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 decide 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it's important for the president to lay out a timetable as to how long they will be involved and when they would be withdrawn.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 openended, that 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. The Pope said:

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 flees.

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 we are counting on 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. Yet 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. Many of my Republican friends across the aisle feel it is time for change. This is the time. I know many of my Republican friends also intend to be part of the solution on the way forward, and I look forward to working with them. We all look forward to continuing negotiations, which we will work on today. I have spoken to Chairman OBEY today. I talked to him Friday. I will continue to talk to him every day until we reach agreement on a bill that fully funds the troops while providing a responsible new course that makes America more secure.

No one wants to succeed in Iraq and make America more secure than I.

RESERVATION OF LEADER TIME

The ACTING PRESIDENT pro tempore. Under the previous order, the leadership time is reserved.

MORNING BUSINESS

The ACTING PRESIDENT pro tempore. Under the previous order, there will now be a period for the transaction of morning business until 4 p.m., with the time equally divided between the two leaders or their designees, with Senators permitted to speak for up to 10 minutes each.

Mr. REID. I suggest the absence of a quorum.

The ACTING PRESIDENT pro tempore. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. REID. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

Mr. REID. Mr. President, I suggest the absence of a quorum and ask unanimous consent that the time in the quorum call be divided equally between the Democrats and the Republicans.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. HATCH. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

HATCH AMENDMENT ON ANTIBIOTICS AND ENANTIOMERS

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.

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.

The 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:

We are running out of bullets for dealing with a number of (bacterial) infections. Patients are dying because we no longer in many cases have antibiotics that work.

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 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—and 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.

A report many of us are familiar with, Bad Bugs, No Drugs, from the Infectious Diseases Society of America, IDSA, highlights the lack of R&D for new antibiotics.

Antibiotics are not profitable compared to medications that treat chronic conditions and lifestyle issues. Also, antibiotics are taken for short periods of time—unlike medications for chronic disease which may be taken daily.

And, when a new antibiotic comes on the market, it is discouraged from use to avoid the development of resistance. As a result, it is fair to say that major pharmaceutical companies have not been making significant investments in antibiotics.

Given that there are few, if any, antibiotics in the drug development pipeline, if Congress fails to act, we walk blindly into a future where we must fear basic infections we have long taken for granted are not a problem.

Medicine changed dramatically when penicillin was discovered and physicians had a tool to treat deadly infections.

Can any of my colleagues imagine life without penicillin? I am sorry to inform you, we are about there.

Over the years, many infections became resistant to penicillin, but we were OK—we moved on to the next antibiotic. We had methicillin—and now serious infections are resistant to that.

We should consider what the health professionals are telling us. Will we listen? We are taking antibiotics and our ability to treat bacterial infections for granted.

Infectious disease doctors from all over the country have been writing to their Senators to express their support for my amendment. They tell heartwrenching stories.

Dr. Helen Boucher, a physician at Tufts Medical Center in Boston, MA, wrote to tell Congress that patients are routinely lost ''to infections caused by resistant bacteria for which we have few to no options. [They] recently lost two bone marrow transplant recipients who survived all the chemo but died of multiply-resistant gram negative infections. In both cases, [physicians] pulled an old antibiotic off the shelf and gave it as a last resort, knowing how toxic it was but having NO other options for these young people. . . .''

She wrote:

> As a doc and an American, it's horrifying to know that few to no companies are investing even in discovery of new antibiotics for these infections . . . just this week [she] was presented a case of a previously completely healthy 33 year-old lady who presented to the hospital in Boston with pneumonia and died within 6 hours from community-acquired MRSA. Her story and so many others that we see ALL the time, make the need for new and powerful options to treat these infections critical.

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 careers as a result of 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 an 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, 14-month-old Bryce Smith had never been sick. At 2 a.m. on New Year's Day, his parents took him to the emergency room, where the seriousness of their 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 has suffered from several 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; otherwise, the Smiths say they would be in financial ruin. Bryce's ongoing care needs are decreasing, but he still has regular visits with the pulmonologist, nephrologist, and his pediatrician. 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 two 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 incentives 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 drug safety, a 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 which only years before were 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 racemic 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 is a glove that fits one hand better than the other. When Hatch-Waxman was passed originally, we didn't contemplate the isolation of 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 never finalized a policy.

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.

I feel we have done a lot of good with this bill, and I voted for it in committee with the understanding the issues I raised on antibiotics and enantiomers would be addressed before we reached final passage. I am glad that, as of yesterday afternoon, we have worked out all remaining concerns and I believe the chairman's commitment at the markup has been honored.

I know that some were concerned about this amendment, specifically because its incentives provisions were fueled by exclusivity. With all due respect, I understand the importance of the generic drug industry. We spoke earlier about the need to get it right for follow-on biologics.

But we should listen to the public health associations, who understand the need to support innovation. Indeed, the Alliance for Aging Research, Infectious Diseases Society of America, National Organization of Rare Disorders, and Immune Deficiency Foundation are dedicated to advocating for patients and doctors and improving public health in this country, and they fully support this amendment in its entirety.

The Infectious Diseases Society of America represents doctors that see the threat of resistant bugs every day. They recognize the need for innovation in their therapeutic area.

This isn't different than 10 years ago when the American Academy of Pediatrics argued passionately for the need for innovation in pediatric research. Some may not remember that the generic drug industry opposed that provision saying that innovation was not necessary.

In contrast, I am pleased that we have achieved an agreement today that recognizes the need for this innovation in research involving antibiotics and enantiomers.

Ten years ago, Congress passed the last major piece of FDA legislation, the Food and Drug Administration Modernization Act, or FDAMA.

Those of us who were here then recall ever-so-vividly the infamous chart of the feet displayed with great effectiveness by our colleague Senator KENNEDY.

I hasten to say many have had recurring nightmares about the horror of these feet. The Senator and his very bright staff were ever-so-clever in their effective use of this chart. Today, I hope to have the same effect, although I do not wish to spawn a new generation of nightmares.

I submit to my colleagues, that if we had adequate antibiotics in development, we never would have had to look at these diseased feet. With passage of my amendment today, perhaps this chart can be relegated to the Russell attic forever.

In closing, I thank my colleagues for recognizing that antimicrobial resistance is not a brand issue or a generic issue. Effective treatment for Alzheimer's, cancer, or type II diabetes is not a brand issue or a generic issue. These are public health issues.

I urge my colleagues to take these issues seriously and appreciate that we have joined together and not let these serious concerns fall subject to politics as usual. These are growing problems and require 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.

The PRESIDING OFFICER (Mr. WEBB). The Senator from Ohio is recognized.

RULES GOVERNING THE FDA

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 medicines that caused injury, that caused birth defects, that even caused death; and Americans were consuming food 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 subcommittee 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