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*Regulating Human Gene Therapy: Legislative Overreaction to
Human Subject Protection Failures*

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Abstract by Lisa Hodes

Modern advancements in gene therapy are promising, but violations of Food and Drug Administration (FDA) and National Institute of Health (NIH) requirements have some questioning whether continuing gene therapy is too dangerous. In this article, the author explains how congressional responses to a few tragedies may hinder development of genetic therapies - a tragedy equal to loss of some individual recipients.

First, the author defines gene therapy and its processes, as well as laying out the structure of relevant statutes and FDA/NIH regulations that seek to protect human subjects. A brief history of gene therapy is also provided. Second, the author admits that gene therapy has disadvantages and identifies recent criticisms. Third, proposed remedies to the above criticisms are presented and discussed. Finally, the author concludes that the benefits of gene therapy outweigh the costs and that additional legislation would be more damaging than helpful to science.