Speaker 1: Welcome to Conversations on Healthcare. This week we welcome former FDA Commissioner, Dr. Margaret Hamburg, on the new Health Affairs Report she co-authored on how to reign in America's exorbitant healthcare costs. Now here are your hosts, Mark Masselli and Margaret Flinter.

Mark Masselli: Each American now spends an average of nearly $13,000 a year on healthcare. We have one of the highest healthcare costs in the world, but we don't lead on the best [00:00:30] outcomes. How can we get more value from the 4 trillion we spend on healthcare? It's a cost that's nearly going to double by the end of this decade.

Margaret Flinte...: Dr. Margaret Hamburg is part of an effort trying to find the answers to that question. She previously led the Food and Drug Administration during a time of rapid change and has had a very distinguished career. Right now, she's the co-president of the InterAcademy Partnership. It's a nonprofit made up of science academies from around the world.

Mark Masselli: Well, Dr. Hamburg, welcome back [00:01:00] to Conversations on Healthcare.

Dr. Margaret Ha...: Thank you so much, delighted to be here with you on an important set of topics.

Mark Masselli: Oh, that's great. You and former Senator Majority leader, Bill Frist, co-chaired the Council on Healthcare Spending and Value, and we'll go through some of the key recommendations of what you call a roadmap to value, but I was surprised that you didn't or you chose not to delve into the social determinants of health. From our organization and many organizations like us, [00:01:30] we're very concerned about the 80 million Americans who are on Medicaid, and the millions who were uninsured. Tell us a little more about why you chose not to delve into this particular area.

Dr. Margaret Ha...: Yeah. Well, let me back up a bit and just say what we were. This was a council that was put together by Health Affairs, really building on their strong and distinguished history of engagement on issues around our healthcare system and issues [00:02:00] that pertain to how we deliver care, quality of care, systems of care, et cetera, and a diverse group of council members came together. I was asked, as you noted, with Senator Frist to co-chair. At the time I was asked, I actually said, "I'm not sure I'm the right person to do this because I'm not an expert on healthcare spending or healthcare economics." My perspective really comes [00:02:30] much more deeply from being a public health professional, including not just at the FDA, but also health commissioner in New York City for six years, where I was deeply exposed to issues of healthcare and delivery, but also social determinants of health.

Our charge was to recommend ways that the United States can take a deliberate approach to moderating healthcare spending growth while maximizing value, and we were really asked to try to [00:03:00] look at what were some critical domains of activity, and what were the levers to make a

difference. We were asked to look at things where we felt that there were actionable steps that could be taken where there was real money in the overall system to be achieved in terms of savings, but we also had to address the critical question of how do you assess the right amount of spending? There's no critical [00:03:30] dollar amount percentage of GDP that everyone can agree on is the right target, but I think what we all could agree on from day one was that we were spending an awful lot of money on healthcare and not getting what we wanted in terms of value, what our country needs.

And especially when you look at other countries who are spending less in terms of all [00:04:00] overall percentage of GDP, our health statistics, our vital statistics, our healthcare statistics are just shockingly poor in many areas. So that was where the foundation [inaudible 00:04:17].

Mark Masselli: And you don't think the social safety net that exist in those countries, which may also speak to the social determinants of health, are a factor?

Dr. Margaret Ha...: Yeah. So that was our charge, and [00:04:30] the group really there, the expertise of the membership, and the focus of our work, and where we felt that we could have value added wasn't so much in the domains of social determinants of health. We made a conscious decision, which to be honest, disappointed me, because I was pushing on that as a very important arena, and I think it's going to be we didn't want this to be a [00:05:00] report that tried to be everything to everybody, because you drown trying to boil the ocean, so to speak, in that way. And so really building on the expertise, experience, and focus of the council members in areas where we felt there was value added.

We didn't look at some areas that I think are vitally important and that our nation and all of our health and [00:05:30] medical care experts need to continue to work on includes social determinants of health, and I think we're seeing that as an increasingly important area of activity and where there are ways to bring both our public health system, and other social services, and community-based activities much closer to the healthcare delivery system in terms of how we think about services, how we integrate services, and how we pay for services. And in fact, CMS is involved [00:06:00] in some very important innovation in that domain right now that I think holds huge promise going forward, but that wasn't the focus of this report, because it in a way demands more focus and attention in and of itself, and I think we still need to demonstrate. We're really sort of working out where is there a fully established database also on which to make our recommendations?

And I think we still need to build out [00:06:30] some of the critical research and understanding about the critical drivers of health in terms of social determinants of health, but we know it's so important. We also didn't look at value at low value care, and I think that's critically important. How much money are we wasting on services that really aren't of value to patients and consumers in terms of promoting and advancing health and actually [00:07:00] may be

harmful? But we felt that there were other entities working on that, that were sort of better situated.

And another area that surprised many people, especially with my involvement as a co-chair, was we didn't look at pharmaceutical spending, and of course we know that's very much on the minds of the public and policy makers. We know there's important innovations going on at the moment, and we know that when we look at the future opportunities to make a difference in terms of harnessing science and technology [00:07:30] for new products to treat, cure, and prevent disease, that there's going to be lots more on the horizon in terms of products and strategies, but that many of those are going to be very costly, and as a nation, we need to figure out how to actually pay for these products that can be so meaningful for health.

Margaret Flinte...: That is a lot that you've just shared with us and couldn't [00:08:00] agree with you more about the need to build the evidence-based and the data on impact, social determinants, on health, and everything else that you just described, but maybe want to pick up a little bit where you gave us a little entree to around the pharmaceuticals, and talk about price regulation, targets on spending growth in general, and where you think the pulse of the country is next week, although, I find it almost impossible to believe it's the 13th anniversary of the Affordable [00:08:30] Care Act becoming the law of the land. Those 13 years flew by, but at the time, as you remember, the town halls, and the community meetings, and the media opponents try to falsely label any attempt at price regulation in that law regarding healthcare as the death panels.

Do you think that that has substantively changed over these years? Do you think there's more public support for price regulation given that people have continued to see, even though certainly big improvements [00:09:00] that came with the Affordable Care Act, they've continued to see a very big chunk of their dollars go to healthcare?

Dr. Margaret Ha...: Yeah. Well, I think that pharmaceutical spending is one area where people feel it in their pockets. People do have a better sense of the cost of drugs than often they have of the cost of other components of healthcare, and I think people also, no matter what [00:09:30] your politics, when you or a loved one needs access to a potentially lifesaving drug or a drug that enables you to go from having a chronic debilitating illness to being functional and active, people want access to it, and I think that as we've seen the rise in the cost of drugs and also as we've looked at comparisons to other countries, [00:10:00] people are concerned.

And I think that in some ways this is an area where there is more bipartisan interest in addressing the problem of pharmaceutical spending, and more outrage, frankly, at some of the prices that people are seeing, some of the rise in cost of drugs that have been in the marketplace for a long time, and some of the concerns about [00:10:30] whether a serious medical illness requiring an

important new treatment will be accessible, or whether it will break the bank of a family budget or of our nation in terms of paying for cost. So I think that this is an area, while it has of course been highly charged and very political, and to me it's a great sadness that [00:11:00] so much of a critical set of health and public health issues have become so politicized. I think this is an area where you can get people wanting to think and work together in important ways around an issue that ultimately is very personal.

I don't think many people think it is the cornerstone [00:11:30] of all issues in terms of our health spending in this country, and I think it doesn't represent that. I think we have many other things we need to work on to help bring down the cost of spending and to also help improve the quality of the healthcare that we pay for, but I think that pharmaceutical spending is and will remain an important area of focus for the public and policy makers. We're, of course, [00:12:00] seeing some new activities get underway, and it will be a very interesting and important time.

Margaret Flinte...: Certainly the news on insulin and making insulin available at more of a fixed price was very welcome news, I think, to the American public [inaudible 00:12:17].

Dr. Margaret Ha...: And also being able to really negotiate price within the government agency, CMS.

Mark Masselli: Very important. Your report calls for supporting healthcare [00:12:30] competition, and certainly no complaints from us on that front, and in fact, antitrust regulators have recently blocked I think four hospital mergers, but the government appears helpless to stop the big ones. If we're all in agreement on this, what set of laws will need to be enacted to get to align with that philosophy, and do you think it's possible in this environment? I agree with you there may be a seam of opportunity [00:13:00] on the prescription area. I wonder if there's much support for this.

Dr. Margaret Ha...: Well, I think the issue of competition is a complicated one. Again, it's not in and of itself the answer, and we looked at a lot of data and talked to a lot of people, and I think that there are times when supporting and enhancing competition can be very helpful, both in terms of [00:13:30] bringing down costs and improving quality and accountability. I think there also are important settings where enhancing competition isn't really a reality in rural areas, et cetera, but I think what we really kind of tried to focus on was the need to increase state and federal monitoring of competitiveness to help encourage [00:14:00] greater competition as appropriate and meaningful, and I think that we've... to identify models that demonstrate value.

Margaret Flinte...: Well, I think one of the places that people are really concerned about value for their healthcare dollars is certainly in the workforce, right? In the healthcare workforce, which is under so much stress, and I'd hazard a guess that the person

in the street, if you ask them where [00:14:30] the money is going in addition to pharmaceuticals and diagnostic machines, they might say it's going to the top, and it's going to compensation. And we noted the North Carolina treasurer just released a report that found that CEOs across the state's nine largest hospital systems doubled their paychecks in less than five years. There was a report of one CEO's pay going up 700%. Did your panel take a look at this? How big a problem is executive compensation [00:15:00] in the healthcare system, especially during this time when we're seeing such dire shortages of some of the rank and file healthcare workers?

Dr. Margaret Ha...: Well, the overall issues of healthcare workforce are enormously important and really in a critical inflection point I think, because the last years of COVID have placed such a toll on healthcare workers, have stretched healthcare workers very, very thin, [00:15:30] and we are seeing many understaffed healthcare systems, and we need to put very targeted attention to how do we both strengthen and enhance our workforce, and how do we also ensure the right mix of healthcare workers? As for CEOs, I [00:16:00] think the issue of CEO salary wasn't a major focus of discussion, at least not that I recall during our council process, but it speaks to bigger issues that there are pockets of really big money in our healthcare system. We also don't have as much transparency as many would like into where the money is, and how [00:16:30] the money flows within the healthcare system, and this relates to pharmaceutical spending as well.

And we do think that it's important to bring more sunshine to all the different components of our healthcare system, and where the money is, and how it's being spent, and is it being allocated in the right ways with the right equities? One question that we [00:17:00] also got asked in the course of our work and subsequently after making our recommendations was, "When you think about healthcare systems, and you think about really making a difference for people, should we be recommending a national health system and universal healthcare through that kind of a mechanism?" And you can certainly see the benefits [00:17:30] of that in other countries, but we also felt we needed to work within the realities of our system, which is a much more multi-faceted approach to healthcare delivery and many different kinds of systems, many different kinds of payers, but it does make it harder to really have both the transparency and the accountability in terms of where the money [00:18:00] is, how it's being spent, and assessing the value sometimes of those investments in our health system.

Mark Masselli: [inaudible 00:18:09].

Margaret Flinte...: One of the areas where some sunlight has been shining that was overdue perhaps was the whole issue of maternity deserts across the United States, and as that becomes front page news in the United States, and we realize just how much of the country lives in a maternity desert, these issues, whether we look at other systems that are more universal or [00:18:30] nationalized, or we look at more accountability for where the investment of dollars go, I can't help but

think that that issue is going to galvanize some action as well, so thank you for your comments.

Dr. Margaret Ha...: Yeah. Well, and we do keep seeing the rise in maternal mortality in this country, which is really quite shocking, the overall numbers.

Margaret Flinte...: That's right.

Dr. Margaret Ha...: But also it is one of the areas that really show the inequities, the disparities in health.

Margaret Flinte...: Exactly.

Dr. Margaret Ha...: And the African American maternal mortality is just so [00:19:00] out of proportion, and I think we all probably can agree that we can and must do better in terms of this important and very fundamental area of healthcare.

Mark Masselli: I was thinking as you were answering before about making a difference in the value for people, and I was thinking about navigating the healthcare system as sort of both an art and a science, and it's overwhelming for most patients. I'm wondering what can the average person do to ensure they're getting value [00:19:30] for the money they spend? And we note the report recommends value-based payment models that patients should lock into a specific delivery system that's accountable for their care, but maybe translate that for the average citizen.

Dr. Margaret Ha...: Well, I think value-based care is an evolving area, and we need to really better define it and better implement it. [00:20:00] Right now, in many instances, there's more jargon than reality, I think, sad to say, but that's one of the reasons we felt it was important to put a focus on it in terms of the importance of it. In terms of taking it to the sort of individual consumer perspective, I do think it's really, really important to sort of have a medical home to as best you can in our complex world [00:20:30] and highly mobile world, to find a healthcare system and a set of providers that you get to know and trust, and they get to know you, where you feel comfortable asking questions. I think we live in a world where there's just such a swirl of information available, but it's hard to always be able to discern what's reliable information, and what's misinformation, [00:21:00] either well-intentioned and inadvertent, or increasingly, sadly, deliberate disinformation in certain arenas of health and healthcare.

So I also think that we have an obligation as healthcare professionals to do a better job educating patients in the public about issues of health, and wellness, and disease, about emerging areas [00:21:30] of medical care, and helping patients and individuals be better consumers of healthcare, which means asking more questions and holding health systems more accountable, but it's a journey. And I think certainly healthcare delivery institutions have to hold themselves to higher standards in terms of not just delivering services because

you can, but delivering services because they're the right ones [00:22:00] for the patient at the right time that will make a difference, and you can demonstrate why they're needed and the benefits that have occurred because of them.

Margaret Flinte...: Well, I really appreciate, Dr. Hamburg, your lead in there to your comments about how important it's for people to have a relationship with somebody with primary care, with a primary care provider in order to be able to both get the healthcare they need and make sense of the whole system, and I'm [00:22:30] reminded of the NASEM report that came out a little over a year ago, towards implementing high quality primary care that emphasizes one of its first elements, the importance of everybody having a relationship with a primary care provider, but they also went on to say it's not just about a provider. It's about a team. It's about team-based care, the integration of behavioral health, the maximum use of everybody on the team, and of course, as part of that, you can't go too far before you look [00:23:00] at things like GME, and how do we train that healthcare workforce?

What model do we train them to? Who do we train to be on that team? And I don't know that that was a consideration within the panels or within any of your area of interest, but what are your thoughts about how we train this next generation to be the generation that delivers on that model of primary care?

Dr. Margaret Ha...: Yeah. Well, again, it wasn't a central focus of discussions in our work, but it certainly [00:23:30] did come up in the broader context of workforce and also how to incentivize the right kinds of care with the emphasis on value, and quality, and accountability of healthcare providers. I am very far away from the day-to-day world of healthcare delivery, I have to say. I'm trained in medicine, and I practiced medicine, but went into public [00:24:00] service and moved farther away from the actual hands-on with patients, but I must say I'm so struck by how much harder it must be to be a healthcare provider in the modern era with so much information, so many demands and expectations, and the increasing constrictions on the time that you have to spend with patients.

And so as you note, the [00:24:30] idea of the team becomes more important, the idea of training people, not just so that they know everything. I mean, I spent so much time memorizing and re-memorizing sets of facts as a medical student, and then in my early days of medical care. Now what's important is to be able to know how to access information, and how to also be able to tap into the right networks [00:25:00] of care. I think one of the things that is also important about the way that training is going on these days and the way that I think the medical profession is reshaping itself goes back to the discussion that we began with about social determinants of health.

I think that medical providers that work in clinical and hospital settings are increasingly aware of the fact that not everything that's important, [00:25:30] in fact, a lot of what's important for health doesn't happen within clinic walls or hospital walls, but this notion of also engaging with patients on a broader set of

issues that have to do with health related behaviors, and lifestyle considerations, also potential community exposures, and also the importance of recognizing that it isn't just what you recommend to your patient. It's also what [00:26:00] they're able to actually do, and it doesn't matter if you make a brilliant diagnosis and you write the prescription. If they can't afford the drug, they don't understand how to take it, or they're lost to follow up, all of your great training and expertise in medical acumen hasn't really served that patient. So I think we need to continue to work on that sort of more integrated approach to medicine and medical care.

Mark Masselli: Well, let me try to get one last question in, and I [00:26:30] want to turn our attention to the agency that you used to head, the FDA. The agency obviously has faced many challenges during COVID. We had Dr. Walensky on from the CDC and just as she was launching sort of a reorganization of the CDC. I'm wondering what your thoughts about what the agency has done right and wrong, and I also want to note that you and a number of other bipartisan FDA commissioners had written a letter [00:27:00] during the Trump administration about meddling politically into the whole process. I'm wondering if you can put that together for us in terms of, one, does the agency need to recast itself in light of sort of the public struggles that it faced, and also sort of this political intervention that's happened in terms of the vaccine approval process?

Dr. Margaret Ha...: [00:27:30] Well, this is a really complicated issue, and one that's very close to my heart. I would say that the importance of enabling the FDA to work as it's been charged to in law and in practice over more than a century now, which is to be a science-based, data driven regulatory agency that reviews data and evidence in order [00:28:00] to inform and then make critical decisions about safety, efficacy, quality, and performance of products, also, of course, it's important oversight of food, and nutrition, and now tobacco, but to be able to do that in a science-based way, protected from the intrusion of politics, or ideology, or other commercial or vested interests, [00:28:30] this is not a problem that emerged in the Trump years. It's not a problem that emerged in the complex cauldron of COVID challenges. This is a problem that has dated back a very long time, and frankly, I think with every administration in the modern FDA experience, we've seen more and more political intrusion and efforts [00:29:00] along those lines with the FDA.

And so that's why I think it really preceded the Trump Administration that the FDA commissioners came together to make this call against political and other intrusion into our decision making. COVID brought so many things into sharp focus, and this was certainly one of them for the FDA. Also, it brought into focus [00:29:30] the fact that we as a society over many years, but intensified during COVID, have seen a devaluation, a denigration almost of scientific evidence, and scientific expertise, and perhaps expertise more broadly, and that's been very damaging as well. And so agencies like the FDA are in a very, very difficult position right now. [00:30:00] Trust has been undermined, partly for reasons of failures of adequate communication and clarity about what they're doing and

why, partly because of politics, and ideology, and divisiveness that has targeted and undermined trust in institutions like the FDA, and partly because of longer historical trends [00:30:30] about tensions around regulatory authorities and public health as well, but FDA is a unique and essential agency.

It's vital to all of us every day in countless ways that matter, and FDA has to do its work with a foundation of trust, public trust, and we have to [00:31:00] earn that trust and prove ourselves trustworthy every single day, and I think that that is something that the commissioner and the employees at the FDA understand, and are working hard, and have a huge set of responsibilities, but are driven by a vital mission to promote and protect the health of all Americans.

Margaret Flinte...: Well, Dr. [00:31:30] Hamburg, we really appreciate you joining us. I appreciate all of your comments and especially that closing comment. Many thanks for that and many thanks to our audience for joining us. There's more online about conversations on healthcare, including a way to sign up for email updates. Our address is CHCradio.com. Dr. Hamburg, thank you so much for all of the work you've done in your career and more to come. Thank you.

Dr. Margaret Ha...: Thank you.