U.S. regulators reject Elon Musk’s insane bid to test brain chips in humans, citing safety risks and Musk's crazy abuses of animals and technology

- Musk's lithium batteries, which are also used in his 'brain chip' are toxic and explosive
- Musk screwed, and got pregnant, his Neuralink staff
- Musk tortured a vast number of animals
- Musk has no scientific experience in biology science

Reuters
Rachael Levy and Marisa Taylor

On at least four occasions since 2019, Elon Musk has predicted that his medical device company, Neuralink, would soon start human trials of a revolutionary brain implant to treat intractable conditions such as paralysis and blindness.

Yet the company, founded in 2016, didn’t seek permission from the U.S. Food and Drug Administration (FDA) until early 2022 – and the agency rejected the application, seven current and former employees told Reuters.

The rejection has not been previously reported. In explaining the decision to Neuralink, the agency outlined dozens of issues the company must address before human testing, a critical milestone on the path to final product approval, the staffers said.

The agency's major safety concerns involved the device's lithium battery; the potential for the implant's tiny wires to migrate to other areas of the brain; and questions over whether and how the device can be removed without damaging brain tissue, the employees said.

A year after the rejection, Neuralink is still working through the agency's concerns. Three staffers said they were skeptical the company could quickly resolve the issues – despite Musk's latest prediction at a Nov. 30 presentation that the company would secure FDA human-trial approval this spring.

Neuralink has not disclosed details of its trial application, the FDA's rejection or the extent of the agency's concerns. As a private company, it is not required to disclose such regulatory interactions to investors. During the hours-long November presentation, Musk said the company had submitted "most of our paperwork" to the agency, without specifying any formal application, and Neuralink officials acknowledged the FDA had asked safety questions in what they characterized as an ongoing conversation.

Musk and other Neuralink officials did not respond to requests for comment on the company's device or its dealings with the FDA. The agency declined to comment on Neuralink, citing laws keeping commercial information private.

The Neuralink sources declined to provide Reuters with the agency's written rejection, a legally confidential document. The staffers, including four who had read the FDA document and others aware of the agency's concerns, described the safety issues in interviews, speaking on condition of anonymity.

Such FDA rejections do not mean a company will ultimately fail to gain the agency's human-testing approval. But the agency's pushback signals substantial concerns, according to more than a dozen experts in FDA device-approval processes.

"Neuralink doesn't appear to have the mindset and experience that's needed to get this to market anytime soon."
Kip Ludwig
FORMER PROGRAM DIRECTOR FOR NEURAL ENGINEERING AT THE U.S. NATIONAL INSTITUTES OF HEALTH (NIH)

The rejection also raises the stakes and the difficulty of the company's subsequent requests for trial approval, the experts said. The FDA says it has approved about two-thirds of all human-trial applications for devices on the first attempt over the past three years. That total rose to 85% of all requests after a second review. But firms often give up after three attempts to resolve FDA concerns rather than invest more time and money in expensive research, several of the experts said.

Companies that do secure human-testing approval typically conduct at least two rounds of trials before applying for FDA approval to commercially market a device.

Neuralink's regulatory struggles stem largely from its culture of setting goals for breakthroughs on extremely ambitious timelines and viewing regulators as obstacles to innovation, according to more than a dozen current and former company employees. That leadership style, mirroring how Musk runs electric-car pioneer Tesla, can create vulnerabilities when applied to developing a medical device that must be tested on human subjects before final approval, the staffers say.

Still, Musk retains the full confidence of many loyal Neuralink staffers and some industry investors, who point to his past successes in taking on extreme challenges as the founder of Tesla and rocket-builder SpaceX.

“I definitely would never bet against him,” said Bob Nelsen, co-founder of venture capital firm ARCH Venture Partners, who said he invested personal money into Neuralink. “If he has some bumps in the road with Neuralink, or any other thing, he’ll regroup and figure it out … Just think about it: Those are hard industries with huge safety barriers – cars and rockets.”

In public comments over the years, Musk has detailed a bold vision for Neuralink: Both disabled and healthy people will pop into neighborhood facilities for speedy surgical insertions of devices with functions ranging from curing obesity, autism, depression or schizophrenia to web-surfing and telepathy. Eventually, Musk has said, such chips will turn humans into cyborgs who can fend off the threat from sentient machines powered by artificial intelligence.

“I could have a Neuralink device implanted right now, and you wouldn’t even know,” Musk said at the Nov. 30 presentation, a livestreamed “show and tell” event, drawing laughs from the crowd. At another public company event in 2020, he said: “You’ll be able to save and replay memories…. The future is going to be weird.”

Such high-flying ambition has contributed to Neuralink’s estimated worth of more than $1 billion, far higher than its competitors, according to four people familiar with the private

valuation.

Neuralink officials have publicly vowed to address any FDA concerns. Musk made headlines late last year when he said he was already so confident in the devices' safety that he would be willing to implant them in his own children.

Musk also has said Neuralink would restore full mobility to paralyzed patients. In February, however, Dongjin "D.J." Seo, Neuralink's vice president of engineering, said at a conference that the "primary short-term goal" was more modest: to help paralyzed patients communicate through computerized text without typing. Seo said full mobility, along with restoring sight to the blind, were "long-term" goals.

Musk's public claims and well-known impatience pose a critical test for the FDA in balancing demands for speedy review with the diligence required to ensure safety and efficacy, said Kip Ludwig, former program director for neural engineering at the U.S. National Institutes of Health (NIH), a federal agency. The FDA in recent years has faced pressure from Congress to accelerate reviews but also criticism over controversial approvals, such as its 2021 authorization of an Alzheimer's treatment without conclusive proof of efficacy.

Industry players closely watching Neuralink's development have long expected a collision between Musk and the FDA, Ludwig said, as the billionaire pushes Neuralink to quickly navigate regulatory reviews.

"Everybody in the industry was saying: 'Oh my God, they're going to run straight into a brick wall,'" Ludwig said of Musk's bid for

FDA approval. “Neuralink doesn’t appear to have the mindset and experience that’s needed to get this to market anytime soon.”

Without commenting on Neuralink, the FDA said it upholds high standards in vetting all brain implants even as it aims to speed reviews. “Innovation and safety are not an either-or scenario,” said Owen Faris, who helps oversee the FDA’s Office of Product Evaluation and Quality.

A company document from last fall said Neuralink expected the FDA to authorize human trials for its brain implant by March 7, 2023. But three Neuralink sources with knowledge of the company’s FDA interactions said they are not confident of any imminent regulatory approvals and that any prediction on the timing is a “gamble,” as one of the sources put it.

Neuralink’s focus on speed has contributed to other problems. Reuters exclusively reported late last year that the federal government was investigating the company’s treatment of its research animals. The probe was launched amid growing employee concern that the company is rushing experiments, causing additional suffering and deaths of pigs, sheep and monkeys. Three Neuralink staffers now tell Reuters that company leaders wanted animal experiments accelerated to gather data to address FDA concerns over the human-trial application.

Reuters also broke the news that the Department of Transportation is separately investigating whether Neuralink illegally transported dangerous pathogens, on chips removed from monkey brains, without proper containment measures.

The Department of Transportation said its investigation is ongoing. The U.S. Department of Agriculture's Office of Inspector General, which is conducting the animal-treatment probe, declined to comment.

Turning down government money, advice

While Neuralink garners outsized attention because of its famous founder, more than a dozen companies are developing or manufacturing devices in the wider $6 billion field of so-called neuromodulation devices, which record or stimulate neural activity.

Researchers have experimented with such devices for more than four decades. The FDA has approved a significant number of them, including those treating Parkinson's disease, epilepsy and obsessive-compulsive disorder. Development typically takes many years. For example, NeuroPace, which makes the brain implant to treat epilepsy, received final FDA approval in 2013 – 16 years after the company's launch.

Neuralink competes in a niche of so-called brain computer interface (BCI) devices. Such devices use electrodes that penetrate the brain or sit on its surface to provide direct communication to computers. No company has received final FDA approval to market a BCI brain implant, the agency said, although the exact definition of the category is debated in the industry.

Neuralink officials touted plans to eventually produce a device with 16,000 electrodes, far more than other currently proposed devices. But that may not break any new ground. Neuralink

plans only 1,024 electrodes in its first implant. That's similar to devices from other firms, which also plan to add thousands more electrodes later, according to Ludwig, the former NIH official. Further, he said, the question of whether more electrodes will significantly help patients remains hotly debated among brain-implant experts.

Neuralink's electrodes are attached to wires thinner than a human hair, which are implanted in the brain, the company has said. It also aims to revolutionize surgeries with a robot to sew its microscopic wires into brain tissue, while avoiding blood vessels, in minutes.

Musk's company, however, trails at least one direct rival in the race for FDA approval. Synchron, a competitor making a BCI implant, has won the agency's blessing for human trials. Like Neuralink, Synchron aims to help paralyzed people type with their minds. With Neuralink playing catch-up, Musk approached Synchron last summer about making an investment, Reuters reported in August.

The NIH, which supports and finances medical innovation, seeks to help brain-implant companies with public-private partnerships as part of its BRAIN initiative (Brain Research through Advancing Innovative Neurotechnologies). The agency finances half a dozen firms including Blackrock Neurotech, a start-up, and medical device giant Medtronic. Launched in 2014, the effort will receive about $680 million this year. Beyond grants, it provides access to government experts who advise on how to gain FDA approval and commercialize a device.

BRAIN initiative team leader Nick Langhals said the agency

reached out to Neuralink to offer help but was declined. “We wouldn’t leave a company like Neuralink off the list, but they were not interested,” Langhals said, adding that the company didn’t explain its reasons.

Musk has told senior Neuralink managers that NIH funding would bring unwanted public oversight and bureaucratic hurdles, according to one person who heard such comments from Musk and a second source with knowledge of Musk’s views about the NIH.

The episode reflects a wider view at Neuralink that the government generally moves slowly and stifles innovation, five current and former employees said. In a presentation to staff last fall, the company set a goal of making the FDA “our #1 Fans by showing that we go above and beyond,” according to a document reviewed by Reuters. The presenter at the internal company meeting, however, also referred to a veteran surgeon and FDA reviewer as a “curmudgeon,” according to two people who heard the comment.

Neuralink could be helped by federal laws passed in recent years aiming to accelerate FDA reviews. Among a host of policy changes, Congress instituted the “breakthrough” designation for novel devices targeting serious conditions. The label gives companies faster agency feedback during the development process.

The breakthrough-device program, among other changes, has helped the FDA substantially reduce the total time companies spend seeking agency approvals, the FDA says. The agency also must respond to human-trial applications within 30 days.

Of 750 devices currently labeled breakthrough, more than 100 are neurological, the FDA says. Neuralink secured the label for its brain implant in July 2020, according to the company. In an undated company document, Neuralink said it hoped that, by December 2021, the FDA would approve testing 10 people, giving “the first humans a mind blowing experience.”

‘This is not a toy’

As Neuralink races to deliver a marketable implant, more than a dozen current and former Neuralink staffers describe a working environment that, while demanding and ambitious, is also loose and disorganized.

Musk has been one of the few constants in leadership: Nearly all eight company founders, which included acclaimed scientists, have departed. Musk himself often pays more attention to his higher profile ventures – Tesla, SpaceX and Twitter – than to Neuralink, three company sources said. Musk’s emails to Neuralink staffers often come from his SpaceX address, said two people who reviewed them.

Hiring and promoting young employees has been a Neuralink hallmark since its founding, the current and former employees said. The company brims with recent college graduates and interns. One team had no members over 30 years old, a Neuralink source recalled. The strategy saves money and aligns with Musk’s view that younger workers often innovate better than older ones, the employees said.

The company’s former president, Max Hodak, had not turned 30 when he joined Neuralink at its founding. Before Neuralink,

Hodak worked in a neural engineering lab while in college at Duke University and launched a cloud-computing startup afterward. Currently, one key company liaison to the FDA is a software engineer in his mid-20s, four current and former employees said.

That lack of experience in medical regulation has contributed to tensions inside Neuralink over development pace, the staffers said. In the company's early years, executives discussed real estate for outpatient centers nationwide before the company had finalized a device, one former employee recalled. The plans sparked a debate among more experienced top scientists, who chafed at the development speed envisioned by generally younger staffers, the employee said.

A different Neuralink source recalled a meeting in late 2020 or early 2021 in which an angry Musk shouted until about 2 a.m. about what he called the company's slow regulatory progress. When executives called his expected timeline unrealistic, Musk replied that he would make the FDA understand the need for fast approvals. Musk has participated in some phone calls between Neuralink and the agency, often seeking to expedite human trials, according to two people with knowledge of the calls.

"He can't appreciate that this is not a car. This is a person's brain. This is not a toy."
Former Neuralink employee on Musk's approach to Neuralink
The source who described the late-night meeting said Musk expects Neuralink to operate like Tesla, which brought several ground-breaking electric vehicles to market relatively quickly. "He can't appreciate that this is not a car," this source said. "This

is a person’s brain. This is not a toy.”

At the meeting, Musk said he would make major changes at Neuralink without faster progress, this source recalled. Several weeks later, in March 2021, Musk fired company president and de facto leader Hodak, according to several current and former employees. Three years later, the company remains without a president.

Musk and Neuralink did not respond to inquiries about why Hodak was fired. Hodak declined to comment.

Since Musk ousted Hodak, a coalition of executives has filled the gap, though employees often disagree on who is truly in charge.

The leadership includes Shivon Zilis, a long-time Musk confidante who formerly worked at a venture capital firm. Zilis recently gave birth to two children fathered by Musk, in a relationship she calls non-romantic. Her LinkedIn page identifies her as Director of Operations and Special Projects. Another key executive is Seo, the engineering chief and only remaining founder besides Musk. In mid-February, Ian O’Hara, an executive who oversaw the robot program, announced his departure, according to four sources familiar with the matter.

Seo declined to comment. Zilis and O’Hara did not respond to inquiries.

Safety concerns

The FDA’s rejection listed dozens of what the agency calls “deficiencies” that the company must address before human trials, five Neuralink sources said. They called some issues

relatively minor.

One serious FDA concern involved the possibility that the device's tiny threads, which carry electrodes, could migrate to other areas of the brain, according to six current and former employees. The company has sought to address the issue through animal tests on dozens more pigs, three Neuralink sources said.

Migrating wires can induce inflammation, impair function in critical areas of the brain and rupture blood vessels, said Victor Krauthamer, a former FDA official for three decades, including a stint as acting director of the office that reviews human-trial requests for brain implants. A migration problem can also erode the device's effectiveness, leading to the risk of surgical removal, he and other experts said.

"The threads can cause damage because brains are very, very soft and very delicate," Krauthamer said.

The FDA's concerns about the battery are also potentially serious, experts in brain devices said. Neuralink proposed making its device with a novel charging system involving lithium batteries that could be recharged remotely. The agency found the company needed to show in animal studies that the battery was very unlikely to fail, six current and former Neuralink employees said. If any component of the device that is connected to the battery current fails, the current could potentially damage brain tissue, three brain-implant experts said.

The FDA also raised questions about whether the device could be removed without damaging brain tissue. In Neuralink's

November presentation, officials acknowledged the FDA concern but downplayed it.

Engineer Alex Wood-Thomas was asked about the potential danger of removing the device in order to implant an upgraded one in the future. He responded that, because of the threads' small size, scarring "within the brain is so minimal that they're actually removed quite easily."

Several employees disputed his characterization as misleading and unsupported by animal studies, according to two Neuralink sources and internal discussions seen by Reuters.

Wood-Thomas declined to comment.

The FDA also flagged concerns that the device could overheat, also potentially damaging tissue.

Neuralink may be able to address all of the FDA's concerns, industry and regulatory experts said.

If the FDA has lingering minor issues with a company's device, it might let the firm move forward with a slower, staged trial, the experts said. The agency has suggested such a path might work for Neuralink, with fewer subjects implanted at first, and more tested months later, according to two people familiar with the discussions. Still, that proposal disappointed Neuralink because it could delay progress toward final FDA approval, one of the sources said.

Neuralink is hardly alone among brain-implant pioneers in slogging through difficult research and regulatory challenges

that can drag on for years, said Gene Civillico, a neurophysiologist who formerly worked for both the FDA and the NIH on neural-implant research.

“The reason we don’t have a (BCI) device yet like Neuralink’s is not because no one has spent any money on it,” Civillico said. “It’s not because Elon Musk hasn’t thought about it enough. It’s because it’s a hard problem.”