

REMARKS OF THE HON. ROSA DELAURO
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For nearly 4 decades the Institute of Medicine at the National Academies has offered a clear and impartial view of the world as it affects our science, health and medicine. As a policy maker and a Member of Congress, I am always searching for independent honest information from sources and advisers I know I can trust, and the Institute has always been one of those sources.

In the Fall of 2006 your report on the Future of Drug Safety confirmed what many of us in the Congress had been arguing for some time – that we need to strengthen the authorities within the Food and Drug Administration (FDA) if we want to empower the agency to take rapid and decisive actions on drug safety.

I know the work of the Science Board has given urgency to those ideas. Its December report illuminated a number of critical

challenges and I commend them for raising the profile of some key problems that have been stuck below the radar for far too long.

However, I and many in the field do not believe the Board's report should serve as our definitive roadmap moving forward. I was particularly concerned that the Board failed to focus on and address the FDA's Office of Regulatory Affairs, the frontline for America's consumers. ORA performs post-market surveys yet there is no direct funding for the office -- no ORA infrastructure inspection, investigation, analysis. The report has no description of agency work planning processes; no explanation of how the agency develops budget requests that are related to outcome matrices. And, with little attention to mismanagement, outdated processes, and inadequate authority, the report fails to raise or address the most basic questions of why so many of the agency's most essential functions are so acutely deficient – nothing at all about a radical change in organization and management methods.

Just last week, we all saw the stories about Merck: after conducting its own studies to trumpet the positive affects of its pain medicine Vioxx, then hired ghostwriters to write them up for medical journals, and brought in scientists to attach their names long after the research and analysis had been done. According to researchers from Harvard, Brown and Yale and the Mount Sinai School of Medicine in Manhattan, about 250 documents show Merck employees worked alone or with publishing firms to write manuscripts and later recruited academic medical experts to put their names as first authors.

I raise these incidents not to get into the story but to elevate our own analysis of the problem. There is something fundamentally wrong in the private sector and the public agencies responsible for public safety when one can be so cavalier about science and about the public good.

Last week in a Senate hearing, Commissioner von Eschenbach described the FDA as [quote] “We are the world’s gold standard.” Which begs the question: how can you be expected to fix a problem, if you do not believe it exists? As both the Institute of Medicine’s reports and the latest headlines have shown -- contrary to the commissioner’s assurances -- our system needs urgent and dramatic reform, a return to its most fundamental mission, and a renewed focus on the safety of the food and drugs it regulates.

Although the focus of my remarks today is not, primarily food safety, it is an integral part of the FDA’s mission, and I continue to dedicate a lot of attention to it. Let me just briefly mention some issues that are of concern to me, and which I hope to confront with a set of reforms in this Congress.

A year ago I called a hearing on the GAO report which deemed federal oversight of food safety a “high-risk” area in need

of reform because of its threat to public health and the economy.

To date there has been no response from either USDA or FDA.

As we saw when Westland/Hallmark recalled more than 143 million pounds of beef produced over the last two years, including 37 million pounds that went to school-lunch programs, our food safety system is broken – from the FDA to the USDA, in this case, from state labs to store shelves, we have failed the American consumer.

With last year's Agriculture Appropriations bill, I worked to tie \$28 million in new FDA funding to an improved food safety plan that would strengthen management and be reviewed by the Appropriations committees.

Ultimately, I believe it is time to create a streamlined federal agency focused exclusively on protecting our food supply. That is why I introduced the Safe Food Act to create a single agency that

would administer all aspects of food safety efforts, including inspections, enforcement, standards-setting, and research to protect public health. Instead of having to balance food safety with competing priorities, a single food safety agency would allow food safety experts, scientists, and researchers to do their jobs.

It was not until this February, that Health and Human Services Secretary Leavitt finally explicitly admitted that the FDA needs greater authority and jurisdiction to work outside our borders toward safer imported foods.

That was just two months ago and it is cold comfort. This administration does not have the strategy, the commitment, and the resources to respond to our growing dependence on food imports from China, Asia, Mexico, and other countries.

The administration's food safety advisory commission released its report last fall listing a series of recommendations that

were either completely inadequate or included common sense initiatives contained in the 2003 Import Strategic Plan. These recommendations could have been easily implemented five years ago.

Meanwhile, I have introduced the Food Import Safety Act which would allow HHS to ban imports from a specific country if it is linked to an outbreak in the U.S. or if they demonstrate a pattern of violations.

I know some of my colleagues on the Energy and Commerce Committee recently introduced new food safety legislation just last week, and the bill contains some provisions I have long supported such as mandatory recall authority and the development and enforcement of performance standards for food contaminants. I am disappointed the bill does not include any steps toward consolidation of food safety activities, but it is not surprising given the Chairman's opposition to this idea. There are other provisions I

want to study more closely such as registration and user fees to ensure they are structured in such a way as to protect against industry influence. I look forward to working with the committee, offering suggestions to improve the bill.

We all know the ultimate goal of our efforts is to move toward an effective food safety system which focuses on prevention not just reaction, makes the most effective use of limited resources, and addresses both domestic and imported products through genuine reform.

That is true, whether the challenge is food safety or drug or device safety. And we know that serious reform on each of these tough issues requires a sea change at the national level. It is about a shift in priorities and a return to our most basic regulatory responsibilities. To that end, I believe we must move forward guided by four key principles.

First we must increase funding to support the FDA's mission.

Second, we must improve the management of the agency and hold it accountable.

Third, we must push back against the influence of the industry over the agency.

Finally, and perhaps most importantly, we must let the scientists do their work, guided by science and not political or ideological interference.

This is where we must go. Yet, the last 7 years have taken the agency in the wrong direction. Better management and resources must, ultimately, go toward supporting independent science in the service of the agency's most important regulatory mission -- protecting public health.

I recognize and support the need to provide more funding for the FDA. Adequate resources are essential and that is why, in my short term so far as chairwoman, I have worked hard to increase

funding for drug safety and other important FDA functions in what we hope marks the beginning of an effort to rebuild the agency's capacity to protect the American public.

Providing the increased funding is only part of the solution. Funds alone cannot fix an agency that routinely fails at its most basic responsibilities: keeping track of clinical trials, preventing conflicts of interest, following up on critical investigations. When sixty-five percent of post-market studies on new medications have not yet begun, it is clear that we have a long way to go.

There is little doubt that the FDA has been starved for far too long. Insufficient resources were a major focus of the Science Board report, and it is a frequent topic of conversation on Capitol Hill. It is a constant and with good reason: FDA managers point to a lack of resources as the reason they cannot carry out their appointed duties. It is a serious problem, I am certain, but it is not the entire problem, and we must not treat it that way.

The Science Board's report justly highlighted this serious need for more resources, yet it failed to mention that the FDA or the Administration never request these critical funds. This administration is taking the bargain basement approach then using it an excuse for its poor performance.

Nevertheless, since 2006, despite overall spending limitations imposed by the Administration, the FDA Agriculture Appropriations Subcommittee and Congress have increased the FDA's total budget by more than \$227 million

And although the President refused to make any reasonable compromises, the Congress still found a way to direct funds toward critical programs and made very real changes to the President's original budget, ensuring a significant funding increase for the FDA.

During the last cycle, working within those confines, our committee provided \$1.7 billion for FDA -- an additional \$145 million above 2007 funding levels. In a strained budget environment, we still increased funding by over 9%. That includes a 35 % increase for the Office of Surveillance and Epidemiology and a 17% increase for generic drug review.

So we are taking critical steps in Congress to provide the resources that FDA needs to do its job to protect public safety. But I believe our job includes oversight and accountability as well. The FDA does need more resources, but those resources will yield very few improvements to a broken system unless there is a parallel commitment to better management.

We recently discovered that the widely-used blood thinner, Heparin -- under investigation after hundreds of allergic reactions and now 62 suspicious deaths among the drug's users -- included an ingredient from a Chinese facility that had not been inspected

by the FDA. Even more startling is the fact that apparently the FDA inspected the wrong Chinese factory and entered the wrong firm into the its database.

Cases like this -- or controversies surrounding Avandia, Vioxx, Trasylol, Ketek the list goes on-- are embarrassing and alarming. To be sure, the whole industry or the entire agency, cannot be blamed for a handful of incidents gone terribly wrong. But with every new case, they are looking less and less like outliers, and more and more like like signals of something far greater – broken management and systemic failures.

In February the FDA announced its Safety First Initiative. It would move more people in the Office of New Drugs and give the Office of Drug Safety two new tasks – that while important – are marginal in terms of the talents at ODS and the needs at FDA. It is unclear what substantive changes, outside of some press attention, this latest effort will yield.

Meanwhile, when you do step back and look at the funds provided for the Center for Drug Evaluation and Research over the last several years, it becomes clear -- drug safety is not solely a question of money. Since 2001 Congress has provided more than \$2.3 billion, not counting user fees, for the Center for Drug Evaluation and Research. It has 62 % more in taxpayer dollars to spend this year than it had in 2001. That is more than three times the rate of inflation and more than the president requested during that period.

We should have a lot to show for that money but unfortunately we do not. There have been a series of GAO and IG reports that have highlighted fundamental problems with the basic systems at the Center.

In August 2006 the Health and Human Services Inspector General found huge problems in FDA's official list of approved drug products. With almost 124,000 drugs listed, the IG found more than 9,000 products were missing and 34,000 products were listed erroneously. Similar problems had come to light 15 years earlier in a 1991 report, yet they are still not fixed today!

How can an agency that regulates drugs not have an accurate list of drugs it has approved? And how could 15 years go by without fixing it? The IG found that FDA has inspected only about 1 percent of all clinical trial sites between 2000 and 2005. How do you regulate clinical trials if you do not have a list of them. Last September, the IG said FDA has no idea how many clinical drug trials were happening. And the problem extends beyond our borders where the FDA has no accurate list of foreign facilities in its inspection inventory.

That may have something to do with the fact that the FDA says it inspects those firms only [quote] “at the request of foreign drug manufacturers.” And when a violation is found, FDA allows the company to correct the problem, but does not necessarily confirm it in reality.

When it comes to drugs like Heparin, it is not just a question of whether inspections were performed but also whether they performed the right tests. In this case, the standard FDA tests did not catch the contaminant – a heparin mimic blended with the real thing. And by failing to significantly update our standards or use modern technology and tests to evaluate modern medicine, we are putting the American people at risk.

So it is clear, more resources, better management. But serious reform must go a step a further, and begin the critical work of reducing industry influence and restoring scientific independence within the agency.

A 2006 survey conducted by the Union of Concern Scientists showed that many FDA scientists from all Centers complained about interference from top level FDA appointees on behalf of corporate and political interests. They feel that factors other than good science play a role in important FDA decisions. And that may be why too many good scientists continue to leave the agency at a time when we should trying to attract them and support their work.

The FDA treatment of whistle-blowers has long been a significant concern with numerous allegations over the years of FDA retaliating against employees who spoke about safety issues, exposing bad decisions that cost lives. We can no longer accept federal agencies tasked to protect the public health that seem only interested in protecting business from embarrassment or cost. Instead, we need a commitment from the agency explaining how it intends to use its funds and meet its goals in a way that matches our national priorities.

In that spirit, a lot of attention has turned to the Reagan-Udall Foundation and the investment we have been asked to make in the project. To be sure, a public-private partnership can be very effective in identifying strategies to benefit patients, consumers, and corporations. But unless the Reagan-Udall Foundation is carefully structured and implemented, the industry could take advantage of its new role to gain undue influence and expedite the approval process, leading to the sale of blockbuster drugs and devices that are ultimately unsafe and ineffective. FDA acknowledges that donors to the Foundation will have the primary say over how funds are used.

We must create a framework for the Reagan-Udall Foundation that minimizes the industry's influence in its research and ensures that this agency is not another tool for the industry. The Reagan-Udall Foundation's goals of modernizing research and fostering innovation make good sense. But when the FDA's own

funds come at such a premium, and this foundation's funding comes from the pharmaceutical companies that sit on its board, we have a particular obligation to ensure its research supports the FDA's primary regulatory responsibility, and does not undermine its independence.

That is why I have reservations about the FDA's Critical Path initiative. Its high science and key objectives are important and commendable. Translating scientific discoveries into new and better medicine, streamlining clinical trials and investigating new biomarkers. But I am afraid we may be sending the unintended message to many FDA scientists that their primary function and first priority is no longer evaluating data on safety and efficacy, but rather to assist regulated industry in selecting faster – not necessarily better – methods for obtaining marketing approval. A recent survey of the medical device and life science industry found that a majority of life science companies (58%) said they are familiar with the Initiative and most (64%) agree with its

importance, but only 41% concurred it is focused on the right issues.

Of course Americans want to see the FDA at the forefront of innovative science, but it must be independent science in the service of the agency's most important regulatory mission -- protecting public health. Only then, can we clear the way to ensure patients get the best information, the best care, and the best medicine possible.

We have the tools to reach that goal. There are so many brilliant, hard-working public servants at the agency – scientists and doctors – motivated by the public good and dedicated to ensuring the public health. I have been invited by the National Treasury Employees Union to visit their members at the FDA and I look forward to seeing them at work.

By working together, we can honor their commitment and make the FDA the gold standard once again. This can be a turning point. We have a real opportunity to truly reaffirm the agency's priorities and reinforce its commitment to its most fundamental regulatory responsibilities.

So what are we doing in Congress to make that happen?

What are our priorities?

First: resources. I believe we must begin by making the right investments at FDA including the Center for Drug Evaluation and Research. Despite last year's significant boost in funding provided by Congress, the Administration once again put forward a budget for 2009 for the entire FDA that was only about one third of that – a \$54 million dollar increase. Ultimately, a good portion of this increase will go simply to maintain current services, ignoring the very real need for a real influx of new resources.

The net increase requested for CDER without user fees in fiscal year 2009 in discretionary funds is \$4.722 million -- an increase of 1.3 percent. As I have said before, we can do better.

Meanwhile, the user fees that PDUFA recently enacted would automatically increase by \$39 million over 2008 allowing the hiring of 219 additional full-time employees. Yet, I still have serious concerns about so much of the budget coming from user fees -- the significant concessions and negotiations the industry demands have the power to undermine a process which should be wholly independent.

At the same time, not one penny of that increase is going to field activities! In fact, in 2008 the entire user fee program at CDER contributes only \$6.9 million for the field and supports only 40 full-time employees. The rest comes out the discretionary budget authority, which of course, saw such a small increase. In

other words it is the worst of both worlds – these funds come at a big price, and we are not even investing them as best we could.

In the year ahead we are going to have to act on other priorities at the same time – trying to improve the agency’s management and restore its scientific integrity.

For one, *The Food and Drug Administration Amendments Act of 2007* included a provision requiring the FDA to make the action package publicly available in a timely fashion available ensuring transparency in the FDA drug approval process and providing the public and physicians with a clear analysis of how the benefits of a product outweigh the risk.

If members of an FDA scientific review team have significant concerns about an approval, they should have the opportunity to voice their concerns publicly. If the FDA has ignored certain

concerns from its own scientific experts, the public deserves to know why.

We also need to act when it comes to funding and implementing a clinical trials reporting database. *The Food and Drug Administration Amendments Act* required clinical trials on serious or life-threatening diseases to submit registration information by Dec. 27, 2007, and to do the same for non-serious diseases by Sept. 27, 2008. We also need to have the results of all of these studies made public as required by the Act.

Yet, another priority will be taking clear steps to push back against industry influence inside the agency.

So the FDA needs to reduce the potential for financial conflicts of interest. And we must expand recruitment efforts for advisory committee members without financial conflicts by reaching out to academic institutions, as well as medical and scientific societies.

Despite the president's continuing veto threats, I hope to provide the funds from the subcommittee to carry out these vital outreach efforts and ensure our advisory committee members are conflict free.

Finally, to strengthen the FDA's capacity to do its job and streamline its system, we must recognize reform must not only look inward but also reach out. We must recognize the wide-reach of Direct to Consumer television ads, and consider language in this year's bill that would direct the FDA to report on the agency's current process and time frame for dealing with adverse event reports from the public through its MedWatch system and how information from MedWatch is used to evaluate potential safety concerns.

The fact is: even though one in six Americans have experienced a side effect serious enough to send them to the doctor or hospital, the majority of consumers -- 65 percent! -- do not know they

should report those side effects to the FDA and that affects us all.

Adverse event reporting by consumers is vital to signaling potential drug safety problems. And there is a straightforward solution to begin improving our broken system and providing consumers the tools they need to report medical problems.

We can start by requiring that all television drug ads include an easy toll-free number and website where people can report any serious side effects to the agency.

In addition, we need to make sure doctors and nurses are aware and well-schooled in reporting what they hear and what they observe themselves from their patients to the FDA.

At the same time, I know the IOM has proposed a moratorium to ban advertisements for a two-year period after a drug's approval while initial questions of that drug's safety are still

being examined and considered. I have proposed legislation along those lines to establish a three-year moratorium, because we must ensure consumers know what they are getting, and drug makers know what they are promising

If we are all flexible, I believe there is a lot of common ground we can find. Together, securing the funding essential for our regulatory agencies to succeed in protecting the public. Together, building a genuine post-market surveillance system to review the safety of drugs after approval to ensure they remain safe for everyone. Together, providing for an easy, effective system in which transparent educational content about drugs reaches more consumers. Together, establishing an effective review system rooted in respected advisory committees with minimal conflicts of interest.

There is a lot we can do, from Congress, from the FDA, as consumers and in the private sector. But the truth is -- this is going

to require a national conversation that leads to action. We need a wake-up call, a chance to step back and see our drug safety system in terms of our mutual responsibility to one another and to our community.

What we learned about Merck and Vioxx last week says to me that we need not just a policy debate, but a serious debate about our values and the leadership of the country.

We need to step back and ask what norms and values are operating here that could allow this to happen – in companies, in government agencies, in government overall. Wouldn't you have thought that a regard for public safety would win over any possible individual gain?

We need a moral renewal – new leadership in the public and private sector including CEOs and our president. Our country is better than this and we need to shift the balance, giving new weight

to the public interest and scientific leadership. And the FDA and public health is a good place to start the process of change – nothing is more fundamental to our way of life.

Thank you.