



# SOVALDI: THE COST OF A CURE [A]

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Examining the release of Gilead's hepatitis C drug, Sovaldi

# The Situation

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- December 6, 2013
- FDA approves Gilead's hepatitis C treatment Sovaldi
  - Successful trial in which >90% of patients cured
- Gilead announces total treatment cost of \$84,000, or \$1,000 per pill
- Immediate backlash
  - Media, NGOs, Congress, public



# Gilead Sciences, Inc.

1979: Michael Riordan contracts dengue fever in Asia

1987: Riordan founds Gilead Sciences, Inc.

1996: Gilead's first product goes to market

2000s: Gilead continues buying companies

1986: Riordan completes M.D. from Johns Hopkins and MBA from Harvard

1992: Gilead goes public, raising \$86M in IPO

1998: Gilead purchases NeXstar, immediately tripling its sales

2011: Gilead completes purchase of Pharmasset, Inc. for \$11B

# Pharmasset, Inc.

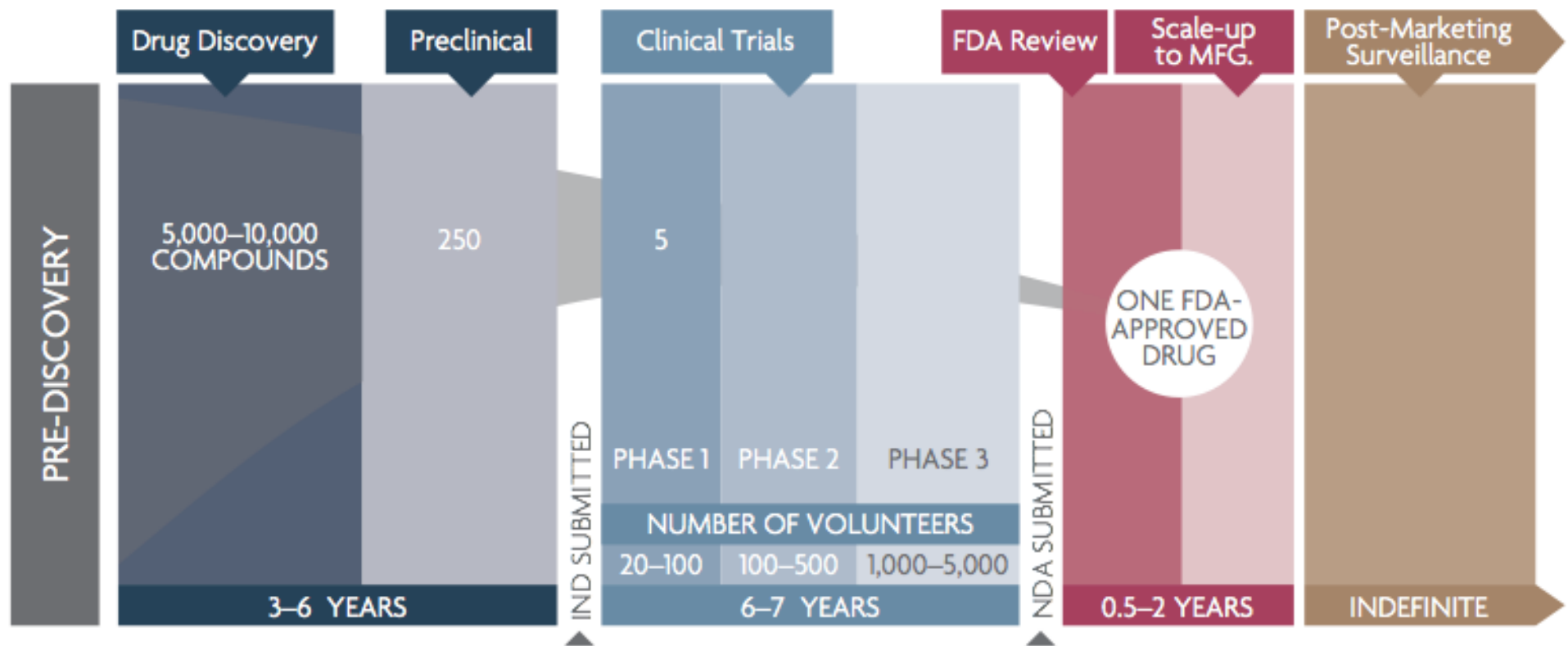
- Founded in 1998 by two professors at Emory University in Atlanta, GA
  - Dr. Raymond Schinazi – professor of pediatrics
  - Dr. Dennis Liotta – professor of chemistry
- Developed main anti-HIV drug used in majority of AIDS “cocktail” treatment programs
- Developed Sovaldi prior to being acquired by Gilead Sciences, Inc.



Pharmasset (VRUS) Stock Price, 10/5/09 - 12/20/11



# Drug Discovery Pipeline



# Drug Discovery

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- Original process: scan for molecules, hope for luck
  - Penicillin discovered by accident
  - Pfizer had a library of 20,000 soil samples
- New process: rational drug design
  - Identify molecular targets
  - Design new molecules through chemical engineering
  - Screening is still used



# Food and Drug Administration: Purpose

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- **Assure safety, efficacy, and security** of human and veterinary drugs, biological products, medical devices, food supply, cosmetics, radiation-emitting products
- Responsible for **advancing the public health** by helping to speed innovations that make medicines more effective, safer, and affordable
- Assist in **counterterrorism by ensuring the safety of the food supply**, and fostering the development of medical products to respond to public health threats

# Clinical Trials Process

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- Purpose: adherence to strict scientific standards
- Explore medical strategy, treatment or device safety and efficacy
  - Drug tested against placebo or current treatment
- Show which medical approaches work best for certain illnesses or groups of people



# Preclinical Testing

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- Animal testing
  - Determine pharmacokinetics - how the drug moves throughout the body
- Scientists look for ADMET
  - **A**bsorption into the blood stream
  - **D**istribution throughout the body
  - **M**etabolism, enzymatic changes undergone by the drug
  - **E**xcretion out of the body
  - **T**oxicity



# P1

- Safety
- Healthy population
- 20-100 test subjects
- ADMET in humans

# P2

- Safety
- Efficacy
- Affected population
- 100-500 test subjects
- Specific endpoint(s)

# P3

- Safety
- Larger affected population
- 300-5,000 test subjects
- Specific endpoints(s)
- Larger statistical significance

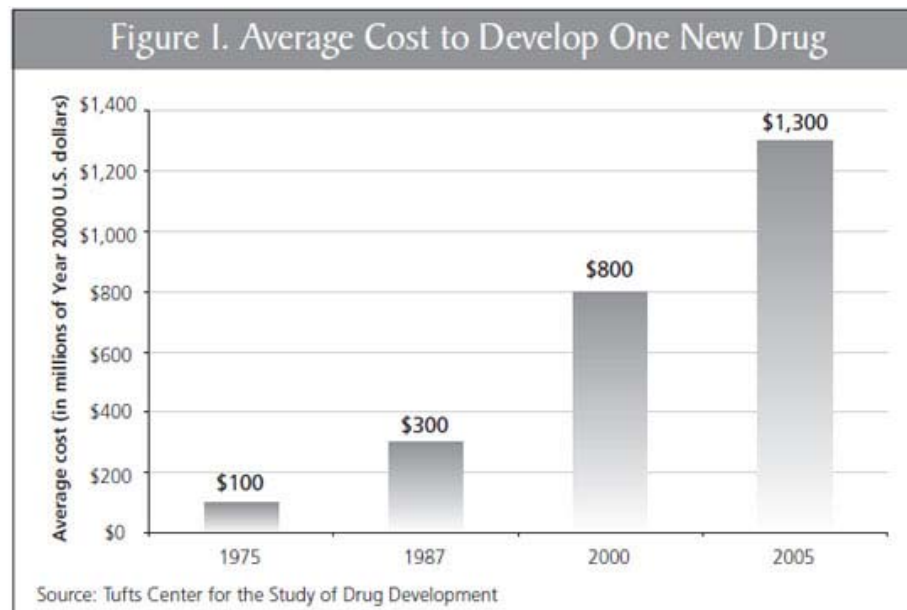
# Success Rates

|                          | <b>Modality</b>       |                       |
|--------------------------|-----------------------|-----------------------|
|                          | <b>Small Molecule</b> | <b>Large Molecule</b> |
| <b>PI to P2</b>          | <b>63%</b>            | <b>84%</b>            |
| <b>P2 to P3</b>          | <b>38%</b>            | <b>53%</b>            |
| <b>P3 to NDA/BLA</b>     | <b>61%</b>            | <b>74%</b>            |
| <b>Subm. to Approval</b> | <b>91%</b>            | <b>96%</b>            |
| <b>P1 to Approval</b>    | <b>13%</b>            | <b>32%</b>            |

*Source: Dimasi, et al. Clinical Pharmacology & Therapeutics  
87, 272-277 (March 2010)*

# Cost of development

- Preclinical trials typically cost \$30-50 million
- Estimated \$30,000 - \$75,000 per patient in clinical trials
- Cost of NDA



## Industry Costs

- Survey of 12 major pharma companies from 1997 - 2011
- R&D expenditure of \$802 billion
  - 139 approved drugs
  - \$5.8 billion per drug!

## Financing

- Little to no debt
- Very high cost of capital
- Must raise enough money from equity investors to conduct trials while not earning

# Key Takeaways

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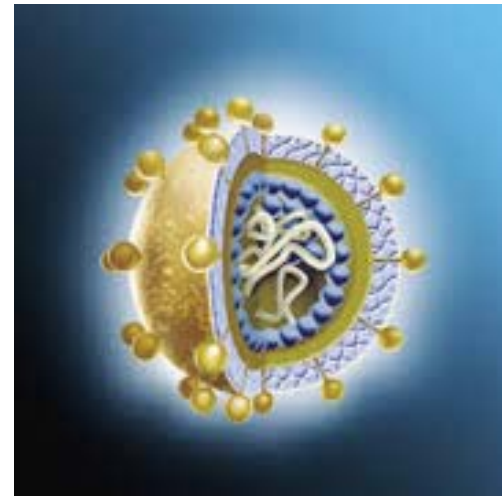
- Approximately 1 in 7,500 from candidate to market
  - 10-15 year process
- Patent protection lasts 20 years
  - Begins from discovery
- Typical cost \$500 million - \$2 billion for a successful drug
- High cost of capital requires potential for high returns



# Hepatitis C

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- Name of a family of viral diseases that cause inflammation of the liver
  - Three types: A, B, and C
  - A and B are preventable with vaccines, C is not
- Hepatitis transmitted through the blood
  - Symptoms typically appear 6-7 weeks after exposure
  - Fever, fatigue, nausea, loss of appetite, jaundice
- Many affected do not show symptoms
  - May experience liver damage over many years
  - Cirrhosis, cancer, death



# Hepatitis C: History

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- Discovered in 1989
  - Previously referred to as "non-A, non-B hepatitis"
- Reliable blood test not developed until 1992
  - Many people who received blood transfusions, organ transplants, or other blood products before 1992 potentially carry the hepatitis C virus
  - Large population in the US, Europe over age 40 carrying the virus
  - Incidence rate has since decreased dramatically
  - Most patients are unaware of infection for many years
    - Cirrhosis can take 30-40 years to develop



# Hepatitis C: Prevalence & Incidence

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- Prevalence

- Estimated 3-4 million in the US, 5-10 million in Europe, 12 million in India
- Egypt 7 - 8 million (10% of population)
  - Approximately 20% of blood donors carry HCV
- Worldwide 100-200 million

- Incidence

- US and Western Europe estimated 150,000-200,000 new cases per year
- Egypt estimated 500,000 new cases per year
- 25% of carriers become symptomatic
  - HCV (Hepatitis C Virus) more likely to become symptomatic with age
  - 60-80% progress to chronic liver disease
    - 20% develop cirrhosis
    - 5-7% death rate due to hepatitis C complications



# Hepatitis C: Cost Burden

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- Cost estimated at \$65,000 per patient
  - Cost increases with life expectancy, stage of liver disease
- Cost of liver transplant estimated at \$577,000
  - HCV is the leading cause of liver transplantation in the US
- HCV is the leading cause of chronic liver disease and cirrhosis worldwide
- Approximately 4% of HCV carriers will develop liver cancer



# Hepatitis C: Treatment history

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- 1991 FDA approves first interferon
  - SVR 9-50%
- 1998 FDA approves ribavirin + interferon
  - SVR 29-62%
- 2001 FDA approves ribavirin + Shering's Peg-intron
  - SVR 41-82%
- 2011 FDA approves incivek + interferon + ribavirin
  - SVR 80%
  - Taken 3x daily
  - 24-48 week course of treatment
- 2013 FDA approves **Sovaldi** + interferon + ribavirin
  - SVR 90%
  - Taken once daily
  - 12-24 week course of treatment

# The World of Expensive Drugs

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- Kalydeco (Vertex Pharmaceuticals)

- Treats cystic fibrosis
  - Affects approximately 70,000 worldwide
- Costs \$300,000 / year



- Soliris (Alexion Pharmaceuticals)

- Treats paroxysmal nocturnal hemoglobinuria
  - Affects approximately 4,000-6000 in the US, worldwide prevalence unknown
- Costs \$500,000 / year

- Many Others

# Reaction to Sovaldi Pricing

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- Nearly universally negative from many different channels
  - Healthcare companies
  - Insurance companies
  - Advisory groups
  - International NGOs
  - United States Legislators
  - Market and investors flat



# Reaction: Managed Care & Benefits

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- Molina Healthcare

- Operates Medicaid managed care programs for 11 states

*“We cannot absorb this kind of hit ... It would cause us and other health plans to potentially become insolvent”*

*- CEO Molina Healthcare*

- Express Scripts

- Largest prescription drug benefit manager in United States
- Advised doctors to avoid prescribing Sovaldi unless patient unable to wait

# Reaction: States

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- Colorado and Pennsylvania
  - Limit use of Sovaldi to sickest of patients

- California

- Medical experts classify Sovaldi as a “low value” treatment
- Estimates show that Sovaldi will raise drug costs in California by billions of dollars



# Reaction: International Groups

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- Doctors Without Borders and partners
  - Strongly and publicly advocate for fair pricing internationally
  - Encourage Gilead to price drug at or near price of production for low and middle income nations
  - Primary concern is ensuring the widest possible distribution of the drug, particularly getting access to high prevalence areas such as the Middle East





# Reaction: United States Congress

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- Three members of Congress draft a letter to Gilead CEO
  - Members of the House Committee on Energy and Commerce
  - Express strong concerns over Sovaldi pricing

*“Our concern is that a treatment will not cure patients if they cannot afford it”  
- Committee on Energy and Commerce*

- Demand answers from Gilead
  - Sovaldi pricing determination
  - Availability for low income individuals
  - How Gilead considered the FDA fast-tracking its drug when setting price
  - Public health impact of insurers refusing to cover Sovaldi for some patients



# Reaction: Stock Market

- Investors did not respond strongly to the pricing news or the negative press



# Gilead's Response

- No intention or mention of price changes in the United States

*“We were surprised by the disproportionate response and focus on Sovaldi, particularly given that its approval was widely anticipated within the payer community, and that we priced the medicine to be in line with the previous standard of care regimen for hepatitis C. Our conversations with payers in the U.S. indicate that the overwhelming volume (patient demand) and subsequent budget impact is driving much of the reaction.”*

*- Amy Flood, VP, Public Affairs, Gilead*

- Willingness to price drug lower for international market
  - Deal specifically with Doctors Without Borders
    - \$900 per treatment
    - India, Myanmar, Kenya, Mozambique
  - Deal on a national level with Egypt



# Gilead's Earnings Report, Q1 2014

- After market, April 22, 2014
- Sovaldi Sales: **\$2.27B**
  - Stock up 4%



|         | Revenue | Product Sales | Diluted EPS | Net Income |
|---------|---------|---------------|-------------|------------|
| Q1 2013 | \$2.53B | \$2.39B       | \$0.43      | \$722.2M   |
| Q1 2014 | \$5B    | \$4.87B       | \$1.33      | \$3.23B    |

# Discussion Questions

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- Who are the key stakeholders?
- Has Gilead priced Sovaldi fairly?
- Has the communication strategy thus far been sufficient?
- How should Gilead adjust and communicate its strategy both domestically and internationally moving forward?

# SOVALDI: THE COST OF A CURE [B]

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Examining the period after Gilead's hepatitis C drug, Sovaldi, earned record profits

# [B] Case: The Rest of the Story

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- Gilead announces deals with generic drug manufacturers
  - Will sell Sovaldi at deeply discounted prices to 91 developing nations
    - Estimates of \$1800 per 24 week treatments

*“Hepatitis C is a significant public health issue worldwide, and Gilead is working to make its chronic hepatitis C medicines accessible to as many patients, in as many places, as quickly as possible.”*

*- Gregg Alton, EVP, Corporate and Medical Affairs, Gilead*

# [B] Case: The Rest of the Story

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- Repeating a past pattern: HIV drugs
  - Gilead has made available HIV therapies at low cost in 125 developing nations
  - Similar licensing structure

*“It has always been our intention to follow a similar approach to access for our [hepatitis C] medicines as we have done with our HIV medicines in developing countries ... Specific to [hepatitis C], we have been in discussions with public health and developing world treatment experts since late stage development of Sovaldi regarding our intent to make the drug available as broadly as possible, as quickly as possible.”*

- Amy Flood, VP, Public Affairs, Gilead



# Not Far Enough?

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- Groups such as Doctors Without Borders call for more
  - Licensing deals do not allow for distribution of generics in middle income nations
    - Mexico, Thailand, Brazil, China
- Gilead states that middle income nations will receive different pricing deals



# Price Increase for the United States

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- Sept 12, 2014: Gilead announces that updated Sovaldi formula will be more expensive than previous version
  - Estimates from \$95,000 to \$100,000
    - 12 week treatment
- Reaction from payers very negative, as expected
- Gilead asserts that the price is based on market comparables



# Discussion Questions

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- Has the nature of the business problem affecting Gilead changed? If so, in what way(s), and what are the implications of this for the business?
- As Gilead increases the price of Sovaldi within the United States, how will the various stakeholders react? Does the increase in cure rate justify the additional cost?
- Has the company been successful in addressing the business problem identified in part (A) of this case? How should success be measured moving forward?



# THANK YOU

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Questions?