He loved his country. He loved his home state of Virginia and he took reasonable pride in his roots, which reached back to Jamestown.

And most of all, he loved his family. Family was everything to him. He adored and revered his parents. His brothers, their wives and children; my mother's sisters, their husbands and children, all were sources of endless interest, enjoyment and satisfaction to him. He shared forty-eight years with my mother, and they were totally devoted to one another.

And how he loved his girls: Augusta, who he was so proud to have bear his name; Christine, in whom he took such delight as his first grandchild; Annie, the only woman I know who he genuinely didn't mind losing arguments to, and Babs, who gave so much of herself to him, especially over the last few months. He was one lucky guy. And now he's come full circle. As a newly minted second lieutenant in 1940, he arrived here at Fort Meyer, his first duty station. He lived just a few steps away from this chapel at Quarters 201–A, and he buried old soldiers. Now the time has come to return the honor.

God bless you, Old Soldier.

TRIBUTE TO WASHINGTON STATE CITIZEN DOUG SCOTT, 1997 RECIPIENT OF THE SIERRA CLUB JOHN MUIR AWARD

• Mrs. MURRAY. Mr. President, I rise to pay tribute to a distinguished citizen of the great state of Washington, Mr. Doug Scott. Doug was recently recognized by the Sierra Club with the 105-year-old organization's highest award, the John Muir Award. The Sierra Club presents this award to honor individuals with a ''distinguished record of leadership—such as to continue John Muir's work of preservation and establishment of parks and wilderness.''

Doug Scott has certainly perpetuated the vision and leadership of John Muir throughout his years of commitment to the environment. Beginning his career of dedication to the environment in 1967 by joining the Sierra Club, Doug moved from his first involvement in the public policy process to be one of the original founders of Earth Day. From 1973 to 1977 Doug was the Sierra Club's Northwest field representative. In 1980, Doug became the National Conservation Director of the Sierra Club and in 1988, the organization's Associate Executive Director. In 1990, Doug left the Sierra Club for the beautiful San Juan Islands in my state of Washington to direct the San Juan Community Theater in Friday Harbor. Doug is now the Executive Director of a local, grass-roots environmental organization, Friends of the San Juans.

It is in this most recent capacity that I have come to most appreciate Doug's skills and abilities. Doug is an essential member of the Northwest Straits Citizen's Advisory Commission that I convened with Congressman METCALF. This local citizen's advisory commission is designed to assess the resource protections needs and values of the Northwest Straits marine environment and to explore the best ways to provide protections for this exquisite natural area. Doug's participation in this process has been invaluable. His deep commitment to protection of the marine environment combined with his thoughtful, innovative, and pragmatic approach has provided real progress for the Commission as it works through its mandate. Doug's ability to work with individuals with differing idealogies and perspectives in a cooperative and productive manner is a true asset to the Commission, and to the Northwest Straits as well.

In Doug's remarks at the Annual Awards Dinner, he said:

Much as this award is personally gratifying. I prefer to think of it as recognition for an era in the growth and growing effectiveness of the Sierra Club and the citizen environmental movement. Each achievement during that era was the work of many hands. This award is for all of the Sierra Club volunteers and other activists that have proven that in this democracy, working together, an engaged citizenry can make a tremendous difference. I discovered the power of citizen activism over 25 years ago in the Sierra Club and now I see its impact every day in my work in the San Juan Islands.

The Sierra Club has chosen well in awarding Doug Scott the John Muir Award. I applaud their decision and I applaud Doug Scott. I thank him for his commitment to the environment of the San Juan Islands, the Northwest Straits, Washington state, and the United States. Great work, Doug. Congratulations.

Mr. President, I ask that the nominating statement for Doug Scott by Bruce Hamilton, Conservation Director of the Sierra Club be printed in the RECORD.

The statement follows:

DOUG SCOTT RECEIVES THE SIERRA CLUB'S JOHN MUIR AWARD

NOMINATING STATEMENT BY BRUCE HAMILTON, CONSERVATION DIRECTOR, SIERRA CLUB

Doug has been a mentor and an inspiration to an entire generation of environmental leaders, myself included. I feel so lucky to have learned my skills at the side of this master.

Doug had a way of turning dreams and visions into reality. Ed Wayburn had the vision for an Alaska Lands Act, but it was Doug Scott who pulled together and directed the 8 year campaign that passed the largest land protection bill in history. Rupert Cutler may have conceived of the RARE II wilderness review, but it was Doug Scott who marshalled the resources and provided the leadership to steer dozens of RARE II wilderness bills through the Congress. When states like Utah couldn't even boast a single wilderness area in the entire state, Doug packaged a group of areas together into the Endangered American Wilderness Act and mobilized a national campaign to pass it. Doug also developed the strategy that enabled us to pass the Superfund (remember the Superactivist we mailed out of SF every Friday?), the Clean Air Act Amendments (remember the Vento-Green medals?), and other anti-pollution campaigns. He was the inspiration and strategist for the California Desert Protection Act even though it did not pass until after he had left the Club.

Doug was also the most inspirational and motivational speaker within the Club, flying tens of thousands of miles every year to appear at Chapter annual meetings and retreats to preach about the power of the grassroots and the importance of combating apathy and cynicism. He was also one of the funniest leaders the Club has known, the source and subject of jokes and follies songs. He was the spark behind the national conservation work of the Club for 15 years.

The Club has been blessed with a series of powerful, inspirational, smart, and articulate leaders that exemplify the best traits of our founder, John Muir. From the late 1970's to the early 1990's Doug Scott lead the Club in the spirit of John Muir. He deserves the Club's highest conservation honor for his service, accomplishments, and inspiration.•

PERFORMANCE GOALS FOR THE PRESCRIPTION DRUG USER FEE ACT OF 1997

• Mr. JEFFORDS. Mr. President, on November 9 the Senate adopted Conference Report 105–399, that accompanied S. 830, the Food and Drug Administration Modernization Act of 1997. This legislation puts into place long-needed reforms in FDA's regulatory procedures and also reauthorizes the Prescription Drug User Fee Act of 1992 [PDUFA] for an additional 5 years.

The original PDUFA has brought faster reviews of drug applications. By all accounts the success is due to the underlying collaboration and partnership between FDA and the developers of innovative new medicines in using the fees paid by industry to bring the necessary review resources to bear on applications for new drugs. The 1992 act did not set the performance goals for activities funded by user fees into the law. Rather, these performance goals were set forth in a side-letter from the administration to the chairs and ranking members of the House Commerce and Senate Labor and Human Resources committees. These performance goals in the side-letter have stood the test of time—FDA has honored and met these goals as if they were in statute. Based on that experience, the Congress has agreed to use this approach again in establishing the performance goals for drug reviews funded by user fees over the next 5 years.

Today, I am submitting for the RECORD a letter addressed to me and signed by Secretary of Health and Human Services, Donna E. Shalala, dated November 12, 1997. This letter specifies the performance goals for the use of PDUFA fees for fiscal years 1998 through 2002. These goals, which were agreed to at the conclusion of negotiations between FDA officials and pharmaceutical and biotechnology industry representatives, are those referred to in section 101(4) of the Food and Drug Administration Modernization Act of 1997.

Mr. President, it is my hope that the next 5 years will see reductions in the drug development time, as well as further reductions in the time taken to actual review an applications.

The letter follows:

THE SECRETARY OF
HEALTH AND HUMAN SERVICES,
Washington, DC, November 12, 1997.

Hon. JAMES M. JEFFORDS,
Committee on Labor and Human Resources,
U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: As you are aware, the Prescription Drug User Fee Act of 1992 (PDUFA) expired at the end of Fiscal Year 1997. Under PDUFA, the additional revenues generated from fees paid by the pharmaceutical and biological prescription drug industries have been used to expedite the prescription drug review and approval process, in accordance with performance goals that were developed by the Food and Drug Administration (FDA) in consultation with the industries. To date, FDA has met or exceeded the review performance goals agreed to in 1992, and is reviewing over 90 percent of priority drug applications in 6 months and standard drug applications in 12 months.

FDA has worked with representatives of the pharmaceutical and biological prescription drug industries, and the staff of your Committee, to develop a reauthorization proposal for PDUFA that would build upon and enhance the success of the original program. Title I, Subtitle A of the Food and Drug Administration Modernization Act of 1997, S. 830, as passed by the House and Senate on November 9, 1997, reflects the fee mechanisms developed in these discussions. The performance goals referenced in Section 101(4) are specified in the enclosure of this letter, entitled ''PDUFA Reauthorization Performance Goals and Procedures.'' I believe they represent a realistic projection of what FDA can accomplish with industry cooperation and the additional resources identified in the bill.

This letter and the enclosed goals document pertain only to Title I, Subtitle A (Fees Related to Drugs) of S. 830, the Food and Drug Administration Modernization Act of 1997.

OMB has advised that there is no objection to the presentation of these views from the standpoint of the Administration's program.

We appreciate the support of you and your staff, the assistance of other Members of the Committee, and that of the Appropriations Committees, in the reauthorization of this vital program.

Sincerely,

DONNA E. SHALALA.

Enclosure.

PDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES

The performance goals and procedures of the FDA Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), as agreed to under the reauthorization of the prescription drug user fee program in the ''Food and Drug Administration Modernization Act of 1997,'' are summarized as follows:

I. FIVE-YEAR REVIEW PERFORMANCE GOALS

Fiscal year 1998

1. Review and act on 90 percent of standard original New Drug Application (NDAs) and Product License Applications (PLAs)/Biologic License Applications (BLAs) filed during fiscal year 1998 within 12 months of receipt.

2. Review and act on 90 percent of priority original NDA and PLA/BLA submissions filed during fiscal year 1998 within 6 months of receipt.

3. Review and act on 90 percent of standard efficacy supplements filed during fiscal year 1998 within 12 months of receipt.

4. Review and act on 90 percent of priority efficacy supplements filed during fiscal year 1998 within 6 months of receipt.

5. Review and act on 90 percent of manufacturing supplements filed during fiscal year 1998 within 6 months of receipt.

6. Review and act on 90 percent of all resubmitted original applications filed during the fiscal year 1998 within 6 months of receipt, and review and act on 30 percent of Class 1 resubmitted original applications within 2 months of receipt.

Fiscal year 1999

1. Review and act on 90 percent of standard original NDA and PLA/BLA submissions filed during fiscal year 1999 within 12 months of receipt and review and act on 30 percent within 10 months of recept.

2. Review and act on 90 percent of priority original NDA and PLA/BLA submissions filed during fiscal year 1999 within 6 months of receipt.

3. Review and act on 90 percent of standard efficacy supplements filed during fiscal year 1999 within 12 months of receipt and review and act on 30 percent within 10 months of receipt.

4. Review and act on 90 percent of priority efficacy supplements filed during fiscal year 1999 within 6 months of receipt.

5. Review and Act on 90 percent of manufacturing supplements filed during fiscal year 1999 within 6 months of receipt and review and act on 30 percent of manufacturing supplements requiring prior approval within 4 months of receipt.

6. Review and act on 90 percent of Class 1 resubmitted original applications filed during fiscal year 1999 within 4 months of receipt and review and act on 50 percent within 2 months of receipt.

7. Review and act on 90 percent of Class 2 resubmitted original applications filed during fiscal year 1999 within 6 months of receipt.

Fiscal year 2000

1. Review and Act on 90 percent of standard original NDA and PLA/BLA submissions filed during fiscal year 2000 within 12 months of receipt and review and act on 50 percent within 10 months of receipt.

2. Review and Act on 90 percent of priority original NDA and PLA/BLA submissions filed during fiscal year 2000 within 6 months of receipt.

3. Review and act on 90 percent of standard efficacy supplements filed during fiscal year 2000 within 12 months of receipt and review and act on 50 percent within 10 months of receipt.

4. Review and act on 90 percent of priority efficacy supplements filed during fiscal year 2000 within 6 months of receipt.

5. Review and Act on 90 percent of manufacturing supplements filed during fiscal year 2000 within 6 months of receipt and review and act on 50 percent of manufacturing supplements requiring prior approval within 4 months of receipt.

6. Review and act on 90 percent of Class 1 resubmitted original applications filed during fiscal year 2000 within 4 months of receipt and review and act on 50 percent within 2 months of receipt.

7. Review and act on 90 percent of Class 2 resubmitted original applications filed during fiscal year 2000 within 6 months of receipt.

Fiscal year 2001

1. Review and act on 90 percent of standard original NDA and PLA/BLA submissions filed during fiscal year 2001 within 12 months and review and act on 70 percent within 10 months of receipt.

2. Review and act on 90 percent of priority original NDA and PLA/BLA submissions filed during fiscal year 2001 within 6 months of receipt.

3. Review and act on 90 percent of standard efficacy supplements filed during fiscal year 2001 within 12 months and review and act on 70 percent within 10 months of receipt.

4. Review and act on 90 percent of priority efficacy supplements filed during fiscal year 2001 within 6 months of receipt.

5. Review and act on 90 percent of manufacturing supplements filed during fiscal year 2001 within 6 months of receipt and review and act on 70 percent of manufacturing supplements requiring prior approval within 4 months of receipt.

6. Review and act on 90 percent of Class 1 resubmitted original applications filed during fiscal year 2001 within 4 months of receipt and review and act on 70 percent within 2 months of receipt.

7. Review and act on 90 percent of Class 2 resubmitted original applications within 6 months of receipt.

Fiscal year 2002

1. Review and act on 90 percent of standard original NDA and PLA/BLA submissions filed during fiscal year 2002 within 10 months of receipt.

2. Review and act on 90 percent of priority original NDA and PLA/BLA submissions filed during fiscal year 2002 within 6 months of receipt.

3. Review and act on 90 percent of standard efficacy supplements filed during fiscal year 2002 within 10 months of receipt.

4. Review and act on 90 percent of priority efficacy supplements filed during fiscal year 2002 within 6 months of receipt.

5. Review and act on 90 percent of manufacturing supplements filed during fiscal year 2002 within 6 months of receipt and review and act on 90 percent of manufacturing supplements requiring prior approval within 4 months of receipt.

6. Review and act on 90 percent of Class 1 resubmitted original applications field during fiscal year 2002 within 2 months of receipt.

7. Review and act on 90 percent of Class 2 resubmitted original applications within 6 months of receipt.

These review goals are summarized in the following tables:

ORIGINAL NDAs/BLAs/PLAs AND EFFICACY SUPPLEMENTS

Submission cohort	Standard	Priority
Fiscal year:		
1998	90 pct. in 12 mos	90 pct. in 6 mos.
1999	30 pct. in 10 mos 90 pct. in 12 mos	90 pct. in 6 mos.
2000	50 pct. in 10 mos 90 pct. in 12 mos	90 pct. in 6 mos.
2001	70 pct. in 10 mos 90 pct. in 12 mos	90 pct. in 6 mos.
2002	90 pct. in 10 mos	90 pct. in 6 mos.

MANUFACTURING SUPPLEMENTS

Submission cohort	Manufacturing supplements that—	
	Do not require prior approval[1]	Do require prior approval
Fiscal year:		
1998	90 pct. in 6 mos	90 pct. in 6 mos.
1999	90 pct. in 6 mos	30 pct. in 4 mos. 90 pct. in 6 mos.
2000	90 pct. in 6 mos	50 pct. in 4 mos. 90 pct. in 6 mos.
2001	90 pct. in 6 mos	70 pct. in 4 mos. 90 pct. in 6 mos.

[1] Changes being effected or 30-day supplements.

RESUBMISSION OF ORIGINAL NDAs/BLAs/PLAs

Submission cohort	Class 1	Class 2
Fiscal years:		
1998	90 pct. in 6 mos 30 pct. in 2 mos	90 pct. in 6 mos.
1999	90 pct. in 4 mos 50 pct. in 2 mos	90 pct. in 6 mos.
2000	90 pct. in 4 mos 70 pct. in 2 mos	90 pct. in 6 mos.
2001	90 pct. in 2 mos	90 pct. in 6 mos.

RESUBMISSION OF ORIGINAL NDAs/BLAs/PLAs—Continued

Submission cohort	Class 1	Class 2
2002	90 pct. in 2 mos	90 pct. in 6 mos.

II. NEW MOLECULAR ENTITY (NME) PERFORMANCE GOALS

The performance goals for standard and priority original NMEs in each submission cohort will be the same as for all of he original NDAs (including NMEs) in each submission cohort but shall be reported separately.

For biological products, for purposes of this performance goal, all original BLAs/PLAs will be considered to be NMEs.

III. MEETING MANAGEMENT GOALS

A. Responses to Meeting Requests

1. Procedure: Within 14 calendar days of the Agency's receipt of a request from industry for a formal meeting (i.e., a scheduled face-to-face, teleconference, or video conference) CBER and CDER should notify the requester in writing (letter or fax) of the date, time, and place for the meeting, as well as expected Center participants.

2. Performance Goal: FDA will provide this notification within 14 days for 70% of requests (based on request receipt cohort year) starting in FY 1999; 80% in FY 2000; and 90% in subsequent fiscal years.

B. Scheduling meetings

1. Procedure: The meeting date should reflect the next available date on which all applicable Center personnel are available to attend, consistent with the component's other business; however, the meeting should be scheduled consistent with the type of meeting requested. If the requested date for any of these types of meetings is greater than 30, 60, or 75 calendar days (as appropriate) from the date the request is received by the Agency, the meeting date should be within 14 calendar days of the date requested.

Type A Meetings should occur within 30 calendar days of the Agency receipt of the meeting request.

Type B Meetings should occur within 60 calendar days of the Agency receipt of the meeting request.

Type C Meetings should occur within 75 calendar days of the Agency receipt of the meeting request.

2. Performance goal: 70% of meetings are held within the time frame (based on cohort year of request) starting in FY 1999; 80% in FY 2000; and 90% in subsequent fiscal years.

C. Meeting minutes

1. Procedure: The Agency will prepare minutes which will be available to the sponsor 30 calendar days after the meeting. The minutes will clearly outline the important agreements, disagreements, issues for further discussion, and action items from the meeting in bulleted form and need not be in great detail.

2. Performance goal: 70% of minutes are issued within 30 calendar days of date of meeting (based on cohort year of meeting) starting in FY 1999; 89% in FY 2000; and 90% in subsequent fiscal years.

D. Conditions

For a meeting to qualify for these performance goals:

1. A written request (letter or fax) should be submitted to the review division; and

2. The letter should provide: a. A brief statement of the purpose of the meeting; b. a listing of the specific objectives/outcomes the requester expects from the meeting; c. a proposed agenda, including estimated times needed for each agenda item; d. a listing of planned external attendees; e. a listing of requested participants/disciplines representative(s) from the Center; f. the approximate time that supporting documentation (i.e., the ''backgrounder'') for the meeting will be sent to the Center (i.e., ''x'' weeks prior to the meeting, but should be received by the Center at least 2 weeks in advance of the scheduled meeting for Type A or C meetings and at least 1 month in advance of the scheduled meeting for Type B meetings); and

3. The Agency concurs that the meeting will serve a useful purpose (i.e., it is not premature or clearly unnecessary). However, requests for a ''Type B'' meeting will be honored except in the most unusual circumstances.

IV. CLINICAL HOLDS

A. Procedure

The Center should respond to a sponsor's complete response to a clinical hold within 30 days of the Agency's receipt of the submission of such sponsor response.

B. Performance goal

75% of such responses are provided within 30 calendar days of the Agency's receipt of the sponsor's response starting in FY 98 (cohort of date of receipt) and 90% in subsequent fiscal years.

V. MAJOR DISPUTE RESOLUTION

A. Procedure

For procedural or scientific matters involving the review of human drug applications and supplements (as defined in PDUFA) that cannot be resolved at the divisional level (including a request for reconsideration by the Division after reviewing any materials that are planned to be forwarded with an appeal to the next level), the response to appeals of decisions will occur within 30 calendar days of the Center's receipt of the written appeal.

B. Performance goal

70% of such answers are provided within 30 calendar days of the Center's receipt of the written appeal starting in FY 1999; 80% in FY 2000; and 90% in subsequent fiscal years.

C. Conditions

1. Sponsors should first try to resolve the procedural or scientific issue at the Division level. If it cannot be resolved at that level, it should be appealed to the Office Director level (with a copy to the Division Director) and then, if necessary, to the Deputy Center Director or Center Director (with a copy to the Office Director).

2. Responses should be either verbal (followed by a written confirmation within 14 calendar days of the verbal notification) or written and should ordinarily be to either deny or grant the appeal.

3. If the decision is to deny the appeal, the response should include reasons for the denial and any actions the sponsor might take in order to persuade the Agency to reverse its decision.

4. In some cases, further data or further input from others might be needed to reach a decision on the appeal. In these cases, the ''response'' should be the plan for obtaining that information (e.g., requesting further information from the sponsor, scheduling a meeting with the sponsor, scheduling the issue for discussion at the next scheduled available advisory committee).

5. In these cases, once the required information is received by the Agency (including any advice from an advisory committee), the person to whom the appeal was made, again has 30 calendar days from the receipt of the required information in which to either deny or grant the appeal.

6. Again, if the decision is to deny the appeal, the response should include the reasons for the denial and any actions the sponsor might take in order to persuade the Agency to reverse its decision.

7. N.B. If the Agency decides to present the issue to any advisory committee and there are not 30 days before the next scheduled advisory committee, the issue will be presented at the following scheduled committee meeting in order to allow conformance with advisory committee administrative procedures.

VI. SPECIAL PROTOCOL QUESTION ASSESSMENT AND AGREEMENT

A. Procedure

Upon specific request by a sponsor (including specific questions that the sponsor desires to be answered), the agency will evaluate certain protocols and issues to assess whether the design is adequate to meet scientific and regulatory requirements identified by the sponsor.

1. The sponsor should submit a limited number of specific questions about the protocol design and scientific and regulatory requirements for which the sponsor seeks agreement (e.g., is the dose range in the carcinogenicity study adequate, considering the intended clinical dosage; are the clinical endpoints adequate to support a specific efficacy claim).

2. Within 45 days of Agency receipt of the protocol and specific questions, the Agency will provide a written response to the sponsor that includes a succinct assessment of the protocol and answers to the questions posed by the sponsor. If the agency does not agree that the protocol design, execution plans, data analyses are adequate to achieve the goals of the sponsor, the reasons for the disagreement will be explained in the response.

3. Protocols that qualify for this program include: carcinogenicity protocols, stability protocols, and Phase 3 protocols for clinical trials that will form the primary basis of an efficacy claim. (For such Phase 3 protocols to qualify for this comprehensive protocol assessment, the sponsor must have had an end of Phase 2/pre-Phase 3 meeting with the review division so that the division is aware of the developmental context in which the protocol is being reviewed and the questions being answered.)

4. N.B. For products that will be using Subpart E or Subpart H development schemes, the Phase 3 protocols mentioned in this paragraph should be construed to mean those protocols for trails that will form the primary basis of an efficacy claim no matter what phase of drug development in which they happen to be conducted.

5. If a protocol is reviewed under the process outline above and agreement with the Agency is reached on design, execution, and analyses and if the results of the trial conducted under the protocol substantiate the hypothesis of the protocol, the Agency agrees that the data from the protocol can be used as part of the primary basis for approval of the product. The fundamental agreement here is that having agreed to the design, execution, and analyses proposed in protocols reviewed under this process the Agency will not later alter its perspective on the issues of design, execution, or analyses unless public health concerns unrecognized at the time of protocol assessment under this process are evident.

B. Performance goal

60% of special protocols assessments and agreement requests completed and returned to sponsor within time frames (based on cohort year of request) starting in FY 1999; 70% in FY 2000; 80% in FY 2001; and 90% in FY 2002.

VII. ELECTRONIC APPLICATIONS AND SUBMISSIONS

The Agency shall develop and update its information management infrastructure to allow, by fiscal year 2002, the paperless receipt and processing of INDs and human drug applications, as defined in PDUFA, and related submissions.

VIII. ADDITIONAL PROCEDURES

A. Simplification of action letters

To simplify regulatory procedures, the CBER and CDER intend to amend their regulations and processes to provide for the issuance of either an ''approval'' (AP) or a ''complete response'' (CR) action letter at the completion of a review cycle for a marketing application.

B. Timing of sponsor notification of deficiencies in applications

To help expedite the development of drug and biologic products, CBER and CDER intend to submit deficiencies to sponsors in form of an ''information request'' (IR) letter when each discipline has finished its initial review of its section of the pending application.

IX. DEFINITIONS AND EXPLANATION OF TERMS

A. The term ''review and act on'' is understood to mean the issuance of a complete action letter after the complete review of a filed complete application. The action letter, if it is not an approval, will set forth in detail the specific deficiencies and, where appropriate, the actions necessary to place the application in condition for approval.

B. A major amendment to an original application submitted within three months of the goal date extends the goal date by three months.

C. A resubmitted original application is a complete response to an action letter addressing all identified deficiencies.

D. Class 1 resubmitted applications are applications resubmitted after a complete response letter (or a not approvable or approvable letter) that include the following items only (or combinations of these items):

1. Final printed labeling;
2. Draft labeling;
3. Safety updates submitted in the same format, including tabulations, as the original safety submission with new data and changes highlighted (except when large amounts of new information including important new adverse experiences not previously reported with the product are presented in the resubmission);
4. Stability updates to support provisional or final dating periods;
5. Commitments to perform Phase 4 studies, including proposals for such studies;
6. Assay validation data;
7. Final release testing on the last 1–2 lots to support approval;
8. A minor reanalysis of data previously submitted to the application (determined by the agency as fitting the Class 1 category);
9. Other minor clarifying information (determined by the Agency as fitting the Class 1 category); and
10. Other specific items may be added later as the Agency gains experience with the scheme and will be communicated via guidance documents to industry.

E. Class 2 resubmissions are resubmissions that include any other items, including any item that would require presentation to an advisory committee.

F. A Type A Meeting is a meeting which is necessary for an otherwise stalled drug development program to proceed (a ''critical path'' meeting).

G. A Type B Meeting is a (1) pre-IND, (2) end of Phase 1 (for Subpart E or Subpart H or similar products) or end of Phase 2/pre-Phase 3, or (3) a pre-NDA/PLA/BLA meeting. Each requestor should usually only request 1 each of these Type B meetings for each potential application (NDA/PLA/BLA) (or combination of closely related products, i.e., same active ingredient but different dosage forms being developed concurrently).

H. A Type C Meeting is any other type of meeting.

I. The performance goals and procedures also apply to original applications and supplements for human drugs initially marketed on an over-the-counter (OTC) basis through an NDA or switched from prescription to OTC status through an NDA or supplement.●

TRIBUTE TO WILLIAM D. MOORE

● Mr. DODD. Mr. President, I want to take a moment to recognize the work of one of my constituents—William D. Moore of Old Saybrook, Connecticut. Bill left his post as Executive Director of the Southeastern Connecticut Chamber of Commerce this month and his work in that post deserves special recognition.

Bill has been at the helm of so many economic and development initiatives in the Southern portion of our state that it is hard to list all of them in this brief statement. But without a doubt, it is Bill's leadership through some of the most difficult economic times in our state that really stand out in my mind.

When the very first round of base closures were being proposed in the Pentagon in 1989, it was Bill Moore who literally marshaled the forces in Southern Connecticut. He recruited some of the most dynamic and brilliant minds in our state to come together and review every single document, every single calculation, and even the very computer model used to analyze the various Groton-New London regional facilities under the Defense Department's review. Bill created one of the most cohesive and effective team strategies ever presented to address the economic impact issues which clearly were not being assessed by the Pentagon.

Although not all of our efforts were successful, it was Bill's foresight and commanding presence that eventually led our team to victory in the fight to remove the New London Submarine Base from the Base Closure list in 1993. As a measure of credit, the Base Closure Commission belatedly admitted that the Navy's assumptions used to evaluate New London were flawed. Bill Moore was the man who first presented that information to the commission.

However, Bill's efforts have gone far beyond that monumental task. He has been the usher at the door of an entire new economic era for Southeastern Connecticut. Just as the defense downsizing efforts were taking their ravenous toll on our state and New London County in particular, Bill encouraged and fostered new development for our state and helped bring about a more level-headed transition for our heavily defense weighted economy. For example, he assisted in the appropriation of funds to rebuild the Connecticut State Pier and helped with the private-public partnerships that have rebuilt downtown New London. That was no small task.

During Bill's tenure, the membership of the Southeastern Chamber has more than doubled. Clearly, the contributions of those members have made New London County what it is today.

Finally, I would be remiss if I did not mention Bill's contributions during the creation and expansion of two of the most successful Indian gaming facilities in the hemisphere. Bill's unique skills and perseverence made this transition for our region a positive and inclusive process.

In closing, let me just add my personal thanks and congratulations to Bill and his family. I wish Bill and Maureen every success in their new endeavors.●

NATIONAL ACADEMY OF SCIENCES STUDY ON IMMIGRATION

● Mr. ABRAHAM. Mr. President, I rise today to discuss the National Academy of Sciences study on immigration that has received so much attention in the past year. This is a study the Senate Immigration Subcommittee held a hearing on this September featuring two of the principal authors of the report.

In releasing the study, the Academy stated quite clearly that ''Immigration benefits the U.S. economy overall and has little negative effect on the income and job opportunities of most native-born Americans.'' Moreover, the recent hearing showed that the study's findings were actually more positive than the initial press reports indicated.

Ronald Lee, a professor of demography and economics at the University of California at Berkeley who performed the key fiscal analysis for the Academy study, testified at the hearing that ''[The NAS] Panel asked how the arrival of an additional immigrant today would affect U.S. taxpayers. According to the report, over the long run an additional immigrant and all descendants would actually save the taxpayers $80,000.'' Lee notes that immigrant taxes ''help pay for government activities such as defense for which they impose no additional costs.'' Immigrants also ''contribute to servicing the national debt'' and are big net contributors to Social Security.

Critics of immigration cite only the study's figures on the annual costs immigrant households are said to impose on natives. However, Lee testified that ''These numbers do not best represent the Panel's findings, and should not be used for assessing the consequences of immigration policies.'' This is a pretty clear statement that citing the household cost figures to urge cuts in legal immigration is an improper use of the study's data.

The problem, Lee found, was that calculating annual numbers requires using an older model that counts the native-born children of immigrants as ''costs'' created by immigrant households when those children are in school, but fails to include the taxes paid by those children of immigrants once they complete their schooling, enter the work force, and become big tax contributors. The key fiscal analysis in the report, performed in Chapter