

**David A. Winston Health Policy Fellowship  
FDA Protecting and Advancing America's Health: A Vision for  
the Future  
October 20, 2003**

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**MS. DORCAS HARDY:** Good evening ladies and gentlemen. I'm Dorcas Hardy and I'd like to welcome you on behalf of the Board of Trustees of the Winston Fellowship to our 5<sup>th</sup> Annual David A. Winston Health Policy lecture. As many of you know the David Winston Fellowship was established in 1986 to honor the contributions and personal qualities of David Winston who, for 20 years, played a significant role in shaping American health policy.

David served as a bridge between the public sector, which he knew well from extensive experience, and the private sector in which he deeply believed. His advice and counsel were sought and accepted by leaders in both sectors and on both sides of the aisle. His knowledge and integrity earned him the respect and trust of the entire health care community.

David Winston moved from being a health policy advisor to the California state legislature, maybe more advice is needed now, to the California Health and Welfare Agency to the faculty of the University Of Southern California School Of Medicine. And when then Senator Richard Schweiker (misspelled?), also a member of our board, tapped him to come to Washington David began his national work of the Senate Labor and Human Resources Committee. And in 1980 David was an important contributor to President Reagan's transition strategy and was particularly influential in shaping the

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administration's positions on deregulation and competition in the health sector.

In 1981 David moved to the private industry where he focused his energies on demonstrating that the private sector could indeed effectively communicate with and positively impact the federal policymaking process. He became President of the National Committee for Quality Healthcare, the predecessor of the Healthcare Leadership Council. And at the time of his tragic death 17 years ago he was Senior Corporate Vice President of VHA.

David was a quiet leader, a behind the scenes man, a gentleman and he always said just a boy from California farmland having picked peaches. To many of us here he was a great friend and mentor, a man of character and wisdom. And to establish his legacy we began the David A. Winston Fellowship, a unique opportunity for a post graduate student to learn about our political system through direct exposure to public and private sector roles in health policy development.

The fellowship embodies David's commitment to the public and private sector partnership necessary for a high quality, market oriented health care system. This year's fellows is Diana Birkett and Chad Shearer are the 16<sup>th</sup> and 17<sup>th</sup> Winston fellows and are here with us this evening as well as several earlier fellows. The financial support of the fellow is provided, and fellows, is provided by your attendance at the

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annual health policy ball to be held again, mark calendars, this year on February 7, 2004.

This health policy lecture is another effort by the fellowship to promote dialogue about the public and private sector roles in health care delivery and financing. And we appreciate your participation. And this year we especially appreciate the financial support of the lecture by several sponsors; the American Medical Association, the Federation of American Hospitals, the American Association of Health Plans, and the VHA, Inc.

Additionally, for the first time the Kaiser Family Foundation is hosting a web cast of the lecture. And we thank all of you very much. I would like to ask Dr. Rubin, Chairman of the Board of Trustees, to introduce our lecturer.

**DR. ROBERT J. RUBIN:** Thank you Dorcas. As you heard this is our 5<sup>th</sup> annual lecture. The first David A. Winston Health Policy Lecture was given by Bill Grattison (misspelled?) who is here in the audience. And I'd like to thank him for that. And George Strait (misspelled?) from Dr. Spock.com was our second lecturer. And then Secretary Thompson followed last year by Tony Fauci from the National Institutes for Allergy and Infectious Disease.

It's a real please and honor to introduce our speaker tonight. I won't take any of his or your valuable time by rereading his biography which is in your program. But I would

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like to say that in the years that Mark has been in Washington I've had occasional opportunities to work with him. And I must say that it's unusual, in fact it's unique, to see an FDA Commissioner who is an economist. But it's even more unique to see an economist who's a pragmatist [laughter].

And I think that you'll agree with me after you hear him talk that Mark brings the disciplines of medicine and economics together with a healthy dose of Texas common sense and wisdom. So without further adieu I'd like to introduce the Commissioner of the Food and Drug Administration Mark McClellan.

[Applause]

**DR. MARK MCCLELLAN:** Thank you. And don't worry, I won't tell my colleagues back at Stanford that remark about pragmatism. It is a real pleasure to be here with you all this evening and to be part of such an important set of endeavors. Just being on the program with Dorcas and Bob is an honor in itself. They've been so important in their own work in shaping good and sensible health care policy. It's even more of an honor to be part of the Winston Fellowship Program. And I want to thank Dorcas and Bob for all their work in that.

I had a chance to meet the fellows for this year, Diana and Chad, earlier in their tenure in Washington. I'm sure they're making the most of the opportunity as well.

This fellowship has done a tremendous amount already for; in honor of a wonderful person who dedicated so much of

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his life to helping others improve their health. I didn't know David personally but I certainly knew about his legacy. And I think his impact came on a couple of different levels. First, obviously, by what he actually accomplished as President for the National Committee for Quality Health Care for example. He helped to set some of the standards through which many people came to enjoy higher quality care. This is not perhaps a glamorous achievement but it's an essential one for identifying and encouraging best medical practices. And we spent a lot of our time at FDS on encouraging appropriate standards today. Some of the most important things we can do.

But second by the seriousness and effectiveness with which he approached health policy problems. He set an example for all of us in how to find solutions for difficult health care problems. President Regan later said of David that he was "the kind of person who made a tremendous contribution by working largely behind the scenes but those who know him were keenly aware of his central role."

Well bio medical technology has advanced dramatically since then. And the details of the health care policy debates here in Washington have changed along with medicine. But some of the most pressing health care problems remain the same as when David was working to advance the health of the public. The mark of good leadership, I think, is in finding ways to achieve often competing goals in health policy to get the best

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care for the most people to achieve the greatest improvements in public health. Even though we all want simple and fair solutions it's often, too often, not easy to get there. But real leadership, like that which David Winston provided, is more important today as a model for us than ever before.

And that brings me to the main topic that I want to talk about in my formal remarks tonight. A lot of public attention has focused on drug importation recently. It's easy to understand why. People walking into a pharmacy and paying list price are facing much higher prices for brand name drugs in the United States than in Canada and France or in any other country for that matter.

Americans now pay about half of all cost of prescription drugs worldwide even though we account for a much smaller share of the prescription drug use around the world. For many Americans who are left on their own when it comes to prescription drugs who don't have good coverage and who receive little or no assistance in getting lower prices the only alternative to high prices here seems to be buying cheap medicines from outside this country. And more and more people seem to be finding themselves with no other alternative.

When it comes to buying drugs internationally outside of our regulatory protections, beyond the authorities of the federal and state watchdogs for drug safety, FDA has consistently said for many years that we can't in good faith

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endorse buyer beware approaches to the problem of affordable drugs. Buying long distance from sources that we can't regulate is simply not the same as walking into a well-regulated pharmacy under the regulatory umbrella of Canada or another country with a very safe drug supply.

People's health is put at risk when doctors and pharmacists or learned intermediaries are replaced by storefronts and bogus Internet sites that are there for private profit not public health. Consequently when Americans import drugs that are not regulated and approved in the United States it presents real safety risks. Risks that are becoming more common; for example we recently reported on a blitz at four airports over three days conducted with our border enforcement partners at the Bureau of Customs and Border Protection. We identified more than 1,100 unapproved drugs coming in from Canada and many drugs that because of labeling, storage or other problems presented real safety risks.

This debate about safety versus affordability makes people angry and it should. Most Americans don't understand why Canadians can get many drugs that are very similar to those available here safely and at a lower price than in the United States. Yet the United States hasn't found a way to provide drugs that are affordable and safe in our own country. And until we find solutions that don't force Americans to make choices between safety and affordability all of us involved in

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policy cannot rest. That's why we're working harder than ever to do what we can with the authorities we have at FDA. And that's why we need effective action from Congress now to improve both drug affordability and drug safety.

So that's what I'd like to talk about, finding ways to keep prescription drugs safe and secure while making them more affordable. And this evening in my remarks I'd like to accomplish three things; first to set forth the serious problems facing the safety and security of our drug supply today which helps make clear why we need to improve the protections for our drug supply and not weaken them. Second to explain why legislative proposals that essentially assume that drug imports are safe doesn't make them so. And third to describe how FDA is working on a better path forward to help ensure that Americans have a prescription drug supply that is both safe and affordable and how we need to help to achieve that goal.

Why are FDA and our partners in law enforcement and in the state regulation of drugs so concerned about having the authorities and resources we need to assure the safety of drugs produced and imported legally into this country? Because a safe and secure drug supply is so valuable to all Americans.

Sixty-five years ago Congress responded to widespread fears of unsafe and ineffective domestic drugs by directing FDA to create a system for assuring that Americans can have a drug

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supply that they can trust. Fifteen years ago Congress responded to serious safety problems created by imported drugs that were not tightly regulated by passing the Prescription Drug Marketing Act. Congress did this because of the importation of significant volumes of adulterated and counterfeit drugs along with legitimate re-imported drugs.

I'll give you just a couple of examples of what was going on in 1985 before the PDMA became law. First over two million unapproved and potentially unsafe and ineffective Ovulin (misspelled?) 21 tablets originally from Panama were widely distributed throughout the United States. Second a counterfeit version of Secor (misspelled?), a widely used antibiotic from that time, found its way into the U.S. drug supply from a foreign source.

Over the years our professional staff has used these authorities to build a drug safety infrastructure that gives our citizens the highest quality drug supply in the world. Unfortunately the drug supply that we have worked so hard to protect is under unprecedented attack from a variety of increasingly sophisticated threats.

There are many reasons for these threats. A lot of money is at stake with today's prescription drugs. And to paraphrase Willie Sutton, people who are only out to make a fast buck are going to go where the money is.

The technologies for getting questionable drugs to

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patients have improved across the board. Everything from pill molding and dyes for counterfeiters to easy Internet access for anyone who wants to set up a web operation; the result more than ever before well organized criminals are ready to make a fast buck at the expense of public health by exploiting any crack in our regulatory system.

This is evident in the recent significant increase in sophisticated efforts to introduce counterfeit drugs into the U.S. market. FDA has seen the number of counterfeit drug investigations increase four fold since the late 1990's. Although counterfeiting was once a rare event we are increasingly seeing large supplies of counterfeit versions of Finnish drugs being manufacture red an distributed by well funded and elaborately organized international criminal networks.

FDA has long been concerned about this growing problem. But because there now appear to be a range of new technologies, regulatory enforcement activities and other opportunities for us to help address it before it gets worse last July I launched a special task force to head off this growing threat to our drug supply. At the same time inadequately regulated foreign Internet sites have also become major portals for unsafe, imported, illegal drugs.

For example, the nature of the drug abuse problem is changing in the United States. And the growing availability of

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prescription narcotics over the Internet is an important contributor. We are working closely with our colleagues in the Drug Enforcement Administration on new approaches to meet this new challenge to drug security. We must not allow the Internet to become the 21<sup>st</sup> century's virtual drug cartel.

With all of these new threats Congress must make sure FDA has the resources and authorities it needs to keep our drug supply secure. Yet the debate in Congress has mainly been about taking away from our existing authorities and simply declaring more non-FDA approved imported drugs to be legal.

I think Congress recognizes the world has changed, that there are more security concerns than ever. And so our vigilance over imports that enter the country must change as well. Just last year Congress passed legislation that will give us an unprecedented ability to protect our food imports from deliberate or accidental attempts to contaminate them. As a result of this legislation FDA has boosted its food security activities at the border substantially with literally hundreds of new inspectors and support staff. And that staff is backed up with important new legal authorities. For the first time we will be notified of essentially all commercial food shipments ahead of time to allow us to target our efforts to the riskiest products before they enter the country.

So thanks to Congress we now have new abilities to take action to prevent the entry of foods that may be unsafe. But

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with respect to drugs some in Congress want to go in the opposite direction. I know of no evidence domestically or internationally suggesting that it is now safe to declare broad new classes of drugs to be legal and to open up our borders to assure that these drugs are safe without allowing many more unsafe drugs from taking advantage of a wide, new legal import channel. You can bet that the same kinds of individuals who are trying hard to exploit the weaknesses in our system of drug security today will make the most of any new paths that are open into America's drug supply. They are trying now.

For example a customer recently purchased an Eronson (misspelled?); an FDA approved anti seizure medication, from a website that claimed to be operating in Canada and shipping FDA approved drugs from Canada to the United States. However the drug the consumer actually received was made in India and unapproved for any use in the United States.

Pharmaceutical peddlers are taking advantage of regulatory gaps to move millions of prescription drugs including controlled substances into the United States from Mexico, Canada and elsewhere. Rogue medical merchants who have dubious or no medical background are selling potentially dangerous drugs to people who never see the prescribing doctor in person or undergo tests.

At a minimum these drugs are of unclear origins and safety. At worst they are improperly repackaged, stored and

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labeled or are out and out fakes. And I don't think it's appropriate for the federal and state governments to try to foist off the responsibilities for a safe and affordable drug supply for Americans on the government of a country that is a tenth of our own size.

Not surprisingly the Canadian government has said themselves repeatedly that they cannot assure the safety of drugs exported to the U.S. even though they are diligent in assuring the safety of drugs purchased from legal channels in Canadian pharmacies.

Buying between the U.S. and Canadian system is not the same thing as buying with any system. The U.S. and Canada do not have integrated systems for taking timely action to prevent harm and protect consumers in the event of a safety problem involving an illegally imported drug in the United States. Protections to assure the appropriateness of a prescription such as requirements for physician contact and monitoring may differ. And each country has only limited resources to devote to their existing systems for assuring drug safety for their own populations let alone to assure the safety of an expanded scope and volume of drug imports.

For example Ontario, Canada's largest province and one of the provinces that purportedly is shipping a large volume of prescription drugs to the U.S., has exactly one investigator tasked with policing all pharmacy operations there including

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both domestic Canadian pharmacies and a growing number of pharmacies serving only or primarily international Internet customers.

Some people have said well, maybe it doesn't meet the standards of a legal prescription in the United States or in Canada but it's cheaper so it's up to the patient to make sure they use the drug right; to count the pills, keep track of the warnings to make sure the product is not expired, and so on.

Now I do think it's very important for patients to be active partners in their health care. But an active partnership is a long way from this sort of buyer beware situation.

This kind of approach to laying open the U.S. border is embodied in HR2724, the Gutnick (misspelled?) bill and similar bills. I've had a number of discussions recently with some of the supporters of these bills including Mr. Gutnick (misspelled?), people who care deeply about the issue of drug pricing. These representatives are clearly in touch with the anger of many Americans, especially seniors, who simply can't afford the best and latest prescription drugs. And Congress should do something about that.

But at the same time these members are out of touch with the realities of keeping our drug supply safe and the clear and present dangers to America's supply of drugs that their bills would create. To give you one example; their

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solution to the large and growing problem of counterfeit, unsafe and unregulated drugs whose makers would be delighted to see new channels in the United States is an optical anti counterfeiting symbol on the drug package. Now although this technology hasn't been widely evaluated for prescription drugs and would cost billions for companies to comply with, it is one of a whole set of anti counterfeiting measures that are used on our paper money supply. Or rather that were used until recently since the U.S. Treasury recently decided that those measures are inadequate to prevent counterfeiting.

Counterfeiters today use special inks to produce near perfect copies. They can crack any ink-based system in less than a year. And so the U.S. Treasury has adopted multiple new strategies. And with drugs much more than money is at stake. An imprint on a box is not a substitute for comprehensive, multi part system for assuring the safety of the actual drug product, not the package, all the way from production to patient.

We've already seen examples of why a focus on labels alone isn't sufficient. Criminals have repackaged unsafe or counterfeit or different drugs into legitimate appearing packages for example with Serostim, Procrit, and Lipitor. We have been working hard recently at FDA on anti counterfeiting technologies including a widely attended public meeting last week that got great perspectives from product developers,

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experts on counterfeiting, law enforcement officials and others. And while there isn't any magic bullet available today there are many promising technologies in development.

We need them because as any counterfeit expert in the Bureau of Engraving and Printing or the Secret Service can tell you, or as any of the growing number of drug counterfeiters themselves could tell you, any single anti counterfeiting technology is essentially useless. Multiple layers of anti counterfeiting are needed to stay ahead of the counterfeiters. But these technologies have not yet been demonstrated and proven for prescription drugs. And while we need to start doing so right away an effective anti counterfeiting system to assure the integrity of our drug supply is still a ways off.

The bill may permit a few more imported drugs from Canada to come in although many are coming in already today. And it's not clear how many more legitimate drugs can be supported through Canada's much smaller drug supply. But the bill isn't really about improving our ability to get safe and affordable drugs to Americans. That's not what the bill says if you read it. Instead what the bill actually does is take away FDA's existing authorities to protect Americans from unsafe imports; authorities that are already being stretched.

It would create unprecedented prohibitions on FDA's abilities to inspect and test drugs and FDA's ability to block the distribution of drugs that we think are unsafe. And it

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provides no clear new resources to handle the flow of imported drugs into the United States, which could become larger than it is today. So in addition to allowing in some drugs that might be safe it would also create wide and poorly regulated channels through which large volumes of potentially unsafe drugs would also be able to enter the country much more easily.

In addition the bill does nothing to stop the dangerous proliferation of uncontrolled, unlicensed and unregulated Internet websites selling potent drugs without proper medical oversight. In many cases without the oversight of any kind of health professional whatsoever. So the bill provides new opportunities to harm Americans for great profit on one hand and does nothing about 21<sup>st</sup> century Internet based and other weapons available to criminals to carry out that harm.

This is not the time to be opening up new avenues for those willing and able to harm patients for their own gain. By choosing affordability over safety rather than taking new steps to address both this legislation is a dangerous solution to our twin challenges of safety and affordability. Instead we need legislation that is in touch with the realities of making drugs both affordable and safe. In the real world, as any of our dedicated field investigators can tell you, as any pharmacy regulator can tell you, and as the major health professional organizations have said just because a bill says drugs are safe doesn't make them so.

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I believe that we can do much better. I believe it is possible to pass legislation to keep our drug supply secure while improving access to affordable drugs. And I hope that Congress will continue to work with us to do so. And based on everything I've seen so far I'm not optimistic that drug importation can be a durable and widely available solution to the problem of safe and affordable drugs and we need to take other steps.

On this issue of legislation to allow importation the AARP has made some good points recently. AARP correctly pointed out that the way drugs are priced around the world is unfair to millions of Americans and something should be done about it. And they also pointed out in order to keep our drug supply safe any such legislation is going to require more resources and more authorities at FDA to assure drug safety and integrity of our drug supply with a broader range of drug products. And that's precisely why the AARP doesn't support the Gutnick (misspelled?) bill.

Other entities including some local and state governments are investigating whether they can improve their own budget picture by entering into formal agreements with store-front operations that purport to be Canadian. All of these endeavors that I've heard about create safety problems as well for many of the same reasons. Much as they would like to state and local governments and private groups cannot provide

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reliable safety assurances when they purchase drugs from foreign sources. It's simply not enough to replace a comprehensive federal and state system for assuring drug safety by picking a company operating outside the United States that appears to be legitimate and hoping that their drugs turn out to be safe.

Once again despite of what they say none of these drugs will have gone through the approval, monitoring and prescribing process of the United States. I know that these governments, these state and local governments, are facing very tight budgets and they have to make very hard choices. But I don't think they should settle for taking an uncertain gamble on patient safety just to save money. And the companies they work with, the companies who encourage purchases of imported drugs, aren't only risking the public health to make some money. By creating significant new international flows of drugs into our system they may be aiding criminal enterprises that can put all Americans at risk by complicating our job of protecting the borders.

One thing should be very clear. Opening America's borders to imported drugs will certainly not help protect our pharmaceutical supply against bogus drugs and would very likely make a growing problem worse. Worst of all it's not even clear that expanding access to such imported drugs will ultimately provide access to more low priced, reliable drugs. If expanded

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importation to the United States threatens the much smaller supply of drugs in Canada or France or elsewhere then it's possible they will take steps to restrict such imports into the United States. The result; a big step back on the security of the U.S. drug supply as the pressures for unsafe imports from other sources increase still further, worsened relations with countries that we need to have working together with us to make drugs more affordable, and little or no progress despite all of this effort on making drugs more affordable within the United States.

After waiting far, far too long for access to drug coverage and more affordable drugs Americans deserve better than an approach that's likely to fail.

I've tried to be very clear about what we're against. We're against large new gaps in the nation's ability to protect its citizens from potentially unsafe drugs at a time when the threats to the safety of our drug supply are greater than ever. Now let me add to what I've said about what we're for.

There are better ways to provide access to safe and affordable drugs that are the most innovative in the world. And no question we need help from Congress, not just in drug coverage, but in keeping our drug supply secure and continuing that 65 year tradition that has been so important that a high level of confidence that Americans can enjoy in their legal prescription drugs.

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First FDA and our partners in regulating prescription drugs must have adequate authorities and responsible private sector partners in assuring drug safety. Over time my hope is that drug safety can be assured by a multi layered strategy of modern anti counterfeiting technologies including track in place technologies that cannot be faked like a paper drug pedigree and verification technologies built not only into tamper resistant drug packaging but into the drugs themselves including both technology that consumers could recognize as well as covert technologies that would not be easily known to counterfeiters which would make our job of verifying the legitimacy of drug products much easier.

We are already working hard on speeding up the availability of these anti counterfeiting technologies, which currently are months to some years away. In the meantime FDA needs all the authorities it has now to assure the safety of legal prescription drugs. This includes the ability to require or conduct tests of product authenticity and potency, the ability to identify and when necessary inspect those involved in the distribution of pharmaceuticals and the authority to issue regulations and when necessary take decisive action to block the distribution of potentially unsafe drugs.

It's certainly not the time to weaken these authorities or to allow products into this country that are not subject to these consumer protections as many of the importation bills

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being considered by Congress would do.

We also need to make sure that everyone involved in getting prescription drugs from the manufacturer to the patients follows good drug security practices to prevent potentially unsafe drugs from entering our drug supply. They are concerning weaknesses now. FDA has worked closely with states such as Florida that have recently taken important steps to assure good business practices and to address security gaps among drug wholesalers and distributors. This is particularly important for certain so called secondary wholesalers, which have historically been a source of introducing many unsafe drugs.

But the same problems arise with any poorly regulated organization involved in getting drugs to patients including storefront operations and Internet sites that do not have meaningful professional standards and that do have the opportunity to take advantage of customers.

As part of our task force activities we are working on a model code of business conduct that we will then work to get widely adopted by the prescription drug distribution industry.

Second we need an adequate ability to monitor the integrity of the prescription drug supply and respond to threats. We are considering further steps until automatic technologies can take care of it for us to improve the quality of drug pedigrees without imposing unnecessary cost or new

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systems that could still be gamed by criminals.

We also need enhanced methods to ensure the legitimacy of Internet sites and the storefronts that sometimes work with them and to take fast action against those sites that are not following good medical practices. This is an especially tough problem when it comes to the growing number of sites operating outside the United States. But we must work with other nations to address this global threat. And at a minimum we need to be extremely careful about adding any legal distribution points and channels to our drug supply; especially stores or sites with no medical regulatory oversight until we have the ability to monitor their integrity.

We also need better methods for identifying and responding to unsafe drugs that make it into our drug distribution system. For unsafe drugs that penetrate our legal system of drug distribution we need a mechanism for faster and more reliable notification of the FDA and other regulatory authorities from manufacturers, distributors, pharmacists and consumers when potential problems are identified. And we need a better mechanism for notifying everyone who may be affected when a problem arises.

We are working with private sector partners on an integrated electronic system to do just that. For drugs that are imported outside of the legal approaches to monitoring imports it's worth noting that we currently have no reliable or

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timely way to identify safety problems and cut off the source when a safety problem occurs.

Third we need to make sure that the scope and volume of the drug products that are deemed to be legal are commiserate with the resources of the FDA and our state partners to assure their safety. Our current resources are being stretched thin especially at the border which is an important line of defense against potentially dangerous drugs from other countries.

This is one reason why Congress made many drug imports illegal in the first place. FDA did not have the resources or authorities to assure their safety and we still don't. The safety risks of some drugs are especially great. For example in recent years we've seen many more drugs that require risk management programs of tight monitoring, biologic and injectable drugs that have especially complex manufacturing and storage requirements and more and more diverse controlled substances.

I believe that by adhering to these principles we can maintain an up to date drug supply that is safe and secure despite the increasingly sophisticated and diverse threats to the safety and integrity of our drug supply. The FDA is working harder than ever to achieve these goals through our new task force initiatives and new collaborations with other government agencies, the private sector and other governments. I hope that Congress will help, not hinder, the efforts to meet

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these unprecedented challenges.

We also need a better global solution for the problem of affordable drug pricing. It is not fair that countries with almost as much ability to pay as the United States are paying prices lower than those in many less developed nations like Poland. This is not a trade issue where one country benefits if another country pays more. It's a global public health issue since the drugs we are buying today and the drugs in development for the future hold the potential to improve health around the world.

If all countries pay their fair share prices can be more affordable for everyone. If all countries keep working apart in their own interests that just pay the incremental cost of making a few more pills none of us will end up benefiting.

FDA is also taking many other unprecedented actions designed to get more affordable drugs to Americans wherever we can without compromising safety. We're taking steps to lower drug costs by helping speed the development and approval of low cost generic drugs after legitimate patents have expired on branded drugs. This includes the biggest expansion ever of our generic drug program and a series of regulatory changes to make it easier for generic manufacturers to compete.

We've taken steps to help improve the development process to lower the high cost of developing new drugs. We've taken steps to improve the process by which drugs are

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manufactured through our current good manufacturing practices initiative. We're working to prevent adverse events through new rules that would require bar coding for drugs and better ways to track adverse events automatically with the goal of preventing billions of dollars in unnecessary health care costs each year. We're striving to promote electronic prescribing to improve quality and reduce prescription cost. And we're taking other steps that provide better information to health care professionals and patients alike including new and better patient information and Internet based information about the risks and benefits of medication choices available to treat a particular health problem.

Of course the most important step that the government can take to solve the problem of safe and affordable drugs extends well beyond FDA. And it requires legislation that the President and bipartisan members of Congress are closer than ever to achieving. It is time for Congress to pass overdue legislation that would improve Medicare by making safe and effective drugs much more affordable for seniors.

Such legislation would cut drug costs for seniors by many billions of dollars each year and would enable seniors to band together to reduce their drug prices substantially. And so I firmly believe that we can and should do a much better job of making safe and innovative drugs affordable in the United States. But we need to work together to do so. And on all of

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these issues I want to pledge FDA's continued assistance to anyone in Congress or elsewhere who wants to work together to find safe and affordable solutions.

David Winston's legacy should show us, to show us all, that there are effective solutions to these kinds of problems if we work hard and work together. A cheap drug isn't a bargain if it puts your health at risk. We owe it to the Americans who sent us here to Washington to find durable solutions that will not be a hazard to people's health. We owe it to the American people to make sure they can enjoy the benefits of new; safe and effective medical technology and that they can meet their medication needs affordably.

Thank you very much for listening to me tonight.

[ Applause]

[ Crosstalk]

**DR. ROBERT J. RUBIN:** Dr. McClellan has very graciously agreed to answer some questions from the audience. So if you raise your hand he'll identify, and identify yourself, he'll be happy to proceed.

**MALE VOICE 1:** (Unintelligible).

**DR. MARK MCCLELLAN:** Very good question. Unfortunately I think the generic train isn't bearing down as much as I would like even though we've got an unprecedented amount of spending on research and development going on now particularly related to applications of new sciences, genetics, pharmacogenomics for

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example, pharmacogenetic testing that can go along with drug development to get more targeted drugs. It really hasn't shown up yet in applications to the agency. We're at a kind of an all time low, 20 year low, in new drug approvals last year. That's bounced back a little bit this year. But so far the actual products that are based on these new sciences haven't come into us yet.

As you well know typically a very long and uncertain process of turning good, new, scientific ideas into safe, effective and reliable treatments and one of the things that we're doing right now is try to speed that process along. Earlier this year we had a major, announced a major new initiative on medical innovation that had as a component of it pharmacogenomics (misspelled?) were first and foremost. And we announced a set of initiatives that we are trying to undertake now to encourage the sharing of applied information on applied genomic and genetic information on drug development, on the development of new medical products to help speed up that development process.

Right now there's an awful lot of information being gathered on genomic features of particular drugs. And micro race studies that are done today can tell us about up or down regulation of a particular agent on literally thousands of genes. The problem is we don't know what that means yet for safe, whether treatment is safe and effective or not in

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patients. And it hasn't yet had a major impact on clinical trial design or the bulk of applications coming into us.

So our focus right now is seeing if we can find ways to help turn that information into decisions that can help improve the efficiency of the development process. We've got a workshop coming up on this in early November that's going to have a much further discussion of some of the ideas that I've been talking about tonight as to how we can integrate genomic information, genetic data more effectively into the drug development process.

But so far it hasn't really made it into an awful lot of the applications hitting us yet. It's still very much in earlier phase of development and we need to find ways to speed that along.

**DR. ROBERT J. RUBIN:** If people could step up to one of these two microphones the people watching the webcast can hear (unintelligible). Yes?

**MR. DAVID SUNVALL:** Hi. David Sunvall (misspelled?), American Clinical Laboratories Association. I understand what you just said. But I think there may be one factor that is putting a chill on some of this development. And that is the agency's reported interest in stepping up the regulation of in house developed diagnostics. And as you know that's a very important part of this whole translation of genomic information of the treatment.

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And representing the commercial labs I know that there's just this anxiety they feel because you've already announced this interest in rewriting the ASR rules. And my only caution would be that as you do that, given the resources you have and whatever, please don't ratchet up the regulation as an important step of the very thing that can translate genomics into new treatments.

**DR. MARK MCLELLAN:** Yeah. That's a very good point. I think what some of the ASR issues were they truly in house tests; that's a, you know, not something where we envision a fundamental change for the increasing number of tests that are, you know, actually complex and go beyond just an in house home brew. There is some questions about what the appropriate regulatory structure is there.

I can guarantee you though that as we approach these questions we are gonna look carefully at cost and benefits. We don't do cost effectiveness evaluations of the drugs we approve. But we sure do it on our regulatory approaches and anything that we come up with will focus in on cases where the clinical consequences of an unexpected test result or an improper test result are greatest and where any regulatory burdens, if there are any, are met by the potential advantages of having good and sensible regulatory standards in place. Very important point. Yes?

**MR. SIDNEY LYGAR:** Sidney Lyngar (misspelled?) from

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the (unintelligible). Questions about counterfeiting; are there, what, how big of a concern do you think this is for the device and diagnostic industry if any? And what have you been doing to maybe work with diagnostic and certain on the distribution end or to preserve supply integrity? Secondly, are there any lessons learned from the device and diagnostic industry to apply toward anti counterfeiting?

**DR. MARK MCCLELLAN:** Yeah I'm not sure. Most of the big problems that we've seen with counterfeiting, international operations that are introducing, you know, or trying to introduce literally thousands if not millions of products in the country are mainly around prescription drugs not around the devices. And they just leave it with, you know, especially the you know the more sophisticated and expensive devices it's just harder to come up with counterfeit versions. And it's harder to slip them into the distribution system than it is for drugs that are, you know, more widely purchased over the Internet and internationally. And a lot of these devices are used by health professionals rather than you know patients directly and it's just harder to get into that system.

But obviously we're gonna try to be vigilant on that. With respect to whether the device and diagnostics industry has any lessons to teach and can anything that helps prevent counterfeiting that they've undertaken we'd want to take a look at for addressing our counterfeit problems as well. But it is

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true that our focus has really been on drugs. And if there are more problems that we need to be aware of and responding to about potential counterfeit threats for devices I hope people will bring those to our attention. It is a big concern. Yes?

**MR. FIONA SHAUNESSEY:** My name is Fiona Shaunessey (misspelled?). I had the pleasure of working with Bob Reuben in the Reagan administration a number of years ago. But I don't speak for anyone officially. I am raising a question on because my brother is the head of, the Director of the Center for Excellence and HIV AIDS up in Vancouver, British Columbia, which is located at St. Paul's hospital.

You've talked a lot about the trade off between safety and quality and affordability. At the Center for Excellence on HIV AIDS in Canada however they only use FDA standards. Nothing other than FDA standards for the administration of drugs is permissible. And they have something of a leadership position with regard to research as shown by the New England Journal of Medicine, Julio Montana, Mark Wainberg (misspelled?) in Toronto. They're all involved in the kinds of work that's done there. Extremely high quality; but when it comes to the procurement of drugs they actually obtain their drugs supply from the major pharmaceutical firms at about a 30 percent discount from what's available in the United States.

As people have described it to me it's simply because they're very, very tough in negotiations. They have a

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tremendous database with regard to all their patients. The database is extremely strong going back 20 years. They have extremely strong clinical work. They have epidemiology that's also very strong. And they tie it all together.

And so when they sit down with the drug companies to talk about what kind of drugs are needed, the state of the art, the absolute latest pharmaceutical products available they're very, very hard when it comes to getting a good price. They don't see that, and I can't speak for them other than what people have said to me, they don't see that in the United States.

And as a result their drugs are about 30 percent less. And again, they only use FDA standards. Isn't there some room in the United States for taking advantage of this kind of negotiations between, on the part of the government and the private sector to get better pricing?

**DR. MARK MCCLELLAN:** Well I don't know the, you know, a lot of the details about this particular program. It sounds like a very innovative and respectable one. I've certainly heard of it before but I'm not familiar with the details of how they get their, how they do their pricing arrangements.

I can tell you that that does sound like the kind of thing that Medicare beneficiaries ought to be able to take advantage of more widely here directly. And that I think that many of the bills that Congress is considering right now, the

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House passed and the Senate passed bills, would provide that kind of opportunity or at least the start to that kind of opportunity for seniors to get together and have a knowledgeable source, knowledgeable benefit manager negotiating on their behalf. You know helping them identify drugs that could be interchanged from each other. And we're trying to do our part to help out with that effort by making as good comparable risk benefit information as possible on different drugs for treating a health problem and by them banding together to negotiate a lower price. I mean it's ridiculous that seniors today have to walk into a drugstore or clinic and pay prices that are the highest in the world.

So I think those kinds of ideas are excellent solutions that don't compromise safety if we can do it directly here within our regulatory system. And I hope that we'll see more steps like that. And that's something I hope you'll talk to your members of Congress as well. That'd be good ideas for them to get into place too. Thank you. Yes?

**MR. DAN AIN:** I'm Dan Ain (misspelled?). I'm a practicing physician in Washington and on the staff at GW. Diversity; a few years ago at an FDA hearing on the conversion of Claritin to over the counter status an FDA representative talked about consideration being given to making other classes of drugs over the counter such as anti hypertensive, lipid lower drugs, anti diabetic medication and so on.

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We haven't heard anything more about that. Could you comment on where that stands what the idea of that also as a cost cutting method?

**DR. MARK MCCLELLAN:** Well sure. Let me as a general matter let me tell you what our basis for making a determination about whether a drug is OTC or prescription. It's basically determined by what the science has to say about whether a patient needs a learned intermediary, doctor or nurse practitioner what have you depending on the case, to help them use that treatment appropriately. Whether they can use the treatment safely and effectively themselves.

And in practice that typically limits the OTC products to ones where patients can very fairly reliably self diagnose or the side effects and complications associated with the drug are, you know, either relatively mild or easy for the patient to observe so that they'll get off the treatment if there's an important complication. And basically where they can manage the problem themselves.

That's not the case for a lot of prescription drug products, you know, from a growing range of products. There has been some speculation about, for example, whether cholesterol-lowering medications might one day be OTC. And that would depend on whether you could have enough, you know, other products along with it like a reliable diagnostic test that a patient could do themselves. And you know, some kind of

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perhaps, some kind of monitoring test, I don't know. But that's why some classes of drugs haven't moved to OTC status.

For the ones that have you know be it you know topical anti infectives, H2 blockers now, you know now the proton pump inhibitors, anti-inflammatory drugs, whole ranges of medications the universal experience has been much broader use and much lower cost. And that's not the basis on which we make our approval decisions. But that has been what's happened universally with the prescription to OTC switches when they've occurred.

So that may be a side benefit that's worth thinking about. And in an era when we're very concerned about rising health care costs having an ability for people to get easier access to products without the hassles of going through seeing a doctor, if they can use them reliably, you can get them for a potentially lower cost, may have some important benefits.

And it's interesting to see that there have been a lot of insurance companies recently this year for example moving toward providing for the first time ever coverage for OTC drugs like non sedating anti histamines. That's starting to happen. I'll be there's going to be more of that as more of these OTC treatments are recognized as being a more cost effective approach for treating some problem.

Some people have also been interested in whether FDA might "force" a switch of an OTC product, of a prescription

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product to OTC status. And that's something that you know we are, we've been asked to do that for some of the other non-sedating antihistamines. And that's something we're considering in house in addition to the issues that I just mentioned. You know there are a couple of other important concerns like whether the switch could be done based on public, (unintelligible) safety and you know clinical appropriateness conclusion based on publicly available information, whether they're you know important liability or other considerations involved. And that's a harder question.

But where the science suggests that drugs can be used appropriately OTC that's something that FDA has been encouraging and may add some valuable benefit.

**THARO:** Tharo (misspelled?) from Georgetown.

**DR. ROBERT J. RUBIN:** We'll take two more questions.

**THARO:** If you implement anti counterfeit devices and the electronic tracking devices wouldn't that increase the cost of manufacturing?

**DR. MARK MCCLELLAN:** Well it is a good question. It depends on the technology you use and how they're imposed. Some of these technologies today are actually fairly extensive. Like some of it, you know one of the new technologies is this wireless transmitter for those of you who, you know, commute and go through the Fast Pass lane or something like that. That's a kind of technology people are talking about using to

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generate an automatic tracking of a drug product from where it's manufactured all the way through to the retail pharmacy.

Those transmitters cost close to a dollar today in many cases we just heard about. But the cost, it cost a dollar per, you know, per unit. And so that's really not cost effective for most drugs at the individual product level. But a number of companies are very close to starting to implement this kind of technology at least at the batch level for the retail freight shipment level to track it along and are particularly interested in doing it for what they view as the higher risk products for diversion or counterfeiting; product drugs that are particularly extensive, controlled substances, things like that.

So this is starting to happen now. The other thing that we've learned from industry is that the cost curve here is very steep. The cost is coming down a lot you know maybe as much as 30, 40 percent per year. So as I was saying earlier that within a year or two this is certainly on track to being a very cost effective element in a system for, you know, 21<sup>st</sup> century system of drug security that yes we are obviously cognizant of the cost of the technology involved.

You know one way of addressing this as we mentioned in a recent interim report we had from our anti counterfeiting task force would be to consider starting the use of these technologies for those high risk products. You know ones that

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are particularly costly or ones that are particularly subject to diversion for other reasons like controlled substances.

**THARO:** Thank you.

**MALE VOICE 2:** Dr. McClellan I have a two-sentence question.

**DR. MARK MCCLELLAN:** I'll probably give you a two-sentence answer.

**MALE VOICE 2:** As this story gets around the country, which I'm sure it's starting to it must be scaring the devil out of a lot of people. I'm one of them as a matter of fact. But what do you tell me? What do you tell the American people about this threat? Can I guard myself against this threat simply by making sure that I buy all my drugs from licensed pharmacies? Or is this stuff sneaking its way into those?

**DR. MARK MCCLELLAN:** Well it helps to buy from licensed pharmacies. When you go outside of the pharmacies that we regulated it really is buyer beware. And if you've ever gone to one of these websites for finding drugs internationally what most of them have is a, you know, in the fine print down at the bottom. Up at the top they'll say FDA approved drugs or just as good as FDA approved drugs. And that's one of the reasons I don't like these sites because they're generally not FDA approved and they're not subject to the same regulatory scrutiny.

Down in the fine print they'll say we don't have any

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liability in this case. You know we can't guarantee you that you're going to get the drug and it's going to be used, the drug you get is going to be exactly what was intended and that you're going to be able to use it properly. There are major disclaimers in there so you can't really fault them for not saying buyer beware. It's just sad that that's the state of affairs that we're in for many drug purchases today.

So yes, I think it is less safe when you go outside the regulating system. Within our regulated system there definitely are more serious and more sophisticated people who are out to make a fast buck that are trying to make money off the, you know, the high cost of prescription drugs by introducing unsafe drugs into the system, by diverting drugs that came from other countries or other things that we are very concerned about.

That said we still have I think when you walk into a drugstore in the United States you can be extremely confident that the prescription you get is going to be safe and effective and will work as intended. We are being more vigilant than ever though about these increasingly sophisticated threats.

**MALE VOICE 2:** That's what I wanted you to do is just tell the American people if you're worried about this just go to the drugstore and then you don't have to worry about it. Is that the case?

**DR. MARK MCCLELLAN:** It will certainly help. We have a

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very high level of quality in the regulated drug products that we approve and we work with states to oversee it.

**MALE VOICE 2:** So stay off the computer huh?

**DR. MARK MCCLELLAN:** Well just be careful.

[ Laughter]

**DR. ROBERT J. RUBIN:** Mark thank you for an insightful talk.

[ Applause]

And if by magic the doors are opening up there to reveal the next part of the agenda which I think involves a bar and some food and Mark you're welcome to stay. And I'm sure there are plenty of people that would like to hear what you have to say. But we'd understand if you have to head back. But again thank you so much. We enjoyed your talk.

**DR. MARK MCCLELLAN:** Thank you all very much.

[ Applause]

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