Regenerative Medicine Therapies

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 Agenda

• Framework For The Regulation of Regenerative Medicine Therapies
  – Definitions And Eligible Therapies

• Expedited Programs For Regenerative Medicine Therapies
  – Fast Track, Breakthrough, Accelerated Approval, Priority Review And RMAT designation
  – CBER’s INTERACT Program

• Emerging Issues Regarding Regenerative Medicine Therapies
  – Gene Editing
  – Exercising regulatory authority over regenerative medicine products
  – Coronavirus Treatment Accelerated Program (CTAP)
Framework For The Regulation of Regenerative Medicine Therapies
Fig. 1.1 Prometheus. “Prometheus”, Gustave Moreau 1868 (Musée Gustave Moreau, Paris). According to some investigators, his torture held for 30,000 years. After having provoked the wrath of Zeus, the eagle Ethon, picked at his liver every night. During the day the liver would regenerate
What is Regenerative Medicine

• **Regenerative medicine** refers to the translation of multidisciplinary biology and engineering science into therapeutic approaches to regenerate, replace, or repair tissues and organs.

• Draws from: **tissue engineering, cell transplantation, stem cell biology, biomechanics prosthetics, nanotechnology, genomics and biochemistry.**
Progression in Complexity of Available Therapy

- **Small molecules**
  - Chemically manufactured active substance
  - Targeted therapies

- **Biologics**
  - Large protein molecules
  - Protein engineering

- **Cell & Gene Therapy**
  - Transfer of genetic materials or cells into a patient
  - Potential to repair the direct cause of diseases through cell or gene programming
Definition of “Regenerative Medicine Therapy”

• Defined in FDCA § 506(g)(8) [21 USC 356(g)(8)] as including:
  – Cell therapy
  – Therapeutic tissue engineering products,
  – Human cell and tissue products
  – Certain combination products

• FDA’s interpretation of the term also includes gene therapies that lead to a sustained effect on cells or tissues
Definition of “Regenerative Medicine Therapy” (cont.)

• Regenerative Medicine Therapies do not include products regulated solely under PHSA § 361 and 21 CFR § 1271 (see FDCA § 506(g)(8)):

1. Minimally manipulated (MM);
2. Intended for homologous use (HU) only;
3. Not combined with another article (with some exceptions); and
4. Either does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and is autologous, for 1st or 2nd degree blood relative, or reproductive use.
PHSA 351 versus 361

• PHSA Section 351
  – Regulates the interstate sale of “biological products,” that are “applicable to the prevention, treatment, or cure of a disease or condition of human beings.” 42 U.S.C. § 262(i)(1).

• PHSA Section 361
  – Separate authority stemming from 19th century statutes establishing federal quarantine power.
  – Authorizes government to “make and enforce such regulations as ... necessary to prevent the introduction, transmission, or spread of communicable diseases.” [42 USC § 264]
FDA Authority under PHSA 361

• Historically, tissue products not subject to active federal regulation.
• Instead, human tissue products were primarily regulated by voluntary quality assurance programs, such as the standards established and maintained by the American Association of Tissue Banks. A small minority of states also regulated tissue bank operations.
• Case-by-case exercise of jurisdiction by FDA
• Issues with disease transmission eventually lead FDA to promulgate regulations.
• Products that meet all the criteria in 21 CFR 1271.10(a) are regulated solely as HCT/Ps and are not required to be licensed, approved or cleared. The regulatory focus on these products is prevention of communicable disease.

• If a product does not meet all the criteria in 21 CFR 1271.10(a) it is regulated as a drug, device, and/or biological product under the Federal Food, Drug, and Cosmetic Act (FDCA) and Section 351 of the PHSA.
Criteria for Regulation as a 361 HCT/P

• Must be minimally manipulated
• Must be intended for homologous use only
• Must not be combined with other articles except water, crystalloids, or a sterilizing, preserving, or storage agent
• Must not have a systemic effect or be dependent upon the metabolic activity of living cells for its primary function (with certain exceptions).

See 21 C.F.R. 1271.10.
21st Century Cures Act

- Signed into law on December 13, 2016

- Increase use of Real World Evidence for regulatory decision-making
- Encourage and expedite development and approval of regenerative medicine therapies
- Incorporate patient experience data in drug development and review
FDA: 21st Century Cures Mentality

“We’re at the beginning of a paradigm change in medicine ... where ... new genes can be introduced into the body to combat disease. This is no longer the stuff of science fiction. This is the practical promise of modern applications of regenerative medicine.”

*FDA Commissioner Scott Gottlieb, M.D., FDA News Release (Nov. 16, 2017)*
November 2017: Comprehensive Policy Framework
21st Century Cures Mentality – CBER

“FDA is witnessing a surge of cell and gene therapy products entering early development . . . We will work with sponsors to make maximum use of our expedited programs including regenerative medicine advanced therapy (RMAT) designation and accelerated approval.”

• More than 1,000 active gene therapy INDs currently on file.
• CBER received 134 IND submissions of gene therapies in 2020
• By 2025, CBER predicts 10-20 cell and gene therapy products to be approved a year
• By 2030, CBER predicts 40-60 product launches and more than 500,000 treated
21st Century Cures Mentality – CDER

- CDER is utilizing Fast Track, Breakthrough, Accelerated Approval, and Priority Review to ensure prompt and efficient expedited review for approval decisions.

“This innovative approval methods can bring a therapy to patients months or even years sooner than if their application went through the standard review process.”

- 68% (36 of 53) of CDER’s 2020 novel drug approvals were designated in one or more of these expedited review categories.
- 75% (40 of 53) of CDER’s 2020 novel drugs approvals were approved in the U.S. before receiving approval in any other country.
- 3 new biosimilars were approved in 2020.
- CDER has now approved a total of 29 biosimilars for 9 difference reference products, which are some of the top selling biological drugs in the U.S. (Humira, Rituxan, Enbrel, Herceptin, Avastin, Remicade and Neulasta).
<table>
<thead>
<tr>
<th>Approval Date</th>
<th>Product Name</th>
<th>Description</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 2010</td>
<td>Provenge</td>
<td>Autologous Cellular Immunotherapy</td>
<td>Asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer</td>
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<tr>
<td></td>
<td>(Dendreon)</td>
<td></td>
<td></td>
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<tr>
<td>June 2011</td>
<td>Laviv</td>
<td>Autologous cell product to improve aesthetics, consisting of collagen-producing fibroblast cells</td>
<td>Improvement of the appearance of moderate to severe nasolabial fold wrinkles in adults</td>
</tr>
<tr>
<td></td>
<td>(Fibrocell)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>March 2012</td>
<td>Gintuit</td>
<td>Allogeneic cellularized scaffold product of human cells and bovine collagen</td>
<td>Topical (non-submerged) application to a surgically created vascular wound bed in the treatment of mucogingival conditions in adults</td>
</tr>
<tr>
<td></td>
<td>(Organogenesis)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>October 2015</td>
<td>Imlygic</td>
<td>A weakened form of Herpes Simplex Virus Type 1</td>
<td>Local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery</td>
</tr>
<tr>
<td></td>
<td>(Amgen)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>December 2016</td>
<td>Maci</td>
<td>Autologous cellularized scaffold product, consisting of cultured chondrocytes on porcine collagen membrane</td>
<td>Repair of single or multiple symptomatic, full-thickness cartilage defects of the knee with or without bone involvement in adults</td>
</tr>
<tr>
<td>August 2017</td>
<td>Kymriah</td>
<td>CAR-T cell therapy product</td>
<td>Acute lymphoblastic leukemia, chronic lymphoid leukemia and diffuse large B-cell lymphoma in patients up to 25 years of age</td>
</tr>
<tr>
<td></td>
<td>(Novartis)</td>
<td></td>
<td></td>
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<tr>
<td>Approval Date</td>
<td>Product Name</td>
<td>Description</td>
<td>Indication</td>
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<td>------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>October 2017</td>
<td>Yescarta (Kite)</td>
<td>CAR-T cell therapy product</td>
<td>B cell malignancies such as non-Hodgkin lymphoma, acute lymphoblastic leukemia, mantle cell lymphoma, chronic lymphoid leukemia and diffuse large B-Cell lymphoma</td>
</tr>
<tr>
<td>December 2017</td>
<td>Luxturna (Spark Therapeutics)</td>
<td>Adeno-associated viral vector gene therapy</td>
<td>RPE65-mediated inherited retinal dystrophies</td>
</tr>
<tr>
<td>May 2019</td>
<td>Zolgensma (Avexis)</td>
<td>Adeno-associated virus vector-based gene therapy</td>
<td>treatment of pediatric patients less than 2 years of age with spinal muscular atrophy (SMA), including those who are pre-symptomatic at diagnosis</td>
</tr>
<tr>
<td>July 2020</td>
<td>Tecartus (Kite)</td>
<td>CAR-T cell therapy product</td>
<td>Relapsed or refractory mantle cell lymphoma (MCL)</td>
</tr>
<tr>
<td>February 2021</td>
<td>Breyanzi (Juno Therapeutics)</td>
<td>CAR-T cell therapy product</td>
<td>Certain types of large B-cell lymphoma who have not responded to, or who have relapsed after, at least two other types of systemic treatment</td>
</tr>
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</table>
Expedited Programs For
Regenerative Medicine Therapies
Expedited Programs for Regenerative Medicine Therapies

Fast Track

Fast track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need.

Breakthrough Therapy

A process designed to expedite the development and review of drugs which may demonstrate substantial improvement over available therapy.

Accelerated Approval

These regulations allowed drugs for serious conditions that filled an unmet medical need to be approved based on a surrogate endpoint.

Priority Review

A Priority Review designation means FDA's goal is to take action on an application within 6 months.

Regenerative Medicine Advanced Therapy (RMAT) Designation

Established under the 21st Century Cures Act
Key Definitions

- All expedited programs for regenerative medicine therapies attempt to address an unmet need in the treatment of a serious condition.

**Serious condition**

- Disease or condition associated with morbidity that has a substantial impact on day-to-day functioning; and
- All conditions that meet the definition of life-threatening:
  - Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted; and
  - Diseases or conditions with potentially fatal outcomes, where the endpoint of clinical trial analysis is survival.

**Unmet Medical Need**

- Condition whose treatment or diagnosis is not addressed adequately by available therapy.
  - Could be an immediate need for a defined population (e.g., to treat a serious condition with no or limited treatment) or a longer-term need for society (e.g., to address the development of resistance to antibacterial drugs).
### Overview of Expedited Programs

<table>
<thead>
<tr>
<th>Nature of Program</th>
<th>FAST TRACK</th>
<th>BREAKTHROUGH THERAPY</th>
<th>ACCELERATED APPROVAL</th>
<th>PRIORITY REVIEW</th>
<th>RMAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qualifying Criteria</td>
<td>• Must treat serious condition • Potential to address unmet medical need • Basis can be nonclinical or clinical data</td>
<td>• Must treat serious condition • Preliminary clinical evidence indicates substantial improvement on clinically significant endpoints over available therapies</td>
<td>• Must treat serious condition with meaningful advantage over available therapies • Demonstrates effect on surrogate endpoint that predicts clinical benefit or intermediate clinical endpoints</td>
<td>• Must treat serious condition • Significant improvement in safety or effectiveness over existing therapy</td>
<td>• Meets definition of regenerative medicine therapy • Must treat a serious condition • Potential to address unmet medical need</td>
</tr>
</tbody>
</table>
## Overview of Expedited Programs (cont.)

<table>
<thead>
<tr>
<th>When to submit request</th>
<th><strong>FAST TRACK</strong></th>
<th><strong>BREAKTHROUGH THERAPY</strong></th>
<th><strong>ACCELERATED APPROVAL</strong></th>
<th><strong>PRIORITY REVIEW</strong></th>
<th><strong>RMAT</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• With IND or after</td>
<td>• With IND or after</td>
<td>• Discuss with the review division early in drug development</td>
<td>• With original BLA, NDA, or efficacy supplement</td>
<td>• With IND or after</td>
</tr>
<tr>
<td></td>
<td>• Ideally, no later than the pre-BLA/NDA meeting</td>
<td>• Ideally, no later than the end-of-phase 2 meeting</td>
<td></td>
<td></td>
<td>• Ideally, no later than the end-of-phase 2 meeting</td>
</tr>
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<table>
<thead>
<tr>
<th>Features</th>
<th><strong>FAST TRACK</strong></th>
<th><strong>BREAKTHROUGH THERAPY</strong></th>
<th><strong>ACCELERATED APPROVAL</strong></th>
<th><strong>PRIORITY REVIEW</strong></th>
<th><strong>RMAT</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Actions to expedite development and review</td>
<td>• All fast track designation features</td>
<td>• Approval based on an effect on a surrogate endpoint or an intermediate clinical endpoint that is reasonably likely to predict a drug’s clinical benefit</td>
<td>• Shorter clock for review of marketing application (6 months compared to the standard 10 months)</td>
<td>• All breakthrough therapy designation features, including early interactions to discuss any potential surrogate or intermediate endpoints</td>
</tr>
<tr>
<td></td>
<td>• Rolling review</td>
<td>• Intensive guidance on efficient drug development</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>• Organizational commitment involving senior managers</td>
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### Overview of Expedited Programs (cont.)

<table>
<thead>
<tr>
<th></th>
<th>Fast Track</th>
<th>Breakthrough Therapy</th>
<th>Accelerated Approval</th>
<th>Priority Review</th>
<th>RMAT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Additional Considerations</strong></td>
<td>- Designation may be rescinded if it no longer meets the qualifying criteria</td>
<td>- Designation may be rescinded if it no longer meets the qualifying criteria</td>
<td>- Promotional Materials</td>
<td>- Designation will be assigned at the time or original BLA, NDA, or efficacy supplement filing</td>
<td>- Designation may be rescinded if it no longer meets the qualifying criteria</td>
</tr>
</tbody>
</table>
Expedited Programs

- Sponsors may apply for and receive *more than one designation for a given product*, but should apply for each designation separately.
- FDA has stressed that *communication with the Agency is crucial* for these programs.
- FDA has shown willingness to meet with sponsors undergoing these expedited programs more frequently than those undergoing the traditional process.
- Expedited programs are very popular, particularly among *oncology* products
  - Between 2012-2019, 90% of initial *oncology* drug approvals used an expedited program, versus 55% of new *non-oncology* drug approvals
- **Priority Review, Fast Track, and Breakthrough Therapy Designation** are most frequently used
A Path Forward for Expedited Programs

• Both FDA and the industry recognize the redundancies in programs
• It is time- and resource- consuming for sponsors to prepare and for FDA to review multiple designation requests per drug
• FDA and the industry have discussed potential redesign and simplification
  – The next user fee authorization may be a ready vehicle for these changes
  – Bundle the requirements for Fast Track and RMAT into a pre-Breakthrough Therapy designation pathway
  – Codify processes and best practices for expedited programs

“We spend a lot of time at the FDA designating all of these different programs, what drugs should go into them, and to be honest there’s a lot of overlap that exists”

Richard Pazdur, Director, Oncology Center of Excellence, FDA (Nov. 2020)
RMAT Designation

- 1 drug approved to date under RMAT
  - Breyanzi (lisocabtagene maraleucel), approved in February 2021
- At least 1/3 of products with RMAT designation have **pivotal trials** underway or in preparation
- RMAT requests received by fiscal year:

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total Requests Received</th>
<th>Granted</th>
<th>Denied</th>
<th>Withdrawn</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>31</td>
<td>11</td>
<td>18</td>
<td>2</td>
</tr>
<tr>
<td>2018</td>
<td>47</td>
<td>18</td>
<td>27</td>
<td>2</td>
</tr>
<tr>
<td>2019</td>
<td>37</td>
<td>17</td>
<td>18</td>
<td>2</td>
</tr>
<tr>
<td>2020</td>
<td>34</td>
<td>12</td>
<td>22</td>
<td>0</td>
</tr>
<tr>
<td>2021</td>
<td>6</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

Currently 59 designations
RMAT Designation (cont.)

- RMAT requests now outpace Breakthrough Therapy Designation requests
- Continuous increase in RMAT designation requests has increased CBER workload and strained Center workforce
- CBER now seeks dedicated RMAT funding as part of next user fee reauthorization:
  - Increase time spent on applications and engagement with industry and stakeholders
  - Support policy and guidance development
  - Support development of treatments for unmet medical needs and individualized therapies
  - Establish permanent resources for the RMAT program

“This resource request is intended . . . to ensure long-term program sustainability . . . .”
RMAT Designation Benefits and Drawbacks

- Increased interaction with FDA (in principle)
  - Increased number of applications has forced CBER to limit sponsor interactions
- Relatively new (only 1 drug approval precedent)
- Significant overlap with Breakthrough Therapy Designation (hard to disaggregate individual benefits)
CBER’s INTERACT
(INitial Targeted Engagement for Regulatory Advice on CBER Products)

- **Pre-IND meetings** with the CBER
- Intended for **novel products** that introduce unique challenges, such as
  - Unknown safety profiles
  - Complex manufacturing technologies
  - Incorporation of innovative devices
  - Use of cutting-edge testing methodologies
- Can obtain **non-binding advice** on CMC, pharmacology/toxicology and/or clinical aspects of the development program
- Submit meeting request and package by email to CBER (See CBER SOPP 8214 for details)
- Generally, sponsors of all regenerative medicine therapies should engage in discussions with the Office of Tissues and Advanced Therapies (OTAT) review staff early during product development
Emerging Issues Regarding Regenerative Medicine Therapies
Genome Editing

- FDA regulates products using genome editing as gene therapy
- Gene therapy is an FDA priority
- FDA incorporates recommendations into guidance
  - Preclinical
  - Clinical
  - CMC
  - Post-marketing/Long term follow-up

- Genome editing currently in early stage clinical trials in human
Since its first approval in August 2017, FDA has approved 6 gene therapy products:

- **KYMRIAH**: B-cell precursor acute lymphoblastic leukemia that is refractory or in second or later relapse in patients up to 25 years of age
- **YESCARTA**: adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy
- **LUXTURNA**: patients with confirmed biallelic RPE65-mediated inherited retinal disease
- **TECARTUS**: adult patients with relapsed/refractory mantle cell lymphoma (MCL)
- **ZOLGENSMA**: SMA in children less than two years of age
- **BREYANZI**: adult patients with relapsed or refractor large-B-cell lymphoma after two or more lines of systemic therapy
Considerations for Gene Therapy and Genome Editing

- Selection of Animal Species and Models of Disease
- Proof of Concept and Toxicology Studies
- Product Delivery Considerations
- Consideration of Long Term Follow-Up

Long Term Follow-Up After Administration of Human Gene Therapy Products; Guidance for Industry (Jan. 2020)
Considerations for Gene Therapy and Genome Editing (cont.)

- **Trial design**
  - Product Characteristics
  - Manufacturing Considerations
  - Preclinical Considerations

- **Long Term Follow-Up Observations**

Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products; Guidance for Industry (June 2015)
Long Term Follow-up After Administration of Human Gene Therapy Products; Guidance for Industry (Jan. 2020)
Considerations for Gene Therapy and Genome Editing (cont.)

- **Quality Information**

- **Manufacturing Process and Control**

Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs); Guidance for Industry (Jan. 2020)
Considerations for Gene Therapy and Genome Editing (cont.)

- **Long Term Follow-Up**

- **Risk Evaluation and Mitigation Strategies (REMS)**
  - Potentially applicable to gene therapy products (e.g., Kymriah)
    - certification of hospitals and associated clinics dispensing Kymriah
    - staff training to recognize and manage Cytokine Release Syndrome (CRS) and neurological events
    - protocols in place to ensure that Kymriah is only given to patients after verifying that tocilizumab is available for immediate administration
    - Informing patients of the signs and symptoms of CRS and neurological toxicities following infusion – and of the importance of promptly returning to the treatment site if they develop adverse reactions after receiving treatment
Exercising Regulatory Authority: Pre-COVID-19

• FDA has stepped up enforcement activity of regenerative medicine products and particularly of stem cell products which it deems to pose risks

• A flurry of Warning and Untitled Letters to stem cell clinics in recent years, reiterating that their products are regulated by the Agency and that they should comply with all applicable regulations

• Sought permanent injunctions to stop stem cell clinics from marketing stem cell products without the Agency’s approval and/or for significant deviations from CGMP requirements
Exercising Regulatory Authority: COVID-19

• Previous enforcement discretion deadline of November 2020 extended to May 2021

• Dr. Marks and Former Commissioner Hahn’s editorial from July 2020 contains strong warning language
  – Unapproved regenerative medicine products are not inherently safe and may be associated with serious adverse consequences
  – Particularly true for products not manufactured under cGMP
  – Ask for engagement from clinicians and patients to identify and remove hidden, potentially harmful unapproved products

“The increasing number of adverse events being reported following the widespread use of unapproved regenerative medicine therapies at hundreds of clinics across the country make it necessary for the FDA to act to prevent harm to individuals receiving them.”
In FY 2020, CBER sent 204 letters to manufacturers, clinics or HCP who may be offering unapproved regenerative medicine products.

CBER and FTC have issued joint Warning Letters for unapproved COVID-19 products, including stem cell products.

Most recent Untitled Letter on February 17 to Pacific Stem Cells LLC:

- Pacific’s products derived from umbilical cord tissue and other placental materials did not meet the regulatory criteria to be regulated solely under section 361 of the PHS Act and 21 CFR § 1271.10.
- For example, the products were not intended for homologous use under 21 CFR § 1271.10(a)(2) -- treating stroke or Lyme disease vs. forming and replenishing the lymphohematopoietic system.
- CBER therefore concluded that the products are not exempt from premarket review.
- High risk routes of administration – intravenously and intraorally – heighted CBER’s concern, for contaminated products could cause a range of adverse events.
- CBER referred Pacific to its comprehensive regenerative medicine policy framework.
In Office Procedures

• FDA has traditionally focused on medical products developed by manufacturers rather than in-office procedures performed by individual doctors.

• **FDA has asserted jurisdiction over in-office procedures** at “rogue” stem cell clinics such as injection of stem cells derived from the patient’s adipose tissue (i.e., stromal vascular fraction (SVF) treatment).

• A federal judge in Florida sided with FDA in 2019, ruling that **SVF treatment is subject to FDA oversight** and does not fall under the “same surgical procedure” exemption.

• Stem cell clinics and physicians should be mindful of **FDA’s enforcement discretion** ending in May 2021.
Coronavirus Treatment Acceleration Program (CTAP)

• A special emergency program that “uses every available method to move new treatments to patients as quickly as possible”

• **Regenerative medicine products** constitute a significant component of COVID-19 treatments currently being studied. Examples include:
  
  – Adipose-derived, allogeneic mesenchymal stem cells, whose IND review was expedited under CTAP
  
  – Allogeneic mesenchymal-like cells used to treat patients under FDA Single Patient Expanded Access Program (part of CTAP)
Questions?

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