

116TH CONGRESS
1ST SESSION

H. R. 5480

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

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 18, 2019

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

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.

○