

Evolution and Outlook for the Consumer-Driven Testing Market

Where are we going and what are the signposts of change?



Market dynamics over the next several years will continue to determine the evolution and trajectory of consumer-driven testing.

As companies consider Rx-to-OTC switches, monitoring the self-testing landscape will be a critical task. Observing and evaluating the signposts of growth outlined in this report will provide a fundamental understanding of the consumer-driven testing space and will alert companies to favorable shifts.

Ultimately, these signposts represent important markers that allow companies to make better-informed investment decisions on OTC programs.

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Introduction

In order to increase consumer accessibility to next-generation medicines, many pharmaceutical companies are considering Rx-to-OTC switches for medicines currently available by prescription only. For example, medicines that treat conditions such as irritable bowel syndrome and high cholesterol¹ are currently available by prescription only in the United States (US), but are available over-the-counter (OTC) in other countries.

Several barriers exist for Rx-to-OTC switches, including concerns over safety and over consumers' ability to independently self-manage treatment without the oversight of a healthcare practitioner (HCP). Though many switches have been pursued by manufacturers, the majority of them have largely been rejected by the US Food and Drug Administration (FDA) for a variety of reasons. In particular, some Rx-to-OTC switch attempts have been thwarted by concerns that consumers will be unable to perform the self-monitoring required to appropriately manage their diseases or conditions. Additionally, apprehensions about the consumer's ability to accurately interpret and respond to self-monitoring data have limited Rx-to-OTC attempts in some classes.

Cholesterol-lowering medicines provide a constructive example. At least three companies have publicly disclosed OTC programs for their respective statin medicines in the past: Merck (Mevacor), Bristol Myers Squibb (BMS) (Pravachol), and Pfizer (Lipitor). The FDA expressed several concerns with the Mevacor applications, including low consumer awareness of cholesterol levels and reservations about how consumers would access and respond to cholesterol testing². This past summer, Pfizer terminated their OTC Lipitor³ program in response to an actual use trial (AUT) that failed to meet its primary objectives of demonstrating patient compliance; in particular, patients were unable to comply with directions to check LDL cholesterol (LDL-C) levels and did not take appropriate action based on test results (Exhibit 1).

Exhibit 1⁴

Company	Product	OTC Attempts
Merck	Mevacor (lovastatin)	NDA submitted in 1999, re-submitted in 2004, re-submitted in 2007
Bristol Myers Squibb	Pravachol (pravastatin)	NDA submitted in 1999
Pfizer	Lipitor (atorvastatin)	NDA not submitted; OTC Lipitor program terminated in July 2015

Given the FDA's negative response to previous OTC statin applications and recent news surrounding the termination of the OTC Lipitor program, the question remains whether greater infrastructure for self-testing is required for successful future Rx-to-OTC conversions in the statin space. Therefore, IMS Health investigated the Rx-to-OTC switch market (using hyperlipidemia as a key example) to understand whether the necessary infrastructure is present for consumers to effectively test and manage their conditions. Specifically, we focused on the consumer-driven cholesterol testing market, which encompasses all cholesterol testing that does not require a physician visit. Overall, this report will:

- **Define the trajectory and scope for growth** in the US consumer-driven cholesterol testing market
- **Highlight and evaluate signposts of growth** in the consumer-driven cholesterol testing space
- **Identify triggers** that might signal a company to initiate or re-initiate an Rx-to-OTC program

Evolution of Consumer-Driven Cholesterol Testing

To understand Rx-to-OTC switches in hyperlipidemia and the consumer-driven cholesterol testing market, four main signposts of growth should be considered: an evolving healthcare infrastructure that provides increased access to consumer-driven testing; the rise of innovative technologies to enable testing; a supportive regulatory landscape; and the growing utilization of consumer-driven testing tools and programs (Visual 1). Overall, the timing for these signposts is flexible; that is, they do not need to appear in a specific sequence. In general, growth in this space will require the existence of sufficient access to testing, as well as broad availability of technology and infrastructure that support and enable testing. Moreover, the emergence of key regulations and consumer utilization (either simultaneously or before/after) can broaden the scope and prevalence of consumer-driven testing. Together, these signposts represent the core requirements for the growth of the consumer-driven cholesterol testing market and its relative alignment with Rx-to-OTC switch programs.

Visual 1: Signposts of Growth in Consumer-Driven Cholesterol Testing

Healthcare Infrastructure and Access to Testing	Technology to Support Testing	Regulatory Environment for Testing	Utilization and Uptake of Testing
<p>Payer evolution, electronic health records, and new settings of care</p> <p>New avenues for consumer testing that do not require physician visit</p>	<p>Increased access to smart phones, internet, and patient portals</p> <p>Advances in technology for self-testing</p>	<p>Specifies who can prescribe and interpret tests, and whether consumers can order tests</p> <p>Varies at state level</p>	<p>Utilization currently low despite infrastructure and access</p> <p>Growth follows convergence of supportive signposts</p>

Healthcare Infrastructure and Access to Testing

Consumers seeking to self-medicate with an OTC drug need to be able to reliably and consistently monitor their health status, including critical health indicators such as cholesterol levels. This capability will invariably require greater access to testing and health information. To that end, healthcare infrastructure is an important signpost for evaluating consumer access and self-testing in the US market. Two key market factors are promoting and creating opportunities for consumer-driven testing: 1) Current trends in the general healthcare infrastructure are encouraging consumers to take greater responsibility for their health, and 2) The growth of non-physician-mediated avenues for testing and healthcare is creating more opportunities for consumer-driven testing.

Healthcare Infrastructure

The evolution of payer models, the expansion of electronic health records (EHRs), and shifting settings of care represent key changes in the US healthcare infrastructure. The points below summarize the most important characteristics and developments in each area:

- **Managed Care Organizations (MCOs):** In general, MCOs are shifting accountability to consumers, often by transferring the cost burden to the patient. According to the Kaiser Foundation, covered workers' average dollar contribution to family coverage has increased 81% since 2004 and 37% since 2009. Moreover, 80% of covered workers have seen their general annual deductible for single coverage continually increase year to year⁵. Beyond cost-shifting, many MCOs are working with employers to incentivize employees to complete health risk assessments. Almost one third of employers that offer health benefits to employees also provide employees with an opportunity to complete a health risk assessment⁵. The biggest opportunity derived from the resulting increase in health assessment numbers is the growing availability and visibility of test results for patients and consumers – a key lever in their ability to make informed health decisions.
- **Accountable Care Organizations (ACOs):** With more than 500 ACOs nationwide, nearly 70% of Americans live in a region served by an ACO⁶. Given their emphasis on value-based care, ACOs are bolstering care coordination and fueling data-driven healthcare systems. In fact, several nationally recognized metrics for ACOs include quality measures which can encourage cholesterol testing (e.g., monitoring the percent of beneficiaries whose HbA1c control < 8%, LDL-C < 100 mg/dL, and blood pressure < 140/90)⁷. In addition, ACOs specify preventive care measures that include screenings for risks and health concerns such as future fall risk, breast and colorectal cancer, influenza immunization, pneumonia vaccination status, body mass index (BMI), tobacco use, high blood pressure, and clinical depression⁷.
- **Electronic Health Records (EHRs):** The expansion of EHR platforms has facilitated greater tracking of patient data across a range of healthcare environments. An EHR is a real-time, digital version of traditional patient paper charts. Among other benefits, a key advantage to EHRs is the ability to efficiently share health information amongst all individuals involved in a particular individual's care. The EHR market grew globally at a 5.5% CAGR from 2012–2015, and is expected to continue growing over the next 5–10 years^{9,10}.

Growth to date has been driven in part by a 2009 federal economic stimulus package called the Health Information Technology for Economic and Clinical Health (HITECH) Act. The HITECH Act contains incentives to accelerate the adoption of EHR systems, including providing payments for ongoing and meaningful use of such systems. This act facilitates two separate payment programs, available through larger payer organizations such as Medicare or Medicaid. Providers who sign up for the program must achieve certain milestones in order to receive payments, and those who do not demonstrate meaningful use are penalized via reduced reimbursement rates.

- **Additional Support for EHRs** has come from lab companies that have invested in developing new electronic reporting mechanisms. Examples include apps such as the Quest Diagnostics Care360 iPad App, which facilitate the integration of lab data into EHRs¹¹. Given the financial incentives and potential benefits of integrating EHRs into the continuum of care, growth in EHRs will likely be both stable and ongoing in the future.
- **Shifting Settings of Care:** New and changing settings of care are also fueling change in the US healthcare infrastructure. These emerging points of access help fill the gap created by an escalating physician shortage and the ensuing trickle-down effects (longer patient wait times, shorter consultations, over-worked physicians, and decreased physician accessibility). The establishment of integrated care models is also leading to increased health screenings at non-traditional locations, such as pharmacies, food stores, online order systems, and employer and public health screenings. Building upon this momentum, collaborations are emerging between once-disparate stakeholders. For instance, soon after CVS Health reported that its MinuteClinic telehealth pilot was well received by patients, it announced partnerships with three telehealth companies (American Well, Doctor On Demand and Teladoc) to expand offerings and explore strategies for retail clinic providers, retail pharmacies, and telehealth providers to collaboratively improve patient care¹².

Avenues for Consumer-Driven Self-Testing

Consumers seeking the means to test and manage important health indicators such as cholesterol currently have a range of options which do not require a physician visit (Visual 2). For example, consumers may go to pharmacy clinics, supermarkets and food stores, employer and public health fair screenings, order mail-kits for direct access to labs, or purchase OTC self-tests at pharmacies. Several of these testing avenues did not exist 10–15 years ago, and thus these options represent a significant increase in access

Visual 2: Avenues for Consumer-Driven Testing and Analysis



to consumer-driven testing. While each avenue has its benefits and drawbacks, cumulatively they are evolving the testing atmosphere and leading to a rise in access to consumer-driven testing.

Pharmacy clinics have expanded enormously in the past decade, leading to an overall increase in the utilization of testing for preventive healthcare. From 2006–2014, the number of pharmacy clinics in the US grew at a 32% CAGR and the number of annual visits to pharmacy clinics grew at a 38% CAGR^{13,14} (Visual 3). According to Walgreens Healthcare Clinic data, preventive services, screenings, and chronic visit utilization (combined) increased from 4% of total visits to Walgreens Healthcare Clinic locations to

Visual 3: Growth in Number of Pharmacy Clinics and Annual Visits^{13,14}

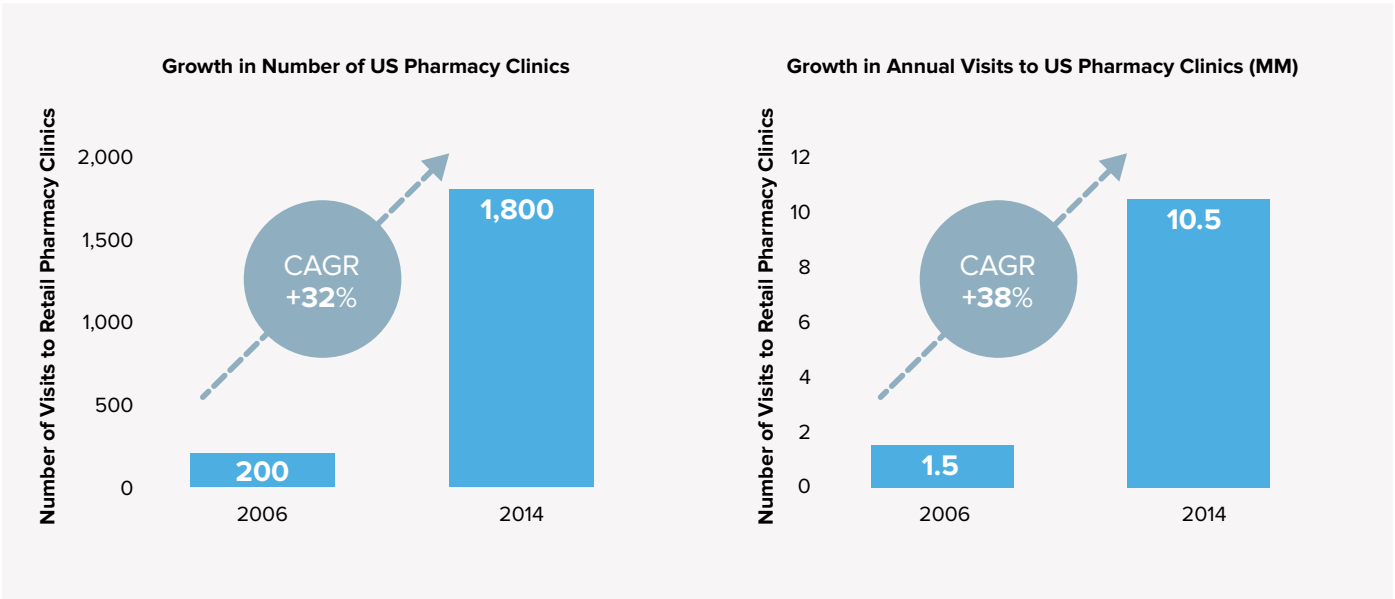








Exhibit 2 ¹⁴

Age group	Increase in visits
0-17 years	Visits for both preventive services and vaccinations increased by 180%
18-64 years	Visits for health testing increased 90%
65+ years	Acute visits increased 84%

17% between 2007 and 2013¹⁴. Furthermore, consumer visits increased significantly across all age groups (Exhibit 2).

CVS and Walgreens are emerging as clear leaders in the retail health clinics space (Visual 4). Although both dominate the mini-clinic space, CVS leads in the number of health system affiliations and in the pursuit of more payer and provider partnerships. These dynamics support a growing integration of retail clinics into the US healthcare infrastructure, and additionally they create a more robust environment for consumers to seek preventive health tests and care outside of the traditional hospital setting.

Visual 4¹³

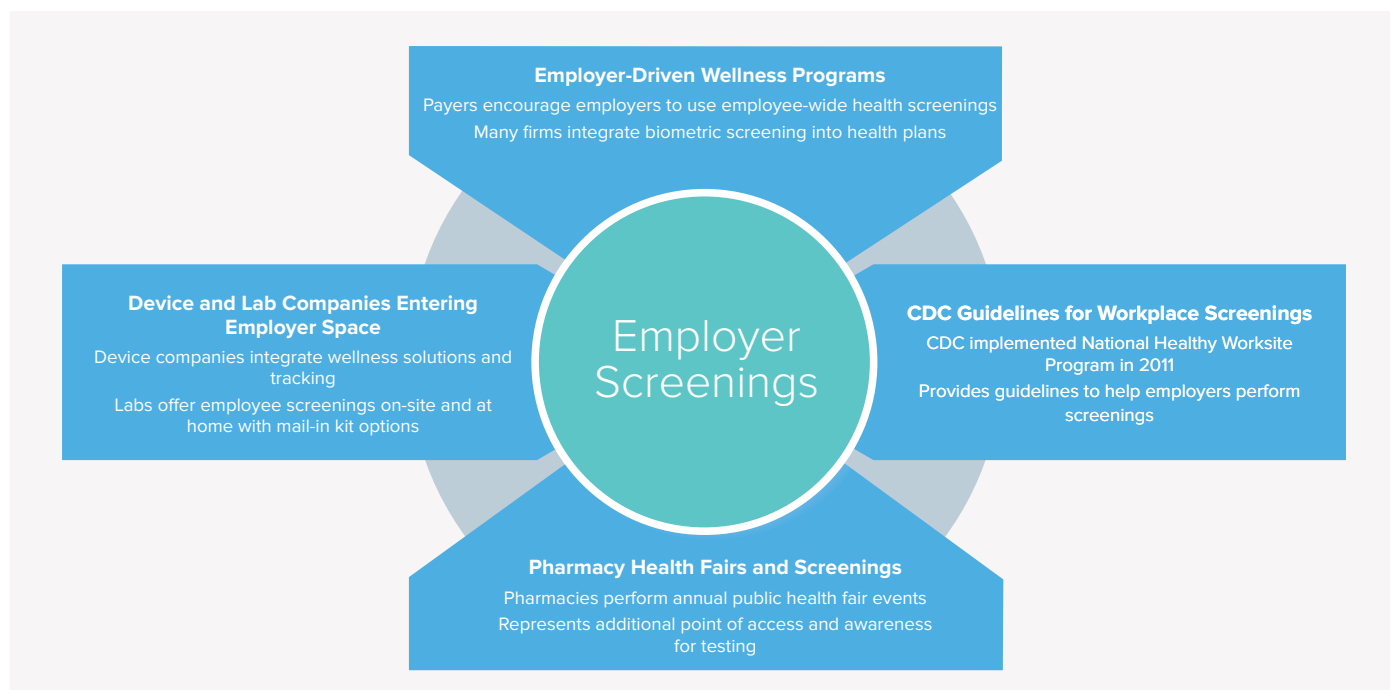
Retail Clinic		Number of Sites	Market Share	Health System Affiliation
CVS Minute Clinic		901	50%	47
Walgreens Healthcare Clinic		437	24%	6
Kroger Little Clinic		140	8%	4
Walmart Retail Clinic		103	6%	46
Target Clinic*		80	4%	2
Rite Aid RediClinic		30	2%	3

* CVS acquired Target's Clinics in 2015

Supermarkets and food stores have also entered the health testing market, thus providing another alternative avenue for care. Several supermarket chains are now offering cholesterol screenings to consumers, including Kroger, Publix, Safeway, ShopRite, and Albertsons. Publix, for example, announced in July 2015 that it will offer biometric screenings at more than 970 of its pharmacy locations¹⁵. Available on a walk-in basis, these screenings are designed to help consumers understand their risk for developing chronic conditions (e.g., diabetes, high blood pressure, or high cholesterol) by evaluating blood pressure, BMI, glucose, and lipid panel levels. By building an easily accessible model for consumers and by establishing complementary platforms for pharmacist consultation, supermarkets and food stores are emerging as an increasingly legitimate and convenient avenue for consumer-driven healthcare and testing.

With elevating healthcare costs in the US, **employer-driven screenings and wellness-based initiatives** are gaining traction as more companies develop initiatives to support healthier lifestyles and lower the risk of developing chronic disease in their employees (Visual 5). In fact, payers and policy makers have encouraged employers to establish employee-wide health screenings in order to avoid higher premiums. Currently, 26% of small businesses and 51% of larger employers offering health insurance are additionally providing biometric screenings (i.e. health examinations that measure an employee's risk factors such as cholesterol, stress, and nutrition)⁵, and these numbers are expected to increase. The Centers for Disease Control (CDC) also supports workplace health programs. In October 2011, the CDC established the National Healthy Worksite Program (NHWP) to assist employers in promoting better health among employees. In 2013, 104 employers with a total of more than 15,000 employees were selected to receive training, tools, processes and resources through the NHWP to achieve a sustainable workplace health program^{16,17}.

Device and lab companies are also crossing into the employer screening healthcare space (Visual 5). Companies such as PTS Diagnostics are beginning to market wellness solutions and screening at employer sites, and LabCorp has offered employee screenings both on-site and at home.

Visual 5: Growth in Employer-Driven Screenings and Wellness-Based Initiatives^{16,17,18}

LabCorp's Lab-in-an-Envelope, which is used as part of employer-driven screenings, is an interesting example of a cost-effective home collection kit that allows a consumer to mail a specimen to a central laboratory for analysis. LabCorp's system tests several areas of health, including cardiovascular assessment (lipid panel), diabetes screening (hemoglobin A1c), and drug testing (cotinine). In addition to employers, pharmacy chains are expanding into public health fairs and screenings. CVS's "Project Health" is responsible for 1000 health fair events annually and has screened over 730,000 patients across the US since 2006. In this time it determined that about 40% of visitors had cholesterol abnormalities. Overall, the environment for employer- and pharmacy-supported screenings is very promising, and it is encouraging other health initiatives and consumer utilization beyond the hospital setting.

Direct access lab testing (DAT) and OTC self-test products represent another growing avenue for consumer-driven testing. In DAT, consumers initiate lab testing of their own specimens without a prior consultation with, or requests from, a physician¹⁸. While regulation for DAT varies at the state level, many companies are offering direct access blood testing. Both large companies (e.g., Quest, LabCorp) and smaller companies (e.g., DirectLabs, WellnessFX) offer DAT services.

In parallel with greater online accessibility to testing, pharmacies are making a variety of self-test products available to consumers over the counter. Although at-home cholesterol tests are available for purchase, the overall market is small. That said, most of these at-home options only provide total cholesterol, not specific LDL-C levels. Moreover, price variability (range from \$20-\$200), consumer lack of understanding of how to interpret test results, and doubts regarding accuracy may also be negatively impacting adoption and interest in self-testing products. Nonetheless, with the visible increase in direct access blood tests and OTC self-test products, consumers can readily access and become more accustomed to a variety of new avenues for testing and personal healthcare.

Technology to Support Consumer-Driven Testing

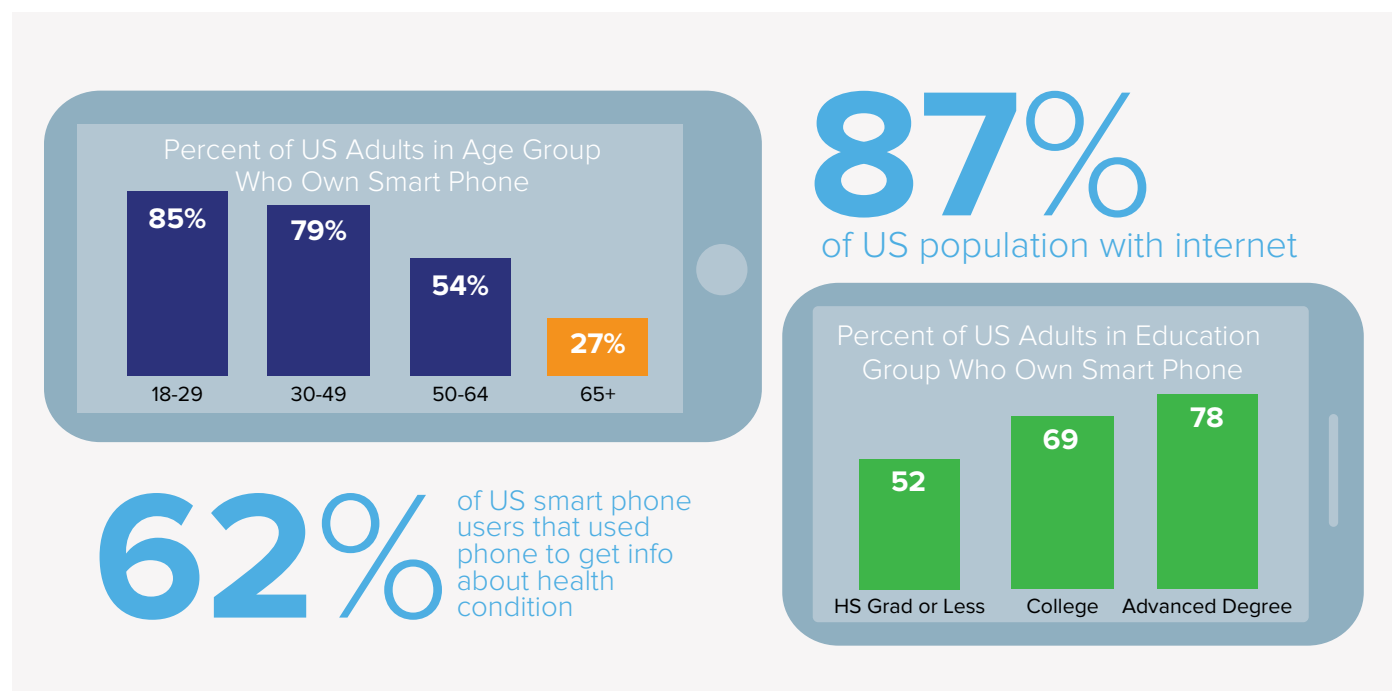
Technology is a powerful enabler of consumer self-care. As the healthcare infrastructure grows and enables greater consumer access to testing, the core advantages of healthcare technology can truly come to the forefront. For instance, technology greatly facilitates the monitoring, sharing, and evaluation of one's own personal health. In addition, technology serves as an efficient interface through which consumers may interact with and inform healthcare professionals regarding factors such as critical health indicators, trends, and outcomes over time.

National regulatory changes have supported the move towards higher usage of technology that complements and enables OTC medication. In 2012, the FDA established the Non-prescription Safe Use Regulatory Expansion (NSURE) task force to investigate new strategies for converting prescription-only drugs to OTC status. Following this initiative, experts cited new technologies (e.g., smart phone apps) as promising strategies for consumer self-care, particularly for conditions such as hyperlipidemia, benign prostatic hypertrophy, and migraines. This heightened focus on technology for the management of OTC medications could generate a new category called "e-OTC drugs". For these select medications, product selection might involve in-store kiosks, online platforms, or smart phone apps to assess patient eligibility and promote better compliance.

In addition to regulatory initiatives, there are additional technology factors which drive consumer behavior towards embracing self-testing devices. In the US, these factors include: rising internet and smart phone access and capabilities, greater access to EHRs and patient portals, and a growing trend towards consumer self-management through constant smart phone integration into consumers' daily lives. For cholesterol testing in particular, the availability of new, convenient, and consumer-friendly testing technology is a paradigm shift which could impact both the growth and longevity of the consumer-driven cholesterol testing market.

Widespread **internet access and broad smart phone ownership** are key contributors to the growth of the consumer-driven cholesterol testing market. Approximately 87% of the US population has access to the internet¹⁹, with continued growth anticipated. Furthermore, by 2017, 1.7 billion smart phones and tablets are forecast to have at least one mobile health app installed²⁰. This increased smart phone access and usage has enabled consumers to more actively track and manage their own health. Out of the total population of smart phone users in the US, 62% have indicated that they used their smart phone to obtain information about a health condition²¹ (Visual 6). Coupled with the rise in technologies designed to better track and manage personal health conditions (an estimated 42 million wearable health and fitness devices were shipped in 2014)²², greater access, awareness, and visibility of health information is empowering consumers to be more directly involved in their own healthcare.

In the US, smart phone usage for care management across different consumer groups varies. Young adults (ages 18–29) have the highest proportion of smart phone ownership (85%), whereas older age brackets exhibit lower smart phone ownership; only 27% of consumers over the age of 65 own a smart phone. Notably, this 65+ age group falls within the target population for statins (45+ for men and 55+ for women), creating a situation in which consumer need is not adequately matched by their technology usage.

Visual 6: Growth in Employer-Driven Screenings and Wellness-Based Initiatives²⁰

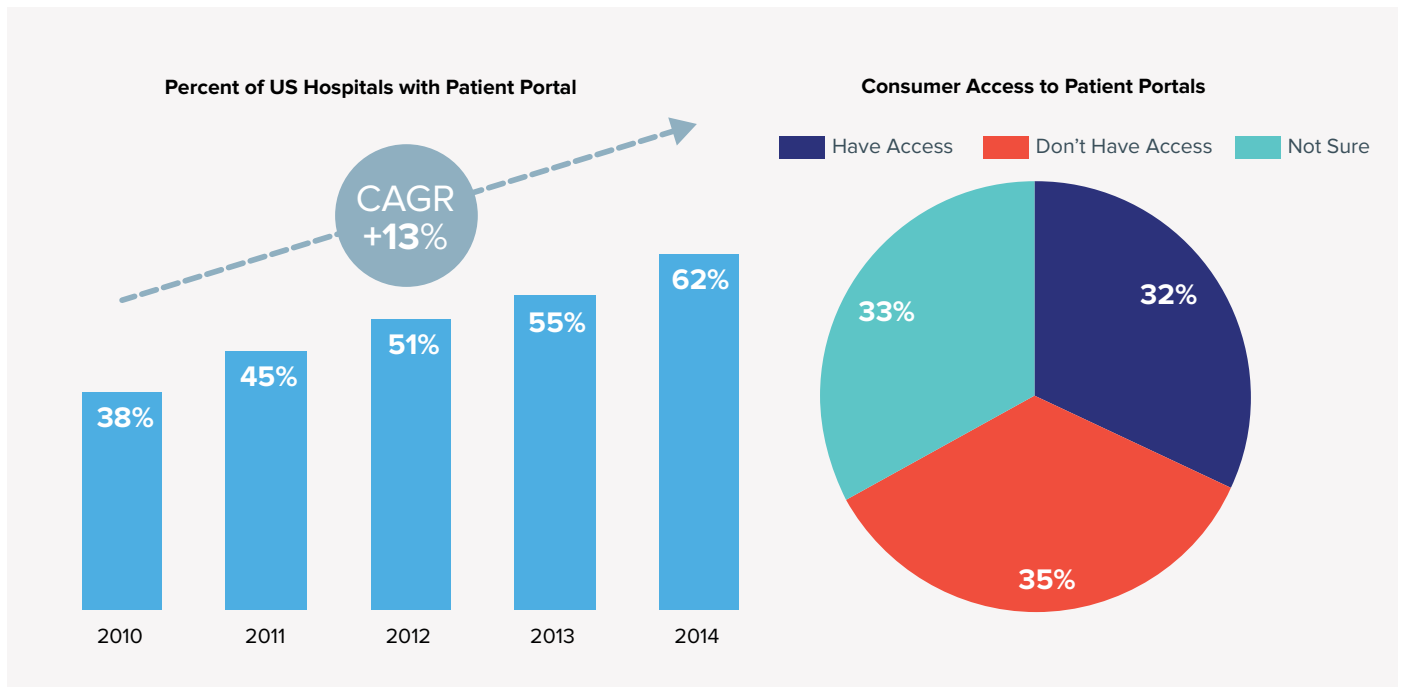
Americans in medically underserved communities, such as African-Americans and Latinos, are also far more likely to be dependent on smart phones for online access and are consequently more likely to use their phones to obtain health information. These variations could present certain challenges for the consumer-driven cholesterol testing market. In order to surmount such obstacles, smart phone and internet access for a variety of population groups will need to be supported.

Beyond internet access and smart phone ownership, the development of **electronic health records and patient portal systems** supports the consumer-driven cholesterol testing market. Most importantly, growth in EHRs will continue to both promote and necessitate data transparency in healthcare, as well as increased coordination across multiple settings of care. Overall, data integration between off-site screenings, retail clinics, and providers will improve consumer awareness, interest, and ability to carry out in self-management and consumer-driven testing. There are, however, significant barriers to EHR adoption that must be addressed, including costs, technical concerns, interoperability, learning curve, and system organization issues.

In addition to EHR systems, patient portals will bolster the cholesterol testing market by enabling greater consumer access to health data. Patient portals are secure online websites that provide consumers with 24-hour access to personal health information (e.g., lab results and medications)²³. In the US, the patient portal market is expected to grow at 26% CAGR between 2012–2017²⁴ (Visual 7). Payers and Integrated Delivery Networks (IDNs) are driving some of this growth by using patient portals to reduce internal operational costs and shift more responsibility to consumers. To date, though greater opportunity and infrastructure growth is present for patient portals supporting consumer-driven cholesterol testing, adoption has still been low – only one third of adults report having access

to a patient portal, and the other two thirds either do not have access or are unsure if they have access. Generally, these trends mirror consumer behaviors in relation to personal engagement with healthcare, and specifically, they reflect critical challenges associated with OTC medicine and self-testing requirements. Looking forward, strategies that are cognizant of shifting attitudes will be important for ensuring improved access to test results, as well as driving growth in the OTC medication and consumer-driven cholesterol testing markets.

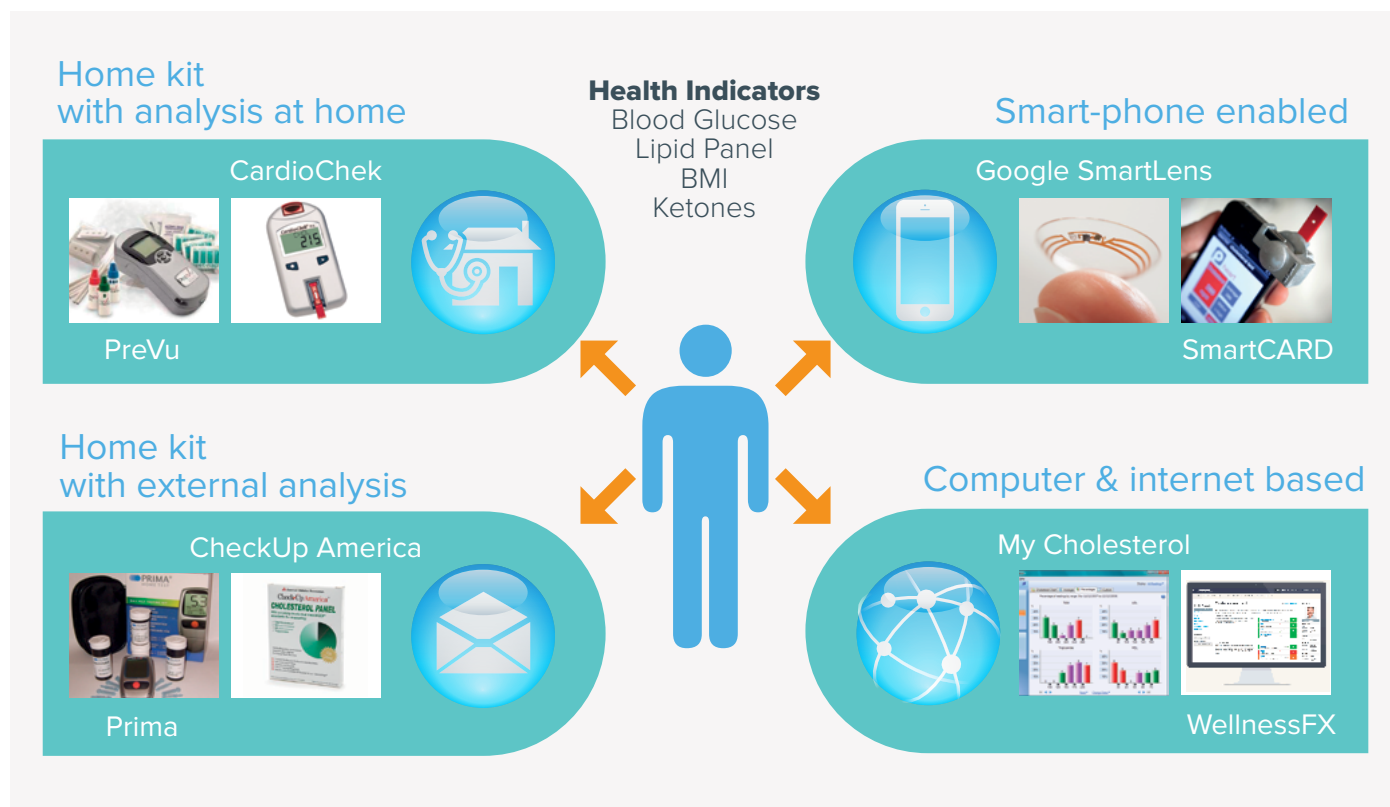
Visual 7: Patient Portal Growth and Access in the US^{25,26}



Finally, **new healthcare technologies** that are designed to test for specific health indicators are poised to jump-start the consumer-driven testing market (Visual 8). A myriad of platforms and technologies are emerging for consumer-driven testing, including those that are smart phone-enabled (apps and accessories) or computer- and internet-based, home kits with external analysis, and home kits with at-home analysis. The smart phone-enabled testing platforms are particularly exciting examples of new this new set of technologies. For example, the Cornell smartCARD is a smart-phone enabled device that optically detects biomarkers in a drop of blood, sweat, or saliva²⁷. To evaluate cholesterol levels, the user puts a drop of blood on a cholesterol test strip, which processes the blood through a series of flow-through separation steps and chemical reactions. The strip then undergoes a colorimetric analysis via the smartCARD accessory, which simply clamps over the phone's built-in camera and allows a clean read-out of the user's cholesterol levels from the test strip. These photos can be further processed and analyzed by **computer and internet-based systems**, making it significantly easier for consumers to access and manage their own care.

Another incredible technology under development (though not currently available for cholesterol testing) is a contact lens that can measure glucose levels. Novartis recently announced a partnership with Google to develop a “smart” contact lens that monitors the wearer’s blood sugar levels with a miniature sensor and transmits this data to a smart phone, which can then inform the lens wearer of his or her glucose reading²⁸. This technology is an innovative example of the self-testing evolution from invasive (e.g., finger-prick) to non-invasive (e.g., tears). These smart phone-enabled devices embody the future of self-testing and are continually breaking self-testing norms. In addition to smart phone-enabled technologies, digital photos from smart phone cameras have been used to detect elevated levels of cholesterol through analysis of creases on fingers²⁹.

Visual 8: Trends in Consumer-Driven Testing Technology



Home kits with external analysis represent another category of testing technologies that further enable consumers to self-test for cholesterol. Consumers can purchase or order a testing and collection kit for preparing and mailing a sample to a collection center for external analysis. The laboratory results become available online, by phone, or by fax. The main concerns for these types of home kits, however, include the limited amount of information which can be accurately retrieved by the consumer, and how reliably consumers can interpret instructions and data. Even with a sophisticated home test, a doctor visit may still be required to fully understand test results within the context of other risk factors such as family history, nutrition, age, or other medications.

Several **home kits with analysis at home** are also available as testing options. These kits can provide rapid readings of total cholesterol, but most do not provide specific LDL-C levels and the accuracy is sometimes brought into question. For these types of kits, non-invasive tests and mini sensors are gaining momentum. An example of a non-invasive test is the skin cholesterol test, which uses a detector reagent that can be deposited directly onto the skin and subsequently read out using a spectrophotometer (e.g., PreVu³⁰, Cholesterol 1,2,3³¹). This technology allows non-invasive cholesterol testing prior to the recommended blood tests, which are more sensitive but also more invasive. Mini sensors can be paper-thin, portable, and disposable, and some examples include printed batteries, nanobiosensors, printed displays, mobile phone interfaces. These non-invasive platforms for completely at-home analyses have several advantages, including providing painless testing, greater convenience, and simpler readouts.

Ultimately, adoption of these testing technologies will depend on consumer and HCP perceptions of their usefulness and accessibility. Moreover, a balance must be struck between simplicity and accuracy – reducing the complexity and sophistication of home-based or smart phone-enabled technologies must not be done in such a way that sacrifices detection sensitivity. Sleep tracking mobile apps provide a useful analogue: they are highly intuitive and simple to use (e.g., FitBit sleep tracking can be turned on/off and automatically synced with the web site or app) but they are still perceived as accurate, which has led to significant consumer uptake.

While there are a variety of platforms for consumer-driven testing, the market is still in its early stages. Consumer adoption and attitudes, broad engagement with cholesterol self-management, and manufacturer support and investment in new technologies are major forces that could significantly impact the growth of technology supporting the consumer-driven testing market.

Regulatory Environment for Consumer-Driven Testing

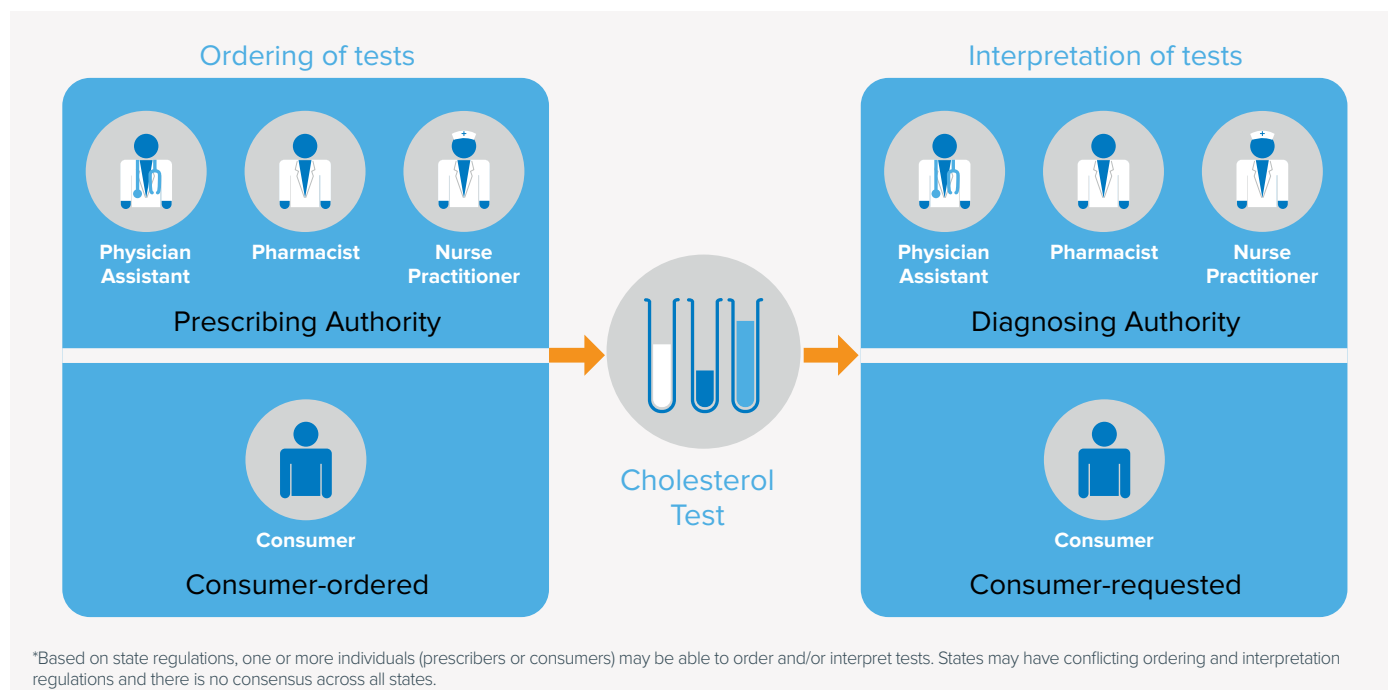
Regulation also strongly impacts access to and interpretation of self-tests. Thus far the regulatory environment, both at the national and state levels, has responded to market changes in the healthcare space in a range of ways. On a national level, the US Department of Health & Human Services (HHS) has issued regulations through the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which stipulate that patients must be allowed direct access to their diagnostic records and health data if they request it³². This action was not taken as a result of law or a pending bill, but rather reflected an evolution in thinking within HHS: consumers should have greater involvement in their own care. In 2014, the passage of the Clinical Laboratory Improvement Amendments (CLIA) further solidified consumer ability to access test results³³. Furthermore, under the Affordable Care Act at least 15 free preventive services (including cholesterol, blood pressure, and obesity screening) and one wellness visit are covered in major medical plans sold after 2014, without requiring copays or coinsurance, regardless of whether an individual's deductible has been met³⁴. While this change in perspective and policy demonstrates the progressive nature of national institutions, it also illuminates the degree to which state laws are lagging.

Beyond the national baseline, states independently set their own regulations and this has led to a wide range of policies regarding the ordering and interpretation of tests. Specifically, each state sets its own regulations for the roles of HCPs and learned intermediaries, including physicians, nurse practitioners, physician assistants, and pharmacists. These regulations widely differ, as some regulations may promote or hinder one or more individuals and stakeholders depending on the state. Some states, such as Arizona, have designed specific regulations on DAT that specify whether consumers can order their own tests, independent of physicians.

Significantly, state legislation is usually enacted to protect patient and consumer privacy, rather than to enable the growth of testing. This underlying motivation should be considered when evaluating the regulatory environment from the perspective of consumer-driven testing. The multiple layers of regulations, coupled with the variability across state lines in terms of specifying who can order tests and interpret health information, greatly increases the complexity of the self-testing environment (Visual 9).

Different HCPs are able to participate in the ordering and interpretation of tests to varying degrees. Most states require physician oversight for a nurse practitioner (NP) to write any prescription, including diagnostic tests. As the roles of NPs and physician assistants (PAs) expand, though, consumer access to testing sites and their ability to interpret data could expand as well. For instance, NPs and PAs are now legally allowed to prescribe cholesterol tests. In addition, non-traditional stakeholders, such as pharmacists are increasingly being allowed to offer and interpret tests. In addition, about half of the states in the US have established provisions for pharmacists to have "provider status". This strengthened role of pharmacists and other stakeholders in prescribing and ordering preventive healthcare tests could drive growth in the consumer-driven testing market.

Visual 9: Regulations Can Limit Consumer-Driven Testing*



On the consumer side, individual state regulations specify whether consumers can order their own tests. In the US, 25 states have laws addressing who may order and/or receive clinical laboratory test results; 20 states do not include laws on testing; and 6 states have laws directly addressing an individual's ability to order tests or access laboratory results. Therefore, even though a 2014 mandate from HHS required that all consumers have access to their health data, state regulations are still severely limiting one of the few pathways for consumers to directly manage their health without needing an intermediary HCP.

IMS Health believes that the regulatory environment does not directly enable growth of the consumer-driven testing market, per se; rather, the market pushes for regulatory changes and healthcare regulation plays a reactive role. This phenomenon is happening in many areas as non-physician stakeholders have been proactively calling for changes in the regulatory landscape. In fact, several regulatory changes have already occurred in response to shifts in market demand, technology, access, and healthcare infrastructure. For example, lab testing companies such as Theranos have been lobbying states to allow consumer-ordered blood tests: In April 2015, Theranos successfully worked with Arizona lawmakers to establish regulation that enables patient-ordered tests³⁵. Prior to that, in January 2015, the American Pharmacists Association (APhA) and National Community Pharmacists Association (NCPA) both supported a senate bill to expand the pharmacist's role in biometric screenings such as blood tests^{36,37}. Initiatives like these have led to important regulatory changes, and multiple states are now engaging in active legislation on several topics including pharmacist status in administering tests, reimbursement and billing of non-physician-ordered tests, and HCP and consumer ability to interpret health data. While there are instances in which regulation can be a barrier to growth in consumer-driven healthcare, there are also clear examples of regulation responding positively to market dynamics in order to enable consumer-driven testing.

Utilization and Uptake of Consumer-Driven Testing

The final signpost of evolution in the consumer-driven testing market is utilization and uptake. Currently, utilization of consumer-driven testing in cholesterol still appears to be low, despite significant infrastructure and accessibility improvements. This low utilization is driven by several factors: low consumer knowledge of LDL-C, limited consumer understanding of how to self-test, and low consumer awareness of existing self-testing options and affiliated resources. Pfizer's recent AUT, which was designed to simulate OTC use of Lipitor 10 mg, illustrated these dynamics. As previously mentioned, this AUT did not meet its primary objectives of demonstrating patient compliance with respect to achieving regular patient re-testing and having consumers take appropriate action based on their LDL-C level test results. In response to the study results, Pfizer terminated the program. It is important to note, though, that the trial's endpoint evaluated the percentage of patients who complied with the direction of checking LDL-C level – it did not specify whether the testing was accessed through a physician or a non-physician-mediated method. In other words, while this AUT suggests a disconnect between sponsors' expectations and consumer understanding of how to determine whether they should use a particular OTC drug, it does not indicate that consumers are not ready to safely and accurately self-manage OTC medicines. Growing consumer adherence to medical tools and systems (e.g., apps and Rx refill call systems) demonstrates that there is indeed promise for consumer-driven testing.

In addition to growing consumer adherence, increasing physician shortages and longer wait times, coupled with shorter consultations, are collectively bolstering the consumer-driven testing market. With respect to the **increasing physician shortages**, the demand for primary care physicians is growing while the supply continues to decline. According to a report by the Association of American Medical Colleges' Center for Workforce Studies, the demand for physicians will outpace supply through at least 2025. If the physician supply and demand pattern remains unchanged, the US will experience a steep shortage of 124,000 full-time physicians by 2025³⁸. This shortage will be particularly acute in primary care settings, which are the first stop for newly insured patients to engage with the healthcare system. As a result of reduced access to primary care, many patients have resorted to seeking non-emergency care from emergency rooms (ERs), leading to a 10% increase in ER volume between 2013 and 2014³⁹. This increase in volume is largely due to limited access to appropriate medical services; less than a third of ER patients truly require treatment in an emergency department⁴⁰. As some common services such as routine testing redirect away from primary care physicians, the consumer-driven testing market will likely grow.

Longer wait times and shorter consultations are also motivating consumers to seek alternative avenues of care. The average amount of time between making an appointment and actually seeing a doctor is 18.5 days⁴¹, and consultations average about 20 minutes⁴². Though consultation times have been increasing in the last decade, almost half of all appointments are now 15 minutes or less, due in large part to the increased demand on a physicians' time⁴². These dynamics may lead consumers to pursue testing through avenues that do not require a physician visit.

Increasing consumers' engagement with their own healthcare and well being will lead to an increase in self-testing, especially in terms of exercise monitoring – wearables such as the FitBit are taking off in the market. In addition to exercise, consumers are adopting apps which help them track their food intake and sleep patterns. This movement could have a positive effect on consumer-driven testing due to growing consumer interest in, perceived ease of use of, and awareness and understanding of, these technologies. For example, FitBit is currently partnering with companies to offer integrated and customized wellness and health tracking tools and systems to help consumers meet their wellness program goals. Companies are also taking steps to provide employees with gym memberships and other health-related tools and benefits.

OTC and new technology availability are also fueling consumer interest and awareness of self-testing. Availability of OTC medicines that require regular monitoring could incentivize utilization of self-testing. As consumers are increasingly exposed to OTC medicines at pharmacies and new settings of care, their mindsets will move toward a new norm in which self-medication and self-management become regular daily routines. Growth in patient portal presence and usage is making personal data more accessible and consolidated, including standard biometric data such as cholesterol levels. This heightened access and interaction with personal healthcare data encourages consumers to take greater involvement and control of their own care programs. Additionally, emerging consumer-friendly testing technologies such as smart phone-enabled devices, home kits, and internet-based platforms may also drive increased demand for, and willingness to adopt, self-testing among consumers. Particularly now, as wearable and smart phone technologies become increasingly popular and OTC medications become more available, growth of consumer-driven testing will likely follow suit.

Conclusion:

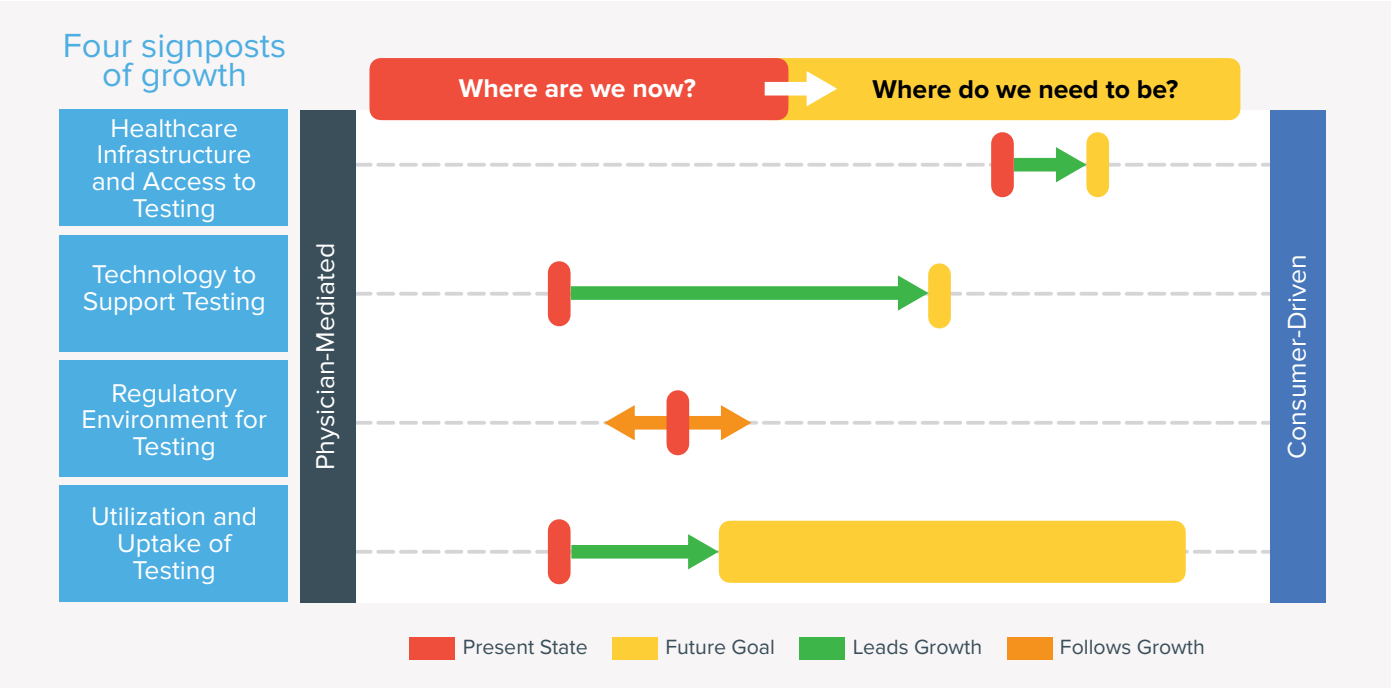
Consumer-Driven Testing Market is Poised for Growth

Considered collectively, the four essential signposts discussed in this report illustrate the current state and potential evolution of the consumer-driven cholesterol testing market (Visual 10). These signposts build an environment in which the market is not only better prepared to shift, but also increasingly primed for growth. In total, the consumer-driven testing market is very well positioned for growth. The magnitude of this growth will ultimately depend on several factors, including: infrastructure and access to healthcare platforms, new and innovative healthcare technology, regulatory environment shifts, and consumer utilization and uptake. More specifically:

- **Infrastructure and Access:** Healthcare infrastructure is changing and promoting greater consumer access. These changes include MCOs shifting cost burdens to patients, emergence of ACOs, expanded EHR systems, and new settings of care. The transfer of responsibility by MCOs to consumers enables consumer-driven testing, particularly because it encourages consumer awareness and self-management. ACOs, EHRs, and new settings of care further broaden the impact of healthcare data availability and enhance care coordination. With systemic healthcare changes driving more consumers to take responsibility over their health, and with numerous avenues available for consumers to access testing without visiting a physician, access is currently very high. As access improves, it will continue to provide a stronger foundation for the consumer-driven testing market.
- **Healthcare Technology:** Given the high, and ever-increasing, access to smart phones and the internet, consumers can, and will, take greater ownership over self-monitoring. For cholesterol testing in particular, technology to support consumer-driven testing is still relatively nascent, but developing. As accessible and user-friendly products like the Cornell smartCARD reach the market, technology will be a leading factor in creating a more consumer-driven and consumer-friendly testing market. Furthermore, expansion of patient portals is facilitating consumer engagement by making personal data more accessible and consolidated, and the increasing number of consumer-friendly testing technologies such as smart phone-enabled devices, home kits, and internet-based platforms will drive increased demand for, and understanding of, self-testing across many consumer segments.
- **Regulatory Environment:** Currently, regulation varies significantly at the state level and is under negotiation in many states. As regulations supporting consumer-driven testing tend to follow in response to market dynamics, the advancement of technology and access will likely drive changes in regulation. As a result, regulation currently still leans toward a physician-mediated testing model, but it is certainly in flux. Testing companies such as Theranos, professional associations such as the American Medical Association, government agencies such as the FDA, and other interested parties are in discussions with lawmakers regarding the regulation of consumer-driven testing, which has yielded some positive outcomes. Ongoing efforts by private companies and advocacy will also help regulation progress in favor of consumer-driven testing.

- Utilization and Uptake:** Utilization of consumer-driven cholesterol testing is currently relatively low, as demonstrated by the recent OTC Lipitor AUT results. However, utilization is primed for growth. The magnitude of growth will depend on a number of factors, including the level of consumer-driven engagement with healthcare, the degree to which employers and health plans shift accountability to consumers, uptake of patient portals, shifts in healthcare infrastructure, evolution in regulatory support, and availability of consumer-friendly testing technology.

Visual 10: Current Outlook on the Consumer-Driven Cholesterol Testing Market



While the infrastructure exists and is growing for consumer-driven cholesterol testing, the market has not yet taken off. Market dynamics over the next several years will continue to determine the evolution and trajectory of consumer-driven testing. As companies consider Rx-to-OTC switches, monitoring the self-testing landscape will be a critical task. Observing and evaluating the signposts of growth outlined in this report, and summarized in Visual 10, will provide a fundamental understanding of the consumer-driven testing space and will alert companies to favorable shifts. Ultimately, these signposts represent important markers that allow companies to make better-informed investment decisions on OTC programs.

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