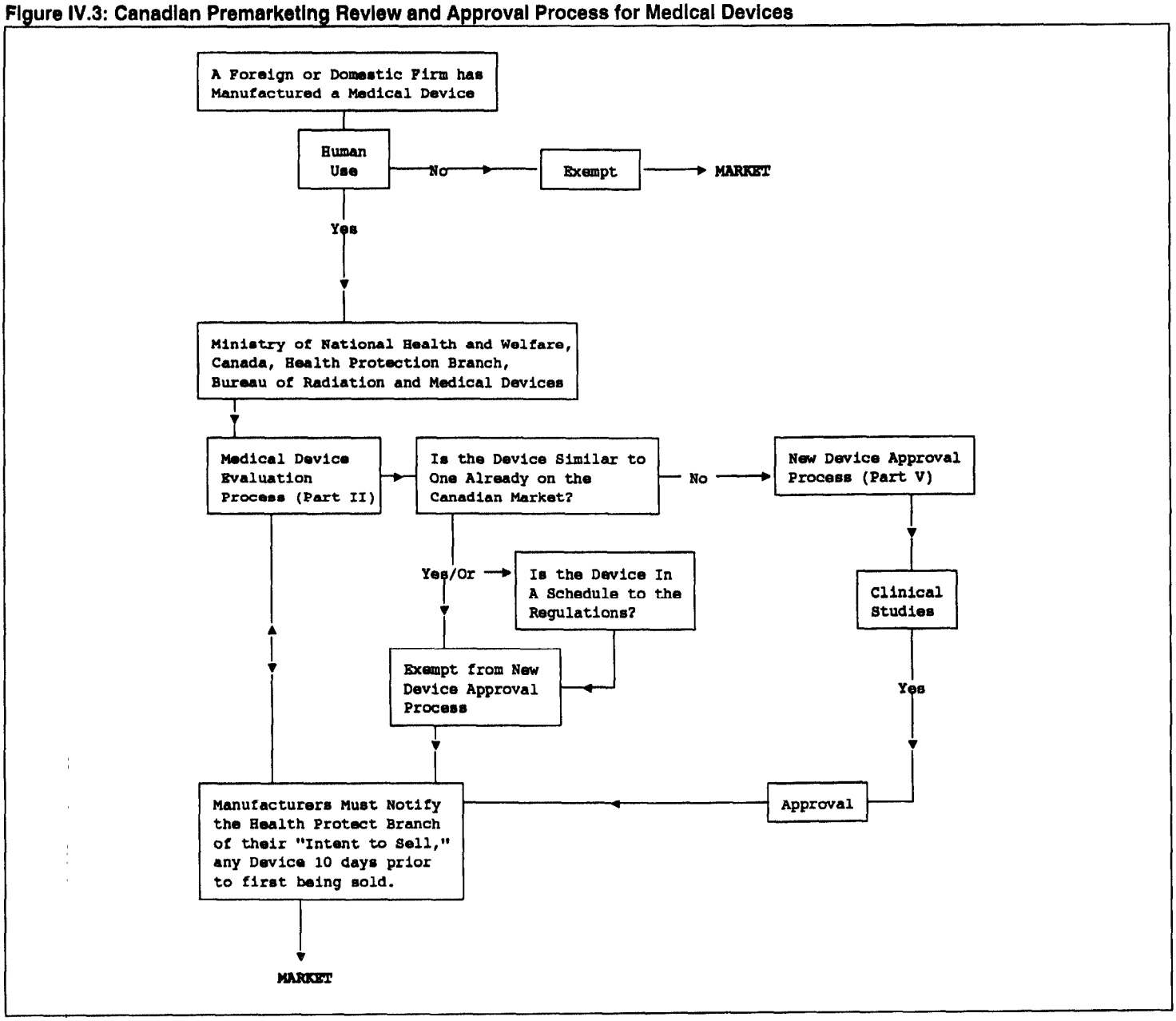
Source: Adapted from U.S. Department of Health and Human Services, Food and Drug Administration, Premarket Notification: 510(k), Regulatory Requirements for Medical Devices—A Workshop Manual (Rockville, Md.: 1990).

Figure IV.2: Japanese Premarketing Review and Approval Process for Medical Devices



Source: Adapted from Ministry of Health and Welfare, Pharmaceutical Affairs Bureau, Medical Devices Division, Guide to Medical Device Registration in Japan, 3rd ed. (Tokyo, Japan: Yakuji Nippo, Ltd., November 1990).

Figure IV.3: Canadian Premarketing Review and Approval Process for Medical Devices



Source: Adapted from Ministry of National Health and Welfare, Environmental Health Directorate, Health Protection Branch, "Food and Drugs Act: Excerpts Applicable to Medical Devices," Medical Devices Regulations (Ottawa, Ontario, Canada: September 1990).

Comments From the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

APR 30 1993

Ms. Eleanor Chelimsky
Assistant Comptroller General
United States General
Accounting Office
Washington, D.C. 20548

Dear Ms. Chelimsky:

Enclosed are the Department's comments on your draft report, "Medical Technology: Quality Assurance Systems and Global Markets." The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely yours,

Bryan B. Mitchell
Principal Deputy Inspector General

Enclosure

COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE GENERAL ACCOUNTING OFFICE (GAO) DRAFT REPORT "MEDICAL TECHNOLOGY: QUALITY ASSURANCE SYSTEMS AND GLOBAL MARKETS"

The Department generally agrees with the report and offers the following comment.

GAO RECOMMENDATION

In light of the increasing trend toward global markets and considering also the differing goals and policies (especially those relating to "substantial equivalence" and product design focus) driving European Economic Community (EEC) and U.S. regulatory requirements, certain activities assume critical importance. In this regard GAO endorses current efforts to revise the U.S. good manufacturing practices (GMP) regulation and other premarketing requirements in a manner that advances international harmonization without compromising the primary objective of protecting the public health from unsafe or ineffective medical devices. Furthermore GAO recommends that the Secretary of Health and Human Services direct the Commissioner of the Food and Drug Administration (FDA) to increase the internal coordination, outreach, and focus on small manufacturers its educational and guidance programs for exporting. [sic]

DEPARTMENT COMMENT

The FDA has a well-established outreach program to assist small businesses to compete in the global market of today. In addition, FDA is planning to revise the GMP regulation to meet the objectives of international harmonization while protecting the public from unsafe or ineffective medical devices. To increase the emphasis of FDA's educational and guidance programs for small manufacturers on exporting issues, FDA has established an Office of International Relations within its Division of Small Manufacturers Assistance. FDA provides extensive guidance to manufacturers concerning export requirements and coordinates activities with other government agencies and foreign countries in its day-to-day assistance activities and in its educational programs as appropriate. However, as noted in the report, FDA's resources available for these activities are limited. FDA will continue to provide leadership and services to the maximum extent possible within current budget constraints.

Major Contributors to This Report

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Glossary

Chi Square	A test of statistical significance to determine whether there is a systematic relationship between two variables. By itself, chi square indicates whether variables are independent or related. It does not indicate how strongly they are related.
Commission of the European Economic Community	The Commission is the executive branch of the European Economic Community and has responsibility for proposing legislation and for ensuring implementation of EEC laws by the member states. Commissioners are appointed by agreement among the governments of the member states for 4-year terms.
Device Classes—U.S. Regulatory System	Class I is one of three regulatory classes established by the Medical Device Amendments of 1976 (Public Law 94-295) and defined in 21 C.F.R. 860.3(c)(1). Class I, general controls, contains devices for which general controls authorized by the amendments are sufficient to provide a reasonable assurance of safety and effectiveness. Manufacturers of class I devices must, among other things, register their establishments, list their devices with FDA, notify FDA 90 days before marketing a device, and conform to good manufacturing practices. Class II is a regulatory class of devices for which general controls alone are insufficient to provide a reasonable assurance of safety and effectiveness and sufficient information is available to establish special controls, including performance standards, to provide such assurance. Class III is a regulatory class of devices for which general controls are insufficient to ensure safety and effectiveness, sufficient information does not exist to establish special controls, and the device supports life, prevents health impairment, or presents a potentially unreasonable risk of illness or injury.
Device Type	All products of a particular type or group of separate types that are similar. FDA classifies device types according to the potential risk posed by their use and the degree of regulation they require. The full definition is in 21 C.F.R. 860.3(i).
Directive	A directive is a document that obliges member states of EEC to subordinate their respective national laws, regulations, and administrative measures to

those that are adopted by the members as Community legislation. Member states are prohibited thereby from introducing national legislation that prescribes or permits the level of protection to be less than or greater than that that is specified within the applicable directive.

Each directive contains the common elements of (1) scope and definition of applicability; (2) the essential requirements that include the technical provisions for safeguarding health, safety, and the environment; (3) conformity assessment procedures and the role of quality systems in meeting the essential requirements and certification to market a device; and (4) safeguards and administrative provisions.

Essential Requirements

The essential requirements indicate a device's technical specifications, standards, and other information that relates to general aspects such as the principle of intrinsic safety and the achievement of performance, side effects, and risk-related aspects—for example, chemical and physical properties, microbial contamination, environmental properties, protection against ionizing radiation, and electrical safety. Other elements included in these requirements refer to labeling and instructions for use.

European Court of Justice

The Court consists of 13 judges appointed by agreement among the governments of the member states for 6-year terms. The Court has original jurisdiction in cases in which the Commission or another Community institution is a party. Actions brought in national courts are referred to the European Court of Justice for preliminary rulings in matters of EEC law, and subsequent rulings are binding on the national courts.

Good Manufacturing Practices

Requirements applicable to all three regulatory classes of devices for their manufacturing, packaging, storage, and installation, according to regulations promulgated under the Medical Device Amendments of 1976.

Harmonization of Standards

The current system of differing national product standards among the 12 member states has restricted the ability of firms to market their products throughout the EEC. Harmonization of national standards will facilitate the flow of goods. Instead of incorporating mandatory technical standards into the directives, the Commission directives now specify "essential requirements" needed to protect the health and safety of consumers and the environment.

Horizontal Standard	Applicable to a wide range of product areas and deals with such broad issues as labeling, symbols, terminology, clinical evaluations, and quality assurance. See also Vertical Standard.
Intellectual Property Rights	The expansion of markets through economic integration in a global economy intensifies competition and necessitates the protection of inventions, trademarks (which often guarantee the commercial origin of a product or service), and the recognized rights of those who create works of the intellect. Nations require that industrial and intellectual property be protected in order to encourage creative effort, innovation, and investment.
Medical Device	Any instrument, apparatus, implement, machine contrivance, implant, in vitro reagent, or similar or related article that is intended to help diagnose a disease or its conditions; to prevent, diagnose, mitigate, or treat a disease; or to affect the structure or function of the body. A medical device does not achieve any of its principal intended purposes through chemical action within or on the human body or the bodies of other animals, and it does not depend on being metabolized in order to achieve any of its principal intended purposes.
Memorandum of Understanding	Memoranda of understanding are written evidence of bilateral agreements for international cooperation between countries for promoting competitive equity. They are set within the framework defined by the national laws of the two countries and provide for the potential for cooperation within these existing laws. Memoranda of understanding are not legally binding but are, rather, a statement of intent.
Mutual Recognition	Initially, the EEC required member states to modify their differing national laws and regulations in order to implement comprehensive, uniform standards established by the Community. This approach was abandoned as it would involve excessive legislation at the Community level and consume an unreasonable period of time. Mutual recognition was the EEC's approach to solving this issue. This approach requires each country to recognize the laws, regulations, and administrative practices of the other member states as equivalent to its own and thereby precludes the use of differences in national rules to

	restrict access. The crucial prerequisite for mutual recognition is the harmonization of essential rules.
Notified Body	A notified body is generally a third party competent to perform the conformity assessment tasks provided for in the directive. Notified bodies are designated by a member state from among the bodies under its jurisdiction, meeting the competence criteria and requirements laid down in the directive and notified to the Commission. These bodies must comply with the relevant harmonized European standards (EN 45000).
Premarketing, or Premarket, Approval Application	An application to FDA for approval to market a new or transitional device. The sponsor of the device must submit information to FDA that documents the safety and effectiveness of the device before it may be marketed.
Premarketing, or Premarket, Notification	A manufacturer's notification of FDA of the intention to market a device. From the information the manufacturer supplies in its document, FDA determines whether the device is substantially equivalent to a preamendment or reclassified device. A device that is substantially equivalent to a class I or class II device is classified in the same class and may be marketed without premarketing approval or reclassification into class I or II. A device that is not substantially equivalent remains in class III as a new device and may not be marketed without such approval or petition to reclassify.
Product Liability	The EEC has enacted three directives that relate to product liability and affect the sale of products. The directives specify that a product will be deemed defective "when it does not provide the safety which a person is entitled to expect, taking into account all of the circumstances." The Commission has established that dangers should be designed out, guarded against if they cannot be designed out, and warned against if they cannot be eliminated by either design or guarding. It is anticipated that postsale obligations will be more clearly defined in the EEC with a greater burden on the manufacturer than is presently the situation in the United States.
Public Procurement Policies	Public procurement refers to government procedures established for the competitive purchasing of goods and equipment from manufacturers or distributors. The single market program includes directives designed to

eliminate barriers to intracommunity competition for public procurement contracts. In the past, discriminatory practices have been used by some national governments as a matter of public policy to exclude nonnational firms from competing against domestic companies. While the directive eliminates intracommunity discrimination, it will continue to allow procuring entities to discriminate against non-EEC products.

Quality Assurance Systems

Four quality assurance systems are in common use: quality control, good manufacturing practices, product assurance, and total quality assurance. Quality control is the minimal system emphasizing testing and inspection. Good manufacturing practices (GMP) is a government-mandated quality assurance system for medical device manufacturers. It emphasizes all aspects of production: facilities, equipment, design, production documentation, correct design transfer, production control, and production records. Thus, GMP systems include classical quality control activities. Product assurance is a quality assurance system that ensures customer needs are determined and product design requirements are established and met. Total quality assurance is a system that emphasizes that design requirements are established and met, process requirements are established and met, all production activities are controlled, and the finished product meets specifications. Note that a total quality system is the sum of a product assurance system and a GMP system.

Reciprocity

A concept that can be used as a means either to encourage trade liberalization or to restrict market access for foreign products. In the broadest sense, it can be defined as an overall balance of competitive opportunities available to the firms of two countries competing in each other's markets. Reciprocity can serve as a guideline for trade negotiations—for example, one country may grant certain concessions in return for concessions by other countries with the object of achieving an overall balance of concessions.

Rules of Origin

Rules of origin relate to laws, regulations, and administrative practices that are applied to ascribe a country of origin to goods in international commerce. They are applied in the customs procedures of importing countries to ensure that trade programs and regulations are properly implemented. They can become protectionist when they are overly strict or interact with other trade policies to create restrictive trade practices.

Substantially Equivalent Device	A device first marketed after the enactment of the Medical Device Amendments of 1976 that FDA has found to be similar to a class I or class II device because it has the same intended use and does not differ markedly in materials, design, energy source, or other features, although it need not be identical to a predicate device. It also includes devices with different technological characteristics that are shown to be as safe and effective as a legally marketed device and that do not raise different questions of safety and efficacy.
Trademark and Service Mark	Trademarks and service marks (logos, names, typographic designs, and so on) are used to apply to a company or institution itself or a proprietary service or product it provides. Trademarks or service marks, if properly registered, are legally protected from use by unauthorized persons.
Type Testing	Within the framework of the EEC, provisions have been established for a harmonized approach to product conformity, including testing of products and certification of conformity to the essential requirements. Testing and certification will be accomplished by accredited national laboratories.
Vertical Standard	Vertical standards relate to given product families and criteria—for example, cardiac pacemakers, compression hosiery, and catheters. The EEC is giving priority to the development of horizontal standards because of their broader application, as well as in the interest of meeting severe time constraints. See also Horizontal Standard.

Related GAO Products

Medical Technology: For Some Cardiac Pacemaker Leads, the Public Health Risks Are Still High (GAO/PEMD-92-20, Sept. 23, 1992).

"Medical Technology: Implementing the Good Manufacturing Practices Regulation," statement of Eleanor Chelimsky (GAO/T-PEMD-92-6, March 25, 1992).

Medical Technology: Quality Assurance Needs Stronger Management Emphasis and Higher Priority (GAO/PEMD-92-10, Feb. 13, 1992).

"Medical Device Problem Reporting: A Case Study of a Home Apnea Monitor," statement of Carl E. Wisler (GAO/T-PEMD-90-10, July 17, 1990).

Medical Devices: Underreporting of Serious Problems With a Home Apnea Monitor (GAO/PEMD-90-17, May 31, 1990).

"Medical Devices: Underreporting of Problems, Backlogged Systems, and Weak Statutory Support," statement of Eleanor Chelimsky (GAO/T-PEMD-90-3, Nov. 6, 1989).

"Medical Devices: The Public Health at Risk," statement of Charles A. Bowsher (GAO/T-PEMD-90-2, Nov. 6, 1989).

Medical Device Recalls: Examination of Selected Cases (GAO/PEMD-90-6, Oct. 19, 1989).

Medical Device Recalls: An Overview and Analysis 1983-88 (GAO/PEMD-89-15BR, Aug. 30, 1989).

Medical Devices: FDA's Implementation of the Medical Device Reporting Regulation (GAO/PEMD-89-10, Feb. 17, 1989).

Medical Devices: FDA's 510(k) Operations Could Be Improved (GAO/PEMD-88-14, Aug. 17, 1988).

Medical Devices: FDA's Forecasts of Problem Reports and FTEs Under H.R. 4640 (GAO/PEMD-88-30, July 11, 1988).

"Medical Devices: Early Warning of Problems Is Hampered by Severe Underreporting," statement of Eleanor Chelimsky (GAO/T-PEMD-87-4, May 4, 1987).

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