FDA REGULATIONS ON GENE THERAPIES

- COVID mRNA "vaccines" are gene therapy products as defined in the FDA's 2015 document on Gene Product Shedding Studies and by a similar European Medicines Agency (EMA) document:

- ***"Gene therapy products are all products that mediate their effects by transcription and/or translation of transferred genetic material and/or by integrating into the host genome and that are administered as nucleic acids, viruses, or genetically engineered microorganisms.***

- The FDA document defines shedding of gene therapy products as:

- ***"The release of viral or bacterial gene therapy products from the patient by any or all of the following routes: feces (feces); secretions (urine, saliva, nasopharyngeal fluids, etc.); or through the skin (pustules, lesions, sores)."***

GENE THERAPY PRODUCTS ALL HAVE SHEDDING AS A RISK IN THEIR INSERTS

- Shedding of LUXTURNA

  Transient and low level shedding of LUXTURNA may occur in patient tears. Advise patients and/or their caregivers on proper handling of waste material generated from dressing, tears, and nasal secretion, which may include storage of waste material in sealed bags prior to disposal. These handling precautions should be followed for up to 7 days following LUXTURNA administration.

Manufactured by:
Spark Therapeutics, Inc.
3737 Market Street
Philadelphia, PA 19104

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- Roctavian was found to shed into semen and the FDA advises those who receive it to **not donate semen or impregnate someone** for at least 6 months after administration.

- Another gene therapy product called Zolgensma was also found to shed for a month, and its package insert advises that during this time, to be **careful of how feces from the patients are disposed of to avoid exposure to others.**

PFIZER KNEW THE RISKS OF SHEDDING

- From their own trial protocol, p. 67: “the investigator is **instructed to report** various "environmental exposures" as follows:
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1) “A **male participant who is receiving** or has discontinued study intervention **exposes a female partner prior to or around the time of conception."**
2) “A female family member or healthcare provider reports that **she is pregnant after having been exposed to the study intervention by inhalation or skin contact**."
3) "A male family member or healthcare provider **who has been exposed to the study intervention by inhalation or skin contact** then exposes his female partner prior to or around the time of conception" (note this refers to “secondary shedding” as defined later in the document)
4) **"A female is found to be breastfeeding while being exposed or having been exposed to study intervention** (i.e., environmental exposure). An example of environmental exposure during breastfeeding is a female family member or healthcare provider who reports that she is breastfeeding after having been **exposed to the study intervention by inhalation or skin contact."**