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Medicine and Society

Interview with Mark McClellan, MD, PhD

Mark McClellan, Commissioner of Food and Drugs, discusses pharmaceutical company research and the problems faced by funding for public health programs.

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Recently *Virtual Mentor* posed several questions about physicians in public life to Mark McClellan, MD, PhD, Commissioner of Food and Drugs.

Q. Why did you get involved in politics and public policy?

A. Throughout my career, my foremost interest has been in improving public health. As a clinician, I was able to bring medical treatments directly to patients. As a health economist, I have been able to understand how different policies and medical innovations truly impact public health. I got involved in politics and public policy so I could use the expertise I have amassed to make a real difference in the nation's health policy and help all Americans live longer, healthier, better lives.

The opportunity has never been greater to improve America's health through the latest biomedical and food innovations. And yet, the challenges have also never been greater. As FDA Commissioner, I have the extraordinary opportunity to lead this agency in filling its vital mission—to protect and advance the nation's health—by fostering a more efficient and effective health care system while also supporting the development of innovative new technologies.

Q. What is the biggest health care problem facing America today?

A. Our biggest public health challenge today is providing high-quality care that is safe *and* affordable for all Americans.

Today, there is more spending on biomedical R&D than ever before, and there are more new drugs and devices in development than ever before, and yet there are fewer new medical products reaching consumers than at any time in more than a decade. The bottom line is it's getting harder and more uncertain than ever to develop new treatments. At the same time, we're also facing unprecedented challenges involving affordability and access to the treatments that do make it to patients, especially prescription drugs. Many Americans cannot afford the necessary treatments for their health ailments and are unable to realize the full benefit of the products that are available. Too often, consumers are forced to make difficult choices between safe and affordable treatments.

The challenge for all of us is to ensure access to safe, affordable medical products and to get critical treatments in the hands of Americans who need them.

Q. What should be done to address this problem?

A. To address this major health challenge, we need to find solutions that do not force Americans to make choices between what they can afford and what they need. Rather, we need solutions that improve both safety and affordability.

The new Medicare legislation represents a major step towards solving this problem. Congress has taken action to meet the needs of the nation's seniors by providing a Medicare prescription drug benefit that will save them billions of dollars each year and will enable seniors to band together to reduce their drug prices substantially.

FDA is taking many other unprecedented actions designed to get more affordable medical treatments to Americans wherever we can without compromising safety. We are taking steps to lower drug costs by helping to 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 improve the process and lower the high cost of developing new drugs. Specifically, we're improving the pathway for developing safe and effective new medical products by making it as clear, as fast, and as cost-effective as possible.

In addition, we need to enhance our capability to use these treatments effectively, to get the most benefits for patients while avoiding costly complications. To this end, FDA is working to prevent adverse events through new rules that will 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 to reduce prescription costs. And we're taking other steps to provide better information to health care professionals and patients alike, including new and better electronic product labels and Internet-based information about the risks and benefits of medication choices available to treat a particular health problem.

Finally, we need a bolder effort to solve the global problem of drug pricing. Prescription drugs are truly global products today, and we need a global strategy to get the most benefit from new medications for all of the people of the world. Specifically, it's time for developed nations, recognizing their shared interest in bringing better treatments to market, to find ways to fairly share the cost of new drug treatments. This need not raise costs worldwide if other countries take steps to improve generic drug development and cost, work together to harmonize regulatory procedures, and ensure the most effective distribution and use of their drugs.

Q. How do you prevent complex health positions and messages from being reduced to more simple, polarized positions when they enter the political arena?

A. Agreeing on effective public health solutions is never easy going because health policy is complex and can make a big difference in the lives of all Americans. My job necessarily involves making tough decisions every day. The key to finding the best solutions to tough policy problems is to focus on the science and to make sure that all views are fairly represented. When I say "science," I am referring to the latest biomedical, managerial, and economic science, along with the latest thinking about how industry and government can best help promote the health of Americans. At the FDA, we try to use a very public process—including

advisory committee meetings, meetings to develop regulatory guidance, and many other steps to make sure we have heard all of the good ideas out there. In this "biomedical century," this is a more challenging process than ever. But the good news is that there are better, more sophisticated tools to help us make the best decisions for the public health.

Mark McClellan, MD, PhD, is the Commissioner of Food and Drugs. Previous to this appointment, he was an associate professor of economics at Stanford University, an associate professor of medicine at Stanford Medical School, a practicing internist, and the director of the Program on Health Outcomes Research at Stanford University. He was also a research associate of the National Bureau of Economic Research and a visiting scholar at the American Enterprise Institute. He was a member of the National Cancer Policy Board of the National Academy of Sciences and associate editor of the *Journal of Health Economics*. From 1998-99, he was Deputy Assistant Secretary of the Treasury for Economic Policy.