

117TH CONGRESS
1ST SESSION

S. 3327

To amend the Controlled Substances Act to require the Attorney General to make procurement quotas for opioid analgesics publicly available, and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 7, 2021

Mr. MARKEY (for himself, Mr. MANCHIN, Mr. BROWN, and Mr. DURBIN) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

A BILL

To amend the Controlled Substances Act to require the Attorney General to make procurement quotas for opioid analgesics publicly available, 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 “Opioid Quota Open-
5 ness, Transparency, and Awareness Act of 2021” or the
6 “Opioid QuOTA Act of 2021”.

1 **SEC. 2. PUBLIC REPORTING OF PROCUREMENT QUOTAS**
2 **FOR OPIOID ANALGESICS.**

3 (a) IN GENERAL.—Section 306 of the Controlled
4 Substances Act (21 U.S.C. 826) is amended by adding at
5 the end the following:

6 “(j)(1) In this subsection, the term ‘opioid procure-
7 ment quota’ means a quota established by the Attorney
8 General for the quantity of opioid analgesics that a reg-
9 istered manufacturer may procure for purposes of manu-
10 facturing dosage forms or other substances.

11 “(2) The Attorney General shall make publicly avail-
12 able, including through the website of the Drug Enforce-
13 ment Administration—

14 “(A) the quantity of the opioid procurement
15 quota for each registered manufacturer for each
16 year;

17 “(B) the quantity of opioid analgesics procured
18 by each registered manufacturer for each year; and

19 “(C) except as provided under paragraph (3)—

20 “(i) a copy of the form or other applica-
21 tion, including any attachments or exhibits,
22 submitted by each registered manufacturer re-
23 questing an opioid procurement quota; and

24 “(ii) a copy of each year-end or annual re-
25 port relating to the procurement or use of
26 opioid analgesics submitted to the Attorney

1 General by a registered manufacturer to whom
2 the Attorney General has issued an opioid pro-
3 curement quota.

4 “(3)(A) Upon request by a registered manufacturer,
5 the Attorney General may redact information identified in
6 clause (i) or (ii) of paragraph (2)(C) from the publication
7 required under paragraph (2) if the Attorney General de-
8 termines that public disclosure of that information is likely
9 to cause substantial harm to the competitive position of
10 the registered manufacturer. For purposes of a determina-
11 tion under this subparagraph, adverse publicity or embar-
12 rassment shall not constitute competitive harm.

13 “(B) A determination of the Attorney General under
14 subparagraph (A) shall be subject to judicial review in ac-
15 cordance with chapter 7 of title 5, United States Code.

16 “(C) The Attorney General shall annually publish a
17 report on the website of the Department of Justice con-
18 taining an accounting of each declination determination
19 made under subparagraph (A), including the reason for
20 the declination, during the time period covered by the re-
21 port.”.

22 (b) GAO REPORT.—The Comptroller General of the
23 United States shall submit to Congress a report that, for
24 the 1-year period beginning on the date of enactment of
25 this Act—

1 (1) details—

2 (A) the number of instances in which a
3 registered manufacturer made a request de-
4 scribed in section 306(j)(3) of the Controlled
5 Substances Act, as added by subsection (a),
6 with respect to a document or information; and

7 (B) the number of instances in which the
8 Attorney General redacted information de-
9 scribed in clause (i) or (ii) of subsection
10 (j)(2)(C) of the Controlled Substances Act, as
11 added by subsection (a), from the publication
12 required under such subsection (j)(2); and

13 (2) evaluates, in a fair, compliant, and trans-
14 parent manner, the extent of the independent eval-
15 uation conducted by the Attorney General of re-
16 quests described in section 306(j)(3) of the Con-
17 trolled Substances Act, as added by subsection (a).

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