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## FDA Allows Plausible Mechanism for Rare Disease Approval

### Description

The Food and Drug Administration (FDA) has announced a new policy to help patients with very rare diseases get advanced treatments more quickly. This change is important because it may give hope to families waiting for solutions to these hard-to-treat conditions.

Under the new guidance, the FDA can approve treatments based on a "plausible mechanism," meaning there is evidence that the treatment should work. This policy aims to speed up the use of modern methods, like gene-editing, for personalized therapies.

Health Secretary Robert F. Kennedy Jr. stated that families often heard that there were not enough patients for research. He said this will change, and individualized medicine is now a reality. FDA Commissioner Marty Makary added that rare diseases previously received little attention.

The new policy could lead to many new treatments for rare diseases that have a clear genetic cause. Researchers are currently working on treatments for genetic blood disorders and other serious illnesses. However, creating treatments for very rare conditions is often costly and lacks financial support.

This policy was influenced by the successful treatment of a baby with a rare liver disorder using gene-editing. Doctors hope to use similar methods for other patients in the future.

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### Vocabulary List:

1. **Plausible** /'plɔː.zə.bəl/ (adjective): Appearing to be reasonable or probable.
2. **Mechanism** /'mek.ə.nɪ.zəm/ (noun): A process or technique for achieving a result.
3. **Therapies** /'θer.ə.peɪz/ (noun): Treatments designed to relieve or heal a disorder.
4. **Individualized** /,ɪn.dɪ.vɪ.dʒ.u.ə.laɪzd/ (adjective): Tailored to meet the specific needs of an individual.
5. **Genetic** /dʒə'netɪk/ (adjective): Relating to genes or heredity.
6. **Disorders** /dɪs'ɔːrdəz/ (noun): A disruption of normal physical or mental functions.

### Comprehension Questions

#### Multiple Choice



1. What is the purpose of the FDA's new policy?
  - Option: To ban certain medications
  - Option: To help patients with rare diseases get treatments more quickly
  - Option: To promote fast-food chains
  - Option: To increase pharmaceutical prices
  
2. Which modern method is being promoted for personalized therapies?
  - Option: Radiation therapy
  - Option: Gene-editing
  - Option: Chemotherapy
  - Option: Acupuncture
  
3. Who stated that individualized medicine is now a reality?
  - Option: FDA Commissioner Marty Makary
  - Option: Health Secretary Robert F. Kennedy Jr.
  - Option: The President
  - Option: A medical journal
  
4. What issue did the FDA's policy aim to address regarding rare diseases?
  - Option: Overpopulation
  - Option: Lack of attention
  - Option: Excessive funding
  - Option: Public awareness
  
5. What kind of disorders are researchers working to treat under the new policy?
  - Option: Common colds
  - Option: Genetic blood disorders
  - Option: Flu
  - Option: Aging
  
6. What was previously a major barrier to research on rare diseases?
  - Option: Too many patients
  - Option: Insufficient funding
  - Option: Too much financial support
  - Option: Lack of interest

**True-False**



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7. The new FDA policy only benefits common illnesses.
  8. The policy allows for treatments to be approved based on a plausible mechanism.
  9. Creating treatments for very rare conditions is often inexpensive.
  10. Health Secretary Robert F. Kennedy Jr. mentioned that there were not enough patients for research.
  11. The successful treatment mentioned in the policy involved gene-editing.
  12. FDA Commissioner Marty Makary stated that rare diseases have received a lot of attention.

### Gap-Fill

13. The FDA has announced a new policy to help patients with very rare diseases get advanced treatments more \_\_\_\_\_ .
14. Under the new guidance, the FDA can approve treatments based on a \_\_\_\_\_ mechanism.
15. Health Secretary Robert F. Kennedy Jr. said that individualized medicine is now a \_\_\_\_\_ .
16. The policy aims to speed up the use of modern methods like \_\_\_\_\_ for personalized therapies.
17. This policy was influenced by the successful treatment of a baby with a rare liver disorder using gene-\_\_\_\_\_. .
18. Creating treatments for very rare conditions is often \_\_\_\_\_ and lacks financial support.



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## Answer

**Multiple Choice:** 1. To help patients with rare diseases get treatments more quickly 2. Gene-editing  
3. Health Secretary Robert F. Kennedy Jr. 4. Lack of attention 5. Genetic blood disorders 6. Insufficient  
funding

**True-False:** 7. False 8. True 9. False 10. True 11. True 12. False

**Gap-Fill:** 13. quickly 14. plausible 15. reality 16. gene-editing 17. editing 18. costly

## Vocabulary quizzes

### Multiple Choice ( Select the Correct answer for each question. )

1. What does the cap refer to in financial contexts?

Option: Borrowing limit

Option: Postage fees

Option: Last-mile delivery

Option: Revenue generated

2. Which of the following is a primary goal for companies regarding revenue?

Option: Maximizing damage

Option: Increasing commission

Option: Reducing costs

Option: Enhancing facilities

3. What is a concern when discussing damage in shipping?

Option: Operational efficiency

Option: Postage rates

Option: Last-mile delivery issues

Option: Shipping costs

4. What can cause tensions in the Strait during shipping?

Option: New legislation

Option: Increased costs

Option: Strikes

Option: Technological advancements

5. Which of the following is essential for mapping in shipping?

Option: Genetic therapies

Option: Interruption management

Option: Tracking technology



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Option: Postage calculations

6. What does commission typically refer to in a business context?

Option: A form of damage assessment

Option: A type of facility

Option: Revenue sharing between agents

Option: Cap on borrowing

7. What are companies often keen to reduce to increase profits?

Option: Prices

Option: Facilities

Option: Damage

Option: Costs

8. What type of legislation is often discussed to regulate shipping?

Option: Proposed policies

Option: Past regulations

Option: Current tariffs

Option: Obsolete laws

9. In logistics what does mapping primarily refer to?

Option: Cost estimation

Option: Route planning

Option: Damage control

Option: Revenue tracking

10. What is last-mile delivery crucial for in the shipping process?

Option: Pricing strategies

Option: Customer satisfaction

Option: Damage assessment

Option: Mapping routes

**Gap-Fill ( Fill in the blanks with the correct word from the vocabulary list. )**

11. The borrowing limit for small businesses is often set by financial institutions at \_\_\_\_\_

12. Postage rates can significantly affect the overall \_\_\_\_\_ of shipping products.

13. Agents often earn a commission based on the \_\_\_\_\_ they generate from sales.



14. In logistics assessing damage is necessary to determine the \_\_\_\_\_ of goods.
15. Power interruptions can severely impact \_\_\_\_\_ in a delivery network.
16. Geopolitical tensions can affect the \_\_\_\_\_ of goods across certain straits.
17. Labor strikes can lead to \_\_\_\_\_ in service delivery and supply chains.
18. Emerging technology can revolutionize the \_\_\_\_\_ of shipping logistics.
19. Accurate mapping is crucial for ensuring timely \_\_\_\_\_ in last-mile delivery.
20. Increasing \_\_\_\_\_ is a fundamental goal for businesses seeking expansion.

**Matching Sentences ( Match each definition to the correct word from the vocabulary list. )**

21. A cap is placed on borrowing limits to ensure financial stability for individuals and businesses.
22. Last-mile delivery refers to the final step of transporting goods to the end customer.
23. Revenue is the total income generated from business operations before any expenses are deducted.
24. Commission is a fee paid to an agent or employee based on the sales they facilitate.
25. Damage assessment is crucial after shipping incidents to determine the loss incurred.
26. Power outages can disrupt various operations leading to delays and increased costs.
27. Technology advancements are shaping the future of logistics and shipping industries.
28. Tensions in international relations can significantly impact trade routes and shipping activities.
29. Mapping technology improves route efficiency and optimizes delivery times in logistics.
30. Strikes in the transportation sector can lead to widespread disruptions in service delivery.

**Answer**

**Multiple Choice:** 1. Borrowing limit 2. Reducing costs 3. Last-mile delivery issues 4. Strikes 5. Tracking technology 6. Revenue sharing between agents 7. Costs 8. Proposed policies 9. Route planning 10. Customer satisfaction

**Gap-Fill:** 11. specific thresholds



12. costs 13. revenue 14. replacement costs 15. operations 16. shipping routes 17. interruptions 18. efficiency 19. dispatch 20. profit

**Matching sentence:** 1. cap 2. last-mile delivery 3. revenue 4. commission 5. damage 6. power 7. technology 8. tensions 9. mapping 10. strikes

## CATEGORY

1. Business - LEVEL2

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