

AMENDMENT TO H.R. 8646, AS REPORTED
OFFERED BY MR. POCAN OF WISCONSIN

At the end of the bill (before the short title), insert the following:

1 SEC. _____. (a) Not later than 180 days after the date
2 of enactment of this Act, the Secretary of Health and
3 Human Services, acting through the Commissioner of
4 Food and Drugs, shall issue or revise guidance for indus-
5 try to clarify that historical control data (including placebo
6 controls) derived from purpose-bred laboratory dogs con-
7 stitutes an acceptable basis for the concurrent control arm
8 in Target Animal Safety studies submitted in support of
9 a new animal drug application under section 512 of the
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b),
11 consistent with similar, scientifically rigorous guidance
12 that allows for flexibilities, such as the guidance of the
13 Food and Drug Administration issued in 2023 titled
14 “Considerations for the Design and Conduct of Externally
15 Controlled Trials for Drug and Biological Products”.

16 (b) The guidance issued or revised under subsection
17 (a) shall specify that a historical control dataset is accept-
18 able when the sponsor demonstrates that—

1 (1) the laboratory dog population used in the
2 historical control studies is of the same species and
3 similar husbandry conditions as the animals in the
4 proposed study;

5 (2) the historical control data were collected
6 within the preceding 10 years, unless older data are
7 shown to be scientifically equivalent;

8 (3) the statistical weight assigned to historical
9 data is formally specified in the study protocol using
10 a preregistered Bayesian or equivalent adaptive de-
11 sign; and

12 (4) individual animal-level data from historical
13 control studies are available for analysis.

