FRESENIUS MEDICAL CARE CORP
Form 20-F
March 02, 2004

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

o REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2003

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number _____

FRESENIUS MEDICAL CARE AKTIENGESELLSCHAFT

(Exact name of Registrant as specified in its charter)

FRESENIUS MEDICAL CARE CORPORATION

(Translation of Registrant s name into English)

Germany

(Jurisdiction of incorporation or organization)

Else-Kröner Strasse 1, 61352 Bad Homburg, Germany
(Address of principal executive offices)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
American Depositary Shares representing Preference Shares	**New York Stock Exchange**
Preference Shares, no par value	**New York Stock Exchange[(1)]**
American Depositary Shares representing Ordinary Shares	**New York Stock Exchange**
Ordinary Shares, no par value	**New York Stock Exchange[(1)]**

Securities registered or to be registered pursuant to Section 12(g) of the Act: None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: 7 7/8% USD Trust Preferred Securities due 2008, 7 3/8% DM Trust Preferred Securities due 2008, 7 7/8% USD Trust Preferred Securities due 2011, 7 3/8% Euro Trust Preferred Securities due 2011 and related guarantees

(1) Not for trading, but only in connection with the registration of American Depositary Shares representing such shares.

Indicate the number of outstanding shares of each of the issuer s classes of capital or common stock as of the close of the period covered by the annual report:

Preference Shares, no par value 26,213,919

Ordinary Shares, no par value 70,000,000

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days.

Yes x No o

Indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 o Item 18 x

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INTRODUCTION

Forward Looking Statements

This report contains forward-looking statements within the meaning of section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are based upon our current expectations, assumptions, estimates and projections about us and our industry that address, among other things:

- our business development, operating development and financial condition;
- our expectations of growth in the patient population regarding renal dialysis products and services;
- our expansion and acquisition plans and our capital expenditures budget;
- the impact of our expansion on our revenue potential, cost basis and margins;
- our ability to remain competitive in the markets for our products and services;
- the effects of regulatory developments, legal proceedings and our settlement of government investigations into our business;
- possible changes in government reimbursement policies and those of private payors;
- our ability to develop and maintain additional sources of financing; and
- other statements of our expectations, beliefs, future plans and strategies, anticipated development and other matters that are not historical facts.

When used in this report, the words expects , anticipates , intends , plans , believes , seeks , estimates and similar expressions are gene intended to identify forward looking statements. Although we believe that the expectations reflected in such forward-looking statements are reasonable, forward-looking statements are inherently subject to risks and uncertainties, many of which cannot be predicted with accuracy and some of which might not even be anticipated. Future events and actual results, financial and otherwise, could differ materially from those set forth in or contemplated by the forward-looking statements contained elsewhere in this report. Important factors that could contribute to such differences are noted in this report under Business Overview in Item 4. Information on the Company , Item 5. Operating and Financial Review and Prospects and Item 8.A.7. Legal Proceedings.

This report contains patient and other statistical data related to end-stage renal disease and treatment modalities, including estimates regarding the size of the patient population and growth in that population. These data have been included in reports published by organizations such as the Center for Medicare and Medicaid Services of the U.S. Department of Health and Human Services, the Japanese Society for Dialysis Therapy and the German registry Quasi-Niere. While we believe these surveys and statistical publications to be reliable, we have not independently verified the data or any assumptions on which the estimates they contain are based.

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PART I

Item 1. ***Identity of Directors, Senior Management and Advisors***

Not applicable

Item 2. ***Other Statistics and Expected Timetable***

Not applicable

Item 3. ***Key Information***

Selected Financial Data

The following table summarizes the consolidated financial information for our business for each of the years 1999 through 2003. We derived the selected financial information from our consolidated financial statements. We prepared our financial statements in accordance with accounting principles generally accepted in the United States of America and KPMG Deutsche Treuhand-Gesellschaft Aktiengesellschaft Wirtschaftsprüfungsgesellschaft, independent accountants, audited these financial statements. You should read this information together with our consolidated financial statements and the notes to those statements appearing elsewhere in this document and the information under Item 5. Operating and Financial Review and Prospects .

	2003[A]	2002[A]	2001[B]	2000	1999
			(In millions)		
Statement of Operations Data:					
Net revenues	$ 5,528	$ 5,084	$ 4,859	$ 4,201	$ 3,840
Cost of revenues	3,699	3,428	3,220	2,734	2,463
Gross profit	1,829	1,656	1,639	1,467	1,377
Selling, general and administrative	1,022	914	966	814	785
Research and development	50	47	36	32	32
Special charge			258		601
Operating income (loss)	757	695	379	621	(41)
Interest expense, net	211	226	223	216	218
Income (loss) before income taxes	546	469	156	405	(259)
Net income (loss)	$ 331	$ 290	$ 63	$ 212	$ (249)
Weighted average of:					
Preference shares outstanding	26,191,011	26,185,178	26,035,330	19,002,118	9,023,341
Ordinary shares outstanding	70,000,000	70,000,000	70,000,000	70,000,000	70,000,000
Basic income (loss) per Ordinary share	$ 3.42	$ 3.00	$ 0.65	$ 2.37	$ (3.15)
Fully diluted income (loss) per Ordinary share	3.42	3.00	0.64	2.36	(3.15)
Basic income (loss) per Preference share	3.49	3.06	0.70	2.43	(3.15)
	3.49	3.06	0.69	2.42	(3.15)

Fully diluted income (loss) per Preference share					
Basic and fully diluted net income (loss) per Ordinary ADS	1.14	1.00	0.22	0.79	(1.05)
Basic and fully diluted net income (loss) per Preference ADS	1.16	1.02	0.23	0.81	(1.05)
Dividends declared per Ordinary share ([a])	1.02(b)	0.94	0.85	0.78	0.69
Dividends declared per Preference share ([a])	1.08(b)	1.00	0.91	0.84	0.75
Dividends declared per Ordinary share ($)[a]		1.10	0.78	0.72	0.64
Dividends declared per Preference share ($) [a]		1.17	0.84	0.78	0.69

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	2003(A)	2002(A)	2001(B)	2000	1999
			(In millions)		
Balance Sheet Data					
Working capital	$ 794	$ 526	$ 402	$ 191	$ (229)
Total assets	7,503	6,780	6,516	5,979	5,752
Total long-term debt (c)	2,354	2,234	2,165	1,611	1,618
Shareholders equity (net assets)	3,244	2,807	2,617	2,679	2,002
Capital Stock Preference shares Nominal Value	70	70	70	64	28
Capital Stock Ordinary shares Nominal Value	229	229	229	229	229

(A) Includes the effect of an accounting change in 2002 relating to the adoption of SFAS No. 142, *Goodwill and Other Intangible Assets*, as of January 1, 2002 (see Note 1 of the Notes to our Consolidated Financial Statements).

(B) Includes the special charge to address 1996 merger related legal matters, estimated liabilities and legal expenses arising in connection with the W.R. Grace Chapter 11 proceedings and the cost of resolving pending litigation and other disputes with certain commercial insurers. You can find a more detailed discussion of this special charge in Note 3 of the Notes to our Consolidated Financial Statements.

(a) Amounts shown for each year from 1999 to 2002 represent dividends paid with respect to such year. The actual declaration and payment of the dividend was made in the following year, after approval of the dividend at our general meeting.

(b) Our managing board and our supervisory board have proposed dividends for 2003 of 1.08 per Preference share and 1.02 per Ordinary share. These dividends are subject to approval by our shareholders at our annual general meeting to be held on May 27, 2004.

(c) Total long-term debt represents long-term debt and capital lease obligations, less current portions and (i) at December 31, 1999 and 2000, the mandatorily redeemable preferred securities of Fresenius Medical Care Capital Trust, Fresenius Medical Care Capital Trust II, and Fresenius Medical Care Capital Trust III, (ii) at December 31, 2001, the mandatorily redeemable preferred securities of Fresenius Medical Care Capital Trust, Fresenius Medical Care Capital Trust II, Fresenius Medical Care Capital Trust III, Fresenius Medical Care Capital Trust IV, and Fresenius Medical Care Capital Trust V, (iii) at December 31, 2002 and 2003 the mandatorily redeemable preferred securities of Fresenius Medical Care Capital Trust II, Fresenius Medical Care Capital Trust III, Fresenius Medical Care Capital Trust IV, and Fresenius Medical Care Capital Trust V. On February 14, 2002, we redeemed the entire $360 million aggregate liquidation amount of the trust preferred securities of Fresenius Medical Care Capital Trust.

RISK FACTORS

Risks Relating to Litigation and Regulatory Matters in the U.S.

If we do not comply with the many governmental regulations applicable to our business or with the corporate integrity agreement between us and the U.S. government, we could be excluded from government health care reimbursement programs or our authority to conduct business could be terminated, either of which would result in a material decrease in our revenue

Our operations in both our provider business and our products business are subject to extensive governmental regulation in virtually every country in which we operate. The applicable regulations, which differ from country to country, relate in general to the safety and efficacy of medical products and supplies, the operation of manufacturing facilities, laboratories and dialysis clinics, the rate of, and accurate reporting and billing for, government and third-party reimbursement, and compensation of medical directors and other financial arrangements with physicians and other referral sources. We are also subject to other laws of general applicability, including antitrust laws.

Fresenius Medical Care Holdings Inc. (FMCH), our North American subsidiary, is party to a corporate integrity agreement with the U.S. government. This agreement requires that Fresenius Medical Care Holdings staff and maintain a comprehensive compliance program, including a written code of conduct, training programs, regulatory compliance policies and procedures, annual audits and periodic reporting to the government. The corporate integrity agreement permits the U.S. government to exclude Fresenius Medical Care Holdings and its subsidiaries from participation in U.S. federal health care programs if there is a material breach of the agreement that Fresenius Medical Care Holdings does not cure within thirty days after Fresenius Medical Care Holdings receives written notice of the breach. We derive approximately 43% of our consolidated revenue from U.S. federal health care benefit programs. Consequently, if Fresenius Medical Care Holdings commits a material breach of the corporate integrity agreement that results in the exclusion of Fresenius Medical Care Holdings or its

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subsidiaries from continued participation in those programs it would significantly decrease our revenue and have a material adverse effect on our business, financial condition and results of operations.

While we rely upon our management structure, regulatory and legal resources, and the effective operation of our compliance program to direct, manage and monitor these activities, if employees, deliberately or inadvertently, failed to adhere to these regulations then our authority to conduct business could be terminated or our operations could be significantly curtailed. Any such terminations or reductions could materially reduce our revenues with a resulting adverse impact on our business, financial condition and results of operations.

A reduction in U.S. government reimbursement for dialysis care could materially decrease our revenues

For the twelve months ended December 31, 2003 approximately 43% of our consolidated revenues resulted from Medicare and Medicaid reimbursement. Legislative changes may affect the reimbursement rates for the services we provide, as well as the scope of Medicare and Medicaid coverage. A decrease in Medicare or Medicaid reimbursement rates or covered services could have a material adverse effect on our business, financial condition and results of operations.

A change in reimbursement for or utilization of EPO could materially reduce our revenue and operating profit

Reimbursement and revenue from the administration of erythropoetin, or EPO, accounted for approximately 23% of dialysis care revenue in our North America segment for the twelve months ended December 31, 2003. EPO is produced by a single source manufacturer, Amgen Inc. Our current contract with Amgen covers the period from January 1, 2004 to January 31, 2006. A reduction in reimbursement for EPO, a significant change in utilization of EPO, a reduction of the current overfill amount in EPO vials, an interruption of supply or our inability to obtain satisfactory purchase terms for EPO after our current contract expires could reduce our revenues from, or increase our costs in connection with the administration of the EPO, which could materially adversely affect our business, financial condition and results of operations.

Creditors of W.R. Grace & Co. Conn. have asserted claims against us

We were formed in 1996 as a result of a series of transactions with W.R. Grace & Co that we refer to as the merger. At the time of the merger, W.R. Grace & Co.-Conn. had, and continues to have, significant liabilities arising out of product-liability related litigation (including asbestos), pre-merger tax claims and other claims unrelated to its dialysis business; in connection with the merger, W.R. Grace & Co.-Conn. and other Grace entities agreed to indemnify Fresenius Medical Care and its subsidiaries against all liabilities of W.R. Grace & Co., whether relating to events occurring before or after the merger, other than liabilities arising from or relating to National Medical Care s operations.

In addition, the merger was consummated as a tax free organization. Pre-merger tax claims or other tax claims that would arise if events were to violate the tax-free nature of the merger could ultimately be the obligation of our subsidiary, FMCH. In particular, W.R. Grace & Co. has publicly disclosed that its tax returns for the years 1993 through 1996 are under audit by the U.S. Internal Revenue Service, that it has paid tax and interest with respect to certain deductions taken prior to 1993 and that similar deductions were taken in the years under audit. Subject to certain representations made by W.R. Grace & Co.-Conn, FMCH and Fresenius AG, W.R. Grace & Co.-Conn. and other Grace entities also agreed to indemnify us against any such tax liability. W.R. Grace & Co.-Conn. and certain of its subsidiaries have filed for reorganization under Chapter 11 of the U.S. Bankruptcy Code (Grace Chapter 11 Proceedings). If W.R. Grace & Co.-Conn. s (and its affiliates in and out of bankruptcy) obligations to indemnify us are terminated or limited as a result of bankruptcy proceedings, and if we are held liable for pre-merger obligations of W. R. Grace & Co.-Conn. or if the merger is determined to be a taxable transaction, our business, financial condition and results of operations could be adversely affected.

In 2002, claims were brought against W.R. Grace & Co. and FMCH by plaintiffs claiming to be creditors of W.R. Grace & Co.-Conn. (asbestos creditors), principally alleging that the merger was a fraudulent conveyance, violated the uniform fraudulent transfer act, and constituted a conspiracy. We are also engaged in litigation with Sealed Air Corporation (with which W. R. Grace & Co.-Conn. conducted a multistep transaction

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subsequent to the merger) over our entitlement to indemnification from Sealed Air for losses and expenses we incur relating to pre-merger tax liabilities of W.R. Grace & Co. and merger-related claims.

In 2003, the Company reached an agreement with the asbestos creditors committees and W.R. Grace & Co. in the Grace Chapter 11 Proceedings to settle these fraudulent conveyance and tax claims. The settlement agreement has been approved by the U.S. District Court. The proposed settlement is subject to confirmation of a final plan of reorganization of W.R. Grace & Co. that meets the requirements of the settlement agreement or is otherwise satisfactory to us. If the proposed settlement with the asbestos creditors committees and W.R. Grace & Co. is not confirmed in such a final plan of reorganization, the claims could be reinstated. If the claims are reinstated and the merger is determined to be a fraudulent transfer and if material damages are proved by the plaintiffs and we are not able to collect, in whole or in part, on the indemnity from any of our indemnitors, a judgment could have a material adverse effect on our business, financial condition and results of operations. We recorded a pre-tax accrual of $172 million at December 31, 2001 to reflect our estimated exposure for liabilities and expenses related to the Grace Chapter 11 Proceedings. See Note 3 to our consolidated financial statements. For additional information concerning the Grace Chapter 11 Proceedings and the settlement agreement see Item 8.A.7 Legal Proceedings.

As health maintenance organizations and other managed care plans grow, amounts paid for our services and products by non-governmental payors could decrease

We obtain a significant portion of our revenues from reimbursement provided by non-governmental third-party payors. Although non-governmental payors generally pay at higher reimbursement rates than governmental payors, managed care plans generally negotiate lower reimbursement rates than indemnity insurance plans. Some managed care plans and indemnity plans also utilize a capitated fee structure or limit reimbursement for ancillary services.

As managed care programs have increased market share, there has been increased pressure to reduce the amounts paid for our services and products. These trends may be accelerated if future changes to the U.S. Medicare ESRD program require private payors to assume a greater percentage of the total cost of care given to dialysis patients over the term of their illness, or if managed care plans otherwise significantly increase their enrollment of renal patients.

If managed care plans reduce reimbursements, our revenues could decrease, and our financial condition and results of operations could be materially adversely affected.

Proposals for health care reform could decrease our revenues

Proposals to modify the current health care system in the U.S. to improve access to health care and control its costs are continually being considered by the federal and certain state governments. See Regulatory and Legal Matters-Reimbursement- U.S. for a discussion of the recently enacted Medicare Prescription Drug Modernization and Improvement Act of 2003. We anticipate that the U.S. Congress and state legislatures will continue to review and assess alternative health care reforms, and we cannot predict whether these reform proposals will be adopted, when they may be adopted or what impact they may have on us. Any spending decreases or other significant changes in the Medicare program could reduce our revenues and profitability and have a material adverse effect on our business, financial condition and results of operations.

Other countries, especially those in Western Europe, have also considered health care reform proposals and could materially alter their government-sponsored health care programs by reducing reimbursement payments. Any reduction could affect the pricing of our products and the profitability of our services, especially as we expand our international business. This potential development could have a material adverse effect on our business, financial condition and results of operations.

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Risks Relating to our Business

Our competitors could develop superior technology or impact our product sales

We face numerous competitors in both our dialysis services business and our dialysis products business, some of which may possess substantial financial, marketing or research and development resources. Competition could materially adversely affect the future pricing and sale of our products and services. In particular, technological innovation has historically been a significant competitive factor in the dialysis products business. The introduction of new products by competitors could render one or more of our products obsolete.

We are engaged in both manufacturing dialysis products and providing dialysis services. We compete in the dialysis services business with many customers of our products business. As a result, independent dialysis clinics, those operated by other chains and dialysis centers acquired by other products manufacturers may elect to limit or terminate their purchases of our dialysis products so as to avoid purchasing products manufactured by a competitor. In addition, as consolidation in the dialysis services business continues and other vertically integrated dialysis companies expand, the external market for our dialysis products could be reduced. Possible purchase reductions could decrease our product revenues, with a material adverse effect on our business, financial condition and results of operations.

We also compete with other dialysis products and services companies in seeking selected acquisitions. If we are not able to continue to effect acquisitions in the provider business in our International segment upon reasonable terms there could be an adverse impact on the growth of our business and our future growth prospects.

We face products liability and other claims which could result in significant liability

Health care companies are subject to claims alleging negligence, products liability, breach of warranty, malpractice and other legal theories that may involve large claims and significant defense costs whether or not liability is ultimately imposed. Health care products may also be subject to recalls. Although product liability claims and recalls have not had a material adverse effect on our businesses in the past, we cannot assure that we will not suffer one or more significant claims or product recalls in the future. Product liability claims or recalls could result in judgments against us or significant compliance costs, which could materially adversely affect our business, financial condition and results of operations.

While we have been able to obtain liability insurance in the past, it is possible that such insurance may not be available in the future either on acceptable terms or at all. A successful claim in excess of the limits of our insurance coverage could have a material adverse effect on our results of operations and financial condition. Liability claims, regardless of their merit or eventual outcome, also may have a material adverse effect on our business and reputation, which could in turn reduce our revenues and profitability.

If physicians and other referral sources cease referring patients to our dialysis clinics or cease purchasing our dialysis products, our revenues would decrease

Our dialysis services business is dependent upon patients choosing our clinics as the location for their treatments. Patients may select a clinic based, in whole or in part, on the recommendation of their physician. We believe that physicians and other clinicians typically consider a number of factors when recommending a particular dialysis facility to an ESRD patient, including, but not limited to, the quality of care at a clinic, the competency of a clinic s staff, convenient scheduling, and a clinic s location and physical condition. Physicians may change their facility recommendations at any time, which may result in the movement of our existing patients to competing clinics, including clinics established by the physicians themselves. At most of our clinics, a relatively small number of physicians account for the referral of all or a significant portion of the patient base. If a significant number of physicians ceased referring their patients to our clinics, this could reduce our dialysis care revenue and materially adversely affect our overall operations. Our operations are also affected by referrals from hospitals, managed care plans and other sources.

The decision to purchase our dialysis products and other services or competing dialysis products and other services will be made in some instances by medical directors and other referring physicians at our dialysis clinics and by the managing medical personnel and referring physicians at other dialysis clinics, subject to applicable

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regulatory requirements. A decline in physician recommendations or purchases of our products or ancillary services could reduce our dialysis product and other services revenue, and materially adversely affect our business, financial condition and results of operations.

If we are unable to attract and retain skilled medical, technical and engineering personnel, we may be unable to manage our growth or continue our technological development

Our continued growth in the provider business will depend upon our ability to attract and retain skilled employees, such as highly skilled nurses and other medical personnel. Competition for those employees is intense. Moreover, we believe that future success in the provider business will be significantly dependent on our ability to attract and retain qualified physicians to serve as medical directors of our dialysis clinics. Our dialysis products business depends on the development of new products, technologies and treatment concepts. Competition is also intense for skilled engineers and other technical research and development personnel. If we are unable to obtain the services of key personnel, the ability of our officers and key employees to manage our growth would suffer and our operations could suffer in other respects. These factors could preclude us from integrating acquired companies into our operations, which could increase our costs and prevent us from realizing synergies from acquisitions. Lack of skilled research and development personnel could impair our technological development, which would increase our costs and impair our reputation for production of technologically advanced products.

We face additional costs and uncertainties from international operations

We intend to expand our international presence. As a result, we expect that revenues from countries other than the U.S. and Germany will account for an increasing portion of future revenues.

Revenues from international operations are subject to a number of risks, including the following:

Fluctuations in exchange rates could adversely affect profitability;

We could face difficulties in enforcing and collecting accounts receivable under some countries legal systems;

Local regulations could restrict our ability to obtain a direct ownership interest in dialysis clinics or other operations;

Political instability, especially in developing countries, could disrupt our operations;

Some customers and governments could have longer payment cycles, with resulting adverse effects on our cash flow; and

Some countries could impose additional taxes or restrict the import of our products.

The continuing financial crisis in Latin America and the decline of many of its major currencies against the U.S. dollar have affected our international operations and caused us to test our Latin America operations for impairment. See Item 5, Operating and Financial Review and Prospects-Financial Condition and Results of Operations. Any one or more of these factors, or any difficulty in integrating businesses we acquire into our operations, could increase our costs, reduce our revenues, or disrupt our operations, with possible material adverse effects on our business, financial condition and results of operations.

Other Risks

Our significant indebtedness may limit our ability to pay dividends or implement certain elements of our business strategy

We are substantially leveraged. As of December 31, 2003, our total consolidated liabilities were $4.26 billion, including obligations with respect to all our trust preferred securities of approximately $1.2 billion, our total consolidated assets were $7.50 billion and our stockholders equity was $3.24 billion. Our substantial level of debt presents the risk that we might not generate sufficient cash to service our indebtedness or that our

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leveraged capital structure could limit our ability to finance acquisitions and develop additional projects, to compete effectively or to operate successfully under adverse economic conditions.

Our senior credit agreement and the indentures relating to our trust preferred securities include covenants that require us to maintain certain financial ratios or meet other financial tests. Under our senior credit agreement, we are obligated to maintain a minimum consolidated net worth and a minimum consolidated fixed charge ratio (ratio of consolidated earnings before interest, taxes, depreciation, amortization and rent (EBITDAR) to fixed charges) and we are subject to a limit on our consolidated leverage ratio (ratio of consolidated funded debt to EBITDA).

Our senior credit agreement and our indentures include other covenants which, among other things, restrict or have the effect of restricting our ability to dispose of assets, incur debt, pay dividends, create liens or make capital expenditures, investments or acquisitions. These covenants may otherwise limit our activities. The breach of any of the covenants could result in a default under the credit agreement or the indentures, which could, in turn, create additional defaults under the agreements relating to our other long term indebtedness.

Because we are not organized under U.S. law, we are subject to certain less detailed disclosure requirements under U.S. federal securities laws

Under pooling agreements that we have entered into for the benefit of minority holders of our Ordinary shares and holders of our Preference shares (including, in each case, holders of American Depositary Receipts representing beneficial ownership of such shares), we have agreed to file quarterly reports with the Securities and Exchange Commission, to prepare annual and quarterly financial statements in accordance with U.S. generally accepted accounting principles, and to file information with the Securities and Exchange Commission with respect to annual and general meetings of our shareholders. However, we are a foreign private issuer, as defined in the Securities and Exchange Commission s regulations, and consequently we are not subject to all of the same disclosure requirements applicable to domestic companies. We are exempt from the Securities and Exchange Commission s proxy rules, and our annual reports contain less detailed disclosure than reports of domestic issuers regarding such matters as management, executive compensation and outstanding options, beneficial ownership of our securities and certain related party transactions. Also, our officers, directors and beneficial owners of more than 10% of our equity securities are exempt from the reporting requirements and short-swing profit recovery provisions of Section 16 of the Securities Exchange Act of 1934. We are also generally exempt from most of the governance rule revisions recently adopted by the New York Stock Exchange, other than the obligation to maintain an audit committee in accordance with Rule 10A-3 under the Securities Exchange Act of 1934, as amended. These limits on available information about our company may adversely affect the market prices for our securities.

Item 4. *Information on the Company*

A. History and Development of the Company

General

Fresenius Medical Care AG is a stock corporation (Aktiengesellschaft) organized under the laws of Germany. It was incorporated on August 5, 1996. Fresenius Medical Care AG is registered with the commercial register of the local court *(Amtsgericht)* of Hof an der Saale, Germany under HRB 2460. Our registered office *(Sitz)* is Hof an der Saale, Germany. Our business address is Else-Kröner-Strasse 1, 61352 Bad Homburg, Germany, telephone ++49-6172-609-0.

History

Fresenius Medical Care AG was created by the conversion of Sterilpharma GmbH, a limited liability company under German law organized in 1975, into a stock corporation under German law *(Aktiengesellschaft)*. A shareholder s meeting on April 17, 1996 adopted the resolutions for this conversion and the commercial register registered the conversion on August 5, 1996.

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On September 30, 1996, we completed a series of transactions to consummate an Agreement and Plan of Reorganization entered into on February 4, 1996 by Fresenius AG and W.R. Grace which we refer to as the Merger elsewhere in this report. Pursuant to that agreement, Fresenius AG contributed Fresenius Worldwide Dialysis, its global dialysis business, including its controlling interest in Fresenius USA, Inc., in exchange for 35,210,000 Fresenius Medical Care Ordinary shares. Thereafter, we acquired:

all of the outstanding common stock of W.R. Grace, whose sole business at the time of the transaction consisted of National Medical Care, Inc., its global dialysis business, in exchange for 31,360,000 Ordinary shares; and

the publicly-held minority interest in Fresenius USA, in exchange for 3,430,000 Ordinary shares.

Effective October 1, 1996, we contributed all our shares in Fresenius USA to Fresenius Medical Care Holdings, which conducts business under the trade name Fresenius Medical Care North America, and which is the holding company for all of our operations in the U.S. and Canada and manufacturing operations in Mexico.

Capital Expenditures

We invested, by business segment and geographical areas, the following amounts during the three fiscal years ended December 31, 2003, 2002 and 2001 and have budgeted the following amounts for the year 2004:

	Actual (in millions)			Budget
	2003	2002	2001	2004
Acquisitions				
North America	$ 43	$ 38	$412	
International				
Germany	13			
Rest of World	45	50	49	
Total Acquisitions	$101	$ 88	$461	$100
Capital expenditures for property, plant and equipment				
North America	$177	$130	$138	
International				
Germany	28	27	34	
Rest of World	86	82	103	
Total Capital Expenditures	$291	$239	$275	$250

During 2003, we finished the construction of three dialyzer assembly lines and two fiber spinning lines in our Ogden, Utah production facility. These expenditures were part of an effort to increase our single use dialyzer manufacturing capacity by 200% as part of our UltraCare program (see Business Overview Dialysis Care Fresenius UltraCare Program). In Asia Pacific we continued investment in production facilities. Other major 2003 capital expenditures were made for the improvement of production facilities in Germany, Italy and France. We finance our capital expenditures through cash flow from operations or under existing credit facilities.

In December 2003, we exercised an option to terminate an operating lease for certain manufacturing equipment in its Ogden, Utah, North American facility. The equipment was purchased for approximately $66 million and is reflected as a capital expenditure in the accompanying consolidated statement of cash flows.

For information regarding recent acquisitions, see Business Overview Acquisitions.

B. Business Overview

Our Business

We are the world s largest kidney dialysis company engaged in both providing dialysis care and manufacturing dialysis products, based on publicly reported revenues and patients treated. We provide dialysis

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treatment to over 119,000 patients at our 1,560 clinics located in 25 countries. In the U.S. we also provide inpatient dialysis services, therapeutic apheresis, hemoperfusion and other services under contract to hospitals. We also develop and manufacture a complete range of equipment, systems and disposable products, which we sell to customers in over 100 countries. We use the information we gain when treating patients in developing new and improved products. We believe that our size, our activities in both dialysis care and dialysis products and our concentration in specific geographic areas allow us to operate more cost-effectively than many of our competitors. For the year ended December 31, 2003, we had net revenues of $5.5 billion, an increase of 9% over 2002 revenues. We derived 70% of our revenues in 2003 from our North America operations and 30% from our International operations.

The following table summarizes net revenues for our North America segment and our International segment as well as our major categories of activity for the three years ended December 31, 2003, 2002 and 2001.

	2003	2002	2001
		(in millions)	
North America			
Dialysis Care	$3,429	$3,294	$3,131
Dialysis Products[(1)]	426	454	471
	3,855	3,748	3,602
International			
Dialysis Care	550	415	426
Dialysis Products	1,123	921	831
	1,673	1,336	1,257

(1) We evaluate North America product sales based on net available external market. See Item 5.A. Operating Results for explanation and analysis.

Renal Industry Overview

End-Stage Renal Disease

End-stage renal disease (ESRD) is the stage of advanced chronic kidney disease that is characterized by the irreversible loss of kidney function and requires regular dialysis treatment or kidney transplantation to sustain life. A normally functioning human kidney removes waste products and excess water from the blood, which prevents toxin buildup, water overload and the eventual poisoning of the body. A number of conditions diabetes, hypertension, glomerulonephritis and inherited diseases can cause chronic kidney disease. Nearly 60% of all people with ESRD acquire the disease as a complication of one or more of these primary conditions.

There are currently only two methods for treating ESRD: dialysis and kidney transplantation. Scarcity of compatible kidneys limits transplants. According to data published by the Centers for Medicare and Medicaid Services (CMS) (formerly the Health Care Financing Administration) of the U.S. Department of Health and Human Services, 14,628 patients of the ESRD patient population, received kidney transplants in the U.S. during 2001 an increase of 2% over 2000. According to the United States Renal Data System (USRDS) 2002 Annual Report only 2 - 3% of all incident patients received a pre-emptive transplant in 2000. In Germany, the third biggest dialysis market worldwide according to our own internal survey, less than 1% of all incident patients received pre-emptive transplants, as published by the German registry Quasi-Niere. Therefore, most patients suffering from ESRD must rely on dialysis, which is the removal of toxic waste products and excess fluids from the body by artificial means. There are two major dialysis methods commonly used today, hemodialysis (HD) and peritoneal dialysis (PD). These are described below under Treatment Options for ESRD. Generally, an ESRD patient s physician, in consultation with the patient, chooses the patient treatment method, which is based on the patient s medical conditions and needs.

Based on data published by the CMS, the number of patients in the U.S. who received dialysis for chronic ESRD grew from approximately 66,000 in 1982 to 285,982 at December 31, 2001, a compound annual rate of 8%. We believe that growth will continue at 4 - 6% per year. According to data from our own internal survey, the

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number of non-U.S. chronic dialysis patients is growing at estimated annual rates of 7 - 8% for patients receiving dialysis. At the end of 2002, an estimated 1.2 million patients were undergoing dialysis treatment worldwide. According to our own market surveys, Japan is the second largest dialysis market in the world. According to data published by the Japanese Society for Dialysis Therapy, more than 200,000 dialysis patients were being treated at the end of 2000. In the rest of the world, we estimate that at the end of 2002 there were approximately 292,000 dialysis patients in Europe, approximately 160,000 patients in Asia (excluding Japan) and approximately 143,000 patients in Latin America. We believe that the continuing growth in the number of dialysis patients is principally attributable to:

- increased general life expectancy and the overall aging of the general U.S. and European population;
- shortage of donor organs for kidney transplants;
- improved dialysis technology that has expanded the patient population able to undergo life-prolonging dialysis;
- greater access to treatment in developing countries.
- better treatment and survival of patients with hypertension, diabetes and other illnesses that lead to ESRD.

Treatment Options for ESRD

Hemodialysis. Hemodialysis removes toxins and excess fluids from the blood whereby the blood flows outside the body through plastic tubes known as bloodlines into a specially designed filter, called a dialyzer. The dialyzer functions as an artificial kidney by separating waste products and excess water from the blood. Dialysis solution flowing through the dialyzer carries away the waste products and excess water, and supplements the blood with solutes that have been depleted due to renal failure. The treated blood is returned to the patient. The hemodialysis machine pumps blood, adds anti-coagulants, regulates the purification process and controls the mixing of dialysis solution and the rate of its flow through the system. This machine can also monitor and record the patient s vital signs.

Hemodialysis patients generally receive treatment three times per week, typically for around three to five hours per treatment. The majority of hemodialysis patients receive treatment at outpatient dialysis clinics, such as ours, where hemodialysis treatments are performed with the assistance of a nurse or dialysis technician under the general supervision of a physician.

According to data from the CMS, as of December 31, 2001, there were 4,081 Medicare-certified ESRD treatment clinics in the U.S. Ownership of these clinics is fragmented. We estimate that there were approximately 4,900 dialysis clinics in Europe at the end of 2002, of which almost 60% are government-owned, more than 30% are privately owned, and around 10% are operated by health care organizations. In Latin America, privately owned clinics predominate, comprising over 70% of all clinics providing dialysis care.

According to the CMS, as of December 31, 2001, hemodialysis patients represented about 90% of all dialysis patients in the U.S. Our most recent studies indicate hemodialysis patients comprise 95% of all dialysis patients in Japan, 89% in the European Union and 85% in the rest of the world.

Peritoneal Dialysis. Peritoneal dialysis removes toxins from the blood using the peritoneum, the membrane lining covering the internal organs located in the abdominal area. Peritoneal dialysis patients administer their own treatments in their own homes and workplaces, either by a treatment known as continuous ambulatory peritoneal dialysis or CAPD, or by a treatment we introduced in 1980 known as continuous cycling peritoneal dialysis or CCPD. In both of these treatments, a surgically implanted catheter provides access to the peritoneal cavity. Using this catheter, the patient introduces a sterile dialysis solution from a solution bag through a tube into the peritoneal cavity. The peritoneum operates as the filtering membrane and, after a specified dwell time, the solution is drained and disposed of. A typical CAPD peritoneal dialysis program involves the introduction and disposal of dialysis solution four times a day. With CCPD a machine cycles solution to and from the patient s peritoneal cavity while the patient sleeps.

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Our Strategy

Our objective is generating revenue growth that exceeds market growth of the dialysis industry, measured by growth in the patient population, while maintaining our leading position in the market and increasing earnings at a faster pace than revenues. Our dialysis care and product revenues have grown faster than the market over the past five years, and we believe that we are well positioned to meet our objectives by focusing on the following strategies:

Continue to Provide High Standards of Patient Care. We believe that our reputation for providing the highest standards of patient care is a competitive advantage.

Differentiated Patient Care Programs from those of Our Competitors. We believe that our UltraCare Patient Care program offered at our North America dialysis facilities will distinguish and differentiate our patient care programs from those of our competitors. UltraCare therapy employs single-use high flux polysulfone dialyzers, on-line quality measurement, and Ultra Pure Dialysate, all of which we feel improves mortality and increases the quality of patient care. The change to single-use dialyzers has increased our per treatment dialyzer costs relative to use of multi-use dialyzers. These cost increases have been offset, however, by our ability to achieve economies of scale in the production of these dialyzers, due to our large-scale single-use dialyzer manufacturing capacity. Moreover, we have implemented a new staffing model based on single-use that reduces our personnel costs per treatment. Finally, automated controls in our new 2008 Series dialysis machine reduces concentrate usage and associated costs.

Expand Presence in Attractive Growth Markets Worldwide. We intend to continue to take advantage of the reputation and market recognition our global product business has created by acquiring and establishing new dialysis clinics within attractive international markets. We believe that we will obtain an increasing percentage of our dialysis care growth from worldwide markets. We believe that increases in per capita income in developing countries will make general health care benefits, which may include payment for dialysis treatment, more widely available and present significant opportunities.

Increase Our Spectrum of Dialysis Services. One of our objectives is to continue to expand our role within the broad spectrum of services for dialysis patients. We have begun to implement this strategy by providing expanded and enhanced patient services, including laboratory services, to both our own clinics and those of third parties. We estimate that our Spectra Renal Management division provides laboratory services for approximately 39% of the ESRD patients in the U.S. We have developed disease state management methodologies, which involve the coordination of total patient care for ESRD patients and which we believe are attractive to managed care payors. We have formed Optimal Renal Care, LLC, a joint venture with The Permanente Federation. We also formed Renaissance Health Care as a joint venture with participating nephrologists. Renaissance provides ESRD and Chronic Kidney Disease programs to more than 3,000 patients. We also operate a surgical center for the management and care of vascular access for patients which decreases hospitalization.

Offer Complete Dialysis Product Lines with Recurring Disposable Products Revenue Streams. We offer broad and competitive hemodialysis and peritoneal dialysis product lines. These product lines enjoy broad market acceptance and enable us to serve as our customers single source for all of their dialysis machines, systems and disposable products.

Extend Our Position as an Innovator in Product and Process Technology. We are committed to technological leadership in both hemodialysis and peritoneal dialysis products. We have an over 388 member research and development team that focuses on developing dialysis systems that are safer, more effective and easier to use and that can be easily customized to meet the differing needs of customers around the world. We believe that our extensive expertise in patient treatment and clinical data will further enhance our ability to develop more effective products and treatment methodologies. Our ability to manufacture dialysis products on a cost-effective and competitive basis results in large part from our process technologies. Over the past several years, we have reduced manufacturing costs per unit through development of proprietary manufacturing technologies that have streamlined and automated our production processes.

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Dialysis Care

Dialysis Services

We provide dialysis treatment and related laboratory and diagnostic services at our approximately 1,560 outpatient dialysis clinics, 1,110 of which are in the U.S. and 450 of which are in 23 countries outside of the U.S. Our operations outside the U.S. generated 14% of our 2003 dialysis care revenue. We currently operate dialysis clinics in Argentina, Australia, Brazil, China, Colombia, Chile, Czech Republic, France, Germany, Hungary, Hong Kong, Italy, Singapore, Mexico, Portugal, Poland, Slovakia, Slovenia, South Africa, Spain, Taiwan, Turkey, United Kingdom and Venezuela. Our dialysis clinics are generally concentrated in areas of high population density. In 2003, we acquired 42 existing clinics, opened 76 new clinics and consolidated 38 clinics. The number of patients we treat at our clinics increased by about 6%, from approximately 112,200 at December 31, 2002 to approximately 119,250 at December 31, 2003.

With our large patient population, we have developed proprietary patient statistical databases which enable us to improve dialysis treatment outcomes, and improve the quality and effectiveness of dialysis products. We believe that local physicians, hospitals and managed care plans refer their ESRD patients to our clinics for treatment due to:

our reputation for quality patient care and treatment;

our extensive network of dialysis clinics, which enables physicians to refer their patients to conveniently located clinics; and

our reputation for technologically advanced products for dialysis treatment.

We treat approximately 26% of the dialysis patients in the U.S. including those patients treated in clinics we manage. Based on publicly available reports, we believe our next largest competitor treats approximately 15% of U.S. dialysis patients. For the year 2003, dialysis services accounted for 72% of our total revenue.

At our clinics, we provide hemodialysis treatments at individual stations through the use of dialysis machines and disposable products. A nurse attaches the necessary tubing to the patient and the dialysis machine and monitors the dialysis equipment and the patient s vital signs. The capacity of a clinic is a function of the number of stations and such factors as type of treatment, patient requirements, length of time per treatment, and local operating practices and ordinances regulating hours of operation.

Each of our dialysis clinics is under the general supervision of a Medical Director and, in some cases, one or more associate Medical Directors, all of whom are physicians. See Patients, Physician and Other Relationships. Each dialysis clinic also has an administrator or clinical manager who supervises the day-to-day operations of the facility and the staff. The staff typically consists of registered nurses, licensed practical nurses, patient care technicians, a social worker, a registered dietician, a unit clerk and biomedical technicians.

As part of the dialysis therapy, we provide a variety of services to ESRD patients in the U.S. at our dialysis clinics. These services include administering EPO, a bioengineered protein that stimulates the production of red blood cells. EPO is used to treat anemia, a medical complication that ESRD patients frequently experience, and we administer EPO to most of our patients. Revenues from EPO accounted for approximately 23% of dialysis care revenue in our North America segment for the year ended December 31, 2003. We receive a substantial majority of this revenue as reimbursements through the Medicare and Medicaid programs. Amgen Inc., is the sole manufacturer of EPO in North America, and any interruption of supply could materially adversely affect our business, financial condition and results of operations. Our current contract with Amgen covers the period from January 2004 to January 2006.

Our clinics also offer services for home dialysis patients, the majority of whom receive peritoneal dialysis treatment. For those patients, we provide materials, training and patient support services, including clinical monitoring, follow-up assistance and arranging for delivery of the supplies to the patient s residence. In the U.S. clinic services include the supplying of EPO. See Regulatory and Legal Matters Reimbursement U.S. for a discussion of billing for these products and services.

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We also provide dialysis services under contract to hospitals in the U.S. on an as needed basis for hospitalized ESRD patients and for patients suffering from acute kidney failure. Acute kidney failure can result from trauma or similar causes, and requires dialysis until the patient s kidneys recover their normal function. We service these patients either at their bedside, using portable dialysis equipment, or at the hospital s dialysis site. Contracts with hospitals provide for payment at negotiated rates that are generally higher than the Medicare reimbursement rates for chronic in-clinic out-patient treatments.

We employ a centralized approach with respect to certain administrative functions common to our operations. For example, each dialysis clinic uses our proprietary manuals containing our standardized operating and billing procedures. We believe that centralizing and standardizing these functions enhance our ability to perform services on a cost-effective basis.

The manner in which each clinic conducts its business depends, in large part, upon applicable laws, rules and regulations of the jurisdiction in which the clinic is located, as well as our clinical policies. However, a patient s attending physician, who may be the clinic s Medical Director or an unaffiliated physician with staff privileges at the clinic, has medical discretion to prescribe the particular treatment modality and medications for that patient. Similarly, the attending physician has discretion in prescribing particular medical products, although the clinic typically purchases equipment, regardless of brand, in consultation with the Medical Director.

Fresenius UltraCare Program

In 2002, we started a new program in the North America dialysis services group called UltraCare. This program combines our latest product technology with our highly trained and skilled staff to offer our patients a superior level of care. The basis for this form of treatment is the Optiflux polysulfone single-use dialyzer. These dialyzers have excellent blood detoxification properties and are the most efficient dialyzers currently available. Optiflux dialyzers are combined with our 2008 Hemodialysis Delivery System series, which has advanced online patient monitoring as well as several systems to allow the tailoring of treatment to meet individual patient needs. Among the other capabilities of this system, staff will be alerted if toxin clearance is less than the target prescribed for the patient, and treatment can be adjusted accordingly.

Laboratory Services

We provide laboratory testing and marketing services through Spectra Renal Management. Spectra Renal Management is the leading U.S. dialysis clinical laboratory providing blood, urine and other bodily fluid testing services to assist physicians in determining whether a dialysis patient s therapy regimen, diet and medicines remain optimal. Spectra Renal Management operates two laboratories, located in New Jersey and Northern California. During the year ended December 31, 2003, Spectra Renal Management performed over 38 million tests for more than 120,000 dialysis patients in 1,758 clinics across the U.S. including clinics that we do own or operate.

Acquisitions

A significant factor in the growth in our revenue and operating earnings in prior years has been our ability to acquire health care businesses, particularly dialysis clinics, on reasonable terms. Worldwide, physicians own many dialysis clinics that are potential acquisition candidates for us. In the U.S., doctors might determine to sell their clinics to obtain relief from day-to-day administrative responsibilities and changing governmental regulations, to focus on patient care and to realize a return on their investment. Outside of the U.S., doctors might determine to sell and/or enter into joint ventures or other relationships to us to achieve the same goals and to gain a partner with extensive expertise in dialysis products and services.

We paid aggregate cash consideration for acquisitions of Fresenius AG s adsorber business and new clinics of approximately $92 million in 2003 and approximately $80 million in 2002, primarily for dialysis clinics. In 2003, we completed new acquisitions and acquisitions of previously managed clinics totaling 42 dialysis facilities. These acquisitions expand our presence in selected key geographic areas.

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We continued to enhance our presence in the U.S. and abroad by acquiring individual or small groups of dialysis clinics in selected markets, expanding existing clinics, and opening new clinics.

Quality Assurance in Dialysis Care

Beginning in 2001, our quality management activities were primarily focused on comprehensive development and implementation of an Integrated Quality Management System (IMS). Our goals in this area included not only meeting quality requirements for our dialysis clinics and environmental concerns, but also managing the quality of our dialysis care. This approach resulted in an IMS structure that closely reflects existing corporate processes. We also were able to use the IMS to fulfill many legal and normative regulations covering service lines. In addition, the IMS offers a highly flexible structure that allows us to adapt to future regulations. The most important of these include, among others, ISO 9001, EN 46001, ISO 13485, and 21 CFR 820 which establish quality control and other performance criteria.

In 2003, internal and external auditors inspected our dialysis clinics. They confirmed the effectiveness of our organization and processes and documented our compliance with relevant regulations. The use of newly developed evaluation methods allowing simpler performance comparisons identified additional improvement possibilities. Another focus of our activities in 2003 was the continuing certification of our dialysis clinics under ISO 9001, EN 46001, ISO 13485, and 21 CFR 820 .

The rapid pace of IMS integration will continue in 2004. The integration of a new risk and complaint management system and the further involvement of our subsidiaries in the Asian-Pacific and Latin American regions are additional goals.

At each of our North America dialysis clinics, a quality assurance committee is responsible for reviewing quality of care data, setting goals for quality enhancement and monitoring the progress of quality assurance initiatives. We believe that we enjoy a reputation of providing high quality care to dialysis patients. In 2003, the Company continued to develop and implement programs to assist in achieving our quality goals. Our Access Intervention Management Program (AIM), started in 2001, detects and corrects arteriovenous access failure in hemodialysis treatment, which is the major cause of hospitalization and morbidity.

Sources of U.S. Dialysis Care Net Revenue

The following table provides information for the years ended December 31, 2003, 2002 and 2001 regarding the percentage of our U.S. dialysis treatment services net revenues from (a) the Medicare ESRD program, (b) private/ alternative payors, such as commercial insurance and private funds, (c) Medicaid and other government sources and (d) hospitals.

	Year Ended December 31,		
	2003	**2002**	**2001**
Medicare ESRD program	61.0%	61.5%	59.7%
Private/alternative payors	29.2%	29.5%	31.2%
Medicaid and other government sources	3.9%	4.5%	4.6%
Hospitals	5.9%	4.5%	4.5%
Total	100.0%	100.0%	100.0%

Under the Medicare ESRD program, Medicare reimburses dialysis providers for the treatment of certain individuals who are diagnosed as having ESRD, regardless of age or financial circumstances. See Regulatory and Legal Matters Reimbursement.

Patient, Physician and Other Relationships

We believe that our success in establishing and maintaining dialysis clinics, both in the U.S. and in other countries, depends significantly on our ability to obtain the acceptance of and referrals from local physicians,

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hospitals and managed care plans. A dialysis patient generally seeks treatment at a conveniently located clinic at which the patient s nephrologist has staff privileges.

Medicare ESRD program reimbursement regulations require that a Medical Director generally supervise treatment at a dialysis clinic. Generally, the Medical Director must be board certified or board eligible in internal medicine and have at least twelve months of training or experience in the care of patients at ESRD clinics. Our Medical Directors also maintain their own private practices.

Competition

Dialysis Services. The dialysis services industry is highly competitive. Our major competitors in dialysis services include Gambro AB, DaVita, Inc. (formerly Total Renal Care), Baxter International Inc., Renal Care Group and the Kuratorium für Dialyse und Nierentransplantation e.V. Ownership of dialysis clinics in the U.S. is fragmented with a large number of operators each owning 10 or fewer clinics and a small number of larger multi-clinic providers, of which we are the largest. Industry consolidation has been ongoing over the last decade. Many of our dialysis clinics are in urban areas, where there frequently are many competing clinics in proximity to our clinics. We experience direct competition from time to time from former Medical Directors, former employees or referring physicians who establish their own clinics. Furthermore, other health care providers or product manufacturers, some of who have significant operations, may decide to enter the dialysis business in the future.

Because in the U.S. government programs are the primary source of reimbursement for services to the majority of patients, competition for patients in the U.S. is based primarily on quality and accessibility of service and the ability to obtain admissions from physicians with privileges at the facilities. However, the extension of periods during which commercial insurers are primarily responsible for reimbursement and the growth of managed care have placed greater emphasis on service costs for patients insured with private insurance.

In most countries other than the U.S., we compete primarily against individual free-standing clinics and hospital-based clinics. In many of these countries, especially the developed countries, governments directly or indirectly regulate prices and the opening of new clinics. Providers compete in all countries primarily on the basis of quality and availability of service and the development and maintenance of relationships with referring physicians.

Laboratory Services. Spectra Renal Management competes in the U.S. with large nationwide laboratories, dedicated dialysis laboratories and numerous local and regional laboratories, including hospital laboratories. In the laboratory services market, companies compete on the basis of performance, including quality of laboratory testing, timeliness of reporting test results and cost-effectiveness. We believe that our services are competitive in these areas.

Dialysis Products

We are currently the world s largest manufacturer and distributor of equipment and related products for hemodialysis and the second largest manufacturer of peritoneal dialysis products, based on publicly reported revenues, with operations in Germany, the U.S., and in 35 other countries. We sell our dialysis products directly and through distributors in over 100 countries. Most of our customers are dialysis clinics. For the year 2003, dialysis products accounted for 28% of our total revenue.

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Overview

The following table shows the breakdown of our dialysis product revenues into sales of hemodialysis products and peritoneal dialysis products.

	Year Ended December 31,					
	2003		2002		2001	
	Total Product Revenues	% of Total	Total Product Revenues	% of Total	Total Product Revenues	% of Total
	(U.S. dollars in millions)					
Hemodialysis Products	$1,326.1	86	$1,181.0	86	$1,114.0	86
Peritoneal Dialysis Products	211.5	14	194.2	14	188.2	14
Total	$1,537.6	100	$1,375.2	100	$1,302.2	100

Hemodialysis Products

We offer a comprehensive hemodialysis product line and believe that our broad range of technologically sophisticated hemodialysis products makes us a leader in the hemodialysis product field. We continually strive to expand and improve the capabilities of our hemodialysis systems to offer an advanced treatment mode at reasonable cost.

Dialysis Machines. We sell our dialysis machines as Series 2008H and 2008K models in North America and Series 4008 models in the rest of the world. Our dialysis machines offer the following features and advantages:

Volumetric dialysate balancing and ultrafiltration control system. This system, which we introduced in 1977, provides for safe and more efficient use of highly permeable dialyzers, permitting faster dialysis with controlled rates of fluid removal;

Proven hydraulic systems, providing reliable operation and servicing flexibility;

Compatibility with all manufacturers dialyzers and a wide variety of blood-lines and dialysis solutions, permitting maximum flexibility in both treatment and disposable products usage;

Modular design, which permits us to offer dialysis clinics a broad range of options to meet specific patient or regional treatment requirements. Modular design also allows upgrading through module substitution without replacing the entire machine;

Specialized modules that provide monitoring and response capability for selected bio-physical patient parameters, such as body temperature, relative blood volume and electrolyte balances. This concept, known as physiological dialysis, permits hemodialysis treatments with lower incidence of a variety of symptoms or side effects, which still occur frequently in standard hemodialysis.

Sophisticated microprocessor controls, and display and readout panels that are adaptable to meet local language requirements;

Battery backup, which continues operation of the blood circuit and all protective systems up to 20 minutes following a power failure;

Online clearance, measurement of dialyzer clearance for quality assurance with the On-Line Clearance Monitor, providing immediate effective clearance information, real time treatment outcome monitoring, and therapy adjustment during dialysis without requiring invasive procedures or blood samples;

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On-line data collection capabilities and computer interfacing with our FINESSE module and FDS08® system. Our machines can:

monitor and assess prescribed therapy;

connect a large number of hemodialysis machines and peripheral devices, such as patient scales, blood chemistry analyzers and blood pressure monitors, to a personal computer network;

enter nursing records automatically at bedside to register and document patient treatment records, facilitate billing, and improve record-keeping and staff efficiency;

adapt to new data processing devices and trends;

perform home hemodialysis with remote monitoring by a staff caregiver; and

record and analyze trends in medical outcome factors in hemodialysis patients.

Dialyzers. We manufacture dialyzers using hollow fiber polysulfone membranes, a synthetic material. We are the leading worldwide producer of polysulfone dialyzers. We believe that polysulfone offers the following superior performance characteristics compared to other materials used in dialyzers:

higher biological compatibility, resulting in reduced incidence of adverse reactions to the fibers;

greater capacity to clear uremic toxins from patient blood during dialysis, permitting more thorough, more rapid dialysis, resulting in shorter treatment time; and

a complete range of permeability, or membrane pore size, which permits dialysis at prescribed rates high flux, medium flux and low flux, as well as ultra flux for acute dialysis, and allows tailoring of dialysis therapy to individual patients.

Single Use Dialyzers. In North America, we have completed a $65 million capital investment program to significantly expand the capacity of our dialyzer manufacturing plant in Ogden, Utah through the addition of three new dialyzer assembly lines.

Other Hemodialysis Products.

We manufacture and distribute arterial, venous, single needle and pediatric bloodlines. We produce both liquid and dry dialysate concentrates. Liquid dialysate concentrate is mixed with purified water by the hemodialysis machine to produce dialysis solution, which removes the toxins and excess water from the patient s blood during dialysis. Dry concentrate, developed more recently, is less labor-intensive to use, requires less storage space and may be less prone to bacterial growth than liquid solutions. We also produce dialysis solutions in bags, including solutions for priming and rinsing hemodialysis bloodlines, as well as connection systems for central concentrate supplies and devices for mixing dialysis solutions and supplying them to hemodialysis machines. Other products include solutions for disinfecting and decalcifying hemodialysis machines, fistula needles, hemodialysis catheters, and products for acute renal treatment.

Peritoneal Dialysis Products

We offer a full line of peritoneal dialysis products. We manufacture peritoneal dialysis solutions in bags, peritoneal dialysis cycling machines for CCPD and disposable products for both CAPD and CCPD, such as tubing, sterile solutions and sterile kits to prepare patients for dialysis. We also distribute other manufacturers peritoneal dialysis products, primarily to our own dialysis clinics.

CAPD Systems. We manufacture standard and specialized peritoneal dialysis solutions. We believe that our peritoneal dialysis products offer significant advantages for CAPD, including:

ease of use and greater protection against contamination by touch than other peritoneal dialysis systems presently available. Our products incorporate our Safe-Lock connection system for introducing and draining dialysis solution into and from the abdominal cavity. Our A.N.D.Y. and A.N.D.Y. Plus systems,

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which include a special drainage bag and a snap-off Y-shaped piece connected to the Safe-Lock connector at the catheter, provide protection from contamination in a dual-bag system;

suitability for all peritoneal dialysis patients through the Inpersol and Safe-Lock product lines. Inpersol products are interchangeable with those of other manufacturers; Safe-Lock products may be used only by peritoneal dialysis patients whose catheters include the Safe-Lock connector, which attaches to a solution bag fitted with the other part;

manufacture with Biofine, a new environmentally friendly, more biocompatible, plastic material for foils, tubings and other parts of peritoneal dialysis systems.

the benefits of Biofine with protection against contamination through our new Stay-Safe system, launched in 1997. The system comprises tubing, connectors and a peritoneal dialysis solution double bag, made entirely from Biofine. It uses a single switching mechanism that replaces three tubing clamps to control solution drainage, flushing of tubes that connect solution bags to catheters, and introduction of new solution. The single switch also provides tight closure of the line and, to further reduce the possibility of contamination, the switch seals catheter access and surrounds the catheter adapter with disinfectant;

higher solution bag volumes with our Premier twin-bag system which provides solution container and pre-attached tubing set in one package. The higher solution volumes permit larger dosages without increasing the number of required daily solution exchanges performed by the patient; and

improved biocompatibility with CAPD stay.safe Balance, a lactate-buffered peritoneal dialysis solution that has a pH balance in the human physiological range.

CCPD Products. We introduced the first peritoneal dialysis cycler machine in 1980. In a standard CAPD program, a patient manually introduces two liters of fresh peritoneal dialysis solution and drains the used solution four times over a 24-hour period. Treatment occurs seven days per week and the patient must perform the treatment while awake. With CCPD therapy, the cycler automatically delivers a prescribed volume of dialysis solution into the peritoneal cavity through an implanted catheter, allows the solution to dwell for a specified time, and completes the process by draining the solution. CCPD therapy offers the following benefits over CAPD:

Solution exchanges take place automatically, which may reduce the risk of peritonitis due to less frequent handling of the catheter and connections;

The patient can cycle at home, throughout the night while asleep. The patient has complete daytime freedom, wearing only the surgically implanted catheter and capping device; and

CCPD delivers more effective therapy than CAPD due to the supine position of the patient during the night, higher volume exchanges and preferable cycle management which can be particularly significant for patients who need more therapy due to body size, ultrafiltration loss or other reasons.

Our cycling equipment incorporates microprocessor technology, and the patient, hospital or clinic staff can easily program it to perform specific prescribed therapy for a given patient. Since all components are monitored and programmable, these machines allow the physician to prescribe any of a number of current therapy procedures. Our CCPD products and therapies include:

the Sleep-Safe Cycler, a new cycler with an extremely compact and light design, that we began marketing in late 1999. Its pumping mechanism and disposable cartridge allow exact delivery of the peritoneal dialysis solution;

PD-PLUS, a variant on CCPD therapy we introduced in 1994. PD-PLUS therapy provides a more tailored therapy than regular CCPD using a simpler nighttime cycler and, where necessary, includes one manual dialysis solution exchange during the day. We believe that PD-PLUS therapy is less costly and easier to administer than typical CCPD. We also believe that PD-PLUS therapy improves toxin removal by more than 40% compared to CAPD. By increasing the effectiveness of peritoneal dialysis treatments, PD-PLUS may also effectively prolong the time period during which a patient will be able to remain on

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peritoneal dialysis before requiring hemodialysis. PD-PLUS therapy can only be performed using the Fresenius Freedom Cycler and special tubing using Safe-Lock connectors; and

IQcard, for use with the Freedom Cycler PD-PLUS to monitor CCPD therapy for a full treatment history and improved therapy compliance.

Other Peritoneal Dialysis Products. We also manufacture and distribute pediatric treatment systems for administration of low volumes of dialysis solutions, assist devices to facilitate automated bag exchange for handicapped patients, catheters, catheter implantation instruments, silicon glue, Pack-PD, a computer program which analyzes patient and peritoneal characteristics to present a range of treatment options for individual therapies, disinfectants, bag heating plates adapters, and products to assist and enhance connector sterility. We also provide scientific and patient information products, including support materials, such as brochures, slides, videos, instructional posters and training manuals.

Marketing, Distribution and Service

We sell most of our products to clinics, hospitals and specialized treatment clinics. With our comprehensive product line and years of experience in dialysis, we believe that we have been able to establish and maintain very close relationships with our clinic customer base on a global basis. Close interaction between our sales force and research and development personnel enables us to integrate concepts and ideas that originate in the field into product development. We maintain a direct sales force of trained salespersons engaged in the sale of both hemodialysis and peritoneal dialysis products. This sales force engages in direct promotional efforts, including visits to physicians, clinical specialists, hospitals, clinics and dialysis clinics, and represents us at industry trade shows. We also sponsor medical conferences and scientific symposia as a means for disseminating product information. Our clinical nurses provide clinical support, training and assistance to customers and assist our sales force. We also use outside distributors to provide sales coverage in countries that our internal sales force does not service.

In our basic distribution system, we ship products from factories to central warehouses which are frequently located near the factories. From this central warehouse, we distribute our dialysis products to regional warehouses. We then distribute peritoneal dialysis products to the patient at home, and ship hemodialysis products directly to dialysis clinics and other customers. Local sales forces, independent distributors, dealers and sales agents sell all our products.

We offer customer service, training and education in the applicable local language, and technical support such as field service, repair shops, maintenance, and warranty regulation for each country in which we sell dialysis products. We provide training sessions on our equipment at our facilities in Schweinfurt, Germany, Chicago, Illinois and Walnut Creek, California and we also maintain regional service centers that are responsible for day-to-day international service support.

Manufacturing Operations

We operate state-of-the-art production facilities world wide to meet the demand for machines, cyclers, dialyzers, solutions, concentrates, mixes, bloodlines, and disposable tubing assemblies and equipment for water treatment in dialysis clinics. We have invested significantly in developing proprietary processes, technologies and manufacturing equipment which we believe provide a competitive advantage in manufacturing our products. We are using our facilities in St. Wendel, Germany and Ogden, Utah as centers of competence for development and manufacturing and to implement similar technologies at our other facilities.

We produce and assemble hemodialysis machines and CCPD cyclers in our Schweinfurt, Germany and our Walnut Creek, California facilities. We also maintain facilities at our service and local distribution centers in Argentina, Egypt, France, Italy, The Netherlands, China, Brazil and Russia for testing and calibrating dialysis machines manufactured or assembled elsewhere, to meet local end user market needs. We manufacture and assemble dialyzers and polysulfone membranes in our St. Wendel, Germany, L Arbresle, France and Inukai, Japan facilities and at production facilities of our joint ventures in Belarus, Saudi Arabia and Japan. At our Ogden, Utah facilities we manufacture and assemble dialyzers and polysulfone membranes as well as

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manufacture PD solutions. We have opened PD production in Mexico. Our facilities are inspected on a regular basis by national and/or international authorities.

In North America we expanded our manufacturing capacity substantially. During 2003, we completed a $65 million capital commitment to significantly expand the capacity of our dialyzer manufacturing plant in Ogden, Utah through the addition of three new dialyzer assembly lines. See History and Development of the Company Capital Expenditures.

Sources of Supply

Our purchasing policy combines worldwide sourcing of high-quality materials with the establishment of long-term relationships with our suppliers. Additionally, we carefully assess the reliability of all materials purchased to ensure that they comply with the rigorous quality and safety standards required for our dialysis products. Our International Purchasing Consulting Center (PCC) ensures that we consistently maintain high standards by entering into global agreements. An interactive information system links all our global projects to ensure that they are standardized and constantly monitored.

PCC focuses on further optimizing procurement logistics and reducing purchasing costs. Supplemental raw material contracts for all manufacturers of semi-finished goods will enable us to improve purchasing terms for our complete network. We will also intensify our use of internet-based procurement tools by purchasing raw materials through special on-line auctions. Our sophisticated routing software enables us to distribute our supplies to best accommodate customer requests while maintaining operational efficiency.

New Product Introductions

Research and development focuses strongly on the development of new products, technologies and treatment concepts to optimize treatment quality for dialysis patients, and on process technology for manufacturing our products. Research and development expenditures were $50 million in 2003, $47 million in 2002, and $36 million in 2001.

New or enhanced products introduced in 2003 included the following:

Patient Online (POL). A software tool to manage PD therapy.

MultiBic. A dialysis substitution fluid registered and introduced this year in Germany.

Patents, Trademarks and Licenses

As the owner of or licensee under patents and trademarks throughout the world, we hold rights under about 1,100 patents and patent applications relating to dialysis technology in major markets. Patented technologies that relate to dialyzers include our polysulfone hollow fiber, an in-line sterilization method, and sterile closures for in-line sterilized medical devices. The more recent generation of DIASAFEplus filters and FX dialyzers are also the subject of patents and pending patent applications.

The Company holds the exclusive license on European patents/patent applications on the Autoprime technology for the automated priming of the extracorporeal hemodialysis blood circuit with dialyzing liquid through the membrane of the dialyzer.

The connector system for our biBag bicarbonate concentrate powder container has been patented in the USA, Norway and Europe while national applications in Japan and Finland are still pending.

Among the Company s more significant protective rights, one patent family protects the Company s polysulfone hollow fiber until 2007 in the United States, and until 2005 in other main markets. The in-line sterilization method is patented until 2010 and the biBag connector is protected until 2013, both in Germany, in the United States, and in other important markets. The dates given represent the maximum life time of the corresponding patents. The Company believes that even after expiration of these patents, our proprietary know-how for the manufacture of these products will continue to constitute a competitive advantage.

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For peritoneal dialysis, the Company holds protective rights on our polyolefine film Biofine, suitable for packaging intravenous and peritoneal dialysis fluids. These patents have been granted in Australia, Germany, and the USA, with patent applications pending in various other countries. A further pending patent family describes a special film for a peelable, non-PVC, multi chamber bag for peritoneal dialysis solutions. A U.S. patent has already been granted.

We believe that our success will depend, in large part, on our technology. As a standard practice, we obtain legal protections we believe are appropriate for our intellectual property. Intellectual property is, however, subject to infringement or invalidation claims. In addition, technological developments in ESRD therapy could reduce the value of our existing intellectual property. Any such reduction could be rapid and unanticipated. Other than as disclosed in this report, we are not dependent to any material extent upon patents, licenses or contracts.

Competition

The markets in which we sell our dialysis products are highly competitive. Our competitors in the sale of hemodialysis and peritoneal dialysis products include Gambro AB, Baxter International, Inc., Asahi Medical Co., Ltd., Bellco S.p.A., a subsidiary of Sorin Biomedica S.p.A., Bieffe Medital S.p.A., which is an affiliate of Baxter International, Inc., B. Braun Melsungen AG, Nissho Corporation, including Nissho Nipro Corporation Ltd., Nikkiso Co., Ltd., Terumo Medical Corporation and Toray Medical Co., Ltd. Some of our competitors possess greater financial, marketing and research and development resources than we do.

Regulatory and Legal Matters

Regulatory Overview

Our operations are subject to extensive governmental regulation by virtually every country in which we operate including, most notably, in the U.S., at the federal, state and local levels. Although these regulations differ from country to country, in general, non-U.S. regulations are designed to accomplish the same objectives as U.S. regulations regarding the operation of dialysis clinics, laboratories and manufacturing facilities, the provision of quality health care for patients, the maintenance of occupational, health, safety and environmental standards and the provision of accurate reporting and billing for governmental payments and/or reimbursement. In the U.S., some states restrict ownership of health care providers by certain multi-level for-profit corporate groups or establish other regulatory barriers to the establishment of new dialysis clinics. Outside the U.S., each country has its own payment and reimbursement rules and procedures, and some countries prohibit ownership of health care providers or establish other regulatory barriers to direct ownership by foreign companies. In all jurisdictions, we work within the framework of applicable laws to establish alternative contractual arrangements to provide services to those facilities.

Any of the following matters could have a material adverse effect on our business, financial condition and results of operations:

failure to receive required licenses, certifications or other approvals for new facilities or significant delays in such receipt;

loss of various federal certifications or termination of licenses under the laws of any state or other governmental authority; and

changes resulting from health care reform or other government actions that reduce reimbursement or reduce or eliminate coverage for particular services we provide.

We must comply with all U.S., German and other legal and regulatory requirements under which we operate, including the U.S. federal Medicare and Medicaid Fraud and Abuse Amendments of 1977, as amended, generally referred to as the anti-kickback statute , the federal False Claims Act, the federal restrictions on certain physician referrals, commonly known as the Stark Law , U.S. federal rules under the Health Insurance Portability and Accountability Act of 1996 that protect the privacy of patient medical records and prohibit inducements to patients to select a particular health care provider (commonly known as HIPAA) and other fraud and abuse laws and similar state statutes, as well as similar laws in other countries. Moreover, there can be

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no assurance that applicable laws, or the regulations thereunder, will not be amended, or that enforcement agencies or the courts will not make interpretations inconsistent with our own, any one of which could have a material adverse effect on our business, reputation, financial condition and results. Sanctions for violations of these statutes may include criminal or civil penalties, such as imprisonment, fines or forfeitures, denial of payments, and suspension or exclusion from the Medicare and Medicaid programs. In the U.S., these laws have been broadly interpreted by a number of courts, and significant government funds and personnel have been devoted to their enforcement because such enforcement has become a high priority for the federal government and some states. Our company, and the health care industry in general, will continue to be subject to extensive federal, state and foreign regulation, the full scope of which cannot be predicted.

Fresenius Medical Care Holdings has entered into a corporate integrity agreement with the U.S. government, which requires that Fresenius Medical Care Holdings staff and maintain a comprehensive compliance program, including a written code of conduct, training programs and compliance policies and procedures. The corporate integrity agreement requires annual audits by an independent review organization and periodic reporting to the government. The corporate integrity agreement permits the U.S. government to exclude Fresenius Medical Care Holdings and its subsidiaries from participation in U.S. federal health care programs and impose fines if there is a material breach of the agreement that is not cured by Fresenius Medical Care Holdings within thirty days after Fresenius Medical Care Holdings receives written notice of the breach.

Product Regulation

U.S.

In the U.S., the Food and Drug Administration (FDA) and comparable state regulatory agencies impose requirements on certain of our subsidiaries as a manufacturer and a seller of medical products and supplies under their jurisdiction. These require that products be manufactured in accordance with Good Manufacturing Practices and that we comply with FDA requirements regarding the design, safety, advertising, labeling, recordkeeping distribution, and reporting of adverse events related to the use of our products. In addition, in order to clinically test, produce and market certain medical products and other disposables (including hemodialysis and peritoneal dialysis equipment and solutions, dialyzers, bloodlines and other disposables) for human use, we must satisfy mandatory procedures and safety and efficacy requirements established by the FDA or comparable state and foreign governmental agencies. Such rules generally require that products be approved by the FDA as safe and effective for their intended use prior to being marketed. Our peritoneal dialysis solutions have been designated as drugs by the FDA and, as such, are subject to additional FDA regulation under the Food, Drug and Cosmetic Act of 1938.

Germany and Other Non-U.S.

Most countries maintain different regulatory regimes for pharmaceutical products and for medical devices. In each regime, there are regulations governing manufacturers and distributors, as well as regulations governing the final products manufactured and distributed. Treaties or other international law and standards and guidelines under treaties or laws may supplement or supersede individual country regulations.

Some of our products, such as peritoneal dialysis solutions, are considered pharmaceuticals. The European Union has issued a directive on pharmaceuticals, No. 65/65/ EWG (January 26, 1965), as amended. Each member of the European Union is responsible for conforming its law to comply with this directive. In Germany the German Drug Law *(Arzneimittelgesetz)* which implements European Union requirements, is the primary regulation applicable to pharmaceutical products.

The provisions of the German Drug Law are typical of the legal standards in other European countries. The German Drug Law states the requirements for the authorization of a company to manufacture pharmaceuticals. A manufacturer must, among other requirements, appoint pharmacists or physicians to be responsible for the quality, safety and efficacy of the pharmaceuticals. At least five responsible persons must be appointed: a marketing manager, a quality control manager, a manufacturing manager, a safety officer, and a drug information

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officer. Each of these persons may be held personally liable under German criminal laws for violations of the German Drug Law.

International guidelines also govern the manufacture of pharmaceuticals and, in many cases, overlap with national requirements. In particular, the Pharmaceutical Inspection Convention, an international treaty, contains rules which are binding on most countries in which pharmaceuticals are manufactured. Among other things, the Pharmaceutical Inspection Convention establishes requirements for Good Manufacturing Practices which are then adopted at the national level. Another international guideline, which is non-binding, is the ISO 9000-9004 system for assuring quality control. This system is more detailed than Good Manufacturing Practices. Compliance entitles the manufacturer to utilize the CE certification of quality control. In addition to regulating the manufacture of pharmaceuticals, countries directly regulate marketing of the pharmaceuticals produced. A drug needs to be registered and authorized in every country in which it is distributed. European Union rules govern the conditions for a registration, such as pre-clinical and clinical testing.

Historically, medical devices have not been regulated as strictly as pharmaceuticals, but more stringent regulatory schemes have been adopted during the last decade. In 1995, Germany implemented the European Union s Medical Devices Directive when it adopted the Medical Devices Act *(Medizinproduktegesetz)*, which is similar in many ways to the German Drug Law. This Directive applies to both the manufacturer s quality control system and the products technical design. Depending on the class of medical devices, a manufacturer may choose alternative regulatory modules to demonstrate compliance with European Union provisions. To assure and demonstrate the high quality standards and performance of our operations, we have subjected our entire European business to the most comprehensive procedural module, which is also the fastest way to launch a new product in the European Union. This module requires the certification of a full quality management system by a notified body charged with supervising the quality management system. A notified body is a group accredited and monitored by governmental agencies that inspects manufacturing facilities and quality control systems at regular intervals and is authorized to carry out unannounced inspections.

When a company receives a European Union certificate for the quality management system of a particular facility, it may assess whether products developed and manufactured in the facility satisfy European Union requirements. European Union requirements for products are laid down in harmonized European Union standards and include conformity to safety requirements, physical and biological properties, construction and environmental properties, and information supplied by the manufacturer. A manufacturer must demonstrate conformity to these requirements by pre-clinical tests, biocompatibility tests, qualification of products and packaging, risk analysis and well-conducted clinical investigations approved by ethics committees.

A manufacturer having a European Union-certified full quality management system has to declare and document conformity of its products to the harmonized European standards. If able to do so, the manufacturer must put a CE mark on the products. The CE mark, which stands for *Conformité Européenne,* demonstrates compliance with the relevant European Union requirements. Products subject to these provisions that do not bear the CE mark cannot be imported, sold or distributed within the European Union.

Our Series 4008, 4008B, 4008E dialysis machines and their therapy modifications, our PD-NIGHT cycler, and our other medical devices distributed in the European market, as well as our dialysis filters and dialysis tubing systems and accessories, all bear the CE mark. We expect to continue to obtain additional certificates as they are required.

Facilities and Operational Regulation

U.S.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) subjects virtually all clinical laboratory testing facilities, including ours, to the jurisdiction of the Department of Health and Human Services. CLIA establishes national standards for assuring the quality of laboratories based upon the complexity of testing performed by a laboratory. Certain of our operations are also subject to federal laws governing the repackaging and dispensing of drugs and the maintenance and tracking of certain life sustaining and life-supporting equipment.

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Our operations are subject to various U.S. Department of Transportation, Nuclear Regulatory Commission and Environmental Protection Agency requirements and other federal, state and local hazardous and medical waste disposal laws. As currently in effect, laws governing the disposal of hazardous waste do not classify most of the waste produced in connection with the provision of dialysis, or laboratory services as hazardous, although disposal of nonhazardous medical waste is subject to specific state regulation. Our operations are also subject to various air emission and wastewater discharge regulations.

Federal, state and local regulations require us to meet various standards relating to, among other things, the management of facilities, personnel qualifications and licensing, maintenance of proper records, equipment, quality assurance programs, the operation of pharmacies, and dispensing of controlled substances. All of our operations in the U.S. are subject to periodic inspection by federal and state agencies and other governmental authorities to determine if the operations, premises, equipment, personnel and patient care meet applicable standards. To receive Medicare reimbursement, our dialysis centers, renal diagnostic support business and laboratories must be certified by CMS. All of our dialysis centers, and laboratories that furnish Medicare services have the required certification.

Certain of our facilities and certain of their employees are also subject to state licensing statutes and regulations. These statutes and regulations are in addition to federal and state rules and standards that must be met to qualify for payments under Medicare, Medicaid and other government reimbursement programs. Licenses and approvals to operate these centers and conduct certain professional activities are customarily subject to periodic renewal and to revocation upon failure to comply with the conditions under which they were granted.

Occupational Safety and Health Administration (OSHA) regulations require employers to provide employees who work with blood or other potentially infectious materials with prescribed protections against blood-borne and air-borne pathogens. The regulatory requirements apply to all health care facilities, including dialysis centers and laboratories, and require employers to make a determination as to which employees may be exposed to blood or other potentially infectious materials and to have in effect a written exposure control plan. In addition, employers are required to provide hepatitis B vaccinations, personal protective equipment, blood-borne pathogens training, post-exposure evaluation and follow-up, waste disposal techniques and procedures, engineering and work practice controls and other OSHA-mandated programs for blood-borne and air-borne pathogens.

Some states in which we operate have certificate of need (CON) laws that require any person or entity seeking to establish a new health care service or to expand an existing service to apply for and receive an administrative determination that the service is needed. We currently operate in 13 states, as well as the District of Columbia and Puerto Rico that have CON laws applicable to dialysis centers. These requirements could, as a result of a state s internal determination of its dialysis services needs, prevent entry to new companies seeking to provide services in these states, and could constrain our ability to expand our operations in these states.

Germany and Other Non-U.S.

Countries outside of the U.S. possess a wide variety of operational regulation at disparate levels. Accordingly, our operations are subject to very different regulations in different countries. Most countries regulate dialysis clinic operating conditions and product manufacturing.

We are subject to a broad spectrum of regulation. Our operations must comply with various environmental and transportation regulations in the various countries in which we operate. Our manufacturing facilities and dialysis clinics are also subject to various standards relating to, among other things, facilities, management, personnel qualifications and licensing, maintenance of proper records, equipment, quality assurance programs, the operation of pharmacies, the protection of workers from blood-borne diseases and the dispensing of controlled substances. All of our operations are subject to periodic inspection by various governmental authorities to determine if the operations, premises, equipment, personnel and patient care meet applicable standards. Our dialysis clinic operations and our related activities generally require licenses, which are subject to periodic renewal and may be revoked for violation of applicable regulatory requirements.

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In addition, many countries impose various investment restrictions on foreign companies. For instance, government approval may be required to enter into a joint venture with a local partner. Some countries do not permit foreign investors to own a majority interest in local companies or require that companies organized under their laws have at least one local shareholder. Investment restrictions therefore affect the corporate structure, operating procedures and other characteristics of our subsidiaries and joint ventures in these and other countries.

We believe our facilities are currently in compliance in all material respects with the applicable national and local requirements in the jurisdictions in which they operate.

Reimbursement

U.S.

Dialysis Services. Our dialysis centers provide outpatient hemodialysis treatment and related services for ESRD patients. In addition, some of the Company s centers offer services for the provision of peritoneal dialysis and hemodialysis treatment at home, and dialysis for hospitalized patients.

The Medicare program is the primary source of Dialysis Services revenues from dialysis treatment. For example, in 2003, approximately 55% of Dialysis Services revenues resulted from Medicare s ESRD program. As described below, Dialysis Services is reimbursed by the Medicare program in accordance with the Composite Rate for certain products and services rendered at our dialysis centers. As described hereinafter, other payment methodologies apply to Medicare reimbursement for other products and services provided at our dialysis centers and for products (such as those sold by us) and support services furnished to ESRD patients receiving dialysis treatment at home (such as those of Dialysis Products). Medicare reimbursement rates are fixed in advance and are subject to adjustment from time to time by the U.S. Congress. Although this form of reimbursement limits the allowable charge per treatment, it provides us with predictable per treatment revenues.

Certain items and services that we furnish at our dialysis centers are not included in the Composite Rate and are eligible for separate Medicare reimbursement, typically on the basis of established fee schedule amounts. Such items and services include certain drugs (such as EPO), blood transfusions and certain diagnostic tests.

Medicare payments are subject to change by legislation, regulations and pursuant to deficit reduction measures. The Composite Rate was unchanged from commencement of the ESRD program in 1972 until 1983. From 1983 through December 1990, numerous congressional actions resulted in a net reduction of the average reimbursement rate from $138 per treatment in 1983 to approximately $125 per treatment in 1990. Congress increased the ESRD reimbursement rate, effective January 1, 1991, to an average rate of $126 per treatment. Effective January 1, 2000, the reimbursement rate was increased by 1.2%. In December 2000 an additional increase of 2.4% was approved for the year 2001. Accordingly, there was a 1.2% reimbursement increase on January 1, 2001. A second increase was delayed until April 1, 2001, when rates were increased 1.6% to make up for the delay.

On December 8, 2003, the Medicare Prescription Drug, Modernization and Improvement Act of 2003 was enacted (the Medicare Modernization Act). This law makes several modifications affecting payment for dialysis services. First, it will increase the composite rate for renal dialysis facilities by 1.6% on January 1, 2005. Second, it requires the Secretary of the Department of Health and Human Services (the Secretary) to establish a new case-mix adjusted prospective payment system for dialysis services furnished on or after January 1, 2005. This system will adjust for a limited number of patient characteristics (the case-mix) and will include two components: (1) those services that currently comprise the Composite Rate; and (2) the difference between the Medicare payment rate for separately billable drugs and biologicals and the acquisition costs of those drugs and biologicals, as determined by OIG reports. The Secretary is required to adjust the basic case-mix adjusted system payment rates by a geographic index. Separate payment would continue to be made for drugs and biologicals that currently are billed separately. All separately billable drugs and biologicals will be reimbursed based upon acquisition cost in 2005. Beginning in 2006, the Secretary is authorized to set payment for all separately billed drugs and biologicals at either acquisition cost or average sales price. Third, the Secretary is required to establish a three-year demonstration project to test the use of a fully case-mix adjusted payment system for ESRD services, beginning January 1, 2006. Under this project, separately billable drugs and biologicals and related clinical

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laboratory tests would be bundled into the facility composite rate. Participating facilities would receive an additional 1.6% composite rate increase.

We are unable to predict what, if any, future changes may occur in the rate of Medicare reimbursement. Any significant decreases in the Medicare reimbursement rates could have a material adverse effect on our provider business and, because the demand for products is affected by Medicare reimbursement, on our products business. Increases in operating costs that are affected by inflation, such as labor and supply costs, without a compensating increase in reimbursement rates, also may adversely affect our business and results of operations.

For Medicare-primary patients, Medicare is responsible for payment of 80% of the Composite Rate set by CMS for dialysis treatments and the patient or third-party insurance payors, including employer-sponsored health insurance plans, commercial insurance carriers and the Medicaid program, are responsible for paying any co-payment amounts for approved services not paid by Medicare (typically the annual deductible and 20% co-insuranc