NATIONAL PRESS CLUB LUNCHEON WITH ANDREW VON ESCHENBACH, COMMISSIONER OF THE FOOD AND DRUG ADMINISTRATION

SUBJECT: FDA AT A TURNING

POINT: MEETING THE CHALLENGES OF A RAPIDLY CHANGING WORLD

MODERATOR: SYLVIA SMITH, PRESIDENT, NATIONAL PRESS CLUB

LOCATION: NATIONAL PRESS CLUB, WASHINGTON, D.C.

TIME: 1:00 P.M. EST

DATE: FRIDAY, FEBRUARY 29, 2008

MS. SMITH: (Sounds gavel.)

Good afternoon and welcome to the National Press Club. My name is Sylvia Smith. I'm the Washington editor of the Fort Wayne Journal Gazette and president of the National Press Club.

I'd like to welcome club members and their guests, as well as those of you who are watching on C-SPAN.

We're looking forward to today's speech, and afterward, I'll ask as many questions from the audience as time permits.

I'd now like to introduce our head table guests and ask them to stand briefly when their names are called:

From your right: Joseph Enoch, investigative reporter for Consumeraffiars.com; Peggy Eastman, president of Medical Publishing Enterprises; M. Montgomery (sp), senior policy advisor to the Senate Committee on Aging; Catherine Larkin, health care reporter for

Bloomberg News; Maureen Groppe, Washington correspondent for the Indianapolis Star and Gannett News Service and secretary of the National Press Club; Lisa Richwine of Reuters; Madeleine von Eschenbach, wife of the commissioner.

And skipping the podium: Melissa Charbonneau of CBN News and vice chairwoman of the Speakers Committee -- and skipping over our speaker just for a moment -- Doris Margolis president of Editorial Associates and the press club Speakers Committee member who organized today's lunch: Thank you, Doris; Susan Winkler, the FDA chief of staff and a guest of our speaker; Larry Lipman, Washington correspondent for the Palm Beach Post, Cox Newspapers and a past president of the National Press Club; Steve Sammy (sp), editor and publisher of Military and Diplomatic World News; and Keith Hill, reporter/editor for BNA and chairman of the National Press Club board of governors. (Applause.)

We couldn't have invited the chief of a more news-making federal agency to speak to us today. The Food and Drug Administration has been in the news almost constantly to date. Some of the headlines have been a comfort to consumers that a federal agency is looking out for their well-being. Others are more worrisome, including news that the Chinese plant that makes ingredients for a commonly used blood-thinner medicine had not been inspected.

The front-page placement of stories like this is clear evidence that the actions and decisions of the FDA affect every man, woman and child in our country. Andrew von Eschenbach heads the agency that is charged with projecting the safety of most food, products, cosmetics, pharmaceuticals and medical devices that are sold in our country. Taken together, these products account for fully a fifth of consumer spending, and an even greater portion of consumers' product safety fears.

Prior to moving to the FDA in late 2006, Dr. Von Eschenbach was director of the National Cancer Institute. Earlier, he was executive vice president and chief academic officer of M.D. Anderson Cancer Center at the University of Texas. A leading authority on cancer, he is himself a former cancer patient. Today he'll describe the FDA as being at a turning point and how it will meet the challenges of a rapidly changing world.

Please join me in a warm National Press Club welcome to Dr. Andrew von Eschenbach, commissioner of the Food and Drug Administration. (Applause.)

DR. VON ESCHENBACH: Thank you, President Smith, for that very kind introduction. I wish my mom and dad could have been here to hear

it, but I'm pleased that my wife Madeleine, and chief of staff at the FDA, Susan Winkler, are here at the head table -- as well as members of the FDA staff. Perhaps maybe my stock will go up at home, as well as at the FDA.

And I want to thank all of you for taking the time to be with us today.

I'm very grateful to the National Press Club for the invitation to be with you. And I'm very honored to join the ranks of so many distinguished leaders who've appeared before you and who are instrumental in changing the world and our nation.

Today I would like to talk to all of you about the changing world and what that change means to the Food and Drug Administration -- and the need to recreate the agency. Changes in our world are affecting every single American in terms of our health and our wellbeing. Change is affecting everything, including the food we eat and the drugs and medical devices we depend upon.

These changes are impacting the Food and Drug Administration and our ability to continue to fulfill our mission to protect and promote the health of every single American. These are changes that are radical in nature and they are rapid in the rate at which they are occurring.

Society has faced radical change before, such as 100 years ago -- about the time of the birth of both the Food and Drug Administration and the National Press Club -- when science was unraveling the secrets of the atom and with the dawn of the atomic age gave the world the awesome power to change its destiny. This change held great promise, but also the potential for great peril.

Radical changes were also occurring at that time in how we lived and worked with urbanization and industrialization. Mass production and transportation of food and transformation of medicine held great promise to improve our lives. Change was producing great promise, but also great peril from contamination of food and the marketing of fraudulent drugs. Our nation had to respond at that time, and one response was the wisdom of Congress to enact -- and President Theodore Roosevelt to sign -- the Food and Drugs Act of 1906. This led to the creation of the organization that would later become the FDA, charged with protecting and promoting our health.

Over the course of the 20th century, FDA has done its job well and has been and is today recognized as the world's gold standard regulatory agency for health. Now, in the first decade of this, the 21st century, the world is again immersed in radical change. And that change is occurring at a rate that is unprecedented. Once again, there is great promise, but also great peril.

Just as with the atom and its nucleus, revolutionary progress in science and technology understanding the cell and its nucleus is

leading to our understanding of genes, molecules and DNA that controls life processes and disease -- and is enabling us to clone animals, genetically modify crops, create x-ray devices that actually see living biology. We're now creating medicines that don't just treat the manifestations of diseases, but actually alter the biology of the living cell.

Exponential advances in science and technology are again coupled with changes in way in which we live. Urbanization has given way to globalization; and industrial age now embraces the information age. As with the past, these changes are filled with promise, but also

peril. As they impact on our health, society must respond, and I believe recreate, the FDA.

The simple truth as I see it today is that the FDA of the 20th century is not adequate to regulate the reality of the food and drugs of the 21st century. A time in which we live in a world where we can catch a fish in Chile today and eat it in Chicago tomorrow, or when throughout the United States watermelon is in season every day and we expect fresh strawberries in supermarkets in February.

We are now a nation that demands foods ready to eat. Clean, cut, cooked -- and even cooked. We now live in a world where medicine cabinets are filled with tablets and capsules that treat nearly every symptom. In offices and medical clinics we have devices that diagnose with certainty nearly every disease.

And our hospitals are equipped with drugs and devices that treat, with maximum effectiveness and minimal risk, all that ails us.

This is a time in which the wind of change in health care, in terms of power and pace, is not a gentle breeze but a jet stream. And the FDA must respond to these changes if it is to continue to fulfill its mission of protecting and promoting your health.

This challenge to change at FDA in itself is radical in scale and scope, because, as you've heard, the portfolio of FDA's responsibilities is vast. And its reach is enormous -- to every single human being, to regulate products you and I touch and use every day.

By law, the FDA must regulate, except for meat and poultry, all the food we eat -- vegetables, fruits, fish, and the spices that go on them, and the bottled water that accompanies them. We regulate vitamins and dietary supplements, every medical product from simple aspirin to more sophisticated drugs, and biologics for every acute and chronic disease; medical devices, from pacemakers to PET scanners, and from surgical masks to surgical robots, and from linear accelerators to microwave ovens; to produce not only things for how we feel, but also how we look, from toothpaste to underarm deodorant to sunscreens and cosmetics.

And our responsibility extends to products not just for humans, but also animals, as we regulate genetically engineered animals and products from pet food to pet turtles and from pet feed to drugs for our livestock.

FDA was created 100 years ago because change had created peril along with promise. And today, FDA must be recreated, because the peril and promise from these products I described is now even greater.

Consider for a moment food safety and nutrition. The perils are many. In processed food, we have recently witnessed the risk of botulism in canned chili sauce and E.coli and salmonella contamination in ready-to-eat fresh produce. But the potential promise is also great- a bountiful supply of fresh fruit and produce available all year round, and processed foods that have benefits such as lowering cholesterol are truly essential prescriptions for health.

We can do more to prevent disease today, just as our ability to genetically engineer crops to improve nutrition and promote health. Consider drugs and medical devices. The perils are many, with sophisticated and miniaturized devices such as cardiac pacemakers that are susceptible to breakdown or failure simply because of their complexity; new materials, such as nano-particles and devices, that present new unknowns; drugs and vaccines containing ingredients obtained from sources around the world, manufactured and distributed through complex supply chains, as is apparent in the recent case of the blood thinner heparin.

But again, the promise is also great. We can design and target drugs for a genetic defect and halt diseases like leukemia, or we can block molecules from affecting blood vessels and reverse blindness from macular degeneration. We can create vaccines to protect us from devastating threats like pandemic influenza or develop a recombinant protein that can control and prevent bleeding in patients with hemophilia.

Today the peril is great, but the promise is unlimited. However, I believe for the FDA to fulfill its mission to protect and promote your health in this context, we must now respond again. And I believe that that was my charge when I became the commissioner of the Food & Drug Administration.

The challenges I face today are perhaps unlike those that were faced by my predecessors. And as I attempt to guide this agency in responding to its day-to-day exhausting responsibilities, I am simultaneously asking them to expend the energy to define and create the reality of tomorrow.

FDA staff are the finest, most dedicated, talented people ever worthy of the title "public servant." But their task is daunting. Just consider the acute risk of pandemic influenza of a few years ago. It was a major public health concern around the globe. It was expected that in the event of an imminent outbreak, FDA would have to assure the safety and effectiveness of every medical intervention, including some not yet invented, like a vaccine for the offending virus.

In addition to responding to specific issues, FDA needed to have an integrated, comprehensive and coordinated plan. In the event of a pandemic, every single component of the agency would be acutely impacted, from our need for rapid dispersal and development of vaccines and antiviral drugs to ensuring adequate medical devices like respirators to being able to implement processes to assure the safety of food, and even methods of safe disposal of infected animal carcasses.

The agency rapidly embraced a strategy to change from a reactive mode of a regulator to a proactive mode of a facilitator and immediately engaged with academia and industry to facilitate that product development and create that regulatory pathway, and to be able

to integrate those efforts as well with our appropriate partners -- federal, state, international, and in the private sector.

Fortunately, we have not had to face the test of an outbreak. But one benefit of that comprehensive, multidisciplinary, integrated approach has been the enhancement of our vaccine manufacturing capacity in this country. Unlike a few years ago, when we only had three licensed vaccine manufacturers capable of making vaccines for seasonal influenza, today we now have in the U.S. six licensed firms.

As a result, rather than shortage that occurred a few years ago, this year we have had excess capacity. And in addition, in 2007 we have licensed the first influenza vaccine against H5N1 virus.

Because of that demand of a changing world, FDA did change, and changed radically and rapidly, with great benefit as a result. Today the Pandemic Response Strategic Plan we developed is a model guide for others internationally.

This theme of the need for radical and rapid change over the past two years has also served to guide a systemic and systematic transformation at FDA that builds on the progress of the past and must continue to extend into the future.

The principles of this systematic and systemic change process include, one, selection of the areas of focus that are based on their critical importance to the mission of FDA. We cannot do everything at once. The issues of drug safety, food protection, the scientific foundation of our regulatory decisions, our workforce development and our essential infrastructure, including facilities and information technologies, are now identified as our immediate priorities.

Second, a disciplined process for assessment of the problem to obtain the information necessary for devising the appropriate intervention. In some cases, the analyses were already available, like the Government Accountability Office reports, or were underway, as with the case of the National Academy of Science Institute of Medicine evaluation of drug safety.

In other cases we commissioned a report such as asking our scientific advisory board to convene a subcommittee of outside experts to do a comprehensive review of our scientific portfolio, and we created a collaborative effort to develop a food protection plan along with processes for internal review that resulted in a revision of our agency wide strategic plan we released in November of 2007.

Third, we developed for each of these strategic initiatives a detailed implementation plan including milestones and outcomes. We were very honored to have had the opportunity to launch such a plan right here at the National Press Club last year when we issued our response to the ION drug safety report. And we have already implemented many of those initiatives outlined in that report such as the creation of our risk communication advisory committee.

And we will be very pleased this week to announce a major initiative which was called Safety First that addresses our process for multidisciplinary determination of risk.

Fourth, we continue a series of external and internal

consultations. In particular assessment of our workforce has demonstrated a critical need to expand the numbers and skillsets required for our regulatory mission in this new era.

We have embarked on an aggressive recruitment and retention effort with the target of hiring an additional 700 new individuals to FDA in 2008.

This has been primarily made possibly by the passage of the Food and Drug Administration Amendments Act of 2007 and the incremental increases that have been provided in our appropriations.

In addition we will be shortly launching plans for an FDA fellowship program which has the potential to attract up to 2,000 individuals of varying disciplines for a two-year training program at FDA.

Other assessments indicated a need for renovation and modernization of our information technologies, and this year we will spend approximately $250 million to employ modern high performance servers and new software systems that will facilitate interoperability across the agency and expansion of our electronic databases.

Within the next year we'll open an integrated data center on the consolidated FDA campus at White Oak. This White Oak site is also the place of the development of our state of the art laboratories for our centers dealing with drugs and biologics, radiologic devices and veterinarian medicine.

Fifth, changes in programs and processes have been accompanied by changes in policy. Again, the realities of the radically and rapidly changing world required new ways of thinking as well as doing. FDA can no longer simply be a gatekeeper assessing the benefit and risk of products that are brought before us before they will be allowed to be delivered to patients or the public, and no longer be able to simply rely on inspections to verify quality.

We must and are engaging in a -- in the philosophy of total lifecycle of the products we must regulate, whether it's food, going from farm to fork, or whether it is medical products from production to their consumption.

Engaging FDA in each stage of discovery, development and delivery of the products we regulate will enable us to better assure their quality. One important aspect of that engagement in the discovery and development portion of the product lifecycle is our commitment to the FDA's critical path initiative, in which this year we'll invest over $5 million to apply the tools of modern science to the product regulatory and development process.

With regard to the delivery end of the cycle we will engage in monitoring the performance of products in an extensive program of post-market surveillance.

So we will unveil a new FDA program we're calling the Sentinel initiative. It is a collaborative effort with public and private partners that will create an integrate nationwide electronic data

system that will allow FDA to conduct observational studies of medical products as they are being used by large diverse populations.

Monitoring and detection must be accompanied by enhancing our ability to mitigate and respond to adverse outcomes. We must enhance our capability for intervention by increasing risk-based inspections,

but now also using modern scientific tools in the field for detection, and our ability to expand our network of assessment.

These efforts emphasize the need for FDA to enhance its collaborations. We are forging multiple partnerships with federal agencies like Customs and Border Protection, the CDC, and USDA, as well as with state, agricultural and health colleagues, private sector organizations, and most importantly, our international counterparts.

As demonstrated by our recent agreements with our counterpart agencies in China, the globalized economy demands nothing less than interoperability, information exchange, cooperation, and especially with regard to enforcement matters.

In an age when a border is not a barrier, we have embarked on an initiative we are calling FDA Beyond our Borders. It's an effort to establish FDA offices and a presence overseas to build capacity at foreign sites in at least five regions of the world beginning with China.

We must also expand our work with foreign regulators to share information more completely and more fully.

Earlier this week our food and feed team discussed with 62 representatives of 48 embassies our food protection efforts, and our commitment to this international collaboration, truly taking FDA beyond our borders.

This requires us to regulate products where they are produced, even before they arrive at our borders.

FDA as part of the Department of Health and Human Services, played a leadership part in the president's import safety working group. Under Secretary Leavitt's leadership, the working group proposed a plan for improving the safety of all imported products. With the same lifecycle approach across prevention, intervention and response, our efforts will further assure the quality of foods, drugs and medical devices from abroad.

Change at the FDA is truly underway from policies and procedures to the processes and programs. Rapid and for some radical change is occurring. For a government agency it may be described as revolutionary evolution.

For those inside the agency, I think it's often feels like the radical nature of a revolution. For those outside the agency it may seem to have the pace of evolution. But the outcomes are clear, and will be achieved, but not without patience and persistence.

All must understand that there will never be an endpoint, because the process of transformation, adaptation, and regeneration must be continuously and ever evolving. That is the nature of the world we live in.

To some of you these initiatives may sound like a collection of individual activities. They are much more. They are the first and perhaps the most critical steps in a critical transformation occurring at a critical time in an agency that is critical to the health of every American.

They are components of a blueprint for change defined by our strategic action plan that was released last fall. The plan focuses us on four goals: strengthening the FDA; improving the safety of patients and consumers; increasing access to new medical and food products; improving the safety and quality of manufactured products and the supply chain.

Each of these goals represents a fundamental public health task that is crucial to fulfilling our mission.

It is no secret in Washington that if FDA's responsibilities have grown, the resources devoted to them have not kept pace. Strengthening the FDA for this new century will require an investment. So that our agency commands a budget as well as authorities that are commensurate with the scale and scope of our mission.

We are on a trajectory of budget increase, granted by Congress in 2007 and 2008, and proposed by the president for 2009. This trajectory must continue, and as justified must accelerate.

Plans and resources at FDA are necessary, but they are not sufficient. We can't transform this agency ourselves. It's a transformation process that requires commitment from others.

This is the time to not just be critical about what is not being done, but to collaborate on what must be done.

The next three to five years from others we will need the following. From the Congress we need authority to better regulate the food supply. Our food protection plan calls for 10 new legislative authorities. And I call on Congress to grant those new authorities by Memorial Day.

I will continue to make my staff available day or night to work with Congress on these important initiatives. Our nation needs this legislation.

From the industries whose products we regulate, we expect strong corporate responsibility and compliance with regulatory standards as well as continued support of our user-fee programs with amounts that are appropriate for the services rendered that bolster our ability to review product applications promptly so that life-saving medical interventions reach patients sooner.

From our stakeholders we need your full support of the Reagan-Udall Foundation, established by Congress as an independent 501(c)(3)

organization committed to supporting the mission of the FDA.

And from the public we are looking for your support and your patience, as well as your trust and your confidence. We at the FDA are committed to serving you, and although these changes will take time, the benefits will be long lasting, and protect and promote your health.

The result of this change should be a recreated FDA with an efficient regulatory pathway that enhances discovery, development and delivery of life-saving products.

We will have greater scientific understanding of product mechanisms of action, and targets, to assure you of their benefit and their risk and their proper use, and we will have earlier and more precise responses to emerging issues.

We will know more, and we will communicate sooner.

In these remarks, I have attempted to explain three things: how the world has radically and rapidly changed; why these changes have brought FDA to a turning point; and what is being done to recreate the FDA in response.

I hope you will share with me the commitment to this change, this effort. As the FDA commissioner, I'm aware of the need for these changes to avoid the peril of failing in our mission to protect and promote your health.

But as a physician and a researcher, I'm aware of the need for change at FDA to achieve the promise -- the promise that comes from us being a bridge and not a barrier to delivering life-saving solutions that will eradicate and prevent the diseases that threaten you now and in the future.

But perhaps for me personally most of all, as a grandfather concerned about the future of our six grandchildren, I am aware of the need for radical and rapid change. About a month ago I traveled with Secretary Leavitt to India to meet with our counterpart government officials, as well as leaders of their food and drug industries to discuss how best to assure the quality of products produced in India for export to you here in the United States.

While I was there in Delhi I had the opportunity to visit a neighborhood, and to vaccinate babies and small children for polio. Afterwards I took the opportunity to hand out lollipops to some of the children. And I was suddenly faced with a mob of grasping hands and squealing voices that expanded more rapidly than my ability to furiously dispense the lollipops. Until that moment came, when there was nothing more for me to give them, I will never forget the outstretched hands and those big brown eyes and little faces whose smiles turned to sad stares because I had nothing more to give them.

As I look at the faces of my grandchildren, I know that for the next generation their expectations will go beyond our past that developed a vaccine for polio, to their future in which food and drugs will be a personal prescription for health.

And I know that FDA must radically and rapidly change, so that their smiles of expectation will not turn to stares of sadness, because without the FDA of the 21st century protecting and promoting your health there will be nothing more we can give them.

Thank you.

(Applause)

MS. SMITH: We've got quite a number of questions, including several that ask for some specificity about some of the things you proposed, including, would you support a reorganization of the government that would remove any food regulation from the Agriculture Department and give it to the FDA?

MR. VON ESCHENBACH: No, I don't think it's a -- need to restructure. I believe that there is great value in terms of what both of these agencies contribute. We are working toward greater integration and collaboration, but I don't believe restructuring at this point would be a productive step.

MS. SMITH: Do you think it's appropriate for the agency that is responsible for promoting and advancing a sector of the economy also regulate it?

MR. VON ESCHENBACH: I will not -- I cannot speak for the USDA. I will speak specifically FDA in terms of the fact that we are engaged in a regulatory activity that moves beyond just simply looking at food from the perspective of safety, but also as the Center for Food Safety and Applied Nutrition indicates, looking at food as a part of our important prescription for health.

And using the scientific data that exist at FDA, keeping that aspect of our food plan vested in FDA I believe is the appropriate step for the future.

MS. SMITH: You suggested that it might be time to increase the fees that -- for applications for -- for new drugs. What -- do you have an idea in mind of how much?

MR. VON ESCHENBACH: We have proposed user fees that first of all were included in the current president's budget for 2009. We have user fees that we have previously negotiated with both -- in the Food & Drug Administration Amendments Act for both drugs and devices.

As we go forward and continue this process, it's important that we first of all compartmentalize those user fees so they are just that, they are fees for a specific service, and they absolutely do not interfere or impact upon the regulatory processes or pathway. But as a fee for service, they have to be commensurate with the service and they have to bear the full cost of those services, including the review and all the other aspects that are associated with the review, including inspections. And so my comments are to the point of a fee structure that is commensurate with the service that's rendered. And as we go forward, that must be a part of that understanding and negotiation.

MS. SMITH: Would that be as much as double, do you think?

MR. VON ESCHENBACH: Well, I think -- I don't have a specific ballpark figure for a percentage increase. I believe it's specific to each individual category of user fees and applicable to the services that are being provided for that fee to determine what that increase in cost will be. It is not just simply a percentage increase that would -- relates to cost of living or inflation -- an increase that relates to the service rendered, and that will vary depending on individual fees.

MS. SMITH: Would it be on a case-by-case basis then --

MR. VON ESCHENBACH: Yes.

MS. SMITH: -- process, okay.

This questioner says, "Please provide details on FDA's plans to base inspectors overseas. What countries and region, when, how many and what kind of State Department clearances might you need?"

MR. VON ESCHENBACH: We're first of all working very closely with the State Department and we're also engaging in discussions and conversations with potential partners in other parts of the world and in other countries. Obviously, as I've indicated, we're anticipating and looking forward to opportunities -- for example, if -- our discussions occurring with China as well as with India. We also anticipate the ability to move into other parts of the world and anticipate regions that could encompass Europe, Central, South America as well as areas around the Middle East.

MS. SMITH: A question about the heparin situation. Can you please explain the internal process for deciding which plants to inspect and why, given the reports in the past year of pig disease in China, plants that made medical -- that make medical ingredients from pig intestines would not be -- would not have been the top priority?

MR. VON ESCHENBACH: First of all, let me indicate that the investigation of the heparin issue is active and underway, occurring on multiple fronts both with regard to investigations that are occurring here locally in collaboration and cooperation with CDC and with the company, and we also have investigations going on within China itself, occurring with our partners at the state Food and Drug Administrations. And quite candidly, that experience has been an extremely productive one and has built upon the Memorandum of Agreement that we negotiated and signed with them following our interactions after melamine and the pet food incident.

With regard to our inspections overseas, they have been based on risk assessment and they have also been based on an application for a new drug or a new product. In circumstances in which we have the ability to identify a particular risk either because of the nature of the product, circumstances that are surrounding that product or previous history with that particular institution or company, then we will -- we focus our investigative effort in that regard. We're beginning to develop a new system called Predict, which will enhance

the amount and kinds of information that we will be able to gather as, if you will, intelligence with which to even further enhance our ability to be discriminating about that level of risk and where those inspections need to be targeted.

MS. SMITH: Well, based on that, it would sound to me that those plants in China or those factories in China certainly would have been

the kind that you would have looked at, given the pig disease. So was it a problem in the system that was set up or was the problem in the execution that they weren't inspected?

MR. VON ESCHENBACH: This appears to be a problem in execution. And it appears to be a problem in execution in the sense that given the names of various plants -- those that were inspected and this one that was not. There was a similarity in those names that was such that there was a confusion with regard to assigning the fact that there had been an inspection. So it was a failure in process, not a failure in strategy.

MS. SMITH: The question says, "There was a news report earlier this month that only 7 percent of foreign plants processing food for export to the U.S. are inspected every year, and that American pharmaceutical plants are inspected only once every two years. A, is that true?; and B, is that something that should bring us comfort?"

MR. VON ESCHENBACH: Well, I think it's important to point out that when one thinks about inspections and thinks about numbers, those numbers have to be put in context. It is clear, as I've indicated before, that we need to utilize resources targeted against where we think there are specific concerns in the areas of risk such that irrespective of overall average numbers, we clearly would not target our resources to inspecting frequently plants that were making tongue depressors whereas we would be targeting our resources that -- to plants that were making complex medical devices. So it is an issue of where we utilize those resources that is as important as how many resources.

Having said that, we are working to increase the overall number of resources, both in terms of having FDA presence abroad where we're able to expand our workforce conducting those resources; two, working collaboratively with counterpart agencies, governments and private institutions that are capable of carrying out third-party inspections that would be supervised and overseen with regard to the nature and quality of those inspections by FDA. And the net result of that initiative is to radically expand our ability to cover those areas that are of concern.

MS. SMITH: We have a couple of questions about appearance of impropriety or conflict. Shouldn't individuals with former ties to the pharmaceutical industry by barred from serving on FDA's commissions and boards because of the appearance of impropriety? Can't the FDA find enough academic scientists and public interest doctors to fill the majority of those policy-making and advisory positions?

MR. VON ESCHENBACH: We've embarked upon a very extensive effort

to create and expand a much larger pool from which we can derive appropriate expertise to inform us about the nature of the products upon which we have to make a regulatory decision. We've reached out to multiple organizations including, for example, the American Medical Association and others. Having said that, we also are complimenting that process of expanding the field with continuously improving our internal processes by which we can begin to eliminate any concerns about conflict of interest or bias.

The fact of the matter always remains that in order for us to have the kind of expertise that's required to give us the kinds of insights we need about these products, we need people who have been engaged in that particular product or in those kinds of disciplines in some form of (sic) another. Some have been engaged in the discovery end in academic institutions, some have been engaged in the development of products as it relates to industry. That in itself is actually a benefit to us by having that kind of knowledge and expertise available to us, provided we have certified and made certain that there is no aspect of that relationship that constitutes a conflict. And that's what our endeavor is about.

But to simply exclude by formula would place us in a position where we might be depriving our regulatory process and the information we need to protect and promote your health from expertise that is essential.

MS. SMITH: It's been reported that many continuing medical education courses which are required of all practicing physicians are sponsored by pharmaceutical companies and taught by physicians and other medical or pharmaceutical professionals paid by those drug companies. Could you please comment on that?

MR. VON ESCHENBACH: First of all, this is not an area that is directly related to my current role as commissioner of the Food and Drug Administration. But obviously, as a physician, it's one in which I have had some experience and some exposure.

I think it's extremely important that we understand the need for continuous, ongoing, intensive medical education. It is a -- ongoing learning process, by virtue of the kinds of radical and rapid changes that I have described, in terms of the products that we as physicians must utilize in order to protect and care for others.

Having said that, it's important that we put that educational context into the right framework. The FDA is taking a role in looking at that, for example, with regard to the dispensing of medical information as it relates to scientific articles from journals that -- with regard to how that could be utilized by pharmaceutical companies in terms of an education process.

So I think the need is to provide education. The importance of, again, creating strong safeguards and guard rails that protect from problems of bias or inappropriate behavior are important.

MS. SMITH: You just mentioned that the FDA is taking a look at the marketing of pharmaceutical companies for -- it's called off-label use of drugs? When you say take a look at, what are you looking at?

(Off mike.)

MR. VON ESCHENBACH: What I was relating to was our looking at the proper ways in which information derived from peer-reviewed medical journals could be appropriately disseminated.

With regard to off-label utilization of drugs, we, the FDA, does not approve the marketing or promotion of off-label use, recognizing, however, that in the practice of medicine, individual physicians with individual patients will make decisions about the use of drugs that are approved by the FDA for other indications. That's a practice of medicine, responsibility an issue on a patient-physician basis, but it is not a practice to be condoned in terms of being promoted by pharmaceutical or drug companies.

MS. SMITH: This question is does the FDA have the legal authority to require drug companies and medical device and medical

supply makers to disclose physician payments? Would you support legislation requiring disclosure, and should payments be banned, or is there an argument to be made for allowing those relationships?

MR. VON ESCHENBACH: I cannot give you a precise answer to what FDA's legal construct is with regard to that specific issue, and I would have to research that. I don't believe in terms of -- if I understood correctly -- it's an area that we have any involvement in at this point.

I think physician reimbursement has been, and I prefer it always remain, a CMS issue, rather than an FDA issue. (Laughter.)

MS. SMITH: Okay. Are you troubled by the aggressive marketing of drugs to consumers?

MR. VON ESCHENBACH: I'm troubled by the inappropriate marketing that may occur with regard to -- I believe that dissemination of information is an extremely important contribution to patients' understanding and knowing and being aware of their own diseases, their need for attention, and the options that may be available to them. But I think that has to be done in the context of what was essentially a relationship equivalent to a doctor-patient relationship.

So whether it's the FDA distributing or disseminating information about products or the pharmaceutical industry, or academic institutions distributing or disseminating information to patients, we must always do that in the context of what is ethically appropriate and what is in the best interest of that patient, rather than serving any of our goals or needs.

So I really do believe there need to be standards. Those standards need to be rigorously applied. I recognize that there's a context of the First Amendment rights. But within that, there really does need to be the sensitivity and appropriateness of this process. And I think that in my conversations with leaderships of the industry, many steps are being taken within the industry to assure that that is the case.

MS. SMITH: In the past you've said that if Congress gives the FDA authority to regulate tobacco, and if the agency ordered nicotine levels to be reduced, it might lead to people smoking more to get more nicotine.

However, proponents of FDA regulation say there are arguments that outweigh that concern, including potentially more restrictions on the tobacco industry's efforts to make products that appeal to kids. Is that argument compelling to you?

MR. VON ESCHENBACH: The issue of the prior statement is in the context of recognizing a need to eliminate what is perhaps the single most important concern or threat to public health in this nation and this world -- smoking -- but to do that in a way that is appropriate

to get the right outcome and the right effect. It is to do the right thing and it is to do it in the right way, and that is a mantra that I've carried with me as a physician.

In the context of making decisions about the issue of reducing nicotine, my caveat was that there are circumstances in which you could increase the need to smoke more in order to reach the level of nicotine one had become addicted to. And as you smoke more to get that same amount of nicotine out of a much larger number of cigarettes, you would be, by nature, getting a lot more of the carcinogens and the other elements that effect cancer, heart disease, and others.

This is a very important explanation, because I think it calls into question the need to define the right thing to do and to do it in the right way. And that is a thoughtful, deliberative process that FDA wants to contribute to, that we want to be a part of, and that we want to work collectively to the most appropriate solution to eliminating smoking as a public health problem.

MS. SMITH: How have your personal experiences with cancer and your professional background with the disease influenced your work at the FDA? Have you reordered any priorities or instituted any initiatives as a result?

MR. VON ESCHENBACH: I don't believe I needed to reorder or to change priorities, but simply perhaps underline and emphasize what was already there -- that as a -- both as a patient as well as a physician, I appreciate the importance of having the patient center and first and foremost with regard to everything we do. That has been the culture of FDA, and perhaps my role was to simply underline and underscore that.

We are there to protect and promote your health, and everything we do must be done with that as the only end and only purpose for why we're doing it. It will remain a science-based regulatory agency making decisions for that reason and that reason only, and no other influence.

MS. SMITH: When you were the director of the National Cancer Institute, you made the bold statement that the NCI planned to eliminate suffering and death caused by cancer by 2015, making it

essentially a manageable disease. Do you still think that goal's realistic?

MR. VON ESCHENBACH: Yes. It's realistic if we're willing to make the commitment and do the things that need to be done to achieve it.

The reason I believe it's realistic is because of the fact that we have entered into a new era and a new age, that I have been trying to describe as it relates to FDA, in terms of the radical and rapid change that's occurred. We now have the ability to not simply observe the manifestations of disease, not simply to feel a lump in a woman's breast and know that she has breast cancer, or to see a shadow on an x-ray and know that a man has lung cancer. We now have the opportunity to understand disease processes at their very fundamental genetic, molecular and cellular level.

And those processes, as we understand them from how a disease begins until it ultimately ends in suffering and death, gives us an

enormous number of opportunities to intervene and either eliminate that process or control that process and prevent that outcome.

This model is not just true of cancer. It's a model that's applicable today to our understanding of Alzheimer's, of macular degeneration that I alluded to earlier, and it's opening up the doorway, the portal, for us to create new interventions, new solutions, that 10-15 years ago were unimaginable.

That is a reality for which there's already proof of principle, but it is not yet assured or within our grasp. It is yet to be attained, but it is attainable. And I believe, just as we recognize we have the scientific and technological capability to put a man on the moon if we chose to do so, I believe we have the scientific and technological capability to eliminate and control disease processes like cancer and diabetes and Alzheimer's, if we choose to do so.

MS. SMITH: We're almost out of time. But before asking the last question, I've got a couple of important matters to take care of.

First, let me remind Club members of future speakers. On March 17th we'll have Terrence Jones, who's the president and CEO of Wolf Trap Foundation for Performing Arts, with his guest, Marvin Hamlisch. On March 21st we'll have the president and CEO of the Mayo Clinic. And on March 31st, kicking off the National Press Club's birthday celebration week, we have Don Ritchie, who's the associate historian of the U.S. Senate. He will discuss "Scoops, PACs and Clubs: A Centennial Survey of the National Press Club and the Washington Press Corps."

Second, I'd like to present our speaker with two centennial gifts. First we have our brand new centennial mug, which features former NPC member and Fourth Estate award winner Eric Sevareid, who will be honored in a series of stamps that the U.S. Postal Service will issue. And this is the NPC centennial medallion.

MR. VON ESCHENBACH: Thank you.

MS. SMITH: Thank you. And now my last question, which is a final food question. In the debate that has embroiled Philadelphians for generations, how do you weigh in -- Pat's Philly cheesesteaks or Geno's?

MR. VON ESCHENBACH: Well, she saved the most dangerous question for last. As a native of south Philadelphia who's come to Washington to hopefully study at the seat of wise and great politicians, I like both. (Laughter, applause.)

MS. SMITH: Thank you very much. We're adjourned.

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