

Senator Orrin G. Hatch
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Thank you for that wonderful introduction.

I am thrilled to be a recipient of the Harvey W. Wiley Award. Dr. Wiley is known as Father of the Pure Food and Drugs Act, a consumer activist, and the first head of the Bureau of Chemistry that later became the Food and Drug Administration. He spent his government career and later at the laboratories of Good Housekeeping magazine studying food adulteration and misbranding. His career was not only admirable, but commendable and we owe him a lot for his commitment to ensuring the safety of our food and drug supplies. To be recognized for my lifelong commitment to public service by an award in honor of Dr. Wiley is truly a blessing.

It is an honor to be with all of you today and to present the Harvey W. Wiley Lecture in honor of Dr. Wiley.

And for the first time, I am actually speaking before Henry – in fact, an entire day before he speaks to your group. I typically end up following him when I speak at this conference. Believe me, I am grateful to go first, especially when we are talking about such non-controversial issues like health care reform, medical research, biosimilars, and of course, what the future holds for the FDA!

Seriously, Henry and I get along well and even though we may not always agree, we were able to work together back in 1984 to pass the landmark Drug Price Competition and Patent Term Restoration Act of 1984 known as Waxman-Hatch. Other times it is known as Hatch-Waxman. I prefer Hatch-Waxman myself! It is so hard to believe that it was 25 years ago!

When I consider my achievements as a United States Senator, I consider this law is one of my proudest legislative accomplishments. For the last 25 years, this law has brought tremendous benefits for both consumers and government.

And while I can vouch for the fact that the negotiations on Hatch-Waxman were, shall we say, trying, at times, the legislation that ended up being signed into law has not only worked well, it has saved consumers billions of dollars. But who knows what would have happened if I hadn't needed a root canal! I am not sure that we would have even passed Hatch-Waxman.

Before speaking to you about FDA-related matters, I would like to take a few minutes to share my perspective on health care reform. We have been grappling with this issue for as long as I can remember. Medical providers, health care analysts, administration officials, and those of us who serve in Congress have been racking our brains, trying to come up with a solution. But it is not an easy task.

I have heard from several health care providers – physicians, hospital administrators, nurses – that they are scared that their income will be cut as a result of health care reform. This clearly explains the sudden rise in enrollment to law school night programs.

You know, I remember Dr. Koop, the former Surgeon General telling me over 25 years ago about the doctor who died and went to heaven. The doctor went to the Pearly Gates and

asked St. Peter if he could talk to God for a few minutes. St. Peter said, *well, since you saved so many people's lives over the years, you may ask God one question. But, please, be respectful of his time. After all, he is God.*

The doctor entered God's chambers and said *God, thank you so much for seeing me. I would really like to know when we are going to be able to pass health care reform legislation?*

God looked at the doctor carefully and said, *Not in my lifetime!*

Maybe that's another reason why law school enrollments are up these days! That is supposed to be another bad joke!

Judging from Capitol Hill's flurry of activity and commitment to passing health care reform by the end of this year, it is very possible that it could happen within God's lifetime after all! And possibly by the end of this year! It is very exciting for those of us who have devoted our lives to health care issues.

Health care reform is one of my top priorities this Congress. We simply cannot continue to leave spiraling costs unaddressed. This is especially true because all that spending has not produced higher quality. Our nation has the highest health care spending in the world, but we don't have the best longevity or the lowest infant mortality or the best outcomes. We simply have an overly expensive and underperforming health care system – Americans deserve better.

Growing health care costs translate directly into higher coverage costs. Since the last decade, the cost of health coverage has increased by 120 percent: three times the growth of inflation and four times the growth of wages. It is not the only problem, but cost is one part of the reason why more than 45 million Americans do not have health insurance.

I believe we need to do more to ensure that we achieve universal access to affordable and quality health care for every American. That's the bottom line. We spend too much, cover too few, and don't get our money's worth. It is time for reform.

Reform is about more than drafting legislation. It is about steering 1/6 of the U.S. economy, in a new direction to deliver better results for American families.

As we move forward to achieve affordable access for every American, we need to ensure that we build on the employer-based system. Similarly, we have to ensure that we do not make it even more difficult for small businesses to survive and thrive in these incredibly tough times.

It is important to recognize that every state has its own unique mix of demographics and each state has developed its own institutions to address its challenges. And each has its own successes.

There will be an important role for the federal government in this partnership, but it will have to give the states flexibility and assistance to meet coverage and affordability objectives. We must not make the mistake of assuming that the federal government is the solution to all problems. The focus should be on families, not Washington.

My seven broad principles for health care reform are to address cost growth; ensure access to affordable and portable coverage for every American; move towards quality and value; promote prevention and wellness; modernize our health care infrastructure; empower patients

and providers with better information; and finally, address the entitlement reform challenge in a bipartisan manner. They are simple. And they will work.

I serve as a member of the Senate Finance Committee and the Senate Health, Education, Labor and Pensions Committee - both of which have jurisdiction over health care reform. Senator Max Baucus, the Chairman of the Finance Committee, started holding hearings on health care reform last Congress to prepare for Congress' inevitable debate this year. Yesterday, the Finance Committee held a roundtable with stakeholders to discuss health care delivery. He intends to have two more health roundtable meetings before marking-up health care reform legislation the second week of June. So members of the Finance Committee have their work cut out for them over the next couple of months.

In addition, HELP Committee Chairman Kennedy and his staff have started roundtable discussions on different health care topics. It is my understanding that Senator Kennedy would like to have a mark-up on health care reform legislation in the near future as well.

In order for any comprehensive health care reform legislation to be successful, it must be done in a bipartisan manner and members of Congress need to be included in the drafting of any health reform proposal. This is a tall order, but in my opinion, it is one of the most important requirements for having legislation signed into law. And I am encouraged that members of the Senate on both sides of the aisle want this legislation to be a bipartisan effort. I feel that is the only way that we will accomplish true reform.

At this point, you are all probably scratching your heads and asking yourselves, okay, Congress is going to work on health reform this year. What does that have to do with the FDA?

And the answer is simple – medical research. The FDA is the key agency that we look to in order to regulate products used to prevent, treat and mitigate chronic illnesses and diseases. It approves drugs, medical devices and biologics and ensures the safety of our food supply. The mission of the FDA is to protect the health of the American public.

But these products rely heavily on medical research and it takes years and a lot of money in order for them to go from the bench to the bedside. In 2006, the estimated cost to develop a drug was \$1.3 billion. Pharmaceutical industry spending on research and development was \$65.2 billion in 2006.

I am very supportive of medical research and believe that any health reform bill needs to encourage innovation and development of new diagnostics and therapies. That is why I strongly support embryonic stem cell research, personalized medicines and the development of biosimilars and I am deeply concerned about the potential negative consequences of comparative effectiveness.

The Food and Drug Administration, as most of you know, has a direct impact on almost all of the major issues in health care reform including comparative effectiveness and innovative therapies discovered through medical research. As far as comparative effectiveness is concerned, \$1.1 billion was included in the American Recovery and Reinvestment Act of 2009 for comparative effectiveness research. This legislation, as most of you know, was signed into law earlier this year. Now, I agree with the value and merits of doing comparative effectiveness studies; however, only in terms of looking at clinical effectiveness, and not for making treatment and coverage decisions.

Patients and providers should better understand their care and be confident of its efficacy. The key here is the understanding that medicine is not an exact science and that there is variability from patient to patient that directly affects treatment outcomes.

Clinical comparative effectiveness, if done right, can provide us with valuable information while preserving and protecting patient choice and medical innovation. We must focus on what works best for an individual patient and not what is simply the cheapest option.

Another issue that I want to raise is embryonic stem cell research. I applaud President Obama for issuing an Executive Order this past February lifting the ban on stem cell research. But let me remind all of you that in August 2001, President Bush became the first President to support federal funding for embryonic stem cell research.

I am pleased that this country will take a step forward to lead in this important area of scientific research. When I was making my decision on whether or not to support federal funding for embryonic stem cell research, I met with many leading experts in the field of science, ethics, law, and religion. One of those experts was the University of Utah's own Dr. Mario Capecchi, co-winner of the 2007 Nobel Peace Prize for his groundbreaking work on mouse stem cell research. All of us in Utah are so proud of Dr. Capecchi and his great work.

Research on embryonic stem cells has the potential to save lives, however, we must show the utmost respect for human life when conducting this research.

I strongly believe that being pro-life means helping the living by allowing these embryos to better mankind through important medical research instead of discarding them. My conclusion was that Federal support of embryonic stem cell research, with appropriate legal and ethical safeguards, is consistent with the pro-life and pro-family values for which I have fought my entire career.

And while the research on skin cells is promising, I still believe it is important for scientists to continue research on embryonic stem cells as well. We can't predict which line of research will eventually cure which diseases. In fact they will probably all benefit us by improving health and limiting disease. We would be foolish to cut off the potential of any one of them before it is realized.

Earlier in the year, Senators Arlen Specter, Tom Harkin, Ted Kennedy, Dianne Feinstein and I once again introduced the Stem Cell Research Enhancement Act. This bill allows federal funding to be used for embryonic stem cell research and is almost identical to the legislation that was vetoed by President Bush last Congress. This year, I have a feeling that the outcome is going to be a little bit different.

Another bill that I have introduced for the last several Congresses is the Human Cloning Ban and Stem Cell Research Protection Act. This bill prohibits human reproductive cloning and imposes criminal penalties for attempting to do so. It provides a firm ethical framework for somatic cell nuclear transfer for therapeutic purposes and establishes stiff civil penalties for not following them. Senator Feinstein and I will be reintroducing this bill in the near future.

I wanted to spend a little time on a topic that I have been interested in for awhile now, personalized medicine. As all of you know, these are exciting times in the field of science, technology, and health care. It is only a matter of time when gene mapping will be done when a person first visits the doctor. People will use their genetic information to improve their health

based on their risks of developing diseases or chronic illnesses. Physicians will prescribe medicines in doses specific to each patient. These are only some of the benefits of personalized medicine.

Personalized medicine has the ability to reduce a tremendous amount of waste in our health care system and to improve the quality of care. To accomplish this, we must recognize the importance of collaboration between the public and private health care sectors. We must come together by talking to one another to identify the challenges and obstacles which stand in our way to advance this area of medicine. I intend to take a greater role in the area of personalized medicine in the next few months.

I know that you are interested in biosimilars and the current status of the various bills on this subject. Biotechnology products are not drugs; they are very complicated molecules that are not easily reproduced. An inadvertent change in the structure of that molecule can lead to very devastating consequences.

The production costs for a biological product are 20 to 100 times more expensive than small molecule compounds. Since biological products are generally more expensive, ways to reduce their costs interest policymakers and other stakeholders, foremost among them employers, insurers, pharmacy benefits managers and, of course, the federal government.

When the Hatch-Waxman Act was passed in 1984, almost all small molecule drugs were created by large, well-established pharmaceutical companies with stable cash flow available to fund new discovery.

The business model is different with biologics. Without venture capital funds, most biotech companies would fail—denying consumers new and promising biological products. Without a robust period of data exclusivity, venture capital funds will dry up.

I believe some fail to recognize the delicate balance between investors and those in the biotech industry. Data exclusivity and patent protection are not the same as intellectual property protection.

Patents protect the earliest forms of the biologic product and manufacturing processes, and defending patent rights may require litigation. The patent may expire before, or shortly after, approval for marketing of the product. This could leave the patent owner very little exclusive market time to break even or profit from the product.

Because, at least today, follow-on biologics companies cannot produce an exact copy of a biotech molecule, manufacturers have the ability to design around patents to gain approval based on safety and efficacy, without infringing on the innovators' patents. Relying solely on the patent system to protect innovator biologic companies is insufficient.

Conversely, during the period of data exclusivity, a competitor is prevented from relying on the innovator's proprietary safety and efficacy data developed to gain FDA approval. From the research and development through obtaining FDA approval is not cheap. It can cost as much as \$1 billion.

Data exclusivity provides the biologic drug innovator an opportunity to earn a return on investment in the product. Data exclusivity is an essential protection afforded to the innovator

company, and is of paramount importance in encouraging continued investment in disease-curing drugs.

Of course, the end goal of the biosimilars legislation is to save Americans in prescription drug costs. But I strongly believe that unless we promote and protect a structure that fosters a strong and vibrant environment for innovators, there will be fewer and fewer biologics for the generics to manufacture – and all, including patients, will suffer.

Not to mention, we need to keep biotech jobs in the United States. With so much of the generic industry located offshore, innovator companies cannot remain economically competitive without strong patent protections and a viable period of data exclusivity.

That is why last Congress' bill, the Biologics Price Competition and Innovation Act of 2007, which I wrote with Senator Ted Kennedy; the HELP Committee's ranking Republican, Mike Enzi; and now, Secretary of State Hillary Clinton, was such a classic bipartisan compromise.

On the one hand, we wanted to create an abbreviated, uncomplicated pathway for biosimilars to come to market. On the other, we wanted to consider the innovators' circumstances, including their complex manufacturing processes and the financial risks investors undertake. That's why we all agreed – let me underscore – we all agreed – to give companies 12 years of data exclusivity.

It is my strong belief that, like Hatch-Waxman, this bill will help consumers – both by supporting the incentive to develop new biosimilars, and by fostering a climate that will lead to lower prices for consumers. I continue to work with Chairman Kennedy and Senator Enzi on our original legislation. The generic industry wants to prevent any protection for the new data in subsequent applications or *second generation products* that relate to a previously approved product. These *second generation* products might have different amino acid sequences – offering needed therapeutic alternatives for patients and improving patient care.

I've committed to working through this issue with Sen. Kennedy. In the meantime, I have serious concerns about some of the pending biosimilars legislation.

Senator Schumer's bill that was recently introduced mirrors Chairman Henry Waxman's bill. The data exclusivity period in both bills cuts by more than half – to five years, from 12 – the time allowed before biosimilars could come to market.

I was surprised to see Senator Schumer pushing for this new approach, especially since he was the one who really sealed the deal for 12 years of data exclusivity last Congress. It's frustrating to me to see that we are so quick to wipe out incentives for innovation. Creating this shortcut really does undermine the ability to develop future cures and therapies.

Again, biologics are not chemical drugs. They are made from living cell cultures and are extremely expensive to produce.

My fear is that some are pushing short-sighted legislation without recognizing the long-term affects this will have on future medicines.

My fear is that in the near future biotech companies will stop producing these life-saving medicines because of a lack of resources or incentives.

My fear is that there won't be anything left for the generic companies to copy.

My fear is that, most importantly, there won't be any new cures and therapies for millions of people who are dying and/or suffering by diseases or debilitating conditions.

It will be interesting to see how Dr. Margaret Hamburg, who has been nominated by the President to serve as the next FDA Commissioner, will approach matters such as biosimilars. Dr. Hamburg is currently making the rounds on Capitol Hill and, quite honestly, with the past drug recalls and recent food borne illnesses, and an erosion of public trust, I don't envy Dr. Hamburg. She is walking into an agency that has been historically under funded and has lacked the necessary resources to adequately conduct its mission. And with Congress considering legislation that would expand the FDA's role and responsibilities, it will be an even more difficult task to get the agency back up on its feet. However, from what I know about Dr. Hamburg, she seems to be very knowledgeable and her experience as a public servant will serve her well as she takes on this uphill battle. I will support and do whatever I can to help Dr. Hamburg in her capacity as the FDA Commissioner and I wish her the best of luck.

I want to end this speech with a series of questions that I would like to pose to all of you regarding the FDA. And all of you need to think long and hard about the answers to each of these questions. That being said, this is not a test!

Does it make sense that the FDA, one of our nation's top research institutions, which ensures the safety of our drugs, medical devices and foods struggles year after year for federal funding, when other more politically popular programs do not?

Does it make sense that the FDA receives its funding through the Agriculture Appropriations Subcommittee instead of the Labor-HHS Appropriations Subcommittee where public health agencies receive not only consistent funding but actually receive generous increases from time to time?

Does it make sense that the Office of Generic Drugs is not funded by a user fee when innovator drugs and, yes, even drugs for animals are?

Does it really make sense to force one of our top health and safety agencies to regulate tobacco, especially when tobacco is known to cause serious illnesses and death? Wouldn't that be contrary to the mission of the FDA which is to protect the health of American consumers?

Does it make sense to split up the responsibilities of the FDA into two separate agencies? I do not think so -- the devil is in the details and I am really worried about those details. That being said, this issue will certainly be discussed as Congress considers food safety issues and what more can be done to protect our citizens from bad peanut butter, contaminated tomatoes and tainted spinach and our animals from adulterated pet food.

Does it make sense that the FDA White Oak campus, something I authorized through legislation in the early 1990s, still isn't completed, almost 15 years later? I don't think it does and let me assure all of you that I am going to keep pushing for White Oak until it is finally done.

Finally, doesn't it make sense that the Congress provides the FDA the resources to do its job? Isn't that a no brainer? And while I am talking about resources, the dietary supplement

industry, as many of you know, is very important to me, however, the FDA needs more money to ensure that the bad actor companies, which are few and far between, are kept off the market.

Well, I hope you have found this helpful and I want to thank you again for inviting me to speak to you this morning. It is always an honor for me to speak to such a distinguished audience and I hope that you will invite me back again next year. Quite honestly, you are one of my favorite groups and I look forward to seeing you each year.