Is the end of the recombinant DNA Advisory Committee (RAC) a good thing?

19 September 2018

The RAC initially set guidelines for DNA research, and its role was later expanded to encompass the review and approval of human gene therapy research. The Committee was composed of stakeholders, including basic scientists, physicians, ethicists, theologians, and patients advocates. "The deliberations often became theatrical and, at times, quite contentious," says Dr. Wilson. Over the years, as the field of human gene therapy matured and became more integrated into the biopharmaceutical industry the potential redundancies between the roles of the FDA and the RAC became an increasingly important issue.

"The 2018 proposal...is to completely eliminate the RAC's role in reviewing or monitoring human gene therapy studies," says Dr. Wilson. "The new recommendations retain the role of local Institutional Biosafety Committees in the review process, while limiting their evaluation to an assessment of biosafety risks."


Recently, the U.S. National Institutes of Health (NIH) and Food and Drug Administration (FDA) called for the eliminating involvement of the Recombinant DNA Advisory Committee (RAC) in human gene therapy experiments, marking the end of an era of federal government oversight. While the RAC played an essential role in helping human gene therapy research evolve to where it is today, James M. Wilson, MD, Ph.D., Editor, Human Gene Therapy Clinical Development, believes this is the right moment for it to exit the stage, as he explains in his Editorial "The RAC Retires After a Job Well Done," Human Gene Therapy Clinical Development.