

This is an Accepted Manuscript of an article published in [The Lancet] in 2016, available online at [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(16\)32051-7/fulltext?rss%3Dyes](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)32051-7/fulltext?rss%3Dyes) (paywalled).

Self-archived in the [Sydney eScholarship Repository](#) by the Centre for Values, Ethics and the Law in Medicine (VELiM), University of Sydney, Australia

Please cite as:

Ghinea N, Lipworth W, Day R, Hill A, Dore G, Danta M. 2017. Importation of generic hepatitis C therapies: Bridging the price - access gap in high-income countries. *The Lancet*. 389: 1268-1272

Importation of generic hepatitis C therapies: bridging the price – access gap in high-income countries

Ghinea N, Lipworth W, Day R, Hill A, Dore G, Danta M. (2016)

Authors/ Preferred Degree / Affiliation / Address:

Narczyz Ghinea; BSc (Hons); Centre for Values, Ethics and the Law in Medicine, University of Sydney; Centre for Values, Ethics and the Law in Medicine, University of Sydney, Medical Foundation Building K25, NSW 2006.

Wendy Lipworth; PhD; Centre for Values, Ethics and the Law in Medicine, University of Sydney; Centre for Values, Ethics and the Law in Medicine, University of Sydney, Medical Foundation Building K25, NSW 2006.

Richard Day; MD, FRACP; St Vincent's Hospital Clinical School, UNSW Australia; Clinical Pharmacology & Toxicology, Therapeutics Centre, St Vincent's Hospital, Darlinghurst, NSW, Australia, 2010.

Andrew Hill; PhD; St Stephens AIDS Trust, Chelsea and Westminster Hospital, London SW6, United Kingdom.

Gregory J Dore; PhD, FRACP; Viral Hepatitis Clinical Research Program, Kirby Institute, UNSW Australia, Sydney, NSW, 2052.

Mark Danta; MD, FRACP; St Vincent's Clinical School, UNSW Australia; Faculty of Medicine, St Vincent's Clinical School, Victoria Road, Darlinghurst, 2010.

Corresponding Author:

Narczyz Ghinea (Narczyz.ghinea@sydney.edu.au; +61 2 9036 3407)

Address: Centre for Values, Ethics and the Law in Medicine, University of Sydney, Medical Foundation Building K25, NSW 2006.

Manuscript Text:

The global burden of hepatitis C infection and the emergence of effective therapies

An estimated 80-150 million people are infected with hepatitis C infection (HCV) worldwide, with the highest prevalence rates in low- and medium-income countries of Africa and Asia. HCV-related liver disease mortality is estimated to be half a million per annum.^{1,2}

Chronic HCV treatment was interferon-based for two decades, with the addition of ribavirin (RBV),³ pegylated-interferon (PEG-IFN)⁴ and initial protease inhibitor direct acting antiviral (DAA) therapies (telaprevir, boceprevir)^{5,6} subsequently providing stepwise improvements in the rate of sustained virological response (SVR). Despite these improvements, interferon-containing HCV therapy uptake remained low in most countries, ranging from <1% to a maximum of 5% of people with chronic HCV initiating therapy each year.⁷ Fortunately, recent years have seen a revolution in HCV therapeutic development, with the advent of interferon-free DAA therapies, which disrupt replication through inhibition of HCV protease, polymerase and NS5A function.⁸ Simple (single daily dosing oral regimens), highly tolerable, short-duration (8-24 weeks) regimens with extremely high efficacy (cure rates above 95%) have been developed and registered internationally. Used in various combinations depending on HCV genotypes and previous treatment exposure, these include: sofosbuvir/ledipasvir,⁹⁻¹¹ paritaprevir/ritonavir/ombitasvir/dasabavir/+/–ribavirin,¹²⁻¹⁴ sofosbuvir/daclatasvir,^{15,16} elbasvir/grazoprevir,^{17,18} and sofosbuvir/velpatasvir.

There is clear evidence that HCV cure impacts HCV-related liver disease and hepatocellular carcinoma (HCC) risk.¹⁹ Early treatment may have greater benefit. Furthermore, as a result of the high efficacy and tolerance, and ease of delivery of these medications, HCV treatment as prevention is being explored in some countries, particularly treating high prevalence populations, such as people who inject drugs and incarcerated populations.²⁰ The broad implementation of these therapeutic regimens has the potential to dramatically impact HCV-related disease burden globally. Indeed, new HCV treatments have been deemed so important that some (sofosbuvir, daclatasvir) were added to the 2015 WHO Essential Medicines List along with a number of their combinations.²¹

Standard channels for accessing new therapies for HCV

High drug pricing for interferon-free DAA regimens (up to USD93,000 per 12 week course) has limited broad implementation in the vast majority of settings, with restrictions based on liver disease stage generally introduced to reduce budget impact.²² Other restrictions, including those based on ongoing drug and alcohol use, have further limited access in many settings, particularly within the United States.²² Even in high income countries, there is considerable diversity in access to and pricing of new HCV therapies.

In the United Kingdom, spending on HCV treatment increased almost 5-fold between 2014 and 2015 to £190 million. It has been estimated that it would cost over £4 billion to treat the estimated 214,000 people with chronic HCV in the UK at a cost of £20,000, so access has generally been restricted to those with advanced liver disease.²³ The Australian government has allocated AUD1 billion to the Pharmaceutical Benefits Scheme to fund HCV DAA therapies for the next 5 years, with no restrictions based on liver disease stage. This is a volume-based pricing deal between the Government and Pharmaceutical companies.²⁴ While details are not publicly available, it is understood that this deal is expected to provide treatment for approximately 60,000 individuals. However, there is also a risk-sharing arrangement in place, so that if more individuals are treated then the cost would be borne by the pharmaceutical companies rather than the by Government which would mean the cost-per-treatment would fall. In the initial five months of the DAA program (March to July 2016), an estimated 26,360 patients initiated therapy, with possibly 40,000 to be treated in 2016 representing 17% of the total chronic HCV infection population in Australia.²⁵

Patients who live in countries that do not have universal government funding schemes, or who do not fit specific criteria for subsidization, must wait until these medicines are funded by their public or private insurers, or find other avenues to access medicines such as through clinical trials, industry access schemes or personal fundraising. All of these means of accessing medicines are, however, *ad hoc* and many patients miss out. This not only affects the individuals concerned, but also greatly limits the public health impact of new HCV therapies.²⁶

Personal importation of hepatitis C therapies

In some lower income countries, voluntary licenses have been issued, which allow generic versions of patented medicines to be manufactured, providing greater access to new HCV medicines. In India 11 generic companies signed voluntary licenses with Gilead for sofosbuvir and ledipasvir/sofosbuvir, and are permitted to supply these medicines to more than 100 low- and middle-income countries around the world.²⁸ However, this agreement explicitly prohibits supply to a number of middle- and high-income countries. The resulting discrepancy between prices in high-income countries and those in lower income countries can be taken advantage of by patients in wealthier countries. Patients may, for example, travel to countries where medicines are less expensive (“medical tourism”). Alternatively, they can import less expensive versions of the medicines they need.

Australia, for example, has legislation permitting individuals to import up to 12 weeks of unlicensed medicines at their own risk. While a prescription and consent is needed, no further regulatory oversight is required for most classes of medicines. Significantly for patients with HCV, a 12 week supply of medicines is generally sufficient for HCV treatment.

Prior to the commencement of the Australian government funded HCV treatment program in March 2016, an estimated 1400 Australian patients were treated with the assistance of FixHepC, a web-based platform for the importation of HCV therapies.²⁸ Through importation and compounding of the active pharmaceutical ingredients (APIs) for sofosbuvir, ledipasvir and daclatasvir from India, patients were able to access a course of 12 weeks of therapy for AU\$1500-\$2000—a fraction of the market price for these treatments. More recently FixHepC has sourced these medicines from generic companies in India and Bangladesh.

Importation schemes were supported by professional bodies such as Australasian Society of HIV, Viral Hepatitis and Sexual Health Medicine (ASHM).²⁹ The ASHM released a position statement in October 2015, which outlined their support for the new treatments, making recommendations about specific antivirals and the methods by which they may be procured - including purchasing these medicines from overseas or over the internet. In addition to having obvious appeal to people with HCV, importation schemes may play an indirect role in securing greater discounts within government and large payer-funded HCV treatment programs.

This raises the question, why are large scale personal importation schemes not more widely implemented?

While importation *per se* is generally legal, in some settings, there are regulations that preclude the importation and/or prescribing of *cheaper* imported medicines. The United States, like Australia, permits personal importation, but officially excludes importing medicines from overseas that are cheaper than those that are available locally.³⁰ In some countries, while personal importation may be permitted, there may be limits regarding what medicines physicians can prescribe. For instance, in Europe, prescribing off-label or unlicensed medicines on the basis of cost-saving alone is illegal, and the UK’s General Medical Council supports this position.³¹ How well this is, and can be, policed is another matter. The FixHepC website provides access to DAA therapy to patients in the United Kingdom,

overcoming this barrier by providing patients an online consultation with an Australian doctor, who provides prescriptions from Australia.

While safety is no doubt a major reason why many hold reservations about personal importations of medicines, it is also likely that economic factors and political pressure plays a part. For example, when Thailand issued a compulsory license for some cancer medicines, the United States responded by downgrading their trading status.³² When France utilized its *Temporary Recommendations for Use* to support the off-label use of Avastin for aged-related macular degeneration at a fraction of the price of the registered alternative, they faced stiff opposition from the European pharmaceutical lobby.³³ While these cases are not instances of personal importation, they demonstrate that even governments aiming to provide access to affordable medicines for their citizens in good-will can face stiff challenges from industry or foreign governments.

There are also barriers to organized forms of personal importation, such as FixHepC. For example, in Australia there appear to be unresolved legal, political, and operational complexities when it comes to large scale forms of importation, where physicians, exporters, prescribers and compounding pharmacists collude to treat patients with cheaper, unlicensed versions of a medicine. This is no doubt in part due to legitimate concerns about the purity of APIs, and the fact there is no guarantee that the manufacturing process meets national standards. Indeed, Australia's Therapeutics Goods Administration recently ordered the FixHepC website to cease 'advertising prescription-only medicines', and in response its operations have subsequently moved to Myanmar.³⁴ This order was, however, dated to May 2016, after Australia had already started subsidising HCV medicines for the general public, and therefore would have had minimal impact on access.

Despite the reservations that many countries seem to have about personal importation schemes, the Australian experience suggests that, if done well, organized importation of unlicensed HCV medicines do not expose patients to unnecessary risks and provides access to effective therapies. In the recent Australian REDEMPTION study (n=412) using DAA HCV therapy accessed through the FixHepC website, outcomes were equivalent to those using branded treatments. The quality of APIs were evaluated using liquid chromatography, nuclear magnetic resonance and mass spectroscopy. The interim week 12 sustained virological response (SVR) for genotype 1 HCV was 95% using imported sofosbuvir and ledipasvir or imported sofosbuvir and daclatasvir. The cohort included 28% of individuals with cirrhosis. Across all genotypes the SVR was 94% revealing equivalent clearance rates at 1/100th the cost.³⁵

Whether or not countries choose to support personal importation schemes for legal, economic and practical reasons, the fact is that there is demand for such schemes, and this demand is not specific to HCV therapy. A case in point is the 'I Want PreEP Now' website which provides recommendations and guidance to UK residents about how and where to buy generic versions of unsubsidised medicines for pre-exposure prophylaxis for HIV. While the brand name medicine is available through private clinics at a cost of £400 for 30 pills, generic products are available through the website at a tenth of the price.³⁶ And in the US state of Maine, laws passed in 2013 permitted residents to purchase cheaper medicines online from countries deemed to have equivalent or greater licensing regulations, until this state law was overturned in 2015 as it was deemed to compromise federal regulation.³⁷ This tension between what people seem to want, and what countries are willing to support, suggests that there must be strong moral and socio-political arguments both for and against personal importation.

Moral and socio-political arguments for and against personal importation

Against such schemes, it could be argued that patients in high-income countries should not have access to cheaper medicines available in low income countries because price discrepancies are legitimate responses to the ability of different markets to pay for medicines. Importing medicines from low-income

countries may compromise the discounting schemes provided to these countries if the practice becomes too widespread. This could mean that the most vulnerable patients may suffer as pharmaceutical companies refuse to discount prices to protect their investments, or refuse to contribute to schemes such as the Medicines Patent Pool which aims to make medicines more accessible in low and middle-income countries (e.g. Bristol-Myers Squibb has added daclatasvir to this pool).³⁸ It could also be argued that these practices undermine intellectual property laws and threaten current and future investment in drug development, which would have negative long-term consequences worldwide.

On the other hand, the fact that medicines *can* be sold at massive discounts in many parts of the world (and presumably not at a loss) calls into question the legitimacy of prices charged in many high-income countries – for instance in Egypt, sofosbuvir sells at a 99% discount to the US price,³⁹ and it has been estimated that HCV treatments could be manufactured for less than US\$200 per patient.⁴⁰ While the issue of drug pricing is complex, and prices cannot be determined solely on the basis of manufacturing costs, concerns about the legitimacy of HCV drug prices have been buttressed by the results of a recent investigation of Sovaldi’s pricing in the United States. The resulting US Senate Report concluded that Gilead aimed to set high pricing precedents ‘in early launch markets’ and to set a high baseline price for successor products.⁴¹ In addition it found that the price of Sovaldi was aimed at maximizing revenue based on expectations of how payers would react to the price, rather than being connected to underlying costs of development, or investment returns. The Attorney-General of one US state has threatened to take legal action against Gilead for the pricing of its medicines, arguing that it ‘may constitute an unfair trade practice’.⁴² In this regard it is worth noting that between 2013 and 2015, Gilead’s sales revenue for Solvaldi and Harvoni was more than \$31 billion, with \$19 billion of these products sold in 2015 alone.^{43,44}

Balancing compassion and industry interests

It is important to keep in mind that the practice of personal importation is driven by the very same imperative that allows companies to charge high prices for life-saving medicines – hope. When hope fades because the cure is too expensive, no one can blame patients for seeking other avenues to access treatments. While it is not an ideal solution, and governments do have options available to them,²⁷ the case of HCV shows that under certain circumstances, personal importation can work as a stop-gap measure until better and longer term solutions are found. We also need to keep in mind that the problem is a global one—while personal importation may provide hope to people in relatively wealthy countries, universal access will not be achieved in this way. While the cost of manufacturing DAAs is rapidly declining, raising the prospect that more people who need these treatments will be able to access them,⁴⁵ there are many other commercial forces at play, which mean that prices will not necessarily fall according to standard market logics.

The generic importation of HCV medication thus highlights the problems of drug cost, regulation and access in both high and low income countries. What is needed in this situation, where values conflict on so many levels, is greater clarity about the threshold at which the well-being of patients and societal health should outweigh corporate interests. To achieve this clarity, we need far greater transparency around why medicines cost the amount they do. In cases where large populations of patients are denied access to life changing medicines because of prices that cannot be justified, we need to have legal frameworks and mechanisms in place that allow patients to access these treatments (on a large scale if necessary) from elsewhere without fear of personal or societal repercussions. Where current legislation and regulation does not permit affordable access to life saving treatments, governments need the political will to take action and change legislation. When mechanisms exist within current legal frameworks for accessing medicines, governments need to leverage them. In short, we need to replace amoral market-logic with fair-mindedness and compassionate rationality.

References

1. WHO. WHO moves to improve access to lifesaving medicines for hepatitis C, drug-resistant TB and cancers. 2015. <http://www.who.int/mediacentre/news/releases/2015/new-essential-medicines-list/en/> (accessed Apr 18. 2016).
2. Gower E, Estes C, Blach S, Razavi-Shearer K, Razavi H. Global epidemiology and genotype distribution of the hepatitis C virus infection. *J Hepatol* 2014; 61 (1 suppl): S45–57.
3. McHutchison JG, Gordon SC, Schiff ER, et al. Interferon alfa-2b alone or in combination with ribavirin as initial treatment for chronic hepatitis C. Hepatitis Interventional Therapy Group. *N Engl J Med* 1998; **339**(21): 1485-92.
4. Manns MP, McHutchison JG, Gordon SC, et al. Peginterferon alfa-2b plus ribavirin compared with interferon alfa-2b plus ribavirin for initial treatment of chronic hepatitis C: a randomised trial. *Lancet* 2001; **358**(9286): 958-65.
5. Jacobson IM, McHutchison JG, Dusheiko G, et al. Telaprevir for previously untreated chronic hepatitis C virus infection. *N Engl J Med* 2011; **364**(25): 2405-16.
6. Poordad F, McCone J, Jr., Bacon BR, et al. Boceprevir for untreated chronic HCV genotype 1 infection. *N Engl J Med* 2011; **364**(13): 1195-206.
7. Dore GJ, Ward J, Thursz M. Hepatitis C disease burden and strategies to manage the burden. *J Viral Hepatitis* 2014; **21** Suppl 1: 1-4.
8. Asselah T, Marcellin P. New direct-acting antivirals' combination for the treatment of chronic hepatitis C. *Liver Int* 2011; **31** Suppl 1: 68-77.
9. Afdhal N, Reddy KR, Nelson DR, et al. Ledipasvir and sofosbuvir for previously treated HCV genotype 1 infection. *N Engl J Med* 2014; **370**(16): 1483-93.
10. Afdhal N, Zeuzem S, Kwo P, et al. Ledipasvir and sofosbuvir for untreated HCV genotype 1 infection. *N Engl J Med* 2014; **370**(20): 1889-98.
11. Kowdley KV, Gordon SC, Reddy KR, et al. Ledipasvir and sofosbuvir for 8 or 12 weeks for chronic HCV without cirrhosis. *N Engl J Med* 2014; **370**(20): 1879-88.
12. Poordad F, Hezode C, Trinh R, et al. ABT-450/r-ombitasvir and dasabuvir with ribavirin for hepatitis C with cirrhosis. *N Engl J Med* 2014; **370**(21): 1973-82.
13. Feld JJ, Kowdley KV, Coakley E, et al. Treatment of HCV with ABT-450/r-ombitasvir and dasabuvir with ribavirin. *N Engl J Med* 2014; **370**(17): 1594-603.
14. Ferenci P, Bernstein D, Lalezari J, et al. ABT-450/r-ombitasvir and dasabuvir with or without ribavirin for HCV. *N Engl J Med* 2014; **370**(21): 1983-92.
15. Leroy V, Angus P, Bronowicki JP, et al. Daclatasvir, sofosbuvir, and ribavirin for hepatitis C virus genotype 3 and advanced liver disease: a randomized phase III study (ALLY-3+). *Hepatology* 2016.
16. Wyles DL, Ruane PJ, Sulkowski MS, et al. Daclatasvir plus sofosbuvir for HCV in patients coinfecting with HIV-1. *N Engl J Med* 2015; **373**(8): 714-25.
17. Rockstroh JK, Nelson M, Katlama C, et al. Efficacy and safety of grazoprevir (MK-5172) and elbasvir (MK-8742) in patients with hepatitis C virus and HIV co-infection (C-EDGE CO-INFECTION): a non-randomised, open-label trial. *Lancet HIV* 2015; **2**(8): e319-27.

18. Zeuzem S, Ghalib R, Reddy KR, et al. Grazoprevir-elbasvir combination therapy for treatment-naive cirrhotic and noncirrhotic patients with chronic hepatitis C virus genotype 1, 4, or 6 infection: a randomized trial. *Ann Intern Med* 2015; **163**(1): 1-13.
19. El-Serag HB, Kanwal F, Richardson P, Kramer J. Risk of hepatocellular carcinoma after sustained virological response in veterans with hepatitis C virus infection. *Hepatology* 2016; **64**(1): 130-37.
20. Martin NK, Vickerman P, Grebely J, et al. Hepatitis C virus treatment for prevention among people who inject drugs: modeling treatment scale-up in the age of direct-acting antivirals. *Hepatology* 2013; **58**(5): 1598-609.
21. WHO. 19th WHO model list of essential medicines. 2015. http://www.who.int/medicines/publications/essentialmedicines/EML2015_8-May-15.pdf (accessed Apr 18, 2016).
22. Barua S, Greenwald, Grebely J, Swan T, Dore GJ, Taylor L. Restrictions for Medicaid reimbursement of sofosbuvir for the treatment of hepatitis C virus infection in the United States. *Ann Intern Med* 2015; **163**:215-223.
23. NHS England. Thousands more patients to be cured of hepatitis C. 2015. <https://www.england.nhs.uk/2015/06/patients-hep-c/> (accessed Apr 18, 2016).
24. Minister for Health. Turnbull government invests over \$1 billion to cure HEP C. 2015. <https://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2015-ley154.htm> (accessed Apr 18, 2016).
25. The Kirby Institute. Hepatitis B and C in Australia annual surveillance report supplement. 2016. <http://kirby.unsw.edu.au/surveillance/hepatitis-b-and-c-australia-annual-surveillance-report-supplement-2016-0> (accessed Oct 13, 2016).
26. Grebely J, Dore GJ. Can hepatitis C virus infection be eradicated in people who inject drugs? *Antiviral Res* 2014; **104**: 62-72.
27. t' Hoen EF. Indian hepatitis C drug patent decision shakes public health community. *Lancet* 2016; **387**: 2272-2273.
28. FixHepC. Cure hepatitis C with sofosbuvir ledipasvir daclatasvir. 2015. <http://fixhepc.com/> (accessed Apr 18, 2016).
29. Australian Society of HIV and Hepatitis. Importation of generic HCV drugs. 2015. <http://www.ashm.org.au/HCV/management-hepc/importation-of-generic-hcv-drugs> (accessed Apr 18, 2016).
30. U.S. Food and Drug Administration. Importation of drugs. 2015. <http://www.fda.gov/ForIndustry/ImportProgram/ucm173751.htm> (accessed Apr 18, 2016).
31. Dickson N. The GMC's stance on Avastin. *BMJ* 2015; **350**: h2043.
32. Hoen E. Access to cancer treatment: a study of medicine pricing issues with recommendations for improving access to cancer medication. 2014. <https://www.ciaonet.org/attachments/27387/uploads> (accessed Apr 18, 2016).
33. Industry complains to EU over French law pushing cheap eye drug. *Reuters*. 2015 Sep 1. <http://www.reuters.com/article/pharmaceuticals-france-avastin-idUSL5N1173RD20150901> (accessed Oct 13, 2016).

34. Therapeutic Goods Administration. Warning letter – promotion of prescription-only medicines must cease. 2016. <http://fixhepc.com/images/misc/tga-complaint.pdf> (accessed Sep 14, 2016).
35. Freeman J. High sustained virological response rates using generic Direct Acting Antiviral treatment for Hepatitis C, imported into Australia. International Liver Congress. Barcelona; 2016.
36. I Want PrEP Now. www.iwantprepnw.co.uk (accessed Apr 18, 2016).
37. Farwell J. Judge overturns Maine law allowing prescription drug imports. *Bangor Daily News*. 2015 Feb 24. <http://bangordailynews.com/2015/02/24/health/judge-overturns-maine-law-allowing-prescription-drug-imports/> (accessed Apr 18, 2016).
38. Medicines Patent Pool. MPP licence for daclatasvir (dcv). 2015. <http://www.medicinespatentpool.org/mpp-licence-for-daclatasvir-dcv/> (accessed Sep 14, 2016).
39. Fick M, Hirschler B. Gilead offers Egypt new hepatitis C drug at 99 percent discount. *Reuters*. 2014 Mar 21. <http://www.reuters.com/article/us-hepatitis-egypt-gilead-sciences-idUSBREA2K1VF20140321> (accessed Apr 18, 2016).
40. Hill A, Simmons B, Gotham D, Fortunak J. Rapid reductions in prices for generic sofosbuvir and daclatasvir to treat hepatitis C. *J Virus Erad* 2016; **2**: 28-31.
41. United States Senate Committee on Finance. Wyden-Grassley Sovaldi investigation finds revenue-driven pricing strategy behind \$84,000 hepatitis drug. 2015. <http://www.finance.senate.gov/ranking-members-news/wyden-grassley-sovaldi-investigation-finds-revenue-driven-pricing-strategy-behind-84-000-hepatitis-drug> (accessed Apr 18, 2016).
42. Weisman R. AG warns maker on hepatitis drug costs. *Boston Globe*. 2016. <https://www.bostonglobe.com/business/2016/01/27/calls-gilead-lower-price-hepatitis-medicines/CNykZWYSat0LiYY4cUZfRO/story.html> (accessed Apr 18, 2016).
43. Gilead sciences announces fourth quarter and full year 2014 financial results. 2015. <http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9MjY4NzU4fENoaWxkSUQ9LTF8VHlwZT0z&t=1> (accessed Apr 18, 2016).
44. Gilead sciences announces fourth quarter and full year 2015 financial results. 2016. <http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9MzIxNTg1fENoaWxkSUQ9LTF8VHlwZT0z&t=1&cb=635899653079912085> (accessed Apr 18, 2016).
45. Gotham D, Barber M, Forunak J, Pozniak A, Hill A. Rapidly falling costs for new hepatitis C direct-acting antivirals (DAAs): potential for universal access. *International Aids Conference*, 2016. http://www.natap.org/2016/IAC/IAC_121.htm (accessed Sep 14, 2016).

Author Contributions

NG conceptualised and wrote the paper. WL participated in the conceptualization and writing of the paper. AH, RD, MD and GD all critically reviewed and contributed to writing the paper.

Financial Support

This work was supported by funding through a grant from the National Health and Medical Research Council. The funding body had no role in the writing or decision to submit for publication.

Declarations of Interest

Narczyz Ghinea is a researcher on a National Health and Medical Research Council funded project relating to improving funding of high cost cancer medicines.

Wendy Lipworth is Chief Investigator on a National Health and Medical Research Council funded project relating to improving funding of high cost cancer medicines.

Richard Day is an Assistant Investigator on a National Health and Medical Research Council funded project relating to improving funding of high cost cancer medicines.

Gregory Dore is a consultant/advisor and has received research grants from Abbvie, Bristol-Myers Squibb, Gilead, Merck, Janssen and Roche; personal fees from Gilead, Abbvie, Merck, Bristol-Myers Squibb, and Roche; and travel support from Abbvie, Merck, Bristol-Myers Squibb, and Roche.

Andrew Hill has received personal fees from Gilead and Jansen.

Mark Danta received support for lecturing and travel bursary from AbbVie, BMS and MSD.