



US Healthcare Trends and Contradictions in 2019

F. Randy Vogenberg, PhD

Over the past several years, many healthcare trends have been identified as micro rather than macro as incremental year-to-year changes dominated the US healthcare market. Looking at 2019 and toward 2020, the shift to macro-level trends returns, reflecting market transformation during the Trump administration. For example, many 2017 and 2018 trends were a continuation of micro themes, such as benefit design offerings, care delivery initiatives, contracting, or early technologies for monitoring personal health status.

Now, structural and broader market changes are part of a bigger economic transformation that includes healthcare as a major beneficiary. As a result, in 2019 many trends are macro-focused, in addition to some continuing micro aspects, all of which are being transformed in parallel. Much of the innovation efforts to date have led to trends that move us from micro to macro perspectives on change.

The forecasted trends identified in this article focus on the macro and micro levels that may emerge or are just emerging, depending on your perspective. Furthermore, some trends may be opposing to other trends, which reflects the uncertainty along with the diversity of change in healthcare, globally and nationally.

1. Consumerism and Populism

There are 3 related terms that are reflected in US consumers and politics today that deserve mention, because they underpin many of the trends and contradictions seen in the following discussion.

The first concept is populism, which has been discussed since the 2016-2017 US presidential and European elections. In the United States, populism has its roots in late 1800s farm-based and labor group movements directed against big business and machine-based politics to champion the “common person.”^{1,2}

Second is consumerism, a more modern theory sug-

gesting that increasing the consumption of goods is economically beneficial, and that consumers should be protected from inferior, dangerous, and unfair pricing of goods.³

Third is conscious consumerism, a term that emerged from a 1972 study by Anderson and Cunningham.⁴ They describe the typical conscious consumer as a “pre-middle age adult of relatively high occupational attainment and socioeconomic status...typically more cosmopolitan, but less dogmatic, less conservative, less status conscious.”⁴

Little has changed regarding conscious consumerism since the 1970s. We are still aware of the implications of what and where we buy things, which has translated into voting with our wallets and accepting the political power tied to our consumption decisions.

All these terms resonate to varying degrees in the US economic and political discussions, and they affect healthcare. For example, current concerns regarding protection from the use of dangerous drugs, while attacking unfair pricing and out-of-pocket costs associated with healthcare insurance are still hot topics for 2019. As we next look at the political landscape, it is fueled by these 3 “-isms,” which have a major influence over the remaining 9 trends discussed below.

2. Post-ACA and Midterm 2018 Electoral Landscape

All 3 branches of the US federal government (ie, executive, legislative, and judiciary) are engaged in issues that were discussed along the campaign trail in the 2018 midterm elections.

The executive branch is led by President Trump. The President’s election campaign had sought to repeal and replace the Affordable Care Act of 2010 (ACA), but the bill failed to pass in Congress. This was replaced by many and relentless changes and rollbacks of orders that had been signed by President Obama, as well as similar Cabinet-level Secretary changes from the previous administration. The ACA extended across multiple agencies, including those under the Department of Health & Human Services (HHS), the Treasury, and the Department of Labor. In addition, many federally enforced or determined issues were passed back to the states to de-

Dr Vogenberg is Principal, Institute for Integrated Healthcare, Greenville, SC; Board Chairperson, Employer-Provider Interface, Council of the Hospital Quality Foundation; and Adjunct Professor, Rutgers University, HOPE Center.

Copyright © 2019 by Engage Healthcare Communications, LLC; protected by U.S. copyright law.
Photocopying, storage, or transmission by magnetic or electronic means is strictly prohibited by law.

cide on or to enforce, which was another campaign promise by President Trump.

The legislative branch, which includes the House of Representatives and Senate and is collectively known as Congress, has been in a lawmaking gridlock, even with Republican control, and is now headed into a greater holdup as control of the House has moved back to the Democrats. Such gridlock could allow greater movement or flexibility given to the states to act on more local interests related to healthcare. For example, Medicaid expansion continues through referendums and State House initiatives in several states and is being allowed by the Centers for Medicare & Medicaid Services (CMS).

Similar shifts in policy determinations are happening regarding abortion, opioid and illegal drug use, tobacco and e-cigarettes, medical marijuana, drug pricing, soda taxes, and sales tax exemptions. In addition, health insurance structure and design have been identified as key issues by the new Congress. Voters across the United States are addressing increasing important healthcare issues through state ballot initiatives that are likely to continue into 2020.⁵

The judiciary branch, which includes the US Supreme Court and the Federal Judiciary Center, continues to play a role in interpreting the ACA and related executive branch actions, as well as state ballot initiatives. Given the midterm election results and the preparations already underway for the 2020 presidential election that would affect the ACA renewal review, the courts should expect appeals to the Supreme Court to quickly work their way through the judiciary system.

3. Health Economics and the US Economy

There is currently no lack of issues related to the US economy, including worldwide trade tensions and drug pricing. Gross domestic product growth in the United States was expected to be 3% in 2018, 2.3% in 2019, and 2% in 2020, according to the most recent forecast by the Federal Open Market Committee.⁶

Economists expect total healthcare spending to increase by 5.1% in 2019, which is down from the 8.2% growth in 2018.⁷ Worldwide, the United States remains the largest pharmaceutical market, particularly in terms of drug spending. The US pharmaceutical industry will continue to be buoyed by the tax reform passed in November 2017 that helped to free up more money for investment in pharmaceutical research and development. Innovations will continue to emerge in 2019, including promising gene-editing technique products. Of note, although the United States is moving away from universal healthcare, some countries in Asia (ie, India, Oman)

and Africa (eg, South Africa, Nigeria) will seek to expand their public health insurance systems.⁷ With artificial intelligence, robotics, stem cells, and other technologies in development, the world's health should continue to improve. Finally, pharmaceutical economic growth is expected to rise by 5.7% in 2019, down from 6.3% in 2018.⁷

Many medical technology rivalries are competing, especially with China, with tariff battles that have resulted in part from trade disputes or intellectual property issues, including medical imaging equipment, medical supply consumables, and some drugs.⁷

Finally, economic impacts emanating from unresolved issues in 2018, such as the opioid crisis, and continuing federal versus state battles regarding the ACA, could have greater economic effects in 2019 to 2020, depending on their resolution.⁸

Economic impacts emanating from unresolved issues in 2018, such as the opioid crisis, and continuing federal versus state battles regarding the ACA, could have greater economic effects in 2019 to 2020, depending on their resolution.

4. Commercial Self-Funded Plans Seek Value

The rise of healthcare costs far faster than inflation has been a major driver for healthcare reform in the United States. The healthcare spending was expected to increase by 5.3% in 2018 versus the 4.6% increase in 2017, which reflected the rising prices of medical goods and services and higher Medicaid costs; this upward trend is forecasted to continue through 2026.⁹ Although CMS forecasted a 5.4% increase in spending in 2017, the actual spending increased by 4.6%, to almost \$3.5 trillion.⁹

This unsustainable spending and the year-over-year increase remain critical issues for CMS, as well as for individuals in commercial plans and self-funded employers. In fall 2017, CMS implemented the Hospital Value-Based Purchasing Program under section 1886(o) of the Social Security Act.¹⁰ This program affects payment in more than 3000 hospitals across the United States and is part of the larger quality strategy to reform care delivery and payment. The program measures 4 domains—safety, clinical care, efficiency and cost reduction, and person and community engagement (formerly patient and caregiver-centered experience of care/care coordination) equally. Various

measures will be used for each domain, and these are subject to change.¹⁰

Value-based models change the incentives to focus on value by rewarding better outcomes and lower spending. Historically, medical treatment services were paid or reimbursed in a fee-for-service environment; basically, every episode of a consultation visit, doctor appointment, surgical procedure, or hospital stay was treated as a siloed event for the purpose of payment for services rendered.

Transitioning from volume-based to value-based payment in healthcare has been slow in the commercial and public sectors. Healthcare organizations, such as Kaiser Permanente, Geisinger Health System, and the Cleveland Clinic, have tested the use of value-based models to assume more financial risk while controlling spending.¹¹

Value-based care models continue to evolve, and employers should partner with providers and/or plan administrators to incorporate value-based care into their organization. Each value-based care model fits different employers' situations and workers, so choosing the right model will depend on the organization's capabilities, market position, financial situation, and company goals.¹¹ Delivering on these promises and avoiding problems with new technologies are goals for optimizing plan performance among employers.

Such approaches to deal with access to care also have a strong care-efficiency component that may lower the total cost of care.

New health economic tools are being developed to help self-insured employers to assess and determine value, improve their risk management, and make better decisions for healthcare coverage as a purchaser. Much-needed medical and economic marketing techniques by manufacturers have to be revamped.

5. Care Delivery: Settings and Efficiency

Integrated care across the continuum of care delivery from acute care to maintenance or home-based services has emerged as a central clinical and economic area for improved efficiency in the US healthcare. Workforce- and population-centered care settings will likely contribute to stakeholder role shifts in terms of where care is provided, such as hospitals functioning as community health systems, retailers as convenient care clinics, and insurers as partners with community-based providers.

These shifts can be seen through the continued expansion of employer-based on-site and near-site clinics to at least one-third of self-insured employers that is likely to grow more rapidly through alternative retail or convenient care clinics.¹² These clinics are expected to be promoted heavily in 2019 and 2020, along with telehealth (ie, telemedicine and telepharmacy) options for emergency departments or even urgent care clinics. Such approaches to deal with access to care also have a strong care-efficiency component that may lower the total cost of care.

Whether through employer-owned on-site clinics or through community-based routine convenient care clinics, consumers will likely have greater options to access care and primarily at none to lower out-of-pocket costs. This can benefit the employer-sponsored plan or third-party insurers, as well as the consumer. New efficiencies in acute or chronic care delivery will likely be offering savings beyond network access, as care systems deploy more efficient services and levels of care through an increasingly more consistent integrated system of care.

The drive to a lowest-cost site with the same or better outcomes is emerging through this more competitive market structure. Role changes among or between direct care or third-party payer stakeholders will become more obvious in 2019 and into the next decade.

Recently completed mergers in late 2018 by CVS Health with Aetna and CIGNA with Express Scripts illustrate such trends, along with a new willingness for collaboration across stakeholders in a patient-centered approach for optimal clinical and financial outcomes. Other firms are likely to become even more interested in mergers, as pressure to optimize healthcare delivery and utilization efficiency increases.

Preventive health efforts are also increasingly more valued, especially those associated with fewer episodes of acute care. As employers and CMS align to seek value, addressing the spectrum of care becomes an obvious need. For example, diseases can be more readily prevented with the use of effective vaccines for influenza or varicella and herpes zoster strains, as well as for curing diseases, such as diabetes, for which they are still being studied. Harnessing technology across medical devices, diagnostics, and drugs will become more obvious in 2019 through the early part of the next decade.

6. Big to Bigger and Vertical Integration

For years, there has been pressure on various segments of healthcare to consolidate and drive more business efficiencies, while remaining competitive with their drug purchasers. Wholesalers have seen consoli-

dation continue to date, along with business separations that allow for an increased focus on business and/or investment in new technologies and other acquisitions. Beyond the typical within-sector or horizontal-sector mergers, we now see some vertical-sector integrations in healthcare. For example, in December 2018, CVS Health/Aetna and CIGNA/Express Scripts completed their respective mergers after extensive reviews by the Federal Trade Commission and the US Department of Justice.

Employers as purchasers of care had also applied pressure on middlemen, along with inefficiencies in the healthcare supply chain. Large employer purchasing collaborations emerged in 2017 (eg, Health Transformation Alliance) and in 2018 (eg, Amazon-Berkshire Hathaway-JPMorgan Chase). Those collaborations, coupled with existing employer advocacy coalitions, sought purchasing power, as well as disruption. Business coalitions sought change in the way healthcare was being paid for, and in what and where healthcare was going to be delivered for their members.

Pressure by employers on third parties and care-delivery organizations (ie, hospitals and retailers) continued through 2018 and is expected to continue into the next decade. At the surface, much of healthcare looks like an iceberg, because many unseen changes below the water are likely in the midst of being incorporated into new or upcoming contracts, plan designs, and structures of healthcare coverage.

Such changes underneath the surface look headed toward sustained change over the next several years, regardless of what happens in Washington, DC. Also, changes are not likely to be an explosion of a disruption of healthcare, but rather more like bubbles popping up from beneath the surface that signal that change is in place, which will come too late for those in the less-informed segments of the supply chain of healthcare.

The combination of purchasing prowess, drive for efficiencies, and restructuring of insurance coverages is also likely to affect medical technology pricing. For example, the pricing of biologic and specialty drugs is already under political and managed care scrutiny, but structural changes in employer commercial health plans make that moot and can threaten drug utilization more quickly. Cross-sector consolidation or expansion may become a greater vehicle to achieve disruption or reduce unnecessary costs factored in healthcare pricing.

Adding to that pricing and efficiencies trend is the arrival of Silicon Valley information technology (IT) firms and start-ups that are seeking disruption in healthcare as a unique business opportunity. Amazon, Apple, Google, Microsoft, and others have established

Table	Common Terms That Make Up the Internet of Things, by Type
Analytics	
Advanced analytics, Analytics of Things, big data analytics, descriptive analytics, predictive analytics, prescriptive analytics, SAS Analytics for IoT, SAS event stream processing, SAS visual analytics, SAS visual statistics, streaming analytics	
Artificial Intelligence	
Artificial intelligence, augmented reality, automation, chat(ter)bot, cognitive computing, deep learning, facial recognition, machine learning, machine to machine, neural network, speech recognition, vehicle to vehicle, virtual reality, voice assistant	
Applications	
Connected customer, connected factory, connected vehicle, smart city, smart grid, smart home	
Capabilities	
Automation, digitalization, digitization, legacy, optimization, real time, ubiquitous	
Computing	
Cloud computing, cognitive computing, edge computing, fog computing, grid computing	
Wireless connectivity and standards	
Botnet, geofencing, GPS, interconnectivity, Internet of Everything, interoperability, network, platform, protocol, proximity network, radiofrequency identification, standards	
<small>GPS indicates global positioning system; IoT, Internet of Things. Adapted from SAS Institute. <i>A Non-Geek's A-to-Z Guide to the Internet of Things</i>. www.sas.com/content/dam/SAS/en_us/doc/whitepaper1/non-geek-a-to-z-guide-to-internet-of-things-108846.pdf.</small>	

footholds that are likely to disrupt the existing drug supply chain, while establishing new and highly efficient systems that can also affect the economics and experience of healthcare for consumers. This is a win-win situation as a result of improving economic performance or member experience for such IT as employers themselves who have become frustrated with the entrenched and costly status quo within the existing healthcare system.

The IoT could provide drug information on demand for consumers or providers at home or at a point of service.

Expect more rapid and sustained changes to emerge in 2019 that address a wide variety of commercial employer insurance market issues that have not yet been resolved. In addition, expect the pace of change to pick up as a result of the way IT firms innovate, as well as the rapid pace established by President Trump to make change happen.

7. Internet of Things

The pace of technological change we have seen has been remarkable, relentless, and amazing compared with the status quo. Today, a broad concept known as the

Internet of Things (IoT) links objects to the Internet and facilitates data and insights that have never been available before.

An IoT network of physical objects contains embedded technology to communicate and sense or interact with their internal states or the external environment. An IoT also describes a world where just about anything can be connected and communicate in an intelligent fashion. In other words, with the IoT, the physical world is becoming one big information system, a concept that many of us may not have thought of or are concerned about now.

HIPAA violations and data breaches are increasingly common and large, resulting in record-setting fines and settlements. This is particularly problematic for large healthcare systems and third-party payers as they become high-value targets for cybercriminals.

The IoT could ensure safety and efficiency in cold chain supply chains for biologic or specialty drug manufacturing or patient shipments, and already are doing so to some extent. The IoT could provide drug information on demand for consumers or providers at home or at a point of service.

A new array of terms defines what makes up the IoT and is also instructive about where healthcare may be headed by harnessing such a network, where almost anything can be connected and communicate in an intelligent fashion. The **Table** lists terms that are identified by the SAS Institute to help novices and experts to understand the IoT.¹³

8. Cybersecurity and Breaches

With a plethora of uses and global access to information now available about healthcare, including personal data, big concerns have arisen about cybersecurity.

Cybersecurity, also known as IT security, is the protection of computers, networks, programs, and data from unauthorized access or attacks that are aimed at exploitation. The major areas in cybersecurity include application security, information security, disaster recovery planning, and network security.¹⁴

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires the Secretary of HHS to develop regulations to protect the privacy and security of specific health information.¹⁵ The HIPAA Secu-

rity Rule has the main goal of protecting the privacy of individuals' health information, while allowing covered entities to adopt new technologies to improve the quality and efficiency of patient care. The Health Information Technology for Economic and Clinical Health (HITECH) Act, which was enacted as part of the American Recovery and Reinvestment Act of 2009, expanded the responsibilities of business associates to access or use such health information under the HIPAA Security Rule.¹⁵

According to the HHS, "the HIPAA Breach Notification Rule, 45 CFR §§ 164.400-414, requires HIPAA covered entities and their business associates to provide notification following a breach of unsecured protected health information. Similar breach notification provisions implemented and enforced by the Federal Trade Commission, apply to vendors of personal health records and their third party service providers, pursuant to section 13407 of the HITECH Act."¹⁶

Nearly every week we hear or read about another breach or issue with cybersecurity of our healthcare information. Such reports are required under the HIPAA and HITECH Acts. The news releases are independent of legal filings or settled cases in court. Also, these rules can be updated by HHS, as needed, to affect healthcare professionals, as well as business associates who are seeking access to and/or the use of health information, to include health record data on specific patients.

HIPAA violations and data breaches are increasingly common and large, resulting in record-setting fines and settlements. In October 2018, Anthem agreed to pay the Office for Civil Rights \$16 million in a record HIPAA settlement after the largest health data breach in US history.¹⁷ This is particularly problematic for large healthcare systems and third-party payers as they become high-value targets for cybercriminals.

As diagnostics technology evolved from decoding the genome, in 2008 Congress passed the Genetic Information Nondiscrimination Act (GINA), which was signed into law by President George W. Bush.¹⁸

Although intended to provide expanded legal protection for genetic information, several loopholes in GINA remain. Because such information covers a broad use of data from life insurance to employment beyond healthcare, GINA's promise of being a civil rights bill has not come to fruition.¹⁹ The emphasis in healthcare has turned to encouraging a healthy lifestyle and is incentivized through lower insurance premiums or other health perks, and employees who refuse certain genetic tests to identify health risks as part of their company's wellness program may pay much more than their colleagues. Statute coverage versus real-world use

of such data is often contradictory, and genetic tests can have unanticipated consequences, such as increased insurance premiums.¹⁹

Awareness and understanding of the law are fine, but the ever-changing technologies and applications of their ensuing results make keeping the law or consumer expectations in sync very difficult.

9. Niche versus Blockbuster Technologies

Changes in disease management paradigms will continue to emerge in 2019, as drug manufacturers experience a blockbuster revival. Investments, acquisitions, and speedier US Food and Drug Administration (FDA) approvals all contribute to the new market landscape. Once considered high-risk drugs, recent first-in-class medicines such as the RNA-based therapy patisiran, the novel gene therapy voretigene neparvovec-rzyl, and the chimeric antigen receptor (CAR) T-cell gene therapies tisagenlecleucel and axicabtagene ciloleucel, are not going to be alone.

In 2019, the blockbuster drug market overall will expand, with many promising new drugs expected to bring in more than \$1 billion in sales by 2025.²⁰ Many of the drugs in the pipeline are “niche busters” that will radically change the treatment paradigm for diseases with a high unmet therapy need. New treatments for blood disorders, such as anemia and RNA interference in patients with hemophilia, are being developed. In immunology, treatments for rheumatoid arthritis and plaque psoriasis are coming, along with gene therapies for various neurodegenerative diseases such as Duchenne muscular dystrophy. Oncology will continue to see the addition of more small-molecule drugs, in addition to biotechnology drugs that pursue niche cancer indications that will lead to broader use, such as the class of the programmed-cell death-1 inhibitors.²⁰

The pharmaceutical industry has been expanding its technology solutions to enhance discovery, development, and supply chain efficiencies through harnessing the IoT. Simple mechanization (1.0) gave way to mass production assembly lines (2.0), and applied computing and automation (3.0).²¹ Today, biopharmaceutical companies and supply chains are starting to connect with other machines at “Industry 4.0.”²¹

Supply chains exist around the world, and we have limited capacity to communicate fast enough as humans. We, humans, are the emerging biologic-limiting condition of pharmaceutical operations. Beyond our ability to “eyeball” or make decisions in a fully informed manner, we now think that finances will drive much of the operations decision-making and outsourcing.²¹ As oncology-led biotechnology in the healthcare delivery system,

patients need a biotechnology reality check related to biopharmaceutical companies and their care-delivery partners or collaborators.

For autoimmune diseases, biologic drugs bring promise and problems, benefits and risks, including side effects. The body may attack itself, or our immune system may be suppressed, which may lead to other illnesses. Major autoimmune diseases in the United States include psoriasis (the most prevalent), rheumatoid arthritis, ulcerative colitis, and Crohn’s disease (the least prevalent).²²

Today, health plans still prefer to focus their management on spending on biologics, which has become increasingly ineffective from an annual trend perspective of plan sponsors. Treatment guidelines or protocols that extend from screening diagnostics through treatment to ongoing monitoring expand the drug-device-diagnostic triad. For example, drugs combined with drug-delivery devices that cross over benefit coverage lines create havoc in third-party management that is focused solely on claim management. Home use device development broadens the lines of devices outside of acute care settings too.

Much of what is reaching the pharmaceutical market today has been in the works for years and has become mature enough for utilization by healthcare providers and consumers. As a result, 2019 is shaping up to be a significant transitional year in healthcare.

Increasing the connectivity of devices across the spectrum of care will add to the market growth for consumer-level devices that may be paid for by the consumer outside of typical plan coverage. Such market dynamics, coupled with technological innovations, will add another level of pressure on traditional plan management by all third-party payers and purchasers. Novel blockbuster agents’ total costs can range from \$100,000 to more than \$1 million annually, or a claim (eg, CAR T-cell therapy, other cancer drugs, or drugs for hemophilia), depending on the treatment regimen.

Personalized medicine as a new standard of care in healthcare, such as immunotherapy and targeted therapies in oncology, illustrates the solutions represented by the new blockbuster drugs. For example, CAR T-cell therapies are novel innovations with high response rates in patients with relapsed disease, representing a

personalized approach to cancer immunotherapy. But this comes with problems—the hallmark of CAR T-cell therapy toxicity is cytokine release syndrome, an inflammatory response that results from supraphysiologic T-cell activation.²³

10. Drug-Device-Diagnostic Innovation Pipeline

As part of improving regulatory processes and new drug approvals, FDA Commissioner Scott Gottlieb, MD, has cleared a backlog of applications and expedited access to drugs in the United States in 2018.²⁴ The FDA's Center for Drug Evaluation and Research approved 46 new molecular entities and biologic drugs in 2017 versus only 22 drugs in 2016.²⁵ This was the highest number of drug approvals since 1996, in which 59 drugs were approved, and more than the average drug approvals (ie, 32 drugs) in the past 10 years.²⁵ This regulatory trend will likely result in a continuously larger number of new drug approvals through 2020, which has implications for all stakeholders. The approvals will include medical devices, diagnostics, and generic, brand-name, and biosimilar drugs.²⁴⁻²⁷

Dr Gottlieb has prioritized expediting the process of reviewing generic drugs to help lower drug prices.²⁴ In addition to setting a new record for generic drug approvals, tentative FDA approvals have also increased, from 174 drugs in 2017 to 190 drugs in 2018.²⁴

Access to gene-based technologies and their efficacy as a therapeutic solution to rare diseases will emerge as key issues in 2019 for most stakeholders, because of the associated excessive costs and the promise of success in a broad mix of rare conditions.

A variety of devices have also benefited from the FDA initiatives, including traditional stand-alone or drug combination devices.^{28,29} The bioprinting of drugs has been in development for many years and is poised to expand rapidly in 2019, which could significantly change the distribution of, and access to, drugs and devices. Expanded bioprinting applications now include medical devices and drugs.³⁰ The ability to print drugs on demand in healthcare could be among the most revolutionary realities that would push change past the tipping point, causing greater and faster change in healthcare to personalized medicine.³¹

Conclusion

Change does not always come fast and is usually preceded by basic developments, with continued improvements that drive innovation over time. This also holds true in healthcare. Much of what is reaching the pharmaceutical market today has been in the works for years and has become mature enough for utilization by healthcare providers and consumers. As a re-

sult, 2019 is shaping up to be a significant transitional year in healthcare, which will see even more change in 2020. All healthcare supply chain stakeholders are likely to be affected in some way in 2019. Stakeholders hanging onto the status quo will be subsumed by the veracity and velocity of consumer- or purchaser-driven changes. By 2020, the questions will likely focus more on how much change has happened, and how fast it occurred. ■

Acknowledgment

The author would like to thank John Santilli, of Access Market Intelligence, for his assistance with drafts of this manuscript.

Author Disclosure Statement

Dr Vogenberg has no conflicts of interest to report.

References

1. The Independence Hall Association. The growth of populism. www.ushistory.org/us/41d.asp. Accessed January 23, 2019.
2. Munro A. Populism. *Encyclopædia Britannica*. March 6, 2018. www.britannica.com/topic/populism. Accessed December 22, 2018.
3. Consumerism definition. Dictionary.com. 2019. www.dictionary.com/browse/consumerism. Accessed January 23, 2018.
4. Anderson WT Jr, Cunningham WH. The socially conscious consumer. *J Marketing*. 1972;36:23-31.
5. Celia D. Health care on the ballot: assessing the impact of the midterm elections. *First Report Managed Care*. November 2018;15. www.managedhealthcareconnect.com/article/health-care-ballot-assessing-impact-midterm-elections. Accessed December 23, 2018.
6. Amadeo K. US economic outlook for 2019 and beyond: experts forecast steady growth. The Balance. Updated January 1, 2019. www.thebalance.com/us-economic-outlook-3305669. Accessed January 23, 2019.
7. The Economist Intelligence Unit. Industries in 2019: a special report from The Economist Intelligence Unit. 2018. <https://bit.ly/2TnI42v>. Accessed December 23, 2018.
8. Beyond Obamacare: what's ahead for U.S. health care in 2018. Knowledge @ Wharton. January 4, 2018. <http://knowledge.wharton.upenn.edu/article/the-future-of-the-aca>. Accessed December 23, 2018.
9. Abutaleb Y. U.S. healthcare spending to climb 5.3 percent in 2018: agency. Reuters. February 14, 2018. www.reuters.com/article/us-usa-healthcare-spending-idUSKCN1FY2ZD. Accessed January 3, 2019.
10. Centers for Medicare & Medicaid Services. Hospital value-based purchasing. ICN 907664. September 2017. www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Hospital_VB_Purchasing_Fact_Sheet_ICN907664.pdf. Accessed December 23, 2018.
11. Sanicola L. What is value-based care? *HuffPost*. February 2, 2017. www.huffingtonpost.com/entry/what-is-value-based-care_us_58939f9de4b02bbb1816b892. Accessed December 23, 2018.
12. Mercer. 2018 Worksite Medical Clinics Survey. www.mercer.us/content/dam/mercer/attachments/private/nurture-cycle/us-2018-worksite-medical-clinics-survey-report.pdf. Accessed February 7, 2019.
13. SAS Institute. Internet of Things (IoT): what it is and why it matters. www.sas.com/en_us/insights/big-data/internet-of-things.html. Accessed December 26, 2018.
14. Definition of cyber security. *Economic Times*. <https://economictimes.india.com/definition/cyber-security>. Accessed December 26, 2018.
15. Department of Health & Human Services. Summary of the HIPAA Security Rule. www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html. Accessed December 26, 2018.
16. Department of Health & Human Services. Breach Notification Rule. www.hhs.gov/hipaa/for-professionals/breach-notification/index.html. Accessed January 28, 2019.
17. Department of Health & Human Services. Anthem pays OCR \$16 million in record HIPAA settlement following largest U.S. health data breach in history.

October 15, 2018. www.hhs.gov/about/news/2018/10/15/anthem-pays-ocr-16-million-record-hipaa-settlement-following-largest-health-data-breach-history.html. Accessed December 26, 2018.

18. National Institutes of Health. The Genetic Information Nondiscrimination Act (GINA). <https://report.nih.gov/nihfactsheets/ViewFactSheet.aspx?csid=81>. Accessed December 26, 2018.

19. Zhang S. The loopholes in the law prohibiting genetic discrimination. *Atlantic*. March 13, 2017. www.theatlantic.com/health/archive/2017/03/genetic-discrimination-law-gina/519216. Accessed December 26, 2018.

20. Salzman S. Outlook 2019: pipeline report: changing the treatment paradigm. *Med Mark Media*. December 2018:34-36, 38-41.

21. Garguilo L. Biopharma supply chains at Industry 4.0. *Life Science Leader*. December 3, 2018. www.lifescienceleader.com/doc/biopharma-supply-chains-at-industry-0001. Accessed December 26, 2018.

22. Adams KT, Wehrwein P. For autoimmune ills, biologics bring promise—and problems. *Manag Care*. 2016;25:16-20.

23. Barlow B, Barlow A, Freyer C. CAR-T cells: driving a new era of oncology immunotherapy. *US Pharm*. 2018;43(Specialty&Oncology suppl):15-22.

24. Elvidge S. FDA sets another record in 2018 for generic drug approvals. *BioPharma Dive*. October 12, 2018. www.biopharmadive.com/news/fda-sets-another-record-in-2018-for-generic-drug-approvals/539539/. Accessed December 23, 2018.

25. Kaul G. FDA on a roll: drug approvals in H1 2018. *DRG Blog*. August 9, 2018. <https://decisionresourcesgroup.com/drg-blog/fda-roll-drug-approvals-h1-2018/>. Accessed December 23, 2018.

26. US Food and Drug Administration. FDA approves first cancer drug through new oncology review pilot that enables greater development efficiency: FDA expands the use of breast cancer drug. July 18, 2018. www.fda.gov/newsevents/newsroom/pressannouncements/ucm613801.htm. Accessed December 23, 2018.

27. US Food and Drug Administration. Novel drug approvals for 2018. www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm592464.htm. Accessed December 23, 2018.

28. US Food and Drug Administration. Webinar - Special 510(k) Program Pilot - November 8, 2018. Updated December 4, 2018. www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm622095.htm. Accessed December 23, 2018.

29. Hunt RE. If at first you don't succeed, try, try, try again: FDA issues plan to increase efficiency of 510(k) Third Party Review Program. *FDA Law Blog*. October 12, 2018. www.fdalawblog.net/2018/10/if-at-first-you-dont-succeed-try-try-again-fda-issues-plan-to-increase-efficiency-of-510k-third-party-review-program/. Accessed December 23, 2018.

30. Use of 3D bioprinting in drug discovery and cosmetics testing expected to reach \$500 million by 2027. *SmarTech Publishing blog*. April 18, 2017. www.smarttechpublishing.com/blog/3d-bioprinting-drug-discovery/. Accessed February 7, 2019.

31. Burton P. How 3D bioprinting is revolutionizing personalized medicine. *PharmaBoardroom*. June 27, 2018. <https://pharmaboardroom.com/articles/how-3d-bioprinting-is-revolutionizing-personalized-medicine/>. Accessed February 7, 2019.