IMPORTANT DOCUMENT

Transcription and video of the intervention of Joan-Ramon Laporte at the Congress of Deputies of Spain concerning the management of Vaccines Covid and the vaccination plan in Spain

“It can be downloaded here. Ladies and gentlemen I thank this Commission for your invitation to appear to comment on aspects related to the Vaccination campaign against the Covid-19 in Spain. First of all, I will introduce myself. I started the FV in Spain and the SEFV in the 1980s, I was director of the Coordinating Center of the SEFV and member of the CNFV until the creation of the AEMPS in 1999, and from this date I have been an external expert from this institution (during a I was president of the WHO Essential Medicines Committee in 2004. I have published more than 250 original works of research in Clinical Pharmacology, Pharmacovigilance and Pharmacoepidemiology, and I directed the WHO Collaborating Center in Faith until 2017. I do not have conflicts of interest related to the pharmaceutical industry or sanitary products. It has been convened to review "problems and difficulties that have occurred to date in the vaccination process, and in the application by the competent public administrations of the Vaccination Strategy against the COVID-19 in Spain and its subsequent updates I have been able to hear much of the appearances before this commission, and I have thought that I can provide comments on three issues: the pharmacovigilance of vaccines and the role of regulatory agencies (the AEMPS in Spain and EMA in the EU), First. Pharmacovigilance, AEMPS and EMA in the field of pharmacovigilance, the compartments in this commission Representatives of the AEMPs have described the complex procedures and coordination mechanisms that have developed to deal with the SARS-CO epidemic Procedures, but few results, if they except those relating to the high vaccination rate achieved. Similarly, the AEMPS pharmacovigilance reports (the last, the 12th, published on January 26, 2022, report more than 55,000 notifications of adverse effects until January 9, 2022. of these, 375 Transparency does not consist only of uploading technical reports to the web (which too), but to illuminate, in helping to look and help understand. Otherwise, the ground is sown to proliferate distrust and suspicions. Who knows if for an intention to hide the information on a data mountain, or perhaps because it is understood (mistakenly) that this commission is not the forum to discuss technical issues, this type of data has not been presented before its ladies, so that the Commission itself has not had the Ladies and gentlemen, I want to comment on some technical issues that any citizen can understand, which I think may be useful. Twelve considerations. The first vaccines available against the VOCID-19 in Spain, and the most used to this day, have been a Comirnaty of Pfizer (54m doses until January 9) and contemporary Spikevax (14 m dose).

These two vaccines are based on a new technology. Just as traditional vaccines are attenuated germs or portions of them that stimulate the immune system, messenger RNA vaccines introduce a nucleic acid that gives instructions to cells of the person vaccinated to make a VIR protein It should be remembered that DRAE defines a vaccine as (CITO) "prepared with antigens that, applied to an organism, causes it a defense response in it." According to this definition, the so-called Vaccines of Pfizer and modern are not real vaccines. They are drug-based technology never used in therapeutics until now, and less in massive campaigns. Hence, mass vaccination supposed a great global experiment, unprecedented in history. The results of the first clinical trials (EC) on the vaccines of Pfizer and modern, published in December 2020, showed preventive efficacy values of 90% or more. They seemed convincing, and the world began to breathe (never better said) with the perspective of vaccines, and to sigh for them. But we should be aware that we entered into a global vaccine preventive experiment, for its extension and by the new technology that involved. An EC gives preliminary information, which must be checked in practice (this is deuting pharmacopidemiology). For example, in EC on the Pfizer-BNT vaccine, from more than 43,000 participants only five were over 85, and only 4% over 74 years. However, as we all know, vaccination began in those over 80; The first person vaccinated in Spain was 96 years old. The EC of medicines and vaccines are designed, carried out and interpreted by the promoter company. The quality control of the data collected also is borne to the promoter, and the control of data management by public administrations is based on inspections, which are occasional. Recently the BMJ described irregularities in the Pfizer's essay, known as Pfizergate. https://www.bmj.com/content/375/bmj.n2635 Fraud is usual, often in the cataloging and archive of adverse events. Fraud is also made in the EC on vaccines. I am authorized to tell you an example. The Rxisk team, self-describe as a group "of high-level medical experts of international reputation in early detection of adverse effects of medicines and the mitigation of their risks, pharmacovigilance and patient care." He was constituted in 2012 and led by Professor David Healy, from the McMaster University of Canada. In collaboration with Rxisk, he said, we have interviewed and reviewed the clinical history of three participants in clinical trials (one in Pfizer adults, one in Pfizer Pediatrics and one in the adult of AZ), which have suffered advers effects I can say that it is not true that there are no serious adverse events in the EC; On the contrary, we began to have a record that some problems were hidden under the carpet. These cases will be made public within a few weeks on the Rxisk website. https://rxisk.org/ In the EC publications, only very general data are offered, and grouped. In addition to fraud, the tendentious presentation of the results of the EC is also common. Tendentiality that consists for example in expressing efficiency in relative terms, and not absolute. For example, in the Pfizer trial, 162 cases of COVID-19 were recorded in the placebo group, compared with 8 in the vaccinated group, a difference of 95% in relative terms. However, the reality was that the incidence of positive PCR (nor only clinical disease) had been less than 1% in the placebo group, compared to 0.04% in the vaccinated group, a difference of less than 0.9% in absolute terms. https://www.nejm.org/doi/full/10.1056/nejmoA2034577 or consisting of hiding certain results in the published article. For example, in the EC with the Pfizer vaccine, 14 deaths were recorded in the Placebo group, and 15 in the vaccinated group. https://www.nejm.org/doi/full/10.1056/nejmulo2110345 In the modern number of deaths (14) in each group. https://www.nejm.org/doi/full/10.1056/nejmulo2113017 (no ladies, EC have not shown that vaccines save lives). The number of deaths registered in each group was not only mentioned in two articles published in the NEJM, and could only be found after reviewing dozens of pages of supplementary material (https://www.nejm.org/doi/full/10. I do not have the time necessary to get bored by extending me in other details. But I assure you that the results of the EC promoted by pharmaceutical companies should be considered rather as indications, and in no way as "evidence". According to Drae, it is "evident" what is "true, clear, patent and without the slightest doubt." Sad irony, what experts and leaders of health institutions continue to insist on evidence before a new and therefore unknown, unpredictable disease and the sequelae that will leave. The so-called evidences about vaccines had no certain, nothing clear, and, yes, many patents. In any case, the results obtained in any EC should be reviewed in detail by experts in the field, which requires time, no doubt, but also transparency. Pfizer, for example, announced that it would make public all of the results of its main EC on the vaccine in 2025. Well, it seems that neither this

date was true. Last January, at the request of several civil organizations for transparency, a US Federal Judge forced the FDA and Pfizer to make public these results within a period of months, instead of the 75 years of the company and had agreed with the In addition, the results of EC should be confirmed by practice, and this requires a very careful epidemiological follow-up of the global vaccination experiment against VOCID-19. Hence the need for the pharmacovigilance. Despite the apparently optimistic results of EC on vaccines against COVID-19, there was at least five areas of uncertainty in January 2021. Decrease of 20-30% of relative efficacy in 6 months. Instead of taking note of this insufficiency of vaccines, the manufacturers welcomed this news with uploads their stock market: if the product is ineffective, it will be necessary to go repeating doses, if possible throughout the life, the dream of any drug vendor for The reality is that we need better vaccines, in terms of protective efficacy. The efficacy of vaccines against Delta strain was lower than its effectiveness against alpha strain. The recent experience has shown that vaccines have not worked against the omicron strain. For example, official data reproduced by Prof. Luis Carlos Silva relating to Catalonia show that between 23/12 and 12/01/22, 37,200 COVID-19 diagnoses were recorded by PCR in vaccinated people, and 30.3 Do they avoid transmission or contagion? It is clear that vaccines do not avoid the transmission of the disease, so that the passport or certified Covid lacked a scientific basis, and it may also have contributed to increasing the number of cases, since it gave a false sense of security to those who obtained it. Adverse effects For example: EMA deplorable response. Sign at the end of January. Pract meets at the beginning of March. Press conference March 31: Pharmacovigilance managers stated that they did not even have either vaccination figures for age and sex in the Member States. https://audiovisual.ec.europa.eu/en/ebs/live/2 In addition, it was insisted on low incidence, without distinguishing the real of the notified. https://www.ema.europa.eu/en/news/astrazeneca-covid-19-vaccine-review-very-rar-cas-unusual-blood-clots-continues infran No more with AZ than with Pfizer or modern. Myocarditis and pericarditis. As with thrombosis, incidence estimates have been rising. Heart problems in athletes, soccer players and vaccinated viewers. https://maryannedemasi.com/publications/f/myocarditis-post-vaccination-%e2%80%93-should-we-be-concancened Access on a global scale. Third part On the other hand, the monitoring of the safety of vaccines has revealed the deficiencies of the pharmacovigilance in the European Union. The EMA has reacted late and inhabitant and insufficiently before the signs of unwanted effects that have been emerging and its hesitation have not helped the authorities of the Member States to guide the vaccination campaign according to the results obtained. Procedures and bureaucracy have prevailed over science, common sense and attention to the uncertainties inherent in the global experiment undertaken. It is not (only) of an incident or the ineptitude of an official. The EMA, financed by more than 80% with the rates contributed by the pharmaceutical companies, is designed to authorize the commercialization of medicines and vaccines, but not to interact with the health systems of the Member States. The pandemic has become apparent that European legislation on pharmacovigilance, based on voluntary notification and risk management plans developed by the manufacturing companies themselves, is more conceived to protect the latter than to protect citizens. In this context, I would also like to comment on the scarce use that has been made from the sanitary databases in Spain, to monitor vaccination and its beneficial and unwanted effects in the context of the epidemic. Probably it is not just a missed and lost opportunity, but rather of the reflection of the lack of will of the National Health System to be a true producer of knowledge, and not a mere liabilities of clara commercial intentionality, an ignorant buyer of The pandemic has also evidenced the existence of a huge market for exploitation of sanitary databases for epidemiological studies, channeled by EMA in a non-democratic, even colonialist, in connivance with university centers "Add Second. Vaccination campaign Residences. The epidemic already incidesed in residences of elderly people, especially at first. Mortality was 57 times higher in the residences. We presume as a health system, but we leave the most vulnerable in the hands of private initiative. What are the risk factors of dying in a residence? Undoubtedly age and pluripatology, but also bad attention and unnecessary polymodedication. A wide variety of drugs, which were already widespread before the epidemic, increase the risk of pneumonia and mortality by pneumonia, so that at the beginning of the epidemic it was expected that they will also increase mortality by Covid-19. For example, years ago that it is known

that neuroleptic drugs (antipsychotics) duplicate or even quadruples the risk of pneumonia. In Catalonia some 100,000 people over 70 years of age consume them continuously, in most cases in unauthorized indications. At the beginning of the pandemic, 22,000 of the 64,000 people living in residences consumed neuroleptics. Many other drugs that have a depressing effect of the central nervous system also significantly increase the risk of pneumonia: opioid analgesics such as tramadol or fentanyl, hypnotic, sedative (also called anxiolytics such as Loracepam, Proton pump inhibitors (omeprazole and the like) also significantly increase the risk of pneumonia. 75 percent of those over 70 years of age consume at least one of these drugs. On April 8, 2020 I sent a report on this issue to the AEMPS (updated version: https://rxisk.org/medications-compromising-covid-infections/. The answer was more or less "Thank you, but what https://bmcmedicine.biomedcentral.com/articles/10.1186/11916-021-01907-8 The most worrying of this issue is that numerous studies have shown repeatedly at least 40% of For some medications, unjustified consumption can be of the order of 80%. Sick or dying PER HAVE TAKED A INNEVENED DRAME IS A Cruel Iony. The health system has an evident responsibility in this issue. This Parliament approved a few years ago the deduction of income in species received for "training" by health professionals. They are income that come from the pharmaceutical industry, which is the main direct or indirect supplier of continuing education in Spain. I wonder, ladies and gentlemen, what conventional company would accept how normal your workers receive gifts and money from the main supplier of raw materials? Several studies and comparative analyzes have shown that Spain is the most permissive EU member on conflicts of interest and opaque relationships of health professionals with pharmaceutical companies. https://doi.org/10.1136/bmj.h6182 The same goes for medical societies and their experts. In this sense, it has been surprised that none of the comprehensive representatives of professional corporations would make the most minimal allusion to the conflicts of interests of most Spanish medical societies, members of their boards and their work groups. And he has called me the attention that you will not ask for the IC. Vaccination strategies The good expression benefit / favorable risk relationship has no specific meaning, if the population groups for which a drug or vaccine is proposed is not defined. The epidemic does not affect all age groups in the same way, and the vaccine does not have the same adverse effects at all ages. Consequently, the magnitude of the beneficial effect and also that of risks varies with age. There is consensus on the protective effect on the community of the 1st and 2nd doses, but not over 3 and 4th. Lack of studies, need to examine the results in real time to solve the main uncertainties. I will not comment on rhetorical effectiveness measures, such as the use of outdoor masks, or the Covid passport). Nor does the compensation for the EI. I presented up here, there was no time for more. I also had this brief text about patents and intellectual property. Third Intellectual Property Rights As Hawksbee, Public Health Professor Martin McKee and Economics Professor Lawrence King in a recently published article, most experts agree that you should be able to vaccinate as much as possible Many discussions have focused on intellectual property rights: Should the companies that developed vaccines against COVID-19 be forced to make available their knowledge so that others can produce these vaccines? Or or an exemption from intellectual property rights or other reforms of the current system of intellectual property threaten future innovation? The debate acquired large proportions when President Biden expressed support for a temporary exemption from intellectual property rights over Vaccines against COVID-19. This proposal has been approved by the US Senate, and WHO, MSF and even the Pope have adhered to it. In spite of this, months later some European countries continue to obstinately opponently opponent such an exemption within the WTO. More than a dozen human rights defense entities, including international amnesty, and patients have been directed to the Governments of Canada, the United Kingdom, Germany and Norway to warn them that they would undertake legal action against them if they obstruct the adoption of the proposal of Meanwhile, the covax mechanism seems to have been designed to preserve the current market mechanisms and power dynamics. The arguments contrary to reform the intellectual property system are that these are necessary to compensate for the financial risks in which a company incurs when it invests in the necessary research and development to develop new products. In the case of vaccines against COVID-19, the magnitude of this risk is debatable, because governments contributed a substantial part of R & D funding and acquired large amounts of vaccines in

advance. For example, these governments deserve a return on their investment in the form of lower prices or greater access to the vaccines of the poor around the world in order to increase global immunity? Or or the exemption of intellectual property rights constitutes a form of state theft that can endanger future vital research for public health? As expected, the pharmaceutical industry maintains that the exemption would reduce the benefits that encourage the development of new drugs. However, the emergence of new variants demonstrates the risks of status quo: maximizing vaccination is not only a moral necessity, but also a potential bulwark against the evolution of new variants that could be more contagious, ma's virul In addition, the exemption would not threaten the future development of drugs, mainly because the relationship between benefits and innovation is tenuous. The arguments of the industry would be solid if there were evidence that they would be unable to attract investors to finance R & D. but this does not seem to be the case. According to the Fortune 500 data, the 1954 net benefits of the pharmaceutical industry were until 1999 of more than double that those of the mean of the other sectors (banking, energy, construction, food, automotive, military, etc.). As of 2000, the difference shot triple. The return on the capital invested is the highest in all sectors. Net benefits already undergo discounted R & D costs. High benefits could be justified with the argument that pharmaceutical companies produce the most needed innovations to improve and protect public health. But the idea that the industry is concentrated in the most necessary drugs is far from reality. On the one hand, only 2 to 3% of new drugs are important advances, and between 9 and 11% offer only some modest advantage over products previously available; The rest does not provide clinical advances. On the other hand, there are great research needs unattended by the industry, such as malaria, multidrug tuberculosis and resistance to antibiotics. At the same time, the role of the industry in the rapid development of vaccines has been fundamental. However, the idea that society can only collect the benefits of medical innovation if intellectual property monopolies produce astronomical benefits to industry is no longer sustainable. The record benefits have not given rise to research on resistance to antibiotics or unattended diseases, and have never guaranteed access to essential medicines from the world's poor. Nor is there any reason to believe that the search for benefits will cause adequate incentives to safeguard global health in the future. On the contrary, it is necessary to reform the structure of incentives on which the investigation and development of new drugs, with greater leadership of the public sector, in which the rewards should be independent of the size of the originated market. If any of your ladies and gentlemen has an interest in consulting the sources of information given in this appearance, do not hesitate to contact me, I have them at your disposal.”