

1 SJR76  
2 159874-1  
3 By Senators Brewbaker, Scofield, Glover, Hightower, Holtzclaw,  
4 Taylor, Dial, Marsh, Ward, Smitherman, Bussman, Figures, Reed,  
5 Singleton and Coleman  
6 RFD:  
7 First Read: 06-MAR-14

8 URGING THE FOOD AND DRUG ADMINISTRATION TO GRANT  
9 ACCELERATED APPROVAL FOR THE DRUG ETEPLIRSEN FOR THE TREATMENT  
10 OF DUCHENNE MUSCULAR DYSTROPHY.

11  
12 WHEREAS, Duchenne Muscular Dystrophy (DMD) is the  
13 most fatal genetic disorder diagnosed in childhood, affecting  
14 approximately one in every 3,500 live male births, or 20,000  
15 new cases each year; and

16 WHEREAS, affecting primarily boys, DMD occurs across  
17 all races and cultures and results in progressive loss of  
18 strength and muscle weakness so that those afflicted generally  
19 require the use of a wheelchair by age 12, face serious  
20 medical issues with their hearts and lungs as teenagers, and  
21 typically succumb to the disease in their twenties; and

22 WHEREAS, Congress passed the Food and Drug  
23 Administration Safety and Innovation Act of 2012 (FDASIA),  
24 providing four expedited drug approval pathways and a larger  
25 and faster pipeline for the approval of new medicines to  
26 advance patient care and public health; and

1                   WHEREAS, remarkable scientific and clinical data  
2 have been gathered on the successful use of the new drug  
3 eteplirsen in the treatment of DMD, and a new drug application  
4 for eteplirsen has been submitted to the FDA; now therefore,

5                   BE IT RESOLVED BY THE LEGISLATURE OF ALABAMA, BOTH  
6 HOUSES THEREOF CONCURRING, That the Food and Drug  
7 Administration is strongly urged to accept and promptly review  
8 the new drug application for eteplirsen using an accelerated  
9 approval pathway under the FDASIA, making eteplirsen available  
10 to more patients while other testing and review of the drug  
11 continue.

12                   BE IT FURTHER RESOLVED, That a copy of this  
13 resolution be provided to the Commissioner of the Food and  
14 Drug Administration and to each member of the Alabama  
15 Congressional Delegation as evidence of our thoughts in this  
16 matter.