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The European Commission's response to Stop Vivisection violates the precautionary principle
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Good morning.

As you all know, in this moment another conference has been convened in Bruxelles by the European Commission, entitled “Non-animal approaches - the way forward”, to discuss the issue of validity – or rather invalidity – of the animal model methodology, and to «advance towards the ultimate goal of phasing out animal testing».

The idea in this eschatological formulation seems to be that the European citizens should prepare to be victimized, in several ways, by other decades of vivisection.

Vivisection is the standard name for any invasive experimentation on live animals (including of course humans), but I shall concentrate on vivisection using non-human animals of some species as models for other species, first and foremost humans.

The organisation of the cited conference by the European Commission seems to have been the only objective outcome of the European Citizens Initiative “Stop Vivisection” collecting more than a million certified signatures to repeal the Directive 2010/63/EU of 22 September 2010.

This is a true case of a mountain giving birth to a mouse – or perhaps to a guinea-pig.

In fact, the most lenient appraisal of the animal model methodology is that it is controversial. Even those who are on the wrong side of this controversy should admit, if they wish to be credited with a modicum of intellectual honesty, that a persistent controversy exists on this issue

– from more than a century, in fact.

To put it short, it is perfectly uncontroversial that vivisection is a highly controversial method of research.

But even this description fails to do justice to the situation. We are not dealing with an ordinary scientific controversy. Much more is at stake than some subtle difference in the expert opinions.

In fact many serious scholars have come to the firm conclusion that vivisection is a damaging and irresponsible Russian roulette played on human health.

When I say 'serious scholars' I am including official representatives of some of the most important health and research institutions in the world, although they may phrase their opinions more suavely than I have just done.

Here is how, for instance, Francis Collins, Director of the NIH, USA, put it in 2011:

«The use of animal models for therapeutic development and target validation is time consuming, costly, and may not accurately predict efficacy in humans. As a result, many clinical compounds are carried forward only to fail in phase II or III trials; many others are probably abandoned because of the shortcomings of the model. […] With earlier and more rigorous target validation in human tissues, it may be justifiable to skip the animal model assessment of efficacy altogether.»

This has been written five years ago. In 2014 Collins came back to the issue in an article on *Nature*, by tackling one of the most serious problems in so-called preclinical research: the lack of reproducibility of results. Here is what he wrote:

«Preclinical research, especially work that uses animal models, seems to be the area that is currently most susceptible to reproducibility issues. Many of these failures have simple and practical explanations: different animal strains, different lab environments or subtle changes in protocol. Some irreproducible reports are probably the result of coincidental findings that happen to reach statistical significance, coupled with publication bias».

In other words, not only are animal models unreliable, they are also fragile:

that is, they often fail to satisfy that cornerstone of experimental science, namely: reproducibility – even within the same species!

This is worse than 'irrelevant': it is not even science.

If 'authoritative' has any meaning in scientific debates, then Collins's statements must be considered as most authoritative statements.

Collins' reference to drugs «carried forward only to fail in phase II or III trials» deserves to be expanded:

in fact 92% of the molecules entering phase I trials – that is, those with *previously* healthy volunteers – will subsequently fail before registration.

The damages suffered by previously healthy volunteers after the first-on-humans trials surface in the mainstream media only when they are very severe, like in the case of the six volunteers at London in March 2006 or the six volunteers at Rennes in January 2016.

I have discussed and referenced Collins' and several other similar statements in my seminar at the European Parliament two years ago [October 16, 2014], and many others have been cited by the Stop Vivisection Committee in its "Dossier" submitted to the European Commission on May 11, 2015.

In toxicology, animal testing has served egregiously for decades two concurrent aims:

1) to make it unpractical, because of costs and time, to test the large majority of industrial chemicals and other agents;

2) to promote doubt on the tiny minority of chemicals and other agents on which animal tests have been performed.

I only need to mention that of the 143,000 chemicals pre-registered by December 1, 2008, according to the requirements of the REACH directive, those to be tested have been reduced to 5,500 – less than 4% of those registered.

The initial number was in fact hardly manageable, in terms of investments and time, if animal tests had to be used. A very good excuse for defusing REACH by those who had profited for so long from marketing unsafe and untested substances!

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Actually citizens are given by mainstream media a deceptively optimistic view of scientific progress in the medical field, particularly when they are asked to contribute with private money to research.

Reality tells a different story, and a sad one. To give a poignant example from the so-called “war on cancer”:

in the 90% of cancer patients – including those suffering from lung, breast, colorectal, and prostate cancers – a study showed that «drug therapy increased five year survival by less than 2.5% – an overall survival benefit of around three months».

I suppose there is no need to detail how most terminal cancer patients spent those added three months.

Has this anything to do with animal experimentation? Yes, certainly.

There are in fact very sound reasons to hold that modelling human cancer on rodents is a major cause for this deplorable record. Here is how a leading cancer researcher – Robert Weinberg, «A professor of biology at MIT and winner of the National Medal of Science» – put it in 2004:

«"A fundamental problem which remains to be solved in the whole cancer research effort, in terms of therapies, is that the preclinical models of human cancer, in large part, stink."».

And this is how a former NIH director, Elias Zerhouni, put it in 2013 in a lecture:

«With the ability to knock in or knock out any gene in a mouse—which “can’t sue us,” Zerhouni quipped—researchers have over-relied on animal data.

[quote]
“The problem is that it hasn’t worked, and it’s time we stopped dancing around the problem…We need to refocus and adapt new methodologies for use in humans to understand disease biology in humans.”»
[endquote]

This shows how far biomedical research has moved away from sheer common sense!

And just think of the huge amount of public and private resources squandered on self-styled medical research projects that have no reasonable hope to give useful medical results – and all too often not even merely *reproducible* results!

It is for these reasons that I consider the European Commission's response to Stop Vivisection as utterly inadequate, and on 9 October I lodged a complaint to the European Ombudsman.

I now quote the central part of my complaint, which also explains the title of my talk:

«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 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». 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*. »

End of quote from my complaint. I come now to the concluding remarks of this talk.

I am aware that a change in the way a whole branch of research is practised is not easy task: there is a huge professional inertia contrasting change, whatever the soundness of the reasons urging it. As has been said by one participant at a conference at the Wellcome Trust in London last year, «“poor methods get results”».

I think this simple concept is an important key to understand how bad methods can thrive for such a long time, even for centuries, with utter indifference of their practitioners to repeated failures.

However, moving away from pseudo-scientific and dangerous methods in such a vital field as medical research cannot be postponed anymore.

It cannot be accepted that scientists should evade their responsibilities when their wrong-doing is relevant to the citizens' lives. As former editor of the BMJ, Richard Smith, stated last year:

«If Volkswagen staff can be criminally charged so should fraudulent scientists.»

To release a new directive “on the protection of animals used for scientific purposes” was not remotely as urgent as it was, and remains, to release a directive on the protection of humans from fraudulent research, especially in the biomedical and environmental fields; this directive should introduce criminal charges for scientists found guilty of serious misconduct, and encourage and protect whistleblowing.

As to a revision of the directive on animal experimentation, only substantial changes can make it,

provisionally, acceptable. In my view here "substantial" means that:

1) the European Commission should acknowledge in the preamble that the animal model methodology is scientifically controversial and deemed unsafe by a qualified portion of the scientific community, so that the precautionary principle is called for to restrict the use of animals in such fields as drug and therapy development and toxicity testing;

2) in particular, new animal studies should not be licensed «until the best use has been made of existing animal studies and until their validity and generalisability to clinical medicine has been assessed» (I am quoting here from a review article published on the BMJ in 2004 [Pound et al. 2004]);

3) the validation of methods not involving animals should be streamlined, based on data directly relevant to humans, and adequately funded;

4) the revised directive should make compulsory the use of the validated non-animal methods.

Point 4) is, of course, not so far from the REACH requirements for skin sensitisation making «non-animal testing the default requirement» from last 11 October.

In my view, these changes in the current text of the directive should be considered as an absolute minimum if the European citizens' rights to health and to democratic participation are to be taken seriously by the government of the European Union.

Thanks for your attention.