PATIENTS FOR AFFORDABLE DRUGS

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FDA Public Meeting
RE: Generic Drug Competition
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In just five months, we have collected 7,000 stories and 10,000 email addresses from patients.
Battle with Blood Cancer

Diagnosed with multiple myeloma in 2010.

Cancer brought me face-to-face with high price drugs.
Revlimid


The retail price for a four-week cycle of Revlimid increased 34 percent to $10,441. More than $500 per capsule.
Keys for FDA

• **Forbid drug corporations from declaring information about REMS to be proprietary.**
  • FDA should collect and issue best practices for REMS so all manufacturers—brand and generic alike—can draw upon previous learnings and easily setup systems.
  • If a drug corporation like Celgene refuses to share REMS information with a generic manufacturer, the FDA should use its authority to waive the requirement for a single shared system.

• **Take additional action to ensure generic companies can obtain samples for testing.**
  • Request immediate Congressional action.
  • If the FDA does not have the proper resources or authority to require the provision of samples, perhaps joint action with the FTC could be undertaken to stop this anti-competitive behavior.
  • Where FDA does not believe it has sufficient authority to stop these abuses, the Agency should request immediate Congressional action.
  • FDA should be explicit in support of solutions such as the CREATES Act and FAST Generics Act, which aim to correct this distortion of the law.
Contact and Resources:

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Patients For Affordable Drugs