VII. MEETING MANAGEMENT GOALS

A. Responses to Meeting Requests

1. Procedure: Within 14 calendar days of the Agency's receipt of a request and meeting package from industry for a BPD Type 1 Meeting, or within 21 calendar days of the Agency's receipt of a request and meeting package from industry for a Biosimilar Initial Advisory Meeting or a BPD Type 2, 3, or 4 Meeting, as defined in section VIII(D–H), below, CBER and CDER should notify the requester in writing of the date, time, place, and format (i.e., a scheduled face-to-face, teleconference, or videoconference) for the meeting, as well as expected Center participants.

2. Performance Goal: FDA will provide this notification within 14 days for 90 percent of BPD Type 1 Meeting requests and within 21 days for 90 percent of Biosimilar Initial Advisory Meeting and BPD Type 2, 3 and 4 Meeting requests.

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.

a) Biosimilar Initial Advisory Meeting should occur within 90 calendar days of the Agency receipt of the sponsor-submitted meeting request and meeting package.

b) BPD Type 1 Meetings should occur within 30 calendar days of the Agency receipt of the sponsor-submitted meeting request and meeting package.

c) BPD Type 2 Meetings should occur within 75 calendar days of the Agency receipt of the sponsor-submitted meeting request and meeting package.

d) BPD Type 3 Meetings should occur within 120 calendar days of the Agency receipt of the sponsor-submitted meeting request and meeting package.

e) BPD Type 4 Meetings should occur within 60 calendar days of the Agency receipt of the sponsor-submitted meeting request and meeting package.

2. Performance goal:

For FY 2013, 70% of Biosimilar Initial Advisory Meetings and BPD Type 1–4 Meetings are held within the timeframe.

For FY 2014, 70% of Biosimilar Initial Advisory Meetings and BPD Type 1–4 Meetings are held within the timeframe.

For FY 2015, 80% of Biosimilar Initial Advisory Meetings and BPD Type 1–4 Meetings are held within the timeframe.

For FY 2016, 85% of Biosimilar Initial Advisory Meetings and BPD Type 1–4 Meetings are held within the timeframe.

For FY 2017, 90% of Biosimilar Initial Advisory Meetings and BPD Type 1–4 Meetings are held within the timeframe.

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: FDA will provide meeting minutes within 30 days of the date of the meeting for 90 percent of Biosimilar Initial Advisory Meetings and BPD Type 1–4 Meetings.

D. Conditions

For a meeting to qualify for these performance goals:

1. A written request (letter or fax) and supporting documentation (i.e., the meeting package) should be submitted to the appropriate review division or office. The request should provide:

a) A brief statement of the purpose of the meeting, the sponsor's proposal for the type of meeting, and the sponsor's proposal for a face-to-face meeting or a teleconference;

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 list of questions, grouped by discipline. For each question there should be a brief explanation of the context and purpose of the question.

e) A listing of planned external attendees; and

f) A listing of requested participants/disciplines representative(s) from the Center.

g) Suggested dates and times (e.g., morning or afternoon) for the meeting that are within or beyond the appropriate time frame of the meeting type being requested.

2. The Agency concurs that the meeting will serve a useful purpose (i.e., it is not premature or clearly unnecessary). However, requests for BPD Type 2, 3 and 4 Meetings will be honored except in the most unusual circumstances.

The Center may determine that a different type of meeting is more appropriate and it may grant a meeting of a different type than requested, which may require the payment of a biosimilar biological product development fee as described in section 744B of the Federal Food, Drug, and Cosmetic Act before the meeting will be provided. If a biosimilar biological product development fee is required under section 744B, and the sponsor does not pay the fee within the time frame required under section 744B, the meeting will be cancelled. If the sponsor pays the biosimilar biological product development fee after the meeting has been cancelled due to non-payment, the time frame described in section VII.A.1 will be calculated from the date on which FDA received the payment, not the date on which the sponsor originally submitted the meeting request.

Sponsors are encouraged to consult FDA to obtain further information on recommended meeting procedures.

3. FDA will develop and publish for comment draft guidance on Biosimilar Initial Advisory Meetings and BPD Type 1–4 Meetings by end of second quarter of FY 2014.

VIII. DEFINITIONS AND EXPLANATION OF TERMS

A. The term ''review and act on'' means 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. Goal Date Extensions for Major Amendments

1. A major amendment to an original application, supplement with clinical data, or resubmission of any of these applications, submitted at any time during the review cycle, may extend the goal date by three months.

2. A major amendment may include, for example, a major new clinical safety/efficacy study report; major re-analysis of previously submitted study(ies); submission of a risk evaluation and mitigation strategy (REMS) with elements to assure safe use (ETASU) not included in the original application; or significant amendment to a previously submitted REMS with ETASU. Generally, changes to REMS that do not include ETASU and minor changes to REMS with ETASU will not be considered major amendments.

3. A major amendment to a manufacturing supplement submitted at any time during the review cycle may extend the goal date by two months.

4. Only one extension can be given per review cycle.

5. Consistent with the underlying principles articulated in the GRMP guidance, FDA's decision to extend the review clock should, except in rare circumstances, be limited to occasions where review of the new information could address outstanding deficiencies in the application and lead to approval in the current review cycle.

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

D. A Biosimilar Initial Advisory Meeting is an initial assessment limited to a general discussion regarding whether licensure under section 351(k) of the Public Health Service Act may be feasible for a particular product, and, if so, general advice on the expected content of the development program. Such term does not include any meeting that involves substantive review of summary data or full study reports.

E. A BPD Type 1 Meeting is a meeting which is necessary for an otherwise stalled drug development program to proceed (e.g. meeting to discuss clinical holds, dispute resolution meeting), a special protocol assessment meeting, or a meeting to address an important safety issue.

F. A BPD Type 2 Meeting is a meeting to discuss a specific issue (e.g., proposed study design or endpoints) or questions where FDA will provide targeted advice regarding an ongoing biosimilar biological product development program. Such term includes substantive review of summary data, but does not include review of full study reports.

G. A BPD Type 3 Meeting is an in depth data review and advice meeting regarding an ongoing biosimilar biological product development program. Such term includes substantive review of full study reports, FDA advice regarding the similarity between the proposed biosimilar biological product and the reference product, and FDA advice regarding additional studies, including design and analysis.

H. A BPD Type 4 Meeting is a meeting to discuss the format and content of a biosimilar biological product application or supplement submitted under 351(k) of the PHS Act.

VIOLENCE AGAINST WOMEN REAUTHORIZATION ACT

Mr. LEAHY. Mr. President, I have been saying for weeks and months that we are overdue to pass into law the Leahy-Crapo Violence Against Women Reauthorization Act, which the Senate approved in April with 68 bipartisan votes. I am disappointed that the House still has not picked up this bipartisan effort and that we are not getting the job done this year. I want everyone to know that I will be back next year, and we will get it done.

Just yesterday we were reminded again why this legislation is so important. In Colorado, a man just released from jail on domestic violence charges shot his way into a house, murdering his ex-girlfriend, and her sister, and her sister's husband, before killing himself. We have seen enough horrific violence. It is past time to act.

The Leahy-Crapo bill would support the use of techniques proven to help identify high-risk cases and prevent domestic violence homicides. It will help

us go further to prevent domestic and sexual violence and to provide services and support to all victims.

For several weeks, I have been advocating a compromise on a key provision aimed at addressing the epidemic of domestic violence against native women. I want to compliment my partner on this bill, Senator CRAPO, who has been working hard to try to bridge the divide and address concerns with the provision in our bill that gives limited jurisdiction to tribal courts to make sure that no perpetrators of domestic violence are immune from prosecution. Senator CRAPO has pushed hard and has indicated a willingness to compromise significantly, as have I. Sadly, others have continued to draw lines which would ultimately deny assistance to some of the most vulnerable victims. That is unacceptable.

I appreciate that there have at last been some renewed discussions about this bill in the House of Representatives but that is not enough. The only way to reauthorize VAWA this year is for the House to take up and pass the Senate-passed bill. If the House Republican leadership refuses to do that in the final days of this Congress, it is a shame.

I remain steadfast in my resolve to get this done and pass a good VAWA bill that protects all victims. I know Senator CRAPO shares my resolve. I know every woman in the Senate and many other Senators and House members share our resolve. I know President Obama and Vice President BIDEN share our resolve.

We will be back next year. We will introduce a good bill, and we will pass it through the Senate. We will continue our discussions, and we will work tirelessly to have a good bill enacted into law. This is not the end of our efforts to renew and improve VAWA to more effectively help all victims of domestic and sexual violence.

We know that the epidemic of violence against native women is appalling, with a recent study finding that almost three in five native women have been assaulted by their spouses or intimate partners. We know that immigrant women are particularly vulnerable, with their immigration status another weapon that abusers can use to keep power and prevent reporting. We know that some victims cannot access needed services because of their sexual orientation or gender identity. We know that women and girls on college campuses are too much at risk, and more must be done to protect them. The list goes on.

We have shown a willingness to compromise but we must make progress on all of these issues. We must make things better, and never make things worse, for the most vulnerable of victims.

The community of advocates and service providers who work every day with victims of these terrible crimes is inspiring. It was their advice on the real needs of real victims that shaped this legislation, and they have fought with us every day to get this bill enacted. I want them to know how much I value the work they do and that I will not abandon their cause. We will continue working together, and we will reauthorize VAWA.

We have seen enough violence. If we cannot get the Leahy-Crapo bill over the finish line this year, we will come back next year, and we will get it done. I look forward to other Senators joining us as we continue this vital effort.

INVEST TAXPAYER DOLLARS IN WHAT WORKS

Ms. LANDRIEU. Mr. President, as Congress continues its work addressing our Nation's looming fiscal crisis, we must also remember that we have a responsibility to our taxpayers to improve outcomes for young people and their families by driving Federal funds more efficiently toward evidence-based, results-oriented solutions.

In August, I shared promising news from my home State, where evidence-based Federal programs, including the Social Innovation Fund, the Investing in Innovation Fund, and the High Quality Charter Schools Replication and Expansion Program, are improving education and other important outcomes for thousands of young people throughout Louisiana.

Bipartisan support for investing in what works has been growing for decades.

Under the George W. Bush administration, the Office of Management and Budget put a priority on improving the performance of Federal programs and encouraged more rigorous evaluations to assess their effectiveness.

In 2010, the Simpson-Bowles Commission Report, the ''National Commission on Fiscal Responsibility and Reform,'' specifically recommended urging all Federal agency heads to ''identify ways to shift from inefficient, unproductive spending to productive, results-based investment.''

And in May of this year, the Office of Management and Budget, OMB, instructed all Federal departments and agencies to demonstrate the use of evidence throughout their fiscal year 2014 budget submissions.

At a time when America is facing enormous social and economic shifts, budget constraints at all levels of government, significant demographic changes, and an increasingly globally competitive, changing workforce, our Federal Government must continue to drive public resources toward evidence-based, results-driven solutions that work.

I believe the following principles can serve as the foundation of an ''invest in what works'' agenda: develop and use a common evidence framework to inform program design and management; use evidence, data and information about performance to inform policy and drive continuous improvement in Federal programs and grantee interventions; promote innovation and flexibility and focus on outcomes rather than simply on compliance; increasingly target investments in interventions with the strongest evidence of effectiveness, as well as support the development and rigorous evaluation of promising, innovative interventions; and, seek opportunities to promote and invest in systems and communities that are collaborating to achieve significant community-wide impact or change at scale.

I would encourage the administration to incorporate these principles in its fiscal year 2014 budget request, and to consider reserving 1 percent of Federal program funds for independent, third-party evaluations. These recommendations, which are consistent with the 2010 Simpson-Bowles report and the 2012 OMB memo on evidence and evaluation, would provide Members of Congress with reliable information to gauge program effectiveness and drive continuous improvement.

In pursuing this approach, we should remain steadfastly focused on equity and serving children and families in greatest need. Done right, an ''invest in what works'' framework can advance an equity agenda. Competitive grants can augment and help maximize the impact of important formula funding. When designing such policies, we must prioritize grantees serving children and families most in need and leverage lessons learned to improve the impact of larger scale programs. Moreover, the Federal Government should make technical assistance a priority to potentially high-impact grantees—including rural grantees—that have less expertise in preparing Federal grant applications.

I am fully committed to working with my colleagues on both sides of the aisle to help improve outcomes for young people and their families through the development and implementation of an agenda that invests in what works.

NEWTOWN, CONNECTICUT TRAGEDY

Ms. KLOBUCHAR. Mr. President, I rise today with a heavy heart to express my deepest sympathy to the families of the 28 people who were murdered last week at Sandy Hook Elementary. These last few days have been immensely painful as our nation has mourned the loss of life and desperately searched for answers that might somehow explain such a senseless act of violence.

Like all Americans, my thoughts and prayers have been and continue to be with the students, teachers, and families. But my heart especially goes out to those mothers and fathers who lost their children. As a mother, I cannot even begin to fathom the depth of their anguish.

The murder of a child is the most heinous of crimes. But the mass murder of 20 children trapped in an elementary school is an act of unspeakable