FDA News

FOR IMMEDIATE RELEASE

November 5, 2007

Media Inquiries:
Christopher DiFrancesco, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Selects Members for Risk Communication Advisory Committee

The U.S. Food and Drug Administration has selected 15 voting members to serve on its Risk Communication Advisory Committee. The Committee will advise FDA about how best to communicate to the public about the risks and benefits of FDA-regulated products so as to facilitate their optimal use.

On June 5, 2007 FDA announced the establishment of the advisory committee and requested nominations for qualified individuals to serve as members. The agency received more than 240 nominations, many for exceptionally qualified individuals.

The establishment of the advisory committee was one of the recommendations of the Institute of Medicine's 2006 report, "The Future of Drug Safety: Promoting and Protecting the Health of the Public."

"Communicating effectively about the safety and effectiveness of drugs and other medical products is one of the central roles of FDA," said Randall Lutter, Ph.D., Deputy Commissioner for Policy. "We were in such strong agreement about the value of the Risk Communication Advisory Committee that we expanded its scope to address communication regarding all products regulated by the agency, including our food supply responsibilities."

The advisory committee's 15 voting members include independent experts and public members. Experts were chosen from the fields of risk communication, risk perception, decision analysis, communication, social marketing, health literacy, journalism, and other behavioral and social sciences. Public members include those who can provide the perspective of users of FDA-regulated products, such as consumers, patients, caregivers and health care providers. For some meetings, one or more industry representatives may be invited to participate in a nonvoting capacity.

Members have been assigned to serve for periods ranging from one to four years. FDA expects to hold the committee's first meeting in the first quarter of 2008. The list of members is available on FDA's Web site at http://www.fda.gov/oc/advisory/OCRCACRoster.htm.

FDA is currently amending the committee's charter to incorporate the provisions of the recently passed Food and Drug Administration Amendments Act of 2007.

#

Update on Post-marketing Drug Safety Activities at the US FDA

Gerald J. Dal Pan, MD, MHS

The last several years have witnessed a remarkable growth in interest in drug safety, and especially in post-approval drug safety. Several factors have contributed to this increased focus on the safety of medicines.

First, the breadth and depth of the science of drug safety have expanded. In many regions, population-based data are available for pharmacoepidemiological studies, which allow researchers to examine the safety of medicines in real-world settings. Pharmacogenomics has allowed scientists to have a better understanding of the molecular basis of human response to drugs. Part of the development of the science of drug safety includes better methods for adverse event collection in special populations. For example, the World Health Organization (WHO) has published a monograph on Pharmacovigilance for antiretrovirals in resource-poor countries. Diverse efforts such as these are evidence of improvements in the science and methodology of drug safety.

Second, there has been an increasing societal interest in the safety of medicines. In the US, patients, health care professionals, advocacy groups, the media, and legislators have all engaged in a national discussion on the importance of drug safety throughout the lifecycle of a product. The US Congress, in September 2007, enacted the Food and Drug Administration Amendments Act, which, amongst other things, acknowledges the importance of a robust post-approval drug safety system.

New initiatives at the FDA

At the US Food and Drug Administration, many new initiatives have begun over the past year in the Center for Drug Evaluation and Research. Selected ones dealing with improving the science of drug safety are summarized below.

Analysis of adverse event reports submitted to FDA remains a critical component of the drug safety system. FDA received approximately 472,000 adverse event reports in 2006.

These reports are stored in a database known as the Adverse Event Reporting System, which contains over four million reports. To evaluate these reports more efficiently and to identify and track more effectively safety signals, we plan to begin an upgrade of this system to a web-based accessible system with signal detection and tracking tools.

Because of the importance of spontaneous adverse event reporting in a pharmacovigilance system, FDA plans to publish a request for proposal from outside organizations interested in conducting an analysis of the public health benefits of reporting serious and non-serious adverse events. This research will focus on the number and type of safety concerns discovered by adverse event collection, the age of products at the time the safety concerns are detected, and the types of actions that are subsequently taken to promote patient safety.

To explore more effective ways of examining post-approval drug safety information, FDA is conducting a pilot program using a new systematic method to review the safety profiles of new molecular entities (NMEs) on a regularly scheduled basis after approval to determine whether these reviews should be initiated for all NMEs. Post-marketing evaluations of NMEs will incorporate data from the Adverse Events Reporting System (AERS), data mining analysis, epidemiologic data, post-marketing clinical trial information, and a review of the Periodic Safety Update Reports (PSURs), and US Periodic Reports, to identify potential safety concerns early in the product life cycle. We anticipate that results of this pilot program will be available by the second half of 2008.

Supplementing ADR information

FDA is also actively exploring additional sources of data to supplement the spontaneous adverse event reports in the AERS system. These additional sources of data are important because not all adverse effects can be reliably detected or quantified using a passive, spontaneous reporting system.

Gerald Dal Pan, M.D. Director, Office of Surveillance and Epidemiology (OSE) at the US Center for Drug Evaluation and Research

FDA has entered into a data use agreement with the Agency for Healthcare Research and Quality (AHRQ) to use data from the Centers for Medicare & Medicaid Services (CMS) to conduct a collaborative research project to develop data structures and methodologies for identifying and analyzing adverse drug events. In addition to studying safety issues relating to these specific drugs, the goal of this program is to gain familiarity with CMS data, in anticipation of the availability of expanded data in the near future.

The Veterans Health Administration (VHA) and FDA are working under a recently signed memorandum of understanding to allow sharing of certain information related to the use of drugs, vaccines, other biological products, and medical devices. The purpose of the project is to enhance knowledge and efficiency through the sharing of information and expertise between FDA and VHA regarding medical product safety, effectiveness, and patterns of use.

FDA also plans to obtain access to additional databases and to hire additional epidemiologists and programmers to conduct and oversee observational epidemiological studies using these databases. In

addition, FDA plans to seek input from pharmacoepidemiologists in academia and industry to develop guidance on conducting scientifically rigorous observational pharmacoepidemiological studies using large population-based healthcare databases. The main purpose of such studies is to confirm hypotheses regarding drug-adverse event association, and to quantify the risk of such adverse events.

Active surveillance

In addition to evaluating spontaneous adverse event reports and examining specific drug/adverse event association in large, population-based databases, FDA is also interested in using external databases to identify drug safety signals earlier than current methods do.

To accomplish this, FDA will explore ways to engage in active surveillance of drugs. To begin this effort, FDA sponsored, on March 7 and 8, 2007, a public meeting to explore opportunities for linking private sector and public sector healthcare databases and postmarketing safety monitoring systems to create a virtual integrated, interoperable nationwide medical product safety system. This effort, known as the Sentinel Initiative, could integrate existing and planned private and public sector databases to enable the collection, analysis, and dissemination of safety information about medical products to healthcare professionals and patients at point of care (ie, in the clinic where this information is needed to make informed decisions about safe and effective treatments).

FDA will continue to engage the public and private sectors in a discussion of opportunities for public and private sector collaboration on activities that could develop the data collection and risk identification and analysis components of such a potential system.

Risk evaluation

Risk management of medicines is also an area of active interest at FDA. With input from academia, industry, and the public, FDA plans to evaluate risk management tools and programs for their effectiveness. In addition, FDA plans to conduct assessment of specific risk management plans. As part of this effort, FDA plans to conduct annual systematic reviews and public discussion of the effectiveness of one or two risk management plans and one major risk management tool.

To assist FDA's safety evaluators and epidemiologists in the quantitative evaluation of safety data, CDER created in 2006 a Quantitative Safety and Pharmacoepidemiology Group, which provides biostatistical expertise to a wide range of drug safety questions.

The safety and risks of medicines cannot be evaluated in isolation; rather, they must be weighed against the benefits the medicine. In May 2006, FDA, along with the Institute of Medicine, sponsored a workshop on new approaches to quantitative risk-benefit assessment. FDA plans to continue exploring the possible uses of best practices in this area.

Guiding better drug use

Other areas in which new approaches to drug safety are being explored at FDA include developing techniques for predictive toxicology, identifying cardiovascular risks of drugs, preventing drug-induced liver injury, and using pharmacogenomic information to guide safer and more effective use of drugs.

In addition to these scientific endeavours, FDA has embarked on a variety of measures to improve communication. Examples of these initiatives include a comprehensive review of current public communication tools, establishing an advisory committee on risk communication, and improving communication amongst staff.

FDA also issued guidance on Drug Safety Information - FDA's Communication to the Public in 2007 www.fda.gov/cder/guidance/7477fnl.pdf. FDA also inaugurated a new Drug Safety Newsletter in the fall of 2007 (www.fda.gov/cder/dsn). The purpose of this newsletter is to provide postmarketing information to healthcare professionals to enhance communication of new drug safety information, raise awareness of reported adverse events, and stimulate additional adverse event reporting.

The above scientific and communication initiatives are accompanied by a variety of organizational and management changes designed to strengthen the drug safety system.

Impacts of legislation

An exciting new challenge for FDA will be the implementation of the recently enacted Food and Drug Administration Amendments Act (FDAAA), which was signed into law in September 2007. Among other provisions, this law reauthorized and expanded the Prescription Drug User Fee Act (PDUFA), which will ensure that FDA staff have the additional resources needed to conduct the complex and comprehensive reviews necessary to new drugs, including drug safety issues. FDAAA also reauthorized other laws, including the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric. Research Equity Act (PREA). Both of these are designed to encourage more research into, and more development of, treatments for children.

FDAAA establishes the Reagan-Udall Foundation for the Food and Drug Administration, a non-profit corporation whose purpose is to advance the mission of the FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety. An additional feature of FDAAA are sections that include drug safety provisions. These provisions address safety-related labelling changes, risk evaluation and mitigations strategies, post-approval clinical trials and observational studies, and active postmarket risk identification and analysis. These provisions add important tools in our work throughout the total lifecycle of these products. FDA is currently in the process of implementing FDAAA.

For more information on FDA, see www.fda.gov.
For more information on FDA's drug safety initiatives, see www.fda.gov/cder/drugSafety.htm

For more information on the Food and Drug Administration Amendments Act, see www.fda.gov/oc/initiatives/advance/fdaaa.html

Speech before

National Press Club
Washington, D.C.

Remarks by

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs

on

"FDA at a Turning Point:
Meeting the Challenge of a Rapidly Changing World"

February 29 , 2008

This text contains Dr. von Eschenbach's prepared remarks. It should be used with the understanding that some material may have been added or deleted during actual delivery.

Thank you, President Smith, for that very kind introduction.

I wish my mom and dad could have been here to hear it but I am pleased that my wife Madelyn and my Chief of Staff at FDA, Susan Winckler, are both here at the head table as well as the members of FDA who are with us.

Hopefully my stock will go up both at home and at the FDA.

I am very grateful to the National Press Club for the invitation to be with you today and I am very honored to join the ranks of so many distinguished leaders who have appeared before you and who were instrumental in changing our nation and the world.

Today I would like to talk to you about that changing world, what that change means to the Food and Drug Administration, and the need to re-create the Agency.

Changes in our world are affecting *every* single American in terms of our health and well being. Change is affecting *everything* from the food we eat to 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 rapid in the rate with which they are occurring. Society has faced radical change before, such as one hundred years ago at the birth of the National Press Club. Science then was unraveling the secrets of the atom and, with the dawn of the atomic age, gave the world the awesome power to alter its destiny.

This change held great promise – but also the potential for tremendous peril.

Radical changes were also occurring 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 but presented also great peril from contamination of food and marketing of fraudulent drugs.

Our nation had to respond.

One response was the wise decision of Congress to enact and President Teddy Roosevelt to sign the Food and Drugs Act of 1906, which empowered the U.S. Agriculture Department's Bureau of Chemistry, the organization that would later become the

FDA charged with protecting and promoting our health.

Over the course of the 20th century, the FDA did its job well and has been and is today recognized as the world's gold standard regulatory agency.

Now, in the first decade of the 21st century, the world is again undergoing radical change, but that change is occurring at a rapid rate that is unprecedented. Once again there is great promise and peril.

Just as with the atom and its nucleus, revolutionary progress in science and technology enables us to study the cell and its nucleus thereby leading to our understanding of genes, molecules and DNA that control life processes and disease. We can clone animals, genetically modify crops, and create X-ray devices that see living biology.

We are now creating medicines that don't just treat the manifestations of disease, but actually alter the biology of the living cell.

Exponential advances in science and technology are again coupled with changes in how we live.

Urbanization has given way to globalization, and the 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 food and drugs of the 21st century, a time when 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: cleaned, cut and cored, 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 clinics we have devices that diagnose with certainty many diseases, and hospitals are equipped with drugs and devices that treat with maximum effectiveness and minimal risk almost all that ails us.

This is a time in which the winds of change in health care in terms of power and pace are 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 FDA is in itself radical in scale and scope because the portfolio of FDA's responsibilities is vast and its reach is enormous—regulating products you and I need and use every day.

By law, the FDA must regulate, except for meat, poultry and some egg products, all the food we eat: vegetables, fruits, fish and the spices that go on them and the bottled water accompanying them. We regulate vitamins and dietary supplements; every medical product from simple aspirin to more sophisticated drugs and biologics for the treatment of acute and chronic diseases; blood products; medical devices from cardiac pacemakers to PET scanners and from surgical masks to surgical robots and linear accelerators. We regulate radiation-emitting equipment including microwave ovens and products that affect not only how we feel but how we look, from toothpaste and underarm deodorant to sun screens and cosmetics.

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

FDA was created one hundred years ago because change had created peril along with promise, and today FDA must be re-created because the peril and promise from these products is now even greater.

Consider 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 cut produce.

But the potential promise is great: a bountiful supply of fresh fruit and produce available all year round and processed foods with benefits, such as lowering cholesterol are truly essential prescriptions for health.

We can do more to prevent disease such as genetically engineering 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 susceptible to breakdown or failure simply because of their complexity. New materials such as nanoparticles and devices that present new unknowns. Drugs and vaccines containing ingredients obtained from sources around the world and manufactured and distributed through complex supply chains as in the recent case of heparin.

But the promise is great.

We can design and target drugs for a genetic defect and halt a disease like leukemia or block molecules from affecting blood vessels and mitigate blindness from macular degeneration. We can create vaccines to protect us from devastating threats like

pandemic influenza or develop a recombinant protein to control and prevent bleeding in patients with hemophilia.

Today the peril is real but the promise unlimited.

However, I believe for the FDA to fulfill its mission to protect and promote your health we must respond now. I believe that was my charge when I became Commissioner two-and-one-half years ago.

The challenges I face today are perhaps unlike those of my predecessors, as I attempt to guide this Agency in responding to its day-to-day exhausting responsibilities while simultaneously expending the energy to define and create the reality of tomorrow. FDA staff are the finest, most dedicated, talented people worthy of the dignity of the title "public servant." But their task is daunting.

Consider the acute risk of pandemic influenza when I arrived in September of 2005 —it was a major public health concern around the globe. It was expected that in the event of an imminent outbreak, FDA would assure the safety and effectiveness of every medical intervention including some not yet invented, like a vaccine for the offending virus.

And in addition to responding to specific issues the 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 by tasks ranging from the rapid dispersal of vaccines and antiviral drugs to ensuring adequate supply of medical devices such as respirators, and processes to assure the safety of food and safe disposal of infected animal carcasses.

The Agency embraced a strategy to change from the reactive mode of a regulator to a proactive mode of facilitator. We immediately engaged with academia and industry to facilitate product development and to integrate our efforts for appropriate delivery with the private sector and our Federal, State, and international counterparts.

Fortunately we have not had to face the test of an outbreak but one benefit of this comprehensive, multi-disciplinary, integrated approach has been the enhancement of our vaccine manufacturing capacity. Unlike three years ago, when we had only three licensed vaccine manufacturers of influenza vaccine licensed in the U.S., we now have six licensed firms. As a result, rather than a shortage that occurred a few years ago, this year we have excess capacity. In addition, in 2007, we licensed the first influenza vaccine against the h5N1 influenza virus. Because of that demand of a changing world, FDA did change radically and rapidly with great benefit as a result. Today, the pandemic response strategic plan we developed is a model guide.

This theme of the need for radical and rapid change over the past two years has guided a systemic and systematic transformation at FDA that builds on the progress of the past and will extend into the future.

The principles of this systematic and systemic change process include:

One: Selection of the areas of focus based on their critical importance to the mission of FDA. We cannot do everything at once but issues of drug safety, food protection, the scientific foundation for regulatory decisions, work force development and essential infrastructure including facilities and information technologies are our immediate priorities.

Two: A disciplined process for assessment of the problem to obtain the information necessary for devising the appropriate intervention. In some cases analyses were already available like Government Accountability Office reports or were underway as with the Institute of Medicine of the National Academies' Evaluation of Drug Safety.

In other cases they were commissioned: for example, we asked our Science Board to convene a subcommittee of outside experts to do a comprehensive review of our scientific portfolio. We collaborated in the development of a Food Protection Plan while conducting an intensive internal revision of our Agency Strategic Plan. Both plans were released in November of 2007.

Three: Development for each of these strategic initiatives a detailed implementation plan with milestones and outcomes. We were very honored to have launched such a plan--our Response to the IOM Drug Safety report--right here at the National Press Club last year and have already implemented many of the initiatives outlined in the report such as creation of our Risk Communication Advisory committee.

We were pleased this week to announce a major initiative called Safety First which addresses our processes for multidisciplinary determination of risk.

Four: We continue a series of external and internal consultations. In particular, an assessment of our work force has demonstrated a critical need to expand the numbers and skill sets required for our regulatory mission in this new era.

We have embarked on an aggressive recruitment and retention effort with a target of hiring an additional 700 new employees in 2008. This has primarily been made possible by the passage of the Food and Drug Administration Amendments Act of 2007 and incremental increases provided in our appropriations.

In addition we will shortly be launching plans for an FDA Fellowship Program which has the potential to attract up to two thousand professionals of varying disciplines for a two year training program.

Other assessments demonstrated a need for renovation and modernization of our information technology infrastructure, and this year we will spend approximately 250 million dollars on employing modern high performance servers and new software systems that facilitate interoperability across the Agency and expansion of our electronic data bases.

Within the next year we will open an integrated data center on the consolidated FDA campus that is under construction at White Oak. White Oak is also the site for our new state-of-the-art laboratories for the centers dealing with drugs, biologics, medical devices and veterinary medicine—CDER, CBER, CDRH and CVM.

Five: Changes in programs and processes have been accompanied by changes in policy. Again the realities of a radically and rapidly changing world require new ways of thinking as well as doing. FDA can no longer be simply a gate keeper assessing benefit and risk before allowing a product to be delivered to patients or the public, or to rely solely on inspections to verify quality.

It must engage in the Total Life Cycle of the products we regulate whether it is food going from farm to fork or medical products from production to consumption. Engaging in stages of discovery, development and delivery of products we regulate will enable us to better assure quality. One important aspect of our engagement in the discovery and development part of the product life cycle is our commitment to the FDA Critical Path Initiative. This year we will invest over five million dollars to apply the tools of modern science to the regulatory and development process of regulated products.

With regard to the delivery end of the cycle, we will engage in the monitoring of performance of products in an extensive program of post market surveillance. Soon, we will unveil a new FDA program that we're calling the Sentinel Initiative. It is a collaborative effort with public and private partners that will create a distributed, nation-wide system that will allow FDA to analyze large databases of information about the safety of medical products as they are used by large diverse populations.

Monitoring and detection must be accompanied by enhancing our response to mitigate adverse outcomes. We must enhance our capability for intervention by increasing risk based inspections now using modern scientific tools of detection and expanding our network.

This emphasizes the need for FDA to enhance its collaborations. We are forging multiple partnerships with Federal agencies like Customs and Border Protection, the Centers for Disease Control and Prevention, and the U. S. Department of Agriculture, as well as State agriculture and health colleagues, private sector organizations, and 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, and cooperation especially on enforcement matters.

In an age when a border is not a barrier, we have embarked on our initiative: "FDA beyond our Borders." It is an effort to establish an FDA presence overseas and to build capacity at foreign sites – in at least five regions, beginning with China. We must also expand our work with foreign regulators, to share information more fully.

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

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

FDA and HHS played a leadership role 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 truly is underway from policies and procedures to 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, it may seem to have 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 perseverance.

All must understand that there never will be the end point—because the process of transformation, adaptation, and regeneration must be continuous and ever-evolving; that is the nature of the world in which we live.

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 the 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, and 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 as the 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, providing our agency with a budget and authorities that are commensurate with the scale and scope of our mission.

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

Plans and resources at FDA are necessary but not sufficient. We cannot transform the Agency ourselves. It's a transformation that requires commitment from others.

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

In the next three to five years, from others we need the following:

From the Congress, we need authority to better regulate the food supply. Our Food Protection Plan calls for ten 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—we need this legislation.

From the industries whose products we regulate, we expect strong corporate responsibility and compliance with regulatory standards as well continued support of the user fee programs with amounts appropriate for the services rendered. These payments bolster our ability to review product applications promptly – so that life-saving medical interventions reach patients sooner. New user fees must, like existing fees, consider all costs of the service at issue.

From our stakeholders, we need their full backing for the Reagan Udall Foundation established by Congress as an independent 501c(3) organization to support the mission of the FDA.

From the public, we are looking for support and patience, as well as trust and confidence in our work. We at FDA are committed to serving the nation and, although these changes will take time, their benefits will be long lasting to protect and promote your health.

We're looking forward to a re-created FDA, with an efficient regulatory pathway that enhances discovery, development and delivery of lifesaving products.

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

We will know more, and communicate sooner.

In these remarks, I've attempted to explain three things:

- How the world has rapidly and radically changed
- Why these changes have brought FDA has to a turning point
- And what is being done to re-create the FDA

I hope you share with me the commitment to this effort.

As FDA Commissioner I am aware of the need for these changes to avoid the peril of failing in our mission to protect your health.

As a physician and researcher, I am aware of the need for change for the FDA to achieve the promise of being the bridge and not the barrier to delivering life-saving solutions to eradicate and prevent diseases that threaten you, now and in the future.

But most of all, as a grandfather concerned about the future of his 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 the food and drug industries to discuss how to best assure the quality of products produced there for export to you here in the U.S.A.

While there in Delhi I had the opportunity to visit a neighborhood and to vaccinate babies and small children for polio. Afterwards I handed out lollipops to some of the children, and suddenly I was faced with a mob of grasping hands and squealing voices that grew more rapidly than my ability to dispense the lollipops -- until that moment came when there was nothing more to give to them.

I will never forget the out stretched hands and those big 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 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 their health, there will be nothing more we can give them.

Thank you.

参考１３

"FDA at a Turning Point: Meeting the Challenge of a Rapidly Changing World" by Andrew C. von Eschenbach, M.D., Commissioner of Food and Drugs at National Press Club Washington, D.C. on February 29, 2008

FDA（米食品医薬品局）長官、アンドリュー・C・フォン・エッシェンバッハ、M.D.
による
ワシントン D.C. のナショナル・プレス・クラブでの講演

「岐路に立つ FDA:　急速に変化する世界への対応」

2008 年 2 月 29 日

これは Dr. フォン・エッシェンバッハが事前に用意しておいた原稿です。実際の講演で話された内容とは一部異なる場合もありますので御了承下さい。

スミス理事長、丁寧な御紹介ありがとうございます。

今日ここに私の両親がいないのが残念ですが、主賓席には妻のマデリンと FDA 首席補佐官のスーザン・ウィンクラー、そして FDA の職員達がいることを嬉しく思います。

これで家でも FDA でも私の株が上がるとよいのですが。

今日こうしてナショナル・プレス・クラブにお招き頂き大変感謝しております。そしてこれまでここで講演を行った数多くの優れた指導者たち、我が国と世界を変えるのに大きく貢献した人々の仲間入りが出来ることをとても光栄に思います。

本日、私はその変わりゆく世界についてお話したいと思います。その変化が FDA にとってどのような意味を持つのか、そして FDA を再生する必要性についてお話します。

この世界で起きている変化はアメリカ人一人ひとりの健康と福祉に影響を与えています。その変化は私たちが食べる食品から私たちが必要とする医薬品や医療機器まであらゆるものに影響を与えています。

FDA もこれらの変化の影響を受けています。その結果、これまで通りの方法ではアメリカ人一人ひとりの健康を保護・増進するという我々の使命を果たすことが難しくなりつつあります。これらの変化の性質は重大であり、そのペースは急速です。我々の社会はこれまでも急激な変化に直面してきました。例えばナショナル・プレス・クラブが誕生した百年前のことです。その当時、科学の力で原子の秘密が解き明かされようとしていました。そして原子力時代の幕開けと共に、世界はその運命を変えてしまう恐ろしい力を手に入れてしまったのです。

この変化には大きな希望がありました。しかし、それはとてつもない危険も孕んでいたのです。

また都市化や工業化によって、私達の生活や仕事にも急激な変化が起こりました。

食品の大量生産と大量輸送、そして医薬品の大きな進歩は私達の生活改善に大きな希望をもたらしました。しかし一方で食品の汚染や不正医薬品など重大な危険も生まれました。

そこで我が国は対策を迫られました。

対策の一つは、賢明な連邦議会とテディ(セオドア)・ルーズベルト大統領が成立させた1906年の食品・医薬品法でした。この法律によって後にFDAとなる農務省化学局に国民健康の保護と増進の任務が課せられたのです。

20世紀を通して、FDAは十分にその任務を果たしました。これまでFDAは世界で最も権威のある規制当局と考えられてきましたし、それは今日でも変わりません。

そして21世紀最初の十年を迎えた今、世界は再び急激な変化を経験しています。しかし今度の変化はかつてない速さで起こっています。そして今度もまた、そこには大きな希望と危険があります。

原子とその核の時と同じように、科学技術の革命的な進歩によって細胞とその核の研究が可能になりました。その結果、私達は生命現象や病気を司る遺伝子、分子、DNAについて理解できるようになり、クローン動物、遺伝子組換え作物、生物の生態を見ることのできるX線機器などが生み出されました。

今や私達は単に病気の症状を治療するのではなく、細胞の生態を変化させてしまう薬を創り出しているのです。

今回もまた科学技術の急激な進歩は私達の生活に変化をもたらしています。

都市化はグローバル化に取って代わられ、工業化時代は今や情報化時代を包含するようになりました。過去にそうであったように、これらの変化は希望に満ちていますが同時に私達の健康に危険をもたらす可能性もあります。私達はこれについて対策を講じ、FDAを再生する必要があると考えます。

"FDA at a Turning Point: Meeting the Challenge of a Rapidly Changing World" by Andrew C. von Eschenbach, M.D., Commissioner of Food and Drugs at National Press Club Washington, D.C. on February 29, 2008

私の考えでは20世紀のFDAは21世紀の食品や医薬品を規制するのに十分ではありません。これは単純な真実です。現在、私達は今日チリで捕れた魚を翌日シカゴで食べることができます。アメリカ中で一年中いつでも西瓜を食べることができ、2月のスーパーマーケットで苺を目にすることもできます。21世紀とはそういう時代なのです。今や我が国はすぐに食べることのできる食品を求めています。洗って、切って、芯を取って、場合によっては調理までしてある食品が求められているのです。また今日、薬箱を開ければほとんどあらゆる症状を治療できる錠剤やカプセルが入っています。診療所に行けば多くの病気を正確に診断できる機器があり、病院にはほぼ全ての病気を最大の効果と最小のリスクで治療することのできる薬や機器が揃っています。

現在、医療の世界に変化の風が吹いています。その風は力と速度の点から言うと、そよ風ではなくジェット気流なのです。そして皆さんの健康を保護・増進するというその使命を引き続き果たして行くためには、FDAはこれらの変化に対応していかなければなりません。

このFDAの変革に向けた挑戦はそれ自体、規模においても範囲においても非常に大きなものです。なぜならFDAは私たちが日常的に必要とし使用するものを規制しているため、その管轄する領域は非常に広く、その及ぶ範囲は膨大だからです。

法律により、FDAは精肉と家禽、一部の卵製品を除いて、私たちが口にする全ての食品を規制するよう義務付けられています。野菜、果物、魚、その調理に使うスパイス、一緒に飲むボトル入りの水など全てです。ビタミン剤や栄養補助食品も我々の管轄です。またFDAは全ての医療製品を規制しています。これにはアスピリンのような簡単なものから急性、慢性の疾病の治療に用いるより高度な医薬品や生物製剤、血液製剤、そして心臓ペースメーカーからPETスキャナまで、手術用マスクから手術用ロボット、線形加速器までの様々な医療機器が含まれます。また我々は電子レンジなど放射線を放出する製品、そして我々の感覚だけでなく外見にも関わる製品、つまり歯磨き粉や脇の下用の消臭剤、日焼け止め剤や化粧品の規制も行っています。

ヒト用だけでなく動物用の製品も我々の管轄です。遺伝子組換え動物、ペットフードやペットの亀から家畜用の飼料、医薬品に至るまでの製品を規制しています。

百年前にFDAが設立された理由は、当時の変化が希望と共に危険をもたらしたからでした。そして今日、FDAは再生されなければなりません。なぜなら今述べたような製品はさらに大きな危険と希望をもたらしているからです。

"FDA at a Turning Point: Meeting the Challenge of a Rapidly Changing World" by Andrew C. von Eschenbach, M.D., Commissioner of Food and Drugs at National Press Club Washington, D.C. on February 29, 2008

例えば食の安全性と栄養について考えてみて下さい。危険は数多くあります。加工食品について言えば、最近缶入りのチリソースによるボツリヌス中毒症の危険性が明らかになりました。また、大腸菌やサルモネラ菌に汚染された調理済み生鮮食品も問題になりました。

しかし潜在的な希望は大きなものです。新鮮な果物や生鮮食品が一年中豊富に出回り、コレステロールを下げる加工食品などが手に入れば、健康にとって非常に大きな助けとなるでしょう。

また例えば遺伝子組換え技術でより栄養価の高い作物を創り出し健康を増進することによって、病気を防ぐこともできます。

医薬品や医療機器について考えてみてください。

確かに危険は多くあります。例えば心臓ペースメーカーのような高度で小型の機器は、その複雑さゆえに故障や不具合を起こしやすいものです。ナノ粒子などの新素材や未知の新しい要素を含む機器もあります。最近のヘパリンのリコールのように、世界中から調達した原料を使用し複雑な製造、流通過程を経た医薬品やワクチンにも危険があります。

しかし、希望は大きなものです。

遺伝的欠陥を治療する薬を開発すれば、白血病のような病気や障害分子が血管に影響を与えるのを防いだり、黄斑変性症による失明を軽減したりすることができます。またインフルエンザ大流行の破壊的脅威から私達を護るワクチンや、血友病による出血を防止する組み換えタンパクを開発することもできます。

今日、危険は現実のものとしてありますが、希望は無限にあります。

しかし、FDA が皆さんの健康を保護・増進するというその使命を果たすためには、今、対策を取らなければなりません。それこそが二年半前に私が長官に就任した時に与えられた責務だと思っています。

現在、私が直面している課題は私の前任者達のそれとはおそらく違ったものでしょう。というのは、私は日々の激務をこなす FDA を指揮しつつ、同時に明日の世界のあるべき姿を明示し、それを創り上げるためにエネルギーを注がなければならないからです。
FDA の職員達は最も優れた、最もひたむきで才気ある、正に敬意を込めて「公僕」と呼ぶに相応しい人々です。しかし彼らの任務は困難なものです。

"FDA at a Turning Point: Meeting the Challenge of a Rapidly Changing World" by Andrew C. von Eschenbach, M.D., Commissioner of Food and Drugs at National Press Club Washington, D.C. on February 29, 2008

2005年9月に私が長官に就任した時の世界的なインフルエンザ大流行の危機を思い出してください。これは当時、世界的な保健衛生上の大問題でした。大流行が起きると判断された場合には、FDA は関連する全ての診療行為の安全性と有効性を確認し保証することになっていました。これには原因となるウィルスのワクチンなど、まだ開発されていないものも含まれていました。

特定の問題への対応に加え、FDA は一体的、総合的、組織的な計画を立てる必要がありました。大流行の際は、FDA の全ての部署が臨時体制でその対応に当たることになっていました。対応しなければならない業務は、ワクチンや抗ウィルス剤の迅速な配布や人工呼吸器などの医療機器の十分な供給の確保、そして食品安全性の確保や感染した動物の死骸の安全な廃棄などでした。

またFDAは規制当局として事後的に対応するのではなく、まとめ役として事前的に対応する戦略を取り入れました。我々は即座に学界や産業界と協力し、製品開発を促進しました。そして民間部門、連邦、州、外国の担当者と共にそれら製品の適切な供給に尽力しました。

幸い、大流行の発生という試練に直面することはありませんでした。しかしこのような総合的、複合的、一体的なアプローチを取っていたおかげで我が国のワクチン生産量は増大しました。三年前、アメリカ国内で認可を受けたインフルエンザ・ワクチンの製造業者は僅か3社しかありませんでしたが、今では6社に増えました。その結果、今年は数年前のように不足するどころか余剰が出たほどです。さらに、2007年には初のh5N1鳥型インフルエンザ・ウィルス用のワクチンを承認しました。変わり行く世界の要求に応えてFDAは急激な変革を実行し、その結果大きなベネフィットを得たのです。今日、我々が築き上げた疫病流行対策の戦略計画は他の模範となるものです。

過去二年間、この急激な変化の必要性というテーマに従って、FDA は全体的で体系的な変革を行いました。この変革は過去の積み重ねの上に築かれ、そこからまた未来につながっていくものです。

この全体的で体系的な変革プロセスの原則は次の通りです。

1：FDAの使命に照らして、特に重要な注力するべき分野を選択。全てを一度に行うことは無理ですが、特に優先順位が高い分野は、医薬品の安全性、食品保護、規制上の判断を下すための科学的基礎、人材開発、施設や情報技術などの重要なインフラなどです。

2：適切な対策の検討に必要な情報を得るための、厳格な問題評価プロセス。これについては会計検査院の報告書などいくつか既に入手可能な評価結果があります。他にも進行中のものとして全米科学アカデミー医学研究所（IOM）の「医薬品安全性の評価」などがあります。

この評価プロセスは委託される場合もあります。例えばFDAの科学委員会に対して、外部専門家による小委員会を開いて我々の科学的な業務成果を総合的に評価させるよう依頼しました。また我々は食品保護計画の作成に協力し、FDA の戦略計画の徹底的な内部改訂を行いました。両計画は2007年の11月に発表されました。

3：これらの評価や計画のそれぞれに対して詳細な実行計画および中間・最終目標を作成。我々は昨年、正にここナショナル・プレス・クラブでそのような実行計画、すなわち IOM の医薬品安全性に関する報告書に対する返答を発表できたことを非常に光栄に思います。またリスクコ・ミュニケーション諮問委員会の設立など IOM の報告書で示された提案の多くは既に実行に移されています。

また今週、我々は「セイフティ・ファースト(Safety First)」と呼ばれる大規模な計画を発表します。これは我々の複合的なリスク判断プロセスを改善するためのものです。

4：外部、内部への諮問の継続。例えば、以前 FDA の人材について評価が行われた結果、この新しい時代の規制業務には増員と新たなスキルの獲得が不可欠だということが明らかになりました。

現在、我々は積極的な人材の採用・維持を行っており、2008年には新たに700名を雇用することを目標としています。これは主に2007年の FDA 改正法の成立と充当金の漸増によって可能になったものです。

さらに、間もなくFDAフェローシップ・プログラムの計画が発表されます。これは様々な分野の専門家を最大2000人まで受け入れる二年間の研修プログラムです。

また別の評価では、FDA の情報技術インフラには刷新と改革が必要だということが明らかになりました。そこで今年、約2億5000万ドルを投じて最新の高性能サーバーとソフトウェア・システムを導入することにしました。これによって局内の相互運用性は高まり、電子データベースは拡張されることになります。

そして来年中に、現在メリーランド州ホワイトオークに建設中の FDA 総合本部に総合デー

タセンターを設置します。またホワイトオークには医薬品、生物製剤、医療機器、動物用医薬品を扱う各センター、すなわち CDER、CBER、CDRH、CVM の最新の研究所も建設されます。

5：業務のプログラムやプロセスが変わると共に政策も変わりました。ここでもまた、急激に変化する世界は新しい思考と行動を要求しています。FDA はもはや単なる門番であってはなりません。つまり、製品のベネフィットとリスクを患者や国民のもとに届く前に評価するだけ、または調査によって品質を確認するだけでは不十分なのです。

そうではなく、FDA はそれが農場から食卓へ届けられる食品であれ、製造され消費される医療製品であれ、規制対象製品のライフサイクル全体に関わらなければならないのです。製品の発見、開発、流通の各過程に関わることにより、その品質はより確かになります。製品のライフサイクルの内、発見と開発の部分に関する重要な取り組みの一つとして、FDA クリティカルパス計画があります。今年、我々は 500 万ドル以上を投じてこの最新の科学的手段を製品の規制・開発プロセスに適用します。

ライフサイクルの内、流通後の部分に関して言えば、大規模な市販後調査プログラムを実施して製品をモニタリングします。また我々は近く「センチネル（見張り）計画」と呼ばれる新たなプログラムを発表します。これは他省庁や民間と共同で立ち上げる全国規模のシステムです。これによって FDA は多数の多様な患者データに基づいた大型の安全情報データベースを分析することができます。

安全性情報をモニタリングし検出するにあたっては、同時に有害事象の軽減対策を強化しなければなりません。有害事象対策を強化するためには、リスクに基づいた、そして最新の科学的検出手段を利用した調査を増強し、ネットワークを拡大することが不可欠です。

そのためには外部との協力強化が重要になります。現在 FDA は税関国境警備局、疾病対策予防センター、農務省といった連邦政府機関と協力関係を構築しています。また、各州の農務・保健当局や民間の組織、海外の当局とも連携を築いています。

最近我々は中国の規制当局と協定を結びました。そこでも明らかだったように、グローバル経済が求めているものは、特に法令の実施に関する相互運用性、情報交換、そして協力に他なりません。

国境が障壁ではなくなった今日、我々は「国境を越えた FDA」という取り組みに着手しました。これは中国を始めとして少なくとも五つの海外地域で FDA の存在感を確立し、その

能力を強化しようという試みです。また我々は海外の規制当局との協力も強化し、より多くの情報を共有するようにしなければなりません。

今週初め、FDA の専門家達は、48 の大使館から集った 62 人の代表者と、食品と飼料の保護、そしてそれに関する国際協力への取り組みについて協議しました。これは正に国境を越えた FDA の活動と言えます。

食品や飼料を保護するには、我が国に輸入される前に生産地で規制を行うことが必要になります。

FDA と HHS（保健福祉省）は大統領直属の輸入安全作業部会で中心的な役割を果たしました。

HHS のリービット長官の指揮の下、作業部会は全ての輸入品の安全性を改善するための計画を提案しました。この計画では先程と同じようにライフサイクル・アプローチを採用し、予防、介入、対策を実施しています。これにより海外から来る食品、医薬品、医療機器の品質はより安心できるものになります。

政策や手順からプロセスやプログラムに至るまで、FDA では正に変化が起こっています。変化は急速で、場合によっては重大です。政府機関にとっては「革命的な進化」と言ってもいいかもしれません。しかし FDA 内部の人間から見れば革命のような急激な変化かもしれませんが、外部の人間から見れば緩やかな変化かもしれません。

しかしその成果は明らかです。ただそれを達成するには根気と忍耐が必要となります。

しっかり理解しておかなければならないのは、変化に終わりはないということです。なぜなら変形、適応、再生というプロセスは継続的なものであり、絶えず進化し続けるものだからです。それが私達の生きるこの世界の性質なのです。

これらの取り組みは、単に個々の活動の集りに過ぎないと思われる方もあるかもしれません。

そんなことはありません。

これらの取り組みは、全てのアメリカ人の健康にとって非常に重要な政府機関において、非常に重要な時に起こっている、非常に重要な変化における、最初の、そしておそらくは

最も重要な段階なのです。

これらは昨秋発表された戦略的行動計画で示された、変化の青写真の一部です。

戦略行動計画には注力すべき四つの目標が示されています。すなわち、FDA の強化、患者と消費者の安全の向上、新しい医療製品・食品へのアクセスの改善、製品とその供給プロセスの安全性と質の向上です。この目標のいずれもが、我々の任務遂行に不可欠な保健衛生上の基本的課題です。

FDA の業務は増えているにもかかわらず、必要な予算や人員はそれに追いついていません。これはワシントンでは誰もが知っていることです。この新しい世紀に FDA を強化するには投資が必要です。我々には任務の規模と範囲に見合った予算と権限が必要なのです。

我々は今、予算増加の軌道に乗っています。増加は 2007 年と 2008 年には連邦議会から承認され、2009 年分については大統領がそれを提案しています。この軌道は継続し、そして当然、加速しなければなりません。

FDA には計画と資源が必要ですが、まだ十分ではありません。我々は自分達だけで FDA を変革することはできません。この変革には外部からの働きかけが必要です。

今は為されていないことを批判する時ではなく、為すべきことのために協力する時です。

この先三年から五年の間、我々が外部から必要としていることを申し上げます。

まず連邦議会には、食糧供給の規制業務を改善するための権限を与えて頂きたいと思います。食品保護計画では新たに十の立法権限が要求されています。その十の権限を戦没者追悼記念日（5 月 30 日）までに我々に付与して頂くよう連邦議会にお願いします。この重要な取り組みのため、引き続き昼夜を問わず FDA 職員を連邦議会との共同作業に当たらせます。我々にはこれが必要なのです。

規制対象である業界からは、強い企業責任と規制基準の順守を期待します。また、引き続きユーザー・フィー・プログラムを支持し、我々が行う業務に見合った手数料を提供して頂きたいと思います。その手数料のおかげで承認審査を迅速に行うことができ、命を救う薬や機器を患者さんのもとに早く届けることができるのです。新しいユーザー・フィーはこれまでと同様に、必要な業務に掛かる全ての費用を考慮に入れたものでなければなりません。

FDA の関係者に対してはレーガン・ユーダル基金の全面的支援をお願いします。同基金は FDA の任務を支援するために連邦議会によって設立された 501c(3)型の独立法人（国税収入局の規約で定められた、免税の対象となる組織）です。

そして国民の皆さんには支持と忍耐、そして我々の仕事に対する信頼と確信をお願いしたいと思います。我々FDA 職員は国のために一生懸命努力しています。変化には時間が掛かりますが、その成果は長期にわたって皆さんの健康を保護・増進することになるでしょう。

我々は再生された FDA を、そして効果的な規制業務によって命を救う製品の発見、開発、流通がさらに改善されるのを楽しみにしています。

我々は製品の作用機序や目的について科学的理解をさらに深め、皆さんにそのリスクとベネフィット、適切な使用についてきちんとお知らせします。そして新たに発生する問題にはより早くより正確に対応します。

我々はより多くの情報を、より早くお知らせします。

今日これまで、私は以下の三つのことを御説明しました。

- 急激に変化する世界について。
- 何故その変化が FDA を岐路に立たせているのか。
- そして FDA を再生するために何が行われているのか。

この取り組みに皆さんのご協力をお願いします。

FDA 長官として私は認識しています。皆さんの健康を護るという使命を間違いなく果たすためには変化が必要だと。

命を救う製品、人々を脅かす病気を撲滅し阻止する製品を届けるのが我々の使命です。現在においても未来においても、FDA はその障壁ではなく架け橋でなければなりません。医師として、研究者として私は認識しています。そのためには FDA には変化が必要だと。

しかし何よりも、六人の孫の将来を案ずる祖父として、私は急激な変化の必要性を認識しています。

一月ほど前、私は HHS のリービット長官と共にインドを訪れました。訪問の目的は規制当

局や食品・医薬品業界のリーダー達と会い、いかにしてアメリカ向け輸出製品の品質を確保するべきかについて話し合うことでした。

デリーに滞在中、ある地区を訪ね、赤ん坊や小さい子供たちにポリオのワクチン接種をする機会がありました。接種の後、私は何人かの子供たちにキャンディーをあげました。すると突然、他の大勢の子供たちが手を伸ばし歓声を上げて私を取り囲みました。その数はキャンディーを配るのが追いつかないほど増え、ついに私の手元は空っぽになってしまいました。

私には決して忘れられません。差し伸べられた子供たちの手、その大きな目と小さな顔、そしてもうキャンディーがないと分かった時に、その笑顔が消え悲しそうな眼で私を見つめていたのを。

自分の孫達の顔を見ながら、私はこの子達が期待するものは大きいと思います。子供達が期待するのはポリオワクチンやそれを作り出した過去にとどまりません。彼らが期待するのは各個人に適した食品や医薬品によって健康が促進される未来なのです。そして子供達の期待に満ちた笑顔が悲しく見つめる表情に変わることがないよう、FDA は急激に変化しなければなりません。なぜなら、子供達の健康を保護・増進する 21 世紀の FDA がなければ、私達が彼らに与えられるものは何もないからです。

御清聴ありがとうございました。