added as cosponsors of amendment No. 4769 intended to be proposed to H.R. 4853, a bill to amend the Internal Revenue Code of 1986 to extend the funding and expenditure authority of the Airport and Airway Trust Fund, to amend title 49, United States Code, to extend authorizations for the airport improvement program, and for other purposes.

AMENDMENT NO. 4773

At the request of Ms. STABENOW, the name of the Senator from South Dakota (Mr. JOHNSON) was added as a cosponsor of amendment No. 4773 intended to be proposed to H.R. 4853, a bill to amend the Internal Revenue Code of 1986 to extend the funding and expenditure authority of the Airport and Airway Trust Fund, to amend title 49, United States Code, to extend authorizations for the airport improvement program, and for other purposes.

AMENDMENT NO. 4790

At the request of Mrs. FEINSTEIN, the name of the Senator from California (Mrs. BOXER) was added as a cosponsor of amendment No. 4790 intended to be proposed to H.R. 4853, a bill to amend the Internal Revenue Code of 1986 to extend the funding and expenditure authority of the Airport and Airway Trust Fund, to amend title 49, United States Code, to extend authorizations for the airport improvement program, and for other purposes.

AMENDMENT NO. 4792

At the request of Mrs. FEINSTEIN, the name of the Senator from New Jersey (Mr. LAUTENBERG) was added as a cosponsor of amendment No. 4792 intended to be proposed to H.R. 4853, a bill to amend the Internal Revenue Code of 1986 to extend the funding and expenditure authority of the Airport and Airway Trust Fund, to amend title 49, United States Code, to extend authorizations for the airport improvement program, and for other purposes.

AMENDMENT NO. 4809

At the request of Mr. SANDERS, the names of the Senator from Rhode Island (Mr. WHITEHOUSE), the Senator from Alaska (Mr. BEGICH), the Senator from New Jersey (Mr. LAUTENBERG), the Senator from Minnesota (Mr. FRANKEN) and the Senator from Maryland (Mr. CARDIN) were added as cosponsors of amendment No. 4809 intended to be proposed to H.R. 4853, a bill to amend the Internal Revenue Code of 1986 to extend the funding and expenditure authority of the Airport and Airway Trust Fund, to amend title 49, United States Code, to extend authorizations for the airport improvement program, and for other purposes.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. SPECTER:

S. 4032. A bill to amend the Controlled Substances Act to more effectively regulate anabolic steroids; to the Committee on the Judiciary.

Mr. SPECTER. Mr. President, I have sought recognition to introduce the Designer Anabolic Steroid Control Act of 2010. This legislation was originally filed as an amendment, number 4693, to the FDA Food Safety Modernization Act S. 510, but did not receive a vote. Therefore, before the 111th Congress ends, I am introducing it as a standalone bill which may be taken up in another Congress.

Anabolic steroids—masquerading as body building dietary supplements—are sold to millions of Americans in shopping malls and over the Internet even though these products put at grave risk the health and safety of Americans who use them. The harm from these steroid-tainted supplements is real. In its July 28, 2009 public health advisory, the FDA described the health risk of these types of products to include serious liver injury, stroke, kidney failure and pulmonary embolism. The FDA also warned:

> [A]nabolic steroids may cause other serious long-term adverse health consequences in men, women, and children. These include shrinkage of the testes and male infertility, masculinization of women, breast enlargement in males, short stature in children, adverse effects on blood lipid levels, and increased risk of heart attack and stroke.

New anabolic steroids—often called designer steroids—are coming on the market every day, and FDA and DEA are unable to keep pace and effectively stop these products from reaching consumers.

At the Senate Judiciary Subcommittee on Crime and Drugs hearing I chaired on September 29, 2009, representatives from FDA and DEA, as well as the U.S. Anti-Doping Agency, testified that there is a cat and mouse game going on between unscrupulous supplement makers and law enforcement—with the bad actors engineering more and more new anabolic steroids by taking the known chemical formulas of anabolic steroids listed as controlled substances in Schedule III and then changing the chemical composition just slightly, perhaps by a molecule or two. These products are rapidly put on the market—in stores and over the Internet—without testing and proving the safety and efficacy of these new products. There is no pre-notification to, or pre-market approval by, federal agencies occurring here. These bad actors are able to sell and make millions in profits from their designer steroids because while it takes them only weeks to design a new steroid by tweaking a formula for a banned anabolic steroid, it takes literally years for DEA to have the new anabolic steroid classified as a controlled substance so DEA can police it.

The FDA witness at the hearing, Mike Levy, Director of the Division of New Drugs and Labeling Compliance, acknowledged that this is a ''challenging area'' for FDA. He testified that for FDA it is ''difficult to find the violative products and difficult to act on these problems.'' The DEA witness, Joseph T. Rannazzisi, Deputy Assistant Administrator for DEA, was even blunter. When I questioned him at the hearing, Mr. Rannazzisi admitted that ''at the present time I don't think we are being effective at controlling these drugs.'' He described the process as ''extremely frustrating'' because ''by the time we get something to the point where it will be administratively scheduled [as a controlled substance], there's two to three [new] substances out there.''

The failure of enforcement is caused by the complexity of the regulations, statutes and science. Either the Food Drug and Cosmetic Act, which provides jurisdiction for FDA, or the Controlled Substances Act, which provides jurisdiction for DEA, or both, can be applicable depending on the ingredients of the substance. Under a 1994 amendment to the Food Drug and Cosmetic Act, called the Dietary Supplement Health and Education Act, DSHEA, dietary supplements, unlike new drug applications, are not closely scrutinized and do not require Pre-market approval by the FDA before the products can be sold. Pre-market notification for dietary supplements is required only if the product contains new dietary ingredients, meaning products that were not on the U.S. market before DSHEA passed in 1994.

If the FDA determines that a dietary supplement is a steroid, it has several enforcement measures available to use. FDA may treat the product as an unapproved new drug, or as an adulterated dietary supplement under the Food Drug and Cosmetic Act. Misdemeanor violations of the Food Drug and Cosmetic Act may apply, unless there is evidence of intent to defraud or mislead, a requirement for a felony charge. However, given the large number of dietary supplement products on the market, it is far beyond the manpower of the FDA to inspect every product to find, and take action against, those that violate the law—as the FDA itself has acknowledged.

The better enforcement route is a criminal prosecution under the Controlled Substances Act. However, the process to classify a new anabolic steroid as a controlled substance under Schedule III is difficult, costly and time consuming, requiring years to complete. Current law requires that to classify a substance as an anabolic steroid, DEA must demonstrate that the substance is both chemically and pharmacologically related to testosterone. The chemical analysis is the more straightforward procedure, as it requires the agency to conduct an analysis to determine the chemical structure of the new substance to see if it is related to testosterone. The pharmacological analysis, which must be outsourced, is more costly, difficult, and can take years to complete. It requires both in vitro and in vivo analyses, the latter is an animal study. DEA must then perform a comprehensive review of existing peer-reviewed literature.

Even after DEA has completed the multi-year scientific evaluation process, the agency must embark on a lengthy regulatory review and public-comment process, which typically delays by another year or two the time it takes to bring a newly emerged anabolic steroid under control. As part of this latter process, DEA must conduct interagency reviews, which means sending the studies and reports to the Department of Justice, DOJ, the Office of Management and Budget, OMB, and the Department of Health and Human Services, HHS, provide public notification of the proposed rule, allow for a period of public comment, review and comment on all public comments, write a final rule explaining why the agency agreed or did not agree with the public comments, send the final rule and agency comments back to DOJ, OMB and HHS, and then publish the final rule, all in accordance with the Administrative Procedures Act. To date, under these cumbersome procedures, DEA has only been able to classify three new anabolic steroids as controlled substances and that process—completed only after the September 29, 2010 Senate Judiciary subcommittee hearing—took more than 5 years to finish.

It is clear that the current complex and cumbersome regulatory system has failed to protect consumers from underground chemists who easily and rapidly produce designer anabolic steroids by slightly changing the chemical composition of the anabolic steroids already included on Schedule III as controlled substances. The story of Jareem Gunter, a young college athlete who testified at the hearing, illustrates the system's failure. To improve his athletic performance four years ago, Jareem purchased in a nutrition store a dietary supplement called Superdrol, a product he researched extensively on the Internet and believed was safe. Unfortunately it was not. Superdrol contained an anabolic steroid which to this day is still not included in the list of controlled substances. After using Superdrol for just several weeks, Jareem came close to dying because this product—which he thought would make him stronger and healthier—seriously and permanently injured his liver. He spent four weeks in the hospital and has never been able to return to complete his college education.

To close the loopholes in the present laws that allow the creation and easy distribution of deadly new anabolic steroids masquerading as dietary supplements, I am introducing today The Designer Anabolic Steroid Control Act of 2010. The bill simplifies the definition of anabolic steroid to more effectively target designer anabolic steroids, and permits the Attorney General to issue faster temporary and permanent orders adding recently emerged anabolic steroids to the list of anabolic steroids in Schedule III of the Controlled Substances Act.

Under the bill, if a substance is not listed in Schedule III of the Controlled Substances Act but has a chemical structure substantially similar to one of the already listed and banned anabolic steroids, the new substance will be considered to be an anabolic steroid if it was intended to affect the structure or function of the body like the banned anabolic steroids do. In other words, DEA will not have to perform the complex and time consuming pharmacological analysis to determine how the substance will affect the structure and function of the body, as long as the agency can demonstrate that the new steroid was created or manufactured for the purpose of promoting muscle growth or causing the same pharmacological effects as testosterone.

Utilizing the same criteria, the bill permits the Attorney General to issue a permanent order adding such substances to the list of anabolic steroids in Schedule III of the Controlled Substances Act.

The bill also includes new criminal and civil penalties for falsely labeling substances that are actually anabolic steroids. The penalties arise where a supplement maker fails to truthfully indicate on the label—using internationally accepted and understandable terminology—that the product contains an anabolic steroid. These penalties are intended to be substantial enough to take away the financial incentive of unscrupulous manufacturers, distributors, and retailers who might otherwise be willing to package these products in a way that hides the true contents from law enforcement and consumers.

Finally, the bill adds 33 new anabolic steroids to Schedule III. These 33 anabolic steroids have emerged in the marketplace in the six years since Congress passed the Anabolic Steroid Control Act of 2004. The bill also instructs the United States Sentencing Commission to review and revise the Federal sentencing guidelines to ensure that sentences will be based on the total weight of the product when anabolic steroids are illegally manufactured or distributed in a tablet, capsule, liquid or other form that makes it difficult to determine the actual amount of anabolic steroid in the product.

By making these changes, we can protect the health and lives of countless Americans and provide an effective enforcement mechanism to hold accountable those individuals and their companies which purposefully exploit the current regulatory system for their selfish gain. The Department of Justice has provided extensive technical assistance in the drafting of this bill over many months. In addition, this legislation is fully supported by the United States Olympic Committee, the National Football League, the United States Anti-Doping Agency, as well as by Supplement Safety Now, a coalition including all the major league sports teams, and other sports and medical associations. I urge my colleagues to take up this much-needed bill in the next Congress.

By Mr. SPECTER:

S. 4033. A bill to provide for the restoration of legal rights for claimants under holocaust-era insurance policies; to the Committee on the Judiciary.

Mr. SPECTER. Mr. President, I have sought recognition to urge my colleagues to support and take up next Congress the bill I just introduced, the Restoration of Legal Rights for Claimants Under Holocaust-Era Insurance Policies. The bill would restore the right of Holocaust survivors and their descendants—many of them United States citizens—to maintain lawsuits in our courts to recover unpaid proceeds under Holocaust-era life insurance policies. Recent decisions of the federal courts about which I have spoken at length in prior floor statements and confirmation hearings have denied survivors and their descendants that right.

The insurance policies at issue were issued to millions of European Jews before World War II. During the Nazi era, European insurers largely escaped their obligations under the policies—sometimes by participating with the Nazis in what one Supreme Court Justice has characterized as ''larcenous takings of gigantic proportions.'' [Am. Ins. Ass'n v. Garamendi, 539 U.S. 396, 430 (2003) (Ginsburg, J., joined by Stevens, Scalia, and Thomas, JJ., dissenting).] In the aftermath of World War II, insurers dishonored the policies for one shameful reason or another. The most shameful of them was that a claimant could not produce a death certificate of a deceased insured who had been murdered in a Nazi death camp.

In the 1990s survivors turned, as a last resort, to the courts of the United States. Numerous suits were filed seeking compensation from European insurers for dishonoring Holocaust-era insurance policies during and especially after the War. Several States, for their part, attempted to facilitate recovery under unpaid policies by requiring insurers doing business in their States, as most did, to disclose information about those policies.

European insures responded to these developments by agreeing to establish a private claims resolution process. Their agreement resulted in the establishment of a voluntary organization in 1998—formed by, among others, the insurers, the State of Israel, and State insurance commissioners in the United States known as the International Commission on Holocaust Era Insurance Claims, ICHEIC. ''The job of ICHEIC,'' according to the Supreme Court, ''include[d] negotiation with European insurers to provide information about unpaid insurance policies and the settlement of claims under them.'' [Garamendi, 539 U.S. at 407.]

Many survivors and their descendants filed claims through ICHEIC. How fairly ICHEIC decided their claims remains a debated question. Testimony before Congress at least raises serious questions as to whether meritorious

claims were denied. I do not wish to enter that debate today except to emphasize that ICHEIC was not a neutral, governmental adjudicatory body. It was, as then-Judge Michael Mukasey said, a ''an ad-hoc non-judicial, private international claims tribunal'' created, funded, and to a large extent controlled by the insurance companies—in short, again in Judge Mukasey's words, ''a company store.'' [In re Assicurazioni Generali, S.p.A Holocaust Ins. Litig., 228 F. Supp. 2d 348, 356–57 (S.D.N.Y. 2002).] I also wish to emphasize that by filing a claim through ICHEIC, a claimant did not waive his right to file suit. Only claimants who received payments under insurance policies did so.

Despite the creation of ICHEIC, litigation continued in American courts. Foreign protests over the litigation led the United States to negotiate several executive agreements with foreign governments. Of these, the most important was the 2000 German Foundation Agreement. It obligated Germany to establish the German Foundation, which was funded by Germany and German companies, to compensate Jews ''who suffered'' various economic harms ''at the hands of the German companies during the National Socialist era.'' As for insurance claims in particular, the agreement obligated German insurers to address them through ICHEIC. Similar agreements between the United States and Austria and France followed. No agreement was reached, though, with Nazi German's principal ally, Italy.

In negotiating the 2000 agreement, Germany sought immunity from suit—''legal peace'' as Germany calls it—in American courts for German companies. The United States refused to provide it, and could not have provided it, in my view, in the absence of a Senate-ratified treaty or some other such authoritative Congressional action. Instead the United States agreed only to the inclusion of a provision obligating the United States to file in any suit against a German company over a Holocaust-era claim a precatory statement informing the court that ''it would be in the foreign policy interests of the United States for the Foundation to be the exclusive forum and remedy for the resolution of all asserted claims against Germany companies arising from their involvement in the National Socialist era and World War II.'' The United States also agreed in any such filing to ''recommend dismissal on any valid legal ground (which, under the U.S. system of jurisprudence, will be for the U.S. courts to determine).'' The 2000 agreement makes explicit, however, that ''the United States does not suggest that its policy interests concerning the Foundation in themselves provide an independent legal basis for dismissal.''

But what the 2000 executive agreement expressly denied Germany companies—that is, immunity from suit—our federal courts have now given them at the urging of the executive branch. I refer first and foremost to the Supreme Court's much-criticized, five-to-four decision in American Insurance Co. v. Garamendi, 2003. The Court held there that the executive branch's foreign policy favoring the resolution of Holocaust-era insurance claims through ICHEIC preempted a California law requiring the disclosure of information about Holocaust-era insurance policies to potential claimants. It did not matter, the Court said, that the executive agreement said nothing whatsoever about preemption, let alone that no federal statute or treaty actually preempted disclosure statute's like California's. It was enough that the agreement embodied a general policy—reaffirmed over the years by statements by sub-cabinet officials—with which California's disclosure state could be said to conflict. Four Justices with very different views on executive power—Ginsburg, Scalia, Stevens, and Thomas—dissented. While conceding the, questionable, argument that the President can under some circumstances preempt state law by executive agreement, they emphasized the obvious flaw in the Court's position on the facts at hand: The 2000 agreement says nothing about preemption. Insofar as it says anything on the subject, it actually disclaims any preemptive effect.

On the authority of Garamendi, the Federal district court before which lawsuits to recover on policies issued by the Italian insurer Generali had been consolidated dismissed those suits as preempted. The court rejected the plaintiffs' argument that the suits could not be preempted because Italy and the United States had never entered into an executive agreement addressing claims against Italian insurers. Appeals to the Court of Appeals for the Second Circuit followed. While the appeals were pending, a class action settlement was reached and approved by the court under which most of the class members received nothing. The plaintiffs' lead counsel has said that Garamendi left them no choice but to settle. Several plaintiffs who opted out of the settlement nonetheless pressed on with the appeals. Early this year the Second Circuit affirmed the dismissal of their cases. [In re Assicurazioni Generali, S.P.A., 529 F.3d 113 (2d Cir. 2010).]

The plaintiffs then asked the Supreme Court to hear their case by filing a petition for certiorari. They raised two main questions. Whether Garamendi preempts the generally applicable state common law under which the plaintiffs sought recovery, as opposed to the disclosure-specific law California enacted. Whether Garamendi should be read to preempt state-law claims in the absence of any executive agreement addressing those claims. Recall that Italy and the United States never entered into an executive agreement with which claims against Generali, an Italian insurer, could be said to conflict. A post-Garamendi decision of the Court, Medellin v. Texas, 2008, suggests that Garamendi cannot be so broadly read—that an executive-branch foreign policy can preempt state law only if it becomes law through the means prescribed by the Constitution or, in some limited class of cases at least, find expression in an executive agreement entered with Congress's acquiescence. Despite the importance of these questions and an apparent split among the lower courts in answering them, the Supreme Court denied certiorari.

My legislation would achieve two narrow, but important, objectives: First, it would restore Holocaust survivors and their descendants to the legal position they occupied before Garamendi and Generali. Second, it would allow states to enforce the sort of disclosure laws at issue in Garamendi. With limited exceptions tailored to achieve these objectives, the legislation would otherwise leave undisturbed any defenses that insurers may have to Holocaust-era insurance claims, including the defense that they were settled and released through ICHEIC.

Of equal significance, my legislation would vindicate two important Constitutional principles—one involving separation of powers, the other federalism. The principle of separation of powers is that the Constitution vests all lawmaking authority in Congress and none in the executive branch. The principle of federalism is that, under the Constitution's supremacy clause, Article VI, only the Constitution, Congressionally enacted law, and Senate-ratified treaties can preempt state law. Some executive agreements, if entered at least with Congress's acquiescence, arguably may also do so. But executive-branch policies plainly do not.

One final point: A similar House bill, H.R. 4596, has been objected to on the ground that it will disserve aging Holocaust survivors because it will create unrealistic expectations of recovery. Claims that were not successful before ICHEIC, the House bill's critics claim, are almost certain to fail in court. That is a debatable objection. It is, in any event, beside the point. Holocaust survivors and their descendants should be allowed to decide for themselves whether to file suit. Neither the executive branch nor the federal courts should make that decision for them.

AMENDMENTS SUBMITTED AND PROPOSED

SA 4810. Mr. BAUCUS submitted an amendment intended to be proposed by him to the bill H.R. 4849, to amend the Internal Revenue Code of 1986 to provide tax incentives for small business job creation, extend the Build America Bonds program, provide other infrastructure job creation tax incentives, and for other purposes; which was ordered to lie on the table.

SA 4811. Mr. DEMINT submitted an amendment intended to be proposed by him to the bill H.R. 3082, making appropriations for military construction, the Department of