The American people believe this overwhelmingly. But now there are signs the Republican leadership in Congress is beginning to think a timeline is necessary as well. According to the L.A. Times, House Republican Leader John Boehner said:

Mr. Bush risks defections in the fall if the war situation hasn’t improved.

By the time we get to September or October, members are going to want to know how well this is working, and if it isn’t, what’s Plan B.

The House Republican leader now seems to be saying that he and his colleagues agree there must be a time limit on the President’s current course in Iraq.

What is also revealing, and somewhat disturbing, is the Republican leader is willing to allow our troops to stay in Iraq with a failing strategy until he and his colleagues agree it is time to part with the President.

President Bush—the same President who vetoed our plan—said this as a candidate about his predecessor, Bill Clinton, and the war in Bosnia, in 1999: I think it’s important for the president to lay out a timetable as to how long they will be involved and when they would be withdrawn.

We hope President Bush will keep his own past words in mind as these negotiations continue.

We are pleased to see the House Republican leader, speaking on behalf of his caucus, adopt our view that this commitment in Iraq must not be open-ended but there must be a timeline. It is surely no coincidence that his views come at a time when conditions in Iraq grow worse.

I am reminded of the Easter sermon of Pope Benedict, delivered only a month ago:

How many wounds—how much suffering there is in the world.

He continued:

Nothing positive comes from Iraq, torn apart by continual slaughter as the civilian population has been abandoned. Since those words were spoken, conditions have indeed deteriorated.

In April, our troops suffered the deadliest month of the year and one of the deadliest of the entire 51 months of the war.

The President’s own Special Inspector General for Iraq Reconstruction released its quarterly report last weekend that painted a dispiriting picture of waste, ineffectiveness, and failure to achieve even minimally satisfactory results.

Despite burning through most of the 20 billion American dollars planned for reconstruction, many Iraqis are without basic necessities such as electricity and clean drinking water. Of course, oil production is down. Only a third of Iraqi children are attending school. Seventy percent of the kids are suffering from symptoms of trauma that could paralyze an entire generation that is now growing up to harvest the seeds of democracy.

Iraqi Prime Minister Al-Maliki is accused of sabotaging efforts for peace and stability by firing some of the country’s top law enforcement officials for doing too good a job of combating violent Shiite militias.

President Bush speaks of pressuring the Iraqi people to take responsibility for their own future. But while American troops are fighting and dying to secure the country, the Iraqi Government is planning a 2-month summer vacation.

Yesterday, eight more courageous American soldiers fell, four the day before.

I have no doubt these developments weighed on Leader Boehner’s mind when he made his comments suggesting a fall timeline to the war in Iraq. But I know he is not alone. Many of my Republican friends across the aisle feel strongly that a change of course in our Iraq strategy is needed—one that holds the administration and the Iraqis accountable for real results.

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The Hatch amendment is intended to be an initial step in the fight against these resistant strains of bacteria by increasing incentives and innovation.

Additionally, the language in the amendment requests FDA to work with companies to apply the Orphan Drug Act to antibiotics wherever possible. Hand-in-hand with this, it reauthorizes the Orphan Drug Act grant and contracts from fiscal years 2008 through 2012. As many of my colleagues know, this act has resulted in important medicines for rare diseases.

The Hatch amendment also ensures that currently existing incentives for new drugs are available for new single enantiomers, which is included in the managers’ package we are adopting today.

I offered this amendment at the HELP Committee markup, but withdrew it with assurances that we would work it out prior to floor action. There have been constructive discussions among all interested parties and I believe we have worked language out that is acceptable.

There is a great urgency to this situation, and I want to make certain my colleagues understand it fully.

Infectious Diseases Society of America, the Alliance for Aging Research, the Institute of Medicine, the Resources for the Future, the Centers for Disease Control, and many others have been sounding the alarm about the growing threat from resistant microorganisms and the need for innovation in the area of antibiotics.

Congress must listen.

Nobel Laureate Joshua Lederberg said it well:

The assistant legislative clerk proceeded to call the roll.

Mr. Hatch. Mr. President, I would like to discuss the amendment which deals with antibiotics and enantiomers, which is included in the managers’ package we are adopting today.

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We are running out of bullets for dealing with a number of bacterial infections.

Patients are dying because we no longer have antibiotics that work.

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The Hatch amendment also ensures that currently existing incentives for new drugs are available for new single enantiomers in new therapeutic areas such as Alzheimer’s, cancer, and type II diabetes among others. In 1997, FDA issued a Federal Register notice acknowledging that the policy needed clarification and this amendment would do that.

Let me start with the issue of antibiotics and the need for new antibiotics to fight drug-resistant infections.

Many of us have become more and more concerned that there is an alarming increase in the number of drug-resistant infections—many of them serious illnesses. We are running out of treatment options.

My first chart is based on data from the Centers for Disease Control and...
Prevention and shows how resistant strains of infections have spread rapidly from 1980 to 2000. My colleagues, this is a very alarming trend and sadly, for all of us, the problem of resistance continues to grow.

Community-acquired MRSA is an infection that was historically acquired while in the hospital, but now is impacting young, healthy people. We have heard stories of high school, college and professional athletes losing their lives or competing with these infections. Sadly, this infection has become far too common, difficult to treat and has few options to fight it. It can leave individuals disfigured, if they survive.

In my own State of Utah, the number of children with MRSA infections at the Primary Children's Medical Center in Salt Lake City has dramatically increased since 1989.

Dr. Andy Pavia of Salt Lake City told me that he "cared for a 2 month old girl who developed MRSA pneumonia and almost died as a complication of an otherwise mild respiratory infection. She survived and will be going home to her parents, but only after 2 weeks of the most sophisticated intensive care and additional 4 weeks of intravenous antibiotics."

Dr. Pavia went on to explain that the Primary Children's Medical Center sees the impact of resistant bacteria almost every day.

In fact, he wrote:

Last week a two year old girl [who] was weeks away from being cured of Burkitt's lymphoma developed shock due to a bloodstream infection with a highly resistant strain of a gram-negative bacteria. Fortunately, the bacteria was sensitive to one remaining antibiotic. If it had been resistant, she would not have left the Pediatric ICU alive.

The doctor related that MRSA is an aggressive, difficult to treat, form of staph that has spread rapidly within communities. Half of the children he sees with severe MRSA infections acquired their infection at home.

This is a picture of Bryce, whose family tells a similar story. He had his first cold 2 days before Christmas. Before then, 4-month-old Bryce Smith had never been ill. On New Year's Day, his parents took him to the emergency room, where the seriousness of his son's condition became immediately apparent.

An X-ray showed that Bryce had pneumonia. A CT scan showed that his right lung was filled with fluid. Four hours after arriving at the ER, Bryce was scheduled for surgery. Doctors found that a methicillin-resistant staph infection had eaten a hole through his lung.

For the first 12 days that Bryce was in the hospital, the doctors didn't know whether he would live. Doctors battled to force air into the child's lungs, but as they told his mom, it was like trying to pump air into a brick.

Doctors prescribed high levels of antibiotics, including vancomycin, in a desperate battle to fight the infections. For 6 weeks, the child did not wake up. During Bryce's stay in the hospital, he was subject to additional infections. Bryce is doing much better now, he was released from the hospital, but he still must relearn how to walk.

His recovery could take several months. As of April 2007, the Smiths' total bill for Bryce's care is just under $1 million.

Fortunately, the family's insurance does not have a ceiling on payments; the Smiths should be in financial ruin. Bryce's ongoing care needs are decreasing, but he still has regular visits with the pulmonologist, nephrologist, and his hematologist. He still tires out easily with exertion.

The fact that children acquire this infection at home is significant because we used to only worry about it in the hospital.

Last month, there were numerous articles about CDC's concern that cases of resistant gonorrhea have dramatically increased and respond to only one antibiotic.

There has been much concern over the past couple months related to extensively-drug resistant—XDR-TB. Right now, there is a man in Phoenix, AZ, whom authorities took action to isolate in order to avoid the spread of the deadly XDR-TB infection he had contracted while out of the country.

This comes in addition to the numerous reports of our soldiers coming home from Iraq with Acinetobactor—a resistant infection that is especially difficult to treat and the only option is a very toxic antibiotic.

One doctor we have heard from, in a local community, indicated he has seen patients just this month with infections resistant to every antibiotic currently available.

That is becoming a common occurrence.

Infections disease specialists can do little more than provide supportive care for those unfortunate patients. Without any new antibiotics in the pharmaceutical pipeline, there is no promise of a treatment for years to come.

Whatever we do to begin to address this serious concern, we can't hope to realize the benefit for more than a decade. Drug development takes time and money. Yet few companies are willing to invest either in the area of antibiotics.

I believe this chart shows that is the case. As you can see from this chart, the number of new antibacterial agents that have actually been approved is minimal. The market forces don't work well for antibiotics. When we cannot rely on the market, government has an obligation to step in.

The Hatch amendment focuses on incentives for research and development of antibiotics. Specifically, my amendment: Provides equitable treatment for so-called "old" antibiotics; promotes communication and education of current law orphan drug incentive by directing FDA to convene a public meeting to clarify what "bad bugs" may qualify for orphan designation; reauthorizes the Orphan Drug grants and contracts program which expired September 30, and requires FDA to establish, update and make publicly available information on antibiotic
breakpoints. This is important to assure that the antibiotics we and our children take are effective against bacterial infections and minimize the progression of resistance.

Antimicrobial resistance is a public health crisis. In many ways, it is even bigger than one point our colleague, Dr. Coburn, made at the HELP mark up.

This is an issue that touches not just the old or the young, but all Americans throughout every walk of life. Antibiotics are as precious a natural resource as water is to a vibrant and healthy community and, guess what, the creek is drying up. The Hatch amendment only takes the first steps to address these issues.

If we cannot work together on these more minor provisions, how will we truly combat antimicrobial resistance? What will we say to the children, soldiers, athletes, elderly and so many others that contract these deadly diseases every year before they are successfully treated with antibiotics? Are we really willing to walk away and leave nothing in our arsenal to fight these bad bugs?

I would like to turn my attention now to a provision in the Hatch amendment which encourages innovation in another area. This provision provides for 5-year exclusivity for enantiomers of previously approved anticancer drugs in different therapeutic areas based on new data.

Enantiomers are mirror images of the same drug. You can think of them as left-handed and right-handed molecules. We now understand that, in some cases, these enantiomers have very different activity and safety profiles.

In simplest terms, imagine the biological target as a glove that fits one hand better than the other. When Hatch-Waxman was passed originally, we didn’t know how to isolate the one enantiomer from an approved drug made up of a mixture of enantiomers and its development for a new use based on all new data.

But today that is exactly what is happening. Sponsors are finding new important uses for enantiomers of drugs previously approved as a mixture of enantiomers.

Where FDA is requiring all new data for approval of these single enantiomers and will not allow a company to rely on any of the data submitted in the original application for the mixture of enantiomers, these single enantiomers are effectively new chemical entities and should be entitled to 5-year exclusivity.

In 1997, in a Federal Register notice, FDA laid out the issue, acknowledging the lack of clarity in the law regarding 5-year exclusivity for enantiomers and the need to incentivize this type of development. FDA requested comments but not yet acted.

The Hatch amendment makes it clear that development of an enantiomer for new use in a new therapeutic area based on new data would qualify for 5-year exclusivity. However, in order to address the potential for abuse the revised provision limits 5-year exclusivity to approvals in a new therapeutic class.

As this chart states, innovation and development of enantiomers may provide treatments in cancer, Alzheimer’s disease, type II diabetes. When it comes to FDA, we need to get it right.

As I told that representative, FDA is not a brand industry or a generic industry. It is the patient safety arm of the generic, and medical device industry. It is the patient safety arm of the patient safety arm of the biotechnology industry and requires attention before it is too late.

We need to make sure that innovation is encouraged in these areas and high scientific standards are maintained and the Hatch amendment does just that.

Mr. BROWN. Today, we are likely to wrap up consideration of legislation that modifies the rules governing the FDA, an agency that oversees all of the medical products we use and most of the food we eat. FDA came into being about a century ago because Americans were being sold something that caused injury, that caused birth defects, that even caused death; and Americans were consuming farm products that too often were not safe. Those kinds of medicines were being sold as cures, but they didn’t cure anything.

FDA’s first responsibility—first responsibility—is to safeguard the health of American consumers. But because the products under FDA’s authority account for 25 cents out of every dollar U.S. consumers spend, there is a pull on the agency that has nothing to do with patient safety and everything to do with drugs, both brand name and generic, and medical device industry profits.

I remember a few years ago, when I served as ranking member of the Commerce Committee’s Health Subcommittee in the House of Representatives, a representative from FDA started his testimony to us in front of that committee by showing us a chart that tracked the U.S. drug industry’s global market share.

As I told that representative, FDA is not the marketing arm of the drug industry. It is the patient safety arm of the Federal Government. to guarantee safe products for Americans who consume medicine, food, and the like.

But FDA’s drug industry dog and pony show is emblematic of the key problem this bill is designed to address. FDA has strayed from its public health mission and this legislation will help to get us back on track.

S. 1082 requires FDA and drugmakers to work together to assure the safety