



(Original Signature of Member)

116TH CONGRESS
2D SESSION

H. R.

To amend the Public Health Service Act to provide for the establishment of the National Center for Alternatives to Animals in Research and Testing, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. HASTINGS introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Public Health Service Act to provide for the establishment of the National Center for Alternatives to Animals in Research and Testing, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Humane Research and
5 Testing Act of 2020”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

1 (1) The mission of the National Institutes of
2 Health (NIH) is to seek fundamental knowledge
3 about the nature and behavior of living systems and
4 the application of that knowledge to enhance health,
5 lengthen life, and reduce illness and disability.

6 (2) Much of NIH's research is carried out on
7 animals. However, the precise number of animals
8 used in research in the United States is unknown.
9 Estimates range between 17 million and 100 million
10 animals used annually. Such imprecise numbers
11 make it impossible to effectively track and reduce
12 the numbers of animals used, as mandated by the
13 NIH policies to ensure the smallest possible number
14 of animals are used.

15 (3) There is widespread agreement among sci-
16 entists and regulatory agencies that animal models
17 are poor predictors of the human response, with over
18 90 percent of new candidate drugs never making it
19 to market.

20 (4) More than 30 percent of promising medica-
21 tions have failed in human clinical trials because
22 they are found to be toxic despite promising pre-clin-
23 ical studies in animal models. An additional 65 per-
24 cent of candidate drugs that pass animal trials fail
25 due to lack of efficacy.

1 (5) Despite the ever-increasing growth in ani-
2 mal procedures, there is no corresponding increase
3 in the number of human medicines making it to the
4 clinic.

5 (6) Dramatically rising costs and extremely
6 high failure rates in drug development have led
7 many to re-evaluate the value of animal studies.

8 (7) Effective alternatives to animals are avail-
9 able and growing. Cutting-edge technology has
10 forged new frontiers in biology and medicine that
11 have produced human-relevant models, including
12 organoid cell cultures, organs-on-chips, genomics, in-
13 duced pluripotent adult stem cells, 3D modeling with
14 human cells, high throughput technology, molecular
15 imaging, computer models, in silico trials, digital im-
16 aging, artificial intelligence, and other innovative
17 methods—all of which have launched a technological
18 revolution in biomedical research.

19 (8) Despite these cutting-edge, human-relevant
20 methods, a preponderance of NIH research is car-
21 ried out on animals. A 2019 news release from NIH
22 indicates that 70 percent of NIH grant applications
23 relate to studies using mice.

24 (9) The American public has expressed concern
25 about subjecting animals to the pain of experimen-

1 tation. This concern grows as alternatives to re-
2 search on animals become available.

3 (10) Under the system of oversight established
4 by the National Institutes of Health Revitalization
5 Act of 1993 (Public Law 103–43), NIH is supposed
6 to outline a plan for reducing the use of animals in
7 research. Section 404C(a)(1) of the Public Health
8 Service Act (42 U.S.C. 283e(a)(1)), as added by sec-
9 tion 205 of the National Institutes of Health Revi-
10 talization Act of 1993, calls for NIH to “conduct or
11 support research into ... methods of biomedical re-
12 search and experimentation that do not require the
13 use of animals and methods of such research and ex-
14 perimentation that reduce the number of animals
15 used in such research”.

16 (11) A dedicated center that provides resources,
17 funding, and training to encourage researchers to
18 utilize humane, cost-effective, and scientifically suit-
19 able non-animal methods is needed to fulfill the in-
20 tent of the National Institutes of Health Revitaliza-
21 tion Act of 1993 (Public Law 103–43).

1 **SEC. 3. NATIONAL CENTER FOR ALTERNATIVES TO ANI-**
2 **MALS IN RESEARCH AND TESTING.**

3 (a) ADDITION TO LIST OF INSTITUTES AND CEN-
4 TERS.—Section 401 of the Public Health Service Act (42
5 U.S.C. 281) is amended—

6 (1) by redesignating paragraph (25) as para-
7 graph (26); and

8 (2) by inserting after paragraph (24) the fol-
9 lowing new paragraph:

10 “(25) National Center for Alternatives to Ani-
11 mals in Research and Testing.”.

12 (b) CONFORMING CHANGE TO NUMBER OF INSTI-
13 TUTES AND CENTERS.—Section 401(d)(1) of the Public
14 Health Service Act (42 U.S.C. 281(d)(1)) is amended by
15 striking “27” and inserting “28”.

16 (c) ESTABLISHMENT; DUTIES.—Part E of title IV of
17 the Public Health Service Act (42 U.S.C. 287 et seq.) is
18 amended by inserting after subpart 5 of such part E (42
19 U.S.C. 287e–21) the following new subpart:

20 **“Subpart 6—National Center for Alternatives to**
21 **Animals in Research and Testing**

22 **“SEC. 485E. ESTABLISHMENT; DUTIES.**

23 “(a) ESTABLISHMENT.—Not later than one year
24 after the date of enactment of the Humane Research and
25 Testing Act of 2020 the Secretary shall establish a Na-
26 tional Center for Alternatives to Animals in Research and

1 Testing (in this subpart referred to as the ‘National Cen-
2 ter’) within the National Institutes of Health.

3 “(b) PURPOSES.—The sole purposes of the National
4 Center shall be—

5 “(1) developing, promoting, and funding alter-
6 natives to animal research and testing; and

7 “(2) developing a plan for reducing the number
8 of animals used in federally funded research and
9 testing.

10 “(c) DUTIES.—The Director of the National Center
11 shall—

12 “(1) provide assistance (including funding) to
13 federally funded researchers to incentivize research
14 and testing without the use of animals, based on ad-
15 vanced cell cultures or technology such as 3D
16 organoids, microphysiological systems, induced
17 pluripotent adult stem cell models, in silico mod-
18 eling, advanced imaging systems, artificial intel-
19 ligence, and other innovative methods;

20 “(2) train and inform scientists about these
21 available methods of research and testing without
22 the use of animals;

23 “(3) establish collaborations among research
24 scientists to assist those working in institutions
25 where research and testing scientists may lack re-

1 sources (such as bioengineering and advanced bio-
2 imaging equipment) to carry out new and emerging
3 high-tech methods of research and testing without
4 the use of animals; and

5 “(4) tally and make publicly available informa-
6 tion on the numbers of animals used in federally
7 funded research and testing in order to implement
8 adequate steps to measure the reduction of animals
9 so used.”.

10 **SEC. 4. REPORTING BY FEDERALLY FUNDED RESEARCH**
11 **ENTITIES ON NUMBERS OF ANIMALS USED IN**
12 **RESEARCH AND TESTING.**

13 (a) IN GENERAL.—Each covered reporting entity
14 shall do the following:

15 (1) Not later than 1 year after the date of en-
16 actment of this Act, report to the National Center
17 for Alternatives to Animals in Research and Testing
18 and make publicly available—

19 (A) the total number of animals used in
20 federally funded research and testing at any fa-
21 cilities of the covered reporting entity,
22 disaggregated by species; and

23 (B) the total number of such animals that
24 were bred or acquired for research or testing
25 purposes, disaggregated by species.

1 (2) Every 2 years thereafter, update the latest
2 report of the entity under this section and make
3 publicly available such updated report to measure
4 the progress of the covered reporting entity in reduc-
5 ing the number of animals used in federally funded
6 research and testing.

7 (3) On an annual basis, develop and submit to
8 the National Center for Alternatives to Animals in
9 Research and Testing and make publicly available a
10 plan for reducing the numbers described in subpara-
11 graphs (A) and (B) of paragraph (1).

12 (b) STANDARDIZED PROCESS.—The Director of the
13 National Center for Alternatives to Animals in Research
14 and Testing shall establish a standardized process for sub-
15 mitting and updating reports and plans under subsection
16 (a), including for making such reports and plans publicly
17 available.

18 (c) DEFINITION.—In this section:

19 (1) The term “animal”—

20 (A) means any vertebrate; and

21 (B) includes all warm-blooded and cold-
22 blooded species.

23 (2) The term “covered reporting entity”
24 means—

25 (A) any entity that—

- 1 (i) receives Federal funds for research
2 or testing; and
3 (ii) uses animals in research and test-
4 ing; and
5 (B) any Federal department or agency
6 that uses animals in research or testing.