Workshop: "Closing the regulatory gap for consumer neurotechnology" Brocher Foundation, Geneva, 25 to 27 November 2019

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Project subject:

The combination of big data and advanced machine learning—often referred to as a form of artificial intelligence (AI) or "intelligent systems"—may increase the efficiency and accuracy of automated systems and of economic processes and is therefore of great interest to industries across all sectors, especially health care and medical technology (Mittelstadt *et al.*, 2016; Echeverría and Tabarés, 2017).

In the area of medical technology, concomitant progress in microsystems engineering has turbocharged the field of intelligent neurotechnology, i.e. devices for decoding brain data for clinical, consumer or military applications. Big information technology and software companies, as well as many "neurotech" startups, are now actively developing neurotechnological systems directly targeted at consumers, often for "paramedical" applications, for example neurofeedback for relieving stress or anxiety or for brain stimulation (lenca *et al.*, 2018; Kellmeyer, 2018; Wexler, 2017; Piwek *et al.*, 2016). As these devices and applications typically fall outside of medical device regulation regimes, a growing (grey) market of direct-to-consumer (DTC) neurotechnology is emerging that creates a number of ethical, legal, social and political challenges (Kellmeyer, 2018; lenca *et al.*, 2018; Yuste *et al.*, 2017).

With regard to intelligent neurotechnologies, scholars have recently raised ethical concerns and indicated issues of privacy, agency, identity, data security, human enhancement, algorithmic biases and discrimination as the main ethical, legal and sociopolitical challenges in this domain (Kellmeyer, 2018, Yuste et al., 2017, Jotterand & lenca 2017). In particular, intelligent neurotechnological devices raise concerns regarding control and responsibility, e.g. in terms of gaps in moral and legal accountability in cases in which decision-making capacity is relegated from human users to a device (or software-based decision-support system), for example in an intelligent brain-computer interface (Kellmeyer et al., 2016; Grübler, 2011). In terms of conceptual philosophical foundations, neurotechnological devices that interact closely with individuals, such as brain-computer interfaces for medical or entertainment purposes, also challenge concepts of agency, autonomy and identity (Friedrich et al., 2018; Kellmeyer et al., 2016; Jotterand 2016; Gilbert, 2015). From the perspective of legal studies and in terms of regulatory guidance, the legitimacy of using intransparent algorithms in safety-critical applications is guestioned (Voeneky and Neuman, 2018). Furthermore, algorithm-based evidence might be inconclusive, inscrutable, or misquided and therefore pose significant barriers for establishing trust between human users and the intelligent device (Kellmeyer et al., 2018; Gaudiello et al., 2016; Battaglia et al., 2014).

Especially the collection of large amounts of brain data in the hands of private companies raises concerns about the security of these data from unwarranted access and misuse. The recent case of data abuse by Facebook has raised awareness for the general risks associated with the acquisition and storage of large quantities of personal data. Particularly, it is unclear whether existing legal frameworks for data protection and governance suffice in protecting consumers from these effects (lenca *et al.*, 2018; Kellmeyer, 2018). Apart from individual privacy, especially mental privacy, the ability of advanced machine learning algorithms to learn on aggregated data collected from many individuals also raises questions on group privacy (Taylor et al., 2017) as well as questions on the privacy of first-person subjective experience ("mental privacy"). Among other sequelae, these concerns have spawned a debate on the moral and legal status of mental states, e.g. the question whether the right to mental privacy should be framed in the context of human rights (lenca and Andorno, 2017).

This project aims at addressing these concerns by engaging in multidisciplinary reflections to examine philosophical, ethical, legal and social challenges arising intelligent neurotechnologies, specifically in the context of consumer applications.

Tentative Program

Monday, November 25, 2019

Day 1: Neurotechnology, consumer application and philosophical implications

11:00 - 13:00 – Informal welcome at Brocher Foundation of arriving participants

13:00 - 13:15 – Introduction and presentation of the workshop by the organizers

13:15 - 13:35 - Tonio Ball (Uni Freiburg) - State of the Art Neurotechnology

13:35 - 13:55 - Philipp Kellmeyer - Ethics of Machine Learning and Brain Data Analytics

13:55 - 14:15 – Marcello Ienca (ETH Zurich) - Consumer Neurotechnology: Ethics & Policy Issues

14:15 - 14:45 - Group discussion on presentations

14:45 - 15:15 - Coffee Break

15:00 - 15:20 – Orsolya Friedrich (FernUni Hagen) - Implications of Consumer Neurotechnology for Autonomy and Agency

15:20 - 15:40 – Fabrice Jotterand (Medical College of Wisconsin / Uni Basel) -- Consumer Neurotechnology and Our Incumbent Anthropological Identity Crisis

15:40 – 16:00 – Group Discussion and collection of important points for Day 2

16:00 – 17:30 – Break-out groups (16:00-17:00) and presentations (17:00-17:30)

19:00 – Dinner

Tuesday, November 26, 2019

Day 2: Brain Data, Health Data, Personal Data and the Need for Legal Regulation

9:00 - 9:20 – Fruzsina Molnár-Gábor (Heildelberger Akademie der Wissenschaften, Heidelberg) - Brain Data and Genetic Data

9:20 - 9:40 – Ralf J. Jox (Uni Lausanne) - What is Specific About Brain Data that Warrants Special Protection?

- 9:40 10:00 Silja Vöneky (Uni Freiburg) -- The Legal Boundaries of Neurotechnology
- 10:00 10:20 Coffee break
- 10:20 10:40 Grischa Merkel (Uni Bremen) "Mind reading" through brain deocding
- 10:40 11:00 Joseph J. Fins (Weill Cornell Medical College) Regulating Neurotechnology a US perspective
- 11:00 11:30 Group discussion on presentations
- 11:30 12:30 Collective writing of draft guideline document (Part I): Logistics, first steps, break-out groups start to draft text from their results from day I
- 13:00 14:00 Lunch
- 14:00 14:20 Hannah Maslen (Oxford) Neuromodulation and the Regulation of Cognitive Enhancement Devices
- 14:20 14:40 Effy Vayena (ETH Zurich) Big Data and Health Data Sharing
- 15:00 15:20 Ricardo Chavarriaga (EPFL): Developing Standards for Neurotechnology and Algorithms

14:40 - 15:00 - Coffee break

15:00 - 15:20 – Hank Greely (Stanford) [via Videocall] -- Neuroethics & International Brain Data Governance

15:20 - 17:00 – Group Discussion & Working Groups: Discussing the afternoon talks and the results of the first round of drafting (telepresence of Hank Greely); break-out groups for editing the first drafts

19:00 - Dinner

Wednesday, November 27, 2019

Day 3: Closing the Regulatory Gap

9:00 - 9:20 - Roberto Andorno (Uni Zurich) - Brain Data and Human Rights

9:20 - 9:40 – Hervé Chneiweiss (INSERM) - Neurotechnologies and Identity: from games to biais? Ethical issues between preserving autonomy and preventing vulnerability

9:40 - 10:00 – Andreas Reis (WHO) [invited, tbc]

10:00 - 10:20 - Coffee Break

10:20 - 10:40 - David Winickoff (OECD)

10:40 - 13:00 - Collective drafting of consensus guideline in break-out groups and the whole group

13:00 - 14:00 - Lunch

14:00 – Coffee and farewell

Literature

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