

116TH CONGRESS  
2D SESSION

# S. 4253

To amend the Federal Food, Drug, and Cosmetic Act with respect to the listing of patents in the Orange Book.

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## IN THE SENATE OF THE UNITED STATES

JULY 21, 2020

Mrs. MURRAY (for herself and Mr. CORNYN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the listing of patents in the Orange Book.

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 “Second Look at Drug  
5 Patents Act of 2020”.

6 **SEC. 2. AMENDMENTS.**

7 Section 505 of the Federal Food, Drug, and Cosmetic  
8 Act (21 U.S.C. 355) is amended—

9 (1) in subsection (b)(1), in the fifth sentence,  
10 by inserting “, subject to the conditions under sub-

1 section (j)(7)(A)(iii)(II) being met” before the pe-  
2 riod;

3 (2) in subsection (c)(2), at the end of the third  
4 sentence, by inserting “subject to the conditions  
5 under subsection (j)(7)(A)(iii)(II) being met” before  
6 the period; and

7 (3) in subsection (j)(7)(A)(iii)—

8 (A) by striking “When patent” and insert-  
9 ing “(I) When patent”;

10 (B) by inserting “, subject to subclause  
11 (II),” after “, include”; and

12 (C) by adding at the end the following:

13 “(II) The Secretary shall include patent infor-  
14 mation on the list pursuant to subclause (I) if the  
15 following conditions are met:

16 “(aa) If the patent has been issued as of  
17 the date on which the application is approved  
18 under subsection (c), the sponsor, within 30  
19 days of the date of such approval, shall submit  
20 to the Under Secretary of Commerce for Intel-  
21 lectual Property and Director of the United  
22 States Patent and Trademark Office (referred  
23 to in this clause as the ‘Director’) a notification  
24 that the sponsor has filed with the Secretary in-

1           formation about the patent as required under  
2           subsection (b)(1) or (c)(2), as applicable.

3           “(bb) If the patent is issued after the date  
4           on which the application is approved under sub-  
5           section (c), the sponsor, not later than 30 days  
6           after the date on which the patent is issued,  
7           shall submit to the Director a notification that  
8           the sponsor has filed with the Secretary infor-  
9           mation about the patent as required under sub-  
10          section (c)(2).

11          “(cc) Upon receipt of a notification under  
12          item (aa) or (bb), as applicable, the Director  
13          shall publish, not later than 30 days of such re-  
14          ceipt, in the Official Gazette of the United  
15          States Patent and Trademark Office, and on an  
16          internet website that the Director shall estab-  
17          lish, maintain, and operate, a notification with  
18          respect to the patent, requesting that any per-  
19          son that is eligible to file a request described in  
20          section 311(b) of title 35, United States Code,  
21          file such a request.”.

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