



4 March 2013

Mr Sean Sherlock  
Minister of State at the Department of Enterprise  
Jobs and Innovation with Responsibility for  
Research and Innovation; Ireland

Cc: Mr Rory Montgomery, Ambassador, Permanent Representation of Ireland to the EU  
Mr Bob Keane, Chair, Research Working Group

**OPEN LETTER TO THE IRISH PRESIDENCY OF THE EU REGARDING HORIZON 2020:  
EUROPE'S OPPORTUNITY TO LEAD IN INNOVATIVE HUMAN-RELEVANT HEALTH RESEARCH**

Dear Mr Sherlock,

I am writing on behalf of the European Policy Office of Humane Society International (HSI) regarding Horizon 2020, the new EU Framework Programme for Research and Innovation for the period 2014-2020, and the objective of advancing safety science and health research with sophisticated non-animal tools.

**HSI urges the Irish Presidency to ensure that strong commitments for boosting innovative, human biology-based health and safety research are reflected in the upcoming Council position.**

Horizon 2020 offers the EU a unique opportunity to lead the world in truly groundbreaking health research—an area of science that has struggled to make progress on important diseases such as cancer, asthma and degenerative neurological disorders. These difficulties are attributable in large part to the limitations of research that uses mice and other animals as “models” for human biology.

The situation is clearly stated in a recent *New York Times* article, “Mice Fall Short as Test Subjects for Humans’ Deadly Ills” (2013-02-11)<sup>1</sup>, which reports the findings of a 10-year study by 39 doctors and researchers from across the United States that, “*the mouse model has been totally misleading for at least three major killers—sepsis, burns and trauma. As a result, years and billions of dollars have been wasted following false leads.*” The article goes on to state that, “*Medical experts not associated with the study said that the findings should change the course of research worldwide...*”

This is not an isolated example. The limitations of research based on animal models can also be seen in the fact that **more than 1,000 potential drugs for tackling stroke have been tested on animals, yet only one of these has proved to be effective in humans**<sup>2</sup>. In extreme cases, misleading animal models can even put human patients at risk, as seen in the tragic UK clinical trial for TGN1412<sup>3</sup>, and the recent death of a patient undergoing hepatitis C experimental treatment using the Bristol-Myers Squibb drug BMS-986094<sup>4</sup>.

<sup>1</sup> G. Kolata, “Mice Fall Short as Test Subjects for Humans’ Deadly Ills”, *New York Times* 11 Feb. 2013. Website [http://www.nytimes.com/2013/02/12/science/testing-of-some-deadly-diseases-on-mice-mislead-report-says.html?\\_r=1&](http://www.nytimes.com/2013/02/12/science/testing-of-some-deadly-diseases-on-mice-mislead-report-says.html?_r=1&)

<sup>2</sup> VE O’Collins VE, et al. 1,026 experimental treatments in acute stroke. *Annals of Neurology* 2006, 59, 467-77..

<sup>3</sup> H. Attarwala, “TGN1412: From Discovery to Disaster.” *Journal of Young Pharmacists* 2010, 2, 332-3, Website <http://www.bmj.com/content/332/7543/677>

<sup>4</sup> Bristol-Myers Squibb Discontinues Development of BMS-986094, Website <http://bit.ly/P57Fd3>.

Taken together, **nine out of every 10 new drugs that appear safe and effective in animal tests turn out to be unsafe and ineffective in human trials**, according to the U.S. Food and Drug Administration<sup>5</sup>. This striking statistic underscores the fallacy of uncritical reliance on animals as substitutes for humans, and the need for genuinely human-relevant research models to support innovation and progress in tackling societal health challenges.

The very same challenge exists in the area of toxicology (safety testing of chemicals, medicines and consumer products). In 2007, the U.S. National Academy of Sciences published the report “Toxicity Testing in the 21<sup>st</sup> Century: A Vision and a Strategy”<sup>6</sup>, which pointed to advances in systems biology, testing in cells and tissues, and related scientific fields offering the potential to fundamentally change the way chemicals are tested for risks they may pose to humans.

The report outlined a new approach that would shift from animal testing to uncovering how chemicals disrupt normal human biology at the level of genes, proteins, and cell-tissue interactions, and developing state-of-the-art human cell tests and computer modelling tools to test for these disruptions and make predictions regarding real-life risks to humans. ***“The new approach would generate more-relevant data to evaluate risks people face, expand the number of chemicals that could be scrutinized, and reduce the time, money, and animals involved in testing,”*** according to the National Academies.

The United States, Japan and other countries are already investing heavily in this so-called “21<sup>st</sup> century toxicology” or “Tox21” approach. For instance, the Harvard University-affiliated Wyss Institute has engineered a series of human organs on micro-chips to serve as faster, cheaper and more human-relevant systems for drug testing<sup>7</sup>. **The EU has been encouraged by the FP7 coordination project AXLR8 (pronounced “accelerate”) to dramatically increase its investment in this rapidly developing global research area—to a level of more than 300 million € under Horizon 2020<sup>8</sup>.**

The promise of Tox21 has also led to the formation of a landmark corporate-NGO partnership—the Human Toxicology Project Consortium—whose membership includes Unilever, L’Oréal, Procter & Gamble, Johnson & Johnson, Dow, DuPont and ExxonMobil, alongside academic and civil society stakeholders. The aim of the Consortium is to accelerate the global implementation of an innovative, non-animal approach to chemical and product safety testing and risk assessment. The Consortium has released the following statement regarding Horizon 2020<sup>9</sup>:

*“Members of the Human Toxicology Project Consortium are key players in the innovation chain for chemicals, medicines and consumer products. We endorse the AXLR8 recommendations, and the positions of Humane Society International on advancing a new paradigm in safety testing, and urge the EU to ring-fence substantial resources under Horizon 2020 and beyond for an ‘innovation flagship’ initiative aimed at:*

- 1. Elucidation of ‘adverse outcome pathways’ relevant to safety testing and health research***
- 2. Development of human biology-based cellular and molecular tests and other key enabling technologies to detect perturbations of these biological pathways***
- 3. Development of next-generation computational, systems biology, pharmacokinetic and related bioinformatic tools to relate mechanistic in vitro data to a whole-body scenario.***
- 4. Creation of the decision tools to apply this information in risk and safety assessments.***

<sup>5</sup> U.S. Food and Drug Administration (2004). “Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products”, Website <http://1.usa.gov/b9Wg6z>

<sup>6</sup> The National Academies (2007). “Toxicity Testing in the 21<sup>st</sup> Century: A Vision and A Strategy”. Website [http://www.hsi.org/issues/advancing\\_science/facts/nrc\\_brief.pdf](http://www.hsi.org/issues/advancing_science/facts/nrc_brief.pdf)

<sup>7</sup> Wyss Institute, “Organs on a Chip”. Website <http://wyss.harvard.edu/viewpage/293>

<sup>8</sup> AXLR8 (2011). “Alternative Testing Strategies: Progress Report 2011”, Website <http://axlr8.eu/axlr8-2011-progress-report.pdf>

<sup>9</sup> Human Toxicology Project Consortium, “Statement on Horizon 2020 and Funding a Human Toxicology Project”, Website <http://htpcconsortium.files.wordpress.com/2012/10/htpc-statement-on-horizon-2020.pdf>

*Such a multinational and multidisciplinary research effort requires a careful strategic focus and ‘top-down’ coordination, which can best be achieved through formal collaborative research agreements, e.g. with the heads of U.S. agencies engaged in the ‘Tox21’ collaboration. This will maximise the potential for synergies arising from international cooperation while enabling the EU to meet its specific policy needs and maintain its longstanding leadership position in this rapidly evolving research area.”*

The European Commission proposals for Horizon 2020 and the recently adopted European Parliament Industry and Research Committee (ITRE) reports highlight that EU investments in large-scale, globally-coordinated projects in human-biology based (rather than animal-based) are key to advance results in human health and safety. These points warrant strong support and augmentation by the Member States based upon the recommendations of the EU AXLR8 project, the multi-stakeholder Human Toxicology Project Consortium, and Humane Society International.

**We respectfully urge the Irish Presidency to ensure that these points are reflected in the upcoming Council position.**

Attached for your reference is a recently published HSI/Europe expert report entitled “Advancing Safety Science and Health Research with Innovative, Non-Animal Tools”. We hope this report will serve as a useful resource for Horizon 2020 political negotiations, and as an inspiring guide for innovative solutions to advance medical progress, create growth and jobs, and address the EU’s longstanding commitment to replace and reduce animal use cosmetic and chemical testing and in life sciences research generally.

Thank you in advance for your attention to this important matter. Please do not hesitate to contact HSI’s EU Policy Advisor, Gaia Angelini, at [gangelini@hsi.org](mailto:gangelini@hsi.org) or +32 (0) 473 985 165 should you have any questions or require additional information.

Yours sincerely,



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Attach.