AMENDMENT NO._____ Calendar No._____

Purpose: To implement an opioid action plan.

IN THE SENATE OF THE UNITED STATES—114th Cong., 2d Sess.

S. 524

To authorize the Attorney General to award grants to address the national epidemics of prescription opioid abuse and heroin use.

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 I of the bill, add the following:

SEC. 104. OPIOID ACTION PLAN.

(a) NEW DRUG APPLICATION.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

''(y) ADVISORY COMMITTEE FOR APPROVAL OF NEW DRUG OPIOIDS.—Notwithstanding any other provision of this Act, the Secretary shall convene an expert advisory committee to review an application submitted under subsection (b) or (j) for a new drug that is an opioid before the Secretary may approve such application.''.

(b) PEDIATRIC OPIOID LABELING.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended by adding at the end the following:

''(q) PEDIATRIC OPIOID LABELING.—Beginning on the date of enactment of the Comprehensive Addiction and Recovery Act of 2015 and notwithstanding any other provision of this Act, the Secretary shall require the Pediatric Advisory Committee to make recommendations regarding a framework for pediatric opioid labeling before the Secretary may approve a new label for a drug intended for pediatric use that is an opioid.''.

(c) CONTINUING MEDICAL EDUCATION FOR PRESCRIBERS OF OPIOIDS.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with the Commissioner of Food and Drugs, shall develop recommendations on what continuing medical education programs that prescribers of opioids should be required to take and how often.

(d) GUIDANCE.—Not later than 1 year after the date of enactment of this Act, the Commissioner of Food and Drugs shall issue guidance on approval standards for generic abuse-deterrent formulations of opioids.