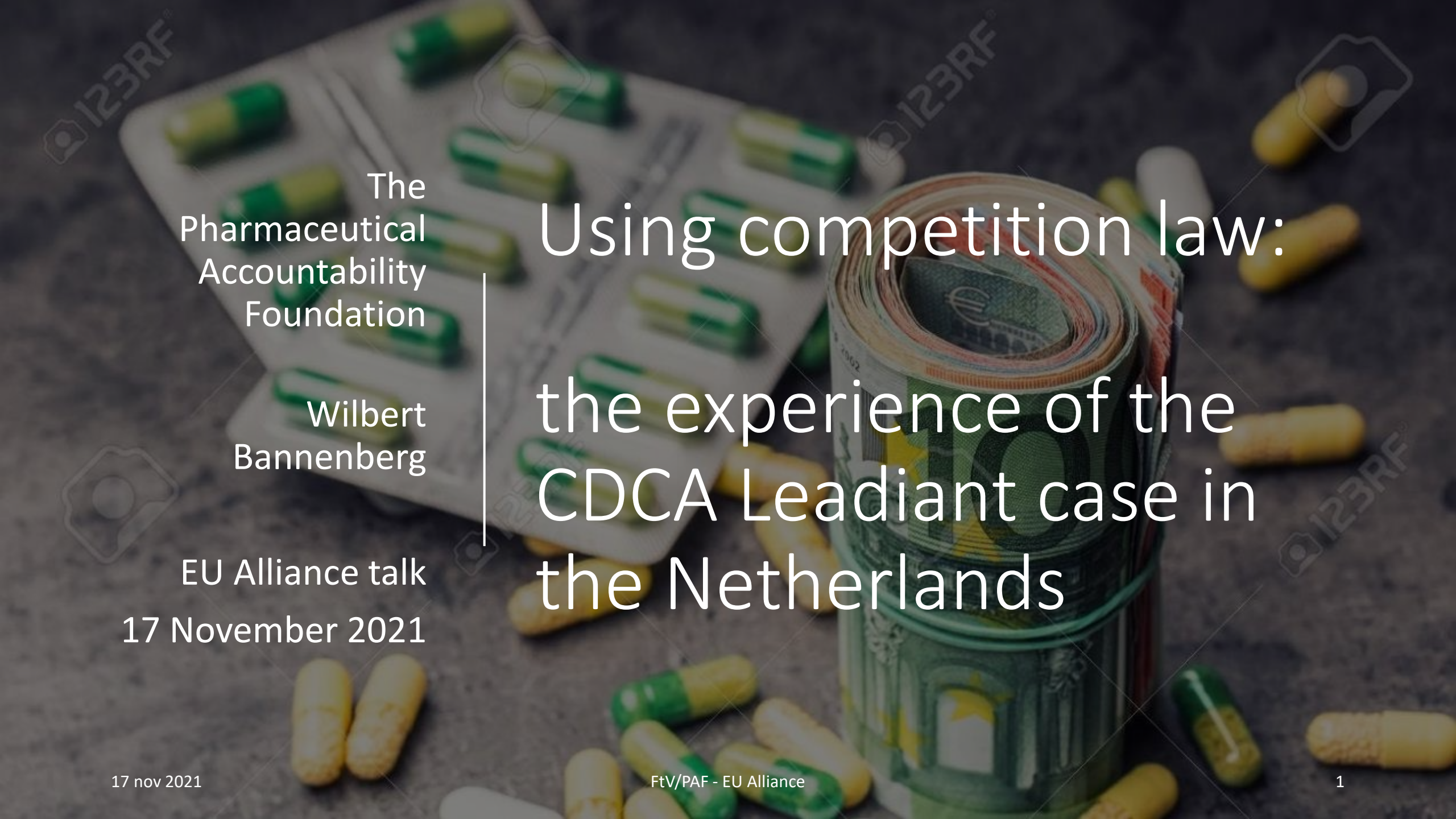


Using competition law:

the experience of the CDCA Leadiant case in the Netherlands

The Pharmaceutical Accountability Foundation

Wilbert Bannenberg

EU Alliance talk

17 November 2021

Pharmaceutical Accountability Foundation (Stichting Farma ter Verantwoording)

- Rationale: Medicine prices are rising exponentially due to patents, SPCs, orphan drug directive, and other market monopolies
- Foundation: doctors, lawyers, pharmaceutical experts and lobbyists
  - Board and Advisory Council composition on www.farmaterverantwoording.nl
  - Part of CIFA consortium; developed Good Covid-19 Company Practices
- Added value: legal procedures against pharma companies, using:
  - Unlawful Act / tort (Dutch Civil law)
  - Competition law
  - IP law
  - Human Rights / Right to Health & Essential medicines
- 102 possible targets identified
- NL for now, but collaboration with European & USA welcome

Our 1st case: CDCA Leadiant

- Chenodeoxycholic acid (CDCA) = human bile acid
  - marketed > 1976 for dissolving gall stones by Dr Falk, Germany.
  - Chenofalk ® cost 28 cents/capsule
- Only known effective therapy for Cerebrotendinous Xanthomathosis (CTX)
  - Affects 1:50,000. 65 cases known in NL, 10 in Belgium. Up to 1000 in EU?
  - Affordably prescribed off-label until 2009 for €308/patient/year
- Sigma-Tau (now Leadiant) buys (and kills) all existing generic products in 2008/9
  - Markets its own brand Xenbilox® at 15x, later 100x price in Germany
- CDCA Leadiant® received EU orphan drug status in 2016, EMA registration in 2017
  - EU Orphan drug law grants 10 years exclusive marketing rights
  - price increase 500x to €140/capsule; €153,300/CTX patient/year
  - USA: CDCA being developed by Retrophin (Travere Therapeutics): target $560,000/yr

CDCA case – how to fight an unjust monopoly

- Minister, Parliament, Drug Industry Association: this is misuse! Bla-bla…
  - But no specific law seems to have been broken…
- Emergency measure: **pharmacy compounding**
  - Amsterdam University Hospital compounds it for €30,000 /pp / year > 5 April 2018
  - Leadiant complained 18 May 2018 about this with Dutch Health Inspectorate
  - Raw material failed European Pharmacopoeia test; Hospital recalled product
  - Health insurers paid €11 million to buy Leadiant's CDCA
  - Amsterdam hospital resumed compounding January 2020 with improved CDCA raw material
- PAF: September 2018 complaint to Dutch Competition Law Authority (ACM)
  - Grounds: misuse of economic power position by Leadiant
  - Complaint published in Dutch/English
  - Belgium, Spain and Italian NGOs also complained to their Competition Authorities

It takes a while - 2.5 years…

Authority for Consumers & Markets

- 19 July 2021: ACM issues Leadiant a fine of €19.6 million
- So far only a summary report (legal battle Leadiant-ACM)
- ACM: Leadiant charged … an **excessive price**… that was **exorbitantly high** because the **price** in combination with the **low costs** and **the low risks** resulted in **exorbitant return.**
- **…unfair** because the drug, under a different trade name, had already been on the market for years at a **much lower price**, while patients **benefitted very little** from the registration as an orphan drug.
- PAF and health care insurers **planning civil case** against Leadiant for €11 million damages(NL)
- Belgium, Spain & Italian Competition Authorities?

Misuse of dominant/economic power position Aspen – EU case

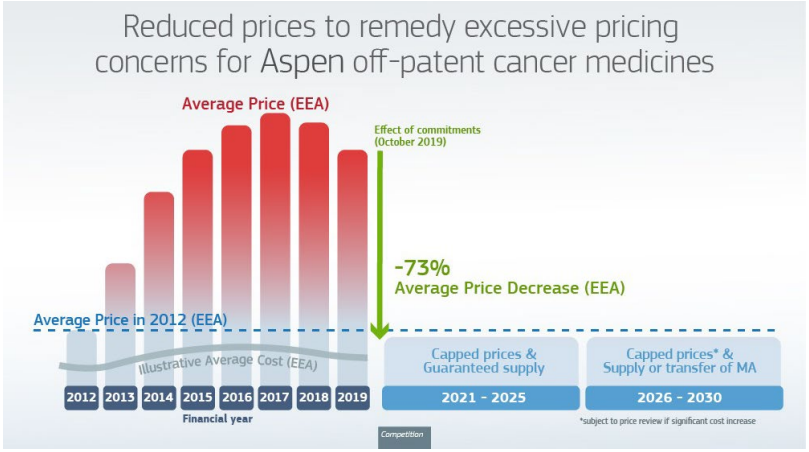
Problem / issue

- 6 old generic cancer medicines
- On WHO list essential medicines
- Obtained from GSK in 2012
- Price 3-7x higher
- Threat to remove product from market

- https://ec.europa.eu/commission/presscorner/detail/en/ip_21_524
- https://europeanlawblog.eu/2021/05/20/the-curious-case-of-aspen-pharmaceuticals-and-excessive-pricing/
- http://competitionlawblog.kluwercompetitionlaw.com/2021/06/01/learning-the-lessons-on-excessive-pricing-from-aspen/

Solution

- EU Competition Law investigation 2017-2021
- Feb 2021: Aspen agreed to
  - Reduce price 73%, fixed for 10 years
  - Keep products 5 years in market, thereafter sell with fair pricing clause



Lessons learned

- Bringing a Competition case is affordable, but **takes ages**
- Competition cases can stop **excessive prices**
  - But evidence and procedures are difficult for Competition Authorities
  - Not suitable in a pandemic?
- The '**pharma pirate**' business model does no longer pay off
- **Pharmacy compounding** is a useful emergency solution
- Better definition of '**fair pricing**' is needed in legislation
- EU orphan legislation needs to be **revised**

Questions? Discussion? Webinar!

- Webinar 22 Nov 1500-1630: Power of Law. How can NGOs Promote Access to Medicines through Legal Procedures?

Contact?

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Extra slides with possibly useful info (not presented)

EU Commissioner support

- *“Take medicines for rare diseases. It can make sense to give companies an exclusive right to sell such what is known as "orphan drugs" if that's the only way to make a treatment available to patients.*
- *But there's **no need to give that protection** if pharmacies already have effective alternatives that are in line with general practice, well-known and safe.*
- *That's why the Commission has made it clear that in the future, companies **won't necessarily get exclusive rights** to sell their product in that case.*
- *And like that, **pharmacies and other suppliers can compete** with their own treatments for rare diseases.”*
- Margrethe Vestager (EU commissionar competition law)
  - Speech in Copenhagen, 20 augustus 2018, NorWHO conference
  - https://ec.europa.eu/commission/commissioners/2014-2019/vestager/announcements/making-markets-deliver-essential-medicines_en

Some amendments for EU Orphan Directive

- **Repurposing of old products** as an orphan drug without adding scientific value should not qualify for an orphan registration (needs EU law change)
- **Removing generic competitors** that provide affordable (off-label) treatment should be investigated by competition authorities
- Orphan 10 years Marketing exclusivity should have an **escape clause** if enough profit made (like Compulsory Licensing in patent law)
- There should be a **fair pricing** clause in the contracts for orphan drug manufacturers before they get 10 year exclusive rights
- There should be **transparency** in R&D costs and compulsory publication of clinical trials used for getting the EMA registration