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A ProAssurance Company

September 28, 2022

Hot Topics in Life Sciences: What does this mean for products liability?

Artificial Intelligence

HEALTHY RETURNS

Next decade will transform health care more than past century: Johnson & Johnson CEO

PUBLISHED WED, MAR 30 2022•2:10 PM EDT | UPDATED THU, MAR 31 2022•10:52 AM EDT

Eric Rosenbaum
@ERPROSE

SHARE

Artificial Intelligence in Medical Devices

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Rise in applications for AI medical devices?

- AI has been a disruptive force in the life sciences industry.
- Does AI stand alone?
- What does this mean for products liability and medical malpractice?


MEDICAL DEVICE NETWORK

ns | News | Analysis | Sectors | Themes | Insights | Companies | Events

COMMENT | August 4, 2022

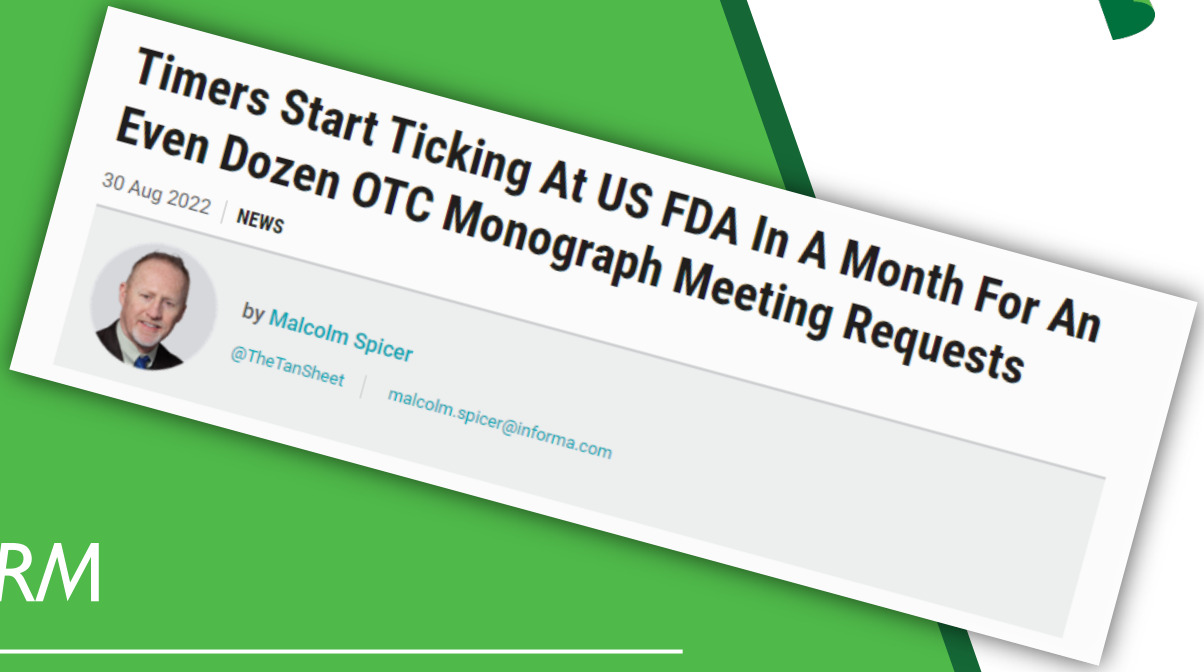
Rising applications for artificial intelligence in cardiovascular medicine

Artificial intelligence technology in the cardiovascular field has seen increased activity in the last few years with notable deals and partnerships.

By GlobalData


NewYork-Presbyterian invests $15M in AI partnership

OTC Drug Reform



Timers Start Ticking At US FDA In A Month For An Even Dozen OTC Monograph Meeting Requests

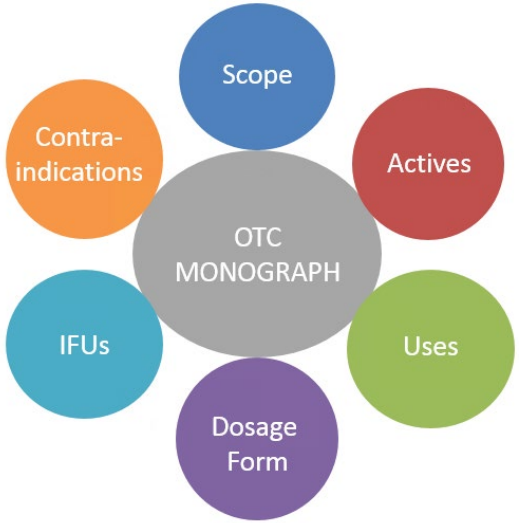
30 Aug 2022 | NEWS

by Malcolm Spicer

@TheTanSheet | malcolm.spicer@informa.com

OTC Monograph System

- Set of conditions that are self-limiting and self-diagnosable
- Identifies permitted actives and concentrations
- Sets out required label statements
- No pre-approval required – if it complies with the monograph, it can be sold
  - Manufacturer must register with FDA and submit annual product listing



OTC Monograph System

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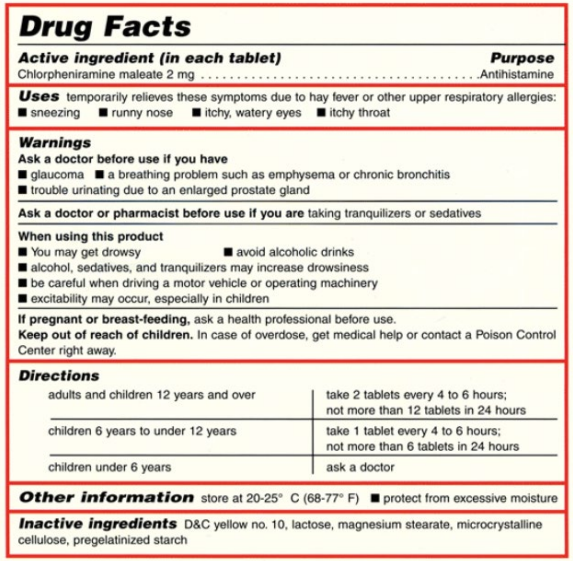

Drug Facts

Active ingredient (in each tablet) — **Purpose**
Chlorpheniramine maleate 2 mg ..... Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat

Warnings
Ask a doctor before use if you have
■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis
■ trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this product
■ You may get drowsy ■ avoid alcoholic drinks
■ alcohol, sedatives, and tranquilizers may increase drowsiness
■ be careful when driving a motor vehicle or operating machinery
■ excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children under 6 years	ask a doctor

Other information store at 20-25° C (68-77° F) ■ protect from excessive moisture

Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

- Required label format
- Nearly every aspect dictated by regulations – fonts, font size, bolding, line widths, bullet use

MONOGRAPH ~~SYSTEM~~ RELIC

- Introduced in 1972 and never completed
- Relied on notice and comment rulemaking that resulted in a codified monograph
  - Significant downsides included the glacial pace of the process, which left tentative monographs pending indefinitely
- Barrier to innovation, as monographs were limited in large part to actives available in 1972

New Route to Market for OTCs

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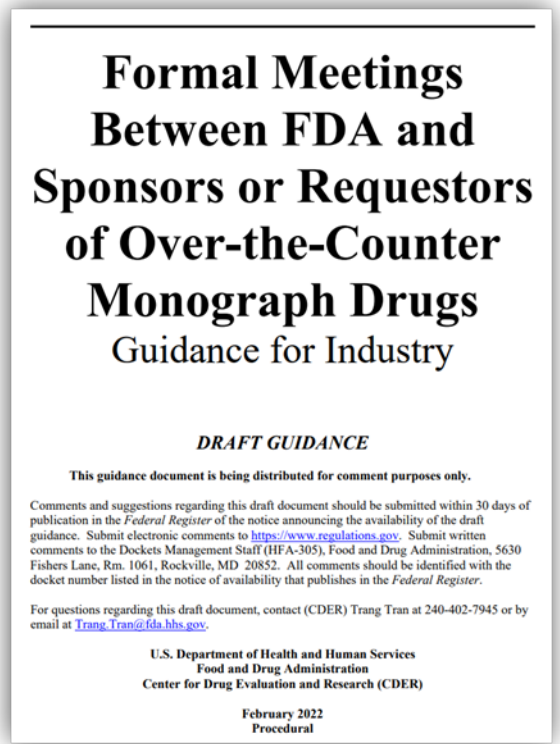
- Monograph reform was tacked onto the CARES Act (Coronavirus Aid, Relief, and Economic Security Act) of 2020
  - Replaced notice and comment rulemaking with an administrative order process
  - Streamlines the way in which FDA can issue, revise, and amend OTC monographs
  - Allows FDA to assess user fees from manufacturers and contract manufacturers of OTC drugs to support program staffing



Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 30 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Trang Tran at 240-402-7945 or by email at Trang.Tran@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

February 2022
Procedural

OTC Drug Reform: Where do we stand?

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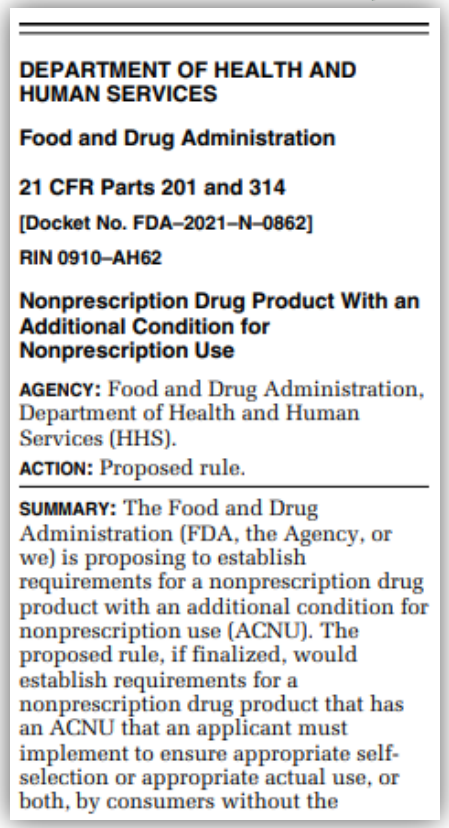
- Final monographs! https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm
- New route to market for OTCs
- Easier Rx to OTC switch: Coming soon?
  - Additional Condition for Nonprescription Use (ACNU)
    - Human factors studies
    - Actual use studies
    - Self-selection and labeling studies



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 314

[Docket No. FDA–2021–N–0862]

RIN 0910–AH62

Nonprescription Drug Product With an Additional Condition for Nonprescription Use

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to establish requirements for a nonprescription drug product with an additional condition for nonprescription use (ACNU). The proposed rule, if finalized, would establish requirements for a nonprescription drug product that has an ACNU that an applicant must implement to ensure appropriate self-selection or appropriate actual use, or both, by consumers without the

Stem Cell Therapy

Future Market Insights

Cell Therapy Manufacturing Market is expected to reach a valuation of US$ 13.9 Billion by the end of 2032, at a CAGR of 14.2% from 2022-2032 | Future Market Insights, Inc.

U.S. dominates the North American region and held a total share of about 96.8% in 2021. The country is expected to continue to remain at the forefront throughout the forecast period. Increasing prevalence of sickle cell disease in the country and presence of a large number of gene & cell and tissue-based therapeutic developers are likely to drive growth.

September 05, 2022 09:00 ET | Source: Future Market Insights Global and Consulting Pvt. Ltd.

Medical Biotechnology: Hot Take

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Column: In blow to public health, judge tosses FDA lawsuit targeting a clinic offering unproven stem cell treatments

- **Stem Cells**
  - As investment rises, FDA becoming increasingly weary of illegal stem cell treatments. But what are the legal implications?
  - Stem-cell derived products and stem cells in cosmetics – when is it regulated as a drug?

Stem Cell Therapy Market worth $558 million by 2027 - Exclusive Report by MarketsandMarkets™

Emergency Use Authorizations: The End May Be in Sight

FDA proposes 180-day transition before terminating COVID-19 EUAs, enforcement policies

Regulatory News | 04 January 2022 | By Michael Mezher, Joanne S. Eglovitch

The US Food and Drug Administration (FDA) is proposing to give medical device makers 180-days' notice before terminating emergency use authorizations (EUAs) and phasing out its enforcement policies for medical devices issued during the COVID-19 public health emergency (PHE).

The transition plan comes in the form of two draft guidances issued in late December, in which FDA explains that the transition policies are intended to "prepare manufacturers and other stakeholders for the transition to normal operations and foster compliance with applicable requirements under the [*Federal Food, Drug, and Cosmetic Act*] and implementing regulations when the relevant EUAs and COVID-19-related enforcement policies cease to be in effect."

EMERGENCY USE AUTHORIZATION

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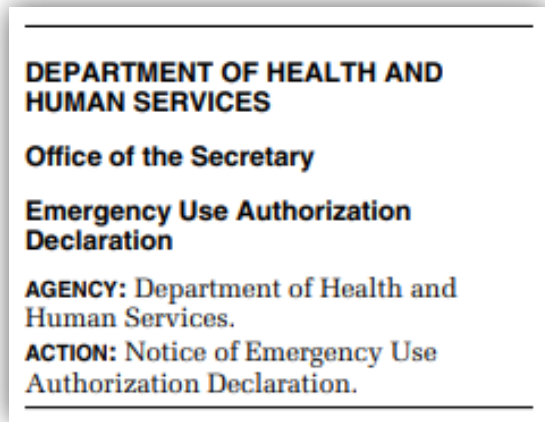
- As a result of the HHS declaration that COVID-19 was a health emergency, FDA was able to bring pandemic-response products to market under Emergency Use Authorizations (EUAs), by passing the normal approval process.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Emergency Use Authorization Declaration

AGENCY: Department of Health and Human Services.

ACTION: Notice of Emergency Use Authorization Declaration.

- But what happens to the products once the health emergency ends?

COVID PRODUCTS IN A POST-COVID WORLD

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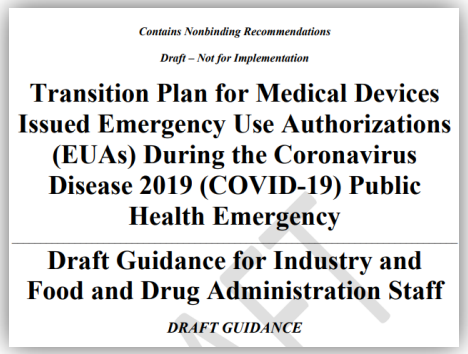
- FDA recognizes that industry will need time to plan for the eventual transition to normal operations
  - EUA Pathway vs. Enforcement Policies
  - Pursuing approval/clearance under traditional pathway
  - Reusable equipment sold under an EUA
    - Non-life-sustaining/supporting vs. life-sustaining/supporting



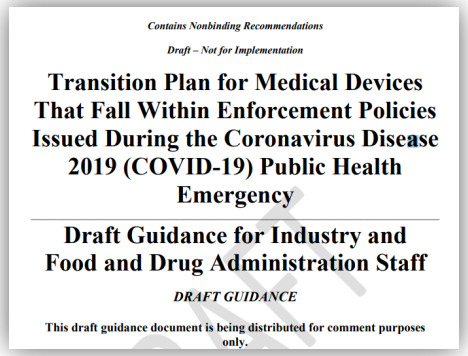
Contains Nonbinding Recommendations

Draft – Not for Implementation

Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE



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Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

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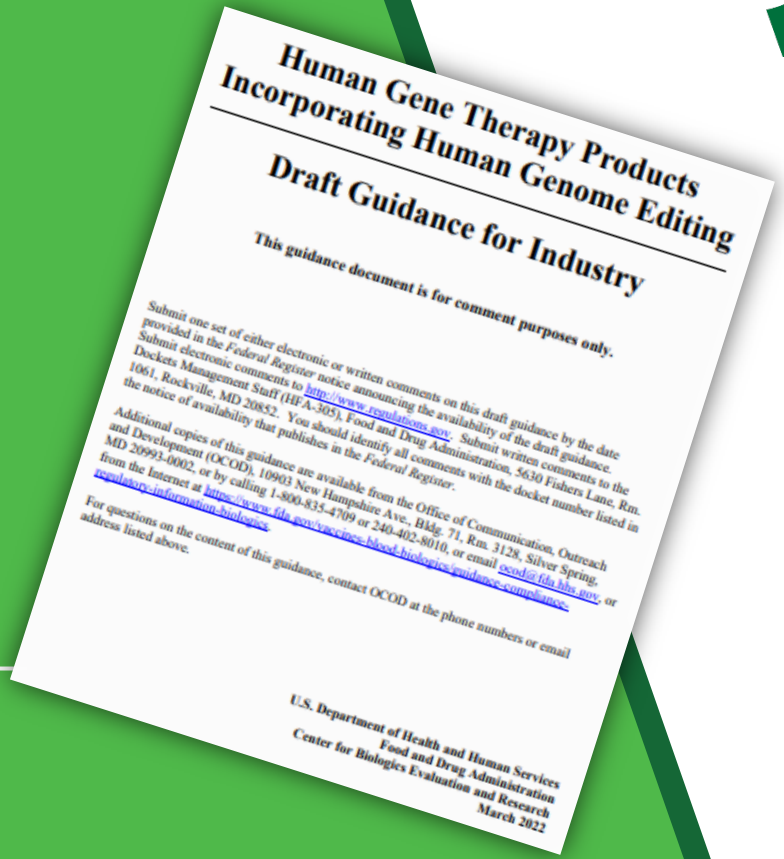
GENE THERAPY



Human Gene Therapy Products Incorporating Human Genome Editing

Draft Guidance for Industry

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Additional copies of this guidance are available from the Office of Communication, Outreach and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-8010, or email ocod@fda.hhs.gov, or from the Internet at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.

For questions on the content of this guidance, contact OCOD at the phone numbers or email address listed above.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
March 2022

Medical Biotechnology: Hot Take

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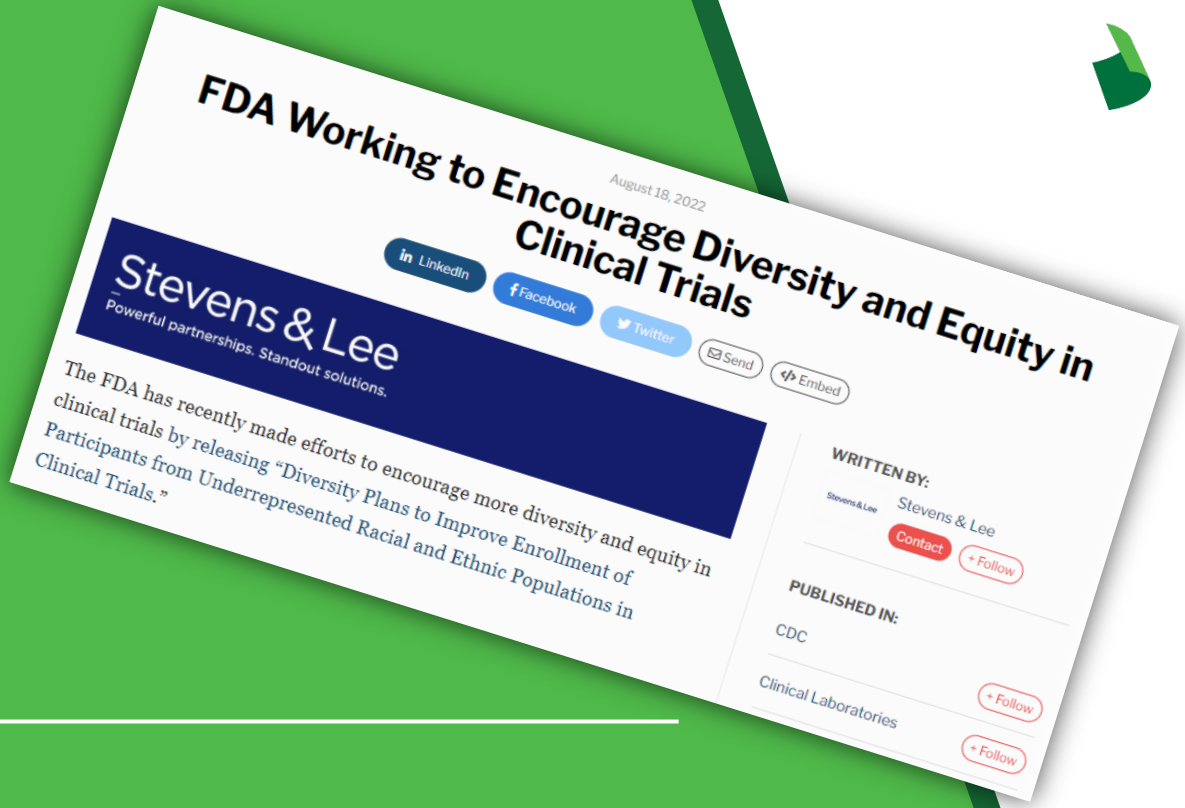
- **Gene Therapy**
  - Groundbreaking approval.
  - Products liability implications.
  - There has been a drastic rise in the number of gene therapy submissions to the FDA.
  - Risks unique to gene therapy clinical trials.
  - What's next?

Health Equity



FDA Working to Encourage Diversity and Equity in Clinical Trials

August 18, 2022

LinkedIn Facebook Twitter Send Embed

Stevens & Lee
Powerful partnerships. Standout solutions.

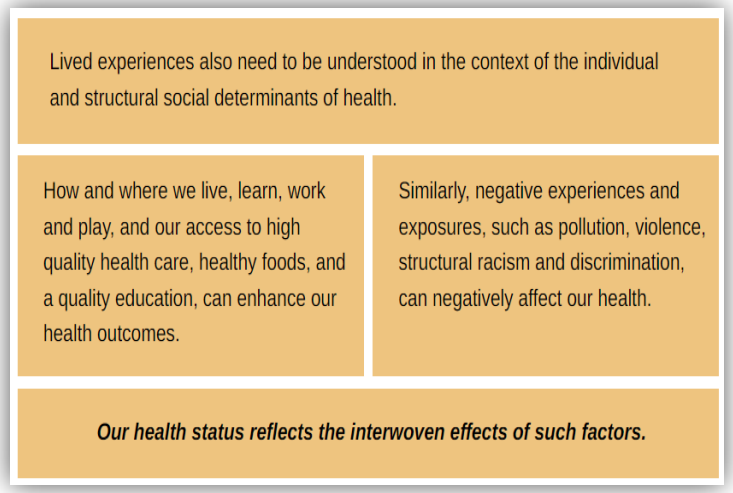
The FDA has recently made efforts to encourage more diversity and equity in clinical trials by releasing "Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials."

WRITTEN BY:
Stevens & Lee
Contact + Follow

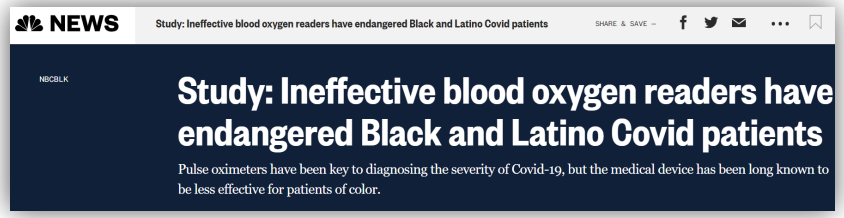
PUBLISHED IN:
CDC
Clinical Laboratories
+ Follow
+ Follow

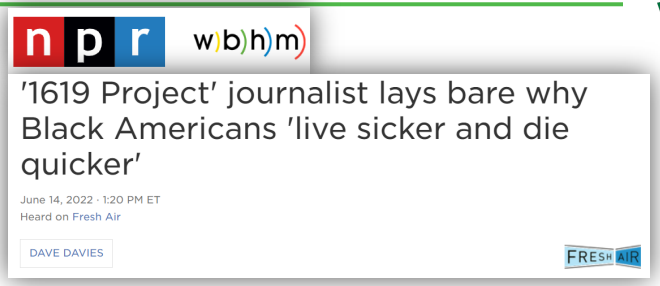
Sociodemographics and Health

- Overall health is a combination of both physical and mental well-being, and these are impacted by various sociodemographic characteristics, including:
  - Race and ethnicity
  - Socioeconomic status
  - Geographic location
  - Sexual orientation and gender identity



Clinical Trials and Diversity

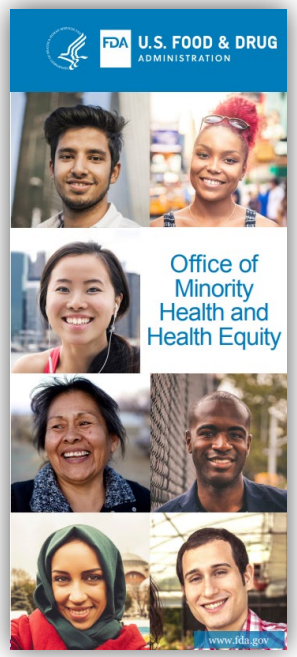




- Clinical trials are intended to evaluate the safety and effectiveness of therapeutic interventions
  - Effective dosage for therapeutic response
  - Establish tolerable limits
  - Identify possible side effects and adverse events
- Historically, white men have constituted the overwhelming majority of clinical trial subjects
  - Genetic differences can impact drug and device efficacy and tolerability, so women and people of color have been left behind

FDA Response

- Promoting diversity and inclusion in clinical trials
  - Draft guidance to industry "recommends" the inclusion of a Race and Ethnicity Diversity Plan with IND/IDE applications for drug and device clinical trials
  - DEPICT Act
    - Diverse and Equitable Participation in Clinical Trials Act, proposed in 2022
      - If passed, would allow diversity action plans as a component of IND/IDE applications to be made mandatory
      - Would permit FDA to mandate post-approval studies/postmarket surveillance when sponsors fail to hit diversity enrollment targets without sufficient justification



Supply Chain Shortages

Expert Opinions

Expert: How Hospitals Can Prepare for Supply Shortages

Determining what is critical, where the supplies are sourced, and inventory soft spots are essential to keeping a hospital running smoothly.

By Will Maddox | August 10, 2022 | 4:00 pm

Supply Chain Shortage: The Battle Continues…

MEDMARC
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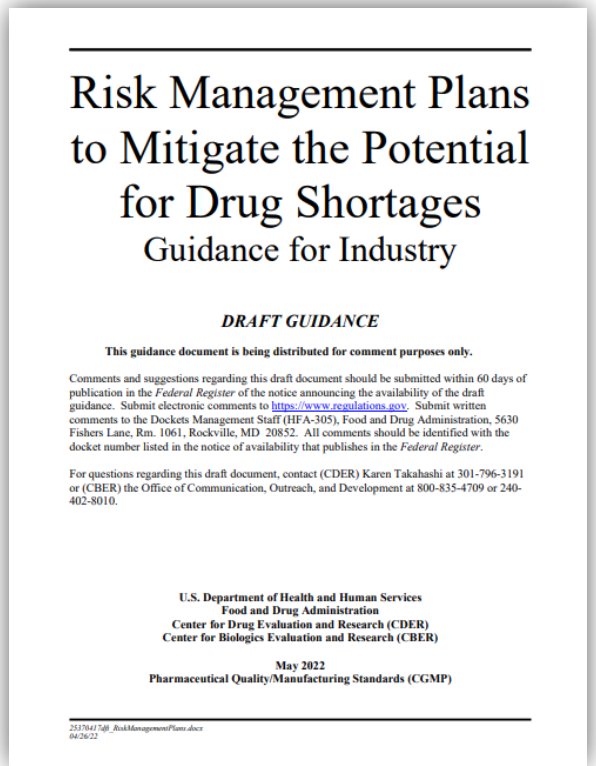
- **Pharmaceutical Supply Chain Issues During COVID19**
  - CARES Act
  - FDA's Risk Management Plan to mitigate the potential for drug shortages
- **The new modification in the Federal Food, Drug, and Cosmetic Act (FD&C Act)**
  - Who does it apply to?
  - Which products does it apply to?



Risk Management Plans to Mitigate the Potential for Drug Shortages

Guidance for Industry

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For questions regarding this draft document, contact (CDER) Karen Takahashi at 301-796-3191 or (CBER) the Office of Communication, Outreach, and Development at 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

May 2022
Pharmaceutical Quality/Manufacturing Standards (CGMP)

2537041Tdft RiskManagementPlans.docx
04/26/22

THANK YOU!

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