

# Hepatitis C Care, Treatment, & Advocacy

**Jules Levin**

Executive Director/Founder

National AIDS Treatment advocacy Project  
**(NATAP)**

**<http://www.natap.org>**

580 Broadway ste 1010

NY, NY 10012

Tel. 212 219-0106

800-26-natap

# Ryan White Care Act Reauthorization and Hepatitis C Virus (HCV) and HIV Coinfection

--ways in which the CARE Act could address the problems created by the Hepatitis C/HIV coinfection epidemic to improve the lives of people living with these co-morbid conditions--

Moderator:

Jules Levin

Executive Director/Founder

National AIDS Treatment Advocacy Project (NATAP)

New York, NY

# Today's Speakers

Debbie Vega

CEO and founder

Latino Organization for Liver Awareness (L.O.L.A.)

Bronx, NY

Heather Wilantewicz, RPA-C

Director of Clinical Services

The PATH Center, The Brooklyn Hospital HIV/Hepatitis Clinic (NY)

David L. Thomas, MD

Professor of Medicine

Johns Hopkins School of Medicine

Baltimore, MD

# Modes of Hepatitis Transmission

- The modes of transmission:
  - Injection drug use for HCV,
  - sex & IDU for HBV,
  - sexual transmission of HCV
  - snorting drugs
  - mother-to-child transmission in HCV & HBV. In HCV, HIV increases rate of transmission 3-fold. In HBV, MTCT is high.
- The Public Health Service Guidelines for Opportunistic Infections recognizes hepatitis C as an Opportunistic Infection

# Background

I've had HIV for 20 years

I had the chronic hepatitis C virus (HCV) for 20+ years, but I'm 'cured'

Completed 18 months therapy with the standard of care, pegylated interferon, administered by once a week subcutaneous injection, plus ribavirin pills taken twice a day

My HCV viral load (HCV RNA) was undetectable 6 weeks after starting therapy, at the end of therapy, 6 months after stopping therapy, and remains undetectable: equates to 'eradication' or 'cure'

HCV therapy is evaluated in this way: if your viral load is undetectable 6 months after stopping therapy. Studies show 98-99% of patients achieving this have eradicated the virus

# Hepatitis C & Coinfection Facts

- 5 million Americans have hepatitis C (antibody+), 4 million chronic hepatitis C (HCV RNA+)
- About 900,000 have HIV in USA
- 20% progress to serious complications in 10-30 years
- 1 million people have HIV
- 30-90% have HCV/HIV coinfection; up to 90% of HCV-infected by IDU have HCV; 5-8% HBV/HIV; some have HIV/HCV & HBV
- HIV accelerates HCV & HBV disease progression 2-5 times faster than HCV monoinfection: much more serious health problem; 5-10yrs
- ***Sulkowski reported at 2005 CROI (n=61): 28% of coinfecting patients progressed 2 stages of liver disease, 2 biopsies performed 2.8 yrs apart. 22% progressed from stage 0-1 to stage 3-6, 8% developed cirrhosis.***
- Hepatitis is leading cause of death in HIV
- Leading cause for hospitalization & only increasing cause for hospitalization in HIV

# Epidemiology

# HCV is treatable

- I've had HIV & had HCV for 23 years
- Finished HCV therapy 2 years ago: peginterferon + ribavirin for 18 months
- Consider myself cured of HCV
- Symptoms associated with HCV: fatigue, cognitive impairment
- Energy & mental faculties never better; improved cognitive function
- Studies in HCV-monoinfected find 56% SVR rates (40% G1, 75-90% G2/3). In coinfecting APRICOT Study found 40% SVR rate (29% G1, 60% G2-3).
- ***PRESCO Study in Coinfected patients: interim analysis found similar responses to monoinfected***
- *Peginterferon slows disease progression*
- *Up to 10 new HCV oral drugs in development*

# NATAP

It's important for you to know something about my work.

I founded NATAP (non-profit CBO based in NYC; recipient of RY grant in NYC to provide treatment education) on a shoestring in 1995 to educate patients about HIV treatment, to make good treatment decisions

About 6 years ago I realized that I probably had HCV, I tested & was HCV+

At that time most at risk HIV+ persons were not getting tested & clinicians & patients did not realize they were at risk for having HCV or perhaps HBV

I started education programs about treatment, prevention & epidemiology then in NYC & nationally:

NATAP website: [www.natap.org](http://www.natap.org)

Printed periodicals: **Hepatitis C & Coinfection Handbook** (over 150,000 & 5 versions printed), newsletters, journals, HCV newsletter, in multiple languages

# NATAP

Myself & NATAP have toured the country providing education in many cities (120 programs in 25+ cities in last 4 years, 15,000 attendees)

Worked with local DOHs AIDS Offices in various cities who were hepatitis friendly who cosponsored our events & often asked me to speak to local groups: Denver, LA, Broward County, NYC, Oakland, Houston, San Antonio, Florida State officials (Tom Liberti)

# **NATAP Hepatitis and HCV/HIV Coinfection National Training Institute (120 in 4 yrs)**

- **New York City**
- **Puerto Rico**
- **Florida: Ft Lauderdale,  
Miami, South Beach, West  
Palm Beach**
- **New Jersey**
- **Oakland**
- **Detroit**
- **Denver**
- **Texas: Houston, Dallas  
Austin**
- **Chicago**
- **Washington DC**
- **Philadelphia**
- **Atlanta**
- **Baltimore**
- **Minneapolis**
- **Phoenix**
- **LA**
- **Maine**

# **NATAP HIV & Hepatitis Forums in fall 2005**

## **Oct-Fall 2005**

New York City

Wash DC

Atlanta

Philadelphia

## **Earlier 2005**

Dallas

Houston

Miami (2)

San Juan

Chicago

Los Angeles

New York City

Jacksonville

# New NATAP Spanish Language HIV & Hepatitis Program

## Forums in 7 regions:

New York City (Oct)

Los Angeles (Dec 15)

Miami (March '06)

New Mexico

Arizona

Chicago

## 2006 English Forums

Miami

Chicago

Wash DC

New York

Atlanta

Oakland

San Juan

# NATIONAL HIV/HEPATITIS C Co- INFECTION COALITION

The coalition was founded two years ago

There are 100 members nationwide who recognize the problems:  
doctors, coinfecting patients, service providers, health  
professionals

1. In 2003, we held a Briefing in the House of Representatives co-sponsored by the CBC- Congressional Black Caucus
2. In Jan 2004, sent Consensus Letter to 600 members of Congress & selected Administration officials
3. In Feb 2004, placed 1-page summary of letter along with 100 member signatories in full page inside cover of ROLL CALL
4. In April 2004, 7 coalition members from all over the country flew into Wash DC several times for several meetings in the Senate & House with Representatives & Staffers

# NATIONAL HIV/HEPATITIS C Co- INFECTION COALITION

Result of these meetings is that we all agreed that the Coalition would submit to Staffers language on Hepatitis for the Ryan White Care Act reauthorized Bill.

This Fall we submitted that language & here we are today thanks to Sen. Kennedy's Office and others

We now have a unique opportunity to help the patients suffering with coinfection, help they need and deserve. Help that only the Care Act is uniquely qualified to provide to the most affected communities.



**Macronodular Cirrhosis**

# **New York State Coalition**

## **Hepatitis C Network**

- 1. 500 members**
- 2. Held open/public community meeting with NYS Hep C Coordinator at AIDS Institute in NYC attended by 150 people**
- 3. Met with Colleen Flannigan, NYS Hepatitis C Coordinator and AIDS Institute official**
- 4. Preparing follow-up with State officials now**
- 5. Goal - funding for programs & integration**
  - Testing & counseling**
  - prevention/transmission education**
  - Treatment education**
  - access to care & treatment**
  - referrals system**
  - education for clinicians & service providers**

# Why is HCV/HBV Coinfection a Problem

- HCV & HBV are more virulent in HIV+ individuals and the numbers of infected people are of epidemic proportions (300,000+)
- HIV accelerates HCV at least 2 times faster than in HCV mono-infection
- *Hepatitis appears to be the number 1 cause of death in HIV today: end-stage liver disease and cirrhosis are the causes of death; many patients with normal/healthy CD4 counts & HIV viral load under control are dying*
- The economic cost of burden of end-stage liver disease is enormous; it is much less expensive to provide care before progression
- Many infected persons contracted HCV in 1970's & large numbers of individuals are expected to develop cirrhosis & end-stage liver disease soon
- HCV disproportionately affects African-Americans and Latinos, and in general underserved communities
- The very communities that the Ryan White Care Act was designed to help
- It is likely that the numbers of infected persons is higher among the populations served by Ryan White due to demographics of RWCA clients
- Hepatitis C and B are treatable but, barriers prevent HIV+ individuals

# Services Needed

## BARRIERS TO CARE MUST BE ADDRESSED TO SAVE LIVES

as we do in HIV; alcohol, mental health, adherence, understanding of benefits of treatment (treatment education), prevention/transmission.

Coinfected individuals have unique problems, they need:

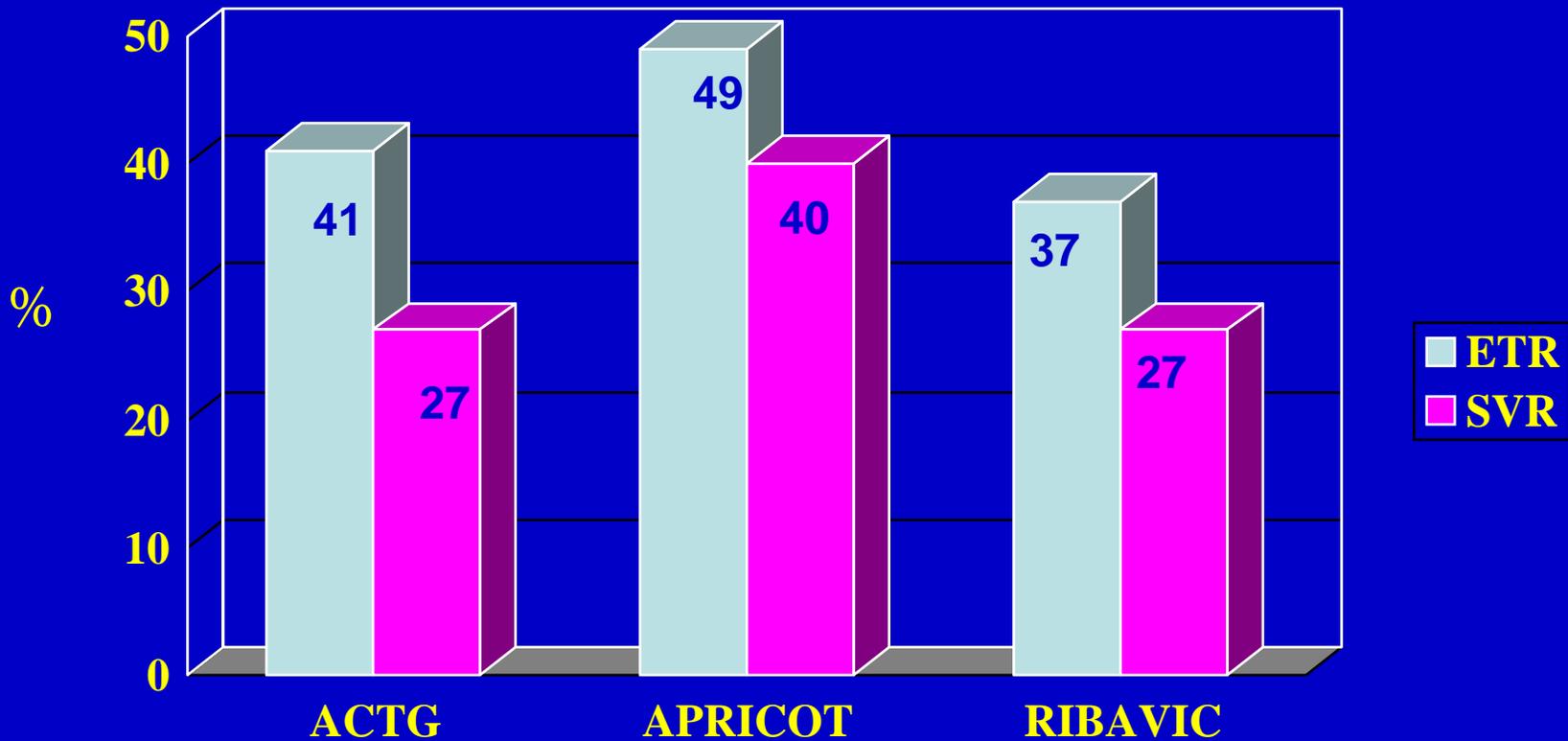
- Testing & counseling for HCV/HBV
- Referral for specialized HCV & HBV services: treatment education, prevention & transmission education, health care & access to treatment, specialized mental health services, ***special adherence & group support services***, specialized case management, *alcohol education*

The Care Act provides all these services for HIV but these specialized services needed for hepatitis are very few & far between

# What Can You Do?

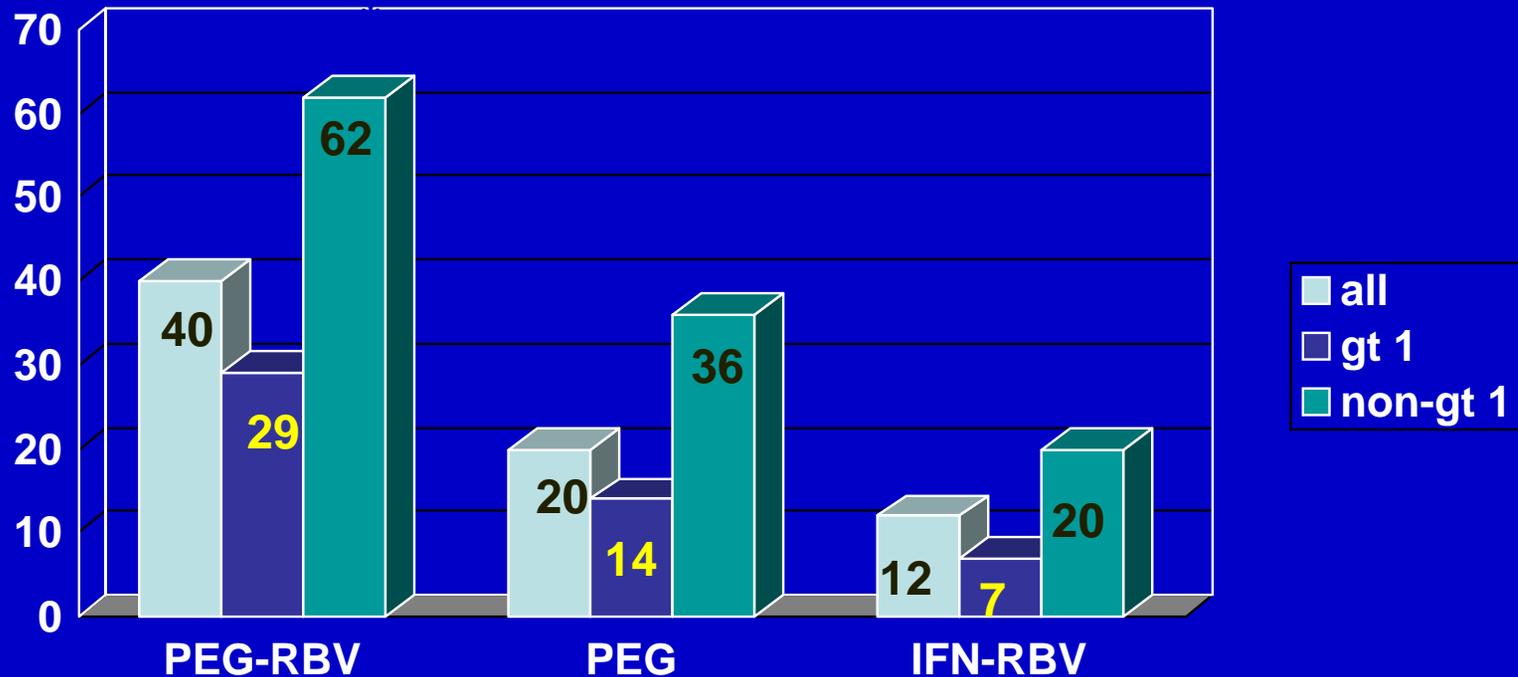
- If the language is inserted in the Care Act, Ryan White Counsels will be able to provide funding for programs in CBOs.
- We will find out next year when RWCA is re-authorized.
- You can integrate hepatitis programs into HIV programs in your CBO:
  - counseling & testing
  - accompany patients to doctor & diagnostic tests, follow-up
  - Psychiatric assessment & referrals
  - Treatment education: care, treatment, biopsy, diagnostic tests, retreatment, new drugs; stress followup through entire process from initial visit to doctor through all diagnostic tests, etc.
  - Literature, printed materials
  - Linkages for referrals with local clinics, coinfection care providers
  - Provide support groups (led by care provider & peers)
- Lobby & speak at Ryan White Counsel
- Lobby/advocate with City & State officials
- Form a Coinfection/hepatitis Coalition

# PEG-IFN virologic response rates across studies



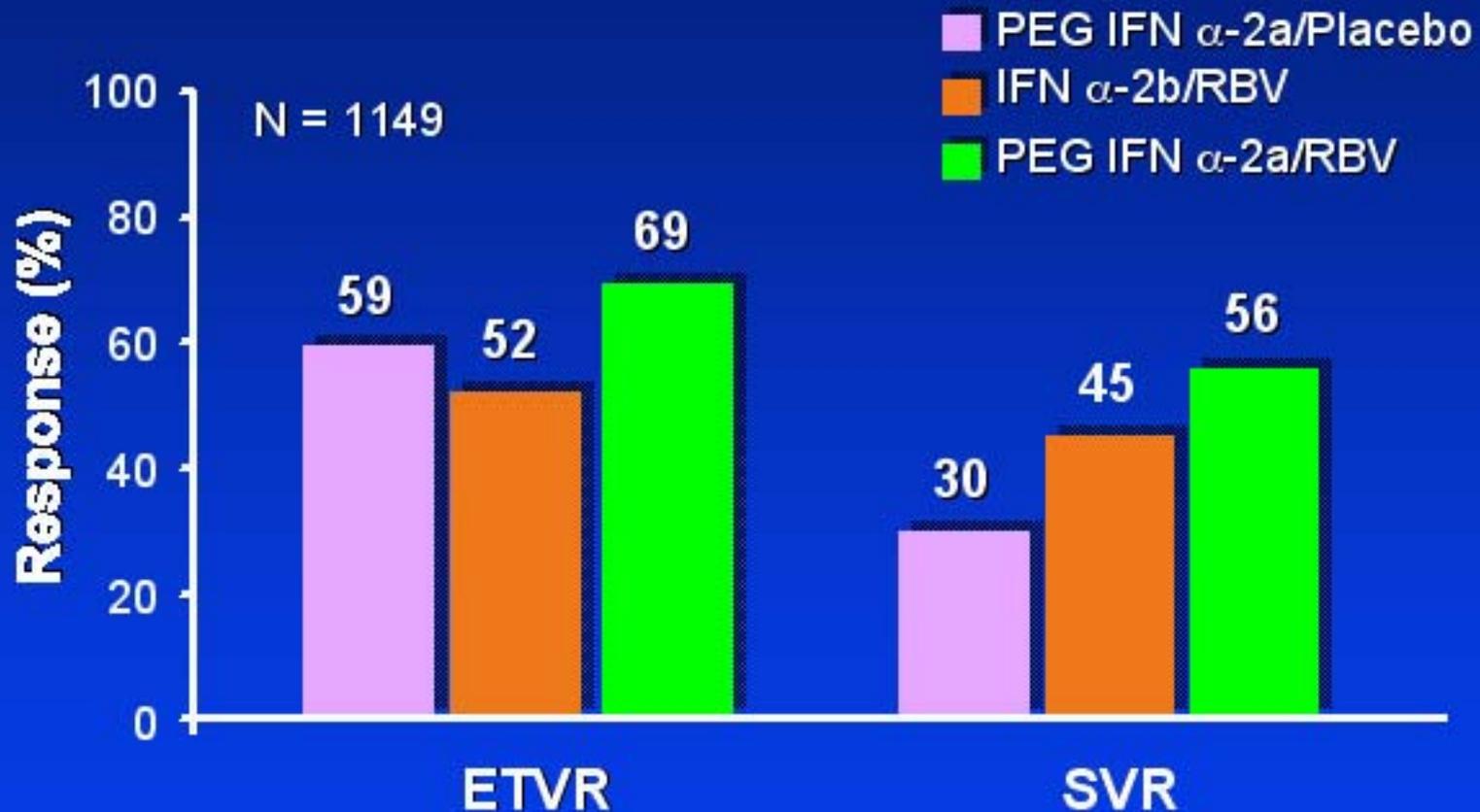
Abstracted from 11<sup>th</sup> CROI

# APRICOT: SVR rates



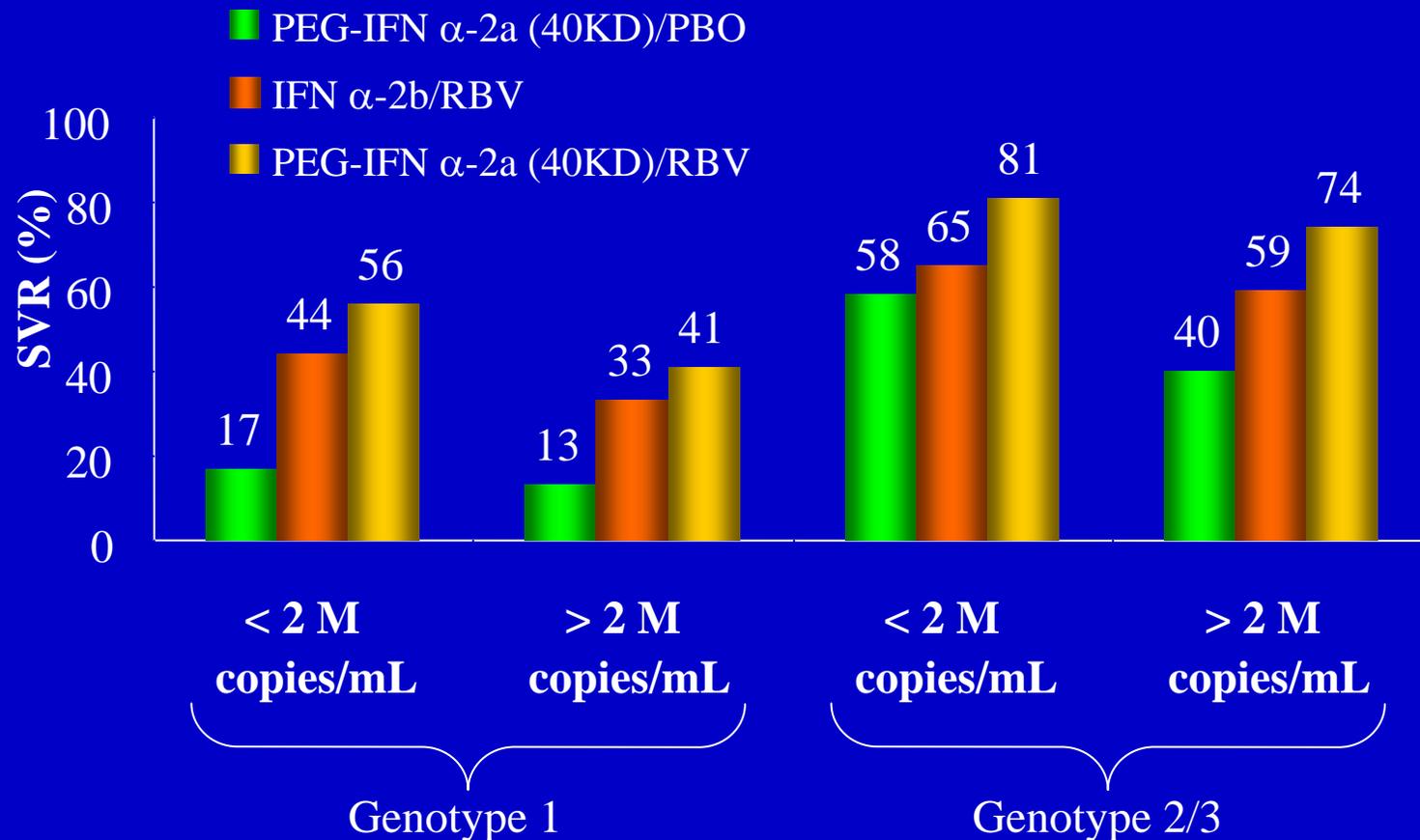
\*p<0.05 compared to IFN/RBV

# Peginterferon alfa-2a/Ribavirin Virologic Response



# PEG-IFN $\alpha$ -2a (40KD) + RBV Combination Therapy

## SVR by Genotype and Viral Load



Hoffmann-La Roche, data on file.

# ADHERENCE MATTERS

## Pegasys + Ribavirin Study at AASLD

- 45% genotype 1 had SVR
- 67% had SVR if > 80% adherent
- 40% had SVR if < 80% adherent
- 76% genotype 2 had SVR
- 86% had SVR if > 80% adherent

In Pegasys/RBV 1000/1200mg 48-week  
NV15942 study:

- 76% SVR with 80% adherence

# Services Needed

Service providers (case managers, prevention counselors, treatment educators, etc): Ryan White funds these positions in HIV

Most service providers have very limited knowledge about HCV & HBV. Therefore they are unable to prepare & teach clients (coinfected individuals) about the impact of HCV/HBV, educate about the disease & treatment, prevention. Furthermore, there is no system of referrals for services or specialized HCV/HBV care & treatment.

Obtaining biopsies is often inaccessible due to lack of reimbursement. Often clients don't understand why a biopsy is important

# Services Needed cont.

- **Ryan White funded community-based organizations (CBOs)** are often the front-line in dealing with patients. It's crucial to have these programs in place on the front line but it is equally crucial these service providers are educated to be competent in implementing programs, HIV testing & counseling sites can easily integrate hepatitis & provide prevention/transmission education & referrals
- For HIV we have a unique infrastructure that provides these services for HIV making it a perfect infrastructure into which we can integrate hepatitis patient services
- **HIV Health Care Providers EDUCATION PROGRAM:** clinicians, PAs, NPs, doctors desperately need a program of education to learn how to treat patients: many providers are unwilling to treat HCV because they are not trained & many poorly understand treatment

# Services Needed cont.

In NYC & all over the country I provide hepatitis education. In the past 4 years I personally have delivered 120 forums & workshops to 15,000 thousand individuals. Between all my programs NATAP reaches over 150,000 people each year.

- Knowledge about HCV/HBV is very low among service providers & patients & HIV care providers
- Coinfected patients are desperately suffering sometimes knowingly & at times unwittingly with the burden of hepatitis
- They don't understand the impact of the disease on them
- Their service providers are mostly unable to educate them about the disease & treatment & care
- The patients don't understand treatment: if they should be treated, when should they begin treatment, can treatment help them, or that HCV can be successfully treated (can be eradicated)

# What & Why

Among patients hepatitis is the biggest concern they have  
It's time for us, for Congress, for the Ryan White Care Act,  
to integrate needed hepatitis programs into our broad HIV  
infrastructure.

## **In summary:**

- 1. Testing & counseling**
- 2. System of referrals for services, Care & treatment**
- 3. Treatment education**
- 4. Prevention education**
- 5. Specialized case management & support services**
- 6. Training for clinicians, service providers & patients**