Public Meeting on Prescription Drug User Fee Act (PDUFA) Reauthorization

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NCL and FDA – A Shared History

- Pure Food and Drugs Act of 1906
- FDA Modernization Act of 1997
- NCL has worked with FDA to ensure:
  - Consumer representation and protections
  - Safe and effective medications

Consumer vs. Patient

- Consumers and patients weigh risks associated with drugs differently
- Patients are more likely to take on greater risk
- Consumers informed about risks and benefits, are more likely to choose a lower-risk option

PDUFA

- Reduce barriers to new drug approval
- Safe, effective, and reduced exposure to harmful medications
- Sometimes too much emphasis on speed

Patient Focused Drug Development

- Patients deserve to have a voice regarding their experiences, perspectives, and needs

- Mutual benefit to information exchange between patients and Agency

- Potential FDA Patient Workshop Travel Fund

Diversity in Clinical Trials

- Greater representation needed among clinical trial participants
- Varying pharmacogenetic responses for the same drug for different demographics
- Representation in clinical trials could mean that patients get a drug that is best suited for their genetic makeup

Off–Label Prescribing

- PDUFA funding should also be directed towards examining consumer awareness towards off-label prescribing
- Tracking use of off-label medications
- Sentinel information on off-label use

Direct-to-Consumer Advertising

- Direct-to-consumer (DTC) drug ads should be:
  - Accurate
  - Not misleading
  - Corrected BEFORE they reach the public

- Address imbalance between the volume of DTC ads and the resources available for monitoring and reviewing ads

Safety and Inspection Amidst COVID-19

- COVID-19-related disruptions include limited foreign travel for FDA personnel
- PDUFA funds should be used to support FDA's safety inspection efforts for imported drugs
- Patients and consumers rely on the Agency to assess medication:
  - Safety
  - Quality
  - Availability

Biologics Review for COVID-19

- PDUFA VII funds should be allocated to the review of COVID-19 vaccine efforts
  - Operation Warp Speed
- Hiring and retention of staff to facilitate review

Post-Market Surveillance

- Post-market surveillance = value for consumers
- Resource allocation for staffing and support of programs like:
  - FDA MedWatch
  - Sentinel Project
  - Post-market studies

Thank You

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