Mainstream medicine? US health officials want to ease restrictions on gene therapy experiments

U.S. health officials are eliminating special regulations for gene therapy experiments, saying that what was once exotic science is quickly becoming an established form of medical care with no extraordinary risks.

A special National Institutes of Health oversight panel will no longer review all gene therapy applications and will instead take on a broader advisory role, according to changes proposed Wednesday. The Food and Drug Administration will vet gene therapy experiments and products as it does with other treatments and drugs.

It's an extraordinary milestone for a field that has produced only a few approved treatments so far, and not all experts agree that it doesn't still need special precautions.

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Gene therapy aims to attack the root cause of a problem by deleting, adding or altering DNA, the chemical code of life, rather than just treating symptoms that result from a genetic flaw.

When it was first proposed, there were so many safety worries and scientific unknowns that the NIH created a panel of independent scientists, called the Recombinant DNA Advisory Committee, or RAC…

It's time to let the FDA review gene therapy proposals on its own without duplicating regulatory efforts, the NIH's director, Dr. Francis Collins, and FDA chief Dr. Scott Gottlieb wrote Wednesday [Aug. 15] in the New England Journal of Medicine. The proposed changes will go into effect after a public comment period.

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