

Letter

Legal Aspects of Personalized Medicine

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Dear readers,

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I am delighted to present the new issue of *Personalized Psychiatry and Neurology Journal*. The main goal of the personalized medicine approach to psychiatry and neurology is to match treatments based on the specific characteristics of each individual patient. New strategies of treatment, such as genomic approaches, neuroimaging techniques or application of artificial intelligence (AI) in a personalized manner can thus potentially enhance accuracy of diagnosis and effectiveness of treatment.

However, to make these innovations possible what would be required is a further progress in science and the implementation of an adequate legal framework in this field. The rapid development in the area of personalized medicine raises substantial legal questions concerning privacy, informed consent, and equality of access. The use of genetic information (including sensitive data associated with the mental health and neurologic status) in patients regarding their psychiatric and neurologic profiles has a risk that cannot be overstated, necessitating strong protective measures against unauthorized access to and use of this information. The new legal framework should work on an assumption that medical patients as data subjects will hold a degree of control over their health data, including consent processes by which the sharing of such becomes a reality.

The incorporation of cutting-edge predictive algorithms and AI technologies in medical practice raises not only clinical but also legal questions about liability and responsibility. If the decision to treat is made by a predictive algorithm and turns out badly, who now takes the blame? The law itself should set those levels of validation and transparency that correspond to what is considered clinically acceptable and ethically defensible for an application when the technologies fail. Alongside liability concerns, concern over access to individualized treatment is also a significant issue.

Healthcare access inequities could exacerbate and perpetuate healthcare access inequities among marginalized populations and stigmatized conditions.

As such, a legal ecosystem for personalized medicine in psychiatry and neurology will need to be active in order to nurture specialized advances of patient care innovations at the same time as safeguarding (and potentially even challenging) solutions to protect patients.

If we could enable this collaboration and partnership development between healthcare providers, researchers, lawyers, policymakers, we could build models by which scientific expansion is embraced, ethically integrated, and that minimize disparities.

The objective of this new issue of the *Personalized Psychiatry and Neurology* journal is to discuss some of these challenges and open up ideas for how thinking about this emerging field in health care can evolve!

Best regards,

**Editor-in-Chief of Lex Genetica Journal,
Head of the Center for Legal Support of Bioeconomics and Genetic Technologies,
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