A HIGH STAKES GAME FOR HEALTH CARE’S MAJOR PLAYERS

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Xiidra is the first and only prescription eye drop FDA-approved to treat both the signs and symptoms of dry eye disease (DED), a multifactorial disease of the tears and ocular surface. DED, which is often chronic and can be progressive, is associated with inflammation of the ocular surface that can be triggered by abnormal tear composition.1-4

**Diagnosing DED is complex.**5

Symptoms of DED are among the most common patient complaints to eye care professionals. DED diagnosis is based on the assessment of both signs and symptoms, which do not always correlate.2,6,7

**Only Xiidra is indicated to treat both the signs and symptoms of DED.**

**Clinical studies demonstrated Xiidra’s effectiveness.**1

The safety and efficacy of Xiidra compared with vehicle were studied in 4 well-controlled, 12-week trials (N=2133). Safety was studied in 1 additional year-long trial (N=331).1,8

**Xiidra demonstrated a larger reduction in inferior corneal staining score (ICSS) in 3 of the 4 studies at Week 12.**1

Xiidra improved ICSS, a well-recognized sign of DED, compared with vehicle.14

ICSS was recorded at each study visit (0=no staining, 1=few/rare punctate lesions, 2=discrete and countable lesions, 3=lesions too numerous to count but not coalescent, 4=coalescent). The average baseline ICSS was ~1.8 in Studies 1 and 2 and 2.4 in Studies 3 and 4.1

**Xiidra demonstrated a larger reduction in eye dryness score (EDS) at Weeks 6 and 12 in all 4 studies.**1

In 2 of the 4 studies an improvement in EDS favoring Xiidra was seen at Week 2.1

EDS was rated by patients using a visual analogue scale at each study visit (0=no discomfort, 100=maximal discomfort). The average baseline EDS was between 40 and 70.1

**Indication**

Xiidra™ (lifitegrast ophthalmic solution) 5% is indicated for the treatment of the signs and symptoms of dry eye disease (DED).

**Important Safety Information**

In clinical trials, the most common adverse reactions reported in 5-25 % of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

To avoid the potential for eye injury or contamination of the solution, patients should not touch the tip of the single use container to their eye or to any surface.

Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.

Safety and efficacy in pediatric patients below the age of 17 years have not been established.

Please see Brief Summary of Prescribing Information on next page.
BRIEF SUMMARY:
Consult the Full Prescribing Information for complete product information.

INDICATIONS AND USAGE
Xiidra™ (lifitegrast ophthalmic solution) 5% is indicated for the treatment of the signs and symptoms of dry eye disease (DED).

Dosage and Administration
Instill one drop of Xiidra twice daily (approximately 12 hours apart) into each eye using a single use container. Discard the single use container immediately after using in each eye. Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.

ADVERSE REACTIONS
Clinical Trials Experience
Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in clinical studies of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. In five clinical studies of dry eye disease conducted with lifitegrast ophthalmic solution, 1401 patients received at least 1 dose of lifitegrast (1287 of which received lifitegrast 5%). The majority of patients (84%) had ≤3 months of treatment exposure. 170 patients were exposed to lifitegrast for approximately 12 months. The majority of the treated patients were female (77%). The most common adverse reactions reported in 5-25% of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

Use in Specific Populations
Pregnancy
There are no available data on Xiidra use in pregnant women to inform any drug associated risks. Intravenous (IV) administration of lifitegrast to pregnant rats, from pre-mating through gestation day 17, did not produce teratogenicity at clinically relevant systemic exposures. Intravenous administration of lifitegrast to pregnant rabbits during organogenesis produced an increased incidence of omphalocele at the lowest dose tested, 3 mg/kg/day (400-fold the human plasma exposure at the recommended human ophthalmic dose [RHOD], based on the area under the curve [AUC] level). Since human systemic exposure to lifitegrast following ocular administration of Xiidra at the RHOD is low, the applicability of animal findings to the risk of Xiidra use in humans during pregnancy is unclear.

Animal Data
Lifitegrast administered daily by intravenous (IV) injection to rats, from pre-mating through gestation day 17, caused an increase in mean preimplantation loss and an increased incidence of several minor skeletal anomalies at 30 mg /kg /day, representing 5,400-fold the human plasma exposure at the RHOD of Xiidra, based on AUC. No teratogenicity was observed in the rat at 10 mg /kg /day (460-fold the human plasma exposure at the RHOD, based on AUC ). In the rabbit, an increased incidence of omphalocele was observed at the lowest dose tested, 3 mg /kg /day (400-fold the human plasma exposure at the RHOD, based on AUC), when administered by IV injection daily from gestation days 7 through 19. A fetal No Observed Adverse Effect Level (NOAEL) was not identified in the rabbit.

Lactation
There are no data on the presence of lifitegrast in human milk, the effects on the breastfed infant, or the effects on milk production. However, systemic exposure to lifitegrast from ocular administration is low. The developmental and health benefits of breastfeeding should be considered, along with the mother’s clinical need for Xiidra and any potential adverse effects on the breastfed child from Xiidra.

Pediatric Use
Safety and efficacy in pediatric patients below the age of 17 years have not been established.

Geriatric Use
No overall differences in safety or effectiveness have been observed between elderly and younger adult patients.

Nonclinical Toxicology
Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenesis: Animal studies have not been conducted to determine the carcinogenic potential of lifitegrast. Mutagenesis: Lifitegrast was not mutagenic in the in vitro Ames assay. Lifitegrast was not clastogenic in the in vivo mouse micronucleus assay. In an in vitro chromosomal aberration assay using mammalian cells (Chinese hamster ovary cells), lifitegrast was positive at the highest concentration tested, without metabolic activation. Impairment of fertility: Lifitegrast administered at intravenous (IV) doses of up to 30 mg/kg/day (5400-fold the human plasma exposure at the recommended human ophthalmic dose [RHOD] of lifitegrast ophthalmic solution, 5%) had no effect on fertility and reproductive performance in male and female treated rats.

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On This We Can Agree

By Peter Wehrwein

There’s not much Democrats and Republicans agree upon these days, and health care is no exception. Hillary Clinton and the Democrats want to push the ACA ball forward, maintain the gains in coverage, and possibly create a public option. Sure, the law doesn’t do well in public opinion surveys, but a successful ACA could redound to Democrats’ benefit in the same way that the creation of Medicare did (Medicaid, not so much) and before that, Social Security.

Of course, Donald Trump and the Republicans believe the country would be far better off if large chunks of the ACA were scuttled. Their proposals to loosen regulations, strengthen health savings accounts, and allow insurers to sell policies across state lines are designed to bring some market dynamics to American health care. Empower consumer-directed health care, they argue, and you’ll lower costs and keep coverage affordable in the process.

In this issue of Managed Care, we have Q&As with Paul Starr (p. 33), the Pulitzer Prize–winning Princeton professor, and Scott Gottlieb, MD, (p. 37) an American Enterprise Institute fellow and former FDA and HHS official in the George W. Bush administration. They’re smart, insightful thinkers from opposite ends of the political spectrum—Starr, the liberal, and Gottlieb, the conservative. Needless to say, though, they don’t agree on much.

Except this.

Both Starr and Gottlieb see the consolidation of providers into large health care systems as a major problem. Starr sees them as local monopolies that extract high prices and is convinced that some kind of price regulation is going to be necessary. Gottlieb worries that their monopoly power will thwart market-based reform. If there is only one health care supplier in town, encouraging Americans to be savvy health care consumers won’t do much good.

Conservatives are not going to agree with Starr about price regulation, but perhaps there is some common ground here. Common enemies often make strange bedfellows and perhaps some compromise.
Election 2016

Insurers Face Uncertain Future No Matter Who Wins

Clinton favors a public option, Trump wants to repeal the ACA, the exchanges are in trouble. The only certainty for insurers—uncertainty.

Drug Costs a Hard Pill To Swallow

This is one everybody can agree on, but in order to cut costs insurers and drugmakers will have to come to terms and cooperate.

Physicians’ Lives Will Get More Complicated

There are so many doctor lobbying groups that a concerted response will be hard to come by for things like MACRA, MIPS, and APM.

Hospitals They Are A-Mergin’

The pace has increased under the ACA. The power to set higher prices seems to be one of the main reasons.

Cadillac Tax Still Taxiing Down the Runway

Shifting more cost onto employees was well on its way before the ACA, but employers’ fear of the Cadillac tax seems to have accelerated the trend.

Parties Offer Divergent Fixes for Medicare

Clinton wants to expand the program, while the Republican platform calls for replacing entitlements with premium support to buy insurance.

Q&A: Paul Starr Calls ACA ‘Minimally Invasive’

A Clinton presidency could mean important adjustments to the law, including fixing the omission of a public option.

Q&A: Scott Gottlieb Warns of the ‘Fatigue Factor’

There’s little support for sweeping change, but exchanges may be targeted. Meanwhile, Medicaid shoulders most of the burden of the newly insured.

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Editor’s Memo
Provider consolidation a common enemy.

News & Commentary
Employers face moderate price hikes.

Eye on the ACA Exchanges
Off-exchange policies still an option.

MediMedia Poll
Our readers are split on the election.

Tomorrow’s Medicine
Big Data helps avoid invasive procedure.

Value-Based Care
Seeking clarity on FDAMA Section 114.
Employers Expect Moderate Cost Increases But Keep Wary Eye on Specialty Pharmacy

Expect overall health benefit cost increases at large employers next year to come in at a moderate 6%, but most of that will be because of specialty pharmacy costs, which are expected to skyrocket, according to a survey by the National Business Group on Health (NBGH).

Nearly a third of respondents (31%) said that specialty pharmacy was the biggest factor in cost increases, and this is a new development. In 2014, only 6% of large employers in the same survey cited specialty pharmacy as the number one driver of costs.

Pharmacy spending is expected to increase by 7.3% next year, with specialty pharmacy, which includes biologics, accounting for most of that. Specialty pharmacy costs are expected to increase by 16.8%.

Employers and health plans are scrambling to get a handle on the spending. “Prior authorization, step therapy, and quantity limits are used by nearly all employers,” the survey stated. Step therapy has come under fire. Stat posted a story about step therapy in August with this title: “Are insurance policies saving patients money, or keeping them from the treatment they need?”

The NBGH survey included 133 large employers (10,000 or more employees) that provide coverage to more than 15 million employees and their dependents.

Some of the techniques used by employers and health plans include use of a freestanding specialty pharmacy (69%), placing specialty pharmaceuticals in their own pricing tier (38%), and using case management that includes efforts like coaching programs and medication therapy management.

Some employers and health plans have implemented programs that more closely monitor the prescribing of the medications, according to the NBGH survey. For example, 83% of employers have worked with their health plans, PBMs, or both, to place restrictions on how compounded medications are prescribed as a response to spikes in compounded medication costs. In addition, 17% of employers have instituted restrictions on medications when the pharmacy manufacturer offers patients coupons or rebates to reduce their copayments or coinsurance. Coupons and rebates can seem like a great deal for patients, but they’re used to build a market for costly brand name drugs instead of cheaper generics.

Difficult Birth For Maternity Bundles

It would seem that bundling payments for maternity care would be a no-brainer, but there are significant hurdles, according to a white paper by the Health Care Payment Learning and Action Network, a collaborative effort that includes payers, providers, employers, and states, under the sponsorship of the federal government.

Bundling could lead to savings. Childbirth accounts for roughly a quarter of all hospitalizations and about $64 billion in payments to hospitals.

“Fortunately, Medicaid (which pays for approximately 45% of births annually), commercial payers, and large purchasers have begun to develop episode payment initiatives for maternity care in recognition of the ways in which episode payment can drive higher quality, lower-cost care,” said the white paper.

Because Medicaid is administered by the states, broadly mandating maternal bundled payments across the country is difficult, if not impossible. There’s also the question about which services and care should the bundle payment include.

There are three general bundling models, comprehensive, comprehensive birth center/midwife, and blended rate for hospital labor and birth, according to the white paper.

Comprehensive defines the episode as prenatal, labor and birth, and postpartum for the woman and, sometimes, for the newborn. “It is agnostic as to both the birth site and who manages the birth, and as to whether the birth is vaginal or a cesarean, but it is typically priced assuming a hospital birth,” the white paper stated.

A comprehensive birth center/midwife bundle is similar to comprehensive, but it’s priced based on midwife management.

The blended rate combines cesarean and vaginal birth reimbursement rates into a blended case for hospitals, with the goal of decreasing cesarean

<table>
<thead>
<tr>
<th>Volume and cost of maternity care</th>
<th>Commercial market</th>
<th>Medicaid</th>
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<tr>
<td><strong>Volume (2013)</strong></td>
<td></td>
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<tr>
<td>Commercial</td>
<td>2,012,584 births (48.99%)</td>
<td>1,811,759 births (44.10%)*</td>
</tr>
<tr>
<td>Vaginal</td>
<td>$18,329</td>
<td>$9,131</td>
</tr>
<tr>
<td>Cesarean</td>
<td>$27,866</td>
<td>$13,590</td>
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</tbody>
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*The remaining births were covered by Medicare or other payers, or the mother was uninsured

rates. Hospital payments and the clinical professional fees are the same in this model, regardless of the delivery method. The episode price also includes the costs of postpartum complications but not other postpartum costs.

**Briefly Noted**

In what could lead to a drastic shift in diabetes care, 45 of the world’s leading diabetes organizations have called for gastric surgery to become a standard treatment for heavy people with the disease. The new guidelines are the first time the surgery is recommended as a treatment for diabetes rather than for obesity that might have a side benefit on diabetes, according to numerous news reports. The guidelines say the surgery should be recommended for people with diabetes whose BMI is 40 or higher and also for those with a BMI in the 35–39.9 range when hyperglycemia can’t be controlled with medications and lifestyle, and that it should be offered as an option to people with diabetes with a BMI in the 30–34.9 range when their hyperglycemia is uncontrolled despite optimal treatment with medications,… **Physician groups and drug companies** are teaming up to fight a proposed Medicare rule that would change the way doctors are paid for administering infusion drugs, reports *USA Today*. The language used by the physician trade group Community Oncology Alliance and the Pharmaceutical Research and Manufacturers Association to oppose the rule is “nearly identical in parts,” the newspaper reported,… **Nursing home residents** in Hawaii had the lowest hip fracture rate in the country while residents in New Mexico had the highest, according to a study conducted by Brown University researchers. Using Medicare Part A claims data from 2007 to 2010, the researchers calculated that the rate in Hawaii was 1.49 hip fractures per 100 person-years compared with 3.60 per 100 person-years in New Mexico. The average for the country was 2.38 per 100 person-years…. **Mental health practitioners** seem to be following the money, getting their degrees and going into private practice to treat those who can afford to pay high-priced sessions (up to $400 an hour), Kaiser Health News reports. It’s also a lot less stressful treating relatively high-functioning professionals than, say, working in a hospital psychiatric ward. One critic says that they are treating the worried well, “people who enjoy the self-exploration of therapy but do not necessarily have a mental health problem,” to the detriment of poorer people who have real problems…. **Because there are** always minute tremors in even the best surgeons’ hands, new robotic surgery technology depends on imaging technology that is guided by a computer program, not a human being. The program incorporates best surgical practices in determining when and how to su-

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“By making the medical experience more like the shopping experience, we’re hoping the patient will have more fun.”
Narcolepsy is an often misdiagnosed, incurable, chronic and potentially disabling neurologic disorder, and is associated with high medical comorbidity burdens and reduced daily function. Narcolepsy has also been shown to have substantial socioeconomic burden resulting from increased healthcare resource utilization and lower work productivity relative to those without narcolepsy.

For more information about narcolepsy, please contact your Jazz Pharmaceuticals Account Manager.

References:
2. Villa KS, Black J, Chervin RD, Flores NM, Witt EA. Resource-use, productivity loss, and economic burden of narcolepsy: Results from the National Health and Wellness Survey. poster presented at: Academy of Managed Care Pharmacy 2014 Nexus; October 7-10, 2014; Boston, MA. Poster G-16.
Despite higher premiums and a declining number of policy options, experts don’t believe individual insurance policies purchased outside state health insurance exchanges are going to vanish any time soon.

Although there are now fewer policies offered off the exchanges than there were in 2015, “it doesn’t tell me they are likely to disappear or wither away,” says Mark A. Hall, coauthor of a June 2016 report on on- and off-exchange policies for the Commonwealth Fund.

As of March, 11.1 million consumers had signed up for coverage and paid their premiums for policies purchased on the ACA exchanges. That was nearly a million more enrollees than in March 2015, according to HHS.

But 9 million Americans are expected to purchase policies outside the ACA exchanges this year, according to the Congressional Budget Office (CBO). Although the number of people buying off the exchanges is expected to eventually drop to 7 million, that won’t happen till 2026.

“The off-exchange market is shrinking, at least in terms of the number of plans, and probably in terms of enrollees,” says Katherine Hempstead of the Robert Wood Johnson Foundation.

People who purchase policies outside of the exchanges tend to earn too much money to qualify for a subsidy to offset premium costs. “Only a certain share of customers look at off-exchange policies,” says Katherine Hempstead, a senior adviser at the Robert Wood Johnson Foundation, noting that about 85% of those who buy coverage on the exchanges receive subsidies. In all states, the upper limit for subsidy eligibility is 400% of the poverty level. For plans purchased during the 2016 open enrollment period, that comes out to $97,000 per year for a family of four. The subsidy comes in the form of a tax credit, but it can be used in advance to lower the price of the premium. Working through the exchanges, insurers apply the credit to the monthly premiums so the out-of-pocket cost is lower.

**Broader networks available**

Of the off-exchange policies themselves, Hempstead says, “from 100 yards, they don’t look all that different from marketplace plans.”

Premiums for policies purchased outside the ACA exchanges are usually $10 to $15 more a month than the premiums for policies bought through the exchanges—and that is before any subsidy is applied, according to Hempstead. But the deductibles for the on- and off-exchange policies are often similar, she says. There tend to be more platinum and gold plans available outside the exchanges, and consumers are more likely to find plans with a broader network of providers.

Nationwide, about 9,200 plans were offered outside the exchanges in 2015; this year, the number fell to about 3,600. The Blues have the most off-exchange plans, followed by Aetna and UnitedHealthcare.

It will be interesting to see if Aetna, Humana, and UnitedHealthcare will add off-exchange plans once they exit many of the ACA exchanges next year.

In some states, there are few differences between policies sold on and off the exchanges, while in other places the differences are vast, says Sabrina Corlette, a research professor at the Center on Health Insurance Reforms at Georgetown University’s Health Policy Institute. “It very much depends on where you live.”
For some health insurance companies, such as Health Care Service Corp. (HCSC), which operates Blues plans in five states, the policies sold on and off exchanges are identical.

Vermont and the District of Columbia don't allow individual or family policies to be sold outside their ACA exchanges, Corlette says. In the District of Columbia, the market wasn't big enough to sustain them, and Vermont was gearing up to create a single-payer system, which has since been abandoned.

Despite the exodus of UnitedHealthcare, Aetna, and Humana from the ACA exchanges, most experts believe that consumers who bought policies on the exchanges will continue to do so rather than switch to coverage outside the exchanges. Why? For the simple reason that they're eligible for subsidies that lower their premiums if they stick to buying coverage through an exchange. According to HHS, the average ACA exchange tax credit has been worth almost $300 a month and has covered nearly three quarters of an individual's monthly premium.

Credit cards not accepted

One thing that could complicate individual enrollment is that two large insurers announced recently that they would no longer allow customers to use a credit card to pay for off-exchange plan premiums. Both Humana and HCSC cited high credit card fees.

In Humana's case, that means the 210,000 Americans who buy off-exchange policies from the company can't use credit cards, whereas its 550,000 customers who bought policies through the exchange can continue to use credit and debit cards. Customers who bought a Humana policy outside the exchange can pay with a check, electronic bank transfer, money order, cashier's check, or with cash at CVS or Dollar General.

“Credit card companies charge transaction fees of around 2.5% of the total amount charged. These fees raise administrative costs,” says Humana spokesman Mitch Lubitz. The decision to ban those forms of payment will help “preserve affordable individual major medical plans,” he adds. For those who purchase policies on the exchanges, federal subsidies typically reduce members' premium payments, reducing the impact of credit card company transaction fees, Lubitz says.

HCSC no longer accepts credit cards for premiums for individual health or dental plans purchased either on the exchanges or outside of them, says spokesman Mark Spencer. "Credit card fees are a significant expense that impacts all members, not just those who use credit as a payment option," Spencer says. About 30% to 35% of the company's individual policyholders had been paying their premiums with credit cards.

Two tiers developing?

Those who purchase policies outside of the exchanges usually have higher incomes than those who buy in them. That makes perfect sense because they wouldn't be eligible for a subsidy, so one of the main reasons for buying on the exchange doesn't apply to them. They also tend to be older than those who purchase policies through the ACA exchanges and have established relationships with providers, notes Hempstead. A study issued in June by the Council for Affordable Health Coverage, a Washington-based group that includes larger insurers, business groups, and pharmaceutical companies, found that exchange participation declines dramatically as income increases and subsidies get smaller. Moreover, the council found that only 2% of Americans who earn too much to get an ACA exchange subsidy buy their health insurance through the exchanges whereas 80% of those with low incomes (less than 150% of the federal poverty level) who could buy on the exchange did so. “To ensure the sustainability and stability of the exchange market into the future, exchanges will need to attract individuals across income levels,” the council’s report said.

Despite the differences in policies that can typically be found off and on exchanges, Hempstead doesn't expect it to lead to a two-tier insurance system with wealthier consumers shopping exclusively outside the exchanges for policies with better coverage while the less well-off are confined to the exchanges.

“The off-exchange market is shrinking, at least in terms of the number of plans, and probably in terms of enrollees. The market as a whole is about one-half unsubsidized, but an increasing share of the unsubsidized market is buying plans that are offered on the marketplace,” Hempstead says.

At the same time, Joel White, president of the council, believes off-exchange policies will be around for the long haul. "I don't think limiting choice will fly in this environment." His organization wants the law changed so people could use their ACA subsidies for policies bought outside the exchanges. "It shouldn't matter where you use your subsidy," says White.
ELECTION 2016

A High Stakes Game
For Health Care’s Major Players

So far, health care hasn’t gotten much attention in an election year amped up on presidential candidates’ personalities and character, immigration, and trade issues.

But insurers, pharma, hospitals, doctors, employers, seniors—all the major players in health care—know they’ve got a lot at stake in this election.

Most obviously, the fate of the ACA will be determined. Some—that’s you, pharma and large hospital systems—have prospered under the law after having a major hand in shaping it. Others—small hospitals, some doctors—have struggled.

The ACA looms large but isn’t the only game in town. Insurers are eyeing pending antitrust decisions; hospitals, mushrooming consolidation; doctors, MACRAfication of their practices; employers, the Cadillac tax.

Some may be more reluctant than others. But in 2016, if you’re a health care player, you’ve got to say, “Deal me in.”

For Insurers, a Battle Between 2 Futures

Both presidential nominees have big plans for changing the health insurance world, but hurdles are many and victory on November 8 is only the beginning. Here’s what may be in store.

For health insurers looking ahead to November 8, the contrast between the two candidates couldn’t be starker. Should Donald Trump win the presidency, the New York businessman has promised to repeal the ACA on his first day in office. “Completely repeal Obamacare,” the Trump plan says. “Our elected representatives must eliminate the individual mandate. No person should be required to buy insurance unless he or she wants to.”

If Hillary Clinton wins, she will undoubtedly block any Republican efforts to undo the ACA. She wants to revive the public option that got dropped in the wheeling and dealing that led to the passage of the ACA and let Americans buy into Medicare starting at age 55.

Of course, the fate of either candidate’s plans will depend on a complex matrix of factors, including competing priorities and which party wins control of the House and the Senate this fall.

Whether insurers are rejoicing at the prospect of a Trump presidency and the end of the ACA or a Clinton presidency and modifications to the law is hard to say because of the industry’s complicated relationship with the law. Its lobbying organization, America’s Health Insurance Plans (AHIP), has been conflicted about the ACA from the beginning. Early on, its leadership threw its support behind core elements of the part of the law that pertained to insurers, including guaranteed issue, subsidies of premiums, and mandated coverage. But later on, large private insurers, such as UnitedHealthcare, actively worked against passage of the ACA.

Now the divisions are even more pronounced. UnitedHealthcare and Aetna have bolted AHIP.
Marilyn Tavenner, the organization’s CEO and director of CMS during the ACA’s early implementation, expressed support for the ACA exchanges in an interview with Managed Care earlier this year. Meanwhile, UnitedHealthcare, Aetna, and Humana have said they are leaving the exchanges in many markets, and the insurers staying in them are proposing large premium hikes. Salvaging the ACA exchanges may be the first order of health care business for a Clinton administration committed to the health care reform law. Otherwise, the law’s signature achievement, reducing the number of Americans without health insurance, could unspool. Earlier this year, results from the federal government’s National Health Interview Survey showed that largely because of the ACA, the number of uninsured Americans had dipped to 9.1% and that 7.4 million fewer people lacked insurance in 2015 than in 2014.

Fewer insured, lower premiums

Trump has alienated many Republicans, but his positions on health insurance don’t venture from Republican orthodoxy. Repealing the ACA has been a rallying cry for the party ever since the law was passed six years ago. Trump would allow sale of health insurance across state lines, a stock GOP idea that is supposed to generate a more competitive insurance market, reduce the burden of state-level insurance mandates, and increase consumer choice. Some commentators have argued that an unintended consequence would be a national insurance market and a move toward federal regulation of health insurance, something no Trump supporter would want.

Trump’s 1,100-word “Healthcare Reform to Make America Great Again” also calls for allowing individual taxpayers to take a full deduction on premium payments, putting them on an equal footing with business. That might not be such a good deal for people with modest incomes, because tax deductibility alone might still leave the cost of insurance premiums out of reach. The ACA and other Republican health care proposals use tax credits, rather than deductions, to offset the cost of insurance premiums for that reason. Moreover, deductibility without any limits may also favor people with higher incomes because they can afford expensive health care coverage with many providers, whereas people with lower incomes will be inclined to buy cheaper plans that provide barebones coverage. The deduction would be worth a lot more for people who can buy expensive insurance.

The Center for Health and Economy, a research group that bills itself as nonpartisan with both conservative and liberal experts, modeled the effects of all of the features of Trump’s plan (including a proposal to turn Medicaid into a block grant program). By its reckoning, the Trump plan would lead to 18 million fewer Americans having health insurance next year than if the ACA were to continue, although the gap would narrow to 13 million by 2026.

On the other hand, the center’s calculations also show the Trump plan as decreasing premiums by between 24% and 37% by 2026. The reason? Eliminating the ACA would presumably mean the end of regulations that limit out-of-pocket expenditures and require coverage of essential health benefits. Health insurers would have lower costs and so could reduce premiums.

“Adding a public option could stimulate competition, particularly in markets with few insurers,” says Christine Eibner of the Rand Corp. But how much leverage would it have to set provider reimbursement rates?

Some of the plans House Republicans have passed to repeal and replace the ACA would reduce the number of Americans with health insurance coverage, but none has approached the 18 million affected by Trump’s plan, says Stephen Parente, a professor at the Carlson School of Management at the University of Minnesota and a Center for Health and Economy board member. “That means there will be pushback, even from House Republicans who will hesitate to make such a big change,” he comments. The GOP is likely to look for alternatives that are more palatable, he adds.

At the very least, a plan calling for eliminating insurance coverage for 18 million starts the discussion. “Once you start that conversation,” he observes, “then we will begin to see whether Paul Ryan and other members of the GOP get involved in moving the conversation forward.”

Parente notes that Trump’s proposal to broaden
the deductibility of insurance premiums would cut into government revenues. “But there are so many savings from eliminating the Medicaid expansion that it kind of counter-balances that loss,” he adds. The center estimates that Trump’s plan would decrease the federal deficit by $583 billion between 2017 and 2026 compared with the ACA.

Public option pushback
Clinton has several proposals that would expand health insurance coverage. She wants to provide incentives to the 19 states that have yet to expand Medicaid. For those living in rural areas, she would increase funding for the National Health Service Corps and provide more funding for primary care in community health centers. She aims to increase health coverage regardless of immigration status and cap out-of-pocket prescription expenditures for individuals and families. But it is the public option that might generate the most political heat. Clinton would face opposition not only in Congress but also from health insurers, who were successful in keeping the public option out of the ACA.

“Adding a public option could stimulate competition, particularly in markets with few insurers.” That’s the upbeat assessment of Christine Eibner, a senior economist and associate director of the Health Services Delivery Systems program at the Rand Corp. “What we don’t know is how much leverage the public option would have to set provider reimbursement rates,” she adds. “If the public plan were able to set provider reimbursement rates based on Medicare payment, the plan could be significantly cheaper than a typical private plan. That could reduce premiums and force private plans to find opportunities to save money in order to be competitive.” At the same time, Eibner says, it could be disruptive to give the public option Medicare pricing power “because it could take us closer to a single-payer system with a monopsony buyer” (the federal government).

The Congressional Budget Office (CBO) has modeled the effect of a public option with and without Medicare prices. Eibner explains: “When the public plan does not use Medicare pricing power, CBO estimates that the public premium will be higher than private premiums, due to sicker people enrolling in the public option. But when the public option is able to set provider payment rates based on Medicare pricing, CBO predicts lower premiums and greater enrollment.”

The consequences of Clinton’s Medicare buy-in are hard to predict, in Eibner’s view. “While the details are not yet known,” she says, “in theory, a Medicare buy-in could affect marketplace premiums by siphoning some older and potentially sicker enrollees from the marketplace risk pool. “Potentially,” Eibner continues, “that could make premiums more affordable for younger people in this market. However, it’s not yet clear how attractive the Medicare buy-in would be to potential enrollees, and what incentives they would have to enroll.” What tax credits and subsidies would be available to anyone who would buy in are unknown, and it’s not known if those credits and subsidies would be more or less generous than those currently available in the exchange plans.

Clinton has also proposed what’s
called a cost-sharing tax credit. It could be applied against health care spending in excess of 5% of income, up to a maximum of $2,500 for an individual, or $5,000 for a family, Eibner explains. Families and individuals could apply the tax credit against the total paid in premiums and out-of-pocket costs during the year. “Because they can be applied against premiums, the tax credits reduce the effective cost of insurance and potentially make it more likely that people will enroll,” Eibner says. But there are tradeoffs. “On the one hand, if the credits bring younger and healthier people into the insurance market, that could reduce premiums,” she says. “On the other hand, the credits could encourage health plan enrollees to use more care. Such so-called induced demand could increase health care spending and put upward pressure on premiums.”

The tax credits will reduce what consumers spend on insurance and health care, but increase federal spending, Eibner adds. To fund the tax credit, Clinton will demand rebates from drug manufacturers and perhaps ask high-income Americans to pay more for care, she says. If Clinton is elected, Eibner concludes, this provision will bear watching because eligibility for the cost-sharing tax credits could extend well beyond those enrolling in the marketplaces, potentially including those who have employer-based coverage and Americans below the poverty line in non-expansion states who purchase private coverage, Eibner concludes.

Several solutions
When the dust settles after one of the most remarkable presidential campaigns in history, the time for rhetoric will be over and the new president and lawmakers will face the task of actually managing a giant, unwieldy and complex health care system, trying to wrestle drug costs into submission before they wreak even more havoc on the budgets of Medicare, Medicaid, and the American consumer.

“What wanting someone to do something about drug pricing is the number one issue for both parties,” says Len Nichols, a professor of health policy at George Mason University and director of its Center for Health Policy Research and Ethics. “Congress has to decide that it wants to address the issue in a serious way. And the president has to be willing to spend time and use the bully pulpit and make it a priority.”

So what might that look like? Nichols notes that Americans are generally wary of aggressive measures to control markets. Policy approaches will need to address the balance between incentivizing innovation and creating monopolies—a balance he says is now out of whack, allowing individual drugmakers to charge whatever they want.

While America’s outrage has been stoked by Shkreli’s smirking visage and a few other small players with the most outrageous price hikes for individual, small-scale drugs, policy solutions will need to address more than just a few outliers. The problem Congress and the White House will really face is the increasing cost
of drugs that millions of Americans swallow every morning with their orange juice. A Reuters analysis earlier this year found that prices for four of the nation’s top 10 selling drugs more than doubled since 2011, and six others went up more than 50%.

Here are several solutions that have been mentioned on the campaign trail:

• authorizing CMS to negotiate with drugmakers for Medicare Part D drugs
• allowing Americans to order lower-cost prescriptions from other countries such as Canada
• placing a ceiling on copayments for drugs covered by health plans.

Drug prices were mentioned briefly in both parties’ platforms. The Democrats had more to say, devoting a few paragraphs in a section about health care to “price gouging” by drug companies, touting support for generics, reimportation, and Medicare negotiations specifically. The Republicans were more circumspect, even though pharma has been one of Trump’s favorite targets in his speeches. When it came down to it, Trump’s support of Part D bargaining didn’t make it into the Republican platform. Rep. Kevin Brady of Texas, the Republican chair of the House Ways and Means Committee, said the concept wouldn’t be subject to a hearing while he’s in charge.

While the platforms offer some sense of what each side thinks is important, they are only vaguely related to what the 115th Congress will likely spend its time on. If pharmaceutical prices get regulated by Congress in some other way it will certainly be a disappointment to the industry, which lent its support to the ACA in 2009 on the condition that it be largely left alone, so the ACA regulatory firepower was aimed largely at the insurance industry. Seven years on, though, there’s nothing keeping legislators from taking aim at pharma.

The House last year approved its version of the 21st Century Cures Act, Republican-led legislation meant to spur drug innovation, increase funding for the National Institutes of Health, and reduce regulation of the drug approval process at FDA. The Senate has been taking parts of the bill and acting on them separately in committee. Opponents view it as a significant gift to the pharmaceutical industry that lacks patient protections.

Industry observers see a more nuanced, perhaps less-contested way forward to getting prices under control, with some of the answers resting in new
payment models and cooperation among the payers, providers and drugmakers.

Pharmaceutical makers, just like providers, are being drawn into value-based purchasing arrangements with payers that link the price of their products with their performance. “These contracts are especially compelling where there are federal quality measures that stipulate increased payment on outcomes that are achieved through appropriate medication use,” notes Dan Mendelson, president of the consulting firm Avalere Health.

Mendelson believes insurers and drugmakers will have to come to terms and cooperate. “The future of these industries and their success in navigating policy will be critically dependent on better collaboration,” he said in an email to Managed Care.

**Big donors**

Overall, it would appear that drug companies haven’t changed their strategies much; they continue to rank among the most generous campaign contributors ($36 million so far in the current election cycle); they schmoozed with politicians at the parties’ national conventions; and they’re pumping big dollars into advertising shown during and after the conventions that paints the industry as a vital innovator selflessly investing in research to save lives.

Jim Greenwood, CEO of the Biotechnology Innovation Organization, vowed to fight his industry’s role as an “easy scapegoat” for the problem, arguing that insurers should shoulder some of the blame for failing to cover key medications or requiring big copays for them.

During spring investment conferences and earnings calls, a number of pharmaceutical executives shared their anxiety about the political atmosphere. At the J.P. Morgan Health Care Conference in January, for instance, Biogen chief executive George Scangos was quoted as saying his company raised prices on three drugs more modestly than it might to avoid placing “a target on our foreheads.”

Novartis’ CEO Joe Jimenez acknowledged that a “difficult pricing environment” is likely no matter who wins the election. “We all have to plan for new pricing models in the U.S. that could help us ensure the sustainability of the system as the population ages,” Jimenez told the Financial Times in late July. He cited his company’s involvement in pay-for-performance deals with Cigna and Aetna that link the level of rebates to Novartis with its new heart failure drug Entresto’s ability to keep patients out of the hospital; Jimenez argued that drugmakers will have to be willing to enter such agreements to weather the intense political pressure on prices.

The Campaign for Sustainable Rx Pricing, a coalition including consumers, health plans, providers, employers—just about everyone but drugmakers—is busy lobbying for a long list of reforms centered around transparency, competition, and value. The coalition advocates such changes as open reporting of drug prices and increases, speedier FDA approval of cheaper generic drugs, and making stronger connections between the cost and benefits of individual medications.

“We’ve come together around a market-based proposal,” explains John Rother, the longtime AARP health care lobbyist who now heads the campaign. “It’s not government price-setting. We hope we can have a more open conversation with industry.”

Rother is optimistic that the pressure on drugmakers will continue into 2017, when the new president and Congress are in office. “No one running for president thinks the current situation is acceptable,” he says.

Nichols sees the universal outrage about prices across the political spectrum as an unusual chance for action, even if there is still a party split between Congress and the White House. “Whoever is president will have to work with both parties to get something done,” he said. “That is an opportunity to build on broad support for addressing the imbalance in the drug marketplace.”

Jan Greene is a veteran health care journalist based in northern California. Her work has appeared in the Los Angeles Times, Health magazine, Hospital & Health Networks, and many other publications.
As the 1972 movie The Candidate closes, the upstart Bill McKay, played by a young Robert Redford, has just won a surprise victory for a Senate seat. He pulls his campaign manager Marvin Lucas (Peter Boyle) into a side room as his election-night after-party begins and asks, "What do we do now?"

Ask that question of physicians in this year’s election campaign and you get a lot of different answers: tweak or repeal and replace the ACA, but don’t disrupt the health system too much; fix Medicare payment reform; make sure lifesaving drugs don’t kill us and our patients financially; for goodness sakes, let the CDC research firearms injuries; and don’t forget the small favors that each specialty needs, too.

Physicians are a disparate lot. At last count, there were more than 300 member organizations of the American Association of Medical Societies. These organizations tread common ground on a host of issues in play in this upcoming election cycle. They all want a delay in the implementation of Medicare’s value-based payment scheme, codified in the MACRA legislation. But they’re all relieved that as part of the negotiation that led to MACRA, the sustainable growth rate (SGR) is no more. For years, the SGR and its largely theoretical 24% cut in their Medicare reimbursement hung over them like a sword of Damocles. Doctors are also political players on hundreds of more granular issues specific to their specialties.

Physicians and other health professionals are a major lobbying force in Washington, having spent almost $90 million last year in political contributions, according to the Center for Responsive Politics. About a quarter of those contributions came from the American Medical Association, which once fought pitched battles against “socialized medicine” and the establishment of Medicare and Medicaid, but was an ally of the Obama administration and the Democrats in the passage of the ACA. Still, health professional groups—that includes nurses, pathologists, podiatrists, and dentists—lag far behind the biggest spenders in health care. Combined, the pharmaceutical and health products industries lead all lobbying sectors, having doled out almost $231 million in 2015. The insurance industry is the runner-up, and although this group includes property and casualty and life insurers, the two largest distributors of largesse in this group are Blue Cross/Blue Shield and America’s Health Insurance Plans. Hospitals and nursing homes...
also spend more than health professionals. So health professionals have a lot of competition in getting heard in Washington.

**Whither the ACA?**

It's clear where the parties stand on President Obama’s signature legislation. “If the Democrats get in and are able to gain good control of the House and Senate, then their primary focus will be to continue consolidating the ACA and to continue to expand some of the activity that didn’t quite get implemented in the last several years,” says Peter Angood, MD, president and CEO of the American Association for Physician Leadership, a group for physician executives and managers in the health care industry. “Obviously on the Republican side, it could either be a full repeal, depending who has full control of the House and Senate, or at minimum a revision of sorts.”

Lobbyists for medical groups tend to be physicians themselves, and they tiptoe around favoring one party or candidate over another on the eve of a national election for fear of spooking their “friends on both sides of the aisle.” They say they’ll accept whatever Congress and the president agree upon with the ACA.

But some physician groups come out and say they’d prefer to keep and improve the ACA. “We’re actually reasonably supportive of the Affordable Care Act,” says Wanda Filer, MD, president of the American Academy of Family Physicians. “It’s not perfect, and it probably needs some tweaking. We are going to work with both sides of the aisle to get it right, to hone it.

But our members have had a significant uptick in demand for patient visits.”

Many of those new patients have complex medical profiles “because they delayed care previously,” Filer says. For that reason, the family physicians’ group is anxious about any disruption for people who gained coverage under the ACA. “Anything that’s going to cause people to be uncovered at any point in their lives, particularly if they have a chronic disease, would be incredibly problematic and probably penny-wise and pound-foolish,” she says.

Another physicians’ group that has come down on the side of the ACA is the American College of Physicians, a national organization of internists and the second-largest physician organization in the country (after the AMA) with 148,000 members. “While we believe that the ACA should continue to be improved, we do not support efforts to repeal it or to substantially weaken its protections, which would cause coverage for millions of people to be put at risk,” ACP says on its website.

Primary care groups seem more receptive to the ACA because it has brought more patients into their practices and placed greater emphasis on the role of family physicians and internists to “quarterback” patient care. Overall, physicians are actually split on their opinions of the ACA, according to a Kaiser Family Foundation 2015 poll. The AMA itself has been more coy lately about its stance on the ACA, although it did put out a statement last year expressing relief at the Supreme Court ruling to uphold the law and has made other statements supporting the law. For this article, the AMA declined to comment on its political advocacy.

**MACRA: New frying pan?**

MACRA has physician lobbyists putting up their antennae in search of any signals coming out of CMS that will affect their members’ interest as the agency cobbles together rules to implement Medicare payment reform. MACRA passed with overwhelming bipartisan support last year, but as CMS gets down to writing the regulations, physician groups are jockeying to influence what they say.

The process may fall onto the shoulders of a new administration. MACRA is scheduled to go into effect next year, but CMS acting administrator Andy Slavitt told the Senate Finance Committee in mid-July that the agency is considering delaying the start date for MACRA. The final rule is due November 1, but even if CMS publishes the rule by then, medical groups have told Slavitt that two months to get ready for MACRA implementation won’t be enough. Most medical groups want a delay of either six months or a year—provided...
the rule is even ready by November 1. And Kavita Patel, MD, a Brookings Institution senior fellow and primary care physician at Johns Hopkins Hospital in Baltimore, speculates that it might not be ready, given the tremendous feedback it has received to date.

Joe Antos, a health care scholar at the conservative American Enterprise Institute, doesn’t think MACRA is much of an upgrade for physicians over the SGR. “For docs, it’s not so much they’re going from the frying pan and into the fire; they’re just changing frying pans,” he says. The raises physicians will get over the next decade are infinitesimal: an average of 0.5% a year, then 0.25% for those who stay in the more traditional payment scheme and 0.75% if they go into the risk-based advanced alternative practice model (APM). “It’s pretty obvious that cost of practice is rising faster than that,” he says.

APMs include ACOs, patient-centered medical homes and some bundled payment models. Besides APMs, the other payment model under MACRA is the Merit-based Incentive Payment System (MIPS), which streamlines several previous CMS value-based programs, including the Physician Quality Reporting System (PQRS) and meaningful use of electronic health records. The model is intended to reflect quality, clinical practice improvement initiatives, and how frequently physicians utilize tests, devices, and drugs.

But congressional leaders and medical groups have raised concerns that MIPS could be too onerous for single-doctor and small practices. They’ve used the term “complexity” to describe the regulatory burdens on these practices. “I don’t know if you’d call that complexity,” says Thad Waites, MD, of the American College of Cardiology, who has reviewed CMS’s preliminary draft rule. “It’s just a sledge hammer.”

For doctors, the choice between MIPS and APMs is a dilemma, says Jim Daniel, a health care attorney in Richmond, Va. “The reaction I get from most physicians is that they want to avoid MIPS, but most of them are not ready to go into advanced alternative payment models,” he says. “There’s a great concern that MIPS is going to be a more arduous reporting system. We’re starting to see physicians question if they can stay in small independent practices because they believe the administrative burden of keeping up with MIPS is so high. Also, it generally takes a large organization to be able to bear the risk of the advanced alternative payment models.”

Under the resource utilization component of MIPS, specialty groups want to make sure their members don’t get penalized for using expensive drugs that patients can get only in their offices. Most oncologists will probably participate in MIPS, the American Society of Clinical Oncologists (ASCO) has said in comments to Slavitt. ASCO asks that CMS not include pricey cancer drugs in the resource utilization measures. Similarly, the American Academy of Ophthalmology is asking that CMS not count expensive physician-administered injections for age-related macular degeneration in the equation.

Getting APMs right
But APMs are not a walk in the park. Patel, at Brookings, outlines physicians’ three primary concerns with the proposed MACRA rule for APMs:

1) CMS sets a high barrier for shared risk “right off the bat,” she says. Physicians would prefer a model that phases in, with lower risk in the early years and increasing risk in the later years.

2) They want more flexibility for individual physicians to propose advanced APMs instead of working through practices and physician groups.

3) They want Medicare to include as APM models some bundled payment programs that were left out of the current version of the proposed rule.

The AMA expressed similar concerns about APMs in a 70-page comment letter to Slavitt, but would also like to see risk requirements based on physicians’ Medicare revenues rather than total Medicare expenditures “so physicians do not have to take risks for expenses outside their control.” The American Association of Orthopaedic Surgeons wants advanced APMs to include the bundled payment models that 3,000 orthopedic surgeons already participate in as well as the Comprehensive Care for Joint Replacement Model mandatory in 67 metropolitan areas.
MACRA at a glance

**MIPS**

**Merit-based Incentive Payment System**
- Adjusts payments up or down based on new reporting system
- Consolidates PQRS, VM, and MU

The MIPS score will account for performance in **four weighted performance categories**:

- Quality (50%)
- Advancing care information (25%)
- Clinical practice improvement activities (15%)
- Cost (10%)

Based on the MIPS composite score, clinicians will receive positive, negative or neutral adjustments.

**MAXIMUM adjustments**
- Quality: +9%
- Advancing care information: +7%
- Clinical practice improvement activities: +5%
- Cost: +4%

Adjustment to provider’s base rate of Medicare Part B payment

Those who score in the top 25% are eligible for an additional annual adjustment of up to 10%.

**APM**

**Advanced Alternative Payment Model**
- CPC+, MSSP Tracks 2 & 3, Next Gen ACO, OCM (2-sided risk), & CEC Model (LDO arrangement)
- 5% annual bonus FFS payments
- Potential expansion of CPCI PCMH model

Initial definitions from MACRA law, APMs include:
- CMS Innovation Center models (under section 1115A, other than a Health Care Innovation Award)
- MSSP (Medicare Shared Savings Program)
- Demonstration under the Health Care Quality Demonstration Program
- Demonstration required by Federal law

Most clinicians who participate in APMs will be subject to MIPS and will receive favorable scoring under the MIPS CPIA performance category.

**Specific agendas**

Beyond Medicare, the American College of Cardiology (ACC) is keeping watch on a proposed FDA rule on generic drug labeling. Since a 2011 Supreme Court ruling, the FDA has supposed to come out with a rule that would require generic drugs to keep their warning labels up to date with recently reported risks. The ACC and other physician groups, along with the Generic Pharmaceutical Association, have lobbied the FDA to not make the rule so onerous that it would drive up the cost of generic drugs.

“We’re very concerned about the change in FDA rules that’ll require some generics to go back and get new licenses—and it could reduce the number of companies putting out some of these drugs and increase their costs,” says Waite of the ACC.

Mass shootings in Orlando and Dallas over the summer renewed physician interest in pushing Congress to lift its 20-year ban on firearms injury research. The AMA House of Delegates passed a resolution to lift its 20-year ban on firearms injury research. The AMA House of Delegates passed a resolution to lift its 20-year ban on firearms injury research. The AMA House of Delegates passed a resolution to lift its 20-year ban on firearms injury research. The AMA House of Delegates passed a resolution to lift its 20-year ban on firearms injury research. The AMA House of Delegates passed a resolution to lift its 20-year ban on firearms injury research.

In a special issue of its journal this summer, the American Association for the Surgery of Trauma called for funding a national database on violent deaths as well as lifting the research ban. “If we don’t know what we’re dealing with we have no idea of how to maneuver within this world,” says Filer of the AAFP, another group backing more firearms research.

Specialty groups have other issues that are dear to their hearts. For family physicians, it’s sustaining funding for training programs. For general surgeons,

Besides worrying about having costly drugs possibly count toward their resource utilization scores, physicians are grappling with CMS over how they’ll get paid under Part B to administer those drugs—again, an issue largely for oncologists and ophthalmologists. “It looks like ophthalmologists and medical oncologists could get hurt significantly,” health care attorney Daniel says. They could see a sharp cut in what they get paid for administering these expensive drugs.

Medicare Part B covers these therapies at their cost plus 4.3%, adjusted downward from 6% since the 2013 sequester. In a large pilot program, Medicare wants to titrate that to 2.5% plus cost along with a flat fee of $16.80 to be adjusted each year. The rationale is to break the link between physician payment and the cost of the drugs themselves—“to make sure that doctors aren’t penalized for choosing the most effective drug if it happens to be inexpensive,” CMS says in a press release.

**ACO=Accountable Care Organization, CEC (LDO)=Comprehensive ESRD Care Model Large Dialysis Organization, CPC+=Comprehensive Primary Care Plus, CPC=Comprehensive Primary Care Initiative, CPIA=clinical practice improvement activities, FFS=fee for service, MSSP=Medicare Shared Savings Program, MU=Meaningful Use (now Advancing Care Information), OCM=Oncology Care Model, PCMH=Patient-centered Medical Home, PQRS=Physician Quality Reporting System, VM=value modifier.**

Source: American College of Physicians
Hospitals are merging like it’s … 1996. That was the year hospitals, facing managed care pressures, went consolidation-crazy. In one year 768 hospitals were involved in 235 mergers and acquisitions, according to the website Global Healthcare IT.

Mergers and acquisitions slowed down significantly in the following years. But in 2010, when the ACA became law, the stars were aligned for Merger Mania Part II. Since then, the hospital industry has been on a buying bender. Mergers, acquisitions, joint ventures, and joint operating agreements have almost doubled, going from 66 in 2010 to 112 in 2015, according to the consulting firm Kaufman Hall.

The trend will likely continue, with hospitals under intense pressure to reduce costs, improve care, and improve patient satisfaction. Other factors in the consolidation equation include the ACA’s alternative payment models, risk contracting, and electronic health records. There’s also no doubt that mergers are motivated, in part, by the market power that larger organizations can use to set higher prices and push back against payers.

Some hospital systems, running out of local hospitals to acquire, are expanding beyond their markets to create regional systems. Philadelphia-based University of Pennsylvania Health System recently entered into merger talks with the Princeton Health System, located 44 miles away in New Jersey. In July, it was widely reported that Long Island-based Winthrop University Hospital had signed a nonbinding letter of intent to integrate with NYU Langone Medical Center in Manhattan, 28 miles away.

Proponents of mergers and acquisitions say they can lower costs by creating economies of scale and smoothing the way for all kinds of clinical integration. But others say the fact that they can doesn’t mean they do. In the New England Journal of Medicine last year, Leemore Dafny, now at the Harvard Business School, and Thomas H. Lee, MD, chief medical officer at Press Ganey and a member of Managed Care’s editorial board, wrote that mergers could “be moments of opportunity” that help hospitals compete on outcomes and costs, but also that “the most consistently documented result of provider mergers is higher prices, particularly when the merging hospitals are in close proximity.” The motivation behind many mergers, said Dafny and Lee, is to eliminate competition “to ensure referral streams (which would otherwise be earned through superior offerings) or to help providers negotiate higher prices and thereby avoid the difficult work of improving outcomes and efficiencies.”

Findings from the National Bureau of Economic Research tend to substantiate Dafny and Lee’s conclusion. A study headed by Zack Cooper, an assistant professor at Yale, found that hospitals with monopoly power charge an average of 15% more than those in an area with four or more hospitals.

Given everything that has happened over the past six years, the ACA so far seems like a pretty good deal for hospitals. But what the ACA giveth, it can also taketh away. Studies suggest that hospitals should brace...
What really drives high hospital prices?

Bivariate correlations of the level of inpatient hospital prices with observable factors

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Source: Cooper Z et al., National Bureau of Economic Research, December 2015

for an uptick in unpaid bills from high-deductible health plans that are increasingly prevalent on the ACA exchanges. A Kaiser Family Foundation and New York Times survey revealed that 20% of Americans with insurance say they or someone in their household has had trouble paying a medical bill in the last year. To avoid getting stiffed, some hospitals are requiring patients to ante up their copay before being admitted, according to Lawton Burns, a professor of health care management at the University of Pennsylvania's Wharton School.

Another looming concern for hospitals is the cutback in the Disproportionate Share Hospital allotments for uncompensated charity care. Starting in 2018, the government will decrease its contribution to the fund by $2 billion; it will continue reducing its subsidy until the fund disappears in 2024. While the increasing number of Americans covered by private health insurance or Medicaid and the ACA ban on lifetime limits will make some hospitals more secure, these factors won't save them all. In May, the New York Times reported that 125-year-old Mount Sinai Beth Israel, one of seven hospitals in the Mount Sinai Health System, would close its 825-bed hospital and reopen as a 70-bed hospital in a new location. The hospital thus became one of 19 in the city to be closed or drastically downsized since 2000.

Of course, many large metropolitan hospitals continue buying competitors as Pac-Man devoured ghosts. But rural and inner-city hospitals serving poorer communities face much gloomier prospects. Unlike their big-city cousins, community and country hospitals often lack the financial wherewithal to purchase the latest technology and attract and retain staff.

Hospital closings outside urban areas are widespread. More than 60 rural hospitals have closed since 2010, while another 673 rural hospitals in 42 states are in danger of closing this year, according to a 2016 report from iVantage Health Analytics, a health care data company in Portland, Maine, that contracts with hospitals. The report says that many of the hospitals in danger of closing are in Southern states.

Repeal and replace?

As late as 2000, Donald Trump championed the idea of universal health care. But since joining the Republican primary race in 2015 and becoming the GOP's presidential candidate, he's stuck to the party mantra of “repeal and replace Obamacare.” Fewer insured patients would mean lost revenue for hospitals and an increase in charity care, although Trump has tepidly endorsed House Speaker Paul Ryan’s “A Better Way” proposals that include high-risk pools and tax credits that people could use to buy insurance on state-regulated markets. Trump's call for price transparency from providers would also affect hospitals.

"Individuals should be able to shop to find the best prices for procedures, exams or any other medical-related procedure," says his proposal, voicing a sentiment shared by many who think American health
care would be less expensive and more effective if it were a retail experience.

Hillary Clinton has consistently said she would improve and "build on Obamacare." To win Bernie Sanders’ endorsement and woo his supporters, she has moved farther left on health care, adopting some of the Vermont senator’s ideas. The nominee now supports allowing states to create a public option, something hospital associations were clearly against back in 2010, partly because a public option might pay at Medicare rates and therefore cut into revenues. Rural hospitals and community health centers will see an infusion of funds as part of her plan.

But here’s the thing: There has been a slew of CMS programs and initiatives over the past several years, most of them related one way or another to the ACA, that have had a major effect on hospitals but are too far into the weeds to be a factor in elective politics, especially at the presidential level. For example, the program that penalizes hospitals with high readmission rates is in its fourth year. It’s designed to push hospitals to improve care, but progress so far has been middling. Kaiser Health News reported in August that CMS is going to punish more than half of the nation’s hospitals this year because of their high readmission rates.

Another example: Bundled payments are designed to make hospitals responsible for patient care several months after discharge, and proponents of value-based care say they may be the best way to break American health care’s addiction to volume and intensity. CMS has launched ambitious programs this year to extend bundled payments to cardiac and orthopedic cases.

And consider ACOs. About 20% of the country’s hospitals are part of an ACO. Participation can put hospitals in an awkward position. Many have the capital to invest in IT and other kinds of systems needed to make an ACO function. But the ACO model may work against a hospital’s short-term interests because to meet cost-saving goals, ACOs need to reduce inpatient stays and the use of other expensive hospital services.

Clinton, with her background in health care, may know something about health care policy and programs at this level. Trump, with his focus on trade and the economy, probably does not. ACA repeal would be disruptive, but the new occupant of the oval office may be irrelevant to whether these programs continue or come back with slightly different rules.

Robert Calandra is an independent journalist in Philadelphia with more than 20 years’ experience writing about health care.

ELECTION 2016

Maybe the ACA Is Here To Stay, But Employers Wish That Cadillac Tax Would Go Away

By Charlotte Huff

Despite worries that the ACA would erode employer-provided insurance, analyses since the law’s passage have shown that neither companies nor workers have shirked coverage. Moving forward, politicians and health policy leaders are looking at ways to modify the law—short of those who support calls by House Republicans and Donald Trump for outright repeal—in ways that alter the structure and tax incentives of employer-provided benefits without unduly driving up total health costs.

A number of concerns about the ACA have not panned out, says Dallas Salisbury, president emeritus at the Employee Benefit Research Institute. Employers have not, for example, dropped coverage and moved their employees to the ACA exchanges. A recently published Urban Institute analysis indicates that employer coverage has even increased slightly, partly because a public option might pay at Medicare rates and therefore cut into revenues. Rural hospitals and community health centers will see an infusion of funds as part of her plan.

But the law’s rollout has aligned with or accelerated—depending upon the perspective—an ongoing move by employers to boost deductibles and shift
other out-of-pocket costs to employees. The transition was “well on its way” prior to the law’s passage but was encouraged by employer fears that their health coverage could become costly enough to trigger the so-called Cadillac tax, says Mike Thompson, CEO of the National Business Coalition on Health. “Employers wanted to avoid that if at all possible.”

The Cadillac tax, which has drawn fire from both Democrats and Republicans, was initially slated to go into effect in 2018 but last year Congress delayed it until 2020. But it remains an election-year point of friction, with proposals ranging from repeal to modifications.

Another goal for those who want to build on the ACA is to ease out-of-pocket costs for employees struggling with high deductibles. To that end, Hillary Clinton has proposed several measures, including tax credits to offset the cost of high medical bills. Meanwhile, proposals by Donald Trump and House Republicans signal strong support for expanded use of health savings accounts.

**Revisiting tax exemption**

In its analysis of employer-based coverage, the Urban Institute didn’t find any shrinkage in the rate at which employers were offering insurance or the rate at which employees were signing up, regardless of the employer’s size or the income level of the workers. The authors cited several factors besides the ACA employer mandates, including the individual mandates and the continuing favorable tax treatment of health benefits that exempts employer and employee premium payments from income and payroll taxes.

But the future of that protected status remains uncertain. The Cadillac tax, initially slated for 2018, was designed to levy a 40% excise tax on employer-sponsored health plans with values that exceed $10,200 annually for individuals and $27,500 for families. (The total value calculation is based on some savings account contributions, such as health savings accounts [HSAs], along with employer and employee premium payments.) Roughly 1 in 4 employers would have been

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**Finding more revenue sources** is important for health care reform, but Linda Blumberg of the Urban Institute worries about the effects of the current proposals on lower-income workers.

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**Share of workers ages 18 to 64 with employer-sponsored insurance coverage**

<table>
<thead>
<tr>
<th></th>
<th>June 2013</th>
<th>March 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>All workers</td>
<td>70.8%</td>
<td>72.1%</td>
</tr>
<tr>
<td>Workers at all firms</td>
<td>49.4%</td>
<td>50.0%</td>
</tr>
<tr>
<td>Workers at large firms</td>
<td>82.5%</td>
<td>83.6%</td>
</tr>
<tr>
<td>Workers at small firms</td>
<td>44.6%</td>
<td>45.5%</td>
</tr>
<tr>
<td>Family income at or below 250% of FPL</td>
<td>58.9%</td>
<td>60.2%</td>
</tr>
<tr>
<td>Family income above 250% of FPL</td>
<td>86.1%</td>
<td>87.8%</td>
</tr>
<tr>
<td>Workers at all firms</td>
<td>69.5%</td>
<td>72.0%</td>
</tr>
<tr>
<td>Workers at large firms</td>
<td>92.3%</td>
<td>93.4%</td>
</tr>
<tr>
<td>Workers at small firms</td>
<td>83.6%</td>
<td>87.8%</td>
</tr>
</tbody>
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FPL=federal poverty level.  
subject to the tax by 2018 unless they changed their health plan designs, according to a Kaiser Family Foundation analysis last year. Clinton has called for repealing the tax, saying that the lost revenue could be offset by other health system reforms, such as reducing prescription drug costs. As of press time, the Trump campaign’s written health plan—the first item is to repeal the ACA—doesn’t address the Cadillac tax specifically.

House Republicans, who also want to wipe the slate clean by repealing the ACA before instituting any new health reform measures, have suggested an alternative to the Cadillac tax that would put a cap on how much health coverage individuals can obtain from their employer on a tax-exempt basis. Their approach, they say, will shift compensation from tax-favored health benefits to take-home pay. It would also be fairer for lower-income employees, they contend, because with the Cadillac tax, their benefits above a certain threshold will be taxed at the same rate as those of higher-income employees. Their 37-page “A Better Way” proposal for health care issued by House Speaker Paul Ryan and Republican colleagues in June, did not specify a dollar amount for that cap; instead, there was the vague assertion that only “the most generous plans” would be affected. They did specify, however, that the cap would be adjusted geographically to account for regional differences in health care costs.

The Cadillac tax and the Republican proposal to put a cap on the tax-exemption of health benefits would raise similar amounts in terms of revenue, according to a joint analysis published last year by the Urban Institute and the Robert Wood Johnson Foundation. Employees might be more directly affected by the House Republicans’ plan, because they might lose some degree of tax exemption, says Linda Blumberg, an economist and a senior fellow at the Urban Institute’s Health Policy Center. But employees are likely to feel the effect of the Cadillac tax, too, if it ever goes into effect. The tax will be paid by the insurance provider, including self-funded employers, but its costs would likely be passed along to employees through various measures, such as high deductibles and other cost sharing. Provider networks may also get skinnier.

Blumberg supports the goal of finding a revenue source, but worries about the effects of either approach on more vulnerable workers. “How do we protect the lower-income workers from getting higher deductibles as a consequence that may really impede their access to affordable care?” Regardless of the revenue provision, some form of subsidy or other protection should be built in, she says.

Easing out-of-pocket stressors
High-deductible plans may predate the ACA but have become more entrenched in recent years. Nearly two thirds of workers have a deductible of at least $1,000 on an individual plan compared with just under half in 2010, according to a survey by the Kaiser Family Foundation and the Health Research & Educational Trust. HSAs are also coming on strong. Last year, 24% of workers were enrolled in a plan with a HSA or other savings account option compared with 13% in 2010, according to the benefits survey.

As these plans have become more common, though, some studies have raised questions regarding to what extent workers curtail basic care along with pricey and perhaps unnecessary treatment. One frequently cited analysis, published last year by the National Bureau of Economic Research, found that health spending declined by roughly 13% annually when a large company shifted its workforce to a high-deductible plan. But those savings nearly all stemmed from workers seeking out fewer medical services rather than price shopping or searching for less costly treatment options.

To discourage people from bypassing the doctor entirely, Clinton has proposed that the ACA require insurers and employers to cover up to three doctor visits annually outside of the deductible. She also has proposed tax credit refunds of as much as $5,000 per family for those who face excessive out-of-pocket bills—defined as insured individuals with health costs that exceed 5% of their income. In the House Republicans’ plan, there are no similar proposals to directly offset out-of-pocket costs. But they strongly...
promote the role of HSAs, advocating for an increase in what employees can pay in and excluding those contributions from healthcare costs that would go toward the tally to which the cap on tax exemption would apply. Trump similarly supports health savings accounts as a way to accrue funds for unanticipated medical expenses.

**Repeal or bust?**

While the House Republicans and Trump promote scrapping the ACA as a leading post-election priority, employers by and large wouldn’t be big fans of a repeal, says Salisbury of the Employee Benefit Research Institute, noting that the law supports high-deductible plans and related savings accounts that employers embrace. “Do I think they’d be up for total and complete repeal? No.”

Already, there are indications that employers view the law as here to stay. When the House Republicans released their health reform plan, the Chamber of Commerce issued a statement supporting certain provisions, such as the repeal of the employer mandate and improvements to health savings accounts. But the business organization didn’t address the Republicans’ stated goal of repeal, instead describing itself as having “long been a leader in the push to improve” the law.

Any effort to revisit the law will venture into the well-trodden territory of balancing cost versus coverage. As one example, Blumberg points out that Trump supports allowing individuals who buy their own insurance to fully deduct the premiums on their tax returns.

“The risk for employers, she says, is adverse selection if higher income and largely healthy employees decide to buy a plan on the individual market. “You may end up then having these situations where the people left wanting employer-based coverage are sicker.”

But if the ACA remains largely intact and the Cadillac tax is ultimately repealed, that would leave a gaping hole on the revenue side of the ACA ledger. Last year, the Congressional Budget Office projected that the excise tax would bring in $87 billion over the next decade.

“I think employers at one level would like [the tax] to just go away,” says Thompson, with the National Business Coalition on Health. “But I think that there is so much revenue associated with it, it may not go away. So then the question is, ‘How do we get it better, how do we make it right?’”

Charlotte Huff is a medical and business writer in Forth Worth, Texas. She has written for many publications, including Slate, Medical Economics, and ACP Internist.

**ELECTION 2016**

**PARTIES OFFER DIVERGENT PRESCRIPTIONS FOR MEDICARE**

Clinton wants to expand the existing program. Trump’s signals are mixed, but the Republican platform calls for replacing entitlements with premium support to buy private health insurance.

When it comes to the ACA, you won’t hear many complaints from Medicare beneficiaries. But then again, why would you? Some of the Tea Party opposition to the ACA was animated by fears that to extend health insurance coverage to more young and poor people the law would expand Medicaid at the expense of Medicare beneficiaries. But by design, the ACA actually sweetened the deal for Medicare beneficiaries in some respects. Most notably, it gradually eliminates the “donut hole” of greater cost sharing in Part D prescription drug coverage, and free wellness visits were added to Part B coverage. The wellness visits have a pitfall, though. If there is a discussion of an ongoing condition, it is no longer deemed a wellness visit and the usual Part B cost sharing applies.

Medicare Advantage under the ACA is a complicated story. At the outset, members of Medicare Advantage plans had some reason to be worried because the law lowers the benchmarks that are used to set payments to the plans, a reflection of the view that the plans have been overpaid (and insurance companies reaped a windfall) relative to per-beneficiary cost in traditional Medicare. The average out-of-pocket limit of the Medicare Advantage plans has increased from $4,313 in 2011 to $5,223 this year, according to a Kaiser Family Foundation analysis. Some senior
organizations have criticized the plans, now operating under ACA rules, for limiting access to specialists and steering more care delivery to nurse practitioners and physician assistants. At the same time, Medicare Advantage is more popular than ever. The percentage of beneficiaries choosing Medicare Advantage coverage has increased from 25% in 2011 to 31% this year.

Hillary Clinton and the Democrats can take heart that senior public opinion is on their side when it comes to Medicare, as it traditionally has been. According to Kaiser’s tracking poll, conducted before the conventions, 45% of senior voters say they trust the Democratic Party to determine the future of Medicare compared with 41% that trust the Republican Party.

The messages from Donald Trump and the Republicans about Medicare have been mixed. In interviews last year, Trump said he agreed with Ben Carson’s plan to replace Medicare with health savings accounts but also described Medicare as a program that has actually worked. The party platform hews to previous Republican proposals to replace the current entitlement to Medicare benefits with “premium support”: payments that would go toward the purchase of private health plans. The premise is that demographics and generous benefits make the current Medicare system unsustainable and that premium support and private health insurers would bring some market discipline to the program. There’s also a reference to raising the age at which someone would become eligible for Medicare, although a specific age is not mentioned.

Rather than restrict the number of Americans covered by Medicare, Hillary Clinton has proposed expanding the program so that those 55 and older could buy into it if they wished. Providers might push back against that change because Medicare payment rates are lower than those of private insurers. Clinton also supports allowing Medicare to negotiate drug prices, a position that Trump took early in the primary season, but that is not mentioned on his website or in the Republican party platform. Instead, the Trump website argues for allowing consumers to buy drugs from overseas suppliers in countries where the price is much lower. The Democratic Party platform has been described as being “oddly silent” about Medicare. It promises that the party will fight Republican efforts to “privatize, voucherize or ‘phase out’ Medicare” and mentions the Medicare-for-more proposal and drug price negotiation but not any changes to the program itself.

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Most polls had Hillary Clinton surging ahead of Donald Trump last month, but among health care executives, the candidates were in a dead heat, according to a MediMedia Research survey.

Forty-seven percent of the 432 respondents to the online survey conducted from August 4 to August 26 said they plan to vote for Clinton, and the exact same percentage said they intend to vote for the Republican nominee.

The tie is a bit surprising. Clinton tends to lead Trump among voters with college and professional school educations. But as Mark Spickler, a MediMedia Research analyst, points out, the respondents to MediMedia Research’s survey tilted Republican (42% indicated they are registered Republicans, compared with 30% who are registered Democrats and 28% who are not registered in either party). And they were Romney supporters by a comfortable margin in the last presidential, with 56% voting for the Republican nominee compared with 43% for President Obama.

MediMedia Research is part of MediMedia Managed Markets, an ICON plc company and owner of MANAGED CARE. The 10-minute survey on election issues was sent to MANAGED CARE readers. About half of the respondents said they worked for a medical group or integrated delivery system, and the group included 132 physicians and 61 pharmacists.

When they were asked about which issues are important in this election, health care and the ACA was in the middle of the pack, with 70% rating them as being very important (6–7 on a scale of 1–7). But even among these health care executives, terrorism and national security, future Supreme Court selections, and the economy rated higher than health care. That’s consistent with what polls are finding—and pundits are saying—about the general electorate.

Most of the respondents to the MediMedia survey for our readers thought Trump would do a better job dealing with health care when it comes to making it more efficient (54% vs. 46% for Clinton) and encouraging more innovation (59% vs. 41%). On the other hand, a clear majority favored Clinton when it comes to limiting cost shifting to consumers (56% vs. 44% for Trump) and bringing about value-based care (53% vs. 47%). Spickler says the split may reflect Trump’s appeal.
as an outsider and a businessman and Clinton’s as the candidate with a background in health policy and an ardent supporter of the ACA. Yet polling by the Kaiser Family Foundation has shown that among voters, most favor Clinton over Trump when asked which candidate represents their views on health care.

The MediMedia survey found an enthusiasm gap. When the respondents were separated by party, Republicans tended to be stronger supporters of Trump’s health care proposals (price transparency, health care savings accounts, allowing health insurance to be sold across state lines) than the Democrats were of Clinton’s (limiting out-of-pocket expenditure, creating a public option, letting people in their 50s and early 60s buy into Medicare). Furthermore, the Republican respondents rated Clinton’s proposals lower than Democrats rated Trump’s. “I think this shows just how polarized the positions of the parties are, even among health care executives,” says Spickler. “Republicans, in particular, do not favor anything proposed by Democrats, so it will be difficult to find any kind of middle ground.”

Not surprisingly, opinion about the ACA is especially divided and skews negative. Among the respondents as a whole, 27% gave the ACA the lowest favorability rating while 12% gave it the highest. In contrast, opinions about MACRA skewed in a positive direction, perhaps because MACRA hasn’t been implemented so there is no experience with it yet.

The pattern of opinion about the Right to Try laws and the 21st Century Cures Act were remarkably similar with the largest group in the middle range of favorability. The Right to Try laws, which have been passed at the state level, and the 21st Century Cures Act, have drawn support from critics of the FDA who believe the agency is too slow and interfering when it comes to approving new therapies.
Q&A WITH PAUL STARR

Obama’s ‘Minimally Invasive’ ACA Could Use Clinton’s Fine-Tuning

The ACA was health care reform that left the health care system largely intact, says Princeton sociologist Paul Starr. A Clinton presidency could mean important adjustments to the law, including addressing the omission of a public option. Trump’s proposals would, in his view, effectively end regulation of insurance, and responsible insurers should be worried about fraudulent forms of insurance entering the market.

Interview by Peter Wehrwein

I have been reading your book on the history of health care reform, Remedy and Reaction. I was wondering whether you see the ACA as fundamentally changing health care reform? You described a pattern in which failed efforts at major reform were followed by partial successes, so Truman’s failure was followed years later by the passage of Medicare and Medicaid in 1965, and then after the failure of Clinton’s managed competition, we got the CHIP program. Has the ACA ended health care reform as we knew it? No, I do not think it has been a fundamental break in American health policy. It is an attempt at what I refer to in Remedy and Reaction as minimally invasive reform. Despite the criticism from Republicans that it is a government takeover, it is actually only a step to complement and correct problems in the health care marketplace. By and large, most of the existing programs and arrangements have been left in place. On the public side, Medicare, Medicaid, CHIP, the Veterans Administration—you can go on and list them all. Most of them are really unchanged in their fundamentals and the same is true of employer-based insurance. The basic structure of health care finance remains the same.

What the ACA addressed were the deep problems in the individual insurance market, which I think many people recognize made it unsustainable. More people in that market were likely to find premiums to be unaffordable and so the market as a whole was headed into a death spiral. The Affordable Care Act and the affordability subsidies in particular, helped sustain that market. They have not sustained it as well as might have been hoped because we see a lot of problems in the health insurance exchanges, but I think without subsidies that market would be in even worse shape.

Did it only come to be because it was minimally invasive? Is that why we have the ACA, because it left existing arrangements largely in place? Yes. I think, as described in Remedy and Reaction, the Affordable Care Act really came out of the negotiations that went on during the preceding years between applicants of universal coverage and the various major trade associations representing pharma, the hospitals, physicians, and other health care groups. Having lost the battle in the 1990s, the advocates of reform wanted to avoid the devastating opposition of the health care industry.
No Harry and Louise this time? Yes. That was what led the formulation of the general approach. Of course, Massachusetts under Romney provided the immediate model, the hope that reform in fact could be bipartisan. That proved to be impossible given the national political environment, the polarization between Democrats and Republicans. But, really, the substance of the Affordable Care Act is a bipartisan compromise even if it did not have bipartisan support. The structure of the plan, the reliance in particular on both Medicaid and the health insurance marketplace without any public options, to me that is the approach that moderate Republicans once would have embraced and there just are not a lot of moderate Republicans left in the party. So, this was a kind of bipartisan compromise with a Republican party that no longer exists.

After reading your book and Steve Brill’s America’s Bitter Pill, I sense that you end up feeling a little bit cynical that it is just a dividing of the spoils. Well, I think that is too harsh because let’s be clear, some 20 million people have gotten health insurance who would be otherwise uninsured. Many people with pre-existing conditions who faced economic ruin now have the opportunity to get coverage, and we have a lot of evidence of people who have become better off as a result of reform.

It is true that the Affordable Care Act, for example, did not really take on the dominance of the health care insurance industry. It did not deal with the problem of increasing consolidation and monopoly in some markets. Those tendencies have increased health care costs. They remain as a threat to reforms because of the potential for higher costs in the future. There are a lot of limitations to what was done.

Let us get into the election a little bit. The latest Kaiser poll has health care ranking fifth after personal characteristics of the candidates, terrorism, gun policy, and the economy and jobs. Does that surprise you at all, that the election is not a little bit more about the ACA? I think one of the principal outcomes of the election will be the fate of the ACA even if that is not foremost in the minds of voters today.

You have written that it takes a couple of elections for political and social reform to take root. Do you see this election as critical in that way? Absolutely. If Trump wins and if Republicans have the majority in both houses of Congress, it is a reasonable expectation that they will repeal the Affordable Care Act. I think they have to be taken at their word. I think the Affordable Care Act is still in play. It is not yet as fixed [in] American health policy as Medicare or even Medicaid.

If Hillary Clinton wins, would you expect the ACA to become a fixture? Is that why the Republicans are fighting it? They knew that if this law were passed it would be woven into the American economy and government? I do not think the Affordable Care Act is, even with a Clinton victory, going to be as entrenched a part of American health policy as Medicare or Medicaid. The Affordable Care Act has many different elements within it, many different provisions. Those, I think, could well be subject to revision or reversal in the future. Expansion of Medicaid could effectively be reversed with a plan at some point in the future to turn it into a block grant to the states. The tax subsidies and the health insurance exchanges may or may not be sustained at a reasonable level in the long run. I do not take it as a given that even with Clinton’s election, the Affordable Care Act is a permanent part of the American policy landscape.

The Kaiser poll, the tracking poll on its favorability ratings, there are some zigs and zags but the unfavorability rating always tracks a little bit higher than the favorability rating. The latest poll shows unfavorability of 46% and a favorability rating of 40%. How much of that do you think is a function of the way it has been spun and argued about, and how much of it is that it may be more fundamental—that broad sectors of Americans do not feel its benefits and therefore do not feel positively inclined toward it? Part of the disapproval is actually coming from people who favor a single payer. If you put them together with the supporters of the law, you actually get a majority who are in favor of what we could call liberal reforms.

I think many people also do not know to what extent the Affordable Care Act is causing changes in their health insurance even if they get their health insurance from their employer. For example, over the last 10 years, there has been a huge increase in deductibles in employer-provided insurance, and many people are very unhappy about that change and they believe their insurance has deteriorated. I suspect many of them think that is the result of the Affordable Care Act. It is not.

I do not want to take you into chapter and verse on this, but if the ACA is not responsible for larger exposure to health care costs, what in your opinion are the forces at play? Let me explain my understanding of this change in employer-provided insurance a little bit more clearly. Since the ACA, there has been no overall increase in cost sharing. There are higher deductibles, but the ACA has also eliminated most annual and lifetime limits. It has provided for more complete coverage of preventive care.
So, people actually have benefited from the ACA in some ways. But I do not think they understand that. There are changes in the insurance they get from their employer, but how do they know which of those changes are due to the law?

That is interesting. You are saying that there is still the same amount of cost exposure, it has just been redistributed from a few very unlucky individuals that went over their lifetime limits to higher deductibles. Yes. I think many policy analysts, looking at this objectively, would say this is actually a very good shift. That it makes sense to cover those preventive costs. It makes sense to protect against catastrophic risks. The offset to that is that people have more exposure to routine medical costs up to their deductible. That clearly makes them more cost sensitive, for better or worse. I am not sure it is totally for better, but in any event it makes them cost sensitive. There has been this tradeoff and it has its advantages and, I think however, from the point of view of many consumers, the disadvantages are the ones that they are most conscious of.

Let us shift a little bit to what the candidates are talking about anyway. I am not sure how many people are really noticing. As you know, it is emblazoned when you hit the Clinton website, “Affordable health care is a basic human right,” which seems to be right in line with a liberal tradition about health care. Then there are various more specific proposals, “Medicare for more” and a vague assertion about a public option. I am wondering if this interests you in terms of how this plays into American politics and social attitudes toward health care. Which of these ideas is most likely to happen? What is she tapping into? She is trying to address some of the problems that clearly remain with the Affordable Care Act. Many people are upset about cost sharing and indeed the plans and the exchanges tend to have relatively high cost sharing. For many people, even with the subsidies, the costs are difficult to afford. So, that is going to be a principal concern for her, if she is elected president.

What about Medicare for more? That is a proposal that Bill Clinton first made as president in the late 1990s. Al Gore proposed that in his 2000 campaign. It is an idea that has been around for a long time, sort of like early bird Medicare to let people buy in to Medicare when they hit age 55. There would be a whole series of questions about what the financing arrangements would be. This would mean, from a provider’s perspective, a reduction in payment rates. That is if it is Medicare as compared to private insurance for these people. But, this has significant implications for the health care industry.

Let me just step back from that specific proposal and talk more generally about the difficulty in many of the health insurance exchanges of getting enough competition. I think President Obama’s article in JAMA raised this point, and there he was calling for

**If you repealed the ACA and you allow insurance companies to sell policies across state lines, then effectively you have no regulation of insurance.**

a public option as a fallback in areas where there are fewer than three alternatives, where we may be down to one option or at some point zero options. The lack of a public option as a fallback in the Affordable Care Act is a really serious omission. There needs to be some way to provide coverage in these counties where at this point there is very little competition.

Let us talk about Trump and the GOP. Their proposals are rather familiar, basically deregulation in health insurance by allowing sign-ups across state lines. At least that is my understanding that would be the consequence. If you repealed the ACA and you allow insurance companies to sell policies across state lines, then effectively you have no regulation of insurance and I think responsible insurers should be concerned about the fraudulent forms of insurance that are going to develop.

Do you think it will be open season for bottom feeders? Yes. I think it certainly would.

What about the Republican proposals for health savings accounts which show up both in Trump’s limited proposals but also in more detail in Paul Ryan’s “A Better Way” proposal? I think the emphasis on high-deductible health plans and health savings accounts shows a lack of understanding of what confronts many low- and middle-income people, especially those who have serious medical problems or chronic illnesses. They are not going to be able to accumulate balances in those health savings accounts. They are going to face much higher costs. Those ideas work very well for healthy, affluent people. High-deductible plans and health savings accounts enable those affluent people to get tax advantages to keep more money in their own pocket. That keeps money out of the insurance pool that pays for the sick. This is an approach which I think clearly has a kind of bias in favor of the healthy and the affluent, which is really at odds with the whole purpose of health insurance.
Do you see something cynical about it or is it just an overattachment to the idea of individuals making their own decisions, some sort of individualistic idea of what it means to be American? Yes. I think it is born of a certain individualism but also of a misplaced confidence in the ability of consumers to discipline the health care marketplace—especially if you think about the concentration of health care spending. That is, in any given year, the 10% most costly individuals account for more than 70% of the total cost. That spending is occurring generally above the deductible, even in a high-deductible plan. Most of that spending is occurring without the constraints that this theory is relying on. That is why, even in the high-deductible plans, there is still managed care. The whole idea that this would be totally consumer driven is an illusion.

What about all the energy and discussion and initiatives around value-based payment and care? The shifting of risk to providers? It is admirable in its goals but at this point limited in achievement.

If that is true, would you wager on it? Do you think it is a way to effectively affect the cost and outcome of health care? I do not see any evidence that it is going to have a big effect on the cost of health care. It might have some positive effects on the quality and there is some suggested evidence that there will be more attention to outcomes and to the measurement of different aspects of quality. It is a good thing if health care providers are more sensitive to those concerns. All of that is fine. It is excellent. But I do not see any evidence that it is actually going to control costs.

Why will it not control costs? The promoters of it say, create incentives, people respond to them, that it will work better than managed care because the providers are on the hook in a different way. Basically, I am concerned that the consolidation of the industry into effectively, local monopolies, is going to make it difficult over the long term to hold down costs. We have seen over the last 20 years the emergence of this hierarchy in local health care systems where the dominant providers are able to extract much higher prices and that issue of price is central to what has produced higher health care costs in the United States over time. Until there is some way to address prices, I do not think we are going to do very much about cost.

Your ideas about how to address price? I am increasingly becoming convinced that there will be no alternative to some kind of price regulation. I am sorry to say that. But do not see any alternative.

Is there any precedent for price regulation in this country? We have hospital rate-setting specifically in this industry in many states, and the evidence is that it essentially works pretty well. I think, inevitably, that has to come back as a discussion.

Do you see that maybe playing out in a sort of laboratories-of-democracy model rather than some sort of massive federal effort? We do have two states that still have hospital-rate setting.

Maryland and…? West Virginia. We will see whether there is some return. It could come in a different form because one of the problems with hospital-rate setting is that with the shift from inpatient to ambulatory care, the focus on hospitals was too limiting. So, if we have a return to some system of price regulation, it will have to be on a different basis.

Is that what bundled payments are about? Yes. I think the experiments in Medicare are going to be very important for thinking about some future means of price regulation.

Some people argue, as you know, that large systems are necessary to take advantage of things like electronic health records, care coordination. I do not buy that. In terms of medical practice, there is very little evidence for economies of scale for practices above 10 physicians. There is also very little evidence for economies of scale in hospital care at the size of the consolidations that we have seen. There just is not the empirical foundation for claiming that this scale is necessary to achieve high quality and efficient health care.

I do not want to pry into your personal life, but I wonder whether you have had a health care experience? Whether you have been sick or injured and your first-hand experience with the system, whether it changed your thinking or affirmed it? This is another long subject. I could go into it, but I think the experiments in Medicare are going to be very important for thinking about some future means of price regulation.

I first got interested in the subject because my father was a pediatrician and his office was in our house in the Midwood section of Brooklyn. So, I grew up in a medical world as a child. That is definitely the origin of my interest in the whole subject of health care.

Did people pay your father with chickens? I have heard that doctors used to accept all kinds of things as payment. I do not know about that. He died in 1965, the year Medicare was passed, but he was a pediatrician so it would not have affected him all that much. As a kid, I sat in the car sometimes when he was out making house calls. So it was definitely a different world back then. Xe
Medicaid expansion often means a hollow benefit, says Scott Gottlieb, MD, a resident fellow at the American Enterprise Institute and a leading conservative expert on health care policy. And the exchanges are in trouble with little political support. But Gottlieb says there will be some reluctance for sweeping reform because of a “fatigue factor,” so targeting the exchanges may be the best way forward for Republicans.

Interview by Peter Wehrwein

Traditionally health care has not been a strong suit for Republicans. Do you see that being different this year? I am not sure I would say it hasn’t been a strong suit for Republicans. In the past when people have evaluated the competing plans from different candidates, Republicans typically were at a disadvantage, insofar as a lot of the estimates that were made in terms of how many people would be insured by various plans always demonstrated or showed that the plans proposed by Democratic candidates would cover more people—in large measure because they relied on government programs to distribute benefits as opposed to relying on people to opt into receiving benefits. That, from a media standpoint, always disadvantaged Republicans and made it look like their plans were not as expansive.

I think that the reality is that what people now realize is that the plans proposed by Democrats don’t fulfill the expectations that were set out and don’t fulfill the estimates that were made at the outset after the experience with the Affordable Care Act. I think that the reality is going to be much different this year. I think people are going to put much less emphasis on those sort of binary estimates made by third party groups that, frankly, have lost a lot of credibility about how many people are going to be insured and what the savings is going to be and the impact on consumers. I think people are going to be more skeptical of those estimates and they are going to look into the details more carefully.

It is said over and over again by supporters of the ACA that whatever problems the law has, the number of Americans without insurance has gone down. Are you saying that characterization is wrong? The simple arithmetic is not wrong but the reality is that the only reason that more Americans are insured today versus before the Affordable Care Act is because of the Medicaid expansion. If you look at the number of individuals who actually are purchasing private coverage in the market, only a small fraction—I think about 4 million people—are actually newly insured. The rest of the people who are getting private coverage through the exchanges are people who previously had private coverage and

The transcript of this interview has been edited for length and clarity.
were transitioned into the exchanges, in many cases forcibly, because their plans were canceled.

If you look at the big expansion in coverage, most of it is Medicaid. I don’t really see it as a political victory or a victory on behalf of consumers to obligate a whole other large cohort of Americans to Medicaid, knowing that the Medicaid program is broken and failing a lot of patients. Medicaid, in many states, has become a hollow benefit where, sure, you have this basic promise of coverage and you have an expansive list of services that are purportedly covered, but when you go to actually use your Medicaid card or go to actually access care, you find you cannot find a provider and you cannot get access, especially to outpatient specialty care.

**Why do you think the exchanges have failed?** You have a very intrusive, gratuitous law implemented by folks who, I think, wrote regulations that were even more intrusive into the functioning of the markets.

**Are you talking here about the essential health benefits?** It is the essential health benefits. It is also the inability to offer plans outside a very narrow rating band. You don’t have any variety in terms of the types of plans that come up to be offered in the market. What happens is managed care companies try to design plans to back them into these narrow rating bands, rather than designing plans from the bottom up based on what they think the best benefit design is going to be for different consumers. If you do not have any competition in the market, you basically have a one-size-fits-all plan.

The other thing that I think was a big mistake was the caps on the medical-loss ratio. A lot of new plans enter the market and, initially, they are going to have higher costs. And so, they are going to need to spend a larger amount of their operating revenue on their overhead costs to enter the market. But if you tell a plan they can only spend 10% or 15% of all their revenue on operations, and they know that they are going to have to spend 20% or 30% for the first five or six years, or however long it takes to get started, that means they are going to have to sustain a loss for multiple years until they can get established in the market.

A lot of plans cannot do that. What you did not get was a lot of new start-up plans. You did not get a lot of investor capital coming in to start new plans. If you look at what happened under Part D or Medicare Advantage when those were first implemented, you literally got—I mean, in the case of Part D—you got thousands of new plans, many of which were started by investors. You also got a lot of investors pooling capital to start Medicare Advantage plans. You did not see that happening here.

Let’s pivot to the election and the Republican proposals. Paul Ryan has proposed a tax credit for individuals and families that would allow them to go into a market and buy health insurance. **Do you think that’s a good idea?** Well, we put out a plan at the American Enterprise Institute that I think mirrors a lot about the aspects of what Paul Ryan put out. I think if you look at a lot of the plans being put out by conservatives and Republican legislators, they all contain very similar elements.

The idea of providing some form of tax subsidy directly to consumers to go into the market and purchase a basic level of care is an element of all those plans, and I think that is a good idea. I think giving states the ability to auto-enroll individuals into plans that will only cost the amount of the subsidy is also a good idea. The plan that we talked about at the American Enterprise Institute gives states the discretion to do that if they want to. That is why, if you look at the scoring on our plan that we put out, it actually shows a higher number of people being insured than even under the Affordable Care Act, because it gives states the discretion to auto-enroll people in basic coverage.

Now, the complaint from the left is going to be that well, the level of tax subsidy that you are providing isn’t enough to pay for all of the benefits that are mandated as part of Obamacare—and that’s true. But the reality is that the Obamacare plans are not providing all the benefits that have been promised, much like Medicaid doesn’t, because the networks have become so narrow and the formularies have become so narrow that, yes, people are promised their essential health benefits but they are going to have a hard time accessing all of them.

I read a piece in which you critiqued one thing that Donald Trump has proposed—the importation of drugs as a way to deal with high prices. The importation of drugs was proposed at a much different time, when senior citizens did not have access to coverage and a lot of seniors were going to Canada, when the exchange rate between Canada and the U.S. was very different so price differences were sharper, and where the drug companies did not control the supply of drugs into Canada. It was easy to pull supply out of Canada into the U.S. All those things don’t exist anymore and...
so they all will diminish the margin gained, if you will, between the U.S. and the Canadian purchased drugs.

I don’t think any candidate or politician would do this outside of any kind of regulated scheme. The regulation itself would add so much cost to the imported drugs that it would just really extinguish any potential savings. So, I don’t think it’s a real viable way to address the underlying issue that I think could be addressed more directly.

More directly, I think you were talking about some scheme that would base drug prices on value. Correct? Well, it would allow drug prices to adjust more readily. We are talking essentially about Part D, also Part B, where drugs have one price in the market, regardless of how they are being used, or that drugs are priced based on volume rather than the indication for which they are being prescribed or the outcome they achieve. You cannot adjust a drug price because of all the regulation. What we propose is providing more flexibility and reforming some of these rules to allow companies to reprice drugs based, for example, on how it might be being prescribed.

You can argue, well, why would the company discount for one purpose and not discount for another if it wasn’t going to help them in the end? Maybe that’s true. Maybe the incentive of the drug companies would be to use selective discounting to try to maximize their profits. Obviously, that is their financial incentive.

But, if the mechanisms existed, it would allow the purchasers to put pressure on the drug companies to discount. I think that’s where you get vigorous competition, because some big purchaser could say look, I’ll use your drug for this indication. I will put it on my formulary but clearly it’s not providing as much benefit for this user than it is providing for that user. So, whenever it is used for this lower value indication, you are going to have to sell it to me at a different price—otherwise, I’m not putting it on my formulary at all. You will get that kind of negotiation if the laws allowed it. Right now they don’t allow it.

What we propose is a series of changes at both CMS and FDA, as well as the Office of the Inspector General, to allow more flexibility in that regard.

One thing that struck me is that under the ACA and the years of the Obama administration, large influential players and interest groups in health care have done very well as sectors: insurance companies, hospitals. I am just wondering—Ryan, your group—have come up with these market-based proposals, but say there is a Trump presidency and the Republicans hang on to majorities in the House and Senate. Which interest groups are going to sort of whack away at these proposals of yours? I am interested in you putting some of these ideas of market-based solutions through the filter of interest group politics. I disagree with you. I don’t think that the different constituencies in health care have made out particularly well under the Affordable Care Act, and patients have made out the worst, let’s be honest, and so have providers. I think that there are a lot of elements of the health care market that haven’t done well, and entrepreneurs certainly have not done well.

That said, there will be some reluctance, I think, of a lot of these constituencies to embrace a new plan, in large measure I think, because of the fatigue. They are going to say, look, we don’t like the Affordable Care Act, but it is a structure we have now accommodated our systems to and if you go and change it again on us it’s going to take another five years to rejigger the market and there is going to be dislocation.

The fatigue factor is going to be a bigger issue than the who-wins-and-who-loses factor this time around.

I will accept your analysis that there is going to be fatigue rather than winners or losers. Who is most fatigued and therefore the most likely resist change? It depends on how big your proposal is. If you try to do what has been proposed by AEI or Paul Ryan, where you address all the different elements of health care, you address Medicaid and Medicare as well as the exchange based sort of private market, there is going to be probably more pushback to that, versus if you just try to address exchanges. I think there is a recognition that the exchange element is not working.

At the same time, I think a lot of consumers, even those who are on Obamacare who are getting coverage through the exchanges, are not happy with it. It is expensive. The networks are narrow. The formularies are restrictive. It is not a good product. I think that if you targeted your reform or your replacement to just address what Obamacare tried to do under the exchanges, it will be easier to get through it. There is really no constituency in my view, other than a political constituency that is wildly supportive of the status quo as it was created by the Affordable Care Act.

Do you see the consolidation of providers and insurers as a trend separate and apart from the ACA that has to do with managing health in a different way or is a product of the ACA? I think the consolidation is a product of the payment reforms that were embedded in the Affordable Care Act, but those payment reforms have been done on a bipartisan basis and they have been recodified. So, a lot of the elements of the Affordable Care Act that dealt with how we were going to change payment to providers were recodified under MACRA. So, this has been done on a bipartisan basis. There is a sort of urge to push risk onto providers and
to find ways to capitate providers to either bundled payment arrangements or ACOs.

I think bundled payment arrangements are going to be the ultimate arrangement that prevails. But, in order to transfer risk to providers, you need to get providers practicing in large enough units that they are capable of taking that risk. So, you want to force providers to consolidate. So, you create financial inducements for providers to consolidate. That is exactly what is happening.

The reality is that the most likely vehicle for provider consolidation is the hospitals, because there is no private capital coming into the market to do this. So, you are seeing providers consolidate around hospitals. You are seeing the creation of these large health systems where they sort of monopolize the provision of care within local markets. I think this is an extreme problem. I think it is going to drive up costs in the future.

You are extinguishing local market competition between providers. It is going to make it harder to refashion a market-based alternative to Obamacare once you have basically regional monopolies over the provision of care. I think that this is the single biggest troubling secular change as a result of the Affordable Care Act, is the consolidation of providers. It is going to be very hard to unwind this. It has been done on a bipartisan basis. As much as some probably might like to blame Obamacare for the consolidation, I think MACRA is as much of a culprit behind this as the Affordable Care Act.

Capitation and consumer-directed health care—if both of those are cost containment vehicles—do you see them as in conflict or compatible or what? I think you can have both existing in the market. You can have providers taking capitated risk in certain instances and being the sort of nexus of the cost consideration, because they are capitated and they are on the hook for the actuarial risk of the provision of care, and you can have consumers exposed to some of the costs of their choices so that they are taking costs into consideration. You could have both exist within the same construct and frankly, that would be preferable because that would be a more diverse and competitive market.

I think that at a political level, the idea of consumer-directed health care is so antithetical to progressives that they did everything they could to dismantle those constructs and move the market toward capitated arrangements, where now providers were going to be the ones taking the consideration. To me, that is the worst possible outcome. I think it is more preferable to have the government do it, because at least if the government does it, you see what the government is doing.

If the government imposes a law saying you cannot get access to treatment X, everyone is going to know it, and they have the right to vote out the government. But when the doctor is the one considering costs, it is much more furtive. It is not as transparent to the patient what kinds of considerations might be being made by the provider or the hospital system. I am not saying providers are sinister. I am just saying that they are not going to sit at every point and explain why they made certain decisions based on certain considerations of costs because they are on the hook for the actuarial cost of the decision that they are making.

That is pretty amazing what you are saying—that there is something cloudy and nontransparent about this thing that everybody loves, which is alignment between delivery and cost. Well, the alignment is one perceived outcome of capitation. The perception is if you transfer risk to providers, they have got to magically align and they are going to introduce all these innovations on how they are delivering care to better coordinate care. That does not necessarily happen. I mean, if you look at a lot of innovation in health care services and where it has come from, it has not come out of large integrated delivery systems. It has come out of entrepreneurial vehicles that pioneered new concepts that were eventually taken up by large integrated delivery systems.

The Mayo Clinic is not the answer for us? The Mayo Clinic is the answer for their market and there are a lot of markets that function very differently. That is the problem with living in a large diverse country and trying to create a one-size solution from Washington. If you listen to the president’s speeches on Obamacare, I don’t think there was a single speech in advance of its passage that didn't reference Kaiser, the Mayo Clinic, Intermountain Health, Geisinger, one of those systems. That was the model for the Affordable Care Act.

You are not going to go into every market and recreate a Geisinger or a Mayo Clinic. And, you know what, there are challenges with Geisinger and Mayo Clinic as well. We have not had a full telling of the story of those entities either. They have their own challenges. But they also have unique attributes. They have unique management. They have unique markets. You are not going to be able to replicate that everywhere.

Managing Editor Frank Diamond assisted with the interview.
A number of years ago, a friend, also a physician, experienced chest pain. His symptoms were serious enough that a reputable cardiologist at a nationally recognized facility performed an invasive coronary angiogram. Afterward he was rushed to the cardiac surgery suite, but not to get a revascularization procedure. Instead, the surgeons worked to repair damage to the heart from the catheterization procedure.

For decades, invasive coronary angiograms have been the gold standard for determining whether a patient has blockage in the coronary arteries and the extent of the blockage. Angiograms involve inserting a long flexible catheter into the bloodstream, usually by way of the femoral artery in the thigh, to deliver contrast agent so the arteries can be seen on an X-ray. Coronary arteries are quite small and moving because the heart is beating, so getting a clear image is technically quite difficult. Still, about 1 million patients have invasive coronary angiography in the United States each year.

The diagnostic angiogram is a fork in the road. It allows the cardiologist to determine if a patient has nonobstructive coronary artery disease (no visible blockages present) or obstructive disease. The former typically leads to medical therapy while the latter may lead to angioplasty and stents or to a coronary bypass graft.

If you perform a Google search on recognized complications of coronary angiography, you will see issues such as renal damage, tears in the heart, stroke, injury to the arteries being visualized, heart attack—the list goes on and on. The risk of serious complications is small (between 1% and 2% of patients), but they do occur.

So patients who present with chest pain present a dilemma to cardiologists. Missing obstructive coronary artery disease could result in myocardial infarction—or worse. Finding and successfully treating obstructive disease does prevent serious heart problems and saves lives, yet an all-comers approach exposes many people to unnecessary risks. It’s also expensive.

**How severe is it?**

When dealing with patients with chest pain, physicians usually start by taking a detailed history concerning the nature of the pain. How severe is it? Does it come on with exercise? Is it shooting or dull? Where does it hurt exactly? Information about family history and risk factors, such as smoking, will be gathered. A physical exam is part of the workup. All of this helps physicians decide whether the patient presenting with chest pain should be categorized as having unstable chest pain, which should lead to an immediate hospitalization, or stable chest pain, which is less critical and buys some time so tests can be performed outside the hospital.

Guidelines for the evaluation of stable chest pain recommend progressive noninvasive testing, such as ECGs, a variety of different stress tests, and CT angiography that involves using a CT scanner to get an image of the coronary arteries. Results of noninvasive tests can be used to stratify patients by risk and to identify those who may need invasive coronary angiography.

The hope had been that the gantlet of noninvasive tests would winnow down the number of invasive tests. But several years ago, Manesh Patel, MD, and colleagues reported the results of a huge study (663 hospitals, nearly 400,000 patients) in the *New England Journal of Medicine*.
that suggested that noninvasive tests didn’t do a good job of identifying patients for whom an invasive test was warranted. Of patients undergoing an invasive test, only about one in three turned out to have obstructive coronary artery disease. In a follow-up study published two years ago in the American Heart Journal, Patel and colleagues reported that only 9% of patients referred for noninvasive tests, like an exercise ECG, had high-risk coronary artery disease. Noninvasive test findings have little value beyond clinical factors for predicting obstructive coronary artery disease, they concluded.

So there’s a need for noninvasive tests that will do a better job of identifying serious blockages in the coronary arteries.

**Fractional flow reserve**

A California company says it has developed just such a test. HeartFlow recently launched the second generation of its HeartFlow FFRCT Analysis. This technology is based on 15 years of scientific research conducted by Charles Taylor and Christopher Zarins at Stanford University. FFR in FFRCT stands for fractional flow reserve, and the CT refers to the fact that it is derived from a CT scan. The fractional flow reserve traditionally has been done during the invasive angiogram. It’s a measurement of the functional consequences of a partial obstruction—basically the impact the blockage has on the blood flow to the heart. If a partially blocked coronary artery is not functionally impairing the heart’s need for oxygen, it can be safely treated with medication and lifestyle modification.

HeartFlow uses advanced algorithms and pure science to balance the risks and benefits of the various coronary tests. By using the enormous amount of data that can be obtained from a CT angiogram, certified analysts, and a well-honed proprietary algorithm containing millions of mathematical calculations based on the physics of fluid dynamics, an accurate and clinically relevant HeartFlow’s FFRCT can be calculated.

Long-term results from HeartFlow’s fourth clinical trial, PLATFORM, were presented at the American College of Cardiology annual meeting in April. PLATFORM was a European, multicenter, controlled, prospective, pragmatic, comparative effectiveness trial utilizing a consecutive cohort design. It compared standard diagnostic strategies to a FFRCT-guided strategy in 584 patients with stable chest pain.

The study compared usual care to a testing strategy using CT angiography and FFRCT when needed in 584 patients with stable chest pain. If a CT scan shows the coronary arteries to be free of blockages, then all the calculations of the FFRCT aren’t needed. Patients were divided into one of two groups: those with a planned invasive angiogram and those with a planned noninvasive test. Patients in each group were then divided between those who followed the usual diagnostic path and those whose diagnosis was guided by the FFRCT test.

The headline was that the use of an FFRCT resulted in the cancellation of a planned invasive angiogram in over 60% of patients. What’s more, during a year of follow-up, only four of the patients whose planned invasive angiograms were canceled wound up needing the procedure, and none of the 117 patients whose invasive angiograms were canceled suffered an adverse event. The study showed that it was safe to follow a diagnostic strategy guided by FFRCT results. FFRCT also provides information that will help doctors distinguish between coronary lesions that require revascularization and those that don’t.

**Meaning for managed care**

One of the beauties of HeartFlow’s FFRCT is that no additional equipment is needed at the thousands of hospitals in the United States that already perform CT angiography. In the past, medical interventions came in two basic flavors, medications or devices. FFRCT adds a third: software. It solves millions of complex equations that simulate blood flow in the coronary arteries and provide mathematically computed fractional flow reserve values. FFRCT marries imaging technology and big data.

Based on PLATFORM data, Pamela Douglas, a researcher at Duke, calculated that an FFRCT strategy saves roughly $4,000, not accounting for the cost of the FFRCT test, which is priced at about $1,500. PLATFORM was conducted in Europe, so U.S. savings will likely be greater.

New technology tends to add to our already staggeringly high health care costs. But if these numbers hold up in the real world (a big if, given everything that can happen) then HeartFlow’s software could be ringing in a new era of software advances that make for smarter and less expensive diagnosis and treatment.
Value-based purchasing in health care has reached the point of no return, no matter who wins the White House or if the ACA were to get scrapped. The health care reform law has enabled or inspired so many changes in the infrastructure of American health care—ACOs and integrated delivery systems, federal and commercial quality-incentive programs, and CMS’s alternative payment models—that it’s hard to imagine that we’ll go back to a time when dollars and outcomes traveled in different orbits.

The pharmaceutical industry may be the next frontier. As specialty drug costs began to challenge payer budgets and providers took on risk, demand for evidence of pharmacoeconomic value was inevitable. But even when manufacturers conduct health economics research, they frequently hesitate to promote it because of legal ambiguities about what they can say and to whom.

During President Clinton’s second term, Congress passed the Food and Drug Administration Modernization Act (FDAMA). The act’s much-talked-about Section 114 gave the pharmaceutical industry a safe harbor from the threat of penalties for off-label promotion when sharing economic information with decision makers. But the FDA issued no guidance on how to interpret the law, neutering it from the outset. A year after the law was passed, Nancy Cahill, a prominent health care attorney, told a International Society for Pharmacoeconomics and Outcomes Research briefing that “the totally positive spin being put on the new legislation is alarming” and warned pharma to educate the FDA about health economics research or risk facing “regulations that run 180 degrees counter” to the intent of Section 114.

In fact, the FDA never issued regulations to clarify the boundaries of promotion of pharmacoeconomic data. In turn, pharma companies, fearful of being penalized for off-label promotion, have erred on the side of caution, hesitating to take advantage of Section 114. “From our perspective, the issue is being able to have access to health care economic information that in some cases companies have but aren’t free to give to managed care pharmacy professionals,” says Susan Cantrell, CEO of the Academy of Managed Care Pharmacy (AMCP).

Why no guidance has been issued after almost 20 years is a matter of speculation, says Peter Neumann, director of the Center for the Evaluation of Value and Risk in Health at Tufts Medical Center in Boston. The FDA could have more pressing priorities, he says, or may recognize the difficulty of drawing fine lines. “It’s hard, and in a way you could argue that the FDA shouldn’t even worry about it, as long as these are companies talking with formulary committees. ‘Let them figure it out’—which is kind of what FDA has said in not saying anything.”

Or, he says, the agency’s inaction could stem from “a feeling in certain places that we shouldn’t allow drug companies to promote health economic information outside the clinical trials because they will mislead customers, including managed care. You’ll take away the incentives to do the trials they should be doing if they can promote based only on database studies and models.”

Another reason for the FDA’s silence may relate to the AMCP’s release of its Format for Formulary Submissions in 2000. Manufacturers often include pharmacoeconomic data or modeling in an AMCP dossier. When a health plan makes an unsolicited request for an AMCP-style dossier, the prevailing opinion is that pharma needn’t worry about running afoul of the law; Section 114 refers only to direct promotion of pharmacoeconomic information. Payers often
question the validity of pharma-generated economic data in the dossiers, but their inclusion has, at least, eased some of the angst over lack of clarity on Section 114 and given pharma an opening for making an economic case for their products to formulary committees, even if on a limited basis.

In recent years, however, with payers scrutinizing the value of high-cost specialty drugs and with provider groups taking on financial risk tied to outcomes, there is renewed interest in clarifying Section 114.

Four troublesome phrases
At an AMCP-sponsored forum last March, pharmaceutical companies, managed care organizations, academics, providers, and patient advocates developed recommendations for clarifying Section 114. AMCP touts the recommendations, published in July in the <i>Journal of Managed Care & Specialty Pharmacy</i>, as representing informed consensus for the development of FDA guidance.

Are pharma’s fears justified?

The degree to which pharmaceutical companies invoke Section 114 of the Food and Drug Administration Modernization Act (FDAMA) when promoting product-related economic information is unclear, but the use of Section 114 is estimated to be low. Vague rules are thought to be the main reason, leaving manufacturers fearful of hidden tripwires when promoting a drug’s potential for, say, cost savings or reduced resource utilization.

Research by Peter Neumann, director of the Center for the Evaluation of Value and Risk in Health at Tufts Medical Center, may offer some insight into pharma’s tepid reception to Section 114. In a 2012 study published in the journal <i>Value in Health</i>, Neumann found that between 2002 and 2011, the FDA’s Division of Drug Marketing, Advertising, and Communications (since renamed the Office of Prescription Drug Promotions) issued 291 warning letters for misleading promotions—12% of which contained what the division considered to be inappropriate economic claims. More than half of these violations related to claims of cost savings stemming from improved functioning or work productivity.

Interestingly, however, none of those letters mentioned a violation of Section 114, “nor have there been any, to my knowledge, since then,” Neumann tells <i>MANAGED CARE</i>. “That tells you something about the difficulty in interpreting Section 114 and the FDA’s reluctance to write [warning] letters about this.”

Four clauses in Section 114 give drugmakers pause. In summary, Section 114 says (ambiguous phrases italicized) that FDA will not consider health care economic information that is provided to a formulary committee or other similar entity to be misleading if it directly relates to an indication and is based on competent and reliable science. At just 217 words, Section 114 is too lean to parse out the meaning of these four phrases, carving a wide path for interpretation.

Start with the difficulty of determining what health care economic information actually is. For instance, what if an insulin maker calculates and promotes lower downstream costs from avoidance of renal disease, based on known adherence rates for its product? That information won’t be in the drug’s labeling. But is it “health care economic information” under Section 114—thus protecting the company from fines for off-label promotion? “There’s a lot of nuance to health economic information,” says Neumann. “All health economic information contains clinical assumptions, and you’re potentially letting drug companies make clinical claims about their products through economic analysis.”

In the end, the AMCP group defined health care economic information as “any analysis that identifies, measures, or compares the economic, clinical, or quality of life consequences for any treatment.”

As for who can receive health care economic information, the group proposed broadening the definition of “formulary committee or other similar entity” to include payer-like organizations that didn’t exist when Section 114 became law, along with their employees “who make health care decisions for patient populations,” such as clinical executives in a risk-bearing ACO. The group also included “organizations that develop value frameworks,” such as the American Society of Clinical Oncology and the Institute for Clinical and Economic Review.

The definition also includes organizations that develop compendia, such as Truven Health Analytics’ MicroMedex DrugDEX and the National Comprehensive Cancer Network’s Drugs and Biologics Compendium. “One of the issues with the compendia is: Where are they getting their information and what kind of information are they getting?” says Mary Jo Carden, AMCP’s vice president for government...
and pharmacy affairs. Including compendia among entities eligible for receipt of health care economic information, she says, would improve the transparency and robustness of compendia information. The compendia form a key basis for Medicare payment—especially in the murky area of oncology, where compendia listings support determinations of medically accepted off-label use of cancer therapies.

All of this assumes the information meets Section 114’s standard for “competent and reliable science,” but what is that exactly? Section 114 does not provide standards. “In a way, that’s the big one,” says Neumann. “It’s not always easy to figure out if something is competent and reliable, but we kind of know what it means: A study should be clear in their methods and transparent. They should do statistical controls in certain ways, they should do sensitivity analysis, they should control for bias as best they can. That’s a competent and reliable study.”

The AMCP group decided that competent and reliable should mean “truthful and non-misleading,” but did not designate a body that would develop standards or serve as referee.

One option, Carden suggests, is to use the principles of the CER Collaborative tool, a joint venture of AMCP, the International Society for Pharmacoeconomics and Outcomes Research, and the National Pharmaceutical Council, as a rubric for judging the credibility of pharma-generated health care economic information.

Section 114’s term “directly related to an indication,” says Neumann, has always caused a lot of debate. “It seems to imply you can’t make off-label claims in an economic analysis, but it leaves open the question of extrapolations across time and populations. Those lines can be fuzzy.” The AMCP group viewed “directly related to an indication” to mean “information about a product that may vary from the parameters utilized in a randomized control trial, such as dosage forms, settings, or populations studied,” as long as the information relates to the approved indication. That could, for instance, give pharma leeway to model savings to the health care system beyond the length of the clinical trial or for subpopulations, to name two examples. The AMCP group’s final recommendation for FDA guidance called for changing “directly related to an indication” to “related to an indication.” That could work for products on the market, but what about products in the pipeline? Cantrell says payers at the AMCP forum made it loud and clear that waiting for product approval is too late to allow for actuarial adjustments. Carden recalls what happened when the new hepatitis C drugs hit the market: Plans were legally constrained from adjusting premiums or formulary tier cost sharing during the plan year, resulting in pharmacy costs running out of whack, and it was too late to file rate changes for the following year. “Had there been more ability to share information 12 to 18 months prior to approval, that planning could have occurred,” she says. A future AMCP gathering will explore solutions to this issue in depth.

Walking the talk

Two years ago, the FDA published a notice that it would, at last, issue a clarification of Section 114. But the world is still waiting. Now, AMCP is moving to force the issue.

“We’ve been speaking to individuals who can help with this on Capitol Hill. We also are hoping to meet with FDA soon to share our recommendations and our members’ perspectives on the issues, as well as the findings that came out of the forum,” says Cantrell.

And AMCP is backing its talk with action, she adds: “We are working on language that could form the basis of guidance on FDAMA 114.”

Congress has kicked the tires of Section 114 reform, inserting clarifying language in the 21st Century Cures Act. But with the bill stuck in an election-year meat grinder in the Senate, the next opportunity for legislative action may come next September, when Congress must reauthorize the Prescription Drug User Fee Act.

“We think there will be something on communication in that package,” says Carden. “What specifically it is obviously will depend on what Congress does, but we think that the clarification of FDAMA Section 114, at a minimum, might be included in there.”

Feedback Please!

Any thoughts about this article? Is there a pertinent angle that we haven’t touched upon? Let us know. Send responses to Managing Editor Frank Diamond at fdiamond@medimedia.com.
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