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USTR SPECIAL 301 2018
Hearing Statement of Public Citizen
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Public Citizen appreciates the opportunity to testify and provide this statement on behalf of its more than 400,000 members and supporters.

Public Citizen is a national, nonprofit consumer advocacy organization with a 45-year history representing consumer interests in Congress, the executive branch and the courts.

Public Citizen's Access to Medicines Program works with partners worldwide to improve health outcomes through use of pharmaceutical cost-lowering measures including generic competition.

We submitted our written comments for the docket USTR- 2017-0024 in February 2018. Our post-hearing statement draws upon those comments and our experiences working on the ground with government agencies, civil society organizations, academics and patients groups. Our testimony and post-hearing statement give particular attention to two countries; namely Malaysia and Colombia.

We would like to highlight commitments articulated in past Special 301 Reports such as "the United States respects a trading partner's right to protect public health and, in particular, to promote access to medicines for all," and "the United States respects its trading partners' rights to grant compulsory licenses in a manner consistent with the provisions of the TRIPS

Agreement.” We support these commitments, which echo the World Trade Organization’s Doha Declaration on the TRIPS Agreement and Public Health.

Malaysia

Public Citizen has been working in Malaysia with health advocates and intellectual property experts since 2011. Malaysia has not been on the Special 301 Watch List since 2012. This year, the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Innovation Organization (BIO) requested in their Special 301 submissions that Malaysia be treated as a Priority Foreign Country for its “decision to expropriate patent rights” of Gilead Sciences. PhRMA said Malaysia exhibited a “blatant disregard of patent rights”. We disagree.

As of 2015, it is estimated that around 143 million people¹ are infected with hepatitis C. Hepatitis C infects and damages the liver, the largest organ inside our bodies. The virus usually spreads through contact with infected blood. Healthcare workers are at risk through needle sticks, as are babies born to mothers with hepatitis C. People are also at higher risk if they received a blood transfusion or an organ transplant before 1992 (improvements in blood-screening technology were only made in 1992).

Most people who are infected with hepatitis C do not have any symptoms for years. For most patients, it is a chronic illness, which means it does not go away, and for many it leads to cirrhosis and liver cancer.

Hepatitis C is found worldwide. An estimated 3.5 million people in the United States are living with chronic hepatitis C infection, and most do not feel ill or know they are infected, according to the Centers for Disease Control and Prevention².

¹ Global, regional, and national incidence, prevalence, and years lived with disability for 310 diseases and injuries, 1990–2015: a systematic analysis for the Global Burden of Disease Study 2015, The Lancet, available at [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(16\)31678-6/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)31678-6/fulltext)

² <https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm>

More than 500,000 people have been suffering from hepatitis C in Malaysia³. Sofosbuvir (Sovaldi), when used with another drug, can virtually cure most cases of hepatitis C in 12 weeks with few side effects. The list price of Sovaldi set by the patent holder, Gilead Sciences, in the U.S. is \$84,000⁴ per treatment and \$71,300 in Malaysia⁵. The median household income in Malaysia is only \$4,500⁶, so this price is about 16 times higher than a family's total annual income.

Apart from the price, the patentability of the drug is also questionable. Despite its medical benefits, the invention is based on old science and it is disclosed in other patent applications. The patent was rejected in some countries⁷.

In 2014, Gilead signed non-exclusive licensing agreements with seven India-based generic pharmaceutical manufacturers to produce and sell sofosbuvir in 91 lower and middle-income countries⁸, but that agreement excluded Malaysia and some other middle-income countries. In subsequent years, the agreement was expanded to include more manufacturers and countries⁹, but Malaysia remained outside its geographical scope.

“Gilead tactically excluded most middle-income countries (MICs) – home to 72 per cent of people living with HCV [hepatitis C] – from their VL [voluntary license], seeing them as lucrative markets for DAAs [direct-acting antivirals]. Prices in these countries are still far

³ “Health Minister Datuk Seri Dr Subramaniam said it is estimated that roughly half a million Malaysians have Hepatitis C. However, most of them are unaware of the infection.”, Mims Today, 25 July 2017, <https://today.mims.com/health-minister-500000-malaysians-suffering-from-hepatitis-c-but-unaware-of-infection>

⁴ ‘How an \$84,000 drug got its price: ‘Let’s hold our position ... whatever the headlines’, The Washington Post, December 1, 2015 https://www.washingtonpost.com/news/wonk/wp/2015/12/01/how-an-84000-drug-got-its-price-lets-hold-our-position-whatever-the-headlines/?utm_term=.66492505a65c

⁵ Malaysian AIDS Council Press Statement, 2017, available at <http://www.mac.org.my/v3/malaysian-aids-council-welcomes-government-move-to-issue-compulsory-license-on-lifesaving-hepatitis-c-medicines/>

⁶ Malaysia Household Income per Capita, available at <https://www.ceicdata.com/en/indicator/malaysia/annual-household-income-per-capita>

⁷ “High Cost of Sovaldi Hepatitis C Drug Prompts a Call to Void Its Patents”, May 19, 2015 available at <https://www.nytimes.com/2015/05/20/business/high-cost-of-hepatitis-c-drug-prompts-a-call-to-void-its-patents.html>

⁸ https://www.gilead.com/~media/files/pdfs/other/2014_original_hcv_licensing_agreement.pdf?la=en

⁹ <http://www.gilead.com/-/media/files/pdfs/other/hcv-generic-agreement-fast-facts-111716.pdf>

out of reach for many governments that wish to implement wide-scale HCV treatment programmes, and also for people who must pay for DAAs out of pocket. Gilead has recently come under increasing pressure from civil society organisations in MICs, and from governments considering the option of compulsory licences (CLs).¹⁰
(Médecins Sans Frontières)

The Malaysian government engaged in negotiations with Gilead for two years to be included in the licenses and reduce the price. The negotiations failed in 2016 because Gilead was unwilling to reduce the price below \$12,000 for a complete course which was still unaffordable for many Malaysians and the government.

Gilead's failure to register the drug in many of the 105 countries within the voluntary licenses territory has delayed or obstructed access to hepatitis C treatment¹¹. As of July 2017, Gilead has registered Sofosbuvir in only 27 countries¹², and Malaysia was not one of them.

Sovaldi® Registration In The Developing World

Approved

1. Argentina	October 2015	10. El Salvador	December 2015	19. Philippines	October 2015
2. Bolivia	December 2015	11. India	January 2015	20. Rwanda	August 2015
3. Brazil	March 2015	12. Georgia	February 2015	21. Tanzania	December 2016
4. Cameroon	May 2016	13. Indonesia	June 2016	22. Thailand	August 2015
5. Chile	April 2015	14. Mexico	December 2015	23. Tunisia	January 2016
6. Colombia	April 2017	15. Mongolia	January 2015	24. Ukraine	October 2015
7. Dominican Republic	July 2015	16. Nigeria	June 2016	25. Uruguay	March 2016
8. Ecuador	November 2016	17. Pakistan	February 2015	26. Uzbekistan	October 2016
9. Egypt	July 2014	18. Peru	May 2016	27. Venezuela	July 2016

Filed

1. Kenya	May 2015	3. Uganda	November 2014
2. South Africa	December 2014	4. Vietnam	January 2016

Note

There can be no guarantee that marketing approval for Sovaldi® will be granted in any of the low- and middle-income countries where registration is pending; any marketing approval, if granted, may have significant limitations on its use.

July 2017

www.gilead.com



¹⁰ Hepatitis C - Not even close, Médecins Sans Frontières, available at <https://www.msfaccess.org/hep-c-not-even-close>

¹¹ *Id.*

¹² <http://www.gilead.com/~media/files/pdfs/other/registration/sovaldi%20registration%20%20071917.pdf>

A year later in September 2017, after consultations with the relevant stakeholders and governmental bodies, Malaysia authorized government use of sofosbuvir patents. Just before the government authorization in August 2017, Gilead announced on Twitter that the scope of licenses would be extended to cover Malaysia. There was no official announcement or notification to the Malaysian government.

Gilead's tweet seems to have been strategic; aimed to anticipate Malaysia's government use decision. By doing so, Gilead hoped to avoid reputational damage.

Governments do not act on tweets. The Cabinet decision to make use of an invention was taken long before Gilead's tweet. For two years during the price negotiations, Gilead neither reduced the price nor applied for regulatory approval of sofosbuvir in Malaysia.

The government use authorization covers only public hospitals and clinics. It is only for importation and not for local manufacturing. It does not override or nullify the patent rights of Gilead. Gilead is free to compete and sell Sovaldi, and retains the exclusive privilege to do so in the private market. According to TRIPS Article 31, paragraph b, non-commercial use of a patent does not require prior negotiation with the patent holder.

The Malaysian government's decision to make use of an invention is a crucial example of a country exercising TRIPS flexibilities to make medicines available to save thousands of people from death or serious ailment. The hepatitis C treatment is now available in all public hospitals and clinics in Malaysia, and costs around \$100 per 3-months treatment. It is estimated that 400,000 Malaysian patients are going to benefit from the treatment.



If Malaysia had acted on Gilead's tweet and stopped the government use procedure, it would have taken at least two years (and possibly many lives) for Malaysian patients to access the medicines (because of drug registration procedures).

The price still would have been high – as seen in the case of other countries with voluntary licenses. The price for sofosbuvir is US\$240 in Indonesia, US\$220 in Myanmar, and US\$570 in Vietnam for a month supply¹³.

The U.S. government should not criticize Malaysia for making use of an invention to protect public health. It is consistent with international obligations and long-established U.S. policy.

Colombia

In Colombia, it is estimated that 400,000 people live with hepatitis C. As of 2015, only 996 people had received treatment.

In May 2017, under the leadership of the PAHO and the Colombian Ministry of Health, the country put in place the first strategic purchase of 1220 medicines (only 250 of them were Sovaldi)¹⁴.

¹³India is getting sofosbuvir at very low prices (US\$55) because of intense generic competition [http://www.worldhepatitisummit.org/docs/default-source/presentations/strategic-direction-2/generic-daas-\(giten-khwairakpam\).pdf?sfvrsn=2](http://www.worldhepatitisummit.org/docs/default-source/presentations/strategic-direction-2/generic-daas-(giten-khwairakpam).pdf?sfvrsn=2)

¹⁴ Colombia bought 1220 medicines (750 Harvoni, 250 Daklinza and 250 Sovaldi). "Strategic purchasing in the medicines to Hepatitis C in Colombia: equity and health financing innovations", <https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/strategic-purchasing-medicines-hepatitis-c-colombia.pdf>

Colombia's health care system still cannot afford to pay the negotiated discount for the drugs¹⁵. Facing a serious public health problem, the Colombian ministry decided to assess the burden of hepatitis C treatment in the country and determine whether there was sufficient evidence to support a public health declaration on compulsory licenses. This created outrage among pharmaceutical companies, some of which sought to intimidate Colombia, including by threatening Colombia's OECD accession. In their Special 301 2018 submissions PhRMA and BIO called for Colombia to be placed on the priority watch list and given an out-of-cycle review.

In fact, this was not the first time the pharmaceutical industry attacked Colombia. In 2016, after protracted talks broke down with the Swiss company Novartis over the price of the cancer drug Glivec, which was priced in Colombia at nearly double the country's GDP per capita, the Colombian health minister issued a declaration of public interest. Please note that this was only a declaration highlighting the need and public interest in the issues; Colombia did not issue a compulsory license.

Following the public health declaration, pharmaceutical companies put on pressure to derail Colombia's legal efforts to lower the price, including through threats to launch an investment dispute¹⁶.

Leaked letters showed that after meeting with U.S. government officials, Colombian diplomats felt that U.S. financial assistance for the Paz Colombia peace initiative may be put at risk if they were to proceed with a compulsory license for Glivec¹⁷. More than 50 years of war in Colombia has claimed 8 million victims and 220,000 deaths. Colombia should not have been put in a

¹⁵ The price for 12 weeks treatment based on a combination drug of Sovaldi (sofosbuvir) + Daklinza (daclatasvir) was 136.000.000 COP (US\$48,960.00) in 2016

¹⁶ A Swiss company, Novartis threatened Colombia with an ISDS dispute:
https://www.publiceye.ch/en/media/press-release/compulsory_licensing_in_colombia_leaked_documents_show_aggressive_lobbying_by_novartis/

¹⁷ "Colombia Fears U.S. May Reject Peace Plan To Protect Pharma Profits", 05.11.2016
https://www.huffingtonpost.com/entry/colombia-gleevec_us_5733d4ece4b077d4d6f224ee

position to choose between support for peace and its people's health. Eventually, the government announced that it would reduce the price of Glivec but stopped short of issuing a compulsory license.

The U.S. government should not criticize Colombia for assessing its disease burden and considering compulsory licenses, both of which are consistent with Colombia's international obligations in human rights and trade. Colombia does not have an obligation to consult with the U.S. government regarding either policy option.

Conclusion

Conservative estimates suggest that hepatitis C kills around 20,000 Americans each year¹⁸. Failure to aggressively treat hepatitis C would have public health ramifications for Americans for decades to come. Indeed, 18 members of Congress have just written the Secretary of Health and Human Services, suggesting that the United States similarly license hepatitis C treatment for generic competition. We need compulsory patent licensing at home¹⁹.

High prices of medicines remain at the top of Americans' priorities in public polling. We are in the midst of debate on legislation and policies that should be enacted to make medicine affordable for all. Malaysia and Colombia are two countries leading the path prioritizing public health. The United States should follow their path, not put new obstacles in it.

¹⁸ <https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm>

¹⁹ <https://khanna.house.gov/sites/khanna.house.gov/files/Final%20Letter%20-%20signed.pdf>