

Presidenza del Consiglio dei Ministri



**Concerning bioethical issues raised by
Article 13, Law No. 96 of August 6, 2013,
“Criteria in view of a Governmental Decree for
the fulfillment of Directive 2010/63/EU of the
European Parliament and of the Council of
September 22, 2010”**

**Response to the query submitted to the National Committee for
Bioethics by Senator Prof. Elena Cattaneo**

24 January 2014

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Presentation

The NBC with this document responds to a query submitted by Senator Elena Cattaneo concerning the bioethical issues raised by the recent debate on animal experimentation, as a result of the Law August 6, 2013, n. 96, art. 13, which transposes Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010.

The document was approved by Profs. Carlo Caltagirone, Stefano Canestrari, Cinzia Caporale, Carlo Casonato, Lorenzo d'Avack, Francesco D'Agostino, Antonio Da Re, Mario De Curtis, Riccardo Di Segni, Carlo Flamigni, Paola Frati, Silvio Garattini, Assunta Morresi, Demetrio Neri, Andrea Nicolussi, Laura Palazzani, Massimo Sargiacomo, Monica Toraldo Di Francia e Giancarlo Umani Ronchi.

Profs. Salvatore Amato, Marianna Gensabella e Grazia Zuffa abstained from voting.

Prof. Luisella Battaglia voted against.

Profs. Bruno Dallapiccola e Lucetta Scaraffia both absent from the session subsequently expressed their approval.

Dr. Carla Bernasconi, a delegate of the President of the National Federation of Italian Veterinarians; Prof. Enrico Garaci, President of the Board of the National Institute of Health; Dr. Carlo Petrini, a delegate of the President of the National Institute of Health, present at the discussion as members by right of the Committee, without voting rights pursuant to the Decree of the President of the Council of 27 September 2013, invited by the President to express their views, declared that they were in favor of the motion.

Prof. Rosaria Conte, delegated by the President of the CNR, absent from the meeting, subsequently approved the motion.

Premise

The Parliament is engaged in the transposition of the new European Directive 2010/63/ EU on the protection of animals used for scientific purposes, with the enactment of Law 6 August 2013, n. 96, Art. 13 Criteria for delegation to the Government for the transposition of Directive 2010/63/ EU of the European Parliament and of the Council of 22 September 2010.

This Italian legislation has given rise to an extensive and important debate among the general public, the media, the research community and within political institutions. The debate on several occasions has become harsh and misleading, with the risk of endorsing false ideas and creating disaffection towards scientific research, its methodology and the bioethical reflection concerned.

The Committee has intervened several times on the issue of animal testing, and refers in particular to the Opinion: Alternative methods, ethics committees and conscientious objection to animal testing, 2009¹.

¹ Other opinions of the Committee on the subject: *Bioethical problems concerning the use of animals in activities linked to human health and well-being*, 2005; *Bioethics and veterinary science, animal well-being and human health*, 2001; *Animal testing and health of living beings*, 1997.

The Committee intends to make some further considerations on this subject, taking into account the query that it has been put.

From a scientific and epistemological standpoint, there must be reiteration of the centrality of experimentation on animals as a cognitive method for studying living organisms and in particular humans. The progress of knowledge advances through the use of models, and those involving animals occupy a prominent place. The question to ask oneself is which models and which research strategies to adopt each time, and how to maximise the scientific result, in accordance with the regulations.

It should be noted that fundamental scientific discoveries on the primary functions of the human body are historically due to the experimentation conducted on animals, as well as some basic biomedical innovations such as vaccines, blood transfusions, anesthesia, transplants and in general surgical procedures, extracorporeal circulation, dialysis, pacemaker, magnetic resonance imaging, gene therapy, the use of stem cells for degenerative diseases and, of course, the discovery and development of drugs and treatments for the very large part of human pathologies.

Indispensable, before all else, has been and will be the contribution made to basic knowledge, including the knowledge we set at the foundation of ethical sensitivity towards animals and which is due to scientific developments and their results.

From an ethical point of view, as stated by the Committee, it is necessary to reconcile, in a balanced and shared manner, different good, each good being worthy of protection, even if of a different order, such as health and human well-being, the promotion of scientific research, the reduction of suffering for the animals subjected to experimentation and their same well-being and interests to receive care, respect for the intimate beliefs of individual researchers in relation to the experimentation. We must always keep in mind that although animal testing is scientifically grounded and useful, it must be a constant exercise of mediation between different values. The privileged moral status of man, and the centrality of his interests and of primary human good - however it may be founded, whether according to beliefs and metaphysical reasons or the recognition that there is an evolutionary rationale for our finding it beneficial and adaptive to assign a different moral value to other living beings on the basis of predispositions that are natural to us and which have a biological basis - this can not make us forget that life in all its dimensions has an immense bioethical value. Consequently animal life deserves attention and respect.

The infliction of unnecessary and disproportionate suffering to animals is therefore unacceptable, particularly if strategies exist which can be fostered to minimise or abolish it. Therefore, animals should always be treated as sentient beings and their use in scientific procedures should be restricted to areas which truly make science advance and produce essential good such as health for humans as well as for animals themselves.

Considerations

Accordingly, the Committee:

1. acknowledges the need for scientific use of animals to test drugs and treatments aimed at the advancement of knowledge and the discovery of therapies for human health as well as animal health;

2. is in favor of limiting the use of animals for experiments (reducing the number) and favourable to the use of animal experimentation only if scientifically justified and relevant, with protocols based on criteria of proportionality and the reduction of suffering, to be examined by independent ethics committees;

3. calls for an increase in the research of so-called alternative methodologies and the use of complementary methods to animal testing (already established practice in all research laboratories);

4. points out that, although the results obtained from animal testing are not automatically applicable to humans, the scientific community agrees that these results are essential in order to prevent testing directly on humans;

5. reiterates its being in favor of animal testing only insofar as it is necessary for human health and to increase knowledge even in the field of animal health, in the belief that the importance of research and the illicitness of conducting experimentation directly on humans regardless of testing on animals to be a shared fact in bioethics and international biolaw;

6. shares the bioethical principles contained in *Directive 2010/63 / EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for research purposes*;

7. stresses that the provisions of Law 6 August 2013, n. 96, aimed at ensuring more extensive protection of animals in relation to the *Directive*, are bioethically questionable; in fact, they introduce additional restrictions giving rise to problems regarding the correct juridical application of that same *Directive*. More precisely, the bioethically controversial aspect of certain points must be emphasised:

- regarding the prohibition of xenotransplantation (i.e. transplantation of organs and tissues in different species), the Committee believes that it is useful experimentation with reference to the transplantation of organs and tissues among different animal species (e.g. for the study of anti-rejection drugs, of tumors, etc.);

- regarding the prohibition of research on the substances of drug abuse, the Committee believes that such experimentation on animals would be of considerable scientific importance, especially today faced with the spread of new drugs sold on the internet whose effects on humans are not yet known;

- regarding the prohibition on breeding on national territory of dogs, cats and non-human primates for experimentation, the Committee considers that this prohibition impedes Italian research within the framework of European research and inevitably entails the importation of animals, causing unavoidable discomfort for the same animals as well as additional costs for research.

Recommendations

The Committee makes a series of recommendations:

1. to proceed quickly to transpose the European Directive 2010/63 / EU on the protection of animals for scientific purposes, without creating conditions that marginalise the Italian research system, which is already fragile, and without betraying the goal of approximation of national legislation pursued by new EU laws;

2. to provide for simplification of the Italian regulatory framework and verification of regulatory coherence, in order to guarantee effective protection of animals;

3. to valorise Ethics Committees for animal testing, in line with the new European Directive, ensuring their independence and impartiality and third party status;

4. to allow for the effective exercise of the right to conscientious objection to animal testing in accordance with the law;

5. to give effect to Circular No. 6 of 14 May 2001 of the Minister of Health, in application of Legislative Decree no. Jan. 27, 1992, n. 116, introducing the principle of so-called adoption of guinea pigs;

6. to promote within the scientific community a culture for ever greater attention to the problems associated with the use of animals for scientific purposes, urging the creativity of researchers aimed also at mitigating the impact of testing on sentient beings.

Lastly, the Committee emphasises, the importance of ensuring greater accuracy of the news and comments in the non-specialist press and makes an appeal to the media to help prevent the spread of radicalism and fanaticism when discussing about science, for example, by not using misleading terms such as vivisection, and vice versa by promoting internal values to science such as recourse to logic and constant verification of the facts, respect for the requirements of objectivity, rigor and clarity of argument and intellectual honesty.

Attachment:

Letter of request from Senator Prof. Elena Cattaneo to the National Bioethics Committee

Senate of the Republic
Sen. Prof. Elena Cattaneo
12th Health and Hygiene Commission

To the President of the
National Bioethics Committee
Prof. Francesco Paolo Casavola

Rome, 22 January 2014

Dear President,

scientific experimentation conducted on animals and the related bioethical profiles are currently at the centre of a heated public debate and Parliamentary attention engaged in the transposition of the new European Directive 2010/63/EU.

However, in my opinion, the debate does not present a sufficient level of in-depth theoretical study and this is likely to create a distorted picture of scientific enterprise among the general public.

I am writing to you as I think the National Bioethics Committee with its diversity of members in terms of subjects and represented authority can and should strongly contribute to a balanced debate starting from facts of science to integrate the various philosophical, historical and moral components, and reaching what I consider may be a useful, even synthetic pronouncement containing guidance on the subject and indications of an ethical nature of general valence.

Trusting in your understanding of the problem,

Best regards

Prof. Elena Cattaneo