Introduction

After decades of obstacles, the prospect of meaningful health care reform has never been more promising.1,2 The election of President Barack Obama and the support of the Democratic majority in Congress make universal health care likely to become a reality in the next few years.3 The present financial crisis has contributed to this momentum by straining the ability of the government and employers to pay for public and private health insurance.7 Although attempts at health care reform had been previously thwarted by groups that preferred the status quo, financial stresses and rapidly escalating health care costs now encouraged prior opponents to participate in the process.1

This article provides an overview of President Obama’s health care reform policies with a focus on several issues of particular interest to P&T committees: an emphasis on generic drug use, the legalization of drug reimportation, the establishment of a national health information technology (HIT) system, and a greater role for the use of comparative effectiveness research (CER) in clinical decision-making.

Elements Contributing to the Growing Cost of Health Care in the United States

In recent years, health care costs in the U.S. have rapidly escalated with little improvement in the nation’s health outcomes.3 Despite increased spending, more than 45 million Americans lack health insurance and U.S. life expectancy, infant mortality rates, and deaths caused by a lack of access to health care are worse than those of other wealthy democracies.4 The cost of U.S. health care has risen from 9.1% of gross domestic product (GDP) in 1980 to 17% in 2008.2 If these costs continue to rise at a rate above income and inflation, health care expenses are projected to be 20.3% of GDP by 2018 (Table 1 and Figure 1).1 During her Senate confirmation hearings, Department of Health and Human Services (DHHS) Secretary Kathleen Sebelius reflected on the health care crisis:

The crushing costs of health care are making it harder for families to make ends meet, and they’re making it harder for businesses to compete in the 21st century. In the last eight years, premiums have nearly doubled [Figure 2]. … As we face deep economic challenges, the number of uninsured is growing. … And, health costs are a major cause of our long-run fiscal deficit. … Lowering health care cost growth is crucial to our long-term economic viability.5

In comparison, most major developed nations spend only 8% to 10% of their GDP on health care—half the percentage of GDP spent in the U.S.3 Although it has been proposed that the U.S. population is unhealthy or that Americans use more medical services, studies have actually concluded that the price of care, not the amount of care delivered, is the primary difference between the U.S. and other countries in health care spending.4

The largest cost difference between the U.S. and other countries is in health care administration—the U.S. spends six times more per capita ($412 vs. $72) than other developed countries.6 Administrative expenses are said to account for 30% of total health care costs in the U.S., amounting to $680 billion of the $2.3 trillion spent in 2007.1 In the U.S., 59.3% of the population is covered by employer-based insurance.3 Government-funded programs such as Medicare, Medicaid, and military programs cover another 27.8% of the total population, whereas 15.3% are uninsured.3 Both employment-based insurance and Medicaid are costly to administer.7 Outlandish administrative costs are accrued by both public and private insurers, as well as by medical groups and hospitals.3 These administrative costs are mostly a result of inefficient record keeping and the practice of defensive medicine because of the fear of mal-

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practice claims. Efficiencies gained from universal coverage and a national HIT system are expected to result in administrative savings that will substantially contribute to financing coverage of the uninsured.

Drug prices also significantly contribute to the excessive costs of health care in the U.S. compared with other developed countries. Proprietary drugs in the U.S. are the most expensive of seven major markets, often costing 50% or more than in other countries. The cost of prescription drugs was the fastest growing sector of U.S. health care costs until 2007. In 1980, prescription drug expenditures in the U.S. were $12 billion (4.9% of total health care spending). By 2003, drug costs had escalated 15-fold to $184.1 billion (11% of total health care expenditures). Drug costs continued to grow at an average rate of 6.9% annually from 2003 to 2006, resulting in an additional $45 billion increase in costs. This increase was attributed to a 3.5% annual growth in prescriptions written as well as to a 4.5% net growth in price.

Regarding rising drug costs, Joseph Hill, Director of Federal Legislative Affairs for the American Society of Health System Pharmacists (ASHP), observed:

> It is important to remember that the drug spend is still a relatively small piece of the health care pie. In the long run you need to evaluate costs within the entire health care spectrum. It can be much more cost-effective to treat someone early with medications than it would be for surgery or to treat complications from nontreatment. There is an overall recognition that medication use is a very effective and very cost-effective means of treating people when you compare it to the rest of the health care spectrum.

A more expensive drug mix is also said to be a reason for rising drug costs. The increasing availability and usage of biologic agents accounted for $45.5 billion in spending in 2007 alone. Cynthia Reilly, Director of the Practice Development Division of the ASHP, agrees in part, noting:

> Certainly, some biologic therapies do have increased costs associated with their use, but some of the other reasons you’re seeing an increase in medication costs is the evolving nature of the evidence. Some evidence points toward the need to use more than one drug to get an optimal response. For example, using drugs with different mechanisms of action for conditions such as diabetes may result in better disease management.

Despite high drug costs and growth in prescriptions written, 10% fewer drugs per capita are used in the U.S. compared with similar countries. Patients in the U.S. were also found to consume 20% fewer prescription drugs in nine therapeutic categories than patients in Germany, Canada, or the United Kingdom (U.K.).

Besides administrative and proprietary drug costs, high cost disparities between the U.S. and other developed countries were also observed in hospital ($224 billion) and outpatient care ($178 billion). The excessive costs of the U.S. health care system have also been attributed to overuse of new technologies, inflated prices, waste, fraud, and abuse.

### President Obama’s Proposals for Health Care Reform

The goal of President Obama’s health care plan is to retain existing providers, doctors, and plans and build on the current health care system to provide accessible, affordable care for all Americans. To this end, President Obama plans to establish a National Health Insurance Exchange (NIE), which will offer a range of private insurance options, as well as a new public plan available to individuals and small businesses that is based on benefits provided to members of Congress. DHHS Secretary Sebelius said during her Senate confirmation hearings:

**Table 1 National Health Care Expenditures (NHE) in Selected Calendar Years, from 1993 to 2018**

<table>
<thead>
<tr>
<th>Spending Category</th>
<th>1993</th>
<th>2006</th>
<th>2007</th>
<th>2008*</th>
<th>2009*</th>
<th>2013*</th>
<th>2018*</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHE (billions)</td>
<td>$912.5</td>
<td>$2,112.7</td>
<td>$2,241.2</td>
<td>$2,378.6</td>
<td>$2,509.5</td>
<td>$3,110.9</td>
<td>$4,353.2</td>
</tr>
</tbody>
</table>

Sources: Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group; and U.S. Department of Commerce, Bureau of Economic Analysis and Bureau of the Census.

* Projected.

Coverage in the Exchange would be accessible, reliable, and meaningful. … The President … proposed a public option alongside private insurance options … He recognizes the importance of giving the American people this choice, which would also challenge private insurers to compete on cost and quality, not cream-skimming and risk selection. At the same time, he recognizes the importance of a level playing field between plans and ensuring that private insurance plans are not disadvantaged.

For individuals who are not eligible for employer-based coverage and who cannot afford insurance, subsidies will be provided to purchase an insurance plan of their choice. The Obama health care plan will also require insurance companies to cover pre-existing conditions so that affordable, reliable, and comprehensive benefits can be obtained despite a patient’s health status or history.

Besides expanding health care coverage, President Obama’s plan also promotes cost reductions (Figure 3). Substantial savings are expected to come from preventive services, HIT, CER, and care coordination. Prescription drug savings are also expected from legalization of drug reimportation; an emphasis on generic drug use; the establishment of an abbreviated approval pathway for generic biologics; and government negotiation with drug manufacturers to lower prices for drugs purchased under Medicare Part D. Through these and other reforms, President Obama plans to lower health care costs by $2,500 per year for a typical family. Further details regarding many of these and other features of the President’s plan for health care reform are discussed in the following sections. It should be noted that President Obama’s proposals for health care reform are yet to be fully debated and authorized by Congress, which will ultimately determine the actual measures that are enacted.

### Specific Legislation and Funding to Improve and Expand Health Care in the United States

Health care reform is an integral part of President Obama’s domestic agenda; however, it comes with substantial cost—approximately $2 trillion over 10 years. When asked if the massive cost of health care reform was a wise remedy for a system that already overspends, DHHS Secretary Sebelius responded:

The President believes we can’t afford not to reform our health care system. … Modernizing our health care system and ensuring affordable coverage will require an up-front federal investment. The President’s budget includes policies to help offset this investment. Moreover, health reform, along with the Recovery Act investments, will yield long-run cost savings for both taxpayers and the federal government. Our goal is to fix our broken system in a fair and fiscally responsible manner, covering all Americans and lowering the long-run growth of health care. … While some suggest that in this recession, we can no longer afford to invest in our nation’s health system, the truth is that we can’t afford not to.

Reflecting this urgency in the very early days of the Obama administration, substantial financing for health care reform policies had already been established. The Children’s Health Insurance Program (CHIP) Reauthorization Act of 2009 and the American Recovery and Reinvestment Act (ARRA) both became law in February of 2009. The CHIP Reauthorization Act extends funding for the program through 2013 and provides an additional $44 billion in allotments above baseline funding levels of $25 billion. This additional funding is expected to provide access to four million newly insured children by 2013 in addition to the 11 million individuals already covered. The legislation will be partly funded by a cigarette tax increase of 61 cents to $1 a pack.

The ARRA provides $787 billion in economic stimulus and a jump start for health care reform (Table 2). The Act appropriates the following: $19.2 billion for HIT, $1.1 billion for CER, $87 billion for Medicaid, and $24.7 billion to subsidize private health insurance for people who have lost their jobs. The stimulus bill also boosts the National Institutes of Health (NIH) budget by one third or $22.4 billion and provides $650 million to support prevention and wellness activities targeting obesity, smoking, and other risk factors for chronic diseases. Health professions training programs will also receive $500 million, including $300 million to revitalize the National Health Services Corps (NHSC). The NHSC provides loan repayment, salary support, and scholarships for physicians and other health care providers who practice in...
The budget President Obama has proposed for 2010 also includes substantial funding for health care reform. The 2010 budget has received preliminary approval from Congress, but the final budget won’t be determined or authorized until later this year. President Obama’s budget establishes a “reserve fund” of more than $630 billion over 10 years to finance health care reform. The reserve is funded by new revenue, as well as savings proposals, to promote efficiency, accountability, and quality. The 2010 budget provides $76.8 billion to fund DHHS, representing an increase of 9% above 2008 funding.

Table 2 Health Care Spending Provisions of the American Recovery and Reinvestment Act of 2009

<table>
<thead>
<tr>
<th>Program or Investment Area</th>
<th>Amount and Purpose of Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparative effectiveness research</td>
<td>$1.1 billion, of which $300 million will be administered by the Agency for Healthcare Research and Quality (AHRQ), $400 million by the NIH, and $400 million by the secretary of health and human services.</td>
</tr>
<tr>
<td>Continuation of health insurance coverage for unemployed workers</td>
<td>$24.7 billion to provide a 65% federal subsidy for up to nine months of premiums under the Consolidated Omnibus Budget Reconciliation Act (COBRA). The subsidy will help workers who lose their jobs to continue coverage for themselves and their families.</td>
</tr>
<tr>
<td>Departments of Defense and Veterans Affairs</td>
<td>More than $1.4 billion for the construction and renovation of health care facilities.</td>
</tr>
<tr>
<td>Health information technology (HIT)</td>
<td>$19.2 billion, including $17.2 billion for financial incentives to physicians and hospitals through Medicare and Medicaid to promote the use of electronic health records and other HIT and $2 billion for affiliated grants and loans to be administered by the Office of the National Coordinator for Health Information Technology. Physicians may be eligible for grants of $40,000 to $65,000 over multiple years, and hospitals for up to $11 million.</td>
</tr>
<tr>
<td>Health Resources and Services Administration</td>
<td>$2.5 billion, including $1.5 billion for construction, equipment, and HIT at community health centers; $500 million for services at these centers; $300 million for the National Health Service Corps (NHSC); and $200 million for other health professions training programs.</td>
</tr>
<tr>
<td>Medicaid</td>
<td>$338 million for payments to teaching hospitals, hospice programs, and long-term care hospitals.</td>
</tr>
<tr>
<td>Medicaid and other state health programs</td>
<td>$87 billion for additional federal matching payments for state Medicaid programs for a 27-month period that began October 1, 2008, and $3.2 billion for additional state fiscal relief related to Medicaid and other health programs.</td>
</tr>
<tr>
<td>National Institutes of Health (NIH)</td>
<td>$10 billion, including $8.2 billion for new grants and related activities and $1.8 billion for construction and renovation of NIH buildings and facilities, extramural research facilities, and research equipment.</td>
</tr>
<tr>
<td>Prevention and wellness</td>
<td>$1 billion, including $650 million for clinical and community-based prevention activities that will address rates of chronic diseases, as determined by the secretary of health and human services; $300 million to the Centers for Disease Control and Prevention for immunizations for low-income children and adults; and $50 million to states to reduce health care–associated infections.</td>
</tr>
<tr>
<td>Public Health and Social Services Emergency Fund</td>
<td>$50 million to the Department of Health and Human Services (DHHS) to improve the security of information technology.</td>
</tr>
</tbody>
</table>

The budget also provides resources to reduce health disparities in subpopulations, such as women and minorities, a goal that the President has identified as important to his administration. Resources will be increased to detect, prevent, and treat HIV/AIDS as well as to expand research, diagnosis, treatment, and support for individuals, families, and communities affected by autism spectrum disorder (ASD). More than $4 billion is provided to the Indian Health Service (IHS) to support and expand health care services and public health programs for American Indians and Alaska Natives. A provision of $73 million is also provided to improve access to quality health care in rural areas. President Obama’s budget also provides support to the FDA to establish a drug re-importation program and a regulatory pathway for generic biologics.

Focus on Health Care Reform Policies Of Interest to P&T Committees

Increased Emphasis on Generic Drug Use

President Obama recognizes that in order to expand health coverage and the availability of drugs to the U.S. population,
it is necessary that medications be available at a reasonable cost.\textsuperscript{16} At the Generic Pharmaceutical Association (GPhA) meeting in September 2008, Obama health policy advisor Dora Hughes, MD, MPH, reportedly stated that reducing barriers to generic drug use should be central to health reform efforts.\textsuperscript{17}

One reason for such a central role in the Obama health care reform agenda is that substantial cost savings from increased generic drug use have already been noted. The Medicare Part D Drug Program is costing the federal government and Medicare enrollees much less than originally projected partly because of greater use of generic medications.\textsuperscript{18} In a report on national health care estimates for 2007, the Centers for Medicare and Medicaid Services (CMS) Office of the Actuary (OACT) reported that the growth rate for drug spending hit a 45-year low.\textsuperscript{19} Expenditures for pharmaceodelicals increased only 4.9% to $227.5 billion.\textsuperscript{19} This growth rate was a little more than half of the 8.6% increase in 2006 and the slowest rate of growth in drug spending observed since 1963.\textsuperscript{19} Prescription drug prices rose by only 1.4% in 2007, even less than the modest price hike of 3.5% in 2006.\textsuperscript{19} Generic drugs accounted for 67% of drugs dispensed in 2007, up from 63% in 2006.\textsuperscript{19} Generic drug use also further increased in volume by 5.4% in 2008, compared with the previous year. Regarding this trend, Joseph Hill observed:

> With few exceptions, payers recognize the value of generic drugs, so there has been a drive toward generic drug use as formularies and preferred drug lists are set up for state Medicaid programs. For Medicare Part D, there is also a sense that generic drugs are, more often than not, the better alternative based on therapeutic value and cost.

The data now indicate that although prescription drug costs were once the most rapidly rising segment of health care costs, these expenditures are now among the slowest-growing categories.\textsuperscript{12} Because of this trend, OACT has reduced its 2008–2016 cumulative projection for prescription drug spending by 14% or $515 billion.\textsuperscript{3} The lower cost of prescription drugs was attributable to several blockbusters, and the extension and introduction of generic drug discount programs by large chain drugstores.\textsuperscript{5,19}

Despite the contribution of lower drug costs to health care savings, this reduction in spending is nowhere near what is required to support President Obama’s health care plan.\textsuperscript{3} Consequently, even greater efforts by both public and private health plans to encourage the use of generic prescriptions over trade-name drugs are expected within the next four years.\textsuperscript{3} Secretary Sebelius reflected, “Despite the slow-down in prescription drug spending growth, I believe that Congress and the administration can continue to reduce prescription drug costs.”\textsuperscript{39}

To this end, several measures are planned to promote an even greater availability and utilization of generic drugs. One proposed strategy is to ban generic settlements, which will outlaw agreements between innovator and generic companies that delay entry of generic drugs to the market.\textsuperscript{3} The market exclusivity of innovator biologics is also expected to be challenged through the re-examination of exclusivity periods and establishment of an abbreviated pathway for the approval of generic biologics.\textsuperscript{3} Generic biologics are also known as “biosimilars” or “comparables” because they are not identical to the innovator drugs.\textsuperscript{3} The biotechnology industry prefers an exclusivity period of 14 years, whereas generic drug proponents believe that three to five years is sufficient.\textsuperscript{3} Market exclusivity for biologic drugs is expected to initially be at least 12 years.\textsuperscript{3}

Establishment of an abbreviated pathway for the approval of biosimilars is expected to reduce drug costs because expensive biologic drugs are contributing to rapidly rising health care costs.\textsuperscript{2} DHHS Secretary Sebelius commented: “It is time that we bring competition to the biologic drug market and allow for an expedited approval process for [biosimilars], while providing appropriate incentives for development and innovation” of innovator products.\textsuperscript{3} The Congressional Budget Office (CBO) estimates that the federal government could save $9.2 billion over 10 years by establishing an abbreviated pathway for the FDA approval of biosimilars.\textsuperscript{19} In this analysis, a 12-year exclusivity period for brand-name biologics and limited requirements for duplicating innovator clinical trials was assumed.\textsuperscript{19} The Medicare program is expected to benefit the most from the cost savings incurred from less expensive biologic drugs, but other public and private health programs are also expected to benefit.\textsuperscript{19}

Although it is agreed that the availability of generic biologics will reduce health care costs, this reform measure does have opponents. The availability of generic biologics could decrease revenues and thus limit the funds available for the research and development (R&D) of new products.\textsuperscript{3} Some biotech manufacturers have also reportedly objected that the availability of biosimilars will increase risks to safety and therapeutic efficacy.\textsuperscript{3} This may be a legitimate concern, as reflected in the statement by Ronald J. Campbell, Jr., PharmD, BCPS, Clinical Specialist, Critical Care for UPMC St. Margaret Hospital, a hospital of the University of Pittsburgh Medical Center:

> Proving that a biologic drug is bioequivalent will be a difficult task because you are dealing with much more complex chemical structures. Safety is always a top concern for any medication, and this would especially be true for generic biologics. Reporting adverse drug reactions is a voluntary process for health care professionals and organizations, so there needs to be thorough reporting of any suspected events to the FDA, so that if a pattern develops with a particular product, a detailed analysis can be undertaken.

Joseph Hill agreed:

> The theory behind a generic drug is that it is completely interchangeable with the brand drug—they have the same molecular structure and therefore the same therapeutic value. …With biosimilars, you will likely see some products that are more easily interchangeable than others. How you establish the notion of equivalency is more difficult because you don’t have the same degree of similarity between biosimilars and innovator products as you do with other generic and brand medications.
President Obama’s Health Care Reform Policies

Overcoming safety and therapeutic efficacy concerns will be extremely important to the success of a biosimilars program. If the availability of generic biologics proves to be favorable, the marketing exclusivity period for branded biologics may be shortened further, especially if health care costs continue to rise in a slow economy.7

Legalization of Drug Reimportation

Another possible health care cost-cutting strategy being considered by President Obama is drug reimportation.11 Allowing the reimportation of medications from other developed countries would theoretically slash prescription drug costs.3,8 Some analysts have estimated that reimportation could cause drug prices to drop by 30% to 40%, based on price spreads between the U.S. and other developed countries.1 Dramatic price reductions on proprietary drugs would come as a welcome relief to Americans who don’t take their medications or skip doses because prescription drug costs are a burden.7 In a 2002 study (conducted before the establishment of Medicare Part D), it was found that 22% of senior citizens did not fill their prescriptions because they could not afford the cost of their medications.7 This percentage was reported as being even higher, at 32%, for the 15% of the U.S. population that is uninsured.7

Other countries do have lower drug costs, but whether there are savings to be had by purchasing or reimporting drugs from abroad is questionable. Countries such as Canada have lower prices than the U.S. for brand-name prescription drugs because they have government price controls.20 Buying medications from a certified Canadian pharmacy can save Americans as much as 20% to 80% for brand-name drugs.7 However, economists have said these cost savings might be overestimated because there are complications involved in comparing medication prices between different nations.7 Instituting safeguards to ensure product quality may also potentially reduce savings.17 For example, using anti-counterfeiting technology on drug packaging to verify authenticity has been proposed.7 However, according to FDA estimates, anti-counterfeiting technology would cost approximately $2 billion.7 Several state and local drug import programs have also been dropped because of high costs and low consumer interest. The decline in consumer interest may be a result of extending drug coverage to seniors through Medicare Part D, which has eliminated potential participants in reimportation programs.17 Joseph Hill acknowledged, “Before there was a Medicare Part D drug benefit, I think reimportation was a bigger issue.”

Another important concern about the reimportation of drugs from a developed country like Canada is that the drug supplies are limited and cannot serve the needs of the entire U.S. population.7 In fact, Canadians oppose legalization of reimportation in the U.S. because it could exacerbate the problem of medication shortages in Canada.7 Joseph Hill said:

It stands to reason that Canada may not have a large enough drug supply for both its own citizens and a good portion of U.S. citizens as well. Therefore, there would likely be issues of supply and demand. There would need to be noticeable increase in supply to drive down drug costs in the U.S. It is simply not a long-term solution.

A few drug companies in the U.S. have even cut off drug supplies to Canadian pharmacies that sell prescription drugs to U.S. consumers, leading to serious drug shortages at those pharmacies.7

In addition, a 2003 FDA study revealed that purchasing some drugs in Canada might actually be more expensive. The FDA found that Americans purchasing drugs in Canada might be paying significantly more than if they had purchased the generic equivalent in the U.S.7 Another study showed that for six of seven top-selling prescription drugs for chronic disease, generic versions available in the U.S. cost significantly less than their Canadian equivalents.7 It has also been reported that the U.S. had higher prices for originator drugs but had the lowest generic prices compared with Canada, France, Germany, Italy, Japan, Mexico, and the U.K.7 The U.S. also had the lowest over-the-counter drug prices.7

Even if cost savings are found to be possible, safety concerns regarding drug reimportation are daunting. Concerns regarding safety, efficacy, and therapeutic equivalency have long been obstacles to legalizing drug reimportation in the U.S.7 President Obama has also put forth the usual caveat that in order for drug reimportation to be legalized, we must be certain that the reimported drugs are safe and effective.17 Cynthia Reilly voiced a similar concern:

ASHIP and other pharmacy associations have raised concerns about product integrity. While there is recognition that there could be some cost savings from reimportation, there would certainly need to be some significant safeguards at the federal and state level to ensure the integrity of the supply chain.

Reimported proprietary drugs are often manufactured in the U.S., but the FDA is not able to monitor packaging and storage conditions in countries from which the drugs are exported.7 Inappropriate storage conditions of reimported medications in transit back to the U.S. may also degrade drug quality.7

The FDA also contends that legalizing drug reimportation might facilitate the entry of counterfeit medications into the U.S.7 In order to boost profits and increase the supply of drugs available for reimportation, pharmacies in developed countries like Canada might order drugs from countries such as India, Thailand, and Africa, where drug counterfeiting is more prevalent.7 It would be difficult to determine whether the drugs purchased from other countries have the same dosage form, potency, and amount of active ingredient as the prescribed medication.7 Ordering medications on the Internet can also be dangerous, because unscrupulous Web pharmacies may make the bogus claim that they are located in Canada.21 Joseph Hill stated:

Our concerns are even more acute because people often buy these prescription drugs via the Internet. Web sites may state that the facility is located in Canada or another developed country, but in fact you as a consumer have no assurance where that actual pharmacy is.

Many Web sites dispense expired, subpotent, contaminated, or counterfeit products.21 Drugs ordered on the Web have been
found to have no or low levels of active ingredients, fake lot numbers, and incorrect expiration dates.\textsuperscript{21} In 2004, the FDA conducted a study of generic drugs purchased from sources on the Web that claimed to be located in Canada. The results were alarming (Table 3).\textsuperscript{22}

The FDA has said that reimportation legislation would also severely burden the FDA regulatory system, noting that the federal government is already responsible for the massive task of checking for illegal drug imports entering through ports and the mail.\textsuperscript{21} The FDA and Customs and Border Protection examination of 1,982 drug packages mailed or shipped to individuals in the U.S. from abroad in 2004 has already given cause for concern.\textsuperscript{7} It was found that approximately 90% of imported products were either unapproved or presented severe health risks.\textsuperscript{7} The examined imports included drugs that had been withdrawn from the U.S. market as unsafe; drugs requiring initial screening and periodic monitoring of patients to ensure safe use; controlled substances such as codeine; drugs intended for animals that had been sold for human use; and drugs that might cause dangerous drug–drug interactions.\textsuperscript{7} The majority of drugs were of unknown quality and originated from Third World countries.\textsuperscript{7} The labeling and packaging of the reimported drugs were also not up to FDA standards because labels and inserts were often in foreign languages.\textsuperscript{7} The World Health Organization (WHO) estimated that in the year 2000, 8% of bulk drugs imported to the U.S. were counterfeit, unapproved, or substandard.\textsuperscript{7}

Congress approved a broad reimportation bill several years ago, despite the FDA’s concern that import expansion would lead to an even greater flood of unsafe medical products into the U.S.\textsuperscript{23} To minimize such risks, a Senate amendment to the bill required DHHS to certify that drug reimportation “will be

### Table 3 “Canadian” Generic Brands: Clinical Significance of FDA Laboratory Analyses (July 13, 2004)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Zolpidem (Ambien)</th>
<th>Atorvastatin (Lipitor)</th>
<th>Sildenafil (Viagra)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Identification</strong></td>
<td>Pass (drug present)</td>
<td>Pass (drug present)</td>
<td>Pass (drug present)</td>
</tr>
<tr>
<td><strong>Potency</strong> (average of 20 tablets for each drug)</td>
<td>Fail</td>
<td>Fail</td>
<td>Fail</td>
</tr>
<tr>
<td>140% of declared potency</td>
<td>81% of declared potency</td>
<td>65% of declared potency</td>
<td></td>
</tr>
<tr>
<td><strong>Dissolution</strong> (single time point determination)</td>
<td>Pass</td>
<td>Fail</td>
<td>Fail</td>
</tr>
<tr>
<td>128% of declared label amount</td>
<td>55% of declared label amount</td>
<td>67% of declared label amount</td>
<td></td>
</tr>
<tr>
<td><em>The “pass” result is likely a result of the superpotency</em></td>
<td><em>The “pass” result is likely a result of the superpotency</em></td>
<td><em>The “pass” result is likely a result of the superpotency</em></td>
<td></td>
</tr>
<tr>
<td><strong>Chromatographic purity</strong></td>
<td>Pass (No impurities detected)</td>
<td>Fail</td>
<td>Fail</td>
</tr>
<tr>
<td>5% impurities</td>
<td>0.7% impurities</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Summary of clinical significance</strong></td>
<td>All 20 sample tablets were more potent than the acceptable limit for the FDA-approved drug (up to 171% of approved potency). Sample tablets that are above the acceptable potency limit could put the patient at risk for central nervous system depression, leading to decreased mental alertness and loss of coordination (especially in an elderly or debilitated person).</td>
<td>There is a risk of clinical failure owing to subpotency. If a patient took the sub-potent sample product (perhaps having switched from the innovator to the sample product), an otherwise unsuspected reduction in efficacy (increase in cholesterol level) could result. While this may not present a problem in the short-term, the fact that the patient is not being treated optimally would put the patient at increased long-term risk for complications of high cholesterol, such as heart disease. The sample tablets may also be less safe because of the elevated impurities.</td>
<td>The sample tablets may be less clinically effective because of their reduced potency and poorer dissolution profile. The sample tablets may also be less safe because of the elevated impurities.</td>
</tr>
<tr>
<td><strong>Comments</strong></td>
<td>Several tablets were above 140% potency, including one tablet that was almost double the potency of the FDA-approved drug (sample = 171%). This potency variability among the sample tablets (relative standard deviation = 11%) is usually indicative of a poor manufacturing process.</td>
<td>The potency variability among the sample tablets (relative standard deviation = 9%) is usually indicative of a poor manufacturing process.</td>
<td>The potency variability among the sample tablets (relative standard deviation = 11%) is usually indicative of a poor manufacturing process.</td>
</tr>
</tbody>
</table>

Data from the FDA.\textsuperscript{22}
safe and provide consumers with ‘significant’ savings.\textsuperscript{3,23,24} This provision allowed the FDA to kill the reimportation program if the agency considered the policy unworkable.\textsuperscript{23} The FDA has consistently refused to guarantee the safety, efficacy, and legitimacy of reimported prescription drugs.\textsuperscript{5,7} The agency has stated that it does not have sufficient financial and technological resources to ensure the safety and authenticity of drugs brought in through a reimportation program.\textsuperscript{7}

Apparentlly, recent high-profile safety scares involving drugs manufactured abroad have also diminished President Obama’s enthusiasm for drug reimportation.\textsuperscript{22} The incident that was perhaps of most concern was a report issued by the FDA in February 2008 about the deaths of patients who had taken contaminated heparin made by a manufacturing facility in China for Baxter International.\textsuperscript{20} Dorn Hughes reportedly stated that President Obama was initially “in favor of reimportation, and … subsequent to the heparin incident [there’s] a lot less enthusiasm. We have a better understanding of the challenges that go along to support the importation.”\textsuperscript{20} DHHS Secretary Sebelius has also stated that “the recent incidents involving heparin and other consumer products has highlighted the potential challenges that must be addressed before we import drugs so we can be assured they are safe and effective.”\textsuperscript{25}

There have also been quality problems with some generic drugs manufactured in India that have caused legislators to be reluctant to increase drug imports.\textsuperscript{17}

The FDA has been severely criticized for its inability to properly inspect overseas manufacturing facilities, where some reimported drugs may originate.\textsuperscript{20} The U.S. Government Accountability Office (GAO) reported in September 2008 that the FDA inspects relatively few foreign manufacturers that make drugs sold in the U.S.\textsuperscript{5} The GAO estimated that the FDA inspects only about 8% of these establishments in a given year; at this rate, it would take the FDA 13 years to inspect every facility once.\textsuperscript{2} The FDA reportedly acknowledged that it had failed to inspect the Chinese facility where the raw ingredient for the heparin was made.\textsuperscript{20} FDA officials have also reportedly stated that they lack enough staff and funding to regularly inspect such facilities.\textsuperscript{20,29} The FDA’s field force appears to be depleted and additional resources are required to inspect the growing volume of overseas manufacturing and clinical research sites.\textsuperscript{24} Secretary Sebelius acknowledged that confidence in the FDA needs to be boosted, stating:

We all know that the FDA has not performed as well as it should in recent years, whether we look at recent food safety outbreaks, unsafe drugs such as Vioxx being pulled off the market, or intentional adulteration of products such as the melamine contaminated pet foods and infant formula.\textsuperscript{5}

As such, reimportation is not likely until FDA reforms and funding are in place and public confidence in the agency is restored.\textsuperscript{3}

President Obama has included funding for the FDA to establish a drug reimportation program in his 2010 budget.\textsuperscript{3,21} The budget also includes a substantial increase in funding to strengthen efforts by the FDA to make food and medical products safer.\textsuperscript{1} The amount of total funding FDA receives will ultimately determine whether the agency will be able to establish a drug reimportation program.\textsuperscript{3,24} The FDA Science Board reportedly suggested that the 2009 budget of $2.4 billion would need to be increased two-fold over the next five years to be able to assess the safety of foreign drugs.\textsuperscript{3} The FDA has looked into measures such as upgrading its computer data systems to obtain better information on drug imports.\textsuperscript{21} New technologies, such as radiographic devices, which will assist law enforcement officials in identifying illegally imported drugs, have also been considered.\textsuperscript{21} Agents who reimport drugs may also be required to provide the FDA with detailed records of the traversed path, as well as proof that each batch passed tests for safety and authenticity.\textsuperscript{24} Official regulations for reimportation are expected to take two or more years to establish because complex matters need to be considered, such as foreign export laws; product tracing, testing, and labeling; and liability.\textsuperscript{24} It is expected that it will take three years for a pilot program and four years to establish a full-scale reimportation program.\textsuperscript{24}

Two potential concerns for drug plans and health care facilities regarding drug reimportation have been suggested.\textsuperscript{24} A DHHS mandate that drug formularies need to include reimported drugs would be precedent-setting and might impede a proper drug mix.\textsuperscript{24} Health care facilities and plans also need to be prepared for liability problems that might arise if a reimported drug is included on formulary and is found to be adulterated.\textsuperscript{24} Regarding liability concerns, Joseph Hill stated:

Full protection against liability issues is difficult to achieve. You would think your supplier is fully compliant with the law, but outside of going up there and inspecting their facilities, you may not have all the information you need to be sure that these products are safe. A program of random sampling or other safety checks would be needed.

**Establishment of a National Health Information System**

President Obama has described health information technology (HIT) as the “low-hanging fruit” of health care reform.\textsuperscript{1} His plan accelerates the adoption and implementation of HIT and the utilization of electronic health records (EHRs).\textsuperscript{11} The Obama administration will invest $10 billion a year for the next five years to create a national state-of-the-art health information system.\textsuperscript{9}

Investment in a national HIT system is expected to promote efficiency and quality and to lead to substantial health care savings.\textsuperscript{8} It is a key element in modernizing the American health care system and accessing other savings by reducing wasteful administrative expenses, integrating care for chronic disease, and aligning reimbursement with the provision of high-quality care.\textsuperscript{9} Computerized health records are expected to improve the quality of health care, prevent unnecessary health care spending, and reduce medical errors.\textsuperscript{11} In her testimony to the Senate, Secretary Sebelius explained:

While improving health care quality is a primary benefit of a nationwide interoperable health IT infrastructure, cost savings from reducing clinical redundancy and error, as well as from reducing greater administrative efficiencies, are fundamental goals that must be realized if we are truly going to reform our health care system.
Electronic processes for the back-office functions of health care will help ease these burdens on physicians and other health care providers, freeing them to spend more time with patients.

A national HIT system is also expected to reduce the costs of medical malpractice. Secretary Sebelius reflected:

I support … preventing medical mistakes from happening in the first place. … Investing in health information technology … can alert doctors when patients have allergies or drug contraindications and [provides] transparency about health care quality through reporting requirements.

President Obama’s 2010 budget also suggests that EHRs be combined with comparative effectiveness research (CER). Theoretically, all available evidence on the outcomes of different treatment options would be distilled into user-friendly electronic pop-up alerts for physicians at the point of care. Joseph Hill feels that such a system would help facilitate good practice decisions, “but we also have to be careful about treating people based solely on computer algorithms because, for example, pharmacists are in the best position to counsel patients on the best time to take their medication and what foods or other medications to avoid. HIT won’t take the place of good patient care.”

Currently, only a small minority of health care facilities and practitioners in the U.S. use a HIT system. Only 17% of physicians and 8% to 10% of U.S. hospitals have at least a basic EHR system. An even smaller fraction have established and routinely use a more comprehensive system that would fully realize the potential of HIT. Starting in 2011, Medicare and Medicaid will provide financial incentives of up to $40,000 to $65,000 per eligible physician and up to $11 million per hospital to assist with the purchase, implementation, and meaningful use of certified HIT, such as electronic exchange of data and reporting of clinical quality measures. The amount of an incentive payment to a hospital that uses EHRs will, in part, be determined by a hospital’s share of charges related to charity care. The more charity care provided, the higher the amount of the payment. These incentives, coupled with other activities authorized in the ARRA, are expected to result in a dramatic increase in the percentage of health care providers using HIT within five years. Beginning in 2015, physicians and hospitals that do not use certified HIT products in a meaningful way will incur financial penalties. The CBO projects that the provided incentives will boost the proportion of physicians and hospitals adopting comprehensive EHRs by 2019 to 90% and 70%, respectively, from the 65% and 45% that would otherwise be expected to do so.

The federal government’s involvement in HIT is not an entirely new development. In 2004, the Office of National Coordinator for Health Information Technology was created as part of DHHS by executive order of President George W. Bush. However, Congress never legally established the office and its funding was limited to $60 million a year. In contrast, the ARRA codifies the National Coordinator Office, provides $2 billion for discretionary spending on grants and loans, and sets the goal of establishing a certified EHR for each person in the U.S. by 2014.

Two federal advisory committees on HIT will also be established: one on policy and the other on standards. These government committees will work with the private sector and consumer groups to develop the specifics of a nationwide HIT network. Interoperable EHRs will be designed that permit the exchange of data among physicians, hospitals, laboratories, pharmacies, and other health care organizations. Methods of ensuring the privacy and security of patient data will also be established. Standards for the HIT system are expected to be developed in 2009, then tested and certified by DHHS in 2010. Secretary Sebelius stated:

The standards and certification process … will help assure providers that the electronic medical record systems they purchase are indeed interoperable, while spurring innovation and competition as vendors develop products that meet these standards and the needs of providers. In addition, the grant and loan programs, the establishment of Regional Extension Centers, and the role of the National Coordinator for Health IT … are all critical components of the successful implementation of the Recovery Act.

After the HIT system and EHRs are established, patients will be able to request a digital copy of their EHRs or have them transmitted directly to a physician, hospital, or another entity they designate. However, safeguards for privacy, security, and preventing commercial exploitation of EHRs are critical to the success of the nationwide HIT network. Secretary Sebelius added:

It is absolutely critical that we ensure the privacy and security of patients’ medical information. Only if we gain the trust of consumers will we ensure an effective system…That way we can … ensure that patients’ information is confidential and secure and that HIT facilitates the appropriate sharing of information that can improve quality of care and save lives.

Ronald Campbell also reflected that privacy “is a concern, but as long as you have the proper safeguards in place for privacy, it should be acceptable. There will always be a fear of security being breached, but that should not prevent the health care industry from moving forward.”

The ARRA incorporates rules that privacy advocates and some lawmakers had been seeking for years. It allows individuals to request an audit trail for all electronic disclosures of their health information and mandates patient notification regarding any unauthorized disclosure or use. These protections also apply to companies that do work on behalf of health care providers, health plans, and health care clearinghouses. Privacy rules also dictate that EHRs be encrypted when transmitted or physically transported outside a health care facility so that they are indecipherable to unauthorized individuals. The ARRA also includes limitations on the sale of patient health information and its unauthorized use in marketing and fundraising, increases penalties for violations, and strengthens enforcement and oversight.

Although HIT holds promise, only if the implementation is done correctly can the technology promote quality of care and cost savings. Proponents of spending on HIT are said to often refer to an analysis conducted by the RAND Corpo-
ration in 2005. This report predicted that HIT would result in $77 billion in annual savings and improved outcomes. The report said the benefits of HIT would include dramatic cost savings from efficiency, greatly increased safety, and health benefits. However, it is feared that the allotted $20 billion for HIT might be wasted on systems that don’t work and can’t be implemented. These concerns are based on the fact that HIT is complex and requires the participation of hundreds of thousands of health care professionals and facilities. Many of the participants have also already invested in legacy systems that work reasonably well, but vary, and therefore, are not coordinated. For example, Ronald Campbell explained:

UPMC St. Margaret has invested in health IT for the past several years, including computerized physician order entry (CPOE). If you look at the current published data evaluating the effect of electronic health records on patient outcomes, there are both positive and negative results. I think as more products become available and refined in this area, it has to improve efficiency and outcomes. Cost is the obvious issue, then getting all staff trained and comfortable using it is another barrier.

Secretary Sebelius also addressed this matter. She stated:

It is very important that providers who currently employ electronic medical records have the support and technical assistance they need. … The Regional Extension Centers program included in the Recovery Act … can support the efforts of providers not only to adopt health IT but also to upgrade, use, and maintain their systems.

There are also concerns that proponents of a national HIT system are confusing association with cause. Although it is true that other nations use EHRs more widely than the U.S., utilization of HIT might not be why these countries spend less on medical care. These countries exhibited superior cost control with respect to health care costs, compared with the U.S., long before the establishment of EHRs. It is reported that no formal studies have definitively identified the low usage of HIT as a significant explanation for why U.S. health care costs far exceed those of other nations.

**Collection and Utilization of Comparative Effectiveness Research**

CER is another tool on the Obama agenda to help cut the costs of the U.S. health care system. It is stated in President Obama’s 2010 budget that the administration will continue efforts to produce state-of-the-science information on which medical treatments work best for a given condition. It is the hope of the Obama administration that an investment in CER will help improve efficiency, cut costs, and increase the quality of care. Research has revealed that expensive treatments do not always result in better results. Medicare data have also shown that large geographic variations in treatment patterns and higher health care spending are not clearly linked to improved outcomes. Although CER holds promise to improve practice decisions, achieve better outcomes, and slow cost escalation, it is highly controversial. The CER gathered will probably need to be based primarily on credible scientific data, without undue emphasis on costs, to garner support.

The CBO has defined CER as “a rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients.” CER studies could compare similar treatments, such as competing drugs, or could analyze the outcomes of entirely different approaches, such as surgery and drug therapy. They might focus on a comparison of the medical benefits and risks of each option, as well as the costs.

The goal of CER is to provide patients, physicians, and payers with evidence to support treatment decisions. President Obama has suggested that when coupled with EHRs, CER can provide clinical decision support tools for physicians at the point of care. Making clinical decisions on the basis of CER data may reduce health care costs by limiting the widespread unnecessary overuse of medical technologies, which decades of research has identified as the primary driver of escalating health care costs in the U.S. The increased emphasis on CER is also timely, because new costly therapeutic alternatives are continuously coming to market. Although promising, a 2008 CBO reportedly estimated that CER would reduce national health care spending by only approximately $8 billion (less than one-tenth of 1%) from 2010 to 2019. Initial costs also have the potential to limit any initial savings gained as a result of CER.

An additional benefit of increased federal support for CER is that the government will sponsor studies that industry isn’t likely to. Drug manufacturers might be hesitant to sponsor head-to-head trials because it can be risky if a competitor’s drug is shown to be superior. Cynthia Reilly also noted that sponsorship of CER by private industry might be more difficult “because you are not just comparing different drug therapies, such as ACE-inhibitors in the same class; you are evaluating watchful waiting and other therapeutic options, such as surgical intervention. That type of research is broader, more complicated, and less likely to be completed by industry.” There are few studies on which a statin is best for lowering cholesterol or which kind of intervention is best for heart disease—drugs, open heart surgery, or angioplasty. It might also be wrongly assumed that insurance companies would want to know what kinds of interventions and drugs are most effective, as much as the government does, but the insurance industry doesn’t sponsor much CER either. The Institute of Medicine (IOM) estimated that because comparative effectiveness data are not required for regulatory approval, less than half of all medical care is supported by adequate effectiveness data.

Even prior to the Obama administration, increased government interest in CER was evident. In 2003, the passage of The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) marked the advent of federally sponsored CER. It required the DHHS Secretary to support research on “outcomes, comparative clinical effectiveness, and appropriateness of health care items and services (including prescription drugs).” In response, The Agency for Healthcare Research and Quality (AHRQ) created the Effective Healthcare Program. AHRQ designated 13 Evidence-Based Practice Centers (EPCs) to conduct systematic CER on topics of importance to Medicare, Medicaid, and CHIP. The reports issued by AHRQ include comparisons of pharmaceutical products; sur-
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gery versus drug therapy or watchful waiting; and in-hospital versus outpatient treatment. These reports may be found on AHRQ’s Web site (www.ahrq.gov). The federal government also provided $750 million to the Agency for Healthcare Policy and Research (AHCPR) to issue 19 treatment guidelines.1

In 2007, a CBO report also emphasized the need for CER as a means to control costs and improve quality and recommended that the federal government take a lead role in producing this research.2 The report also emphasized that government-sponsored CER must be produced independent of political pressure and must be respected by medical professionals in order to be successful.2 In 2008, the AHRQ budget for CER was doubled to $30 million, and the 110th Congress introduced at least six bills increasing support for CER.2 Under President Obama, the $1.1 billion appropriated in 2009 for CER in the ARRA dwarfs the current $334 million total annual budget for AHRQ, which will administer $300 million of the CER funds.1 The NIH and DHHS will administer the rest.2,10

The additional funding for CER will allow the government to fund many more trials as well as clinical data networks, registries, and systematic reviews.1

Despite this increased funding, the demand for information may still far outweigh the resources available to conduct expensive, highly focused, randomized clinical trials.2 It is therefore expected that much of CER data will be observational, providing information on long-term patient follow-up or broad or vulnerable populations that are usually not studied in clinical trials.2 Cynthia Reilly stated:

In some ways, observational data may be more valuable because a broader and more diverse group of patients is included, such as patients with multiple disease states, compared to controlled clinical trials, which have strict inclusion and exclusion criteria.

Joseph Hill also sees value in such data, saying the ARRA provides funding for “government resources that will be able to perform CER from a broader scale than any individual researcher. It will produce data from independent non-biased sources that will be available to everyone.”

Traditional good practice guidelines for the clinical trial industry don’t apply well to observational studies, so new initiatives have been developed to guide the conduct, evaluation, and reporting of observational CER.2 One such initiative is the development of the Grace Principles (www.graceprinciples.org), which were created by Outcome Sciences, with seed funding from The National Pharmaceutical Council (NPC).2 These principles were developed to guide observational studies and to use evidence-based analysis to make coverage decisions, with the focus being mainly on drugs.2,21

The greater availability of CER data is expected to be a boon to formulary development and P&T committees. Cynthia Reilly stated that CER will be beneficial to P&T committees because most facilities currently do their own literature research regarding a particular treatment and dedicate significant staff time to do so. The availability of more CER will help lessen that burden. There are some caveats in that you need to make sure that the research population matches your patient mix. So there will still be a role for P&T committees to evaluate if the data [are] appropriate.

Similarly, Ronald Campbell stated:

We need more comparative effectiveness studies in order to make the best decisions for drug therapy. If there [are] comparative data available and it is determined the data [are] collected in an acceptable statistical manner, a hospital P&T committee would definitely find it useful in decision making. [However], the P&T committees will remain critical in performing analysis of the data for formulary considerations. It should be left up to the individual hospitals to decide what drugs to use on formulary because they may have different patient populations.

The fear that the collection of cost-effectiveness data will lead to treatment mandates and government rationing is by far the biggest concern regarding government-sponsored CER.17 Critics point to the U.K. and Australia as examples where national health plans have denied coverage of treatments based on comparative and cost-effectiveness research.2 In the U.K., the National Institute for Health and Clinical Excellence (NICE) is considered controversial because it reportedly operates as a formulary committee for the entire country.13 NICE is often cited by American advocates of CER as an organization that should be modeled in the U.S.4 It is especially feared that the inclusion of cost-effectiveness data in CER will result in government rationing of available treatments, when they can be obtained, and at what price.14 Secretary Sebelius has stated:

Currently, too many Americans find their choices of doctors and treatments dictated by their ability to afford care. And today, insurance companies make decisions all the time to not cover care,
which ends up restricting patient choice. … One of the best ways to protect choice and freedom when it comes to health care is to make it affordable. … No one is proposing the rationing of health care as part of health reform. In fact, health reform is needed to prevent the rationing by income and pre-existing conditions that is rampant in the system today. One way to prevent arbitrary health care decisions is to empower providers and patients with high-quality information. Comparative effectiveness is about gathering and sharing information on what’s most effective; it has nothing to do with government dictating choices or rationing care.

Some trade groups have also expressed concern that CER will become a tool for public and private payers to limit the availability of treatment choice because of cost. A key concern for medical manufacturers is the stream of highly priced new biotech therapies and medical diagnostics that are emerging. The Biotechnology Industry Organization (BIO) has reportedly asserted that the goal of CER should be to improve patient outcomes, not to constrain costs. BIO was also said to have argued that CER should encompass all treatments, including health care delivery, preventive services, diagnostics, and medical procedures, not just drugs, biologics, and medical devices. Even if comparative effectiveness analysis doesn’t cause an insurer to deny coverage, it is possible that a health plan might put a more costly drug in a reportedly higher formulary tier. Pharmaceutical industry leaders have reportedly taken the stance that payers should cover all medications that the FDA deems to be safe and effective and disregard cost-effectiveness calculations. BIO was also said to have issued a report that questioned whether CER methods are sufficiently developed to deal with the complexities of and variations in individual response to biotech therapies. AdvaMed, the trade organization for medical device manufacturers, also reportedly emphasized the importance of maintaining patient access to therapies and advocated that the focus of CER should be solely on clinical effectiveness, not cost-effectiveness.

Legislators have also expressed concern regarding how CER will be used if cost analyses are included. During the debate surrounding the passage of the ARRA bill, several Republican legislators, as well as lobbyists for drug groups and the insurance industry, strongly objected to CER funding. They feared CER would be used to deny treatment on the basis of cost. This concern was addressed in the ARRA bill that Congress passed, which states that CER will compare:

- clinical outcomes effectiveness, not cost: That the funding appropriated … shall be used to accelerate the development and dissemination of research assessing the comparative effectiveness of health care treatments and strategies through efforts that … conduct, support, or synthesize research that compares clinical outcomes effectiveness, appropriateness of items, services, and procedures that are used to prevent, diagnose, or treat diseases, and other health conditions.

To address concerns, the wording of the bill intentionally specifies that CER efforts should focus on clinical outcomes effectiveness rather than cost-effectiveness. The conference report addressed this matter even more directly, stating that “the conferees do not intend for the comparative effectiveness research funding included in the conference agreement to be used to mandate coverage, reimbursement, or other policies for any public or private payer.”

A report from the House Appropriations Committee does, however, reportedly mention lowering health care costs by reducing the use of less effective, more expensive therapies. The NIH also reportedly issued a number of Challenge Grants In Health and Science Research that explicitly fund cost-effectiveness research. Concern has also been expressed in the Senate that the Obama administration might be considering “invoking least costly alternative authority,” which would use CER to decide which test or treatment is, on average, the least costly alternative and deny Medicare patients access to other options. When questioned about the role of cost-effectiveness studies in CER, DHHS Secretary Sebelius responded: Congress did not limit this research when authorizing it in both the Medicare Modernization Act and the American Recovery and Reinvestment Act … Health care costs present a growing economic challenge in our system, so all serious proposals to reduce them should be considered. At the same time, ensuring quality coverage— for every patient—is a critical goal of the President’s. The goal of [cost] efficiency must never come at the expense of quality, and the President’s budget offers a number of proposals that enhance both.

With regard to the use of CER to dictate Medicare coverage, Secretary Sebelius stated:

In keeping with the provisions of [the] 2003 law, comparative effectiveness research will be used to allow patients and their providers to make the best, most informed decision possible as to which treatment is best. As specified in the law, Medicare cannot make coverage decisions based on this research.

Even if CER does include an analysis of costs alongside the clinical advantages of treatment options, the information is not guaranteed to lead to significant savings. CER alone does not save money; savings depend on whether the research encourages changes in treatment or coverage decisions. As noted, health care costs in the U.K. and many other countries are much lower than those in the U.S. The NICE does make recommendations on the basis of cost; the main focus of NICE has been to rationalize coverage decisions rather than to constrain spending. It does not operate as an instrument of cost control. In fact, since the establishment of the institute in 1999, spending in the National Health Service in the U.K. has dramatically increased (from 7.2% of the GDP in 2000 to 8.4% in 2006). This example may indicate that a health care system might not be able to control expenditures without efforts to establish and enforce cost targets. The same observation has been reported in many other countries, including Canada, Sweden, France, Germany, and Japan. Advocates for cost control recommend strong government leadership to set targets and spending caps in the various sectors of medical care (hospital, pharmaceutical, and physicians) either directly or through insurers. These proponents suggest that spending targets don’t need to be rigid and can be changed, if necessary, and that total expenditures should be subject to payment caps.
rather than individual services.4 In Germany, spending caps adopted in 1986 were said to have a dramatic effect in lowering costs for physician services.4

To date, President Obama has not indicated support for establishing the health care spending caps and cost controls in the U.S. that are observed in some other countries.4 The mention of cost controls on health care immediately inspires alarm about rationing in patients, health care professionals, manufacturers, and the insurance industry and are therefore highly political.4 The limited discussion of cost control by the Obama administration is likely necessary to avoid political controversy.4

Conclusion

President Obama has put forth an ambitious, complex, and sophisticated plan for health care reform. It is too early to tell whether his plan will meet all the necessary goals of reducing costs, providing greater accessibility, and improving the quality of health care in the U.S. Despite any shortcomings that might be perceived in his plan, such a comprehensive and serious effort is a significant step forward, compared with the deadlock and piecemeal advances that have been experienced in health care reform over many years. Exactly where the boundaries between widespread access to health care, cost savings, and preservation of treatment choice ultimately fall will likely take many more years to determine.

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