

103^D CONGRESS
2^D SESSION

H. R. 5222

To provide for nonanimal acute toxicity testing by the Federal Government.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 6, 1994

Mr. LANTOS (for himself, Mr. ACKERMAN, Mr. BEILENSON, Mr. BROWN of California, Mr. DEFazio, Mr. DELLUMS, Mr. GEJDENSON, Mr. HAMBURG, Mr. HOCHBRUECKNER, Mr. JOHNSON of South Dakota, Mr. JOHNSTON of Florida, Mr. KLECZKA, Mr. MANTON, Mr. MINETA, Mr. MORAN, Mr. NEAL of Massachusetts, Mr. RAVENEL, Ms. ROYBAL-ALLARD, Mr. SHAYS, Mr. SWETT, Mr. SWIFT, and Mr. TOWNS) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To provide for nonanimal acute toxicity testing by the
Federal Government.

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 “Consumer Products
5 Safe Testing Act”.

6 **SEC. 2. FINDINGS AND POLICY.**

7 (a) FINDINGS.—The Congress finds that—

1 (1) nonanimal acute toxicity tests have been de-
2 veloped in recent years that have shown a level of re-
3 liability sufficient for the reduction or replacement
4 of animal acute toxicity tests such as the Draize test
5 for many products regulated by the Federal Govern-
6 ment;

7 (2) many manufacturers have found nonanimal
8 acute toxicity tests to be adequate for evaluating the
9 safety of products for the purposes of complying
10 with Federal regulations or guidelines;

11 (3) the Federal Government has discouraged
12 the use of these alternatives through regulations
13 that mandate or encourage the use of animal acute
14 toxicity tests, or by not prescribing other, less costly,
15 more accurate and humane alternatives;

16 (4) many manufacturers are reluctant to use
17 nonanimal tests without encouragement from the
18 Federal Government; and

19 (5) private industry and the consumer will ben-
20 efit from the promotion of alternative methods of
21 testing when these alternatives are as accurate and
22 more humane than animal tests.

23 (b) POLICY.—Federal departments and agencies shall
24 encourage the development and use of product testing pro-
25 cedures that accurately reflect the acute health effects on

1 humans of certain products, including consumer products
2 and products containing hazardous or toxic substances,
3 but which do not rely upon animals.

4 **SEC. 3. FEDERAL ACTION.**

5 (a) REVIEW OF REGULATIONS, GUIDELINES, OR
6 RECOMMENDATIONS CONCERNING THE DRAIZE TEST
7 AND OTHER ANIMAL ACUTE TOXICITY TESTS.—Not later
8 than one year after the date of enactment of this Act, each
9 Federal department or agency head shall—

10 (1) review and evaluate any regulation, guide-
11 line, or recommendation issued by that department
12 or agency which requires, recommends, or encour-
13 ages the use of the Draize or other animal acute tox-
14 icity test for the purpose of evaluation of the safety
15 of a regulated product;

16 (2) review and evaluate nonanimal alternatives
17 with the potential for partial or full replacement of
18 the Draize or other animal acute toxicity test for
19 some or all of the products regulated; and

20 (3) promulgate regulations, guidelines, or rec-
21 ommendations that specify a nonanimal acute tox-
22 icity test or battery of tests should be used instead
23 of an animal acute toxicity test unless that Federal
24 department or agency head determines that the
25 nonanimal acute toxicity test or battery of such tests

1 is less likely to predict the acute health effects on
2 humans of a product than the animal acute toxicity
3 test.

4 (b) ANIMAL ACUTE TOXICITY TESTS.—If a deter-
5 mination is made that no nonanimal acute toxicity test
6 or battery of tests is as likely to predict the human reac-
7 tion to the regulated product as the Draize or other animal
8 acute toxicity test, the appropriate Federal department or
9 agency head shall publish in the Federal Register an ex-
10 planation of all options considered and the justification for
11 continuing the animal acute toxicity test, which shall be
12 subject to public comment.

13 (c) PERIODIC REVIEW OF ANIMAL ACUTE TOXICITY
14 TESTING REGULATIONS.—At least every 2 years (begin-
15 ning 3 years after the date of enactment of this Act), each
16 Federal department or agency head, after considering the
17 most recent technological advances available, shall deter-
18 mine whether continued use of any animal acute toxicity
19 test is justified. If a Federal department or agency head
20 determines that such use is justified, then that Federal
21 department or agency head shall publish an explanation
22 and justification of such continued use in the Federal Reg-
23 ister, which shall be subject to public comment.

1 **SEC. 4. APPLICATION.**

2 This Act shall not apply to regulations, guidelines,
3 or recommendations related to medical research.

4 **SEC. 5. DEFINITIONS.**

5 For purposes of this Act:

6 (1) ANIMAL.—The term “animal” means any
7 vertebrate.

8 (2) ANIMAL ACUTE TOXICITY TEST.—The term
9 “animal acute toxicity test” means an acute toxicity
10 test on animals, including (but not limited to) the
11 Draize eye or skin irritancy test, LD-50 test, ap-
12 proximate lethal dose test, and the limit test.

13 (3) FEDERAL DEPARTMENT OR AGENCY
14 HEAD.—The term “Federal department or agency
15 head” means the head of a Federal department or
16 agency who—

17 (A) has authority to promulgate regula-
18 tions, guidelines, and recommendations with re-
19 spect to procedures to be used in the safety
20 testing by manufacturers of products, including
21 consumer products, veterinary products, and
22 products containing hazardous or toxic sub-
23 stances; or

24 (B) licenses or approves products, labeling
25 requirements or the transportation of products
26 based on the results of these tests.

1 (4) MEDICAL RESEARCH.—The term “medical
2 research” means research related to the causes, di-
3 agnosis, treatment, or control of physical or mental
4 impairments of humans or animals. The term does
5 not include the testing of a product to determine its
6 toxicity for the purpose of complying with protocols,
7 recommendations, or guidelines for testing required,
8 recommended, or accepted by a Federal regulatory
9 agency for a product introduced in commerce.

10 (5) NONANIMAL ACUTE TOXICITY TEST.—The
11 term “nonanimal acute toxicity test” means an
12 acute toxicity test not conducted on animals. Such
13 tests include (but are not limited to) cell culture,
14 computer modeling, protein alteration, and
15 chorioallantoic membrane techniques.

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