SENATOR ELIZABETH WARREN REMARKS AT THE FAMILIES USA HEALTH ACTION CONFERENCE JANUARY 22, 2015 | WASHINGTON, DC

Thank you very much for having me here today.

I'm glad to be with you to discuss the successes and challenges that we face in building a better health care system and a healthier country.

Any conversation about improving health in America today starts with the Affordable Care Act. Many of you played critical roles in the design, passage, and early implementation of this law. And, despite the endless stream of attacks, misinformation, and scare-mongering that has been thrown at the ACA, the law is still standing. More importantly, it's improving the health of millions of Americans.

Consider just a few facts –

- Thanks to the ACA, 10 million previously uninsured people now have insurance.
- Since the ACA has started holding insurance companies accountable for wasting money on administrative costs, people have saved \$9 billion on their health insurance bills.
- Now that the ACA has begun closing the doughnut hole in Medicare, the average senior has saved more than \$1,400 on prescription drugs.
- And here's the real payoff: According to the Congressional Budget Office, we're actually spending less total federal money on health care this decade than we expected to spend before we passed the Affordable Care Act. Think about that. We've already brought health insurance to 10 million more people, and yet our total spending is lower than if we'd done nothing at all.

Even by the sometimes low standards of political debate in Washington, rarely in our history have so many said so much that turned out to be so wrong. The facts are in: the Affordable Care Act is working!

There is much to cheer about—and much work to work on.

But for all the work—past and future—on access to health care, it is important to remember that access is only half the job. The other half is advancing our ability to improve health itself.

Today, I'd like to focus on that other half. Over the past fifty years, the American system of medical innovation has transformed the health of literally billions of people around the world. But today, that incredible system is in trouble. I'd like to talk about why – and about how we can fix it.

For decades, American medical innovation has been a remarkable success. American science has transformed medicine. The huge improvements in genetic detection and treatment in areas like

breast cancer, cervical cancer, and leukemia would have been unthinkable 20 years ago. In one generation, AIDS in the United States has gone from a death sentence to a condition that can be managed. Improvements in diabetes management have added decades to the lives of chronic sufferers. Our understanding and treatment of mental illnesses has evolved to help millions of people lead fuller lives.

We now live in the era of blockbuster drugs. About a hundred different drugs are used by so many people that each drug brings in more than a billion dollars a year in revenue. Many have called these blockbuster drugs the holy grail of the pharmaceutical industry, literally transforming the treatment of high cholesterol, diabetes, HIV, asthma, rheumatoid arthritis, breast cancer, colon cancer, and leukemia.

These blockbuster drugs have also made a handful of drug companies wealthy beyond imagination. According to the World Health Organization, just ten drug companies generate more than \$100 billion in drug sales. And it's not just sales revenue. Look at profits. While the companies in the S&P 500 have averaged profits of 5-10% over the past 20 years, the giant drug companies' profits have typically ranged between 18% and 24%.

We celebrate the accomplishments of our pharmaceutical industry, because these blockbuster drugs let people live longer, healthier lives. But we are also mindful that these companies did not do it alone.

Blockbuster drugs that generate billion dollar profits and are used by millions of consumers don't just appear overnight as if by magic. Rarely do they appear as the result of a single, giant company's individual genius. Drug companies make great contributions, but so do taxpayers. In other words, we built those medical innovations together.

During much of the twentieth century, America increased its support for medical research, principally through federal investments in the National Institutes of Health. Today, the NIH supports more than 300,000 health scientists and researchers at more than 2,500 universities, medical schools, and other institutions across America.

NIH support helps to train each new generation of scientists, and develop each new generation of medicine. NIH-supported discoveries often get picked up by small, creative, nimble biotechnology companies, which in turn get picked up by large pharmaceutical companies and sometimes result in those wildly-successful blockbuster drugs that transform lives. The President's new Precision Medicine Initiative will be another step toward more personalized medicine and better treatments for our most vexing diseases.

NIH-supported research built the foundation of many of our blockbuster drugs.

• Nearly all of the important, innovative vaccines of the past quarter century can be traced to public sector research.

- Of the 21 drugs with the highest therapeutic impact that came to market between 1965 and 1992, two-thirds stem <u>directly</u> from a discovery that occurred as a result of government-supported research.
- Nine of the ten breakthrough new uses for existing drugs approved by the FDA from 1990 to 2007 came directly from public funding.

Put simply, the astonishing scientific and financial successes of the pharmaceutical industry have been built on a foundation of taxpayer investment.

With revolutionary new treatments and a drug industry built on blockbuster drugs, this should be a moment of great triumph. But in recent years, the American engine of medical innovation has begun to sputter.

The first problem is the government. Congress used to work in a non-political, bipartisan way to expand NIH funding. But since the early 2000s, Congress has been strangling the funding needed for medical research. Instead of increasing the NIH budget at the pace of potential scientific innovation, budget cuts, sequestration, and other pressures mean that the NIH budget over the last decade hasn't even kept up with the pace of inflation.

And now we're starting to pay the price for abandoning our historical commitment to medical innovation. NIH leaders say that the ideal success rate for funding NIH projects is about 30%, which is exactly what it was in 2003. But by last year, funding dropped to 18% – one of the lowest rates in history.

And the costs are multiplied because, without research support, we risk losing a generation of young scientists. Promising researchers are so discouraged by the dismal funding situation that they are abandoning careers in medical research. In a recent survey of thousands of scientists around the country, more than half said that they had been forced to turn away a promising young researcher because of too little funding, and nearly half had laid off a researcher to deal with budget cuts.

Who knows how many breakthroughs have been lost – breakthroughs that might have unlocked the key to a dramatic advancement in the war on cancer, a therapy for autism, or a remedy for ALS -- because a study wasn't funded and a young scholar was turned away? Less federal support for medical research is a problem with real consequences—and we need to fix it.

The second problem is with the drug companies. Over the last ten years, some of our wealthiest drug companies – those that capitalize on government research to generate billions of dollars in revenues through the sale of blockbuster drugs – have found another way to boost profits.

In addition to selling life-changing cures, some of these companies are increasingly making money by skirting the law. They've been caught defrauding Medicare and Medicaid, withholding critical safety information about their drugs, marketing their drugs for uses that aren't approved, and giving doctors kickbacks for writing prescriptions for their drugs.

These companies are not getting caught up in minor paperwork mistakes. They are not victims of overly eager regulators. Between 2007 and 2012, the world's largest pharmaceutical companies paid over \$13 billion – that's billion with a "B" – in fines and settlements stemming from violating federal laws. That doesn't happen without serious wrongdoing.

It seems that the biggest drug companies are increasingly playing by a different set of rules than everyone else. The government has kicked thousands of small and medium sized physician practices out of the Medicare program for fraud, but not one of these major drug companies has ever been kicked out. The government convicts hundreds of people of health care fraud every year, but not one of these major drug company cases has even gone to trial.

In fact, several of these companies have been caught breaking the law, have paid a fine, and then broken the law again. And why not? Even the biggest pharmaceutical settlement ever – a \$3 billion penalty for withholding safety data and engaging in illegal marketing practices – accounted for less than 10% of what the company made selling those drugs. And the day the settlement was announced, that company's stock price actually went up. Fines for big drug companies have increasingly become just another cost of doing business.

Between these two problems – shrinking government support for research and increased rule-breaking by companies that have blockbuster drugs – lies a solution: requiring those big-time drug companies that break the law to put more money into funding medical research.

Next week, I plan to introduce legislation – the Medical Innovation Act – that would substantially increase federal funding for the National Institutes of Health. We can increase this funding without raising taxes or stealing support from other critical programs. Instead, funding would come from blockbuster drug companies whenever they break the law and enter into major settlement agreements with the government. In such cases, the government settlements would go forward as they normally do, but the blockbuster drug company would also be required to reinvest a relatively small portion of the profits it has generated as a result of federal research investments right back into the NIH.

We should make it easier for the biggest drug companies to help develop the next generation of cures – and harder for them to profit from breaking the law and defrauding taxpayers.

Only the biggest and most successful pharmaceutical companies would be required to reinvest in NIH. No small or medium-sized innovator would ever pay. And the cost to the giant pharmaceutical companies is modest – just one percent of an offending company's annual profits for each of its blockbuster drugs that can be traced to government research support. The penalties would run for a period of five years, which, by the way, is the typical length of these federal settlement agreements.

This isn't a tax. It is simply a condition of settling to avoid a trial in a major case of wrongdoing. If a company never breaks the law, it will never pay the fee. If an accused company goes to trial instead of settling out of court, it'll never pay the fee – even if it loses the case.

It's like a swear jar: Whenever a huge drug company that is generating enormous profits as a result of federal research investments gets caught breaking the law – and wants off the hook – it has to put some money in the jar to help fund the next generation of medical research.

It's a swear jar – but it's also a simple form of accountability. Instead of letting companies that break the law get off with a slap on the wrist, the Medical Innovation Act will make sure that they pay up in a way that really makes a difference – a difference to the health of all Americans, and a difference to all of the company's competitors who are playing by the rules.

We can also make sure that these new investments in medical research go where they are needed the most -- to fund basic research, to fund new transformative research, and to support younger scientists so that we don't lose our brightest medical minds to other fields or other countries.

If this policy had been in place over the past five years, NIH would have had about <u>six billion</u> more dollars every year to fund thousands of new grants to scientists and universities and research centers around the country. That's nearly a <u>20% increase</u> in NIH funding. And that money would have headed right back into the economy. Every dollar invested in medical research though the NIH generates more than two dollars in economic growth.

Congress will need to do more. I believe we should double NIH funding. But a potential 20% increase in NIH funding that also holds drug companies accountable when they break the law is great first step.

I don't kid myself. I know how difficult it is to get things done in Washington. But I am hopeful that everyone – Democrats, Republicans, hospitals, researchers, scientists, disease advocates, small biotechnology companies, and even big drug companies – will be able to come together to support this idea.

I am hopeful about this because after more than a decade of stagnant federal investments, the Medical Innovation Act is a major move toward substantially increasing federal support for medical research that doesn't increase the deficit or cut other critical programs.

I'm here today because I need your help in this fight. Hundreds of thousands of scientists and researchers, doctors and professionals, in every corner of this country, have stepped forward and committed themselves to saving lives. They are waiting – waiting for us to support their work, so that they can protect us and our families. And there are millions of families, families waiting for new medicines and better treatments for their children, for their aging parents, for themselves. It's time for us to take on the fight in Congress and put more money into medical research.

This is about our future. It is about economics and accountability. But it is also about our values, about who we are as a people.

With too many in Congress willing to sit by and watch the NIH starve – and too many in the pharmaceutical industry willing to make a quick buck by breaking the law, it's easy for cynicism to set in – and it's easy for us to forget the commitments that we've all made to each other.

Today we are choking off support for projects that could lead to the next major breakthrough against cancer, heart disease, Ebola, Alzheimer's, diabetes, or other deadly conditions. We're starving projects that could transform the lives of our children on the autism spectrum. We're suffocating breakthrough ideas that would give new hope to those with ALS.

That's not who we are. We are not a nation that abandons the sick. And we are not a nation that says "I've got mine, the rest of you are own your own." We are a nation of people who work together. We are nation of people who invest in each other – because we know that when we work together, we all do better. We've done it for generations – and for generations, we have led the world in medical innovation.

It is time to renew our commitment—our commitment to our children, to our parents and to ourselves. I'm proud to stand with you today, and I hope you'll stand with me in this fight.