Mark Masselli: This is Conversation on Healthcare, I am Mark Masselli.

Margaret Flinter: And I am Margaret Flinter.

Mark Masselli: Well, Margaret the tune has started to change, coming from the congressional leadership and the president about the quest to rapidly re-appeal the Affordable Care Act and the operative word now seems to be repair.

Margaret Flinter: And it's been very interesting to see some of the health industries medical societies weighing in as Republicans work to now replace the legislation, they are hearing from the number of health industry groups are asking, no leave certain aspects of the law intact.

Mark Masselli: The American Congress of Obstetrician and Gynecologist ardently opposed to the ACA in 2010. Now they are urging Congress to keep intact certain measures of the law such as the rule that women can't be charged higher premiums due to their gender, they know the law has had some positive impact on women's health.

Margaret Flinter: Top representatives from a number of these organizations have been meeting with the GOP leadership to ensure that certain aspects of the law do remain intact. And I think we will hear more language like this in the coming months as this new reality sinks in for the leadership in Congress as well as for the President. I guess we can say, market forces do come to bare on these issues.

Mark Masselli: Absolutely and the President has started to sound a similar tune as well, he may not have a replacement sorted out until earlier 2018, with the pharmaceutical industry looking at some significant changes we decided to invite an expert on matters of drug safety and how the FDA works.

Margaret Flinter: Allan Coukell is the Senior Director for Health Programs at the Pew Charitable Trust where he oversees a variety of health topics including FDA, drug and medical device safety, the pharmaceutical supply chain. He is bringing us a depth of understanding on how the FDA works and how it might be recalibrated to accelerate the drug approval process, so we look forward to that conversation.

Mark Masselli: Lori Robertson, also checks in, the Managing Editor of FactCheck.org is always looking to shine a light on misstatements spoken about health policy in the public domain. But no matter what the topic, you can hear all of our shows by going to www.chcradio.com.

Margaret Flinter: And as always if you have comments, please email us at www.chcradio@chc1.com or find us on Facebook or Twitter because we would

love to hear from you. Now we will get to our interview with Allan Coukell in just a moment.

Mark Masselli: But first, here is our producer Marianne O'Hare with this week's Headline News.

Marianne O'Hare: I am Marianne O'Hare with these Healthcare Headlines. Tom Price has been approved to secretary of health and human services, the party-line vote, going through in a late night session in the Senate. The conservative orthopedic surgeon from Georgia, has long been making a case for the appeal of the Affordable Care Act, even though President Trump has recently said, he may not have a replacement plan in place until early next year. Senator Lamar Alexander, Chairman of the HELP Committee which governs health policy is urging more support in Congress for the repair approach which he says, will be far less disruptive to the healthcare market place.

Meanwhile at a recent meeting of the Conservative Heritage Foundation, a cadre of Republicans vowed to move ahead with their plans for a swift repeal, planning to eliminate certain taxes that help pay for the law, by passing budget reconciliation measures that don't require a 60-vote majority in the Senate. Still there is a high degree of confusion and concern within the healthcare industry as CEOs and budget planners catch their eyes towards an uncertain future under President Trump and an HHS secretary who are so vocally committed to repealing the healthcare law.

The numbers are in, in spite of tremendous downward political pressure from the incoming presidential administration. 12.2 million Americans manage to sign-up for health coverage on the insurance marketplace exchanges. This in spite of spike in premiums for some markets around the country this year and fewer insurers to choose from. Still those spikes are offset by commensurate tax subsidies under the Affordable Care Act.

An estimated 91 Americans per day are dying from opioid overdoses while the nation's Public Health officials try to get a hand on this deadly crisis, the company that makes the version of the overdose antidote naloxone, is being accused of price gouging, price for the drug was hiked 550% in recent months. Missouri Senator Claire McCaskill demanding answers from Kaleo Pharmaceuticals which makes and markets the drug. I am Marianne O'Hare with these Healthcare Headlines.

Mark Masselli: We are speaking today with Allan Coukell, Senior Director for Health Programs at the Pew Charitable Trusts where he oversees a variety of health topics including the FDA drug and medical device safety, the pharmaceutical supply chain, prescription drug dependency, opioid overdose, food safety and school nutrition. Prior to joining Pew, Mr. Coukell was a clinical pharmacist in oncology at the London Health Science Center in the Ontario

Regional Cancer Center. He is a Vice Chair of the Medical Device Innovation Consortium and a board member of the Reagan Udall Foundation for the FDA. He earned his Bachelors of Science in Pharmacy at the University of Manitoba and did his residency at the Winnipeg Health Sciences Centre. Allan, welcome to Conversations on Healthcare.

Allan Coukell: Good to be with you.

Mark Masselli: Yeah, at Pew you cover sort of this really wide swath within the pharmaceutical industry, which is covered largely by the food and drug administration. And we have a new administration in-charge now, President Trump has talk tough about changes he wants to see at the FDA. I wonder if you could help our listeners understand the scope of work done at the FDA and how making sweeping changes are not quite so simple.

Allan Coukell: Yeah, I think a lot of people when they think of the FDA, they think of approving new drugs, but they also have oversight over for lot of the food supply, medical devices, tobacco, things that we never even think of, microwave ovens. There are 300,000 over-the-counter drug products that FDA oversees and 55,000 dietary supplements. And I have heard new commissioners after they come in say, you sort of come into the job with a vision of what you want to do and on day one, you get hit with a food and safety outbreak and it's like drinking from the fire hose. And so there is a lot going on at the agency, a lot of staff and things change slowly there.

Margaret Flinter: You know and I am reminded of our interview a while back with Dr. Margaret Hamburg who served as FDA Secretary under President Obama. And she really gave us an insight into just the shear enormity of the scope of work conducted by the FDA. And certainly you know we have seen lots of criticism for what some view as the slow pace of progress for the drug testing protocols, but she gave us an insight into the deficit of personnel, research personnel. Where are we now with this shortage of person power at the FDA, how has it hampered productivity and what do you see happening with that as we move forward.

Allan Coukell: That would mean that real challenge just within the center that reviews new drug applications there are about 700 unfilled positions out of a total of about 5000. So that's a pretty big staffing deficit and that makes it hard for the agency. They do pretty well reviewing new drug applications and generic drug applications, the thing that often get short shrift though is all of the other things that would really help the industry and consumers and patients which is the ability to have scientists thinking about what should the guidelines be, how should we approach clinical trial design. And so having a lot of unfilled positions is a real challenge.

Mark Masselli: You know I know you have been concerned about the rapid expediting of the approval process at the FDA. Just wondering if you look at the opioid crisis and you know the role that the manufacturers of the drugs play that really enticing people, I think to overprescribing, any reflections on how we might prevent that type of problem again?

Allan Coukell: You know it is, you called it a crisis and that's exactly right more than 33,000 Americans died from an opioid overdose last year and of course that's only the tip of the iceberg for every person who died, there is somebody who is struggling with substance-use disorder and so it's really big. You mentioned in your introduction that I was an oncology pharmacist at one stage of my career and so I certainly recognize that these drugs are an essential part of the armamentarium for managing pain. And people who have pain has to get effective pain control at, but it's certainly true that this increase in opioid misuse has tracked very closely the increase in prescribing, in the country. And I think the problem there is we collectively use the drugs sometimes in places where we would be better off using non-pharmacological management and so on.

Margaret Flinter: You know the reality of this opioid crisis has been devastating. Communities are trying to grapple with it, clinicians are trying to grapple with it. You recently wrote an analysis at Pew on what some of the best ways might be to confront the addictions dilemma and you said that the medication assisted treatment approach has so far yielded the best results. Maybe share with our listeners the national policies that were hearing and have seen some progress on, what should people know has been going on?

Allan Coukell: Yeah it's an epidemic that really requires a multipronged response and changes in prescribing. But once people have developed a dependence on the drug, we have to be able to get them into effective treatment. And we are not doing so well, only about one in 10 people are receiving any kind of treatments. And then within publicly funded treatment programs only a tiny fraction of those, include FDA approved medications to manage the disease. And that is something that the evidence has shown is, by far in a way that most effective strategy. Once the brain has undergone a chemical change where its dependent on these molecules, it's usually not just a question of personal determination to get off the drugs, it really helps it in combination with cognitive support and peer support, you have a drug that helps reduce the cravings or replace the need for that opioid or elicit heroin or what have you.

And so increasing access to MAT, Medication-Assisted Therapy is crucial, but we also need treatment systems that are ready when somebody decides they are ready for treatment. If you have somebody who has a substance-use disorder and they say, you know I want to get off these drugs, we can't afford to wait three weeks while they get into a treatment program. And so there are states and jurisdictions that have been getting much better and making treatment available the sort of no wrong door idea where whether somebody hasn't encountered with

the criminal justice system, when they walk into Federally Qualified Health Center and say, I would like to have some help to get off the drugs, we have to have systems that take people, manage them acutely and then transition them to long-term management. So some of that is how we organize the care delivery and some of that is how we pay for it and the expansion of Medicaid has been beneficial in getting more people into treatment, Congress in the last year has increased federal funding to states to support treatment programs so those are all good things. But as Congress grapples with the future of health coverage, there are real risks, we can take some comfort I think in the fact that there is bipartisan recognition of how crucial it is to address this crisis.

Mark Masselli: We are speaking today with Allan Coukell, Senior Director for Health Programs at the Pew Charitable Trusts where he oversees a variety of health topics including the FDA, the pharmaceutical supply chain, opioid overdose, food safety and school nutrition. You know the President has been very busy meeting with lots of people including representatives from some of the largest pharmaceutical entities. And he has promised to take action on reducing regulations in taxes, but they have to do more to bring prices down. And on the other hand he did receive a degree of praise from the rare disease community for promising to advance the Right to Try bill, which would make experimental drugs more readily available to those with terminal illness. You just raised the issue of bipartisan support, I assume that all this is going to take a willing Congress to make all of this happen.

Allan Coukell: So if we talk about the challenge of drug spending which is very much front and center, it's a real challenge. The big challenge on the drugs spending front is that right now, 1% of prescriptions that account for 30% of our national spending. And those tend to be the new high cost specialty medications. It's sort of good news, bad news, we are in really exciting era, scientifically for therapeutic advances, but as more and more of us get access to and need those innovations, that kind of price growth looks unsustainable. And I think we have to make sure that where we can inject competition in the market we do, both with generic drugs and the generic equivalent of biological drugs.

We also have to make sure that we somehow correlate rising prices with clinical value and not overpay something that we haven't historically been very focused on in healthcare in general in the U.S. So there is a lot of policy interests as you mention both from the President and from the Congress. In terms of the speed of approval, FDA makes it determinations much faster than it used to. And I think it's important to recognize that in the overall timeline of drug development, the months that the application sits at the FDA is a pretty small part of the overall cost. So the big costs are actually discovering the drug, developing the molecule, writing the clinical trials, that's where the sort of long-term savings are in terms of being able to reduce drug development cost.

Mark Masselli: I don't think people realize that it's like nine months at the FDA on average or maybe it's a little less from bench to bedside that's really not where all the time is taking, is that right?

Allan Coukell: Yeah I mean it depends on the product you are talking about and FDA, now has a mechanism for taking the drugs that are kind of newest and most novel and the ones they consider breakthroughs and putting them at the front of the queue and moving them through the process really fast, but yeah people often say, it takes a dozen years to develop a drug, the first 11 years say, are doing the science that leads to eventually being able to submit an application to FDA.

Margaret Flinter: You know and I think, we were caught somewhat off-guard when all of a sudden there was a stir within the scientific and public health communities that the Trump administration was appointing, known opponents of vaccinations to some key positions. I think we are surprised to find ourselves maybe having to fight this battle again. What's your read on that and how do we keep the current administration and congressional leaders focused on the need to really rely on evidence-based science as we look at these potential new policies and legislations that affect the population health so much.

Allan Coukell: We are certainly tracking it very closely and as you say vaccines have been one of the great public health successes of the past century. And the concerns about side-effects of vaccines have been very extensively studied by scientist at the CDC and Academia. And so it really is crucial that as we move forward, we not take a stance but frankly put the children at risk, because as we know there are a lot of vaccines that only work if you have a certain level of immunization in the population. And so if my neighbor doesn't vaccinate, my child may be at risk.

Mark Masselli: You know certainly the 21st Century Cures Act which had bipartisan support, was advancing some of the activity that's going on and the act, year marks money for the Cancer Moonshot as well as the Precision Medicine Initiative. And as you look out over the future of biomedical research, drug and device deployment, what types of transformations are going to be required to confront some of the more significant 21st century problems that we are going to face in the areas of food and drug safety.

Allan Coukell: Yeah, as you say it's an amazing time and last year a number of new drugs came to market that cure Hepatitis C, there was a lot of focus on the cost of those drugs, but lost a little bit was just the excitement of a cure. You know and as we look forward, you know hopefully there will be a lots more of those but you can sort of think in a concrete way, well what if we had a drug that we thought might prevent Alzheimer's disease, but people had to take it you know for 20 years before they started to develop symptoms. What would a clinical trial for that look like? What would be the ethics of enrolling healthy

people into a clinical trial of a drug with unknown affects? And so we need a lot more thinking about clinical trial design and what are the you know validating the kind of biological markers that are good predictors of how people will eventually do in terms of real [inaudible 18:16] what are the different kinds of evidence. So beginning to shift from I think and old model of thinking of drug approval is really binary, to beginning to see it as a long-term process of continuing to refine and evaluate evidence.

I don't think anything will ever replace the randomized clinical trial as the gold standard of figuring out in a scientific way, what something works, but we also have to get so much better at learning from real-world experience, when some things is on the market and being able to pull data from health records and insurance claims and maybe eventually even people's own wearable devices or personal reports and continue to learn and refine our understanding. And along with that shift, has to come a shift in communicating about evidence, so that we move into a market place of ideas where there is sort of an ongoing refinement of what we know and collectively understand about products. And also frankly how much we are willing to pay for them.

Margaret Flinter: We have been speaking today with Allan Coukell, Senior Director for Health Programs at the Pew Charitable Trusts where he oversees a variety of health topics including the FDA, drug and medical device safety, the pharmaceutical supply chain, prescription drug dependency and the opioid crisis. You can learn more about his work by going to www.pewtrust.org or follow him on Twitter by going to @coukell, C-O-U-K-E-L-L. Allan thank you so much for joining us on Conversations on Healthcare today.

Allan Coukell: Had a great pleasure to be with you.

Mark Masselli: At Conversations on Healthcare we want our audience to be truly in the know when it comes to the facts about healthcare reform and policy, Lori Robertson is an award-winning journalist and Managing Editor of FactCheck.org, a non-partisan, nonprofit consumer advocate for voters that aim to reduce the level of deception in U.S. politics. Lori, what have you got for us this week?

Lori Robertson: Well, Senator Bernie Sanders and Senator Ted Cruz appeared in a CNN debate to discuss the future of the U.S. healthcare System. And both man repeated claims we have checked before. Sanders said that the United States spend "twice as much per capita on healthcare as do the people of any other country". Sanders has a point that United States spends a lot more per capita than other countries on healthcare but twice as much, no that's not correct. The U.S. spends twice as much as the average spent by other developed nations. According to 2015 figures from the Organization for Economic Cooperation and Development the U.S. healthcare spending was $9,451 in 2015 per person. The average for 35 countries was $3,814 but the

second place country Luxemburg spent $7,765 or 18% less per capita than the U.S.

Senator Cruz meanwhile said that the Affordable Care Act had “driven up the cost of healthcare.” He said the average families premiums have gone up $5,000. That’s a misleading take on premium growth. For one that’s the rise in the average premium for an employer sponsored plan for a family including both the premium paid by the employee and the portion paid by the employer. The total average cost for a family plan rose $5,462 between 2008 and 2016. The average employee paid portion rose $1,923 also that increase an employer sponsored premium is lower than the premium increase for the previous 8 year period, both in raw dollars and in the rate of growth. The total average family plan cost increased by 97% from 2000 to 2008, but it went up by 43% from 2008 to 2016. And that’s my FactCheck for this week; I am Lori Robertson, Managing Editor of FactCheck.org.

Margaret Flinter: FactChecks.org is committed to factual accuracy from the country’s major political players and is a project of the Annenberg Public Policy Center at the University of Pennsylvania. If you have a fact that you would like checked, email us at www.chcradio.com we will have FactCheck.org Lori Robertson, check it out for you, here on Conversations on Healthcare.

Margaret Flinter: Each week conversations highlights a bright idea about how to make wellness a part of our communities and to everyday lives. Diabetes is a chronic illness for which behavioral choices such as diet and exercise are extremely important. But incentivizing behavior change and large patient populations is very challenging. A recent study done by Emory University and a nonprofit organization focused on improving the health of India’s population of a billion people, found the text messages sent through smartphones, might be a powerful tool in promoting diabetes prevention behaviors. They partnered with India’s leading provider of mobile phones Nokia to harness a research cohort of the million clients to receive diabetes prevention text messages.

Nalini Saligram: So the text messages themselves were developed with Emory University, Rollin School of Public Health and then we adapted them with lots of consumer feedback.

Margaret Flinter: Nalini Saligram CEO of the Arogya Foundation, the text messaging study was designed to generate improved activity around four simple goals, consume more fruits and vegetables, avoid fried foods and exercise regularly.

Nalini Saligram: The sequence of the messages and how frequently they were texted was all based on behavior change theory as well as on Nokia’s experience. So we ended up sending it twice a week for six months.

Margaret Flinter: Participants who received just two text messages per week, remind me then to keep their diet and exercise goals, showed an average 40% more compliance with those activities than those who did not receive the messages. Dr. Saligram says, it could prove a useful tool for clinicians trying to affect behavior change across large patient populations. A low cost targeted text messaging system sent directly to consumers, reminding them of the power they have to maintain simple lifestyle changes that can improve their chances of preventing or better managing diabetes and other chronic illnesses, now that's a bright idea.

Margaret Flinter: This is Conversations on Healthcare, I am Margaret Flinter.

Mark Masselli: And I am Mark Masselli, peace and health.

Conversations on Healthcare broadcast from the campus of WESU at Wesleyan University streaming live at wesufm.org and brought to you by the community health center.