

Dr James Freeman

FixHepC

The use of generic DAA medications in Hep C

Conflicts of Interest

- I have received travel support from EEPI, Beker and Beacon, I have seen their factories, and I have broken bread with their founders,
- I have eaten food provided by Gilead, BMS, Abbvie and Merck,
- I have deliberately prescribed medication from all of the above companies (and others) and...
- I run <https://fixhepc.com> which assists patients wishing exercise their legal rights to make a personal medication importation of generic DAAs.

The invention of DAAs was a triumph that rivalled the invention of penicillin, but...

**...the fact they are not being
deployed at mass scale must
be one of the greatest
tragedies of modern times.**

**Until recently the
deployment problem
was price...**

Hep C CURE

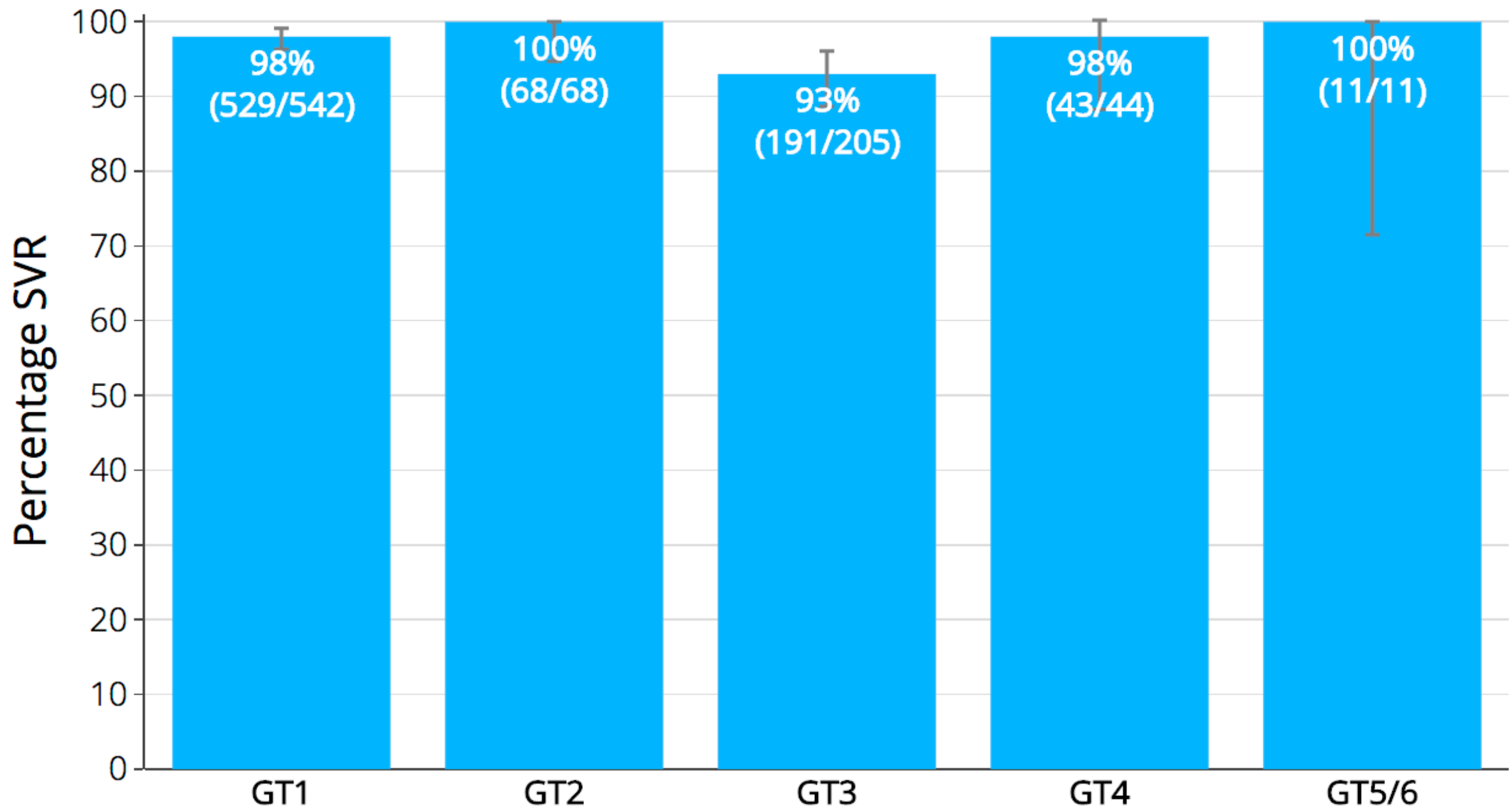
ENTRY FEE

~~\$84,000~~

Generic Hep C
Cure

~~\$1,500~~

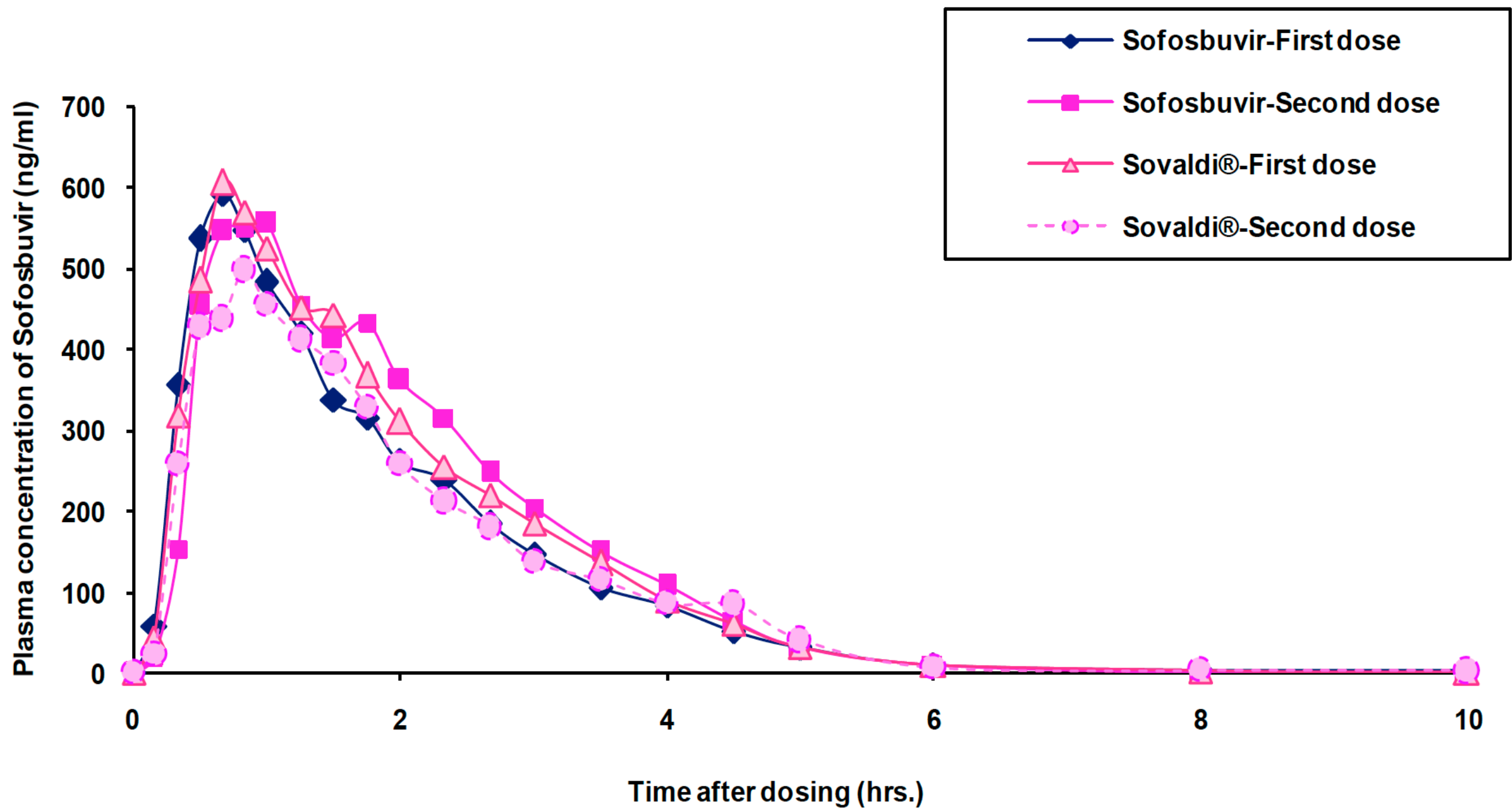
**Our generic DAA results
have been presented at
EASL, AASLD & CROI and
here is a new cohort of 870**



Presented At AASLD 2017...

Table 1: Geometric mean ratios (90% Confidence Intervals)

DRUG	TRIAL TYPE	COMPANY	NUMBER	C _{MAX}	AUC _{0-∞}
Sofosbuvir	Four-way, four-period, fully replicated, single oral dose	EEPI	36	101.0 (88.1-115.7)	103.0 (97.6-109.7)
Daclatasvir	Two-way, two-period, single oral dose	Dawood	35	106.9 (100.2-114.0)	103.7 (98.3-109.4)
Sofosbuvir	Three-period, two-treatment, three sequence, semi-replicate	Beker	35	95.4 (84.7-107.5)	98.5 (91.6-106.0)
Daclatasvir	Three-period, two-treatment, three sequence, semi-replicate	Beker	35	104.1 (93.1-116.3)	103.0 (94.4-112.4)
Sofosbuvir	Three-period, two treatment, three sequence, partial replicate	Hetero	54	95.7 (87.2-105.2)	100.8 (96.2-105.6)
Sofosbuvir	-	Natco	-	96.1 (81.0-114.0)	100.7 (94.2-107.8)
Daclatasvir	-	Natco	-	94.5 (83.1-107.4)	96.5 (87.1-106.8)
Sofosbuvir	Two-period, two-treatment, single dose	Virchow	22	94.8 (83.3 – 107.9)	95.8 (86.9 – 105.7)



Supertramp
CRISIS? WHAT CRISIS?

The World's Medication Crisis in
12 slides and 60 Seconds



5g of Diamonds

25 1-carat @ \$2000 each

Cost = \$50,000



5g of Daclatasvir

12 weeks @ 60mg/day

Cost = \$53,000 (UK price)



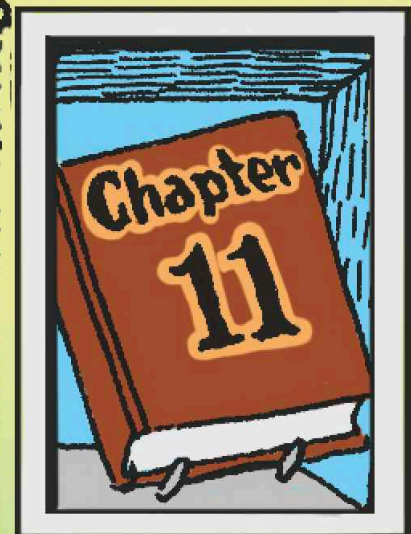
YOUR MONEY
OR
YOUR LIFE!



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MARTY
Two Bulls
m2bulls.com

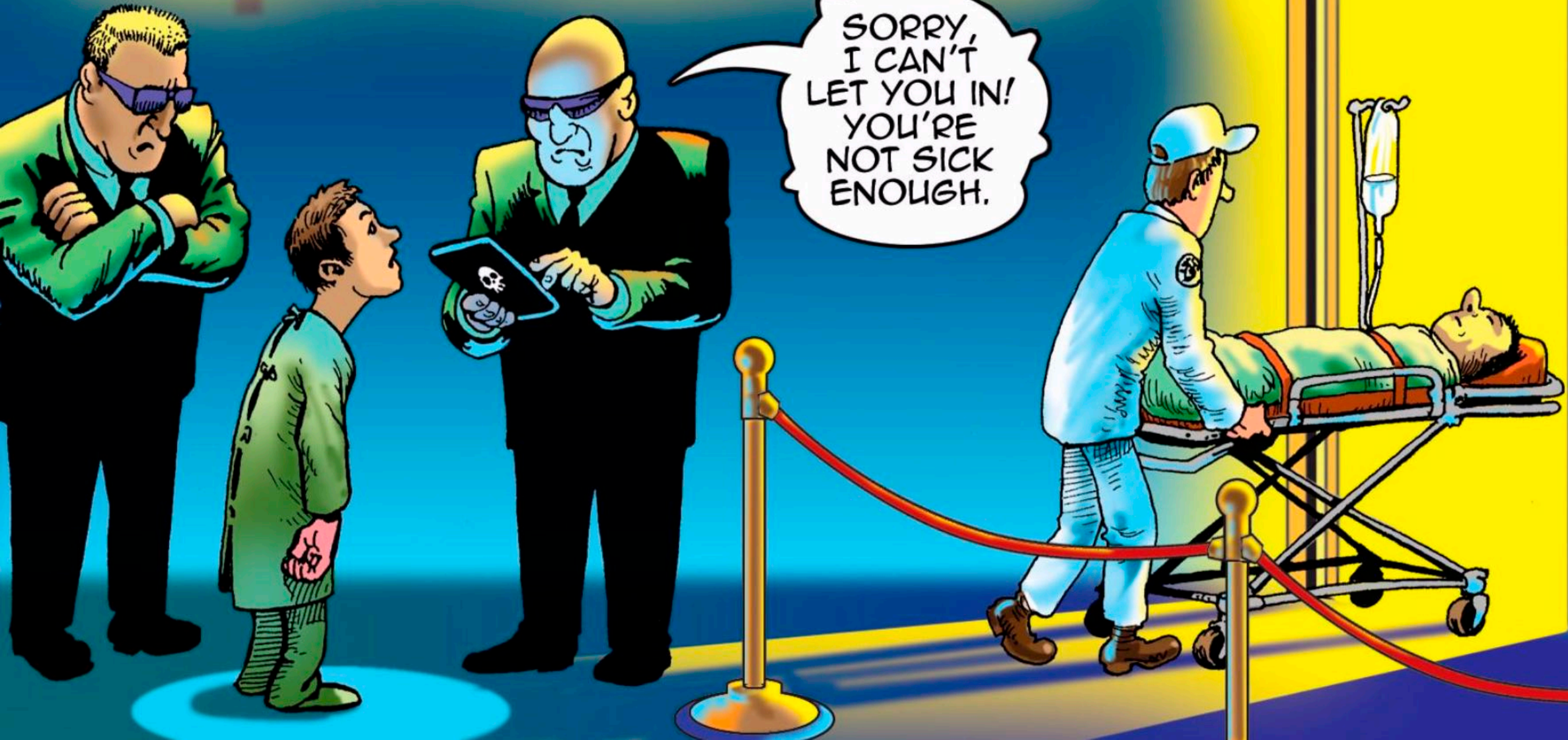
U Allstate HEALTH INSURANCE COM

THOUSANDS OF OUR PATIENTS
STILL NEED THE NEW HEP C
CURE BUT HOW CAN WE
CONTINUE TO PAY?



Hep C Cure Club

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SORRY,
I CAN'T
LET YOU IN!
YOU'RE
NOT SICK
ENOUGH.

APPLY

DENIED

APPEAL

CLASS ACTION

Hepatitis C

1 out of every 3 Inmates are infected



**Medication cost
\$54 to 94 thousand
dollars per cure,
insuring that
only the sickest inmates
may get treatment.**

**Injection opioid abuse
nearly triples hepatitis C
infections in 2015.**

Be safe get tested



**YOU HAVE
JUST BEEN**

TRUMPED

**Lower
Prescription
Drug Prices**

**Don't Lower
Prescription
Drug Prices**

FLIP



FLOP

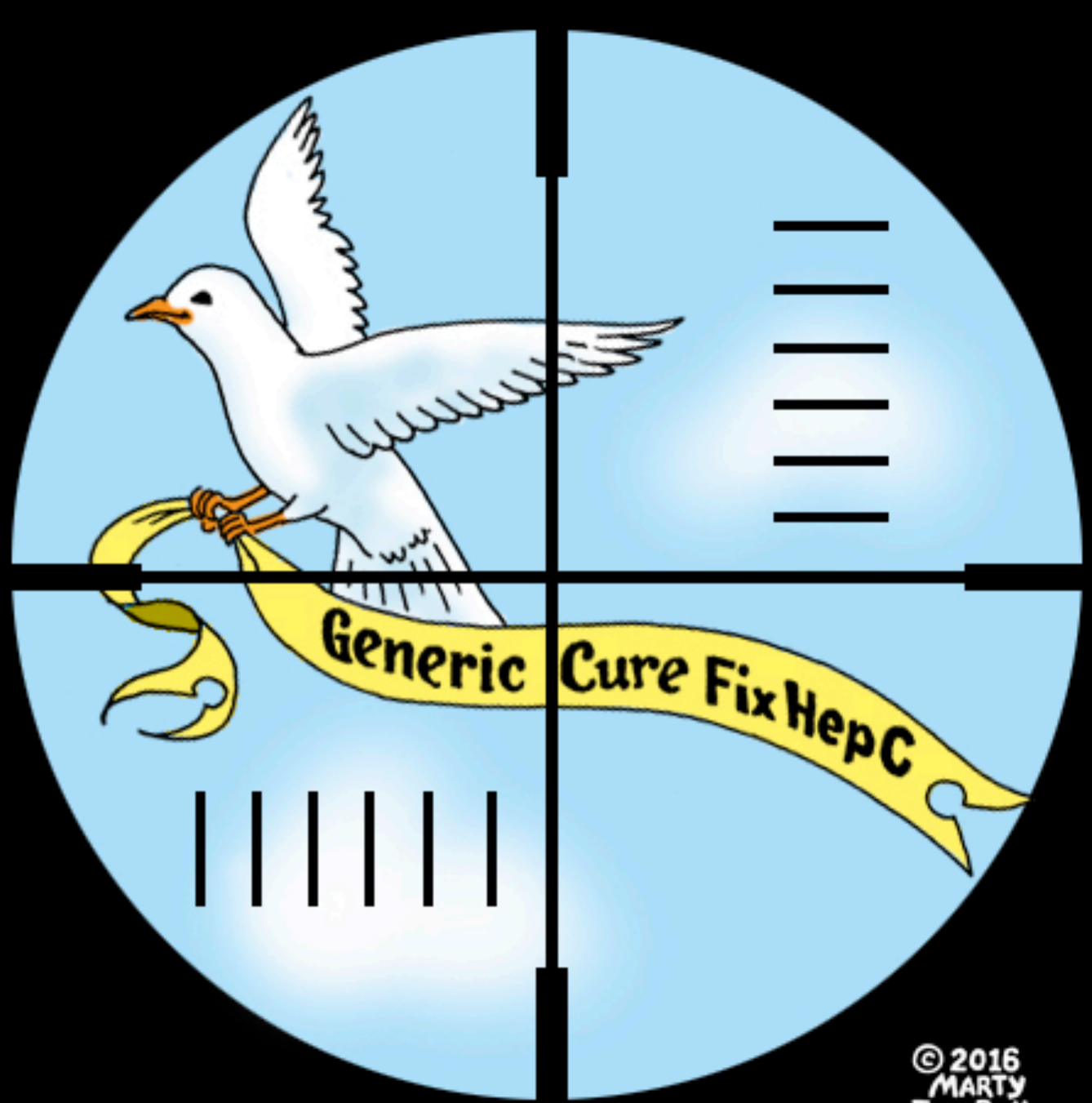
HepC Low Income Patient's Hospital



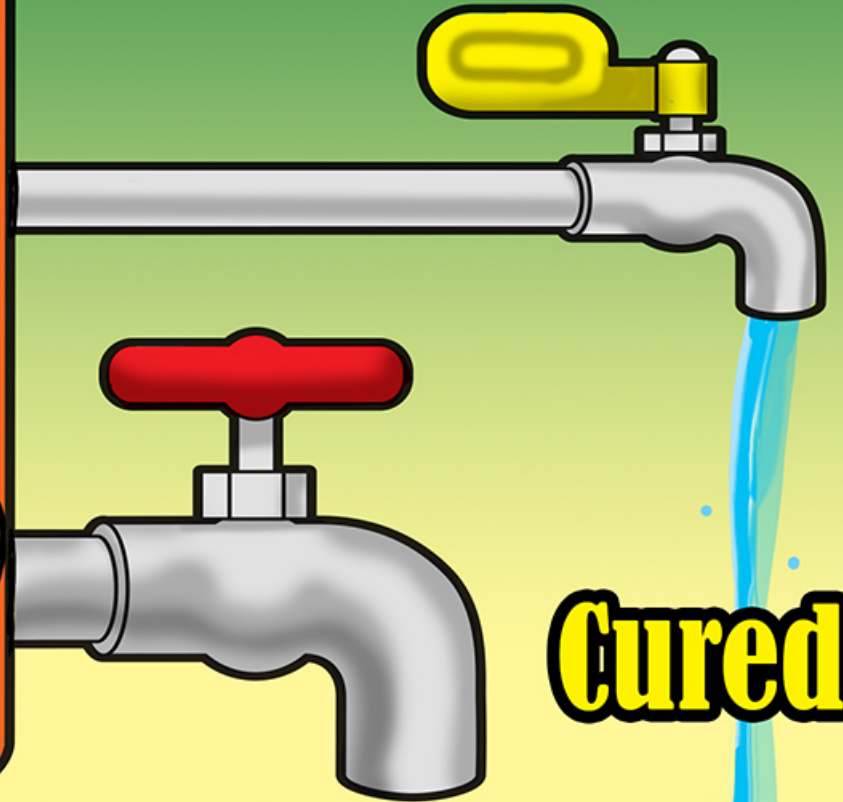
A DOG HAS TO MAKE A LIVING.

BEWARE OF ADVOCACY GROUP WATCH DOG

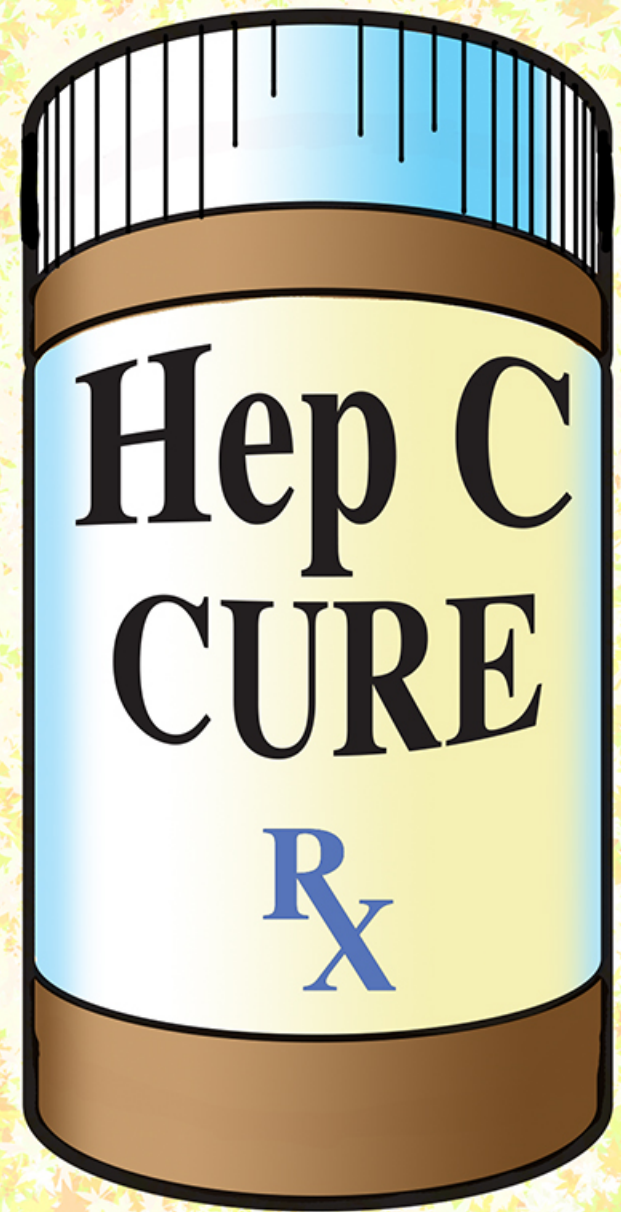
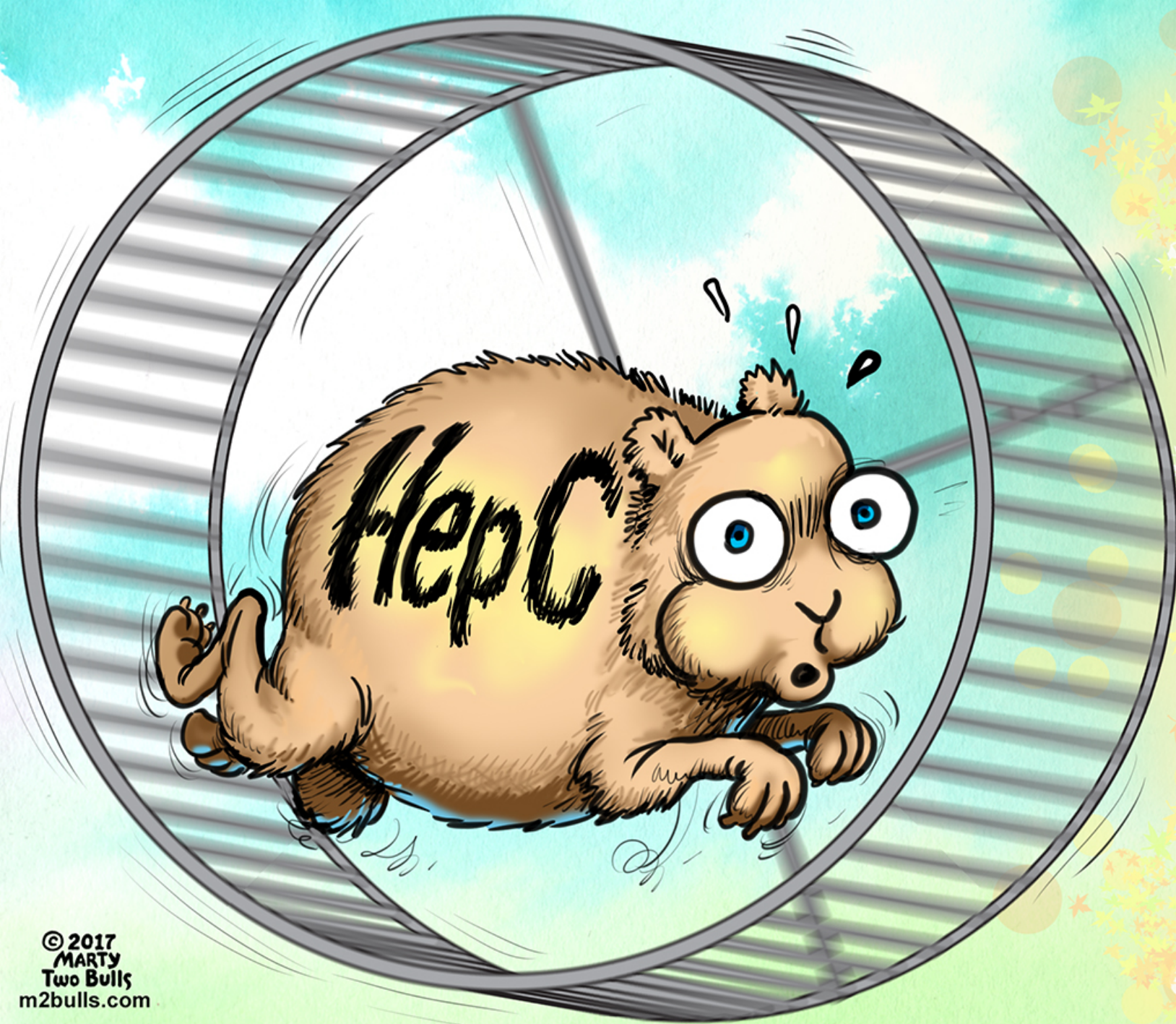
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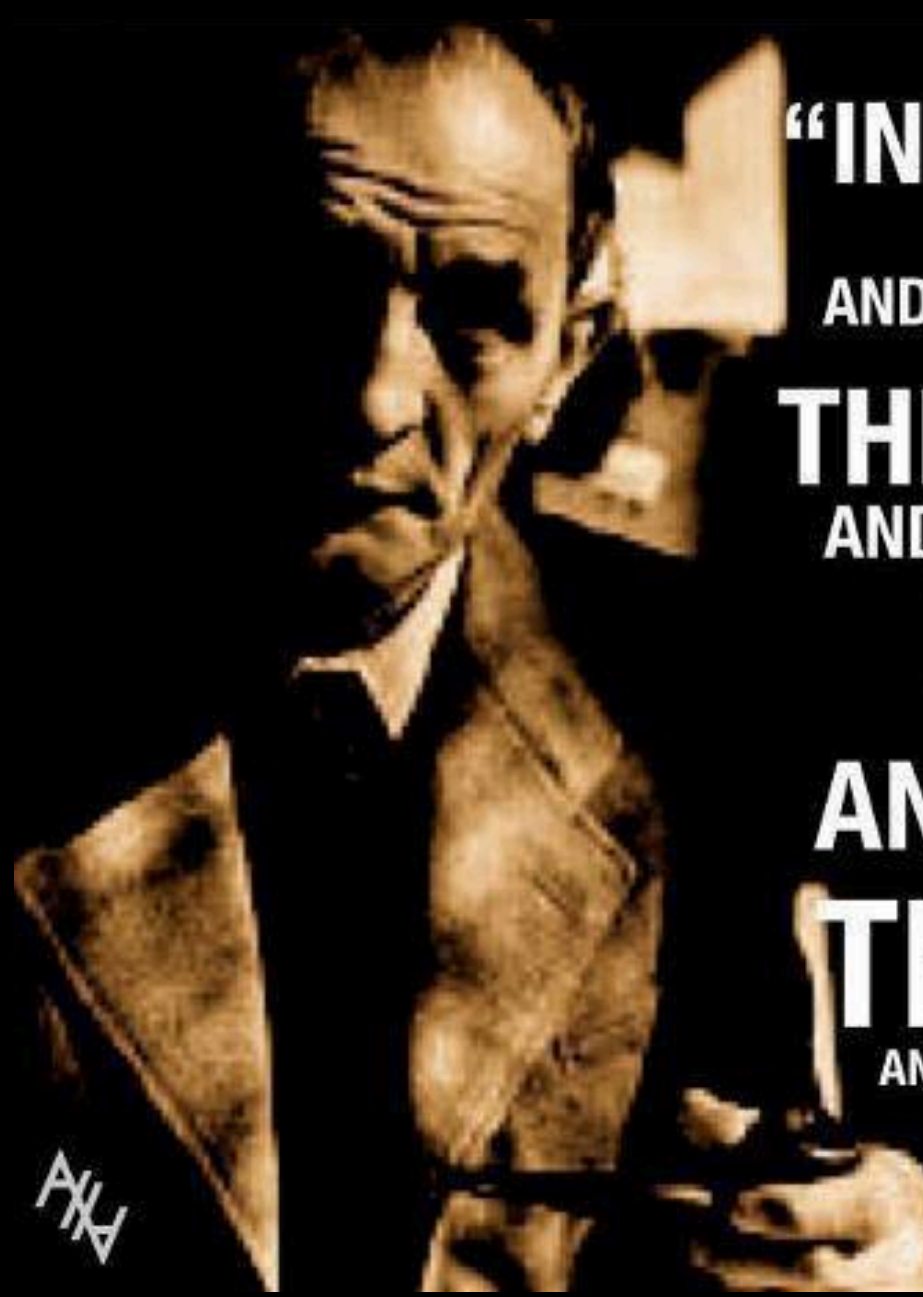


New Hep C Infections



Cured





“IN GERMANY

THEY CAME FIRST FOR THE COMMUNISTS,

AND I DIDN'T SPEAK UP

BECAUSE I WASN'T A COMMUNIST.

THEN THEY CAME FOR THE JEWS,

AND I DIDN'T SPEAK UP BECAUSE

I WASN'T A JEW.

...THEN THEY CAME FOR THE CATHOLICS,

AND I DIDN'T SPEAK UP

BECAUSE I WAS A PROTESTANT.

THEN THEY CAME FOR ME

AND BY THAT TIME NO ONE WAS LEFT

TO SPEAK UP.”

-REV. MARTIN NIEMOLLER

PH

The Law Is Not About Justice

- *“The law is not about justice, the law is about the law”*
 - So said the Professor of law at Sydney University in 1985
 - I know, I was there; I was shocked, I dropped out of law, and I became a doctor instead
- But years later hearing those words became useful when a patient of mine needed HCV treatment and I thought...
 - *“Ok, we need better laws, but what are the loopholes?”*
 - *“How can we go with the law, but still access treatment?”*

I Am A Practivist

- And Practivists love loopholes (so do corporate lawyers)
- Fortunately TRIPS provides some flexibilities
 - TRIPS Article 30 provisions a research exemption
 - TRIPS Article 31 provisions compulsory licensing
 - **TRIPS Article 60 - De Minimis Imports**

“Members may exclude from the application of the above provisions small quantities of goods of a non-commercial nature contained in travellers' personal luggage or sent in small consignments.”
- These loopholes can be successfully “re-purposed”

Personal Medication Importation

- In line with Article 60 most countries allow personal medication importation
 - **In many countries delivery of a 3 month supply of medication by post is entirely legal**
 - In some only importation by personal carriage is allowed
- Buyers Clubs around the world facilitate this...
 - Buyers Clubs help patients navigate an unfamiliar and potentially dangerous process

Amazon

- Amazon proves it could work at scale
 - If Amazon can make a business shipping low priced items like books...
- The fundamental barrier is that medications are more expensive than books and still out of reach for the majority of patients
- But what if we could...

Decouple The Funding

- Buyers clubs could operate at scale if funding was decoupled from the patient, but...
- Personal importation rapidly rebalances monopoly negotiations and...
- We can observe that for Australia, New Zealand, Italy and Switzerland active personal importation preceded deals with Gilead, Abbvie and Merck.
- **Coincidence or Market Forces?**

Swiss Practavists In Action

- Swissmedic changed their personal importation laws
- A quick regulation change, not a slow legislative change
 - From 1 month to 3 months for HCV medication import
- Swiss insurer Concordia started funding patients
 - Concordia decided that, while it could not directly fund generics, it could define generic HCV treatment as a reasonable medical expense and reimburse the cost...
- A group of practavists achieved that in under 1 year

Other Key Practavist Strategies

- Hep C has no funding because it has no voice
- Getting patients to speak to it is vital
- We need real inventiveness to get the message out because Big Pharma owns our media, doctors and politicians
- The stories “drug prices unaffordable” or “patient gets generics, gets cured” are becoming old news...
- But controversy fuels media fires so let's be Practavists and **FACT UP then ACT UP!**

**I have given you numbers
I have given you statistics
And they are all abstract**

Here is the reality...



Life's most persistent and urgent question is,
What are you doing for others?

Martin Luther King, Jr



Let's Not Forget Our Stateswomen

“Never doubt that a small group of thoughtful, committed citizens can change the world; indeed, it's the only thing that ever has”

- Margaret Mead



A single act of caring creates an endless ripple

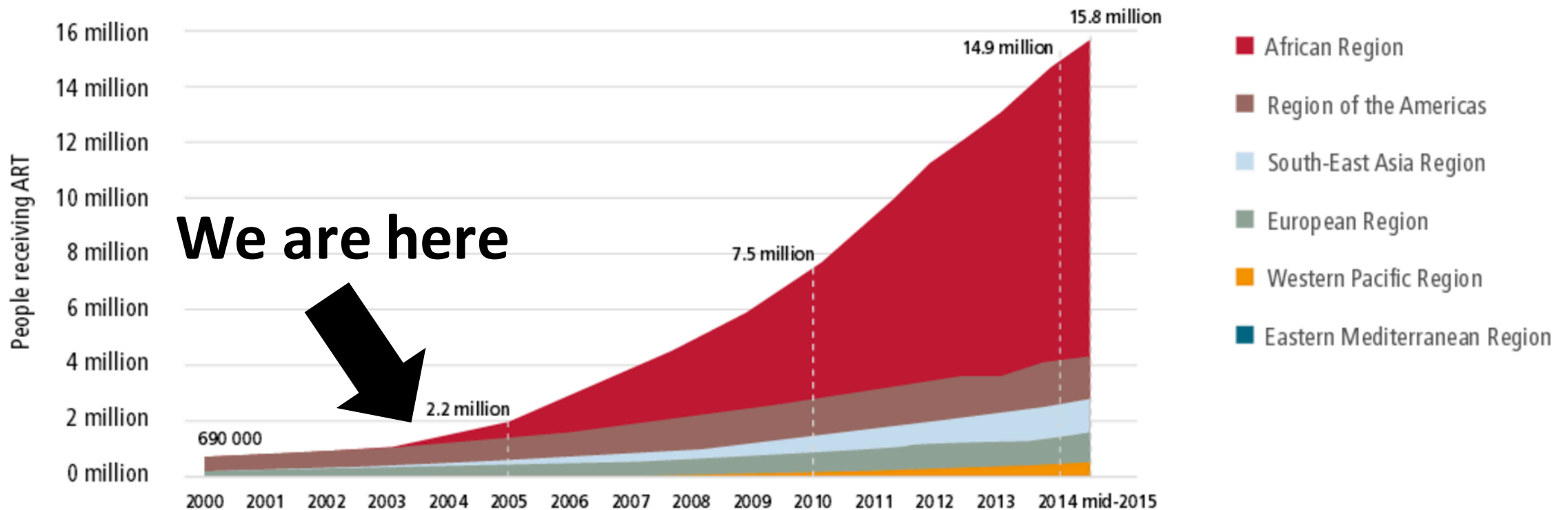
We Have Been Here Before With HIV

- In 2001 Yusef Hamied announced that Cipla would produce generic HIV medication for \$1/day (when it cost \$30/day)
- In 2004 the Lancet published an MSF study demonstrating that this generic HIV medication worked as expected
- Bioequivalence studies and WHO prequalification followed
- At the same time the South African government got serious
 - **Parallel imports of generic HIV medication forced the drug companies back to the negotiating table, with the direct result that the \$10,000/year cost fell out of the stratosphere and back into the real world**

This Graph Shows The Impact

Estimated numbers of people receiving antiretroviral therapy globally and by WHO Region and percentage coverage globally, 2000–2015

1 year, if we were here..



**We have got the clinical
We have got the bioequivalence
We have got the pricing...**

So my question is simple:

What are we waiting for?

We have the power to FixHepC

The real question is....

Do we have the will power?

More Information

<http://fixhepc.com/fixers>

[http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(16\)32051-7/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)32051-7/fulltext)

<http://onlinelibrary.wiley.com/doi/10.1111/liv.13157/full>