SA 1054. Mr. FEINGOLD submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1055. Mr. DINN submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1056. Mr. REED (for himself and Mr. ISAKSON) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1057. Mr. GREGG submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1058. Mr. DEMINT (for himself, Mr. COBURN, and Mr. MARTINEZ) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1059. Mr. SESSIONS (for himself, Mrs. LINCOLN, Mr. FYROR, Mr. LOTZ, and Mr. SHEPPARD) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1060. Mr. HATCH (for himself and Mr. KENNEDY) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

**TEXT OF AMENDMENTS**

SA 1045. Mr. REID (for Mr. OBAMA) submitted an amendment intended to be proposed by Mr. Reid to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table.

SA 1046. Ms. STABENOW (for herself, Mr. KOHL, Mr. HATCH, and Mr. COBURN) submitted an amendment intended to be proposed by her to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1047. Mr. ROBERTS (for himself, Mr. HARKIN, Mr. BUSH, and Mr. COBURN) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1048. Ms. SNOWE submitted an amendment intended to be proposed by her to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1049. Mr. ENZI (for himself and Mr. KENNEDY) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1050. Mr. ENZI (for himself and Mr. KENNEDY) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1051. Mr. STEVENS (for himself and Ms. MUKOWSKI) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1052. Mr. CORKER submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1053. Mr. ENZI (for himself, Mr. KENNEDY, Mr. DOBB, and Mrs. CLINTON) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1054. Mr. FEINGOLD submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1055. Mr. DINN submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1056. Mr. REED (for himself and Mr. ISAKSON) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1057. Mr. GREGG submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1058. Mr. DEMINT (for himself, Mr. COBURN, and Mr. MARTINEZ) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1059. Mr. SESSIONS (for himself, Mrs. LINCOLN, Mr. FYROR, Mr. LOTZ, and Mr. SHEPPARD) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1060. Mr. HATCH (for himself and Mr. KENNEDY) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

**TEXT OF AMENDMENTS**

SA 1045. Mr. REID (for Mr. OBAMA) submitted an amendment intended to be proposed by Mr. Reid to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

**SEC. 2. IMPROVING GENETIC TEST SAFETY AND QUALITY.**

Not later than 30 days after the date of enactment of this Act, the Secretary shall enter into a contract with the Institute of Medicine to conduct a study to assess the overall safety and quality of genetic tests and prepare a report that includes recommendations to improve Federal oversight and regulation. Such study shall take into consideration relevant reports by the Secretary’s Advisory Committee on Genetic Testing and other groups and shall be complete not later than 1 year after the date on which the Secretary entered into such contract.

**SA 1046. Ms. STABENOW (for herself, Mr. KOHL, Mr. HATCH, and Mr. COBURN) submitted an amendment intended to be proposed by her to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:**

At the appropriate place, insert the following:

**SEC. 3. CITIZENS PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.**

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by this Act, is amended by adding at the end the following:

"(g) Citizen Petitions and Petitions for Stay of Agency Action.—

(i) In general.—With respect to a pending application submitted under subsection (b)(2) or (j), if a petition is submitted to the Secretary that seeks to have the Secretary order the FDA to refrain from taking any form of action relating to the approval of the application, including a delay in the effective date of the application, clauses (ii) and (iii) shall apply.

(ii) No delay of consideration or approval.—Except as provided in clause (iii), the receipt and consideration of a petition submitted under subsection (b)(2) or (j) while a petition described in clause (i) is considered unless the Secretary determines, not later than 25 business days after the submission of the petition, that a delay is necessary to protect the public health.

(b) Determination of delay.—With respect to a determination by the Secretary under subparagraph (A)(iii) that a delay is necessary to protect the public health the following shall apply:

(i) Not later than 5 days after making such determination, the Secretary shall publish on the Internet website of the Food and Drug Administration a detailed statement providing the reasons underlying the determination. The detailed statement shall include a summary of the petition and any clarifications and additional data that is needed by the Secretary to promptly resolve the petition.

(ii) Not later than 10 days after making such determination, the Secretary shall provide notice to the sponsor of the pending application submitted under subsection (b)(2) or (j) and provide an opportunity for a meeting with appropriate staff as determined by the Commissioner to discuss the determination.

(c) Timing of final agency action on petitions.—

(i) In general.—Notwithstanding a determination made by the Secretary under paragraph (1)(A)(iii), the Secretary shall take final agency action with respect to a pending application submitted under subsection (b)(2) or (j) while a petition described in clause (i) is considered unless the Secretary determines, prior to the date that is 180 days after the date of submission of the petition, that a delay is necessary to protect the public health.

(ii) Determination of delay.—With respect to a determination by the Secretary under paragraph (1)(A)(iii) that a delay is necessary to protect the public health the following shall apply:

(i) Not later than 5 days after making the determination under subsection (b)(2) or (j), the Secretary shall publish on the Internet website of the Food and Drug Administration a detailed statement providing the reasons underlying the determination. The detailed statement shall include a summary of the petition and any clarifications and additional data that is needed by the Secretary to promptly resolve the issues, and any additional information that has been requested by the Secretary of the petitioner or needed by the Secretary in order to consider the petition and an application submitted under subsection (b)(2) or (j).