

FDA will designate it as an original submission. Revisions that require a consult to another division will be considered to introduce “significant new concepts or creative themes.”

APPENDIX B-1
EXAMPLE 1: ORIGINAL SUBMISSIONS
If participants indicate the intent to submit 150 submissions in fiscal year 2008; 200

submissions in fiscal year 2009; 224 submissions in fiscal year 2010; 200 submissions in fiscal year 2011; and 250 submissions in fiscal year 2012, the review metrics will be as follows:

| | FY 08: 150 submissions | FY 09: 200 submissions | FY 10: 224 submissions | FY 11: 200 submissions | FY 12: 250 submissions |
|---------------------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|
| Cohort 1 (150 submissions) | 75 (50% of 150) | 90 (60% of 150) | 105 (70% of 150) | 120 (80% of 150) | 135 (90% of 150) |
| Cohort 2 (50 submissions) | | 25 (50% of 50) | 30 (60% of 50) | 35 (70% of 50) | 40 (80% of 50) |
| Cohort 3 (24 submissions) | | | 12 (50% of 24) | 0 (60% of 0) | 17 (70% of 24) |
| Cohort 4 (0 submissions) | | | | 0 (50% of 0) | 0 (70% of 0) |
| Cohort 5 (26 submissions) | | | | | 13 (50% of 26) |
| Total Target for 45 Day Review Metric | 75 | 115 | 147 | 155 | 205 |

EXAMPLE 2: ORIGINAL SUBMISSIONS
If participants indicate the intent to submit 150 submissions in fiscal year 2008; 200

submissions in fiscal year 2009; 250 submissions in fiscal year 2010; 300 submissions in fiscal year 2011; and 350 submissions in fiscal

year 2012, the review metrics will be as follows:

| | FY 08: 150 submissions | FY 09: 200 submissions | FY 10: 250 submissions | FY 11: 300 submissions | FY 12: 350 submissions |
|---------------------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|
| Cohort 1 (150 submissions) | 75 (50% of 150) | 90 (60% of 150) | 105 (70% of 150) | 120 (80% of 150) | 135 (90% of 150) |
| Cohort 2 (50 submissions) | | 25 (50% of 50) | 30 (60% of 50) | 35 (70% of 50) | 40 (80% of 50) |
| Cohort 3 (24 submissions) | | | 25 (50% of 50) | 30 (60% of 50) | 35 (70% of 50) |
| Cohort 4 (50 submissions) | | | | 25 (50% of 50) | 30 (60% of 50) |
| Cohort 5 (50 submissions) | | | | | 25 (50% of 50) |
| Total Target for 45 Day Review Metric | 75 | 115 | 160 | 210 | 265 |

EXAMPLE 3: RESUBMISSIONS
If participants submit 75 resubmissions in fiscal year 2008; 99 resubmissions in fiscal

year 2009; 123 resubmissions in fiscal year 2010; 147 resubmissions in fiscal year 2011;

and 171 resubmissions in fiscal year 2012, the review metrics will be as follows:

| | FY 08: 75 resubmissions | FY 09: 99 resubmissions | FY 10: 123 resubmissions | FY 11: 147 resubmissions | FY 12: 171 resubmissions |
|---------------------------------------|-------------------------|-------------------------|--------------------------|--------------------------|--------------------------|
| Cohort 1 (75 submissions) | 37 (50% of 75) | 45 (60% of 75) | 52 (70% of 75) | 60 (80% of 75) | 68 (90% of 75) |
| Cohort 2 (24 submissions) | | 12 (50% of 24) | 14 (60% of 24) | 17 (70% of 24) | 19 (80% of 24) |
| Cohort 3 (24 submissions) | | | 12 (50% of 24) | 14 (60% of 24) | 17 (70% of 24) |
| Cohort 4 (24 submissions) | | | | 12 (50% of 24) | 14 (60% of 24) |
| Cohort 5 (24 submissions) | | | | | 12 (50% of 24) |
| Total Target for 30 Day Review Metric | 37 | 57 | 78 | 103 | 130 |

IRAQ STUDY GROUP

Mr. SALAZAR. Mr. President, last night, we passed the Department of Defense Authorization bill. I want to comment briefly on the debate we had during consideration of that legislation related to the war in Iraq. I am frustrated that we did not reach a bipartisan consensus on a new way forward that could begin to bring an end to this conflict.

When I introduced the Iraq Study Group Recommendations Implementation Act last spring with Senator ALEXANDER and a bipartisan group of our colleagues, I was hopeful we could work constructively with the President toward the goal of having our troops redeployed by the spring of 2008. I was hopeful that we would send a strong signal—with a bipartisan group that eventually grew to 17 Senators—that we should get out of the combat business in Iraq as quickly as possible.

The Iraq Study Group Report was issued 10 months ago. Its core recommendation was that we transition our military mission from combat to training, supporting, and equipping Iraqi security forces. The report said that we should condition our support of the Iraqi Government on its performance in meeting important milestones. The report contemplated that we could be out of the combat business by March 31, 2008.

The report was anticipated with great fanfare. But when it came out, the Bush administration failed to embrace it. The Iraqi Government has failed to meet most of the benchmarks described in the report. General Petraeus has testified, essentially, that

we should maintain our combat mission for the foreseeable future. And that March 31 date is only 6 months away.

I still believe in the report. It is still relevant, and it is still important. It sets forth a comprehensive military, political, and economic strategy for bringing a responsible end to the war in Iraq.

But I believe we must build upon the report and take decisive action now to redefine our mission in Iraq and set a clear course for the redeployment of our troops.

Ten months after the Iraq Study Group issued its report, we have failed to begin the transition of our mission that was central to their recommendations. That transition in mission is the key to encouraging the Iraqi Government to take responsibility for the future of their country. The Government Accountability Office has concluded that the Iraqi Government has failed to take that responsibility by meeting the reasonable benchmarks set forth by the Iraq Study Group.

I continue to believe that we must follow the core principles laid out in the Iraq Study Group Report. I continue to believe we need a bipartisan solution to bring this conflict to a responsible end. And I thank each of the cosponsors of our amendment, Republicans and Democrats, for their willingness to join in this important effort. They include Senators ALEXANDER, BENNETT, COLEMAN, COLLINS, DOMENICI, GREGG, SPECTER, and SUNUNU from the Republican side and Democratic Senators PRYOR, CASEY, CARPER, CONRAD,

LANDRIEU, LINCOLN, MCCASKILL, and BILL NELSON.

I believe now is the time to build upon the principles set forth by the Iraq Study Group. We must begin a transition of mission from combat to training and support. We must demand more from the Iraqi Government and send a strong and unequivocal message that our commitment is not open-ended. I believe these actions are consistent with the recommendations of the Iraq Study Group, and I remain hopeful that our legislation can be the basis for a constructive, bipartisan solution to the war in Iraq.

HONORING OUR ARMED FORCES

SECOND CLASS CHARLES LUKE MILAM

Mr. SALAZAR. Mr. President, I wish to reflect on the life and service of Navy Hospital Corpsman Second Class Charles Luke Milam. Luke was killed last Wednesday in a rocket attack near the town of Musa Qula, Afghanistan. He was 26 years old.

Luke Milam was a giant of his generation, a man who served his country and those around him with dignity, courage, and honor. I cannot begin to paint the picture of someone so deeply respected by those with whom he served, so committed to helping others.

Luke Milam grew up in Littleton, CO, the youngest of four siblings. He was smart, friendly, and athletic. He loved the mountains of Colorado and spent his time biking, backpacking, hiking, and canoeing.

I do not know what inspired Luke's strong sense of virtue or what led him to join the military. Perhaps it was the service of his grandfather Charles or his brother Keith that moved him to enlist after graduating from high school.

I imagine, though, that Luke's own experiences as a witness to one of the worst tragedies of our time, the shootings at Columbine High School, strengthened his resolve to bring healing, peace, and good to areas torn by violence. Luke Milam was a senior at Columbine when, on April 20, 1999, 2 shooters killed 12 people and wounded 24 others before turning their guns on themselves.

I was Colorado's attorney general when the shootings occurred. The time I spent with the Littleton community in the aftermath—sorting through the events, finding out what went wrong and then helping to rebuild—affirmed my unmatched admiration for the young people who endured one of the darkest moments of American history. So many of Columbine's survivors have gone on to do extraordinary things—it is as though they have committed themselves to overcoming the evil they witnessed by planting hope, decency, and goodness wherever they can. Luke Milam was among them.

Serving as a Navy corpsman with a unit of marines—a special operations unit no less—requires great skill and courage. The corpsman is tasked with providing medical care for marines on the field of battle. It is an incredibly dangerous job that entails carrying a loaded weapon along with the tools of your trade. Some of America's most renowned heroes on the battlefield were hospital corpsmen: people such as Wayne Caron, David R. Ray, and Francis Hammond—Medal of Honor recipients who gave their lives in combat to save others.

Hospital Corpsman Milam served in this tradition. He was highly decorated for his service, earning a Purple Heart, the Bronze Star, two Combat Action ribbons, two Navy and Marine Corps Achievement Medals, two Good Conduct Medals, the National Defense Service Medal, the Global War on Terrorism Medal, and two Sea Service Deployment Ribbons. More importantly for the corpsman, though, Luke Milam earned the deepest respect and admiration of the marines with whom he served.

Luke was on his fourth tour, having served three tours in Iraq. He "felt it was his calling to help the guys around him," his brother Keith said. "If there were guys in harm's way, he needed to be there to take care of them."

Almost a century ago, Teddy Roosevelt told a Paris crowd that the model citizen is the man who is willing to take action in pursuit of that which he thinks is right. His speech draws on the same words that family and friends use to describe Luke Milam's virtues.

When evaluating mankind's progress, said Roosevelt, "it is not the critic who

counts; not the man who points out how the strong man stumbles, or where the doer of deeds could have done them better. The credit belongs to the man who is actually in the arena, whose face is marred by dust and sweat and blood; who strives valiantly; who errs, who comes short again and again, because there is no effort without error and shortcoming; but who does actually strive to do the deeds; who knows great enthusiasms, the great devotions; who spends himself in a worthy cause; who at the best knows in the end the triumph of high achievement, and who at the worst, if he fails, at least fails while daring greatly, so that his place shall never be with those cold and timid souls who neither know victory nor defeat."

Hospital Corpsman Luke Milam sacrificed his life for this Nation as a man who knew that his country needed him to be "in the arena," helping others. He accepted the risks of his job with extraordinary professionalism and served with honor in the best tradition of the corpsman. We cannot repay our debt nor replace his loss.

To Luke's parents, Rita and Michael, to his sister, Jaeme, and to his brothers, Keith and Andrew, I know that no words can describe or assuage the pain you feel. I pray that you can find comfort in the knowledge that Luke was doing something which he truly loved, that he was doing it well, and that he will never be forgotten. His country is eternally grateful. He will endure in our hearts and prayers.

IN RECOGNITION OF SCOTT GUDES

Mr. GREGG. Mr. President, today I wish to pay tribute to Scott Gudes, who leaves his post at the helm of my Budget Committee staff this week. After 29 years of loyal service to the Federal Government, Scott has chosen to become vice president for government relations for the National Marine Manufacturers Association—a job well suited for a man who loves the sea as much as he does.

When I became chair of the Senate Budget Committee in 2005, I asked Scott if he would serve as my staff director. In under a year, under Scott's stewardship, we passed both a budget for the first time in 2 years, specifically the fiscal year 2006 budget resolution, and a reconciliation bill, the Deficit Reduction Act, DRA—marking the first time in 10 years Congress had passed a reconciliation bill to reduce spending.

The DRA was a notable achievement in that it saved \$39 billion, a feat which is practically unheard of around here, as the last time it was done was in 1997. These accomplishments could not have been done without Scott, who worked tirelessly to shepherd each authorizing committee through the often confusing reconciliation process. His unique combination of intellect, humor, and humbleness was a key component in navigating the complex waters of the com-

promise that was necessary to pass the first substantive deficit reduction legislation in 10 years.

Scott followed up his initial year of success by spearheading efforts to develop a more comprehensive approach to restraining spending. His efforts contributed to the introduction of the Stop Over-Spending Act, a budget process reform bill that helped focus the national debate on solutions to our long-term fiscal challenges. Just this year, Scott helped structure the Conrad/Gregg Bipartisan Task Force for Responsible Fiscal Action Act of 2007, legislation that will encourage bipartisan action to put our fiscal house back in order. At heart, Scott is a true nonpartisan who recognizes that the best policy is made when both sides of the aisle work together, and his first instinct is to seek out common ground rather than partisan differences.

However, much like Thomas Jefferson chose to be remembered as author of the Declaration of Independence rather than various elected offices he held, including President, I expect that Scott would rather be remembered for spearheading efforts to write, edit, and publish the "Budget Committee History" rather than his impressive legislative credentials. Scott took it upon himself to initiate a historic accounting of the Senate Budget Committee. This labor of love reflects countless interviews and hours chronicling the birth, history, and importance the committee has held in shaping the Federal budget and fiscal policy. His devotion to this project is an example of Scott's love of history and respect for the institution of the Senate.

The handful of aforementioned achievements merely reflects Scott's latest accomplishments in an achievement-filled career. It would be nearly impossible to chronicle the numerous programs and projects he created, funded, and oversaw—programs that improved and enriched both individual lives and the environment.

In addition to his tour of duty at the Senate Budget Committee, Scott has held key positions on both sides of the Capitol, both ends of Pennsylvania Avenue, and a point I like to forget, Scott has even worked on both sides of the aisle. Included in this impressive list are stints as the clerk of the Commerce, Justice, and State Appropriations Subcommittee, professional staff on the Defense Appropriations Subcommittee, and Acting NOAA Administrator, where he championed science, service, and environmental stewardship programs and greatly improved agency morale. In NOAA circles, Scott is a virtual god—king of satellites, staunch advocate of the NOAA Corps and its ships and planes, and an addict of the NOAA label, which I understand is plastered on literally everything under and around his home, car, and office.

But the true bearing of Scott's 29 years of Federal service is not the remarkable list of the jobs he has held, although the list is long and distinguished, but the manner in which Scott