115TH CONGRESS
2D SESSION

H. R. 5806

To require the Secretary of Health and Human Services to issue guidance
with respect to the expedited approval of certain drugs, and for other
purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 15, 2018

Mr. BURGESS (for himself, Mr. BUCSHON, and Mr. GRIFFITH) introduced the
following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To require the Secretary of Health and Human Services
to issue guidance with respect to the expedited approval
of certain drugs, and for other purposes.

1   *Be it enacted by the Senate and House of Representa-*

2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4   This Act may be cited as the "21st Century Tools

5 for Pain and Addiction Treatment Act".

6 **SEC. 2. CLARIFYING FDA REGULATION OF NON-ADDICTIVE**

7   **PAIN AND ADDICTION THERAPIES.**

8   (a) PUBLIC MEETINGS.—Not later than 1 year after

9 the date of enactment of this Act, the Secretary of Health

1 and Human Services, acting through the Commissioner of

2 Food and Drugs, shall hold not less than one public meet-

3 ing to address the challenges and barriers of developing

4 non-addictive medical products intended to treat pain or

5 addiction, which may include—

6　　　(1) the application of novel clinical trial designs

7　　　(consistent with section 3021 of the 21st Century

8　　　Cures Act (Public Law 114–255)), use of real world

9　　　evidence (consistent with section 505F of the Fed-

10　　　eral Food, Drug, and Cosmetic Act (21 U.S.C.

11　　　355g)), and use of patient experience data (con-

12　　　sistent with section 569C of the Federal Food,

13　　　Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c)) for

14　　　the development of non-addictive medical products

15　　　intended to treat pain or addiction; and

16　　　(2) the application of eligibility criteria under

17　　　sections 506 and 515B of the Federal Food, Drug,

18　　　and Cosmetic Act (21 U.S.C. 356, 360e–3) for non-

19　　　addictive medical products intended to treat pain or

20　　　addiction.

21 (b) GUIDANCE.—Not later than one year after the

22 public meetings are conducted under subsection (a) the

23 Secretary shall issue one or more final guidance docu-

24 ments, or update existing guidance documents, to help ad-

25 dress challenges to developing non-addictive medical prod-

ucts to treat pain or addiction. Such guidance documents
shall include information regarding—

    (1) how the Food and Drug Administration
may apply sections 506 and 515B of the Federal
Food, Drug, and Cosmetic Act (21 U.S.C. 356,
360e–3) to non-addictive medical products intended
to treat pain or addiction, including the cir-
cumstances under which the Secretary—

        (A) may apply the eligibility criteria under
such sections 506 and 515B to non-opioid or
non-addictive medical products intended to
treat pain or addiction;

        (B) considers the risk of addiction of con-
trolled substances approved to treat pain when
establishing unmet medical need; and

        (C) considers pain, pain control, or pain
management in assessing whether a disease or
condition is a serious or life-threatening disease
or condition; and

    (2) the methods by which sponsors may evalu-
ate acute and chronic pain, endpoints for non-addict-
ive medical products intended to treat pain, the
manner in which endpoints and evaluations of effi-
cacy will be applied across and within review divi-
sions, taking into consideration the etiology of the

1   underlying disease, and the manner in which spon-

2   sors may use surrogate endpoints, intermediate

3   endpoints, and real world evidence.

4   (c) MEDICAL PRODUCT DEFINED.—In this section,

5 the term "medical product" means a drug (as defined in

6 section 201(g)(1) of the Federal Food, Drug, and Cos-

7 metic Act (21 U.S.C. 321(g)(1))), biological product (as

8 defined in section 351(i) of the Public Health Service Act

9 (42 U.S.C. 262(i))), or device (as defined in section

10 201(h) of the Federal Food, Drug, and Cosmetic Act (21

11 U.S.C. 321(h))).

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