

# Fair Pricing Coalition Pricing, Access, Advocacy

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Lynda Dee & Murray Penner  
FAPP Meeting  
September 10, 2014



## FAIR PRICING COALITION

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- FPC History
- Programs and Initiatives
- Pre-ACA and ACA Pricing, Access and Advocacy
- HIV and HCV Pipeline and Pricing
- FPC members and contact information



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## Fair Pricing Coalition



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## FAIR PRICING COALITION

**Martin Delaney**

**Linda Grinberg**

**1999**



## HISTORY

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- Worked with ADAP Directors before creation of the ADAP Crisis Task Force (ACTF)
- First ever price freeze (2 years - 2002)
  - Resulted in \$50MIL savings for ADAPs
- Currently works in conjunction with ACTF
- Involved in HCV since 2010

## PROGRAMS & INITIATIVES

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- Negotiates with HIV & HCV drug companies for:
  - Initial pricing after FDA approval
  - Price freezes and annual increases
  - Medical CPI for price increases (3%)
  - Patient Assistance Programs (PAPs)
  - Co-Pay Programs for the privately insured
  - Co-Pay Programs for the publicly insured
  - PAP coverage for the underinsured???
  - Other access programs (HarborPath, PAN)

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## Pricing, Access and Advocacy

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## FPC DEMANDS & HIV PRICING

Company	Drug	Year	Price
Janssen	Prezista	2006	\$13,090
Merck	Isentress	2007	\$12,889
Janssen	Intelence	2008	\$10,411
Janssen	Edurant	2008-2011	\$17,078
Gilead	Stribild	2012	\$28,109
ViiV	Triumeq	2014	\$26,488

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## HIV PRICE INCREASES SINCE FDA APPROVAL

Company	Drug	Price Increase
Janssen	Prezista 2006	56% - 8.5%
Janssen	Intelence 2008	43% - 7.2%
Janssen	Edurant 2008	22% - 8.9%
Merck	Isentress 2007	39% - 6.3%
ViiV	Combivir 1997	118% - 8.1%
ViiV	Lexiva 2003	96% - 9.6%
ViiV	Epzicom 2004	78% - 9.1%
ViiV	Tivicay 2013	4.9% - 4.9%

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## HIV PRICE INCREASES SINCE FDA APPROVAL

Company	Drug	Price Increase
AbbVie	Norvir 1997	478% - 38%
AbbVie	Kaletra 2005	50% - 3.7%
BMS	Sustiva 1998	144% - 9.3%
BMS	Reyataz 2003	79% - 7.9%
BMS	Atripla 2006	78% - 9.8%
Gilead	Viread 2001	168% - 13.4%
Gilead	Emtriva 2003	107% - 10.2%
Gilead	Truvada 2004	97.2% - 10.2%
Gilead	Complera 2011	20.4% - 8.2%
Gilead	Stribild 2012	4.9% - 2.5%

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## RECENT PRICE INCREASES: BRISTOL-MYERS SQUIBB

Date of Increase	Drug	Price Increase
January 2013	Sustiva	9.7%
January 2013	Reyataz	7.9%
January 2014	Sustiva	9.7%
January 2014	Reyataz	7.9%
June 2014	Sustiva	7%

Sustiva price increases inflate Atripla prices.

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## GILEAD & ViiV PRICE INCREASES

- **Gilead**
  - Price increases taken between 2009-2012
    - Viread: 31.81%
    - Emtriva: 24.4%
    - Truvada: 24.5%
    - Atripla: 27.2%
- **ViiV**
  - Price increases taken in 2014:
    - Tivicay: 4.9%
    - Epzicom: 6.9%
    - Added \$1,500 to Triumeq price

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## **PAP ELIGIBILITY CRITERIA**

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- **Patient Assistance Programs:**  
[Fairpricingcoalition.org/projects/](http://Fairpricingcoalition.org/projects/)
  - 500% of Federal Poverty Level (FPL)
  - \$4,862.50 per month/\$58,350 per year
  - Janssen: 200% FPL with exception process
  - Part D co-pay assistance with varying criteria
  - HarborPath for ADAP waiting list patients

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## **CO-PAY PROGRAMS**

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- **Co-pay Assistance Programs:**  
[Fairpricingcoalition.org/projects/](http://Fairpricingcoalition.org/projects/)
  - \$200 (single drug) to \$400 (FDCs) per month
  - Merck: Isentress & ViiV: Tivicay - \$400
  - Janssen: 100% after first \$5.00
  - AbbVie (Norvir): \$50 only per prescription

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## **HARBORPATH**

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- **PAP concept with “one-stop shopping”**
- **Licensed in all 50 states**
  - **One portal**
  - **Clinics register with access for case managers**
- **All companies participate with HP, except Janssen**
- **HarborPath.org/ - 855-300-8916**

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## **COMMON PAP FORM**

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- **Standardizes the application form for PAPs:**
  - **Patient name & contact information**
  - **Healthcare coverage**
  - **Physician’s name and contact information**
  - **Alternate shipping information**
  - **Prescription information**
  - **Signature of patient and provider**
- **[www.bit.ly/CommonPAPForm](http://www.bit.ly/CommonPAPForm)**

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## HCV ACCESS PROGRAMS

Company	Patient Assistance Program	Co-payment Assistance Program
Merck	500% of FPL	20% of 12 Rxs - 44 weeks
Vertex	\$100,000 income maximum	\$10,000 maximum
Janssen	500% of FPL	\$25 per Rx - \$25,000 maximum for OOPs
Gilead	\$100,000 or 500% of FPL	20% of regimen cost - \$25 per Rx - \$16,800 maximum for OOPs (\$5 for 90%)

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## CURRENT 2014 HIV PRICES

Company	Drug	Price
Merck	Isentress	\$12,889
ViiV	Tivicay	\$14,105
Gilead	Stribild	\$28,109
ViiV	Triumeq	\$26,488

The price of Triumeq is less than the price of its component parts and less than the price of Stribild, Tivicay + Truvada and Tivicay + Epzicom.

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## HIV PIPELINE

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- **Single Drugs:**
  - **Gilead: Cobicistat, elvitegravir (two of the component parts of Stribild)**
  - **Merck: MK1439 (doravirine) - NNRTI**
  - **BMS: 663068 - attachment inhibitor**
  - **BMS: 955176 - maturation inhibitor**
  - **BMS: 936559 - anti-PDL1 for cure research**

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## HIV PIPELINE

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- **Single tablet regimens (STRs), AKA fixed dose combinations (FDCs):**
  - **ViiV and Janssen: Tivicay + Edurant**
  - **Gilead and BMS: Cobi + Reyataz**
  - **Gilead and Janssen: Cobi + Prezista**
  - **GSK and Janssen: Long-acting injectables GSK1265744 + TMC278 - AEs, adherence?**

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## 2014 HCV PRICES

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- Vertex Incivek \$66,152 21.8% 2011-13
- Merck Victrelis \$40,118 25% 2011-13
- Janssen Olysio \$66,360 0% Nov 2013
- Gilead Sovaldi \$1000/\$84,000
- Gilead 2 drug regimen - \$84,000 + ???
- AbbVie 4 or 5 regimen (3 or 4 pills) ± RBV???
- BMS 2 drug regimen + Sovaldi - \$84,000 + ???

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## 12 WEEK HCV PIPELINE

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- Gilead: Sovaldi (nuc) + ledipasvir (polymerase)??
- AbbVie: ABT450/r (PI - paritaprevir + Norvir) + ABT267 (ombitasvir) + ABT333 (NS5A - dasabuvir) ± RBV???
- BMS: Daclatasvir (Daklinza) + Sovaldi??
- 90-100% cure rate (SVR) - interferon free - no SAEs
- Cost-effectiveness, not if drugs are not accessible

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## 8-24 WEEK HCV PIPELINE

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- BMS: Asunaprevir (Sunvepra) + Daklinza (NS5A polymerase) + BMS791325 (NS5B) - 12 wks
- BMS: Asunaprevir (Sunvepra) + Daklinza - 24 wks
- Merck: MK5172 + RBV, (PI) 12 wks vs 24 wks
- Merck: MK5172 + MK8742 (NS5A) ± RBV 8 vs 12
- Sovaldi + ledipasvir 8 wks???
- [Treatmentactiongroup.org/pipeline-report/2014s](http://Treatmentactiongroup.org/pipeline-report/2014s)

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## ACA ACCESS ISSUES

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- Lack of capacity: ADAPs vs all states and payers
- ACA mandated OOP maximums - \$6,350/\$12,700 = underinsured. (FCP Ask: \$6350 for OOPs. Gilead has agreed to cover \$6000 for HIV OOPs.)
- Specialty Tiering: Tier 4 and 5
  - Cost sharing and preauthorization
  - Adherence issues and discrimination
- Co-pay programs in jeopardy - federal programs?

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## **ACA ADVOCACY**

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- **FPC: \$6350 vs Gilead's \$6000 vs PAN's \$4000???**
- **Patient Access Network Foundation (PAN) - ViiV**
- **Co-Pay program for Medicare/Medicaid patients**
  - **Avoids OIG inducement issues**
- **Underinsured program coverage for all patients:**
  - **Eligibility criteria: 500% of FPL**
  - **Provides up to \$4,000 for annual OOPs**
  - **Privately underinsured subject to funds**

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## **MEDICAID ACCESS ISSUES: HIV MEDICATIONS - SECT 1937**

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- **Pre-ACA: Drugs from all companies participating in Medicaid rebate programs are covered**
- **Fewer drugs available to ACA designated Medicaid expansion clients because of a switch in CMS policy on Essential Health Benefits (EHBs) - 2013**
- **States may now cover a minimum of one drug per class consistent with the state's "benchmark" plan**
- **Dramatically limits required number of drugs to be covered by state ACA Exchange plans**
- **At worst only, one drug per therapeutic class might be included on a state Exchange formulary**

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## **MEDICAID ACCESS ISSUES: HEPATITIS C MEDICATIONS**

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- **Medicaid Utilization Management Examples:**
  - Prescribed by Hepatologist, GI or ID specialists
  - No illicit drug and/or alcohol: 3, 6 or 12 months
  - Testing before or during treatment; counseling
  - Evidence of Stage 3 or 4 fibrosis

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## **PRICING/ACCESS ADVOCACY**

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- **Direct Actions:**
  - AIDS Healthcare Foundation (AHF)
  - Treatment Action Group, Vocal NY, Health GAP, 1199SEIU United Healthcare Workers East
- **Media and Web Actions:**
  - AHF, Campaign for Rx Affordability, FPC
- **Access Actions:**
  - CHLPI & PI; IDSA, HIVMA and AAHIVMA
  - FPC: Co-Pay Programs for Medicare/Medicaid and PAP coverage for the underinsured

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## LEGISLATIVE ADVOCACY

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- **Senate Investigation of Gilead**
- **Federal and State Legislation**
- **Federal: Patients' Access to Treatment Act of 2013 H.R. 460 - David B. McKinley (R-WV)**
  - **Limits specialty tiering and cost sharing**
  - **10% difference between same tier drugs**
  - **Avalere: \$3 annual premium increase**
  - **3% chance passing - ACA lobbying???**
- **State: CA, DE, HI, IL, LA, MD, NY, VA (≤ \$150)**

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## ACA ADVOCACY

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- **Discrimination lawsuits:**
  - **Federal vs state court actions**
  - **Federal: HHS vs DOJ actions**
  - **State Actions: State by state**
    - **CHLPI: Louisiana**
    - **AIDS Institute: Florida**
  - **County vs county differences: Ohio**
- **Medicaid expansion in ALL states**

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## **FAIR PRICING COALITION**

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### **Fair Pricing Coalition: HIV**

Bill Arnold  
Paul Arons  
Jeff Berry  
Lanny Cross  
Lynda Dee  
David Evans  
Tim Horn  
Murray Penner  
Britten Pund  
Daniel Teitz  
Andrea Weddle

### **Fair Pricing Coalition: Hepatitis C**

Bill Arnold  
Paul Arons  
Bruce Burkett  
Daniel Church  
Lanny Cross  
Lynda Dee  
David Evans  
Emalie Huriax  
Michael Ninburg  
Murray Penner  
Britten Pund  
Dennis Simon

[www.fairpricingcoalition.org](http://www.fairpricingcoalition.org)

