TO THE PUBLIC PROSECUTOR OF THE REPUBLIC OF FRANCE JUDICIAL TRIBUNAL OF PARIS

COMPLAINT
"REMDESIVIR"

ARTICLE 40 OF THE CRIMINAL CODE

COMPLAINANT:

REACTION 19, a non-profit association established in accordance with the French law of 1901, registered at the Prefecture with number W751256495, situated at 63 rue la Boétie 75008 in Paris and chaired and represented by Mr. Carlo Alberto Brusa and Mr. Riccardo Mereu.

AGAINST:

1. GILEAD SCIENCES Inc., a company incorporated under U.S. law headquartered at 333 Lakeside Drive Foster City, CA 94404, USA, acting through its legal representative.

2. The World Health Organization, a specialized international agency in accordance with the Charter of the United Nations, headquartered at 20 Avenue Appia in Geneva, Switzerland, acting through its legal representative;

3. The European Commission located at rue de la Loi, B-1049 BRUSSELS BELGIUM, acting through its President;

4. The European Medicines Agency, a decentralized agency of the European Union with headquarters at Domenico Scarlattilaan 6, 1083 HN AMSTERDAM, THE NETHERLANDS.

5. The Minister of Solidarity and Health headquartered at 14 Avenue Duquesne 75007 PARIS.

6. Any named person that the investigation will reveal.

CHARGES:

- **Conspiracy to defraud and criminal association** (Article 313-1 and following of the Criminal Code)
- **Deception** (Article L213-1 of the Consumer Code)
- **Failing to fight a disaster** (Article 223-7 of the Criminal Code) ;
- **Endangering the life of others** (Article 223-1 of the Criminal Code)

HAS THE HONOR OF EXPOSING

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The RÉACTION 19 Association, which has nearly 55,000 members and more than 70,000 sympathizers, has been informed by many citizens of a very worrying situation regarding treatment choices and recommendations during the COVID-19 epidemic in France.

The RÉACTION 19 Association intends to denounce, through the present complaint, the actions of political leaders and health authorities who participated, *via* the European Commission, in the placement of two massive orders with GILEAD SCIENCES for REMDESIVIR, commercially known as VEKLURY®, a manifestly ineffective treatment that is also dangerous for people's health, representing over one billion euros.

II. OVERVIEW OF THE CASE

I.1 CONTEXT: THE COVID-19 EPIDEMIC AROUND THE WORLD

The Covid-19 epidemic is the result of an emerging infectious disease, called Coronavirus 2019 or Covid-19, caused by the coronavirus SARS-CoV-2, which is believed to have appeared in Wuhan on November 17, 2019, in Hubei Province (Central China), before spreading to the rest of the world[1] .

On February 20, 2020, after having spread to Asia, the epidemic reached Europe.

On March 11, 2020, the outbreak of Covid-19 was declared a pandemic by the WHO[2] .

Most of the world's leaders have taken unprecedented restrictive measures.

This global pandemic has led to a series of cancellations of sporting and cultural events around the world, the implementation by many countries of containment measures to curb the formation of new outbreaks of contagion, the closure of borders in many countries, and a stock market crash due to the uncertainties and fears it has brought to the global economy.

[1] Xingguang Li, Junjie Zai, Qiang Zhao, Qing Nie, Yi Li, Brian T. Foley et Antoine Chaillon, " Evolutionary history, potential intermediate animal host, and cross-species analyses of SARS-CoV-2 ", Wiley, vol. 92, no 6, 27 février 2020, p. 602-611 (PMID 32104911, DOI 10.1002/jmv.25731)(print:June 2020) ; Kristian G. Andersen, Andrew Rambaut, W. Ian Lipkin, Edward C. Holmes et Robert F. Garry, " The proximal origin of SARS-CoV-2 ", Nature Medicine, vol. 26, no 4, 17 mars 2020, p. 450-452.

[2] Le Monde with AFP, " Aéroports fermés, mesures de confinement... le monde s'organise face à la pandémie ", Le Monde, March 12, 2020 (read online [archive], accessed March 12, 2020).
(en) Jamie Gumbrecht, "WHO declares novel coronavirus outbreak a pandemic" [archive], on CNN.

On May 21, 2020, more than 5,000,000 cumulative cases are said to have been confirmed worldwide, with more than 2,000,000 recovered people and more than 330,000 deaths[3].

In this context, finding a drug likely to reduce the mortality rate of this emerging disease appeared to be a health, economic and political challenge.

I.2 THE COVID-19 EPIDEMIC IN FRANCE

The epidemic declared in WUHAN quickly affected France.

On February 26, 2020, the French government announced three hospitalizations:

- In Paris, a 33-year-old Franco-Chinese woman who had returned from China on February 7th;
- In Annecy, a 64-year-old Frenchman, who had returned from Lombardy, Italy;
- In Compiègne, a 55-year-old soldier from the Creil military base was transferred to Amiens University Hospital in "serious condition".

After a health campaign recommending hygienic "*barrier gestures*" and physical distancing, Emmanuel Macron, President of the Republic, announced the decision to implement the first national lockdown on Monday evening, March 16, 2020 during an address to the Nation.

He repeatedly indicated that France was at "*war*" with Covid-19, claiming that the country, at "Stage 3" of governmental health measures, was in the midst of a growing epidemic[4].

Thus, by law n° 2020-290 of March 23, 2020, the first state of health emergency was established across the national territory of the Republic, as of March 24 and was extended until July 10, 2020.

[3] "Coronavirus: more than five million Covid-19 infections detected worldwide since the beginning of the epidemic" [archive], on sudinfo.be, 21 May 2020 (accessed 21 May 2020).

[4] "Emmanuel Macron announces a ban on non-essential travel as of Tuesday noon" [archive], on Marianne, March 16, 2020 (accessed March 16, 2020); Cédric Pietralunga and Alexandre Lemarié, "Nous sommes en guerre" : face au coronavirus, Emmanuel Macron sonne la "mobilisation générale" [archive], on lemonde.fr, March 17, 2020 (accessed June 3, 2020).

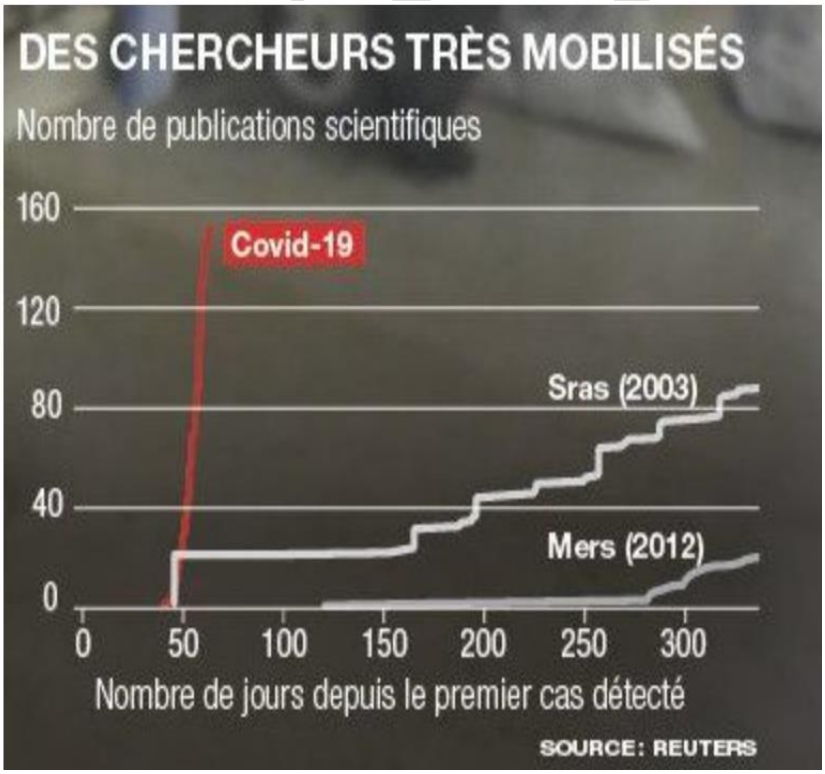
On this basis, numerous measures restricting liberties were implemented by decree during what is now commonly known as the *"first lockdown".*

"These restrictive measures are supposed to delay the spread of the virus as much as possible, and save time in finding a treatment," said Bruno Lina, head of the International Centre for Research in Infectious Diseases (Ciri) in Lyon.

Law n° 2020-856 of July 9, 2020 ended the state of health emergency which was then re-established by the decree n° 2020-1257 of October 14, 2020.

I.3 CONTROVERSY SURROUNDING TREATMENT

After the Covid-19 genome was made public by Chinese scientists on January 10, 2020, scientists around the world embarked on an unprecedented race for treatments:



In the end, two treatments were considered for treating Covid-19: hydroxychloriquine (***A)*** and REMDESIVIR (***B),*** the former ultimately being discarded in favor of the latter.

I.3.1 Ban on prescribing hydroxychloroquine as a treatment for COVID-19

1. Definitions

Chloroquine is an antimalarial drug of the 4-aminoquinoline family which has been widely marketed in the form of salts (sulphate or phosphate).

Together with quinine, of which it is a synthetic substitute, and hydroxychloroquine, a closely-related molecule, it is the **most widely used** treatment in **the history of malaria medicine**, both **preventively** and **curatively**.

It is also widely used against autoimmune diseases such as lupus and rheumatoid diseases such as rheumatoid arthritis.

It shows antiviral effects *in vitro,* but cannot be reproduced in *vivo* or only with difficulty.

It was marketed in France and the USA in 1949 under the trade name Nivaquine in France.

Chloroquine has been on the World Health Organization's list of essential medicines since 1977.

Its safety profile is considered so high that in March 2020, the Centre de Référence sur les agents tératogènes (CRAT) estimated that it could be prescribed to pregnant women at **all stages of** pregnancy, regardless **of its indication**[5] .

2. An inexpensive, potential treatment for COVID-19 with few side effects

The Covid-19 pandemic in early 2020 rekindled interest in chloroquine and hydroxychloroquine as potential antivirals, while studies on SARS in 2002 appeared to show their *in vitro* efficacy[6] .

[5] https://lecrat.fr/spip.php?page=article&id_article=441

[6] - Vincent, M.J., Bergeron, E., Benjannet, S. et al. Chloroquine is a potent inhibitor of SARS coronavirus infection and spread. Virol J 2, 69 (2005) ;
- Els Keyaerts, Leen Vijgen, Piet Maes, Johan Neyts, Marc Van Ranst, In vitro inhibition of severe acute respiratory syndrome coronavirus by chloroquine, Biochemical and Biophysical Research Communications, Volume 323, Issue 1,2004,Pages 264-268 [archive]

As early as February 2020, scientists examined and discussed the measurement of their *in vivo* efficacy against the SARS-CoV-2 virus responsible for the Covid-19 pandemic.

This research was not new, as a team of eight scientists, including five from the U.S. CDC, published a study in *Virology Journal* on August 22, **2005** demonstrating the positive effects of chloroquine on the SARS-CoV virus.

Exhibit 71 "Chloroquine is a potent inhibitor of SARS coronavirus infection and spread", *Virology Journal,* August 22, 2005

Starting on February 20, 2020, chloroquine and later hydroxychloroquine were widely promoted in France after Professor Didier Raoult and his team from the University Hospital Institute of Infectious Diseases of Marseille (IHU Méditerranée Infection) [7] presented very encouraging results.

Hydroxychloroquine thus appeared to be a particularly effective treatment option in this emergency context because it had manageable side effects and was rapidly available and inexpensive.

3. The publication of a fallacious study in the medical journal THE LANCET

- On May 22, 2020, quite surprisingly, and even though this treatment had been used by **millions of people for nearly 70 years**, THE LANCET, the most prestigious and recognized medical journal, published a study allegedly conducted on 96,000 patients.

This first large-scale study claimed that chloroquine and hydroxychloroquine would not be effective against Covid-19 in hospitalized patients and worse still, these molecules would even increase the risk of death and cardiac arrhythmia.

While many clinical trials were testing the effectiveness of this treatment, hopes for it seemed dashed, given the scale of the study and the reputation of the journal.

Exhibit 1: Merah et al. retracted study from the LANCET of 22.05.2020

[7] https://www.youtube.com/watch?v=mJl2nPHAo2g&t=31s

The spectacular impact of the publication of this study was such that many countries, including France, immediately stopped chloroquine treatments.

So much so that the WHO itself immediately suspended its clinical trials on the subject.

It should be pointed out at this stage that the authors of this study refused to make the raw data of their work public, making it impossible for the scientific world to verify their data.

- Nevertheless, in the days following the publication of the study, many scientists raised serious doubts about the integrity of the study, citing a lack of ethical review, inconsistencies in the doses administered in some countries or in the comparison between the data cited and those produced, as well as ethical questions about the collection of the information.

Indeed, the summary analysis of the study data revealed glaring inconsistencies, such as patient populations reported in the study that had similar patterns of obesity or diabetes, whether they were African or North American, or the fact that the number of deaths reported in the "*Australia"* section far exceeded the official death toll of Covid-19 announced by the Australian government at the time of publication in the medical article.

Exhibit 2: "Game over" for hydroxychloroquine: An intellectual swindle by Le Club de Mediapart of 28.05.2020

Exhibit 3: For Didier Raoult's right hand man, The Lancet study on Hydroxychloroquine is a farce

Thus, as of May 28, 2020, more than 120 researchers from around the world published an open letter to the Lancet criticizing the methodology of this study and asking the authors to disclose their sources along with their preliminary assessments.

Exhibit 4: Open Letter: The statistical analysis and data integrity of Mehra et al_Final of 28.05.2020

In the days that followed, the authors maintained their position: They recognized an error in the data but not in the conclusions leading to the dangerousness of the molecule.

- SURGISPHERE, the American company which appears to have provided the main data that made it possible to carry out this large-scale statistical study covering more than five continents in record time, is also in the crosshairs for its role.

Indeed, the tiny company behind the data used in the massive LANCET study reported that it had access to data from over 570 hospitals worldwide. However, these hospitals denied sharing even the slightest data with SURGISPHERE.

Furthermore, this company is unknown in the world of *Big Data* and has no notoriety in this field.

The GUARDIAN raised these questions in an investigation dated June 3, 2020 which showed that indeed two employees of SURGISPHERE had little or no scientific training, one is an author of science fiction novels and the other, presented as "marketing director", is in fact an adult-content model and events hostess.

The GUARDIAN notes that SURGISPHERE's LinkedIn page has less than 100 followers and mentions only six employees, and that the company has virtually no online presence.

Exhibit 5: The GUARDIAN Article of June 3, 2020

- On June 4, 2020, faced with the scale of the international scandal now known as *"Lancetgate",* The LANCET announced the **total retraction of the** study published on May 22, 2020.

Exhibit 6: "The Lancet" announces the retraction of its study on hydroxychloroquine, by Le Monde on June 4, 2020.

Professor Merah made a public apology and indicated that he conducted his **study without ever having access to the raw data, although this was the**

essential foundation of the research.

Exhibit 7: Professor Merah's apology in the LANCET of 13.06.2020

Exhibit 8: "I am really sorry" The mea culpa of the coordinator of The Lancet's study on hydroxychloroquine - Le Parisien

The editor of *THE LANCET* medical journal said:

> ***"This is a shocking example of scientific misconduct in the midst of a global health emergency.***

- The amateurism with which this study was carried out raised questions around the world. The international press claimed the publication of the *"falsified study"* was a real *"scandal"* rooted in blatant corruption.

Moreover, the identity of the people who financed this study, which was ultimately unanimously recognized as **fraudulent,** remains unknown.

Exhibit 9: LancetGate: Saga of a Corrupted Study by Les Échos

Exhibit 10: Game Over for the controversial study of the Lancet doubting hydroxychloroquine by Le Figaro

Exhibit 11: "LancetGate": Surgisphere, The company that provided the data under study, are they for real? by France Soir

Exhibit 12: LancetGate: Surgisphere Season 1 Episode 3 The Fall, by FranceSoir

As a result, less than two weeks after its publication, an international consensus deemed the study was fraudulent.

4. Prohibition of all curative uses and research on hydroxychloroquine

However, the health authorities, particularly the French ones, who immediately banned the use of chloroquine on the basis of this obviously fraudulent study, never realized any useful consequences from this scandal.

This excessive caution was however completely unjustified.

On May 24, 2020, the High Council of Public Health and the French Medicines Agency (ANSM), without any verification, based its decision to discourage the use of the chloroquine derivative in the treatment of patients with COVID-19 on **this blatantly fraudulent study** despite the criticism.

Exhibit 13: Negative opinion of HCSP and ANSM of 24.05.2020

Three days later, treatments were stopped and ongoing clinical trials, including those conducted by Europe and the WHO, the DISCOVERY and SOLIDARITY trials, were all suspended.

On the same day, the Minister of Health and Solidarity, Mr. Olivier VERAN, outright banned the prescription of this molecule by city doctors or hospitals in the fight against COVID-19.

Exhibit 14: HYDROXYCHLOROQUINE: Press Release from the Ministry of Solidarity and Health of May 27, 2020

Worse still, following the retraction of the LANCET study by its authors, this prescription ban was not questioned and the DISCOVERY trials did not resume **despite the request - on June 4, 2020 - of those in charge**!

Exhibit 15: Discovery trial may again include Hydroxychloroquine following green light from the competent authorities, INSERM press release of June 4, 2020

And yet, many studies show a positive effect of taking hydroxychloroquine, associated or not with a macrolide, at the onset of COVID-19.

Exhibit 20: Analysis of 192 studies around the world showing high efficacy for early HCQ treatment

Nevertheless, despite the voluminous scientific research published at the end of 2020, no consensus has yet been reached on the lack of efficacy of hydroxychloroquine.

Moreover, no study has shown that this molecule is dangerous.

In this context, it seems astonishing, to say the least, that **on October 23, 2020,** the ANSM still refused to grant a temporary recommendation for the use of hydroxychloroquine for the treatment of COVID-19.

Therefore, although the government based its decision to ban the use of chloroquine and its derivatives on a **fraudulent** study **without any precautions or verification,** it must be noted that the revelation of the fraudulent nature of this study did not prompt the government to reconsider the ban.

The French decision to suspend all research on this molecule with the DISCOVERY trials was never reconsidered.
This is all the more unjustified since the RECOVERY trial, led by Oxford University, and the SOLIDARITY trial, led by the WHO, had both resumed inclusion as of June 3, 2020, i.e. immediately after the LANCET study was withdrawn.

Exhibit 16: RECOVERY Trial: Letters in favor of including hydroxychloroquine, from May 24, 2020

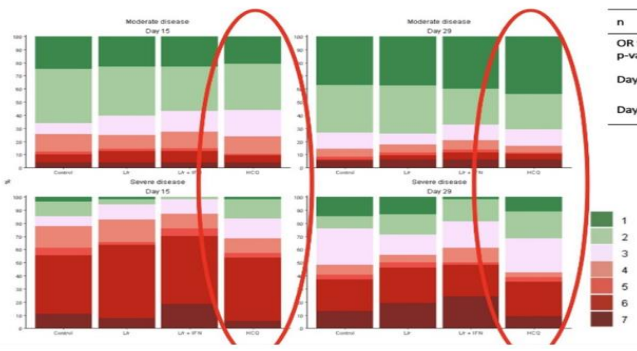
Exhibit 17: Covid-19 The WHO reconsiders its opinion on hydroxychloroquine

Moreover, the scientists behind the clinical trial DISCOVERY never officially released the results of their work on hydroxychloroquine when it was stopped.

Only Dr. Peiffer Smadja, member of the steering committee of the clinical trial DISCOVERY, tweeted the excerpts of the results:

DISCOVERY

Primary end-point : 7-point ordinal scale



n	151	148	149	150
OR 95% CI p-value	Control (SoC)	L/r	L/r + IFN	HCQ
Day 15	Ref	0.86 [0.57-1.31] p=0.491	0.73 [0.48-1.11] p=0.141	0.93 [0.62-1.41] p=0.742
Day 29	Ref	0.92 [0.61-1.4] p=0.703	0.79 [0.52-1.2] p=0.275	1.20 [0.79-1.81] p=0.395

L/r, lopinavir/ritonavir
L/r + IFN, lopinavir/ritonavir + interferon β-1a
HCQ, hydroxychloroquine
SoC, standard of care
Calculated from ordinal logistic regression model adjusting for baseline severity.
For these models, the clinical score is reversed so that ORs > 1 are in favour of active treatment groups.

Proportions calculated based on the database extracted on June 30th, 2020 following interruption of 3 treatment arms

These graphs showed that **hydroxychloroquine had a positive effect,** but the findings were not considered statistically significant due to the low number of patients enrolled in this arm of the trial.

Exhibit 18: "Discovery: French research, serious misconduct along with medical misconduct?" by France Soir

These initial results make the refusal to reincorporate hydroxychloroquine into clinical trials even more incomprehensible.

The French HYCOVID trial was also suddenly stopped as it too was showing very encouraging results for the treatment.

Exhibit 19: Reinforming the French about the results of the studies. Independent Audit Required

As a result, the French authorities deliberately refused to reinstate research on hydroxychloroquine:

- Research was halted hastily and on the basis of a scandalous, fraudulent study that was ultimately retracted by its authors who issued public apologies ;

- They refused to take into account the likely positive effects that had been scientifically demonstrated.

<u>In doing so, the French authorities deliberately deprived the people of France and the world of an effective treatment devoid of serious risks.</u>

This decision is all the more surprising since, at the same time, it delivered a conditional TUR (Temporary Use Recommenation) to GILEAD SCIENCES for its REMDESIVIR despite unfavorable data on the safety and efficacy of this drug.

Exhibit 21: ANSM refusal notice for HCQ TUR of October 21, 2020

I.3.2 REMDESIVIR (VEKLURY®) misrepresented as a safe and effective treatment

1. Definition

REMDESIVIR (code GS-5734) is a monophosphate derivative of an adenine nucleoside analog created by GILEAD SCIENCES.
It was used rather unsuccessfully against the Ebola virus during the 2013-2016 epidemic in West Africa.

Indeed, **it did not show any particular effectiveness against filoviruses**, the family of viruses responsible for Ebola, in particular. Treatments based on monoclonal antibodies, such as mAb114 (en) and REGN-EB3, have shown greater efficacy.

Exhibit 72 NIHDirector's Blog

GILEAD SCIENCES had never obtained any marketing authorization for this molecule, for which it had funded the research and development, and had never been able to market it until now.

2. A treatment presented as likely to treat COVID-19

In January 2020, based on its *in vitro* and *in vivo* activity on MERS-CoV and SARS-CoV[8] [9] coronaviruses, the French High Council of Public Health identified the antiviral REMDESIVIR as a likely drug treatment to be evaluated for Covid-19.

It was studied on SARS-CoV-2 following an encouraging result with a COVID-19 patient.

Together with chloroquine and lopinavir/ritonavir, it was one of the three drugs considered to be the most promising against SARS-CoV-2 following a Chinese study published on February 4, 2020 where it was combined with chloroquine, and yielded significant results exclusively[10] *in vitro*.

[8] Timothy P. Sheahan, Amy C. Sims, Rachel L. et al., " Broad-spectrum antiviral GS-5734 inhibits both epidemic and zoonotic coronaviruses ", Science Transactional Medicine, vol. 9, no 396, 28 juin 2017, article no eaal3653

[9] T. Sheahan et al., " Comparative therapeutic efficacy of REMDESIVIR and combination lopinavir, ritonavir, and interferon beta against MERS-CoV ", NatureCommunication, 2020.

[10] Manli Wang, Ruiyuan Cao, Leike Zhanget al., " REMDESIVIR and chloroquine effectively inhibit the recently emerged novel coronavirus (2019-nCoV) in vitro ", Cell Research, vol. 30, no 3, 4 février 2020

On March 18, 2020, the same Chinese team reported another study demonstrating the *in vitro* efficacy of hydroxychloroquine.

Exhibit 22: Hydroxychloroquine, a less toxic derivative of chloroquine, is effective in inhibiting SARS-CoV-2 infection in vitro

3. The unjustified enthusiasm of the health authorities for this treatment despite serious side effects.

As early as March 5, 2020, even before the COVID-19 pandemic was declared, the High Council of Public Health (HSCP), in its opinion on the management of confirmed cases of infection with the SARS-CoV-2 virus, **exclusively** recommended the use of REMDESIVIR in **severe forms of** COVID-19, in these terms:

> *"Therapeutic Options:*
>
> *To date, in line with the conclusions of the WHO issued in January 2020 and pending the results of clinical trials on COVID-19 that will validate a specific therapeutic option, the specific treatment to be favored, in accordance with a compassionate approach (framed by article L31-31-1 of the Public Health Code) is REMDESIVIR in severe forms.*
>
> *[…]*
>
> *c) Infection with the SARS-CoV-2 virus with signs of severity at the outset: Reminder of severity criteria (See chapter 4.4)*
>
> *- **treatment with REMDESIVIR is to be preferred,** as it is the only formalized therapeutic option (cf. 7.1)".*

Let us recall that on that date:

- There were no clinical studies to enable anyone to predict the efficacy and safety of REMDESIVIR in patients with COVID-19.

- That the known elements showing REMDESIVIR's efficacy against the SARS-CoV-2 virus were *in vitro* only;

- That hydroxychloroquine's powerful antiviral effect was proven *in vitro,* and that contrary to REMDESIVIR, its safety was already known due to its use for treating various pathologies for nearly 70 years.

However, on March 11, 2020, the High Council of Public Health maintained its recommendation "on a *compassionate basis",* for serious cases of Covid-19, while recalling in a complementary opinion of March 23, 2020:

> *"The safety data available for this drug, at this stage, is mainly derived from data published on its clinical development for treating patients infected with the Ebola virus"*;

It is also noted in this report:

> *"Follow-up of patients treated with REMDESIVIR should include close clinical monitoring for possible injection reactions (including hypotension) and monitoring of renal and hepatic function consistent with the risk profile of the patient.*
>
> ***In non-clinical studies, it has been shown to be toxic to the kidneys and in clinical studies, transient increases in ALT and/or AST have been reported**.*

Exhibit 23: HCSP Notice of March 23, 2020

The High Council of Public Health seemed to be satisfied with the effects of this treatment and was concerned by the highly undesirable effects on kidney function.

However, on the same date, in the United States, Zhang Zuofeng, professor of epidemiology and associate dean of research at the School of Public Health at the University of California at Los Angeles (UCLA), considered the effects of the drug to be **scientifically unconvincing *in vivo*** and called for further research.

Exhibit 24: More tests required for the antiviral REMDESIVIR in the treatment of coronavirus, Zhang Zuofeng

At any rate, from that date on, **one thing became clear. Not only was REMDESIVIR unable to reduce mortality, it was also nephrotoxic.**

Exhibit 25: REMDESIVIR, an antiviral treatment named desire? by France 24

Exhibit 27: Wang et al. study, THE LANCET, April 29, 2020

In addition, according to a notice issued by the HCSP dated May 15, 2020, the HCSP considered that:

> *"After analyzing and taking into account **data from the literature available as of May 31, 2020** on the efficacy and safety of REMDESIVIR for the treatment of patients with Covid-19, **this data is insufficient to estimate this treatment's risk-benefit ratio based on the severity of Covid-19**."*

Exhibit 28: HCSP Notice of May 15, 2020

In spite of this, the molecule became the one and only one recommended in the development of a treatment for COVID-19.

4. Marketing authorizations granted to REMDESIVIR despite an unfavorable risk-benefit ratio

Despite the limited data available to demonstrate the efficacy of the treatment, on June 25, 2020, the European Medicines Agency (EMA) announced that it had granted a conditional Temporary Use Authorization (TUA) for REMDESIVIR, making it **the first treatment officially approved by a health authority for the treatment of COVID-19.**

In order to continue to benefit from this authorization, this conditional TUA required GILEAD SCIENCES to provide mortality data **by August 2020** and to submit its final report by the end of December 2020.
However, that data and that report were never provided.

The EMA therefore granted a marketing authorization for a specialty drug in the absence of literature and sufficient data on its efficacy and safety.

Exhibit 30: EMA TUA of June 25, 2020

This position is in every way contrary to the attitude adopted for hydroxychloroquine.

5. France and the European Commission scandalously place massive orders for this dangerous, expensive and clearly ineffective drug in July 2020

Starting on June 30, 2020, GILEAD SCIENCES began selling REMDESIVIR in the United States at the exorbitant price of **$3,100 per treatment**!

This price was considered by many to be very high when compared to its production costs and **low efficacy**.

Exhibit 31: Coronavirus. Treatment at REMDESIVIR will be billed up to $3,120 in the United States by Ouest France.

At the same time, a French study co-signed by Professor Yazdan YAZDANPANAH, head of Infectious Diseases at the Bichat Hospital and member of the scientific council, reported that of the first five French patients treated with REMDESIVIR, four did not tolerate the planned treatment and two ended up with severe kidney failure requiring **an emergency kidney transplant**.

REMDESIVIR therefore had life-threatening side effects.

Exhibit 32: Case Study of the First Five COVID-19 Patients Treated with REMDESIVIR in France

This study therefore confirms the side effects mentioned by the HCSP in its above-mentioned report of March 23, 2020.
On July 15, 2020, despite the known dangers and the absence of demonstrated efficacy, the Agence française de Santé du médicament (French Agency for Drug Health), following the favorable opinion of the European Medicines Agency (EMA) dated July 3, 2020, also granted a cohort TUA for the drug REMDESIVIR, so that patients could benefit from it in France.

Exhibit 34: REMDESIVIR TUA from July 15, 2020 by ANSM

On July 8 and 22, 2020, the French National Authority for Health (Haute Autorité de Santé) evaluated this drug on the basis of preliminary data provided by GILEAD SCIENCES in the context of its request for health care reimbursement of the specialty drug filed on July 3.

In an opinion **that was not made public until September 17, 2020,** it was reported that as early as July 22, 2020, the French High Authority for Health **had qualified the** effectiveness of REMDESIVIR as ***"weak*".**

This draft opinion was communicated **directly to GILEAD** so that it may assert its right to rebuttal.

It was under these circumstances that GILEAD initially requested a hearing before the Commission, **before retracting and withdrawing its application for reimbursement without any explanation.**

Exhibit 35: Haute Autorité de Santé - Press Release on REMDESIVIR of September 17, 2020

It is clear that GILEAD SCIENCES was hoping that the High Authority of Health would not publish its negative preliminary opinion, which would have called into question the negotiations underway with the European Commission in particular.

On August 31, 2020, GILEAD withdrew its request after learning, **before the public,** of the provisional conclusions of the HAS health transparency commission (CT)**.**

Notwithstanding, **on July 29, 2020,** the European Commission, claiming a risk of shortages, signed a contract with the pharmaceutical company GILEAD SCIENCES to guarantee access to treatment doses of VEKLURY®, the new brand name of REMDESIVIR.
The Commission's emergency aid fund financed the contract for a total amount of **€63 million**, or €2,100 per dose.

Exhibit 36: European Commission Ensures EU Access to REMDESIVIR for

The company therefore requested a counter-examination and then withdrew its request so as to quell the public stance of the HAS and thus avoid jeopardizing the contract with, and knowingly hide the conclusions from, the European Commission.

It must also be noted that the information the HAS had in its possession was not communicated to the European authorities.

6. The authorities ignore the ineffectiveness of REMDESIVIR

On **September 4, 2020**, **following the publication of a meta-analysis,** the WHO published guidelines in which **it advised against using REMDESIVIR in all COVID-19 indications.**

Exhibit 37: A living WHO guideline on drugs for Covid-19 of September 4, 2020

The WHO's position is devoid of any ambiguity.

Why wasn't the European Commission aware of the impending arrival of the results of this meta-analysis and why didn't it wait to have the WHO's conclusions on September 4, 2020 before signing the first contract? It must be noted that the epidemic in Europe was slowing down in August and no one knew if it would pick up again. There was therefore no urgency.

Moreover, on September 16, 2020, several months after having noted the ineffectiveness of this treatment, the HAS made its conclusions public, namely:

- **Refusal** for reimbursement in the treatment of patients aged 12 years or older and weighing at least 40 kg, hospitalized for COVID-19 with pneumonia requiring high-flow oxygen therapy, or oxygen therapy during non-invasive or invasive assisted ventilation or extracorporeal membrane oxygen therapy (ECMO);

- **Approval** for reimbursement only in the treatment of patients aged 12 years or older and weighing at least 40 kg, hospitalized for COVID-19 with **pneumonia requiring low-flow oxygen therapy** and at the dosages stipulated for the marketing authorization, with the **condition that GILEAD submit data at D-28, namely the mortality data from the American ACTT study as soon as it was available and by no later than October 31, 2020.**

Exhibit 38: HAS CT Notice of September 16, 2020

On **October 8, 2020,** the results of the final analysis of the ACTT-1 study were also published[11].

Exhibit 26: Final Report. New England Journal of Medicine, October 8, 2020

The final analysis of the data confirmed the results of the preliminary analysis with a statistically significant effect demonstrated on the 5-days reduction in the clinical recovery period (10 days versus 15 days; HR = 1.29 [1.12-1.49]), in the overall population **but without proven impact on mortality at day 28**.

Even worse: the subgroup analyses suggested a statistically significant difference in the clinical recovery time **only in patients requiring low intake oxygen therapy** (**only** 7 days versus 9 days).

No data as regards the effect of Remdesivir on the viral load was available.

However, exactly the same day, namely on 8 October 2020, the European Commission, again, signed a new joint procurement framework contract with the pharmaceutical company Gilead for the supply, this time, of up to 500,000 treatment courses of Veklury, the brand name for Remdesivir, and the opportunity to increase supply beyond the 500,000 treatment courses.

And this even though the signatory countries to the first agreement, including France, could not even have disposed of the previous stock, as will be demonstrated below.

[11] John H. Beigel et al. REMDESIVIR for the Treatment of Covid-19 - Final Report. N Engl J Med. 8 octobre 2020

All EU countries, Iceland and Norway, the United Kingdom as well as six candidate countries and potential candidates (Albania, the Republic of North Macedonia, Montenegro, Serbia, Bosnia and Herzegovina and Kosovo) were parties to the joint procurement agreement, namely 36 signatories, including France.

Thus, the contract was worth above EUR 1 billion.

Exhibit N. 39: Press release of the European Commission

This contract, having extremely significant financial interests, was therefore concluded by the European authorities in the fullest lack of knowledge of scientific studies and of international consensus at that date relating to the ineffectiveness or even the danger of Remdesivir.

7. Beyond ineffectiveness, manifest knowledge of the dangers of Remdesivir

Unlike hydroxychloroquine, known information on Remdesivir was particularly lacking, as most of the publications were written either directly by Gilead or by collaborators remunerated by the latter.

Worse, the first publications on the use of Remdesivir at the time of the Ebola outbreak show not only its proven lack of effectiveness but also data incomplete, to say the least, as to its side effects.

In this respect, Barbara F. Young, editor in chief at the American Society of Health-System Pharmacists, an American foundation offering pharmacovigilance carried out by pharmacists, explained:

> *"The first human safety data for Remdesivir came from the Ebola virus treatment setting, where the nucleotide analogue and polymerase inhibitor drug had what one called* ***an "acceptable safety profile****", although it was not more effective than other experimental options tried.*
>
> *The only adverse events reported in this trial were deaths, and the only one adjudicated as possibly related to Remdesivir was one case of hypotension followed rapidly by cardiac arrest."*

The pharmacist then added about the noted side effects:

> *"It was **surprising** when these came out; there was a very short side effects list. It is either the safest drug there is, or..."*

Exhibit. 64: REMDESIVIR Safety Forecast_ Watch the Liver, Kidneys _ MedPage Today

In fact, Remdesivir is made of products known for their toxicity.

Indeed, Remdesivir is a nucleotide analogue and many nucleotide analogues are known for their toxicity (such as, in particular, the infamous AZT, major treatment for HIV in the late 1980s).

Moreover, the Remdesivir molecule on the PubChem website is labelled with a "HEALTH Hazard" pictogram, which shall be understood as *"hazard to health".*

Exhibit N. 65: REMDESIVIR _ C27H35N6O8P - PubChem

The hazard is, in any case, established by the warnings contained in the manufacturers' safety data sheet.

The safety data sheet warns about the major toxicity of the product: acute toxicity, skin corrosion/irritation, serious eye damage/irritation, respiratory or skin sensitization, germ cell mutagenicity, reproductive toxicity, specific target organs toxicity (unique exposure), specific toxicity of target organs (repeated exposure).

Exhibit n. 66: Safety Data SHEET REMDESIVIR

Thus, the proprietary medicinal product features all the potential damages to be found in the most toxic nitriles.

As regards the precautions to take when handling these products, the manufacturer states that leather should not be used because the product pierces the leather and that rubber clothing must be washed immediately after use.

The manufacturer recommends the use of an oxygen mask as the product attacks the pulmonary epithelium.

Exhibit N. 67: Material Safety Data Sheet

Exhibit N. 68: Data SHEET GS 441524 sds-AG167808

Hence, the substance toxicity was manifest.

However, Gilead Laboratory opposes the low dosage (< 3 mg/kg/day) as well as the short duration of exposure to minimise the toxicity with regard to the supposed benefit.

By way of reminder, no benefit has been demonstrated.

On the other hand, it was precisely because of its toxicity and side effects that Gilead sought the use of Remdesivir only in the COVID-19 late phase.

Thus, the side effects and the toxicity of the molecule could be "confused", at that late stage, with COVID-19 damages, so to delay the attribution of serious complications to Remdesivir.

It is noteworthy that the Phase III trial published in the NEJM carefully avoids giving the final mortality rate (at 28 days) per Veklury (Remdesivir) compared to placebo, which is particularly striking.

Exhibit N. 69: Remdesivir for the treatment of Covid-19 nejmoa2007764

Furthermore, in France, the toxicity of this product was highlighted as soon as a study was published, on 6 July 2020, on the first patients treated with Remdesivir at the Bichat Hospital, study which reported serious side effects:

> *"This case series of five COVID-19 patients requiring intensive care unit treatment for respiratory distress and treated with Remdesivir, highlights* ***the complexity of Remdesivir use in such critically ill patients****. Remdesivir was interrupted for* ***side effects in four patients, including*** *two ALT elevations (3 to 5 N) and two renal failures requiring renal replacement".*

Exhibit N. 32: Case reports study of the first five COVID-19 patients treated with Remdesivir in France

All these data should have been verified by health authorities as well as politicians in order to avoid the damages suffered by treated patients.

8. The new order of millions of doses by the European authorities in disregard of the scientific studies proving the Remdesivir ineffectiveness and the inconsistencies of the French authorities

- On 15 October 2020, the general public became aware that Remdesivir was ineffective and dangerous

The results announced on 15 October 2020 by the WHO as a preprint of the Solidarity Trial did **not reveal any effect of the medicinal product compared to standard care** on mortality among hospitalised patients for COVID-19.

It was thus official that this medicinal product was costly, dangerous and ineffective.

However, it turns out that Gilead Sciences Laboratory had been informed of the study results as early as 23 September 2020, that is to say, a few days before Gilead Laboratory signed the second procurement contract with the European Commission, which will get to know the results only on **10 October 2020.**

Exhibit N. 40: Preprint SOLIDARITY of 15 October 2020

Once again, Gilead Sciences Laboratory was able to take full advantage of the timeline in order to conceal from its counterparty, which was, to say the least, not very observant, the inside information available to it on the effects of the product sold.

- In a contradictory way, the Ministry and the French National Agency for Medicines and Health Products Safety (ANSM) nonetheless encouraged the caregivers to order Remdesivir

It was at that precise time that the Ministry of Health took the most questionable path.

On **21 October 2020**, a rapid alert message from the Ministry of Health and Solidarity signed by the Director-General for Health, the Director-General for healthcare and the Secretary-General of the Minister for Social Affairs was sent to all the directors of healthcare facilities stating that:

> "*In order to ensure that patients have access to this treatment in the epidemiological context linked to COVID-19, the doses of Veklury® allocated by the European Commission, which are currently stored by SpF, are made available to hospital prescribers from week 42 in order to meet therapeutic needs not otherwise covered. […]*
>
> ***The proprietary medicinal product VEKLURY ® is distributed free of charge to healthcare facilities."***

The same document stated, however:

> *"This proprietary medicinal product was granted a cohort Temporary Authorisation for Use (ATU) in the same course, which will* ***be interrupted by the National Agency for Medicines and Health Products Safety as of 23 October 2020****."*

Exhibit n. 41: INSTRUCTION N° DGS/CORRUS/PP2/DGOS/PF2/2020/174 of 21 October 2020

Thus, the Ministry of Health and Solidarity proposed that a medicinal product should be made available "*free of charge*" where he knew that it would no longer hold a prescription authorisation because of its manifest ineffectiveness and the unfavourable risk-benefit ratio.

Also, it is debatable the meaning of the *term "free of charge*" used in the mentioned Ministerial Instruction, since it is known that Gilead Sciences Laboratory has never offered to donate its treatment, whether for clinical research or public health purposes.

Above all, however, what is most perplexing is the sudden and coordinated pressure from the Ministry and the ANSM to want to dispose at all costs of the Remdesivir stocks a few days before its ban.

- The health authorities in France have withdrawn the Remdesivir authorisations in complete discretion

On 23 October 2020, the FDA definitively approved Remdesivir as emergency treatment for COVID-19 patients in the United States, so making the Gilead Sciences product the first and only treatment against COVID-19 approved in the United States.

In France, on the same day, the French National Authority for Health (*Hauté Autorité de santé* - HAS) took note of the fact that Gilead Sciences Laboratory withdrew its application for reimbursement from the national solidarity of the proprietary medicinal product Remdesivir on 31 August 2020, that is to say, **one month and 23 days later**.

Even less understandably, on **24 October 2020**, the ANSM withdrew the cohort ATU to the proprietary medicinal product Remdesivir **in complete discretion** by simply updating the list of the product information sheet on its website, **and without the slightest official communication**.

The public was never informed of the change in the proprietary medicinal product administrative status by the national media outlets, except for the notable exception of the newspaper *France Soir*.

Exhibit N. 44: ANSM withdrawal of Remdesivir cohort ATU of 24 October 2020

The withdrawal did not, however, prevent Gilead Sciences Laboratory, with the approval of Dominique Martin, who recently resigned from his position as Director of the ANSM, from sending **promotional e-mails** for Remdesivir as of **23 October 2020** to all pharmacists and hospital doctors and from organising its "*free of char*ge" distribution, as revealed by Professor Didier Raoult in a Tweet on the same day.

Exhibit N. 45: Promotional letters Gilead Science with the agreement of ANSM

Once again, Gilead Sciences Laboratory, the ANSM and the Ministry of Health acted in concert to encourage prescribing agents to order a **manifestly ineffective and dangerous proprietary medicinal product, no longer having any marketing authorisations.**

- It will take a very late WHO's positioning for the scandal to finally come to public attention

On **30 October 2020,** the newspaper *France Soir*, reported:

> "*The FDA (Federal Drug Administration) decision and the deal with the EU, which came about under **unusual circumstances**, gave Gilead Company significant advantages.*
>
> *The FDA never consulted a group of outside experts who is at the ready to weigh in on complex antiviral drug issues.*
>
> *That group, the Antimicrobial Drugs Advisory Committee (ADAC), brings together infectious diseases clinicians with biostatisticians, pharmacists and a consumer representative to review all available data on experimental treatments and to make recommendations to FDA about drug approvals, **yet it has not convened once during the pandemic.***
>
> *Meanwhile, the European Union, **decided to set the Remdesivir price exactly one week before the disappointing the Solidarity trial results were published**.*
>
> *It was unaware of those results, although Gilead, as trial promoter, began to examine the WHO data **on 23 September** and **knew the trial was a bust**."*

Exhibit N. 46: Article, France Soir of 30 October 2020

Faced with the lack of response from health authorities and public officials, it was the European Society of Intensive Care Medicine that decided to take the first step on 13 November 2020, in the light of the Solidarity trial outcomes **disclosed**, stating **that the medicinal product should not be routinely used in COVID-19 patients, as there is no evidence that it improves survival or reduces the need for ventilation and that it may have serious side effects.**

Exhibit N. 47: Worlds's top intensive care body advises against Remdesivir for sickest patients, Reuters

Finally, it was not until 20 November 2020 that the WHO had to officially declare Remdesivir ineffective in the treatment of COVID-19, in the light of the **Solidarity trial** results which demonstrated the lack of effectiveness of this treatment in this course and the **possibility of significant side-effects involving the patients vital prognosis**, as well as **its complexity and particularly high cost.**

However, it's already too late, the contracts have already been concluded.

Exhibit N. 48: WHO recommends against the administration of Remdesivir in COVID-19 patients

Exhibit N. 49: Following the agreement at EUR 1 billion between the EU and Gilead, WHO points out the dangers of REMDESIVIR, RT France.

Exhibit N. 49a: Solidarity clinical Trial Results

9.The extraordinary profit made by Gilead Laboratory and the colossal loss to public finances

Between 31 January 2020 and 30 April 2020, the Gilead's share price increased by USD 25 after a peak by more than 10 % of its market capitalisation following the American study dated April 2020.

Exhibit N. 50: Evolution of the share price over a year

Exhibit N. 51: Gilead Sciences + 10 %, after a study in favour of Remdesivir against COVID-19

However, an analysis of Gilead's share price shows a steady decline in the outstanding amount as from 20 July 2020, proof that investors knew that Remdesivir would not keep its promises.

As regards the contract concluded on 8 October 2020 by the European Commission, it cannot be revised and its price is definitively paid.
To date, the European Commission has shown no intention to challenge the agreement before an international court.

The Laboratory clearly concealed key information from the European Commission in such a way as to convince it to conclude a financial agreement and will therefore clearly not be concerned.

Ultimately, European taxpayers, including France and its residents, will have to bear the cost of this major deception.

10.The manifest prior agreement to cover up a health and financial scandal

- The silence of the press

Since March 2020, information on the health crisis had been piling up, with the media and the government showing their intention to inform the general public, by means of daily and then weekly press conferences.

It is therefore all the more surprising to observe that public communications on the developed facts and relating to the management of COVID-19 treatments have been, to say the least, discrete, late or even non-existent.

Apart from the newspaper *Le Monde* on 27 November 2020, only the newspaper *France Soir* reported on the Remdesivir case.

Exhibit N. 52: COVID-19 conflicting studies on the Remdesivir effectiveness

Thus:

- On 1 June 2020, the newspaper *France Soir* questioned the role played by Gilead Sciences, including in *The Lancetgate.*

Exhibit N. 53: LancetGate_ what is the role of the Gilead laboratory, which is developing Remdesivir _ LancetGate _?

- On 4 June 2020, the newspaper *France Soir* revealed connection links between Gilead Laboratory and the authors of the study retracted from the Lancet.

Exhibit N. 54: from coincidence to coincidence, the Boston connection serves Remdesivir?

- On 18 June 2020, the newspaper *France Soir* criticised Gilead "wheeling and dealing" marketing.

Exhibit N. 54a: Clinical trials on the Remdesivir, the wheeling and dealing of Gilead and The Lancet

- On 5 July 2020, *France Soir* raised the question whether the European Medicines Agency was endangering our health, and **EMA's Director-General replied not being the right person to speak about this drug.**

Exhibit N. 55: Remdesivir: does the European Medicines Agency endanger our health?

- On 8 July 2020, *France Soir* warned about the toxicity of this medicinal product and questioned whether Gilead Sciences had not hidden its toxicity.

Exhibit N. 56: Did the Gilead company hide the true toxicity of Veklury© (REMDESIVIR) _

- On 20 October 2020, the newspaper *France Soir* denounced *"double standards"* in treatment strategy choices.

Exhibit N. 57: COVID-19_double standards for the treatments. Unfair

The real-time reporting by a newspaper with limited human and financial resources of this European scandal, involving a sum of more than EUR 1 billion, raises the question of how the information is handled by the media outlets.

The fact that this newspaper is systematically discredited and accused of conspiracy by its peers also raises the question about the role of these peers in the present health crisis.

These questions will have to be clarified by an investigation, in order to restore French people confidence in their media outlets, which are the guarantors of freedom of expression and the right to information, and thus a pillar of democracy.

- On TV sets: a series of doctors who do not declare their interest links

Throughout the health crisis, many healthcare professionals have been appearing on television and clearly promoting Remdesivir, without, however, taking the trouble to declare any conflict of interest, as provided for by law.

Examples include Doctor Gilbert Deray, Professor of Medicine and Head of the **Department of Nephrology** at the Pitié-Salpêtrière Hospital, claiming, in particular, both on television and on Twitter that he has no conflict of interests and that Remdesivir is not nephrotoxic.

Exhibit N. 58: Gilbert Deray's Twitter of 26 June 2020

However, the Health Transparency Database (*base transparence santé*) indicates that various laboratories pay more than EUR 160,000 in addition to a partnership agreement between Gilead and LVDG Company, of which Mr Deray is a partner, for almost EUR 50,000.

Moreover, the Remdesivir nephrotoxicity is at the time of public knowledge, a factor which a nephrologist cannot disregard.

Exhibit N. 59: Statutes LVDG

Exhibit N. 60: Health Transparency Database LVDG Gilead

Doctor Karine Lacombe, Head of the Infectious Diseases Department of Saint-Antoine Hospital, in Paris, spoke out on television on numerous occasions in favour of Remdesivir, which she regularly considered "very promising" without ever taking the trouble to indicate that she had significant interests linking her and the laboratory holding the patent.

Exhibit N. 61: Remdesivir is an encouraging treatment according to Professor Karine Lacombe on RTL on 30 April 2020

In fact, the Health Transparency Database shows over EUR 227,130 in benefits of various laboratories, including EUR 31,044 provided by Gilead Group, without the person concerned ever deeming it useful to mention it during her very numerous appearances on TV.

Exhibit N. 62: Euros For Docs Lacombe GILEAD

Many other doctors have done the same without ever having been questioned by the Medical Council (*Conseil de l'Ordre*), whose wrongful failure to act is very suspicious when it is known that this professional authority is responsible for ensuring compliance with the Health Transparency Law on the obligations to declare conflicts of interest.

It may also be noted that journalists never took the trouble to question their guests on their possible interest links when the latter were invited to express their views on the treatments.

Thus, it is established that:

- The treatment with hydroxychloroquine was banned on the basis of a fraudulent study;

- Despite the scandal on the study, this treatment has never been reintroduced either as a treatment or in clinical trials;

- In parallel, a barely known treatment, namely the Remdesivir, has been widely acclaimed despite its serious side effects;

- The uncontested scientific studies, calling this treatment into question, have been hidden and/or ignored;

- All these facts point to a prior agreement between the public authorities, or even a wrongful failure to act.

All these findings characterise infringements of exceptional seriousness.

II. THE ACTS COMMITTED TO THE DETRIMENT OF THE PERSONS REPRESENTED BY REACTION 19 ASSOCIATION CONSTITUTE CRIMINAL OFFENCES OF PARTICULAR SERIOUSNESS

The facts as set out above constitute several criminal offences which Réaction 19 Association intends to denounce.

II.1 THE HUGE SWINDLING COMMITTED IN AN ORGANISED GROUP

Article 313-1 provides for and punishes the offence of swindling:

> *"Swindling is the act of deceiving a natural or legal person, either by the use of a false name or a fictitious capacity, by the abuse of a genuine capacity, or by means of unlawful manoeuvres, and thereby to lead such a person, to his prejudice or to the prejudice of a third party, to transfer funds, valuables or any property, to provide a service or to consent to an act incurring or discharging an obligation.*
>
> *Swindling shall be punished by five years' imprisonment and a fine of EUR 375,000."*

II.1.1. Use of fraudulent practices

The method used by both Gilead Laboratory and the public authorities to market and impose on patients a treatment that is as ineffective against COVID-19 as it is dangerous to health was carried out in several stages:

- ***STAGE 1: the unjustified ban of the only treatment competing with Remdevisir, namely Hydroxychloroquine***

  - On 22 May 2020, a study now unanimously recognised as fraudulent, highlighted the alleged danger of hydroxychloroquine;

  - Mr Olivier Veran, Ministry of Health, banned the delivery of hydroxychloroquine treatment, the alternative to Remdesivir, relying on the conclusions of a manifestly fraudulent study and did not review the mentioned ban following the withdrawal and apology from its authors;

- The ANSM and the French High Council for Public Health (*Haut Conseil de la santé publique,* HCSP) blithely relied on the study published on the Lancet to advise against the use of this treatment, whereas many researchers indicated that a mere medical student could see that the study was fraudulent;

- The ANSM knowingly prevented the resumption of the Discovery Trial on the chloroquine arm while a leak of its preliminary outcomes (which have never been officially made public) later indicated that chloroquine has a positive effect.

➢ ***STAGE 2: the enshrining of Remdesivir, namely a treatment unanimously recognised as ineffective or even dangerous***

- As of 23 March 2020, although the issue of Remdesivir effectiveness was still pending, its toxicity on kidney functions in particular was established and noted by the HCSP;

- On 15 May 2020, the HCSP acknowledged that it was impossible at that stage to estimate the treatment effectiveness;

- The first French patients who received the treatment suffered proven renal damages;

- No scientific consensus has ever demonstrated any effectiveness of Remdesivir in the COVID-19 treatment;

- On 22 July 2020, the French National Health Authority (*Haute Autorité de Santé*) found the drug to be *"weak"* in the COVID-19 treatment but did not publish its opinion until 17 September 2020;

- However, the Commission's Emergency Support Instrument, of which France is a party, financed a contract for the supply of millions of Remdesivir doses;

- On 4 September 2020, the WHO preliminary report has highlighted the Remdesivir ineffectiveness and sent its report to Gilead;

- Gilead Laboratory deliberately concealed WHO's conclusions;

- On 8 October 2020, the European Commission ordered more than 500,000 Remdesivir treatment courses from Gilead for several billion euros without inquiring about scientific studies on this treatment;

- On 15 October 2020, the WHO released a new preliminary report in line with the one dated 4 September 2020.

- On 30 October 2020, the WHO advised against Remdesivir use and prescription.

➢ ***STAGE 3: Manipulation of public opinion and pressure brought to healthcare professionals to prescribe Remdesivir***

- On 21 October 2020, the ANSM and Ministry of Health sent instructions to healthcare professionals to encourage them to place orders for a proprietary medicinal product when they knew that it would no longer have a marketing authorisation and was ineffective and dangerous to patients' health;

- Gilead Laboratory acted in concert and with the approval of the Director of the ANSM at the time, Mr Dominique Martin (**who resigned on 27 November 2020**), at the very least to send emails on 23 October 2020 to healthcare professionals with the aim of pushing them to prescribe Remdesivir;

- Doctors have appeared on numerous television programs claiming that Remdesivir was neither toxic nor pointless without declaring their interest links to the laboratory and without being questioned by the Medical Council (*Conseil de l'Ordre des Médecins*);

- Hardly any of the most widely circulated newspaper dealt with the Remdesivir subject, but, on the contrary, they discredited the investigative journalists and whistle-blowers who denounced the scandal in real time, by accusing them of conspiracy when they spoke about the medical-financial scandal in progress;

- On the contrary, in a climate of anguish due to the global health crisis, the media have widely reported an alleged shortage of Remdesivir treatment.

It is therefore established that a ploy thus characterising the fraudulent practices referred to in Article 313-1 of the French Criminal Code has been implemented.

II.1.2 Practices that played a decisive role in the Remdesivir purchase, put into market and prescription

It is clear that, without these fraudulent practices, the European Commission and the authorities would in no way have purchased millions of vials from Gilead Laboratory.

By unjustifiably banning chloroquine, the Remdesivir treatment was mispresented as the only treatment that could treat COVID-19, thus granting an undisputable monopoly to Gilead Laboratory.

Furthermore, the failure to take into account serious and uncontested scientific studies attesting Remdesivir lack of effectiveness has enabled the European Commission to legitimise in the eyes of the public opinion a staggering order, which is devoid of any meaning.

Without this unjustified attitude, not in line with the public health objectives which these agencies are supposed to pursue, Gilead Laboratory would never have succeeded in concluding the framework procurement contract, concluded with the European Commission for the massive supply of Remdesivir.

II.1.3 The considerable damage suffered and the profit made by Gilead Laboratory

In July 2020, the European Commission placed an order for over 30,000 doses of Remdesivir, to be redistributed in the Member States, including France.
The amount of this first transaction exceeded EUR 63 million.

On 8 October 2020, more than 500,000 treatments courses were ordered by the European Commission for EUR 2,000 per dose.

The damage suffered as a result of this second order far exceeds EUR 1 billion.

However, these treatments will never be administered, since a few days later, the WHO will strongly advise against its use in the COVID-19 treatment.

At the same time, Gilead generated a net profit of USD 360 million in just a few months.

II.1.4 The swindling offence was committed by an organised group

Article 313-2, paragraph 2, provides for the aggravating circumstance relating to the action carried out by an organised group:

> *"The penalties shall be increased to ten years' imprisonment and a fine of EUR 1,000,000 where the fraud is committed by an organised group".*

The concept of organised group is defined in Article 132-71 of the French Criminal Code:

> *"An organised group within the meaning of the law is any group formed or any agreement established with a view to the preparation, characterized by one or more material facts, of one or more offences"*

In the light of all the above, it is clear that a real prior agreement was essential to the scheme implementation and the fraudulent practices that made it possible to characterise the swindling offense.

All these actions therefore appear to be manifestly coordinated and constitute fraudulent practices designed to mislead public opinion and the European Commission in order to lead it, to the prejudice of all the Member States and hence their nationals, to submit funds through the conclusion of a framework procurement contract for Remdesivir to the benefit of Gilead Pharmaceuticals Group.

The aggravating circumstance of organised group is thus consistent in the present case.

II.2 The crime of deception

Article L213-1 of the French Consumer Code provides:

> *"Anyone, whether or not a party to the contract, who has deceived or attempted to deceive a party to the contract, by any means or practice*

whatsoever, even through a third party, shall be liable to a term of imprisonment of up to two years and a fine of EUR 300,000:
1° Either on the nature, kind, origin, essential qualities, composition or content of necessary ingredients of any goods; or

2° Either on the quantity or identity of the things supplied, by supplying a good other than the specific thing that formed the subject matter of the contract; or

*3° **Either on the suitability for use, the risks inherent in the use of the goods, the controls carried out, the instructions for use or the precautions to be taken**.*

The amount of the fine may be increased, in proportion to the advantages derived from the offence, to 10 % of the average annual turnover, calculated on the basis of the last three annual turnovers known on the date of the facts".

II.2.1 The material element of the deception offence

In order to be characterised, the offence of deception presupposes the use of means intended to deceive others.

In the present case, the Gilead Laboratory was aware of the Solidarity Trial outcomes concluding that its proprietary medicinal product was ineffective in the COVID-19 course as of 23 September 2020, that is to say several days before the date on which the procurement contract with the European Commission was concluded, which, a priori, did not know the official results until 10 October 2020.

Gilead Laboratory also withdrew its application for reimbursement of its proprietary medicinal product in France on 31 August 2020 after becoming aware of the opinion which had not been disclosed on **22 July 2020** and requested an adversarial procedure before the French Health Transparency Commission of the High Authority for Health *(Commission de la Transparence Santé de la Haute autorité de santé française)*, that is to say, just before the conclusion of the agreement signed on 28 July 2020 by the European Commission.

By such processes, Gilead Pharmaceutical Group therefore intentionally misled the other party to the contract, the European Commission, as to the ability of its product to treat populations for COVID-19, in order encourage it to order its proprietary medicinal product.

Moreover, even though it had committed itself to doing so, Gilead Laboratory deliberately failed to provide the counterparties with data on mortality and dangers of its product.

Finally, it will be pointed out that Gilead used fraudulent practices designed to suggest, prior to any order, the possible scenario of a Remdesivir shortage.

Such remarks, widely reported by the international press, created a certain distress over the entire international community, leading to a real battle in order to be able to acquire Remdesivir.
In addition to having the European authorities to conclude the contract, such practices had the effect of allowing Gilead Laboratory to set its prices unilaterally.

Thus, the European Commission agreed to pay that treatment at the rate of USD 390 per vial, that is to say EUR 2,100 for a dangerous treatment that is not at all effective.

Gilead justified such a price by the interplay of supply and demand and by *"an earlier hospital discharge [which] would result in hospital savings of approximately USD 12,000 per patient*".

Researchers in the United Kingdom, the United States and Australia have shown that the Remdesivir total manufacturing cost is around 0,93 dollar per vial, namely USD 5,58 for treatment course of six vials, that is 420 times cheaper than the price set by Gilead.

II.2.2 The moral element of the deception offence

In the present case, it is clear that Gilead Laboratory deliberately omitted to provide key information on the treatment ineffectiveness but also on its dangerous side effects.

WHO itself alleged that Gilead was aware as of September 2020 of the Solidarity clinical trial outcomes, namely the very basis of the WHO's decision to advise against Remdesivir use.

It was for the sole purpose of misleading the European Commission about its product that Gilead acted so.

The deception offence is characterised in all respects.

II.3 The crime of abstention from combating a harm

Article 223-7 of the French Criminal Code provides:

> *"Anyone who voluntarily abstains from taking or initiating measures, which involve no risk to himself or to third parties, to combat a harm likely to create a danger to the safety of persons shall be punished by two years' imprisonment and a fine of EUR 30,000."*

II.3.1 The material element of the offence

It is apparent from the factors set out above that hydroxychloroquine was considered, from the beginning of the epidemic, as one of the antiviral treatments that could be administered for any COVID-19 condition.

Such treatment has been known for more than 70 years and has been delivered to millions of people worldwide and has never been called into question for its dangerous or disproportionate side effects.

However, this treatment, immediately available for millions of persons, and, in addition, very inexpensive, was thrown into the wind by the study published in The Lancet medical journal on 22 May 2020.

It is clear that the mentioned study created a real scandal in that it was deliberately based on misleading data.

However, it was on the basis of this study, and only a few days after its publication, that the WHO and then France simply banned the hydroxychloroquine prescription in the COVID-19 treatment.

Manifestly scientifically unfounded, the study has since been withdrawn.

Nonetheless, the French government and health authorities continue to ban its prescription in the COVID-19 treatment, without, however, providing any scientific justification for this decision.
And for good reason, it emerges from the data published by the Steering Committee member Nathan Peiffer-Smadja that the first results of the Discovery clinical trial have highlighted a relative rate of effectiveness.

Finally, to date, <u>there is no treatment able of treating Covid-19</u>, so that if, on the one hand, uncertainties persist on the actual hydroxychloroquine effectiveness, as with all other treatments however administered, on the other hand, no study demonstrates a risk-benefit ratio allowing the molecule to be banned.

It is in that sense that the Italian Council of State decided in its judgment dated <u>7 December 2020</u>:

> **"Persistent uncertainty as to the therapeutic efficacy of** hydroxychloroquine, as declared by AIFA itself to justify the further evaluation in randomised clinical trials - **is not a sufficient legal reason to justify the unreasonable suspension of its use on national territory by the treating physicians**."

Exhibit N. 70: judgment of the Italian Council of State dated 7 December 2020

Consequently, in the absence of proven treatment against COVID-19, the failure to withdraw the ban on prescription, which could get patients to receive, under **<u>medical prescription</u>**, a potential treatment against this virus characterises the material element of the offence referred to above.

II.3.2 The moral element of the offence

In view of the state of scientific knowledge on the subject and also of the fact that many countries around the world restarted with hydroxychloroquine prescriptions, it is clear that the refusal to withdraw the ban prescription in France is necessarily deliberate.

The French authorities cannot reasonably ignore that, by acting in this way, they are depriving patients of the possibility of treating a condition which is presented as particularly dangerous.

The offence is characterised in all its elements.

II.4. The crime of endangerment of the life of others

Article 223-1 of the French Criminal Code provides:

> *"The direct exposure of another person to an immediate risk of death or injury likely to cause mutilation or permanent disability by the manifestly deliberate infringement of a specific obligation of prudence or safety imposed by law or regulation shall be punished by one year's imprisonment and by a fine of EUR 15,000."*

II.4.1 The material element of the intentional endangerment crime

(i) Existence of a specific obligation of prudence or safety imposed by law or regulation

- **The obligation of the State to ensure the public health safety**

The law imposes on the State specific safety obligations in relation to public health.

Article L1411-1 of the French Public Health Code provides:

> *"The Nation shall define its health policy in order to ensure the right to health protection for everyone."*

Thus, it must be noted that, in order to ensure everyone's safety and health, each Member State must, in particular*, "'produce, use and disseminate relevant knowledge"* for the health policy development and implementation.

- **The obligation of the pharmaceutical laboratories to ensure the safety of products offered for sale and to produce all data in their possession**

(i) Existence of a specific obligation of safety or prudence imposed by law or regulation

French law and the European Regulations impose on pharmaceutical laboratories specific obligations relating to the safety of persons as regards medicinal products and their side effects.

Thus, Article L521-24 of the French Public Health Code provides:

> *"Any company or organisation operating a medicinal product or product mentioned in Article L. 5121-1* ***shall comply with its pharmacovigilance obligations, in particular, implement a pharmacovigilance system and record, declare and monitor any suspected adverse effect being due to a medicinal product or product referred to in Article L. 5121-1 of which it is aware and conduct the post-authorisation studies referred to in Article L. 5121-8-1 within the time limits set.****"*

"Pharmacovigilance" must be understood as monitoring any possible harmful effects of a medicinal product.

Moreover, **Article 16 of European Regulation** No 726/2004 provides:

> *"2. The marketing authorisation holder shall forthwith provide the Agency, the Commission and the Member States with any new information which might entail the amendment of the particulars or documents referred to in Article 8(3), Article 10, 10a, 10b and 11, or Article 32(5) of Directive 2001/83/EC, in Annex I thereto, or in Article 9(4) of this Regulation.*
>
> *In particular, the marketing authorisation holder shall forthwith inform the Agency and the Commission of any prohibition or restriction imposed by the competent authorities of any country in which the medicinal product is marketed and of any other new information which might influence the evaluation of the benefits and risks of the medicinal product concerned. The information shall include both positive and negative results of clinical trials or other studies in all indications and populations, whether or not*

included in the marketing authorisation, as well as data on the use of the medicinal product where such use is outside the terms of the marketing authorisation.

3. The marketing authorisation holder shall ensure that the product information is kept up to date with the current scientific knowledge including the conclusions of the assessment and recommendations made public by means of the European medicines web-portal established in accordance with Article 26.

3a. In order to be able to continuously assess the risk-benefit balance, the Agency may at any time ask the marketing authorisation holder to forward data demonstrating that the risk-benefit balance remains favourable. The marketing authorisation holder shall answer fully and promptly any such request."

(ii) Deliberate infringement of the specific obligation of prudence imposed by law or regulation

In the present case, the Remdesivir toxicity was known to Gilead Sciences laboratory, which omitted to warn the health authorities by failing to provide data on the safety of its medicinal product.

Furthermore, Gilead Laboratory voluntarily omitted to provide the data requested by the authorities in August 2020.

Such danger was also known, as of 23 March 2020, to the French High Authority for Health (*Haute Autorité de Santé*), which highlighted the kidney problems which could result from the Remdesivir treatment.

However, it must be stated that the authorities omitted to obtain all the relevant studies, produced in particular by the WHO, attesting to the product dangerous nature.

Gilead Laboratory acted in concert and with the approval of the Director of the ANSM at the time, Mr Dominique Martin (**who resigned on 27 November 2020**), at the very least to send emails on 23 October 2020 to healthcare professionals with the aim of encouraging them to prescribe Remdesivir, even if they knew perfectly well that Remdesivir would no longer hold a marketing authorisation and that it was ineffective and dangerous to patients' health.

The ANSM and the Ministry of Health also sent instructions to healthcare professionals on 21 October 2020 to encourage them to place orders for a medicinal product when they knew that it would no longer hold a marketing authorisation and was ineffective and dangerous to patients' health.

Therefore, it seems that Gilead Sciences Laboratory, the health authorities and health agencies, who were aware of the molecule toxicity profile in their capacity as medical experts and manufacturers, manifestly deliberately exposed patients directly to an immediate risk of death or injury which may entail mutilation or permanent disability.

(iii) The existence of an immediate risk of death or serious injury to others

Remdesivir toxicity is well established, the WHO having ultimately contraindicated its use.

Moreover, the risks have been demonstrated in 4 of the first 5 French patients, some of whom had to undergo a kidney transplant.

The immediate risks of death or serious illness are fully established in the present case.

*

* *

The Public Prosecutor (*Ministère Public*) is requested to open an investigation into the facts set out above which constitute the following offences:

- **Crime of swindling in an organised group and of conspiracy** (Article 313-1 et seq. of the French Criminal Code)

- **Crime of deception** (Article L213-1 of the French Consumer Code)

- **Crime of abstention from combating a harm** (Article 223-7 of the French Criminal Code);

- **Crime of endangerment of the life of others** (Article 223-1 of the French Criminal Code)

The attention of the Public Prosecutor is drawn to the urgent need of conducting a criminal investigation, which is the only way of bringing to an end the infringements suffered by the victims who can still be offered Remdesivir treatment by carers who would be misinformed by the health authorities.

Moreover, Réaction 19 Association is at the disposal of the investigating services in order to be heard on these facts and to provide any clarification that might be useful in establishing the truth.

Paris, on

Attachments:

Exhibit N. 1: Study retracted Merah and others of The Lancet of 22 May 2020
Exhibit N. 2: "Endgame" for hydroxychloroquine: An intellectual fraud by Le Club of Mediapart of 28 May 2020
Exhibit N. 3: Hydroxychloroquine for Didier Raoult's right-hand man, The Lancet study is a joke
Exhibit N. 4: Open Letter the statistical analysis and data integrity of Mehra et al_ Final of 28 May 2020
Exhibit N. 5: Guardian's article dated 3 June 2020
Exhibit N. 6: 'The Lancet' announced the withdrawal of its study on hydroxychloroquine, Le Monde of 4 June 2020
Exhibit N. 7: Professor Merah's apologies in The Lancet of 13 June 2020
Exhibit N. 8: "I am truly sorry", mea culpa of The Lancet Coordinator on hydroxychloroquine — Le Parisien
Exhibit N. 9: The 'Lancet Gate': Saga of a corrupted study, Les Échos
Exhibit N. 10: End of the game for the controversial study of The Lancet doubting of hydroxychloroquine, Le Figaro
Exhibit N. 11: 'LancetGate': Surgisphere – is the company which provided data to the study serious?
Exhibit N. 12: LancetGate: Surgisphere season 1 episode 3 the fall, France Soir
Exhibit N. 13: Negative opinion of the HCSP and ANSM of 24 may 2020
Exhibit N. 14: Press release — HYDROXYCHLOROQUINE of 27 May 2020, Ministry of Solidarity and Health
Exhibit N. 15: Hydroxychloroquine may be reintroduced to Discovery after the green light of competent authorities, InSERM of 4 June 2020
Exhibit N. 16: Recovery Letters to maintain the inclusion of hydroxychloroquine of 24 May 2020
Exhibit N. 17: COVID-19 — the OMS reconsiders its opinion on hydroxychloroquine
Exhibit N. 18: Discovery, serious fault of French research in addition to a serious medical error, France Soir
Exhibit N. 19: To re-inform the French people about the Study's results. Independent audit required
Exhibit N. 20: Analysis of 192 worldwide studies showing high effectiveness for early HCQ treatment
Exhibit N. 21: ANSM's refusal to grant HCQ, 21 October 2020
Exhibit N. 22: Hydroxychloroquine, a less toxic derivative of chloroquine, is effective in inhibiting SARS-CoV-2 infection in vitro

Exhibit N. 23: HCSP's Opinion, 23 March 2020
Exhibit N. 24: More testing required for antiviral Remdesivir in treating Coronavirus (Zhang Zuofeng)
Exhibit N. 25: Remdesivir, an antiviral treatment called desire? by France 24
Exhibit N. 26: Article posted by the National Institute of Health on 29 April 2020
Exhibit N. 27: Wang and others, The Lancet, 29 April 2020
Exhibit N. 28: HCSP's Opinion, 15 May 2020
Exhibit N. 29: Before the Committee of Inquiry, Didier Raoult criticises the scientific council and the French strategy, by 20minutes
Exhibit N.30: ATU EMA of 25 June 2020
Exhibit N. 31: Coronavirus. Remdesivir Treatment will be charged until USD 3,100 in the United States, Ouest France
Exhibit N. 32: Case reports study of the first five COVID-19 patients treated with Remdesivir in France
Exhibit N. 33: Conflict of interest in the Scientific Council, by France TV INFO
Exhibit N. 34: ATU Remdesivir, of 15 July 2020, ANSM
Exhibit N. 35: Haute Autorité de Santé — Press release on Remdesivir of 17 September 2020
Exhibit N. 36: The European Commission secures European Union access to Remdesivir for treatment of COVID-19
Exhibit N. 37: A Living WHO guideline on drugs for COVID-19 of 4 September 2020
Exhibit N. 38: Opinion CT HAS of 16 September 2020
Exhibit N. 39: European Commission's Press release
Exhibit N. 40: Preprint Solidarity of 15 October 2020
Exhibit N. 41: Instruction N. DGS/CORRUS/PP2/DGOS/PF2/2020/174 of 21 October 2020 relating to the supply of health estblishments with doses of the proprietary medicinal product VEKLURY® (REMDESIVIR) held by the National Public Health Agency (SPF).
Exhibit N. 42: Monitoring of the medicinal products of COVID-19, HAS of 20 October 2020
Exhibit N. 43: HAS' opinion Remdesivir of 23 October 2020
Exhibit N. 44: ANSM withdrawal of Remdesivir cohort ATU of 24 October 2020
Exhibit N. 45: Promotional letters Gilead Science with the agreement of ANSM of 23 October 2020
Exhibit N. 46: Article, France Soir of 30 October 2020
Exhibit N. 47: World's top intensive care body advises against REMDESIVIR for sickest COVID patients, Reuters

Exhibit N. 48: WHO recommends against the use of Remdesivir in COVID-19 patients
Exhibit N. 49: Following the agreement at EUR 1 billion between the EU and Gilead, WHO points out the Remdesivir dangers, by RT FRANCE
Exhibit N. 49a: Solidarity clinical trial results
Exhibit N. 50: Evolution of Gilead's share price over one year
Exhibit N. 51: Gilead SCIENCES + 10 %, following a study in favour of Remdesivir against COVID-19
Exhibit N. 52: Covid-19 - conflicting studies on the effectiveness of Remdesivir
Exhibit N. 53: LancetGate_what is the role of the Gilead laboratory, which is developing the Remdesivir?
Exhibit N. 54: From coincidence to coincidence, Boston connection serves Remdesivir?
Exhibit N. 54a: Clinical trials on Remdesivir, the wheeling and dealing of Gilead and The Lancet
Exhibit N. 55: Remdesivir: does the European Medicines Agency endanger our health?
Exhibit N. 56: Did the Gilead company hide the true toxicity of Veklury© (REMDESIVIR) _
Exhibit N. 57: COVID-19_double standards for the treatments. Unfair
Exhibit N. 58: Gilbert Deray's Twitter of 26 June 2020
Exhibit N. 59: Statutes LVDG
Exhibit N. 60: Health Transparency Database LVDG Gilead
Exhibit N. 61: Remdesivir is an encouraging treatment according to Professor Karine Lacombe on RTL on 30 April 2020
Exhibit N. 62: Euro For Docs Lacombe Gilead
Exhibit N. 63: Has Gilead concealed the toxicity of its product? Article by France Soir
Exhibit N.64: REMDESIVIR Safety Forecast_ Watch the Liver, Kidneys _ MedPage Today
Exhibit N.65: REMDESIVIR_C27H35N6O8P - PubChem
Exhibit N.66: Safety Data SHEET REMDESIVIR
Exhibit N. 67: Material Safety Data Sheet
Exhibit N. 68: Data SHEET GS 441524 sds-AG167808
Exhibit N. 69: Remdesivir for the treatment of Covid-19 nejmoa2007764
Exhibit N. 70: Judgment of the Italian Council of State of 11 December 2020
Exhibit N. 71: Study, *Virology Journal* of 25 August 2005