NATIONAL PRESS CLUB LUNCHEON WITH COMMISSIONER MARGARET HAMBURG

SUBJECT: THE FDA, REGULATORY SCIENCE AND PROGRESS FOR PATIENTS

MODERATOR: ALAN BJERGA, PRESIDENT, NATIONAL PRESS CLUB

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ALAN BJERGA: (Sounds gavel.) Good afternoon, and welcome to the National Press Club. My name is Alan Bjerga. I'm a reporter for Bloomberg News and the President of the National Press Club. We're the world's leading professional organization for journalists and are committed to our profession's future through our programming and by fostering a free press worldwide. For more information about the Press Club, please visit our website at www.press.org. To donate to our program, please visit www.press.org/library.

On behalf of our members worldwide, I'd like to welcome our speakers and attendees at today's event, which include guests of our speaker as well as working journalists. I'd also like to welcome our C-SPAN and Public Radio audiences. After the speech concludes, I'll ask as many audience questions as time permits. I'd now like to introduce our head table guests.

From your right, Matt Perrone, health reporter with the Associated Press; Joyce Frieden, news editor from MedPage Today, and a new member of the National Press Club; Jeff Cronin, communications director for Center for Science in the Public Interest; Craig Palmer, Washington editor, American Dental Association News; Linda Kramer Jennings, Washington editor for *Glamour* magazine; Dr. David Hamburg, M.D., father and guest of our speaker.

Skipping over the podium, we have Melissa Charbonneau, executive producer for Newshook Media, and vice chair of the National Press Club's Speakers Committee; skipping over our speaker we have Doris Margolis, the president of Editorial Associates,

and the National Press Club Speakers Committee member who arranged today's luncheon. And thank you, Doris. Betty Hamburg, M.D., mother and guest of our speaker. Martha Craver, health editor for the Kiplinger Letter; Alicia Mundy, health reporter for the *Wall Street Journal*; and Steve Usdin, host of TV's "BioCentury this Week." (Applause)

Dr. Margaret Hamburg was unanimously confirmed as Commissioner of the U.S. Food and Drug Administration last year. The second woman to serve in the job, she's a graduate of Harvard Medical School and one of the youngest people ever elected to the Institute of Medicine, an affiliate of the National Academy of Sciences. Prior to heading the FDA, Dr. Hamburg held key positions at the Nuclear Threat Initiative, a foundation dedicated to reducing the threat to public safety from nuclear, chemical, and biological weapons. Earlier, she served as Assistant Secretary for Policy and Evaluation in the U.S. Department of Health and Human Services under President Clinton.

But in the 1990s, as Commissioner of the New York City Department of Health and Mental Hygiene, she was celebrated for curbing the spread of tuberculosis, which in the 1990s had resurged as a major public health threat, largely because many patients failed to complete the full course of treatment and the disease became resistant to standard drugs. She faces no challenges from that and other issues today, including the impact of healthcare reform on her agency, the need for more inspectors for food and drug safety; and more efficient clearances for life saving medicines, as well as faster response to food safety scares, including the Iowa egg recall this summer.

Today, Dr. Hamburg will discuss regulatory science, the science of developing better and new tools, standards and approaches to assess safety, efficacy, quality and performance of all FDA-regulated products. Welcome to the National Press Club, Dr. Margaret Hamburg. (Applause)

COMMISSIONER HAMBURG: Well, thank you very much. It's a pleasure to be here, and I enjoy looking out and seeing some friends and colleagues in the audience. And, of course, it's wonderful to have my parents with me as well. I have to confess that when I first agreed to come give a talk at the Press Club today, I had a very clear idea about what I was going to talk about, and it was going to be about the passage of the new food safety legislation. However, that food safety legislation is still being debated in the halls of Congress, and so instead I decided to talk about another subject close to my heart, the other part of FDA, not food safety, but medical products. And to talk about regulatory science, which is an issue that more and more people are recognizing as critical to progress for patients.

We live in a time of huge opportunities to improve health, to translate breakthrough discoveries and innovations into benefits for people, enabling better diagnosis, better treatment, and hopefully new opportunities to prevent or cure disease. We're more poised than ever to deliver the promise of science in the service of patients. But to do so, in my view, will require the advancement and more effective application of regulatory science, the discipline at the very heart of our mission at FDA.

If our efforts are to be successful, we will need the full engagement of the scientific community and beyond. This must be a top priority for us at the FDA, and for our nation. This is something that actually I hadn't focused on that much before I became FDA commissioner. But in this role, I have really become profoundly impressed by the importance of advancing regulatory science. And so this afternoon, I'd like to offer some thoughts on this important issue and what FDA can and will do going forward to better serve the public's health and realize the promise of biomedical research.

I'm also pleased to announce that today we're releasing a white paper entitled "Advancing Regulatory Science for Public Health," a framework for FDA's regulatory science initiative. And this document provides a broad blueprint for progress in the field, as well as our agency's role in promoting this progress.

And let me begin by making sure that we're all on the same page about what is meant by regulatory science. Some of you have probably heard me talk about this before, some of you have probably worked on related issues. Some of you probably have no idea what I mean when I say regulatory science. But I'm referring to the science and tools needed to assess and evaluate a product's safety, efficacy, quality and performance. Regulatory science involves the development of new methods, standards and models that we can use to speed the development, review, approval and ongoing oversight of medical products.

Science underlies the very foundation of the Food and Drug Administration, and even today, a century after Teddy Roosevelt signed the Pure Food and Drug Act that led to the creation of our agency, our goal at the FDA remains to embrace our origins as a science-based agency that relies on data-driven decision making to promote and protect the health of the public.

But today, we sit at a critical juncture. Science and technology are changing our world in dramatic and far-reaching ways. We're seeing explosion of knowledge and capabilities emerging from many domains of research and from around the globe. But do any of us believe that we've adequately delivered on the opportunities of science today? Though science and technology have progressed rapidly, we have not seen the equivalent progress in treatment and solutions for many of the diseases and conditions that afflict our friends, neighbors and families.

For example, we've been fighting a war on cancer since it was so declared in the National Cancer Act of 1971. Forty years later, many cancers are still difficult to treat and some are incurable. And if you're diagnosed with cancer today, especially one of the more complex, elusive forms, the standard best practice treatments you receive from your doctor will likely include toxic drugs that were approved for treatment more than 20 years ago. In another realm, there's increasing alarm about the problems of antibiotic resistance. And we worry with good cause. Today, antibiotic resistance mechanisms have been reported for virtually all known antibacterial drugs currently available for clinical

use, which affects everything from global infectious diseases to ear infections in school children to staph infections in locker rooms.

People actually talk today about a potential return to the “pre-antibiotic era” where we no longer have effective tools to treat serious infectious disease. Clearly, we must encourage more judicious use of these important drugs through improved infection control, rational prescribing, and better patient compliance. But even if we improve these practices, resistant bacteria will continue to develop. No matter what, we need new and better drugs and we need them now. Yet, the research and development pipeline is distressingly low. The number of newly-approved antibiotics, not just new formulations of previously existing drugs, have fallen steadily since the 1980s. And the range of new antibiotics is disturbingly limited in terms of the types of classes of antibiotics available, and the diseases that they can treat.

Overall, the reality is that billions of dollars have been invested in biomedical research. In 2008, more than $80 billion by the private sector, and more than $30 billion in the National Institutes of Health, an effort that is clearly imperative for medical progress. And we've witnessed the resultant discoveries that hold major promise of therapeutic advance in fields as diverse as genomics, synthetic biology, stem cells, and nanotechnology.

But right now, we lack the ability to effectively translate many of these developments into vital products for those who need them. The number of new therapies is actually in the decline while the costs of bringing them to market have soared. But to put it simply, there's a troubling gap between advances in science and available patient care. We need to build a bridge across this gap; and that bridge, in my view, is regulatory science.

A bench scientist may develop a new approach to a disease. A clinician may be able to show that it can work, but regulatory scientists must help develop the knowledge and tools to translate discovery and innovation into those products that hold so much promise. We cannot take advantage of the breakneck speed of biomedical research unless we also emphasize innovation in regulatory science. Just as biomedical research has evolved over the past few decades, regulatory science must also evolve in important and in powerful ways.

Regulatory science is an essential part of our overall scientific enterprise, yet it has been underappreciated, and frankly under funded. Because of this, we've been unable to apply the best possible science and technology to the task before us. And we are left relying on 20th century approaches for the review, approval and oversight of the treatments of the 21st century.

So now is the time to move forward. A robust field of regulatory science will allow us to effectively and efficiently translate many of those breakthroughs into therapies and cures. It can enable us to use our knowledge of biological pathways and gene variance to help eliminate ineffective drug candidates earlier in the pipeline. It will

foster the use of advanced genetic data and biomarkers to find faster paths to disease targets. It will support efforts to optimize clinical trial design to speed the regulatory process and get products to patients faster. Without advances in regulatory science, promising therapies may be discarded during development because we lack the tools to recognize their potential, and because outdated, inefficient review methods unnecessarily delay the approval of critical treatments.

On the other hand, both significant dollars and many years may be wasted assessing a novel therapy that with better tools might be shown to be unsafe or ineffective at an earlier stage. I should emphasize that regulatory science comprises an array of disciplines and approaches. It takes place in laboratories, but it also involves clinical research and epidemiologic and statistical tools, things like bio imaging, and information gathering systems as well. Unlike work performed by specific sponsors or companies, regulatory science is important for multiple products and stakeholders. The knowledge generated from such studies forms a whole body of innovation rather than a single product.

It will take new investments, approaches and partnerships for regulatory science to evolve the way that biomedical and life sciences research has in recent times. But, we must pursue it. Some $2.7 billion and over a decade of time was spent sequencing the human genome, which was successfully completed about ten years ago. And yet, some 30 therapies or fewer actually have genetic tests as part of their labeling for guiding their use. That's why we need regulatory science. Even though we know that there are promising cell-based therapies for treating a variety of now incurable diseases, we still don’t know how to define the right number of cells to infuse, or what happens to these cells after they're placed in the body. And that's why we need regulatory science.

We don’t have good models for predicting toxicity in humans, which leads to a lot of time and money spent by biotech and pharmaceutical companies each year development new therapies with a failure rate often as high as 90 percent. That's why we need regulatory science.

We increasingly call on the safety focused science of Pharmacovigilance to use data sets and reported information to monitor the post-market environment for safety signals and risk concerns. But we still need meaningful strategies to quickly evaluate concerns and assure the proper balance of risks and benefits for patients. And that is why we need regulatory science. We need regulatory science to place the emerging, promising areas of science and technology fully at the service of public health.

So how do we move forward? We make investments in projects driven by regulatory science that really work. And I want to give you a few examples. For one, FDA’s working to optimize delivery and dosing of drugs and therapies so that patients receive the most benefit at the lowest risk. A case in point is the updated labeling for warfarin, a widely-prescribed anticoagulant that about two million new American consumers take each year to prevent blood clots, heart attacks and strokes. Warfarin’s

optimal dose varies and was known to be influenced by several factors, including a patient's age, diet, and use of concomitant medications.

Then FDA validated the determination that a person's genetic makeup also influences how they respond to the drug. And that led us to approve changes to warfarin's label. This change provides healthcare providers with the genetic test that can improve their estimate of a reasonable warfarin dose for individual patients. This is an example of the personalization of medicine, or tailoring a particular therapy for a particular patient. And it is regulatory science at work.

Then, there's TB. You heard a little bit about TB and my background dealing with TB in New York City. It is, in fact, a worldwide scourge that has eluded us for centuries. I worked hard to turn the tide on TB in New York City back in the 1990s, and although I pushed hard, as did others, dealing with this resurgence of tuberculosis and tuberculosis in a more dangerous drug-resistant form, which was occurring in the United States some 20 years ago, we still lack effective diagnostic tests, as well as the combination drug products that would make a real difference to treatment.

But with regulatory science comes promise. This past week, the FDA awarded $2.9 million in grants to support regulatory science for tuberculosis, including projects to develop new biomarkers for vaccines, to create a TB specimen repository, to design new preclinical models for drug combination products, and to develop and validate new point of care tests. In addition, the Reagan-Udall Foundation has been working with the Gates Foundation, and others, to advance the critical path to TB drug regimens program, a collaborative initiative involving companies with TB drug candidates, as well as multilateral stakeholders to accelerate the development of new TB drug regimens.

Promising research is under way using stem cells to restore brain function lost in patients with Parkinson's Disease and to treat various other medical conditions. FDA is helping to scientifically develop valid standards and manufacturing processes for stem cell therapies so that they can be produced reliably and safely. And without these, the technologies promise can not be realized.

Basic research studies are identifying potential tumor markers that can indicate whether a patient's cancer will respond to a specific therapy or combination of therapies. But for these markers to be applied in clinical practice, ushering in an era of personalized medicine, the agency is using new science to guide the assessment of sub populations of responders and the evaluation and use of new diagnostic tests in that context.

Another important challenge is the development of medical countermeasures. In August, Health and Human Services Secretary, Kathleen Sebelius, announced an important initiative to develop the countermeasures that we need to strengthen and speed our nation's response to bioterrorism and to naturally occurring infectious disease threats. This is a top priority for this administration, and for our nation.

Because FDA evaluation of product safety and efficacy so significantly impacts the course of product development, the review identified our agency as critical to the success of the overall enterprise, and we were awarded $170 million to support our efforts. Activities will include enhanced review and novel manufacturing approaches for the highest priority medical countermeasures, assessment and optimization of the legal policy and regulatory framework for countermeasures, and advancing our regulatory science base and collaboration to improve regulatory evaluation, create viable regulatory pathways, and speed development. This is the greatest infusion of regulatory science dollars in any FDA project to date, and shows recognition across governments of the importance of regulatory science in fulfilling the mission at hand and the key role of the FDA in making it happen.

FDA has also been working hard with NIH, foundations and industry, to develop something called an artificial pancreas for juvenile diabetes. It's designed to continuously monitor blood sugar levels and inject the right amount of insulin automatically. And you can just think of the potentially enormous value this has to patients with type I diabetes and for their families. But this is a complex task, and for patients to benefit we must develop a scientifically solid testing path that insures that the devices control blood sugar levels without risking hypoglycemia. And next month, we're holding a meeting on establishing standards for approval of this artificial pancreas. This kind of innovation exemplifies the type of progress we hope to make across a wide range of diseases and disease conditions.

All this is just the beginning, though through FDA's new regulatory science initiative, I've made it our priority to work with our partners to lead the effort to advance the field. The bulk of our resources will be used to mobilize external collaborations and partnerships, particularly with academia, and support studies in major regulatory science research areas.

In 2011, we will continue to make strategic, targeted investments in areas that support our regulatory science plan, and to establish pilots and feasibility studies. We hope to expand these activities in the next few years to establish centers of excellence in regulatory science funded by FDA and focused on collaborative, multidisciplinary and multi-sectoral research activities, most likely housed in academic settings. And these centers will be true collaborations, bringing academia, industry and FDA scientists together to conduct regulatory science research in targeted priority areas.

We're also working with the National Institutes of Health to a new NIH/FDA regulatory science initiative to collaboratively encourage research in the field. Just last week, we jointly awarded more than $9 million to four projects. The projects include research on nanoparticles and their characterization, a heart/lung model to test the safety and efficacy of new drugs, innovative clinical trial design strategies, and a novel strategy to predict eye irritation.

So, let me begin to move towards the end. But I want to really underscore the leadership in the FDA requires more than just a vision for what's needed and the external

partnerships to work together on these projects. We must also possess the tools and knowledge necessary to advance regulatory science from the inside out. Which means that we're accelerating efforts to recruit, train and retain outstanding scientists and build the science base within the agency. After all, I think it seems obvious that the agency charged with evaluating the safety and efficacy of essential products must possess a scientific capacity equal to, if not greater, than that task.

All of these issues, as well as the promise of regulatory science for seven critical public health areas are outlined in this FDA white paper that I referred to earlier, "Advancing Regulatory Science for Public Health." You can find a copy of the white paper on the FDA website, and I think we also have copies for distribution today as well, I think maybe outside the doors for when you're leaving. Hopefully, this paper will persuade you that regulatory science really matters and that the time to act is now. Regulatory science can deliver us better, more targeted therapy, and more swiftly. It can impact not just individual health, but improve our healthcare system more broadly. And it can lead to significantly lower costs for the drugs and medical products we need.

But the power of regulatory science is greater still. As a nation, a major priority is to focus on investments that benefit the entire nation, investments that will grow our economy, that will increase high value jobs in key sectors, that will foster innovative products that will drive economic development, that will enhance the safety and value of our exports and elevate our global economic competitiveness and overall national prosperity. And investing in regulatory science is, in fact, uniquely positioned to do all of this as well.

But probably what matters most to all of us on a day to day basis is that a robust field of regulatory science will truly enable us to reap the benefits of modern science. We are living in the century of biology where scientific advances are ripe. With a collective effort, these can be transformed into therapies to alleviate or prevent much suffering, and products to enhance our quality of life. This will take time, this will take effort, but we can do it and it will make a difference. So thank you very much for your time and attention. And I hope you will join me in support for strengthening regulatory science. (Applause)

MR. BJERGA: And thank you very much for your time today, Dr. Hamburg, and being able to speak with us. It's certainly been a challenging schedule for you the last few weeks with the legislation before Congress and all. We have a lot of questions here, please keep them coming up. I'll ask as many as I possibly can. But let's just jump right into them.

Earlier this week, your agency announced a two-day meeting to implement a pathway for genetic or follow-on biologic drugs called for under the healthcare law that was passed in March. How soon will companies and consumers see cheaper alternatives to expensive biologics, and when could your administration approve the first of such a drug?

COMMISSIONER HAMBURG: Well, we are very pleased to be able to begin to really implement this new program. For those of you that aren't sure what follow-on biologics are, they're basically the sort of genetic equivalent of biologic drug products, and they're complex molecules in many cases. So that the science of evaluating follow-on biologics is not as straightforward as with chemical genetic drugs. So we have a complex set of scientific issues to address as we look at establishing the regulatory pathway for follow-on biologics. We also, of course, have some operational and logistical and really clarifying the pathway kinds of issues to develop within the agency.

But we are moving forward in a concerted way. We have a team that cuts across the agency that is working on this. But I think it's important to recognize that the follow-on biologics, for the reasons of science I mentioned are more complex. We will not have a one size fits all approach to the evaluation of these follow-on biologics, but each one or different categories of these products will have to be assessed in terms of what is the level of data and evidence that will be needed to be able to show equivalence and substitutability of these so-called follow-on biologics to the original innovator product. Because we, of course, want to be able to assure patients and their healthcare providers that when these new products are substituted for the original innovator products that they will, in fact, have the same biologic effect.

So it's a complex challenge. I can't put dates on our timelines for implementation. But we recognize that these are important products to the health of people, they're expensive products as they currently exist in terms of the innovator products. So we see a lot of opportunity to make these important products more available to people at lower cost as we move forward in this effort.

MR. BJERGA: How does Congress's continuing resolution impact your new plan to boost the agency's investment in science, as well as the agency overall? The President had sought a 23 percent increase in funding for fiscal 2011?

COMMISSIONER HAMBURG: Well, these are challenging economic times, and I think we all recognize that. On the other hand, I do feel strongly that FDA is a very unique agency in government. We have an extraordinarily wide array of products that we are responsible for overseeing, drugs, medical devices, biologics and vaccines, cosmetics, dietary supplements, certain products that emit radiation, now tobacco products and of course food safety and nutrition. We regulate products that account for somewhere between 20 and 25 percent of every dollar that consumers spend on products in this country. We regulate products that really matter to people. They use them every day from the time they get up in the morning and have breakfast to the time that they take their medications, put on their sunscreen or their cosmetics, brush their teeth at night. Just in so many ways, we impact people's lives, and in ways that really matter.

And we are unique. There is no other agency in government, no other entity in the private sector or in academia or the not for profit sector that does what we do and has the authorities and expertise to do what we do. So if we can't do our job and do it well, there's no one there to backstop behind us. And I think there is a growing recognition that

the FDA has not been adequately funded over a period of many years. The last couple of years have been a very positive recognition of the fact that FDA needs to be strengthened and that a strong FDA is in everyone's best interests.

And so I'm guardedly optimistic that despite these difficult economic times, that we are going to continue to get some of the critical support in key areas that we need moving forward.

MR. BJERGA: You discussed a bit antibiotics and the problem of antibiotics resistance. In view of this growing resistance to antibiotics, this questioner asks, "Why are antibiotics still routinely administered to cows, chickens and other food animals?"

COMMISSIONER HAMBURG: Well, it's a very important question and there historically has been a very considerable use of antibiotics as part of animal husbandry and also agriculture. And I think that for many years, individuals and organizations in public health, in medicine, have raised those very concerns about what is the impact of the use of antibiotics in animal populations on human health and the availability of effective antibiotics to treat disease.

We are in the midst of very serious scrutiny of these issues and we have made recommendations in support of judicious use of antibiotics. Nobody wants to deny antibiotics to animals that need medical treatment. But, the use in certain preventive contexts where it's not clearly medically indicated is of growing concern and it's an area that working with our partners in government, both the CDC and USDA and others, that we're taking a very serious look at.

MR. BJERGA: This questioner refers to a recent *New York Times* article that told the story of two brothers with cancer. One entered a clinical trial and is doing well. The other brother was refused the trial and died. What concerns do these real world stories of how FDA rules touch lives raise for you?

COMMISSIONER HAMBURG: Well, I think that situation really speaks to the importance of regulatory science. It speaks to the importance of continuing to advance our knowledge of certain biomarkers and tumor markers that can indicate potential opportunities for targeted treatment and the importance of continuing to understand underlying mechanisms of disease so we can target therapies more effectively.

It also speaks to the importance of developing new strategies for clinical trials, new more adaptive clinical trial designs that can enable us to get the kind of answers we need to know whether something really works or not. But without putting individuals at any unnecessary additional risk.

So I think that it is obviously a circumstance that is very poignant for the individuals involved and where we feel a real responsibility to make sure that we are working with the company to support the appropriate technical and ethical scientific

studies. But at the end of the day, what it really speaks to is the importance of strengthening regulatory science so that we can serve the public better.

MR. BJERGA: This member of the audience comments, "Yesterday, I was at a small gathering of top scientists and one reported a stressing incident he had experienced. According to the story, a respected and skilled scientific investigator needed a certain liquid to complete a very promising study. FDA, he said, had an abundant supply but refused to let him have any saying, 'We're the FDA, you're the NIH, and we don't share.' A few other scientists in the room nodded knowingly--" there's a little bit of a chuckle in this room too--" apparently having had similar experiences. Do you think this goes on, and how do you combat it?

COMMISSIONER HAMBURG: You know, I'm sure that there's an occasional episode of that kind of behavior, but I think it is far from the norm. There's an enormous amount of collaboration including the fact that for many years, FDA scientists actually worked on the NIH campus side by side with NIH scientists and we are involved in many collaborative projects and activities, including this new one that just began this year that's an FDA/NIH initiative to support regulatory science. We've also created a new FDA/NIH council with representatives from NIH and FDA that meet on a regular basis that develop shared research agendas and share information and strategies for working on important public health concerns. So I think that is probably an isolated case.

MR. BJERGA: How do intellectual property concerns slow research, and what can you do about that?

COMMISSIONER HAMBURG: Well, that's a very complex set of questions and probably best answered by a lawyer, not a doctor. But I think that intellectual property obviously influences the patents on drugs in terms of market share and incentives for other companies to develop new products. There are sometimes technologies and assays that are patented and affect people's ability to use them as well.

I think from my perspective at the end of the day, we have to always keep our eye on public health and the importance of achieving important public health outcomes and addressing unmet public health needs and intellectual property should not be the kind of barrier to achieving what's necessary to meet medical needs. But that we must have systems that recognize the intellectual property framework in our country, support it, but we must always collaborate around important science.

MR. BJERGA: And regulatory science has been the dominant theme here today. This person asks, "Can regulatory science keep up with the pace of scientific change? And if so, how?"

COMMISSIONER HAMBURG: Well, I think that right now, regulatory science is not as robust a field as it needs to be. And part of the challenge is to strengthen with regulatory science, to expand the capacities in the field both in terms of the trained individuals, the resources to support regulatory science and the depth and breadth of the

research agenda so that regulatory science can go forward in parallel and in concert with advances in biomedical research. If we fail to do that, we will continue to fail to fully realize the potential of the investments we're making in biomedical research.

MR. BJERGA: One of the advances that you were talking about during your address was the artificial pancreas and dealing with juvenile diabetes as a growing health, public health, problem. But, of course, it was very rare two generations ago. This is something that has happened along with the rise in childhood obesity. What meaningful strategies has FDA under your leadership implementing to address obesity in America?

COMMISSIONER HAMBURG: Well, obesity, as I'm sure you're all aware, is a major priority for this administration with important efforts being spearheaded by our First Lady her Let's Move campaign. FDA, along with many other entities of government, has an important role to play. Our involvement really comes in terms of our nutrition activities and in terms of what we do to provide consumers with accurate, reliable and accessible nutrition information, things like the nutrition facts panel on the back of packaged foods that lays out some of the nutrients and the percentage of daily values in those products so that people can make more informed choices.

We're currently working now on how to present that kind of information in a simpler, more accessible, more understandable way on the front of package so that those of us that lead busy, harried lives can just run down the grocery store aisle and quickly assess which is the high sodium product or which is the high calorie product and hopefully make more informed choices. So, that is really the main focus of our activities that support that.

MR. BJERGA: In general, what is FDA doing in the area of preventive medicine? Offering and promoting effective preventive medicine programs could save huge amounts of money and, more importantly, prevent unnecessary pain and suffering.

COMMISSIONER HAMBURG: Well, prevention is the cornerstone of public health and it is an important principle to organize many of our activities around. I would say first on the food safety side, prevention is key and our goal is to try to make sure that we have the systems in place that will better position us to work with food producers, manufacturers, distributors, to prevent contamination and food borne outbreaks from occurring in the first place in the Food Safety Bill, is an important potential tool to help support us in those efforts.

On the medical side, we're very involved in various kinds of medical products to prevent disease, vaccines, is obviously one of the premier modalities that we regulate that is at the core of prevention, but in many other domains. And it's obviously very, very important from both a human and an economic point of view if you can prevent a problem from happening in the first place. That is our primary goal.

MR. BJERGA: How does a robust regulatory science program compete in the current media and litigation environment where well publicized anecdotes and allegations can erode public confidence in FDA's expert risk/benefit analysis?

COMMISSIONER HAMBURG: I think a stronger and more robust field of regulatory science will enable us to have the best possible data for decision making, and that's the best possible position to be in as we struggle with difficult, challenging questions where we do have to balance risks and benefits. But I see regulatory science as a huge asset as we try to strengthen our programs and try to really stick to our mission of being a science based regulatory agency with a public health mission to promote and protect the health of the public.

MR. BJERGA: During your time as commissioner, FDA has made transparency a priority through its transparency initiative. However, FDA recently published a final rule on safety reporting requirements for investigational new drugs nearly seven years after the closure of the rules public comment period. During the last seven years, FDA has not offered the public any information on its deliberations on the rule, nor has it provided the public any opportunity to update its comments. How do you reconcile this?

COMMISSIONER HAMBURG: Well, first I would have to admit that transparency doesn't necessarily mean speed and I have been amazed during my tenure at FDA how long it can take to move things through the system and the complexity of those pathways. You know, I am not familiar with the specifics in that instance, but all the rule-making that we do and the regulations that we develop and ultimately implement have a quite elaborate notice and comment period and public meetings and open dockets and other mechanisms to get input. We feel that that's very important, we do take that input very seriously. But I just can't speak to the specifics of that instance.

MR. BJERGA: This questioner asks, "How does Europe approve new medical devices so much more quickly than the USA? Is USA's medical technology global leadership at risk?"

COMMISSIONER HAMBURG: Well, it is true that there is a substantially different regulatory framework for device approval in Europe and it's one that actually is variable in different countries in Europe. And it's one that does enable a product to be moved through more quickly in many instances with less--fewer requirements to actually present data for evaluation.

I think that there is real value at working with other regulatory authorities in Europe and around the world to try to look at how we do our regulatory decision making when possible to try to harmonize standards, approaches. And approaches, again, based on the best regulatory science. And we have been engaged in conversations with our colleagues in the EU. They are looking at their framework for the oversight of devices, and I think they are thinking about whether they, in fact, need to make some of their oversight more stringent.

We also are in a period of looking at our device review systems, and I won't go into all the details, but one of the things that can happen in regulatory agencies is that laws are put in place at one era in time and the world can change dramatically. And certainly the world of medical devices has changed very significantly in recent decades in terms of the complexity and the invasiveness of many medical devices. And so I think it is appropriate that periodically we reassess, and I think it's appropriate that we also work with our sister regulatory authorities as we define our thinking and approaches.

MR. BJERGA: Going more deeply into the process issues, there have been reports that medical cocktails such as those that have been shown to be effective with HIV, may be the future of cancer treatment. But doing so would involve multiple companies and researchers. Can this be done without developing restraint of trade charges?

COMMISSIONER HAMBURG: Well, I'm more focused on the complexity of the science of how do you evaluate combination products in a way that is accurate and efficient? And it is a complex scientific challenge but it's one that we are grappling with in a number of areas. And in fact, one aspect of the TB regulatory science activities that I mentioned briefly in my presentation has to do with how can we combine different TB drugs to be evaluated as a combination product. If you were evaluating each new drug individually in a sort of serial way, that would take quite a long time. When you combine them together and tried to evaluate them together, it's obviously much more scientifically complex and challenging. But I think the public health demands that we really look to see how swiftly we can meaningfully assess these new kind of products, we're looking at combination products in the cancer arena as well.

And I think that there are ways that these different companies do come together to work on these products together. But it's somewhat new territory and we're learning as we go.

MR. BJERGA: What can the FDA do to encourage or require publication of negative studies; that is, research showing a drug does not have a beneficial effect?

COMMISSIONER HAMBURG: Well, that's a very important question and it's a topic of considerable discussion within the FDA and outside. The rationale for publishing negative studies is that it then would enable people who might be pursuing similar paths to understand why a given product failed so that they wouldn't then invest considerable time and money to develop a product that would likely hit the same brick wall.

For any individual company, there's understandable reluctance to necessarily, after having invested a lot in developing product, to have everything opened up for others to see. On the other hand, if you look at it in terms of sort of the big picture and over time, one company might be making themselves a little bit vulnerable in one case, but they'd have the opportunity to learn from the experiences of others in another. So it's

something that we're looking at. The FDA equivalent in the European Union has moved in that direction.

MR. BJERGA: What is the FDA doing to attract and retain young scientists who receive more lucrative research-based opportunities from private industry and academia?

COMMISSIONER HAMBURG: Well, it's very important to us to both recruit and retain these promising young scientists, as well of course we want to make sure that we retained our tried and true scientists at FDA as well. But we are trying to reach out to recruit, and then we're trying to make sure that when they come into the FDA that they, in fact, not only have interesting jobs, which is almost a guarantee, but also career ladders for development, opportunities for continuing education. We'd like to create more opportunities for professional scientific exchange with their professional colleagues outside of the agency including even potentially some sabbatical leaves and other things. We've created a fellowship program to bring scientists early in their careers into the FDA and expose them to what we're doing. They make a contribution to FDA while they're there and many of them choose to stay on. It's an exciting place to work, there's a real sense of mission and you know that every day you're coming to work and doing something that matters.

MR. BJERGA: And the answer to that question would seem to tie into a broader perception that actually is the substance of the next question being asked here, which is of the FDA worker, the government worker in general at times, being less well paid than counterparts in private industry, not as good of working conditions and possibly waiting to leap to private industry at the first chance they get simply for the pay and the work conditions.

And this feeds into the phenomenon that you'll hear some people discuss from time to time, which is when people say that the FDA has its hands tied when the judgment and integrity of its scientists conflict with the pocketbooks of the pharmaceutical and food industries. The issue of corporate influence on the FDA process is a perennial one. And this questioner is asking if you could share your thinking with the audience on that topic today.

COMMISSIONER HAMBURG: You know, FDA, as I said before, is a science-based, science-driven agency and we need to look to the data to make our decisions. And I think that we really are very committed to that and we really make science be our guide.

MR. BJERGA: We're getting near the end, but there'll be two more questions. First, this is the penultimate question. This person asks, "Could the FDA please order drug manufacturers to write warning labels in English." How can the average user know what a tricyclic anti-depressant is or a phenol thiazine. I don't even know if I'm pronouncing this correctly.

COMMISSIONER HAMBURG: Not bad.

MR. BJERGA: Yet, the warning states that the use of those and other particular drugs can lead to a dangerous abnormal heart rhythm if taken with the new drug, Multaq for certain heart conditions. Another for use of Vagifem for women's use, which lists contraindications, whatever they are, such as neoplasia, porphyria. What is it? Could you explain

COMMISSIONER HAMBURG: Well, I can't argue with what you just read. We actually do have an initiative called Plain Language, I think, which is to try to really, not just on our labels, but in many of our publications, to try to really be mindful of the fact that we need to communicate in plain English. Or, in other languages that consumers may need to access so that they can understand the medical issues at hand.

It is hard sometimes to find other ways of describing certain of those conditions, but we do need to really pay attention. This kind of feedback is always helpful, and it is certainly the case that even for some fairly sophisticated readers of some of these labels, myself included, one can get a bit lost. So I think it's something that we need to continue to work on.

MR. BJERGA: Yes, and I cannot challenge that question either, because I have no idea what I just read. We are almost out of time, but before asking the last question, we have a couple of important matters to take care of. So thank you for your patience. First, to remind our members and guests of our future speakers. On this Friday, October 8th, we're going to have Brian Moynihan, the President and CEO of Bank of America who will discuss observations on U.S. and global financial markets and economic growth.

On October 12th, General Norman Schwartz, Chief of Staff for the U.S. Air Force will be speaking. He will discuss the service's ongoing efforts to organize, train and equip itself amid two wars in Iraq and Afghanistan. And then a week from Friday, on October 15th, Condoleezza Rice, former Secretary of State, will be discussing her new book and undoubtedly her time in the Bush Administration. Second, I would like to present our guest with the traditional National Press Club mug. (Applause)

COMMISSIONER HAMBURG: Thank you. I hope it's lead-free.

MR. BJERGA: We don't know if it's lead-free, but we will ask. That's a good question.

COMMISSIONER HAMBURG: The FDA could test it.

MR. BJERGA: FDA can test it. Thank you all for coming here today. We have one more question. And this one came actually out of a conversation with your father that I was having here earlier. He is very pleased with the recent move from New York to Washington, says that you're doing a wonderful job caring for the whole family. And the

last question is what is the best health advice that you can give your own family each generation?

COMMISSIONER HAMBURG: You know, early on in this job I was warned never to answer personal questions. But my best health advice is do what your mother always told you. (Laughter) Can I stop at that?

MR. BJERGA: Always a good answer with your mom in the audience. Thank you, Dr. Hamburg. (Applause) And thank you all again for coming today. I would also like to thank the National Press Club staff including its library and broadcast operation center for organizing today's event. For more information about joining the National Press Club and on how to acquire a copy of today's program, please go to our website at www.press.org. Thank you so much for coming out here today and for all of your wonderful questions. This meeting is adjourned. (Sounds gavel.)

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