AMENDMENT NO._____ Calendar No._____

Purpose: To direct to Secretary of Health and Human Services to develop a standardized protocol for obtaining informed consent from an older individual with dementia prior to administering an antipsychotic to the individual for a use not approved by the Food and Drug Administration and to provide for the implementation of prescriber education programs.

IN THE SENATE OF THE UNITED STATES—112th Cong., 2d Sess.

S. 3187

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by

_____

Viz:

At the end of title XI, add the following:

SEC. 11____. STANDARDIZED PROTOCOL FOR OBTAINING INFORMED CONSENT FROM AN OLDER INDIVIDUAL WITH DEMENTIA PRIOR TO ADMINISTERING AN ANTIPSYCHOTIC FOR A USE NOT APPROVED BY THE FOOD AND DRUG ADMINISTRATION.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

"SEC. 399V–6. STANDARDIZED PROTOCOL FOR OBTAINING INFORMED CONSENT FROM AN OLDER INDIVIDUAL WITH DEMENTIA PRIOR TO ADMINISTERING AN ANTIPSYCHOTIC FOR A USE NOT APPROVED BY THE FOOD AND DRUG ADMINISTRATION.

''(a) PROTOCOL.—Not later than 180 days after the date of the enactment of this section, the Secretary shall develop a standardized protocol for designated health care providers to obtain informed consent from an older individual with dementia prior to administering an antipsychotic to the individual for a use not approved by the Food and Drug Administration. Such protocol shall include an alternative protocol for obtaining such informed consent in the case of emergencies.

''(b) DEFINITION OF INFORMED CONSENT.—In this section, the term 'informed consent' means, with respect to an older individual with dementia, that—

''(1) the health care provider has informed the individual (or, if applicable, the individual's designated health care agent or legal representative) of—

''(A) possible side effects and risks associated with the antipsychotic;

''(B) treatment modalities that were attempted prior to the use of the antipsychotic; and

''(C) any other information the Secretary determines appropriate;

''(2) the individual (or, if applicable, the individual's designated health care agent or legal representative) has provided authorization for the administration of the antipsychotic; and

''(3) the administration of the antipsychotic is in accordance with any plan of care that the individual has in place, including non-pharmacological interventions as appropriate that can effectively address underlying medical and environmental causes of behavioral disorders.''.

SEC. 11___. PRESCRIBER EDUCATION PROGRAMS.

(a) IN GENERAL.—Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.), as amended by section 11__, is amended by adding at the end the following:

"SEC. 399V–7. PRESCRIBER EDUCATION PROGRAMS.

''(a) IN GENERAL.—The Secretary, acting through the Director of the Agency for Healthcare Research and Quality and in consultation with the Commissioner of Food and Drugs, shall establish and implement prescriber education programs.

''(b) IMPLEMENTATION.—The Secretary shall establish and begin implementation of prescriber education programs under this section by not later than 6 months after the date on which funds are first made available under section 3734 of title 31, United States Code.

''(c) PRESCRIBER EDUCATION PROGRAM DEFINED.—In this section, the term 'prescriber education program' means a program to promote high quality evidence-based treatment and non-pharmacological interventions through the provision of objective, educational, and informational materials to physicians and other prescribing practitioners, including such a program developed by the Agency for Healthcare Research and Quality.''.

(b) FUNDING.—

(1) IN GENERAL.—Chapter 37 of title 31, United States Code, is amended by adding at the end the following:

"SEC. 3734. FUNDING FOR PRESCRIBER EDUCATION PROGRAMS.

''(a) FUNDING.—In each fiscal year, the Attorney General may make some portion of the covered funds paid to the United States in that fiscal year available for prescriber education programs in accordance with section 399V–7 of the Public Health Service Act.

''(b) DEFINITIONS.—In this section:

''(1) COVERED FUNDS.—The term 'covered funds' means all funds payable to the United States Government from any judgement or settlement of a civil action brought by the Attorney General under section 3730 of this title, relating to off-label marketing of any prescription drug.

''(2) OFF-LABEL MARKETING.—The term 'off-label marketing' means the marketing of a prescription drug for an indication or use in a manner for which the drug has not been approved by the Food and Drug Administration.''.