

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.