US Congress moves to block human-embryo editing

Spending bill would also require religious experts to review recommendations for reproductive technique.

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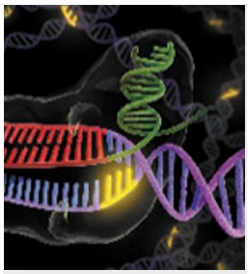
The US House of Representatives is wading into the debate over whether human embryos should be modified to introduce heritable changes. Its fiscal year 2016 spending bill for the US Food and Drug Administration (FDA) would prohibit the agency from spending money to evaluate research or clinical applications for such products.

In an unusual twist, the bill — introduced on 17 June — would also direct the FDA to create a committee that includes religious experts to review a forthcoming report from the US Institute of Medicine (IOM). The IOM's analysis, which considers the ethics of creating embryos that have three genetic parents, was commissioned by the FDA.



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The House legislation comes during a time of intense debate on such matters, sparked by the announcement in April that researchers in China had edited the genomes of human embryos. The US National Institutes of Health (NIH) moved quickly to remind the public that a 1996 law prevents the federal government from funding work that destroys human embryos or creates them for research purposes.

Privately funded research on editing the human germline remains legal in the United States. But the pending House bill seeks to make it harder to test embryo editing in clinical trials. A provision in the legislation would prevent the FDA from using federal funds to evaluate or permit research that involves either viable embryos with heritable genetic modifications, or sperm or eggs that could be used to create such an embryo.

“This step seems dumb — or ill-advised,” says Hank Greely, a bioethicist at Stanford University in California. It might also be premature because the FDA has not shown any indication that it would approve such research. And such a ban would not apply to the type of research that the Chinese scientists performed, because the embryos they used were not viable.

Moreover, the provision — as it stands — could backfire. Applications to the FDA to investigate a potential drug are approved automatically unless the agency moves to block them. But Patricia Zettler, a law professor at Georgia State University in Atlanta and a former FDA attorney, says that blocking an application would require the use of public funds — which the House bill would prohibit.

Greely suspects that the Republican majority in Congress “is trying to throw a (cheap) bone to some of its supporters; regrettable (to me), but not important”. The House appropriations committee, which drafted the FDA spending bill, did not respond to requests for comment.

Although the bill has been approved by a subcommittee, it would need to win approval from the full House, the US Senate and US President Barack Obama to become law. The provisions that would affect the FDA are contained in a report that accompanies the bill and has not yet been publicly released.

Watch the watchers

The FDA has been considering the implications of modifying human embryos for some time. Last year, it commissioned an IOM report on the ethical and social implications of “three-parent embryos”. These embryos could help women to avoid passing genetic diseases on to their offspring, because faulty mitochondria in the mother's egg are replaced with healthy mitochondria from another woman.

The FDA seems to be waiting for the IOM's peer-reviewed analysis, due this winter, before it decides whether to permit clinical trials on mitochondrial replacement.

The House legislation calls for another layer of review. It would direct the FDA to establish “an independent panel of experts, including those from faith-based institutions with expertise on bioethics and faith-based medical associations” to review the IOM report once released. The panel would have 30 days to evaluate the report and provide its own recommendations to the House Appropriations

Committee.

William Kearney, a spokesman for the IOM's parent organization, the US National Academy of Sciences (NAS) in Washington DC, declined to comment on the House bill. But he says that the NAS has occasionally included religious specialists on its committees when appropriate. “We always strive to balance our committees with the expertise necessary to carry out the study in a scientific manner in order to produce an evidence-based report.”

In fact, the IOM committee that is evaluating mitochondrial transfer includes a bioethicist, James Childress, who teaches religious studies at the University of Virginia in Charlottesville.

But experts who have served on committees that were convened by the IOM or the NAS, say that the House bill's provisions are highly unusual.

“It’s hard for me to understand what Congress thinks can be added by another layer of taxpayer-supported ethics reflection,” says Jonathan Moreno, a bioethicist at the University of Pennsylvania in Philadelphia. “You don’t have to be a faith-based bioethicist to recognize that there’s some global responsibility for modifying the human germline.”

Zettler says that Congress frequently orders the agency to include certain types of experts on independent advisory committees. But Zettler is not aware of any previous situations in which lawmakers mandated the participation of religious specialists, and she says that the purpose of such a requirement is unclear.

The FDA is charged with evaluating the safety and efficacy of medical products, but it is not allowed to let ethical and social implications of research influence its decisions — except to ensure that human subjects are protected in clinical trials.

Moreno worries that if the House bill becomes law, it could set a precedent for Congress to require other agencies to second-guess the NAS. “It is a signal that the culture wars aren’t dead,” he says.

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