## AMENDMENT 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                  |
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| 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 Sec- |
| 5  | 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—                        |
| 18 | (A) increase the approval timeline for new                 |
| 19 | opioid overdose reversal drugs or treatments for           |
| 20 | opioid use disorder;                                       |

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

