

A woman wearing a white lab coat and a blue hairnet is focused on her work in a medical device manufacturing facility. She is seated at a table covered with a blue cloth, handling a white, bag-like component. In the background, other workers in similar attire are visible, along with various medical supplies and equipment. The scene is brightly lit with overhead fluorescent lights.

# HEALTHCARE AND MEDICAL DEVICES IN TENNESSEE



## **Healthcare and Medical Devices in Tennessee**

January 2018

Center for Economic Research in Tennessee (CERT)  
Tennessee Department of Economic and Community Development

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## Highlights

- Tennessee's healthcare and medical devices cluster encompasses a broad range of industries including eight subclusters.
- This cluster does not include local health services, such as hospitals, nursing homes, and ambulatory services. Instead, industries in this cluster create the products that make local healthcare delivery possible.
- Nashville is home to a strong hospital management sector. However, information regarding that sector does not appear in this research paper.
- Businesses in this cluster employ 27,427 Tennesseans.
- Tennessee has 923 healthcare and medical device businesses, as compared with 759 in 2012.

## Workforce

- Average wages in this cluster are \$107,764, which includes wages and supplements.
- Tennessee's average wages for this cluster are the second highest in the Southeast region and the 11<sup>th</sup> highest in the nation.
- More than 48% of all employees are between the ages 45 and 64, and an additional 6% are senior citizens.

## Key Industries

- Medical Equipment and Supplies
  - The medical equipment and supplies sub-cluster includes four industries: surgical and medical instrument manufacturing, surgical appliance and supplies manufacturing, ophthalmic goods manufacturing, and dental equipment and supplies manufacturing.
  - Businesses in this sub-cluster employ 8,003 Tennesseans, a 2.7% increase since 2012.
  - The majority of this employment is concentrated in the surgical appliance and supplies manufacturing industry. Tennessee's employment in this industry is the highest in the Southeast and the fourth highest among all U.S. states. Industry employment increased from 6,273 to 6,978 employees over the last five years, an 11.2% increase.
  - Since 2012, Tennessee has ranked third in the nation and first in the Southeast for employment concentration in surgical appliances and supplies.
- Electromedical and Electrotherapeutic Apparatus Manufacturing
  - This industry manufactures medical devices that utilize electrical currents, either for diagnostic or therapeutic purposes.
  - Diagnostic equipment includes magnetic resource imaging devices, ultrasound equipment, endoscopic devices, electrocardiographs, and other monitoring equipment.
  - Businesses in this industry currently employ 576 Tennesseans, an 18.7% increase since 2012.
  - Tennessee now has 18 companies that manufacture electromedical and electrotherapeutic apparatuses, up from 8 in 2012.
  - Average industry salaries in Tennessee are \$124,875, with \$102,753 in wages and \$22,122 in supplements.
- Pharmaceuticals
  - The pharmaceutical sub-cluster is composed of four industries: medicinal and botanical manufacturing, pharmaceutical preparation manufacturing, in-vitro diagnostic substance manufacturing, and biological product (except diagnostic) manufacturing.
  - Businesses in the pharmaceutical sub-cluster currently employ 2,230 Tennesseans, a 21.3% increase in employment since 2012.
- Equipment and Supplies Wholesalers
  - This sub-cluster encompasses two industries: medical, dental, and hospital equipment and supplies merchant wholesalers as well as ophthalmic goods merchant wholesalers.
  - Currently, these industries employ a total 6,300 Tennesseans, more than 6,000 of which work in the medical wholesale industry.

- However, employment in medical wholesaling has declined in recent years. In 2012, Tennessee ranked second in the region for industry employment but now ranks fourth.
- Research and Development in the Physical, Engineering, and Life Sciences
  - This industry encompasses nearly all types of life sciences research, with the exception of nanotechnology and biotechnology.
  - Currently, 7,247 Tennesseans are employed in life sciences research and development.
  - Tennessee ranks fourth in the region for total employment and is predicted to add more than 100 jobs in coming years.

### **Cluster Exports**

- Tennessee's healthcare and medical device businesses exported \$5.7 billion in products in 2016.
- The biggest export markets were Belgium (\$928.6 million), Japan (\$684.6 million), Singapore (\$679.7 million), China (\$562.9 million), and Canada (\$471.9 million). Exports to these countries accounted for 58.2% of all healthcare and medical device exports in 2016.
- In 2016, Tennessee manufacturers exported \$3.3 billion in medical equipment and supplies, more than any other state besides California.

### **TNECD Projects**

- Since 2011, the Tennessee Department of Economic and Community Development has received 76 project commitments to create 15,498 new jobs. Total capital investment has nearly reached \$1.4 billion.

### **Industry Trends and Opportunities**

- The key trends in US healthcare have been new settings, alternative providers, and changing management structures.
- Healthcare practice is transitioning away from traditional settings, in which a single hospital housed all types of medical providers, to a new system that emphasizes specialized care administered in out-patient settings. These settings include mobile health units, outpatient surgical and diagnostic centers, telephonic and online consultations, home-based services, and other types of remote/ambulatory care.

### **Impact on the Cluster**

- Changes in healthcare structures have significantly impacted the business strategies of downstream industries. Medical device manufacturers are facing greater pressure to consolidate. Group purchasing organizations (GPOs), which coordinate purchases for providers, enter into contracts with manufacturers with diverse product lines rather than doing business with individual suppliers.
- Despite the benefits of consolidation, large manufacturers are also hurt by cost-containment programs. Competitive bidding, as part of the Patient Protection and Affordable Care Act's (PPACA) changes to Medicare, has forced large companies to drop prices.
- Large manufacturers rely on consolidation to streamline distribution channels, benefitting U.S. companies at a time when domestic producers are at an inherent disadvantage to foreign competitors.
- Reasons for this disadvantage include an appreciating dollar, growing domestic demand relative to foreign demand, and booming research and development in places like China and Singapore.
- Increased revenue from exports may slow the trend of offshoring of medical device manufacturing. More and more U.S. manufacturers are moving operations overseas not only to reduce tax costs but also to be closer to foreign industry clusters that have popped up as a result of heightened global competition.
- The importance of niche product development will increase for the foreseeable future due to demographic changes and stalled innovation.
- Niche products will perform better in export markets than traditional medical goods.
- Currently, Tennessee is one of the main healthcare hubs in the U.S., with a number of nationally-ranked hospitals and major companies like the Healthcare Corporation of America. Manufacturers in Tennessee are fortunate to already have so many customers in close proximity.

## Overview

Tennessee's healthcare and medical devices cluster encompasses a broad range of industries, from research and development of new technologies to the manufacturing of drugs and equipment used by medical professionals. Tennessee businesses are known for manufacturing some of the world's most effective and cutting-edge healthcare technologies. This cluster does not include local health services, such as hospitals, nursing homes, and ambulatory services. Instead, industries in this cluster create the products that enable local healthcare delivery.

Industry Category	NAICS	2017 Employment	Business Locations
<b>Medical Equipment and Supplies Manufacturing</b>			
Surgical and Medical Instrument Manufacturing	339112	520	28
Surgical Appliance and Supplies Manufacturing	339113	6,979	78
Dental Equipment and Supplies Manufacturing	339114	242	5
Ophthalmic Goods Manufacturing	339115	262	14
<b>Medical Apparatus Manufacturing</b>			
Electromedical and Electrotherapeutic Apparatus Manufacturing	334510	576	18
Analytical Laboratory Instrument Manufacturing	334516	132	6
Irradiation Apparatus Manufacturing	334517	126	7
<b>Pharmaceuticals</b>			
Medicinal and Botanical Manufacturing	325411	199	11
Pharmaceutical Preparation Manufacturing	325412	1,927	33
In-Vitro Diagnostic Substance Manufacturing	325413	70	3
Biological Product (except Diagnostic) Manufacturing	325414	35	5
<b>Equipment and Supplies Wholesalers</b>			
Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	423450	6,079	511
Ophthalmic Goods Merchant Wholesalers	423460	222	35
<b>Scientific Research and Development Services</b>			
Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology)	541715	7,248	172
<b>Commercial and Service Industry</b>			
Optical Instrument and Lens Manufacturing*	333314	21	3
<b>Architectural, Engineering and Related Services</b>			
Testing Laboratories*	541380	2,047	161

\*Included in the cluster but not exclusively a healthcare and medical devices industry

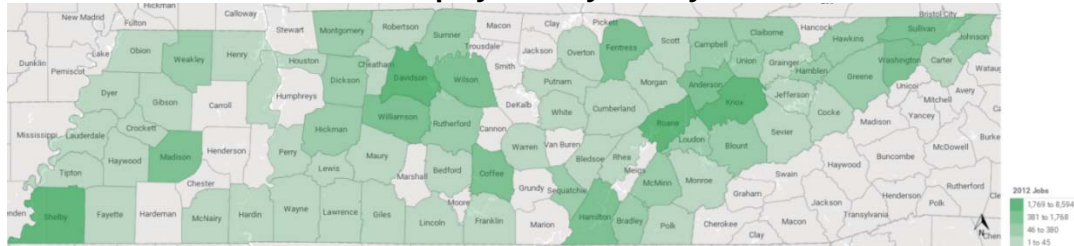
Businesses in this cluster employ 26,685 Tennesseans, a decrease of roughly 100 jobs since 2012.<sup>1</sup> Most industries have been adding employment, particularly medical apparatus manufacturers. However, a substantial decline in medical wholesale employment created a net job loss for the overall cluster. Analysts predict a reversal of this slump in coming years. By 2022, the cluster is expected to employ more than 28,000 Tennesseans. The driving force behind this job creation will likely be medical equipment and supplies manufacturing, a sector in which Tennessee has ranked highly for many years. Tennessee's employment currently ranks fourth among all Southeastern states.

The number of businesses has been steadily increasing, even as total employment waned. Currently, Tennessee has 923 healthcare and medical device businesses, as compared with 759 in 2012. More than half of

<sup>1</sup> Industry data related to employment, business locations, earnings, and inputs-outputs were obtained from Economic Modeling Specialists (EMS).

these businesses belong to the equipment and supplies wholesale sub-cluster. Tennessee's wholesale businesses tend to be small-sized, whereas many manufacturers in this cluster have large-scale operations. For example, Tennessee has five times as many wholesalers as medical equipment and supplies manufacturers, but manufacturers of these products employ 1,000 more workers than the entire wholesaling sub-cluster.

### Employment by County



In 2016, Tennessee businesses in this cluster generated \$3.0 billion in earnings. Total sales for these industries exceeded \$9.1 billion, \$2.7 billion of which were in-region. Key buying industries for this cluster are general medical and surgical hospitals, offices of physicians, and research laboratories. Transactions between industries in this cluster also account for a significant percentage of total sales. Inputs for the manufacturing process vary greatly based on the type of product being made. However, all industries in this cluster rely on services from corporate managing offices, lawyers, management consultants, and wholesale trade agents and brokers.

### Workforce

Average wages in this cluster are \$107,764, almost double the salary of the average Tennessean (\$57,229). Tennessee's average wages for these industries are the second highest in the Southeast region and the 11<sup>th</sup> highest in the nation. Healthcare and medical device businesses require many high-skilled, specialized workers for the manufacturing process.

SOC	Description	2017 Employment	Median Hourly Earnings
<b>Management Occupations</b>			
11-1021	General and Operations Managers	655	\$40.97
<b>Computer and Mathematical Occupations</b>			
15-1133	Software Developers, Systems Software	311	\$39.97
15-1151	Computer User Support Specialists	263	\$21.88
<b>Architecture and Engineering Occupations</b>			
17-2112	Industrial Engineers	523	\$36.93
17-2141	Mechanical Engineers	341	\$41.11
17-3026	Industrial Engineering Technicians	380	\$20.93
<b>Life, Physical, and Social Science Occupations</b>			
19-1042	Medical Scientists, Except Epidemiologists	499	\$32.39
19-2031	Chemists	326	\$28.83
19-4031	Chemical Technicians	352	\$21.96
<b>Sales and Related Occupations</b>			
41-4011	Sales Representatives, Wholesale and Manufacturing, Technical and Scientific Products	1,068	\$31.93
41-4012	Sales Representatives, Wholesale and Manufacturing, Except Technical and Scientific Products	507	\$25.45
<b>Office and Administrative Support Functions</b>			



SOC	Description	2017 Employment	Median Hourly Earnings
43-1011	First-Line Supervisors of Office and Administrative Support Workers	305	\$23.70
43-4051	Customer Service Representatives	750	\$14.21
43-5071	Shipping, Receiving, and Traffic Clerks	416	\$14.26
43-5081	Stock Clerks and Order Fillers	309	\$11.24
43-6014	Secretaries and Administrative Assistants, Except Legal, Medical, and Executive	526	\$14.62
43-9061	Office Clerks, General	440	\$14.26
<b>Production Occupations</b>			
51-1011	First-Line Supervisors of Production and Operating Workers	398	\$25.22
51-2092	Team Assemblers	1,510	\$14.51
51-9061	Inspectors, Testers, Sorters, Samplers, and Weighers	812	\$15.77
51-9081	Dental Laboratory Technicians	360	\$15.69
51-9082	Medical Appliance Technicians	718	\$15.43
51-9111	Packaging and Filling Machine Operators and Tenders	302	\$14.54
51-9198	Helpers--Production Workers	318	\$11.49
<b>Transportation and Material Moving Occupations</b>			
53-7062	Laborers and Freight, Stock, and Material Movers, Hand	419	\$12.41

Tennessee's businesses in this cluster are facing the challenge of an aging workforce. More than 48% of all employees are between the ages 45 and 64, and an additional 6% are senior citizens. The percentage of older workers in these industries is higher than the overall Tennessee work force, in which only 44% are between the ages 45 and 64.

Healthcare and medical device businesses in Tennessee employ a lower percentage of females than the average industry in Tennessee. Only 41.5% of employees working in this cluster are female, as compared with 49.1% in the total labor force. Employees in this cluster are predominantly Caucasian (76.9%). African-Americans account for 15.3% of employment. 4.8% of employees are Asian, and 2.1% are Hispanic. American Indians, Pacific Islanders and individuals identifying as two or more races make up less than 1% of total employment.

## Key Industries

### Medical Equipment and Supplies Manufacturing

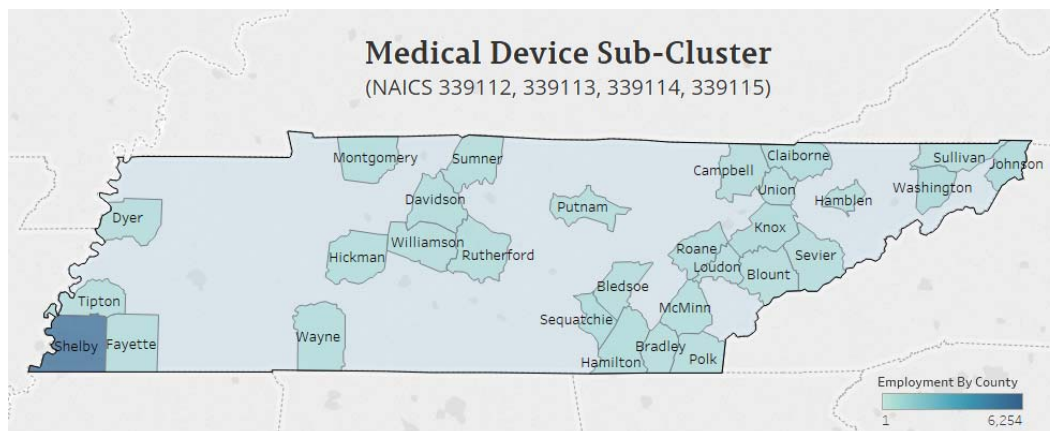
The medical equipment and supplies sub-cluster includes four industries: surgical and medical instrument manufacturing, surgical appliance and supplies manufacturing, ophthalmic goods manufacturing, and dental equipment and supplies manufacturing. Surgical appliances are devices used to ameliorate a medical condition, such as orthopedic implants or prosthetic limbs. Medical instruments are the apparatuses used in the practice of medicine, such as syringes, needles, clamps, and thermometers.

Businesses in this sub-cluster employ 8,003 Tennesseans, a 2.7% increase since 2012. The majority of this employment is concentrated in the surgical appliance and supplies manufacturing industry. Tennessee's employment in this industry is the highest in the region and the fourth highest among all U.S. states. Industry employment increased from 6,273 to 6,978 employees over the last five years, an 11.2% increase. Most of these new jobs were created in Shelby County, offsetting job losses in places like Bradley, Polk, and Loudon Counties. Shelby County remains Tennessee's epicenter for surgical appliance manufacturing, in large part due to companies like Smith & Nephew and Medtronic Sofamor Danek. Tennessee's employment growth was particularly impressive given that total regional and national employment did not expand during this period. In addition, Tennessee has succeeded despite lacking some of the natural advantages that other well-ranked states enjoy. California, for example, benefits greatly from a high concentration of technology companies and easy access to export markets in Asia. Despite lacking these innate advantages, the Southeast region is the



second best-performing region for medical device manufacturing and home to 18.3% of industry establishments in the United States. Manufacturers in Tennessee and neighboring states benefit from access to infrastructure like roadways, waterways, and major highways.

The same employment trend occurred in surgical and medical instrument manufacturing. Tennessee added 156 new jobs over the last five years, a 42.9% increase, while the national growth rate for this industry was only 0.1%. Job creation occurred almost exclusively due to expanded manufacturing capacity by employers in Johnson and Shelby Counties. Dental equipment and supplies manufacturers in Tennessee experienced a slight drop in employment (8.1% fewer jobs), which corresponded with both regional and national trends. The ophthalmic goods manufacturing industry contracted in recent years, but to a much more significant degree in Tennessee than elsewhere in the nation. This industry currently employs 261 Tennesseans, as compared to 891 in 2012. Almost half of these job losses occurred in Knox County.



Tennessee currently has 122 businesses in the medical devices sub-cluster. The most substantial part of this sub-cluster is the surgical appliance and supplies manufacturing industry (77 companies). Tennessee has a long-standing reputation for excellence in this industry. Since 2012, Tennessee has ranked third in the nation and first in the Southeast for employment concentration in surgical appliances and supplies. The state is predicted to maintain this ranking through at least 2022. This industry expanded in recent years, although it is becoming increasingly concentrated in a handful of counties. Since 2012, Shelby County added 11 new manufacturers of this kind, and Davidson and Sumner Counties each added three. At the same time, seven counties in Tennessee lost all pre-existing presence in this industry. These counties were Dyer, Bradley, Wilson, Warren, Anderson, Tipton, and Obion. Major manufacturers in this industry include Medtronic Sofamor (Shelby), Deroyal Industries Inc. (Claiborne & Knox), Microport Orthopedics Inc. (Shelby), Albahealth LLC (Roane), Peromobil Inc. (Wilson), and Allegiance Healthcare Corporation (Washington).

For the other industries in this sub-cluster, Tennessee has yet to establish a reputation equal to that of surgical appliances and supplies. The location quotients for these industries are 0.22 for surgical and medical instruments, 0.50 for ophthalmic goods manufacturing, and 0.77 for dental equipment and supplies. Surgical and medical instrument manufacturing has been experiencing the most rapid growth in the sub-cluster in recent years. Since 2012, Tennessee added 11 companies in this industry, with a few counties (specifically, Rutherford, Tipton, Sumner, and Williamson) welcoming their first-ever manufacturer of this kind. Tennessee now has a total of 27 medical equipment and supplies manufacturing. Major employers include Smith & Nephew (Shelby), Abbott Laboratories (Knox), Kimble Chase Life Sciences (Roane), Amsino Medical USA (Davidson), and Medical Action (Fayette).

Ophthalmic goods manufacturing in Tennessee experienced a precipitous decline in recent years. In 2012, Tennessee ranked fifth in the nation and second in the Southeast for employment concentration. Since then, Tennessee's location quotient has dropped from 1.63 to 0.50. Tennessee is now ranked fourth in the Southeast. The driving force behind this decline was layoffs in Knox County, in which approximately 90% of industry workers lost their jobs. In 2013, sunglasses manufacturer Luxottica closed its Knoxville plant, resulting

in the loss of 300 jobs.<sup>2</sup> Shelby County also lost roughly two-thirds of its workforce in this industry and lost an additional 200 jobs at the end of 2017 due to permanent layoffs at Luxottica's Hickory Hill facility.<sup>3</sup> However, Tennessee managed to gain three new manufacturers in recent years even as employment shrank drastically. New businesses in Williamson, Shelby, Davidson, and Montgomery Counties offset the closing of locations in Sullivan and Gibson. Tennessee's major ophthalmic goods manufacturers are Cumberland Optical Company Inc. (Davidson), Southern Optical Service Inc. (Davidson), and Morgan Optical Inc. (Knox).

In regards to dental equipment and supplies manufacturing, Tennessee ranks third in the Southeast and has maintained this ranking for the last several years. This industry is the smallest part of the sub-cluster. Tennessee only has five businesses that manufacture these products. Similar to ophthalmic goods manufacturing, employment in dental equipment manufacturing declined even as the total number of businesses increased. In 2012, Washington was the only county in Tennessee with presence in this industry. Since then, Shelby County has added two companies, and Washington welcomed its third. Similar trends have been occurring across the U.S., explaining why Tennessee's ranking of sixteenth in the nation for employment concentration has not changed despite fluctuating employment. Major employers in this industry include Dentsply (Washington) and D&S Dental (Washington).

The sub-cluster reports strong wages across the board. Average wages in Tennessee's surgical and medical instruments industry is \$129,335 per year, with \$96,784 in salaries and \$32,551 in supplements. When adjusting for cost of living, these wages are almost \$20,000 higher than regional and national averages. Average wages in surgical appliance and supplies manufacturing is \$117,414 per year, the second highest in the sub-cluster. Tennessee's wages for this industry are the highest in the region and the fourth highest among all U.S. states. Average wages in surgical and medical instrument manufacturing (\$129,334) are the second highest regionally and sixth nationally. Ophthalmic goods manufacturing in Tennessee provides similarly strong wages. Average wages for this industry are \$101,145, significantly more than the national average of \$69,950. Tennessee's wages for this industry rank second among Southeastern states and third nationwide. Dental equipment manufacturing in Tennessee provides the third strongest wages in the region. Despite the differences in average wages, industries in this sub-cluster rely on the same type of occupations. The most common occupations for medical device manufacturers are team assemblers, medical appliance technicians, laboratory technicians, inspectors and testers, and production workers.

In 2016, the medical devices sub-cluster generated \$3.4 billion in sales and \$932 million in earnings, with more than 85% of this revenue coming from the surgical appliance and manufacturing industry. Surgical and medical instrument earnings accounted for 7% of total earnings. Revenue from ophthalmic goods and dental equipment combined for less than 5%. Many of the inputs utilized by these manufacturers are provided by other industries in the sub-cluster, particularly appliance and instrument manufacturers. Plastic materials and resin are integral to the production of ophthalmic goods. Nonferrous metals are essential inputs for dental equipment manufacturing. Moreover, surgical appliance and supplies manufacturing has the third highest jobs multiplier of any industry in this cluster.

### **Medical Apparatus Manufacturing**

The medical apparatus sub-cluster includes three industries: electromedical and electrotherapeutic apparatus manufacturing, analytical laboratory instrument manufacturing, and irradiation apparatus manufacturing. This sub-cluster encompasses a broader range of industry activities than medical equipment and supplies. The manufacturing process varies substantially based on the type of medical apparatus being produced.

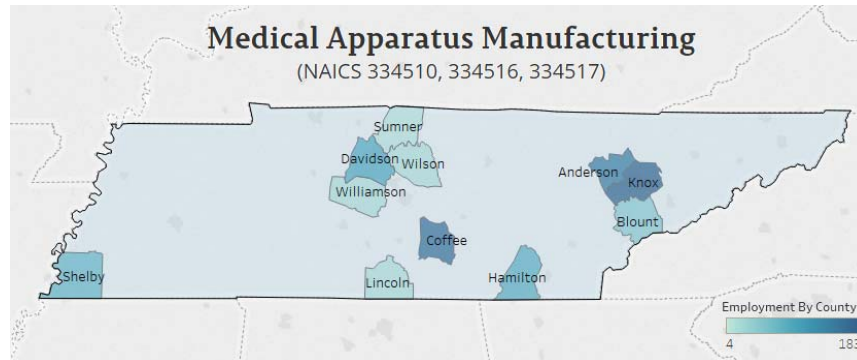
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<sup>2</sup> WVLT TV Knoxville. (2013). *Sunglasses giant Luxottica shutting down Knoxville plant, cuts 300 jobs*.

<http://www.local8now.com/home/headlines/Sunglasses-giant-Luxottica-shutting-down-Knoxville-plant-cuts-300-jobs-225044882.html>

<sup>3</sup> Risher, W. (Oct. 27, 2017). *Luxottica eyewear giant trimming 208 jobs at Hickory Hill facility Dec. 31*.

<http://www.commercialappeal.com/story/money/industries/2017/10/26/luxottica-eyewear-giant-trimming-208-jobs-hickory-hill-facility-dec-31/804792001/>



### Electromedical and Electrotherapeutic Apparatus Manufacturing

This industry manufactures medical devices that utilize electrical currents, either for diagnostic or therapeutic purposes. Diagnostic equipment includes magnetic resource imaging devices, ultrasound equipment, endoscopic devices, electrocardiographs, and other monitoring equipment. Some industry products are strictly therapeutic, such as hearing aids, pacemakers, diathermic units, nerve stimulators, and heart-lung machines.

Businesses in this industry currently employ 576 Tennesseans, an 18.7% increase since 2012.<sup>4</sup> Tennessee now ranks fourth in the region for total employment. Most states in the Southeast region have seen industry employment steadily grow over the last few years. Tennessee's biggest gains occurred in Coffee and Hamilton counties, both of which added roughly 40 jobs.

Tennessee now has 18 companies that manufacture electromedical and electrotherapeutic apparatuses, up from 8 in 2012.<sup>5</sup> The counties that added the most businesses were Davidson, Lincoln, Wilson, and Williamson. These counties now collectively have 9 companies of this kind, despite having zero in 2012. Like medical equipment and supplies manufacturing, businesses in this industry are becoming smaller and less labor-intensive. Knox County, home to major employer Siemens Molecular Imaging Inc., saw total employment decrease by 36 jobs, even as total number of businesses in the county increased from one to three. Shelby County experienced similar changes.

The location quotient for this industry is 0.44, compared with 0.42 in 2012. Despite being such a small industry, employees in these businesses enjoy some of the highest wages in the cluster. Average industry wages in Tennessee are \$124,875, with \$102,753 in salaries and \$22,122 in supplements. These wages are roughly \$30,000 higher than both the regional and national average, when taking into account cost-of-living differences. In addition, Tennessee's average wages for this industry are the second highest among Southeastern states and sixth highest in the nation. Employees tend to garnish high wages because this industry relies heavily on high-skilled workers, including industrial engineers, software developers, electrical engineers, mechanical engineers, biochemists, and biophysicists. Like other industries in the cluster, other key occupations are assemblers, inspectors and testers, production workers, and sales representatives.

In 2016, this industry generated \$256.5 million in sales, yielding more than \$69.8 million in total earnings. In-region sales accounted for one-fifth of total sales. In-region purchases made by this industry are unique to the electromechanical manufacturing process, including copper and alloys, adhesives, semiconductors, basic organic chemicals, printed circuit assembly, and wired telecommunication carriers. However, manufacturers of these devices also rely on basic inputs that all companies in the cluster utilize, such as corporate managing offices, lawyers and lessors, wholesale agents and brokers, and general management consulting services.

<sup>4</sup> Total industry employment is closer to 800 Tennesseans. Employment data for this industry does not include some of Tennessee's key manufacturers, including Philips Medical Systems Mr Inc. (Davidson), Fillauer Inc. (Hamilton), and American Endoscopy Services Inc. (Williamson). These companies are sometimes classified as surgical appliance or medical instrument manufacturers due to the diversity of their product portfolios.

<sup>5</sup> These statistics also do not account for the closing of Orchid Orthopedic Solutions' Jackson plant. Orchid is sometimes classified as a surgical appliance manufacturer. Source: Thomas, J. (2015). *Orchid Orthopedic closes in Jackson*. <http://www.jacksonsun.com/story/money/business/2015/08/19/orchid-orthopedic-solutions-closes-jackson/32025321/>

### **Analytical Laboratory Instrument Manufacturing**

Businesses in this industry manufacture a variety of analytical instruments, many of which have medical applications. Some of these products fall strictly under the purview of the medical devices cluster, including blood and body fluid analyzers, audiological equipment, bronchoscopes, respiratory analysis equipment, and hematology instruments. Other products are utilized in the medical field and other life sciences as well, such as protein analyzers, microscopes, thermogravimetric analyzers, immunology instruments, and amino acid analyzers. This industry also produces a small number of sampling analysis instruments unrelated to medicine.

Manufacturers of these products currently employ 132 Tennesseans, adding 61 jobs since 2012.<sup>6</sup> This percent job growth was the largest in the region and eighth largest in the nation during this time period. Industry employment in Tennessee is now the fourth highest in the region, and analysts predict growth to accelerate through 2022, increasing Tennessee's position to the third largest employer in the region. Nearly all of these jobs are located in Anderson County, specifically Oak Ridge. Major employers in Oak Ridge are Nanomechanics Inc., Berthold Technologies U.S.A. LLC, and Spectrum Techniques LLC. Sumner County, the only other county besides Anderson to add a business location during this time period, has less than 10 total jobs in this industry. Tennessee has 6 companies in this industry.

The location quotient for this industry (0.19) appears low but is actually one of the stronger scores in the Southeast. Tennessee is currently ranked fourth in the region for employment concentration and is predicted to be tied with Kentucky for second by 2022, a vast improvement over Tennessee's position as eighth in the Southeast just five years ago. The region with the highest employment concentration is the Northeast. Four of the top six states in location quotient rankings are Northeastern states (Delaware, Massachusetts, Vermont, and Connecticut), likely due to the number of research universities in the region. Correlation between universities and location quotient explains why North Carolina's employment concentration (0.70) is higher than other states in the Southeast. North Carolina, home to the "Research Triangle," has had success in creating linkages between industry and university research.

Average wages in this industry are \$91,693, with \$75,449 in annual salary and \$16,244 in supplements. These wages are the second highest in the region behind Mississippi. The most common occupations in analytical laboratory instrument manufacturing are assemblers, especially electronic equipment assemblers. Technicians are also crucial to the manufacturing process, specifically those related to electronics engineering, electro-mechanics, medical appliances, and industrial, mechanical, and materials engineering. In 2016, this industry netted nearly \$12.5 million in total earnings, with \$41.6 million in sales. Industry inputs overlap somewhat with electromechanical apparatus manufacturing (printed circuit assembly, copper and alloys, plastics, and chemical products) as well as the overall cluster (corporate offices, lawyers and lessors, and wholesale agents and brokers). Inputs unique to analytical instrument manufacturing are machine shops, iron and steel mills, ferroalloy manufacturing, and sheet metal work.

### **Irradiation Apparatus Manufacturing**

Companies in this industry produce irradiation apparatuses for a variety of medical purposes, including diagnostic, therapeutic, and research. Products with diagnostic utility include X-ray machines and tubes, computerized axial tomography scanners, and fluoroscopes. Some products in this industry are used to treat conditions, such as irradiation equipment and medical radiation therapy equipment. These products are not strictly medical devices and have far-reaching applications in industry and general scientific research.

Irradiation apparatus manufacturing is one of Tennessee's smallest medical device industries. As of 2017, this industry employed 126 Tennesseans, an increase of 34 jobs since 2012. Tennessee ranks third in the Southeast for total employment, nearly tied with Florida for second (132 jobs) and not far behind Virginia (176). Nearly a quarter of all regional employment for this industry is located in Tennessee alone. Employment in Tennessee is predicted to grow by an additional 50 jobs over the next five years. The vast majority of these jobs

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<sup>6</sup> Total employment is closer to 250 employees due to the omission of some manufacturers from this employment data. Companies like Thermo Fisher Scientific Inc. (Davidson and Roane) and WITec Instruments Corp. (Knox) are sometimes classified as measuring and controlling device manufacturers.

are located in Davidson and Blount Counties. The major employer in Davidson County is Techno-Aide Inc., a manufacturer of X-ray markers as well as other surgical and medical instruments. Blount County is home to Pronova Solutions Inc., a company that specializes in position emission tomography. Proton therapy, a form of advanced radiation therapy that targets cancerous cells to minimize over-radiation of the patient, is becoming increasingly common, and Pronova's parent company is opening a proton therapy treatment center in Williamson County in 2018.<sup>7</sup>

Tennessee currently ranks eleventh in the nation and second in the Southeast for employment concentration in this industry. Tennessee's location quotient of 0.47 is expected to increase to 0.60 over the next few years. Analysts predict that by 2022, Tennessee will rise to ninth in the national rankings and overtake Virginia as first in the Southeast. Tennessee continues to improve in this industry while other states have begun to decline. Wisconsin's current location quotient of 19.23, far and away the highest in the nation, is predicted to drop to 13.96. Vermont, which once ranked second nationally, saw its location quotient plummet from 16.76 in 2012 to 3.19 in 2017. Currently, Tennessee has seven companies of this kind, the same number that existed in 2012. The folding of businesses like Delta Imaging Systems (Davidson) was offset by new manufacturing operations in Shelby County.

The most common occupations in this industry are team assemblers, electrical and electronic equipment assemblers, various types of technicians (including electricals engineering, electro-mechanical, and medical appliance), electronics drafters, and mechanical and materials engineers. Average wages in Tennessee for this industry are \$94,247, roughly equal to regional average. In 2016, Tennessee manufacturers generated \$8.9 million in earnings and \$31.4 million in total sales, 25% of which were in-region. Major in-region purchases for this industry included iron and steel forging, printed circuit assembly, copper rolling and alloying, and power, distribution and specialty transformer manufacturing. Sales between irradiation apparatus manufacturers also accounted for a substantial percentage of purchases.

## **Pharmaceuticals**

The pharmaceutical sub-cluster is composed of four industries: medicinal and botanical manufacturing, pharmaceutical preparation manufacturing, in-vitro diagnostic substance manufacturing, and biological product (except diagnostic) manufacturing. Medicinal and botanical manufacturers produce the uncompounded ingredients used in pharmaceutical preparation manufacturing. In-vitro diagnostic substance manufacturers create substances used to measure and monitor toxin levels in the body. Biological product manufacturers produce treatments with no diagnostic value, like vaccines, gene therapies and plasmas.

Businesses in the pharmaceutical sub-cluster currently employ 2,230 Tennesseans, a 21.3% increase in employment since 2012. This growth in employment exceeded both the regional job growth rate for these industries (7.8%) as well as the national rate (6.7%). Employment in Tennessee's medicinal and botanical manufacturing industry tripled during this time-frame, with nearly all of this job creation occurring in Hamilton County alone. This percent increase in employment was the eighth largest of any U.S. state during this time period. Pharmaceutical preparation manufacturing also experienced exceptional gains since 2012. This industry added employment at the annualized rate of 3%, even though industry employment was contracting in most states during this time. Industry growth was uneven in Tennessee. Maury County saw a decrease of more than a hundred jobs when Capstone Nutrition closed its Spring Hill facility last year.<sup>8</sup> Shelby County lost several hundred jobs due to several downsizings in the last few years. In-vitro diagnostic manufacturing employment increased in Tennessee by 29.6% since 2012 due to expanded capacity at existing locations in Davidson and Washington Counties. Tennessee and the overall Southeast region experienced a slight decrease in biological product manufacturing employment in the last few years, while many states in the U.S. saw a double-digit increase in employment.

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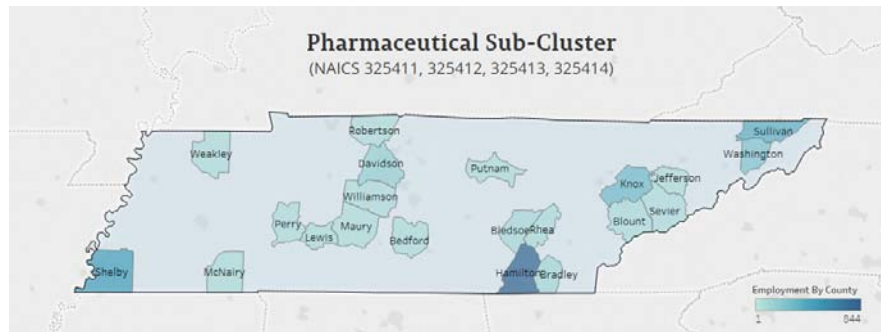
<sup>7</sup> Provision Admin. (Dec, 2017). *New proton therapy center to open across from Williamson Medical Center.*

<http://provisionhealthcare.com/2017/12/13/its-like-nasa-landed-in-franklin-proton-therapy-center-nears-completion-2/>

<sup>8</sup> Ward, G. (2016). *125 workers to lose jobs in Spring Hill plant closing.*

<http://www.tennessean.com/story/money/industries/2016/05/24/125-workers-lose-jobs-spring-hill-plant-closing/84873368/>





Tennessee currently has 51 businesses in the pharmaceutical sub-cluster, up from 31 business locations in 2012. Nearly all of this increase occurred due to the pharmaceutical and preparation manufacturing sector. Tennessee now has 14 more pharmaceutical manufacturers than it did several years ago. Many of these businesses emerged in counties with a pre-existing reputation for pharmaceutical production, like Hamilton and Shelby Counties. However, Williamson County now has two pharmaceutical manufacturing operations for the first time in its history. Bedford County now has the second highest concentration of botanical product manufacturing in the state, despite having zero businesses in this industry five years ago. Despite these gains, Tennessee lags behind most states in employment concentration for the industries in this sub-cluster. Tennessee's location quotient scores in 2017 were 0.36 for medicinal and botanical manufacturing, 0.47 for pharmaceutical preparation manufacturing, 0.14 for in-vitro diagnostic manufacturing (fourth highest location quotient in the region), and 0.05 for biological product manufacturing. The location quotient for medicinal and botanical manufacturing, which was 0.17 in 2012, is predicted to reach 0.44 by 2022.

Major employers in Tennessee's pharmaceutical sector include: Chattem Inc. (Hamilton), UPM Pharmaceuticals, formerly King Pharmaceuticals (Sullivan), PETNET Solutions Inc. (Knox), Bayer Healthcare (Bradley, Shelby), Juice Plus Company (Shelby), Crown Laboratories Inc. (Washington), and Cumberland Pharmaceuticals (Davidson). Bayer's Cleveland location in Bradley County is the company's third most productive plant in the world.<sup>9</sup>

The most common occupations in this sub-cluster are packaging and filling machine operators and tenders, inspectors and testers, health and safety engineers, industrial engineers, and team assemblers. In-vitro diagnostic substance manufacturing and biological product manufacturing also have a strong need for chemists, chemical equipment operators, and biophysicists. Average wages in this sub-cluster are \$110,892 per year. Pharmaceutical preparation manufacturing has the highest average wages (\$115,204) in the sub-cluster. Tennessee's average wages in this industry are the third highest in the region. Average wages for in-vitro diagnostic manufacturing in Tennessee (\$105,132) are the second highest in the Southeast and the ninth highest in the nation. Medicinal and botanical businesses compensate workers on average \$71,703 per year.

In 2016, Tennessee's pharmaceutical businesses generated \$248.6 million in total earnings, of which the pharmaceutical preparation manufacturing industry accounted for 90%. In-region sales are crucial to revenue in this sub-cluster, particularly in-vitro diagnostic substance manufacturing. For manufacturers in this industry, 93% of all sales were made in-region. Most of these sales are between pharmaceutical companies. Manufacturers rely heavily on the uncompounded substances produced by the medicinal and botanical industry. The pharmaceutical sub-cluster also provides indirect benefits to Tennessee's economy. For every one job created by a pharmaceutical manufacturer, 3.09 additional jobs are created in the region. This job multiplier is the highest in the entire cluster.

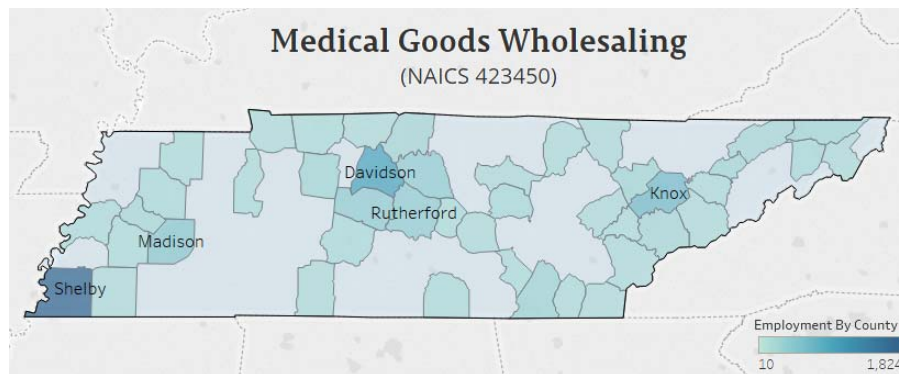
### Equipment and Supplies Wholesalers

This sub-cluster encompasses two industries: medical, dental, and hospital equipment and supplies merchant wholesalers as well as ophthalmic goods merchant wholesalers. Tennessee's medical wholesale

<sup>9</sup> Armstrong, C. (2016). *Site Manager Pete Ochel: Cleveland Bayer plant has company's third largest global output*. <http://clevelandbanner.com/stories/site-manager-pete-ochel-cleveland-bayer-plant-has-companys-third-largest-global-output,41211>

industry, consistently ranked as second in the nation, is one of the state's best performing industries in this cluster.

Currently, these industries employ a total 6,300 Tennesseans, more than 6,000 of which work in the medical wholesale industry. Employment in medical wholesaling has declined in recent years. In 2012, Tennessee ranked second in the region for industry employment but now ranks fourth. Medical wholesale businesses now employ 1,000 fewer Tennesseans than five years ago. Of the 58 counties with these types of businesses, 35 have sustained net job losses during this time period. Fentress County experienced the biggest decline, with industry employment dwindling from 804 to 11. Employment in Madison County decreased from 834 to 318. Other counties were more fortunate and managed to expand their workforces in this industry. Shelby County added 515 new jobs, and Rutherford County gained 180. These job losses were characteristic of what has been happening across the country. Medical device manufacturers have begun to negotiate directly with hospitals and medical providers, cutting wholesalers out of the process altogether.



The same trend is occurring in ophthalmic goods. Wholesalers of these goods employ 222 Tennesseans today, as compared with 308 in 2012. Tennessee now only has four counties with these types of businesses, and counties that historically led the state in this industry (Shelby, Knox, and Madison) experienced double-digit decreases in employment. However, analysts predict that employment in these industries will rebound in coming years due to economic growth. Tennessee is already seeing a recovery of some of these jobs, as demonstrated by TwelveStone Health Partner's plan to create 200 jobs across the state in the next five years.<sup>10</sup>

Interestingly, while total employment in medical wholesaling declined, the number of businesses significantly increased. Tennessee now has 511 medical wholesale businesses, 100 more than just five years ago. The decline in employment did not impact Tennessee's employment concentration ranking. Tennessee's location quotient (1.49) is the second highest in the nation behind Florida and has been for several years. Shelby County, Davidson, and Knox Counties have been the primary contributors to Tennessee's success in medical wholesaling. Major employers include Ammed Direct LLC (Davidson), Infolab LLC (Shelby), Philipps Medical Systems MR Inc. (Davidson), Johnson & Johnson Healthcare Services (Shelby), TwelveStone Health Partners (Rutherford), and Olympus Corporation of the Americas (Shelby).

Tennessee's ranking in ophthalmic goods wholesaling did not fare as well. Employment concentration for this industry declined from 0.82 to 0.56, unseating Tennessee from its ranking of fifteenth in the nation. Currently, Memphis-based Mid-South Premier Ophthalmics is Tennessee's largest wholesaler for ophthalmic goods.

In this sub-cluster, the most common occupations are sales representatives, customer service representatives, computer network support specialists, and order clerks. Average wages are strong for both types of wholesaling. Tennessee's average salary for medical wholesaling (\$100,548) is higher than the national average and comparable to those found in most Southeastern states. Average wages in ophthalmic goods

<sup>10</sup> Ward, G. (2016). *Murfreesboro company to create 200 new jobs*. <http://www.tennessean.com/story/money/real-estate/2016/02/15/murfreesboro-company-create-200-new-jobs/80403964/>



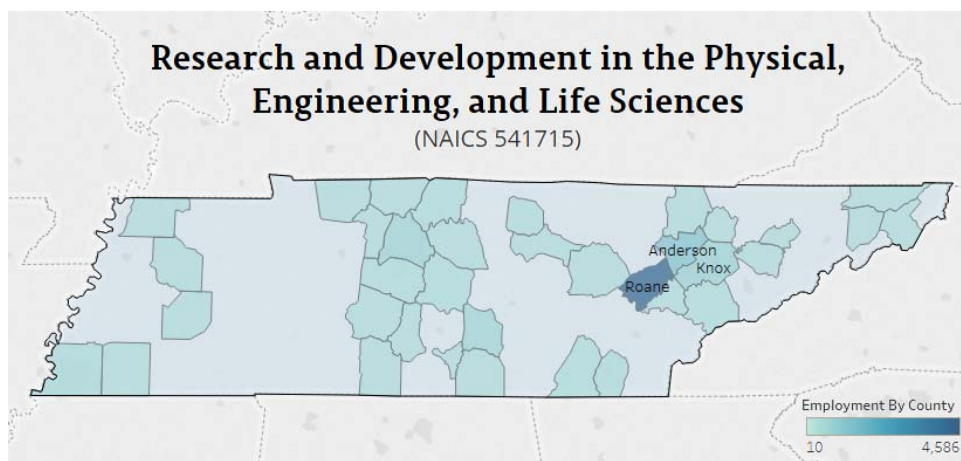
wholesaling are the silver lining to recent setbacks in this industry. As of 2017, the average salary in Tennessee for this industry is \$90,843, the highest among Southeastern states and fifth highest nationwide.

Tennessee's wholesale sub-cluster brought in \$617.6 million in earnings in 2016. These businesses made \$1.8 billion worth of sales, \$455.8 million of which were in-region. Since these industries do not manufacture their own products, the most common in-region purchases for this sub-cluster were couriers and express delivery services, general warehousing and storage, lessors of residential buildings, offices of real estate agents and brokers, and corporate managing offices.

### **Research and Development in the Physical, Engineering, and Life Sciences**

This industry encompasses nearly all types of life sciences research, with the exception of nanotechnology and biotechnology. The different branches of medical research fall under this umbrella, such as those related to genetics, human biology, dental, bacteriological, veterinary, and more. However, many of the research areas included in this industry are unrelated to healthcare. These areas include agriculture, forestry, oceanography, entomology, mathematics, guided missiles, space vehicles, electronics and computers, botany, geology, photonics, and astronomy. Industry data referenced below does not distinguish between the different types of research.

Currently, 7,247 Tennesseans are employed in life sciences research and development. Tennessee ranks fourth in the region for total employment and is predicted to add more than 100 jobs in coming years. While more than a third of all Tennessee counties have at least some jobs in this industry, employment is heavily concentrated in a handful of counties. Roane County, which added 300 jobs since 2012, has 4,585 individuals working in life sciences research. Anderson County is another important location for this industry, with employment nearly reaching 1,000. Knox and Davidson Counties both employ more than 350. Davidson County, in which 200 new jobs were created, rose from seventh to fourth in total employment among Tennessee counties. Changes in employment were uneven across the state. Anderson County lost more than 300 jobs since 2012, and Williamson County saw employment drop from 272 to 48.

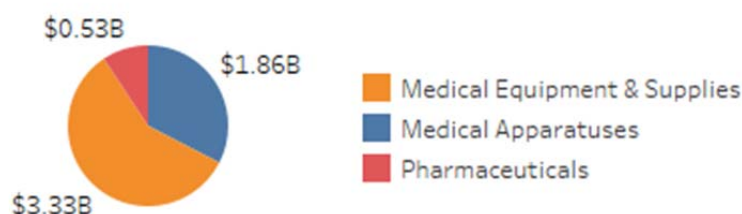


The total number of business locations increased from 168 to 172. Several counties with pre-existing industry lost a small percentage of its total business, while eleven counties added their first ever life sciences research facility. These counties included Bradley, Jefferson, Jackson, Washington, and Maury. Bradley County now has more than 100 jobs in this industry, one of the highest employment totals in the state. Moreover, Tennessee has many large- and small-sized businesses in this industry. Roane County, in which nearly two-thirds of total employment is located, only has two life sciences companies. Washington County has three companies but less than 10 employees between them. Oak Ridge National Laboratory, managed by non-profit organization UT-Battelle LLC, is undoubtedly Tennessee's biggest employer in general life sciences research. Major medical research enterprises are Vector Oncology Solutions LLC (Shelby), Gregory Pharmaceutical Holdings Inc. (Sullivan), and Chiltern International Inc. (Sullivan).



## Exports by Industry

Medical equipment and supplies are the biggest source of export revenue for businesses in this cluster. In 2016, Tennessee manufacturers exported \$3.3 billion in medical equipment and supplies, more than any other state besides California. Tennessee's exports accounted for 10.1% of U.S. exports for these types of products (and 19.51% for U.S. medical instruments and appliances exports). In 2016, the top export markets for these industries were Belgium (\$569.1 million), Singapore (\$417.7 million), Japan (\$407.5 million), China (\$297.7 million), and the Netherlands (\$254.9 million).



Tennessee businesses also earned a substantial amount of revenue from exports of medical apparatuses. In 2016, businesses exported \$1.9 billion in medical apparatuses, the seventh highest of any U.S. state.<sup>12</sup> Exports from these industries have increased 39.75% since 2011. Most of this export growth occurred due to the irradiation apparatus manufacturing industry. Tennessee's manufacturers have increased exports of these products by 700% in the last few years. This growth is particularly impressive given that U.S. exports for these products have declined overall. In 2012, electromedical companies made 33.6% of their revenue in export markets, as compared with 25% today. One company for which international sales have not slowed is Medtronic, which garners 40% of its annual revenue from exports.<sup>13</sup> The biggest export markets in 2016 were Belgium (\$311.8 million), Singapore (\$254.6 million), Japan (\$250.3 million), Germany (\$191.6 million), and Canada (\$187.2 million).

Pharmaceutical products are the smallest contributor to export revenue in this cluster, although total revenue for these exports has grown 16.21% since 2011. In 2016, Tennessee pharmaceutical and medicinal manufacturers exported \$530.6 million in product. The biggest export markets were China (\$85.7 million), Canada (\$74.0 million), Belgium (\$47.7 million), the Netherlands (\$35.1 million), and Japan (\$26.8 million).

## Recent Growth

The Haslam administration has made great strides in strengthening Tennessee's healthcare and medical device industries. Since 2011, the Tennessee Department of Economic and Community Development has received 76 project commitments to create 15,498 new jobs. Total capital investment has nearly reached \$1.4 billion.

Company	New Job Commitments	Capital Investment (\$)	County	Date
Community Health Systems Inc.	1,500	66,150,000	Davidson	May, 2015
Philips HealthTech	815	17,000,000	Davidson	August, 2017
Parallon Business Solutions, LLC.	800	87,600,000	Davidson	September, 2012
Aegis Sciences Corporation	740	31,100,000	Davidson	December, 2015
Team Health	700	17,000,000	Blount	September, 2011
Fresenius Medical Care	665	140,000,000	Knox	March, 2014
CGS Administrators, LLC	527	5,600,000	Davidson	January, 2015
Pronova Solutions, LLC	525	52,834,167	Blount	February, 2013

<sup>12</sup> This estimate includes exports of some non-medical apparatuses.

<sup>13</sup> IBISWorld. (2017). *Medical device manufacturing in the US: Industry Report*.

XPO Logistics	468	23,000,000	Shelby	January, 2013
Smile Direct Club, LLC	439	4,500,000	Davidson	February, 2017

## **Trends and Opportunities**

In the last decade, healthcare in the United States has undergone substantial changes. New forms of service delivery and changing payment structures have radically altered the way healthcare is practiced. These trends have impacted Tennessee's medical device companies by altering supply chains and creating new priorities for product development.<sup>14</sup>

### **Key Trends**

The key trends in US healthcare have been new settings, alternative providers, and changing management structures. Healthcare practice is transitioning away from traditional settings, in which a single hospital housed all types of medical providers, to a new system that emphasizes specialized care administered in out-patient settings. These settings include mobile health units, outpatient surgical and diagnostic centers, telephonic and online consultations, home-based services, and other types of remote or ambulatory care. In these settings, new types of medical professionals are the care provider. Nurse practitioners, community health workers, and outpatient specialists are now assuming the role traditionally played by physicians.

Several factors are driving this transition to a new healthcare model. Out-patient and home-based services are generally more convenient for patients, and patient-centered care has been a major cultural and legislative priority in recent years. More Americans are now able to access these services and types of providers, thanks to the Patient Protection and Affordable Care Act (PPACA). This legislation also reinforced the new model of healthcare by increasing consolidation among providers. Hospitals and nursing homes are being acquired by large healthcare corporations for reasons of cost containment. PPACA incentivizes consolidation due to rising regulatory costs, the medical device excise tax, and a transition from fee-for-service to metrics based on health outcomes. PPACA also uprooted old payment structures and put new organizations in charge of financial decisions. Healthcare payers, like managed care and accountable care organizations, are requiring patients to utilize out-patient, specialized services in an effort to control service costs. The current shortage of doctors and nurses in the U.S. has compounded cost inflation. Most physicians are older and nearing the age of retirement, and nursing schools are not producing as many graduates as in previous years. In 2013, nursing schools in the U.S. denied admission to nearly 80,000 qualified applicants due to budget cutbacks. Wages for these professions have gone up as hospitals are forced to compete for limited talent.

In coming years, the Republican-led effort to deregulate healthcare may prove successful, but the old model of healthcare is unlikely to return independent of PPACA's fate. Technological changes have solidified the new model. In particular, electronic health records allow data to be shared across healthcare environments, enabling fragmented service delivery and coordination between multiple providers.

### **Impact on the Cluster**

Changes in healthcare structures have significantly impacted the business strategies of downstream industries. Medical device manufacturers are facing greater pressure to consolidate. Group purchasing organizations (GPOs), which coordinate purchases for providers, enter into contracts with manufacturers with diverse product lines rather than doing business with individual suppliers. This arrangement benefits manufacturers and providers alike. Companies that secure these contracts capture greater market share and maximize revenue, and GPOs ensure greater operational efficiency for providers. Small-scale companies with niche product portfolios have little choice but to merge with large manufacturers.

Despite the benefits of consolidation, large manufacturers are also hurt by cost-containment programs. Competitive bidding, as part of PPACA's changes to Medicare, has forced large companies to drop prices. For example, the medical device wing of Johnson & Johnson, which has some presence in Shelby County, lost revenue for its surgical precision and imaging systems due to PPACA. Consolidation is already the norm among industries in this cluster. In electromechanical and electrotherapeutic apparatus manufacturing, the top

<sup>14</sup> Data and analysis based on 2017 IBISWorld industry reports.

four performing companies earn 78.3% of industry revenue. In medical device manufacturing, the top four companies control 21.4% of the market.

Large manufacturers rely on consolidation to streamline distribution channels, benefitting U.S. companies at a time when domestic producers are at an inherent disadvantage to foreign competitors. Reasons for this disadvantage include an appreciating dollar, growing domestic demand relative to foreign demand, and booming research and development in places like China and Singapore. Foreign investments in R&D threaten revenue for U.S. researchers and testing laboratories. Economists anticipate the dollar to depreciate in 2018, which will renew the strength of U.S. industries in export markets.<sup>15</sup> Increased revenue from exports may slow the trend of offshoring of medical device manufacturing. More and more U.S. manufacturers are moving operations overseas not only to reduce tax costs but also to be closer to foreign industry clusters that have popped up as a result of heightened global competition. Offshoring and foreign clusters decrease demand for U.S. healthcare and medical device companies by incentivizing American citizens to travel abroad to receive care, a phenomenon known as “medical tourism.”

Medical goods wholesalers are uniquely disadvantaged by the merging of upstream buyers. GPOs eliminate the need for wholesalers, drastically cutting into industry revenue. Ophthalmic goods wholesalers have fared worse than perhaps any industry in the cluster. Online eye-care businesses make it convenient and affordable for patients to shop for their own eyeglasses and contacts, eliminating the need for traditional retailers. Even the patients who prefer in-person shopping are buying their eye-wear at supercenters like Costco and Walmart instead of retail chains like Pearl Vision and Lens Crafters.

The upside of consolidation for small companies will be that niche products have greater market share due to the specialized nature of care. Large and small manufacturers enter into a mutually beneficial relationship in which large manufacturers prioritize mergers and acquisitions over research and development. In this scenario, product innovation is driven by small-scale manufacturers, which piggyback off the purchasing power of large companies. Businesses with 20 or fewer employees account for 83.2% of all industry establishments in medical device industries, with 56% of new products being developed by companies of this size. GE Healthcare's recent business strategy demonstrates the interaction between large and small manufacturers. In 2014, the company acquired several healthcare services businesses, many of which had a specialized focus like healthcare management software or biotechnology. Investing heavily in R&D can still be a risky proposition for small businesses since new products take on average eight and a half years to receive FDA approval.

The importance of niche product development will increase for the foreseeable future due to demographic changes and stalled innovation. The number of people in the U.S. aged 65 and older, currently 47.3 million, continues to rise. Elderly Americans utilize healthcare services on average three to five times more than people under the age of 65. Aging of the U.S. population increases the incidence of age-related conditions and spurs demand for specialized instrumentation and disposables. Revenue will grow for companies that produce pharmaceuticals, cardiovascular devices, neuromodulation treatments for incontinence and gastrointestinal disorders, respiratory aides, spinal devices, corrective eyewear, and monitoring equipment for conditions like diabetes and glaucoma. An aging population also benefits this cluster because older Americans are more interested in healthcare than previous generations, generating demand for home-based health services and premium care options. Moreover, Tennessee companies now have export opportunities to aging countries like Japan and places with a growing middle class, such as Central and Eastern European nations.

Niche products will also perform better in export markets than traditional medical goods. Most foreign companies in these industries compete on price rather than quality. For instance, Mexican producers have been successful at challenging U.S. companies in markets for disposable medical goods. These products sell well in developing countries that rely on cheap, disposable alternatives to expensive electromechanical apparatuses. Manufacturers still have export opportunities for premium medical products, although countries like Ireland have proven capable of competing on the basis of quality. U.S. companies sometimes acquire these foreign competitors to preserve revenue. Medtronic, for example, moved its headquarters to Dublin, Ireland, after the acquisition of Covidien.

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<sup>15</sup> Verma, S. (2017). *It looks like another rough year for the dollar in 2018*. [www.bloomberg.com/news/articles/2017-12-05/dollar-bears-to-grow-louder-next-year-as-global-growth-widens](http://www.bloomberg.com/news/articles/2017-12-05/dollar-bears-to-grow-louder-next-year-as-global-growth-widens)

Another factor behind niche product development is that many medical products no longer require innovation, incentivizing a race toward the development of new devices. For example, electromedical manufacturers are competing to create the best ventricular assist apparatus rather than re-invent the pacemaker. The industry to benefit the most from this trend has been glasses and contacts lens manufacturing. In this industry, 89.6% of all industry establishments employ less than 50 workers. Small manufacturers have thrived by specializing in a particular type of contact lens. The wide variety of contact lens, such as daily disposables, multifocals, extended wear, and specialty lens, have enabled a great number of companies to carve out a modest market share for themselves. Of course, the danger of basing one's entire revenue stream on a single product is that medical advancements could eliminate demand for the product altogether. Large manufacturers with diverse product lines are not threatened by changing demand. For example, Medtronic, one of Tennessee's largest medical device operations, has diversified its portfolio to include four different segments: cardiac and vascular (46.2% of total sales), restorative therapies (33.3%), minimally invasive technologies (11.8%), and diabetes management (8.7%). This diversification allows the company to maintain revenue.

PPACA impacts some industries in this cluster more than others. The cost-containment framework for healthcare prioritizes prevention over treatment, increasing demand for preventative healthcare solutions rather than surgical equipment. Biotechnological treatments, like bone, organ, and tissue replacements, may prove more restorative to patient health than surgical devices. Similarly, effective pharmaceutical treatment or early detection using new diagnostic equipment will undercut demand for surgical devices. The silver lining for surgical equipment manufacturers will be a rise in cosmetic surgery, enabled by growing disposable income in the U.S. and a decline in the culturally-accepted age for elective procedures. Rising disposable income should benefit all industries in this cluster. Patients cut back on visits to the physician or optometrist during economic slowdowns. In the U.S., people visit the doctor on average three times per year, and analysts predict this number to rise as the economy improves. The percentage of Americans with private health insurance is expected to increase at a per annual rate of 0.5% through 2022. Insurance coverage through Medicaid and Medicare should increase annually by 6.3%. An improved economy also enables medical professionals to replace apparatuses (particularly irradiation apparatuses) rather than constantly repair them. Currently, the average lifespan for equipment of this kind is three to five years, although it can be as short as 18 months. Rising disposable income also creates self-generating demand for medical device manufacturers. When patients become aware of new medical technologies, they request to receive this treatment. Manufacturers are able to invest resources in R&D and later recoup this investment as the technology gains widespread usage.

Recent trends in healthcare have altered the supply chains of industries in this cluster as well as the priorities for product development. To function in ambulatory and out-patient settings, medical devices must now be portable. These new products must also be interoperable with other products in the market. The "paperlessness" of modern medicine, achieved through electronic health records, necessitates that medical devices be capable of syncing with other devices. The importance of inter-operability was demonstrated by the flop of St. Jude's recent pacemaker, which was MRI incompatible. The company neglected to notice surging demand in U.S. and Japan for pacemakers with MRI compatibility, and therefore St. Jude's product did not sell. Digitization will likely hurt revenue for irradiation apparatus manufacturers and other diagnostic device manufacturers. Patients will need fewer X-rays as providers have access to recent scan results.

Tennessee has several great opportunities to improve this cluster in coming years. One such way is to support and strengthen the industries on which medical device manufacturers purchase their supplies. Key supplies include fabricated metal, circuit boards, plastic, and steel. Nearly 40% of revenue for medical device manufacturers currently goes toward purchases. In addition, Tennessee companies in this cluster would benefit from regional growth of high-tech industries like microelectronics and biotechnology. Biotechnology will transform medical device industries in coming years, and states with thriving technology clusters will be able to capitalize on this development. Currently, Tennessee is one of the main healthcare hubs in the U.S., with a number of nationally-ranked hospitals and major companies like the Healthcare Corporation of America. Manufacturers in Tennessee are fortunate to already have so many customers in close proximity. The opportunity now is to create connections between device manufacturers and industries outside the cluster.