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

Page 9, after line 15, insert the following:

“(5) Public sector research institution.—The term ‘public sector research institution’ means any university, hospital, non-profit foundation or institution, government agency, or official representative of the Federal Government in the United States.”.

Page 11, line 3, strike “and”.

Page 11, line 6, strike the period at the end and insert “; and”.

Page 11, after line 6, insert the following:

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

Page 14, after line 3, insert the following:

“(D) Taxpayer-funded drug.—The term ‘taxpayer-funded drug’ means a drug or biological that is—
“(i) a drug approved under section 505(c) of the Federal Food, Drug and Cosmetic Act or licensed under section 351(a) of the Public Health Service Act after December 31, 2019, with at least one patent that claims the drug, a use of the drug, a form of the drug, a method of use of the drug, or a method of manufacture of the drug on which the assignee is a public sector research institution, as defined under subsection (c)(5) of section 1191; or

“(ii) a drug approved under section 505(c) of the Federal Food, Drug and Cosmetic Act or licensed under section 351(a) of the Public Health Service Act after December 31, 2019, with at least one patent that claims the drug, a use of the drug, a form of the drug, a method of use of the drug, or a method of manufacture of the drug, which includes a government interest statement as required under a funding agreement pursuant to section 202(e)(6) of title 35, United States Code.”.