



**TUTELA**  
pharmaceuticals

***For Patients***

March 2021

# Background

- ▶ Pharma companies have single-source products that:
  - ▶ are no longer strategic
  - ▶ may not provide meaningful profit
  - ▶ absorb resources that could be better applied to important innovative growth opportunities
- ▶ Patients, however, rely on these drugs and have often been stabilized on them.

***What to do?***

# What is Tutela?

- ▶ A new model of a 501(c)(3) not-for-profit pharmaceutical company

- ▶ **Our Vision:**

To advance public health and enhance trust in the pharmaceutical industry by driving collaboration between for-profit and not-for-profit organizations that uniquely benefits patients

- ▶ **Our Mission:**

*To ensure continued and affordable access of single-source medications to patients*

# Discontinued US Products

## 1994 through 2015

- 215 drugs withdrawn from sale
- *Only 5.1% withdrawn for reasons of safety or effectiveness<sup>1</sup>*

## Current Examples

- Potiga (ezogabine, GSK): Antiepileptic (2017)
- Tridione (trimethadione, Abbvie): Antiepileptic (2018)
- Zurampic and Duzallo (lesinurad or lesinurad/allopurinol, Ironwood): Antihyperuricemic (2019)
- Rescriptor (delavirdine, ViiV Healthcare): HIV antiviral (2018)
- Peganone (ethotoin, Recordati Rare Diseases): Antiepileptic (2020)

<sup>1</sup> <https://www.drugpatentwatch.com/blog/reviving-a-discontinued-drug/> Accessed July 7, 2020.

# Options for Pharma Companies

## Divest Product

- Potential for significant price increase by acquiring for-profit entrepreneurial company
- Reputational issue for innovator and new company
- Provides one-time revenue to innovator through acquisition sale but creates future P&L gap

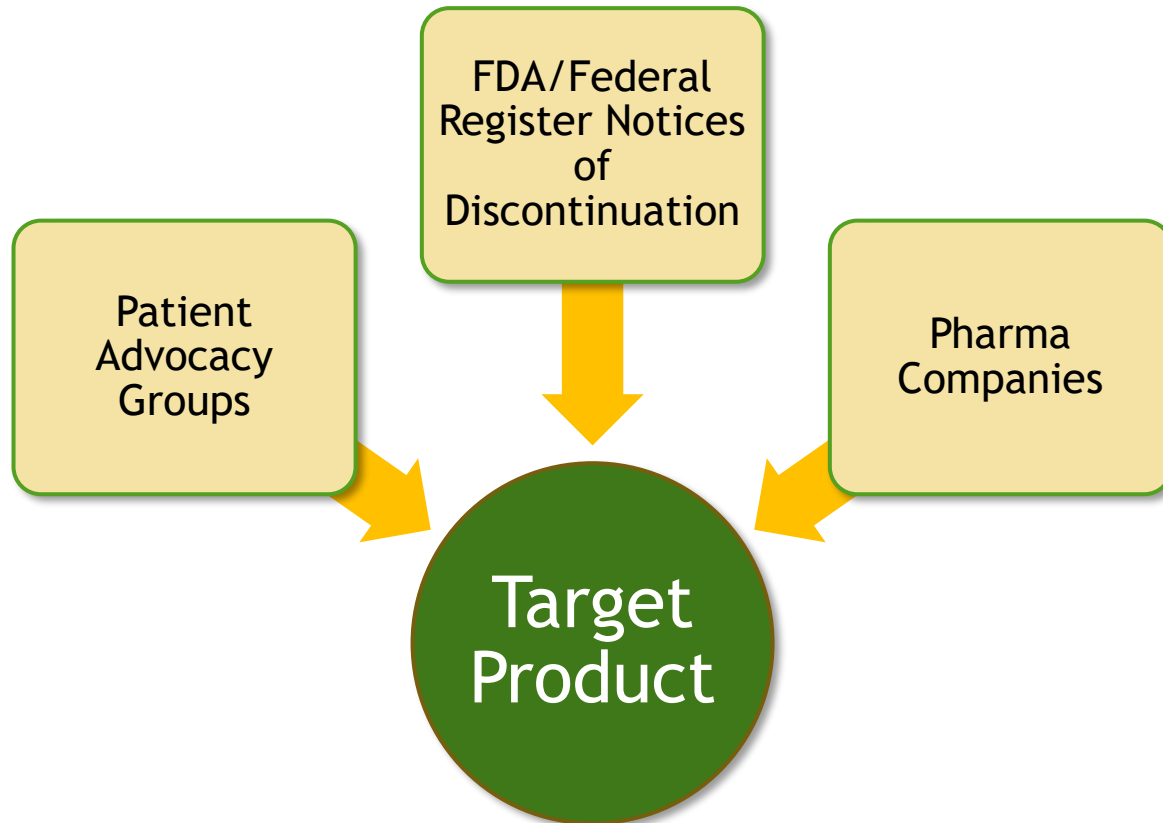
## Discontinue Marketing

- Disrupts patient care
- Negative external reputation with patients, caregivers, & HCPs for innovator company
- Inconsistent with “patient focused” corporate culture
- Lose revenue, no tax-exempt write off

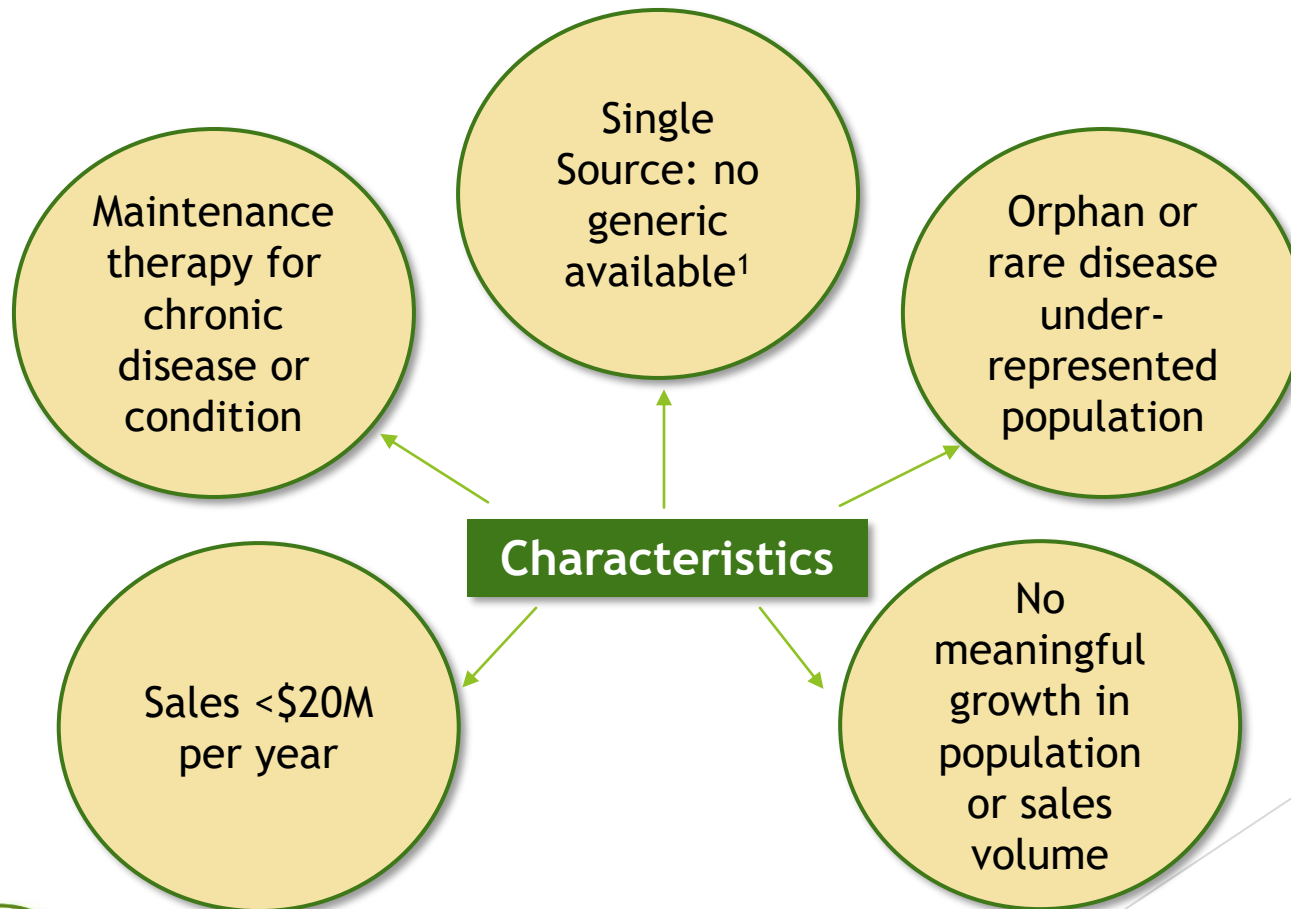
## Donate to Tutela

- Maintains affordable patient access
- Avoids significant price increase to patient and insurance company
- Same process as divestiture for product transfer
- Positive reputation and image for innovator and pharmaceutical industry
- May provide tax deduction of up to FMV of product

# Identifying Target Products



# Characteristics of a US Target Product in First Phase



# Maturation Model

## First Phase: Demonstration

Start with a single product  
Prioritize Rare/Orphan Diseases  
Secure more functional expertise  
Create and refine:

- Manufacturing
- Distribution
- Patient awareness & identification
- Reimbursement

## Second Phase: Product/Patient Expansion

Expand to multiple products  
Move beyond Rare diseases  
Build reliable, durable processes  
Broaden partnerships with for-profit Pharma  
Seek & secure philanthropic funding

## Third Phase: Geographical Expansion

Implement model in ex-US markets meeting defined criteria  
Continue to broaden Pharma partnerships & philanthropic funding sources  
Explore additional product delivery models to enhance program impact



# Example of Financial Consideration for Donor\*

(\$ millions)

## Option A: Retain Product A

	<u>2021</u>	<u>2022</u>	<u>2023</u>	<u>2024</u>	<u>2025</u>
Net Sales	9.8	9.6	9.4	9.2	9.0
Op Profit	2.5	2.4	2.4	2.3	2.3
PAT	1.7	1.7	1.6	1.6	1.6
NPV Range					
After Tax		\$6.3	to	\$9.2	
Pre Tax		\$9.0	to	\$13.2	

## Option B: Donate Product A to Tutela

	<u>2021</u>	<u>2022</u>	<u>2023</u>	<u>2024</u>	<u>2025</u>
Net Sales	-	-	-	-	-
Op Profit	-	-	-	-	-
PAT	-	-	-	-	-

## 2020 Theoretical Possible Value of Tax Break:

After Tax	\$1.9	to	\$2.8
Pre Tax	\$2.7	to	\$4.0

i.e., effective tax rate times NPV of Option A.

Timed divestiture at the beginning of the calendar (fiscal) year could buffer that year's Operating Profit loss via a Tax break for the donation



- Note that NPV is used as a proxy for more complex implementation of Tax Code Section 170(m) and may not be applicable to certain tax filers.

For complete details of the financial model: <..\..\Downloads\Tutela NPV v2.xlsx>

# Pricing Model

**Patients  
& Payers**



Continue to pay for prescription drugs

**Tutela**



- ▶ Establish price based on the cost of providing the drug (manufacturing, distribution, and infrastructure)
- ▶ Commit to provide the product for as affordable a cost as possible while reliably operating in a true not-for-profit model

**Philanthropic  
& Pharma**



Support may further offset patient costs