

AMENDMENT TO
RULES COMMITTEE PRINT 116-41
OFFERED BY MR. DOGGETT OF TEXAS

Page 9, after line 15, insert the following:

1 “(5) PUBLIC SECTOR RESEARCH INSTITU-
2 TION.—The term ‘public sector research institution’
3 means any university, hospital, non-profit foundation
4 or institution, government agency, or official rep-
5 resentative of the Federal Government in the United
6 States.”.

Page 11, line 3, strike “and”.

Page 11, line 6, strike the period at the end and in-
sert “; and”.

Page 11, after line 6, insert the following:

7 “(4) all negotiation-eligible drugs described in
8 subsection (d)(1)(D).”.

Page 14, after line 3, insert the following:

9 “(D) TAXPAYER-FUNDED DRUG.—The
10 term ‘taxpayer-funded drug’ means a drug or
11 biological that is—

1 “(i) a drug approved under section
2 505(c) of the Federal Food, Drug and
3 Cosmetic Act or licensed under section
4 351(a) of the Public Health Service Act
5 after December 31, 2019, with at least one
6 patent that claims the drug, a use of the
7 drug, a form of the drug, a method of use
8 of the drug, or a method of manufacture
9 of the drug on which the assignee is a pub-
10 lic sector research institution, as defined
11 under subsection (c)(5) of section 1191; or
12 “(ii) a drug approved under section
13 505(c) of the Federal Food, Drug and
14 Cosmetic Act or licensed under section
15 351(a) of the Public Health Service Act
16 after December 31, 2019, with at least one
17 patent that claims the drug, a use of the
18 drug, a form of the drug, a method of use
19 of the drug, or a method of manufacture
20 of the drug, which includes a government
21 interest statement as required under a
22 funding agreement pursuant to section
23 202(c)(6) of title 35, United States
24 Code.”.

