Mike Braun
Amendment #1

AMENDMENT NO._____ Calendar No._____

Purpose: To require the Commissioner of Food and Drugs to convene a meeting to review the use of the enriched enrollment randomized withdrawal methodology in clinical trials of opioid analgesic drugs.

IN THE SENATE OF THE UNITED STATES—118th Cong., 1st Sess.

S. 3393

To reauthorize the SUPPORT for Patients and Communities Act, 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 Mr. BRAUN

Viz:

At the appropriate place in title I, insert the following:

SEC. ___. CONSIDERATION OF ENRICHED ENROLLMENT RANDOMIZED WITHDRAWAL METHODOLOGY.

(a) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the Commissioner of Food and Drugs, shall convene a meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee of the

Food and Drug Administration to review the use of the enriched enrollment randomized withdrawal methodology in clinical trials of opioid analgesic drugs and consider and make recommendations regarding the use of alternative clinical study methodologies. In conducting such review, the Secretary shall consider the report issued by the National Academy of Sciences under subsection (c).

(b) PRESENTATIONS.—If the Secretary allows for formal presentations in support of the use of the enriched enrollment randomized withdrawal methodology at the meeting described in subsection (a), the Secretary shall also allow for equal time at such meeting for presentations that are critical of such methodology.

(c) NAS STUDY AND REPORT.—The Secretary shall seek to enter into a contract with the National Academy of Sciences under which the National Academy—

(1) conducts a study on the effectiveness of enriched enrollment randomized withdrawal methodology in demonstrating the efficacy of opioid analgesic drugs in treating chronic pain; and

(2) not later than 1 year after the date of enactment of this Act, submits a report on such study to the Secretary.

(d) REVIEW OF OPIOID ANALGESIC DRUGS.—In connection with the meeting described in subsection (a), the

Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee of the Food and Drug Administration shall review the approved labeling and action package for approval (as described in subsection (l)(2) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)), on all opioid analgesic drugs approved using enriched enrollment randomized withdrawal methodology under such section 505 as of the date of such meeting. The findings from such review shall be made publicly available on a website operated by the Secretary, acting through the Commissioner of Food and Drugs.

(c) DEFINITION OF OPIOID ANALGESIC DRUG.—In this section, the term "opioid analgesic drug" means a drug that has a labeled indication approved by the Food and Drug Administration to produce analgesia by acting upon the body's opioid receptors.