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US Device Market ♦ Analysis

Acceleration, Unpredictability



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Complexity & Opportunity

A Few Global Themes

At 17.9% of US GDP¹ the US healthcare market is ripe for revolution; remaining, barriers to entry are staggering. A young chap in his garage creating a bit of wicked patient tracking code is likely to fail to deploy; he lacks 'access.' A large multinational holds the engineers to revolutionize medicine without the necessary risk tolerance or alacrity to adapt to market change, access without flexibility. The engineer that wants to revolutionize healthcare will find entrenched systems resistant to her brilliant ideas. Software programmers will bemoan the massive, inflexible structures of modern day ACOs and corporate healthcare systems. Moreover, software engineers today are leaving closed architectures (MSFT, Salesforce, Sitefinity) in favor of

¹ <http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS>

open source platforms (Drupal, Android, SourceForge, Github, Python). It can be said that software (proof, validation, big data) will be king and devices queen (cost reduction, outpatient, accountability).

Robotics, life extension, genomics, and nanomedicine offer extraordinary developments in enabling longevity and extended health in those with suitable finances and risk-tolerance. US healthcare total spend will slow based on projected slow economic growth. Some 30 million jobs within the US are low-skill, low-wage many of which are likely to be replaced by computers/robots within the decade; consider 3mm fast food workers, 2mm drivers, etc. Whether $\frac{3}{4}$ of these individuals learn new skills or millions of new types of jobs open is uncertain. Strong arguments exist both in favor of robot teams tolerating inefficient humans and in recognizing new classes of emergent occupations, i.e. in engineering, code, admin, etc. US position as an 80% service-economy vs. less than 15% manufacturing may indicate that vast wealth polarization will unfold, much worse than we observe today. Global health market will expand significantly, fueled by demand within China, Brazil, India, and other emerging economies. In absolute dollars, healthcare and quality of life investment will likely comprise the largest, or close thereof, component of global technology spend. Cost of devices will drop to nearly nothing. We project that healthcare and wellness will become currencies, top areas of investment, and essentially the primary areas in which cultures invest. Technology and healthcare will become inseparable.

Barriers to entry remain staggering for virtually anyone entering the healthcare space other than providers. Consolidation is the soup of the day and will remain as such through 2020. While engineering and software systems are experiencing reduced barriers to entry per accessibility in building IOS/Android apps, per 3D printing and the consumerification of electronic manufacturing, moving from idea to implementation in healthcare systems will be prohibitive. R&D spending is up slightly across the largest researchers, but we project R&D spend will level out per consolidation/acquisition as well as per delayed and expensive costs to clinical studies. We question whether or not the current insurance model and its concomitant requirement for multiple independent randomized control trials (RCTs) will sustain given the speed at which consumers seek access to deploy current strategies, drug and device inventions targeting chronic health conditions. Drug trials should be accelerated as individuals choose to bear more risk. Medtronic's R&D spend reflects overall slowing of R&D growth, 2011 \$1.47B, 2012 \$1.49B, and 2013 \$1.55B²; while slightly up, overall medical sector R&D is down based on cost of trials and long development timeframes.

Consolidation & Standardization

The major themes across healthcare over the next 15 years will be:

- Consolidation
 - All types of healthcare systems, providers, networks will consolidate. Small facilities will lose contracts and will fail to meet operational efficiency demands.
- Standardization
 - Systems will standardize clinical protocols across all verticals.
- Disintermediation
 - Per cost cutting all players will strive to reduce duplication.
- Risk Adjustment
 - Risk and associated cost will be shifted onto otherwise risk-reduced parties based on overall insolvency within the system. As there is not enough capital to meet overall healthcare demand, patients will increase in risk share, physicians will be paid less and bear more or the same risk, manufacturers/vendors will bear increased risk in a 'pay-for-performance' model.

US Medical Device Market

Global medical device market was estimated at \$330B 2013, expected growth by 6% through 2017, including durable and consumable medical equipment and supplies sold to healthcare institutions and professionals,

² <http://www.mn2020hindsight.org/view/medical-device-taxes-rd-impact>

including implants, genetic analyzers, and bent metal (beds) as example.³ Market cap estimates underweight a likely revolution in available devices per 3D printing and novel therapeutics.

Medical devices primarily span the following market segments: 1) anesthesia, critical care, patient monitoring, 2) cardiology/vascular, 3) diagnostics, 4) dental, 5) diabetes, 6) gastrointestinal, 7) general hospital, 8) neurology, neurosurgery, pain, 9) ophthalmology, 10) orthopedic, 11) radiology/imaging, 12) renal, 13) spine, 14) general surgery, 15) urology, obgyn, 16) wound care, infection management/prevention.⁴

4 Primary Opportunities for Major Growth

1. Firstly, we anticipate a massive opportunity per population demand for large, entrenched manufacturers and new entrants to develop new therapeutic and/or diagnostic devices.
2. Secondly, a major growth arena will be private payer consolidation across vendors, reduction in size of networks (fewer providers), downward price negotiation and proof of work modeling and/or shared risk models. Alliances between payers, both commercial and federal, and large provider systems or ACOs will emerge.
3. Thirdly, we observe major opportunity for value chain disintermediation, meaning that manufacturers should begin to eliminate and/or consolidate distribution methodologies (e.g. similar to Wal-Mart and Amazon). Manufacturers should embrace direct shipping, reduced patient-provider interaction per cost cutting, and general consolidation of manufacturer distribution across fewer models (direct-to-patient web, large pharmacy chains, large regional players).
4. The fourth and final encompasses integration and process standardization en masse. Large care delivery systems will move to clinical policy guideline / disease pathway driven care, employing devices, telemedicine, and integrated teams of providers. Systemic integration within healthcare systems will act as a counterbalance to downward payer price pressure and conflict consolidation.⁵

Rise of Wearables Impending

- Global wearable medical device market was \$2.0B 2012, expected rise to \$5.8B 2019, CAGR 16.4%.⁶
- Wearable and mobile technology growth will increase rapidly, opening new ecosystems for data analysis and integration into IOS/Android platforms, smart personal home integration.
- Devices will be split between Therapeutic (pain, glucose/insulin, respiratory) and Diagnostic (vital signs, fetal, obgyn, neuromonitoring) aids.
- Applications will include sports/fitness/lifestyle/wellness, remote patient monitoring, home health, telemedicine.
- Wearable devices will emerge and become standard use for nearly all individuals in developed world in heart rate, pulse oximetry, blood pressure, electrocardiogram, neuromonitors, and fetal monitors.

Medical Device Market Drivers

- US, Europe aging population growing by 3% vs. <1% overall pop growth, 10k hitting 65/day.
- Barriers to entry for technological innovation lowered, high demand for mobile, portable, devices that improve quality of life, mobility.
- Clinical trial prohibitively expensive, major players like Medtronic reducing R&D, devices will favor cash-pay consumer market based on challenges, years+ in obtaining payer approval.
- Continued broadening of and pecuniary challenges in regulatory requirements in developed countries.
- High adoption of developed market devices and medical structures expected in China, Asia-PAC, LATAM
- State and federal other post-employment benefits (OPEB) will outstrip tax base, care determinations will need to make sense financially vs. economic output as opposed to being a 'right to care.' A de facto restriction in care based on ability to pay, location, payer plan will force a multi-tiered system.

3 <http://decibio.com/globalmedicaldevices>

4 <http://decibio.com/medical-devices.php>

5 http://www.researchandmarkets.com/research/5f7559b9/durable_medical_eq

6 <http://www.transparencymarketresearch.com/wearable-medical-devices.html>

Market Moderators

- Venture capital investments in health tech devices down based on regulatory, study cost. A less favorable risk-reward profile is observed by VC per longer development time-lines and increased regulatory burden. While more consumer devices may hit, fewer will move through insurance billing.
- Medical device taxation a near guarantee; Medicare insolvency likely during 2020s.
- US economic system ripe for correction based on cycles (1989/1990, 2000/2001, 2008, 2015-2016 ??). Volatility at near all-time low, debt to GDP, service-based economy, no room for errors in Fed policy based on 0% interest rates since 2008. Overall public healthcare spend will be lowered mitigated by slow US economic growth (3% growth in Q2'14 is mitigated by -1% growth in Q1'14).
- Downward price pressure for all medical devices (non-services) via hospital consolidation and GPOs.

Other Market Factors

- Anti-aging market will reach \$191B global 2019; nanomedicine market \$177B 2019.⁷
- Risk sharing models emerging with manufacturers, hospitals, and customers. Market moving away from transaction-based to model in which vendors hold responsibility for long-term outcomes, examples would be joint implants, internal pain/neuromodulators.
- Risk sharing emerging in which payers will price rapid deployment through future risk sharing, e.g. CMS' Technology Innovation Committee which will bypass clinical trials.
- Service-based models emerging along multiple vectors. Physicians moving towards concierge care (\$1500/year all inclusive) vs. episodic care, patients carry catastrophic coverage but assume responsibility for all small out-of-pocket.
- Manufacturers moving into service business models via pay-for-performance and to reduce hospital readmits or never events, example being Medtronic's 2013 \$200m acquisition of Cardiocom, partnership entity to provider in CHF management.
- Customized solutions needed for emerging markets. Entitlement to 'one solution for all' unlikely to scale in emerging markets; patients prefer low-cost devices and bear high personal cost. Tiered structures in partnership with local systems (India, China) expected.⁸

US Durable / Home Medical Equipment Markets

- US DME market cap of \$27B 2009 is estimated at \$34B in 2013, continued growth through 2020 expected in mid to high single digits (Reuters, 2012).⁹
- Global cardiac medical device market expected at \$68.6B by 2015, annual growth rate of 9.8%. The US market comprises 40% of global market in cardiac devices, Europe at 30%. Asia-Pacific cardiac market at 11.6% of total (highest growth potential across all verticals).¹⁰

Key Trends within HME/DME

- Consolidation expected among all top-tier entities (e.g. Covidien/Medtronic) for product diversification, operational scale, tax inversion.
- Healthcare provider consolidation resulting in fewer unique customers, larger individual customers increase purchasing power.
- EHR/EMR integration and interoperability across enterprises suggests that coordination of providers, ancillary care, devices may all be required; integration in large EHR systems required.
- Consolidation of medical devices expected per demand for multifunction devices vs. specialized products, improved price metrics, reduced footprint/space for customers.
- Redistribution expected leading to US growth and market dominance secondary to emerging markets China, Mexico, Brazil.
- Rise of 'Big Data' and 'proof-of-work' methodologies expected to require manufacturers and providers to utilize data to prove efficacy, movement from event- to outcome-based medicine.

7 <http://www.transparencymarketresearch.com/wearable-medical-devices.html>

8 <http://decibio.com/medical-devices.php>

9 <http://www.reuters.com/article/2012/03/26/idUS188949+26-Mar-2012+BW20120326>

10 <http://www.healthmarketscience.com/industry-news/medical-device-field-see-large-growth-2015>

DME Market Ripe for Consolidation / Process Innovation

- DME market is highly fractured without great penetration and coordination with national chains. Major opportunities exist for consolidation, process standardization, and cost control per efficiency.
- Strong national providers, Lyncare & Apria Healthcare, control respiratory, oxygen, aspects of mobility.
- Fastest growing areas are diabetic and obesity-related management.
- No consolidation, disparate groups of providers in women's health, maternity, ortho, wound care.
- Large opportunity for effective web portals for consumption of info and purchase of products

US Job Market, a Function of Healthcare

The US Bureau of Labor Statistics (BLS) data on the 20 fastest growing occupations speaks volumes about the health of our society and its demographic underpinnings. Healthcare is heavily represented as 13 of top 20.

OCCUPATION	GROWTH RATE, 2012-22	2012 MEDIAN PAY
<u>Industrial-organizational psychologists</u>	53%	\$83,580 per year
<u>Personal care aides</u>	49%	\$19,910 per year
<u>Home health aides</u>	48%	\$20,820 per year
<u>Insulation workers, mechanical</u>	47%	\$39,170 per year
<u>Interpreters and translators</u>	46%	\$45,430 per year
<u>Diagnostic medical sonographers</u>	46%	\$65,860 per year
<u>Helpers--brickmasons, blockmasons, stonemasons, and tile and marble setters</u>	43%	\$28,220 per year
<u>Occupational therapy assistants</u>	43%	\$53,240 per year
<u>Genetic counselors</u>	41%	\$56,800 per year
<u>Physical therapist assistants</u>	41%	\$52,160 per year
<u>Physical therapist aides</u>	40%	\$23,880 per year
<u>Skincare specialists</u>	40%	\$28,640 per year
<u>Physician assistants</u>	38%	\$90,930 per year
<u>Segmental pavers</u>	38%	\$33,720 per year
<u>Helpers--electricians</u>	37%	\$27,670 per year
<u>Information security analysts</u>	37%	\$86,170 per year
<u>Occupational therapy aides</u>	36%	\$26,850 per year
<u>Health specialties teachers, postsecondary</u>	36%	\$81,140 per year
<u>Medical secretaries</u>	36%	\$31,350 per year
<u>Physical therapists</u>	36%	\$79,860 per year

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Of the 20 fastest growing work fields, 11 are hands-on healthcare professionals, meaning patient-care and non-administrative. We observe two distinct segments, one is high-skill (radiology techs, genetics, PT, OT, PA with incomes of \$50-90k), and one is low-skill (home health, personal care, PT and OT aides, skincare). Two categories are support staff to healthcare professionals, health teachers and secretaries/admins. A few other interesting kernels being, 1) skincare specialists at \$28k with 40% growth suggests that the aging population will spend disposable income on youthful appearance, 2) demand for low skill health workers vastly outnumber

demand for high-skill implying a transfer of burden of care to assistants. We would expect to see drastic rise in the 20-40 fastest growing arena among field such as APRN, RN, LPN, x-ray tech, weight-loss counselors, dieticians, and additional support staff related to disease management, specifically diabetes and obesity.

Our question is simple: What comes after 2022-2032 when the nation has, possibly, met the needs of its 68 million boomers? What is the future path for these unskilled healthcare workers? Moreover, how will they invest in a better, high-skill future for their children, let alone make ends meet on a \$30-40k median salary. From 2022-2032, the nation will continue to stratify, predicting further wealth polarization, based on the low-skill, high-skill divide. While all of these healthcare workers will arguably secure moderate incomes in the coming years, likely through 2030, upward growth and class mobility is unclear.

Future Health is Likely to Surprise

At TED 2014, television-legend, Charlie Rose, asked Google co-founder, Larry Page, what state of mind has best served him. Rose noted that Rupert Murdoch offered 'curiosity' and Bill Gates and Warren Buffet noted 'focus' as their go-to state. Rose specifically asked, "What has enabled you to think about the future *and* change the present." One of the greatest visionaries to walk this planet, Page offered: [quote]

Lots of companies don't succeed over time. What do they fundamentally do wrong? They usually miss the future. I try to focus on that: What is the future really going to be? And how do we create it? And how do we power our organization to really focus on that and really drive it at a high rate? When I was working on Android, I felt guilty. It wasn't what we were working on, it was a start-up, and I felt guilty. That was stupid! It was the future. [end quote]

We say in healthcare that if your assumptions are right, you have a reasonable shot at predicting the future. The mobile OS, Android took 79% of global share of smartphones in 2013; Page's pet project will likely move to power the majority of consumer electronics, period. Apple's IOS is a relatively closed architecture. Google has made massive bets that open-source languages like Android will be faster, safer, more secure, and more widely adopted than closed codebases. Page informs us adaptability is elusive; likewise, inflexibility / incorrect assumptions are sticky. Unspoken is our predilection to hold to inaccurate positions in the face of unpleasant recognitions.

To know the future of healthcare, we need not look too much further than the 15-25 y/o demographic. Gaming and the gaming behavioral modification layer, devices of all kinds, interaction/social, community/shared experience, and challenges in diet/exercise/nutrition are all near-givens. While great strides have been realized in smoking cessation, mapping long-term rewards (future health) to unpleasant present action (delayed gratification, reduction in immediate satiation, lack of discipline) remains a massive challenge.

Small startups health apps, smart watches, vital sign tracking, telemedicine platforms all predict integrated care, behavior tracking, and data. We break here from the traditional care model of doctor-patient visits and emerge into something akin to computational therapeutics, diagnostics, disease management, and tracking. At first glance, one might argue that the opportunities in transforming outcomes through incentive and behavior hacking could be game-changing. At second glance, one might ask whether or not consumers will be well-enough incentivized by payers to adapt and how providers will thereof monetize the mobile-connected, always-transmitting patient.

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