

Announcer: Welcome to the Science is the Best Medicine podcast with your host Dr. Abhinav Sharma. Exploring the pressing scientific and healthcare issues of our time.

Dr. Abhinav Sharma: Health care costs in the United States are absolutely skyrocketing. What can we do about it? We hear the dire warnings of how much it will cost to treat our aging population. What can we do to help deliver the care that can help people be healthy, keep them out of the hospital, and live longer?

Today we'll have a discussion with Dr. [Mark McClellan](#) to address some of these issues. He is a physician, former FDA commissioner, and is the current director of the Margolis [Center for Health Policy] at Duke University. Let's get into it.

So, Mark, why don't you tell us a little bit about your journey until this point.

Dr. Mark McClellan: Well Abhinav it's been a long journey but I'm glad to be here and part of the Duke system.

I started out in medicine and economics back in a joint graduate degree program, went from there to an internal medicine residency and that was in Boston. I came from Texas originally, so fourth generation Austin-ite, that was a bit of a change. After residency, I joined the faculty at Stanford University and I was planning on doing research in economics and health care, but much of my research was about ways in which things that aren't really directly related to patients, like how doctors get paid, or where facilities are located, or what the medical liability laws and regulations might be, how those affected medical treatments and also because they affect treatments it gave us a way of looking at some of the implications for outcomes of patients who get treated differently. A lot of practical real world questions are hard to study in traditional randomized trials. But if you get good data on non-medical factors that influence how patients are treated, it can tell you not only about some questions of policy interests but also can tell you about what those changes and treatments really mean for patient outcomes, and also health care costs, so much of my research focused on that.

And I got involved in policy issues, most directly first in the Clinton administration as a Deputy Assistant Secretary of the Treasury, worked with Secretary Bob Rubin and Larry Summers who had been on the faculty at Harvard while I was going to graduate school there, so I guess it's a small world, and went from there back to Stanford and got a call to help out with a small Transition Project for the George W. Bush administration in January of 2001. One thing led to another, and I ended up on the White House staff, working on health policy and then the FDA, and then a CMS administrator.

Abhinav: By the way, by FDA administrator, Mark is specifically referring to when he was appointed to be the FDA Commissioner.

Mark: Subsequent to all of that, I stayed in Washington for a while with the Brookings Institution where I was a Senior Fellow, and more recently had an opportunity to form a new university wide program here at Duke, the Margolis Center for Health Policy which was endowed by Dr. Bob Margolis a Duke alumnus, who along with a lot of the leadership at Duke, is committed to Duke being an even stronger voice, an even stronger source of evidence to guide informed health care policy, decision making, and informed decision making about a range of other policies that affect health, and we're just getting that program going now.

Abhinav: Well it seems like we've had an absolutely fascinating trajectory going to multiple

places—you were the former FDA Commissioner, you had some time at the Brookings Institute, now you're the director of [Margolis Center for Health Policy] as well. How has your job title changed, or how has your description of your job changed essentially?

Dr. Mark McClellan: I think over all that period of time, I've always had the privilege of working on a mixture of clinical issues. I'm not in clinical practice anymore, I did that for quite a while and am still working on issues that directly matter to patients. One of the things that I most enjoyed about medical practice was the opportunity to really have an impact on people's lives, and help them with some of the most important and meaningful issues that they were dealing with. Often they are very challenging, but that's what health policy is like, too. The decisions that we make about health care coverage, about how we pay, about how we regulate, have important consequences for many people, the people in our community, the people throughout the country—really throughout the world, and at the FDA and CMS, one thing you could count on is that when you get up every morning, you can kind of go in and do what you think is the right thing because no matter what you do, you're going to get criticized. And a nice thing about working on the issues here at the Margolis Center is that we're still focusing on things that really matter to people. But we have more of a chance to think deeply about them and really try to develop good new ideas, and good new sources of evidence, that's I think a unique strength of Duke, it's perhaps the world's largest infrastructure for doing clinical studies, for tracking clinical epidemiology, not just in the United States but really all over the world. And we're going to be taking some steps to try to apply that kind of infrastructure even more deeply to important health policy questions.

Abhinav: So, you mentioned your time here at Duke. You get a little bit more time to think about these complex issues of cost and delivery of care, and you hear almost weekly and monthly and very regularly in the media that health care costs are absolutely exploding. Why is this happening, and what are some of the factors that have led to this explosion in health care costs?

Dr. Mark McClellan: Yeah, health care costs are continuing to go up. This has been a sort of fact of life not just in the U.S. but in developed countries around the world for really the last four or five, six decades or even further back. And there are several reasons for that. One is demographic. As people live longer and better lives, due in part to insights about health factors, the behavioral and other medical factors that they can change to influence their lives, as they live longer lives they develop more chronic diseases, more opportunities for health care interventions that matter. That adds to costs.

And on top of that, we're developing more and better treatments, and many of these new technologies help improve and save lives. A good recent example is some of the new curative technologies for Hepatitis C, which no question that's really valuable to cure a patient of a chronic viral infection that otherwise might have led to cirrhosis, other liver complications, even the need for a liver transplant. And people have highlighted that while this is valuable, in part because it can avoid these downstream medical costs complications. But I think the main reason that many medical technologies end up costing a lot, especially when they are first developed, is because they are valuable in their own right for improving people's lives. And what Americans, and really everybody really values, is you know it's great to have an iPod and now an iPad. And great to have, you know, jet travel and 400 cable stations and YouTube and social media. But what people really enjoy is the time to use all of those services, or just be around for another sunset, or have more time with a loved one, a grandparent or something like that. And so, that's one reason why there's a lot of costs associated with some of these new technologies. When they first come out as that, they really are in many cases extending and improving lives. All that said, health care costs are now the biggest factor in Federal budgets, in state budgets, in many families' budgets, and many people, and many policymakers are facing tradeoffs.

And we spend money on the health care services, or spend money on other valuable things, and one of the things that's happened at the Federal level is with more spending on health care, we're now spending about twice as much on health care Federal expenditures as we spend on say national defense and national security. Other things have been squeezed out at the Federal level at so-called discretionary spending. So, defense spending, which itself includes a lot of health care spending now, that's one of the fastest growing parts of the defense budget, but also other non-defense important investments in activities of the Federal government, like spending on infrastructure, spending on research and development, spending on programs for low-income assistance, spending on education. These are also programs that can have a big impact on the health of the population. Probably the best investment that we can make in terms of Federal or state dollars is better educational programs, better pre-K programs. These have long-term impacts, and those are getting squeezed by the additional health spending. So, one of the most challenging issues I think this country is facing—that most developed countries are facing—is: How do we get both? How do we both encourage continued innovation and improvements in care that are leading to longer and better lives, and a better understanding of how we can improve health. But at the same time, do it more efficiently. So, a lot of the work that we do focuses on this broad notion of value, and how can we not have our cake and eat it too, but make sure that we're developing and using medical treatments effectively that we're finding that the most effective ways to extend and improve lives.

But we're doing it without unnecessary waste, and avoidable health care costs. I think there's a lot of room for improvement there. And something that policy can help with. But it's also something that would be increasingly important for all of us who are in the health care sector, doctors, other clinical leaders especially are going to be increasingly called on to think about not only how can they keep their patients well, but how can they help them through some of those difficult health challenges of their lives. And how can they do it in more creative and innovative ways that avoid unnecessary health care costs.

Abhinav: So it seems like there's such a myriad of complex issues here from trading off health expenditure to other very important public services, the need for innovation and advancement of technology. Now how do we actually rein all of these things in. You mentioned the transition from volume to value. Can you describe a little bit about exactly what that means in terms of delivery of healthcare and how physicians conduct their day-to-day practice?

Dr. Mark McClellan: Yeah before talking about that, just to highlight again what we spend in health care: As economists think about it, there are two main components there. There are prices that we pay for services and there are the quantities of those services and products that we use. So, anything that's going to affect healthcare spending is going to do it by affecting one or both of those components, the prices or the quantities. And a lot of health care policies try to get both right, we move prices in the right direction, try to move quantities in the right direction, and some of the reforms that we're involved with here, things like moving to more accountable payment systems are really about that. And that's moving from the way that we've traditionally paid for services and health care, which is on a fee-for-service basis, so Medicare private insurers will set or negotiate a price for a visit to the office, an ultrasound, a bypass surgery operation, and then the providers who deliver those services get paid for them.

The problem with this approach is that it really isn't directly connected to value. And as we increasingly move into a more personalized era of medicine, where you know, number one, the range of relevant technologies and services that could have an impact on patients' health is getting much more broad. So, you know, certainly the traditional office visits and lab tests and procedures. But today if you look at any other industry, there are lots of other things that are making services more convenient and better, like apps that let people get reliable information, personalized information directly at home, like telecommunications services, remote monitoring. Again, these

are starting to have an impact on healthcare but not really big yet. And then with more knowledge about what exactly matters for patients, based on their genomics, based on their preferences, and based on other factors, you know we're getting better at identifying that's the right way to customize services, and that means things like team-based care, and complex care coordination. Well those are all things that are either not paid for at all, or are not paid for well under our traditional payment systems.

You can understand why Medicare, and I've had actuaries that I talked to about this regularly, might not want to open the floodgates to, hey, let's just cover all telecommunication services, you can end up paying for a lot of things that really aren't very high value, and it kind of shows the limits of fee-for-service payment systems where in some cases these treatments, or these combinations of treatments or these new approaches to cure may be really valuable. In other cases, they may not. And one way to think about a lot of the payment reforms that are being implemented now is that some of the ideas and so-called alternative payment models in the new Medicare physician payment legislation, things like the bundled payments for episodes of care that Medicare is implementing, and things like accountable care organizations. One way to think about that is giving health care providers more flexibility in how they determine the right treatments, and provide treatments to particular patients. So, under these models it's easier to do things like use telemedicine, or get a nurse practitioner involved in care, or answer a patient's email. But on the other hand, it's not sort of unlimited resources either, there's some accountability for making sure that health care costs aren't too high. Making sure that with this flexibility is coming better results for patients and lower overall costs.

This is a hard transition to make for a lot of doctors out there who are already feeling really stressed by lots of the restrictions on what's covered already, it's basically like, "Oh my gosh now I've got to report on new kinds of things, I've got to retool my practice to think about longitudinal patient management, and to think about financial implications that I really didn't think about before." No question, this is very hard. But if you look at the big picture, the people who I'd like to see even more involved in thinking about how we solve these big social problems of getting innovative treatments, the best treatments for patients, and keeping costs down at the same time to deal with all of these other national priorities—I think the best people to be involved in that are the clinicians who know the most about the science, know the most about the patient's needs along with the patient, and could potentially play a really important role in getting us to better health care and lower costs.

Abhinav: So, it seems that this sort of transition away from the fee-for-service model in some areas appears to be one strategy to help rein in these costs, although fee-for-service may be useful in some places, it may not be so useful in other places, and I just want to [focus] on a point you mentioned about bundle payments. What exactly does that refer to, and how is that different from fee-for-service payments? Because we do often hear this, that you know their transitioning to a bundle payment model, what exactly does that refer to?

Dr. Mark McClellan: So just give you an example, recently Medicare has proposed a transition to bundled payments for a number of hospital-based episodes of care. These include joint replacements, like knee or hip replacement, includes treatment now for acute myocardial infarction. Medicare recently announced some bundled payments for heart attacks. And the idea there is not to pay separately for a hospital admission, for physician services, for post-acute care services, for the associated post-hospital management by a clinician, for nursing home services that might be needed, but to try to roll those up. What Medicare has found, and many other private plans have found as well in the U.S., is that there is a lot of variation out there and how often patients get readmitted to the hospital and how often they experience complications, and going along with that, the costs of these, what you might call episodes of care, sort of dating from the time the procedure

begins, or the time the hospital base diagnosis like a heart attack is made, to say 90 days after that. And the goal of these episode-based payment models is to encourage all the different providers who are delivering care in these increasingly complex and interrelated settings, to work together more with the explicit goal of improving outcomes of care measured by things like preventing readmissions to the hospital and, hopefully soon, things like improvements in patient-reported functional health status and functional outcomes, and at the same time, bringing overall costs down. So in these episode models, instead of just getting a payment for a hospital stay, or a payment for a day in a nursing home, or a payment for a rehab service, all of these providers are encouraged through the hospital to take a look at the overall cost of care, to take a look at the complication rates that they're getting, and to improve on those to shift the way that services are used, and again going back to our earlier discussion, to maybe spend more money in areas that are not reimbursed at all now by Medicare, like to support care coordination. A case manager, or home monitoring, you know getting an iPad connected to remote monitoring for a patient so that you could potentially identify the patients who are likely to be readmitted and take less expensive steps to prevent that and help the patients get better outcomes at the same time. So, this is a shift in payment.

These accountable models usually put some particular provider as the focal point of the models, in the case of these Medicare bundles, it's the hospital. And there's some controversy about that. There are many types of episodes of care that perhaps shouldn't involve the hospitalization at all, you know maybe the best outcome for a heart attack, and the lowest cost for a heart attack is to prevent it in the first place through steps that would happen earlier on in kind of more of an episode focus coordinated approach to managing coronary artery disease. So, we're just in the early stages of figuring out the best way to do this. I don't think the current Medicare payment bundles are the last word on this subject and once again there's a comeback to what I think is going to be a recurring theme here Abhinav, is there are some opportunities for clinicians who are coming up with better ways to deliver care, say for coronary artery disease, more prevention oriented to identify how those approaches are not well reimbursed under current fee-for-service payment models, and think about ways in the directions that we've been talking about to get there. So, one could imagine an episode payment for heart disease care that doesn't start with the hospitalization but it starts earlier on. And that really is focused on preventing the heart attacks and the other complications and those downstream costs. So, I'm hopeful that we're going to be able to move more in that direction.

Abhinav: As we wrap up our podcast here, we have our rapid-fire science questions, so a few rapid-fire questions for you here. Are you a social media user? Do you tweet, Instagram—anything of that sort?

Dr. Mark McClellan: I personally don't have enough time or talent to tweet really effectively, but with the Margolis Center, we are setting up a [Twitter] and social media presence. Right now, we're recording this in late summer of 2016, so as we head into the fall and especially 2017, look for people who are working with me, who know how to tweet about what we're doing at the [Margolis Center](#).

Abhinav: Excellent. And the final question here. You mentioned you're not in clinical practice anymore, do you ever have the pang to go back into the clinic?

Dr. Mark McClellan: Yeah I really miss that, and you know one of the nice things about working on these policy issues is that we're not too far away from having any impact on people's lives. It's not as immediate, and personal as clinical medicine and that was the thing that I always loved the most. I actually think becoming a doctor is good training for going into politics and going into policy work because you have to learn how to listen to lots of different kinds of people, and how to communicate effectively with them about complex and difficult topics, so I feel like I'm still getting some of that experience from my current work in policy. But boy I do miss the clinical practice and

just how much of a difference doctors and other health professionals can make in people's lives.

Abhinav: One final question Mark—what exactly is the Margolis Center and what are some of its goals and missions?

Dr. Mark McClellan: So, this is a center whose mission is to improve health and health care in the community, in the country, and around the world through developing better evidence on policies that can impact health and health care and through helping with actually implementing those policies. Today we know we've got a lot of areas where we can improve to get to better value, to improve outcomes for patients, to lower costs. The hard part is just actually doing it. So, you need evidence, and you need the practical skills and capabilities, and education support and training to help make it happen. That's what the center is all about.

Abhinav: Today we had a discussion with Dr. Mark McClellan about the complexities of why health care costs are rising across the United States. While there are a lot of issues, which include our population getting older, the cost of drugs and new therapies increasing, the fact that there are often more tests and investigations done, [from] my time on the clinical service, I can see that patients who are being admitted tend to be older, they tend to be sicker, and often they're staying in hospital for longer periods of time. This most definitely is going to be driving up health care costs. There are a number of solutions being evaluated. Hopefully we can come up with a plan that will help to lower costs while providing the quality of care that we'll need to help our population. I would like to thank everyone who made today's episode possible. This is your host Abhinav Sharma and I hope you enjoyed your dose of Science is the Best Medicine podcast.

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