

Ray W. Marshall

AMENDMENT NO. _____ Calendar No. _____

Purpose: To protect patient access to current and future treatments for a range of serious conditions, such as cancer, Alzheimer's disease, HIV/AIDS, Parkinson's disease, and sickle cell disease, among numerous others.

	AMENDMENT N^o 5389	
IN THE		ess.
By	<i>Marshall</i>	
To:	<i>Amnt - No. 5194</i>	
To p		n.
	<i>3</i>	
Refer	Page(s)	nd

GPO: 2010 63-070 (mac)

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. MARSHALL to the amendment (No. 5194) proposed by Mr. Schumer

Viz:

- 1 At the end of title I, add the following:

1 **Subtitle E—Ensuring Patient Ac-**
2 **cess to Drugs and Biological**
3 **Products That Treat Serious**
4 **Conditions**

5 **SEC. 14001. ENSURING PATIENT ACCESS TO DRUGS AND BI-**
6 **OLOGICAL PRODUCTS THAT TREAT SERIOUS**
7 **CONDITIONS.**

8 Section 1192(e)(3) of the Social Security Act, as
9 added by section 11001, is amended by adding at the end
10 the following new subparagraphs:

11 “(D) SIX PROTECTED CLASSES.—A cov-
12 ered part D drug in a category or class that is
13 identified under section 1860D-4(b)(3)(G)(iv).

14 “(E) BREAKTHROUGH THERAPIES.—A
15 drug or biological product designated under sec-
16 tion 506(a) of the Federal Food, Drug, and
17 Cosmetic Act (21 U.S.C. 356(a)) as a break-
18 through therapy and approved under section
19 505 of such Act (21 U.S.C. 355) or section 351
20 of the Public Health Service Act (42 U.S.C.
21 262).”.

22 **SEC. 14002. REDUCTION OF ADDITIONAL IRS FUNDING FOR**
23 **ENFORCEMENT AND OPERATIONS.**

24 Section 10301(a)(1)(A)(i) of this Act is amended—

1 (1) in subclause (II), by striking
2 "\$45,637,400,000" and inserting
3 "\$10,326,400,000"; and
4 (2) in subclause (III), by striking
5 "\$25,326,400,000" and inserting "\$326,400,000".