

Innovative Medicine: The Balance Between Benefits and Costs

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Executive Summary

There are two ongoing debates around the impacts of innovation in medicine: to what degree are rising health care costs attributable to new technologies and are those costs worth the outcomes benefit? "New or expensive" shouldn't be the sole criteria for judging whether we adopt new therapies as a society.

Health care costs across both the developed world and countries with emerging economies have risen too drastically in recent years due to increases in economic well-being, population, and the price of the industry's products and services.

Many argue that these costs have expanded from the introduction of new, more expensive medical goods and services. Two controversial debates exist in the current literature on what degree of the cost increases are attributable to new technologies, and more importantly, whether or not the rise in costs are justifiable in actually improving patient outcomes.

The Great Recession and other economic forces have pressured governments, private health care providers, and payors around the world to constrain cost growth by reducing the prices of these new products, prolonging the approval process, and utilizing health technology assessments.

Some of the existing methods of cost containment are poorly conceived, incompletely executed, or inferior to alternative approaches that offer more promise. The ultimate test for any medical intervention must satisfy the following guidelines:

- (1) whether or not a product or procedure truly advances patient welfare, and
- (2) whether or not it improves outcomes at a sustainable cost across the American population.

Any balanced value proposition for health care treatment must incorporate these two factors. Innovative interventions, drugs, devices, and procedures can meet both these guidelines and should not be discarded solely because they are new or expensive.

Existing Health Care Paradigm and its Fundamental Flaws

Finding a viable and sustainable set of policy solutions to address the rising cost of health care and improve outcomes is clearly needed. However, a leading expert on health care spending, William Baumol, argues that there are valid reasons to spend more on health care as a society improves its economic situation.

The benefits of improved health outcomes are not merely determined by clinical measures, but also by economic productivity gains at the societal level. When–in part as a result of productivity improvements–people see income gains coupled with lower overall relative levels of spending on food, housing, or transportation, it is natural to escalate the value associated with improved health outcomes.

Health spending on genuine innovation should not be jeopardized by efforts to thwart incorporation of new products into the existing pool of health care intervention options. There are simply too many alternative policy options and choices to secure savings that can be pursued instead of putting in jeopardy initiatives to find cures for major chronic diseases, whose consequences are part of the root cause of increased health spending.

In the United States, for example, current improvements in the treatment of cardiovascular disease do not outweigh the influence of rising population age, obesity, and other demographic factors on cardiovascular disease risk. The average 10-year risk of cardiovascular disease for men and women may rise from 12.7% and 6.8%, respectively, in 1991 to 15.1% and 8.6%, respectively, in 2030. Clearly, the impact of chronic illnesses such as cardiovascular disease is one of many important factors that will continue to fuel the rise in health care costs.

That doesn't mean any health spending is good spending. The rise in health care costs in the United States relative to its GDP growth in recent years is clearly not sustainable.

In the U.S., there is currently no coherent health care system.² Together, the federal and state governments act as: (1) a regulator and standard setter, (2) an enforcer of the rules of competition, (3) an arbiter of intellectual property rights, and (4) a purchaser or payor.

Over several decades, instead of a single payor or government-run health care function, we have adopted a system that includes—in the main—private delivery of care at the physician and hospital level.³

The complicated and layered nature of the existing health care system and its associated downsides require that new policies, laws, or programs need to be implemented beyond just the governmental level. To properly address escalating costs, it must also include private medical providers, insurance companies, employers, and patients.⁴

The non-system health care regime in the United States leads to "wasteful public and private spending, and avoidable health problems for patients. Health care providers tend to practice medicine in silos and fail to coordinate care when patients transition across health care providers and settings," according to what the Brookings Institution's Mark McClellan and Alice Rivlin say in a 2014 paper on improving health while reducing costs. "This fragmented delivery system leads to duplicative and avoidable services and complications, particularly for the growing number of patients with complex chronic conditions who account for most health care costs."

Nearly 50 years ago, Harvard professor Joseph Newhouse offered an assessment of spending that strongly suggested that more than one half of the growth in health care costs was attributable to new technologies. In the intervening decades, researchers—including Newhouse himself—have refined that measurement.

In 2013, health care spending in the United States was \$ 2.8 trillion, and overall spending on prescription medicines was \$329 billion, according to National Health Expenditure data. The most current independent reviews by United States and European officials suggest that between 27% and 48% of health spending increases are tied to the rise of new technologies. What is less clear, however, is how much benefit these new products and services have delivered.

McClellan and David Cutler, among other leading scholars, have demonstrated that some new products have improved outcomes for certain major diseases such as heart attack, depression, and low birth weight in babies. Improvements in outcomes for AIDS as well as Hepatitis C have also been phenomenal in the past 20 years. Others have offered similar data for other diseases or conditions, especially including the benefits that flow from the use of vaccines and targeted cancer treatments. Yet, it is also beyond doubt that some products and interventions either do not work or are too expensive to justify their costs.

The central debate about how to respond to technological interventions presents a paradox: on one hand, virtually every government worldwide is seeking to encourage the development of biotechnology by pursuing inventions from the genome revolution and new life sciences-based interventions to improve health outcomes. On the other hand, these same entities, as well as their counterparts in the private sector, seek to constrain the application of what they claim are products that are not "worth it."

Current methods of cost containment are not effective overall and can stifle innovation. The most common tool used by governments to contain spending has been price controls. Among the leading markets in the world, virtually all use some form of direct price controls on drugs and medical devices. ¹³

While this approach is commonplace, it is dependent on the United States' relatively freer market bearing a disproportionately larger share of the burden of research and development risks. Without this U.S. subsidy, a global price control regime would dramatically reduce the number and quality of new medicines and medical devices.

Most jurisdictions also contain growth by applying overall health budget ceilings, rationing new products, and/or setting budgets for hospitals and doctors. ¹⁴ Many governments have also sought to layer onto those methods additional steps at the approval process stage (e.g. limitations on which type of physician can use certain new products or de facto constraints upon approval through mandated comparisons between new drugs and the standard of care, rather than a placebo) or at the stage of coverage and reimbursement.

Health authorities now routinely require health technology assessments (HTAs) that use relatively crude instruments to weed out what intervention is allegedly worth the cost. More often than should be the case, these assessments are superficial rationales to deny or limit coverage and/or leverage for a lower price. The unfortunate effect is that HTA reviews and payment systems often end up being too restrictive to reward innovation.

The fundamental flaw in the existing methods of cost containment revolves around two different contextual realities. First, by assessing only new drug and devices, other cost advancing techniques—including unnecessary use of expensive tests, diagnostics, surgery or other interventions—are left out. ¹⁷ Importantly, when the U.S. government and its affiliated payors look only at new products, they run the risk of precluding a thoughtful analysis of pre-existing and often unproven or ineffective interventions.

Second, the methods of price control, rationing, or HTA-like reviews also ignore the need to better align the interests of patients, providers, and payors. These two factors help make the existing methods of cost containment difficult to achieve both innovation for new medical products and a significant reduction in health care costs.

Proposed Policy Changes and Alternative Solutions

Ultimately, any effective health care policy must address two questions laid out at the beginning: whether patient welfare is improved and whether such improved outcomes come at a sustainable cost.

Follow the Willie Sutton Rule of going where the money is. The principal focus for cost containment needs to be on where the money is. Current levels of health spending in the United States clearly show that over 50% of the spending flows to doctors and hospitals, ¹⁸ compared to 19% total for all drugs, biologics, generic drugs, medical devices, and diagnostic tests. ¹⁹

Thus, aiming to secure a bulk of savings from constraining new drugs, biologics, and devices is misplaced. More money can be saved from cutting waste and fraud.^{20,21} It is estimated that federal savings for the Centers for Medicare and Medicaid Services in Medicare and Medicaid could be up to \$98 billion per year from cutting waste.

Focus on the most burdensome diseases and conditions. The prevalence of obesity and diabetes is exceedingly high: 69% of the United States population is either obese or overweight. The health care costs of these twin epidemics are staggering at \$250 billion per year, according to the American Diabetes Association and the trade group AdvaMed.²² The Congressional Budget Office used slightly

different metrics to reach the conclusions that treatment of overweight patients costs about 70% more than treatment for people with normal weight.²³ The prevalence of obesity is responsible for 12% of the spending growth between 1987 and 2001.²⁴ However, no country in the developed world can affect the cost curve from obesity and diabetes by treatment improvements alone.²⁵ Policy initiatives must go beyond the treatment-oriented targets used for these conditions to incorporate a massive concentrated prevention effort in both the public and private spaces. Behavioral interventions—or, as Richard Thaler and Cass Sunstein called them, "nudges"—are required. Societal and behavioral interventions will need to be comprehensive and, in the era of social media dominance, linked to mobile and ubiquitous communication applications.

Especially for diseases or conditions that are amenable to behavioral interventions—including diet and exercise—it is important to aggressively focus on the use of behavioral economics to alter personal actions. The level of smoking in most developed countries has dropped markedly over the past two decades. These developments are due to comprehensive, behavioral policy changes (e.g. tax increases, limits on sales to minors, and health education campaigns funded in part by those who profit from smoking) and subtle changes in social attitudes. Decades ago, the act of smoking was very trendy, whereas today that storyline is less prevalent. Obesity has formed the basis for considerable humor in film and television, but recently it has taken a more balanced public health approach.

Policy or other social interventions for obesity and diabetes have focused on nutrition charts publicized by the government. A careful review of the relevant literature points away from some common reforms, ²⁶ but offers encouragement that a combination of policy measures can work. ²⁷ Empowering consumers to make more intelligent and informed choices has the possibility of "nudging" different behaviors and can lead to more positive health outcomes.

Organizational alignment in the US. Greater use of measures to put "skin in the game" by patients through rational co-payment policies. Varied deductibles are good first steps.²⁸

For organizations like health insurance companies, full consideration and implementation of value based insurance—i.e. benefit plans that use financial incentives to promote cost effective health care services and patient choices—should move to the front of the line. ^{29,30}

For example, plans that cover wellness visits, preventive care, and other lower cost treatments may allow both patients and payors to save money by reducing the risk of needing more expensive procedures in the future. Plans that incorporate high cost-sharing for medical choices that may be unnecessary or repetitive can also create an effective disincentive for consumers to pursue, which can ultimately bring down costs and improve outcomes.

Hospitals and others can see the power of positive and negative incentives already underway in the Medicare system through hospital readmission rules.³¹ Under the Affordable Care Act (ACA), CMS is required to reduce payments to hospitals with excess readmissions based off of an excess readmission ratio calculation on risk adjusted expected readmissions. More "nudges" to hospitals are needed.

For the combination of payors and providers, a more rapid adoption of bundled or capitated (or fixed, pre-arranged payment schemes regardless of patient needs) payment schemes can—if implemented with sufficient patient quality standards—permit the use of the best products and processes without an arbitrary bias in favor of older interventions.^{32,33}

Aligning the interest and incentives for the various stakeholders in health care: Under the ACA, a system of shared savings helps to coordinate the interest of various stakeholders. Expansion of that program and accelerating its implementation can help deliver more value for money. Ultimately, the faster the movement from fee-for-service and its concomitant incentives to practice medicine by volume-oriented metrics and the sooner we can get to a treatment/payment paradigm based on episodes of care and payment for performance, the better off we will be.

Accountable care organizations (ACOs) and the use of "medical homes" in care delivery have just begun to make a dent in the structure of health care delivery in the United States.³⁶ More rapid adoption of this model can integrate care choices with risk, while still permitting a patient-oriented set of choices to be made.

Defensive medicine. The Congressional Budget Office (CBO) estimates federal savings from medical malpractice reform at \$57 billion over a ten year period from 2014 to 2023.³⁷ Despite the political posturing of our two major political parties and the self-interested advocacy of the medical profession and the legal community, there is something profoundly wrong with the current application of our civil liability or tort system to medical injuries.

Too few injured parties receive compensation, and those few who make it through the process can be disproportionately benefited. More importantly, the overall practice of medicine has not shown significant improvement as a result. The costs associated with the practice of defensive medicine—meaning the unnecessary use of tests or treatments—in anticipation of potential or hypothetical financial exposure, the increased costs of unnecessary care, and the accompanying malpractice costs for the health care system are too high.

There are better, fairer, and faster ways to respond to medical injuries that do not get in the way of improved practice guidelines or add unnecessary costs to the system. The use of "practice guideline" compliance as a safe harbor defense in medical malpractice cases would be a good first step.³⁸

Evaluations of value. In making technology assessments, government and private payors should operate on the following principles: (1) use facts and sound science for decision making, (2) act with openness and transparency, (3) make conclusions derived from valid data, (4) act with fairness, and (5) maintain incentives for innovative new products.

These reviews should not start with just new products, but should also apply to all products, especially with those that drive costs up the most and those which are most prone to conflicts of interest and abuse. The best way to evaluate new products or interventions is not at the time of approval, but after a period of years beyond approval based on real world data. Experimentation on pay-for-performance or warranties should also be undertaken.^{39,40}

In sum, health care spending is growing faster than what is economically sustainable, but we need to be cautious about how to cure the underlying problems. The flawed structure of our health system and hence the prevalence of fraud and abuse are major contributing factors to year-over-year health spending increases. While it is a mistake to ignore those issues, it will be equally mistaken to enact poorly targeted and counterproductive measures like adopting price controls or rationing and screening only new products. Instead, we need to adopt structural changes to our health delivery system that put consumers more in the game, better align the economic interests of payors and providers, and maintain sufficient incentives for the development and application of new technologies.

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Endnotes

² The Institute of Medicine's *Best Care at Lower Cost: A Path to Continuously Learning Health Care for America* (2013) makes a compelling case that health care delivery in the United States is inefficient and uncoordinated.

⁶ Smith et al. 2009

- ⁷ See McClellan and Rivlin in "Improving Health" (2014) and Cutler in "The health-care law's success story" (2013).
- ⁸ See Economic Report to the President (2013).
- ⁹ See Sorenson, Drummond, and Khan in "Medical technology is a key driver" (2013).
- ¹⁰ See European Commission's European Economy: The role of technology in health care expenditure in the EU (2010).

¹¹ See Volpp, "Choosing Wisely" (2012).

Regarding cost and reform for cancer treatment, the American Society for Clinical Oncology (ASCO) has called for "...a more rational system for drug pricing... coupled with efforts to ensure that drug companies are still able to recoup their investments in high-risk, high cost research ... to sustain innovation". The article "Turning the Tide Against Cancer Through Sustained Medical Innovation: The Pathway to Progress" (2014) also stresses the need to use evidence-based medicine and change in insurance coverage. The article "Delivering High Quality Cancer Care: Charting a New Course for a System in Crisis" (2013) stresses the need for better translation of best practices into regular care, improving the performance of health care providers and better measurements of quality. See also Fuchs and Milstein's "\$640 Billion Question" (2011) on dissemination of best practices in medicine.

¹³ While this approach is commonplace, it is dependent on the United States' relatively freer market bearing a disproportionately larger share of the burden of research and development risks. Without this U.S. subsidy, a global price control regime would dramatically reduce the number and quality of new medicines and medical devices.

¹⁴ See Henry J. Kaiser Family Foundation's "Snapshots: How Changes" (2007).

¹⁵ See Knight's and Male's "NICE methodology" (2013).

¹⁶ See *BioCentury* (2014) report. For a useful and relatively neutral review of the structure and techniques used to conduct health technology assessment, see the World Health Organization's report, "Health Technology Assessment of Medical Devices" (2011) funded, in part, by the Bill and Melinda Gates Foundation. This report makes excellent reading by describing the regulatory reviews of health products, such as product safety and efficacy, and contrasts those mechanisms with the private sector and governmental review of such products after product approval. It is the later stage of review that is often used to determine the conditions of use of a product, permit or deny the product to be covered by insurance, and occasionally help set the price of the product. The report also distinguishes the implementation role played by medical providers such as hospitals and physicians in determining how and when to use a product—drug, biologic, medical device or diagnostic—in medical practice.

Some—including the trade association representing the medical device association in the United States (ADVAMED)—have asserted that health technology assessment can work if one fully takes into account the clinical outcome of the product, the patient experience in terms of both economic, social factors, and quality of life factors, as well its ability to sufficiently reward innovation. These groups have also pointed out the flaws in making technology assessments at the time of marketing authorization. Newly approved products often—of necessity—lack real world data about how the product will be used in routine medical practice. In addition, the cost of using a new technology may vary over time and location from the data collected during a clinical trial. Lastly, new products, especially new drugs and biologics, can secure additional value through the use of such products in new diseases or indications. In the United States, in particular the oncology field, the off-label use of cancer agents is common. It is difficult to completely measure the value of such products until a more macro picture emerges on how the product will be used across all conditions or indications.

¹⁷ For an analysis of current health care spending on old ineffective services and products, see Reinhardt's "Can Medical Technology Solve the Health Care Problem?" (2010) Reinhardt argues that new medical technologies, such as imaging devices and other diagnostic tools that can be available at a fraction of their current cost, can economize on the use of labor in health care, which currently remains highly intensive in all health systems. According to the article, there currently are 4.5 working-age Americans for each person over 65 and 2.2 for each person over 65 or under 20.

¹⁸ It is also worth noting that some doctors—for example, those in the Federal Medicare program—are "super users". The top 1% of doctors (out of a total of 825,000) accounted for 14% of all Medicare spending (*WSJ*, April 2014). 344 physicians and other health care

¹ For his arguments, please see *The Cost Disease: Why Computers Get Cheaper and Health Care Doesn't* (2012).

³ For a review of the role of government in promoting technology in American history a worthwhile review is found in Michael Lind's book, *The Land of Promise: An Economic History of the United States* (2013). See also Mariana Mazzucato's *The Entrepreneurial State: Debunking Public and Private Sector Myths* (2014) and William H. Janeway's *Doing Capitalism in the Innovation Economy: Markets*, *Speculation and the State* (2012).

⁴ See McClellan and Rivlin in "Improving Health" (2014) from the Brookings Engelberg Center for Health Care Reform (Hereinafter in the Endnotes section referred to as *McClellan/Rifkin*). The non-system health care regime in the United States leads to "wasteful public and private spending, and avoidable health problems for patients. Health care providers tend to practice medicine in silos and fail to coordinate care when patients transition across health care providers and settings. This fragmented delivery system leads to duplicative and avoidable services and complications, particularly for the growing number of patients with complex chronic conditions who account for most health care costs." Also, see Cosgrove in *The Cleveland Clinic Way* (2014), which demonstrates how quality care can be delivered.

⁵ Source of total health spending can be found in the Centers for Medicare and Medicaid's "National Health Expenditures" (2013). Source for prescription data can be found in the IMS Institute for Health Care Informatics' "Medicine Use and Shifting Costs of Healthcare" (2014) (Hereinafter, *IMS 2014 Report*). In 2013, the most important factor putting downward pressure on prescription drug costs was the page in use of generic drugs, which now account for 86% of all prescriptions.

¹² There has been a relatively dramatic increase in dialysis and joint replacements in the past several decades. See Skinner's "The Costly Paradox" (2013) and the CBO's *Technological Change and the Growth of Health Care Spending* (2008). Recent research also points to overuse of brain scans for headaches.

providers received more than \$ 3 million in compensation each in 2012, and the top 1,000 doctors received \$3 billion in payments. Interestingly one third of the top earning doctors are ophthalmologists and one out of every ten is a radiation oncologist. See Whoriskey, Keating, and Sun's "Data uncover nation's top Medicare billers" (2014) for some of the reasons for high ophthalmology payments.

¹⁹ In 2012, for the first time in 58 years, Americans spent less on prescription drugs than the previous year, according to a report by the *IMS Institute for Healthcare Informatics* (\$325.8 billion vs. \$329.2 billion) and average spending dropped by \$33 per person per year. Some of the drop comes from a number of brand name products losing their patent protection and facing dramatic price competition from generic drugs. Others come from seasonal factors such as a milder flu and cold season. But importantly, this drop also reflects, in part, the increase in patient payment responsibility and increased out of pocket payments (e.g. co-payments, or self pay).

See Institute of Medicine's Best Care at Lower Cost (2013).
 See Lowrey's "Study of U.S. Health Care System" (2012).

²² The following are diabetes statistics obtained from ADA and ADVAMED that illustrate the need for preventative approaches:

- 1) Cost of treatment: \$245 billion in 2012, up from \$174 billion in 2007 (\$176 billion in direct costs and \$69 billion in lost productivity)
- Number of patients: 26 million, with up to one in three adults to have diabetes by 2050
- 3) Costs per patient: More than 2.3 times the average patient without diabetes
- 4) Diabetic health cost breakdown: Hospital (43%); Rx to treat the complications of diabetes (18%); antidiabetic agents and supplies (12%). Overall, 62.4% of the cost of diabetes is born by the US Government

ADVAMED claims that evidence shows that between \$34,000 and \$57,000 is saved every year for every 100 patients who use insulin pumps. Moreover, medical device price increases over the past 20 years have only been 1% per year, and devices are only 6% of overall health care spending.

²³ See CBO's "How does Obesity in Adults Affect Spending on Healthcare?"

²⁴ See Thorpe in "The Impact Of Obesity" (2004).

²⁵ See Waidmann, Ormond, Bovbjerg in "The Role of Prevention in Bending" (2011) and the Robert Wood Johnson Commission to Built a Healthier America's "Time to Act" (2014) for a more expansive view of how to best address population health with a special focus on engagement of communities and early childhood interventions.

Also, see Sunstein's *Simpler: The Future of Government* (2013). Patients play a key role in their own care. Incentives or "nudges" for patients to adhere to their medication schedule, maintain a healthy diet, exercise regularly, and seek to lower their stress levels can also beneficially improve outcomes and lower health care costs.

²⁶ Examples of policies that may be suboptimal include the following: (1) limiting food stamps only to healthy foods, (2) taxing food based on sugar content, or (3) ending farm subsidies. For more information, see Alston, Okrent, Parks in "U.S. Food Policy" (2012). ²⁷ Examples include innovation in food production and manufacturing or the elimination of junk food from schools. See Alston, Okrent, Parks in "U.S. Food Policy" (2012). For examples of possible policy impediments to the development and marketing of obesity products, one needs to go no further than the usual Medicaid rule against reimbursement for "weight loss" drugs. The other hurdles for new drugs in this space are outlined by *Prevision Policy* in their paper "Obesity Rx Policy Update" (2014). Some FDA related hurdles for marketing approval, the increasing cost and scope of post-approval surveillance, and post-marketing surveillance responsibilities are highlighted.

An excellent example of the merging focus between diabetes/obesity as a therapeutic area and cost reduction through the imaginative use of on-line tools is Omada. This firm is a venture-backed enterprise aimed at educating patients about weight loss, measuring their health progress, and securing both improved health outcomes and reduced costs. Early adopters of this approach include Kaiser Permanente and Blue Cross Blue Shield of Louisiana. For more information, see Business Wire's "Omada Health Closes \$23 Million Series B" (2014).

See Herzlinger in "Why Innovation In Health Care" (2006). Michael E. Porter also makes similar arguments.

In the case of co-payments, extreme caution is advisable. As Dana Goldman and Tomas Philipson have noted, there could a serious discriminatory effect of co-payment policy that disadvantages the sickest patients (e.g. those with cancer and who have to use expensive biotechnology products and also have a high absolute out of pocket co-payment). Note: In the *IMS 2014 Report*, it was stated that "30% of patient prescription out of pocket costs came from just 2.3% of prescriptions, often high-cost specialty medicines or seniors in the donut hole port of their Medicare Part D coverage."

According to IMS 2014 Report, 20% of patients now have a high deductible health insurance plan.

²⁹ A. Mark Fendrick was one of the individuals who named the concept "Value-Based Insurance Design." See also Volpp et al. "Choosing Wisely" (2012).

For a comprehensive review of the relevant literature on the possible cost savings consequences of payment and insurance reform see *McClellan/Rikfin*.

For an example of an innovation in insurance, see Oscar: this firm uses on-line techniques to gather, store and easily disseminate to consumers health care data. Importantly, Oscar also seeks to make the choice of doctors and treatment options more transparent and consumer-friendly. Information can be found in *The Economist's* "The geek guide to insurance" (2014).

In addition to the extensive experimentation with innovative payment schemes the private insurance market is taking steps in this regard as well. See Raskas' "Early Results" (2012) and Shewry's "Health Reform: How Philanthropy" (2012), all describing work by WellPoint Inc., WellPoint Foundation, and the California HealthCare Foundation to focus on the use of medical homes, accountable care organizations (AOs), and bundled payment systems. See also *Solving Disparities* website (www.solvingdisparities.org) for incentives like payments for reaching certain HbA1c goals (applicable especially to Blacks and Hispanics.

³⁰ See Hansard, "Bloomberg BNA: Value-Based Insurance" (2014). Also see *The Better Care, Lower Cost Act (S. 1932)* Senate bill introduced by Senator Ron Wyden (D – Oregon) and *Securing Care For Seniors Act of 2013 (H.R. 2753)* House bill introduced by Representative Diane Black (R – Tennessee). While value-based insurance design has some promising results for high risk patients, even with free medicine, there are compliance and adherence issues.

² See Emanuel's Reinventing American Healthcare (2014).

CA) and Andy Barr (R. - Kentucky).

³⁵See Antos' "Bending the Curve" (2013) for a comprehensive and long term agenda

³⁶ Brookings points out that ACOs and their participation in the Medicare Shared Savings Accountable Care Organization Program (MSSP) have led nearly one half of the MSSP ACO participants to save money (but only 29 of the 114 participants saved enough to receive a financial benefit under the terms of the program). While still in its early days, ACOs seem be following a trend that suggests that physician-led ACOs are more likely to save enough to earn funds under the program than hospital-led enterprises. This program may or may not have broader applicability as structured. There may be a bias in the program that rewards ACOs from higher cost states because if one starts higher, there could be additional ineffective treatments or a more suboptimal structure to cut or alter.

³⁷ See CBO's *Limit Medical Malpractice Torts* (2013). For an example of legislation that codifies the concept of "safe harbors" for medical providers who follow practice guidelines, see H.R. 4106 (The Saving Lives, Saving Costs Act) by Congressmen Ami Bera (D –

38 It is important to aim for the benefits of the genomic revolution and move in a measured manner toward precision or personalized medicine. As Bill Gates warned in another context, we need to avoid excessive hype in the short term, but also recognize that deeper changes can take longer. See Gates' *The Road Ahead* (1996). While there are risks of overhyping the application of big data or the latest scientific advance in gene sequencing and analysis, the preliminary and early steps for some diseases like cancers of various sorts are encouraging. Although we all have a long way to go before we get to a truly personalized standard of care, if we process with modesty what we truly know and underplay the potential cost savings in the short term, there is a high likelihood of medical productivity improvements.

See Cosgrove in *The Cleveland Clinic* (2014) for a comprehensive review of the remarkable progress made by the Cleveland Clinic in personalized medicine.

Just as Economist Robert Solow famously stated that the only place information technology showed productivity gains was in economic models, in fact productivity gains lagged behind Moore's Law by several years. Advances in medicine from surges in computing power for sequencing will take some time before the insights from sequencing and analysis are routinely applied to most common diseases.

39 See DeCoundres in "How Will We Bend" (2013).

⁴⁰ See "Dissenting Opinions" by David Beier in *HHS in the 21st Century* report (2009). Also see *MEDCAC* May meeting summary (2012).

³¹ See the Bipartisan Policy Center's "A Bipartisan Rx for Patient-Centered Care" (2013), which focuses on delivery and payment reform with Medicare as a center piece.

³³ See DeCoundres in "How Will We Bend" (2013).

³⁴ Michael E. Porter has made similar arguments.

CBO Publications

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Options For Reducing The Deficit: 2014 to 2023 (November 2013).

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