

PLASTICS MARKET WATCH

A SERIES ON ECONOMIC-DEMOGRAPHIC-CONSUMER & TECHNOLOGY TRENDS IN SPECIFIC PLASTICS END MARKETS
FALL 2015 | ISSUE II

WATCHING:

Healthcare & Medical Devices



More information:
www.plasticsmarketwatch.org



A SERIES ON ECONOMIC-DEMOGRAPHIC-CONSUMER &
TECHNOLOGY TRENDS IN SPECIFIC PLASTICS END MARKETS

Contents

Foreword 1

Introduction 3

Utility of Plastics 7

Demographic Trends 13

Technology Trends..... 17

Economic Trends..... 27

Public Policy Trends..... 33

 Federal Healthcare Policy 34

 Regulatory Environment 36

The Big Picture 39

Sources 43

Special thanks to the SPI Plastics Market Watch work group for their guidance and input on this Healthcare & Medical Devices Report.

■ Jim Buonomo, JRB Advising

■ Jay Cude, ITW Medical

■ Fred Daniell, Kureha America Inc.

■ Theresa Hermel-Davidock, BD

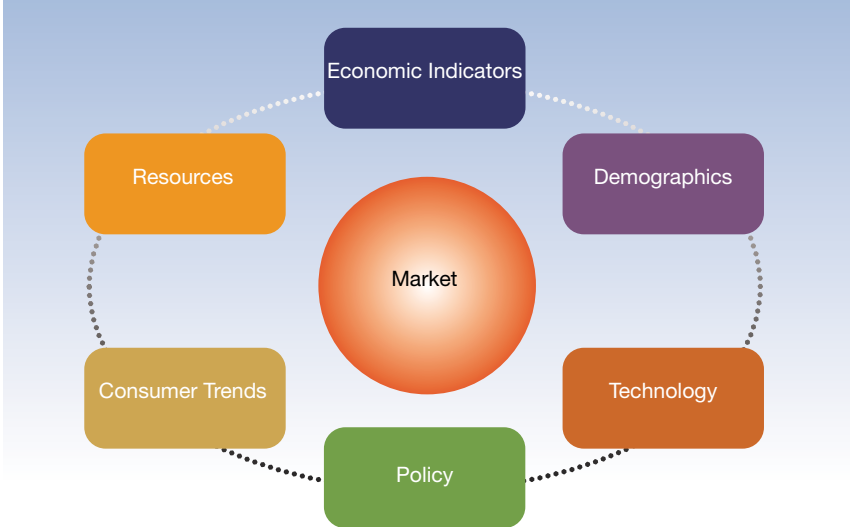
■ Phil Wilson, BASF

Materials compiled, written and edited by Hansel (Hank) Cox, with editorial assistance from Michael Taylor, George Southworth, and Kendra Martin, SPI.

Foreword

Welcome to our second “Plastics Market Watch” report. Our goal is to provide forward-looking reports for our members and the industry that blend economic and demographic data to paint an accurate picture of where we are headed in these important end markets. Where it is relevant, we will weave in other factors such as public policy, technology trends, and resource issues. These reports can then be used to present information on key drivers back to company personnel as input for their own strategic planning activities.

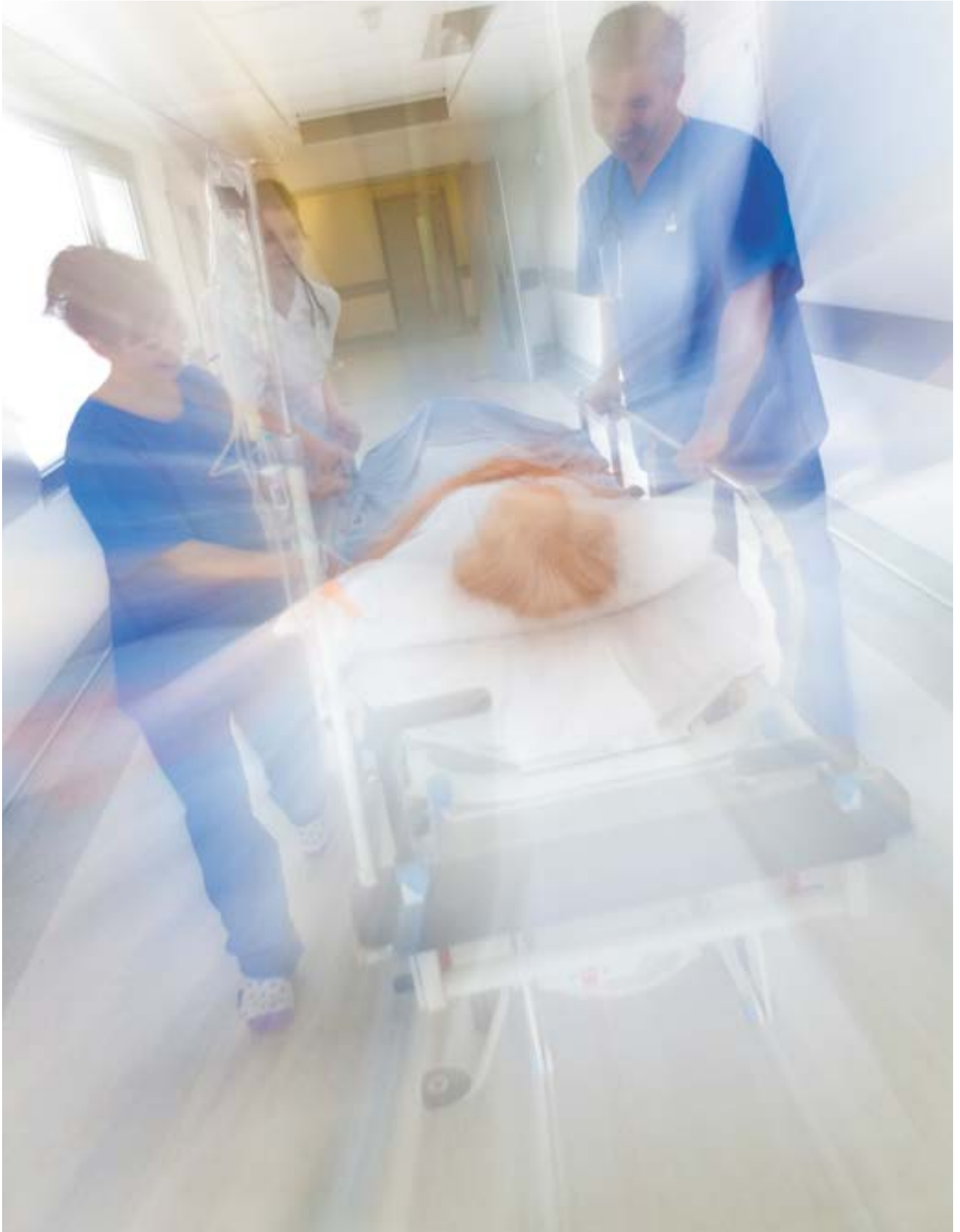
Key Drivers for End Markets



Our first in this new series covered Automotive & Transportation, while our second is focused on Healthcare and Medical Devices. In this report, we will provide insights on the current state of the role of plastics in this sector, and look into what the future holds for the material. This report also continues the discussion on what the impact of consumers is on the plastics industry. A variety of factors impact the way that we make our products, how they are consumed and how successful our businesses will continue to be.

The role of plastics in the future of healthcare will be significant. Globally, the demands for healthcare goods and services will be great, maybe even overwhelming. Healthcare is currently dependent on plastic and that dependency will only grow with time and innovation. Single use everything will play an important role.

We plan to conduct presentations and webinars in conjunction with this report to discuss our findings, and hope that these will provide important food for thought, whether you are an equipment manufacturer, materials supplier, processor, recycler or brand owner. As always, we welcome your feedback. Future reports issued later this year will focus on Plastics in Packaging and Plastics in Housing & Construction.



Healthcare &
Medical Devices

Introduction



Evolution of Healthcare and the Expanding Role of Plastics

Anyone who has visited a medical facility in recent years—which is to say everyone—has surely noticed the proliferation of medical devices comprised of plastics and plastic derivatives.

Anyone who has visited a medical facility in recent years—which is to say everyone—has surely noticed the proliferation of medical devices comprised of plastics and plastic derivatives. In ancient times when the true nature of human physical afflictions was little understood, our ancestors employed a variety of devices ostensibly to aid in the treatment of various conditions—mostly made of wood, glass, stone, metal and ceramics.

The physicians of earlier times could and did treat a variety of common ailments with some success. Doctors gave great attention to diet, exercise and mental attitude—priorities that have stood the test of time. For many centuries they have been able to set broken bones, extract teeth, remove bladder stones, remove cataracts of the eye with a silver needle and restore a mutilated face with a graft from the arm.¹ During the Civil War, surgeons routinely removed mangled arms and legs from wounded soldiers, a remarkable number of whom survived.

By fits and starts, the medical profession made uneven progress that began to accelerate in the 19th century. With the discovery of ether, chloroform and nitrous oxide as anesthetic agents, new surgical instruments were invented to penetrate inner parts of the human body. With understanding of the nature of infection, the importance of sterility became a major focus.² The end of the 19th century saw a variety of new medical instruments coming into use, most of them made of stainless steel, titanium, vanadium and ceramics.

We are privileged to live in a time when medical science has finally emerged from its Dark Ages and can offer effective therapies for a wide range of human diseases, afflictions and associated physical and mental disorders. Sophisticated medical devices have been a major contributor to advances in medical treatment as the need for precision instruments for microsurgery in neurosurgery, ophthalmology and otology became evident. More recently, energy-based instruments such as electrocauteries, ultrasound, electric scalpels, surgical tools and surgical robots have enhanced the powers of modern medicine. Today, we stand on the threshold of a new era in medicine as advances in gene sequencing and nanotechnology portend breakthroughs heretofore unimaginable.

Over the past three decades or so, plastics have assumed a dramatically important role in modern medicine. In the early 1970s, manufacturers were using materials such as glass, rubber and metal to assemble syringes, surgical instruments and other devices. Products made from such materials were typically machined, molded or assembled with fasteners.

¹ *A Distant Mirror*, Barbara W. Tuchman, 1978.

² In 1881, President James Garfield was shot by an assassin. Today it is understood that the wound would not have been fatal had it not been treated by doctors probing the wound with their bare hands, creating the infection that killed the President.

Metals that are suitable for use in the human body are relatively few in number: stainless steel, cobalt-chrome, titanium, vanadium and more recently nickel-titanium (Nitinol) alloys. These are normally formed by casting, machining, grinding and polishing, and newer methods like metal injection, molding and rapid prototyping/direct manufacturing methods, such as laser sintering and electron beam melting.

With the advances of technology in the 1980s, the need for engineered plastics soon became indispensable for use in intricate, high-performance device designs. A shift to single-use devices required design engineers to experiment with polymers such as acrylic, polycarbonate and polyvinyl chloride (PVC).

The concept of medical devices today is understood to mean articles intended for the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure of any function of the human body, but which do not create their effect by chemical or metabolic action. The global market is comprised of about 8,500 types of medical devices, ranging from simple bandages and spectacles through life-maintaining implantable devices and equipment to screen/diagnose disease and health conditions, to the most sophisticated diagnostic imaging and minimally invasive surgery equipment.



Advances in high-performance polymers and the associated merits of plastics over other materials have expanded the opportunities of plastics in the practice of medicine. Plastics can be made to dimensions from millimeters to meters, from thin walls to thick walls, and in a range of shapes and colors. As devices become functionally more complex and smaller, their components such as gears, levers, buttons, axels, activators and counters need to also be smaller while maintaining high performance, dimensional stability, durability and reliability. The micro-molding of such components with plastics allows for the manufacturing of precision parts with tight tolerances. Price pressures are also a factor driving development of high-quality, low cost alternative polymers—and plastics are generally less expensive than other materials.

The practice of medicine has recently entered an age of rapid progress—in part driven by advances in technology that facilitate development of new therapies which, in turn, are often made possible by development of new lifesaving materials—most notably plastics. Clearly, the market for plastics in medical devices is substantial and growing. However, there are changes on the horizon that will have a profound impact on this market—specifically in demographics, technology and economics. We examine each of these in detail in this report.

Clearly, the market for plastics in medical devices is substantial and growing. However, there are changes on the horizon that will have a profound impact on this market—specifically in demographics, technology and economics.

Healthcare &
Medical Devices

Utility of
Plastics



[Plastics] are lightweight compared to metals, ceramics, and glass and have an excellent balance of strength, stiffness, toughness, ductility and impact resistance. Many applications are using plastics to replace either metal or glass to reduce costs, leverage design flexibility and still maintain performance.

The Utility of Plastics in Healthcare and Medical Devices

“Plastics have superior design flexibility compared to metals, ceramics and glass,” said Vinny R. Sastri in *Plastics in Medical Devices: Properties, Requirements and Applications*. “They can be processed into innumerable shapes, sizes, thicknesses and colors and their properties can be tailored to meet a wide spectrum of physical, mechanical, chemical and biochemical requirements. Additives and fillers can be used to render plastics flexible or rigid, insulating or conductive, hydrophilic or hydrophobic, transparent or opaque, and chemically resistant or sterilization resistant.”

Plastic medical devices come in two categories—disposables and non-disposables.

- Disposable medical devices include bandages, gloves, blood bags, colostomy bags, catheters, syringes, IV kits and tubing. Infection control products and devices, including gloves, masks, drapes and gowns, must be fitable, non-irritating, chemically resistant and stain resistant. Antimicrobial additives in drapes and gowns can significantly reduce infection and growth of microorganisms.
- Non-disposable medical devices include a broad range of surgical devices and equipment used in cardiology, orthopedics, wound care, surgical instrumentation, diagnostics, drug delivery, ophthalmology, respiratory and endoscopy infection control and technology. Durable medical devices generally fall into five categories: surgical equipment and instruments; diagnostic systems; general hospital technologies; therapeutic devices; and self-care and rehabilitation products. Endoscopy uses a lot of electronics and ancillary products such as cameras, light sources, monitors and recording equipment. Electric power and thermal management are important. Thus, all materials being used must be durable and tough.



Surgical devices that are used and re-used must be sterilized repeatedly and thus must be made of materials that can withstand repeated steam sterilization—which is the most common method used for sterilization. They must have good hydrolytic and thermal stability. Identification methods, such as color coding, are important.

Drug delivery utensils including needles, tubing, bags, manifolds, Y-sites, clips and connectors are primarily disposable. They need excellent chemical and/or lipid resistance, flexibility, transparency and clarity, sterilization resistance, toughness, tear and burst strength, softness, not leachable and extractable properties.

“Plastics can be processed by many different methods varying from injection molding and extrusion to machining to form needed parts, films and fibers,” said Sastri. “They are lightweight compared to metals, ceramics, and glass and have an excellent balance of strength, stiffness, toughness, ductility and impact resistance. Many applications are using plastics to replace either metal or glass to reduce costs, leverage design flexibility and still maintain performance.”

“In contrast to the relatively small number of metals used in medical devices and implants, plastics come in a bewildering array with myriad properties and strange trade names and acronyms,” said Ted Kucklick, Co-Founder and Chief Technical Officer of Cannuflow, Inc. “New varieties are invented all the time. Plastics may be as soft as skin or hard as steel. They can have a range of colors, alloys, fillers and modifiers.”

There are four primary categories of plastics used in medical devices:

- About 70 percent consist of commodity thermoplastics—including PVC, polyolefins and polystyrene.
- About 20 percent are engineered thermoplastics which have improved thermal and mechanical properties over commodity thermoplastics.
- The remaining 10 percent consist of high temperature thermoplastics having very high temperature resistance along with strength, stiffness and toughness, including polyimides, polyetherimides, polysulfates, polyarylether ketones, liquid crystalline polymers and fluoropolymers.
- Others—styrenics, silicones, thermoplastic elastomers and thermosets.

Leapfrog Gains in Prostheses

The lengthy military conflicts in Iraq and Afghanistan have left many service men and women badly injured. A disproportionate number of their injuries have been caused by improvised explosive devices (IEDs) that are the weapon of choice for militants with minimal resources who do not have access to advanced military hardware. The U.S. military has acquired extensive skills in identifying and disarming IEDs, but it is never a certain process, and the nature of the devices and their placement continues to change.

It is truly remarkable how effectively the U.S. military has become at providing quick treatment to wounded service personnel, many of whom would have died in earlier wars. All too often the wounded pay a severe price in terms of lost limbs and psychological injuries, most notably traumatic brain injury (TBI) that often results from explosions and post-traumatic stress disorder (PTSD) that are extremely difficult to manage.

But medical science has made great strides in developing advanced prostheses to enable wounded veterans to surmount their injuries and return to productive lives. One young Marine corporal named Rob Jones, who lost both legs above the knee to an IED, recently rode a bicycle from Maine to San Diego to raise funds for wounded veterans (and also to prove he is NOT handicapped). Today’s prostheses are vastly superior to the technology of only a few years ago thanks in large measure to the use of advanced plastics that have tensile strength, resistant to exposure to liquids and—most importantly—are lighter than metal.

The advanced prostheses have revolutionary designs that enable the synthetic limb to anticipate the body’s movements and adjust accordingly. Minicomputers are increasingly in the mix as the devices become more sophisticated. The next step in the developmental stage is to surgically implant tiny sensors into a person’s residual muscle tissue to measure and interpret the signals traveling between the nerve endings and the brain—allowing for both conscious and unconscious control of the limb. Current technologies require transplant of muscle tissue from another part of the body, but researchers expect to soon make that unnecessary. Of course, the evolving technologies have implications far beyond treatment of wounded warriors and can be used to enhance the lives of millions who have lost limbs through a variety of causes.

From Blood Bags to the Ebola Epidemic

In the early years of blood transfusions, donations were collected in glass bottles. Today, donated blood is collected into specially designed polyvinyl chloride (PVC) plastic bags/packs. The move from glass to plastic significantly improved the viability of donor banks, extending the shelf life of blood donations, and decreasing bacterial contamination. The integrity and sterility of blood bags is of critical importance to patient safety.

The importance of plastics in disposable medical equipment was dramatically underscored during the recent outbreak of the deadly Ebola virus in Western Africa. The TV news was, for many weeks, filled with dramatic scenes of doctors and nurses striving to deal with the outbreak while protecting themselves from exposure. They were all covered virtually from head to foot in a variety of plastic materials which are the ideal material for personal protection from contagious agents.

Though the worst of the epidemic seems to have passed, the U.S. Centers for Disease Control (CDC), our nation’s lead public health agency, continues a major effort to deal with isolated pockets of the disease and to prevent another outbreak. The World Health Organization (WHO) estimates there are currently more than 18,000 active Ebola cases worldwide.

The role of flexible vinyl and other plastic-based products has been crucial to virus containment efforts. Those products include isolation suits, chambers and gowns, goggles, masks, hair covers, filters, helmets and hoods for both isolation and healthcare worker protection. Disposable gloves, shoe covers, utensils, meal trays, trash bags and burial bags are all constructed using flexible PVC. In addition, fluid bags and blood bags are made predominantly from flexible PVC.

Hood
\$6

Goggles
\$15

Gloves
\$5

Mask
\$4

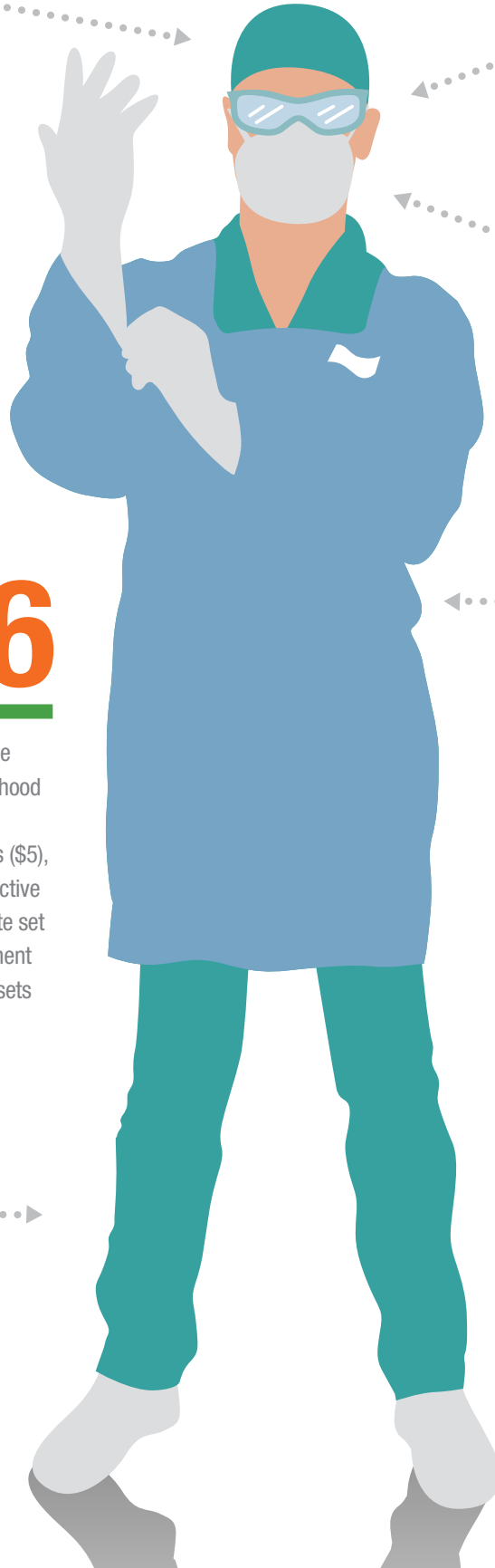
Complete Set
\$76

Apron
\$22

One complete set of personal protective equipment (PPE) would consist of one hood (\$6), reusable goggles (\$15), a double surgical mask (\$4), examination gloves (\$5), reusable apron (\$22), disposable protective suit (\$20), and boots (\$4). One complete set costs \$76. The Red Cross Ebola Treatment Center in Sierra Leone uses 150–180 sets a day—\$330,000 per month.

Suit
\$20

Boots
\$4





The overall demographic picture, for the United States and the world at large, suggests the market for plastics in medical devices will continue to grow, and at an accelerating pace, for the foreseeable future.

Healthcare &
Medical Devices

Demographic
Trends

Demographic Trends

The overall demographic picture, for the United States and the world at large, suggests the market for plastics in medical devices will continue to grow, and at an accelerating pace, for the foreseeable future. Not only will the population continue to expand, but the elderly segment of the population—the one that makes the greatest demands on healthcare—will grow at a much faster pace than the overall population.

The world population today is about 7 billion people and is expected to reach about 8 billion by the end of 2015, and perhaps 10-12 billion by 2050. The proportion of older people requiring support from adults of working age increased from 10.5 percent in 1955 and 12.3 percent in 1995, and is expected to reach 17.2 percent in 2025. In 1955,

Average life expectancy at birth in 1955 was just 48 years; in 1995 it was 65 years; in 2025 it will reach 73 years. By 2025, it is expected that no country will have an average life expectancy of less than 50 years.

there were 12 people aged over 65 for every 100 aged under 20. By 1995, the old/young ratio was 16/100. By 2025, it will be 31/100.

The total number of people aged over 65 will rise to 800 million by 2025, reaching 10 percent of the world population. By 2025, possible increases of up to 300 percent of the older population are anticipated in many developing countries, especially in Latin America and Asia. Globally, the population of children under the age of 5 will grow by just 0.25 percent annually from 1995 to 2025, while the population over 65 years will grow by 2.6 percent. The average number of babies per woman of child-bearing age was 5.0 in 1955, falling to 2.9 in 1995, and reaching 2.3 in 2025. While only three countries

were below the population replacement level of 2.1 babies in 1955, there will be 102 such countries by 2025.

Average life expectancy at birth in 1955 was just 48 years; in 1995 it was 65 years; in 2025 it will reach 73 years. By 2025, it is expected that no country will have an average life expectancy of less than 50 years. The transition from high to low mortality and fertility that accompanied socioeconomic development has also meant a shift in the leading causes of disease and death. Demographers and epidemiologists describe this shift as part of an “epidemiologic transition” characterized by the waning of infectious and acute diseases and the emerging importance of chronic and degenerative diseases.

“In the United States, aging is becoming a huge issue,” said William J. Cude III.³ “The train at the end of the tunnel is coming our way. The prime time group moving through the health care system are those aged 65-85, the so-called Silent Generation. The Baby Boom generation is now coming up entering the health care prime time. The demand based on sheer numbers is staggering. Even politicians can do the math.”

Evidence from the multi-country Global Burden of Disease project and other international epidemiologic research shows that health problems associated with wealthy and aged populations affect a wide and expanding swath of world population. Over the next 10 to 15 years, people in every world region will suffer more death and disability from such non-communicable diseases as heart disease, cancer, and diabetes than from infectious and parasitic diseases.

In 2008, non-communicable diseases accounted for an estimated 86 percent of the burden of disease in high-income countries, 65 percent in middle-income countries, and a surprising 37 percent in low-income countries. By 2030, non-communicable diseases are projected to account for more than one-half of the disease burden in low-income countries and more than three-fourths in middle-income countries. Infectious and para-

³ William J. Cude III, Principal, Cude Advising LLC/SPI Member.

sitic diseases will account for 30 percent and 10 percent, respectively, in low- and middle-income countries. Among the 60-and-over population, non-communicable diseases already account for more than 87 percent of the burden in low-, middle-, and high-income countries.

The Growing Middle Class

The middle class—loosely defined—is growing all over the world which means not only higher living standards, but growing demand for all aspects of medical services. The middle class will increase from 1.8 billion in 2009 to 3.2 billion by 2020, and 4.9 billion by 2030. Most of this growth will come in Asia which by 2030 will represent 66 percent of the global middle class population and 59 percent of middle-class consumption, compared to 28 percent and 23 percent respectively in 2009.

The developing world's "emerging middle class" represents a critical economic and social actor as a result of its potential as an engine of growth. History tells us that those in the economic middle have vigorously accumulated capital, be it physical or human. If this incipient middle income group can be consolidated into a stable middle class, then it can provide a solid foundation for economic progress by driving consumption and domestic demand.

Despite having the requisite incomes, these middle classes in many cases remain vulnerable. Their employment (many work in the informal sector), education (few have university degrees) and consumer behavior do not coincide with perceptions of a middle class that drives domestic consumption and growth. In most cases, social protection systems fail to reach a majority of this population, as coverage rates of informal workers are



extremely limited. This vulnerability is particularly troubling, since if those in the middle have precarious incomes and unstable employment, their consumption cannot be counted upon to drive national development.

Middle class expectations in emerging and developing countries are rising and evolving as their countries' economic situations improve. They are no longer satisfied with simply having access to public services; they are increasingly concerned with their quality. Providing the quality services that the middle class demands is far more complicated than simply providing access to them and can be a source of friction, conflicts and political upheaval.

The graying of societies along with the global rise in a middle class unlike those previously seen is driving growth in the healthcare and medical device market. At the same time, many countries are not growing wealthier at a rate necessary to keep up, therefore it may be questionable as to how sustainable the levels of spending in certain growth markets are.

Meanwhile, in the U.S., the much remarked "baby boom" generation—those born in the years immediately following World War II—is beginning to march into retirement at an accelerating pace, placing tremendous demands on government retirement programs, especially Social Security and Medicare. Social Security is already paying out more money than it takes in and the gap will widen as more boomers retire. Medicare and Medicaid together are spending 45 percent of the nation's total healthcare expenditure.

Healthcare "prime time" can be defined as ages 65-85. Right now that group is comprised largely of the so-called "silent generation" or people who grew up during the Great Depression and World War II. That is a relatively small group. But now the Baby Boom generation is entering that "prime time" and the nation is headed for a major economic crisis.

There is a general consensus among economists that both of these programs will require significant adjustments to remain solvent including gradual raises of the retirement age and increased taxation, neither of which is politically palatable.

Conclusion

According to Ken Gronbach, multi-generational marketing expert and author of *The Age Curve: How to Profit from the Coming Demographic Storm*, the aging of the world's population is setting up healthcare's perfect storm. There will be a collision of the largest generations ever to become elderly with the age sector that demands the most healthcare services. In many cases, worldwide the number of 70 plus year old people will double. When a market doubles in demographic size, the demand for products and services related to that market more than doubles—a phenomenon called "the multiplier effect."

In the United States, it is projected that Baby Boomers will use more than double the healthcare goods and services than the Silent Generation it follows even though the Silent Generation is just 40 percent smaller than the Boomers. This seems counter-intuitive but it points to the fact that Baby Boomers will inhale healthcare, and plastics will benefit accordingly. At the same time, the dramatic increase in costs associated with providing medical care to hundreds of elderly will place unprecedented economic strains on society, leading to more intense pressure for cost containment.

A Closer Look

By 2009, the middle class consisted of 61 million people in Brazil (up from 39 million a decade earlier), and 75 million in Russia (up from 31 million). In Brazil, the middle class comprises one third of the population and in Russia more than half, though both nations are today experiencing economic turmoil that may impact this trend. In India, which has about 1.3 billion people, roughly the same as China, only 9 million people, or less than 1 percent of the population, had achieved middle class status by 2010.



Because of its tremendous growth and wealth, China offers a potentially important market for medical devices, but there is disagreement among experts regarding how many Chinese can be properly considered middle class. Helen H. Wang, author of the award-winning book, “The Chinese Dream:

The Rise of the World’s Largest Middle Class and What It Means for You,” defined China’s middle class as households with a “third of its income available for discretionary spending.” That, according to Wang, would be somewhere between \$10,000 and \$60,000 in China, a significant gap. Where one lives in China can make a big difference in living standards and what comprises the middle class.

Wang puts the number of middle class consumers in China at “more than 300 million” or “more than the entire population of the United States.” She suggested it would reach 700-800 million by 2022. McKinsey & Company estimates China’s middle class will number 630 million by 2022. That would be 75 percent of the urban population and 45 percent of the nation’s total population. Any way you slice it, China is a large and growing market for medical devices. China’s official goal is to provide universal healthcare for 100 percent of its population by 2020.



Everywhere a growing middle class means growing demand for medical services, including plastic medical devices, and the aging of the population enhances that demand. But the aging populations present economic complications that will impede the ability of governments and individuals to accommodate demand for more medical care. Japan, for example, is seeing a steady decline of population with an ever smaller workforce striving to provide for an exploding number of elderly people.

Japan’s population quandary is largely due to cultural factors that have thus far resisted efforts of reform. Young Japanese

women are reluctant to marry and have families because of the strict constraints that are imposed upon married women by social custom. Likewise, the Japanese resist assimilation of people from other countries. Even second and third generation Koreans living in Japan are routinely denied citizenship. Absent some dramatic turnabout in Japanese culture, the nation is demographically challenged from a growth perspective.



China, likewise, is facing a demographic crisis of its own making. The longstanding one-child policy of the earlier communist era has left a major void in the younger population that will be expected to support a massive population of elderly in the not too distant future. The shortage of younger people is also exacerbated by an imbalance between males and females, with an estimated excess of 90 million young men who will never be able to marry, or at least not marry Chinese women. Indeed, demographic projections show that within a few years, China will cease to be the world’s most populous country, ceding that honor to India.

The population of the continent of Africa is one billion. The average age people die on this continent is 35 to 40 years old, exacerbated by very high infant mortality. Africa is the last primitive continent that has not benefited from education, technology, modern healthcare, hygiene or nutrition. Gronbach notes that all of this will change as the continent is welcomed into the modern age and exploited for its resources. The big story in Africa will be a population explosion as the average age people on this continent die is elevated from 40 years old to 80 years old like the rest of the world. This will increase the population of Africa by the equivalent of 40 birth years bringing its population mass to an astounding 4 billion by 2050. Is this an opportunity for plastic in healthcare? Overwhelmingly, yes!



Europe and the United States face their own challenges related to aging and demographics. The birth rates in the more advanced nations are below the level needed to sustain current population levels. Europe and the U.S. continue to report marginal increases in population primarily because of immigration from less developed countries.



Healthcare &
Medical Devices

Technology
Trends

Technology Trends

Plastics are appearing in medical devices in a variety of innovative uses that would have been unimaginable even a few years ago—medical breakthroughs that can dramatically enhance and prolong human life. Some of the more notable examples:

- **Unblocking arteries**—in the latest approach to heart surgery, catheters (thin tubes) are used to unblock arteries or blood vessels while deposits obstructing them are broken down with a tiny spiral-shaped implant—a vessel support. Abbott Labs has developed a new type of heart stent that may solve a quandary of patients with clogged arteries: to stent or not to stent? Heart stents, typically made of metal mesh tubing, are a common way to improve blood flow in clogged or blocked arteries by holding the damaged artery open. But permanent metallic stents are not a perfect medical solution—after initial stabilization, arteries can reclose or the stents can cause additional cardiac problems. Even drug-eluting stents, which are coated with drugs that prevent an artery from reclosing, have been shown to be too risky in patients with coronary artery disease. Abbott has created a stent made of corn-based plastic, a material that has become common in biodegradable food packaging and toys, which will dissolve when it's no longer needed. Officially called “bioresorbable vascular scaffold,” the corn-based plastic stent has a drug coating that allows it to stay in place for two years before the body begins to absorb the device. It takes between fifteen to eighteen months for the absorption process to finish. Abbott hopes the BVS will, “reset the clock on the disease progression,” said Dr. Richard Rapoza, the chemical engineer responsible for developing the BVS. The company expects the devices to come online this year 2015.
- **Prosthesis**—as mentioned earlier, plastics are now being used as orthopedic devices to align, support or correct deformities. They can even improve the function of movable parts of the body or replace a body part assuming its primary function.
- **Artificial corneas**—eye injuries or chronic inflammations such as corneal erosion can impair sight and if a transplant has little chance of success, prosthesis is the only hope. Artificial corneas made from special silicone are now available for treatment. Only 0.3 to 0.5 millimeters thick, highly transparent, flexible and made of bio-mechanics similar to a natural cornea, they can restore clear vision.
- **Hearing aids**—people with severely impaired hearing can now have a plastics implant that brings sound back to their ears. This implant consists of numerous components—a microphone, a transmission device connected to a micro-computer worn on the body, a stimulator and an electrode carrier with 16 electrodes for 16 different frequency ranges. As it transforms acoustic impulses into electrical ones, it bypasses the damaged cells and stimulates the auditory nerve directly.
- **Plastics pill capsules**—release exactly the right dosage of its active ingredients at the right time. The tartaric acid-based polymer gradually breaks down releasing the active ingredients over a longer period of time. These tailor-made pharmaceuticals help to avoid having to frequently ingest large quantities of pills.

“The pace of innovation in medicine—and in particular the applications of evolving plastics technology in medical devices—is accelerating at a breathtaking pace,” said Jim Buonomo. “Everything is going faster.”⁴

For example, the Global Cardiovascular Innovation Center (GCIC) at the Cleveland Clinic in Cleveland, Ohio, works with universities, technology companies and economic development officials. A \$60 million Ohio Third Frontier grant launched the project in 2007. Gene Jung, the group’s director of product development, said the GCIC has helped 18 new businesses start in Ohio, which in turn have attracted \$700 million in follow-on

⁴ Jim Buonomo, JRBAdivising/ SPI Member.

The pace of innovation in medicine—and in particular the applications of evolving plastics technology in medical devices—is accelerating at a breathtaking pace.

financing. At present, 28 startups are housed in a business incubator the center manages. “Our role is really more of a match-making role,” Jung said. “We facilitate innovation.”⁵

The Cleveland Clinic, a nationwide leader in heart care, is a natural venue for the GCIC said Jung, who noted that the center defines “cardiovascular” broadly to include the heart and circulatory system, stroke and other areas. The GCIC’s goal is to commercialize medical products and foster economic development. Jung said much of his job is to link together business people with technical experts already in Ohio. Healthcare is undergoing big changes, from treating single episodes of illness to prevention in what he calls a “care continuum model.” That means products now have market potential if they can reduce overall healthcare costs and fill an unmet need.

Jung said heart failure is a large unmet condition and an under-served area ripe for innovations. “Anything that is a less invasive approach to deal with heart failure is something we like,” he said. “What we look for is devices that really touch pain points in medicine. Is there an unmet need? What is the potential? Is it going to be broadly adopted and treat a large population? Will it take cost out of the system?”

For the plastics industry, minimally invasive products could be implants and devices for delivering drugs directly to the heart. “We really look to polymers to advance medical devices,” Jung said, adding that it’s really the breakthroughs in material science from plastics companies that enable the GCIC to develop better minimally invasive devices. The movement is really towards less-expensive care models. And less expensive means less, shorter recovery times and lower mortality rates.

⁵ *Plastics News*, May 28, 2014

Some examples of the GCIC’s emerging technologies offered by Jung:

- An anti-fouling composite polymer which reduces the chance for bacterial infection. “Infection remains a very unmet medical need,” Jung said. GCIC helped a physician/inventor license the technology and a venture capital company is now developing it.
- A neuro-stimulation catheter to deliver intravascular drugs to heart patients.
- A very small circulatory heart pump called a ventricular assist device. In the future, surgeons will place these devices using minimally invasive operations instead of open-heart surgery. “We’re looking at things that can be inserted, expanded and delivered and can remain for a long period of time,” Jung said. “There are a number of cable-and-polymer solutions” in the pipeline.
- A single-use catheter/filter to capture embolic debris.
- A customized, patient-specific airway stent made of silicone. The engineers use data from a CT scan and make the mold using 3-D printing, then use molding to make the individual stent. “It fits the airway much better than a standard tubular stent,” said Shengqiang Gao, a polymer specialist who is senior principal research engineer at GCIC. “We’re using more and more 3-D printing” for prototypes.
- A cardioscope—basically a camera and a light that can show live images of a heart valve. The scope must be bendable with “bi-directional steering” and, yet, hold up in a demanding environment.

BD Insyte

Another example of the breathtaking innovation afoot in medical plastics is the BD Insyte “Autoguard” IV catheter which helps reduce healthcare workers’ risk of accidental needle-stick injuries and resultant exposure to HIV and other blood-borne pathogens. BD (Becton, Dickinson and Company) is a global medical technology company (and a member of SPI).

The “trifecta” for product design decisions at BD is based on a stringent sustainability model, said Theresa Hermel-Davidock, WW Director R&D for BD Medical. “Is the product maintainable from a business, environmental and societal perspective? BD’s engineers and product managers plug those inputs into their thinking caps as they go about their work.”⁶

In the case of BD Insyte “Autoguard” IV catheters, BD conducted a 360-degree analysis of the product family during a two-year period, taking into consideration both the expressed desires and unmet needs of its customers, which included such factors as material reduction, recyclability and packaging waste without compromising quality and safety.

In 2012, BD adopted design changes that improved the environmental impact of the product across all three sustainability measurement points:

- The polycarbonate barrel was replaced with polypropylene to increase the recyclability content of the catheters, as polypropylene is preferable in many hospital environmental sustainability programs.
- Attention was then turned to the plastic cover that shields the catheter and needle. The volume of the needle cover was reduced by 26 percent which allowed for significantly decreased medical waste generation without affecting the safety or usability of



⁶ *The SPI Magazine*, Fall 2014

the product for either the clinician or the patient. This also saved hundreds of thousands of kilowatt hours of electricity during manufacturing.

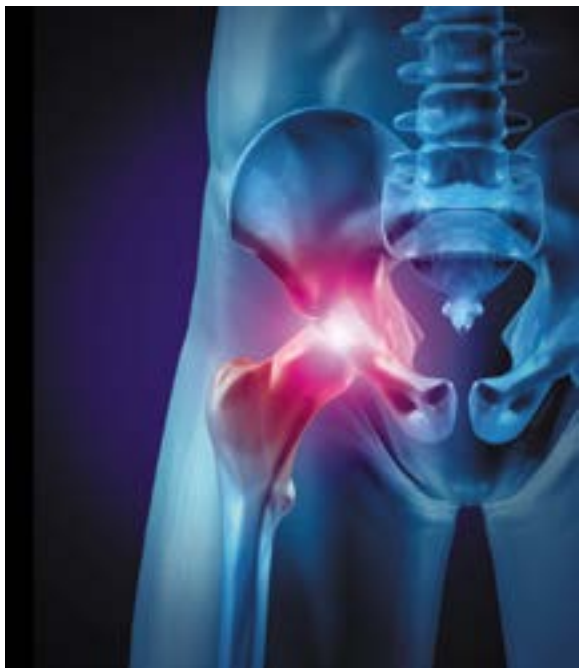
- Shortening the needle cover had the added benefit of reducing the product's packaging size. A shorter product allowed for a reduction in the overall unit package material by 13 percent. Again, less packaging means less waste. And smaller unit packages mean smaller shelf carton package as well, which enables BD and its distributors to increase the number of cases per pallet.
- The redesign allows BD to ship 264,000 additional units per truck resulting in the elimination of approximately 25 semi-truck trips between the BD Insyte "Autoguard" IV catheter manufacturing site in Sandy, Utah, and BD's various distribution centers around the country, annually. This also reduces consumption of fuel and carbon emissions.

Hermel-Davidock said BD's innovations have led to stronger customer and supplier relationships. "They deeply appreciate the commitment to constantly improving the environmental and societal credentials of their products, and this appreciation has grown into the expectation that BD will deliver incremental improvements across all product lines," she said. "This is a challenge BD fully embraces."

Implantable Medical Devices

Implantable medical devices are creating bionic boomers and increasing demand for plastic material advances that can survive the harsh environment of the human body over extended periods of time or bioresorb to completely disappear after the job is done, without harm to the patient. Some of the more recent innovations include a totally bioabsorbable PLA stent, various polymer microfibers for biotextile components used in tissue engineering, artificial joints with microchip monitors and implantable drug delivery and/or patient monitoring systems.

An artificial aortic valve that can be implanted without open-heart surgery has been introduced to the market. The valve is made of cow tissue and polyester supported with a stainless steel mesh.



Hip Socket Development

Plastics are finding a home in the ever-popular hip replacement surgery which is one of the most frequent operations carried out in Europe and North America. Some hip replacements—metal on metal implants in particular—that are not positioned optimally are often susceptible to premature failure. Some physicians are calling for a ban on artificial joints made of cobalt-chromium alloys in which the joint's metal ball rubs against its metal socket. Poorly designed

or positioned metal-on-metal implants can lead to higher wear rates that can release elevated cobalt-chromium ion levels that spread through the circulatory and lymphatic systems, potentially damaging organs and triggering inflammation. Metal ions are also suspected carcinogens.

The Fraunhofer Institute IPA partnering in the European Commission-funded "ENDURE" (Enhanced Durability Resurfacing Endoprosthesis) project has developed a novel kind of hip implant—a metal free solution that has bone line elasticity. The high-tech composite hip socket is made of carbon-fiber reinforced polyetheretherketone (PEEK), a high-strength, wear resistant, biocompatible polymer composite.

Ceramic is used for the femoral head. A hydroxylapatite coating at the bone interface helps ensure bone tissue will fuse with the implant surface structure. Cobalt-chromium implants still in use are rigid, therefore load transfer to the bone is nonoptimal, leading to potential adverse bone adaption. By using this new material combination, force transmission through the PEEK plastic hip socket to the pelvic bone replicates natural conditions, and there are no metal ions released.

The development team was able to confirm the good wear resistance in initial tests of the novel hip replacement using a robot that simulated various series of movements. The ENDURE implants follow the bone-preserving principle using thin-walled shells that replace the bearing surface of the joint articulation alone, instead of employing large metal stems for support which require a substantial volume of bone to be removed.

Hospital Infections

An alarming increase in hospital-acquired infections, along with concerns related to the spread of pandemics such as swine flu and Ebola, are leading to

The quest to reduce infections is reflected in dramatic innovations in adhesives, sealants and fasteners.

surging demand for antimicrobial plastics for medical devices that are expanding into implantables. New developments include non-leaching antimicrobials and new microbial-growth inhibitors based on sharkskin biomimicry that help avoid the potential for superbug development.

The quest to reduce infections is reflected in dramatic innovations in adhesives, sealants and fasteners. For example, Incisive Surgical Inc.'s patented Insorb 20 subcuticular skin stapler is a sterile, single-patient-use device that deploys up to 20 absorbable staples sufficient to close a 17-centimeter incision. The Insorb 20 represents a new skin closure modality designed to combine the cosmetic result of an absorbable suture with the rapid closure times associated with metal skin staplers.

The absorbable staple offers increased patient comfort over metal staples while eliminating the need for metal staple removal post-operatively. The product also provides lower risk of infection and may shorten operative time compared to other wound-closure methods. The new staple is composed of a copolymer of polylactic acid and polyglycolic acid, which is absorbed by the body over a period of a few months. The disposal stapler is composed of sterilizable acetal.

Meanwhile, 3M has come up with a highly-absorbent, breathable wound dressing that is constructed from a conformable polyurethane foam pad, and an additional absorbent nonwoven layer from National Wovens, with a border transparent adhesive film impermeable to liquids, bacteria and viruses.

The polyurethane foam pad prevents exudate pooling and migration onto surrounding tissue while the film barrier helps prevent external contamination and exudate strike-through, and evaporates moisture vapor out of the dressing. The 3M foam adhesive dressing is used for treating moderate to highly exuding dermal wounds such as pressure ulcers, neuropathic ulcers, abrasions, and first- and second-degree burns.

Heavily draining wounds often result in skin maceration, frequent dressing changes and patient discomfort. The 3M foam adhesive dressing provides total fluid management by a combination of fast wicking, high absorbency and breathability and uses an innovative "moist" skin adhesive technology. The unique spoke-shaped delivery system allows for fast, easy application for wounds over body contours.

Also, ProPen XL, manufactured by Closure Medical Corporation, is an applicator system for Johnson & Johnson Ethicon's Dermabond topical skin adhesive, 2-octyl cyanoacrylate. The polyethylene disposable, sterile, single-use delivery system is designed for precise application of the topical skin adhesive which can replace sutures and staples in surgical procedures. A key design goal of the ProPen XL was to make the device intuitive to the user while maintaining a high level of product performance. Rapid prototyping methods were used to quickly modify and adapt early design concepts that were then taken directly to clinicians for evaluation.

The glue in the ProPen XL applicator is packaged in a glass vial. A twist of the applicator breaks the glass vial and depressing the integrated plunger dispenses the glue through a felt applicator, similar to a pen. Simplistic as this may seem, the designers spent considerable time getting to this level of ease of use.

The topical adhesive can be applied with the same intuitiveness as a drawing on a tablet. No mixing is required and cleanup is a matter of disposing of the applicator. While the adhesive product itself is not new, ProPen XL significantly improves its ease of use.

Personal Medical Care Devices

Reliance on personal medical care devices is expected to explode in the next few years. Already there is a smart phone app that enables patients to administer EKGs to themselves. A wide variety of disposable items once used in traditional surgery are no longer needed. Use of IV pump lines, for example, is down 30 percent over the last five years. "The implications for testing labs are grim," said Cude. "All those consumables—slides, petri dishes—will become obsolete. Not tomorrow or next year, but soon."



Increasing reliance on personal care medical devices is raising concern in some quarters. New research has found that patients with chronic diseases are often overconfident when it comes to administering their own medication using drug delivery devices, despite having little training on how to use them correctly. A study conducted by Team Consulting, based in the United Kingdom, looked at a range of delivery options and in many cases patients felt that they would not require training or support to use the device correctly. Some 85 percent of patients using wearable patches believed that minimal training would be required, 63 percent using injector pens and 50 percent of patients using needles and syringes.

This is an important area of concern because cost pressures are driving the medical establishment to greater reliance on personal responsibility for many therapies. “In order to reduce the overall costs of healthcare, there are many in the industry who feel it is inevitable that patients will self-administer more medicines in coming years,” said Charlotte Clark, Senior Consultant at Team Consulting. “In theory, this relieves the burden on healthcare systems, professionals and infrastructure, but it increases the emotional and physical burden on patients. Patients frequently disregard instructions for use as they often resist risk management documentation full of lists of Dos and Don’ts in tiny print. We need to reduce the burden on patients if they are going to be able to rise to the challenge of increasing self-administration.”

Paul Greenhaigh, Director of Design at Team Consulting, said acceptance of alternative training methods will change as people are becoming more “digitally literate” and have real experience of using well-designed interactive training aids. “After all, 15 years ago there were no smart phones, and even two years ago many people wouldn’t imagine doing their banking or grocery shopping via an app,” he said.

Despite the concern of improper patient use, there is evidence that innovations in the plastics industry will be needed to meet this increasing demand. “Telemedicine will be huge,” said Cude, “and personal medical devices of all kinds will contain plastics.”

As the old saying goes, you ain’t seen nothing yet. After eons of marginal progress, medical science today is embracing technology in a big way and it has both positive and negative implications for the plastics industry.

A Brave New World of Medicine

As the old saying goes, you ain’t seen nothing yet. After eons of marginal progress, medical science today is embracing technology in a big way and it has both positive and negative implications for the plastics industry. In the near term, most all of the information is positive as daily advances in technology bring plastics into play in new and marvelous ways and a growing population, mostly middle class, assures expanding demands on the medical system.

But in the long term, there are trends in medicine that may raise questions about reliance on plastics at least in traditional applications. Major advances in genomics, preventive medicine, diagnostics and

treatment of disease will bring radically new ways of treating patients. There are new ways of testing that will not require the drawing of blood and transporting it to laboratories for analysis. Sensors placed on the skin will perform a blood analysis on the spot and can be adjusted to identify all sorts of issues. Presumably, these sensors themselves will contain some plastics, but they will be small and will replace an array of standard medical devices in use today that are plastic-based. The implications for testing laboratories—and all those slides, petri dishes, syringes—are not so bright.

Medicine is shifting with accelerating speed to less invasive forms of surgery, growing now 8-10 percent a year. The simple insertion of a stent into a heart artery, for example, is achieved today by sending a tiny catheter up to the heart through the femoral artery in the groin area—a much less invasive procedure that has mostly replaced open heart surgery. A patient enters the hospital or other medical facility, has the procedure without losing consciousness, and returns home in the evening.

Many plastics products used in traditional medicine—IV lines, cups, basins, lab wear—have stopped growing and are trending down. We have been making the same basic products for the past 20 years or so, but that is changing. Use of these standard products is expected to decline 15-30 percent over the next 10 years. Plastics will always be in widespread use but the strong growth curve of the last several years is about to flatten out.

Nanotechnology

Nanotechnology is the study and application of extremely small things—a relatively new field of study with broad implications for medicine as well as chemistry, biology, physics, materials science and engineering. It is difficult to grasp just how small a nanometer is. It is one



billionth of a meter. There are 25,400,000 nanometers in an inch. A sheet of newspaper (remember those) is about 100,000 nanometers thick.

Nanoscience and nanotechnology involve the ability to control individual atoms and molecules—the very foundation of everything on earth, including humans. It has quite obvious implications for treatment of medical conditions. Today's scientists are finding a wide variety of ways to deliberately make materials at the nanoscale to take advantage of their enhanced properties such as higher strength, lighter weight, increased control of light spectrum and greater chemical reactivity than their large-scale counterparts.

Thanks to nanotechnology, medical research is moving quickly towards a future where intelligent medical implants can continuously monitor their conditions inside the body and autonomously respond to changes such as infection by releasing anti-inflammatory agents. Examples that researchers are already working on today are, a sensor that can be placed under the skin for measuring

the blood glucose level; the use of polypyrrole films as electrically controlled drug release devices on implant surfaces to improve bone implants; an electronic under-the-skin sensor to monitor blood flow; and pressure sensors to improve medical implants.

Sensors planted inside the bodies of people with rheumatoid arthritis offer around the clock monitoring of symptoms and the effectiveness of treatment. “Implantable medical monitoring and therapy

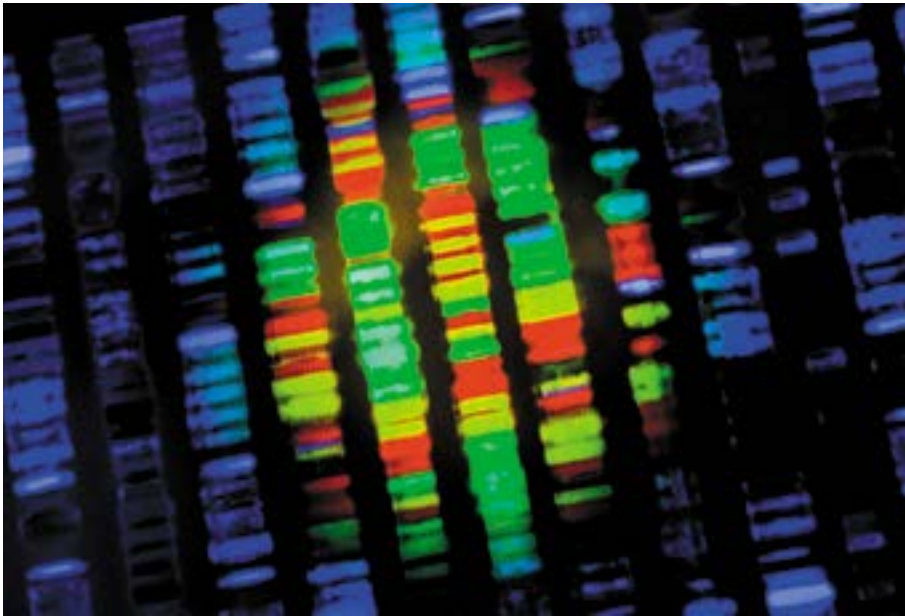
is the future of healthcare,” said Sam Bierstock, MD, BSEE, president and founder of Champions in Healthcare, a healthcare information technology company in Delray Beach, Florida. “The patient will become the interface with the electronic health record in many instances, allowing for augmented clinical decision support—computerized assessment and decision-making that assists doctors and caregivers in their diagnosis and treatment approaches.”

Researchers are exploring the possibilities of using implantable biomedical sensors for a variety of ailments. Depending on the health issue and data desired, Bierstock said a device can be implanted either on or under the skin or superficial tissues or implanted deeper within the body, as in the case of cardiac stent flow sensors. The device then monitors the condition and transmits signals that contain the desired information. This could include anything from the flow rate of blood through the blood vessels to pressure in the eye. The measurements are transmitted to a machine that receives them and either directs the information to caregivers or stores it for future review and analysis. This takes place 24/7.

Gene Sequencing

Yet another potential medical revolution is occurring in gene sequencing (not to be confused with DNA sequencing) which is leading to a fundamental breakthrough in the understanding of the human body and how it works on the most basic level. Gene sequencing is a process in which the individual base nucleotides in an organism's DNA are identified. This technique is used to learn more about the genome of the organism as a whole and to identify specific areas of interest and concern.

As soon as DNA was identified and its role understood, researchers started sequencing it because they were interested in the construction of the genome. Sequencing first successfully occurred with RNA and later DNA. Biological samples like hair, skin scrapings and blood can all be used. As long as a few cells are present, it is possible to extract their DNA and run it through a sequencer.



In DNA sequencing, the sample is tested to determine the order of the nucleotides. Researchers have been able to uncover specific genes that code for a variety of traits, from congenital heart conditions to brown hair. By looking at genetic variations across multiple individuals, researchers can identify the precise nucleotides used to code specific traits, and they can sometimes learn more about when the trait first appeared in the organism and what kinds of factors can influence that trait.

“DNA sequencing will greatly improve our ability to understand tumors and craft more effective pharmaceuticals,” said Cude. “The problem with chemotherapies today is that you almost kill the patient. In the past it has been carpet bombing. With the new technology it will be more like a laser-guided missile. Nanobots will be used as carriers for some of these pharmaceuticals to seek out and destroy the target.”

Medical researchers are very interested in gene sequencing because the process can be used to identify genetic abnormalities. The majority of disease risk, health conditions and therapies used to treat those conditions have a genetic and/or genomic element influenced by environmental, lifestyle and other factors. Researchers are also optimistic that the technique may someday lead to cures for specific conditions, along with additional general knowledge about the genomes of humans and other animals that could be useful. It is used today to test samples of material from fetuses to check for common genetic conditions and from parents who are concerned about passing down hereditary diseases.

Inexpensive, time-efficient full genome testing will be a major accomplishment not only for the field of genomics but all of human civilization because for the first time, individuals will be able to have their entire genomes sequenced. This information will enable medical professionals to predict what diseases a person is likely to develop in the future and to try to either minimize the impact of the disease or avoid it altogether through preventive medicine. Full gene sequencing will enable healthcare professionals to analyze the entire human genome of an individual and detect all disease-related variants regardless of the variant's prevalence or frequency.

The American Cancer Society suggests that genetic testing is already being used for many reasons such as:

- Its predictive value (identification of gene mutations that might put a person at risk of developing a disease such as cancer, cystic fibrosis, sickle-cell anemia, or Tay-Sachs disease).
- Its ability to determine carrier status or whether a person has a gene mutation which could be passed on to a child.
- Prenatal screening to diagnose some conditions in utero.
- Newborn screening to determine the existence of a variety of inherited conditions such as phenylketonuria (PKU), cystic fibrosis or sickle cell disease.
- As a means of checking cancer cells to determine prognosis or potential benefits of certain types of treatment.

Gene sequencing/genetic testing indicates a major shift from a medical care system that repairs people after they are sick to one that treats patients for conditions they are likely to develop. Healthcare professionals already encounter patients who arrive for diagnosis or treatment with their genotyping or genetic sequencing in hand. Patients today can send a saliva

Gene sequencing/
genetic testing indicates
a major shift from a
medical care system
that repairs people
after they are sick to
one that treats patients
for conditions they are
likely to develop.

sample to websites such as *23andMe* and receive a comprehensive genotyping (DNA analyzed by genetic variants) with periodic updates on the latest biomedical literature for less than \$100.

Genetic advances are also likely to eliminate the need for organ transplants, since new organs will be grown from a patient's own tissues. Researchers are already beginning to grow individual tissues, tendons and cartilages from stem cells. In January 2013, Japanese researchers announced they had succeeded in growing human kidney tissue from stem cells for the first time; a potential breakthrough for millions with damaged organs that depend on dialysis. Similarly, thyroid cells can now be grown in laboratories, a new ear has been grown in the skin of a woman's arm, and cells are being reprogrammed so that they can turn into a variety of cell types. There may be no limit to the kinds of organs and body parts that can be grown from stem cells. This ability to grow major organs and body parts will eliminate the need for external donors, and since organs will be genetically matched to patients, the chance of rejection should be minimal or non-existent.

In the future, stem cells will be used to generate replacement cartilage tissue to repair damaged joints, especially for osteoarthritis patients. The process of autologous chondrocyte implantation (ACI) involves removing a small piece of healthy cartilage from the knee and growing millions of new cartilage cells (chondrocytes) in a laboratory before re-injecting them back into the knee.

It is too early to clearly define all of the potential impacts of gene sequencing, but it is a given that it will dramatically change medical care and that many standard treatments today will be superseded by gene sequencing and its related technologies. Clearly, having genetic data

can ultimately lead to better care and patient empowerment, and the applications of plastics will be changing accordingly.

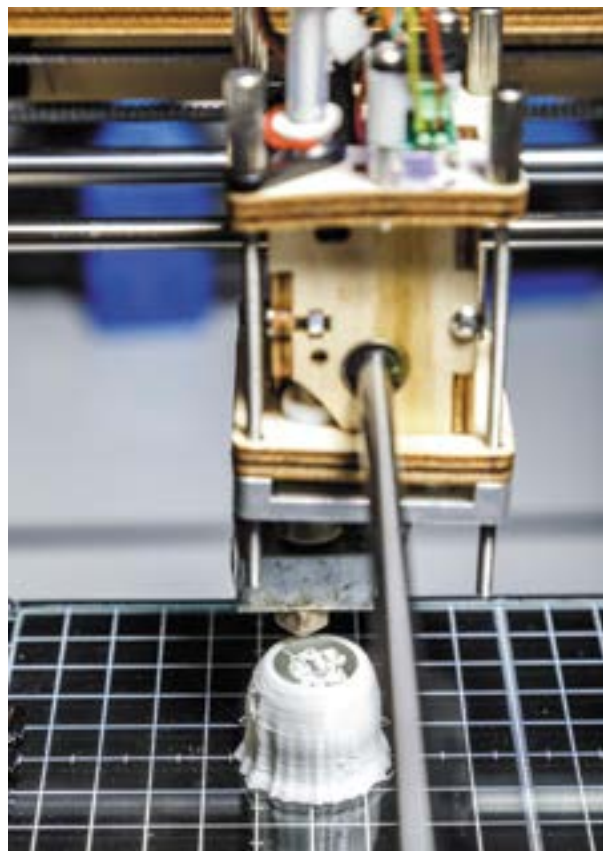
3D Printing

In our previous report on transportation, we discussed the use of 3D printing to create not only parts for vehicles but the entire vehicles themselves. 3D printing will also be used to forge new organs and other body parts for human beings—a system that mimics human flesh. This requires scanning an existing object with a 3D scanner which gathers the data necessary to print on a 3D bioprinter. Bioprinters using a “bio-ink” made of living cell mixtures can build a 3D structure of cells, layer by layer, to form human tissue and eventually human organs for replacement. The bioprinter prints the object by adding layer after layer of materials such as plastics, glass, metal or ceramics (mainly plastics). In this way, three dimensional objects can be created from a digital model.

The application of 3D printing in healthcare literally makes the body into a system of interchangeable parts. For example, in February 2013, doctors and engineers in the Netherlands collaborated on the 3D printing of a prosthetic lower jaw which was subsequently implanted into an 83-year old woman who suffered from chronic bone infection. The printer produced the prosthetic jaw from 33 layers of titanium powder that were heated, fused together and then coated with bioceramic artificial bone. Artificial limbs can be created by the same technology, as can custom hearing aids. Using 3D images of a human ear, scientists at Cornell University used 3D printing to create an ear remarkably similar to a natural one—using a plastic mold.

Another example—Organovo, a cutting edge company based in San Diego, designs and creates functional, three-dimensional human tissues for use in medical research, cosmetic, and therapeutic applications. The company develops 3D human tissue models through internal development and in collaboration with pharmaceutical, cosmetic, and academic partners. Organovo's 3D human tissues have the potential to accelerate the discovery process, enabling drug treatments and active agents to be developed faster and at lower cost.

Organovo recently launched its initial product of the planned *exVive3D™* portfolio offering, a 3D Human Liver Tissue for use in Toxicology and other preclinical drug testing. Additional products are in development, with anticipated



release for an exVive3D™ Human Kidney Tissue in the latter half of calendar year 2016. The company also actively conducts early research on specific tissues for therapeutic use in direct surgical applications. Most recently, Organovo announced collaboration with beauty brand L'Oréal to print 3D skin, a development that could have extraordinary implications for people disfigured in accidents.

In sum, advances in technology are leading dramatic progress in medical therapies and offer at least a partial solution for governments that must deal with growing healthcare needs with limited resources. But new technologies and therapies will take time. “I see a lot of stresses and pulls on the medical care industry,” said Buonomo. “All of these new technologies will take time to work into the system. Some of them may impact the use of plastics, but not for a while.”

Conclusion

Where all of this will lead and its impact on use of plastics is impossible to foresee, and indeed it may actually lead to greater use of plastics, albeit in different ways than the present. Companies that are able to use technological advances to make medical devices more intelligent, faster and more cost-effective are making great strides in the industry. Breakthrough advances have improved patient monitoring, safety and outcomes, reduced patient recovery time and prevented costly complications. This progress promises longer, healthier lives for the people of our country and billions more around the globe. As we live healthier and longer, the demands for advanced medical services can only grow, and the uses of medical devices—a growing number of them employing plastics—will also expand in tandem. As medical technology changes, it is inevitable that some current uses of plastic based materials will decline, but the nature of medical applications argues strongly that other uses will materialize. Due to its extraordinary versatility and the constant development of new blends of plastic, it seems extremely unlikely that it will ever be replaced by another material, at least not in the foreseeable future. The change now underway is exciting and foretells longer and healthier lives for our species—and new applications for plastics.



Due to its extraordinary versatility and the constant development of new blends of plastic, it seems extremely unlikely that it will ever be replaced by another material, at least not in the foreseeable future.

Healthcare &
Medical Devices

Economic
Trends

Economic Trends

The U.S. medical technology industry is projected to grow at an impressive 6.3 percent Compound Annual Growth Rate (CAGR) to \$156 billion by 2018 driven by significant capital investment generated by two key factors—lower reimbursement risk than most other healthcare sectors and an expected increase in patients requiring care under the Affordable Care Act.⁷ Implantable devices, including reconstructive joint replacements, spinal implants, cardiovascular implants, dental implants, and intraocular lens and breast implants are expected to grow at a CAGR of 8 percent to nearly \$74 billion by 2018.

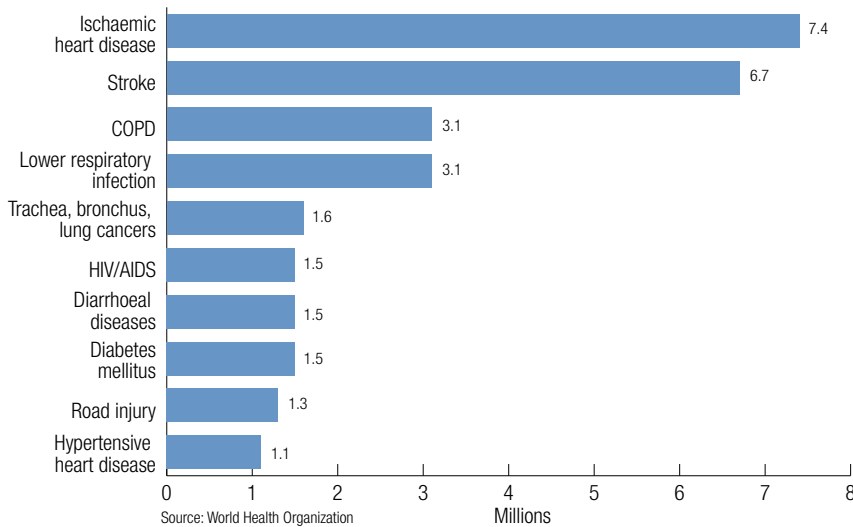
In almost all countries worldwide, per capita healthcare spending is rising faster than per capita income. Healthcare costs have outpaced economic growth by an average of 2 percent in Organization for Economic Cooperation and Development (OECD) countries for the past 50 years. Emerging economies are rapidly moving in the same direction. If current trends hold, by 2022 around one-third of all global health expenditures will occur in emerging economies, and for every additional \$100 spent on health in 2022 (compared with 2012), \$50 will come from emerging economies. These levels of spending are driven largely by major changes in global demographics and disease patterns. Overall, healthcare spending is expected to double by 2050, claiming 20-30 percent of GDP for some economies. Already, in the U.S. healthcare spending is consuming 17 percent of GDP.

⁷ Stout/Risius/Ross, Middle Market Investment Banking

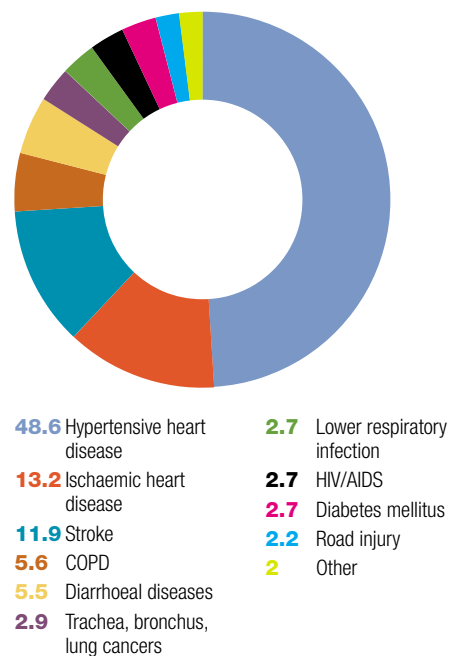
A growing number of original equipment manufacturers (OEMs) of medical devices are shifting focus to innovation and design rather than manufacturing, depending on outsourcing to supply the goods. The medical device outsourcing industry is a large market of about \$10 billion and is growing faster than the underlying medical device market itself.

Medical utilization, Europe's market softness and the rollout of the new healthcare law, including the potential medical device tax, are the primary concerns facing this industry. Pressures to increase cost efficiencies, pricing pressures and the increasing difficulty of

The 10 leading causes of death in the world—2012

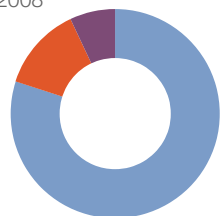


The 10 leading causes of death in the world by percentage



The increasing burden of chronic noncommunicable diseases—2008 and 2030

2008



High-income Countries



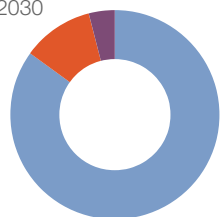
Middle-income Countries



Low-income Countries

■ Communicable, maternal, perinatal, and nutritional conditions
 ■ Noncommunicable diseases
 ■ Injuries

2030



realizing a return on product innovation had fed a growing trend to offshoring of production of simpler, lower-end medical devices, but this trend is now leveling out. While margins are expected to remain healthy relative to other sectors, the pressure on OEMs to restructure costs is likely to put increasing pressure on the supply chain, especially in the U.S.

Reliance on outsourced manufacturing such as injection molders is expected to increase as medical device manufacturers further restructure and downsize their in-house manufacturing capabilities. Because of the tight tolerance, highly-regulated and critical nature of medical devices, OEMs are scrutinizing prospective outsourced manufacturers carefully in terms of product reliability, proven ability to assist in medical device design, a history of strong performance and financial health, product performance in the marketplace, cost and value-added capabilities including assembly, packaging and sterilization. OEMs are looking for suppliers that are largely, if not wholly dedicated, to the medical device field with full production and clean room capabilities and systems in place to adhere to stringent regulatory and quality requirements.

Over the past several years, the Stout/Risius/Ross Medical Plastics Index and MedTech Index both outperformed the S&P 500 growing 39.7 percent and 16.3 percent respectively, compared to 13.8 percent for the S&P 500.

Compared to packaging, industrial and automotive plastics manufacturers, medical plastics companies typically trade at higher valuation multiples and are more profitable on average due to less cyclical product offerings, better resin price strategies and stronger pricing leverage.

Medical plastics transaction volume decreased 7 percent during 2012, although the sector has generated some of the highest valuations in the industry. Strategic buyers accounted for 74 percent of medical plastics transactions in 2012 which is a driving factor in the high valuations seen in medical devices as strategic buyers are able to realize greater synergies than financial buyers. The relatively few transaction opportunities in medical devices have created a large disparity between supply and demand, also driving valuations higher. There is an increasing trend for medical plastic processors to be focused exclusively on this sector divesting or separating operations that serve other lower margin end markets.

Injection molding accounted for nearly 60 percent of all medical plastic M&A volume in 2012 followed by extrusion and thermoforming which make up 30 percent and 7 percent of volume respectively.

Future Demand

The U.S. medical device industry is expected to remain highly competitive globally, due in part to national characteristics that facilitate bringing new and innovative technologies to market. An increasing number of companies are seeking regulatory approval for their products in more countries worldwide. These firms are focusing greater attention on international sales, joint ventures, and mergers and acquisitions.

Global demand for medical devices is being driven by increasing expenditures and greater attention to healthcare by developing markets, construction of hospitals and clinics, and establishment of public health insurance. In addition, global demand should continue to grow due to aging populations in major markets, new and significant emerging markets and rising global income levels in developing countries. Further, global

harmonization of standards and regulatory requirements should help facilitate overall market growth.

The U.S., European Union, Japan and Canada are extremely large and lucrative medical device markets; however, they are mature markets with stable but relatively low (3 - 5 percent) annual growth rates. In order to facilitate expansion, medical device companies recognize that they must look increasingly at developing countries to drive future growth.

With marked increases in the average age of U.S. and foreign populations, the medical device industry has seen a shift in thinking on how and where senior citizens will be treated. As pressures mount to contain costs, expensive and/or extended stays in healthcare facilities will be discouraged and healthcare will be increasingly delivered in alternative settings such as nursing homes, hospices, and, especially, the patient's own home. Home healthcare is one of the fastest growing segments of the industry, and is branching out into new areas. A segment that previously was limited to only the lowest technology products is now encompassing a proliferation of high technology medical devices intended to be used by unskilled healthcare workers or patients.

The medical devices industry will witness significant opportunities for growth in the coming decade. This market expansion will be driven by the introduction of innovative devices into the market and also by the demand generated by illnesses associated with the aging global population. Cardiac and respiratory diseases generally affect people above the age of 65, and with the global over-65 population expected to rise up to 1 billion by 2020, devices used in the treatment of age-related illnesses will see significant growth in their revenues.

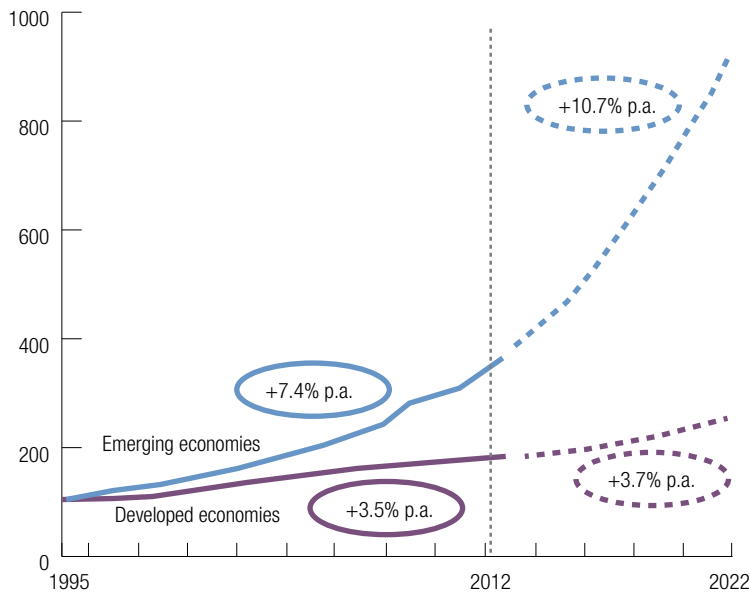
A recent spike in demand for dialysis treatments—a therapy heavily dependent on plastics—underscores the growing impact of an aging population on the medical care industry.

The increasing move towards personalized therapy will also contribute to the expansion of the medical devices market, particularly between 2017 and 2023. Innovations in the field of diagnostics will propel the launch of devices which incorporate biomarkers; leading to swifter patient diagnosis and monitoring.

Reimbursement will remain a major issue for the medical devices industry in the coming years, as rates in established markets such as the US and Europe will most likely continue to drop. Competition within some of the currently fast growing segments, such as the cardiology and neurological segments will intensify due to the expected launch of innovative products by major companies in mature markets. Moreover, medical device manufacturers will be required to display a high level of cost-effectiveness for their products due to tighter regulatory and reimbursement policies, especially in the emerging economies.

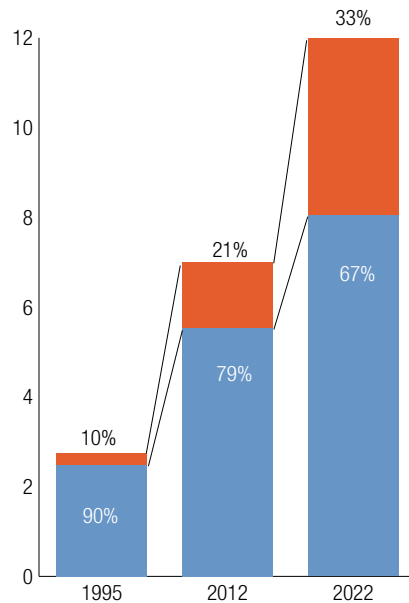
Over the past generation, the medical device industry has provided

Health expenditure (index: 1995 = 100)



Source: World Bank, Business Monitor International, BCG

Global health expenditure (trillion U.S. \$)





growing demand for plastics that have gradually displaced traditional reliance on devices made of metal, ceramics and other substances. Increasing reliance on plastics has in turn generated remarkable breakthroughs in technology that not only enhance delivery of medical care but also provide increased usage of plastics. This has been, and continues to be, a win-win for the plastics and healthcare industries.

Expanding populations here and abroad, enhanced by rapidly growing middle class income populations, and aging populations in developed countries, promise continued reliance on medical devices containing plastics in the near future—meaning more business for the plastics industry.

However, major shifts in the provision and funding of healthcare in this country will drive increased focus on reducing costs at all levels of the medical care industry. And, a series of breakthroughs in medical science augur a variety of less physically intrusive medical therapies that will reduce the need for disposable medical devices, which are largely composed of plastics. In the distant future, these forces will to some extent counter the generally positive trajectory for use of plastics in medical devices. But for the foreseeable future, the role of plastics in modern medicine is dominant and likely to remain so. “There will be pressure on health care costs,” said Buonomo, “but also pressure to provide more treatments.”

Conclusion

The growth of the overall population coupled with the increase in middle class income people and the elderly, here in the United States and around the world, will inevitably lead to a steady increase in demand for medical devices of all kinds, which means more devices made of plastic or using plastic. Over time, new technologies will obviate the need for certain devices, but will inevitably lead to adoption of others. The advantages of plastics over other materials will remain. All signs point to rising demand and consumption.



There will be dramatic changes in the nation's healthcare system within the next few years that will have far-ranging implications for the plastics industry.

Healthcare &
Medical Devices

Public Policy
Trends

Public Policy Trends— Federal Healthcare Policy

There will be dramatic changes in the nation's healthcare system within the next few years that will have far-ranging implications for the plastics industry. At present, the U.S. is spending 17 percent of its Gross Domestic Product on healthcare. In contrast, the other industrialized nations are spending around 10-11 percent, or about 50 percent less. Meanwhile, by most standard indices, the typical U.S. citizen is no better off medically than those of other industrialized nations. In fact, we are in many ways worse off though that may be partly due to factors such as drug abuse, gun violence, eating habits and others.

The cost of healthcare is soaring as the Baby Boom generation enters the prime retirement years of 65-85 when their demands on the healthcare system will accelerate. Today, the typical family of four pays about \$18,000 a year for health insurance. Many do



not grasp the significance of the cost because it is borne at least in part by their employers.

The U.S. is the only major industrial nation that built its healthcare system on the employment connection. This was, in fact, a happenstance that

occurred during World War II when companies needed labor badly but were not allowed to offer higher wages to attract them. (During WWII, the government closely regulated wages and prices.) Thus, employers hit on the idea of offering health insurance as an extra non-monetary bonus.

Today, millions of Americans are unemployed, partially employed, work independent of employers in the so-called "gig economy," or work for employers that do not provide health insurance. About one out of 6 Americans is uninsured and cannot afford to pay \$18,000 a year for health insurance (the going average for a family of four).

This is not to suggest the unemployed do not have access to healthcare. Under federal legislation enacted in 1985, no doctor or hospital can deny treatment to anyone who needs it. The result is that poor people generally receive little or no basic medical care until they are in dire need, at which time they go to a hospital emergency room. It would be difficult to imagine a more cost inefficient system than this one. Hospitals charge people with insurance an added premium to cover the emergency room overages.

There is a general consensus among healthcare experts and politicians that the current system is not sustainable in the long term as the Baby Boom generation enters retirement. Big changes are coming that will attempt to rein in the soaring cost of healthcare.

It is clear the American people are facing profound changes in the way they obtain and pay for healthcare—which will have a profound impact on daily life in myriad ways. On a basic level, there will be a sea change in our attitude toward healthcare as we embrace the concept of universal health insurance, not necessarily because there is a consensus that everyone deserves health insurance, but rather because we cannot afford to continue the existing system of providing free health treatments to everyone in hospital emergency rooms.

The Federal Government cannot and will not ignore the soaring cost of healthcare driven primarily by a growing population of the aged as well as dramatic breakthroughs in medical technology, including new generations of pharmaceuticals.

This is a uniquely American dilemma. Most of the other industrialized nations have in place national healthcare systems through which everyone is insured, regardless of income or employment status. As early as the late 1940s, the Truman Administration made a serious push to adopt such a national system in this country, but it was resisted and eventually killed by Congress. Then, as now,

there was an abiding lack of confidence in the ability of the federal government to handle anything so complex and personal.

The death of national healthcare paved the way for further expansion of the employer-based healthcare system. But now, the aftereffects of the Great Recession and the impact of the digital revolution are exposing vast gaps in the traditional employer-based health insurance system. It is abundantly clear we cannot indefinitely sustain a system in which one out of six Americans has no health insurance and must depend on emergency rooms for treatment.

The Affordable Care Act does little to control costs directly, except that getting millions of the uninsured to enroll in healthcare plans will help. Even if they pay less than what their care actually costs, at least they will be paying something into the system and, assuming they receive basic medical care, there will be far fewer emergency room visits which are often the result of a lack of basic care.

Under the radar, the system itself, partly prodded by the federal government, but also by normal economic forces, is shifting in subtle ways that are radically changing the way healthcare is delivered and paid for, and which eventually will bring everyone into the system.

Already, major shifts in medical financing are emerging. A growing number of Americans are leaving private health insurance in favor of public health insurance. This is in part a result of the severe recession of 2009-2013 in which millions of people lost their jobs and hence their health insurance. Many of these went on Medicaid (for the poor) or else did without health insurance. At the same time, another major shift is underway as the Baby Boom generation, those born in the years immediately following World War II, are beginning to retire en masse and sign up for Medicare.

An unexpected effect of this migration to Medicare has been to reduce the rate of growth of Medicare spending because the younger people entering the system tend to have fewer health issues than older people. At the same time, the millions of people still in the workforce who obtain their health insurance through their employment are assuming a greater share of the cost of their healthcare through higher premiums and deductibles. The latter item—deductibles—have seen the most growth from 2002 to 2013. In 2002, less than half of employer healthcare plans had a deductible. By 2013, more than 80 percent had a deductible and the amount paid by consumers was rising fast.

Premiums are steadily rising, said Douglas Holtz-Eakin, president of the American Action Forum and former director of the Congressional Budget Office (CBO). “Employers tried to manage this expanding price tag by shifting costs to their employees in the form of higher deductibles and increased co-pays.” Thus, while overall data suggest healthcare costs have plateaued, what it may really mean is the consumers are bearing an increasing share of the costs.

Thus, the most recent 10-year projections from government budget analysts show that healthcare costs will continue to increase, but that they will increase at a slower rate than in the past, and at a lower rate than projections of previous years.

“I cannot see the healthcare field diminishing even with the price pressure,” said Buonomo. “I may be too optimistic on plastics, but until the services they provide can be done with other materials, plastics will be the material of choice.”



Conclusion

In sum, in the years ahead, healthcare costs will tend to stabilize as citizens bear a greater share of their healthcare costs and more people are brought into the system—assuring a greater flow of revenue and reducing demands on emergency facilities. In any event, policy and budget considerations in whatever form will not mitigate the rise in demand for medical devices, as the population increases, the middle class grows and the average age rises. To the extent that cost pressures impact medical practice, they can only serve to enhance the importance of plastics which are much more cost-effective than alternative materials.

Public Policy Trends— Regulatory Environment

Dramatic breakthroughs are the order of the day in the world of medical devices, and plastics appear prominently among them, but the fact remains that medical devices are one of the most highly-regulated groups of products manufactured in the world. In all countries with major markets, a complex series of regulatory requirements must be met prior to launching a medical device into the market.

Unquestionably, regulatory requirements are essential to assure the utility and safety of new products. At the same time, the regulatory hurdles present a major challenge for companies trying to introduce promising new products into the marketplace—especially when it intends to market its products in other countries.

Medical devices are covered by the Medical Device Regulation Act (or Medical Device Amendments of 1976) signed into law by President Gerald Ford on May 28, 1976. The law was largely driven by public concern roused by the Dalkon Shield intrauterine device that injured several thousand women. The law provides among other things that devices considered having high risk for human use must have premarket approval from the U.S. Food and Drug Administration (FDA). In recent years, there have been growing concerns about the effectiveness of this system driven by news reports of metal hips that fail, bloodstream filters that fracture and prove lethal, and defibrillator wires that break down. However, the vast majority of medical devices today reach the market through an abbreviated pathway called 510(k) in which manufacturers must demonstrate only that a new device is substantially the equivalent of a device already legally marketed.

“FDA’s approach to regulating devices, in contrast to its requirements governing drugs, was designed by Congress to recognize that not all devices pose the same degree of risk,” said Scott Gottlieb, former FDA deputy commissioner and resident fellow at the American Enterprise Institute.⁸ “Therefore, the volume of data that the FDA requires should be closely matched to the risk of the product in question. The problem today is that the FDA has deviated from the original spirit of that idea. It’s trying to apply a much more uniform and drug-like approach to its regulation of medical devices, increasing the hurdles that new products must clear. At the same time, the FDA is treating more low-risk devices like they were high risk.”

Dr. Rita Redberg, cardiology professor at the University of California San Francisco, contends the FDA errs in the other direction. “As a cardiologist taking care of patients every week, I see too many whose lives have been harmed and who have suffered greatly from untested or inappropriate devices. And that doesn’t begin to address the billions of dollars these devices add to health care bills.”

Among all advanced nations, the new medical device review is time-consuming and expensive, though it varies considerably from country to country. Israel ranks first in

Unquestionably, regulatory requirements are essential to assure the utility and safety of new products. At the same time, the regulatory hurdles present a major challenge for companies trying to introduce promising new products into the marketplace—especially when it intends to market its products in other countries.

terms of speed and ease of gaining regulatory approval, while Japan has the most complex and time-consuming process, averaging more than two years according to a study conducted for the *Journal of Medical Devices*.

Though some think the FDA review process for new medical devices is too lax, it is almost twice as long as that of its European counterpart, the European Medicines Agency, for devices not requiring clinical data and almost three

⁸ *The Wall Street Journal*, March 23, 2015

times as long for devices that do require clinical data. On average, the U.S. takes six months while the Europeans take three months.

Opinions about this process vary. Some complain of the time it takes and others that it is too easy to obtain exemptions from the rules when there is insufficient information. A recent report from the Institute of Medicine urged the FDA to develop a new framework for regulating medical devices, but the federal bureaucracy moves with glacial speed.

Citizens of countries with efficient and less uncertain and complex regulatory processes can often gain earlier access to innovative medical technology, and healthcare providers in those countries benefit earlier from experience with new devices.

These are issues of the safety of the specific medical device in question, but there are also lingering issues related to the use of plastic itself, or more particularly the various components that comprise different forms of plastic. A major one is vinyl chloride which is a key ingredient in polymer polyvinyl chloride and ethylene which figure prominently in plastics production. Vinyl chloride is widely recognized both for its explosive properties and also its toxicity in its liquid form.

Another plastics constituent that garners health and safety concerns is di-(2-ethylhexyl)phthalate, also known as DEHP, a compound used as a plasticizer (softener) in many products made of polyvinyl chloride (PVC) plastic. Exposure to DEHP has produced a range of adverse effects on the development of the testicle and the production of sperm in young animals. It is possible that the effects observed in animal studies could occur in humans. However, there are no human studies to date that show such effects. DEHP-containing devices have been used on newborn babies for many years

without apparent ill effects, although studies have not been conducted which would rule out effects on humans.

The FDA believes the greatest concern would be for very young male infants who are critically ill and have prolonged exposure to multiple devices containing DEHP. Also at risk would be the male fetus through exposure of his mother, and peripubertal males. The National Toxicology Program, a component of the National Institutes of Health, has recently reached a similar conclusion. In contrast, there is little concern for adults receiving intravenous solutions or undergoing peritoneal dialysis.

The FDA has examined the potential risks posed by patient exposure to DEHP by comparing the doses that patients may receive to a Tolerable Intake (TI) value for DEHP. A TI value is the dose of a compound that is not expected to produce adverse effects in exposed patients. The FDA has issued a Public Health Notification to the medical community, identifying procedures that could result in exposure to relatively high levels of DEHP in sensitive patients (e.g. male neonates). It has recommended that devices made of alternative materials, or that are made of PVC that does not contain DEHP, be used for these procedures. If PVC devices containing DEHP must be used, the FDA recommends that steps be taken to minimize the exposure by using the freshest, coldest blood products available, or by using heparin-coated blood tubing. *The FDA emphasized that the risks of DEHP exposure are far less than the risks of foregoing critical procedures.*

Materials Challenges

There have been incredible strides made with the use of plastic in the medical industry. These strides, among other things, have decreased the costs of healthcare, reduced infections and, most importantly, saved lives. Life is generally better, due to plastic, for both the patient and the medical community in general.

Unfortunately, these strides continue to be hampered by the misrepresentation of materials used in plastic. For example,

certain phthalates are being reviewed by several regulatory bodies within the federal government, including the EPA and the Consumer Product Safety Commission. This examination has caused intense media hype and distorted the importance of plastic in the medical industry. Unfortunately, the media hype is based more on misinformation than fact.

Let's look at phthalates. There is most definitely confusion surrounding media claims related to the presence of phthalates in medical devices, even when the materials have been deemed safe by regulatory authorities for their intended use. While manufacturers can attest to whether there has been an intentional addition of phthalates to a product, it is not possible to guarantee the complete absence of phthalates in a product. In addition, cross-contamination can occur at any point during the manufacturing process. Lastly,



there is no recognized level for trivial or de minimis amounts of phthalates that might be permitted in a product.

The intense media scrutiny on the deselection of materials in products will, ultimately, be harmful to the medical industry, especially at a time when great advances are being made.

Global Regulation

Predictably, the more advanced nations have the most rigorous standards for approval of new medical devices. For the medical device industry to fully realize its potential in developing markets, standards and criteria for regulatory approval, risk management, and quality must be improved and most importantly harmonized to meet global international best practices.

To this end, the Global Harmonization Task Force (GHTF) was founded in 1992—a voluntary group of representatives from national medical device regulatory authorities (such as the FDA) and the members of the medical device industry whose goal was the standardization of medical device regulation across the world. The representatives from its five founding members (the U.S., the European Union, Canada, Japan and Australia) were divided into three geographical areas: Europe, Asia-Pacific and North America, each of which actively regulates medical devices using their own unique regulatory framework.

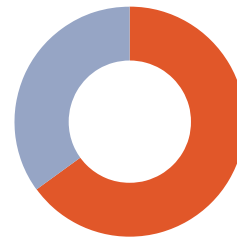
The GHTF disbanded late in 2012. Its mission has been taken over by the International Medical Device Regulators Forum (IMDRF), a successor organization composed of officials from regulatory agencies—not industry—around the world.

According to the World Health Organization, of its 145 participating member nations, 65 percent have some sort of authority responsible for implementing and enforcing medical device specific product regulations; 34 percent have a health technology national policy that is part of their national health programs; and only 9 percent have an independent health technology national policy. To some extent, less wealthy nations depend on more advanced nations for medical technologies, and thus benefit from their more rigorous standards.

Conclusion

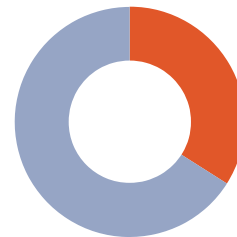
The regulatory environment in this country and most of the developed world imposes strict standards on the introduction of new medical devices which can serve as barriers to the marketplace. In general terms, the FDA protocol for introduction of new devices is more flexible and reality-based than in Europe and some other places. The public concerns about the efficacy of medical devices are reasonable and to be respected. But the use of plastics in new medical devices does not appear to be an issue. The concerns about the use of DEHP are typical of the FDA's balanced approach, recognizing that the chemicals involved could potentially be harmful to certain groups particularly male infants, but declining to overreact and impose burdensome restrictions on an important chemical that are not warranted by the risk. It does not appear likely that regulatory restrictions will have a detrimental impact on the expanding use of plastics in new medical devices.

World Health Organization 145 participating member nations



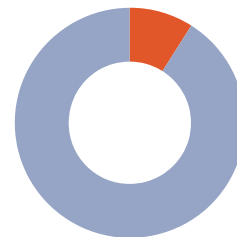
65%

Some sort of authority responsible for implementing and enforcing medical device specific product regulations



34%

A health technology national policy that is part of their national health programs



9%

An independent health technology national policy

Healthcare &
Medical Devices

The Big Picture



The Big Picture

All of the critical data—soaring populations, rising middle classes, aging population, advances in medical technologies—point to an ever stronger market for medical devices which today are largely comprised of plastics.

Over the past generation, the medical device industry has provided growing demand for plastics which have gradually displaced traditional reliance on devices made of metal, ceramics and other substances. Increasing reliance on plastics has, in turn, generated remarkable breakthroughs in technology that not only enhance delivery of medical care but also provide increased usage of plastics. This has been, and continues to be, a win-win for the plastics and healthcare industries.

Expanding populations here and abroad, enhanced by rapidly growing middle class income populations, and aging populations in developed countries, promise continued reliance on medical devices containing plastics in the near future—meaning more business for the plastics industry.

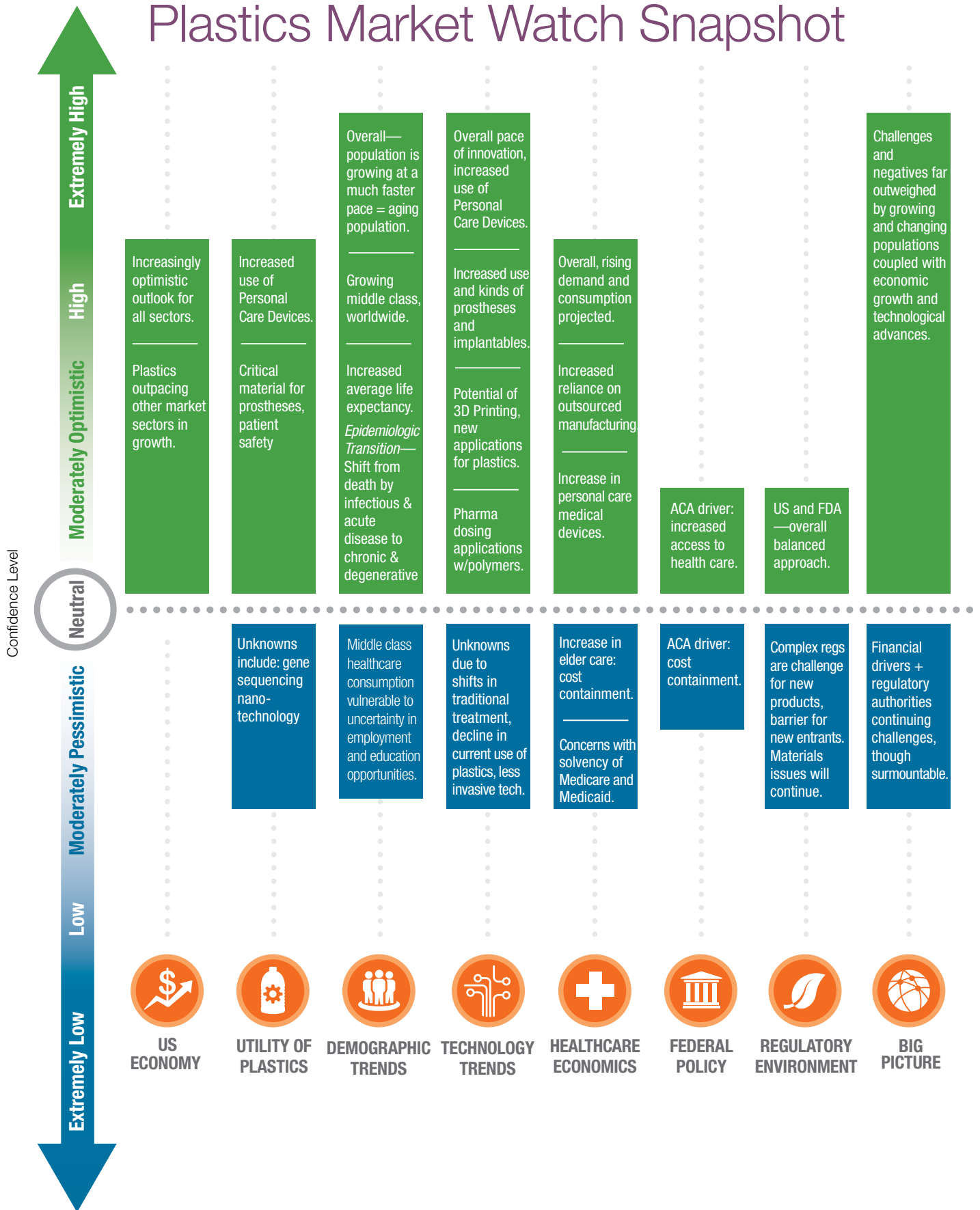
All of the critical data—soaring populations, rising middle classes, aging population, advances in medical technologies—point to an ever stronger market for medical devices which today are largely comprised of plastics. In earlier years, the past growth of plastics in healthcare, particularly medical devices, came largely from material substitution, but that transition has been accomplished. Now the growth of the markets for medical devices is almost synonymous with rising demand for plastics, or so it would seem.

But as Mr. Spock (of *Star Trek* fame) wisely said, “Change is the one absolute law of the universe.” Rising demand for health services along with advances in technology are rapidly changing the way medical care is delivered and paid for. The shift to non-invasive medical protocols in particular will reduce the demand for many plastic basics of medical care. Personal care devices promise to be a major shift in the way medical care is delivered, and will likely reduce the demand for plastic materials.

For equipment manufacturers, the changing face of modern medicine means smaller equipment, but that will not directly impinge on plastics. Resin suppliers will not see much change because not a huge amount of resin goes into medical equipment. The market for plastics in medical devices is stable and growing, but producers must monitor the market carefully, anticipate changes coming down the road and be prepared to meet them. They must also keep tabs on the regulatory landscape for one can never be sure which way the political fortunes will blow in response to inflammatory news stories or consumer complaints.

Major shifts in the provision and funding of healthcare in this country will drive increased focus on reducing costs at all levels of the medical care industry, and a series of breakthroughs in medical science promise a variety of less physically intrusive medical therapies that will reduce the need for disposable medical devices, which are largely composed of plastics. In the distant future, these forces will to some extent counter the generally positive trajectory for use of plastics in medical devices. But for the foreseeable future, the role of plastics in modern medicine is dominant and likely to remain so.

Plastics Market Watch Snapshot



Sources

- Barton, Dominic; Chen Yougang; and Jin, Amy; "Mapping China's Middle Class." *Insights & Publications*. McKinsey & Company: June 2013.
- Bregar, Bill, "Clinic Focuses On Commercializing Medical Products." *Plastics News*, May 28, 2014.
- Burton, Thomas M., "Do The FDA's Regulations Governing Medical Devices Need to be Overhauled." *The Wall Street Journal*, March 23, 2015.
- Deligio, Tony, "Injection Molder or Medical Device Supplier?" ptonline.com.
- en.wikipedia.org/wiki/Medical_Device_Regulation_Act. "Medical Device Regulation Act." July 23, 2015.
- Flexible Vinyl Alliance, *Flexible Vinyl Matters*. "CPSC Rule-Making Moving Forward." December 2014.
- Gronbach, Kenneth W, "The Age Curve: How to Profit from the Coming Demographic Storm." 2008.
- Kucklick, Ted, "Plastics for Medical Devices: a Primer." Cannuflow, Inc. BONEZone, summer 2007.
- Landro, Laura, "Hospitals Find New Ways to Monitor Patients 24/7." *The Wall Street Journal*, May 25, 2015.
- money.cnn.com. "China's Growing Middle Class." April 26, 2012.
- nano.gov/nanotech. "What Is Nanotechnology?"
- Putrich, Gayle S., "3D Printing Already Aiding Thousands of Patients Worldwide." *plasticsnews.com*, May 7, 2014.
- Quinn, Alice, "On The Horizon: Medical Devices to Watch." *medicalplasticsnews.com*, May 14, 2015.
- Rickard-White, Linksey, "Will It Be Worth It? L'Oreal Teams Up With Organovo to 3D Print Skin." *medicalplasticsnews.com*.
- Rosato, Don, "Innovative Medical Plastic Applications Breaking into New Areas." *exclusivemultibriefs.com*, February 2, 2015.
- Rosato, Don, "Global Medical Plastics Device Trends Keep Expanding." *exclusive.multibriefs.com*, January 6, 2015.
- Rosato, Don, "Medical Device Market Trends and the Headwinds of Change." *exclusivemultibriefs.com*, December 2, 2013.
- Sastri, Vinny R., "Plastics in Medical Devices: Properties, Requirements and Applications." December 5, 2013.
- SPI: The Plastics Industry Association. About Plastics, A Few Fast Facts on Plastics in Medicine. *www.plasticsindustry.org*.
- SRR (Stout/Risius/Ross). "Plastics in Medical Devices Snapshot." Summer 2013.
- supermarketnews.com, "Boomers Still Have Lots to Spend, Study Says." March 16, 2015.
- Taylor, Michael D., "Global Growth Markets in Medical Devices." SPI: The Plastics Industry Trade Association, December 12, 2013.
- U.S. News & World Report. "U.S. News Health Care Index Shows Massive Increase in Consumer Costs." May 7, 2015.
- Waldman, Cliff, "The Most Important Story in the World: MAPI Webinar on the Global Demographic Dynamic."
- www.fda.gov*. U.S. Food and Drug Administration. "DEHP In Plastic Medical Devices."
- www.nursingworld.org/ojin/*. "The Impact of Emerging Technology on Nursing Care: Warp Speed Ahead." *The Online Journal of Issues in Nursing*. May 2013.



SPI: The Plastics Industry Trade Association
1425 K Street NW., Suite 500
Washington, DC 20005
202.974.5200
202.296.7005 fax
plasticsindustry.org

