

# PRESS RELEASE

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### Ethics Council focuses on rare diseases

**In Germany alone there are about four million people living with a rare disease – reason enough for the German Ethics Council to meet 25 April with over 200 guests to focus on the situation of the patients and their families, and discuss how their needs could be better catered for by the health care system.**

A rare disease is one which affects no more than five in 10,000 people. People with a rare disease face a number of problems: false or late diagnosis, a lack of information and practical support in daily life, psychological stress due to isolation, and a dearth of adequate specialized units. Structural, medical and financial factors hinder both the provision of medical care to those affected and research aimed at improving diagnosis and treatment.

“The challenge is to provide effective and fair support for all people with complex rare diseases, and to ensure that they have adequate therapies and symptomatic treatments,” said the Chair of the Ethics Council, Peter Dabrock, at the beginning of the meeting.

In his introductory talk, Council member Stephan Kruij, who is himself affected by a rare disease, gave a graphic description of the difficulties faced by people with rare diseases. He asked how the legitimate demands of people with rare diseases can be met within the structural and financial limitations of the health care system.

Antje Behring of the Federal Joint Committee (G-BA) outlined the regulations which provide the basis for the G-BA’s decisions on reimbursing costs for the treatment of rare diseases. In Germany, there is a simplified procedure for authorising drugs to treat rare diseases (orphan drugs), but a lack of guidelines and caps on prices has, Behring said, led to a steep rise in annual therapy costs for orphan drugs. This area, she said, needed significant improvement; furthermore, the benefit of specialist outpatient care for the diagnosis and treatment of rare diseases needed to be empirically investigated.

Daniel Strech from Hanover Medical School gave a talk on the ethical challenges of rare diseases. According to Strech, it is widely agreed that a solidary society has to give all its members a fair chance of treatment, and that simplified regulations on authorising drugs to treat rare diseases are desirable. But the debate, he said, becomes more controversial, as soon as real-life decisions on questions of allocation and incentives are at issue – concerning the fair distribution of financial resources for care services and research programmes, for instance, or the question of whether simplifying the authorisation of orphan drugs really helps provide medication that is of real benefit to those affected.

In the panel discussion that followed, moderated by Ethics Council member Elisabeth Steinhagen-Thiessen, the two speakers were joined by Jörg Richstein from the Alliance for Chronic Rare Diseases and Sabine Sydow from the Association of Research-Based Pharmaceutical Companies (vfa bio), to discuss what can be done to ensure that people with rare diseases are in the future offered the best possible diagnosis and therapy. In this discussion, which was open to the public, various possible solutions were listed, from creating greater transparency through restructuring the way patients are informed, to better integrating self-help groups into the development of care concepts, to

#### Members

Prof. Dr. theol. Peter Dabrock (Chair)  
 Prof. Dr. med. Katrin Amunts (Vice-Chair)  
 Prof. Dr. phil. Dr. h. c. Dipl.-Psych. Andreas Kruse (Vice-Chair)  
 Prof. Dr. med. Claudia Wiesemann (Vice-Chair)  
 Constanze Angerer  
 Prof. Dr. iur. Steffen Augsberg  
 Prof. Dr. theol. Franz-Josef Bormann  
 Prof. Dr. med. Alena M. Buyx  
 Prof. em. Dr. iur. Dr. h. c. Dagmar Coester-Waltjen  
 Dr. med. Christiane Fischer  
 Prof. em. Dr. phil. habil. Dr. phil. h. c. lic. phil. Carl Friedrich Gethmann  
 Prof. Dr. rer. nat. Dr. phil. Sigrid Graumann  
 Bishop Prof. Dr. theol. Martin Hein  
 Prof. Dr. med. Wolfram Henn  
 Prof. Dr. iur. Wolfram Höfling  
 Prof. Dr. (TR) Dr. phil. et med. habil. İlhan İlkilic  
 Prof. Dr. rer. nat. Ursula Klingmüller  
 Stephan Kruij  
 Prof. Dr. phil. Adelheid Kuhlmei  
 Prof. Dr. med. Leo Latacsch  
 Prof. Dr. iur. Dr. h. c. Volker Lipp  
 Prof. Dr. theol. Andreas Lob-Hüdepohl  
 Prof. em. Dr. iur. Reinhard Merkel  
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expanding clinical studies and supporting the development of registers for rare diseases.

Peter Dabrock summed up the lively discussion by saying that the bioethics panel had given many people affected by rare diseases the chance to explain their situation and the challenges it involved. It was important, he said, to develop solutions that focused on people with rare diseases.

Further information on the event can be found here:  
<https://www.ethikrat.org/en/bioethics-forum/rare-diseases/>.