



ML Strategies Update

Alexander Hecht, AHecht@mlstrategies.com
Eli Greenspan, EGreenspan@mlstrategies.com
Erin Morton, EMorton@mlstrategies.com

FOLLOW US ON TWITTER: [@MLStrategies](https://twitter.com/MLStrategies)

ML Strategies, LLC
701 Pennsylvania Avenue, N.W.
Washington, DC 20004 USA
202 434 7300
202 434 7400 fax
www.mlstrategies.com

FEBRUARY 8, 2016

Health Care Update

Martin Shkreli Not the Big Story on the Hill Last Week

Congress's complex relationship with prescription drugs was on display last week in the House of Representatives. In the House Committee on Oversight and Government Reform (OGR), Martin Shkreli pleaded the 5th at a [hearing investigating drug pricing](#). Meanwhile, the Energy and Commerce Committee (E&C) held a [hearing regarding implementation of biosimilars](#). While all the attention will be on the former, the latter was more important, especially for participants in the biosimilar space.

First, the OGR Committee was a media show built around the flamboyant Shkreli. [Shkreli took the 5th](#) when given the opportunity to testify and later tweeted – after being excused from the hearing for refusing to answer any of the Members questions – that the Committee Members were ‘imbeciles’. The tone of the hearing was very aggressive towards drug pricing and what were described as unsavory business practices. Members were also critical of the FDA generic drug programs. However, Member interest in strengthening the program to bring competition to the marketplace was clear. Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research at the FDA, stated that funds collected as a result of the Generic Drug User Fee Amendments (GDUFA) helped expedite the review process and that by October there will be a 10-month review process on all new applications. The Senate HELP Committee held a hearing last week on reauthorization of GDUFA, which will expire next year, and this bipartisan interest, coupled with the prescription drug cost crisis, could lead to increased resources for the FDA review process. Beyond some public shaming of specific drug companies, there was little suggestion of substantive action on drug pricing.

Second, the E&C Committee was less about drug pricing, but more so about the ability of manufacturers to get new biosimilar products to the market. Notably, Committee Members on BOTH sides of the aisle were critical of CMS for trying to price biosimilars more like generic drugs and categorize different products under a single billing code. They said the CMS ruling undermines the intent of the Biologics Price Competition and Innovation Act of 2010 (BPCIA) by removing incentives for a robust marketplace. Biologics make up a \$200 billion market, so the consequences of policy decisions are significant.

While 2016 may be devoted to campaigning against drug prices, the Committees responsible for the regulatory regimes for drugs are still very focused on preserving the ability of manufacturers to successfully bring drugs to the market. That is a much bigger deal than the plethora of Martin Shkreli smirks you will be subjected to in the media.

ML Strategies will continue following Congressional efforts to address drug pricing and how policy considerations impact the market. For more coverage on this issue, please visit the Mintz Levin [Health Law & Policy Blog](#).

All Things ACA

Third Open-Enrollment Draws to a Close: Open Enrollment for 2016 is over and about four million new people are enrolled in coverage through the federal marketplaces. According to HHS, 7 of 10 consumers who returned to the marketplaces actively shopped for a new plan, an increase of about 20 percent from last year. Still, overall public feelings of the law haven't changed and the lingering issues surrounding the law continue to persist. Seeing as Congressional budget analysts projected nearly double enrollment this year, expect some commentary that the ACA has plateaued.

Insurers Still Adapting to New Environment: The Affordable Care Act set in motion a series of chain reactions in how health care is delivered. All actors in the industry have made behavioral changes and were still seeing the fallout from those decisions. Aetna and UnitedHealth Group, two of the big five insurance carriers, have since ditched AHIP to manage their own interests. How this will impact AHIP remains to be seen – but one thing is clear, insurers are increasingly looking at new ways to meet their bottom line.

Hospitals Benefiting from Medicaid Expansion in Indiana: Only in its second year of Medicaid expansion, hospitals are already seeing benefits from expanded coverage for low-income individuals. A hospital in [Indiana](#) has seen the number of unpaid bills they can't collect drop by 40 percent, and another said the number of uninsured patients has dropped from 35 to 25 percent.

More Providers Accepting Medicaid Than Previously Thought: A new study by MACPAC found that more providers are accepting Medicaid patients, despite prior analysis suggesting the opposite. While many of the providers surveyed handle less than five patients, it's worth noting as a handful of states consider Medicaid expansion.

Ways and Means Health Subcommittee to Draft ACA Replacement: Ways and Means Health Subcommittee Chairman Pat Tiberi (R-OH) indicated that one of his top priorities would be getting an ACA replacement in front of party leadership before the party's convention this summer. Any proposal would need to have significant buy-in from Members in an election year.

President Obama Considers Cadillac Tax Tweak: President Obama's FY2017 budget request will outline a tweak to the 40 percent excise tax, which Congress successfully delayed until 2020, accounting for regional differences in health care costs. This tax was intended to help fund the law so this tweak should receive consideration; however, there are more people who want to eliminate the tax now that it is delayed than actually fix it – dimming its prospects of ever being enacted.

News from the Hill

President's Budget Includes \$755M Request for Cancer Moonshot: President Obama's FY 2017 budget request will include \$755 million for his recently announced cancer moonshot, to be led by Vice President Joe Biden. Ample resources are critical to getting this initiative off the ground and getting buy-in from the nation's leading cancer researchers. NIH is set to benefit the most from federal investment, but the Department of Defense, the Department of Veterans Affairs, and the FDA will all receive federal investments as well with the goal being to make a decade's worth of progress in five years.

President's Budget Requests \$1.8B for Fight against Zika Virus: President Obama's budget request will also include a \$1.8B request for funds to be used against the Zika virus, which is ravaging communities throughout Brazil. The funds would be used for mosquito control programs, vaccine research, and health services for low-income women.

CDC Issues Zika Guidance: Last week, the CDC issued [guidelines](#) regarding prevention of sexually transmission of the Zika virus. There's no telling the toll this may have on the United States as we inch closer to warmer weather, but with a case already confirmed in Texas, federal agencies are trying to avoid being caught flat footed.

HELP Committee to Consider Oversight Measures for Medical Identity Theft: Following a response to an inquiry regarding medical identity theft, Chairman Lamar Alexander (R-TN) indicated that the committee will consider oversight measures necessary to ensure the Administration has the tools it needs to support the more than 100 million Americans who were victims of health industry breaches last year.

E&C Dems Introduce Mental Health Legislation: Democrats on the House Committee on Energy & Commerce introduced legislation last week to counter the mental health reform bill introduced by Rep. Tim Murphy (PA-18). This is the result of stalled negotiations over the Murphy legislation, which Democrats contend would dismantle SAMHSA. This legislation brings the views of Democrats to the table in a way that could advance the conversation if negotiations continue. Text of the legislation can be found [here](#).

Chronic Care Legislation Coming in March?: Senator Johnny Isakson (R-GA) is eyeing a March release date of the chronic care legislative package that is being worked on through the Senate Committee on Finance. How CBO scores the bill will give

us a better sense of whether this package will move forward and how quickly. Of note, Chairman Orrin Hatch (R-UT) said that this measure should be budget neutral.

Prescription Drug Costs

Turing, Valeant Bare Brunt of Oversight Hearing: Last week, the House Committee on Oversight & Government Reform reprimanded two of the pharmaceutical industry's bad actors for its business practices surrounding several high-profile prescription drugs. A recent [investigation](#) into both companies found that business decisions to hike the cost of a number of drugs were motivated purely by profit.

Campaign Politics Distorting Broader Drug Pricing Issue: In Washington, and on the campaign trail, members have made addressing prescription drug costs a top priority. While this is an easy campaign strategy, ensuring this effort does not stifle medical innovation has taken a back seat to doing something – anything – about prescription drug costs.

Opioid Crisis Coverage

President Obama Requests \$1.1 Billion to Combat Opioid Crisis: With increased bipartisan interest, and a number of states compelled to act by the devastating effects of prescription painkillers and heroin, President Obama is requesting \$1.1 billion to address the nation's opioid crisis. Within that, \$90 million will be directed towards increasing the use of naloxone, and programs at the Department of Justice and HHS designed to prevent drug overdoses. The White House also intends to issue guidance designed to rein in overprescribing of painkillers by primary care doctors.

Collaboration Is Key for Congress and White House: With Congress and the White House actively exploring ways to address this issue, ensuring that one's effort supports the other is critical. In addition, stakeholder input will be necessary to ensure that people in need do not lose access to care as Washington takes aim on this issue.

Opioid Issue Holding Up Califf Nomination: FDA commissioner nominee Robert Califf has still yet to have a confirmation vote scheduled, meaning the holds placed on his nomination will likely continue. Senator Joe Manchin (D-WV) and Senator Ed Markey (D-MA) object to the FDA's decision regarding opioid prescribing for children. Senator Manchin has feuded with the FDA's approval of new painkillers that lack abuse deterrent properties, and he is encouraging other Members to back his hold. Senator Bernie Sanders' (I-VT) hold is over Califf's ties to the industry and how it could impact efforts to achieve lower drug costs. With this issue on center stage in Washington and on the campaign trail, it's possible some form of action could occur by way of compromise. What that is – and what its impact will be – remains to be seen.

Telemedicine

Senators Introduce Telemedicine Legislation: Last week, a bipartisan group of Senators led by Senator Brian Schatz (D-HI) and Senator Roger Wicker (R-MS) have unveiled legislation that would expand the use of telemedicine and remote patient monitoring under Medicare. The [CONNECT for Health Act](#) (S.2484) is not seeking to overhaul telemedicine statutes overnight. Rather, it's creating an opening for providers to incorporate telemedicine into their practices in a way that enables the federal government to further study and evaluate its application in health care delivery.

Two interesting quick initial observations about the measure. First, this bipartisan measure has attracted a host of stakeholder support from across the spectrum – including from groups like the American Telemedicine Association and American Medical Association, which haven't exactly seen eye-to-eye on previous efforts to address telemedicine-related issues. Second observation is the "score" of the bill – or how much it would potentially cost to enact. According to the bill's proponents, an analysis by Avalere of the bill's major provisions (mentioned above) show \$1.8 billion in savings over 10 years. If true, that's a significant development. For years, telemedicine advocates have heaped praise on the potential cost savings associated with telemedicine through increasing access to care, whether it be through video conferencing or remote patient monitoring services.

For our complete coverage of this legislation and other telemedicine related matters, please visit the Mintz Levin [Health Law & Policy Blog](#).

Text Messaging Meds to Take Drugs Works, Study Finds: A [study](#), published in JAMA Internal Medicine, found that text message reminders to patients to take their medications had an impact. In fact, patients in the study went from having a 50 percent rate of keeping up with their regimen to a 68 percent rate. The authors of the study caution that more research is needed on this issue, but with telemedicine discussions in full swing, this type of care warrants consideration given its potential cost savings.

Hearings

House of Representatives

On Wednesday, February 10th, the House Energy & Commerce Subcommittee on Health will hold a hearing titled, “Examining Medicaid and CHIP’s Federal Medical Assistance Percentage.”

On Wednesday, February 10th, the House Committee on Ways and Means will hold a hearing on the Department of Health and Human Services’ Fiscal Year 2017 Budget Request.

U.S. Senate

On Tuesday, February 9th, the Senate Committee on Health, Education, Labor, and Pensions will hold an executive session, the first round of mark-ups for the Senate Innovations bill (21st Century Cures).

On Thursday, February 11th, the Senate Committee on Finance will hold a hearing on the Department of Health and Human Services’ Fiscal Year 2017 Budget Request.

The Last Word

Can Piecemeal Strategy Advance Senate Innovations Package?: The Senate Committee on Health, Education, Labor, and Pensions (HELP) held an executive session today, the first of at least three rounds in reviewing legislation that would have made up the Senate version of the House-passed 21st Century Cures Act. For months, staffers from both parties have worked through differences with the hope of getting one legislative package introduced by the end of 2015. That did not happen, in part because of Democratic insistence on increased funding for the National Institutes of Health (NIH), among other issues. Chairman Alexander did indicate he is open to proposals to include increase mandatory funding for NIH, as long as that funding is found by reducing mandatory funding elsewhere.

Democrats were reportedly upset by the move to split the bill up, but how that changes the dynamic of this process will likely come into view at the first round of mark-ups. Seeing as whatever comes out of the Senate would have to be reconciled with the House-passed 21st Century Cures Act, timing is important. At the end of the day, can Democrats live with a process that does not have funding for NIH?

Stay tuned for ML Strategies’ coverage of the mark-up on the Mintz Levin [Health Law & Policy](#) blog.