

# Health Care Reform's Impact on the Pharmaceutical Market and Costs

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My topic today is health care reform and its impact on the pharmaceutical market and related costs. As an overview, my talk today will include a discussion of the role of health care in the U.S. economy. If you have listened to the news in the last few years, you have heard lots about these topics. Next, I will talk about the Affordable Care Act, Accountable Care Organizations (ACO's) and health homes (aka medical homes). If you've never heard these terms, you need to find out what they are and you need to pay attention to them. After that, we will talk about new models of pay for performance in health care, about delivering value, and about drug use, costs, and value. Finally, I will comment on the need for more R&D.

## Health Care & the Economy

I always like to ask the audience a few questions to put health care in perspective. First, "Is there anybody here who has never been sick a day in your life?" Now, go ahead and raise your hand if you've never been sick a day in your life. I don't see any hands. Next, "Is there anyone here who has not needed or used a prescription drug ever in your life?" Again, please raise your hand. Again, I don't see any hands.

The reason I ask these questions is to remind us that nearly everyone needs, has used, or will use prescription drugs in their lifetime. There is virtually a universal demand and need for prescription drugs, and for that matter, for most of health care. We're not talking about one out of every 100 people needing health care, or even one out of every two people needing health care. We're talking about essentially everyone needing health care. Everyone also needs or will need prescription drugs at some point in their lifetime. So we're talking about something that has a universal demand. That's good news and bad news. The good news is there is a lot of demand out there for prescription drugs; the bad news is we don't have all the resources we need to pay for all of that demand. The health care market, whether it works or not, is in operation and creates many issues that have come to our attention.

Let me illustrate this concept of a nearly universal demand for prescription drugs. An epidemiological study of the drug use by the U.S. population has been done.<sup>1</sup> So first, let me ask you about the adult population (i.e., the non-elderly who are age 18 to 64). What do you think is the percentage of the adult population who would use a prescription drug in any given week? Note that I am not talking about in their lifetime, in a year, or in a month, but rather in any given week. What percent would use a prescription drug in a given week? It's about 50% of all

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<sup>1</sup> DW Kaufman, JP Kelly, L Rosenberg, TE Anderson, AA Mitchell, "Recent Patterns of Medication Use in Ambulatory Adult Population of the United States: The Slone Survey, JAMA, Vol. 287, No. 3, Jan. 16, 2002, pp 337-344.

adults, or one out of two adults, who will use prescription drugs in a week. If we talk about “any type of medication” rather than just prescription drugs, 81% percent of the adult, non-elderly population will use one or more medications in a given week. Now, when I say “any type of medication” what does that include? It includes prescription drugs, over-the-counter medications, vitamins and minerals, dietary supplements, natural and herbal remedies, and contraceptive drugs and devices. So, five out of 10 adults will use a prescription drug in a given week and more than eight out of 10 adults will use some type of medication in a given week.

So now let’s focus on the elderly population—persons age 65 and older. What percent of the elderly population uses one or more prescription medications in any given week? For the elderly population, it is about 77% in any given week. And if we ask about any type of medication, 93% of the elderly population uses one or more medications of any type in any given week. So, for the elderly, this universal demand is essentially a reality on a weekly basis. If this data was reported for longer periods such as a month, a year, or a lifetime, the percent of the population using medications would be even higher and would actually reach the level of universal demand.

Now, let’s turn to trends in U.S. National Health Expenditures. How much do we spend on health care? How is the expenditure changing over time? In general, health care expenditures are going up steadily and rapidly. They’re doubling about every 10 years. On the other hand, our economy does not double every 10 years, so what does that mean? It means that whether you are an individual, a government, or a corporation, health care costs take a bigger bite out of your wallet each year. We’re at a point where the public, corporations, and policymakers are asking, “Can we afford health care if it continues to grow much faster than the rest of the economy?” And, “Can this difference in growth rate continue forever?”

Another perspective on health care costs comes from the patient’s point of view. When a patient is sitting in the doctor’s examination room waiting for the doctor to come in, the patient is thinking, “Doctor how sick am I in dollars and cents? How much will this visit cost? Will I need any prescriptions and how much will they cost?”

So, how much does health care cost per person per year? If we look at the average cost per person per year for health care, back in 1990 it was less than \$3,000 per person. By 2000 it was nearly \$5,000. And, by 2013, the health care expenditure per person per year reached about \$9,600.<sup>2</sup> That’s the average, of course, and we know there is a wide variation across the population. Certainly, there are some people that spend a lot more than \$9,600 per year and there are some folks who spend a lot less. But, on average, in 2013 the health expenditure per person per year was about \$9,600.

For additional perspective, keep in mind that the average annual per capita health expenditure is nearly as high as the federal poverty rate for a single individual—which is about \$11,000 per year. In other words, if a person has income at the federal poverty line (i.e., \$11,000 per year) and if that same person has average annual health care costs of \$9,600 that would leave less than \$2,000 per year for all other costs of living. Examining the costs of health care in relation to the poverty line paints a pretty grim picture for persons living at, or near, that poverty line.

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<sup>2</sup> Hartman M, Martin A, Benson J, Catlin A, National Health Accounts Team, “National Health Spending in 2011: Overall Growth Remains Low, But Some Payers and services Show Signs of Acceleration,” *Health Affairs*, 32, No. 1 (2013): pp 87-99.

At the national level, what percentage of our economy has been spent on health care over time? Back in 1950, National Health Expenditures (NHE) accounted for 4.3% of our economy (i.e., Gross Domestic Product, GDP). By 1990 we spent 9%, by 2000 we spent about 13.8%, and by 2012 we spent 17.9% to 18% of our economy on health care. When one examines the share of our economy spent on health care over time, that share appears to be continually growing. There was, however, a brief period in the mid-1990s when health care as a percent of the economy (NHE as % of GDP) leveled off or hit a plateau. What was going on in the mid-1990s? Recall that Bill Clinton took office as President in 1992 and his wife, Hillary, was overseeing a series of 'secret commissions' to re-design and reform health care. At the time, the players in the health care market place were a little nervous. Health providers of all types were a bit on edge, and they appear to have 'behaved' in the market for a little while. They took steps internally to hold down cost growth, at least temporarily. But after the threat of major health reform went away, the share of the economy spent on health care resumed its continuous climb upward.

In some ways, we may be in a similar plateau today, perhaps for different reasons. Health care as a share of the economy has slowed a bit in 2010 to 2012. This plateau may be due, in part, to the reality of health reform from the Affordable Care Act which was passed in 2010 and which has been implemented incrementally over the past few years. In addition, this plateau may be due in part to the fact that the American economy just went through a major crisis – a deep recession or near depression. We're still not sure what to call it. Even though growth of the share of the economy spent on health care has slowed, health care is still growing. If the health care share continues its long-term trend upward, by 2050 we may be spending more than one-half of our entire economy on health care. Thus, we are faced with the critical question: Is continued growth of our national health expenditures as a share of the economy sustainable?

The growth rate of health care as a share of the economy has to change at some point. There are other things we like to spend money on, such as food, housing, education, or even entertainment. While some of these other things are discretionary, some are essential. We cannot crowd out all of these other expenditure categories, so this trend of health care share growth cannot continue forever. At some point, that growth curve has to bend or change. We don't know what the magic level of health care share is. I would ask that each of you think for a minute—what do you think is the maximum share of the GDP that health care will reach? Do you have a point in mind? When I ask my students that question, I get numbers that usually range from 20% to more than 50%, a pretty wide range. A few students suggest that the health care share will continue to grow forever, but at a slowing rate. They rationalize that the overall economy will grow so much that “the rising tide will float all boats, including health care.” We really don't know what will happen.

How much do we spend on the federal budget, as a whole, and where does the money go? In 2010, for example, total GDP was about \$14.6 trillion.<sup>3</sup> Two pieces of the federal budget pie that represent direct health care spending by government are Medicare (15%) and Medicaid with CHIP (8%). Those two areas combined account for about one-fourth of the federal budget. Then, if we add in social security (20%), we have accounted for almost 50% of the entire federal budget in entitlement programs, which are largely health care related. We also need to remember that there is some health care in the defense budget, too. Both active military personnel and their dependents, as well as veterans, receive health care from federal programs.

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<sup>3</sup> EconPost, “US GDP 2010,” EconPost, April 25, 2011 found on website: <http://econpost.com/gdp/us-gdp-2010>. See, also, Id., p.88.

When we add up Medicare and Medicaid, federal employees, state employees, VA health service, and all the other government programs, government is the largest purchaser of health care and prescription drugs in the U.S.

Also, notice that net interest accounts for only 6% of the federal budget. We are fortunate that interest rates have been historically low in the last few years; otherwise the effect of net interest as a share of the federal budget would be much greater. If we had interest rates of 8%, 10%, or 12%, as we have seen in past times, net interest as a share of our federal budget would be squeezing health care and every other expense category far more than it is now.

## International Health Care Comparisons

Keep in mind that what's going on in U.S. health care, like other sectors of the economy, is part of a global market these days.<sup>4</sup> There are global forces that affect both the demand for and delivery of health care. Health care costs are a growing expense in every employer's budget, and may affect their competitiveness with other corporations from around the world. In addition, issues of free trade, immigration, and employment come into play. For example, we can look at the relative amount of the GDP that other countries spend on health care. Data from 2010 on the percentage of GDP spent on health care show that countries in South Asia (e.g., Pakistan and India) spent from 2% to 4% of their GDP on health care.<sup>5</sup> Countries in Southeast Asia (e.g., the Philippines, South Korea and Japan) spent from 3% to 9.5% of their GDP on health care. In the developed countries of the southern hemisphere the health care share of GDP ranges from 8% to 10% (e.g., South Africa, Brazil, New Zealand) and in the Middle East it ranges from 6.7% to nearly 8% (e.g., Israel and Turkey). In Europe, health care as a percentage of GDP ranges from 7% to nearly 12%. Closer to home, in North America, Mexico spent 6.3% of GDP on health care and Canada spent 11.3%.

So, where does the U.S. stand compared to other major developed countries with respect to the percentage of GDP spent on health care? In the U.S. we spend a substantially larger share of our GDP on health care than any other major country. This fact alone is neither good nor bad, but one does have to ask "Are we getting our money's worth for the amount that we spend on health care in America?" An economist may answer that question by saying, "On the one hand, if you have money and can afford health care, the U.S. has the best quality health care in the world. On the other hand, if you don't have sufficient resources, you don't have access to that high quality health care." The divergent answers to this question capsule, in part, the debate that surrounded passage of the Affordable Care Act.

Since nearly all other countries spend 12% or less of their GDP on health care, how do the outcomes of their health care compare to those found in the U.S.? There are many health care indicators that could be examined. One overall endpoint measure is the average life expectancy at birth. In general, across developed countries in the world, data from 2010 show that as the total health expenditure per capita increased, the average life expectancy at birth also increased.<sup>6</sup> The data across major developed countries shows a steady upward trend line. For example, Mexico and Hungary spent less than \$2,000 per capita per year on health care and

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<sup>4</sup> Reinhardt, UE, PS Hussey, GHF Anderson, "U.S. Health Care Spending in an International Context," *Health Affairs*, 23, No. 3 (2004): 10-25.

<sup>5</sup> Total Health Expenditures as a % of GDP, Organization for Economic Cooperation & Development (OECD), found on website at: <http://stats.oecd.org/Index.aspx?DataSetCode=SHA>. See, also, The World Bank, "Health Expenditure, Total (% of GDP)," found on website at: <http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS>.

<sup>6</sup> Dan Munro, "U.S. Health Care Hits \$3 Trillion," *Forbes*, Jan. 19, 2012, found on website at: <http://www.forbes.com/sites/danmunro/2012/01/19/u-s-healthcare-hits-3-trillion/print/>.

they have a life expectancy of less than 75 years. Other countries (e.g., the United Kingdom and Japan) spent around \$3,000 per capita per year on health care, and have a life expectancy at birth ranging from 79 to 83 years. So, where does the U.S. fall on this trend line?

The U.S. is far below the trend line. We spend a whole lot more per capita per year on health care (about twice as much) than any other country; yet, we are in the middle of the pack in terms of life expectancy at birth among other major developed countries around the world. Life expectancy at birth is not determined entirely by health care, but it is a useful overall endpoint marker that is influenced, at least in part, by health care. One could examine many other measures that are related to the quality and distribution of health care across countries. In most other measures of health care outcome, the U.S. is in the middle of the pack or, even at times, at the bottom of the top 30 developed countries in the world.

Why does the U.S. fair so poorly on various health care outcome measures despite spending substantially more on health care than most other developed countries? Part of this poor return on our health care spending is due to health care distribution issues rather than quality of care issues. If we just look at the people covered by health care, we would be near the top of the pack in terms of most outcome and quality measures. But in the United States, we still have a lot of people who don't get, or even have access to, health care. This lack of access to health care brings down our performance on outcome and quality measures. Recently, I heard about an analysis of income levels in the U.S. which found that we are at a point of the greatest income disparity between the haves and the have not's that we've seen in 50 years. Such strong disparities tend to breed societal unrest and this pot is near boiling again. If these income disparities continue, we may see conditions get to a point where we have Watts-type riots like we saw back in the late '60s.

How do we summarize the role of health care in the U.S. economy? We have growing health care needs. We have advancing technology. We are the source and the engine of a lot of the innovations in health care, pharmaceuticals and devices. But at the same time, we have limited resources. We have substantial health care access and income disparities. The current trend is simply not sustainable, so something has to change. The current health care system does not meet the demands out there. An interesting read is the book titled, *Health Care Will Not Reform Itself*, by George Halverson who is the chairman and CEO of Kaiser Permanente. His basic premise is that health care just won't change nor structurally do the things it has to do to reform itself. This book outlines the situation we are in and some possible directions of how we get out of this situation.

## **The Affordable Care Act & Other Policy Options**

In recent years we have seen Washington and Congress fighting over the budget, the deficit, and the cost of health care. These factors are all tied together. So what are the options for policymakers? Well, they can raise revenue, cut spending, cut beneficiaries, cut the benefit package, or take some combination of these actions. Basically it appears to be simple, but of course it is never that simple. One approach could be raising revenue to get more money to pay for health care by raising taxes, raising premiums, or raising deductibles. Think about all three of these approaches. Do you pay taxes? Do you pay premiums? Do you pay deductibles? These resources all come out of your pockets at some point. Another approach would be to cut the number of beneficiaries. Recently, we've enacted the Affordable Care Act (ACA) to expand coverage and access, although certain groups have been explicitly excluded from the ACA. At various points in the past, we have seen policymakers trim back access to health care programs such as Medicaid.

Yet another approach would be to cut the benefit package. Health plans may limit the scope of health services covered or place limits on the type and amount of health care that is provided to covered individuals. Another alternative would be for policymakers to cut payments to providers, which in essence is saying to hospitals and doctors, “You make too much money.” Many hospitals, for example, are non-profit entities, but it is not unusual for them to have excess revenue that seems to get funneled off to other activities or to disappear somewhere. In recent years, Congress has enacted laws to reduce payments to physicians, but the implementation of these provisions has been continually postponed. It has not been easy to cut payments to providers.

Still, another approach would be to improve efficiency or to identify and eliminate fraud, waste, and abuse. The federal government is looking for fraud, waste, and abuse in health care programs. This approach has been a major focus of CMS. Just last night *60 Minutes* had a story on the disability market and people getting on the government roll for disability payments. There is a lot of fraud and abuse in that system. Periodically you hear about Medicare mills and Medicaid mills cranking out bills for services and prescriptions that were not needed or not delivered. These operations may pay somebody for their social security number or Medicare number so it can be used to bill for fraudulent services. Yet a different approach would change the incentives for provision of health care and would reward behaviors that lead to an increase in the efficiency of the health care delivery process. Certainly there is room for changing incentives and for increasing efficiency in the health care system.

Unfortunately, none of the above approaches provides a quick fix or a simple solution to financing issues in health care. In reality, we will need to pursue a combination of these approaches to resolve our health care financing and access issues. Congress passed the Patient Protection and Affordable Care Act (PPACA), or more commonly called the Affordable Care Act (ACA), in March of 2010. The Supreme Court upheld the ACA’s constitutionality in June of 2012, except for a couple of provisions, such as the requirement for states to expand their Medicaid population coverage. The ACA is real; it is Public Law 111-148. It is the law of the land, at least for now. There are people in Congress still debating whether we want to keep the ACA as the law of the land. Do we want to change it? Do we want to amend it? Do we want to repeal it? We will all watch that debate play out over the next several years.

The ACA law has over 1,000 pages. I’ve read through it three times; and, by the way, I fell asleep several times. This law is very detailed and complex. As this law was being developed, policymakers were essentially asked to put forth all of the health care proposals on which they had been working. It appears that they almost literally just stacked up all of these proposals, called it a bill, and passed it. What I mean is that there are pieces of this Act that are novel concepts, but they are not integrated very well. The law wasn’t put together in a way that allows the wide variety of provisions to articulate well. There are pieces of the law that cannot be implemented given other pieces of the law that are also being implemented. The point of these comments and this critique is to say that there will have to be technical changes at a minimum, if not major policy changes in specific details of the ACA.

## **Changes in Health Insurance Policy**

The ACA mandates a number of major changes in health insurance policy. Among the health reforms included in the ACA is guaranteed issue of insurance even for persons with pre-existing conditions. Guaranteed issue results in a major change to the structure of the insurance market. It also changes the nature of health insurance premiums. Other changes include the prohibition on lifetime caps, reforms to small business health insurance, establishment of health insurance

exchanges, and a shift toward a community rating approach with risk bands. Perhaps the most visible and most contested ‘hot button’ policy change was the requirement of mandatory health care coverage. The constitutionality of this provision was contested and the Supreme Court upheld the individual mandate. Other provisions of the ACA include low income subsidy (LIS) of premiums as well as provisions aimed at provider payment reform. Also notable is what the ACA did not include among its provisions. After reading the ACA three times, I did not find the rumored death panels. There are no death panels in the law, despite the fact that they were much talked about during the policy debate.

The ACA will establish a set of essential health benefits that will be defined at the state level. At this point, the process for determining each state’s essential health benefit set appears to be normative, as it will be based on the two or three best plans to be selected within each state. Once each state picks their exemplary plans, policy analysts will analyze and compare the essential benefit packages across all of the states. These policy analysts will look for the similarities and differences, and then will estimate the actuarial difference among these essential benefit sets. Keep an eye on variations in the essential health benefit sets across the states; because one way to cut down the costs in the short run is to just keep removing things from the covered set of the essential health benefit package. This tactic may arguably appear to save money in the short run, although it may cost money in health and life in the long run.

There are more than 75 specific programs that have to be implemented to fully put the ACA in place. This massive amount of change specified in the ACA will require 8 to 10 years to fully implement. What is the goal of the health reform program? In broad terms, its goal is provision of quality care that delivers the most health outcome for the limited dollars spent on health care. It is about managing costs and achieving value while delivering quality and improved health care outcomes with limited dollars.

It is hoped that the ACA will move us toward what has come to be known as “the triple aim.”<sup>7</sup> The “triple aim”, on its surface, is very straightforward and simple. It’s about care, about health, and about cost. However, while there are a lot of health care providers and systems that are good at any two of these goals, there are very few that are good at all three. We’re going to have to adapt and change our health care systems to take all three aims into account. In fact, when training health care professionals (i.e., physicians, pharmacists, nurses, doctors, or dentists), we don’t spend a lot of time on how to make value-based decisions—that is, decisions that balance care, health and cost. Health professionals can usually tell you what the best care is or what drug therapy can produce the best health outcome, but they often don’t know the cost or the marginal value added, if any, over other therapies. Also, providers may not know whether certain drugs or services are covered by a given health plan. If certain services or drugs are not covered, their cost may be so much that the patient cannot afford the needed therapy. If the patient cannot afford and access a needed drug, is the drug effective for that patient? Can a patient get better by staring at the needed drug on the shelf at the pharmacy? No. A person has to be able to afford and access the drug, and to take it properly in order to use it safely and effectively. Thus, cost plays a role that is critically important to achieving improved care and health.

Health care reform within and beyond the ACA will change the structure and practice of health care. Actuarial science will make important contributions by tracking health status and health care trends in new ways. A lot of what we normally do is look at the trends and assume that the

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<sup>7</sup> Berwick DM, Nolan TW, Whittington J, “The Triple Aim: Care, Health, and Cost,” *Health Affairs*, 27 No.3 (2008):759-769.

same trends will continue. We measure and model trends. We ask, “Are the trends linear or exponential or are they going up or down?” We are, however, at a point in health care where there will be dynamic structural and behavioral changes in how health care is delivered and in the underlying incentives behind health care. These dynamic changes will necessitate new models not just simply monitoring the same old trends. This means that we will see the normal trend patterns and trend curves being bent. Some will bend up; some will bend down. There will be innovative care models that require us to develop new models and measures for estimating their impact on outcome and cost. We’re in a period where the traditional health care structures are being unfrozen, redesigned, and rebuilt brick-by-brick from the foundation up. While it may not feel like it yet, and you may not see these changes yet, the major players in health care are redesigning the health system and their care models—looking for ways to be more efficient and effective.

## **New Health Care Structures**

Major structural changes are occurring in health care. Some are related to the ACA while others are independent of the ACA. Among these structural changes are new entities such as Accountable Care Organizations (ACOs) and health homes and new processes such as aligned incentives, pay-for-performance, and real-time use of electronic health records to build big data sets to improve quality and efficiency of care.

First, there are health provider entities called Accountable Care Organizations (ACOs) that are being developed.<sup>8</sup> ACOs preceded the passage of the Affordable Care Act (ACA),<sup>9</sup> although the ACA references and defines several specific types of ACOs. On the surface, ACOs look like what we were trying to do with HMO’s (Health Maintenance Organizations) when they were first being created in the 1970s. In a sense, ACOs are like a “do-over” for the HMO concept, yet there are some fundamental differences from HMOs.

Basically, an ACO agrees to be accountable for care, quality, and cost of a defined population of persons enrolled in a comprehensive health care program. ACOs typically have three essential characteristics: (1) ability to provide and manage care across the continuum and across settings of care; (2) ability to prospectively plan budgets and resource needs; and (3) sufficient size to support valid performance measurement.<sup>10</sup> There are a variety of types of ACOs including: (1) state-defined ACOs such as Medicaid ACOs in Minnesota; (2) ACA-defined ACOs such as Medicare ACOs or pioneer ACOs; and (3) private market ACOs that have developed independently from government programs. ACOs will be accountable for improving health outcomes. They will be accountable for using resources efficiently. The observed outcomes and costs of these systems will be measured and reported in transparent and publicly accessible places.

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<sup>8</sup> National Conference of State Legislatures, “Accountable Care Organizations, Health Care Cost Containment and Efficiencies, NCSL Briefs for State Legislators, No. 5, May 2010 (4pp.).

<sup>9</sup> Minnesota Medical Association, “Accountable Care Organizations (ACOs),” MMA Issue Brief, 3pp., accessed on Minnesota Medical Association website on March 25, 2013.

<sup>10</sup> Snowbeck C, “From HMOs to ACOs: Meet the newest model in health care management,” Twin Cities.com-Pioneer Press, found on March 25, 2013 on the website: [http://www.twincities.com/business/ci\\_21602399](http://www.twincities.com/business/ci_21602399).

Another recent structural development in health care is the emergence of the ‘medical home’ or ‘health home’.<sup>11</sup> Other similar names for this concept are ‘patient-centered health homes’ and ‘coordinated primary care centers.’ Health homes are essential building blocks of an ACO. There will be multiple health homes within a single ACO. Health homes are an approach to primary care in which providers (in interprofessional teams), families, and patients work in partnership to improve health outcomes and quality of life for individuals and especially those with chronic conditions and disabilities. A health home is typically at the clinic level, is located at a specific place, and is made up of a certain set of interprofessional primary care providers (i.e., physicians, nurses, pharmacists, social workers, and others) who deliver care while also assuring quality and efficiently managing costs.

Health homes are really about a team caring for the patient. It’s not just the physician in charge and the physician makes all the decisions, and everything is centered on the physician. Yes, physicians will still be the quarterback of the team. They’ll still be an essential part of that team, but there will be other health professionals around the patient who are empowered to make decisions working in collaboration with the physician and the patient. Interprofessional, team-based primary care is what health homes are all about. Health homes will deliver physician-led coordination of care. However, this model of care will move away from the physician-driven, eminence-based model of care and toward more evidence-based care.

Health homes will be responsible for evidence-based care, coordinated care, and transitions of care. They will be managing medications especially during transitions of care, supporting patient self-management, making specialist referrals, and measuring and tracking results and outcomes of care. We will be tracking and making comparisons across specific health homes within an ACO to determine their quality of care, the health outcomes produced, and their relative and absolute cost. The performance of an ACO, as a whole, will essentially be the weighted average of the health homes that participate in that ACO. The quality, outcomes, and cost performance of each health home will be tracked, and the performance of ACOs as a whole will also be tracked. The quality, outcome and cost information will be reported in a publicly accessible manner to allow consumers (and patients) to track their providers and their ACO and to hold them accountable.

A critical health work force issue is the shortage of primary care providers and in particular primary care physicians. Since physicians are paid more as specialists, the vast majority of medical school graduates choose to enter a specialty rather than primary care practice. There is also a geographic mal-distribution of physicians and other health care providers with shortages, particularly in rural and economically-distressed areas. Because of these work force issues, the new models of health care are exploring ways to change the payment system to encourage more physicians to enter in primary care and to incentivize more health care providers of all types to practice in rural and underserved areas.

Along with the new ACO and health home models that are developing, there are changes in the payment model with a movement toward pay-for-performance. These pay-for-performance models will measure and link quality, outcome, and value by using information in the big data sets that are emerging in health care. We are entering an era of big data in health care, and big

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<sup>11</sup> AcademyHealth, “Medical Homes and Accountable Care Organizations: If We Build It, Will They Come?”, Research Insights, June 2009, found on the website:  
<https://www.google.com/url?url=https://www.academyhealth.org/files/publications/RschInsightMedHomes.pdf&rct=j&frm=1&q=&esrc=s&sa=U&ei=wmLBU6vRLI-cyAT8kYDABg&ved=0CCMQFjAB&usg=AFQjCNHD4Fs-z7sO16zLmLOI2QQOOmYeGQ>.

data will be used in health care like we have never seen before. Big data will be used not just retrospectively or not just to pay claims, but also to measure quality of care, health outcomes, and cost of care in real time. The big data sets will be built using clinical data as well as claims data from electronic health records. In the past few years, the federal government has been pouring a lot of resources into strengthening health informatics and into encouraging physicians and other health care providers to use electronic health records for routine patient care.

The point of this discussion has been to acknowledge that the dynamic changes in health care structure will require new models for how we evaluate and reward health care organizations. Just monitoring trends measured against the past will not be sufficient to understand or improve the future of health care.

### **Strategies for the Success of ACOs & Health Homes**

ACOs are in existence in many parts of the country, but they are not very visible to the public yet. Over time they will become as visible as the major insurers or managed care companies. Some insurers and managed care firms may even transform themselves into an ACO. There are a number of strategies that are expected to be present in successful ACOs. As ACOs emerge, they will be built by aggregating patient-centered health homes. Effective ACOs will be using interprofessional primary care teams including physicians, nurse practitioners, pharmacists, social workers and various other types of health care providers. These ACOs are expected to use primary care nurses and nurse practitioners as case managers. They are expected to use pharmacists to manage complex medication problems and to manage medications during transitions across settings to prevent emergency room visits, hospitalizations, or re-hospitalizations. They are expected to have better transitions of care when a patient goes from a hospital to a nursing home, from a nursing home to a private home or to another type of facility.

ACOs will need to provide guidance for patients and care givers to participate in their health care. This new health care approach is not just about health care doing things to patients, it's also about patients being activated to take responsibility for their own health care. As ACOs collect their big data sets to monitor care, outcomes, and costs, they will need to find ways to use this data in predictive models to anticipate and prospectively improve decision-making. Also, they need to find ways to use the data in as close to real time as is possible. They will develop models that give feedback to the doctor in real-time while he or she is seeing a patient. Real time, direct feedback that tells the doctor that a given patient with a certain profile, with these conditions, these lab tests, and these diagnoses is best treated with the following course of therapy, and here are the odds that this drug therapy will work. The capabilities are there for this type of evidence-based practice and decision-making, and we can expect such systems to be more common in the future.

Successful ACOs will also develop remote monitoring systems for evaluating the status and outcome of care using technology such as Skype or other means to see patients in remote areas where there are currently access problems. Tele-health processes will become more common. As the ability to track health care quality, outcome and cost improves, this information will be linked to provider payment methods. Payment again will be linked to delivering improved quality and outcomes while using resources efficiently.

## The Payment Model Is Evolving

For decades health care has been dominated by fee-for-service payment systems where you pay for the health care services you get whether they were needed or not and whether they worked or not. Insurance largely has, in part, emboldened the fee-for-service process because we pay for specific individual services without knowing whether or not the outcomes or results were positive. This ‘piece work’ nature of fee-for-service may be part of what drives fee-for-service away in the future. Our health insurance payment models are experimenting with new payment approaches such as a ‘bundle payment’ for a given set of services. For example, the End Stage Renal Disease program has a bundled payment for the set of services related to dialysis. Some health programs have also set bundled payments for a set of services related to cancer treatment or a set of services related to transplant. Rather than paying providers for each and every service or product used, there is a single payment for an episode of care. This is somewhat like Diagnosis-Related Group (DRG) payments for a stay in the hospital.

Competitive bidding is being used by some payers to select vendors for individual or bundled sets of products or services. Also we are seeing a renewed interest in various forms of ‘capitated’ or ‘global’ payments. Payment systems in the future are likely to involve some form of global and/or partial capitations—where the health care provider organization gets a fixed amount of money to care for a patient’s health for a given time period.

Another novel payment method being developed is collaborative value contribution. If we have a team-based care model, how do we figure out how much the physician contributed, versus the nurse, versus the pharmacist, versus the electronic big-data system giving us feedback? Research is being done to find conceptual and statistical models that can parse out the value and contribution of each player in the process and system. Once we can identify the contribution of each component, then we can reward the people who have contributed to that quality, care, and cost savings.

Newer concepts encouraged by the Affordable Care Act and in other health programs are payments known as ‘shared savings’, ‘shared risk’, or ‘gain-sharing’. If you can demonstrate that you have a better model of care—a way of caring for patients that improves quality and reduces cost, and you can show that you saved a certain amount of health care cost for a defined population of patients, then the payer, such as Medicare or Medicaid or a private insurer, will share with you part of that savings. You may get to keep a certain share of the amount saved.

Shared savings is really about payment that is linked to quality and outcomes. Compared to fee-for-service, this is a transformational change. Shared savings is a totally different way of thinking about provider payment. You will get paid for ‘doing better’, ‘not for doing more’. You will get paid for ‘delivering outcomes’, not for ‘delivering visits, tests, and prescriptions’. Right now, health providers get paid for doing more. If you do more office visits, if you do more procedures, if you dispense more prescriptions, you get more money. But this does not assure that the services and products delivered were either needed or effective. The newer provider payment systems are going away from counting the volume of what providers do as the basis for payment. The system will measure and look at the outcome of what the provider has done. Did the provider improve the patient’s health or not? If the provider did improve the patient’s health and quality of life, the provider gets rewarded. If the provider does not improve the patient’s health, the provider does not get paid or may even be penalized. Also, the results of the provider’s care, quality and outcomes will be publicly reported. In other words, the provider’s disincentive may be both economic and informational. The information will be reported to the public in a transparent and accessible format. If one has a choice of going to a provider with a

95% success rate for a certain surgery versus one that has a 75% success rate on that same surgery, which provider do you think patients will choose? The patient may also look at the relative cost and consider that when choosing a provider.

Transparent and accessible information related to health care providers and services can be transformational. State-level organizations in some cases have been formed to collect and report this quality and cost data on health providers such as Minnesota Community Measures.<sup>12</sup> CMS has developed quality measures for various Medicare-related programs. They have been measuring the quality and outcomes of ACOs created under the Affordable Care Act and under state programs. The CMS quality rating system is sometimes referred to as the '5-star' rating system. The CMS 5-star rating for nursing homes has been in operation since 2006 or before. More recently CMS has developed 5-star ratings for Medicare health plans, for ACOs and for other types of health care programs. The CMS 5-star data are published—some on a quarterly basis and some on an annual basis. The 5-star system includes measures of: (1) the patient-caregiver experience; (2) the coordination of care; (3) patient safety; (4) preventive health; and (5) vulnerable and at-risk populations such as the frail elderly, the disabled, or low income patients. These measures are tracked across the entire population being served by a given health program.

Each of these broad 5-star measures has anywhere from four to ten or more specific measures. These measures are clearly and explicitly defined. For example, you can look them up online, and then you can look up any health care organization such as an ACO serving Medicare patients and you can see what their 5-star performance was last year. You can also compare their rating to other ACOs. The provider organizations that get more stars get paid more. Above a certain level, the provider organization gets a bonus payment from Medicare. That's what pay-for-performance is all about—pay for measurable results over time for a defined population. A better score means more payment. This movement toward measurement of quality, outcomes, and cost is still using fairly crude measures, but the models and measurement techniques continue to evolve. There are several important issues to watch in the future as rating systems evolve, such as choosing which additional quality and outcome measures should be added to the rating system, refining and re-defining the existing measures when needed, and evaluating the reliability and validity of those measures with respect to their actual effect in producing better health care.

Many of the measures used now are what can be referred to as 'intermediate' measures rather than 'endpoint' measures. These intermediate measures are not really measuring the outcome or end result of health care, but rather, they measure the status of the patient at a specific point in time or the direction of change over time. With one year of data, you don't really know if you've improved the life expectancy of the patient or if you have prevented a heart attack. Measuring and tracking more comprehensive endpoint measures is important, but will take large numbers of patients covered and longer time periods (several years).

## **Defining & Delivering Value**

Does the health care system deliver value? What do we mean by value? In a simplistic sense 'value' can be described as the cost per outcome. First, we must decide, "What is the health care outcome we want?" and then we can determine, "How much does it cost to get there?" If

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<sup>12</sup> Minnesota Community Measures reports and data can be found at the website: <http://mncm.org/reports-and-websites/reports-and-data/>.

there are alternative systems, providers, services or products for producing an outcome, we can then compare the cost per outcome across these various alternatives.

I would like to ask that each of you think for a minute about the last time you went to visit a physician. Take a minute and get that situation in your mind. Now let me ask you a few questions about that experience. First, let's talk about the quality of care you received. Do you know if that physician actually went to medical school and, if so, do you know where they went to medical school? Do you know what their grade point average was? Was this a C– or a B+ or a straight-A physician? Did the physician complete a residency? Was the physician board certified? Has the physician ever been reported to the state medical board and, if so, for what? Do you know each of these things about your physician's training and competence? You may know some of these things about your physician or you may not know any of them. So, what do you really know about the quality of care that you received? If you had a source to examine the above types of precursors to quality or other measures shown to be valid indicators, would you use it? Most people choose their physician based on word of mouth by talking to their family, neighbors, friends, or somebody at church.

Some parties want to focus on quality or value without ever addressing cost or resource use. While it is certainly true that cost (or price) is not the only issue related to quality or value, cost (or price), however, is *always* a necessary factor in determining value. How can good value-based decisions be made without real cost or price data? It cannot. Therefore, transparency and real price data are essential to value-based decision-making. Hidden prices, discounts, rebates and other forms of economic consideration that are not transparent become major barriers to value-based health care.

Let me ask you this: how much did your last physician visit cost? How much did it cost for each service or product that was delivered to you during that visit? Now when I ask you about cost, you are probably thinking about your out-of-pocket costs such as your co-pay rather than the total cost of the service or product no matter who paid for it. So, how much did you pay out-of-pocket? How much was billed to your insurance company or health plan? How much was actually paid for the services and products you received? Chances are that you know what your copay amount was, but you may not know other costs for specific products and services beyond the copay. You probably don't know all of the cost to your health plan or to you.

Of all people, you as actuaries realize that the cost to you is more than just your copays or other out-of-pocket costs such as deductibles. The total amount paid by your insurance company or health plan affects the experience rating of your plan for the next year, and will affect the premium you pay (or someone else pays on your behalf) in the next year. The patient usually does, in one way or another, pay that higher premium – either through higher premium contributions or through not getting as much of a salary raise due to increased health care costs to the employer. The premium is just as much a part of the cost (although delayed somewhat) as is the out-of-pocket co-pay you paid. I find it frustrating when policymakers or journalists focus only on the copay or out-of-pocket cost for prescription drugs or other services rather than the total cost.

My point is, in health care today, we are isolated and insulated from the cost of care and the quality of care. We have a system where we rely pretty much on word of mouth and confidence in others around us. We need to have better systems of measuring, reporting, and understanding quality, outcome, and cost. Transparency is essential to value-based decision-making, and information about health plans, institutions, physicians, pharmacists and nurses is needed by patients and other decision-makers. Everyone (i.e., consumers, payers, insurers,

health plans, providers, and producers) needs to be much more aware of quality, care, outcome, and cost, and the information on these factors needs to be more transparent, accessible, and usable.

Even if we can agree upon a definition of value, the health care system needs to encourage evidence-based decision-making rather than eminence-based decision-making. In health care there are some old habits that need to be changed. Historically, physicians have made decisions based on their 'eminence'—that is their prestige, experience, or power position over other health providers and patients. While many aspects of this approach to decision-making may have served society adequately in the past, there is 'evidence' that evidence-based decision-making may produce results that are superior to the results from the classic eminence-based decisions of individual physicians. With the growth of health informatics and electronic health records, evidence-based health care becomes more practical and more achievable.

There are many things we do in health care that aren't necessarily the best choice or the best value. Let's examine the prescribing pattern for one class of pharmaceuticals to understand the role of price and value in prescribing patterns. This illustration will use data from a self-insured employer with 40,000 covered lives which are covered by a carve-out prescription drug plan.

The focus of this example will be the proton pump inhibitor drugs—used for gastroesophageal reflux disease (GERD) and other indications. An objective, evidence-based review of the literature concluded that each of the PPI drugs has essentially the same efficacy and a very similar side effect profile. For all practical purposes, the PPIs were considered to be therapeutically interchangeable with very few and very rare exceptions. Among the PPIs are two drugs known as the 'purple pill'. The first purple pill was Prilosec (omeprazole). This was also the first PPI on the market. Prilosec was heavily advertised direct to consumers and was the leading PPI on the market when it was about to face patent expiration and generic competition. The second 'purple pill' was a closely related stereo-isomer known as Nexium (esomeprazole).

If all of the PPIs are considered therapeutically similar, then it is appropriate to consider the entire set of PPIs in choosing the correct drug therapy. The prescription claims data for the self-insured employer were examined using 2009 data to determine the actual amount paid by the plan for PPI prescriptions. First, the price of the original purple pill (Prilosec) was \$5.12 per day of therapy and the price of the new purple pill (Nexium) was \$7.04 per day. In November of 2002 a generic version of omeprazole came on the market at a price of about \$4 per day of therapy, and it declined rather slowly but by 2009 the generic price had fallen to \$0.81 per day of therapy. The brand name company also introduced Prilosec OTC (over-the-counter) in June of 2003. Consequently, after that time, you could walk into any pharmacy and buy Prilosec OTC at a price around \$0.78 per day of therapy.

The generic omeprazole is the same drug as the brand Prilosec and very similar to the brand Nexium. The health plan was paying \$5 to \$7 per day of therapy for the branded products when, at the same time, a similar drug was available in pharmacies as a generic prescription for \$0.81 per day and as an OTC for \$0.78 per day of therapy. When the evidence-based literature shows little or no clinically significant difference among the PPIs, what would be the best value-based choice here? Either the generic omeprazole at \$0.81 per day or the Prilosec OTC at \$0.78 per day would be reasonable value-based choices. Despite the dramatic price difference, many prescriptions continued to be written for Nexium when two reasonable value-based choices were available on the market at one-sixth to one-eighth of the price. Particularly ironic here is the fact that most health plans in the country were paying \$5 to \$7 per day of therapy for the brands Nexium and Prilosec and about \$3 to \$4 per day for generic omeprazole from 2003 to

2007 (before the generic price declined), when there was a value-based choice (Prilosec OTC) at \$0.78 per day out there.

The historical posture of most PBMs and insurance plans has been that they do not cover OTC drug products. Our health plans need to rethink the issue of OTC coverage as an insured benefit. If there is an OTC at prescription strength with evidence-based effectiveness at a substantially lower price (\$0.78), why not pay for the OTC (if it is prescribed by the doctor) in lieu of a prescription that would cost \$5 to \$7 per day? Wouldn't that be a reasonable value-based choice? The better managed health plans are starting to cover OTC drugs as part of their drug benefit plans (if the OTC is prescribed by the doctor) in lieu of a higher cost prescription medication. There were other proton pump inhibitors on the market such as Aciphex, Prevacid, and Protonix. The best evidence-based studies of these other PPI products show that there is very little difference, if any, among the PPIs in terms of safety or effectiveness, and they are all pretty much interchangeable. These other PPIs still cost the plan from \$4 to \$8 per day of therapy, even though Prilosec OTC was available on the market for \$0.78 per day of therapy. From this example, we learn that we need to re-evaluate old rules that may not be the wisest policy anymore. When a plan did not cover Prilosec OTC (from 2003 to 2007), was it making a wise value-based choice? Not really.

Who makes the value decisions for health care and, in particular, drug therapy? Is it the patient? Not really because the patient does not know the price until after the prescriber has already made a choice. The apparent price the patient faces even when they get their prescription filled is the copay amount and not the total cost of the prescription. Does the physician, nurse, or pharmacist make the value decision? They could; but, in general, physicians and nurses don't know the relative or absolute price of the drugs, let alone the evidence-based value of the drug. Physicians and nurses usually can't tell you the actual total price of a prescription. For example, they can't tell you that Nexium is 8 times the price of the Prilosec OTC product. Pharmacists could, perhaps, influence a value-based decision. However, even if the pharmacist wanted to take the price into account in a value-based decision, the pharmacist in most cases cannot find out the actual total price of the prescription to the plan or to the patient because rebates and certain discounts through the PBM are hidden and not disclosed even to pharmacists and physicians, let alone patients. If physicians and pharmacists don't know the information, it is hard for them to make value-based decisions.

Does the health plan, or the employer, or the payer make the value decision? As we found in the PPI example discussed earlier, very few health plans were covering Prilosec OTC—which was clearly the best value-based choice for several years. PBMs could make value-based decisions, but PBMs generally will not agree to take fiduciary responsibility when contracting with health plans. Also, PBMs often make more money from rebates and rebate administration fees that they receive from the brand name drug companies than they receive in administrative fees from their clients. If a PBM is making more money from drug companies than from their health plan clients, whose interests are they going to serve? I am not arguing against using PBMs since they do provide some very valuable services. However, there are times when reverse and perverse economics happen in the health care system. If you do not understand the hidden pricing behaviors of PBMs, a health plan is likely to make some wrong choices and wrong value-based decisions. PBMs do make value-driven decisions, but it's the value to the PBM's bottom-line, not to the health plan's bottom-line. Do drug companies make the value-based decision? In one sense they do determine the value (price) that they will charge for their drug products (and that will influence the revenue that shows up on their books), but the price charged by the drug company isn't necessarily a measure of the drug's value to society or to the patient.

In other words, I would argue that there is no clear value decision-maker for drugs in the health care system. At present, we aren't very good at value-based decisions for drugs which are a major part of our health care system. Similarly, the process for value-based decisions in areas such as devices and medical procedures don't appear to be much better.

## **The Cost & Value of Drugs**

The vast majority of new drugs coming on the market in the past few years are biologicals and other types of drugs sometimes referred to as specialty drugs. These drugs are often new therapies for treating rare or orphan conditions. Many of these new drugs have another notable feature—their unusually high prices. *Forbes* magazine a couple of years ago published an article titled, “The World’s Most Expensive Drugs.”<sup>13</sup> This list contains newer drugs that cost from \$200,000 to more than \$400,000 per year of therapy in 2010. The prices of these high-cost specialty drugs have been increasing at rates of 10% to 25% per year, so the prices for the drugs on the *Forbes* list would be even higher in 2013. Some of these specialty drugs represent major therapeutic advances and treat previously untreated conditions. Other specialty drugs are alternative therapies that add only limited marginal value clinically to therapies already on the market; yet, many of these alternative therapies have prices that are similar to or even higher than the superior drug product.

Access to these high-cost specialty drugs can be a major issue. If you are insured in a plan with a large enrolled population that covers the drug on the formulary, you most likely would have access. But imagine, if you will, that you are not enrolled in an insurance plan and you are diagnosed with one of these rare diseases that can only be treated with a drug that costs \$300,000 per year. Could you afford the drug? How long could you afford to pay for it? You might be able to pay for it for a year or two and, then, you could sell the house and mortgage the farm or the cabin up north. Even for those who have insurance, some insurance plans use co-insurance for these high-cost specialty medications. Even if you had 50% co-insurance for a needed medication that costs \$300,000 per year, most people couldn't pay for that drug for very long. We have to ask if these drugs are being priced in an economically functional market. It appears that they really are not. These drugs do have a monopoly, and they deserve a return on their research as well as a reasonable profit, but the price is not being set by an economically competitive market process.

The ACA does provide health insurance coverage for most, but not all people living in America. With broad, nearly universal coverage, we must do something to assess the value of these new drugs, or we are going to see the cost just sky rocket. Without some visible and effective price pressure from the market, it is like writing a ‘blank check’ to the pharmaceutical industry.

Most of these new drugs are specialty drugs rather than classic drugs that you ‘take one or two tablets a day and call me in the morning’. Many of these drugs are injectable products and large complex molecules. Many of these specialty drugs are administered in the physician’s office, in a cancer clinic, or in the outpatient department of a hospital. Often these drug products don’t even show up in the pharmacy claims database; but rather, they are included in medical claims. Their cost adds to the medical cost instead of the pharmacy cost, and most employers and health plans cannot even identify how much they are actually spending on specialty drugs. Also, they don’t even know what drugs are being paid for in the medical budget, and they don’t know how much the cost of these drugs is increasing their medical expenditures, because the costs

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<sup>13</sup> Matthew Herper, “The World’s Most Expensive Drugs,” *Forbes*, Feb. 22, 2010.

are somewhat hidden. The AARP routinely tracks the rate of price inflation for drugs in general, and specialty drugs in particular.<sup>14</sup> Specialty drugs are high-priced to begin with, and their prices have been increasing in the past decade at rates that are two to ten times the rate of general inflation.

Even for traditional prescription drugs, price increases are sometimes a major problem and are not reflective of an economically competitive market. For example, imagine for a moment that you are a diabetic patient and your diabetes medication price went up 20% last year. Does that mean that your diabetes condition will get 20% better next year? While the medication may work and may be the right drug for you, the increase in price does not reflect additional value added. When a drug can raise its price 10% to 25% without adding additional value to the product being sold, this is a signal that something is broken in the market and its structure. I am not against markets; in fact, I believe that they are very important to our economy. However, the structure of the pharmaceutical marketplace is not working as an economically competitive and efficient market—a market where we have price being effectively measured against value and outcome.

Targeting drug therapy to the right population can increase the value delivered. We need to be more conscientious of the target population for specific drug therapies. A lot of times drugs are prescribed for an indication that is not FDA-approved, and for which there is little to no evidence that the drug will be effective or safe. We need to make sure that when prescription drugs are prescribed, there is a reasonable likelihood that the drug will be used in a manner that is safe, that effectively treats the intended medical condition, and that it is used as intended. Paying for drugs that are not known to be effective, or even that are clearly known to be not effective for a given condition, does not provide value to society. One example where we have paid for a lot of ineffective drug use comes from the drug Neurontin. While this drug does have indications for which it is clearly safe and effective, Neurontin has been tried for many unapproved uses with little to no evidence that the drug works, or even in some cases, with evidence that the drug does not work. Use of the drug Neurontin was studied in the Medicaid program, and 70% of the Neurontin use was found to be for off-label, inappropriate, and ineffective uses.<sup>15</sup> Basically the inappropriate prescribing of Neurontin means that we wasted 70% of the dollars spent on Neurontin in our Medicaid programs. There are other drugs which are widely prescribed with little evidence of effectiveness for certain indications such as use of the anti-depressants for mild to moderate depression.<sup>16</sup> The failure to prescribe appropriately means that we are actually losing value for the resources that are being spent.

How can we focus on the value of drug spending? There are some forms of increased spending on drugs that add little value. For example, a substantial increase in the price of an existing drug (such as that diabetic drug we talked about) doesn't improve its value. A switch to a new patented dosage form of an old drug does not always add value. Neither does prescribing a drug for a patient when the drug is ineffective for the condition being treated. Molecular manipulations of drugs such as stereo-isomers often do not improve therapy, and thus, do not add value. Drug use when a drug is ineffective for the condition being treated does not add value. Inappropriate prescribing is not of value. For some reason, we seem to implicitly assume that all drugs being prescribed add value.

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<sup>14</sup> Schondelmeyer S and Purvis L, "Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Medicare Beneficiaries," AARP Public Policy Institute, Pub No. 2012-01.

<sup>15</sup> "Court Papers Suggest Scale of Drug's Use," New York Times, May 30, 2003.

<sup>16</sup> Fournier JC, et al., "Antidepressant Drug Effects and Depression Severity, A Patient-Level Meta-analysis," JAMA, Jan 6, 2010, Vol. 303 (1):47-53 (doi:10.1001/jama.2009.1943).

We also hear a lot about compliance and the need to increase compliance. I agree that compliance is very important and adds value when the drug is appropriately prescribed. If you don't use the medicines, you won't get any value from them. However, if you don't need the medication, you won't get any value from using it. Unfortunately, the methods used to measure compliance are not reliable and may not even be valid in many cases. Most often, when PBMs or mail order pharmacies tout high compliance rates, they are referring to high "medication possession ratios" or a similar measure. What this means is that for a given time period, enough drug was shipped to the patient to have treated the condition—if the drug was used appropriately. Note that medication possession ratios do not indicate whether or not the drug was used and, if so, whether it was used appropriately. A patient may have a very high medication possession ratio, but that same patient may also have a medicine cabinet full of unused prescriptions. Is a medicine cabinet full of unused prescriptions really a measure of compliance? No. Additionally, the greatest source of drugs being abused by teenagers these days is drugs out of their parents' medicine cabinets—not the ones they are buying on the street. I'm not saying that young persons are no longer buying other drugs on the street; but rather, that the drugs leaking through the health care system and disappearing from the medicine cabinet have become a major new source of drugs for abuse. The point here is that compliance—that is appropriate use of medicines—is of great value, but medication possession is not an adequate measure of appropriate and effective drug use.

While not all increases in spending on prescription drugs add value, some increases in spending on prescription drugs add great value. Examples of increased drug spending with greater value are described below.

*Coverage expansion with financial access to needed medications:* When persons who cannot afford their medications are by some means enrolled in health insurance and thus have access to needed medications, great value is added. The ACA has provided coverage expansion through low income subsidies (LIS) to many persons who could not otherwise afford health insurance. Also, persons with severe pre-existing conditions may have been dropped in the past from insurance coverage or had substantial rate increases, making the insurance coverage unaffordable. Again, the ACA has made a structural change in the way our insurance market deals with pre-existing conditions.

*Use of effective medications for previously untreated conditions:* If a drug company comes up with a new medication to treat a condition for which there is currently no effective therapy, that innovation is a great advance and is of great value.

*Targeted use of effective therapies based on evidence:* Targeted use of existing medications that are appropriately prescribed and used in the right patients to effectively treat medical problems based on scientific evidence adds great value.

*Appropriate use of more cost effective medications:* There are times when a medication with a higher price is substantially safer and/or more effective than existing therapies. When used to deliver substantially improved health outcomes, this higher-priced medication may be adding value, despite its higher cost.

In other words, while not all increases in drug spending are beneficial to health care outcomes, there is spending on drugs that does add value.

## How Much is Your Life Worth?

Next, I will address value from a different perspective. Think about this: How much is your life worth? Get a number in mind, a real, concrete number. Now, how much do you have in the bank? Can you afford yourself? These questions capsulize what the health care debate is all about. If you think you are worth more than you have in the bank, then you have a structural financial problem. As a society, we have a structural financial problem with health care as a part of our economy and with the expectations we all have from our health care and health insurance systems. If we expect more health care than we can afford, individually and collectively, we're going to be disappointed. We're debating that disappointment right now in Washington. What do we do about it? This is a very real problem and it is very sobering. How do we bring down the cost? How do we bring down our expectations? How do we also deliver value and efficiency in health care, and how do we deliver it at a reasonable price? A normal economic market usually means that if the price is too high, you simply don't purchase the product; but, is that an acceptable response for health care? Is that how health care should work?

We need to realize that health care will never be a normal market; because, when you're lying on a stretcher in an emergency room after an accident, you don't sit up and say, "Wait, wait how much will this emergency room visit cost?" We don't make rational decisions at times of great need in health care. We never will. So we need a market place that has some gentle regulations that can make the competition work well. If we totally leave the health care market alone, it won't work properly. Even now it is not working properly.

## Use, Expenditures and Cost of Pharmaceuticals

The Office of the Actuary for CMS publishes the National Health Accounts every year to show where our money in health care is going. The National Health Expenditure Accounts Team is very thorough and diligent in compiling estimates of the total as well as the various components of National Health Expenditures (NHE). One piece of the pie in the NHE is sometimes labeled in graphs as simply 'Drugs.' In 2011, the 'Drugs' piece accounted for 9.7% of the NHE pie.<sup>17</sup> Some well-respected journalists, policy analysts, and economists will look at this number and declare that drugs at 9.7% of NHE are a very small piece of the pie. However, this component of NHE often labeled as "Drugs" is actually "retail outlet sales of prescription drugs." The Office of the Actuary very carefully and correctly defines this term, but many, if not most people, misunderstand what this actually represents. The 9.7% of NHE for drugs in retail outlet sales is not the total amount spent on prescription drugs in the U.S. health care system.

Think about it. Are drugs used in any other sector of the health care system other than retail outlets? Well, yes they are. Actually, prescription drugs are used in nearly every other component of the National Health Accounts data. Prescription drug spending occurs in hospitals, physicians' offices and clinics, dentists' offices, nursing homes, public health clinics, government-run health facilities such as prisons, schools, the Veterans Administration, the active military health system, and other programs. In fact, specialty drugs most often used in these non-traditional distribution outlets are the fastest growing sector of the pharmaceutical market.<sup>18</sup> The PRIME Institute at the University of Minnesota has carefully compiled an estimate of the share of the NHE represented by all prescription drugs in all settings in the U.S. What

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<sup>17</sup> Hartman M, Martin A, Benson J, Catlin A, National Health Accounts Team, "National Health Spending in 2011: Overall Growth Remains Low, But Some Payers and Services Show Signs of Acceleration," *Health Affairs*, 32, No. 1 (2013): pp 87-99.

<sup>18</sup> "Timeline and Evolution of the Specialty Pharmacy Industry," Chapter 1, *Specialty Pharmacy, Trends and Strategies: 2013*, Atlantic Information Services, Inc. (2013), pp 1-3.

was found is that “Drugs (in all settings)” represent about 17.5% of national health expenditures and not just 9.7% or 10%.<sup>19</sup> When journalists, policy makers and economists declare that “Drugs are only a small part of health care”, they diminish and minimize the amount spent on drugs.

By the year 2020, we expect to be spending about 20% of our national health expenditures on prescription drugs in all settings—that will be one out of every five dollars spent on health care. The total amount spent on prescription drugs in all settings for 2015 is expected to be about \$788 billion. Recall, if you will, the price of that infamous ‘bailout package’ for Wall Street that Congress enacted back in September of 2008—it was \$700 billion and the ‘bailout package’ for the economic stimulus enacted in February of 2009 was about \$787 billion. For the price of these two ‘bailout packages’ we could have paid for all of the prescription drugs needed by everyone in the U.S. for two whole years. And, no one would call the ‘bailout packages’ a small part of our economy. Comparison of the expenditures on prescription drugs to the size of the bailouts certainly provides a new perspective on the role of drugs in the U.S. economy.

The price of a prescription as well as the growth in prescription drug prices should be understood and monitored. During most of the past decade, brand name prescription drug prices have far exceeded the general inflation rate as measured by the Consumer Price Index for All Items (CPI-All). In fact, brand name price inflation has exceeded the CPI-All inflation by two-fold to four-fold in most of the past decade, according to research published by AARP. These AARP studies of drug prices have examined the manufacturer and retail prices of prescription drugs widely used by the elderly.<sup>20</sup> Drugs among those most commonly used by the elderly were divided into three groups: brand name, generic, and specialty.

The retail prices of brand name prescription drugs increased, on average, 6% to 8% per year from 2005 to 2010. At the same time, generic prescription drug prices decreased, on average, 0.1% to 14% per year in the same time period. Specialty prescription drugs had price increases ranging from 7% to 14% per year from 2005 to 2010. A weighted average of price change for the overall market basket (i.e., a combined index of brand, generic, and specialty drugs) ranged from 2.4% to 5.0% between 2005 and 2010. For most of the time from 2005 to 2008, the overall drug price index and the CPI-All had similar increases each year. What does all of this mean? Generic prescription drug prices have decreased every year from 2005 to 2010. Generics cost less and their prices decreased even further each year. The presence of generics has saved consumers money versus what brand name prescriptions for the same drug would have cost them. Generics have really helped us hold down the cost of drugs. While generics account for about 75% of all prescriptions, they represent only about 20% of the dollars we spend on prescription drugs. Generics do add a lot of value in the market place. On the other hand, brand name and specialty drugs both increased in price at rates well above the CPI-All. The savings from generics were more than off-set by the higher prices seen for brand name and specialty prescriptions. The net effect is that we did not realize a net benefit from savings in prescription drug expenditures. In the aggregate, prescription drug prices went up about 5% in 2009 while, the CPI-All remained essentially flat at 0%.

More recent data from a self-insured health plan show that the average price for brand name prescriptions (for a one month’s supply) has grown from about \$100 in 2004 to nearly \$400 per

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<sup>19</sup> Schondelmeyer SW, “Recent Economic Trends in American Pharmacy,” *Pharmacy in History*, Vol. 51 (2009), No. 3, pp 103-126.

<sup>20</sup> Schondelmeyer SW and Purvis L, *Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Medicare Beneficiaries: 2005-2009*, AARP Pub. No. 2010-06, August 2010, 33 pp.

claim by the end of 2012. Generic prescriptions grew from a price of about \$16 in 2004 to \$27 by the end of 2012. Again, generics clearly helped hold down the average prescription price, but the increases in brand name prescriptions more than offset the savings so that drug prices and expenditures did increase every year. Specialty prescriptions averaged a price of about \$1,200 per month in 2006, and that average increased to nearly \$3,000 per claim per month at the end of 2010. A well-run health plan needs to be monitoring specialty prescriptions carefully for appropriateness of use, safety and effectiveness. The health plan should also carefully monitor the use of specialty claims both in terms of the cost per claim and the number of claims that are really needed. Dispensing an unneeded \$3,000 prescription is a big waste, and you can't take it back to the pharmacy and put it on the shelves once it's been dispensed. So a lot of money can get wasted very quickly with inappropriately prescribed and dispensed specialty drugs.

The increasing generic use rate has helped to keep the overall prescription expenditure trend line down in recent years. Back in 2003 the generic use rate was about 43% of all prescriptions. By 2012 the generic use rate had risen to 78% of all prescriptions. The generic rate is approaching the maximum possible level, and the number of brand name drugs going off patent is slowing dramatically over the next few years. Health plans will have to find other means to manage prescription expenditures. One possibility to help hold expenditures down in the future is the selective coverage and use of OTC drugs that are prescribed by a physician as an alternative to a higher cost brand name prescription. Increased OTC coverage and use may well be the 'new generic' factor to help hold down health plan drug expenditures.

### **Does the Market Really Work?**

We have talked about a lot of signals that the pharmaceutical market may not be working like a normal economic market. We can learn from the wisdom of the Nobel Prize winners in economics—(2001)—Joseph Stiglitz, George Akerlof, and A. Michael Spence.<sup>21</sup> These three Americans were selected for the Nobel Prize in Economics for their seminal work which defined the market for lemons. What were they talking about? It wasn't little yellow fruits. Their initial paper, "The Market for "Lemons": Quality Uncertainty and the Market Mechanism", was on the market for lemons—meaning used cars.<sup>22</sup> They talked about how markets don't work when there is asymmetry of information—that is, when the seller knows a lot more than the buyer, the seller can take advantage of that buyer. Since then, Joseph Stiglitz and some of his colleagues have developed much further the concepts of asymmetric markets, market signals, and their economic impact. If there was ever a market that was asymmetric, it is health care and especially pharmaceuticals. The lessons we can learn from these Nobel Prize winners are that: (1) the imperfect markets are not "all-knowing and self-correcting," (2) "imperfect information corrupts markets," (3) "markets, when confronted with imperfections, may not be the best way to allocate resources," and (4) "government must play a strong role in a market system, to prevent damage from imperfect information."<sup>23</sup>

Policymakers and legislators continue to call health care a market—and in one sense health care is a market; however, health care is replete with imperfect information. While health care has some structural features that appear to be a market, the information in this market is very asymmetric. With so much 'imperfect information' throughout health care, efficient and effective policy decisions will not necessarily follow. We must recognize and address the issues of

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<sup>21</sup> Louis Uchitelle, "3 Americans Awarded Nobel for Economics," *The New York Times*, October 11, 2001.

<sup>22</sup> George A. Akerlof, "The Market for "Lemons": Quality Uncertainty and the Market Mechanism," *The Quarterly Journal of Economics*, Vol. 84, No. 3 (Aug., 1970), pp. 488-500.

<sup>23</sup> Louis Uchitelle, "3 Americans Awarded Nobel for Economics," *The New York Times*, October 11, 2001.

imperfect information in health care and assure that accurate, transparent, and useful information is available in the market in order for more effective market-based decisions to be made.

As noted earlier, the advice of the Nobel Prize winners is that government must play a strong role in an imperfect market. Government doesn't have to run or dominate health care, but government has to set the rules for the game to correct for the many types of imperfect information. Government has to put some boundaries on the health care market so that it begins to function like an economically efficient market again. Finally, the health care market is very asymmetric for a whole lot of reasons, such as the isolating effect of directed demand, and the insulating effect of insurance coverage. Insurance is a great thing, but in some ways it takes away the market function. Health insurance programs give the appearance of having a fairly low cost when one only focuses on the amount of copays made at the time of service. The consumer only sees the impact of the full cost of their health care a year later (if ever) when the premiums increase, or when the employer does not provide a wage increase because health care cost went up.

Consider the last prescription you got filled at a pharmacy. How much did it cost? What was the copay? How much did the insurer or health plan pay the PBM? How much did the PBM pay the pharmacy? How much did the pharmacy pay the wholesaler? How much did the wholesaler pay the manufacturer? Did any of the parties involved with the flow of the prescription through the system make a value-based decision? Was it the same value-based decision you would have made if you had 'perfect' information? There are many forms of imperfect information about prescription drugs including hidden prices, rebates, and discounts; undisclosed relationships and transactions; and complex technical products. This imperfect information may inhibit, or even prevent, value-based decisions at every level. Even for someone experienced in the market, one cannot make value-based decisions with information that they do not possess.

### **What Does the Future Hold?**

With all of this change in health care, what does the future hold? First, there will continue to be more prescriptions and devices used in the future. And, more prescriptions will be covered, but that doesn't assure better health. If I could just pass out more prescriptions to everybody in this room, your health wouldn't necessarily improve unless I really knew what drugs you needed, you got the right ones, and you used them properly. Just passing out more drugs doesn't mean things will get better. In fact, your health may get worse if you use drugs you don't need or you inappropriately use drugs you do need. Increasingly, medication therapy management will be an important part of assuring that we get value from drug therapy.

Prices will continue to rise, although probably at a slower rate. Price growth has leveled off somewhat in certain sectors of health care. The business models for all players in health care will undergo substantial change. It's changing right now – such as the structural changes we talked about earlier. The models that actuaries use to estimate the value of health care are going to have to change. You will need different measures and different trends to predict the market trends of the future.

Intense scrutiny will occur on all levels, and transparency will be expected at all levels. Look at the scrutiny that's going on for these health insurance exchanges. They are publishing their premium price information and benefit designs. They're trying to make more information available. But whether they get it right or wrong, policy analysts and patient advocates are watching at every step, and their assessments will be reported publicly.

## Summary

Drugs are essential to health care. Drug-related problems are costly. We must manage drug therapy for individual patients to assure safety, effectiveness, and value. We must target the sources of growth in health care and we must manage those things that are driving the growth of expenditures as a whole. We must deliver better value for the resources being spent.

This market is all about the size of the health care resource pie and how to divide it up. Eventually, society will determine the size of the pie—that is, how much are we going to spend on health. The share of the economy spent on health care may reach 20%, 25%, 40%, or even more than 50%. At some point, however, society will say enough—and that's the percent we're going to spend on health. The health care share of the economy may even go down at some point in the future.

The performance of each player will determine the absolute size and the relative share of the pie that the player you will get. If you are an effective player, you will get a bigger share of that pie. If you are not effective, if you're not delivering value, you won't have a place in the future U.S. health care system. You need to understand the concept of value and how to measure and deliver value. Whether you are adding risk or you are delivering the care, and organizing the models of care, you need to understand the new health care market.

U.S. health care is going to be a lot like a hockey match. There's going to be a lot of rough play in the health care game, like high-sticking and body slams; and some players will get black and blue while playing in the health care market. A few players may be put in the penalty box for doing inappropriate things such as fraud, waste, and abuse. Some will become better hockey players. Health care is going to be a rough game in the next decade, but it will also be constantly changing and improving.

We need more R&D in health care. Now this R&D is a little different than what you normally think. While we do need more research and development, what we really need in health care is more 'R' (Rational care and drug use) and more 'D' (Delivered outcomes). Health care is pretty good at delivering more drugs, more devices and more office visits, but health care is not very good at delivering better outcomes at a reasonable cost. Increased R&D (Rational care and Delivered outcomes) will result in improving value in health care.

I'd like to close with some bipartisan advice. First, I draw from a democrat, President Harry Truman, from my home state of Missouri. His presidential desk had a plaque on it that said, "The Buck Stops Here." Applied to health care, it means providers, producers, and insurers must be accountable for the quality, outcomes and cost of the health care that they provide. And we're beginning to stand up in health care and demand, 'The Buck Stops Here' at the desk of the provider. Providers must be held accountable for what they do.

Second, I draw from a republican, Ronald Reagan. He had a philosophy on nuclear disarmament that we should adopt for health care. His philosophy was "Trust and verify." Applied to health care, it means trust that the health care market will work, and verify to see that it does work to improve health outcomes at a reasonable cost. Just trusting that the market will work doesn't mean that it will; and in fact, it really hasn't been working all that well. We need to hold the market accountable, and then regulate the market when imperfect information prevents the market from working properly. We need to set the ground rules for the market and then tweak the market at the edges so that various parties in the market have a level playing field and can compete on quality, care, and cost.

Health care reform is moving rapidly. The train has already left the station. If you're not on board, good luck catching up.

Thank you very much.