

**AMENDMENT**  
**OFFERED BY MR. SCHRADER OF OREGON**  
**TO THE AMENDMENT IN THE NATURE OF A**  
**SUBSTITUTE TO H.R. 2026**

Page 3, lines 10 and 11, strike “and relates to an investigational product or investigational use of a drug or device” and insert “and relates to an investigational use of a drug or device approved, granted marketing authorization, cleared, or licensed pursuant to section 505, 510(k), 513(f), or 515 of this Act or pursuant to section 351 of the Public Health Service Act”.

Page 4, lines 9 through 13, amend subparagraph (C) to read as follows:

1       “(C) For purposes of this subparagraph, scientific in-  
2 formation includes clinical and pre-clinical data and re-  
3 sults relating to an investigational use described in clause  
4 (A).

