

S.L.C.  
*Mike Braun*  
*Amendment #2*

AMENDMENT NO. \_\_\_\_\_ Calendar No. \_\_\_\_\_

Purpose: To allow the Secretary of Health and Human Services to consider whether applications for opioid analgesic drugs demonstrate a substantial improvement over another opioid analgesic drug.

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 (for  
himself and Ms. BALDWIN)

Viz:

1 At the appropriate place, insert the following:

2 **SEC. \_\_\_\_ . APPROVAL OF NEW OPIOID ANALGESIC DRUGS.**

3 Section 505(c) of the Federal Food, Drug, and Cos-  
4 metic Act (21 U.S.C. 355(c)) is amended by adding at  
5 the end the following:

6 “(6) Notwithstanding any other provision of this sec-  
7 tion, in making a determination to approve or deny an  
8 application submitted under subsection (b) for an opioid  
9 analgesic drug, the Secretary may consider whether such  
10 drug provides a substantial improvement, in terms of

1 greater safety or greater effectiveness, or major contribu-  
2 tion to patient care, compared to an approved opioid an-  
3 algesic drug. For purposes of this paragraph, the term  
4 'opioid analgesic drug' means a drug that is approved  
5 under this section to produce analgesia by acting upon the  
6 body's opioid receptors.”.