



# TOXIC TESTING

**Wasteful Animal  
Tests in the National  
Toxicology Program**



WHITE COAT  
**WASTE**  
PROJECT



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## Wasteful Animal Tests in the National Toxicology Program

A report by



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## REPORT HIGHLIGHTS

- National Toxicology Program’s (NTP) most common animal tests have used more than 115,000 animals and \$186,000,000 taxpayer dollars in current chemical assessments
- Animal tests comprise 82% of all NTP tests conducted for chemical safety
- Less than half (48%) of individual chemicals currently being assessed by NTP have non-animal tests planned; 100% of listed chemicals call for animal tests
- Only 1 of 103 (0.97%) yet-to-be-conducted NTP tests uses a non-animal method
- NTP uses 100+ different animal tests, and only 7 non-animal tests despite approving over 70
- A lack of transparency and accountability makes it impossible to assess NTP’s stated goal of reducing and replacing wasteful taxpayer-funded animal tests

## OVERVIEW OF NATIONAL TOXICOLOGY PROGRAM

NTP is an interagency program charged with evaluating the safety of chemicals and other substances encountered by the public. NTP is housed within the National Institute of Environmental Health Sciences (NIEHS), and is a partnership with the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). NTP’s core responsibilities include coordinating toxicological studies of substances of potential public concern, and developing and implementing modern testing technologies that reduce animal use, save time and money, and improve testing accuracy.<sup>1</sup> NTP’s budget—funded by allocations from NIEHS, CDC, and FDA—was \$131 million in FY2016.<sup>2</sup>

## REPLACING WASTEFUL NTP ANIMAL TESTING WITH SUPERIOR ALTERNATIVES

Historically, animal testing has been the primary method NTP uses to assess the safety and potential hazards of industrial chemicals, natural supplements, cosmetics ingredients, and other substances. For more than two decades, however, NTP has acknowledged the wastefulness of this approach and the need for more efficient testing tools.<sup>3,4</sup> NTP explains,

***“animal-based testing has a number of recognized limitations: it can be expensive and time consuming, it raises moral and ethical issues, and it does not always identify toxic effects relevant to humans.”***<sup>5</sup>

White Coat Waste Project (WCW) has previously criticized a number of NTP’s tests.<sup>6,7</sup> Indeed, a single NTP test for an individual chemical can take five years, cost taxpayers \$4 million, use over 800 animals in painful procedures, and, as New England Anti-Vivisection Society (NEAVS) scientists have documented, provide dubious results.<sup>8,9</sup> As reported by the National Academies of Science (NAS) in a landmark 2007 study, “Test animals are typically observed for overt signs of adverse health effects, which provide little information about biological changes leading to such health effects. Often controversial uncertainty factors must be applied to account for differences between test animals and humans.”<sup>10</sup> As a result, the NAS advocated for “a new toxicity-testing

<sup>1</sup> National Toxicology Program (NTP). “About NTP.” <https://ntp.niehs.nih.gov/about/index.html>

<sup>2</sup> NTP. “Funding.” <https://ntp.niehs.nih.gov/annualreport/2016/about/funding/index.html>

<sup>3</sup> NTP. “Validation and Regulatory Acceptance of Toxicological Test Methods: A Report of the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods.” [https://ntp.niehs.nih.gov/iccvam/docs/about\\_docs/validate.pdf](https://ntp.niehs.nih.gov/iccvam/docs/about_docs/validate.pdf)

<sup>4</sup> NTP. “A National Toxicology Program for the 21st Century: Roadmap to Achieve the NTP Vision.” [https://ntp.niehs.nih.gov/ntp/about\\_ntp/ntpvision/ntproadmap\\_508.pdf](https://ntp.niehs.nih.gov/ntp/about_ntp/ntpvision/ntproadmap_508.pdf)

<sup>5</sup> ICCVAM Strategic Roadmap (January, 2018). [https://ntp.niehs.nih.gov/iccvam/docs/roadmap/iccvam\\_strategicroadmap\\_january2018\\_document\\_508.pdf](https://ntp.niehs.nih.gov/iccvam/docs/roadmap/iccvam_strategicroadmap_january2018_document_508.pdf)

<sup>6</sup> Carlin Becker. “The Federal Government is Still Testing Cosmetics on Animals, Despite Wanting to Ban the Practice.” Rare, June 23, 2017.

<https://rare.us/rare-politics/issues/our-right-to-know/the-federal-government-is-still-testing-cosmetics-on-animals-despite-wanting-to-ban-the-practice/>

<sup>7</sup> Jennifer Wishon. “Big Government Gone Wild: Your Tax Dollars to Fund Gruesome Tests on Abortion-Inducing Herbs.” CBN News, December 4, 2017.

<http://www1.cbn.com/cbnnews/us/2017/december/big-government-gone-wild-your-tax-dollars-to-fund-gruesome-tests-on-abortion-inducing-herbs>

<sup>8</sup> Reza Farmahin, et al., *Recommended Approaches in the Application of Toxicogenomics to Derive Points of Departure for Chemical Risk Assessment* (Archives of Toxicology, 2017). <https://link.springer.com/content/pdf/10.1007/s00204-016-1886-5.pdf>

<sup>9</sup> New England Anti-Vivisection Society (NEAVS), *Animals in Research: Overview. “Alternative Action: Non-Animal Toxicology Testing.”*

<https://www.neavs.org/news/post/alternative-action-non-animal-toxicology-testing>

<sup>10</sup> National Academies of Science Engineering Medicine (NASM). “Toxicity Testing in the 21st Century: A Vision and a Strategy.” (National Research Council, 2007). [http://dels.nas.edu/resources/static-assets/materials-based-on-reports/reports-in-brief/Toxicity\\_Testing\\_final.pdf](http://dels.nas.edu/resources/static-assets/materials-based-on-reports/reports-in-brief/Toxicity_Testing_final.pdf)

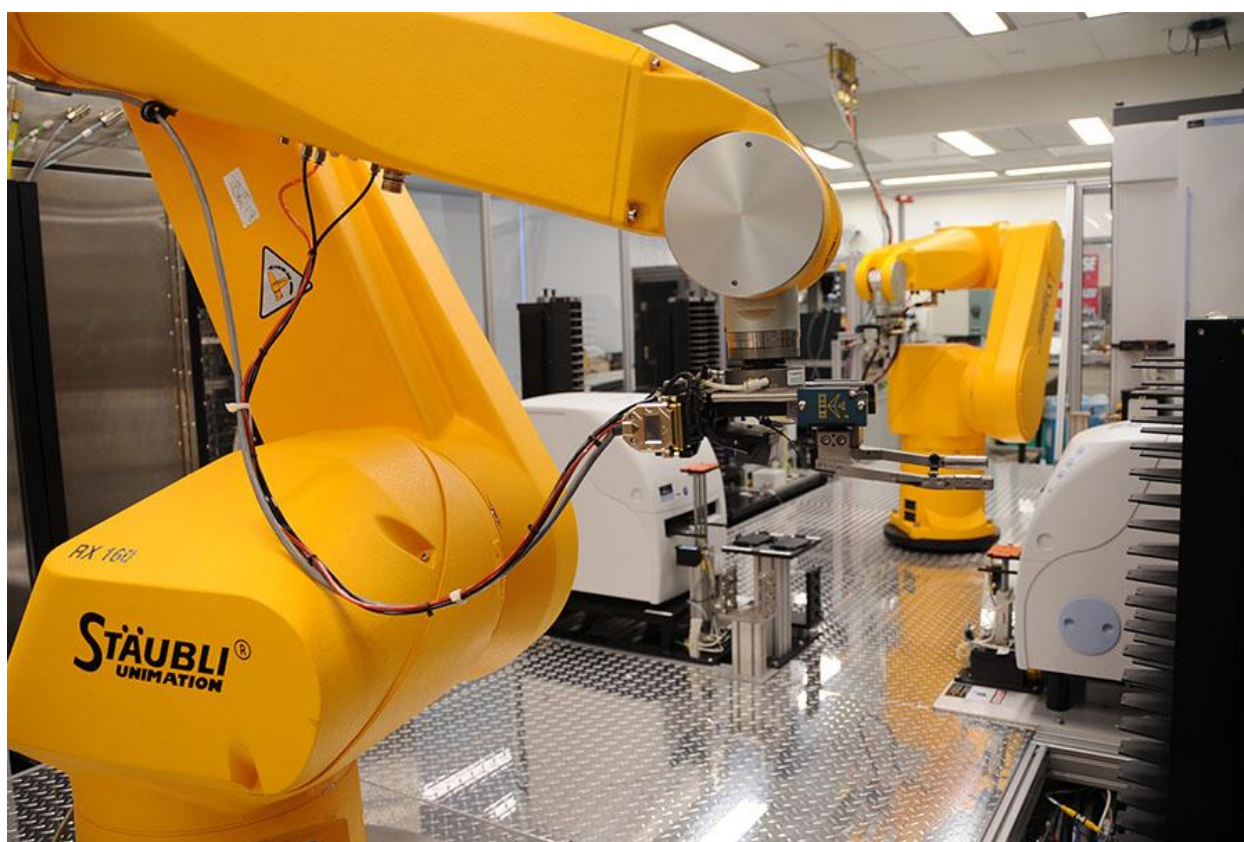
system that relies mainly on understanding ‘toxicity pathways’—the cellular response pathways that can result in adverse health effects when sufficiently perturbed. Such a system would evaluate biologically significant alterations without relying on studies of whole animals.”<sup>11</sup>

To its credit, among other initiatives, NTP has spearheaded the Toxicology in the 21<sup>st</sup> Century (Tox21) program that uses robotic testing to rapidly screen chemicals’ safety.<sup>12</sup>

The stated goal of NTP’s Tox21 program is,

***“to shift the assessment of chemical hazards away from traditional experimental animal toxicology studies to...in vitro assays.”***<sup>13</sup>

One of the Tox21 researchers explained, “The system is very efficient...We can test all the chemicals at 15 different concentrations each and in three independent experiment runs in one week. With animal testing, this would take years.”<sup>14</sup>



*Tox21’s robotic chemical screening system (SOURCE: NIH)*

Additionally, NTP—through the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM)—has overseen the development and validation of more than 70 alternative test methods that can reduce and replace animal testing.<sup>15</sup>

<sup>11</sup> National Academies of Science Engineering Medicine (NASM). “Toxicity Testing in the 21st Century: A Vision and a Strategy.” (National Research Council, 2007). [http://dels.nas.edu/resources/static-assets/materials-based-on-reports/reports-in-brief/Toxicity\\_Testing\\_final.pdf](http://dels.nas.edu/resources/static-assets/materials-based-on-reports/reports-in-brief/Toxicity_Testing_final.pdf)

<sup>12</sup> NTP. “Toxicology in the 21st Century (Tox21).” <https://ntp.niehs.nih.gov/results/tox21/index.html>

<sup>13</sup> Maull, Elizabeth. “The National Toxicology Program and Alternatives to Traditional Toxicity Testing.” Presentation, NTP Interagency Center for the Evaluation of Alternative Toxicological Methods. [https://www.niehs.nih.gov/research/supported/translational/peph/webinars/alternative\\_models/maull\\_presentation\\_508.pdf](https://www.niehs.nih.gov/research/supported/translational/peph/webinars/alternative_models/maull_presentation_508.pdf)

<sup>14</sup> Anna Azvolinsky, “Animal-Free Toxicity Testing.” The Scientist, January 26, 2016. <https://www.the-scientist.com/?articles.view/articleNo/45173/title/Animal-Free-Toxicity-Testing/>

<sup>15</sup> NTP. “NICEATM: Alternative Methods NTP Interagency Center for the Evaluation of Alternative Toxicological Methods.” <https://ntp.niehs.nih.gov/pubhealth/evalatm/index.html>

This is a rapidly growing field, with non-animal toxicology testing currently a \$14 billion industry and expected to exceed \$37 billion by 2023.<sup>16</sup> North America holds the largest market share, with businesses and researchers across the country pioneering efforts in this area.

A recent cleaning product industry report concluded that through their use of alternatives to animal testing, “the use of 115,000–150,000 test animals and the expenditures of \$50,000,000 to \$70,000,000 (US) were avoided.”<sup>17</sup>

### **DUBIOUS PROGRESS TO SPARE ANIMALS AND CUT GOVERNMENT WASTE**

Despite these important technological developments and policy advances, it remains difficult to objectively assess progress being made at NTP and elsewhere to reduce and replace wasteful animal testing with superior non-animal tests that improve the accuracy of safety assessments, spare animals, and save money.

NTP acknowledges that, “Measuring the impact of implementation of new testing approaches is particularly difficult in the United States due to the limited ability to quantify animals used for toxicity testing.”<sup>18</sup> Specifically, because the animal species most commonly used in toxicity testing (mice and rats) are excluded from federal reporting requirements, NTP and other government agencies do not comprehensively report how many animals are used in their tests. NTP also does not report the costs of its animal testing.

Additionally, NTP has noted that technological advances, “have not yet resulted in similar improvements in our ability to predict adverse human health effects caused by exposure(s) to chemicals and medical products. This limited translational impact can be partly attributed to the inability of relevant institutional practices to keep pace with rapid scientific advancements.”<sup>19</sup> Ironically, the current analysis has found this to be a problem within the NTP itself. At other agencies, recent reports indicate that despite a recent federal law that prioritizes the use of non-animal methods for chemical safety assessments required by the EPA, certain animal testing may have increased—rather than decreased—since passage of the legislation.<sup>20</sup>

This is an issue of significant public interest, with Americans overwhelmingly supportive of efforts to reduce and replace government animal testing. A February 2018 national poll found that 79% of Republican voters and 68% of Democrat voters support cuts to federal spending on animal testing.<sup>21</sup> A March 2017 national poll found that 75% of Republicans and 73% of Democrats believe federal agencies should be required to replace animal testing with non-animal methods.<sup>22</sup>

For the sake of lawmakers, taxpayers, and animals, it is critical that federal programs be able to objectively evaluate and measure the effectiveness of government efforts to reduce and replace wasteful animal testing. Currently, such assessments are nearly impossible, but this report uses existing government data to begin to consider the state of these initiatives and offer recommendations for reforms.

<sup>16</sup> Statistics MRC, “In Vitro Toxicology Testing - Global Market Outlook (2017-2023).” <https://www.reuters.com/brandfeatures/venture-capital/article?id=32738>

<sup>17</sup> American Cleaning Institute. “Innovative Safety Assessment Techniques Avoid Animal Testing.”

[https://www.cleaninginstitute.org/innovative\\_safety\\_assessment\\_techniques\\_avoid\\_animal\\_testing/](https://www.cleaninginstitute.org/innovative_safety_assessment_techniques_avoid_animal_testing/)

<sup>18</sup> NTP. “A Strategic Roadmap for Establishing New Approaches to Evaluate the Safety of Chemicals and Medical Products in the United States.”

<https://ntp.niehs.nih.gov/pubhealth/evalatm/natl-strategy/index.html>

<sup>19</sup> ICCVAM Strategic Roadmap (January, 2018). [https://ntp.niehs.nih.gov/iccvam/docs/roadmap/iccvam\\_strategicroadmap\\_january2018\\_document\\_508.pdf](https://ntp.niehs.nih.gov/iccvam/docs/roadmap/iccvam_strategicroadmap_january2018_document_508.pdf)

<sup>20</sup> Kelly Franklin, “TSCA New Chemicals Programme Causing ‘Dramatic’ Rise in Animal Tests.” Chemical Watch, May 1, 2018.

<https://chemicalwatch.com/66450/tsca-new-chemicals-programme-causing-dramatic-rise-in-animal-tests>

<sup>21</sup> Lincoln Park Strategies, National Omnibus Poll, February 2018

<sup>22</sup> Lincoln Park Strategies, National Omnibus Poll, March 2017

## WCW AND NEAVS ANALYSIS OF NTP TESTING PROGRAM

In an effort to determine the state of animal testing and alternatives use within NTP, WCW and NEAVS performed a first-of-its-kind analysis of publicly-available information on current NTP testing plans.

### *Method*

Using the NTP's Management Status Report webpages, we compiled data on 86 industrial chemicals, natural supplements, foods, cosmetics ingredients, and other substances actively being evaluated by NTP.<sup>23</sup>

### *Results*

#### Total tests planned

For the 86 different substances being evaluated by NTP, a total of 639 individual tests are being planned, conducted, or have been completed.

#### **Current NTP Testing**

Total # of substances	86
Total # of NTP tests	639
Total <b>animal</b> tests	527 (82%)
Total <b>non-animal</b> tests	112 (18%)

Overall, 82 percent of listed NTP tests are animal-based, while only 18 percent use *in vitro* methods and other non-animal tests.

Nineteen percent (102) of 527 listed animal tests have not yet been conducted, meaning they have either been selected or assigned for testing. The remainder are completed, or in various stages of being conducted, analyzed, and written up. Of all 637 listed tests, just one forthcoming test uses a non-animal method.

#### Animal tests

The current analysis found that more than 100 different animal test methods are being used by NTP. Ninety-nine percent of NTPs testing is performed on mice and rats, with monkeys, rabbits and guinea pigs used in a small number of cases. According to the NTP's 2016 annual report, all of the tests it approved that year were animal tests.<sup>24</sup>

The five most common NTP animal tests comprised 48% (252/527) of all animal tests listed (see table below). These tests alone have consumed an estimated 115,000 animals and \$186.8 million taxpayer dollars. With the other half of the NTP's animal tests included, these figures would be significantly greater, potentially as high as 200,000 animals and \$250 billion tax dollars. The NTP's most common tests involve administering massive, human-irrelevant doses of substances to animals by force-feeding, forced inhalation, injection, spiked food and water, and

<sup>23</sup> NTP. "Management Status Report." <https://ntp.niehs.nih.gov/testing/types/cartox/msr/msr.html> (last accessed May 3, 2018)

<sup>24</sup> NTP. "Annual Report for Fiscal Year 2016: Project Review Committee Approved." [https://ntp.niehs.nih.gov/annualreport/2016/research/testing\\_tox\\_studies\\_subsec/prc\\_pac\\_review/index.html](https://ntp.niehs.nih.gov/annualreport/2016/research/testing_tox_studies_subsec/prc_pac_review/index.html)

application to their bare skin, including to pregnant animals and their offspring.<sup>25,26,27,28</sup> Animals used in these poisoning tests are typically not provided with any pain relief.

### 5 Most Common NTP Animal Tests<sup>29</sup>

Test name	# of times used	Animals per test	Total animals used/planned	Cost per test	Total cost
Micronucleus	84	50	4,200	\$18,100 <sup>30</sup>	\$1,520,400
13-week toxicity (oral, dermal, inhalation, dosed-feed/water, IV)	63	360	22,680	\$170,912 <sup>31</sup>	\$10,767,456
14-day toxicity (oral, dermal, inhalation, dosed-feed/water, IV)	51	120	6,120	\$25,000 <sup>32</sup>	\$1,275,000
2-year toxicity (oral, dermal, inhalation, dosed-feed/water, IV)	40	860	34,400	\$4,000,000 <sup>33</sup>	\$160,000,000
Modified One-Generation Reproduction Study	14 <sup>34</sup>	3,400	47,600	\$949,254 <sup>35</sup>	\$13,289,556
Totals			<b>115,000</b>		<b>\$186,852,412</b>



*Rats confined in forced inhalation chambers (SOURCE: EPA)*

### Non-animal tests

Despite NTP's commitments to replacing animal tests with high-tech alternatives, less than half (48%) of the 86 substances being evaluated by NTP include any non-animal testing component. The non-animal tests being used by NTP (see table below) employ a combination of sophisticated

<sup>25</sup> NEAVS, Animals in Science. "Harm and Suffering." <https://www.neavs.org/research/harm-suffering>

<sup>26</sup> NTP, Testing Information. Study Types: Toxicology/Carcinogenicity. <https://ntp.niehs.nih.gov/testing/types/cartox/index.html>

<sup>27</sup> NTP, Testing Information. Study Types: Developmental & Reproductive Toxicity. <https://ntp.niehs.nih.gov/testing/types/devrepro/index.html#MOG>

<sup>28</sup> NTP, Testing Information. Study Types: Genetic Toxicology. <https://ntp.niehs.nih.gov/testing/types/genetic/index.html>

<sup>29</sup> Because NTP does not publish cost information or complete animal use data, figures are based on industry standards.

<sup>30</sup> Product Safety Labs. Acute Mammalian Toxicology, Pricing Schedule, 2017. <https://www.productsafetylabs.com/media/1029/price-schedule-2017.pdf>

<sup>31</sup> Knight, J., Rovida, C., *Safety Evaluations Under the Proposed US Safe Cosmetics and Personal Care Products Act of 2013: Animal Use and Cost Estimates* (ALTEX, 2014). <https://www.ncbi.nlm.nih.gov/pubmed/24468774>

<sup>32</sup> Product Safety Labs. Acute Mammalian Toxicology Pricing Schedule, 2017. <https://www.productsafetylabs.com/media/1029/price-schedule-2017.pdf>

<sup>33</sup> Reza Farmahin, et al., *Recommended Approaches in the Application of Toxicogenomics to Derive Points of Departure for Chemical Risk Assessment* (Archives of Toxicology, 2017). <https://link.springer.com/content/pdf/10.1007/s00204-016-1886-5.pdf>

<sup>34</sup> Fourteen Modified One-Generation Reproduction Studies are active, comprised (as of May 3, 2018) of a total 52 separate animal tests

<sup>35</sup> European Chemicals Agency (ECHA). *Analysis of Capacities and Capabilities of Laboratories to Conduct OECD TG 443 Extended One-Generation Reproductive Toxicity Study (OECD TG 443)*, (Risk & Policy Analysts Limited, 2015). [https://echa.europa.eu/documents/10162/13630/echa\\_sr26\\_eogrts\\_en.pdf](https://echa.europa.eu/documents/10162/13630/echa_sr26_eogrts_en.pdf)

computational methods, robotics, and *in vitro* techniques using bacteria and cultured cells from humans and animals. While NTP uses more than 100 different animal test methods, it is using only 7 different non-animal tests, despite approving the use of more than 70.

### Non-Animal Tests Used by NTP

Non-animal test name	# of times used	Cost
Ames mutagenicity test	73	\$ 4,590 <sup>36</sup>
Micronucleus test ( <i>in vitro</i> )	16	\$20,000 <sup>37</sup>
<i>In vitro</i> cytogenetics (sister chromatid exchange and chromosomal aberration)	14	\$ 29,891 <sup>38</sup>
ADME	4	N/A <sup>39</sup>
Metabolism ( <i>in vitro</i> )	3	N/A <sup>38</sup>
Structure Activity Relationship Analysis	1	N/A <sup>38</sup>
Other	1	N/A <sup>38</sup>
	<b>112</b>	

### CASE STUDIES

#### *Cell phone tests on animals*

The NTP website indicates that at least 14 different tests—all using animals—were conducted to assess the safety of cell phone radiation.<sup>40,41</sup> NIH reports that the experiments took 10 years to complete, used 3,000 animals, and cost taxpayers \$25 million.<sup>42</sup>

In the tests, mice and rats were placed in custom-built chambers and exposed to large blasts of radiation—greater than ten times that of an iPhone—all day long for two years. The NTP admitted that,

***“The levels and duration of exposure to [cell phone radiation] were much greater than what people experience with even the highest level of cell phone use, and exposed the rodents’ whole bodies. So, these findings should not be directly extrapolated to human cell phone usage.”***<sup>43</sup>

The contrived NTP studies in rats and mice found that these enormous doses of radiation caused cancer in male rats, but not female rats, nor in any mice. NTP told the *Washington Post*,

***“Given the inconsistent pattern of the findings, the fact that the subjects were rats and mice rather than people and the high level of radiation used, [NTP] could not extrapolate from the data the potential health effects on humans.”***<sup>44</sup>

<sup>36</sup> Knight, J., Rovida, C., *Safety Evaluations Under the Proposed US Safe Cosmetics and Personal Care Products Act of 2013: Animal Use and Cost Estimates* (ALTEX, 2014). <https://www.ncbi.nlm.nih.gov/pubmed/24468774>

<sup>37</sup> Knight, J., Rovida, C., *Safety Evaluations Under the Proposed US Safe Cosmetics and Personal Care Products Act of 2013: Animal Use and Cost Estimates* (ALTEX, 2014). <https://www.ncbi.nlm.nih.gov/pubmed/24468774>

<sup>38</sup> Knight, J., Rovida, C., *Safety Evaluations Under the Proposed US Safe Cosmetics and Personal Care Products Act of 2013: Animal Use and Cost Estimates* (ALTEX, 2014). <https://www.ncbi.nlm.nih.gov/pubmed/24468774>

<sup>39</sup> Not enough information available on NTP site to determine tests details or estimate cost

<sup>40</sup> NTP. “Testing Status of Cell Phone Radiation: CDMA 08015.” <https://ntp.niehs.nih.gov/testing/status/agents/ts-08015.html>

<sup>41</sup> NTP. “Testing Status of Cell Phone Radiation: GSM 08013.” <https://ntp.niehs.nih.gov/testing/status/agents/ts-08013.html>

<sup>42</sup> Jacqueline Howard, *Cell Phone Radiation Study Finds More Questions Than Answers*. CNN Health (February 7, 2018). <https://www.cnn.com/2018/02/02/health/cell-phone-radiation-cancer-nih-study-bn/index.html>

<sup>43</sup> National Institutes of Health (NIH). *High Exposure to Radiofrequency Radiation Linked to Tumor Activity in Male Rats*. News Releases (February 2, 2018)

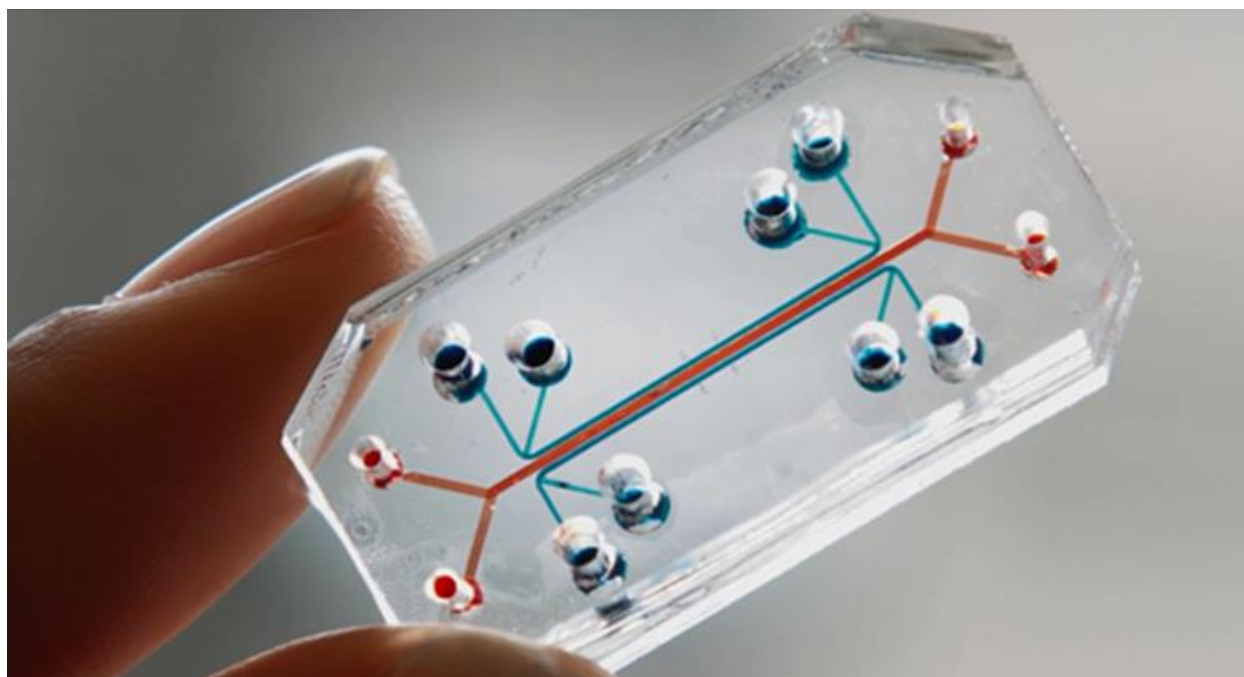
<https://www.nih.gov/news-events/news-releases/high-exposure-radiofrequency-radiation-linked-tumor-activity-male-rats>

<sup>44</sup> Ariana Eujung Cha, *Cellphone Radiation Study Finds Mixed Effects in Rodents, Without Clear Implications for Human Health*. Washington Post (February 2, 2018).

<https://www.washingtonpost.com/news/to-your-health/wp/2018/02/02/cellphone-radiation-shows-mixed-effects-in-rodents-without-clear-implications-for-human-health/>



The NTP website does not indicate that any non-animal testing was used, even though the FDA—which is a core partner of NTP—has been involved in developing cutting-edge “organ-on-a-chip” technology to replace animal tests in studies of radiation prevention and exposure.<sup>45</sup>



*Organs-on-chips—built using cultured human tissues and cells—are being developed and used by FDA, NIH, and other agencies to mimic human biological systems to rapidly screen chemicals and drugs (SOURCE: NIH)*

### *Cancer-causing coffee?*

Among the substances actively being evaluated by NTP is acrylamide, a by-product of roasting coffee, and baking and frying starchy foods, including French fries, potato chips, and bread.<sup>46</sup> A total of 36 different tests—only 3 of which are non-animal tests—have been scheduled or conducted by NTP. The NTP animal tests—which have cost taxpayers at least \$5 million—involve force-feeding mice and rats massive doses of acrylamide, dosing their food and water, and injecting it into them, including when they’re pregnant. The NIH reports that these tests use “doses 1,000 to 10,000 times higher than the levels people might be exposed to in foods.”<sup>47</sup>

Based on these inherently-flawed rodent tests, NTP concluded that there is “clear evidence” that acrylamide causes cancer, and that it can “reasonably be anticipated to be a human carcinogen.”<sup>48</sup>

The National Cancer Institute—which, like NTP, resides within the NIH—reports, “a large number of epidemiologic studies (both case-control and cohort studies) in humans have found no consistent evidence that dietary acrylamide exposure is associated with the risk of any type of cancer.”<sup>49</sup> Similarly, the American Cancer Society writes that, “there are currently no cancer types for which there is clearly an increased risk related to acrylamide intake.”<sup>50</sup>

<sup>45</sup> U.S. Food and Drug Administration (FDA), Emergency Preparedness and Response. “Organs-On-Chips for Radiation Countermeasures.” <https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMRegulatoryScience/ucm364491.htm>

<sup>46</sup> NTP. “Testing Status of Acrylamide 10949-Y.” <https://ntp.niehs.nih.gov/testing/status/agents/ts-10949-y.html>

<sup>47</sup> American Cancer Society. “Acrylamide and Cancer Risk.” <https://www.cancer.org/cancer/cancer-causes/acrylamide.html>

<sup>48</sup> NTP Report on Carcinogens, Acrylamide (14<sup>th</sup> ed., 2016). <https://ntp.niehs.nih.gov/ntp/roc/content/profiles/acrylamide.pdf>

<sup>49</sup> National Cancer Institute. “Acrylamide and Cancer Risk.” <https://www.cancer.gov/about-cancer/causes-prevention/risk/diet/acrylamide-fact-sheet#q3>

<sup>50</sup> Jamie Ducharme, *California Coffee Shops Will Warn Customers About This Possibly Cancer-Causing Chemical. Here's What to Know About It*. Time Health (March 30, 2018). <http://time.com/5222563/what-is-acrylamide/>

The public health and policy impacts of this misleading animal testing are not trivial. Based on animal tests of acrylamide by NTP and others, a California court ruled that Starbucks and other coffee sellers must now include cancer warnings on coffee cups, despite there being no evidence of health risks in humans.<sup>51</sup>

## CONCLUSION AND RECOMMENDATIONS

Despite NTP's laudable commitments and efforts to reduce and replace wasteful animal testing, this analysis found that 82% of NTP's testing is still performed on animals, costing taxpayers tens of millions of dollars annually and subjecting countless animals to painful procedures with little relevance to human health. It also found a troubling lack of transparency regarding details of test methodologies, costs, animal use, human relevance of test outcomes, and progress towards their own stated goal of reducing animal tests. Ironically, this illustrates concerns recently raised by NTP itself that institutional testing practices generally are not keeping pace with technological advances.

A decade ago, in its landmark *Toxicity Testing in the 21<sup>st</sup> Century* report, the NAS advocated for a paradigm shift to non-animal chemical testing that would, among other things, “reduce the cost and time of testing, increase efficiency and flexibility, and make it possible to reach a decision more quickly.”<sup>52</sup> In testimony to support the NIH's FY17 budget request, NIH Director Francis Collins predicted, “Animal safety testing for environmental chemicals and drugs will largely be replaced by tissue chips and [cultured stem cells] in 10 years.”<sup>53</sup>

In order to ensure these important goals are met, we agree with NTP's recent assessment that, “effective metrics need to be created to track progress and identify objective criteria for measuring success without creating additional regulatory burden” and that “agency-specific mechanisms that can be used to estimate the impact of a given activity may exist.”<sup>54</sup> This report using NTP's published data—despite its limitations—is a starting point.

The following five recommendations would improve accountability and transparency about NTP's animal testing and efforts to develop and implement non-animal testing tools:

1. Pass the bipartisan Federal Accountability in Chemical Testing (FACT) Act (HR 816) to improve progress reporting by NTP and other agencies about efforts to reduce and replace animal use in toxicity testing
2. Redirect funds from NTP's wasteful animal tests to the development and use of superior alternatives
3. Halt planned NTP animal testing and commission an independent audit to identify opportunities to avoid wasteful animal use
4. Require that all NTP reports clearly indicate how much taxpayer money was spent and how many animals were used
5. Restrict funding available for animal testing at NTP and other agencies

<sup>51</sup> Elizabeth Llorente, *Cancer Experts Say Coffee is Safe, Despite California's New Warning Label Requirement*. Fox News (March 30, 2018). <http://www.foxnews.com/health/2018/03/30/cancer-experts-say-coffee-is-safe-despite-californias-new-warning-label-requirement.html>

<sup>52</sup> National Research Council (NRC), Committee on Toxicity Testing and Assessment of Environmental Agents. *Toxicity testing in the 21st century: a vision and a strategy*. Washington, D.C.: The National Academies Press, 2007.

<sup>53</sup> U.S. Senate Committee on Appropriations. “Hearing on FY2017 National Institutes of Health Budget Request.”

<https://www.appropriations.senate.gov/hearings/hearing-on-fy2017-national-institutes-of-health-budget-request>

<sup>54</sup> NTP. “A Strategic Roadmap for Establishing New Approaches to Evaluate the Safety of Chemicals and Medical Products in the United States.” <https://ntp.niehs.nih.gov/pubhealth/evalatm/natl-strategy/index.html>