Would the US prosecute a rogue scientist like China's He Jiankui who illegally gene edited an embryo?

<u>13 months</u> after He Jiankui announced that he had created the world's first gene-edited babies, the Chinese scientist was sentenced to three years in prison and fined \$430,000.

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If He Jiankui had been a U.S. scientist, his alleged misleading of research participants and forging an ethics approval would have been considered unethical, and he would likely have been subject to sanctions from his employer, loss of research funding, and disqualification from clinical research. But the work would also have been illegal, although in a somewhat circuitous and distinctly American way.

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No directly analogous laws were ever passed in the U.S. until December 2015, when Congress included a brief <u>101-word provision</u> in a budget appropriations bill that effectively outlawed human germline editing in the U.S.

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The 101 words amount to a ban because the FDA has asserted jurisdiction over all clinical uses of genetically manipulated human cells. As a result, anyone planning to use gene-edited cells in humans must submit an investigational new drug (IND) application to the FDA.

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Sanctions for proceeding without an IND application include administrative actions. ... But violations of the Federal Food, Drug and Cosmetics Act also carry criminal penalties, including fines of up to \$250,000 and imprisonment for up to 10 years.

**Read full, original post:** He Jiankui is going to jail. Would the U.S. criminally prosecute a rogue geneediting researcher?