

# Many Things Can be Done at Home. Editing Your Genes is Not One of Them.



By Julianna LeMieux — November 29, 2017



Person at home, working [1]

From CAR-T cancer therapy to the power of CRISPR-Cas9, the recent advancements in gene therapy are astounding. For a particularly impressive example, please read [the story of how scientists created a new skin for a dying boy](#) [2].

The floodgates of gene therapy have opened and the promise of therapies coming down the pike is beyond exciting. New gene-based treatments are being developed that could change the course of cancer and other genetic, infectious, and other diseases.

That said, like most things, there is a time and a place for new developments to be implemented. And, the place to edit genes is not in your living room according to the US Food and Drug Administration (FDA) and, well, common sense. You must be thinking that no one would really do such a thing, right? Wrong.

A few biohackers (fans of do-it-yourself (DIY) science experiments) recently designed a gene therapy for HIV. Not only that, [they posted a video last month of one of them injecting it into his body](#) [3] in an effort to cure his HIV. Although this is not the first time that DIY gene therapy has been attempted, the publicity of this particular video may have been the seed that prompted FDA to issue a letter on their website this week.

The FDA does not mince words when it comes to this idea. They state in [a letter on their website](#) [4]

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*The sale of these products is against the law. FDA is concerned about the safety risks involved. Consumers are cautioned to make sure that any gene therapy they are considering has either been approved by FDA or is being studied under appropriate regulatory oversight.*

The FDA has a specific center in charge of regulating gene therapy products, the Center for Biologics Evaluation and Research (CBER). In order to gain FDA approval, gene therapy products require both testing and scrutiny. In fact, passing through the FDA requires several steps of approval - both an investigational new drug application for clinical studies and that of a biologics license application for marketing. However, fifteen gene therapies have gone through the process and been granted FDA approval (1).

If a gene therapy hasn't been approved, it's probably not safe.

Look, you can do a lot of things at home... make beer, color your hair, refinish furniture, play fantasy football, bathe your dog, knit, build a life-size LEGO Batman or take on a fun papier-mâché project.

But, one thing that you cannot do is edit your genes. At least, not until the FDA says that its ok.

#### References:

<https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/A...> [5]

#### Notes:

The list of FDA approved gene therapy products:

- [ALLOCORD \(HPC Cord Blood\)](#) [6]  
SSM Cardinal Glennon Children's Medical Center
- [LAVIV \(Azficel-T\)](#) [7]  
Fibrocell Technologies
- [MACI \(Autologous Cultured Chondrocytes on a Porcine Collagen Membrane\)](#) [8]  
Vericel Corp.
- [CLEVECORD \(HPC Cord Blood\)](#) [9]  
Cleveland Cord Blood Center
- [GINTUIT \(Allogeneic Cultured Keratinocytes and Fibroblasts in Bovine Collagen\)](#) [10]  
Organogenesis Incorporated
- [HEMACORD \(HPC, cord blood\)](#) [11]  
New York Blood Center
- [Ducord, HPC Cord Blood](#) [12]  
Duke University School of Medicine
- [HPC, Cord Blood](#) [13]  
Clinimmune Labs, University of Colorado Cord Blood Bank
- [HPC, Cord Blood - LifeSouth](#) [14]

LifeSouth Community Blood Centers, Inc.

- [HPC, Cord Blood - Bloodworks](#) [15]  
Bloodworks
- [IMLYGIC \(talimogene laherparepvec\)](#) [16]  
BioVex, Inc., a subsidiary of Amgen Inc.
- [KYMRIAH \(tisagenlecleucel\)](#) [17]  
Novartis Pharmaceuticals Corporation
- [PROVENGE \(sipuleucel-T\)](#) [18]  
Dendreon Corp.
- [Sterile Cord Blood Collection Unit with Anticoagulant Citrate Phosphate Dextrose Solution USP \(CPD\)](#) [19]  
MacoProductions, S.A.S.
- [YESCARTA \(axicabtagene ciloleucel\)](#) [20]  
Kite Pharma, Incorporated

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#### Links

- [1] <https://static.pexels.com/photos/7066/man-relax-couch-study.jpg>
- [2] <https://www.acsh.org/news/2017/11/10/how-science-repaired-boys-skin-and-saved-his-life-12117>
- [3] <https://www.youtube.com/watch?v=jpYE3cUogh0>
- [4] <https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm586343.htm>
- [5] <https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/default.htm>
- [6] <https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm354689.htm>
- [7] <https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm260485.htm>
- [8] <https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm533177.htm>
- [9] <https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm518869.htm>
- [10] <https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm295465.htm>
- [11] <https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm279608.htm>
- [12] <https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm322728.htm>
- [13] <https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm305600.htm>
- [14] <https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm356850.htm>
- [15] <https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm483851.htm>

- [16]  
<https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm469411.htm>
- [17]  
<https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm573706.htm>
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<https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm210012.htm>
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<https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm581222.htm>