

Hepatitis C Elimination In New York State

Clifton Garmon, Senior Policy Analyst at VOCAL-NY

PRESENTATION OBJECTIVES

1. Walk through the foundation that was laid in New York State to reach today's victories
2. Understanding BIG PHARMA's role in NYS' Hep C history.
3. Understand recent developments that bring New York closer to establishing a hepatitis C elimination plan
4. Discuss next steps in this process and barriers to elimination and recommendations for overcoming barriers

THE FOUNDATION: The State of The Epidemic

- x Well over 250,000 New Yorkers are living with HCV, with 50% unaware of their status.
- x Nearly 15,000 new cases were reported in 2016, roughly 5X the number of newly reported HIV cases in the state.
- x For nearly a decade New York State has flat-funded HCV initiatives at just over \$1million a year.

THE FOUNDATION:

Progress Toward HCV Elimination

- **2014:** HCV Testing Law Implemented
- **2014-2015:** NYS Ending the HIV/AIDS Epidemic plan and process
- **2015-2016:** Established a statewide coalition, and raised HCV awareness across the state (via regional town halls) to bring attention to the state of the epidemic and the unique issues in each region of NY.
- **2016:** Removal of Drug Utilization Review Board disease prognosis and severity restrictions for HCV treatments for Medicaid fee-for-service (and similar changes in private insurance)
- **2016:** Expanded ADAP coverage to include HCV treatment for people living with HIV
- **2016:** Establish NYS DOH Office of Drug User Health
- **2016-2017:** Summit and Consensus Statement on HCV Elimination in NYS (signed by over 147 organizations, including county health departments), and establish the **HCV Elimination Campaign**.

BIG PHARMA: **Consequences of Pricy HCV Drugs**

Confusion, doubt, and fear from providers and patients about testing without available treatment.

Rationing of treatment

Conflict between provider, patient, and payer over rationing.

BIG PHARMA: Pricing vs. Principles

Cost - Relatively unchangeable without developing new methods or technologies.

Price - Decision made by corporate executives.

Lifesaving Hep C Medicine - Not difficult or even expensive to manufacture!

HEP C TREATMENT IS NOT COSTLY, IT'S PRICEY!

Sovaldi & Harvoni: Sofosbuvir-based regimens

BIG PHARMA Pricing vs. Principles

Costs of new drugs for hepatitis C per person, 12-week course
New generation drugs for HCV

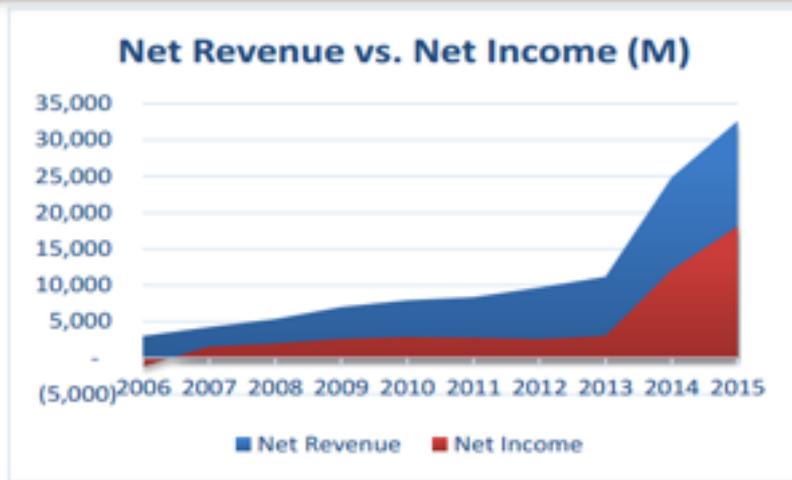


BIG PHARMA: A Monopoly On Misfortune

- Gilead's patent on Sofosbuvir expires in 2029.
- This means other corporations can only start production of **cheaper** generic versions 11 years from now.
- By that time an estimated 6 to 7.5 million more people will have died from hep C if left untreated.

BIG PHARMA: A Monopoly On Misfortune

- Between 2003 and 2013, Gilead grew faster in revenue than any other major prescription drug corporation.
- In 2003, Gilead made less than \$900 million in total revenue for that year.
- By 2013 Gilead grew more than 12 times in size, earning over \$11 billion.

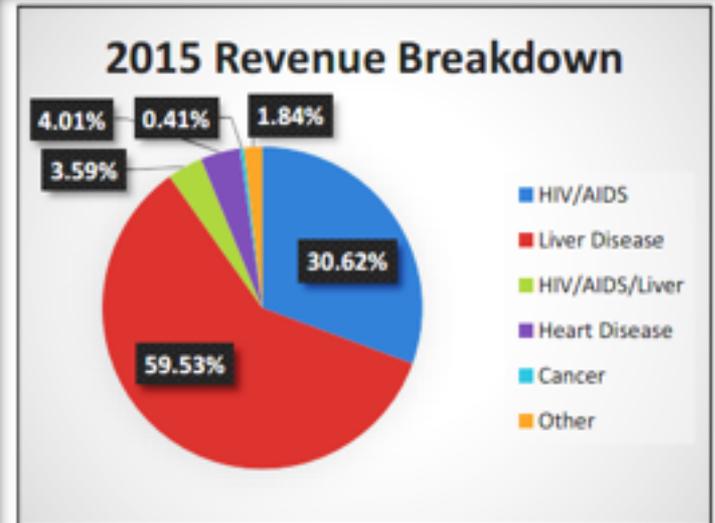


Source: GILD 2015 10K

- In 2014 Gilad more than doubled their revenue.
- This made Gilad's revenue nearly \$25 billion, growing 122% in a single year.

○ 75% of that growth was attributed to Sovaldi.

○ Hep C medication provides **the largest portion** of Gilad's profit!



Source: GILD 2015 10K

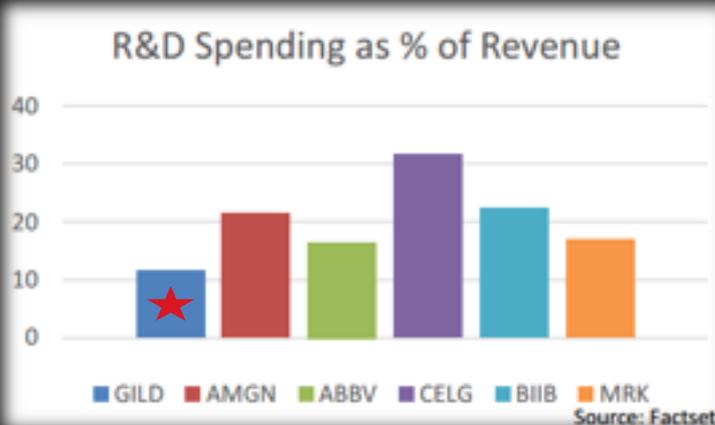
BIG PHARMA:

Disguised Prices as Research Costs

	Revenue	R&D	R&D/ Rev
GILD	24,890,000	2,854,000	11% ★
MRK	39,498,000	6,704,000	17%
AMGN	20,063,000	4,297,000	21%
ABBV	19,960,000	3,297,000	17%
CELG	7,670,400	2,430,666	32%
BIIB	8,507,935	1,893,422	22%

Data Source: Yahoo Finance (figures are in thousands)

- It's common for a firm to spend 15-30% of revenues on Research & Development.



	ROA	ROE	Profit Mar.
GILD	32.17%	103.61%	55.48% ★
MRK	5.14%	9.53%	11.25%
AMGN	7.73%	25.77%	32.03%
ABBV	-	155.76%	22.50%
CELG	11.53%	26.92%	17.31%
BIIB	18.54%	35.60%	32.95%

Data Source: Yahoo Finance

BIG Pharma: Disguised Prices as Research Costs

- Gilead's lower relative investment in R&D could be a signal of their expectations of growth in the coming years (Gilead then releases Epclusa).
- Epclusa was the first all-oral, pan-genotypic single tablet regimen for HCV, and Gilead's 3rd Sofosbuvir-Based Regimen.

Life And Health Should Not Be For Sale!

THE FOUNDATION: HCV Elimination Summit

- X Community orgs partnered with NYS/C Health Departments to consider and build consensus on statewide opportunity for HCV elimination.
- X 94 stakeholders came together in working groups to develop recommendations to inform a statewide HCV elimination plan.
- X Five working groups were established: 1) Prevention, 2) Testing & Linkage, 3) Care & Treatment Access, 4) Data, Surveillance & Metrics, 5) Social Determinants of Health.



THE FOUNDATION: Consensus Statement

1. Enhance HCV prevention, testing and linkage to care services for people who inject drugs, people who are incarcerated, men who have sex with men and other populations disproportionately impacted by HCV infection.
2. Expand HCV screening and testing to identify people living with HCV who are unaware of their status and link them to care.
3. Provide access to clinically appropriate and affordable HCV treatment without restrictions and ensure the availability of necessary supportive services for all New Yorkers living with HCV.
4. Enhance NYS HCV Surveillance, set and track HCV elimination targets and make information available to the public.
5. Commit NYS government and elected officials, public health professionals, HCV experts and industry partners to leadership and ownership of the NYS Plan to Eliminate HCV alongside community members living with and affected by HCV.

THE FOUNDATION: Our Call To Action

- X New York State faces a growing hepatitis C epidemic with a rising death toll. Given the availability of new highly effective, well-tolerated curative treatments, we can no longer settle for a low cure rate that perpetuates the high fiscal and human costs of inaction.
- X The committee that organized the NYS Hepatitis C Elimination Summit, along with the other providers, community based organizations and individuals living with and affected by hepatitis C that sign this consensus statement, **call on Governor Andrew Cuomo, the NYS Legislature, and industry partners to make a joint commitment to hepatitis C elimination, and for appointment of a formal NYS Hepatitis C Elimination Task Force.**



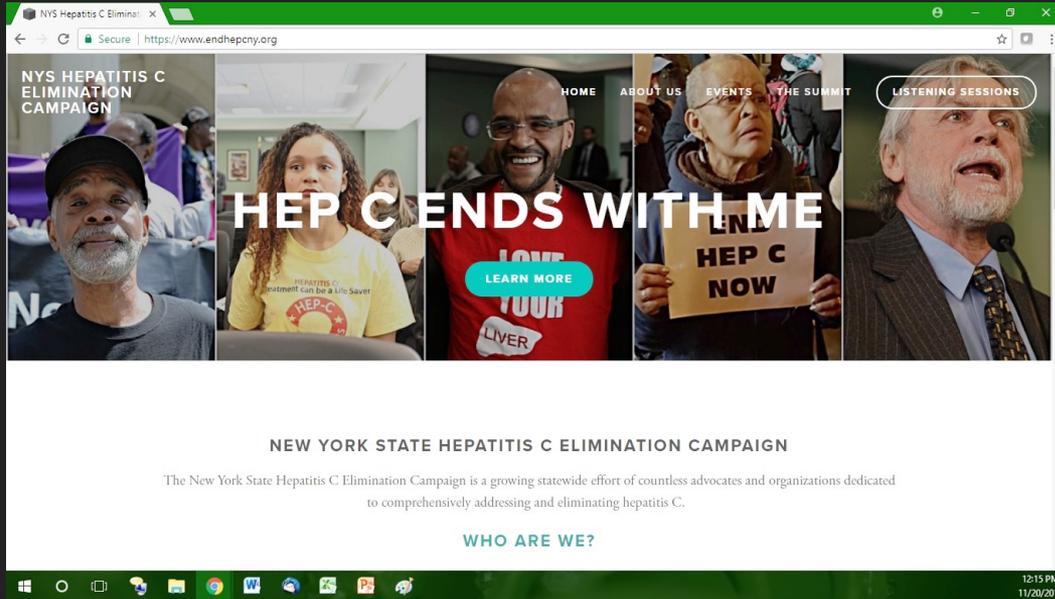
RECENT DEVELOPEMENTS

Following new curative treatments that show over 90% efficacy, a downward trend in prices, and a national/international consensus that HCV elimination is feasible....

- ✓ Two HCV treatment manufacturers (Merck & Gilead Sciences) are in the process of negotiating a multi-year deal, allowing NYS to scale up treatment
- ✓ March 16, 2018, Governor Cuomo made a public commitment to eliminating hepatitis C in NYS
- ✓ Final NYS FY 19 Budget includes \$5 million in new funding for hepatitis C (\$10 million over 2 years)

NEXT STEPS

1. We need hepatitis C treatment targets from NYS/C Health Departments to establish how many people we need to treat per year to achieve elimination.



The screenshot shows the homepage of the NYS Hepatitis C Elimination Campaign website. The browser address bar displays "https://www.endhepcny.org". The main navigation menu includes "HOME", "ABOUT US", "EVENTS", "THE SUMMIT", and "LISTENING SESSIONS". The hero section features a collage of five images: a man in a cap, a woman in a yellow shirt, a man in a red shirt with "LOVE YOUR LIVER" text, a man holding a sign that says "END HEP C NOW", and a man in a suit speaking. Overlaid on the collage is the text "HEP C ENDS WITH ME" and a "LEARN MORE" button. Below the images, the text reads "NEW YORK STATE HEPATITIS C ELIMINATION CAMPAIGN" and "The New York State Hepatitis C Elimination Campaign is a growing statewide effort of countless advocates and organizations dedicated to comprehensively addressing and eliminating hepatitis C." At the bottom, there is a link for "WHO ARE WE?".

2. We need a finalized volume-based deal with treatment manufacturers
3. We need the Governor to appoint a NYS Hepatitis C Elimination Task Force
4. We need continued support from the Executive and Legislature to take budget and legislative action to achieve the statewide elimination of HCV

NEXT STEPS: Regional HCV Listening Sessions

20 listening sessions were conducted as a way to raise awareness and collect data on the unique HCV-related issues different regions of NYS faces.

A Few Highlights

- A lack of syringe exchange programs- especially in rural counties
- A need for expansion of peer/outreach services
- A need for mobile units- especially in rural areas
- A need for education on the severity of HCV, and info on new, non-interferon based treatments
- Issues with stigma from healthcare providers and community members
- A lack of treatment providers- hard to get in and easy to get kicked out of treatment due to drug use and/or behavioral issues.
- Issues experiencing stigma at Expanded Syringe Access Programs (ESAP) pharmacies
- Having very few syringe disposal points
- Virtually no coalition building between agencies and networks doing local HCV work/services
- Very little community understanding of what harm reduction is
- Extremely limited transportation (getting to SEPs and screening/treatment appointments)

THANK YOU

Questions? Reach out to:

○ Clifton Garmon: clifton@vocal-ny.org