knowing Captain Dalley. I was proud to nominate him to the United States Naval Academy; however, he decided to pursue his career in public service with the Army and attended West Point. It should also be noted that he was also accepted to the Air Force Academy; remarkable achievements by any standard.

While preparing these remarks, I went through my files and found these words from this young man's Advanced Placement History teacher, who wrote a nomination recommendation:

As impressive as [Nathan Dalley's] academic qualities are, I find his personal qualities to be even more impressive . . . His kindness and friendliness to everyone set him apart in the classroom, and in the larger school setting. In my class he was a remarkably effective cooperative learner and peer tutor. Nate understands that his contributions to the community as a whole are as important as his personal academic success, and I have every confidence that he will be successful in his future pursuits.

Captain Dalley not only met these high expectations, but exceeded them.

To his mother, his sisters and his fiancee, I would like to say that, although I have no words to minimize your grief, I hope there is some comfort in knowing that all who knew your son respected him and knew him to be a good friend.

I will never forget Nathan Dalley or the others from Utah's list of honor. Their sacrifice will make a difference, their will be freedom in Iraq, and those who would destroy liberty will be brought to justice. So today we add CPT Nathan S. Dalley to this illustrious list that includes SSG James W. Cawley, United States Marine Corps Reserve; SSG Nino D. Livaudais of the Army's Ranger Regiment; Randall S. Rehn, of the Army's 3rd Infantry Division; SGT Mason D. Whetstone of the United States Army; SP4 David J. Goldberg of the Utah-based 395th Finance Battalion, Army Reserve and former Special Forces soldier Brett Thorpe.

We will honor them always and stand fast behind their families.

PATENT CHALLENGE PROVISIONS OF THE MEDICARE REFORM BILL

Mr. HATCH. Mr. President, I rise to make a few comments about the historic Medicare legislation that President Bush signed into law yesterday.

I will center my remarks today on the provisions of the bill that amend the Drug Price Competition and Patent Term Restoration Act of 1984. I am a coauthor of the 1984 law and it is of particular interest to me. This law, often referred to as the Waxman-Hatch Act or Hatch Waxman, is of great importance to my fellow Utahns and the rest of the American public as it saves an estimated $8 to $10 billion for consumers each year.

Over the past 2 years, the Senate has spent considerable time and effort debating refinements to the 1984 law designed to close some loopholes that emerged and were exploited. While I would have preferred a more comprehensive reexamination of the statute with the goal of assessing how the law might be changed to facilitate new biomedical research and how best to disseminate the fruits of this research to the public in a quick and fair fashion, the amendments made to Hatch-Waxman made under the leadership of Senators GREGG, SCHUMER, MCCAIN, KENNEDY, COLLINS, and EDWARDS are very significant.

It has been my position for some time that once the Congress adopts and the President signs, as he did yesterday, Medicare reform legislation that includes a prescription drug benefit, pressure will grow on Congress and the Food and Drug Administration to find new ways to bring new biotechnology products to the public when the patents expire. The Center for Medicare and Medicaid Services will be compelled to look for ways to economize on the purchase of drugs and it seems likely to me that the Department of Health and Human Services will have to explore regulatory measures that can produce saving. The Commissioner of Food and Drugs, Dr. Mark McClellan, has indicated a willingness to examine this issue. Few, if any, of my colleagues in Congress have to date joined in the discussion surrounding whether and, if so, how to create a fast track approval system for biologic products, but I believe the bill signed into law yesterday will encourage this debate. I welcome this debate and recognize that very important public health matters are at its heart. As well, retaining America's worldwide leadership in biomedical research is at stake whenever we consider legislation that affects pharmaceutical related intellectual property.

We must proceed carefully but we must proceed. Critical to the success of this debate is a need to observe the principle of balance contained in the original 1984 law so that both research based firms and generic firms receive new incentives that will allow them to continue to produce and distribute the products that the American public deserves.

As more and more biological products come to the market, the pressures on the Federal Government, State governments, private insurers, and private citizens to pay for these products will result in considerable pressure to create a fast track FDA approval system for off-patent biological products. Such a mechanism was not discussed in the 1984 negotiations that resulted in Hatch-Waxman largely because the biotechnology was still in its infancy. This is not the case today. Few, if any, of my colleagues in Congress have to date joined the discussion surrounding creating a fast track approval for off-patent follow-on biologic products, but I believe the new law signed yesterday will encourage this debate.

As part of an appraisal of the laws relating to the development and approval of pharmaceutical products, I would also hope that my colleagues and the public will examine the full complement of incentives that Senator LIEBERMAN and I have included in our bi-partisan bioterrorism bill, S. 666. These incentives, which include day-to-day patent term restoration and a harmonization of the marketing exclusivity period to the 10-year term employed by the EU and Japan, will be helpful for the development of countermeasures to bioterrorist attacks and they should also be carefully considered with respect to developing new vaccines, diagnostics, and preventive and therapeutic agents for a host of other diseases and conditions.

With respect to the patent challenge provisions of the Medicare bill, I want especially to commend the efforts of Senator GREGG, Chairman of the HELP Committee and the Majority Leader, Senator FRIST, for working so hard to improve this legislation. There can be no doubt that the bill the President signed yesterday is a big improvement compared with the McCain-Schumer bill of last year, S. 812, that passed the Senate.

I must also commend my colleagues in the House including, Commerce Committee Chairman BILLY TAUZIN, Commerce Committee Ranking Democrat JOHN DINGELL, and my colleagues from the House Judiciary Committee, Chairman JIM SENSENBRENNER and Ranking Democrat JOHN CONYERS, and Intellectual Property Subcommittee Chairman LAMAR SMITH for their help in vastly improving the Gregg-Schumer-Kennedy amendments that passed the Senate by a 94–1 vote this summer.

As the sole dissenter in the Senate, I am pleased the conferees were able to work in a bipartisan, bicameral spirit to correct the constitutional flaw in the Senate-passed bill. I commend the Department of Justice for its work that helped dislodge the unconstitutional ''actual controversy'' language from the declaratory judgment provision of the bill.

I am also pleased that the conferees decided to reject the provision of the Senate bill that would have resulted in the so-called parking of exclusivity in cases in which a generic challenger could show that the patents held by a pioneer drug firm were not infringed or were invalid. In order to give an incentive for vigorous patent challenges, the 1984 law granted a 180-day head start over other generic drug firms when the pioneer firm's patents failed or were simply not infringed. As I will explain in some detail, I think there may be a way to improve this language further and to save consumers a considerable sum of money in the process.

The 180-day marketing exclusivity rules were first enacted as part of the Waxman-Hatch Act. The policy behind these provisions is to benefit the public by creating an atmosphere that ensure vigorous challenges of the patents held by innovator drug firms.

The intent of this section of the 1984 law was to award the 180-day head start

to the first successful challenger of a pioneer firm's patents. Unfortunately, we drafters of the statute employed language that has been interpreted by the courts to grant the 180-days of exclusivity to the first generic drug applicant to file an application with the FDA that challenges the patents.

I must say that in most cases the first filer and first successful applicant was the same applicant. But I believe that the line of court decisions that include the Mova and Granutec cases has resulted in the establishment of a first filer regime that is not without unintended consequences and perverse incentives. The mismatch between the rights accorded to the first applicants and first successful challenger contributed to an atmosphere in which anticompetitive agreements were entered into between certain pioneer and generic drug firms.

I am pleased that the Medicare reform bill signed into law yesterday contained Senator LEAHY's Drug Competition Act, which is designed to increase enforcement of longstanding provisions of antitrust law that prevent anti-consumer agreements. The 2002 FTC study, ''Generic Drug Entry Prior to Patent Expiration,'' catalogs the agency's actions in this arena including such cases as those involving Hoescht and Andryx and Abbott and Geneva.

I am also pleased that the Senate language prevailed on Senator LEAHY's Drug Competition Act so that potentially anticompetitive agreements between research-based and generic drug firms will be reported to both the Department of Justice and the Federal Trade Commission. I worked extensively with Senator LEAHY on his bill in the 107th Congress and took the lead, with his cosponsor, Senator GRASSLEY, in convincing the House conferees of the wisdom of the Senate's dual reporting requirement.

So, the conferees made a number of important improvements to provisions of the legislation affecting challenges to drug patents. At our August 1, 2003, Judiciary Committee hearing, both the FDA and FTC expressed reservations about some elements of the Senate bill's rules pertaining to the 180-day marketing provision. The Administration, correctly in my view, took exception to the provisions in the Senate bill that would have allowed a sue now/use the exclusivity later—and perhaps years later at that—policy on marketing exclusivity.

At the August 1st hearing, Mr. Robert Armitage, General Counsel of the Eli Lilly Company, presented compelling testimony on the matter of ''parking'' or delaying, the use of the 180-day exclusivity until the basic patents expire. The question confronting policymakers centered on the wisdom of retaining the Gregg-Schumer-Kennedy provision that would have encouraged very early lawsuits by those with, for examples, noninfringing formulations of the pioneer product, in order to gain the potentially very lucrative 180-days of exclusivity down the road.

I welcome and expect that day will come when Congress will reexamine the whole rationale and operation of the 180-day marketing exclusivity provisions. The day will come when the Congress will be forced to confront the incongruity in the statute, pointed out by my friend and skilled patent-challenging lawyer and philanthropist, Al Engelberg, is awarding 180 days both for a successful invalidity challenge and an non-infringement action. The former, a finding of invalidity, accrues to all generic firms while the latter benefits only the specific non-infringer. This is a distinction with a difference in a sector of the economy where a whole cottage industry has grown up fueled in large part by non-infringement suits to non-basic patents. It is less than clear that the public benefits as much as it can or should under the present system which is left largely in place by the new bill language. This issues deserves further discussion.

Nevertheless, I am pleased that the Senate language that allowed long-term parking of exclusivity was modified in an important way by the conferees. I want to commend the FDA and especially the Chief Counsel for Food and Drugs, Mr. Dan Troy, and the soon-to-be betrothed Associate Commissioner for Legislative Affairs, Mr. Amit Sachdev, for their contributions in this area.

Having now commended the administration for helping to improve materially the Senate version of the 180-day provisions, I must also unfortunately report to my colleagues in the Senate and to the American public that we have not accomplished as much as possible with respect to the 180-day provisions.

First off, I continue to believe that it is both unfair and ill-advised to retain the bill language that does not reward a non-first-filer to gain the 180-days marketing exclusivity in the case, which will admittedly be rare, in which the subsequent filer prevails on a patent invalidity challenge. I am told that conferee staff first thought that the provision as drafted, and now signed into law, would result in a subsequent filer's successful invalidity challenge forfeiting the first filer's 180 days of marketing exclusivity. Although the successful challenger does not get the 180-day head start, at least under this reading, the subsequent successful challenger is not penalized with respect to market entry. Upon further scrutiny of the statutory language, it is my understanding that in such circumstances the language may actually work to grant the 180-days of marketing exclusivity to the first filer, so that the successful subsequent challenger not only does not get the 180-day benefit, but actually receives a 180-day penalty for invalidating the patent.

If this is the correct way to read the statute, the law should be changed.

I am told that the staff of any conferee nor the FDA strongly defended this policy. Unfortunately, nor was there agreement to change the language to at least clarify that the subsequent challenger's success was at least a forfeiture event or, preferable from my perspective, would result in the granting of the 180-days to the successful challenger in a patent invalidity challenge rather than benefitting the fastest paper shuffler.

This is bad policy.

Finally, I must unfortunately report to my colleagues that the new statute retains the Gregg-Schumer-Kennedy provision that may cost the Federal government, according to the CONGRESSIONAL BUDGET OFFICE, $700 million over the next 10 years. Moreover, it is my understanding that the total cost of this provision to consumers over the next 10 years could exceed $3 billion.

At issue are the sections of the bill that essentially give the first filer an exclusive right to the potential 180-day marketing exclusivity until its case is decided at the appellate court level. The question arises of what happens if a subsequent filer is not sued by the pioneer firm and is ready, willing and able to go to market but for waiting for the disposition of the first filer's challenge in the appellate court? If the first filer prevails in the appellate court, it will receive the 180-days of exclusive marketing even though one or more subsequent filers were ready, willing, and able to go to the market long before the first filer's challenge was resolved.

I would also note the FTC study documents that when the first filer wins in the district court, they almost always prevail on appeal. The FTC opposed reinstating the earlier policy of the appellate court trigger because it believes that, on average, consumers will lose out while generic firms get an extra measure of certainty.

In any event, subsequent to the Judiciary Committee hearing in August and throughout the fall as the conference committee met, I was involved in participating and facilitating discussions designed to craft language to close this new loophole sanctioned by the Gregg-Schumer-Kennedy language as well as to make a few other clarifications to the parking language. Specifically, I preferred statutory language that would automatically convert unsuccessful Paragraph IV invalidity/noninfringement challenges to standard Paragraph III—''the patents expire on''—applications. FDA believes it can accomplish this by rule or guideline, but the courts have not been kind to FDA rulemaking with respect to Hatch-Waxman in recent years.

While I am mindful that the forces behind the first filer system of challenge have won the day in this legislation, I think in the circumstance when the subsequent challenger has not been sued, and may have even been issued a covenant not to be sued by the pioneer firm, that the first filer should at least forfeit its 180 days if it is not prepared to go to market in the 75-day grace period the new provision creates. This is

good for the consumer and sound policy since the rationale behind the 180-day provision is to create an incentive for challenges to the pioneer's patents, not to create an entitlement to the first applicant to file a patent challenge with the FDA in the Parklawn Building. It seems to me that the first time that a blockbuster product is kept off the market, perhaps for over a year, due to the application of this new law and there is a second generic ready, able and willing to go to market, there will be a great public clamor, as there should be.

At one point, I thought I was close to agreeing to language with Senator KENNEDY and others to close this new loophole. Unfortunately, we did not reach agreement and since this was a part of the legislation in which the Senate and House language was virtually identical, it is understandable the conferees concentrated their efforts on those many provisions in which there were substantial differences. On the very last days before the conference report was completed, Senator SCHUMER and I also came close to closing this newly created loophole, but time ran out on this effort.

Let me just say I am mindful that the politics and financial interests with respect to this issue among those in both the research-based firms and generic drug companies are a very sensitive matter. I also recognize it will be exceedingly difficult to reopen these provisions now that the President has signed the bill into law. Nevertheless, I think we got this aspect wrong and we should try to fix it. I pledge to continue to work with Senator GREGG, MCCAIN, SCHUMER, KENNEDY as well as Representatives TAUZIN, DINGELL, SENSENBRENNER, SMITH, and CONYERS and other interested members of Congress and other affected parties to fix this problem before consumers have to pay for this ill-advised policy.

In the interest of moving this issue along in a constructive fashion, I have developed a discussion draft that emerged out of my discussions with Senator KENNEDY and others that addresses these issues. Frankly, much of this draft reflects refinements to a draft that Senator KENNEDY prepared in part as a response to a draft prepared largely by several private sector parties earlier this year that I submitted to the Medicare conferees for their consideration. It is my understanding that the administration does not oppose this language but, unfortunately, neither did it support this approach due, in some measure, to the fact that it was not anxious to open new issues in the already complex Medicare conference.

Although they both opposed the underlying Medicare reform bill, I commend my colleagues, Senators KENNEDY and SCHUMER for their interest in improving this particular aspect of the legislation.

In closing, let me say again that Senators GREGG, KENNEDY, SCHUMER, MCCAIN, and FRIST have worked hard to improve the patent challenge provisions of current law and all deserve our thanks.

I am very proud of the Drug Price Competition and Patent Term Restoration Act, which has done so much to help consumers have access to more affordable medications.

The underpinning of this great consumer measure is a very complex, legal framework. Any changes to the law must be carefully scrutinized to assure they achieve their intended effect.

I plan to monitor very carefully the implementation of the first, substantial Waxman-Hatch amendments in almost two decades and intend to work with my colleagues to make certain they achieve their intended purpose.

I welcome the views of any interested parties who wish to comment on this discussion draft, as well as other implementation issues that the Congress should consider.

At the same time, I think there are broader issues here it behooves the Congress to consider. These include the issue of follow-on biologics as well as whether the law today contains the appropriate incentives, including intellectual property incentives, for pharmaceutical research and development in light of the fact that science appears to be moving away from an era of large patient population, small-molecule medicine to small patient-population, large biological molecule therapies.

Mr. President, I ask unanimous consent that the draft be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

S. 812

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.

(a) MAINTENANCE OF CERTIFICATION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—Section 505(j)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)) (as amended by section 1101(a)(1)(B) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003) is amended by adding at the end the following:

''(E) MAINTENANCE OF CERTIFICATION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—An applicant shall not be permitted to maintain a certification under subparagraph (A)(vii)(IV) with respect to a patent as of the date on which any of the following occurs:

''(i) The Secretary notifies the applicant that the Secretary has granted and made effective a request by the holder of the application approved under subsection (b) to withdraw the patent that is the subject of the certification or the information with respect to the patent is otherwise no longer contained in the application approved under subsection (b), except that no request to withdraw the patent, if based on a court decision or court judgment with respect to the patent, shall be made effective for at least 75 days after the court decision or court judgment and shall not be made effective during the 180-day exclusivity period of the applicant if the exclusivity period commences during the 75-day period.

''(ii) The patent that is the subject of the certification expires.

''(iii) A court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent that is the subject of the certification is infringed by the product at issue in the application submitted by the applicant, or a court signs a settlement order or consent decree that enters a final judgment and includes a finding that the patent that is the subject of the certification is infringed by the product at issue in the application submitted by the applicant and, in addition, the patent that is the subject of the certification is not found to be invalid or unenforceable in the final decision or the final judgment.''.

(b) FAILURE TO MARKET.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as amended by section 1102(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003) is amended

(1) in subparagraph (B)(iv)—

(A) in subclause (I), by inserting after ''certification,'' the following: ''is thereafter permitted to maintain such a certification, and has thereafter maintained such a certification with respect to a patent for which such a certification was submitted by the first applicant on the first applicant date,''; and

(B) in subclause (II)—

(i) by redesignating items (cc) and (dd) as items (dd) and (ee), respectively; and

(ii) by striking item (bb) and inserting the following:

''(bb) FIRST APPLICANT.—The term 'first applicant' means an applicant that submits on the first applicant date a substantially complete application for approval of the drug that contains the certification described in paragraph (2)(A)(vii)(IV) with respect to a patent for which information was filed under subsection (b) or (c) and is thereafter permitted to maintain and has thereafter maintained the certification described in paragraph (2)(A)(vii)(IV) with respect to the patent.

''(cc) FIRST APPLICANT DATE.—The term 'first applicant date' means the first day on which a substantially complete application is submitted for approval of a drug containing the certification described in paragraph (2)(A)(vii)(IV) with respect to a patent for which information was filed under subsection (b) or (c)''; and

(2) in subparagraph (D), by striking subclause (I) and inserting the following:

''(I) FAILURE TO MARKET.—

''(aa) IN GENERAL.—Except as provided in item (bb), a first applicant fails to market the drug by the earlier of the date that is—

''(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

''(BB) 30 months after the date of submission of the application of the first applicant;

''(bb) EXCEPTION.—If the first applicant has on the first application date submitted the certification described in paragraph (2)(A)(vii)(IV) with respect to a patent, and the first applicant is thereafter permitted to maintain and has thereafter maintained the certification with respect to the patent, the forfeiture under this subclause shall not take effect before the date that is 75 days after the date on which any of the following occurs with respect to the patent:

''(AA) In an infringement action brought against the first applicant or any other applicant (which other applicant has obtained tentative approval) with respect to the patent or in a declaratory judgment action brought by the first applicant or any other

applicant (which other applicant has obtained tentative approval) with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed (including any dismissal for lack of subject matter jurisdiction as a result of a representation of the patent owner, and any other person with the right to enforce the patent, that the patent will not be infringed by, or will not be enforced against, the product of the applicant).

''(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment and includes a finding that the patent is invalid or not infringed.

''(CC) The Secretary notifies the first applicant that a certification has been received by the Secretary from another applicant that had obtained tentative approval and was eligible as of the date of the certification to receive final approval, but for 180-day exclusivity period, stating that the 45-day period referred to in subparagraph (B)(iii) had ended without a civil action for patent infringement having been brought against such other applicant and, in addition, such other applicant had received from the patent owner (and from and any other person with the right to enforce the patent) a written representation that the patent will not be infringed by the commercial manufacture, use, offer for sale, or sale of the product at issue in the application submitted by such other applicant, or will not be enforced against the commercial manufacture, use, offer for sale, or sale of the product at issue in the application submitted by such other applicant.''.

[Alternative language for (CC)—equivalent treatment to (AA) and (BB).]

[''(CC) The Secretary notifies all applicants that, after the forty-five day period referred to in subparagraph (B)(iii) has expired without a civil action for patent infringement having been brought against the first applicant or against any other applicant that has obtained tentative approval, that applicant has certified to the Secretary that that applicant has received from the patent owner (and from and any other person with the right to enforce the patent) a written representation that the patent will not be infringed by the commercial manufacture, use, offer for sale, or sale of the product at issue in the application submitted by that applicant, or will not be enforced against the commercial manufacture, use, offer for sale, or sale of the product at issue in the application submitted by that applicant.]

THE TVPA REAUTHORIZATION

Mr. BROWNBACK. Mr. President, I am pleased to report the success of a bipartisan effort in which Senators, Members of the House, their key staff aides and a broad variety of religious and human rights groups have engaged.

This effort has produced a greatly strengthened Trafficking Victims Protection Reauthorization Act which has passed the House, and which it is my honor to bring to the Senate floor. I am pleased to note that my colleague, the distinguished Senator from New York, Mr. SCHUMER, has joined me in cosponsoring this important legislation. The act will greatly strengthen America's hand in combating the slavery issue and the women's issue of our time—the annual trafficking of as many as 2 million women and children into sex and slave bondage. As such, this act will give needed tools to President Bush, and to all future Presidents, to take on the world's trafficking mafias and to protect the traffickers' victims. It will thus also greatly facilitate the pledge made by President Bush in his United Nations speech of September 23 to make the war against trafficking a major commitment of his administration.

But I am pleased and deeply honored to bring this bill before my colleagues for yet another reason—one that I know will resonate with every Member of this body. Both in spirit and substance, the measure now before the Senate captures the hopes and the ideals of Paul and Sheila Wellstone, without whose passion and commitment no U.S. anti-trafficking initiative against worldwide sex and slave trafficking would have been possible. It is one of my greatest sources of satisfaction and fulfillment as a member of this body to have worked with Paul and with Sheila to sponsor the Trafficking Victims Protection Act of 2000. In doing so, I and others were regularly inspired by these two friends to go the extra mile for the bill. After our first Foreign Relations Committee hearing on the bill, Paul remarked that the victims who testified on behalf of the bill had produced his most moving experience as a Senator. This says much about the man Paul was, and about the manner in which his and Sheila's priorities were always directed on behalf of abused, vulnerable, and powerless victims.

We honor Paul and Shelia today by taking up this bill. As pleased as they would be by that gesture, it would be a much more meaningful tribute if we are able to pass the Trafficking Victims Protection Reauthorization Act, for there are a number of vital, strengthening provisions in the act that will greatly improve the fight against trafficking.

First, the Director of the State Department Office to Combat and Monitor Trafficking in Persons has been raised to ambassadorial rank. This step will elevate the status of the office precisely as it will befit its present incumbent. John Miller, a former House Member known to many of us, is an able, respected, committed, and moral man who is now the Federal Government's chief antislavery and antitrafficking official. He has served as head of the TIP Office with great effectiveness and skill, and I am confident that, as Ambassador Miller, he will continue to do so.

Next, the reauthorization act resolves one of the original act's greatest operational failings by ensuring that ''Tier II'' designations—given to counties that neither satisfy the act's high standards for anti-trafficking performance nor clearly merit the act's automatic sanctions—will not become an overbroad catchill category. Under the act, countries on the cusp of Tier III designations will be placed in a Tier II Special Watch List category and their performance in eliminating trafficking will be subject to special scrutiny, and the issuance of a special February 1 progress report and designation evaluation. Thus, the Special Watch List category will maintain strong pressure on countries that may ''almost but not quite'' merit a sanctions-bearing Tier III designation, and will permit clear differentiation between those countries and others placed on Tier II because they have not met the very high standards required for Tier I designations.

Three points should be made in connection with the act's Special Watch List category. First, countries otherwise meriting Tier III designation but placed on the Tier II Special Watch List because they have made section (e)(3)(A)(iii)(III) ''commitments . . . to take additional future steps over the next year'' should only avoid Tier III designation under extraordinary circumstances, and only where they are engaged in implementing important and curative steps likely to be rapidly completed. Next, the provisions of section (e)(3)(A)(iii)(II) that authorize Special Watch List treatment of countries that have failed to engage in increased efforts to limit trafficking, prosecute traffickers and protect trafficking victims should not be construed to automatically bar Tier II designations when such efforts have not been made. Finally, to address a matter of legitimate concern to the State Department, the act's mandate that special Feburary 1 reports are to be issued for all Special Watch List countries needs to be understood in terms of our intention that only countries on the Tier II-Tier III cusp are to be the subjects of full and complete reports. Finally, as an overall matter, it should be made clear that failure to be placed on the Tier II Special Watch List will not bar a country from being placed on Tier II in the following year.

A third major category of change established by the act involves the establishment of additional ''minimum standards'' criteria for determining appropriate tier designations. First, the reauthorization makes clear that countries may not escape more severe tier designations if they fail to keep meaningful records of what they have done to investigate, prosecute, convict and otherwise monitor their performance in the war against trafficking. Next, the reauthorization establishes an ''appreciable progress'' standard evaluating a country's performance—a standard not intended to exculpate countries still significantly complicit in trafficking activities, but to ensure that countries failing to make measurable progress on a year-to-year basis will be negatively affected. In other words, the reauthorization establishes a bottom-line ''performance standard'' to supplement the original act's ''effort standards.'' Next, and critically, the reauthorization adds a standard based