

**“The Role of Consumer Information in Today’s FDA”**

**Mark B. McClellan, M.D., Ph.D.  
Commissioner, Food and Drug Administration  
Rockville, MD**

**Presented at**

**“BE MEDWISE: A PRESCRIPTION FOR PATIENT SAFETY”**

**14<sup>th</sup> National Conference of the  
National Council on Patient Information and Education  
Marriott @ Metro Center, Washington, DC**

**December 9, 2003**

## **Introduction**

### **Linda Golodner, Chair, National Council on Patient Information and Education**

Good morning, everyone. And thank you for joining us today. Now, on behalf of the Board of Directors and the staff, we welcome you and hope that you will enjoy the day and participate in all of the sessions.

Now, just 24 hours ago, the President signed into law the Medicare Prescription Drug Benefit Bill, and this redoubles the importance of NCPIE and organizations like NCPIE to educate consumers, to help inform them how to promote safe use and appropriate use of medicines.

Now, as more consumers, and especially those who are high-risk patients, have greater access to medicines, appropriate use becomes a very critical issue. And NCPIE's campaigns, such as the "Be MedWise" and "Educate Before You Medicate," for example, are much more than public relations activities and advertising. They get to the core of how consumers should use products that affect their lives. And they may reduce medical errors. They may improve health outcomes, and even save lives.

Now, it is now my pleasure to introduce this morning's keynote speaker, Dr. Mark McClellan, Commissioner of the Food and Drug Administration. He was sworn in as Commissioner just a little over a year ago, and I think most important is that he has placed consumer information about medications as one of his top priorities. He mentioned that, I think, when he was first sworn in, and he has continued to do that as Commissioner. He's an economist and an internist. Dr. McClellan.

## **“The Role of Consumer Information in Today’s FDA”**

Dr. Mark McClellan, Commissioner, Food and Drug Administration

Good morning to all of you. It’s a real pleasure to be back here with NCPIE again. I’ve enjoyed interacting with you all, both in your formal meetings like this one over the past year, and also with Linda and her staff on an ongoing basis with the FDA staff, Pat Kuntze and others who are here today, and others who have been working with you all on an ongoing basis addressing together the critical public health goal of improving patient safety and improving consumer information.

Through the leadership of the National Consumers League and NCPIE, you all have helped encourage better dialogue on some of the absolutely critical health issues, leading to better health for consumers.

We’ve got a strong history of working together. It goes back more than two decades, all the way back to NCPIE’s founding many, many years ago. And, in addition to serving continuously on the NCPIE Board of Directors, FDA has collaborated closely with this organization on many educational and public awareness campaigns over the years. NCPIE continues to play an important role in promoting patient involvement in a number of healthcare issues, more important today than ever because there’s more that patients can do than ever before to help improve their own health.

And so, I look forward to continuing to build on our work together to advance the public health.

I’d also like to thank Phil Schneider for his work with NCPIE; Ray Bullman, whom you just heard from, for helping to bring this event together and for promoting this close relationship with FDA over the years. Ray’s been promoting consumer involvement in public health for a little over two decades.

Phil and his team at the National Association of Chain Drugstores have worked closely with

FDA's Office of Women's Health on several important recent projects, and NACDS has also been instrumental in helping us address some new challenges when it comes to the safety of medicine, particularly counterfeit medicines that are an increasing threat to the security of our drug supply in this country.

And finally, Lee Rucker (NCPIE Senior Vice President, Policy and Public Affairs) for her help in working with all of these—with us on all these issues, as well.

Well, I'm glad to be here today. And I'm glad to have an opportunity to talk again about how we can use information about medical products more effectively to improve health and safety, to promote patient safety.

A well-informed public means that consumers and doctors can make better healthcare decisions and make more high-value use of the medical products that are available to them-- an increasingly impressive array of medical products today.

As Linda said, NCPIE's mission, all of our missions, to help consumers use medications effectively, is more important than ever. It's more important than ever for consumers to have high-value, accurate information to play an active role in their own healthcare and medical decision-making.

Medical products available today more than ever have the power to produce dramatic health gains. But the increasing choices that are available to consumers also mean that they often need to make important tradeoffs. They need to make choices when considering the different treatments that are available for their conditions; the decision about whether to use a newer medication or an older generic version that may offer the same benefits; the decision to weigh subtle differences and risks and benefits of similar drugs within a class of medicine; the decision to trade off waiting and monitoring a condition or going ahead with surgery or to choose between the intervention up front and hopefully preventing an illness or dealing with it later.

Many of these different considerations require careful patient understanding, and a lot of

information, and it certainly is benefited by well-informed consumers. So, it's important to keep consumers involved in medical decision making today more than ever for fulfilling our core public health mission of protecting and advancing the health of the public.

Being able to make these kinds of decisions is a good thing, because consumers who make them, they've got an opportunity to choose a medical regimen that meets their individual needs based on their disease, based on the broadening array of treatments available, based on accommodating the unique demands of their lifestyles, their personal expectations, other factors that matter to them.

But this variety in medical treatments, this variety of options, means that more than ever consumers need to have accurate information, easy to use and relevant information if they're going to make decisions that best suit their personal needs.

For people to see how options can stack up against one another, to make the most high-value use of drugs and other treatments available today, they need to be able to line up the information easily, to make comparisons, side by side.

Making better information available to consumers can also help them be more active participants in their own healthcare, and I hope can help us avert some of the serious and costly medical problems that arise when patients don't know or don't fully understand what can go wrong with a medicine or simply don't have enough information available to make the best use of new medical products; and that accounts for a large part of our healthcare spending today.

Many adverse medical events involve errors in medications or prescriptions that doctors make. We're trying to address this, as I'll talk more about in a minute, with our bar coding rules and other measures.

But there are still many more adverse events that are not going to be eliminated this way. It happens, for example, as a result of poor compliance for treatment regimens.

Compliance with prescriptions today is too low. There are many factors behind this, among them cost and access. But also, in too many of these cases, people just don't understand that skipping doses or stopping a prescription drug early can fundamentally interfere with how well that prescription works.

Now, as Linda mentioned, we are doing something about this in an unprecedented way.

The President yesterday signed new legislation in Medicare that will have a tremendous impact on the health of our seniors and persons with disabilities because of the help it provides not only in paying for medicines, but in helping people get a better value of using those medicines effectively.

The bill provides comprehensive coverage for low-income seniors and persons with disabilities, so that they may pay, at most, a few dollars out of pocket for a prescription, and will have a low deductible, \$50 at most for a year as well.

It also provides help for all seniors who encounter high drug costs --catastrophic costs --and the many thousands of dollars, which too often today are interfering with full compliance with medicines. And it will help all seniors get lower prices for all of the medicines that they purchase.

Today, seniors pay often the highest prices in the world when they walk into a drugstore off the street and have no help at all when negotiating a lower price, like all of us involved in federal employees health plans do.

That's going to change. It'll change starting next year with the Medicare discount card, and it'll change even more fundamentally when the full drug benefit is phased in in 2006. Prices will come down on all prescriptions for seniors.

All of this will help address cost and access. In addition, the steps included in the bill to promote electronic prescribing, to promote the development of better information on medications fits in well with some of the other things that I'm about to talk about today.

But there is more that needs to be done to help reduce costs for seniors and all Americans.

At FDA, we've implemented a number of new programs to help drive down the cost of developing medicines, the cost of manufacturing medicines, and the cost of using medicines effectively, through better information, through regulatory reforms and other steps. All this is part of the same urgent goal of improving access by making high-value medications more affordable.

But we also need to do better when it comes to understanding how medicines available can be used. It's not enough to bring down their costs and address the access problems. In fact, one out of every four of the medication errors that occurred in Medicare patients in 1999 and 2000 could have been prevented with better information and understanding, according to a number of studies.

Closing the gap between what we know is the best medical care possible versus the medical care that our patients actually receive requires, in part, that patients become more active partners in their healthcare decisions and their healthcare delivery.

And that's not something they can do by themselves. It's something that we need to help with by empowering them through better information. It's only possible if patients understand their physicians' instructions. It is only possible if they know how medicines are supposed to work and when and how to use those medicines, what can go wrong, and what to do about it if something does go wrong.

The best defense against a bad medical outcome is a well-informed patient. Clearly, that's not happening as much as it should, despite all of our best efforts.

Also, better information can lead to better, less expensive medication choices. As I said, there are more medications available today, more treatment options, than ever before. And many times, consumers aren't fully informed about the full range of choices that are available.

So, for all of these reasons, FDA is taking new steps to make improvements in our existing system, and I want to mention a few of them.

Earlier this year, we proposed a comprehensive new regulation for companies to report drug-adverse events. This system is designed to give more extensive and timely information when we need it the most. Again, that's when the adverse events involve new drugs or important, substantial complications--adverse events that are not yet well understood. This system was designed with international input, with the goal of creating one worldwide standard that all regulatory agencies can use to get the best information possible on adverse events worldwide at a lower cost rather than having different standards, different systems for reporting adverse events in the United States versus Europe, versus Japan and Canada, and other places.

We've also upgraded our systems for collecting and analyzing adverse event information, including Web-based reporting systems for adverse events and new steps through collaborative agreements and new statistical data mining techniques to make these adverse event systems and the data that comes into them easier to analyze.

We're using new authority from legislation that was enacted last year to implement new programs to monitor the safety of new drugs after they're approved.

And we've developed new guidances and are implementing new techniques for improving risk management programs for prescription drugs that require special steps in order to be used safely.

These, and other steps, mean more safety monitoring, more response activities in place than at any time in FDA's history.

But we're now well into the information age, where modern technology is having a fundamental impact on many parts of our lives. And I think there's no good reason why we can't do an even fundamentally better job of helping to protect consumers and assuring the safe and effective use of new medical treatments.

With the highest healthcare costs in the world, Americans shouldn't have to tolerate the thousands of deaths, millions of hospitalizations, and many billions of dollars in added healthcare costs from preventable medical errors and adverse events.

Americans deserve better than settling for serious health consequences that can't be spotted until many years after a product has been on the market.

And, conversely, for benefits of products, in particular groups of the population that just aren't well understood today.

And Americans and their physicians deserve better than having to rely on limited and sometimes outdated information about risks and benefits and costs of medical treatments when they're making decisions, which, these days, are among the costliest and the most important decisions in their lives.

So, in short, Americans deserve a lot more value and up-to-date protections when it comes to their medicines. And if we don't take more steps now to use modern technologies to make that happen, to prevent the errors, to make sure people who use medicines are getting real health benefits, and to avoid complications whenever possible, then we may end up with a future that doesn't reflect the great potential of what should be the biomedical century. We may end up with a future that's not marked by continuing breakthroughs in curing and

preventing diseases, because we can't afford it anymore, because we're spending too much time on dealing with complications or inappropriate choices of medicines. Instead, it will be a future marked by rising concerns and rising anger about healthcare costs and about healthcare that costs too much and does too little.

So, with all this at stake, with much needed improvements in the safety and quality of healthcare delivery, the need for better systems for monitoring the risks and benefits of new medical products, and the need to do all of these things in less time and at a lower cost so people can benefit, more people can benefit and afford the new medical products, we can't really wait to change our healthcare system.

And, so, today, I want to talk a little bit further about one part of the needed change that hasn't received the attention I think it deserves, and that's speeding up the use of modern information technology to help make medicines safer and more effective, to give people more health benefits for the money they're spending on healthcare.

One of the problems that NCPIE has long been helping to address is that consumers often don't have the medical information they most need at the time that they're using medications. The truth is that often, too often, information is presented to them in a way or in places where it's not as helpful as it could be.

And sometimes, it's simply hard to understand. For example, the so-called brief summary that accompanies drug ads in this country often is neither brief nor a summary. And the information that accompanies medicines in those package inserts, that thin, flimsy paper, or on the back of an advertisement, is written not so much with a consumer in mind but perhaps a lawyer or someone else who's looking for technical information rather than looking for a way to make a timely and appropriate medical decision.

And, so, FDA is trying to make major steps forward right now to enhance consumer information and improve patient safety by improving the quality of this information. In fact, the two goals that I've been talking about, better-informed consumers and patient safety, are

so important that they're both key elements of FDA's strategic action plan that the agency announced back in August. There are five core goals in that plan, and two of them intersect right here.

We're focusing on reducing preventable medical errors and adverse events through better use of information, and we're trying to help consumers help themselves through more informed health decisions. We think that consumer information starts with the labels on medical products and the information that accompanies new drugs and medical devices, but it includes a lot more as well.

Improving consumer information involves our ability to efficiently use the best scientific data available and to translate it into clear language that enables people to make informed healthcare decisions; that people understand how they're supposed to use the drugs that their physicians prescribe, they'll derive more of the benefit of new drugs and fewer of the side effects. This will lead to better health outcomes and also lower costs for the healthcare system.

We know that many of today's pharmaceuticals, when used properly, reduce the long-term consequences of many chronic diseases, such as heart disease and diabetes. Consumers need to be able to use the best scientific information to fit these medical products effectively into a lifestyle that makes the best use of what we know about medicine, diet, and healthy living overall. Medicines are just one piece.

And we need to make this information more people friendly. We need your help in this. This means organizing labels and fact sheets and Med Guides and other sources of information so that key information is highlighted, and labels on different products follow the same format so that patients can compare more easily.

It also means moving to an electronic label that can be updated, and sorted, and searched easily. And it means eventually replacing those paper package inserts with up to date product information that can be printed out at local pharmacies.

We've got a series of initiatives underway at FDA to do all of these things. We're working to transform everything, from the information that drug manufacturers submit with new applications to the labeling and advertising of products, all the way to the reporting of adverse events after a product is approved. And we need to do a better job communicating this information once we know it.

Technology can't solve all of these information gaps. It's not a panacea, but it can make a difference in the way that we haven't yet fully exploited. There's been growing recognition of this fact in government, but by Secretary Thompson's E-Health Initiative, FDA is looking to capitalize on its promise, to capitalize on the potential benefits offered by IT tools today.

So, we're using this through the full cycle of information about the medical products available today. There are opportunities to improve the flow of information at every step of the process, from clinical development to marketing, to physicians' offices, to retail pharmacies and even patients' homes. We can and we need to collect better information and distribute it and use that information better so that it can ultimately help people use medicines more effectively.

At the development stage, the stage where new products are being developed, we recently announced a joint effort with the National Cancer Institute to support electronic submission of new cancer drug applications. This effort I intend to be a model for how we receive and manage data in all the clinical trials that go into FDA approval decisions. The electronic submission of these investigational applications not only speeds up evaluation and analysis, but it makes it possible for FDA to develop better information about clinical research by supporting comparisons of what we learn and from one trial, one product, to the next.

For example, our new demographic information and data repositories are going to help us track important, yet sometimes subtle, findings of clinical trials in particular subgroups of patients, effects that may not be apparent in any one trial or even in any one product, but that, if we're able to look more effectively across data that we have electronically, we may be able to find patterns in classes of drugs or find patterns across different kinds of information

submitted to us. We'll have a better capacity to provide general and specific analysis and analysis across other demographic subgroups to support good labeling information. And we'll be able to more easily monitor differences in drugs and dose responses across these subgroups in clinical trials without requiring costly new studies every time we need to ask these important questions about a particular product.

The information we learn during the developmental stage must continue to flow to the decisions we make about how we use the medical products that FDA has approved. And once patients start using those products, we need to continue to collect information about its risks and benefits in the real world and cycle that back into this provision of information.

To begin with, we need to find better ways to identify and to address severe adverse events even faster. Then, we need to update prescribing information and distribute that information right away to patients and consumers and health professionals that need to know.

Even with the best available data, drugs are sometimes found outside of that that couldn't easily be predicted or uncovered in any feasible clinical trial before a product is approved; before it's actually used in real populations in the real world.

All medicines do have inherent risk. But if we identify and understand these possible side effects more quickly, we can be more certain that we can address them before they manifest themselves as serious medical problems in large numbers of patients. And we can be more certain that the benefits to the products that we approve will outweigh their risks in actual use in the population.

We can also use this information to make smarter decisions about products to be approved that might have similar clinical profiles or similar molecular structures.

With this in mind, we're putting in place some active reporting systems. We're doing it first on a pilot basis, but we're expanding to enable us to uncover problems in real time or near real time by tapping directly into electronic medical records and monitor them for subtle

signs of problems with drugs, such as rising number of function tests or blood test results that could indicate problems with new medicines in certain types of patients. Perhaps this would enable us to spot a drug that causes liver inflammation in a few patients, identifying the problem before these people become seriously ill, providing information and providing better understanding of how this kind of complication can be prevented before patients go on to permanent liver damage or require transplants or worse.

These kinds of quality improvement initiatives are only possible if electronic systems are designed to interact with each other and with us. So, the development of some widely recognized data standards is a core part of FDA's ongoing patient safety and consumer information efforts today.

It doesn't sound very glamorous or high tech, but if different health information systems can't talk to each other, can't communicate about particular drug products or particular complications, then it's impossible to take advantage of modern IT systems in healthcare.

And, we need to provide in this process essential safeguards so that patients can be assured that their medical information is secure and confidential, and it is only being used for purposes of public health protection.

Of course, collecting and analyzing information about adverse events isn't much good unless we can take that information and communicate it rapidly and effectively once we have clear data, once we have clear results and knowledge.

In October, we alerted physicians to reports of suicidal thinking and suicide attempts in clinical trials for various antidepressant drugs in pediatric patients who have major depression. Issuing this kind of public health advisory is one of the important ways that FDA can help protect people once we have information about potential risks.

On a more routine basis, we need to implement a system that enables manufacturers, product developers, and the FDA to update labeling much faster, and get that information out more

effectively. The product label contains a wealth of information about safety, about side effects, about dosing and proper use, but our methods for updating labels and for presenting the information on labels has hardly been modified since the FDA was created. And I'm pleased to report to you this morning that that's about to change.

Today, we're announcing significant changes to FDA regulations that will require manufacturers to submit the labeling information electronically. These new provisions mean it will be easier and faster to review labeling content and easier and faster to get changes in the label or new labels out to doctors and patients at the point of care in a timely way. And it is the first step towards developing an electronic library of all FDA labels that can be readily searched and used by professionals and consumers alike.

With electronic labels, doctors will no longer have to navigate through the thousands of pages of the book form of the PDR just to find the single, subtle drug-drug interaction or piece together the causes of an unusual drug side effect. With electronic labels, doctors will be able to query an up-to-date database in just a fraction of the time and with much better results.

Having this kind of information available also makes it easier for consumers and doctors to make head-to-head comparisons between drugs so that they can make the best choices on the parameters that are most important to them, on the features, the side effects, the benefits, that are most important to them. This is the first step toward the day when we will have a two-way electronic information highway of better safety and effectiveness data coming to the FDA so that we can identify these problems; and, conversely better information coming out of the FDA based on knowledge, based on what we learn, from better monitoring and more real-time monitoring of adverse event data.

These new rules I'm talking about today will take effect in six months. We expect that most labels will be submitted in electronic form within about a year or so from now.

And we're going to start making those labels available on the FDA Web site right now. That means that physicians, pharmacists, consumers, and everyone else will have a single, reliable source for the most current labeling information available for a product.

This is an important change to help us use the power of today's technology to improve public health. Using modern information technology to inform patients and doctors about medicines is no longer optional at the FDA. The provision of more comprehensive, up-to-date electronic information is another place where NCPIE has played a major role, with your promotion of on-line medical literacy through the CyberSmart Safety Coalition. This is a great program.

To make the best use of the new electronic label, consumers will need to be able to navigate their computer to get help from others who can to download the best and latest up-to-date health information for their particular needs.

And this kind of assistance is another place where we very much look forward to continuing to work with you. I think we're complicating your job a bit, but I definitely believe it's for the better, for making for better-informed consumers.

I'm optimistic about the ways in which technology can help advance the public health, but there are also some simple challenges that transcend our authority at FDA to require us to work together to find better solutions. Even the best technology can't replace a good, direct conversation or a simple-to-understand label. And when three out of four people in the United States with a chronic illness say they have trouble reading the labels and half of the English-speaking population can't fully understand common health information, we still have a way to go.

It's not just that people ignore the important information on drug and food labels. Many simply can't find the information useful to them. You can look at the words, but if it's not presented as effectively as possible, it's not going to be useful. We need to find better ways, building on all the work we've done so far to communicate risk and benefits and the proper

use of health products.

Working with our partners in product development, working with consumers throughout the country, working with NCPIE, FDA will continue to identify tangible steps that we can take to make medical information, including product labels more understandable.

Our recently announced partnerships in this area, for example, with the Administration on Aging, to boost Hispanic health education, is one of these examples. Nationwide information campaigns like the ones we're doing with the Administration on Aging are not only important for overcoming communication barriers, they're also vital to educating American consumers on the new, more sophisticated health risks and opportunities for health benefits that they're facing today.

Our electronic labeling initiative and our E-Health initiative represent an important step toward speeding the flow of information from product developers to the FDA to consumers and then back again from product users and healthcare professionals through this loop of more informed and reinforcing clinical decision making.

Our goal is to demonstrate the value and the potential of this important information and to start using it on a steadily progressing basis to increase value and improve patient decision making, making it more complete, more timely, and more easily understood to support effective decision-making.

These steps are going to take a lot of work, but implementing electronic labeling and other modern health information systems will significantly advance our public health.

I look forward to continuing to work with you all to achieve this shared vision of better health for all Americans through better information and better patient safety.

Thank you all for your leadership in this area and for your continued collaboration with the FDA.