

To the European Ombudsman
Ms. Emily O'Reilly

from: Marco Mamone Capria
Perugia, Italy

October 9, 2016

Dear European Ombudsman,

as an European citizen and activist supporting the European Citizens' Initiative (ECI) "Stop Vivisection", I am writing to object to the response, released on 3 June 2015, of the European Commission¹, and to ask for your intervention.

"Stop Vivisection" was one of the three ECI's, out of 39, which reached the stage of being entitled to a response by the Commission, having totalled 1,173,130 certified signatures.² The citizens who signed "Stop Vivisection" urged the Commission «to abrogate the Directive 2010/63/EU of 22 September 2010 "on the protection of animals used for scientific purposes" and put forward a new proposal aimed at phasing out the practice of animal experimentation, making compulsory the use – in biomedical and toxicological research – of data directly relevant for the human species».³

Vivisection is the standard name for any invasive experimentation on live animals. There are of course experiments on animals, for instance to verify their cognitive abilities, which do not qualify as 'vivisection'. However, under this label falls the virtual totality of biomedical research using what are called 'animal models', that is populations of individuals of an animal species supposed to represent conditions of interest in another species, typically the human species in fields like toxicology and drug development and in the related 'basic research'.

Vivisection has always been criticized for two main reasons, both clearly stated in the text of the "Stop Vivisection" Initiative: because it is ethically repugnant to a large majority of citizens (and inconsistent with any claim to "protection of animals"), and because, from a medical and sanitary point of view, it fails to deliver what it promises, and disastrously so. In more than a century of controversy in the public record the case for conceiving of the "animal model" methodology as a dangerous variety of pseudoscience has strengthened to such a degree that any delay in expelling it from regulations concerning medicine and health has a grievous daily cost in terms of human lives and wellbeing.

In its response of 3 June 2015, following the public hearing of 11 May 2015, the European Commission dismissed the scientific side of the criticism of vivisection in a tendentious section titled "The role of animal studies", which starts by outlining a highly controversial view (and in fact a largely refuted one) concerning the historical merits of vivisection, and ends by stressing its contemporary «predictive value for pharmacology and toxicology». *Not even a single specific remark is made on the abundant, authoritative references contained in the Dossier⁴ presented to the European Commission by the representatives of "Stop vivisection" and which in my opinion amount to a fatal indictment, on scientific and methodological grounds, of the reliability and, indeed, safety of the "animal model" methodology.*

In the "Assessment" section, the Commission did not think it improper to rely for its estimate of the value of the "animal model" methodology on the European Animal Research Association, an organisation with *statutory* vested interests in the indefinite continuance of animal experiments («a European organisation that communicates and *advocates biomedical research using animals*»), and

1 <http://ec.europa.eu/transparency/regdoc/rep/3/2015/EN/3-2015-3773-EN-F1-1.PDF>

2 <http://ec.europa.eu/citizens-initiative/public/initiatives/successful/details/2012/000007/en?lg=en>

3 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:EN:PDF>

4 http://www.stopvivisection.eu/sites/default/files/dossier_-11_may_2015.pdf

which in its web site gives only a list of propagandistic and unsubstantiated statements,⁵ most of which have been refuted in the scientific and methodological literature, and also in a detailed and referenced fashion during the seminar "Protecting Our Health from the Business of Disease" I held on 16 October 2014 at the European Parliament.⁶

It must be admitted that there exists a conflict between scientists on this issue, though it is doubtful that it may be grounded on purely scientific reasons, since it is easy to verify that several well-known experts in the field (listed for instance in the Dossier and in the cited seminar) have concluded to the *invalidity* of animal experimentation, particularly as regards its use in trying to improve or safeguard human health. In order to convince themselves of this fact the members of the Commission had simply to consult the "Quotes" provided in the "Stop Vivisection" Initiative's web site.⁷

When the Commission promised in its response that by end 2016 it «will organise a conference engaging the scientific community and relevant stakeholders in a debate on how to exploit the advances in science for the development of *scientifically valid non-animal approaches* and advance towards the goal of phasing out animal testing» (italics added), it omitted to mention that *animal testing itself has never been validated*. This is not a secondary issue, it is *at the core* of the whole argument against vivisection, and whatever is said concerning the supposed "importance" of animal experimentation which does not take into account this crucial circumstance is basically flawed. Faulty and misleading methods *should be given a moratorium*, not be treated as 'golden standard' for other methods, and those scientists or regulators who still think they are needed are under the burden of proving in the first place that they are valid – a task very unlikely to be accomplished, since it means contradicting the vast and authoritative literature which has undermined in the last decades the "animal model" methodology.

To sum up, in its response to the "Stop Vivisection" Initiative the Commission *has endorsed a controversial scientific opinion which is deemed not only wrong, but damaging to science and to the European citizens' vital interests by a qualified sector of the scientific community*.

This is not only an unsatisfactory and disrespectful way to respond to the request signed by over a million European citizens: it is also a self-evident violation of the Precautionary Principle, according to which in dealing with «risks that science is not yet able to evaluate fully», one should take «due account» of the advice of «a minority fraction of the scientific community [...] provided the credibility and reputation of this fraction are recognised».⁸ These conditions are satisfied in the case of the criticism of the "animal model" methodology (except for the size of the critical fraction of the scientific community which may be much greater than it is commonly assumed). Surely there is no need for a new conference to establish this point.

Therefore by not taking into due account the views of the scientists who have published on some of the best biomedical journals their damning assessments of the "animal model" methodology, the Commission has *acted in contradiction with the most important principle of the European legislation concerning management of risk in a condition of scientific uncertainty*.

The citizens who signed for "Stop Vivisection" were not engaged in a «mobilisation [...] in support of animal welfare», as the Commission misleadingly wrote in the last section of its response. They were fighting for their basic rights to health, that is for a truly scientific and reliable medicine and drug development, and for protection from environmental, chemical, and food 'legal' poisoning. If the European Commission is allowed to dismiss the substance of a European Citizens Initiative the way it did in the case of "Stop Vivisection", then more than a million European citizens have been deluded into thinking that their opinions and reasons could count, and they have

5 <http://eara.eu/en/campaigns/forty-reasons-why-we-need-animals-in-research/>

6 https://www.youtube.com/watch?feature=player_embedded&v=MenfCa61C7w; the complete set of slides shown at the seminar is available from the first page of <http://www.hansruesch.net/indexe.html>.

7 http://www.stopvivisection.eu/content/quotes_articles_en

8 "Communication from the Commission on the precautionary principle"
<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52000DC0001>

wasted their resources – money, time, mental energy – for having wrongly believed that the European Union care for shared decisions and for the vital interests of citizens.

For these reasons I ask for your intervention, in order to voice my concerns about the costs European people are daily paying as a consequence of the adoption of regulatory requirements mandating a discredited and obsolete technique, and to elicit second thoughts from the Commission in conformity with the Precautionary Principle.

Yours sincerely,

Marco Mamone Capria