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Mark Masselli: This is Conversations on Health Care I'm Mark Masselli.

Margaret Flinter: And I'm Margaret Flinter.

Mark Masselli: Well Margaret there are some cause for celebration among those who had been watching the steady decline of funding for biomedical research in this country. The House of Representatives in a rare show of bipartisanship recently pass the 21st century cures bill which increases funding for research; it also facilitates ways to expedite their research process.

Margaret Flinter: Well while the US has led the world in support for biomedical research funding has been hampered for more than a decade Mark. And that $30 billion budget for the National Institute of Health has really stayed flat during that time which means its buying power has actually dropped, drop by 22% over a decade. And as we've heard from a number of guest on our show that's jeopardize research and also the careers of talented young scientist. So this is very welcome news.

Mark Masselli: It really is, the 21st century cures bill sets aside 1.75 billion dollars per year for research over the next five years. And would also tweak the government's drug approval process, that particular provision has some observers worried, however some are concern that would bypass long health safeguards aimed at keeping dangerous drugs off the market. But however the final agreement looks biomedical and drug research in the United States is likely to get a long overdue shot in the arm.

Margaret Flinter: And that is something that our guest today knows quite intimately Mark. Dr. Margaret Hamburg has recently stepped down as the Director of the US Food and Drug Administration and she has a unique insight into the complex role of keeping the nation's food and drug stream safe for consumption for all Americans. And that is really quite a herculean task.

Mark Masselli: It really is, and there have been many challenges and changes under her watch. So really looking forward to that conversation.

Margaret Flinter: And Lori Robertson will stop by the Managing Editor of FactCheck.org, she's always on the hunt for misstatement spoken about health policy in the public domain.

Mark Masselli: But no matter what the topic you can hear all of our shows by going to chcradio.com.

Margaret Flinter: And if you have comments please email us at chcradio@chc1.com or find us on Facebook or Twitter because we love hearing from you. We'll get to our interview with Dr. Margaret Hamburg in just a moment.

Mark Masselli: But first here is our producer Marianne O'Hare with this week's headline news.

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Marianne O'Hare: I'm Marianne O'Hare with these Health Care Headlines. The senate has voted to defund the Plant Parenthood as part of a long standing GOP effort to remove federal funding from the organization. It comes on the heels of the recent release of a series of doctored videos edited to look as though Plant Parenthood officials were paddling fetal body parts for money. Only 3% of Plant Parenthood's expenditures go towards abortion services the rest go for routine exams and preventive screenings for the nation's largely poor or uninsured population offering basic health services to 2.7 million American women and men as well.

The Department of Defense has decided on a contract for upgrading electronic health records for the veterans administration with the consortium led by **Sonor [PH]** a $4 billion plus contract aim at improving interoperability between systems that care for the nation's roughly 10 million veterans the military's goal is to use its new system to achieve health IT interoperability with thousands of civilian health care partners. That's because 60% to 70% of the care provided to the 9.6 million military health system beneficiaries is delivered by providers in the private sector.

Another goal be to enhance the military health systems interoperability with the veterans health administrations Vista EHR. Other analyst are looking towards this new experiment to see if it will break through the interoperability barrier plugging the current configuration of EHR vendors across the country.

Another large poultry manufacturing company is jumping in the no-antibiotics wagon Purdue announced it was facing out antibiotics use in their poultry populations, Tyson announced the program that would phase out their use within three years. High use of antibiotics in meat production has led to an increase in antibiotic resistant bacteria. I'm Marianne O'Hare with these Health Care Headlines.

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Mark Masselli: We're speaking today with Dr. Margaret Hamburg, Foreign Secretary at the Institute of Medicine now called the National Academy of Medicine. She recently stepped down as the Commissioner of the US Food and Drug Administration where she serve since 2009. Dr. Hamburg also served as Commissioner of the New York City

Department of Health and Mental Hygiene, Dr. Hamburg was elected to the board of the Institute of Medicine in 1994 and has received numerous awards among them the National Consumers League Trumpeter Award in 2011. She was listed as the 51st most powerful women in the world by Forbs. She earned her undergraduate degree from Radcliffe and her medical degree from Harvard. Dr. Hamburg welcome to Conversations on Health Care.

Dr. Margaret Hamburg: Well thank you very much.

Mark Masselli: You are appointed by President Obama in 2009 and like any new commissioner you probably ran into problems that you didn't expect and so talk about the climate when you arrived and how did you ride the ship?

Dr. Margaret Hamburg: It was a surprise to me to be honest when I got to the FDA to realize how broad and diverse the responsibilities of the FDA are from being responsible for overseeing the safety effectiveness and quality of medical products drugs, devices, vaccines, biologics to ensuring the safety of the nation's blood supply. The safety and security of the majority of the nation's food supply. It's estimated that about 20 cents maybe more of every dollars that consumer spend on products or in products that in fact are regulated by the FDA. And products that people care about, you know, whether it's the medicine that they take, the food they put on their table.

So we're an agency that makes a difference in the lives of people and in our economy in terms of the industries that we regulate. But an industry that people like to blame sadly for a lot of things. But I have to say that, you know, FDA really does an extraordinary job trying to weigh risks and benefits responding quickly when problems do happen and, you know, really trying to engage in a positive constructive way with all of our partners.

Margaret Flinter: Well, Dr. Hamburg I think you have just given me a really good understanding of why the job of heading the FDA has been described by Time Magazines as one of the toughest jobs in government and there must be quite a sort of seen and unseen matrix of partnership that the FDA works with to keep Americas food and drug safe. What is the relationship between the FDA and other health and safety organizations?

Dr. Margaret Hamburg: There isn't anybody else that's going to backstop behind the FDA to do the job. And in that context it's important to recognize that the world is getting more and more complex and the FDA role more challenging and frankly more resource intensive. And globalization has really change the contours of FDA work and responsibility.

The products that FDA regulates are increasingly coming in holler and part from other countries in other parts of the world. And for FDA to fulfill its mission which is to

promote and protect the health of the American public it actually has to engage a new and important ways with partners around the world about 40% of the finished drugs that are taken in the United States are actually made somewhere else. And about 80% of the active pharmaceutical ingredients in drugs are being manufactured in other countries. But the food side is actually equally startling about 50% of the fruits and nuts eaten in this country are coming from other countries, over 85% of the sea food coming from other countries.

And these products are often coming in holler and part from countries with much less sophisticated systems for safety and regulatory oversight. The notion that the old model for the FDA of just inspecting things as they came over the border could no longer apply, we were seeing, you know, tens of millions of import lines coming in dramatically in, you know, more than 300 different crossings around the country.

So we really felt we needed both to push our presence out closer to where the products were coming from and establish offices in countries around the world that could be hubs for activity. But also engage in new ways with our counterparts and with industry to really try to raise quality and standards and oversight throughout the whole supply chain for these products. So we've actually help to create whole new governance mechanisms that cut across national and regional boundaries, new authorities that congress has given us in recent years that enable us to work in a more collaborative way with our counterparts.

Mark Masselli: You know, I wanted to pull the thread on the statement you made about the work being complicated and certainly the plan B birth control making it available to teens and adults over counter. And then also the serious problems with compounding pharmacies and I'm wondering could you describe your administrations response to those issues and what did you learn from those and other challenges you encountered?

Dr. Margaret Hamburg: You really have to have science as your guide and that was certainly what happened with the plan B case FDA scientist and companies had been really looking at both the science and the best practice and use about indications for use and approval of a plan B product for over the counter use.

Studies had been done and the data demonstrated that even the younger ages safety risk were extremely minimal that health benefits were measurable and it met the criteria for FDA approval. I was disappointed by the decision to overwrite the recommendation of the FDA which had been arrived at over a period of many years, looking at data but coming to the conclusion about safe and appropriate use.

And in fact the case ended up going to the courts and the decision of the FDA was supported. But that was very difficult, I felt that clearly my role was to take a clear eyed look at the data and to make the best recommendation based on that and have to

navigate across waters that are rather choppy with very different political and social perspectives.

The FDA's responsibility is really a life ban approach and it would be very unrealistic to think that you can know everything about a product at the time of approval. So really FDA takes a life ban approach and always doing course adjustments when appropriate.

Margaret Flinter: You are credited I think with significantly increasing the number of drugs that were approved for use in the market place. Maybe you could talk about some of the challenges and your solutions around approving things in a shorter timeframe or getting drugs that offer real promise out there in the market place sooner.

Dr. Margaret Hamburg: You know, I mentioned earlier that FDA's mission is to promote and protect the health of the public but there also is a real responsibility to ensure that FDA's facilitating the availability of facing effective products as timely way as possible. We took a very serious look at our business processes and our systems to make them as streamlined and modern as possible.

The critical issue is not how long does it take for the FDA to review a drug, it's actually a very short timeframe people are astounded by how quickly some of the review times in fact are. But the critical thing is how long does it take to go from that important discovery that shines a light on a new opportunity to getting that product into the clinic or into your medicine cabinet. And that’s where I think we did some of our most dramatic work in changing the thinking because we really understand the FDA really understands about what it takes to demonstrate the safety and advocacy of a product to ask and answer a set of critical questions about what are the risks and what are the benefits and for whom.

Also questions about quality manufacturing and how do you scale up from something that you might be able to make for a limited number of people but can actually be manufactured in a way that’s reliable. And so all of those things are part of the, you know, day in day out experience and expertise of the FDA. And so we try to create new partnerships with academia and with industry scientist to try to really create an approach that reflected a much more modern streamlined R&D process as well.

What we've learned in recent years is that the more FDA engages provides feedback about what kinds of studies need to be done, how best to frame the research as something move along the product development pipeline. That you can actually decrease the R&D time and cost which at the end of the day matters enormously for patients and matters in terms of more efficient use of research dollars. And certainly makes for a more robust industry as well. So it's a win-win-win I think and of course FDA has a unique and special role as the regulator that always has to be accounted for and address.

But this notion that FDA should sort of fit in a isolated place waiting for the application to cross our threshold has slowed the process and that it is, you know, really a much more dynamic research environment now. And we're seeing a lot of exciting work that is effecting whole classes of products, how do you use genomic information, how do you design and implement much more innovative clinical trial design, how do you use big data into, you know, who response to certain products. So there's an enormous opportunity to really integrate the knowledge and experience of FDA to have a much more effective R&D approach to really deliver its promise.

Mark Masselli: We're speaking today with Dr. Margaret Hamburg she recently step down as Commissioner of the US Food and Drug Administration where she serve since 2009. Dr. Hamburg also served as Commissioner of the New York City Department of Health and Mental Hygiene. Dr. Hamburg there have been some important and dramatic rulings at the FDA in a recent months and I'm sure many of those started under your tenure. The recent FDA ruling to eliminate trans fats from the food stream within three years. And also a call for the meat and poultry industries to scale back their rampant use of antibiotics in food production. Could you tell our listeners about some of these recent developments and the research that led to it?

Dr. Margaret Hamburg: The removal of trans fat in the American diet I think is going to be one of the things that’s recognized overtime as making the most difference in terms of preventing disease and truly saving life. It was a number of years ago back in the mid 2000s when FDA first started requiring companies note the presence of trans fat and company started to reduce the levels of trans fat in processed foods.

FDA fairly recently took the step to actually move towards elimination of artificially added trans fats. We do learn more about risks and benefits of products then it does need to be reflected in information for health care providers and for consumers. And in some instances it does lead to more aggressive action including sometimes recalls of products but that's part of, you know, what is I think the normal cycle of understanding and the need to keep deepening knowledge about products and their use.

Margaret Flinter: Well Dr. Hamburg I suspect that your very broad and very global perspective is going to be of immense value for you in this new chapter as the Foreign Secretary at the Institute of Medicine. And, you know, we follow the work of the IOM, we had the former institute director Harvey Fineberg on the show talking about the broad scope of the IOM's work. What does it mean to be the IOM foreign secretary and what will you be doing in this capacity on the global front?

Dr. Margaret Hamburg: We officially are the National Academy of Medicine, part of what is a great historic institution the National Academy of Science is about three branches. My interest in serving as the foreign secretary is to be able to continue and

extend my interest in global health which began before I was at the FDA working on biological threats to help infectious disease threats that are naturally occurring as well sadly as biological threats including biological weapons and biological terrorism. Working on global health problems like TB, malaria, HIV and then at FDA working on globalizations and global health issues from the perspective of consumer products safety, globalization of supply chains and the growing issues of counterfeit and substandard medical products as well as food supply

And you know, it's really more important than ever before for organizations that maybe domestic in their organization but really now operating in a world that is globalized. And certainly science, medicine and public health are global enterprises. The problems are shared across borders and regions and the solutions have to be shared. And so I think it's an exciting way to interact with other academies of medicine to work on the important core mission of the academies which is to use science to inform policy to make the world a better safer place. And I think that this role of foreign secretary will allow me to work in important and powerful ways.

Mark Masselli: We've been speaking today with Dr. Margaret Hamburg recently the Commissioner of the US Food and Drug Administration and now Foreign Secretary of the Institute of Medicine now called the National Academy of Medicine. You can learn more about her work by going to IOM National Academies.org Dr. Hamburg thank you so much for joining us on conversations today.

Dr. Margaret Hamburg: My pleasure thank you.

(Music)

Mark Masselli: At Conversation on Health Care we want our audience to be truly in the know when it comes to the facts about health care reform and policy. Lori Robertson is an award-winning journalist and managing editor of FactCheck.Org a nonpartisan nonprofit consumer advocate for voters that aim to reduce the level of deception in US politics. Lori what have you got for us this week?

Lori Robertson: Former New York Governor George Pataki who is running for president said that the Affordable Care Act is preventing economic growth and forcing millions and millions of Americans to work only part-time. But economic evidence contradicts that, Pataki made the claim at a GOP candidate forum in New Hampshire. Let's start with the part-time claim which many republicans have made, the ACA defines a full-time workers as one working 30 hours a week and there have been news reports of employers of low wage workers saying they might cut hours to avoid a requirement to provide insurance to full-time employee.

But data from the bureau of labor statistic show the trend is in the opposite direction. The number of those working part-time involuntarily for economic reasons has gone down. It was 6.5 million in June, 1 million lower than last years and 2.7 million lower than it was in March 2010 when the ACA was enacted. As for the economy it has been growing, real grow domestic product grew at a yearly rate of 2.3% in the second quarter of this year says the commerce department. And final estimate show positive growth in 8 of the 9 previous quarters, that's my fact check for this week, I'm Lori Robertson Managing Editor of FactCheck.org.

Margaret Flinter: FactCheck.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 chcradio.com. We will have FactCheck.org's Lori Robertson check it out for you here on Conversations on Health Care.

(Music)

Margaret Flinter: Each week Conversations highlights a bright idea about how to make wellness a part of our communities and to everyday lives. As the saying goes music soothes the savage beast. And according to a recent study conducted by Queen's University in Belfast, Ireland there is some empirical data to back that up. In a first of a kind longitudinal study children suffering from a variety of behavioral and emotional conditions who are expose to music therapy in addition to traditional therapies had far better outcomes than those children in a control group that offer traditional therapy without music therapy.

Dr. Sam Porter: Basically it's by treating children with emotional and behavioral problems with music therapy in addition to normal psychiatric care. It's not a matter of them been given music or choosing music they actually make music along with music therapist assisting them. So the idea is for them to express themselves through music.

Margaret Flinter: Lead researchers Dr. Porter said there's been anecdotal evidence that music improves mood in children and adolescence as well as adults. But his study reveal just how effective the music therapy was.

Dr. Sam Porter: Our primary item was an improvement in communication, there were two very interesting secondary outcomes, levels of depression and levels of self-esteem. And then the secondary outcomes we find is statistically significant difference between the control group and the intervention group.

Margaret Flinter: Dr. Porter says in the group given musical therapy it showed over time more interaction with their surroundings and a better response to the traditional therapies as well. And he says the effects were sustained overtime.

Dr. Sam Porter: I mean that's one of the marvelous things about music therapy is the things that (inaudible 23:50) there are no side effects it is not a dangerous therapy to get kids involved and that it is a -- it's a productive way of getting kids to improve health and that is just such a good way and a harmless way doing thing so it's really satisfying to know there is also an effective way of doing it.

Margaret Flinter: The study was conducted in conjunction with the Northern Ireland Music Therapy Trust which sees the promising findings as an incentive to incorporate this relatively low cost non invasive therapy into standard protocols as an additional tool to enhance outcomes for the youth population which often suffers negative side effects from a powerful medications. A simple targeted music therapy approach age appropriate and showing great advocacy and improving outcomes for young patients with minimal side effects and lasting benefits, now that's a bright idea.

(Music)

Margaret Flinter: This is Conversations on Health Care. I am Margaret Flinter.

Mark Masselli: And I am Mark Masselli. Peace and health.

Conversations on Health Care broadcast from the campus of WESU at Wesleyan university. Streaming live at wesufm.org and brought to you by the community health center.