The Affordable Care Act
Conundrum: Facing Reality in America’s Giant Social Experiment

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The Affordable Care Act (ACA) is the law of the land, but its implementation so far has been fraught with serious problems. The initial launch of www.healthcare.gov was a disaster. It is unclear whether the Centers for Medicare & Medicaid Services (CMS) or the office of the Department of Health and Human Services Secretary told the White House that the October 1 deadline for the launch was not doable or highly risky, or if anyone suggested a delay.

It seems that everyone in the Obama Administration went into a stay-on-message-at-all-costs mode, which is understandable: it is the norm in the federal government. But it comes at the cost of poor public administration. Internally, staff within CMS always knew that the ACA implementation would be problematic. In today’s Washington, optics trump honesty and transparency. It is hard to say how much this culture kept the White House from facing, or even internally admitting, the practical issues or risks involved in the launching of the website and the backroom data functions critical to actual enrollment in coverage. Where do we go from here?

A Giant Social Experiment

The ACA is a giant social experiment with few precedents. It is impossible to predict precisely what will happen next with the implementation of the law, or how consumers and employers will respond in the post-ACA world.

It is easier to predict the behavior of health insurers and providers, as well as the overall impact on them, but this is still complex. Americans and the US media have a short attention span. Change happens rapidly, and the law is so complex, that few people or organizations have the patience to understand even parts of the ACA. The enrollment numbers in the first 3 weeks of December will be critical to assessing how well the federal exchange is working, as well as the response of the public to the repaired website.

The number of new Medicaid enrollees will likely remain higher than new enrollees in the subsidized exchange plans in the first 2 years. We know that this is the case of states that have state-run exchanges, and Medicaid enrollment increases will be especially high in the states with Medicaid expansion; but nationwide, there is every reason to believe that Medicaid enrollment will outpace the subsidized exchange enrollment. In addition to a massive jump in enrollment through expansion eligibility to millions of low-income adults in half of the states, Medicaid rolls will increase in every state from a streamlined eligibility and enrollment process mandated nationwide by the ACA.

Furthermore, Medicaid enrollment is year-round, not tied to an open enrollment period, and an easier, no-cost decision-making process for consumers, unlike the enrollment process in the exchanges. The enrollment in subsidized exchange plans could outpace the rise in Medicaid rolls if and when more small and midsize employers drop their current healthcare coverage. Sign-ups during January through March 2014, the second half of the initial open enrollment period, will be important to watch, when outreach and marketing efforts are expected to restart.

Under the special enrollment rules, many consumers will be able to sign up for exchange coverage after the open enrollment period, which ends on March 31, 2014, if they have a significant change in family or financial circumstances. However, that volume will not be nearly as large or as important as the exchange sign-up during the open enrollment period or the continuous, always-open Medicaid enrollment.

But volume by itself is not enough information to assess the ACA’s success. For that we will need to know, for example, the impact on the uninsured rate, the age and the health risk characteristics of those enrolled, the benefit design choices, the number of people losing individual or employer-sponsored coverage, and the effect of Medicaid expansion and streamlined Medicaid eligibility.

The law is also a moving target as a result of a series of Obama Administration decisions to delay enforcement of key ACA provisions, for a mixture of practical and political reasons. Major provisions of the ACA, in-
cluding the employer mandate and small employer exchanges in most states, are delayed until 2015, the start of the open enrollment period for 2015 has been shifted until after the November 2014 elections, states are encouraged to temporarily allow short-term renewal of insurance policies outlawed by the ACA, and CMS is proposing changes to how exchange plans are paid.

Overall, most people have not yet experienced the effects, positive and negative, of the ACA. In terms of coverage and costs, the ACA creates a giant game of musical chairs, which has just begun. Every American will be affected by the ACA in some way.

The biggest winners are the uninsured, who are or will be newly covered through Medicaid or through federally subsidized exchange coverage. Some of the losers, including people facing higher premiums, are starting to feel the pain, but the main disadvantages of the ACA are yet to be experienced. The law is all about improving equity through the use of a maze of redistributive mechanisms. It will take time before this plays out.

The short experience with the ACA can only shed light on issues that should have been addressed a long time ago, but for which there was not an interested audience.

Payers’ Perspective

The majority of health insurance companies know that the original strategic reasons for entering the insurance exchange market are still valid, assuming that CMS is able to get the website and the data transfers working soon. Companies that have Medicaid plans are also anxious to see how Medicaid enrollment evolves, and how soon will enrollment problems be resolved. The initial disaster with rollout of the federal exchange complicates payers’ strategy, business planning, and forecasts.

Payers know that they may need to adjust their expectations and future plans to some extent, but they have little information from the federal government, which makes their job difficult. This situation is further exacerbated by the larger unknowns, such as how consumers will react to the new exchange plans, including their costs and choices. While their business dynamics are inherently complex and vary by state, health insurers specializing in the Medicaid market are naturally in a better position under the ACA, given the substantial increase in enrollees.

Facing a double-edged sword of an uncertain payer marketplace and deep payment cuts—to help pay for the cost of ACA—hospitals and health systems are worried. A decrease in the number of uninsured Americans will help trim uncompensated care costs, but it will generally not offset lower reimbursement from Medicare, Medicaid, and the new exchange plans and a shift of patients from higher-paying private plans to lower-paying taxpayer-financed health plans. Insurance companies know that they may need to reconfigure their 2014-2015 budgets to cover more Medicaid patients and fewer members with commercial plan coverage or with exchange-based coverage than was expected.

Hospitals in states that are seeking Medicaid reform waivers—notably, Wisconsin, Iowa, and Pennsylvania—are generally eager to see those get approved and implemented soon, because the waivers would expand access to coverage.

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Manufacturers’ Perspective

Pharmaceutical, biotechnology, and medical device companies vary considerably in their understanding of the implications of the ACA. Some companies are fairly well-versed, but others have limited understanding of what it all means. It is harder for drug or device companies than, say, for insurance companies or for large healthcare providers, to understand the potential implications of the ACA on them, because the effects of the ACA, although significant, are indirect and nonlinear. Indirect, because the ACA and changes in the marketplace are fundamentally transforming the economics, incentives, and decision-making of coverage, payment, and care delivery. Nonlinear, because, in this time of unprecedented, polygonal change, the new policy and market spheres appear chaotic, unpredictable, or counterintuitive, and therefore defy traditional assessment. We have a tough environment for these companies to make strategic, operational, or tactical decisions.

Impact on Individual Insurance

It was never in doubt that the ACA would require cancellation of most policies in the individual health insurance market. It was also known that consumers would face a very different health insurance world under the ACA, with some people seeing their premiums go down and some seeing them go up, and the majority of Americans seeing higher deductibles, higher copays, and a smaller pool of providers. We also knew that the exchanges and the ACA market rules would negate the need for state high-risk pools, meaning that most of these chronically ill consumers would see their policies ending in December 2013 or early in 2014.

It is puzzling why it took more than 3 years, the failed launch of the federal exchange, and the news media to
start questioning the Obama Administration’s core approach to regulating existing health coverage. Whether you like or dislike the ACA policies, the 19.4 million Americans in various parts of the individual market deserved a heads-up.

Cost-Sharing and Premiums

The ACA requires people to buy a richer benefit package. It is possible to argue that this policy is good for society, but there is no free lunch, and this does eliminate choices that were acceptable to many consumers. Some can argue that federal premium subsidies in the exchange will more than absorb the higher costs of the ACA for moderate-income Americans, but that is just another way of saying, “Don’t worry, the taxpayer will pick up the tab for the cost of government regulations.”

Premiums, in and outside the exchanges, must be set using adjusted community rating, requiring the healthy, the young, and men to cross-subsidize the premiums of the unhealthy, the older, and women. Again, the foundation of the ACA is a collective redistribution intentionally creating winners and losers. You can argue the merits of this policy, but it does mean that many Americans will face vastly different premiums under the ACA.

The widely anticipated higher cost-sharing many people are now seeing in the exchanges is an inevitable by-product of the ACA insurance market rules, the brave new actuarial risks of the post-ACA marketplace, and competition based on premiums and insurer brand names.

Few laws are truly self-implementing, but virtually everything in the ACA, from a political, regulatory, or technical perspective, requires countless decisions and an astonishing amount of work before it is implemented.

Medicaid Expansion

Medicaid covers approximately 74 million Americans today. As a result of Medicaid expansion under the ACA, including waiver-based expansions, the crowd-out effect, the streamlined eligibility and enrollment mandated by the ACA, and the normal growth of the program, Medicaid could conceivably reach between 95 million and 100 million enrollees by the year 2020. Although it is early, state data already indicate a surge in Medicaid enrollment.

Considering all the unknowns related to Medicaid expansion, including current and future economic conditions, it is safe to assume that the role of Medicaid in the US healthcare system, and the impact of Medicaid on federal and state budgets, will continue to grow.

Implementation Lessons

The Obama Administration, so enamored with the law and the law’s intentions and optics, grossly underestimated the push back from states and the sheer magnitude of the task. The administration’s painfully slow, opaque decision-making process hampered the state-run exchanges as well, and made life in state Medicaid agencies a nightmare. But the states, by experience and temperament, are typically far more adaptable and problem-solving oriented than the federal government. States with their own exchanges jumped in much earlier than CMS, making preliminary decisions, bringing on contractors, and pulling the pieces together as best they could.

Although unprecedented in its scope and complexity, the ACA as legislation deferred most of the decisions to federal agencies, especially CMS and the Internal Revenue Service. The law was also poorly written in key areas and poorly thought-out. Few laws are truly self-implementing, but virtually everything in the ACA, from a political, regulatory, or technical perspective, requires countless decisions and an astonishing amount of work before it is implemented.

Author Disclosure Statement

Mr Piper has no conflicts of interest to report.
Take a closer look at who should carry an EpiPen® (epinephrine) Auto-Injector

As food allergies rise, the risk of anaphylaxis may also increase.1-3 Which is why it’s important to identify patients at risk for anaphylaxis and help them create an action plan: avoid the allergen first, and always carry an EpiPen 2-Pak®.3 For more than 20 years, EpiPen has been the #1 prescribed epinephrine auto-injector,4† with over 41 million units dispensed.5‡ There is no FDA-approved therapeutic equivalent.6

Indications
EpiPen® (epinephrine) 0.3 mg and EpiPen Jr® (epinephrine) 0.15 mg Auto-Injectors are indicated in the emergency treatment of type 1 allergic reactions, including anaphylaxis, to allergens, idiopathic and exercise-induced anaphylaxis, and in patients with a history or increased risk of anaphylactic reactions. Selection of the appropriate dosage strength is determined according to body weight.

Important Safety Information
EpiPen Auto-Injectors should only be injected into the anterolateral aspect of the thigh. DO NOT INJECT INTO BUTTOCK, OR INTRAVENOUSLY.

Epinephrine should be used with caution in patients with certain heart diseases, and in patients who are on drugs that may sensitize the heart to arrhythmias, because it may precipitate or aggravate angina pectoris and produce ventricular arrhythmias. Arrhythmias, including fatal ventricular fibrillation, have been reported in patients with underlying cardiac disease or taking cardiac glycosides or diuretics. Patients with certain medical conditions or who take certain medications for allergies, depression, thyroid disorders, diabetes, and hypertension, may be at greater risk for adverse reactions. Other adverse reactions include transient moderate anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache, and/or respiratory difficulties.

EpiPen and EpiPen Jr Auto-Injectors are intended for immediate self-administration as emergency supportive therapy only and are not intended as a substitute for immediate medical or hospital care.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see Brief Summary of the full Prescribing Information on the adjacent page.

References:
EnPen® 0.3 mg EPINEPHRINE AUTO-INJECTOR
EnPen Jr® 0.15 mg EPINEPHRINE AUTO-INJECTOR

BRIEF SUMMARY. See package insert for full Prescribing Information.

DO NOT REMOVE ACTIVATION CAP UNTIL READY FOR USE. THIS UNIT CONTAINS NO LATEX.

INDICATIONS AND USAGE: EpiPen and EpiPen Jr Auto-Injectors are indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects (e.g., order Hymenoptera, which include bees, wasps, hornets, yellow jackets and fire ants) and biting insects (e.g., triatoma, mosquitoes), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g., radiopaque contrast media) and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis. EpiPen and EpiPen Jr Auto-Injectors are intended for immediate administration in patients, who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions. Selection of the appropriate dosage strength is determined according to patient body weight (See DOSAGE AND ADMINISTRATION section of the full Prescribing Information).

Such reactions may occur within minutes after exposure and consist of flushing, apprehension, syncope, tachycardia, tachyarrhythmia, or unobtainable pulse associated with a fall in blood pressure, convulsions, vomiting, diarrhea and abdominal cramps, involuntary voiding, wheezing, dyspnea due to laryngeal spasm, pruritus, rashes, urticaria or angioedema.

EpiPen and EpiPen Jr Auto-Injectors are intended for immediate self-administration as emergency supportive therapy only and are not a substitute for immediate medical care.

CONTRAINDICATIONS: There are no absolute contraindications to the use of epinephrine in a life-threatening situation.

WARNINGS: EpiPen and EpiPen Jr Auto-Injectors should only be injected into the anterolateral aspect of the thigh. DO NOT INJECT INTO BUTTOCK. Injection into the buttock may not provide effective treatment of anaphylaxis. Advise the patient to go immediately to the nearest emergency room for further treatment of anaphylaxis.

Since epinephrine is a strong vasoconstrictor, accidental injection into the digits, hands or feet may result in loss of blood flow to the affected area. Treatment should be directed at vasodilation in addition to further treatment of anaphylaxis. (see ADVERSE REACTIONS). Advise the patient to go immediately to the nearest emergency room and to inform the healthcare provider in the emergency room of the location of the accidental injection.

DO NOT INJECT INTRAVENOUSLY. Large doses or accidental intravenous injection of epinephrine may result in cerebral hemorrhage due to sharp rise in blood pressure. Rapidly acting vasodilators can counteract the marked pressor effects of epinephrine if there is such inadvertent administration.

Epinephrine is the preferred treatment for serious allergic reactions or other emergency situations even though this product contains sodium metabisulfite, a sulfite that may, in other products, cause allergic-type reactions including anaphylactic symptoms or life-threatening or less severe asthmatic episodes in certain susceptible persons. The alternatives to using epinephrine in a life-threatening situation may not be satisfactory. The presence of a sulfite in this product should not deter administration of the drug for treatment of serious allergic or other emergency situations even if the patient is sulfite-sensitive.

Epinephrine should be administered with caution in patients who have heart disease, including patients with cardiac arrhythmias, coronary artery or organic heart disease, or hypertension. In such patients, or in patients who are on drugs that may sensitize the heart to arrhythmias, e.g., digitalis, diuretics, or anti-arrhythmics, epinephrine may precipitate or aggravate angina pectoris as well as produce ventricular arrhythmias. It should be recognized that the presence of these conditions is not a contraindication to epinephrine administration in an acute, life-threatening situation.

Epinephrine is light sensitive and should be stored in the carrier tube provided. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) (See USP Controlled Room Temperature). Do not refrigerate. Protect from light. Before using, check to make sure the solution in the auto-injector is not discolored. Replace the auto-injector if the solution is discolored or contains a precipitate.

PRECAUTIONS:

(1) General
EpiPen and EpiPen Jr Auto-Injectors are not intended as a substitute for immediate medical care. In conjunction with the administration of epinephrine, the patient should seek immediate medical or hospital care. More than two sequential doses of epinephrine should only be administered under direct medical supervision.

Epinephrine is essential for the treatment of anaphylaxis. Patients with a history of severe allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs, and other allergens as well as idiopathic and exercise-induced anaphylaxis should be carefully instructed about the circumstances under which epinephrine should be used. It must be clearly determined that the patient is at risk of future anaphylaxis, since the following risks may be associated with epinephrine administration (see DOSAGE AND ADMINISTRATION section of the full Prescribing Information).

Epinephrine should be used with caution in patients who have cardiac arrhythmias, coronary artery or organic heart disease, hypertension, or in patients who are on drugs that may sensitize the heart to arrhythmias, e.g., digitalis, diuretics, quinidine, or other anti-arrhythmics. In such patients, epinephrine may precipitate or aggravate angina pectoris as well as produce ventricular arrhythmias. The effects of epinephrine may be potentiated by tricyclic antidepressants and monoamine oxidase inhibitors.

Some patients may be at greater risk of developing adverse reactions after epinephrine administration. These include: hyperthyroid individuals, individuals with cardiovascular disease, hypertension, or diabetes, elderly individuals, pregnant women, pediatric patients under 30 kg (66 lbs.) body weight using EpiPen Auto-Injector, and pediatric patients under 15 kg (33 lbs.) body weight using EpiPen Jr Auto-Injector. Despite these concerns, epinephrine is essential for the treatment of anaphylaxis. Therefore, patients with these conditions, and/or any other person who might be in a position to administer EpiPen or EpiPen Jr Auto-Injector to a patient experiencing anaphylaxis should be carefully instructed in regard to the circumstances under which epinephrine should be used.

(2) Information for Patients
Complete patient information, including dosage, direction for proper administration and precautions can be found inside each EpiPen/EpiPen Jr Auto-Injector carton.

Epinephrine may produce symptoms and signs that include an increase in heart rate, the sensation of a more forceful heartbeat, palpitations, sweating, nausea and vomiting, difficulty breathing, pallor, dizziness, weakness or shakiness, headache, apprehension, nervousness, or anxiety. These symptoms and signs usually subside rapidly, especially
with rest, quiet and recumbency. Patients with hypertension or hyperthyroidism may develop more severe or persistent effects, and patients with coronary artery disease could experience angina. Patients with diabetes may develop increased blood glucose levels following epinephrine administration. Patients with Parkinson’s disease may notice a temporary worsening of symptoms.

In case of accidental injection, the patient should be advised to immediately go to the emergency room for treatment. Since the epinephrine in the EpiPen Auto-Injector is a strong vasoconstrictor when injected into the digits, hands or feet, treatment should be directed at vasodilatation if there is such an inadvertent administration to these areas. (see ADVERSE REACTIONS).

(3) Drug Interactions

The carrier tube is not waterproof.
The blue safety release helps prevent accidental injection and should be kept on until it will be used.

Patients who receive epinephrine while concomitantly taking cardiac glycosides or diuretics should be observed carefully for the development of cardiac arrhythmias.

The effects of epinephrine may be potentiated by tricyclic antidepressants, monoamine oxidase inhibitors, levodopa, levothyroxine sodium, and certain antihistamines, notably chlorpheniramine, triprolamine and diphenhydramine.
The cardiotonic and bronchodilating effects of epinephrine are antagonized by beta-adrenergic blocking drugs, such as propranolol.
The vasoconstricting and hypertensive effects of epinephrine are antagonized by alpha-adrenergic blocking drugs, such as phentolamine. Ergot alkaloids may also reverse the pressor effects of epinephrine.

(4) Carcinogenesis, Mutagenesis, Impairment of Fertility

Epinephrine and other catecholamines have been shown to have mutagenic potential in vitro and to be an oxidative mutagen in a WP2 bacterial reverse mutation assay. Epinephrine had a moderate degree of mutagenicity, and was positive in the DNA Repair test with B. subtilis (REC) assay, but was not mutagenic in the Salmonella bacterial reverse mutation assay.

Studies of epinephrine after repeated exposure in animals to evaluate the carcinogenic and mutagenic potential or the effect on fertility have not been conducted. This should not prevent the use of epinephrine under the conditions noted under INDICATIONS AND USAGE.

(5) Usage in Pregnancy

Pregnancy Category C: There is no study on the acute effect of epinephrine on pregnancy. Epinephrine has been shown to have developmental effects when administered subcutaneously in rabbits at a dose of 1.2 mg/kg daily for two to three days (approximately 30 times the maximum recommended daily subcutaneous or intramuscular dose on a mg/m² basis), in mice at a subcutaneous dose of 1 mg/kg daily for 10 days (approximately 7 times the maximum daily subcutaneous or intramuscular dose on a mg/m² basis) and in hamsters at a subcutaneous dose of 0.5 mg/kg daily for 4 days (approximately 5 times the maximum recommended daily subcutaneous or intramuscular dose on a mg/m² basis). These effects were not seen in mice at a subcutaneous dose of 0.5 mg/kg daily for 10 days (approximately 3 times the maximum recommended daily subcutaneous or intramuscular dose on a mg/m² basis). Although, there are no adequate and well-controlled studies in pregnant women, epinephrine should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

It is not known if epinephrine passes into breast milk.

ADVERSE REACTIONS: Adverse reactions to epinephrine include transient, moderate anxiety; apprehensiveness; restlessness; tremor; weakness; dizziness; sweating; palpitations; pallor; nausea and vomiting; headache; and/or respiratory difficulties. These symptoms occur in some persons receiving therapeutic doses of epinephrine, but are more likely to occur in patients with hypertension or hyperthyroidism. Arrhythmias, including fatal ventricular fibrillation, have been reported in patients with underlying cardiac disease or certain drugs [see PRECAUTIONS, Drug Interactions]. Rapid rises in blood pressure have produced cerebral hemorrhage, particularly in elderly patients with cardiovascular disease. Angina may occur in patients with coronary artery disease. The potential for epinephrine to produce these types of adverse reactions does not contraindicate its use in an acute life-threatening allergic reaction.

Accidental injection into the digits, hands or feet may result in loss of blood flow to the affected area (see WARNINGS). Adverse events experienced as a result of accidental injections may include increased heart rate, local reactions including injection site pallor, coldness and hypoesthesia or injury at the injection site resulting in bruising, bleeding, discoloration, erythema or skeletal injury.

OVERDOSAGE: Epinephrine is rapidly inactivated in the body and treatment following overdose with epinephrine is primarily supportive. Epinephrine overdosage sometimes results in extreme pallor and coldness of the skin, metabolic acidosis and kidney failure. Suitable corrective measures must be taken in such situations.

Rx only.
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