Unintended Consequences of Health Care Legislation

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Unintended consequences of health care legislation threaten the financial and social well-being of the United States. Examples of major legislation resulting in unintended and unforeseen consequences include the Social Security Amendments Acts of 1989 and 1993 (the Stark laws), the Balanced Budget Act of 1997, and the Social Security Amendments Act of 1965 (Medicare and Medicaid). Each of these has had unintended financial and social outcomes. Spending for Medicare and Medicaid now equals an unsustainable 23% of the federal budget. Major reasons for unintended consequences include failure to appreciate the complexity of the issues, the open-ended nature of medical advances with attendant increases in costs, the inducement of change in behaviors in response to legislation, and the moral hazard of people spending other people's money. Actions that should be considered to avoid unintended consequences include more involvement of health professionals in the design of legislation, the inclusion of triggers to target review of legislatively defined programs, and the setting of time limits for sun-setting legislation. The ACR has played an important advocacy role and should continue to offer input to legislators, federal policymakers, and other stakeholders. Many opportunities exist to address the current financial situation by reducing the amount of unnecessary care delivered. Both major US political parties need to find the political will to compromise to chart the way forward. Some level of sacrifice is likely to be necessary from patients and providers and other stakeholders.

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Unintended consequences of health care legislation enacted over the past forty-five years threaten the financial and social well-being of the United States. The Social Security Amendments Acts of 1989 and 1993 offer a sobering introduction to the concept of legislative unintended consequences and their impact on the health system [1]. These acts established the so-called Stark laws. Together, Stark I and Stark II define the legal circumstances under which physicians may refer patients to facilities for services in which the referring providers have financial interest. The intention of the Stark laws was to prevent the abuse of self-referral and to hold unnecessary Medicare costs in check.

The Stark laws have had exactly the opposite of their intended effect. Instead of preventing self-referral, the laws created a bulletproof safe harbor through the in-office ancillary services exception [1]. With the Stark laws in place, what had been regarded as an unethical and shady practice suddenly became clearly defined as legal. As a result, billions of dollars are siphoned from the health system each year to no benefit of patients. Moreover, when radiation or surgery is involved, unnecessary use exposes patients to unnecessary risks. The now infamous story of medical practice in McAllen, Texas, by Dr Atul Gawande [2] that appeared in the *New Yorker* magazine provides an indication of how egregious and widespread self-referral and overutilization can be.

Beyond siphoning money out of the health system, self-referral has had other negative long-term consequences that directly affect radiologists. Unnecessary use of imaging due to self-referral resulted in higher growth in imaging services compared with other Medicare physician services for many years. This, as much as anything else, put imaging costs in the spotlight as a target for cost cutting, leading to a succession of cuts to imaging reimbursement.

A second example of unintended consequences comes from the Balanced Budget Act of 1997 and the notorious "sustainable growth rate" (SGR) formula [3]. This legislation has so many birth defects, it is surprising that it is still alive. The idea behind the SGR was to replace the Medicare volume performance standard with a new formula that encompassed more dimensions and could govern the growth in Part B spending in a reasonable and sustainable way.

For the first few years, smallish single-digit increases were calculated, and the legislation seemed to work. Life was good. Doctors were happy. However, because of the

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way the SGR formula incorporates the gross domestic product, the recession of 2001 led to a negative update number in 2002. In essence, health care costs continued to go up despite the recession—no surprise to anyone involved in medical practice. The cumulative spending provisions in the SGR then resulted in negative updates each year thereafter [4].

Doctors are rightly upset about this legislation and the failure of Congress to address it in a long-term fashion; the unintended consequences of annual negative update numbers hang over physicians like a sword of Damocles, creating constant tension about their financial well-being and damaging their morale. Apart from 2002, Congress has intervened each year for the past 8 years to stop increasingly draconian SGR-based reductions from occurring in physician fees for Medicare; the projected number for 2010 was an eye-opening decrease of 21.5%. The prospect of continuous negative fee updates was never envisioned when the SGR was passed.

Flaws in the SGR formula include its linkage to the gross domestic product, failure to account for changes in medical practice, and inclusion of cost categories that are not physician services, such as costs for certain drugs. The massive shift in imaging from inpatient to outpatient was not factored in, nor were the effects of office based self-referral.

Other flaws in the SGR formula include the fact that the law does not take quality into account and neither rewards good behavior nor punishes the bad behavior of individuals with respect to appropriate utilization of services.

The "granddaddy" of unintended consequences comes from the Social Security Amendments Act of 1965, which created Medicare as Title XVIII and Medicaid as Title XIX [5]. This initiative was part of President Lyndon Johnson's Great Society program, which had 2 overarching goals, the elimination of the effects of poverty and the elimination of racial injustice in the United States. Addressing health disparities for the aged and the poor was a key component of this ambitious program and a laudable goal.

Medicare cost the federal government less than $3 billion in its first full year of operation in 1967, or less than 2.0% of federal spending (total federal spending in 1966 was $157.5 billion) [6]. On the basis of what was known and envisioned in 1965, it was projected that Medicare would cost the astonishing sum of $12 billion by 1990, a large number but still a small fraction of the total projected federal budget.

However, Congress, on both sides of the aisle, has expanded eligibility and the range of covered services almost from the very beginning. Today, 8 million people with disabilities are enrolled in Medicare. These additions to eligibility have never been offset numerically or financially and were never intended in the original legislation that was directed at the elderly. By 1990, Medicare cost not $12 billion but $98.1 billion and with Medicaid accounted for $145.7 billion, or almost 12% of total federal spending ($1.253 trillion) [6].

In fiscal year 2011, the projected total for Medicare and Medicaid is a staggering $841.3 billion, equaling 23% of total federal spending ($3.8 trillion) [6]. More than 85 million Americans receive all or part of their health coverage through Medicare and Medicaid. At balanced federal expenditures of $2.15 trillion, Medicare and Medicaid would account for 40% of the federal budget, a completely unintended consequence of the original legislation. The magnitude and rapid rate of growth of Medicare and Medicaid expenses threaten to bankrupt the United States unless they are brought under better control.

Health reform initiatives under President Obama that led to the Patient Protection and Affordable Care Act (PPACA) were aimed in part at reining in health costs, and it is logical to ask whether this major health care legislation will result in unintended consequences. The answer is yes; the way the legislation was written makes unintended consequences inevitable.

One such unintended consequence has already been presaged in Massachusetts. Current state law aimed at providing universal coverage requires that insurance companies provide coverage for preexisting conditions, similar to provisions set to go into effect under PPACA in 2014.

Insurance companies in Massachusetts now report an increasing trend toward short-term maintenance of coverage by policyholders. For 2009, Blue Cross reported that 936 people held policies for 3 months or less. Their premiums averaged $400 per month, and their claims averaged $2,200 per month, or roughly 6 times the average for longer term policyholders. Other companies have reported similar data [7].

Clearly, people are buying insurance opportunistically when they need it. The maximum penalty in Massachusetts for not buying insurance is $93 per year, which is obviously much lower than the cost of insurance. Why buy now when you can buy later? Without some modification of the original provisions in PPACA, under which the initial penalty will be $95 a year or 1% of income, the same phenomenon will be seen nationally for the same reason. The heartfelt desire to prevent denial of coverage because of preexisting conditions can perhaps be best described as "good intentions gone awry."

Other examples abound, but it is now time to ask how such unintended consequences happened. The first overarching theme about how and why unintended consequences occur is the sheer complexity of the issues and how challenging it is for Congress to understand them. Attempting to capture the almost infinite complexity of medical science and medical practice through laws having finite dimensions has clearly not worked as intended in many cases. Moreover, these laws are often largely crafted by people with limited knowledge of the health

care system, an approach that has not worked in the past and will not work in the future.

The complex interplay of gross domestic product vs medical cost inflation was not adequately taken into account in the SGR, leaving it on perpetual life support. The shift from an inpatient focus to a progressive outpatient focus in the US health system and associated implications for where technology would likely be used completely escaped those writing both the Stark laws and the Balanced Budget Act.

The second overarching theme is the open-ended nature of medical science and medical practice, which march on relentlessly regardless of legislative intent. When new lifesaving and life-extending treatments are available, doctors want to provide them to patients, and patients want to receive them. The natural political response is to add benefits and expand eligibility. It has been a one-way street. The addition of people with renal failure and requiring renal dialysis is a seminal example in the history of Medicare of new technology driving political decisions and leading to an enormous expansion of Medicare costs and eligibility [8].

Life expectancy at birth has risen steadily since 1965, about 8 years for both men and women, largely because of medical breakthroughs [9]. Everyone is grateful for this, but the tsunami of new medical technologies and their associated costs have defeated attempts up to this point to control them.

The third overarching cause of unintended consequences is that legislation has the capacity to effect major changes in people's behavior. Perhaps the most stunning example in the health system is coverage by Medicaid for nursing home care. In the mid-1960s, the number of indigent elderly perceived to need financial help with accessing nursing home care was relatively small. Families took care of their own elderly.

Today, Medicare and Medicaid cover 60% of nursing home care in the United States. The combined number for home health care is 72% [10]. An indeterminate percentage of people with substantial means even transfer their wealth to their children and other family members in order to qualify for Medicaid nursing home coverage. Law firms advertise their services to help make the transfer arrangements—never wanted, intended, or envisioned. Self-referral induced by Stark law safe harbors and the experience in Massachusetts of people buying insurance on the "spot market" are other examples of changes in behaviors directly resulting from legislation.

The fourth overarching factor that is clearly in play is the moral hazard of people spending other people's money. The moral hazard arises from the fact that neither Medicare beneficiaries nor providers are at financial risk for the vast majority of expenditures and do not have much motivation to spend less or make the system more efficient.

Beneficiaries feel that they have "paid their dues" through their own contributions to the generations that proceeded them and are not really interested in resolving issues around scope of services or the outsized increases in the costs of those services. They are certainly not interested in paying more for their coverage.

Providers paid on a fee-for-service basis are rewarded financially for doing more and are notoriously resistant to cutbacks or constraints that would disadvantage them financially. Radiologists must acknowledge that they feel the same way.

Eighty-seven percent of the money spent on Medicare beneficiaries comes from sources other than beneficiary premium payments. The transfer of wealth from younger to older generations will become increasingly problematic with the aging of the baby boom generation. In 2000, there were 4 workers per Medicare beneficiary. In 2030, the number of beneficiaries is projected to equal 80 million people, with just 2.3 workers per recipient [10]. This brings into sharp question whether Medicare can any longer be regarded as a "sacred trust between generations." Future generations of workers may regard their taxes for Medicare and Medicaid as millstones around their necks, preventing them from realizing the American dream.

This brings the discussion to thoughts about what might be done: thoughts about general principles that should be used in formulating health legislation and a few somewhat more specific thoughts about managing costs.

When unintended consequences of health care legislation are analyzed, it is clear that legislative initiatives are typically a response to current perceived circumstances and exigencies. As a nation, the United States needs to change its outlook from thinking that it can draw a line in time and pass legislation on the basis of current conditions in the belief that the nation's problems have been solved for the future. Rather, the assumption should be the opposite, that changes in social behavior and social norms on one hand and changes in science, technology, and medical practice on the other will inevitably take the country and society in unenvisioned directions and that the country will inevitably need to challenge its original assumptions to effectively respond and adapt. Congress should consider building in timelines and milestone events that trigger automatic review or even sun-setting of legislation so that it is forced to address issues more definitively and in a more timely fashion in the future.

It must be acknowledged that sincere attempts have been made to "fix" Medicare and Medicaid in response to changing conditions. But the process has been wrong, and the results are not what the country has needed. The process has been too ad hoc, too superficial, and driven too much by people with little or even no real-world health care experience.

For example, policymakers often look upon medical practitioners, people who actually take care of patients, as having unacceptable conflicts of interest and not as people with crucial sources of knowledge about how medical practice works and how it might be changed for the better. The attempts by the ACR to bring the issues of self-referral forward to Congress and CMS strongly support this contention. For 15 years, the ACR has provided Congress, the Medicare Payment Advisory Commission, and CMS with objective economic analyses of the harmful effects of self-referral but has been treated, until recently, as pursuing nothing more than a turf battle. Instead of listening to reality and seriously considering the ACR's proposed solutions, CMS and Congress cut reimbursement for imaging across the board, punishing ethical providers and stimulating self-referring physicians to do more of the same to make up for lost income.

The ACR must not give up. It has made progress on many fronts, and it must continue to provide information and ideas to legislators, federal policymakers, and other stakeholders. The ACR must promote a richer dialogue and insist that people with expertise not be looked down upon and dismissed simplistically as people who have inherent conflicts of interest but looked upon as people with valuable and necessary information to inform the legislative and policymaking process.

The need for more domain expertise in forming legislation clearly goes beyond the specialty of radiology, and the ACR should join with colleagues from other disciplines to see how best to create new and more dynamic interactions with legislators and policymakers while recognizing the necessity and the value of input by other categories of stakeholders.

With respect to more specific thoughts for addressing the high costs of health care in the United States, rather than cutting reimbursement to providers, the elimination of unnecessary care of all kinds is the single greatest opportunity to reduce costs while improving quality and safety at the same time. Reducing unnecessary care would go far in addressing the unsustainable national financial dilemma in health care.

Unnecessary care occurs for 5 primary reasons: financially motivated self-referral, fear of malpractice, lack of knowledge by providers, lack of care coordination, and outright fraud and abuse. Self-referral goes well beyond imaging to the provision of surgery, radiation oncology, laboratory testing, rehabilitation, and other services. Every study undertaken of self-referral of any kind has found gross overutilization [11-13]. Congress nibbled at the issue in PPACA, but ethical providers and other key stakeholders must demand that Congress find the political will to act much more decisively. Cutting reimbursement across the board is not the right approach. As noted previously, such cuts punish ethical providers while stimulating self-referring physicians to do more of the same [14]. Eventually, cuts in per unit reimbursement will challenge the ability of ethical providers to stay in business, thereby undermining quality and unduly restricting access.

It is an embarrassment to the medical profession that outside of radiology and a few other specialties, most medical professional societies, including the American Medical Association, have rejected the endorsement of anti–self-referral policies. This must change. All physicians must insist that their physician colleagues individually and through their respective professional organizations join in the commitment to ensure that precious health care resources are used only for valid and beneficial purposes, keeping patients' interests and rights foremost.

Addressing the culture of defensive medical practice in the United States through meaningful tort reform is another important opportunity largely missed in health reform, although the issue is being considered in Congress again. Society must find the golden mean between protecting patients' rights while taking the demoralizing threat of malpractice litigation out of the examination room.

It is difficult to monetize the potential benefits of tort reform but the unique medical-legal climate in the United States is a substantial contributor to our high health costs. Survey data obtained by the Massachusetts Medical Society indicate that approximately 25% of high-technology imaging, 18% of laboratory tests, and 13% of hospital admissions are ordered on a defensive basis [15]. Even if these numbers are higher than the savings that could ever be achieved or realized through tort reform, these and other data are staggering in their implications, suggesting that tens of billions of dollars are being spent defensively and unnecessarily and not for the likely benefit of the medical outcome of patients.

It should be a point of pride for ACR members that the organization has been the absolute leader in the development of appropriateness criteria to help fill in knowledge gaps and guide ordering providers to ensure that the right test is done on the right patient at the right time using the best protocol. The ACR began its work more than 20 years ago. This year, a congressionally mandated demonstration project is being undertaken by CMS that will use ACR Appropriateness Criteria® to determine their effect on ordering patterns. Other disciplines should follow the example of the ACR and undertake the development of criteria to guide their respective areas of work.

The US health care system is on the threshold of the era of accountable care organizations (ACOs), which are aimed at improving coordination of care. Bibb Allen Jr, MD, and coauthors [14] are to be congratulated for their outstanding white paper just published in *JACR* that provides a blueprint for radiologists in the ACO era. Through the ACR Appropriateness Criteria and other ACR programs, radiologists are well equipped to work within these organizations to promote and apply best

practices and to better integrate the care process. Experience at Massachusetts General Hospital suggests that applying the ACR Appropriateness Criteria as part of a computerized physician order entry system can promote better communication and care coordination and reduce unnecessary imaging substantially.

However, as originally defined, ACOs are unlikely to have their intended effect either medically or financially. They are too complex, with too many costly new requirements. Most provider organizations do not have the resources to convene effective ACOs that will require substantial upfront investment to achieve targeted savings and improvements in quality.

Fraud and abuse contribute to skyrocketing health system costs. Medicare and Medicaid are beset with greed and dishonesty above and beyond self-referral. The hemorrhaging of resources to fraudulent activities is only occasionally punctuated by stories of criminal prosecution, and it is largely unknown how many billions of dollars per year are lost to these criminal behaviors.

Medicare fraud and abuse must be dealt with far more effectively. Simple audit concepts such as correlating services to individual patients and benchmarking services by doctor and by patient would go a long way to uncovering illegal behavior.

The magnitude of the social and financial challenges facing the country with respect to Medicare and Medicaid is well illustrated by the fact that both of the country's major political parties are scrambling to find solutions that go far beyond anything included in PPACA. So far, in the legislative debate, no practical short-term or long-term alternatives have been brought forward that even begin to establish a middle ground between our two dominant political parties.

It is crystal clear that to get the health care genie back in the bottle, all stakeholders are going to have to give up something and take some risks. Politicians on both sides of the aisle will have to spend political capital to find middle ground. Those who are brave enough to put the interests of society before their own political survival will risk rebuke at the polls. Patients are likely to have to contribute more for their coverage and have less choice. Providers are likely to see decreases in reimbursement and less autonomy in their decision making. Insurance companies will be held to standards for medical loss ratios.

Winston Churchill once said, "Americans can always be counted on to do the right thing . . . after they have exhausted all other possibilities." Indeed, the United States has been on a journey of exhausting possibilities in health care legislation. The challenge remains for the country to learn from its mistakes and adapt to its constantly changing health care environment to do the right things legislatively.

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