(c) ASSISTANCE.—In carrying out this Act, the Commission shall consult, cooperate with, and seek advice and assistance from appropriate Federal departments and agencies, including the Department of the Interior.

(d) COORDINATION OF ACTIVITIES.—In carrying out the duties of the Commission, the Commission, in consultation with the Secretary of State, may coordinate with the Government of Spain and political subdivisions in Spain for the purposes of exchanging information and research and otherwise involving the Government of Spain, as appropriate, in the commemoration of the Quincentennial.

SEC. 5. POWERS OF THE COMMISSION.

(a) IN GENERAL.—The Commission may provide for—

(1) the preparation, distribution, dissemination, exhibition, and sale of historical, commemorative, and informational materials and objects that will contribute to public awareness of, and interest in, the Quincentennial, except that any commemorative coin, medal, or postage stamp recommended to be issued by the United States shall be sold only by a Federal department or agency;

(2) competitions and awards for historical, scholarly, artistic, literary, musical, and other works, programs, and projects relating to the Quincentennial;

(3) a Quincentennial calendar or register of programs and projects;

(4) a central clearinghouse for information and coordination regarding dates, events, places, documents, artifacts, and personalities of Quincentennial historical and commemorative significance; and

(5) the design and designation of logos, symbols, or marks for use in connection with the commemoration of the Quincentennial and shall establish procedures regarding their use.

(b) ADVISORY COMMITTEE.—The Commission may appoint such advisory committees as the Commission determines necessary to carry out the purposes of this Act.

SEC. 6. ADMINISTRATION.

(a) LOCATION OF OFFICE.—

(1) PRINCIPAL OFFICE.—The principal office of the Commission shall be in St. Augustine, Florida.

(2) SATELLITE OFFICE.—The Commission may establish a satellite office in Washington, D.C.

(b) STAFF.—

(1) APPOINTMENT OF DIRECTOR AND DEPUTY DIRECTOR.—

(A) IN GENERAL.—The co-chairpersons, with the advice of the Commission, may appoint and terminate a director and deputy director without regard to the civil service laws (including regulations).

(B) DELEGATION TO DIRECTOR.—The Commission may delegate such powers and duties to the director as may be necessary for the efficient operation and management of the Commission.

(2) STAFF PAID FROM FEDERAL FUNDS.—The Commission may use any available Federal funds to appoint and fix the compensation of not more than 4 additional personnel staff members, as the Commission determines necessary.

(3) STAFF PAID FROM NON-FEDERAL FUNDS.—The Commission may use any available non-Federal funds to appoint and fix the compensation of additional personnel.

(4) COMPENSATION.—

(A) MEMBERS.—

(i) IN GENERAL.—A member of the Commission shall serve without compensation.

(ii) TRAVEL EXPENSES.—A member of the Commission shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for an employee of an agency under subchapter I of chapter 57 of title 5, United States Code, while away from the home or regular place of business of the member in the performance of the duties of the Commission.

(B) STAFF.—

(i) IN GENERAL.—The co-chairpersons of the Commission may fix the compensation of the director, deputy director, and other personnel without regard to the provisions of chapter 51 and subchapter III of chapter 53 of title 5, United States Code, relating to classification of positions and General Schedule pay rates.

(ii) MAXIMUM RATE OF PAY.—

(I) DIRECTOR.—The rate of pay for the director shall not exceed the rate payable for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

(II) DEPUTY DIRECTOR.—The rate of pay for the deputy director shall not exceed the rate payable for level V of the Executive Schedule under section 5316 of title 5, United States Code.

(III) STAFF MEMBERS.—The rate of pay for staff members appointed under paragraph (2) shall not exceed the rate payable for grade GS-15 of the General Schedule under section 5332 of title 5, United States Code.

(c) DETAIL OF FEDERAL GOVERNMENT EMPLOYEES.—

(1) IN GENERAL.—On request of the Commission, the head of any Federal agency or department may detail any of the personnel of the agency or department to the Commission to assist the Commission in carrying out this Act.

(2) REIMBURSEMENT.—A detail of personnel under this subsection shall be without reimbursement by the Commission to the agency from which the employee was detailed.

(3) CIVIL SERVICE STATUS.—The detail of the employee shall be without interruption or loss of civil service status or privilege.

(d) OTHER REVENUES AND EXPENDITURES.—

(1) IN GENERAL.—The Commission may procure supplies, services, and property, enter into contracts, and expend funds appropriated, donated, or received to carry out contracts.

(2) DONATIONS.—

(A) IN GENERAL.—The Commission may solicit, accept, use, and dispose of donations of money, property, or personal services.

(B) LIMITATIONS.—Subject to subparagraph (C), the Commission shall not accept donations—

(i) the value of which exceeds $50,000 annually, in the case of donations from an individual; or

(ii) the value of which exceeds $250,000 annually, in the case of donations from a person other than an individual.

(C) NONPROFIT ORGANIZATION.—The limitations in subparagraph (B) shall not apply in the case of an organization that is—

(i) described in section 501(c)(3) of the Internal Revenue Code of 1986; and

(ii) exempt from taxation under section 501(a) of the Internal Revenue Code of 1986.

(3) ACQUIRED ITEMS.—Any book, manuscript, miscellaneous printed matter, memorabilia, relic, and other material or property relating to the time period of the discovery of Florida acquired by the Commission may be deposited for preservation in national, State, or local libraries, museums, archives, or other agencies with the consent of the depositary institution.

(e) POSTAL SERVICES.—The Commission may use the United States mail to carry out this Act in the same manner and under the same conditions as other agencies of the Federal Government.

(f) VOLUNTARY SERVICES.—Notwithstanding section 1342 of title 31, United States Code, the Commission may accept and use voluntary and uncompensated services as the Commission determines to be necessary.

SEC. 7. STUDY.

The Secretary of the Interior shall—

(1) in accordance with section 8(c) of Public Law 91–383 (16 U.S.C. 1a–5(c)), conduct a study to assess the suitability and feasibility of designating an area in the State of Florida as a unit of the National Park System to commemorate the discovery of Florida by Ponce de Leon; and

(2) not later than 3 years after the date on which funds are made available to carry out the study, submit to the Committee on Energy and Natural Resources of the Senate and the Committee on Resources of the House of Representatives a report that describes—

(A) the findings of the study; and

(B) any conclusions and recommendations of the Secretary of the Interior with respect to the study.

SEC. 8. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—Subject to subsection (b), there is authorized to be appropriated to carry out the purposes of this Act $250,000 for each of fiscal years 2005 through 2013.

(b) AVAILABILITY OF FUNDS.—Amounts appropriated under this section for any fiscal year shall remain available until December 31, 2013.

SEC. 9. TERMINATION OF AUTHORITY.

The authority provided by this Act terminates effective December 31, 2013.

INFLUENZA VACCINE

Mr. FRIST. Mr. President, in a few minutes we will be closing down for the night. While we are waiting for some of the final paperwork to be provided, I wanted to take this opportunity to speak to an important issue that affects all children today but also our seniors—an issue that reflects to me a longstanding problem that we must address in this body yet we failed to address it adequately thus far, although we have attempted on several occasions. It has to do with the influenza vaccine.

As we all know, this week Chiron, the company that makes the influenza vaccine, actually one of two companies licensed to sell the vaccine in the United States, announced 48 million doses could not be sent to the United States because of contamination problems.

I thought I would take a few minutes and put that in perspective because people say, Why don't we have more manufacturers? What happened to the U.S. manufacturing base?

A couple of facts: Influenza is a type of virus that kills 36,000 Americans a year; about 100 people a day die from influenza, and about one-half million people die worldwide.

This week, the influenza vaccine supply coming into the United States was cut in half when the manufacturer Chiron announced it would not be able to produce those 48 million doses for the United States—seniors and Americans really of all ages—because some of it may have been contaminated.

As I mentioned, Chiron is only one of two companies licensed to sell the vaccine in the United States. As a result, as we all know, public service announcements and other announcements

of the Department of Health and Human Services asked healthy adults to forego getting flu shots this year. Up until that point in time, it encouraged everyone, in essence, to get flu shots.

We know it is quite benign, with very few side effects, and it has a real therapeutic impact.

This change in policy is required because of the fall-off in the number of doses that are available. Before this week's announcement, we had expected about 100 million doses ready for this year. Last year, it was 87 million doses. We were going to have 100 million doses this year. So it was appropriate planning but also only two companies are producing here. One company had its supply contaminated and we find ourselves in the current situation.

General background: We have had this discussion before. I am really going back and repeating something we have already done on the floor and debated on the floor about 8 months ago. So this is not new information, but it is worth people thinking about because it is a real call to action. There are now only five major vaccine manufacturers worldwide that have production facilities in the United States. This is for all vaccines. Only two, Merck and Wyeth, are U.S. companies.

The five large vaccine manufacturers are Aventis Pasteur, which produces here in the United States and over in France; Merck produces here in the United States; Chiron, which produces in Europe and in several places throughout Europe, Italy, Germany, United Kingdom; Wyeth/Lederle, which produces here in the United States; and GlaxoSmithKline with production in Belgium.

There are some other manufacturers of much smaller scale around the world, but it is hard to get a real good estimate of how many there are, especially with developing country manufacturers. But there are mainly five. That is for all vaccines.

If I focus just on the influenza vaccine, there are approximately a dozen manufacturers worldwide, if you put everybody together. Yet only two manufacturers of influenza vaccines are located in the United States, Aventis Pasteur and MedImmune. Aventis also has a French-based manufacturing plant, which I mentioned, but that vaccine is not licensed here in the United States.

Chiron became a major player in the influenza market when it combined really three other companies—bought three companies that were in the existing influenza manufacturing business in the United Kingdom and in Italy and Germany.

None of the influenza vaccines in Italy or Germany are licensed in the United States. The facility in Liverpool has a capacity of about 56 million doses a year, and almost all of that—90 percent—comes to the United States. The other player, MedImmune, is a new player and it has that live vaccine nasal spray called FluMist. It was introduced last year—quite revolutionary at the time. The company made slightly more than 4 million doses last year but it only sold about 800,000. So it made 4 million, only sold about 500,000 to 800,000, and now they will say they will only have about 1 to 2 million doses in the market. The CDC says it is about 1.1 million doses.

That is all really one needs to know about the manufacturing base. The whole point is, it is small and has gotten smaller and smaller over time.

Why is that? That is really what I want to speak to because that is what I believe this body must act upon or otherwise it is not going to change.

My point is, the manufacturing base has been weakened, devastated in this country in part because of lawsuits. It is the same old story—frivolous, unnecessary lawsuits, but these frivolous lawsuits are tolerated into many fields.

We talked about asbestos and medical liability on the floor. We talked about class action lawsuits. But once again, it is lawsuits that call out for tort reform because it drives companies from a manufacturing base—from a score down to really two in the flu vaccine.

Our Nation's commitment to immunization: Why are vaccines so important? Our Nation's commitment has been one of the most effective public health interventions in the history of medicine. Our country has been proactive, it has been aggressive, and it has been the world leader.

We have been able to reduce the incidence of a whole range of disease, whether it is measles, mumps, or polio. I spoke earlier on the floor today about the HIV/AIDS virus which killed 23 million people. We don't have a vaccine for it. That little virus, which knows no borders. It can't be smelled or felt. It just travels across the world. We need a vaccine to eradicate it.

We did have smallpox. We eradicated smallpox which killed between 300 million and 500 million people in the 20th century alone—that little smallpox virus.

However, because we had a vaccine, we killed it. We eradicated that virus, which had killed between 300 million and 500 million. That is the power of vaccines. They can and they do protect individuals. That is why we recommend them to not only individuals but entire populations.

Now the overall safety record and frivolous lawsuits. This is not Dr. FRIST trying to beat up on the trial lawyers. Frivolous lawsuits are a huge problem. If there are all of these lawsuits, people must think there is a huge safety problem; otherwise why sue everybody? The overall safety record of vaccines has been remarkable. That is why today, looking at the relative benefits and disadvantages, the balance is huge for the benefits, largely because the vaccines have not only worked but have been safe, again and again and again.

However, in spite of that safety, the escalating cost and the continuing threats of litigation, which drive the cost of those vaccines up and the manufacturers have to pay those huge premiums to be protected, have become major disincentives to the production and distribution of these products. It is obvious, if you are a manufacturer today in America or wherever in the world—it is just that our legal system is much more aggressive than any country in the world—if you were a manufacturer, why would you make a vaccine if you know you will be sued even if the product is safe? The answer is obvious.

Indeed, during the past two decades, the number of manufacturers who make vaccines for kids, for children, has dwindled from 12 down to 4. Only two of the four manufacturers that make vaccines for children are in the United States of America. I contend and the data and the evidence is that a large part of that is because of the devastating impact of these frivolous lawsuits. In fact, only two major manufacturers of vaccines for children and adults are based in the United States, coupled with the fact that there are only five major companies worldwide for all vaccines.

There are significant barriers to entry into this market. Again, I am addressing primarily the high cost of lawsuits. Why do I say that? If you look during the early and middle 1980s, litigation threatened to cripple our vaccine industry. Things got better for a while, but now, once again, there is a whole new wave of lawsuits that seek to circumvent a program that is called the Vaccine Injury Compensation Program, or VICP, a program that historically has been very successful, but the lawsuits go around the program, they circumvent the program, and with that you had the huge settlements, huge potential threats to our manufacturing base. The impact today is on our children's well-being and on the well-being of all Americans, especially if we have a huge influenza outbreak.

Why do I point my finger at the legal system, which is almost chaotic? We have the Vaccine Injury Compensation Program, which can work very well, but it needs to be reformed so you do not have the frivolous lawsuits going around it and going after the deep pockets. An example, and I will just give one although there is a whole list of examples—the overall worldwide vaccine market, every vaccine made everywhere in the world, is worth $6 billion. Yet just one class action lawsuit pending last year sought $30 billion in damages. That is one class action lawsuit seeking $30 billion. The overall market, every vaccine in the world, is only valued at $6 billion. Why would any manufacturer subject themselves to this potential liability? It is occurring right here in the United States. It is not occurring in other countries. So we have a weakened manufacturing base because they will not stay in the business due to the threat of lawsuits, leaving us in a situation of only two manufacturers.

No matter how big the demand, if we buy only from two people and there is a contamination problem, we are in trouble. In the announcement earlier this week, we saw what happened to Chiron and with that the consequences of what has happened there on Americans and on children abroad. That is our protection from life-threatening illnesses.

Again, 36,000 people die every year of this little virus which can be prevented, and the vaccine helps prevent it. We have the demand, we have the money, but we do not have the manufacturing base because of this chaotic lawsuit frenzy, the frivolous lawsuits.

We have seen shortages in childhood vaccines in recent years. We have experienced shortages in the influenza vaccine in recent years. After this week's announcement, we will clearly experience another shortage in the United States this year despite the tremendous planning and the unprecedented Federal efforts, including the wonderful work done by Dr. Julie Gerberding at the CDC and Secretary Tommy Thompson at HHS. We have to address the underlying causes. We have to address the root causes of the vaccine shortages in the near term. The long-term effects can even be more devastating if we do not.

That is why I bring it to the Senate's attention late on a Sunday evening. It is our responsibility. The Senate must act. No one else has been able to address that underlying problem that deals with our tort system, but we can. We should. If we are not able to stabilize the world's vaccine supply and make the market stable, give it a firm foundation, it will not be viable. This will affect not only our ability to manufacture vaccines that exist today, but what about that HIV/AIDS virus which has killed 23 million people, has 45 million people infected, and will likely kill another 60 million people—and maybe more than that unless we act. Figure out a vaccine. People are not going to have an incentive to research and invest in research and development in a vaccine if there will not be a market because of frivolous lawsuits which destroy anybody entering that manufacturing base.

I talked earlier today about Alzheimer's disease. Right now, could there be a vaccine for Alzheimer's disease? The answer is yes. Will we have appropriate research and development? Well, I don't know; it depends on whether people are given some incentive to enter that field. To do that, we have to have a strong manufacturing base.

We have to have companies willing to do the research and willing to take the risks to develop safer vaccines that, ultimately, we know will protect us, will save lives, not just for adults, but for kids, against these biological agents, against these viruses, whether it is HIV/AIDS, or smallpox, where we were successful, or influenza that is of current concern.

What have we done in the past? In the past, I have sponsored two pieces of legislation that go a long way toward moving us to stabilization of this market. One of those bills, the Improved Vaccine Affordability and Availability Act, which was S. 2053 in the 107th Congress and S. 754 in the 108th Congress, would restore balance to the litigation system for childhood vaccines by clarifying the congressional intent that all vaccine litigation regarding childhood vaccines should proceed through the Vaccine Injury Compensation Program.

The program that I mentioned that is set up has worked well in the past. We just need to fix the program so we will not have these frivolous lawsuits circumventing the program.

These bills would expand the remedies to help compensate those who are injured, those who suffer serious side effects from vaccines, while at the same time ensuring that unwarranted litigation does not further destabilize the supplies.

The legislation—again, this is legislation in the 107th Congress and the 108th Congress which, in effect, the lawyers have beat back and have not let us pass; but it is going to come forward again—would also require the Federal Government to maintain a stockpile of prioritized vaccines. This will help stabilize supplies and help us prepare for years ahead in which vaccine production may or may not be able to keep pace with the need.

These bills—again, it was S. 2053 in the last Congress and S. 754 in this Congress—would also expand the funding available for State and local efforts to boost immunization rates among children, especially those in underserved areas or those at a high risk to vaccine-preventable diseases.

Each of the major provisions included in the legislation was recommended by the Advisory Commission on Childhood Vaccines. That is a Federal expert panel composed of vaccine manufacturers, health care providers, and trial lawyers. The legislation also has been endorsed by a broad range of medical and children's health groups, including the American Academy of Pediatrics, Every Child By Two, and Parents of Kids with Infectious Diseases.

We must return to this legislation in the next Congress. And we will consider other steps to address the vaccine situation in the future.

Recently, over the course of the week—and really it plays off in the Presidential election again and in other discussions—people are trying to seize upon hot issues and turn them to their political advantage. Let me just say several things.

No. 1, it is irresponsible to say that there is a quick fix. It is complex. It takes study. We have done that study. We are ready to legislate. But there is no quick fix.

Again, there have been people—I believe it has been on the floor of the Senate, but I know it has been in the press—who are terribly misinformed. Yet when they say something, people accept it as fact. And a statement to suggest somehow that this is an issue that arises by brand drugs keeping generics off the market does not make sense. People can say that, and people nod their head, but it does not make sense.

Why do I say that? Because a flu vaccine has to be unique each year. The generic is standardization; you just produce a lot of it. The flu vaccine has to be tailored. It has to be modified. And it takes several years to do those modifications.

No. 2, I do want to applaud the Bush administration, the CDC, the Department of Health and Human Services, Dr. Julie Gerberding, who I mentioned, and Secretary Tommy Thompson. They had virtually as close to perfect as you can planning in terms of vaccines. They took immediate and prompt action as soon as this shortage became available.

A third point I want to close with is, we have to create a stable environment through a combination. This is where there is no quick fix. We need to address the future stockpile, perhaps with some guaranteed purchase by Government, public-private partnerships for research and development, increased funding for safer vaccines, and perhaps—I would argue most importantly—legal reforms. The flu vaccine shortage we are seeing right now is a symptom of the broader issues of risk and low return of developing any vaccines.

Lastly, healthy adults and kids not in the CDC-recommended categories should withhold this year so that we will have sufficient vaccines available for those who are at higher risk.

Mr. President, again, I bring this to the floor because it is a current topic. I do not want to see it politicized. We have an obligation in this body to address it head-on. It is a tort reform issue. It is the sort of issue that we are obligated to take on, and we will take on very directly in the next Congress.

Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

The PRESIDING OFFICER. Without objection, it is so ordered.

UNANIMOUS CONSENT AGREEMENT—SENSE OF THE SENATE RESOLUTION

Mr. FRIST. Mr. President, I ask unanimous consent that the previous order be modified so that on Monday, Senator BOXER be recognized for up to 30 minutes, and that at that time the sense-of-the-Senate resolution submitted by Senator BOXER, which is currently at the desk, be considered and