

NATIONAL PRESS CLUB LUNCHEON WITH DR. MARGARET HAMBURG

SUBJECT: DR. HAMBURG IS THE OUTGOING COMMISSIONER OF THE U.S. FOOD AND DRUG ADMINISTRATION.

MODERATOR: JOHN HUGHES, PRESIDENT OF THE NATIONAL PRESS CLUB

LOCATION: THE HOLEMAN LOUNGE, WASHINGTON, D.C.

TIME: 12:30 P.M. EDT

DATE: FRIDAY, MARCH 27, 2015

(C) COPYRIGHT 2008, NATIONAL PRESS CLUB, 529 14TH STREET, WASHINGTON, DC - 20045, USA. ALL RIGHTS RESERVED. ANY REPRODUCTION, REDISTRIBUTION OR RETRANSMISSION IS EXPRESSLY PROHIBITED.

UNAUTHORIZED REPRODUCTION, REDISTRIBUTION OR RETRANSMISSION CONSTITUTES A MISAPPROPRIATION UNDER APPLICABLE UNFAIR COMPETITION LAW, AND THE NATIONAL PRESS CLUB RESERVES THE RIGHT TO PURSUE ALL REMEDIES AVAILABLE TO IT IN RESPECT TO SUCH MISAPPROPRIATION.

FOR INFORMATION ON BECOMING A MEMBER OF THE NATIONAL PRESS CLUB, PLEASE CALL 202-662-7505.

JOHN HUGHES: (Sounds gavel.) Good afternoon, and welcome. My name is John Hughes. I'm an editor for Bloomberg First Word, that's our breaking news desk here in Washington. And I am the President of the National Press Club. The Club is the world's leading professional organization for journalists. We are committed to our profession's future through programs like this, and we work for a free press worldwide. For more information about the Club, visit our website press.org. To donate to programs offered through our Club's Journalism Institute, visit press.org/institute.

On behalf of our members worldwide, I'd like to welcome our speaker and those of you attending today's event. Our head table includes guests of the speaker as well as working journalists who are Club members. Members of the public attend our lunches, so applause you hear is not necessarily evidence that journalistic objectivity is lacking.

I'd also like to welcome our C-SPAN and Public Radio audiences, you can follow the action on Twitter using the hashtag NPCLunch. After our guest's speech, we'll have a question and answer period. I will ask as many questions as time permits.

Now it's time to introduce our head table. I would ask each of our guests to stand briefly as names are announced. From the audience's right, Dr. Charles Snyderman, Health and Science Correspondent for Audio Visual News. Ferdous Al-Faruque, Health Reporter for The Gray Sheet. Paula Dellow, President of Paula Dellow and Associates and former Executive Editor of NASW Press. Varun Saxena, News Editor at Fierce Medical Devices.com. Matthew Perrone, Health Reporter for Associated Press. Dr.

Beatrix Hamburg, guest and mother of our speaker. Jerry Zremski, Chair of the NPC Speakers Committee, Washington Bureau Chief for the Buffalo News, and a former National Press Club President.

Skipping over our speaker for a moment, Doris Margolis, President of Editorial Associates Health and Science Communications and the NPC member who arranged today's program. Thank you Doris. Dr. David Hamburg, guest and father of our speaker. Susan Heavey, Correspondent for Reuters News. Sarah Reardon, Biomedical Research and Policy Reporter for Nature Magazine. Anthony Shop, a member of the National Press Club Board of Governors and Chief Strategy Officer and cofounder for Social Driver.

[applause]

Keeping consumers safe when they take prescription drugs or eat food or use medical devices or consume tobacco products or wear cosmetics or get vaccinated, these are not small tasks. And these tasks fall to the Food and Drug Administration. These products are important to consumers and to companies and the economy. So of course, there can be controversy when the FDA plays the role of referee. For instance, we've heard questions such as, "Are products safe enough? Is the FDA taking too long to approve a new drug or device?"

Well, for nearly six years, Dr. Margaret Hamburg has led the FDA as its 21st Commissioner. No surprise, the agency has been the target of both criticism and commendation as it has touched a broad range of issues during Dr. Hamburg's leadership. For example, three years ago, an outbreak of fungal meningitis traced to a compounding pharmacy resulted in criticism that the FDA hadn't provided adequate oversight. On the other hand, the agency's accelerated vetting process, which has sped drugs to the market faster, has been welcomed by patients and their families as well as the pharmaceutical industry.

Dr. Hamburg is a graduate of Harvard Medical School. She has a background in infectious disease, bioterrorism, neuroscience, neuropharmacology, and health policy. Before her appointment as FDA Commissioner, she was the senior scientist at the Nuclear Threat Initiative, a nonprofit dedicated to reducing the risk of nuclear chemical and biological weapons.

Hamburg will retire next week as one of the longest serving Commissioners in FDA history. Please give a warm National Press Club welcome to Dr. Margaret Hamburg.

[applause]

DR. MARGARET HAMBURG: Well thank you so very much. I'm very pleased to be here and really delighted to be joined by my parents, as you heard, and also by many of my friends and colleagues. This is probably my last formal address as FDA Commissioner. So I thought it would be a nice opportunity for me to reflect a bit on what

I have learned about this agency. And what I really want to communicate to you is how firmly I believe, now more than ever, that this is an agency that is absolutely essential to the lives and health of every American, every day. And I think it's hard to overstate, really, the unique and vital importance of this agency for all of us.

But I'll confess that I really didn't arrive at the FDA with a fully formed perspective. I guess I said yes to the job a little bit early. I didn't appreciate the vast scope of FDA until I was actually ensconced in the job. It still amazes me that the products that we regulate account for somewhere between 20 and 25 cents of every dollar that consumers spend on products in this country. More specifically, FDA is responsible for promoting and protecting the public health by ensuring the safety, efficacy and security of human and veterinary drugs, vaccines and biological products, medical devices, the safety of most of the food supply, the blood supply and other tissue products, cosmetics, and products that emit radiation. And then, most recently, FDA is responsible for regulating the manufacturing, marketing and distribution of tobacco products.

And some things might surprise you about some of the products that we regulate, ranging from things like bionic eyes and replacement body parts that are made by 3-D printers, to the use of medicinal leeches. That was one that surprised me. We oversee the safety of the food that dignitaries eat at government events, like the State of the Union. And I just learned last week, actually, that we are responsible for regulating the waste that is discarded from moving trains.

So you can see that, wherever you are, the FDA is working for you. But it's not just the diversity of the products that we oversee that some might find surprising. It's the way that we bring our enormous expertise to bear. In this age of skepticism about government, it's easy to imagine FDA regulators simply as bureaucrats focused on a narrow set of responsibility. Yet nothing could be farther from the truth. What a remarkable group of physicians, scientists, lawyers, policy analysts, and other professionals and support staff, committed to helping people get the products that they need and count on. And I'm so happy that some of those FDA employees are here with us today.

I also was really very struck by the fact that FDA employees do far more than just use their knowledge and expertise to review applications or investigate safety concerns. But they also undertake vital research to advance medical product innovation and improve food safety. For example, scientists from our Center for Biologics made a crucial contribution to the development of the MenAfriVac meningitis vaccine, by developing a needed conjugation technology. And this vaccine has now protected more than 217 million people from what was a deadly killer across the so-called meningitis belt in Sub Saharan African.

FDA's food scientists have helped develop sophisticated genome sequencing technologies to more rapidly identify and stop food-borne outbreaks. And during the Gulf oil spill, I was surprised but very grateful when another team of FDA scientists developed a new laboratory technique that significantly accelerated the testing process that was

necessary for detecting certain oil-related chemicals in the seafood itself. And that enabled the FDA and the states to open up the Gulf waters to fishing much more rapidly. And it also meant that the rather agitated Congressional Gulf Delegation stopped calling me all the time. So that was really a worthy undertaking.

And it was also a surprise to me, as FDA Commissioner, that during that period, I was actually ordered by the White House, twice, to go to New Orleans and eat seafood, to show that it was safe. So there are some hardship duties in this job. [laughter]

Obviously, there are a lot of things that we could talk about. But I want to focus on a few key issues today, issues that I've really been intent to work on since I began, and that I believe have really made an important difference in strengthening and reaffirming FDA's critical role in American society.

I think that most would probably agree that I came to FDA at a time when the agency faced considerable difficulties and uncertainties. A series of visible food-borne outbreaks had resulted in disease, nationwide anxiety, and economic disruption. Several drug safety crises, Vioxx for one, had eroded public confidence. At the same time, FDA was facing serious resource threats. Budgets were tightening with the economic crisis. But chronic underfunding had already stretched the agency thin in many critical areas, and jeopardized our ability to keep up with inspectional demands, product reviews, and with evolving science and cutting-edge biomedical products, at the very time that scientific and technological discoveries were revolutionizing medical products.

FDA's challenges were exacerbated by the increasingly global marketplace for the products that we regulate. Imports of FDA regulated products were growing dramatically. And there was a series of serious episodes associated with adulterated products coming from overseas, most notably the imports from China of tainted heparin, some of you may remember that, and the melamine-laced dairy products and pet foods that cause deaths and serious illness.

These effects and a constant negative drumbeat from our friends in the media, combined with the congressional criticism, took a toll. Public trust was flagging. Yet it was clear there was so much good work going on. Indeed, as I took stock of the agency, its vast responsibilities, and its enormously talented and committed workforce, it was clear that FDA was at a crossroads, and decisions made then would matter in fundamental ways and for a very long time.

If FDA was truly to fulfill its mission in the modern era, this was a critical time to reposition, in several fairly fundamental ways. To do this, I focused on three priority areas, increasing public engagement, accountability in partnership, reinvigorating our scientific base by advancing regulatory science, and underscoring the need for science-based decision-making, and scientific integrity as the foundation for all that we do.

And lastly, addressing the challenges of globalization and its huge implications for health, safety and security of the products we regulate. Six years later, thanks to an

extraordinary leadership team at the FDA and all of the dedicated employees, I think we have seen enormous progress and really important advance. We've renewed, expanded and refined our mission and activities in important and powerful ways.

Notably as well, Congress has given us important new authorities to regulate cigarettes and other tobacco products, to transform our nation's food safety system with a new focus on prevention, and to use more flexible and streamlined approaches to bring exciting new medical products to patients in record time.

To be effective, FDA must do its vital work with input from stakeholders and with the trust and confidence of the public. That's why it was imperative to increase transparency, enhance stakeholder engagement, and strengthen partnerships across sectors, disciplines and components of government. And I really think we have. Soon after I arrived at FDA, we launched an agency-wide effort to make useful, understandable information about the FDA more readily available to our stakeholders. This transparency initiative brought greater clarity and understanding as to what we do, how we do it, and why, for the general public, for industry, for patient and consumer groups, and for other key stakeholders.

We also worked to increase collaborative efforts, including establishing many important public/private partnerships. We enhanced our communications, including listening sessions with leaders, experts and advocates, seeking ideas and feedback, as well as a focus on patient-centered medicine, which involves holding dozens of public meetings with patient advocacy groups for input on specific diseases.

With stronger stakeholder engagement, there's been much better information sharing, more predictability, and ultimately a better process and products to the people we serve.

My second priority, science, really builds on and reinforces the efforts just mentioned. As a science-based regulatory agency, our credibility and success depends on our ability to deliver on the promise of science through smart, data-driven decisions that benefit patients and consumers. Smart regulation also requires the ability to respond to changing situations, new information and new challenges. We cannot have a one-size-fits-all approach. But we always must bring the best science to bear.

And it requires that we advance regulatory science. The knowledge and tools necessary for the meaningful and timely review of products for safety, efficacy, quality and performance, and to inform a more efficient product development process as well. Building on greater understanding of the underlying mechanisms of disease and human biology, a robust field of regulatory science, can help us leverage opportunities for innovation and more quickly bridge the gap between scientific discovery and the real world products that will make a difference in people's lives.

So advancing regulatory science has been a huge priority, not just within the walls of FDA, but as an active dynamic field of scientific research. We're continually working

to find new and better ways of doing things, to seize new opportunities that exist in science and technology, and to work with industry and our scientific partners in academia and government, in a collaborative way, to discover and apply new regulatory tools.

But what does this really mean? In the foods area, using regulatory science, we've taken critical actions that will improve the safety of the food Americans consume for years to come. Importantly, the development of science-based standards to create a food safety system focused on preventing food-borne illness has been key, thanks to the passage of the Food Safety Modernization Act, as well as new tools to help us in the detection and rapid response to outbreaks, as I mentioned earlier.

We've also taken several significant steps to help Americans make more informed and healthful food choices. These include working to reduce trans fats in processed foods, more clearly defining when baked goods, pastas and other foods can be labeled "gluten-free," updating the iconic nutrition facts label, based on current nutrition science, and most recently finalizing the rules to make calorie information available on chain restaurant menus and vending machines. And some of you may be asking, "Well where is the science there?" But believe me, and Mike Taylor, our Deputy for Foods knows these areas are based on sound and current nutrition science and involve some very complicated analyses.

Turning now to the medical product domain, we're pursuing such things as enhancing the use of pharmacogenomics and qualified biomarkers, developing innovative clinical trial designs, which enable clinical studies to be smaller, more efficient, and more adaptive, and developing new strategies using bio informatics to more effectively mine large databases, to learn more about issues of both safety and efficacy, as well as such things as how can we identify sub-populations of responders to a given treatment, based on certain indicators.

These efforts matter in our ability to swiftly and surely review product applications that come before us. And they're also essential for reducing the time and cost and increasing the likelihood of success in the product development process itself. In the ecosystem for biomedical product development, FDA plays a critical role, because we more fully understand what it takes to translate a good idea into a product with demonstrated safety, efficacy and quality, and a product that can be scaled up and reliably manufactured.

Simply waiting until we see what comes through our doors cannot be the going model. FDA is uniquely situated to examine important unmet medical and public health needs. And how they match up with what's actually in the development pipeline. And indeed, a growing part of our focus in recent years has been to try to identify what's in the development pipeline, provide guidance and incentives to address gaps, and to accelerate progress, and to foster the kind of innovation that will make a real difference for patients.

Also, we've seen how early and continuing engagement between the FDA and researchers in the product development plan makes a huge difference in streamlining the

process and making sure that the right questions get asked and answered from the very beginning.

As you may know, we have now in place a number of expedited review programs that help to speed the development and availability of medical products that treat serious diseases. For prescription drugs, we have fast track, priority review, accelerated approval. And now, thanks to recent legislation, we have the breakthrough therapy designation. And we're seeing both development and review times decrease significantly, with exciting new therapies entering the marketplace much sooner for the patients who need them.

And last year, we approved the most new drugs in almost 20 years, and more orphan drugs than ever before. Forty-one percent of these new drugs were first in class products, resulting in a breathtaking array of truly innovative new therapies for patients. And the majority of these new drugs were approved using some kind of expedited pathway.

Today, contrary to what many would say, FDA approves drugs faster, on average, than all other advanced nations. And the vast majority of the time, the U.S. is the first country in the world to approve important and novel medicines. And substantial improvements are being made in the efficiency of medical device reviews as well.

Moreover, we have accomplished this while remaining the world's gold standard for safety and effectiveness. Yet we all recognize that, despite these successes, too many diseases still await treatments and cures. Serious public health needs such as treatments for Alzheimer's disease are not being met. In response, some have said that FDA regulation is the principal obstacle to the development of innovative treatments, and suggested that FDA's authorities and procedures be fundamentally reconsidered.

I strongly disagree. In actuality, regulation, when it's done right, is not a roadblock. It's the actual pathway to achieve meaningful and lasting innovation. Smart, science-based regulation instills consumer confidence in the products and treatments. It levels the playing field for businesses. It decreases the threat of litigation. It prevents recalls that threaten the industry reputation and consumer trust, not to mention levying huge preventable costs on individual companies, and, in fact entire industries. And it spurs industry to excellence.

The fact is, when done right, smart regulation allows us to deliver on the promise of science in the service of patients, consumers and yes, even industry. It is foolish, in fact dangerous, to believe that reducing regulatory standards will make new treatment interventions appear if the science is not there. Alzheimer's, I think, is a good example. I've heard comments of late that something must be wrong at FDA because we're not approving as many drugs for Alzheimer's as we are for cancer. And we're certainly not doing it as quickly.

Yet the reality is not the problem of unnecessary regulatory hurdles, but rather the need for medical research to increase our understanding of the underlying disease process, the natural history of the disease, and where are the best targets for therapeutic development. We're working closely with the Alzheimer's research community and patient groups to do everything we can to help advance possible treatment strategies and product development approaches. And I hope that, in fact, we will see meaningful progress soon.

And of course, there are sometimes tensions between moving new, potentially promising products, swiftly out into the marketplace, and making sure that they have been adequately studied. As FDA Commissioner, I have been surprised by how many people ask whether I favor safety or innovation. And in fact, at my confirmation hearing, now quite a while back, I was really, I guess, a bit of an unknown commodity to both the consumer and patient groups and industry. And they were trying to figure out what perspective I would bring to this new position.

And I was surprised to learn that someone supposedly went through and counted how many times during the course of the hearing I said "Safety," and how many times I said, "Innovation." And this was supposed to be a measure of whether I was going to be consumer-friendly or industry-friendly. And I'm told that it was actually about equal. But I never went back to actually check.

But I certainly don't believe that the two are mutually exclusive. Why should we have to choose protecting the public health while encouraging, not discouraging innovation, must be the goal? And for us at FDA, it is. After all, innovation is only meaningful if it makes a real difference, a positive difference, in the lives of patients and consumers. And that's why we must have standards and science to assess the benefits and risks.

And, when it comes to the treatment of disease, we must understand the broader context of ease, the nature of that specific disease or condition, the other treatment options, and such things. We must also better understand the patient's experience to the disease and its treatment, their perception of the risks and benefits, and of course, their willingness to accept risks.

The balancing of risks and benefits is absolutely fundamental to the FDA's role. And it's always a challenge. We joke that the FDA, we have only two approval speeds, too fast and too slow. We're perceived as too quick to approve a drug or device when a significant safety issue is identified in the post-marketing context once the product is in widespread use.

On the other hand, we're too slow when a drug that has undergone a lengthy development and review is finally approved and provides a real therapeutic benefit for patients. So it's a hard task. But the challenge for FDA scientists is to strike the right regulatory balance.

I also want to speak briefly about the importance of striking the right balance between fast access and good science. In the race for the newest treatment, we must remember the point that innovation doesn't matter if the product doesn't work. I can't emphasize enough the critical need to maintain the standards of safety and effectiveness for medical products in this country. It wasn't that long ago that companies were allowed to market drugs without proving that they were effective. We've only got to look back at that time to see the devastating consequences for patients and for medicine.

Drugs were marketed for thousands of unproven uses, most of them unsupported by adequate research. When in the mid 1960s Congress gave FDA authority to require evidence of effectiveness, almost 80 percent of the drug uses that companies were promoting turned out to be ineffective. Many of them were also dangerous. For example, before companies had to show that their drugs worked, drug companies widely promoted powerful toxic antipsychotics like Thorazine for low level anxiety.

And there was little or no incentive to conduct the research necessary to find out what were true medical advances. Most promotion was based on unscientific studies or no studies at all. It's important, I think, to understand that FDA strongly supports responsible communication of scientific information. But we do not support an approach that will harm patients or undercut the incentives for the necessary studies to be done to prove that a specific use of a drug product is both safe and effective.

History has shown that patients have been harmed from physician reliance on preliminary or incomplete scientific information regarding unproven uses. History has also shown the enormous patient benefits that result when a sponsor conducts rigorous clinical studies and demonstrates that a promising medical product is in fact safe and effective in treating a serious disease or condition.

FDA's objective is to strike the right balance between respecting the usefulness of communicating scientific data in certain circumstances on the one hand, and preventing harm to the public on the other. We must not forget that the great leaps forward in evidence-based medicine of the last 50 years have come in large part as the result of the high standard for product approval that Congress put in place after a series of disasters involving unsafe and ineffective medical products.

Those standards have boosted the confidence that Americans place in medical products and the world places in the American biomedical product industry. We must move forward, not backwards as a nation, and embrace the opportunities, cutting-edge medical advances, and the promises that they hold for public health.

I want to just talk about one other important issue that's been a priority. Globalization. When FDA was first established, our regulated industries were predominantly local. And the volume of imported products was very low. Today, however, other nations increasingly produce, in whole or in part, the food and medical products that American consumers and patients use in their daily lives. Nearly 40 percent

of finished drugs Americans consume today are made elsewhere. And 80 percent of the active pharmaceuticals in those drugs are manufactured outside our borders.

And for the food supply, the numbers are equally startling. More than 85 percent of seafood that's eaten here comes from other countries. About 50 percent of our fresh food and 20 percent of our fresh vegetables. And these changing dynamics obviously introduce new complexities, new risks for American consumers as these products fall increasingly in your kitchen cupboard.

We can no longer rely on simple inspections at the border to track the products that are coming through. The volume has quadrupled over the last decade. We have introduced new high tech risk-based screening systems at the borders to allow us to target the most vulnerable commodities, the ones with the highest risk. But we really have to step beyond our borders to the places where these products are being manufactured, processed, distributed.

And that has caused us to have to undertake a whole new shift in how we do business. We now have foreign outposts around the world to be a hub for inspections and for collaboration with industry, counterpart regulators, and other stakeholders. We're working closely with counterpart regulatory authorities to harmonize standards, to share information, and in fact, to share the workload of inspections and assessment of the products that we're all struggling to regulate in a globalized world.

And we are working together with other organizations and nations to try to actually build regulatory capacity in many of these countries, with very immature systems, but where an increasing volume of products are coming and being consumed by Americans who expect the same standards in the products they're taking wherever they've come from in the world. So that has been a major focus of time and attention, and I think represents a huge and under-recognized area that challenges health, safety and security in our nation.

So I think that, though I've got lots more I had wanted to talk about, I think that I've gotten the indication that I ought to be winding down. So with that, let me just make a couple of points. One is that FDA is a unique and essential agency that has a set of roles and responsibilities that are not done by anyone else. If we can't do our job and do it well, there's nobody else to backstop behind it.

Moreover, we're regulating products that are so important to each and every one of us, every day, and to the health of our nation, our nation's economy, and in fact, our global economic competitiveness. As I look forward, I worry. FDA has constantly been underfunded with responsibilities that outstrip the resources we get to do our job. If you look at what it costs every American in this country to support the services of FDA, believe it or not, it's eight dollars per American per year. And I suspect some of you may spend more than that at Starbucks later this afternoon. And yes, we regulate Starbucks.
[laughter]

So as I stand here, not only concluding my remarks but concluding my tenure very soon as FDA Commissioner, I really am proud to be able to tell you that FDA is a stronger, more engaged, more effective agency, better positioned for the challenges of the 21st century. We're an organization that embraces smart science-driven regulation. We're an organization that understands in the modern world the importance of partnership. We have a wonderful mission and an extraordinary group of employees. We have big challenges before us. And we do need your help and support.

So, while I will not be present any longer, I do want to leave you with the fact that the FDA, as a public health agency, is central to the health of all of you. We need to strengthen it rather than weaken or undermine it. And to do so will require support and partnership of all our stakeholders. And every American who uses FDA regulated products is a stakeholder.

So I look forward to watching that vital collaboration amongst all of the stakeholders, and just seeing the work of this relatively small in size, but truly mighty in purpose, agency, be both appreciated and supported. Thank you.

[applause]

JOHN HUGHES: Thank you, Dr. Hamburg. You mentioned in your talk striking the right balance. When it comes to approval of products and devices, and from the experience of your tenure, what percentage of the time would you say that FDA got it right? And what percent of the time did you realize that we didn't do our job there, and maybe we should not have let that one out?

MARGARET HAMBURG: Well, I think that's a very hard question to answer and to quantify would be a dangerous task. I think one of the things that's important to understand, though, is that we are always having to make decisions with partial information, because when you are doing the studies before a drug is actually approved, you can learn a lot. And if the drug really works, and really reflects, you know, a good match between the target of the drug and the underlying mechanism of the disease, you know, you'll know it quickly, and the decision will be obvious.

But, with many things that don't work quite as well, it would be almost impossible to know everything about the drug, and even the things that actually are extremely effective, you still can't know everything about them in the context of a preapproval development process. It's when they go out into the marketplace and are used by many more people, and are used by people with other coexisting diseases, and taking other medications etcetera, that you begin to learn a whole lot more.

And that's why, actually, FDA takes a lifespan approach to the regulation of drugs. And we continue to monitor drugs after they have been approved, both through what we call post-market surveillance, and sometimes by requiring post-market studies, to collect more information.

So, you know, in my view, people are quick to jump on us if a safety issue emerges in the post-market setting, and think that it's a failure of the system, and someone had to have made a mistake. But I think we know that everything has risks. And that the nature of the process is that some of those risks will emerge when many more people are taking the drug in these more complex settings.

And so I think that when we can detect it early, and make the determination about how to address it, whether we need to change the indications for use, whether we need to actually recall it from the market, or whether we need to provide additional warnings, all of those things are possible. And all of those things are part of a comprehensive regulatory process.

JOHN HUGHES: So you mentioned several things that you're proud of, about the agency. What would you consider the number one contribution that you have been able to make to public health in your tenure? What is the one thing that you would talk about, you know, a couple years down the road, when we're talking about your service, that one thing that you're most excited about?

MARGARET HAMBURG: Well that's an impossible question, number one, because there are many things in many different arenas. And given the scope of our responsibilities, it's unfair to even ask. [laughter] But you know, you think about the many different ways that you can answer the question also. If you mean in terms of potential impact on burden of disease, I would say we haven't realized the potential yet. But the new authority we have to regulate tobacco clearly is historic and transformative.

Tobacco products remain the leading cause of preventable death in this country and, frankly, around the world. And with the new tools we have over time, we will, I think, be able to make a profound impact on health and wellbeing in this country. And as regulatory authority, with a fairly unique regulatory responsibility for tobacco, we also, I think, are showing the way for many other countries around the world and the global burden of tobacco related disease.

JOHN HUGHES: I had a couple different questions passed up on what you think of the 21st century cures initiative in Congress to overhaul healthcare industry regulations.

MARGARET HAMBURG: Well I think we all can agree that this is a critical time to really look at what can be done to really leverage the opportunities in science and technology today to ensure that we are developing the safest, best, most innovative and effective medical products for people who need them. And that's the goal of 21st century cures. We are sort of in a golden age for this undertaking. And we want to make sure that all of the parts of the biomedical product innovation ecosystem are aligned towards that goal.

I do think that it needs to be approached in a very thoughtful and careful way, because many of the things that need to be done, perhaps are not best achieved through

legislation. I think, you know, for us, there are certainly concerns about issues that I touched on in my remarks, of the misperception that you might be able to speed innovation by lowering standards for safety and efficacy. And we think that would be a terrible mistake and ultimately would not just damage patients, but would damage industry as well.

We also are concerned that through this process we might be given what we call in Washington “unfunded mandates,” where we would be asked to take on a set of new tasks, but there wouldn’t be adequate resources to go with it. And that, I think, not only would be difficult for that specific activity, but would have ripple effects on other important regulatory activities that really matter to patients and consumers.

JOHN HUGHES: What, if any, steps is FDA taking to ensure truth in labeling of ingredients in vitamin and nutrition supplements, given recent findings on Wal-Mart shelves?

MARGARET HAMBURG: We have authority to regulate dietary supplements in a limited set of activities. Many people in this country think that the FDA regulates dietary supplements in the same way that we regulate prescription drugs with a pre-approval process. But we do not. We oversee and have the authority to ensure good manufacturing practices at their plants to-- There's a requirement that they report serious adverse events to us. And we do regulate claims that they make. And, when we find a product that has unapproved drug, for example, that shouldn’t be there, a steroid or a Viagra-like compound, frequently show up in dietary supplements, then of course we will take action. I'm not familiar with the specific Wal-Mart case, though, I have to say.

JOHN HUGHES: There have been concerns raised by patient advocacy groups and FDA officials that the agency’s medical device approval process is too lax. I think you referenced some criticisms in your talk. And how do you feel about the process now? And have you felt political pressure to accelerate product approvals? And what changes need to happen in that product approval process?

MARGARET HAMBURG: Well, the medical devices have a different regulatory pathway than drugs, and I think for some of the points that I was talking about in terms of the different perspectives that people have on FDA too fast or too slow, too lax or too stringent applies with medical devices. The majority of medical devices that FDA oversees, or what are called 510Ks, not the highest risk devices but the sort of middle category of devices, and there are very, very limited requirements for new data to be generated as a part of that approval process. You need to demonstrate that your product is similar to an existing product in the marketplace, using a predicate mechanism.

And some people find that just totally lax and inadequate to assess a changing device array over time. Others think that it’s more than enough and they would like to see even the standard that currently exists relaxed a bit. So, it’s one that I have been fascinated during my tenure as FDA Commissioner to see the differing responses and I think that we need to continue to look at how we regulate devices, because the world of

devices is getting increasingly complex on one end and then there is a set of other devices that really don't need much attention.

So, I think that this is an area where I don't know that the U.S. has gotten it completely right, I don't know that the European Union has gotten it completely right. I think it's an area that we need to continue to learn more about, and I think that we are encouraged by some of the activities, partly through public/private partnerships that have been developed to look at innovative strategies to do research that is necessary to better assess devices through a recent new requirement for unique device identifiers on devices so that we're going to be able to track devices and their use in the post-market setting more efficiently and learn a lot more about risks and benefits.

So I think it's a dynamic area.

JOHN HUGHES: I had a few questions come in on the relationship between the agency and those that it regulates, and this questioner says that within the ranks of the FDA there are many scientists and administrators who have served at the agency for decades, and one of the criticisms is that the leaders become too cozy with industry after working with years with the same officials. While FDA obviously strives to retain its best staffers is there a risk that staffers can overstay their welcome and then this problem creeps in?

MARGARET HAMBURG: Well, again, this is one of those areas where different people have very different perspectives. Some people believe that there are lifers at the FDA that have no use for industry and are always skeptical and then there are others who worry about the issue you were describing. What I would say is my experience at the FDA, which is now almost six years, is that the employees who work there have just remarkable commitment to their jobs and the highest integrity, scientific and personal integrity.

We obviously operate in a framework where there are very clear conflict of interest rules, very clear requirements about how certain kinds of interactions are structured, and I think that we need to work in partnership with industry, because we are regulating the products that they make and we need to understand those products, we need to have a full and open exchange of information. And in many instances there is great value in having industry, academia, and government actually work together in shaping research in critical areas.

I think people sometimes get worried about that, but you do it in a way that clearly defines this as pre-competitive research, it's not a collaboration where there is a particular product that is being developed where an FDA scientist might be working in the partnership, but it's where information is being developed that can be applied across a whole category of products and help us to advance our knowledge and develop the regulatory tools that are needed to advance our ability to do adequate and full reviews of the products and to enhance product development.

JOHN HUGHES: You have been a champion of advocating sodium reduction, and the majority of your statements reference blood pressure benefits of lower sodium consumption. However, some recent studies cited by this questioner, including one by the IOM, have suggested that low sodium consumption for healthy individuals can lead to significant health problems, and another article found that for healthy people there is no, or very minimal blood pressure impact from sodium reduction. The questioner is saying does the agency need to reevaluate what it says on sodium and is there any examination of shifting the view?

MARGARET HAMBURG: Well, this has been a topic of ongoing discussion. I think that clearly there have been some recent studies that have raised some questions and there have been individuals who have obviously been representing that position over time, but I think the body of evidence does really demonstrate a linkage between sodium in the diet and negative health consequences, and that American diets on average do contain a very large amount of sodium, and most of that sodium is in processed food where we as individual consumers really can't control our exposures in terms of what is in that food, it's not the salt shaker where you can control it, it's what you're eating.

So, we feel that we are providing very important information to consumers through things like the nutrition facts label which enables you to know what is in the product that you're eating, and we do think that there is clearly very positive health benefits by trying to bring down sodium levels in the American public.

JOHN HUGHES: I've got a couple questions on bio similars. I'll try to combine them since we're running short of time. But one questioner wants to know how you envision this new era of copycat versions of biotechnology drugs playing out in the U.S. marketplace, and the other wants to know if devices such as generics and bio similars may actually discourage the development of lower cost options for the public.

MARGARET HAMBURG: Well, bio similars are biological molecules that are similar to existing biological therapeutics that are innovator drugs and in the marketplace. They have a parallel relationship to generic drugs and innovator drugs, but they are much more complicated molecules in terms of their size and how you make them and the human response to them. So it's a much more complex process than just generic chemical tablets. And we have actually only just recently approved our first bio similar, which was an existing event for us, and the pathway for bio similars actually is relatively new at the FDA. It was part of the Healthcare Reform Act, the ACA actually, one of a few things for FDA that was sort of embedded in that larger piece of legislation.

And we imagine that these drugs will be available to the public at much lower cost than the innovator biologics, which are very, very important drugs in medical practice, making a huge difference in the lives of many patients, but very, very costly. It remains to be seen whether some of the most optimistic estimates of cost savings will really be true, but if we can help make important therapeutics available in a more accessible way I think overall in terms of the American healthcare system that would be a

huge benefit and the FDA role is to ensure that these bio similars can be used in these patients in a manner that is safe and effective.

JOHN HUGHES: Could you update us on the current listeria problem and we're especially interested in any specific foods or brands involved in the recall.

MARGARET HAMBURG: Now, I don't know that-- We have got a couple listeria problems floating around. We've got listeria in Bluebell Creamery's ice cream, which actually resulted in several deaths in a Kansas hospital, but this may be the listeria in spinach products where the companies did a voluntary recall after finding listeria. You know, I don't know that there is much more that I can say except that it's a powerful reminder that foodborne illness is very real in this country and it can be low grade where you get sick and have a few days off from work, some one in six Americans suffer from foodborne illness every year, but it also does result in many, many hospitalizations and deaths each year in this country. And we're in the midst of implementing the Food Safety Modernization Act which is a historic opportunity to transform our food safety system from one that is reactive where you respond after an outbreak occurs to one that puts the emphasis on prevention and understanding where are the points of vulnerability in the lifespan of that product and how can you shore up those risks so that we can prevent problems from occurring in the first place.

So I hope that we will, as we implement the Food Safety Modernization Act, be able to report fewer listeria and other foodborne illnesses. But in the meantime, I think one of the other things that's striking about listeria outbreaks that we have been seeing, is that we are seeing listeria in certain food products where we hadn't seen it before. So it also is a reminder that microbes can be unpredictable, that they can take up new homes, and that we have to always come back to the best strategies for food, handling and hygiene, and the implementation of the Food Safety Modernization Act to prevent problems from occurring.

JOHN HUGHES: Okay. I'm going to ask you one more question. But before I do that, I just wanted to remind the audience of our upcoming speakers. On Tuesday, IRS Commissioner John Koskinen will speak to us. On April 7th, Ayaan Hirsi Ali, a bestselling author and outspoken critic of radical Islam will address a luncheon. And on April 16th, Ban Ki-moon, Secretary-General of the United Nations will speak.

Second, I would like to present you with your National Press Club mug, which is perfect for enjoying FDA approved liquids in. [laughter]

MARGARET HAMBURG: Excellent. And we actually do regulate some forms of ceramics as well. [laughter]

JOHN HUGHES: Wouldn't you know it? So the final question is, you were named one of the world's 100 most powerful women by Forbes in 2014. What do you think our country can do to encourage more young women to pursue careers in science,

technology, engineering and math, in other words, to follow in your own footsteps? And you've only got less than two minutes to answer.

MARGARET HAMBURG: I think it's really important. And I think we need to start early. We need to have exciting, engaged knowledgeable teachers in our children's schools. And then I think we have to help with mentoring, career pathways, and we have to make sure that they're good jobs for women. And at the FDA, I have to say that we have a very strong representation of women in our scientific and leadership team. And I have been proud to be at the helm.

JOHN HUGHES: Ladies and gentlemen, could you join me in thanking Dr. Margaret Hamburg. [applause] Thank you. [applause] I would also like to thank National Press Club staff including its Journalism Institute and Broadcast Center for organizing today's event. If you would like a copy of today's program, or to learn more about the National Press Club, go to our website, press.org. Thank you very much. We are adjourned.

(gavel)

END