NATIONAL CENTER FOR HEALTH RESEARCH

The Voice For Prevention, Treatment And Policy

OMUFAReauthorization What do Consumers Need?

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Disclosures

The National Center for Health Research is a nonprofit think tank that focuses on the safety and effectiveness of medical and consumer products and does not accept funding from companies that make those products.

I inherited and own stock in J & J

Risks of GRASE vs. Evidence

- Delay in care creating missed opportunities for use of more effective treatments (including a doctor's visit if needed).
- To avoid the risks of potential allergic reactions or other side effects
- To avoid the inherent risks (especially for combination therapies) of taking too many meds in order to seek some benefit.

Benefits of Evidence vs. GRASE

- To avoid unnecessary costs and to restore consumers' trust that FDA approval means a product has benefits compared to placebo.

- The recent example of Sudafed PE and related cold products is the poster child for spending on products that experts now agree do not work.

Enhancements

- We don't have enough evidence yet to know how best to improve OMUFA

- BUT, based on PDUFA and MDUFA, we know that consumers deserve a stronger voice:

  * Negotiations should NOT be behind closed doors; Consumers should be at the table

  *Performance goals should benefit consumers in terms of safety and effectiveness

Performance Goals

- Speed of review is not as important as proving meaningful benefits to consumers

- Effectiveness should be as important as safety because all medications have costs and risks, even if modest.

Metrics in the Commitment Letter

- Label changes: Enhancing safety info re: warnings, contraindications, etc.

- Responses to citizen petitions to determine whether and when a medication was withdrawn from the market because of safety or effectiveness

- Percentage of facility re-inspections carried out within 6 months after the letter to the facility indicating FDA's intent to reinspect

Adding & Strengthening Warnings

- We agree there should be no extra fees for changes to enhance safety: e.g. if the FDA finds that the OMOR seeks to change the drug facts labeling of an OTC monograph drug in a way that would add or strengthen;
  * a contraindication, warning, or precaution;
  * a statement about risks of misuse or abuse;
  * or revise dosage info to increase safe use.

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