Elon Musk’s brain implant company is approved for human testing. How alarmed should we be?

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Elon Musk’s brain-implant company Neuralink last week received regulatory approval to conduct the first clinical trial of its experimental device in humans. But the billionaire executive’s bombastic promotion of the technology, his leadership record at other companies and animal welfare concerns relating to Neuralink experiments have raised alarm. “I was surprised,” said Laura Cabrera, a neuroethicist at Penn State’s Rock Ethics Institute about the decision by the US Food and Drug Administration to let the company go ahead with clinical trials. Musk’s erratic leadership at Twitter and his “move fast” techie ethos raise questions about Neuralink’s ability to responsibly oversee the development of an invasive medical device capable of reading brain signals, Cabrera argued. “Is he going to see a brain implant device as something that requires not just extra regulation, but also ethical consideration?” she said. “Or will he just treat this like another gadget?” Neuralink is far from the first or only company working on brain interface devices. For decades, research teams around the world have been exploring the use of implants and devices to treat conditions such as paralysis and depression. Already, thousands use neuroprosthetics like cochlear implants for hearing. But the broad scope of capabilities Musk is promising from the Neuralink device have garnered skepticism from experts. Neuralink entered the industry in 2016 and has designed a brain-computer interface (BCI) called the Link – an electrode-laden computer chip that can be sewn into the surface of the brain and connects it to external electronics – as well as a robotic device that implants the chip. The design appears to use a novel kind of electrode, said John Donoghue, a neuroscientist at Brown University who led the team that developed the brain-computer interface ‘BrainGate’ to restore movement for people with paralysis. Musk has claimed Neuralink’s device could be used for a range of therapeutic uses, to treat conditions like blindness, paralysis, depression. But he has also said that the eventual aim is to create a “general population device” that could connect a user’s mind directly to supercomputers and help humans keep up with artificial intelligence. He has also suggested that the device could eventually extract and store thoughts, as “a backup drive for your non-physical being, your digital soul.” The company is not there yet. So far, Neuralink has tested its chips on animals. A video released in 2021 shows a monkey using the device to play the video game Pong with his mind and another from 2022 appeared to show a monkey typing on a computer telepathically. The FDA approval cleared the first hurdle toward a human clinical trial, but the scope, focus and design of any such study remains unclear. FDA applications and approval processes are not available to the public. As a private company, Neuralink is also not required to disclose such regulatory interactions to investors. Neuralink’s website indicates it is seeking participants with conditions including paralysis, blindness, deafness or the inability to speak. But the company did not respond to the Guardian’s request for further details. In a statement, a spokesperson for the FDA would only confirm that Neuralink was

approved for an investigational device exemption (IDE) – the FDA process that allows a device to be used for clinical studies. Equally unclear is when such a trial would take place. The company would need to assemble an institutional review board to approve and monitor the research. The FDA's approval last week comes after the regulator initially rejected Neuralink's previous bid for clinical trials in 2022, citing "dozens of deficiencies" the company had to address before human testing, according to a report from Reuters. According to the news agency, safety concerns related to the implant's lithium battery and potential overheating, questions over whether the machine's small wires could migrate to other parts of the brain and that the device cannot be removed without damaging brain tissue. It is unclear how these concerns were resolved. The FDA declined to comment specifically on Neuralink's application process, but the spokesperson commented generally that the agency has a "scientifically rigorous process to evaluate the safety and effectiveness of medical devices". She added that the FDA has "a deep commitment to ensure the responsible and humane care of animals" involved in testing. Neuralink declined to comment on its plans for clinical trials. Grueling timeline, botched operations The FDA approval also comes amid ongoing scrutiny of Neuralink's testing practices, and allegations of animal cruelty. The company has killed more than 1,500 animals since it began experimenting on them in 2018, according to another report from Reuters. While death of animal test subjects is not uncommon in labs, employees told the news service the mortality rate has been higher than necessary due to Musk's grueling development timeline, which they allege has led to more mistakes and botched operations. Former employees interviewed by Reuters characterised some experiments as "hack jobs". In one botched experiment, the wrong size of devices was installed in 25 of 60 pigs used for testing. In another, Neuralink's device was accidentally implanted into the wrong vertebra of two different pigs during two separate surgeries, leading to their euthanasia due to pain and suffering. Neuralink did not respond to Reuters request for comment at the time. And the FDA declined to comment, citing laws keeping commercial information private. Most of the company's founders, which included top scientists in the field, have quit. As of July 2022, only two of the eight founding members remained at Neuralink. "I would love to know what the FDA was thinking," said L Syd M Johnson, a neuroethicist at the Center for Bioethics and Humanities in SUNY Upstate Medical University. "One of the concerns about Neuralink is that it's not functioning in the way that many other research laboratories or organisations function," Johnson added. "There's concerns about the potential that they are performing a kind of sloppy work and that their data may not be reliable." The allegations have led to ongoing investigations of Neuralink from multiple government agencies and members of Congress, including an inquiry from the Department of Agriculture over allegations of animal abuse and the Department of Transportation over mishandling of bio-hazardous materials across state lines. Earlier this month, Democratic representatives Earl Blumenauer and Adam Schiff called on the US Department of Agriculture to investigate conflicts of interest in the board responsible for oversight of animal testing at Neuralink. In an email, the USDA said it could not confirm or deny the investigation. The Department of Transportation did not respond to a request for comment. "I would want to wait to hear how those investigations go and what are the findings before giving the company a greenlight for trials," said Cabrera. "If the allegations turn out to be true, it certainly raises concerns about the handling of human subjects' brains." Neuralink did not respond to a request for comment regarding the allegations. In a previous blog post responding to "recent articles" raising "questions around Neuralink's use of research animals", the company said it is "absolutely committed to working with animals in the most humane and ethical way possible". It said at the time, in February 2022, it had "never received a citation from the USDA inspections of [its] facilities and animal care program". The FDA does not typically inspect laboratory facilities as part of their clinical trial application reviews, said Victor Krauthamer, an adjunct biomedical engineering professor who spent three decades at the FDA. He said it is impossible to know if it did in this case. "The FDA is not really charged with animal protection – it is more concerned with the quality of the data," he said. "If there were irregularities in the testing, maybe they should have done an inspection to see whether the results were trustworthy or not. But we don't have enough information to know." Musk's track record of mishandling user data at Twitter also raises questions about his company's ability to handle highly sensitive data extracted from the participants of its eventual clinical trials, both Johnson and Cabrera said. "There are some ethical concerns about privacy, anytime you're using a brain device," said Johnson. "Things to look out for are: will Neuralink have access to the brain data of the people that they implant these devices in? What are they going to do with it? And how are they going to protect user privacy?" Neuralink did not respond to questions about how it plans to handle the data of trial participants. Musk's marketing sets Neuralink apart from other companies and teams at public institutions working in the BCI field, which have focused on using the devices to treat specific medical conditions such as seizures, Parkinson's tremors or paralysis. The industry of "neuromodulation devices," which record or stimulate neural activity, has surpassed $6bn. Synchron, another BCI manufacturer, received FDA approval to test brain implant devices in July 2021 and Blackrock Neurotech, which installs brain implants that enable people with paralysis to control digital devices and prosthetics, has been carrying out human trials for more than a decade. Musk, meanwhile, has said he founded the company largely in response to concerns that artificial intelligence would gain too much power over humans. The Neuralink device would allow humans to compete with new sentient AI, Musk has argued, stating "I created [Neuralink] specifically to address the AI symbiosis problem, which I think is an existential threat." Even as Neuralink secures FDA approval for clinical trials, it will be a long road for its products to reach consumers, experts say. After being approved for clinical research, companies typically conduct at least two rounds of trials before applying for FDA approval to commercially market a device. Neuralink would first have to prove that its implant is safe and then establish its efficacy in treating specific conditions. The latter is a domain in which

researchers around the world are doing difficult, but promising work, said Donoghue, the Brown University neuroscientist. “The technology to implant something in the brain is very mature, but where to put it in the brain and how to stimulate it is still being worked out, especially for complicated diseases,” he said. Still, he said he doesn’t like the hyped up marketing. Musk’s advertising of the Neuralink device has parallels to his plans for Twitter, which he purchased for $44bn in 2022 and has promised to pivot to an “everything app”, that can meet all users’ needs at once. “I think it dismisses the level of complexity of the whole thing,” Donoghue said. “Tackling each condition is a big effort, right? And it could take a long time. And so, I think we have to be very careful to respect the dignity of the people we’re trying to help.”