



Stopping the spiral of exorbitant prices

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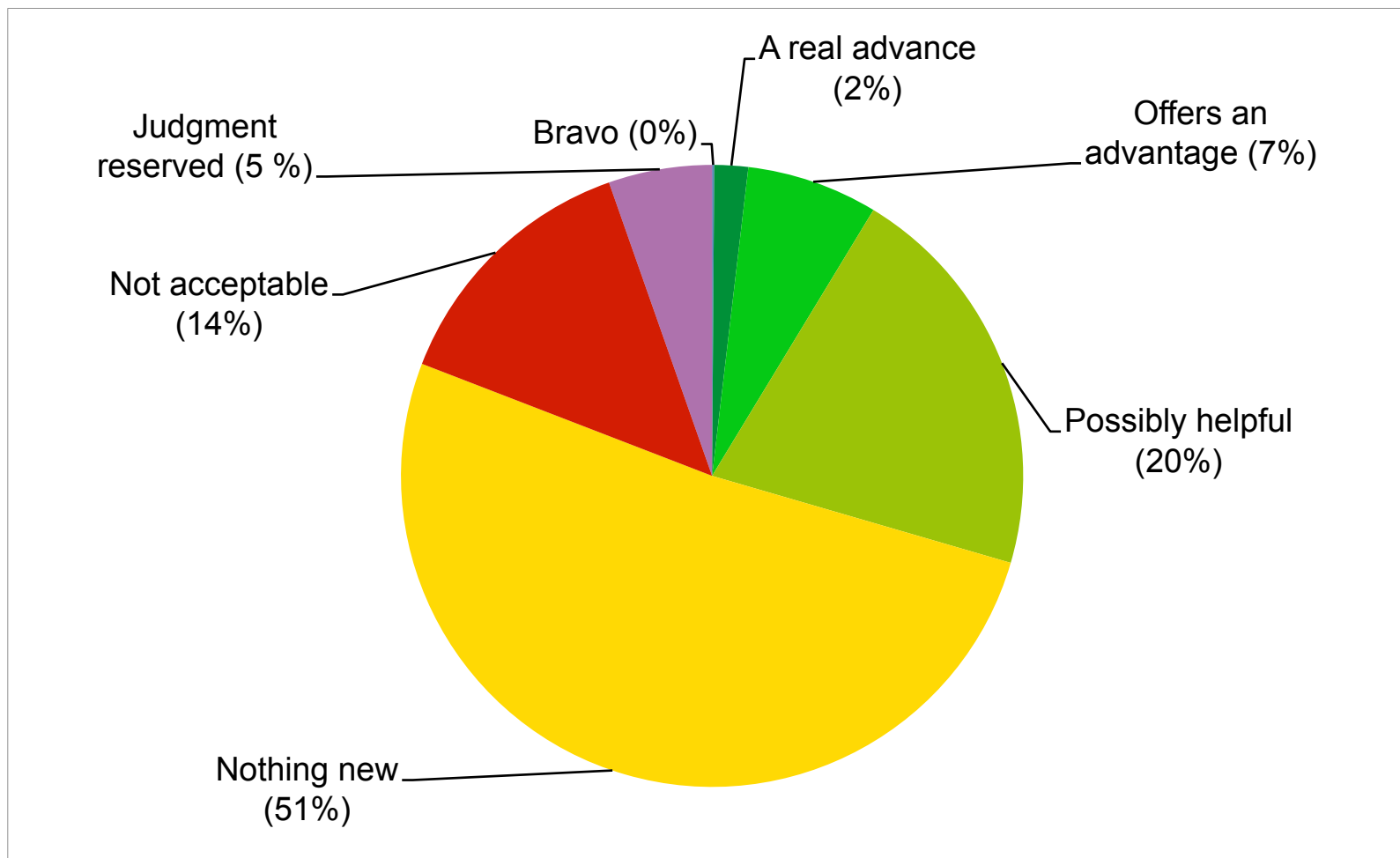
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Prescriber's ratings 2000 to 2013

Percentages per category

N=1345



Current scenario

- Clinical research (funded) by pharmaceutical companies
 - Not enough R&D focusing on unmet health needs (low return on investment)
 - Aim is to obtain marketing authorisation, no need to show therapeutic advance
 - Clinical trials used as marketing tools
- Faster and faster marketing approvals
 - Based on weak evidence
 - Post-marketing 'Risk-minimisation' measures are often insufficient
 - Dangerous drugs being approved and subsequently withdrawn (1)

1- Carpentier D et al. "Drug review deadlines and safety problems" N Engl J Med 2008

High medicines prices

- Are often set/negotiated in opacity.
- Not based on real cost of production, which remains unknown.
- Little therapeutic advance – disconnection between a drug's price and its therapeutic value assessment; prices reflect “willingness to pay”.
- More than 100 influential oncologists have described current prices of cancer medicines as: *“astronomical, unsustainable and even immoral”* (1)
- High prices put at risk:
 - Universal access to care: a human right!
 - Health protection system

1- Laurance J “Makers of anticancer drugs are “profiteering,” say 100 specialists from around the world” *BMJ* 2013; **346**:f2810

If we spend our money paying high prices for drugs with little or no added value...

...no wonder that we do not have the money to spend on what is needed!

Sofosbuvir: reaping profits at what cost? (I)

- Sofosbuvir, Solvadi^o: Used to treat hepatitis C
- Prescrire rating: Offers an advantage, particularly in genotype 1
- Contribution of publicly funded research to this drug's development was essential
- Production cost estimated at 100 USD per patient (1)
- US price: 1000 USD per day = 7 x 12 x 1000 USD = 84 000 USD per person per treatment
- Clinical trials: just enough to obtain marketing authorisation (few participants, no cirrhotic patients)
- Uncertainty about adverse drug reactions and interactions

1- Hill A et coll. "Minimum costs to produce hepatitis C direct acting antivirals for access programs in developing countries" *Clin Infect Dis* 2014 ; **58**(7) : 928-936.

2- Prescrire Redaction "Sofosbuvir - Sovaldi^o. Actif sur le virus de l'hépatite C, mais une évaluation clinique incomplète" *Rev Prescrire* 2014 ; **34** (372) : 726-732

3. Prescrire Redaction "Traitement de l'hépatite C chronique. Ne pas se précipiter sur les nouveaux antiviraux quand il est raisonnable d'attendre" *Rev Prescrire* 2014 ; **34** (372) : 757-765

Sofosbuvir: reaping profits at what cost? (II)

- Why such a high price? “Expected” savings: reduction in medication use, transplants, hospitalisations, etc
- Health technology analysis contested forecast: savings only to be obtained in 20 years, if severely-ill patients are treated (1)
- 300 USD: price for sofosbuvir under compulsory licensing for 91 countries
 - Other 50 low and middle-income are excluded => window-dressing? (2)
- Other Hep.C drugs coming along: are we to expect similar prices?

1- Institute for economic and clinical review "The comparative clinical effectiveness and value of simeprevir and sofosbuvir in the treatment of chronic hepatitis C infection" 15 april 2014. Site ctaf.org consulted 16 september 2014 : 132 pages

2- ITPC Mena “ITPC-MENA, l’ALCS et le CDSM dénoncent la licence GILEAD qui va priver 625.000 personnes infectées par le VHC au Maroc du traitement” 18 September 2014. Site: itpcmena.org consulted on 10 november 2014: 1 page.

Sofosbuvir: financial speculation

- Raymond Schinazi, Emory University, created Pharmasset (1)

"It's actually 'pharmaceutical assets' and the idea was to create assets that would be sold to companies. That was the initial business plan." (2)

- 9 USD: price per stock PharmAsset in 2006
- 139 USD: price per stock PharmAsset in 2011
- Gilead purchases PharmAsset in 2011 for 11 billion USD
 - => *"Someone made a huge mistake"* (2)
 - => It must sell 4 billion USD/year to recoup investment!

1- Burrell J "Drug linked to hepatitis C cure has Atlanta tie" 25 october 2013. Site biomed.emory.edu accessed 15 september 2014 : 2 pages.

2- Berkrot B "Gilead could have had Pharmasset cheap : founder" 22 november 2011. Site www.reuters.com accessed 9 july 2014 : 1 page

What is needed? (1)

- **Rethinking the R&D system:**
 - More research for **unmet medical needs**
 - More **comparative clinical trials** to demonstrate therapeutic advance
 - More **publicly-funded research** including independent clinical trials
 - Set **prices that reward real innovation**
 - Appropriate prices for useful medicines with proven added therapeutic value

What is needed? (2)

- **To dare:**
 - **Refuse** exorbitant prices
 - Member States should **use flexibilities** at hand => compulsory licensing
 - To demand evidence of “**therapeutic advance**” as a criteria in marketing authorisation
 - To open the black box:
 - **Transparency and access** to clinical, regulatory and pricing data
 - Allow **independent analysis and information sharing**
 - Encourage **public scrutiny**
 - Identify **real innovation = therapeutic advance!**



Thank you

More information?
Please email talves@prescire.org
or visit
www.prescire.org/english



Extra Slides

Prescriber's Ratings

Added Therapeutic Value



BRAVO:

The product is a major therapeutic advance in an area where previously no treatment was available.



A REAL ADVANCE:

The product is an important therapeutic innovation but has certain limitations.



OFFERS AN ADVANTAGE:

The product has some value but does not fundamentally change the present therapeutic practice.



POSSIBLY HELPFUL:

The product has minimal additional value, and should not change prescribing habits except in rare circumstances.

No (or questionable) Added Therapeutic Value



NOTHING NEW:

The product may be a new substance but is superfluous because it does not add to the clinical possibilities offered by previous products available. In most cases it concerns a me-too product.



JUDGEMENT RESERVED:

The editors postpone their rating until better data and a more thorough evaluation of the drug are available.



NOT ACCEPTABLE:

Product without evident benefit but with potential or real disadvantages.

Prescriber's ratings 1981 to 2010

Trend in added therapeutic value

14

