Bioteknologinemnda
The Norwegian Biotechnology Advisory Board

The Norwegian Directorate of Health
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Comments regarding DH-Bio's draft recommendation on the use for insurance purposes of personal health-related information

The Norwegian Directorate of Health has invited the Norwegian Biotechnology Advisory Board to comment on the Council of Europe's Committee on Bioethics' (DH-Bio) working document "Draft Recommendation on the use for insurance purposes of personal health-related information, in particular information of a genetic and predictive nature." The Biotechnology Advisory Board discussed the document during its meeting on 11 March 2014.

The Norwegian Biotechnology Advisory Board commends DH-Bio and the Directorate of Health for initiating the work towards this recommendation. As the use of genetic tests increases both among consumers as well as in public and private health care, the need for laws and guidelines for the use and distribution of genetic information grows. Such laws and guidelines are vital both for securing the public's right to affordable health care and for ensuring a viable insurance system for health care service providers.

The Norwegian Biotechnology Advisory Board has not yet had an opportunity to discuss in detail all the various aspects concerning the commercial use of genetic information outside the health care sector. In its comments to the DH-Bio's draft recommendation, however, the Advisory Board does wish to point to some relevant questions currently not addressed in the document. In addition, the Advisory Board would like to comment on how the draft recommendation relates to Norwegian laws and regulations within the field, in particular the "Act relating to human medical use of biotechnology etc." (The Norwegian Biotechnology Act) from 2003.

Taking genetic non-discrimination as an instructive principle, while acknowledging the need for a just and viable system for health insurance, the Norwegian Biotechnology Advisory Board wishes to make the following comments to the DH-Bio's draft recommendation:

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- *The definition of predictive data and genetic tests.*

In the draft recommendation's glossary, predictive data is defined as "Data obtained from a predictive genetic test or a non-genetic predictive examination." Genetic tests are defined as "[…] tests involving analysis of biological samples of human origin, aiming at specifically identifying the genetic characteristics of a person which are inherited or acquired during early prenatal development." In the Norwegian Biotechnology Advisory Board's understanding of these definitions, the term "predictive genetic data" is used here as a collective term for data from genetic predictive, presymptomatic and carrier testing. It may be clarifying to include in the glossary or elsewhere in the document a discussion of the relationship between these three types of genetic data in the context of the draft recommendation.

- *The use of existing predictive data.*

Paragraph 29 of the draft recommendation states that: "Where it is permitted by law, the use for insurance purposes of existing data resulting from predictive genetic tests should not be allowed in all cases." The Norwegian Biotechnology Advisory Board wishes to emphasize that the Norwegian Biotechnology Act makes no distinction between performing *new* predictive genetic tests and the use of *existing* predictive data for insurance purposes. The Norwegian Ministry of Health and Care Services has stated regarding the use of data from genetic predictive, presymptomatic and carrier testing for commercial purposes, that the interests of insurance companies should yield to the principle of genetic non-discrimination and respect for human dignity.[1] Allowing insurance companies to utilize existing predictive genetic information may also discourage uninsured patients from performing genetic tests out of fear of being refused insurance coverage later. However, if the draft wording of paragraph 29 will remain in the final text, the Advisory Board supports the wording of article 30 and 31, which limit the prospective use of existing predictive genetic information.

- *Use of predictive genetic information from members of the insured person's family.*

The Norwegian Biotechnology Advisory Board supports the notion in article 32 that use of such information should be prohibited, as is currently the case in Norway.

- *Predictive genetic information as a result of diagnostic genetic testing.*

The document does not mention the question of predictive genetic information that emerges as a result of diagnostic testing. One example of this would be a BRCA test of a woman diagnosed with breast cancer, where the diagnostic result of the test may also reveal predictive information about the woman's risk of developing ovarian cancer. This is a real issue for a number of patients, and should be discussed and addressed in the final recommendation.

- *Preventive treatment that indirectly reveals predictive genetic information.*

[1] Ot.prp. nr. 64 (2002-2003), p. 105.

As is the case with predictive genetic information emerging from diagnostic testing, the question of preventive treatment that indirectly reveals predictive genetic information is not addressed in the draft recommendation. One possible example of such indirect predictive information is a patient who, without a clinical diagnosis, takes beta-blockers due to an increased genetic risk of heart failure. The Advisory Board would also like to see this question addressed in the recommendation.

Concluding remarks: The Norwegian Biotechnology Advisory Board would like to thank the Directorate of Health for this opportunity to comment on the DH-Bio's draft recommendation. The Advisory Board would appreciate an opportunity to comment on the final draft of the document before it is passed in the Council of Europe. Thus, we kindly ask the Directorate to present the final draft to the Board before it is passed.

Yours sincerely,

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Chairperson

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