PATIENTS FOR AFFORDABLE DRUGS™

David Mitchell

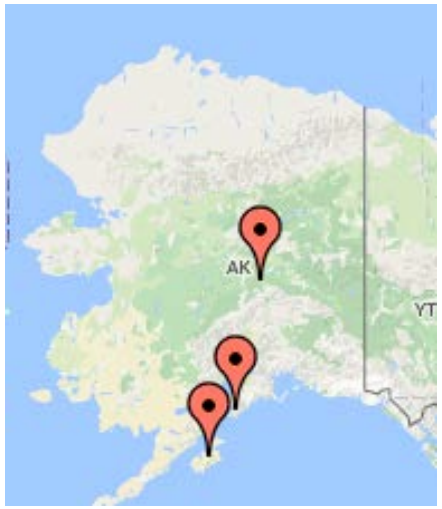
Founder & President

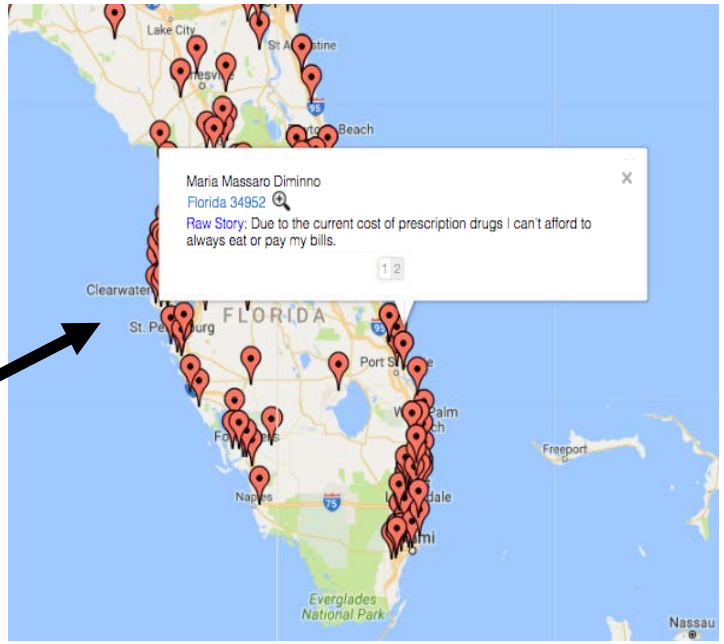
FDA Public Meeting

RE: Generic Drug Competition

July 18, 2017

Patient Stories





In just five months, we have collected 7,000 stories and 10,000 email addresses from patients.

Battle with Blood Cancer

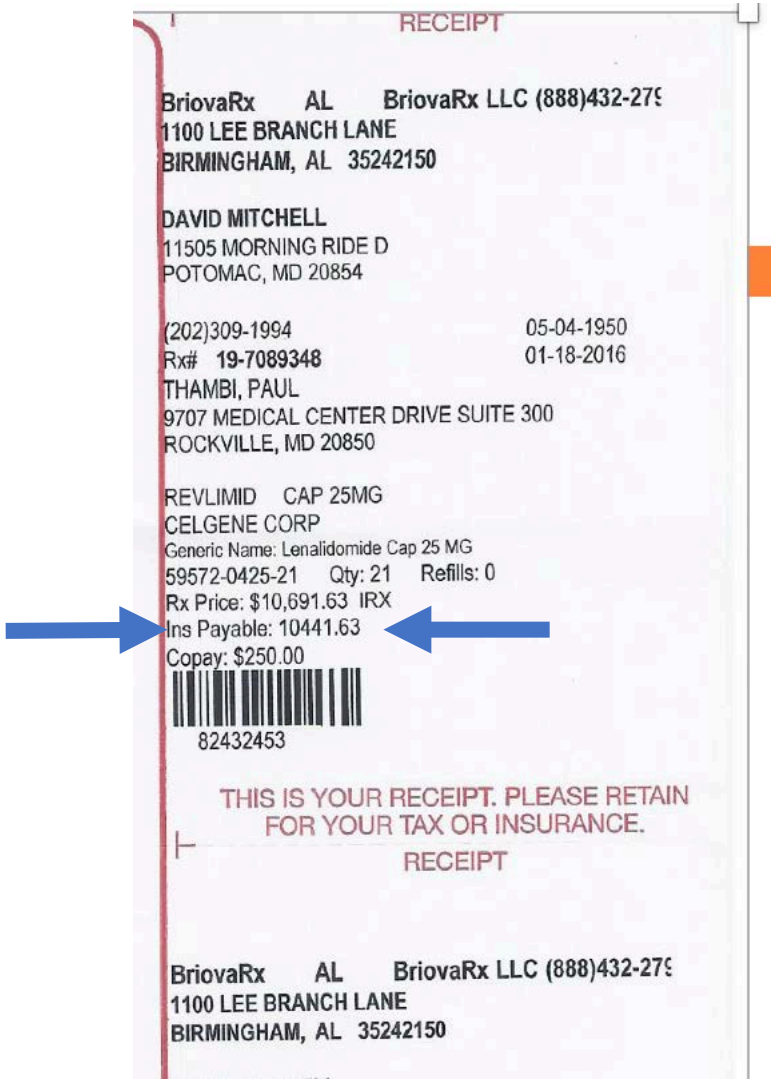
Diagnosed with multiple myeloma in 2010.

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

Revlimid

Out-of-pocket cost for Revlimid went from $42 a month in 2011 to $250 in 2016.

The retail price for a four-week cycle of Revlimid increased 34 percent to $10,441. More than $500 per capsule.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11505 MORNING RIDE D
POTOMAC, MD 20854

(202)309-1994 05-04-1950
Rx# 19-7089348 01-18-2016
THAMBI, PAUL
9707 MEDICAL CENTER DRIVE SUITE 300
ROCKVILLE, MD 20850

REVLIMID CAP 25MG
CELGENE CORP
Generic Name: Lenalidomide Cap 25 MG
59572-0425-21 Qty: 21 Refills: 0
Rx Price: $10,691.63 IRX
Ins Payable: 10441.63
Copay: $250.00
82432453

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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