

HENRY SCHEIN INC
Form 10-K
February 10, 2016
UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-K

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

For the fiscal year ended December 26, 2015

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

Commission file number 0-27078

HENRY SCHEIN, INC.

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction of
incorporation or organization)
11-3136595
(I.R.S. Employer Identification No.)

135 Duryea Road
Melville, New York
(Address of principal executive offices)
11747
(Zip Code)

(631) 843-5500

(Registrant's telephone number, including area code)

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

Title of each class	Name of each exchange on which registered
Common Stock, par value \$.01 per share	The NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

YES: NO:

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

YES: NO:

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: NO:

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during

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the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).
YES: NO:

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer: Accelerated filer: Non-accelerated filer:
 Smaller reporting company:
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
YES: NO:

The aggregate market value of the registrant's voting stock held by non-affiliates of the registrant, computed by reference to the closing sales price as quoted on the NASDAQ Global Select Market on June 27, 2015, was approximately \$12,167,497,000.

As of February 5, 2016, there were 81,942,080 shares of registrant's Common Stock, par value \$.01 per share, outstanding.

Documents Incorporated by Reference:

Portions of the Registrant's definitive proxy statement to be filed pursuant to Regulation 14A not later than 120 days after the end of the fiscal year (December 26, 2015) are incorporated by reference in Part III hereof.

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PART I

ITEM 1. Business

General

We believe we are the world's largest provider of health care products and services primarily to office-based dental, animal health and medical practitioners. We serve more than 1 million customers worldwide including dental practitioners and laboratories, animal health clinics and physician practices, as well as government, institutional health care clinics and other alternate care clinics. We believe that we have a strong brand identity due to our more than 83 years of experience distributing health care products.

We are headquartered in Melville, New York, employ nearly 19,000 people (of which more than 8,500 are based outside the United States) and have operations or affiliates in 33 countries, including the United States, Australia, Austria, Belgium, Brazil, Canada, Chile, China, the Czech Republic, Denmark, France, Germany, Hong Kong SAR, Iceland, Ireland, Israel, Italy, Japan, Luxembourg, Malaysia, the Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Slovakia, South Africa, Spain, Sweden, Switzerland, Thailand and the United Kingdom.

We offer a comprehensive selection of products and services and value-added solutions for operating efficient practices and delivering high quality care. We operate through a centralized and automated distribution network with a selection of more than 110,000 branded products and Henry Schein private brand products in stock, as well as more than 150,000 additional products available as special order items. We also offer our customers exclusive, innovative technology solutions, including practice management software and e-commerce solutions, as well as a broad range of financial services.

We have established over four million square feet of space in 61 strategically located distribution centers around the world to enable us to better serve our customers and increase our operating efficiency. This infrastructure, together with broad product and service offerings at competitive prices, and a strong commitment to customer service, enables us to be a single source of supply for our customers' needs. Our infrastructure also allows us to provide convenient ordering and rapid, accurate and complete order fulfillment.

We conduct our business through two reportable segments: (i) health care distribution and (ii) technology and value-added services. These segments offer different products and services to the same customer base.

The health care distribution reportable segment aggregates our global dental, animal health and medical operating segments. This segment distributes consumable products, small equipment, laboratory products, large equipment, equipment repair services, branded and generic pharmaceuticals, vaccines, surgical products, diagnostic tests, infection-control products and vitamins. Our global dental group serves office-based dental practitioners, dental laboratories, schools and other institutions. Our global animal health group serves animal health practices and clinics. Our global medical group serves office-based medical practitioners, ambulatory surgery centers, other alternate-care settings and other institutions.

Our technology and value-added services group provides software, technology and other value-added services to health care practitioners. Our technology group offerings include practice management software systems for dental and medical practitioners and animal health clinics. Our value-added practice solutions include financial services on a non-recourse basis, e-services, practice technology, network and hardware services, as well as continuing education services for practitioners.

Industry

The health care products distribution industry, as it relates to office-based health care practitioners, is fragmented and diverse. This industry, which encompasses the dental, animal health and medical markets, was estimated to produce revenues of approximately \$45 billion in 2015 in the global markets. The industry ranges from sole practitioners working out of relatively small offices to group practices or service organizations ranging in size from a few practitioners to a large number of practitioners who have combined or otherwise associated their practices.

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Due in part to the inability of office-based health care practitioners to store and manage large quantities of supplies in their offices, the distribution of health care supplies and small equipment to office-based health care practitioners has been characterized by frequent, small quantity orders, and a need for rapid, reliable and substantially complete order fulfillment. The purchasing decisions within an office-based health care practice are typically made by the practitioner or an administrative assistant. Supplies and small equipment are generally purchased from more than one distributor, with one generally serving as the primary supplier.

The health care products distribution industry continues to experience growth due to the aging population, increased health care awareness, the proliferation of medical technology and testing, new pharmacology treatments and expanded third-party insurance coverage, partially offset by the effects of unemployment on insurance coverage. In addition, the physician market continues to benefit from the shift of procedures and diagnostic testing from acute care settings to alternate-care sites, particularly physicians' offices.

We believe that consolidation within the industry will continue to result in a number of distributors, particularly those with limited financial, operating and marketing resources, seeking to combine with larger companies that can provide growth opportunities. This consolidation also may continue to result in distributors seeking to acquire companies that can enhance their current product and service offerings or provide opportunities to serve a broader customer base.

In recent years, the health care industry has increasingly focused on cost containment. This trend has benefited distributors capable of providing a broad array of products and services at low prices. It also has accelerated the growth of HMOs, group practices, other managed care accounts and collective buying groups, which, in addition to their emphasis on obtaining products at competitive prices, tend to favor distributors capable of providing specialized management information support. We believe that the trend towards cost containment has the potential to favorably affect demand for technology solutions, including software, which can enhance the efficiency and facilitation of practice management.

Competition

The distribution and manufacture of health care supplies and equipment is highly competitive. Many of the health care distribution products we sell are available to our customers from a number of suppliers. In addition, our competitors could obtain exclusive rights from manufacturers to market particular products. Manufacturers also could seek to sell directly to end-users, and thereby eliminate or reduce our role and that of other distributors.

In North America, we compete with other distributors, as well as several manufacturers, of dental, animal health and medical products, primarily on the basis of price, breadth of product line, customer service and value-added products and services. In the dental market, our primary competitors are the Patterson Dental division of Patterson Companies, Inc. and Benco Dental Supply Company. In addition, we compete against a number of other distributors that operate on a national, regional and local level. In the animal health market, our primary competitors are the MWI Animal Health division of AmerisourceBergen and the Patterson Veterinary division of Patterson Companies, Inc. Our primary competitors in the medical market are McKesson Corporation and Medline Industries, Inc., which are national distributors. We also compete against a number of regional and local animal health and medical distributors, as well as a number of manufacturers that sell directly to veterinarians and physicians. With regard to our dental practice management software, we compete against numerous companies, including Carestream Health, Inc. and the Patterson Dental division of Patterson Companies, Inc. In the animal health practice management market, our primary competitors are IDEXX Laboratories, Inc. and the Patterson Veterinary division of Patterson Companies, Inc. The medical practice management and electronic medical records market is very fragmented and we compete with numerous companies such as the NextGen division of Quality Systems, Inc., eClinicalWorks and Allscripts Healthcare Solutions, Inc.

We also face significant competition internationally, where we compete on the basis of price and customer service against several large competitors, including the GACD Group, Pluradent AG & Co., Lifco AB, Planmeca Oy, Billerica Dental Supply Co. Ltd., National Veterinary Services Limited (Patterson Veterinary division of Patterson Companies, Inc.), Centaur Services Limited (MWI Animal Health division of AmerisourceBergen) and Alcyon SA, as well as a large number of dental, animal health and medical product distributors and manufacturers in Australia, Austria, Belgium, Brazil, Canada, Chile, China, the Czech Republic, Denmark, France, Germany, Hong Kong SAR, Iceland, Ireland, Israel, Italy, Japan, Luxembourg, Malaysia, the Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Slovakia, South Africa, Spain, Sweden, Switzerland, Thailand and the United Kingdom.

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Significant price reductions by our competitors could result in a similar reduction in our prices. Any of these competitive pressures may materially adversely affect our operating results.

Competitive Strengths

We have more than 83 years of experience in distributing products to health care practitioners resulting in strong awareness of the Henry Schein® brand. Our competitive strengths include:

A focus on meeting our customers' unique needs. We are committed to providing customized solutions to our customers that are driven by our understanding of the market and reflect the technology-driven products and services best suited for their practice needs.

Direct sales and marketing expertise. Our sales and marketing efforts are designed to establish and solidify customer relationships through personal visits by field sales representatives, frequent direct marketing and telesales contact, emphasizing our broad product lines, including exclusive distribution agreements, competitive prices and ease of order placement. The key elements of our direct sales and marketing efforts are:

- Field sales consultants. We have approximately 3,725 field sales consultants, including equipment sales specialists, covering major North American, European and other international markets. These consultants complement our direct marketing and telesales efforts and enable us to better market, service and support the sale of more sophisticated products and equipment.
- Direct marketing. During 2015, we distributed approximately 34.0 million pieces of direct marketing material, including catalogs, flyers, order stuffers and other promotional materials to existing and potential office-based health care customers.
- Telesales. We support our direct marketing effort with approximately 1,850 inbound and outbound telesales representatives, who facilitate order processing and generate new sales through direct and frequent contact with customers.
- Electronic commerce solutions. We provide our customers and sales teams with innovative and competitive Internet, PC and mobile e-commerce solutions.
- Social media. Our operating entities and employees engage our customers and supplier partners through various social media platforms.

Broad product and service offerings at competitive prices. We offer a broad range of products and services to our customers, at competitive prices, in the following categories:

- Consumable supplies and equipment. We offer over 110,000 Stock Keeping Units, or SKUs, to our customers. Of the SKUs offered, approximately 52,000 are offered to our dental customers, approximately 13,000 to our animal health customers and approximately 53,000 to our medical customers. We offer over 150,000 additional SKUs to our customers in the form of special order items.
- Technology and other value-added products and services. We sell practice management software systems to our dental, animal health and medical customers. Our practice management solutions provide practitioners with electronic medical records, patient treatment history, billing, accounts receivable analyses and management,

appointment calendars, electronic claims processing and word processing programs. As of December 26, 2015, we had an active user base of more than 90,000 practices, including users of Dentrrix® Dental Systems, Dentrrix® Enterprise, Dentrrix® Dental Vision®, Dentrrix Ascend®, Easy Dental®, Oasis™, Evolution® and EXACT®, Gesden®, Julie®Software, Power Practice® Px, AxiUm™, EndoVision®, PerioVision®, OMSVision® and Viive® for dental practices; Advantage+™, AVImark®, DVM Manager®, Infinity™, Sunpoint™, Triple Crown™, Vetech Advantage™, VisionVPMTM and Robovet® for animal health practices; and MicroMD® for physician practices.

- Repair services. We have 199 equipment sales and service centers worldwide that provide a variety of repair, installation and technical services for our health care customers. Our technicians provide installation and repair services for: dental handpieces; dental, animal health and medical small equipment; table top sterilizers; and large dental equipment.

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- Financial services. We offer our customers solutions in operating their practices more efficiently by providing access to a number of financial services and products (including non-recourse financing for equipment, technology and software products; non-recourse patient financing; collection services and credit card processing) at rates that we believe are generally lower than what our customers would be able to secure independently. We also provide consulting services, dental practice valuation and brokerage services.

Commitment to superior customer service. We maintain a strong commitment to providing superior customer service. We frequently monitor our customer service through customer surveys, focus groups and statistical reports. Our customer service policy primarily focuses on:

- Exceptional order fulfillment. We ship an average of approximately 165,000 cartons daily. Approximately 99% of items ordered are shipped without back ordering and are shipped on the same business day the order is received.
- Streamlined ordering process. Customers may place orders 24 hours a day, 7 days a week by mail, fax, telephone, e-mail, Internet and by using our computerized order entry systems.

Integrated management information systems. Our information systems generally allow for centralized management of key functions, including accounts receivable, inventory, accounts payable, payroll, purchasing, sales and order fulfillment. These systems allow us to manage our growth, deliver superior customer service, properly target customers, manage financial performance and monitor daily operational statistics.

Cost-effective purchasing. We believe that cost-effective purchasing is a key element to maintaining and enhancing our position as a competitive-pricing provider of health care products. We continuously evaluate our purchase requirements and suppliers' offerings and prices in order to obtain products at the lowest possible cost. In 2015, our top 10 health care distribution suppliers and our single largest supplier accounted for approximately 34% and 7%, respectively, of our aggregate purchases.

Efficient distribution. We distribute our products from our strategically located distribution centers. We strive to maintain optimal inventory levels in order to satisfy customer demand for prompt delivery and complete order fulfillment. These inventory levels are managed on a daily basis with the aid of our management information systems. Once an order is entered, it is electronically transmitted to the distribution center nearest the customer's location and a packing slip for the entire order is printed for order fulfillment.

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Products

The following table sets forth the percentage of consolidated net sales by principal categories of products offered through our health care distribution and technology reportable segments:

	2015	2014	2013
Health care distribution:			
Dental products (1)	49.6 %	51.9 %	52.3 %
Animal health products (2)	27.5	27.9	27.2
Medical products (3)	19.5	16.8	17.2
Total health care distribution	96.6	96.6	96.7
Technology:			
Software and related products and other value-added products (4)	3.4	3.4	3.3
Total	100.0 %	100.0 %	100.0 %

(1) Includes infection-control products, handpieces, preventatives, impression materials, composites, anesthetics, teeth, dental implants, gypsum, acrylics, articulators, abrasives, dental chairs, delivery units and lights, X-ray supplies and equipment, equipment repair and high-tech and digital restoration equipment.

(2) Includes branded and generic pharmaceuticals, surgical and consumable products and services and equipment.

(3) Includes branded and generic pharmaceuticals, vaccines, surgical products, diagnostic tests, infection-control products, X-ray products, equipment and vitamins.

(4) Consists of practice management software and other value-added products, which are distributed primarily to health care providers, and financial services on a non-recourse basis, e-services, continuing education services for practitioners, consulting and other services.

Business Strategy

Our objective is to continue to expand as a global value-added provider of health care products and services to office-based dental, animal health and medical practitioners. To accomplish this, we will apply our competitive strengths in executing the following strategies:

- Increase penetration of our existing customer base. We have over 1 million customers worldwide and we intend to increase sales to our existing customer base and enhance our position as their primary supplier.
- Increase the number of customers we serve. This strategy includes increasing the number and productivity of field sales consultants, as well as using our customer database to focus our marketing efforts in all of our operating

segments. In the dental business, we provide products and services to traditional dental practices as well as new emerging segments, such as dental service organizations and community health centers. Leveraging our unique assets and capabilities, we offer solutions to address these new markets. In the medical business, we have expanded to serve customers located in settings outside of the traditional office, such as urgent care clinics, retail and occupational health settings. As settings of health care shift, we remain committed to serving these practitioners and providing them with the products and services they need.

- Leverage our value-added products and services. We continue to increase cross-selling efforts for key product lines utilizing a consultative selling process. In the dental business, we have significant cross-selling opportunities between our dental practice management software users and our dental distribution customers. In the animal health business, we have opportunities to cross-sell practice management software and other products. In the medical business, we have opportunities to expand our vaccine, injectables and other pharmaceuticals sales to health care practitioners, as well as cross-selling core products and electronic health record and practice management software. Our strategy extends to providing health systems, integrated delivery networks and other large group and multi-site health care organizations, that include physician clinics, these same value added products and services. As physicians and health systems closely align, we have increased access to opportunities for cross-marketing and selling our product and service portfolios.

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- Pursue strategic acquisitions and joint ventures. Our acquisition strategy includes acquiring businesses and entering into joint ventures complementary to ours that will provide, among other things, additional sales to be channeled through our existing distribution infrastructure, access to additional product lines and field sales consultants and an opportunity to further expand into new geographic markets.

Markets Served

Demographic trends indicate that our markets are growing, as an aging U.S. population is increasingly using health care services. Between 2015 and 2025, the 45 and older population is expected to grow by approximately 12%. Between 2015 and 2035, this age group is expected to grow by approximately 25%. This compares with expected total U.S. population growth rates of approximately 8% between 2015 and 2025 and approximately 15% between 2015 and 2035.

In the dental industry, there is predicted to be a rise in oral health care expenditures as the 45 and older segment of the population increases. There is increasing demand for new technologies that allow dentists to increase productivity, and this is being driven in the U.S. by lower insurance reimbursement rates. At the same time, there is an expected increase in dental insurance coverage.

We support our dental professionals through the many SKUs that we offer, as well as through important value-added services, including practice management software, electronic claims processing, financial services and continuing education, all designed to help maximize a practitioner's efficiency.

The animal health market, impacted by growing companion pet ownership and care, as well as increased focus on safety and efficiency in livestock production, continues to provide additional growth opportunities for us. We support the animal health practitioners we serve through the distribution of biologicals, pharmaceuticals, supplies and equipment and by actively engaging in the development, sale and distribution of veterinary practice management software.

There continues to be a migration of procedures from acute-care settings to physicians' offices, a trend that we believe provides additional opportunities for us. There also is the continuing use of vaccines, injectables and other pharmaceuticals in alternate-care settings. We believe we have established a leading position as a vaccine supplier to the office-based physician practitioner.

Additionally, we are expanding our dental full-service model, our animal health presence and our medical offerings in countries where opportunities exist. Through our "Schein Direct" program, we also have the capability to provide door-to-door air package delivery to practitioners in over 190 countries around the world.

For information on revenues and long-lived assets by geographic area, see Note 15 of "Notes to Consolidated Financial Statements," which is incorporated herein by reference.

Seasonality and Other Factors Affecting Our Business and Quarterly Results

We experience fluctuations in quarterly earnings. As a result, we may fail to meet or exceed the expectations of securities analysts and investors, which could cause our stock price to decline.

Our business is subject to seasonal and other quarterly fluctuations. Revenues and profitability generally have been higher in the third and fourth quarters due to the timing of sales of seasonal products (including influenza vaccine, equipment and software products), purchasing patterns of office-based health care practitioners and year-end promotions. Revenues and profitability generally have been lower in the first quarter, primarily due to increased sales

in the prior two quarters. We expect our historical seasonality of sales to continue in the foreseeable future. Quarterly results may also be materially adversely affected by a variety of other factors, including:

- timing and amount of sales and marketing expenditures;
- timing of pricing changes offered by our suppliers;
- timing of the introduction of new products and services by our suppliers;

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- timing of the release of upgrades and enhancements to our technology-related products and services;
- changes in or availability of supplier contracts or rebate programs;
- supplier rebates based upon attaining certain growth goals;
- changes in the way suppliers introduce or deliver products to market;
- costs of developing new applications and services;
- our ability to correctly identify customer needs and preferences and predict future needs and preferences;
- uncertainties regarding potential significant breaches of data security or disruptions of our information technology systems;
- unexpected regulatory actions, or government regulation generally;
- exclusivity requirements with certain suppliers may prohibit us from distributing competitive products manufactured by other suppliers;
- loss of sales representatives;
- costs related to acquisitions and/or integrations of technologies or businesses;
- costs associated with our self-insured medical and dental insurance programs;
- general market and economic conditions, as well as those specific to the health care industry and related industries;
- our success in establishing or maintaining business relationships;
- unexpected difficulties in developing and manufacturing products;
- product demand and availability or recalls by manufacturers;
- exposure to product liability and other claims in the event that the use of the products we sell results in injury;
- increases in shipping costs or service issues with our third-party shippers;
- fluctuations in the value of foreign currencies;
- restructuring costs;
- the adoption or repeal of legislation; and
- changes in accounting principles.

Any change in one or more of these or other factors could cause our annual or quarterly financial results to fluctuate. If our financial results do not meet market expectations, our stock price may decline.

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Governmental Regulations

Operating, Security and Licensure Standards

Certain of our businesses involve the distribution of pharmaceuticals and medical devices, and in this regard we are subject to various local, state, federal and foreign governmental laws and regulations applicable to the distribution of pharmaceuticals and medical devices. Among the United States federal laws applicable to us are the Controlled Substances Act, the Federal Food, Drug, and Cosmetic Act, as amended, and Section 361 of the Public Health Service Act. We are also subject to comparable foreign regulations.

The Federal Food, Drug, and Cosmetic Act (“FDC Act”) and similar foreign laws generally regulate the introduction, manufacture, advertising, labeling, packaging, storage, handling, reporting, marketing and distribution of, and record keeping for, pharmaceuticals and medical devices shipped in interstate commerce, and states may similarly regulate such activities within the state. Section 361 of the Public Health Service Act, which provides authority to prevent the spread of communicable diseases, serves as the legal basis for the United States Food and Drug Administration’s (“FDA”) regulation of human cells, tissues and cellular and tissue-based products, also known as “HCT/P products.”

The federal Drug Quality and Security Act of 2013 brought about significant changes with respect to pharmaceutical supply chain requirements and pre-empts state law. Title II of this measure, known as the Drug Supply Chain Security Act (“DSCSA”), will be phased in over 10 years, and is intended to build a national electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. The law’s track and trace requirements applicable to manufacturers, wholesalers, repackagers and dispensers (e.g., pharmacies) of prescription drugs began to take effect in January 2015, subject to certain enforcement delays by the FDA. For example, the FDA announced that in light of difficulties experienced by some dispensers in establishing electronic systems to handle required product tracing information, it would delay to March 1, 2016 its enforcement of certain track and trace requirements scheduled to apply to dispensers on July 1, 2015, although this delay does not affect current DSCSA requirements that apply to other trading partners, such as manufacturers and wholesale distributors. The DSCSA product tracing requirements replace the former FDA drug pedigree requirements and pre-empt state requirements that are inconsistent with, more stringent than, or in addition to, the DSCSA requirements. Also in January 2015, the DSCSA required manufacturers and wholesale distributors to have systems in place by which they can identify whether a product in their possession or control is a “suspect” or “illegitimate” product, and handle it accordingly.

The DSCSA also establishes certain requirements for the licensing and operation of prescription drug wholesalers and third party logistics providers (“3PLs”), and includes the creation of national wholesaler and 3PL licenses in cases where states do not license such entities. The DSCSA requires that wholesalers and 3PLs distribute drugs in accordance with certain standards regarding the recordkeeping, storage and handling of prescription drugs. Beginning January 1, 2015, the DSCSA required wholesalers and 3PLs to submit annual reports to the FDA, which include information regarding each state where the wholesaler or 3PL is licensed, the name and address of each facility and contact information. According to FDA guidance, states are pre-empted from imposing any licensing requirements that are inconsistent with, less stringent than, directly related to, or covered by the standards established by federal law in this area. Current state licensing requirements will likely remain in effect until the FDA issues new regulations as directed by the DSCSA, which to date, the FDA has not yet issued.

We believe that we are substantially compliant with applicable DSCSA requirements.

The Food and Drug Administration Amendments Act of 2007 (“FDAAA”) and the Food and Drug Administration Safety and Innovation Act of 2012 (“FDASIA”) amended the FDC Act to require the FDA to promulgate regulations to implement a Unique Device Identification System. The FDA issued a final rule on September 24, 2013 implementing

the Unique Device Identification System, requiring the labels of most medical devices to bear a unique device identifier (“UDI”), and prescribing the content and format of the UDI. The rule also requires the submission of certain information concerning UDI-labeled devices to an FDA database, the Global Unique Device Identification Database (“GUDID”). Additional FDA UDI guidance has subsequently been issued, and the FDA’s UDI regulations are being phased in over seven years from the rule’s promulgation in September 2013, beginning with the highest-risk devices (i.e., Class III medical devices) and ending with the lowest-risk devices. For the lowest-risk, Class I medical devices, a Universal Product Code may take the place of a UDI on the device’s label.

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The FDA's UDI regulations require certain entities, referred to as "labelers," to develop and include UDIs on the labels of medical devices, and to directly mark certain devices with UDIs. Labelers are entities that cause a device's label to be applied or modified, without any subsequent replacement or modification. Typically, these entities are device manufacturers, specification developers, single-use device reprocessors, convenience kit assemblers, repackagers and relabelers.

Violations of the UDI regulations, including failure to include a UDI on a device's label after the effective date for the device type, result in the misbranding of the device. The FDC Act makes it unlawful to introduce or deliver for introduction into interstate commerce a misbranded device. It is also unlawful to cause a device to become misbranded.

We believe that we are substantially compliant with applicable UDI requirements.

Under the Controlled Substances Act, as a distributor of controlled substances, we are required to obtain and renew annually registrations for our facilities from the United States Drug Enforcement Administration ("DEA") permitting us to handle controlled substances. We are also subject to other statutory and regulatory requirements relating to the storage, sale, marketing, handling and distribution of such drugs, in accordance with the Controlled Substances Act and its implementing regulations, and these requirements have been subject to heightened enforcement activity in recent times. We are subject to inspection by the DEA.

Certain of our businesses are also required to register for permits and/or licenses with, and comply with operating and security standards of, the DEA, the FDA, the United States Department of Health and Human Services, and various state boards of pharmacy, state health departments and/or comparable state agencies as well as comparable foreign agencies, and certain accrediting bodies depending on the type of operations and location of product distribution, manufacturing or sale. These businesses include those that distribute, manufacture and/or repackage prescription pharmaceuticals and/or medical devices and/or HCT/P products, or own pharmacy operations, or install, maintain or repair equipment. In addition, Section 301 of the National Organ Transplant Act, and a number of comparable state laws, impose civil and/or criminal penalties for the transfer of certain human tissue (for example, human bone products) for valuable consideration, while generally permitting payments for the reasonable costs incurred in procuring, processing, storing and distributing that tissue. We are also subject to foreign government regulation of such products. The DEA, the FDA and state regulatory authorities have broad inspection and enforcement powers, including the ability to suspend or limit the distribution of products by our distribution centers, seize or order the recall of products and impose significant criminal, civil and administrative sanctions for violations of these laws and regulations. Foreign regulations subject us to similar foreign powers. Furthermore, compliance with legal requirements has required and may in the future require us to institute voluntary recalls of products we sell, which could result in financial losses and potential reputational harm. Our customers are also subject to significant federal, state, local and foreign governmental regulation.

Certain of our businesses are subject to various additional federal, state, local and foreign laws and regulations, including with respect to the sale, transportation, storage, handling and disposal of hazardous or potentially hazardous substances, and safe working conditions. There have also been increasing efforts by various levels of government globally to regulate the pharmaceutical distribution system in order to prevent the introduction of counterfeit, adulterated or misbranded pharmaceuticals into the distribution system.

Certain of our businesses also maintain contracts with governmental agencies and are subject to certain regulatory requirements specific to government contractors.

Health Care Fraud

Certain of our businesses are subject to federal and state (and similar foreign) health care fraud and abuse, referral and reimbursement laws and regulations with respect to their operations. Some of these laws, referred to as “false claims laws,” prohibit the submission or causing the submission of false or fraudulent claims for reimbursement to federal, state and other health care payers and programs. Other laws, referred to as “anti-kickback laws,” prohibit soliciting, offering, receiving or paying remuneration in order to induce the referral of a patient or ordering, purchasing, leasing or arranging for or recommending ordering, purchasing or leasing, of items or services that are paid for by federal, state and other health care payers and programs.

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The fraud and abuse laws and regulations have been subject to varying interpretations, as well as heightened enforcement activity over the past few years, and significant enforcement activity has been the result of “relators,” who serve as whistleblowers by filing complaints in the name of the United States (and if applicable, particular states) under federal and state false claims laws. Under the federal False Claims Act relators can be entitled to receive up to 30% of total recoveries. Also, violations of the federal False Claims Act can result in treble damages, and each false claim submitted can be subject to a penalty of up to \$11,000 per claim. Most states have adopted similar state false claims laws, and these state laws have their own penalties which may be in addition to federal False Claims Act penalties. The Health Care Reform Law significantly strengthened the federal False Claims Act and the federal Anti-Kickback Law provisions, which could lead to the possibility of increased whistleblower or relator suits, and among other things made clear that a federal Anti-Kickback Law violation can be a basis for federal False Claims Act liability.

The United States government (among others) has expressed concerns about financial relationships between suppliers on the one hand and physicians and dentists on the other. As a result, we regularly review and revise our marketing practices as necessary to facilitate compliance.

We also are subject to certain United States and foreign laws and regulations concerning the conduct of our foreign operations, including the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act and other anti-bribery laws and laws pertaining to the accuracy of our internal books and records, which have been the focus of increasing enforcement activity globally in recent years.

Failure to comply with fraud and abuse laws and regulations could result in significant civil and criminal penalties and costs, including the loss of licenses and the ability to participate in federal and state health care programs, and could have a material adverse effect on our business. Also, these measures may be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that could require us to make changes in our operations or incur substantial defense and settlement expenses. Even unsuccessful challenges by regulatory authorities or private relators could result in reputational harm and the incurring of substantial costs. In addition, many of these laws are vague or indefinite and have not been interpreted by the courts, and have been subject to frequent modification and varied interpretation by prosecutorial and regulatory authorities, increasing the risk of noncompliance.

While we believe that we are substantially compliant with applicable fraud and abuse laws and regulations, and have adequate compliance programs and controls in place to ensure substantial compliance, we cannot predict whether changes in applicable law, or interpretation of laws, or changes in our services or marketing practices in response to changes in applicable law or interpretation of laws, could have a material adverse effect on our business.

Health Care Reform

The United States Health Care Reform Law adopted through the March 2010 enactment of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act increased federal oversight of private health insurance plans and included a number of provisions designed to reduce Medicare expenditures and the cost of health care generally, to reduce fraud and abuse, and to provide access to increased health coverage.

The Health Care Reform Law requirements include a 2.3% excise tax on domestic sales of many medical devices by manufacturers and importers that began in 2013 (a moratorium was imposed beginning January 1, 2016 and ending December 31, 2017 and therefore the tax does not apply to sales during that period) and a fee on branded prescription drugs and biologics that was implemented in 2011, both of which may affect sales. The Health Care Reform Law has also materially expanded the number of individuals in the United States with health insurance. The Health Care Reform Law has faced ongoing legal challenges, including litigation seeking to invalidate some of or all of the law or the manner in which it has been interpreted. As a result, while upholding the law generally, the United States

Supreme Court has effectively made the Health Care Reform Law's Medicaid expansion voluntary for each state. There has been an effort by the political party in control of Congress to repeal some or all of the law. The uncertain status of the Health Care Reform Law affects our ability to plan.

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A Health Care Reform Law provision, generally referred to as the Physician Payment Sunshine Act or Open Payments Program, has imposed new reporting and disclosure requirements for drug and device manufacturers with regard to payments or other transfers of value made to certain practitioners (including physicians, dentists and teaching hospitals), and for such manufacturers and for group purchasing organizations, with regard to certain ownership interests held by physicians in the reporting entity. On February 1, 2013, the Centers for Medicare and Medicaid Services (“CMS”) released the final rule to implement the Physician Payment Sunshine Act. Under this rule, data collection activities began on August 1, 2013, and as required under the Physician Payment Sunshine Act, CMS publishes information from these reports on a publicly available website, including amounts transferred and physician, dentist and teaching hospital identities.

Under the Physician Payment Sunshine Act we are required to collect and report detailed information regarding certain financial relationships we have with physicians, dentists and teaching hospitals, and we believe that we are substantially compliant with applicable Physician Payment Sunshine Act requirements. The Physician Payment Sunshine Act pre-empts similar state reporting laws, although we or our subsidiaries may also be required to report under certain state transparency laws that address circumstances not covered by the Physician Payment Sunshine Act, and some of these state laws, as well as the federal law, can be ambiguous. We are also subject to foreign regulations requiring transparency of certain interactions between suppliers and their customers. While we believe we have substantially compliant programs and controls in place to comply with these requirements, our compliance with these rules imposes additional costs on us.

Regulated Software; Electronic Health Records

The FDA has become increasingly active in addressing the regulation of computer software intended for use in health care settings, and has developed and continues to develop policies on regulating clinical decision support tools and other types of software as medical devices. Certain of our businesses involve the development and sale of software and related products to support physician and dental practice management, and it is possible that the FDA or foreign government authorities could determine that one or more of our products is a medical device, which could subject us or one or more of our businesses to substantial additional requirements with respect to these products.

In addition, our businesses that involve physician and dental practice management products include electronic information technology systems that store and process personal health, clinical, financial and other sensitive information of individuals. These information technology systems may be vulnerable to breakdown, wrongful intrusions, data breaches and malicious attack, which could require us to expend significant resources to eliminate these problems and address related security concerns, and could involve claims against us by private parties and/or governmental agencies. For example, we are directly or indirectly subject to numerous and evolving federal, state, local and foreign laws and regulations that protect the privacy and security of such information, such as the privacy and security provisions of the federal Health Insurance Portability and Accountability Act of 1996, as amended, and implementing regulations (“HIPAA”). HIPAA requires, among other things, the implementation of various recordkeeping, operational, notice and other practices intended to safeguard that information, limit its use to allowed purposes and notify individuals in the event of privacy and security breaches.

We also sell products and services that health care providers, such as physicians and dentists, use to store and manage patient medical or dental records. These customers are subject to laws and regulations, such as HIPAA, which require that they protect the privacy and security of those records, and our products may be used as part of these customers’ comprehensive data security programs, including in connection with their efforts to comply with applicable privacy and security laws. Perceived or actual security vulnerabilities in our products or services, or the perceived or actual failure by us or our customers who use our products to comply with applicable legal requirements, may not only cause us significant reputational harm, but may also lead to claims against us by our customers and/or governmental agencies and involve substantial fines, penalties and other liabilities and expenses and costs for remediation.

Federal initiatives provide a program of incentive payments available to certain health care providers involving the adoption and use of certain electronic health care records systems and processes. The initiatives include providing, among others, physicians and dentists, with financial incentives, if they meaningfully use certified electronic health record technology (“EHR”) in accordance with applicable requirements. In addition, Medicare-eligible providers that fail to timely adopt certified EHR systems and meet “meaningful use” requirements for those

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systems in accordance with regulatory requirements are to be subject to cumulative Medicare reimbursement reductions, which reductions for applicable health professionals (including physicians and dentists) began on January 1, 2015. Qualification for the incentive payments requires the use of EHRs that have certain capabilities for meaningful use pursuant to evolving standards adopted by CMS and by the Office of the National Coordinator for Health Information Technology (“ONC”) of the Department of Health and Human Services (“HHS”). Generally, initial (“Stage 1”) standards addressed criteria for periods beginning in 2011, and more demanding “Stage 2” standards addressed criteria for periods beginning in 2014. On October 6, 2015, CMS and ONC released comprehensive final rules with respect to the EHR program that, among other things, establish the more challenging “Stage 3” criteria, make certain adjustments to Stage 1 and Stage 2 standards (e.g., reducing the 2015 reporting period from a full year to 90 days), and finalize 2015 edition health information technology (HIT) certification criteria (which is now added to the existing 2014 edition HIT certification criteria, but not required until 2018). Notably, under the new rules, compliance with Stage 3 standards will be optional for providers in 2017, and would generally be required for all eligible providers (regardless of prior participation in the EHR incentive program) for 2018 reporting periods and subsequently. Developers and others involved in the manufacture of EHR program technology will have this interim period to develop and certify products, and work with customers to implement products for the 2018 EHR program period. In connection with the release of the October 6 rules, HHS has also stated it will continue to modify applicable EHR program standards. In addition, under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), which establishes the Merit-Based Incentive Payment System (MIPS), over the next few years the EHR program is expected to become part of a more comprehensive federal quality measurement and incentive program, apparently with modified applicable requirements, and CMS has indicated that it may even supplant certain Stage 3 rules with more streamlined MIPS approaches.

Certain of our businesses involve the manufacture and sale of certified EHR systems and other products linked to incentive programs, and therefore we must maintain compliance with, and are affected by, these changing governmental criteria.

HIPAA requires certain health care providers, such as physicians, to use certain transaction and code set rules for specified electronic transactions, such as transactions involving claims submissions. Commencing July 1, 2012, CMS required that electronic claim submissions and related electronic transactions be conducted under a new HIPAA transaction standard called Version 5010. CMS has required this upgrade in connection with another new requirement applicable to the industry, the implementation of new diagnostic code sets to be used in claims submission, called the ICD-10-CM. The ICD-10-CM standard was implemented on October 1, 2015, and claims with dates of service of October 1, 2015 or after must be submitted using ICD-10-CM code sets. Certain of our businesses provide electronic practice management products that must meet these requirements, and while we believe that our products have timely adopted the new standards, it is possible that the transition to these new standards, particularly the transition to ICD-10-CM, may result in a degree of disruption and confusion, thus potentially increasing the costs associated with supporting these products.

There may be additional legislative initiatives in the future impacting health care.

International Transactions

In addition, United States and foreign import and export laws and regulations require us to abide by certain standards relating to the importation and exportation of products. We also are subject to certain laws and regulations concerning the conduct of our foreign operations, including the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act and other anti-bribery laws and laws pertaining to the accuracy of our internal books and records, as well as other types of foreign requirements similar to those imposed in the United States.

While we believe that we are substantially compliant with the foregoing laws and regulations promulgated thereunder and possess all material permits and licenses required for the conduct of our business, there can be no assurance that regulations that impact our business or customers' practices will not have a material adverse effect on our business. As a result of political, economic and regulatory influences, the health care distribution industry in the United States is under intense scrutiny and subject to fundamental changes. We cannot predict what further reform proposals, if any, will be adopted, when they may be adopted, or what impact they may have on us.

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See “ITEM 1A. Risk Factors” for a discussion of additional burdens, risks and regulatory developments that may affect our results of operations and financial condition.

Proprietary Rights

We hold trademarks relating to the “Henry Schein®” name and logo, as well as certain other trademarks. We intend to protect our trademarks to the fullest extent practicable.

Employees

As of December 26, 2015, we employed nearly 19,000 full-time employees, including approximately 1,850 telesales representatives, 3,725 field sales consultants, including equipment sales specialists, 3,900 warehouse employees, 600 computer programmers and technicians, 950 management employees and 7,900 office, clerical and administrative employees. Approximately 301, or 1.6%, of our employees were subject to collective bargaining agreements. We believe that our relations with our employees are excellent.

Available Information

We make available free of charge through our Internet website, www.henryschein.com, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, statements of beneficial ownership of securities on Forms 3, 4 and 5 and amendments to these reports and statements filed or furnished pursuant to Section 13(a) and Section 16 of the Securities Exchange Act of 1934 as soon as reasonably practicable after such materials are electronically filed with, or furnished to, the United States Securities and Exchange Commission, or SEC.

The above information is also available at the SEC’s Office of Investor Education and Advocacy at United States Securities and Exchange Commission, 100 F Street, N.E., Washington, D.C. 20549-0213 or obtainable by calling the SEC at (800) 732-0330. In addition, the SEC maintains an Internet website at www.sec.gov, where the above information can be viewed.

Our principal executive offices are located at 135 Duryea Road, Melville, New York 11747, and our telephone number is (631) 843-5500. Unless the context specifically requires otherwise, the terms the “Company,” “Henry Schein,” “we,” “us” and “our” mean Henry Schein, Inc., a Delaware corporation, and its consolidated subsidiaries.

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Executive Officers of the Registrant

The following table sets forth certain information regarding our executive officers:

Name	Age	Position
Stanley M. Bergman	66	Chairman, Chief Executive Officer, Director
Gerald A. Benjamin	63	Executive Vice President, Chief Administrative Officer, Director
James P. Breslawski	61	President, Henry Schein and CEO, Global Dental Group, Director Senior Vice President, Corporate & Legal Affairs and Chief of Staff,
Michael S. Ettinger	54	Secretary
James A. Harding	60	Senior Vice President, Chief Technology Officer
Stanley Komaroff	80	Senior Advisor
Peter McCarthy	56	President, Global Animal Health Group Senior Vice President, Global Human Resources and Financial
Lorelei McGlynn	52	Operations
David C. McKinley	63	President, Medical Group
Bob Minowitz	57	President, International Dental Group
Mark E. Mlotek	60	Executive Vice President, Chief Strategic Officer, Director
Steven Paladino	58	Executive Vice President, Chief Financial Officer, Director
Michael Racioppi	61	Senior Vice President, Chief Merchandising Officer
Paul Rose	58	Senior Vice President, Global Supply Chain
Lonnie Shoff	57	CEO, Global Strategic Portfolio Group
Walter Siegel	56	Senior Vice President and General Counsel

Stanley M. Bergman has been our Chairman and Chief Executive Officer since 1989 and a director since 1982. Mr. Bergman held the position of President from 1989 to 2005. Mr. Bergman held the position of Executive Vice President from 1985 to 1989 and Vice President of Finance and Administration from 1980 to 1985.

Gerald A. Benjamin has been our Executive Vice President and Chief Administrative Officer since 2000 and a director since 1994. Prior to holding his current position, Mr. Benjamin was Senior Vice President of Administration and Customer Satisfaction since 1993. Mr. Benjamin was Vice President of Distribution Operations from 1990 to 1992 and Director of Materials Management from 1988 to 1990. Before joining us in 1988, Mr. Benjamin was employed for 12 years at Estée Lauder, Inc., in various management positions where his last position was Director of Materials Planning and Control.

James P. Breslawski has been our President since 2005 and a director since 1992. Mr. Breslawski is also the Chief Executive Officer of our Henry Schein Global Dental Group. Mr. Breslawski held the position of Executive Vice President and President of U.S. Dental from 1990 to 2005, with primary responsibility for the North American Dental Group. Between 1980 and 1990, Mr. Breslawski held various positions with us, including Chief Financial Officer, Vice President of Finance and Administration and Corporate Controller.

Michael S. Ettinger has been Senior Vice President, Corporate & Legal Affairs, Chief of Staff and Secretary since 2015. Prior to his current position, Mr. Ettinger served as Senior Vice President, Corporate & Legal Affairs and Secretary from 2013 to 2015, Corporate Senior Vice President, General Counsel & Secretary from 2006 to 2013, Vice President, General Counsel and Secretary from 2000 to 2006, Vice President and Associate General Counsel from 1998 to 2000 and Associate General Counsel from 1994 to 1998. Before joining us, Mr. Ettinger served as a senior associate with Bower & Gardner and as a member of the Tax Department at Arthur Andersen.

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James A. Harding has been our Corporate Chief Technology Officer since 2005 and Senior Vice President since 2001. Prior to holding his current position, Mr. Harding was Chief Information Officer since 2001, with primary responsibility for worldwide information technology.

Stanley Komaroff has been our Senior Advisor since 2003. Prior to joining us, Mr. Komaroff was a partner for 35 years in the law firm of Proskauer Rose LLP, counsel to us. He served as Chairman of that firm from 1991 to 1999.

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Peter McCarthy has been President, Global Animal Health Group since 2015. Prior to holding his current position, Mr. McCarthy was President, Henry Schein International Animal Health from 2012 to 2015 and President, Henry Schein Animal Health, Europe from 2010 to 2012. Prior to joining us, Mr. McCarthy was employed with Schering-Plough Animal Health (now Merck Animal Health), serving as Senior Director, Global Operations and General Manager, China. Mr. McCarthy also worked at Wyeth/American Cyanamid for 14 years, helping to grow the human pharmaceutical business.

Lorelei McGlynn has served as Senior Vice President, Global Human Resources and Financial Operations since 2013. Since joining us in 1999, Ms. McGlynn has served as Vice President, Global Human Resources and Financial Operations from 2008 to 2013, Chief Financial Officer, International Group and Vice President of Global Financial Operations from 2002 to 2008 and Vice President, Finance, North America from 1999 to 2002. Prior to joining us, Ms. McGlynn served as Assistant Vice President of Finance at Adecco Corporation.

David C. McKinley has been President of Henry Schein's Medical Group since 2008. Before assuming his current position, Mr. McKinley was President of Henry Schein Practice Solutions from 2006 to 2008 and President of Dental Prosthetic Solutions from 2005 to 2006. Prior to joining us, Mr. McKinley served as the Group Executive for Olympus Medical North America and as General Manager for the Bard Urology and Bard Germany businesses. Mr. McKinley currently serves on the Health Industry Distributors Association (HIDA) Education Foundation.

Bob Minowitz has been President of Henry Schein's International Dental Group since 2012. Before assuming his current position, Mr. Minowitz held a number of key roles with increasing responsibility throughout the Company, including President, Henry Schein European Dental Group from 2009 to 2012, President, Henry Schein Western Europe, Middle East and Pacific Regions from 2006 to 2009, Managing Director, Henry Schein U.K. Holdings from 2004 to 2006, President Henry Schein Western Europe from 2004 to 2006 and President Henry Schein Europe from 2001 to 2004. Prior to joining us, Mr. Minowitz was employed by Bristol-Myers Company as a Senior Internal Auditor.

Mark E. Mlotek has been Executive Vice President and Chief Strategic Officer since 2012. Mr. Mlotek was Senior Vice President and subsequently Executive Vice President of the Corporate Business Development Group between 2000 and 2012. Prior to that, Mr. Mlotek was Vice President, General Counsel and Secretary from 1994 to 1999 and became a director in 1995. Prior to joining us, Mr. Mlotek was a partner in the law firm of Proskauer Rose LLP, counsel to us, specializing in mergers and acquisitions, corporate reorganizations and tax law from 1989 to 1994.

Steven Paladino has been our Executive Vice President and Chief Financial Officer since 2000. Prior to holding his current position, Mr. Paladino was Senior Vice President and Chief Financial Officer from 1993 to 2000 and has been a director since 1992. From 1990 to 1992, Mr. Paladino served as Vice President and Treasurer and from 1987 to 1990 served as Corporate Controller. Before joining us, Mr. Paladino was employed in public accounting for seven years, most recently with the international accounting firm of BDO USA, LLP. Mr. Paladino is a certified public accountant.

Michael Racioppi has been our Senior Vice President, Chief Merchandising Officer since 2008. Prior to holding his current position, Mr. Racioppi was President of the Medical Division from 2000 to 2008 and Interim President from 1999 to 2000, and Corporate Vice President from 1994 to 2008, with primary responsibility for the Medical Group, Marketing and Merchandising departments. Mr. Racioppi served as Senior Director, Corporate Merchandising from 1992 to 1994. Before joining us in 1992, Mr. Racioppi was employed by Ketchum Distributors, Inc. as the Vice President of Purchasing and Marketing. He currently serves on the board of National Distribution and Contracting and previously served on the board of Health Distribution Management Association and Health Industry Distributors Association (HIDA).

Paul Rose has served as Senior Vice President, Global Supply Chain since 2013. Prior to holding his current position, Mr. Rose held a number of key roles with increasing responsibility throughout the Company, including serving as Vice President, Global Supply Chain from 2008 to 2013, Vice President, Global Inventory Management from 2004 to 2008 and Vice President, Inventory Management, North America from 2001 to 2004. He also served on the HIDA Supply Chain Advisory Council and as the National Wholesale Druggists' Associations Pharmaceutical Market Committee Chairman.

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Lonnie Shoff has been Chief Executive Officer of the Global Strategic Portfolio Group since 2015. Prior to holding her current position, Ms. Shoff was Chief Executive Officer of the Global Animal Health and Strategic Partnerships Group from 2012 to 2015 and President, Global Healthcare Specialties Group from 2009 to 2012. Prior to joining us, Ms. Shoff was employed with Roche Diagnostics, where she held a series of positions of increasing responsibility in the United States and Switzerland over the past 20 years, most recently as Senior Vice President and General Manager, Applied Science.

Walter Siegel has been Senior Vice President and General Counsel since 2013. Prior to joining us, Mr. Siegel was employed with Standard Microsystems Corporation, a publicly traded global semiconductor company from 2005 to 2012, holding positions of increasing responsibility, most recently as Senior Vice President, General Counsel and Secretary.

ITEM 1A. Risk Factors

The risks described below could have a material adverse effect on our business, reputation, financial condition and/or the trading price of our common stock. Although it is not possible to predict or identify all such risks and uncertainties, they may include, but are not limited to, the factors discussed below. Our business operations could also be affected by additional factors that are not presently known to us or that we currently consider not to be material to our operations. You should not consider this list to be a complete statement of all risks and uncertainties. The order in which these factors appear should not be construed to indicate their relative importance or priority.

The health care products distribution industry is highly competitive and consolidating and we may not be able to compete successfully.

We compete with numerous companies, including several major manufacturers and distributors. Some of our competitors have greater financial and other resources than we do, which could allow them to compete more successfully. Most of our products are available from several sources and our customers tend to have relationships with several distributors. Competitors could obtain exclusive rights to market particular products, which we would then be unable to market. Manufacturers also could increase their efforts to sell directly to end-users and thereby eliminate or reduce our role and that of other distributors. Industry consolidation among health care product distributors, price competition, the unavailability of products, whether due to our inability to gain access to products or to interruptions in supply from manufacturers, or the emergence of new competitors also could increase competition. There has also been increasing consolidation among manufacturers of health care products which could have a material adverse effect on our margins and product availability. Additionally, in this competitive market, some of our contracts contain minimum purchase commitments. We could be subject to charges and financial losses in the event we fail to satisfy minimum purchase commitments. In the future, we may be unable to compete successfully and competitive pressures may reduce our revenues and profitability.

Because substantially all of the products that we distribute are not manufactured by us, we are dependent upon third parties for the manufacture and supply of substantially all of our products.

We obtain substantially all of our products from third parties. Generally, we do not have long-term contracts with our suppliers committing them to supply products to us. Therefore, suppliers may not provide the products we need in the quantities we request. While there is generally more than one source of supply for most of the categories of products we sell, some key suppliers, in the aggregate, supply a significant portion of the products we sell. Additionally, because we generally do not control the actual production of the products we sell, we may be subject to delays caused by interruption in production based on conditions outside of our control, including the failure to comply with applicable government requirements. The failure of manufacturers of products regulated by the FDA or other

governmental agencies to meet these requirements could result in product recall, cessation of sales or other market disruptions. In the event that any of our third-party suppliers were to become unable or unwilling to continue to provide the products in required volumes, we would need to identify and obtain acceptable replacement sources on a timely basis. There is no guarantee that we would be able to obtain such alternative sources of supply on a timely basis, if at all. An extended interruption in the supply of our products, especially any high sales volume product, could have a material adverse effect on our results of operations, which most likely would adversely affect the value of our common stock.

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Our revenues and profitability depend on our relationships with capable sales personnel as well as customers, suppliers and manufacturers of the products that we distribute.

Our future revenues and profitability depend on our ability to maintain satisfactory relationships with qualified sales personnel as well as customers, suppliers and manufacturers. If we fail to maintain our existing relationships with such persons or fail to acquire relationships with such key persons in the future, our business may be materially adversely affected.

Our future success is substantially dependent upon our senior management.

Our future success is substantially dependent upon the efforts and abilities of members of our existing senior management, particularly Stanley M. Bergman, Chairman and Chief Executive Officer, among others. The loss of the services of Mr. Bergman could have a material adverse effect on our business. We have an employment agreement with Mr. Bergman. We do not currently have “key man” life insurance policies on any of our employees. Competition for senior management is intense and we may not be successful in attracting and retaining key personnel.

We experience fluctuations in quarterly earnings. As a result, we may fail to meet or exceed the expectations of securities analysts and investors, which could cause our stock price to decline.

Our business is subject to seasonal and other quarterly fluctuations. Revenues and profitability generally have been higher in the third and fourth quarters due to the timing of sales of seasonal products (including influenza vaccine, equipment and software products), purchasing patterns of office-based health care practitioners and year-end promotions. Revenues and profitability generally have been lower in the first quarter, primarily due to increased sales in the prior two quarters. We expect our historical seasonality of sales to continue in the foreseeable future. Quarterly results may also be materially adversely affected by a variety of other factors, including:

- timing and amount of sales and marketing expenditures;
- timing of pricing changes offered by our suppliers;
- timing of the introduction of new products and services by our suppliers;
- timing of the release of upgrades and enhancements to our technology-related products and services;
- changes in or availability of supplier contracts or rebate programs;
- supplier rebates based upon attaining certain growth goals;
- changes in the way suppliers introduce or deliver products to market;
- costs of developing new applications and services;
- our ability to correctly identify customer needs and preferences and predict future needs and preferences;
- uncertainties regarding potential significant breaches of data security or disruptions of our information technology systems;
- unexpected regulatory actions, or government regulation generally;

- exclusivity requirements with certain suppliers may prohibit us from distributing competitive products manufactured by other suppliers;
- loss of sales representatives;
- costs related to acquisitions and/or integrations of technologies or businesses;

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- costs associated with our self-insured medical and dental insurance programs;
- general market and economic conditions, as well as those specific to the health care industry and related industries;
- our success in establishing or maintaining business relationships;
- unexpected difficulties in developing and manufacturing products;
- product demand and availability or recalls by manufacturers;
- exposure to product liability and other claims in the event that the use of the products we sell results in injury;
- increases in shipping costs or service issues with our third-party shippers;
- fluctuations in the value of foreign currencies;
- restructuring costs;
- the adoption or repeal of legislation; and
- changes in accounting principles.

Any change in one or more of these or other factors could cause our annual or quarterly financial results to fluctuate. If our financial results do not meet market expectations, our stock price may decline.

Expansion of group purchasing organizations (“GPO”) or provider networks and the multi-tiered costing structure may place us at a competitive disadvantage.

The medical products industry is subject to a multi-tiered costing structure, which can vary by manufacturer and/or product. Under this structure, certain institutions can obtain more favorable prices for medical products than we are able to obtain. The multi-tiered costing structure continues to expand as many large integrated health care providers and others with significant purchasing power, such as GPOs, demand more favorable pricing terms. Additionally, the formation of provider networks and GPOs may shift purchasing decisions to entities or persons with whom we do not have a historical relationship. This may threaten our ability to compete effectively, which would in turn negatively impact our financial results. Although we are seeking to obtain similar terms from manufacturers, obtain access to lower prices demanded by GPO contracts or other contracts, and develop relationships with provider networks and new GPOs, we cannot assure that such terms will be obtained or contracts will be executed.

Increases in shipping costs or service issues with our third-party shippers could harm our business.

Shipping is a significant expense in the operation of our business. We ship almost all of our orders through third-party delivery services, and typically bear the cost of shipment. Accordingly, any significant increase in shipping rates could have a material adverse effect on our operating results. Similarly, strikes or other service interruptions by those shippers could cause our operating expenses to rise and materially adversely affect our ability to deliver products on a timely basis.

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Uncertain global macro-economic and political conditions could materially adversely affect our results of operations and financial condition.

Uncertain global macro-economic and political conditions that affect the economy and the economic outlook of the United States, Europe and other parts of the world could adversely affect our customers and suppliers, which could materially adversely affect our results of operations and financial condition. These uncertainties, including, among other things, sovereign debt levels, the inability of political institutions to effectively resolve actual or perceived economic, currency or budgetary crises or issues, consumer confidence, election results, unemployment levels (and a corresponding increase in the uninsured and underinsured population), interest rates, availability of capital, fuel and energy costs, tax rates, health care costs and the threat or outbreak of terrorism or public unrest, could adversely impact our customers and suppliers, which could materially adversely affect us. Changes in government, government debt and/or budget crises may lead to reductions in government spending in certain countries, which could reduce overall health care spending, and/or higher income or corporate taxes, which could depress spending overall. Additionally, recessionary conditions and depressed levels of consumer and commercial spending may cause customers to reduce, modify, delay or cancel plans to purchase our products and may cause suppliers to reduce their output or change their terms of sale. We generally sell products to customers with payment terms. If customers' cash flow or operating and financial performance deteriorates, or if they are unable to make scheduled payments or obtain credit, they may not be able to pay, or may delay payment to us. Likewise, for similar reasons suppliers may restrict credit or impose different payment terms. Any inability of current and/or potential customers to pay us for our products and/or services or any demands by suppliers for different payment terms may materially adversely affect our results of operations and financial condition.

Disruptions in the financial markets may materially adversely affect the availability and cost of credit to us.

Our ability to make scheduled payments or refinance our obligations with respect to indebtedness will depend on our operating and financial performance, which in turn is subject to prevailing economic conditions and financial, business and other factors beyond our control. Disruptions in the financial markets may materially adversely affect the availability and cost of credit to us.

The market price for our common stock may be highly volatile.

The market price for our common stock may be highly volatile. A variety of factors may have a significant impact on the market price of our common stock, including:

- the publication of earnings estimates or other research reports and speculation in the press or investment community;
- changes in our industry and competitors;
- changes in government or legislation;
- our financial condition, results of operations and cash flows and prospects;
- stock repurchases;
- any future issuances of our common stock, which may include primary offerings for cash, stock splits, issuances in connection with business acquisitions, issuances of restricted stock/units and the grant or exercise of stock options from time to time;

- general market and economic conditions; and
- any outbreak or escalation of hostilities in areas where we do business.

In addition, the NASDAQ Stock Market can experience extreme price and volume fluctuations that can be unrelated or disproportionate to the operating performance of the companies listed on NASDAQ. Broad market and industry factors may negatively affect the market price of our common stock, regardless of actual operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted against companies. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which could have a material adverse effect on our business.

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The health care industry is experiencing changes that could materially adversely affect our business.

The health care industry is highly regulated and subject to changing political, economic and regulatory influences. In recent years, the health care industry has undergone, and is in the process of undergoing, significant changes driven by various efforts to reduce costs, including: trends toward managed care; consolidation of health care distribution companies; consolidation of health care manufacturers; collective purchasing arrangements and consolidation among office-based health care practitioners; and changes in reimbursements to customers, as well as growing enforcement activities (and related monetary recoveries) by governmental officials. Both our profitability and the profitability of our customers may be materially adversely affected by laws and regulations reducing reimbursement rates for pharmaceuticals and/or medical treatments or services, changing the methodology by which reimbursement levels are determined and, in the case of animal health practitioners, changes in the use of feed additives (including, without limitation, antibiotics and growth promotants) used in the production of animal products due to trade restrictions, animal welfare and/or government regulations; and changes in customer buying habits (including customers purchasing animal health pharmaceuticals outside the veterinarians' offices). If we are unable to react effectively to these and other changes in the health care industry, our financial results could be materially adversely affected.

The implementation of the Health Care Reform Law could materially adversely affect our business.

The United States Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act, each enacted in March 2010, generally known as the Health Care Reform Law, significantly expand health insurance coverage to uninsured Americans and changes the way health care is financed by both governmental and private payers. We expect expansion of access to health insurance to increase the demand for our products and services, but other provisions of the Health Care Reform Law could have a material adverse effect on our business, and the Health Care Reform Law may be invalidated, in whole or in part, or it may be repealed. Additionally, further federal and state proposals for health care reform in the United States are likely, and foreign government authorities may also adopt reforms of their health systems. We cannot predict what further reform proposals, if any, will be adopted, when they may be adopted, or what impact they may have on us.

The Health Care Reform Law contains many provisions designed to generate the revenues necessary to fund the coverage expansions and to reduce costs of Medicare and Medicaid, including imposing a 2.3% excise tax on domestic sales of many medical devices by manufacturers and importers that began in 2013, and a fee on branded prescription drugs and biologics that was implemented in 2011, both of which may adversely affect sales and cost of goods sold. As part of H.R. 2029 – Consolidated Appropriations Act, 2016 a moratorium was imposed on the Medical Device Excise Tax for the period beginning January 1, 2016 and ending on December 31, 2017. As such, the Medical Device Excise Tax does not apply to sales during that period.

The implementation of the reporting and disclosure obligations of the Physician Payment Sunshine Act provisions of the Health Care Reform Law could adversely affect our business.

A Health Care Reform Law provision, generally referred to as the Physician Payment Sunshine Act or Open Payments Program, imposes reporting and disclosure requirements for drug and device manufacturers with regard to payments or other transfers of value made to certain practitioners (including physicians, dentists and teaching hospitals), and for such manufacturers and for group purchasing organizations, with regard to certain ownership interests held by physicians in the reporting entity. On February 1, 2013, CMS released the final rule to implement the Physician Payment Sunshine Act. Under this rule, data collection activities (which began on August 1, 2013) as required under the Physician Payment Sunshine Act, CMS publishes information from these reports on a publicly available website, including amounts transferred and physician, dentist and teaching hospital identities. Under the Physician Payment Sunshine Act we are required to collect and report detailed information regarding certain financial relationships we have with physicians, dentists and teaching hospitals, and we believe that we are substantially compliant with

applicable Physician Payment Sunshine Act requirements. The Physician Payment Sunshine Act pre-empts similar state reporting laws, although we or our subsidiaries may also be required to report under certain state transparency laws that address circumstances not covered by the Physician Payment Sunshine Act, and some of these state laws, as well as the federal law, can be ambiguous. We are also subject to foreign regulations requiring transparency of certain interactions between suppliers and their customers. While we believe we have substantially compliant programs and controls in place to comply with these reporting requirements, our compliance with these new rules imposes additional costs on us.

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Failure to comply with existing and future regulatory requirements could materially adversely affect our business.

Our business is subject to requirements under various local, state, federal and international laws and regulations applicable to the distribution of pharmaceuticals and medical devices, and human cells, tissue and cellular and tissue-based products, also known as HCT/P products, and animal feed and supplements. Among the federal laws with which we must comply are the Controlled Substances Act, the Federal Food, Drug, and Cosmetic Act, as amended, and Section 361 of the Public Health Services Act. Among other things, such laws, and the regulations promulgated thereunder:

- regulate the storage and distribution, labeling, packaging, handling, reporting, record keeping, introduction, manufacturing and marketing of drugs, HCT/P products and medical devices;
- subject us to inspection by the FDA and the DEA;
- regulate the storage, transportation and disposal of certain of our products that are considered hazardous materials;
- require us to advertise and promote our drugs and devices in accordance with applicable FDA requirements;
- require registration with the FDA and the DEA and various state agencies;
- require record keeping and documentation of transactions involving drug products;
- require us to design and operate a system to identify and report suspicious orders of controlled substances to the DEA;
- require us to manage returns of products that have been recalled and subject us to inspection of our recall procedures and activities; and
- impose reporting requirements if a pharmaceutical, HCT/P product or medical device causes serious illness, injury or death.

Applicable federal, state, local and foreign laws and regulations also may require us to meet various standards relating to, among other things, licensure or registration, sales and marketing practices, product integrity and supply tracking to the manufacturer of the product, personnel, privacy and security of health or other personal information, installation, maintenance and repair of equipment, and the importation and exportation of products. Our business also is subject to requirements of similar and other foreign governmental laws and regulations affecting our operations abroad. The FDA and DEA have recently increased their regulatory and enforcement activities.

The failure to comply with any of these regulations, or new interpretations of existing laws and regulations, or the imposition of any additional laws and regulations, could materially adversely affect our business. There can be no assurance that current government regulations will not adversely affect our business. The costs to us associated with complying with the various applicable statutes and regulations, as they now exist and as they may be modified, could be material. Allegations by a governmental body that we have not complied with these laws could have a material adverse effect on our businesses. If it is determined that we have not complied with these laws, we are potentially subject to penalties including warning letters, civil and criminal penalties, mandatory recall of product, seizure of product and injunction, consent decrees, and suspension or limitation of product sale and distribution. If we enter into settlement agreements to resolve allegations of non-compliance, we could be required to make settlement payments or be subject to civil and criminal penalties, including fines and the loss of licenses. Non-compliance with government requirements could adversely affect our ability to participate in federal and state government health care programs,

and damage our reputation.

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If we fail to comply with laws and regulations relating to health care fraud or other laws and regulations, we could suffer penalties or be required to make significant changes to our operations, which could materially adversely affect our business.

Certain of our businesses are subject to federal and state (and similar foreign) health care fraud and abuse, referral and reimbursement laws and regulations with respect to their operations. Some of these laws, referred to as “false claims laws,” prohibit the submission or causing the submission of false or fraudulent claims for reimbursement to federal, state and other health care payers and programs. Other laws, referred to as “anti-kickback laws,” prohibit soliciting, offering, receiving or paying remuneration in order to induce the referral of a patient or ordering, purchasing, leasing or arranging for or recommending ordering, purchasing or leasing, of items or services that are paid for by federal, state and other health care payers and programs. Health care fraud measures may implicate, for example, our relationships with pharmaceutical manufacturers, our pricing and incentive programs for physician and dental practices, and our dental and physician practice management products that offer billing-related functionality.

The fraud and abuse regulations have been subject to varying interpretations, as well as heightened enforcement activity, over the past few years, and significant enforcement activity has been the result of “relators,” who serve as whistleblowers by filing complaints in the name of the United States (and if applicable, particular states) under federal and state false claims laws. Under the federal False Claims Act relators can be entitled to receive up to 30% of total recoveries. Also, violations of the federal False Claims Act can result in treble damages, and each false claim submitted can be subject to a penalty of up to \$11,000 per claim. Most states have adopted similar state false claims laws, and these state laws have their own penalties which may be in addition to federal False Claims Act penalties. The Health Care Reform Law significantly strengthened the federal False Claims Act and the federal Anti-Kickback Law provisions, which could lead to the possibility of increased whistleblower or relator suits, and among other things made clear that a federal Anti-Kickback Law violation can be a basis for federal False Claims Act liability.

The United States government (among others) has expressed concerns about financial relationships between suppliers on the one hand and physicians and dentists on the other. As a result, we regularly review and revise our marketing practices as necessary to facilitate compliance.

We also are subject to certain United States and foreign laws and regulations concerning the conduct of our foreign operations, including the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act and other anti-bribery laws, anti-corruption laws, and laws pertaining to the accuracy of our internal books and records, which have been the focus of increasing enforcement activity globally in recent years. Our businesses are generally subject to numerous other laws and regulations that could impact our financial results, including, without limitation, securities, antitrust and marketing laws and regulations. Failure to comply with laws or regulations could have a material adverse effect on our business.

Failure to comply with fraud and abuse laws and regulations and other laws and regulations could result in significant civil and criminal penalties and costs, including the loss of licenses and the ability to participate in federal and state health care programs, and could have a material adverse effect on our business. Also, these measures may be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that could require us to make changes in our operations or incur substantial defense and settlement expenses. Even unsuccessful challenges by regulatory authorities or private relators could result in reputational harm and the incurring of substantial costs. In addition, many of these laws are vague or indefinite and have not been interpreted by the courts, and have been subject to frequent modification and varied interpretation by prosecutorial and regulatory authorities, increasing the risk of non-compliance. We may determine to enter into settlements, make payments, agree to consent decrees or enter into other arrangements to resolve such matters. For example, one of our subsidiaries recently resolved an investigation by the Federal Trade Commission (“FTC”) related to the manner in which it advertised certain data security features of its

dental practice management software, which resulted in a consent order and fine. Failure to comply with consent decrees could materially adversely affect our business.

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While we believe that we are substantially compliant with applicable fraud and abuse and other laws and regulations, and believe we have adequate compliance programs and controls in place to ensure substantial compliance, we cannot predict whether changes in applicable law, or interpretation of laws, or changes in our services or marketing practices in response to changes in applicable law or interpretation of laws, could have a material adverse effect on our business.

If we fail to comply with laws and regulations relating to the confidentiality of sensitive personal information or standards in electronic health data transmissions, we could be required to make significant changes to our products, or incur substantial fines, penalties or other liabilities.

Our businesses that involve physician and dental practice management products include electronic information technology systems that store and process personal health, clinical, financial and other sensitive information of individuals. These information technology systems may be vulnerable to breakdown, wrongful intrusions, data breaches and malicious attack, which could require us to expend significant resources to eliminate these problems and address related security concerns, and could involve claims against us by private parties and/or governmental agencies. For example, we are directly or indirectly subject to numerous federal, state, local and foreign laws and regulations that protect the privacy and security of such information, such as HIPAA. HIPAA requires, among other things, the implementation of various recordkeeping, operational, notice and other practices intended to safeguard that information, limit its use to allowed purposes and notify individuals in the event of privacy and security breaches. Failure to comply with t