Neurotechnology, Stakeholders, and Neuroethics: Real Decisions and Trade-Offs from an Insider's Perspective

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1 Introduction

For now, most public discourse around the advancement of neurotechnology comes from academia, certain large organizations, and, primarily, startups. The term neurotechnology usually refers to brain–computer interface (BCI) technology, which is defined "as a computer-based system that acquires brain signals, analyzes them, and translates them into commands that are relayed to an output device to carry out a desired action" [1]. We think it is critical for pioneers in the BCI space, among other critical technology areas, to think holistically about what their work means in terms of its impact on humanity. Since larger companies tend to be more reserved in statements made publicly, have relatively fewer resources dedicated to specific emerging technologies, and acquire smaller companies, we emphasize the need to map and understand decisions made from these smaller organizations that set ripple effects for larger technological involvement, use, and adoption.

1.1 Why Focus on Smaller Companies?

Smaller organizations, such as startups, are able to move more flexibly and are often the first to give momentum to new technologies. Reasons for focusing on the role that startups play in setting the tone for new technologies are that they (1) can disrupt larger organizations; (2) are small enough to change how and why their companies operate to accommodate a specific change they envision for the world; and (3) have unique challenges with regard to making decisions that have specific trade-offs due to resource limitations.

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Technological advances made in recent years have evolved BCIs from assistive devices to technologies with a variety of applications, spanning basic neuroscience research to human augmentation [2–4]. BCIs have also broadened their scope from technologies mainly used in clinical or research lab settings to consumer devices that can be used in our everyday lives, which has spawned more neurotechnology companies today than in any past period. For clarity, the word *neurotechnology* has been introduced to represent all technologies that use neural activity as input, such as a brain-controlled prosthesis, or output, such as brain stimulation devices, identifying BCIs as a particular type of neurotechnology. For the rest of this paper, we will refer to neurotechnology in the broad sense.

1.2 How Hard Is Neurotechnology Development?

Really hard. A general consensus in the academic community is that neurotechnology capabilities, especially with consumer products, tend to be exaggerated and overhyped. Reliably collecting data from the brain, analyzing them in real-time to extract specific patterns associated with a given mental task, and building end-to-end systems that work across multiple people are among the greatest challenges faced by neurotechnology devices. The high cost and technical competency required to develop new neurotechnology represent additional burden. In other words, the neurotechnology business is really hard.

As a result, to date, the majority of developments in neurotechnology have been academic and driven by laboratories around the world. Nonetheless, as neurotechnology receives more attention, they generally see an increase in funding, which accelerates development addressing some of the critical choke points preventing mainstream adoption.

The opportunities to significantly improve our understanding of ourselves provided by neurotechnology go hand in hand with novel questions and concerns related to the ethical considerations relevant to the development, application, and commercialization of these technologies. The lack of regulation in this field leaves small and large organizations with a key decision making spectrum; ignore such ethical concerns and be fully driven by profit-oriented stakeholders, or use their expertise and experience to direct and educate the field on how to tackle them. It is important to acknowledge that these decisions are often not clear cut. Nonetheless, as a small startup in the field, we embraced this second route. The rest of the paper will share our unique perspective in this domain.

2 What Is Neuroethics?

The first use of the term neuroethics, although not necessarily aligned with the current field of neurotechnology, was in a 1973 paper entitled “Neuro-ethics of ‘walking’ in the newborn” by Harvard physician Anneliese A. Pontius [5]. However,

writer William Safire is widely credited with giving the word its current meaning in 2002, defining it as "the examination of what is right and wrong, good and bad about the treatment of, perfection of, or unwelcome invasion of and worrisome manipulation of the human brain [6]." In another definition of neuroethics, Martha J. Farah, a pioneer in the field and researcher at the Center for Neuroscience and Society at the University of Pennsylvania, makes and contextualizes a relevant comparison to neuroethics with the field of genetics: "Like the field of genetics, neuroscience concerns the biological foundations of who we are, of our essence. The relation of self to brain is, if anything, more direct than that of self to genome. Perhaps more important, neural interventions are generally more easily accomplished than genetic interventions. Yet until recently there has been little awareness of the ethical issues arising from neuroscience [7]."

Neuroethics encompasses a large and varied set of issues. Some of these concern the practical implications of neurotechnology for individuals and society. Technological progress is making it possible to monitor and manipulate the human mind with ever more precision through a variety of neuroimaging methods and interventions [7]. For the first time, it may be possible to breach the privacy of the human mind and judge people not only by their actions, but also by their thoughts and predilections. The alteration of brain function in normal humans, with the goal of enhancing psychological function, is increasingly feasible and, indeed, increasingly practiced. The sooner neuroethical concerns are addressed, the earlier companies can start translating new findings in neuroscience into products. As Farah states, "progress in basic neuroscience is illuminating the relation between mind and brain, a topic of great philosophical importance. Our understanding of why people behave as they do is closely bound up with the content of our laws, social mores, and religious beliefs. Neuroscience is providing us with increasingly comprehensive explanations of human behavior in purely material terms. Although the field of neuroethics is young, the time seems ripe for a review in which the key issues of neuroethics, both practical and philosophical, are surveyed and placed in relation to one another [7]."

2.1 Neurable: Who Are We?

Neurable is a leading BCI company that commercializes sensor, signal processing, and algorithm advances into more practical, everyday form factors. We spun the company out of the University of Michigan's Direct-Brain Interface (UM-DBI) Laboratory in 2015 and have since gone on to commercialize BCIs in the consumer space. Having worked in this domain for nearly a decade, we have seen maturation and development in the field, alongside key technologies and considerations.

As pioneers in the space, we believe it is paramount to get ahead of potential ethical issues. This falls under the field of "neuroethics" and, to this end, we have been involved in relevant conversations and initiatives as a way to proactively further the space in regard to neuroethical responsibility and policy. To date, we have

presented and published on the topic, openly tried to inform the community, promised not to sell user data, and consulted with the United Nations, the United States' Cybersecurity and Infrastructure Security Agency (CISA), and multiple world-renowned academic institutions.

3 Stakeholders

Knowing who influences decision-making allows one in and/or outside of an organization to understand how to best understand, influence, and/or shape outcomes, especially when it pertains to neuroethics. We define "stakeholder" in this chapter as an entity, either specifically or conceptually, that affects how decisions pertaining to neurotechnology and relevant neuroethical considerations are made. A stakeholder could be a group or a single individual that directly or indirectly influences how decisions are made. The following presents a breakdown of key stakeholders involved in decision-making for neurotech companies with a special emphasis on neuroethics. It should be noted that this is not an exhaustive list but a summary of key influencing forces.

3.1 Companies

Companies or organizations are directly involved in the planning, development, and commercialization of neurotechnology devices. They play a critical role in deciding which technological advances are translated into products and are made available to the end user. Neurotech companies are also composed of three main subcategories of stakeholders: founders, employees, and advisors.

Founders establish directions, priorities, and goals of the company, having a direct impact on what problems to solve through neurotechnology. They also communicate with and receive input and feedback from other stakeholders, such as investors and end users, ensuring the company's direction is aligned with their needs.

Employees are the key players in implementing neurotechnology, translating advances in science and engineering into products and services. They include engineers, scientists, assistants, interns, and managers. They are the ones responsible for ensuring that data are collected rigorously and ethically, that algorithms are fair and robust across different user populations, and that personal data are transmitted and stored safely and securely. As such, employees play a critical role in effectively implementing neurotech solutions.

Advisors help founders and employees with setting feasible directions and goals for the success of the company. They usually are world-leading experts in a specific area related to the company, such as neuroscience, engineering, or manufacturing. Advisors use their broad view of the market and scientific breakthroughs to counsel the company on opportunities that might not be evident internally.

3.2 Investors

BCI or other neurotechnology companies tend to be considered "Moonshot" initiatives that likely require investment capital to help move promising technology toward commercialization [8]. For this reason, it is important to understand who the investors are and what their role is in the space. Investors tend to be high-net worth individuals, venture-capital corporations, and/or other forms of equity-based investment vehicles that generally invest money into a company in exchange for a percentage of ownership.

In addition to investment, they may also act in an advisory or support capacity, helping the company navigate opportunities, networks, and other benefits.

They are relevant when considering neuroethics because they play a strong role in how the company develops, matures, and ultimately exits. An exit is when a company returns value back to its shareholders either through an acquisition, initial public offering (IPO), or some other financial structure that allows equity holders to "cash out."

Investors also have a responsibility to their fund. For this reason, investors generally invest in companies they expect to make a return on their investment and advise toward protecting said investment.

3.3 Academia

Academia represents the community of people concerned with the pursuit of research and education. It includes students, postdocs, researchers, scientists, professors, as well as professional organizations aimed at promoting the collaboration and exchange of knowledge among community members. The main role of academia is pushing the frontier of a field forward through the scientific method. In the context of neurotechnology, academia is particularly concerned with extending our knowledge of how the brain functions and what technologies can be built to interface with it. Academia is also broadly involved in the development of neuroethics and new neural rights, advocating for rigorous protection of user's data and fair and equitable access to neurotechnology [9]. Another key role of academia is guaranteeing rigor via the strict application of the scientific method to ensure unbiased and well-controlled experimental design and methodology, as well as analysis, interpretation, and reporting of results.

Professional organizations in the neurotech field include the Society for Neuroscience and the Organization for Human Brain Mapping, which are particularly focused on connecting researchers in basic neuroscience. The BCI Society and the Institute of Electrical and Electronics Engineers (IEEE) mainly focus on promoting research around the development and use of neurotechnology. NeuroTechX and BrainMind facilitate the advancement of neurotechnology development via professional training opportunities. Scientific journals are also part of these organizations, with the main goal of making new knowledge available to the

whole community. Together, these organizations play a critical role in scientific discovery by providing tools and opportunities for exchanging ideas, validating discoveries via peer reviews, and making new knowledge available to key stakeholders in society.

Overall, academia's interests in neurotechnology development are to ensure that scientific rigor is maintained throughout product development, and that the field keeps advancing and innovating with new discoveries that can enable new products.

3.4 General Public

Although members of the general public may not be directly involved with neurotechnology or neuroscience, they are nonetheless important stakeholders from an ethical standpoint. The reason for this is twofold. First, members of the general public may become more involved with the field in the future, perhaps in the form of end users or patients. Second, it is the general public's perception of the field that determines its reputation as a whole. Without a positive reputation, neurotechnology will be harder to move forward.

Advanced neurotechnology has the potential to reshape society, which could affect the general public even if they are not end users. Social media provides a good analogy. Although many people today abstain from using social media, they are nonetheless affected by its presence. Therefore, like social media and other transformative technologies, neurotechnology's broad effect on the general public should be considered.

3.5 Customers

Customers are individuals, entities, or organizations who ultimately pay for a product or service. They generally evaluate these relative to alternatives and make a decision, such as whether or not to make a purchase. It can be the company, organization, or individual who buys the product. This often represents one of the largest considerations, since companies strive for growth through sales, which means successfully bringing a product or service to customers. They give feedback on how the product is working, both directly and indirectly. When it comes to thinking about the customer's role in neuroethics as a stakeholder, we think it is also beneficial to think of it as a direct and indirect influence. In regard to direct influence, some customers have explicit needs or requirements on how their data is collected, managed, and ultimately used. We can think of the customer's indirect influence before and after purchasing the product or service and how their sentiments influence a greater perspective on the field as a whole.

3.6 End Users

Quite often, the customers and the end users are the same. However, a company may purchase a batch of neurotech devices for use by its employees. In this case, the employees would be the end users but not the customers. The end users are the individuals who are actually interacting with the neurotechnological device. The end users are of primary ethical importance because they are the ones who are at risk if the device is unsafe or has other negative effects, or if privacy is violated. The end users play a role in consuming the outputs that the neurotechnological device produces, providing feedback and serving as the primary source of neurological data. To this end, it is imperative that their informed consent be protected and that their input be considered throughout the course of product design.

3.7 Government

The government is an important stakeholder, as it is ultimately beholden to the general public. It is responsible for defining the regulations within which neurotechnology must operate so as to be both safe and beneficial to the public. Its role in regulating neurotechnology is similar to its role in other fields, such as biotechnology and medical devices. For example, the government defines various classes of medical devices, each with increasingly stringent safety criteria as devices become more invasive. A similar process should exist for neurotech devices but with additional criteria for user privacy, given the sensitive personal nature of neurological data. The government's role is critical in neuroethics because many of the policies they implement will derive from neuroethical principles. Similarly, government agencies will be important players in shaping neuroethics literature and discourse.

4 Case Studies

4.1 Building a Profitable Company Versus Building a Company We Want

In 2017, Neurable showcased technology to the world for the first time at a marquee technology conference called SIGGRAPH. We debuted a demo wherein one could control a virtual reality experience using brain signals, specifically, P300 event related potentials (ERPs). The demo garnered us much attention and was illustrative of never-before-seen capabilities made possible through intellectual property (IP) in signal processing and algorithm development. We even found ourselves on the cover of the New York Times with a headline, "A Game You Can Control With Your Mind" [10]. Neurable was catapulted to the front of the BCI space and then tried to commercialize its product, which was built in alignment with our vision of creating a world without limitations, i.e., allowing people of all different states of ability to control technology leveraging neural activity. It was an exciting time.

In 2018, virtual and augmented reality began to falter and the momentum that carried us through our first investment in 2016 was starting to slow down. Immersive systems were struggling to find the elusive "product-market fit," a term used in entrepreneurship to define when a company has found, built, and established a product or service that successfully addresses a customer's need.

Neurable could no longer depend on virtual reality as a market to commercialize, since virtual reality's install base was too low and the technology was still struggling with other key pain points, which needed to be solved before the addition of a neural interface could be considered. For this reason, our company needed to "pivot" or reconsider its path to market in order to continue raising capital to survive and grow. One of the benefits of being catapulted to the front of BCI attention was that we were able to conduct some of the best customer discovery, a term used to identify potential problems to be solved from potential customers, which we continued to do in 2018 as we were considering our pivot. One of the markets that we looked at was neuromarketing, a field that uses various brain-imaging and interpretation modalities to reveal greater insights from customers. This field has been subject to dubious claims and questionable technology, but indeed has a well-defined business problem and paying customers. Specifically, neuromarketing seeks to identify marketing perspectives, such as buyer intent, decision-making, interest and, to some degree, measurements along the arousal-valence spectrum, the former being more psychologically rooted and the latter being a more questionable and less proven estimate of emotion.

In doing customer discovery, speaking with companies big and small from the consumer-packaged goods (CPG) space, marketing, and more, we actually received opportunities to commercialize and start generating revenue. We had found a path for product-market fit! We were even offered contracts with Fortune 500 companies to work with them. However, herein lay a predicament. Neurable's vision is to help people transcend their limitations and create technologies that ultimately empower the end user. In weighing this aspect, we concluded that the path toward neuromarketing, albeit potentially lucrative, went against the company's core values.

We had to wrestle with two options

1. Do we take the paying opportunities, which would allow us to keep the proverbial and literal lights on, continue to pay our employees, grow as a business, and progress toward our investors' interest of de-risking our success? *or*
2. Do we stick true to our vision, find a way to product-market fit that better aligns with our vision and principles, which may jeopardize the livelihoods of our employees, increase the risk to our investors, and potentially waste all the blood, sweat, and tears spent to make the most out of this opportunity?

In reflecting, speaking with our team, advisors, and investors, we ultimately decided to go with option two. Proceeding as a neuromarketing company, although potentially de-risking the future of the company, was not a company we wanted to be a part of or build. Our founders, investors, and team had no interest in creating tools to help engineer better ads, effectively taking advantage of people and potentially breaching neuroethical principles by invoking an unwelcome manipulation of

the human brain. While there may be potentially "good" or ethical applications of neuromarketing, our company's vision was not one that wanted to be spent building them.

Working on a problem that you are not passionate about is a recipe for disaster since, especially with small companies, there will always be something that goes wrong. It is very hard to push through the tough times for a product or service you are not inherently passionate about, which is why this is often a piece of feedback given to aspiring entrepreneurs when they begin to think about what to work on.

If our vision is to be the company that brings neurotechnology to everyone, the path of neuromarketing did not help; in fact, it would probably hurt in the long run. We wanted to build a brand that the end users, i.e., people who would actually use or be affected by our BCI, had reason to trust. For this reason, we decided to create technology that directly benefited and empowered the end user as opposed to taking advantage of them. This allowed us to stick to our vision, justify the opportunity and risk to our investors, and feel good about saying no to easy revenue.

4.2 Differing Strategies to Research and Development: Agile vs Conservative

A key goal of neurotechnological development is the availability of large amounts of brain data, which enable feature discovery, model training, and validation. Similar to other players in the neurotechnology space, Neurable includes a dedicated team of research engineers who design and conduct experiments by collecting electroencephalography (EEG) data.

A key consideration for startups is focus and prioritization. We would argue that most companies do not *intentionally* do harm but end up prioritizing other aspects that may lead to harm. A difficult decision that we have to make every day at Neurable, for example, is the trade-off between taking a very slow, methodical, well-understood, and safe approach to experimentation and a quick and iterative process, which is a hallmark of lean startup methodology. One area, for example, that we debate at Neurable concerns Institutional Review Board (IRB) oversight, which is not a legal requirement for product development.

There are numerous considerations for neurotechnology development that range from access to implementation but, for the sake of this chapter, we will focus on an area we think is most important: data collection, use, and management. Key requirements for ethical data collection include ensuring that participants understand what type of data is being collected, who is collecting the data, and for what purpose it will be used. This is done using informed consent, both written and oral. Academic research labs and large organizations rely on independent committees (IRBs) to oversee the process of collecting and analyzing data from human populations. In the United States of America, IRBs were established in 1974 by the Department of Health Education and Welfare through regulations on the protection of human subjects engaged in federally funded research [11]. An IRB consists of at least five members of varying backgrounds with professional experience to provide

appropriate scientific and ethical review. When academic investigators want to collect and analyze new human data, they first need to seek IRB approval through the submission of a detailed and thorough plan for data collection and analysis [12]. After reviewing the application, the IRB typically provides feedback to the investigators and asks them to make amendments, for example, clarifying certain aspects of the analysis. Obtaining IRB approval is typically a long process that may take between 2 and 9 months, depending on the experience of the investigator and complexity of the study.

At Neurable, we have to weigh these considerations every day. In an ideal world, we would have an IRB approval for every experiment we run. However, that is often not the case. As a startup company, it is critical for Neurable to react to market shifts and to continuously explore and develop new features for its products. For example, while exploring new business opportunities, a stakeholder may ask if we could detect fatigue in automobile drivers from brain activity. While in academic settings, this investigation could represent a multi-year research project, in a startup environment, the timeframe between the proposal and the presentation of a first prototype can be much shorter, for example, 2–4 months or even weeks or days! As such, seeking IRB approval is often unfeasible, as it can slow down innovation and reduce the opportunities for the startups to successfully commercialize.

Generally, at Neurable, our workflow for feature development includes several stages

1. Draft requirements
2. Review scientific literature
3. Develop a new experiment for data collection
4. Recruit participants, gather their written consent, and collect data
5. Develop a prototype solution
6. Test the prototype

We generally go through these steps much faster than researchers in academia would. The pros: we are able to move much more nimbly and react to changes quickly. The cons: we accept more risk that something may go wrong. With that being said, we know that EEG is considered a harmless technology, even by IRB standards, but we still accept greater risk by not consulting with external stakeholders.

The reality of a company is that it is extremely impractical to follow the same level of protocol or rigor as an academic institution, particularly so since the push and pull by key stakeholders is different. If experiments were conducted 1–1 in a startup as they would be in academia, we would venture to say that the company would run out of money before being able to bring a product to market, which is especially so for emerging and hardware-based companies. The startup executive team has to keep in mind the well-being of its employees as well as the interests of their funders. If the company does not innovate, grow, sell products, or increase its value, it may not receive further funding. If the company does not receive funding, the employees do not get paid, which illuminates the need for lean experimentation. This being said, choosing not to pursue IRB approval does not mean ignoring ethical policies for data collection. It now becomes the responsibility of the startup to

guarantee and demonstrate that ethical guidelines for data collection are still followed.

Neurable fosters neuroethical considerations into our culture by hiring people who care about using technology for ethical applications in the first place. Our company also fosters discussion on this topic, using it as a point of conversation and consideration for all employees, regardless of domain or title. When situations arise that warrant deeper ethical consideration, such as to procure an IRB or go faster with an experiment, each stakeholder responsible has the ability to voice concerns, and is encouraged to do so. There are multiple avenues in which opinions, criticisms, and objections can be raised including town halls, retrospective meetings, 1–1 s, and anonymized surveys. Neurable breeds a culture of intentional conflict and open communication to allow for these kinds of opinions to flow and better the organization. Lastly, we use our networks and other organizations to help inform and drive ethical decision-making, leveraging network accountability. For example, if the company is quoted as proceeding in a certain fashion, those with whom the company interfaces and shares commitments then make the company beholden to those claims.

These case studies represent a fraction of the types of decision-making problems startups encounter and the trade-offs that must happen, which are affected by the relevant stakeholders who influence decision-making.

5 Conclusion

Neurotechnology is an emerging but disruptive technology. Historically, society has seen signals of negative impact from technology left unaddressed with relevant ethical fallout that could have been mitigated and/or buffeted with some preemptive ethical consideration and policy development. This chapter provided an honest insider's perspective to help illustrate the challenges that startups face in making decisions, especially as they pertain to neuroethical implications. By understanding and being able to empathize with those involved in a small organization, one is able to more effectively recommend policy and/or other interventions to help prevent bigger problems.

However, this responsibility does not solely lie on the small organization but rather on multiple influencing forces, deemed stakeholders, who govern, either directly or indirectly, the outcomes of neurotechnology development. We believe that by understanding both what decisions companies make and why and how they make these decisions, we can more effectively come up with ways to (1) reward organizations setting positive tones for the industry; (2) punish or remediate organizations who take advantage of the system; and (3) contextualize multi-componential decision-making to those who may not have as much experience.

Organizations, both public and private, for-profit and non-profit, can do better to anticipate social needs as they pertain to ethics and apply them when building new technologies or products. This can be aided or made more difficult by external stakeholders especially when it comes to process, incentives, and auditing. It is

important to note that this chapter largely deals with the use of non-invasive devices for passive brain recording. There are a number of key topics that were not addressed but should be studied and discussed further in future developments, including: (1) how incentives (especially within the context of capitalistic economies) drive product development and innovation pipelines; (2) the philosophy of neuroethics and how we, as individuals and societies, determine what is right and wrong; (3) how equity and access to technology lead to fair or unfair advantages, especially in regard to even more powerful future neurotechnology and an ever-growing disparity between developed vs. underdeveloped nations; and (4) future capabilities in terms of how humans as a species are able to understand ourselves and each other through the analysis of data for varied benefits or malicious intent.

Driving ethical considerations as a company in an emerging technology field is a challenging endeavor with real implications. Understanding how and why organizations make their decisions is critical to empathizing and assisting in this regard. Neurable, as a for-profit organization, sews ethical values into its cultural fabric to help guide decision-making and invention. This actualization of ethical values happens through formal and indirect conversations, intentional efforts to study and learn from other domains, and frequent communication with customers, partners, and stakeholders. Neurable also consults with various agencies dealing with data to help learn and ensure proper accountability. We aim to set an example by leveraging precedent, momentum, and standards to help move the neurotechnology field toward ethical decision-making. Similarly, we strive to leverage case studies, policy, and the experience of other fields to illuminate growing developments in the neurotechnology domain. Neurotechnology is significant today and will become ever so more important moving forward. Neurable urges stakeholders across the spectrum to heed the considerations made in this chapter, challenge assumptions, and educate themselves to ensure the most ethical future of this new and very important technology.

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