

116TH CONGRESS  
1ST SESSION

# H. R. 5480

To ensure that ALS patients have access to treatment within clinical trials.

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## IN THE HOUSE OF REPRESENTATIVES

DECEMBER 18, 2019

Mr. FORTENBERRY introduced the following bill; which was referred to the  
Committee on Energy and Commerce

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## A BILL

To ensure that ALS patients have access to treatment within  
clinical trials.

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 “ALS Placebo No More  
5 Act”.

6 **SEC. 2. AUTHORITY FOR HHS AND AGENCIES TO DEVELOP**  
7 **RESOURCES AND POLICIES TO PROVIDE AC-**  
8 **CESS TO PROMISING TREATMENTS FOR PA-**  
9 **TIENTS WITH ALS.**

10 The Food and Drug Administration (FDA) and the  
11 National Institutes of Health (NIH) shall collaborate on

1 any current amyotrophic lateral sclerosis (ALS) trial to  
2 ensure that all patients in treatment and placebo arms are  
3 provided access to the drug.

4       The FDA shall move expeditiously to implement its  
5 guidance on ALS clinical trials to assure that all trials  
6 going forward shall require treatment arms for all pa-  
7 tients.

8       The Federal Government shall develop incentives to  
9 expand access to investigational therapies for life-threat-  
10 ening conditions with fewer than two treatments.

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