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Nederlandse Vereniging Voor Pathologie

Mr. López Aguilar
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Mr. López Aguilar
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Dear Mr. LópezAguilar,

Dear Members of the Civil Liberties, Justice and Home Affairs (LIBE) Committee,

Since 1994, Europe has beenboth a leader in the development of research infrastructures such as populational biobanks and in the development of knowledge of disease etiology and targeted therapies.
After the publication of the draft LIBE report, many research and patient organisations have expressed their concerns that the current leading position of Europe would be seriously jeopardised if the LIBE texts were to be adopted. Concrete examples were given which research would become impossible.

Even though the final LIBE Compromise text of 21 October 2013 contains some minor improvements, we would still like, as active members of the European scientific and biobanking community, to express ourutmost concern regardingcertain amendments as proposed by LIBE to the Commission proposal.

These amendments jeopardize international efforts to enhance and promote global health and medical research. They have major implications for the European epidemiological and biobanking research community. In fact, the new amendments would make an essential part of epidemiological, medical and biobanking research activities extremely difficult, if not practically impossible.The rapidtranslation of technology and therewith the progress in medical and public health research is at stake. Currently:

at least 108European biobanks have used a broad consent from their research participants, allowing for a wide range of research uses on the collected samples and associated data;
these biobanks are located in more than 23 European countries;
research based on biobanking activities has led to the publication of more than 17,094 peer-reviewed scientific publications; and, more importantly;
all this was made possible by the participation of more than 11,760,479 European citizens, who voluntarily agreed to provide a broad consent for biomedical research as approved by an ethics committee.

Notably, especially public health research and medical research aboutrisks for disease implementing new technology into carefully stored samples cannot always be carried out with consent. The effects of occupational or environmental risks requires that the data of all who were at risk are taken into account. Data need to be combined and working with fully anonymous data is impossible in this context. Hazardous side effects treatments and off-target effects of medication cannot be examined with consent because the effects were not foreseen at the time of introduction.At the time of storage of samples when the patients were treated, the new technologies were not available and it is impossible to re-

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contact everybody. Various more detailed examples of such research have been submitted to the EP already. The amendment to Article 81(2a) introduces a disproportionate threshold for the consent exemption. Currently in many Member States, consent is often not required to process pseudonymised (i.e. coded) data as there are multiple, successful governance mechanisms and technical standards in place to ensure data security and privacy, including research ethics committees, data access committees, codes of conduct, and encryption and key management to restrict data access. Requiring a 'high public interest' for the processing of medical and health data implies an exceptional, emergency situation disproportionate to the risks and benefits of such processing. 'High' adds no value to the judgment that needs to be made about the use of data and will only create confusion and ideological or political bias as to which research is allowable.. Such a bias is contrary to a free society. The only relevant questions are whether the research cannot be carried out otherwise, is methodologically correct, will be properly published to improve our knowledge and whether proper data safety is assured. In that case there is always a public interest in such data being used.

Articles 81 1 b and 83 as proposed by LIBE relate to the use of data with consent.
As currently drafted, Article 81(1b) is ambiguous. The current phrasing seems to exclude broad consent for future 'health-related research' as approved by an ethics committee. If LIBE indeeds intends that specific or multiple layered consent is necessary that would cause a major burden for and threat to genomic research and to large-scale studies and research infrastructures such as biobanks where broad consent is currently the standard as accepted by almost all ethics committees.

By adopting the text of 81.1 (b), the EP would deny the autonomy and legitimate interest of these almost 12 million participants, and of those of future generations, to freely and knowingly provide data and biological samples to support long term longitudinal research.

Regarding art. 83 as proposed by LIBE we are gravely worried about the term 'highest technical standards'. The EP should consider that the technical standards for the safe processing of data as prescribed in Chapter IV of the proposed GDPR, are sufficient for health research as well. There has not been a single data breach of significance reported regarding such research, in spite of millions of data processed yearlyto further public health and health care provisions in Europe.

In the last decade, substantive funding in the FP5, FP6 and FP7programmes of the EC supported the development of research resources such as biobanks based on broad consent. Indeed, the European approach to this kind of biomedical research infrastructures has made remarkable progress in recent years with the implementation of the European Strategy Forum on Research Infrastructures (ESFRI) roadmap, which culminated in 2013 in the formal incorporation by the European Union of the pan European Biobanking and Biomolecular Resources Infrastructure (BBMRI ERIC). This infrastructure is one of the underpinnings of Horizon 2020. By funding these initiatives, the EC has recognized the scientific imperative of such research and demonstrated its willingness to position Europe as a leader in the domain of medical and biobanking research.The Compromise Text approved by the LIBE Committee will affect on the sustainability of current resourcesand hamper the leadership of Europe in medical research. Notably, the realization of a major EU target of Horizon 2020 - adding more healthy years to life, active and healthy ageing - will be severely compromised. This can only be achieved by following people longitudinally from the time that they are not yet

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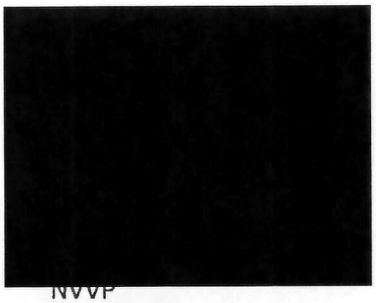
affected by disease, mandatory requiring broad consent as diseases cannot yet be specified.

In conclusion, we respectfully, but urgently ask that the latest Compromise Text be amended so as to respect the wishes of research participants and make possible common forms of broad consent in research and to enable public health research into health threats without consent to continue when appropriate safeguards are met.



NVVP

About The Dutch Scientific Society for Pathology
(Nederlandse Vereniging Voor Pathologie -NVVP-)

The Dutch Scientific Society for Pathology aims to promote knowledge and professional practice of pathology of humans and animals. We look after the scientific and societal interests in the broadest sense of her members, in the fields of clinical/surgical pathology, veterinarian pathology, toxicological pathology, research animal pathology, pathobiology and molecular biology in pathology. The society promotes and warrants the quality in these areas by drawing up protocols and guidelines for professional practice, and participating in multidisciplinary workforces and contributing to multidisciplinary guidelines.

The NVVP has over 600 members, about 350 being clinical/surgical pathologists. The society is organized in a board and special committees for professional practice, quality assurance, professional interests, postgraduate education, molecular biology, national cancer screening programs, and legal affairs. The Society facilitates and organizes visitations for professional quality assurance (National Visitation Committee) and for training and education of pathology residents (*concilium pathologicum*).

Find us at www.pathology.nl - contact The NVVP at secretariaat@pathology.nl

The NVVP endorses the BBMRI Dutch National Tissuebank Portal