SENATE RESOLUTION 278—DESIGNATING OCTOBER 2013 AS ''SCHOOL BUS SAFETY MONTH''

Mr. THUNE (for himself and Mr. ROCKEFELLER) submitted the following resolution; which was considered and agreed to.:

S. RES. 278

Whereas approximately 450,000 public and private school buses carry 26,000,000 children to and from school every weekday in the United States;

Whereas America's 450,000 public and private school buses comprise the largest mass transportation fleet in the Nation;

Whereas during the school year, school buses make more than 55,000,000 passenger trips daily and students ride these school buses 10,000,000,000 times per year as the Nation's fleet travels over 4,000,000,000 miles per school year;

Whereas school buses are designed to be safer than passenger vehicles and are 13 times safer than other modes of school transportation, and 44 times safer than vehicles driven by teenagers;

Whereas in an average year, about 25 school children are killed in school bus accidents, with one-third of these children struck by their own school buses in loading/unloading zones, one-third struck by motorists who fail to stop for school buses, and one-third killed as they approach or depart a school bus stop;

Whereas The Child Safety Network, celebrating 25 years of national public service, has collaborated with the school bus industry to create public service announcements to reduce distracted driving near school buses, increase ridership, and provide free resources to school districts in order to increase driver safety training, provide free technology for tracking school buses, and educate students; and

Whereas the adoption of School Bus Safety Month will allow broadcast and digital media and social networking industries to make commitments to disseminate public service announcements designed to save children's lives by making motorists aware of school bus safety issues: Now, therefore, be it

Resolved, That the Senate designates October 2013 as ''School Bus Safety Month''.

AMENDMENTS SUBMITTED AND PROPOSED

SA 2007. Mrs. GILLIBRAND submitted an amendment intended to be proposed by her to the bill H.R. 3204, to amend the Federal Food, Drug, and Cosmetic Act with respect to human drug compounding and drug supply chain security, and for other purposes; which was ordered to lie on the table.

SA 2008. Mrs. GILLIBRAND submitted an amendment intended to be proposed by her to the bill H.R. 3204, supra; which was ordered to lie on the table.

TEXT OF AMENDMENTS

SA 2007. Mrs. GILLIBRAND submitted an amendment intended to be proposed by her to the bill H.R. 3204, to amend the Federal Food, Drug, and Cosmetic Act with respect to human drug compounding and drug supply chain security, and for other purposes; which was ordered to lie on the table; as follows:

At the end, add the following:

TITLE III—USE OF ANTIMICROBIAL DRUGS IN FOOD ANIMALS

SEC. 301. SHORT TITLE.

This title may be cited as the ''Delivering Antimicrobial Transparency in Animals Act of 2013''.

SEC. 302. PURPOSE.

The purpose of this title is to provide the Food and Drug Administration and the public with better information on the use of antimicrobial drugs in animals used for food to—

(1) enable public health officials and scientists to better understand and interpret trends and variations in rates of microbial resistance to such antimicrobial drugs;

(2) improve the understanding of the relationship between antimicrobial drug use in animals used for food and antimicrobial drug resistance in microbes in and on animals and humans; and

(3) identify interventions to prevent and control such antimicrobial drug resistance.

SEC. 303. RESEARCH PROGRAMS TO STUDY ANTIMICROBIAL RESISTANCE.

(a) DEFINITIONS.—In this title—

(1) the term ''Commissioner'' means the Commissioner of Food and Drugs; and

(2) the term ''Secretary'' means the Secretary of Health and Human Services.

(b) ESTABLISHMENT OF PROGRAMS.—The Secretary, acting through the Commissioner, shall develop a research program or programs to study the relationship between the sales, distribution, end-use practices of animal drugs containing an antimicrobial active ingredient in food-producing animals and antimicrobial resistance trends.

(c) PURPOSE OF PROGRAMS.—Any research program developed under subsection (b) shall be developed in order to better determine—

(1) the relationships between sales data, distribution data, and end-usage data of animal drugs containing an antimicrobial active ingredient in food-producing animals to inform policies of Food and Drug Administration regarding data collection and regulation of antimicrobial products in agriculture, including consideration of the potential value of data from veterinary feed directives; and

(2) the relationships between antimicrobial resistance and use of animal drugs containing an antimicrobial active ingredient in food-producing animals and trends in antimicrobial resistance, including by using the data collected through the National Antimicrobial Resistance Monitoring Program or other studies regarding resistance levels in bacteria associated with food-producing animals.

(d) CONSULTATION.—Any research program developed under subsection (b) shall be developed in consultation with the Under Secretary for Food Safety, the Under Secretary for Marketing and Regulatory Programs, and the Under Secretary for Research, Education, and Economics at the Department of Agriculture. To the extent practicable, such Under Secretaries shall provide assistance in developing and conducting such research programs.

(e) IMPLEMENTATION.—Not later than 1 year after the date of enactment of this Act, the Secretary shall implement the research program or programs developed under subsection (b). The Secretary shall analyze data from such program or programs to determine the contribution of such data to studying antimicrobial resistance, protecting public health, and establishing the coordinated data collection strategy as described in section 305.

(f) PUBLICATION.—The Secretary shall publish the results of any research program developed under this section as soon as practicable.

SEC. 304. ENHANCED REPORTING AND PUBLICATION OF SALES DATA.

(a) IN GENERAL.—Section 512(l)(3)(E)) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(l)(3)(E)) is amended—

(1) by redesignating clauses (i) and (ii) as subclauses (I) and (II);

(2) by striking ''The Secretary shall make summaries of the information reported under this paragraph publicly available, except that—'' and inserting ''(i) Not later than a date established by the Secretary for 2014, and on such date in each year thereafter, the Secretary shall make publicly available a summary of the information (including dosage form information, if practicable) reported under this paragraph for the previous year, except that—''; and

(3) by inserting after subclause (II), as redesignated by paragraph (1), the following:

''(ii) In making the summaries available under this subparagraph, the following shall apply:

''(I) The Secretary shall segregate the categories of amounts reported into the following 2 subcategories, after consultation with the applicable classifications of the World Health Organization:

''(aa) The volume of drugs of importance to human medicine.

''(bb) The volume of drugs not of importance to human medicine.

''(II) As practicable, the Secretary shall segregate amounts reported into the following 2 amounts:

''(aa) The volume of drugs labeled or eligible for use in food-producing animals.

''(bb) The volume of drugs that are not labeled or are ineligible for use in food-producing animals.

''(III) In any cross-tabulation of the amounts reported with any reporting category, the Secretary shall include the categories 'Not Independently Reported' and 'Not Independently Reported Export'.''.

(b) REISSUANCE.—Not later than 3 years after the date of enactment of this Act, the Secretary shall reissue the summary reports issued before 2012 under section 512(l)(3)(E) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(l)(3)(E)) using the format designed for the 2012 summary report. The Secretary shall publish the reissued reports in one combined publication.

SEC. 305. IMPLEMENTATION AND PUBLICATION OF ANTIMICROBIAL RESISTANCE DATA COLLECTION STRATEGY.

(a) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, the Secretary, acting through the Commissioner, shall implement an Antimicrobial Data Collection Strategy, based on information received in the comments to the Advanced Notice of Proposed Rulemaking entitled ''Antimicrobial Animal Drug Distribution Reporting''(77 Fed. Reg. 44177 (July 27, 2012)) and any research program developed under section 303.

(b) REEVALUATION.—Not less than every 5 years after the implementation of the Antimicrobial Data Collection Strategy under subsection (a), the Secretary shall reevaluate such Strategy and propose modifications as such Secretary determines appropriate, based on scientific data.

(c) AVAILABILITY.—The Secretary shall—

(1) submit to Congress the Strategy implemented under subsection (a), and any modification made to such Strategy pursuant to subsection (b); and

(2) make such Strategy and any such modification available to the public.

SEC. 306. ACTION BY GOVERNMENT ACCOUNTABILITY OFFICE.

(a) PUBLICATION OF FINAL GUIDANCE.—Not later than 180 days after the date of enactment of this Act, the Secretary shall publish

a final version of the draft Voluntary Guidance #213 of the Food and Drug Administration (entitled ''New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209'').

(b) REPORT BY GAO.—

(1) IN GENERAL.—Not later than 3 years after the publication of the final guidance described in subsection (a), the Comptroller General of the United States shall commence a study to evaluate—

(A) the voluntary approach used by the Food and Drug Administration to eliminate injudicious use of antimicrobial drugs in food-producing animals; and

(B) the effectiveness of the data collection activities conducted by the Food and Drug Administration regarding antimicrobial resistance.

(2) REPORT.—Not later than 1 year after commencing the study described in paragraph (1), the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes the results of such study.

SA 2008. Mrs. GILLIBRAND submitted an amendment intended to be proposed by her to the bill H.R. 3204, to amend the Federal Food, Drug, and Cosmetic Act with respect to human drug compounding and drug supply chain security, and for other purposes; which was ordered to lie on the table; as follows:

At the end, add the following:

TITLE III—PATIENT MEDICATION INFORMATION FOR PRESCRIPTION DRUGS

SEC. 301. SHORT TITLE.

This title may be cited as the ''Cody Miller Initiative for Safer Prescriptions Act''.

SEC. 302. PATIENT MEDICATION INFORMATION FOR PRESCRIPTION DRUGS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505E the following:

''SEC. 505F. PATIENT MEDICATION INFORMATION FOR PRESCRIPTION DRUGS.

''(a) IN GENERAL.—Not later than 2 years after the date of enactment of this section, the Secretary shall issue regulations regarding the authorship, content, format, and dissemination requirements for patient medication information (referred to in this section as 'PMI') for drugs subject to section 503(b)(1).

''(b) CONTENT.—The regulations promulgated under subsection (a) shall require that the PMI with respect to a drug—

''(1) be scientifically accurate and based on the professional labeling approved by the Secretary and authoritative, peer-reviewed literature; and

''(2) includes nontechnical, understandable, plain language that is not promotional in tone or content, and contains at least—

''(A) the established name of drug, including the established name of such drug as a listed drug (as described in section 505(j)(2)(A)) and as a drug that is the subject of an approved abbreviated new drug application under section 505(j) or of an approved license for a biological product submitted under section 351(k) of the Public Health Service Act, if applicable;

''(B) drug uses and clinical benefits;

''(C) general directions for proper use;

''(D) contraindications, common side effects, and most serious risks of the drug, especially with respect to certain groups such as children, pregnant women, and the elderly;

''(E) measures patients may be able to take, if any, to reduce the side effects and risks of the drug;

''(F) when a patient should contact his or her health care professional;

''(G) instructions not to share medications, and, if any exist, key storage requirements, and recommendations relating to proper disposal of any unused portion of the drug; and

''(H) known clinically important interactions with other drugs and substances.

''(c) TIMELINESS, CONSISTENCY, AND ACCURACY.—The regulations promulgated under subsection (a) shall include standards related to—

''(1) performing timely updates of drug information as new drugs and new information becomes available;

''(2) ensuring that common information is applied consistently and simultaneously across similar drug products and for drugs within classes of medications in order to avoid patient confusion and harm; and

''(3) developing a process, including consumer testing, to assess the quality and effectiveness of PMI in ensuring that PMI promotes patient understanding and safe and effective medication use.

''(d) ELECTRONIC REPOSITORY.—The regulations promulgated under subsection (a) shall provide for the development of a publicly accessible electronic repository for all PMI documents and content to facilitate the availability of PMI.''.

SEC. 303. PUBLICATION ON INTERNET WEBSITE.

The Secretary of Health and Human Services shall publish on the Internet website of the Food and Drug Administration a link to the Daily Med website (http://dailymed.nlm.nih.gov/dailymed) (or any successor website).

AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON FINANCE

Mr. UDALL of Colorado. Mr. President, I ask unanimous consent that the Committee on Finance be authorized to meet during the session of the Senate on October 30, 2013, at 11 a.m., in room SD–215 of the Dirksen Senate Office Building, to conduct a hearing entitled ''The Transatlantic Trade and Investment Partnership: Achieving the Potential.''

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

Mr. UDALL of Colorado. Mr. President, I ask unanimous consent that the Committee on Health, Education, Labor, and Pensions be authorized to meet during the session of the Senate on October 30, 2013, at 9:15 a.m., in room SD–430 of the Dirksen Senate Office Building.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON INDIAN AFFAIRS

Mr. UDALL of Colorado. Mr. President, I ask unanimous consent that the Committee on Indian Affairs be authorized to meet during the session of the Senate on October 30, 2013, at 2:30 p.m., in room SD–628 of the Dirksen Senate Office Building.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON THE JUDICIARY

Mr. UDALL of Colorado. Mr. President, I ask unanimous consent that the Committee on the Judiciary be authorized to meet during the session of the Senate on October 30, 2013, at 2:30 p.m., in room SD–226 of the Dirksen Senate Office Building, to conduct a hearing entitled ''Nominations.''

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON VETERANS' AFFAIRS

Mr. UDALL of Colorado. Mr. President, I ask unanimous consent that the Committee on Veterans' Affairs be authorized to meet during the session of the Senate on October 30, 2013, at 2 p.m., in room SR–418 of the Russell Senate Office Building.

The PRESIDING OFFICER. Without objection, it is so ordered.

SUBCOMMITTEE ON SECURITIES, INSURANCE, AND INVESTMENT

Mr. UDALL of Colorado. Mr. President, I ask unanimous consent that the Committee on Banking, Housing, and Urban Affairs Subcommittee on Securities, Insurance, and Investment be authorized to meet during the session of the Senate on October 30, 2013, at 10 a.m., to conduct a hearing entitled ''The Jobs Act at a Year and a Half: Assessing Progress and Unmet Opportunities.''

The PRESIDING OFFICER. Without objection, it is so ordered.

PRIVILEGES OF THE FLOOR

Mr. LEVIN. Mr. President, on behalf of Senator MENENDEZ, I ask unanimous consent that Christopher Landberg, a detailee from the State Department and the Foreign Relations Committee, be granted floor privileges for the consideration of the nomination of Jacob Lew.

The PRESIDING OFFICER. Without objection, it is so ordered.

JOINT REFERRAL—RHEA SUN SUH NOMINATION

Mr. REID. Mr. President, I ask unanimous consent as in executive session that the nomination of Rhea Sun Suh, of Colorado, to be Assistant Secretary for Fish and Wildlife, sent to the Senate by the President on October 30, 2013, be referred jointly to the Committee on Energy and Natural Resources and the Committee on Environment and Public Works.

The PRESIDING OFFICER. Without objection, it is so ordered.

CHIMP ACT AMENDMENTS OF 2013

Mr. REID. Mr. President, I ask unanimous consent that the Senate proceed to the consideration of Calendar No. 228, S. 1561.

The PRESIDING OFFICER. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (S. 1561) to amend the Public Health Service Act to improve provisions relating