Amendment to the Amendment in the Nature of a Substitute to H.R. 2483 Offered by Mrs. Trahan of Massachusetts

At the end of the bill, add the following:

1 SEC. _____. SAFEGUARDING OPIOID OVERDOSE REVERSAL 2 AND TREATMENT ADVANCEMENTS.

3 (a) IN GENERAL.—This Act, and the amendments
4 made by this Act, shall be made effective only if the Sec5 retary certifies to the Congress that—

6 (1) the activities and authorities specified in 7 subsection (b) of the Department of Health and 8 Human Services and the Food and Drug Adminis-9 tration will not be impaired, delayed, or otherwise 10 hindered by any agency action (including any reduc-11 tion in force conducted pursuant to subchapter I of 12 chapter 35 of title 5, United States Code or any 13 agency reorganization) of the Department of Health 14 and Human Services or the Food and Drug Admin-15 istration intended to reduce the workforce of such 16 Department and Administration; and

17 (2) such an agency action will not—

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1	(A) increase the approval timeline for new
2	opioid overdose reversal drugs or treatments for
3	opioid use disorder;
4	(B) reduce resources allocated to reviewing
5	applications for new treatments related to
6	opioid addiction or overdose prevention; or
7	(C) adversely impact public health initia-
8	tives aimed at expanding access to life-saving
9	medications.
10	(b) Activities and Authorities Described.—
11	The activities and authorities described in this subsection
12	are the following:
13	(1) The research, review, and approval of new
14	formulations of naloxone, including over-the-counter
15	and long-acting versions.
16	(2) The expedited approval and availability of
17	opioid use disorder treatments, including medica-
18	tions for addiction treatment.
19	(3) The conduct of essential oversight to ensure
20	the safety, efficacy, and timely patient access to
21	opioid-related interventions.

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