

## The Relationship between the Spanish Government and the Pharmaceutical Company (Gilead) during the Hepatitis C crisis in Spain

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### Abstract

*This research note investigates the pattern of governance that underpinned the management of the Hepatitis C crisis that took place in Spain in 2014. By navigating through the facts, one can see how the private interests of a multinational company – Gilead, the patent holder of the new treatment for the Hepatitis C virus – were capable of exerting pressure on Spain, a highly developed state, to a point where the government applied measures that contradicted the country's Constitution and caused 4000 avoidable deaths. Different theories of governance will be used to try to explain the new dynamics. The main conclusion of this research note is that the power of the state is diminishing in many cases, and that this has consequences for the public interest and the population in general.*

### Keywords

Gilead; Hepatitis C; Patent; Private-Self Regulation; Sovaldi™; TRIPS Agreement; Welfare States

## Introduction

In a globalized and interconnected world in which private actors are increasingly capable of exerting pressure on public ones, even developed states find it challenging to regulate the practices of global businesses (Abbott and Snidal 2009, 15). Consequently, situations such as the Spanish Hepatitis C crisis may be understood as irremediable.

Although Spain is considered a welfare state and has established a universal and unlimited health care system, the Spanish government nonetheless imposed a restrictive criterion among Hepatitis C patients after the patent holder of the new Hepatitis C drugs (Sovaldi™ and Harvoni™) set exorbitant prices for its products in 2014. The management of this crisis contravened the article 43 of the country's Constitution and caused numerous avoidable deaths. The theories of Christoph Knill and Dirk Lehmkuhl (2012) as well as Kenneth Abbott and Duncan Snidal (2009) are used in this research to explain the decisions of the Spanish government during this crisis.

This crisis portrays how today in many cases governance does not depend on the capacity of the state to organize and provide public goods, but instead, the interests and decision-making capacities of private actors play a decisive role. However, international regimes often also provide states with means for overriding the decisions of private actors, especially when it comes to public health, thus providing governments with the ability to decide whether or not to make use of them.

The topic of this research note is important because nowadays, in Western Europe, the enormous power that transnational companies exert upon governments endangers the maintenance of essential public services, such as healthcare. Thus, new patterns of governance are affecting many of the constitutional rights that were realised throughout the twentieth century, and it is necessary to analyse how they work within specific cases of crises.

## Contemporary State Capacity: A Theoretical Framework

Nowadays, globalization seems universal and unstoppable. One of the direct effects of this process has been the reduction of the role of the state in the provision of public goods and, consequently, the reduction in its governance capacity. The concept 'governance capacity' could be defined as "the formal and factual capability of public or private actors to define the content of public goods and to shape the social, economic, and political processes by which these goods are provided" (Knill and Lehmkuhl 2002, 43).

Public good is understood as: 'non-rival', since its consumption by one does not preclude consumption by someone else; and 'non-excludable', as it is difficult or costly to prevent those who do not pay from enjoying it (Sagasti and Bezanson 2004).

According to the classical theory of public goods, only state intervention can end the tension between individual and collective rationalities with regard to public goods (Knill and Lehmkuhl 2002, 50). However, today both the internationalization of markets and the emergence of transnational information and communication networks challenge the autonomy and effectiveness of national governments in defining and providing public goods – “a function classically associated with the nation-state” (Knill and Lehmkuhl 2002, 41).

These difficulties have led to the emergence of alternative forms of governance both ‘above’ the state – in the form of international regimes – and ‘below’ the state – in the form of nongovernmental organizations (Abbott and Snidal 2009, 2). National governments, in an attempt to retain power over addressing their countries’ issues, often adhere themselves to the international regimes developed for specific areas (Brahm 2005).

As a result, “‘modern governance’ can hardly be understood in terms of either purely public or private governance”, as “it is instead characterized by complex interdependencies” (Knill and Lehmkuhl 2002, 49).

The Triangle of Governance Theory is an adequate starting point for explaining the patterns of ‘modern governance’ that exist nowadays. According to Abbott and Snidal, the transnational regulatory space – where there is a direct participation of states, business (firms) and non-governmental organizations – can be portrayed by the surface of a triangle. This space is then divided into seven zones that represent the possible combinations of actor participation (Abbott and Snidal 2009, 7).

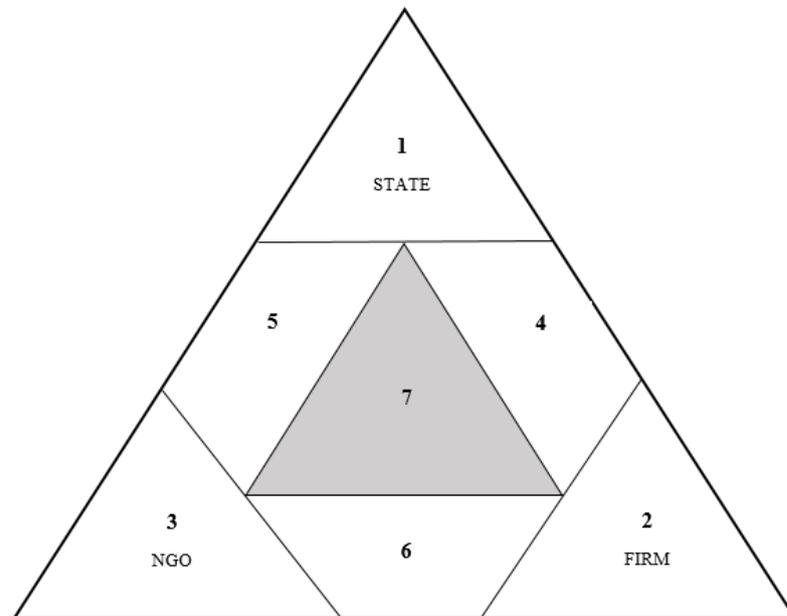
The Zone number 7, the centre of the triangle, includes those situations in which actors of all three types play a vital role in the governance of a specific issue (Abbott and Snidal 2009, 8). Within this Zone, Private Self-Regulation – one of the ideal-typed patterns of governance theorised by Knill and Lehmkuhl – emerges.

In addition, the pattern of governance followed in a specific situation will depend on the ‘strategic constellation’ that underlines it. Thus, the specific “configurations of public and private capacities formally or factually influence the social, economic, and political processes by which certain public goods are provided” (Knill and Lehmkuhl 2002, 40).

Private Self-Regulation is a ‘strategic constellation’ where there is a strong common interest in the provision of the good but, at the same time, there is disagreement about the way to provide it. In this scenario, even though “bargaining between actors can still resolve agreement problems in principle, the prospects for both public and private governance are gloomier for *defection problems*” (Knill and Lehmkuhl 2002, 46). Should a defection problem

arise, private actors may decide not to contribute anymore to the provision of the public good (Knill and Lehmkuhl 2002, 46).

Table 1. Abbott and Snidal's Triangle of Governance (Abbott and Snidal 2009, 7).



Source: Author.

As a result, due to the public actor's fear of the arousal of a defection problem, the provision of the public good starts depending on the interests and the governance capacity of the private actor. Although the state has no capacity to directly provide the specific good itself, it may still play a role in providing complementary governance contributions, such as mediation or moderation between conflicting interests (Knill and Lehmkuhl 2002, 51).

Within this theoretical framework, an important question arises: was the management of the Spanish Hepatitis C crisis an example of the governance pattern known as Private Self-Regulation?

## A Case Study of the Spanish Hepatitis C Crisis

### *Hepatitis C Contextualization*

The Hepatitis C virus (HCV) was discovered in 1989. This virus may cause chronic liver disease and other health problems, such as cirrhosis and cancer (Alonso 2015, 1). Although asymptomatic at first, the infection will lead to one of the two possible scenarios. In the first scenario, a person's immunological system is capable of suppressing the virus during the first six months without need for treatment (this happens in 10-30% of cases). In the second scenario the virus becomes chronic. The HCV is a bloodborne virus, which

means that unsafe injections, drugs, and poorly tested blood products are the most common ways of contagion (WHO 2019).

There are six different genotypes of HCV, the 1.1b being the most common in Europe, US, and Japan. Since these are the wealthiest countries on earth, the pharmaceutical industry has so far had great incentives for conducting research for effective treatment for this genotype (Alonso 2015, 1). According to the World Health Organization, there are over 70 million people infected with HCV around the globe, and 95% of them could be cured with antiviral medicines (WHO 2019).

### ***Spanish Legislative Framework***

Article 43 of Spain's Constitution establishes the population's 'right to health protection'. Accordingly, no one shall be deprived of appropriate medical treatment. This constitutional premise imposes the duties on the Spanish public authorities of both organizing and endowing the public health care system (Spanish Constitution 1978). As a result, in Spain the public health care system can be defined as a public good – since it is 'non-rival' and 'non-excludable'. Moreover, the Spanish pharmaceutical market is characterized by being both heavily regulated and highly subsidized, with 80% of all pharmaceutical expenditure coming from the public budget (Campillo, García and Bernal 2016, 976).

To access the Spanish market, new drugs require approval through the national procedure, the mutual acknowledgement mechanism, and the centralized approval mechanism by the European Medicines Agency (EMA) (Campillo, García and Bernal 2016, 976).

### **Development of the Crisis**

The above was the legal framework when Sovaldi™, the new drug for Hepatitis C, was released by the pharmaceutical company Gilead. The novel treatment had a considerably higher cure rate than its predecessors (Ortega and Vicioso 2015) and was granted a marketing authorization by the EMA. From then on, the governments of the European Union members started to bargain with the patent holder to determine the price of the treatment (La Caixa 2016).

Spanish authorities estimated that there were about 95,000 Hepatitis C patients in Spain, out of which 52,000 were in an advanced phase of the disease, thus needing the treatment as soon as possible (Ortega and Vicioso 2015). Hence, the country's Ministry of Health, Social Services and Equality decided to acquire Sovaldi™ through the National Health System from August 2014 (Campillo, García and Bernal 2016, 977).

Nevertheless, in the beginning it was unaffordable for the Spanish state to treat every HCV patient with the novel drugs because the baseline price for a twelve-month period individual treatment was 60,000€ (Campillo, García and Bernal 2016, 977). Hence, the Spanish government established a restrictive criterion according to which only 50% of HCV patients would receive the Sovaldi™ drug (Ortega and Vicioso, 2015) and allocated 125 million euros for delivering the treatment to those patients who met the eligibility criterion (Campillo, García and Bernal 2016, 977).

In February 2015, the EMA approved a combination of drugs, the Harvoni™, which was also used for treating HCV with great success. The Spanish government decided to buy this product as well, establishing in this case an expenditure ceiling of 70 million euros (Campillo, García and Bernal 2016, 978). Afterwards, in March 2015, a committee summoned by the Ministry of Health designed the *Strategic Plan for Tackling Hepatitis C in the Spanish National Health System* (PEAHC) (2015). This document encouraged national authorities to shorten the length of time necessary for HCV patients to receive the novel treatments.

Throughout this period of negotiations, patients' expectations and pressures to be treated had been escalating, leading to the creation of a protest platform in early 2015, called 'Platform for Those Affected by Hepatitis C'. This platform, in conjunction with the 'National Federation of Liver Patients and Transplants', started organizing demonstrations and sit-in strikes with patients and their families at a number of public hospitals to show their growing impatience with the treatment delivery arrangements (Campillo, García and Bernal 2016, 978).

Likewise, political parties, such as Podemos and UPyD began to demand from the Spanish government to invoke the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). By applying the provisions of this international regime, the Spanish government would have been entitled to grant a compulsory licence for Sovaldi™ or Harvoni™ treatments, thus opening the door to generic production of the drugs (Ortega and Vicioso 2015). Although this would have been a legitimate solution to the crisis, the government rejected the proposal and continued seeking an agreement with Gilead.

Finally, after a nine-month period of negotiations between the Ministry of Health and Gilead (Campillo, García and Bernal 2016, 977), a substantial reduction of the initial price was achieved. Hence, soon it was announced that every patient would have access to the treatments regardless of the gravity of their case (Perez 2017). However, the initial

imposition of an eligibility criterion nonetheless ran counter to the country's Constitution and was also the cause of numerous avoidable deaths (El Mundo 2015).

### **Explaining the Spanish Government's Management of the Policy Issue**

The protection granted to Sovaldi™ and Harvoni™ by the European Patent System generates an 'above the state' form of governance; while both the 'Platform for Those Affected by the Hepatitis C', and the 'National Federation of Liver Patients and Transplants' structure a 'below the state' form of governance. In addition, each of the actors involved – Gilead, civil society associations and the state – is driven by their own interests.

As a pharmaceutical company, Gilead is a *profit-seeker*. Thus, its main objective is to maximize its profits, and its great bargaining power emanated from the protection that the European Patent granted to Sovaldi™ and Harvoni™.

When it comes to the 'Platform for Those Affected by the Hepatitis C', and the 'National Federation of Liver Patients and Transplants', their main interest is that the Hepatitis C patients receive the novel treatment, and its bargaining power emanated from their *agenda-setting* power: first, they captured public attention (e.g. by staging successive demonstrations throughout the country); then, they gathered and disseminated information (e.g. the legal means that existed in order to bypass the firm's price-setting power); and finally, they formulated appropriate ways to proceed in that situation (granting a compulsory licence and starting to produce a generic drug) (Knill and Lehmkuhl 2002).

Regarding the Spanish state, its main interest is public welfare, especially since it presents itself as a 'welfare state'. Thanks to the TRIPS Agreement and its compulsory licensing mechanism, this actor acquired significant bargaining power (World Trade Organization 2006).

As a result, even though there existed a common interest in the distribution of the good among the public, the means proposed for doing so were quite different. Hence, while the state demanded affordable prices to guarantee the population's right to health, Gilead sought to maximize its profits.

This agreement problem could have evolved into a defection problem had the Spanish state decided to make use of the TRIPS Agreement and set in motion the generic production of the drug. In such a case, the private actor may have decided to no longer contribute to the provision of the good (Knill and Lehmkuhl 2002, 61) and to cut off trade relations with Spain. However, on the other hand, the health of HCV patients would have been endangered by the absence of effective treatment, and the right to health granted by

the Spanish Constitution stipulates that no one shall be deprived of such treatment. In the end, by not applying the compulsory licensing tool, the Spanish government avoided an eventual deception problem, but it also acted against the article 43 of the country's Constitution and worsened the health of HCV patients.

## Conclusion

After analysing the events that took place in Spain in 2014, it can be concluded that the Spanish Hepatitis C crisis indeed exemplifies the Private Self-Regulation pattern of governance, as well as its consequences. The extremely high prices set by Gilead for its product generated an agreement problem between the public and private interests. The state, unable to provide the public good on its own and by trying to avoid the defection problem, reduced its role to complementing the existing governance and mediating between the conflicting interests. Hence, even though after the bargaining process every HCV patient received access to the treatment, many of those patients had by then reached further stages of their diseases because they were not able to immediately receive treatment, and some of them even passed away.

This case, however, also sheds light on a broader problem: the provision of services as important as public health – which in countries like Spain used to be managed by the state – increasingly depend on the decisions of private actors. The danger of this tendency is obvious, given that private actors are both profit-seekers and self-interested. Thus, they are unlikely to make the right decision for the general public, as they will always try to maximize their own benefits. On the other hand, the state is driven by public interest and looks out for the welfare of its population. Hence, the state is able to make decisions regardless of the economic benefit they may generate. For this reason – and while accepting globalisation as an unstoppable phenomenon – it is necessary to strengthen international regimes, such as the TRIPS Agreement, and to encourage states to apply them when necessary. To sum up, sometimes, the only way to preserve fundamental human rights is to force the economic interests to yield.

## References

- Abbott, Kenneth and Duncan Snidal. 2009. "The Governance Triangle." In *The Politics of Global Regulation*, edited by Walter Mattli and Ngaire Woods, 44-88. Princeton: Princeton University Press. <https://doi.org/10.1515/9781400830732.44>.
- Alonso, Adrián. 2015. "Marketing Analysis for New-Generation Medicines for Hepatitis C." Bachelor Thesis. [https://ddd.uab.cat/pub/tfg/2015/133550/TFG\\_aalonsovivanco.pdf](https://ddd.uab.cat/pub/tfg/2015/133550/TFG_aalonsovivanco.pdf) (29 October 2017).

- Brahm, Eric. 2005. "International Regimes". In *Beyond Intractability*, edited by Guy Burgess and Heidi Burgess. Conflict Information Consortium, University of Colorado, Boulder. Posted: September 2005. [https://www.beyondintractability.org/essay/international\\_regimes](https://www.beyondintractability.org/essay/international_regimes) (24 June 2019).
- Campillo, Carlos, Sandra García and Enrique Bernal. 2016. "The Merry-go-round of Approval, Pricing and Reimbursement of Drugs against the Hepatitis C Virus Infection in Spain." *Health Policy* 120: 975-981. <https://doi.org/10.1016/j.healthpol.2016.07.005>.
- El Mundo. 2015. "Afectados por la Hepatitis C Presentan una Querrela contra Ana Mato por 'Dejar Morir' a 4.000 Pacientes." <https://www.elmundo.es/salud/2015/01/12/54b2e32922601dce4e8b457b.html> (05 August 2019).
- Knill, Christoph and Dirk Lehmkuhl. 2002. "Private Actors and the State: Internationalization and Changing Patterns of Governance." *Governance*, 15, no. 1: 41-63. <https://doi.org/10.1111/1468-0491.00179>.
- La Caixa. 2016. "Hepatitis C: 'The New Battleground for Access to Essential Medicines.'" <https://www.isglobal.org/documents/10179/5353835/Informe+25+Hepatitis+C+eng/4fa21b0d-9199-4e99-9f0b-c056126a77eb> (24 May 2019).
- Ministry of Health, Social Services and Equality. 2015. *Strategic Plan for Tackling Hepatitis C in the Spanish National Health System*. 21 May. Madrid: Office of the Secretary for Health and Consumer Affairs. [https://www.mscbs.gob.es/ciudadanos/enfLesiones/enfTransmisibles/hepatitisC/PlanEstrategicoHEPATITISC/docs/PEAHC\\_eng.pdf](https://www.mscbs.gob.es/ciudadanos/enfLesiones/enfTransmisibles/hepatitisC/PlanEstrategicoHEPATITISC/docs/PEAHC_eng.pdf).
- Ortega, Eduardo and Jesús Vicioso. 2015. "Hepatitis C, Manual para Entender la Polémica." *Revista Médica* 226. <http://www.rmedica.es/edicion/226/hepatitis-c-manual-para-entender-la-polemica> (24 June 2019).
- Pérez, Oliva Milagros. 2017. "El Alto Coste de un Pelotazo Farmacéutico." *El País*. [https://elpais.com/elpais/2017/06/23/opinion/1498208958\\_256026.html](https://elpais.com/elpais/2017/06/23/opinion/1498208958_256026.html) (24 June 2019).
- Sagasti, Francisco and Keith Bezanson. 2004. "Global Public Goods: opportunities and threats." *The Courier* 202: 15-16.
- Spanish Constitution. 1978. [http://www.congreso.es/portal/page/portal/Congreso/Congreso/Hist\\_Normas/Norm/const\\_esp\\_texto\\_ingles\\_0.pdf](http://www.congreso.es/portal/page/portal/Congreso/Congreso/Hist_Normas/Norm/const_esp_texto_ingles_0.pdf).
- World Health Organization. 2019. "Hepatitis C". <https://www.who.int/hepatitis/topics/hepatitis-c/en/> (24 June 2019).
- World Trade Organization. 2006. "Philosophy: TRIPS Attempts to Strike a Balance." [https://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm01\\_e.htm#patent\\_right](https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm01_e.htm#patent_right) (24 June 2019).