Administrative Litigation de Tribunal de Apelacion
Administrative Contentious Court
***TYPE OF PROCESS:* Tribunal de Apelacion de lo Contencioso y administrative Medida Cautelar Ante Causan, Factual circumstances have changed that gave rise to the rejection of the requested measure**
File number: 22-001917-1028-CA
Actor: *Interest Of Justice, Lord Dustin Bryce* [redacted] *Lady Xylie Desiree* [redacted]
Defendant: Estado, CCSS, Secretario de la CNVE Roberto Tijerino, Ministerio de Salud et al. - Organic Regulations of the National Health Research Council (CONIS)

Dear Judge Friend,

The undersigned, Interest of Justice or "IOJ" is a Private Institute, Internationally Domiciled Civil Society Organization Established in November of 2016, a group with diffuse interests based in the southern zone of San Jose, Costa Rica, Neighbor of [redacted], IOJ's key mission is to help the Global Community of Citizens ensure government accountability to the people. IOJ's mission is safeguarding the interest of the international community as a whole and to give effect to the letter and intent of the supreme international law, it's peremptory norms and customs.,

The undersigned Lord Dustin Bryce [redacted] Associates degree in [redacted], *Not married* , Profession is a Defender of *Human Rights starting in the year 2015*, identification passport *number* [redacted]

The undersigned Lady Xylie Desiree [redacted], *Not married*, Profession as a Defender of *Human Rights starting in the year 2015*, identification passport *number* [redacted], in accordance with articles of the administrative contentious procedural code, Appellants present this appeal for review arising from a precautionary measure numbered **22-001917-1028-CA filed in the CIVIL AND ADMINISTRATIVE COURT OF FINANCE (GOICOECHEA) on the seventh day of October in the year two thousand twenty two.** Appellants requested that *"PRECAUTIONARY MEASURE AS PRIOR ACTION be issued, to guarantee the effective result of a full contentious process and preferential processing that will be filed in due course., in order to declare the absolute nullity of administrative conduct that is the object of the process and the material actions of the public admin and The omissive conducts of the Public Administration which consists of a public servant who has acted with intent or gross negligence in the performance of their duties. Such acts is a manifest illegality, because the Administration has departed of Expert advisory opinions in which now show the illegality. measure involves active administrative conduct or omissions with discretionary elements, or vices in the exercise of its discretion. The misuse of power shall constitute grounds for challenging. The law shall protect, at very least, the personal rights and legitimate interests of those governed administrative acts which was also published by the administration regarding COVID-19 pediatric vaccines for populations from six months to five years*", and explained later in the record that the COVID-19 [non] vaccine shall be removed for all Costa Rican human inhabitants not only children and babies.

In the denial of the petition, the *CIVIL AND ADMINISTRATIVE COURT OF FINANCE (GOICOECHEA). At sixteen hours and thirty minutes on March thirteenth, two thousand and twenty-two. VOTE N° 133-2022* mentioned:

on the requirements necessary for the granting of the precautionary measure: a) on the appearance of good faith: b) on the danger of delay: c) on the bilaterality of the damage:

Appellants point out that the court responded and Appellants met 2 of the 3 budgets necessary to grant the measure:

"In addition to the foregoing, in view of the fact that the danger in the delay (actual or potential serious damage) has not been demonstrated and therefore, since it is not considered that the assumption of the weighing of interests (bilateral nature of the damage) has not been overcome, the request for precautionary measure formulated by the plaintiffs will be denied. Due to the nature of these precautionary matters, a decision will be rendered without a special condemnation in costs."

Request to again consider the appropriateness of the requested measure or any other precautionary measure:

- Court omitted to factor in the main issues of legality regarding the definition of "Vaccine" which does not conform to the vaccine regulation law 32722 Article 1 section (p), which makes the use and all contracts regarding COVID-19 vaccines absolutely null.
- The court ruled based on one part of the law and deferred to the legislators intent to put the health agencies in charge in the discretionary health acts, but failed to consider that the biological research product in question does not conform to the definition of vaccine and therefore CNVE acted in access of authority to authorize or recommend the use of the COVID-19 biological agent in Costa Rica. This omission is the very definition of injustice when a court rules based on one part of the law but fails to consider the whole of the law especially when the court in this instance omitted to consider and address the relevant issues of the act being in excess of CNVE authority based entirely on the administrations mis-characterizations of the definition of "Vaccine".
- The court presumed good faith of the Administrations which does not exist and omitted to address all the evidence of the administrations false testimony which misrepresented CDC vaccine safety data (see record for extreme details). Under common law this is fraud on the court and immediately impeaches the witnesses who are no longer to be believed after misrepresenting their own data under play the dangers of their unproven intervention outside of clinical trial. The serious allegations we made should have been addressed about the Administrations false testimony to our precautionary request, especially when human life is at risk from the lies and excess of law to experiment on humans with no informed consent.

- We showed the court about how CCSS and Ministerio de Salud's reply blatantly misquoted CDC data to say children are 0% harmed, but in reality their own "evidence" proves children were up to 5.7% seriously injured by covid-19 vaccine biological agents and they lied about the amount and type of seizures in their own CDC data. The legislator gave a statute to REMOVE the CONIS from their positions, not give them the presumption of good faith and free rein to further continue manifestly illegal acts! It is very appropriate to issue the preventative measure, and suspend all CONIS, because the legislators MANDATE precaution and removal in this type of instance under 9234 a mandatory compliance law so far not being applied. This was not considered. Instead, the court presumed the Ministry of Health and CCSS are created by the legislator, so they must be functional. In reality the 9234 law says the research in Costa Rica under CONIS can only work if they are functional. CONIS is the State and headed by the Minister of Health. The legislator provides instructions that CONIS is so important it cannot be allowed to exist without meeting their duties, which they are not. Please read entire intro to the CONIS law.
- The new facts of CONIS reply completely contradicts CNVE and the Health Minister January 24, 2022 insofar as the laws which apply that CONIS is in charge of overseeing. CONIS says it's not their department to oversee covid-19 research, its only a "study", but CNVE says its biomedical research and 3rd phase experiential which the law mandates CONIS monitor. CONIS gets out of monitoring by pretending they are approved.
- We got the proof from https://registrelo.go.cr/ the COVID-19 vaccines are merely in tramites, not approved.
- The court failed to acknowledge the evidence of the experimental nature and our objections to no informed consent for the research! That's a big deal and totally illegal. We show CONIS registering investigational research and the court ignored our entire argument and request to prevent serious undue experimentation!!! The stress of this never-ending ordeal of all courts and the administration ignoring our claims of serious undue experimentation since 2020 is causing extreme stress, denial of prompt and fulfilled justice and damages. THIS IS ALSO THE DANGER IN THE DELAY!!!!
- The court said they are not a scientist so he has to trust the Administration, but that fails to acknowledge or respect our expert testimony in the record not refuted by the Administration which the law says all facts in the record are documentary evidence and must be presumed true. Our expert is not being taken seriously as he came all the way to Costa Rica to defend this country, and he is ignored and ridiculed by the Administration - THAT is a danger in the delay in itself!
- **The court failed to incorporate the evidence to the facts in the initial complaint**
- Pfizer trial fraud docs – Daily Clout/war room document
- two page documentary evidence On March 13, 2019, Moderna submitted their Form 10-K Annual Report to the Securities & Exchange Commission (SEC) (Security and exchange commission) in which they claimed on (page 150 Link to full document here) that *"Currently, **mRNA is considered a gene therapy product by the FDA**". [1, 2]*In that same filing they state *"because no product in which **mRNA** is the primary active ingredient has been approved, **the***

regulatory pathway for approval is uncertain. *The number and design of the clinical and preclinical studies required for the approval of these types of* ***medicines*** *have not been established...* and more

- Ten page documentary evidence of the history of human research and moratorium *In the latter part of the twentieth century, it became a popular site for clinical trials funded by multinational pharmaceutical companies. In light of concerns about ineffective oversight and alleged research abuses, the Constitutional Chamber of the Supreme Court passed a moratorium on all biomedical studies involving hu- mans*
- PDF Documentary evidence and Video link with photos of injured children after taking the "*Pfizer COVID-19 vaccine"*
- The court failed to consider Dr. Michael Yeadon former vice president of Pfizer Pharmaceutical company, two authenticated declarations authenticated in Costa Rica on the safety issues of Children and Mothers and People and Gene editing products. Received many times to defendant and undisputed.
- The court failed to take into consideration A thirteen page Document for FDA-2022-N-0905 Monday June 27, 2022 Participation package as relevant interested stakeholders from International Civil Society Organization Interest Of Justice and Video link https://www.youtube.com/watch?v=BFdzNUus_CE with transcripts and timestamps

Regarding the weighing of interests (bilateral nature of the damage):

Petitioners were so traumatized that we focused on the dangers in the delay to human life and safety (which also shouldn't be overlooked). The main issue we tried to convey in **HECHOS: Primero:**, albeit unartfully, is actually the "Danger in the delay" of the continued execution of the manifestly illegal act of use of covid-19 vaccines which are mislabeled as vaccines in order to give CNVE authority in excess of legislative intent. The legislators defined vaccine and gave CNVE power over "vaccines" as defined only in vaccine regulatory law 32722 article 1 section p.

Of great importance, and which was not disputed in the original hearing, is that the evidence shows when CNVE asked a simple question from Plaintiffs about how is the covid-19 vaccine in conformity with 32722 article 1and defined as a vaccine, the CNVE testified the definition they are using is not from the legislators of Costa Rica, instead the CNVE rambles on about WHO definitions which clearly conflict with the legislator's intent. Can the court find anywhere in the following administrative testimony that shows the national definition is being applied, or just the WHO's spurious illegal definition? If the weighing of interests in this case is to give the legislators the final say, the following should have been considered and the precautionary measure should have been granted because no legislator authorized CNVE to have authority over non vaccines just because the WHO says so:

MS-DM-0318-2022
San José, 24January 2022

In reference to letter **MS-0273-2022**, in which we respond to 2022,your e-mail dated January 4, 2010, entitled *"SUBJECT: Cease and desist of the experimental gene therapy "COVID-19 [NON] Vaccine" for its use in humans",* I add information provided by the National Commission of Vaccination and Epidemiology, in letter **MS-CNVE-0059-2022** , signed by Dr. Roberto Arroba- Tijerino, Technical Secretary, which indicates the following, and I quote verbatim:

"The vaccines used by the country against covid-19 are licensed by WHO and, in addition, have approval for use by Strict Regulatory Agencies, such as FDA and EMA.

I would like to respond to your questions regarding the vaccines in question:

The World Health Organization defines vaccines very broadly as follows: vaccines contain attenuated or inactivated parts of a specific organism (antigen) that elicit an immune response in the body. Newer vaccines contain the 'instructions' to produce antigens, rather than the antigen itself. Regardless of whether the vaccine contains the antigen or the instructions for the body to produce it, that attenuated version will not cause disease in the vaccinated person, but will induce the immune system to respond as it would have done in its first reaction to the actual pathogen (Information available at: https://www.who.int/es/news- room/feature-stories/detail/how-do- vaccines-work).

The COVID-19 vaccines being administered to the Costa Rican population Pfizer-BioNTech COVID-19 Vaccine and COVID-19 Vaccine are authorized by the World Health Organization for inclusion in the Emergency Use List (EUL) as can be verified in the web page of this organization: https://extranet.who.int/pqweb/vaccines/covid-19-vaccines

It is important to clarify that before they are in Phase I, II and III studies they are referred to as "vaccine candidates", but that these types of vaccines after they obtain their approval either an emergency use authorization, a conditional authorization, or even a formal authorization can continue in Phase III and IV clinical studies for follow-up and post-marketing, or even new Phase III studies in new population groups, for example, in the case of a vaccine candidate, but also in the case of a vaccine candidate in a new population group what can always be referred to as "investigational vaccines" and it is completely acceptable.

According to Executive Decree No. 39061-S Regulation of the Biomedical Research Regulatory Law, an investigational product is defined as a registered or unregistered product of health interest that is being tested or used as a reference or comparator in biomedical research. Included in this definition are pharmaceuticals, biomedical equipment and material, food and dietary or nutritional supplements, diagnostic test, natural products, cosmetics and hygiene products.

As a pharmaceutical product (a drug) is one used for the treatment of diseases and medical conditions, as well as the prevention and diagnosis of diseases, vaccines are drugs. ***A vaccine, which is any preparation intended to generate immunity against a disease by stimulating the production of antibodies.***

Given the rapid development of COVID-19 vaccines as well as their early approval has raised concerns among some people about whether all vaccine safety and efficacy standards were met, we would like to clarify a bit about the research phases of the vaccines and a bit about the vaccine approval process by FDA and EMA who are founding members of the International Council on Harmonization of Technical Requirements for Pharmaceutical Substances for Human Use and meet the WHO definition of a Strict Regulatory Authority (available at https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs).

The phases of vaccine development and the various research studies that prioritize the safety of use of a vaccine and then its efficacy (information taken from the World Health Organization website, available at https://www.paho.org/es/documentos/covid-19-fases- desarrollo-vacuna) are as follows:

· Preclinical phase: Experimental results on efficacy and tolerance in animal models support subsequent research in humans. Preclinical studies use tissue culture or cell culture systems and tests in animals, which may be mice or monkeys, to evaluate the safety of the candidate vaccine and its immunogenic capacity, or ability to elicit an immune response.

· Phase I: Usually tests a new experimental stage vaccine in a small number of humans, generally fewer than adults100 in order to initially evaluate its safety and biological effects, including immunogenicity. This phase may include dose and route of administration studies.
· Phase II: Tests a vaccine that was considered safe in Phase I and requires a larger group of humans (generally between 200 and 500) to monitor safety and also the trials that will determine the efficacy of the vaccine. The goals of Phase II trials are to study the candidate vaccine for safety, immunogenicity, proposed doses, and method of administration.

· Phase III: Aims to more fully evaluate safety and efficacy in disease prevention and involves a larger number of volunteers participating in an adequately controlled multicenter study. They may include hundreds to thousands of human subjects in a country or several countries. Phase III trials are randomized and double- blind, and involve the experimental vaccine being tested against a placebo (the placebo can be a saline solution, a vaccine for another disease, or some other substance). It is generally the step prior to approval of a vaccine.

· Phase IV: These are studies that occur after the approval of a vaccine in one or several countries. These studies aim to evaluate how the vaccine works in the "real world". They are generally effectiveness studies and also continue to monitor adverse events.

When the World Health Organization (WHO), on March 11, 2020, elevated the public health emergency situation caused by COVID-19 to an international pandemic given the rapid evolution of the facts, it caused health authorities at national and international level to adopt immediate and effective measures to deal with these extraordinary circumstances of an unprecedented health crisis of enormous magnitude, both because of the very high number of people affected and the extraordinary risk to their lives and rights.

The various regulatory authorities for products of health concern around the world implemented existing national mechanisms or began to develop special mechanisms to address this global state of emergency and allow access to diagnostic tests, medical devices and drugs to treat COVID-19 disease that have demonstrated a quality, safety and efficacy profile appropriate for human use.

FDA has for these purposes an Emergency Use Authorization (EUA), which as described on the FDA website (available at: https://www.fda.gov/vaccines-blood-biologics/vaccines/explicacion- de-la-autorizacion-de-uso- de-emergencia-para-las-vacunas), is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current pandemic caused by COVID-19. ***Under an EUA, FDA may permit the use of unapproved medical products, or unapproved uses of approved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions, when certain regulatory criteria have been met, including that there are no suitable, approved, and available alternatives****. Taking into account FDA input, manufacturers decide if and when to submit an EUA application to the FDA.*

Taking into consideration the above, in the case of most of the COVID-19 vaccines **started as investigational new vaccines (or vaccine candidates), which passed preclinical *studies to start their use in clinical investigations of phase I, II, III studies could only be used in the framework of clinical studies.***

When Phase II/III or Phase III studies of the experimental vaccine begin to show positive safety and efficacy results with at least 2 months of follow-up following implementation of the full vaccination schedule, an FDA emergency use authorization (EUA) may be requested (guidance is available at: https://www.fda.gov/regulatory-information/search- fda-guidance- documents/emergency-use-authorization-vaccines-prevent-covid-19). FDA may issue an EUA when certain criteria are met, including that there is no acceptable, approved and available alternatives. In addition, FDA's decision is based on the totality of available scientific evidence showing that the product can be effective in preventing COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh its known and potential risks (adverse effects). ***This allows mass use of the vaccine, not just in the clinical trial setting like experimental vaccines, and is generally in effect as long as emergency use of the vaccine is warranted.*** *Which was the case with the Pfizer- BioNTech vaccine.*

In the case of approval or formal authorization of a vaccine by the FDA, it is also required to submit all the quality information, non-clinical studies and Phase I, II and III clinical studies with at least months6 of follow-up after completion of the proposed vaccine schedule. And if, after the analysis of the information, a risk-benefit balance of the use of the drug is performed for the authorization of the drug. That is why the FDA authorization for the Pfizer-BioNTech vaccine was only authorized for the vaccination of children over 16 years of age, since these are the only studies that have completed the 6 months of follow-up, the vaccination in adolescents 15and12 the recently approved vaccination in children 10is under5 the figure of authorization for emergency use, since, as previously clarified, formal authorization in these populations requires a 6-month follow-up (information from the

Pfizer-BioNTechCOVID-19 VaccineInformation Sheet for Recipients and Caregivers available at :https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019- covid-19/comirnaty-and-pfizer-biontech- covid-19-vaccine#translated).

The emergency use authorization supports the evaluation of all the information that these are quality, safe and effective vaccines to prevent a disease for which no other effective therapeutic option has been approved so far.

And, just as the FDA in the United States is considered a Strict Regulatory Authority by the WHO, so is the agency of the European Union, the European Medicines Agency (EMA), which last 21December granted authorization to Pfizer-BioNTech's COVID-19 vaccine, and on January 29, 2021 approved AstraZeneca's

COVID-19 Vaccine, In this case, EMA used the "rolling review" process, which is an exceptional mechanism by which the authority evaluates the data as they are received, and as the information is quite complete and robust to reach a conclusion on the quality, safety and efficacy of the vaccine, the conditional authorization was granted.

As explained in different EMA communications and I quote the following communication of the Spanish Agency of Medicines and Health Products (AEMPS): "the conditional marketing authorization of EMA is an instrument contemplated in the European legislation that allows an authorization in the face of an unmet medical need, to the extent that the benefit to public health of its immediate availability is greater than the uncertainty derived from the limitation of the available data. This type of authorization is not specific to this situation; it has been granted outside and within the pandemic and requires more data than an emergency authorization such as that granted in other regulatory https://www.aemps.gob.es/informa/notasinformativas/laaemps/2020-laaemps/la-ema-recibe- la-solicitud-de-autorizacion-condicional-de-las-vacunas-contra-la-covid-19-de-biontech-pfizer-y- moderna/).

Once the conditional authorization has been granted, they can be marketed in all member states of the European Union, as is the case with all authorized drugs; however, in this case, vaccines against COVID-19 have not been marketed in private pharmacies, because the production of these vaccines is still committed to comply with the marketing agreements made by the laboratories with the different governments for national vaccination companies.

Importantly, COVID-19 vaccines licensed by both the FDA, EMA as well as other SRAs (including AstraZeneca's COVID-19 vaccine), have been licensed based on the safety and efficacy results available at the time of the licensure decision (non-clinical studies, and Phase I, II and III studies), but these studies continue to be conducted to obtain data on the duration of protection shown over time and to document efficacy in special populations (e.g., children, pregnant women), as well as clinical studies to demonstrate efficacy against newly identified variants of the virus: Children, pregnant women) as well as clinical studies to demonstrate efficacy against newly identified variants of the virus.

The WHO, for its part, has the Emergency Use List mechanism mentioned above, where an external committee of experts convened by the WHO analyzes the results of clinical trials and recommends the vaccines to be used and how to use them. Subsequently, it is up to the authorities of each country to authorize or not the use of each vaccine in their jurisdictions and to develop policies for administering them, based on WHO recommendations.

In the case of Costa Rica, Article 117 of the General Health Law states that: The Ministry of Health, the Costa Rican Social Security Fund and any other state entity, with public health or social security functions, may acquire unregistered medicines, at any time or circumstance. In case of emergency or public necessity, such Ministry may authorize the importation of unregistered medicines. Thus, when the 2020,state of national emergency was declared by Executive Decree No. - 42227MP - S, of 16March of the year 2008 in the whole territory of the Republic of Costa Rica, due to the sanitary emergency situation caused by the disease caused by COVID-19, both the CCSS and any other state entity may import vaccines against COVID-19 without sanitary registration.

Executive Decree No. 42571-S Regulation for the sanitary authorization for the destocking and acquisition of medicines not registered by state entities with public health or social security functions and for the

authorization of destocking in case of public necessity, details the import requirements for medicines in cases of public necessity as in the case of COVID-19 vaccines.

Similarly, Executive Decree No. 38414-COMEX-MEIC-S Central American Technical Regulation 11.03.59:11 Pharmaceutical Products, Medicines for Human Use, Requirements for Sanitary Registration, applicable for the sanitary registration of Medicines, in its article 13 indicates that: The Regulatory Authority may authorize the importation and use of medicines without sanitary registration in the following cases: . 13.2 National emergencies and officially declared public need.

However, since these vaccines would be used for the first time in humans, and in order to ensure rapid access to the vaccines and safeguard the health of the Costa Rican population, the National Commission on Vaccination and Epidemiology decided to include in its selection criteria for COVID-19 vaccines that the information is approved by a Strict Regulatory Authority or approved in the WHO Emergency Use List, so that we ensured that the expert committees of these authorities, which have very strict regulations and robust regulatory processes, would review the information and give their recommendation and Costa Rica would provide an authorization based on the recognition made by these Strict Regulatory Authorities as described in the administrative resolutions DM-RM-7905-2020 of December 3, 2020 and DM-RC-0486-2021 of February 22, 2020, and DM-RC-0486-2021 of February 22, 2020, as described in the administrative resolutions DM-RM-7905-2020 of December 3, 2020 and DM-RC-0486-2021 of February 22, 2020. 2021.

Vaccines are the most effective approved preventive treatment available to prevent disease; and it is for this reason that when the first developments of COVID-19 vaccines in 2020 began to show results, the world had high expectations of their efficacy in preventing disease, or at least preventing the development of the severe disease that causes hospital overcrowding and further compromises people's lives.

In the case of Pfizer-BioNTech's COVID-19 Vaccine, the vaccine's initially reported efficacy in the elderly 16in preventing symptomatic disease was 95%, while the results of the U.S. Food and Drug Administration (FDA)-compliant analysis of vaccine efficacy - First Occurrence of Severe19 COVID- Severe in participants with or without prior SARS-CoV-2 infection after the first dose or from days7 after the second dose in placebo-controlled follow-up supported the benefit of the vaccine in preventing severe COVID-19, with 96.7% efficacy after the first dose and 95.3% efficacy days7 after the second dose (Information extracted from the Summary of Product Characteristics of Comirnaty - known as Pfizer-BioNTech COVID-19 Vaccine in Costa Rica - available at: https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product- information_en.pdf).

AstraZeneca's COVID-19 vaccine during the primary efficacy clinical study for licensure by the European Medicines Agency, the vaccine reports an overall efficacy of 74% for the prevention of symptomatic COVID-19 disease in the elderly18; However, severe or critical symptomatic COVID- 19 disease was evaluated as a key secondary endpoint, among all subjects in the per protocol analysis group, no cases of severe or critical symptomatic COVID-19 were reported in the vaccine group, compared to 8 cases reported in the placebo group.

There were 9hospitalized cases, cases8 that were adjudicated as severe symptomatic or critically ill COVID-19, and one additional case in the vaccine group (Information extracted from the Summary of Product Characteristics of Vaxzevria-previously known as

AstraZeneca's COVID-19 Vaccine-available at:

https://www.ema.europa.eu/en/documents/product-information/vaxzevria- previously-covid- 19-vaccine-astrazeneca-epar-product-information_en.pdf).

Already evaluating a little more the efficacy of the vaccine on risk of death in real life, not in clinical studies, a study by the Public Healh England Institute in the UK (available at: https://www.medrxiv.org/content/10.1101/2021.05.14.21257218v1.full.pdf+html), published in May 2021, where they estimated the risk of death in COVID-19 cases of the vaccinated compared to the unvaccinated, found that cases of individuals vaccinated with 1 dose of BNT162b2 (Pfizer-BioNTech vaccine) had a 44% reduction in risk of death, 55% with doses1 of ChAdOx1 (AstraZeneca vaccine) and a 69% reduction in risk of death with 2 doses of BNT162b2. This is in addition to the protection provided to avoid becoming a case of symptomatic disease.

The UK Health Safety Agency (UKHSA) reported on the number of hospitalizations directly prevented by vaccination. In total, up to September 19, 2021, about 261 500 hospitalizations have been avoided in people aged over years45. The UKHSA and the MRC Biostatistics Unit at the University of Cambridge reported that estimates suggest that 127 500 deaths and 24 144 000 infections have been prevented as a result of the COVID-19 vaccination program, as of 24September 19.

The UKHSA also has comparative information on hospitalizations and deaths of vaccinated and unvaccinated persons available at the following link: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1027511/Vaccine-surveillance-report-week-42.pdf , which demonstrates that vaccination is a measure that helps to avoid the rates of severe cases of the disease and to prevent deaths.

Clinical trials include large numbers of participants of all ages, sexes and ethnicities, and even with known health problems, but they cannot perfectly represent the entire population. The efficacy observed in clinical trials is restricted to the specific results in a trial, whereas the actual efficacy is measured by calculating the protection conferred to communities as a whole. This actual efficacy may differ from the theoretical efficacy measured in a trial, because it is not possible to predict exactly what the efficacy of vaccination will be in practice in a much larger and variable population vaccinated under real conditions. This information is available at: https://www.who.int/es/news-room/feature- stories/detail/vaccine-efficacy-effectiveness- and-protection .

Vaccines can prevent most people from getting COVID-19, but not all. Even after receiving the recommended doses and waiting a few weeks to develop immunity, there is still a chance of becoming infected. Vaccines do not provide complete (100%) protection, so the virus may infect some people, even if they are fully vaccinated.

For this reason, it has been emphasized that vaccines against COVID-19 are critical to address the pandemic and protect against severe disease and death. While they provide at least some protection against infection and transmission, the protection they confer against severe disease and death is far greater. And after vaccination, it has been urged to maintain some simple precautions: keep physical distance, wear a mask, keep rooms well ventilated, avoid crowds, wash hands, among others.

As we have seen over the course of the pandemic, as cases increase and transmission accelerates, new dangerous and more transmissible variants are more likely to emerge, which may spread more easily or cause more severe symptoms. As far as we know so far, vaccines are effective against existing variants, especially in preventing severe disease, hospitalization and death. However, some variants are slightly affecting their ability to protect against infection and mild symptoms.

Vaccines will probably remain effective against variants because of the broad immune response they generate, meaning that changes or mutations in the virus are unlikely to lead to a complete loss of efficacy, but vaccine boosters may be needed to boost the body's immunity to continue to prevent disease.

With respect to the request for an oral hearing on the absolute nullity claim, it should be pointed out that there is a sufficiently broad legal framework that establishes and supports the power of the competent authorities to establish the obligatory nature of a vaccine, in this case, against COVID-19, depending on its availability, because it is considered necessary to guarantee the protection of the right to health and life, as well as the safeguarding of public health.

Specifically, it is a matter of compliance with the constitutional mandate set forth in ordinals 21 and 50 of the fundamental text and which has been supported by constitutional jurisprudence, which within the current context of the national emergency due to COVID-19, becomes an essential measure to guarantee fundamental legal rights. Therefore, the request to repeal the executive decrees on the obligatory nature of the COVID-19 vaccination is unacceptable.

Sincerely yours,

Dr. Daniel Salas Peraza

MINISTER OF HEALTH

C: Dr. Roberto Arroba Tijerino, Technical Secretary CNVE

[end of quote]

1.In plaintiffs original filing of the precautionary measure, under the Facts "First", plaintiffs argument was not taken into consideration that the laws which normally apply to the CNVE do not apply to this particular product called COVID-19 vaccine because it is a Bio-medical research product which is supposed to be regulated under 9234 and 39061-S. This is critical oversight because we were trying to explain that this legal situation renders the entire use of the COVID-19 Vaccines absolutely null because they were authorized by CNVE who acts in excess of authority.

2. The CNVE and the health minister have failed to explain how a de-facto definition from the WHO would give CNVE authority over a product that our legislators would not define as a vaccine. In order to use a foreign private de facto WHO definition to grant themselves authority, plaintiffs believe there would first need to be motivated reason which allows them to legally adopt the foreign definition of vaccine. In the absence of proof that the WHO is authorized to define "Vaccine" in contrast to our legislators who already define vaccine in 32722(p), the court has a

duty to grant the precautionary measure in order to prevent the manifestly illegal act of COVID-19 biological agent “vaccines” being used in excess of Costa Rica legal limits.

3. The court is requested to address the legality, because:

- So far, even after winning 4 Amparos, and filing over 40 cases there is no way to get adequate or truthful information, or to give effect to the superior law, or enforce the violations of Siracusa Principles, medical morality law article 10 which includes nuremberg code articles 1,3,5,7-8 as well as the declaration of Helsinky and every law in article 10 which is intended to protect the health, life and safety involved in biomedical research.
- So far no one will address the fac the WHO is also in breach of function and not trustworthy to oversee the unproven interventions outside clinical trials and failed to ensure safety and efficacy as promised for their EUL list that CR relies on: see: Dr. Soumya Swaminathan, W.H.O.Chief Scientist, stating in a PSA November 28, 2019 that vaccines are safe and then 5 days later saying the opposite and that some countries are not adequately monitored at a summit. Do you trust the "experts"? Precaution is warranted because the WHO is on recording lying about vaccine safety and admitting the dangers are inadequately monitored for the EUL list! https://www.bitchute.com/video/gq6CDGgNcFRA/
- WHO Chief scientist stating they have zero evidence that the vaccines will even work https://www.bitchute.com/video/ILuQvyHbGVZP/
- There is a pathological slowness of the entire state of Costa Rica including this court to effectively assist petitioners in their mission of giving effect to the law which prevents this exact type of act which is defined by the legislators as serious undue experimentation under article 78-79 of the bio medical research law 9234:
    - The court first failed to serve petitioners the order to integrate PANI for one month causing an undue delay and harm to petitioners interest for prompt justice
    - The court secondly failed to serve us the final resolution Ordered by the judge to dismiss the precautionary measure on March 2023. Until July 17, 2023, over 4 months after the judge ruled!
        - The four month delay in being served caused us a four month delay in being able to address these issues. Petitioners had filed a request to consider new facts on June 7, 2023 wholly unaware that the court had already ruled and that our facts were sitting in the docket being unattended (new facts to amplify the record)
        - Petitioners claim damages due to the pathological slowness of the court in this particular instance where the stakes are so high that both human life, prompt justice to petitioners and the public interest is at serious risk due to the continued execution of manifestly illegal acts of serious undue experimentation that so far we have been unable to prevent but which the legislative clear intent is that this particular act must be prevented immediatel

The factual circumstances have changed that gave rise to the rejection of the requested measure:

*The FDA denied the citizens petition with not duly motivated or pertinent

The FDA updated their site after the filing of the injunction which plaintiffs just found and the FDA does not find the investigational products to be safe or effective and furthermore FDA insists that investigational product can cause serious adverse reactions. Serious adverse reactions are defined as Hospitalizations and death. Based on the following update to the FDA website, petitioners beg the court to due it's duty to issue the precautionary measure in the petitioners interest and in the public interest to protect the safety and welfare of the people who are being subjected to COVID-19 [non] "Vaccine" bio medical research in the Republic.

See FDA extrajudicial irrevocable confession: Investigational drugs, biologics or medical devices have not yet been approved or cleared by FDA and FDA has not found these products to be safe and effective for their specific use. Furthermore, the investigational medical product may, or may not, be effective in the treatment of the condition, and use of the product may cause unexpected serious side effects. https://www.fda.gov/news-events/public-health-focus/expanded-access-Content
current as of: 12/21/2022

First: Comptroller of Costa Rica

The comptroller of Costa Rica has agreed to open an investigation with Plaintiffs to obtain more information in regards to the Pfizer contract in which we have been requesting since 2021 and 2022 between almost every single agency in the government of Costa Rica

The comptroller agreed that there were enough irregularities shown by Plaintiffs regarding the Pfizer contract to open the investigation into the absolute nullity of thecovid-19 vaccine contracts. Please see the documentary evidence provided please

CONIS (The Health Minister is the head)

Judicial Notice: The regulatory agency for experimental biological products in Costa Rica is NOT regulating Pfizer when they are mandated by law to apply the biomedical research laws 9234 and 39061-S, please see judicial confession and documentary evidence

Our updated evidence from our interactions with CONIS in their final resolution. The noted resolution is not duly motivated and pertinent. CONIS-0067-2023 . The foregoing March 27, 2023 CONIS resolution outrageously allows Defendants (and 3rd parties Pfizer, WHO, FDA, et al) to continue to execute the act of applying unproven medical interventions outside clinical trial by not applying the Biomedical Research laws to the covid vaccines.

Ministry of Foreign affairs

Considering the Ministry of Foreign affairs has the duty of multilateral relations internationally, Plaintiffs have requested from them the Pfizer contract and also for more information regarding the directors and controllers of the Health ministry such as the World Economic Forum, World Health Organization, PAHO Pan American Health Organization who are funded by the pharmaceutical companies. All of this will be connected in the process.

a) Sent 5/8/22 - !Email Attachments Sent to Xavier, MDS and 5 others.zip EXTRAS/Attachments/Notice of protest and demand for immediate response and duty of substantiation May 8, 2022.pdf as well as emails notes messages text and all communications from WEF, Bill Gates foundations etc..

FDA October 3, 2022 - final resolution not duly motivated and pertinent

1. President of Costa Rica

Chaves omits administrative duty to review denial of claim of absolute nullity of decree 42227 MP-S, PHEIC and all subsequent measures including the covid-19 non vaccine experiments, and based on the facts and law declare the absolute nullity of the emergency, all measures and the covid vaccines. Chaves omits to explain why he keeps refusing our complaints and instead sending the complaints about the health ministers omissions in circles right back to the health minister. The President refuses his duty to resolve our complaints with no motivation or reason.

Department of Defense United States Of America

Interest of Justice has pending information requests coming from the United States Health and Human services Office of Global affairs which is supposed to be forwarded to the Department of defense and then the DoD shall give those reports to the committees of the US Senate and House.

The Department of Defense of United States i.e. the Secretary of Defense has agreements with the Secretary of Health and Human Services to provide support

for covid-19 vaccination programs of the Secretary of Health and Human Services in the United States through use of the excess peacetime biological weapons defense capability of the Department of Defense.

Interest of Justice has requested this information as well as more pertinent information described in the facts below. The Health and Human Services of the United States has had email correspondences to plaintiffs freedom of information request and is late according to the statute regulating information requests in the United States.

"Because you seek records which require a search in another office, "unusual circumstances" apply to your request, automatically extending the time limit to respond to your request for ten additional days. See 5 U.S.C. 552 § (a)(6)(B)(i)-(iii) (2012 & Supp. V. 2017)."

Further, we estimate needing more than 10 additional days to respond to your request and so, in the next paragraph.

It is still pending as you can see due to the large number of files on the human experimentation for COVID-19 vaccine research conducted on the international community. The use of the investigational biological agent COVID-19 vaccine is authorized by DOD and FDA for use in Costa Rica and export to Costa Rica while knowing of the experimental nature of the medical intervention needs a lengthy discussion. The precautionary should be granted.

World Health Organization

The server or the head of the body that appears as the alleged perpetrator of the offense (The Costa Rican Health Authorities):** now called "The Health Monopoly"

The Costa Rican Health Authorities acted in compliance with orders or instructions issued by a superior, or with his authorization or approval, protection against both shall be considered established:

Plaintiffs have contacted the WHO several times including filing 2 charges in the ethics department. The WHO or the ethics department never responded to the claims. After some time On May 3, 2023 Plaintiffs explained to HHS OGA about the lack of substantiation of our presumed facts and how the WHO refuse to answer to charges filed in their ethics oversight complaint office the violations which involved all of the parties listed in this notice and much much more. Please see video here https://rumble.com/v2lwy0c-ioj-speaking-truth-to-power-exposing-w.h.o.-crimes-may-3-2023-hhs-stakehold.html

On May 21, 2023 Plaintiffs sent a final “Notice Of Claim” To every single responsible party stated in this notice. Please see attached Final Notice of claim to the WHO, HHS OGA, Ministry of Foreign affairs Costa Rica, President of Costa Rica and all regulatory agencies FDA etc...

The notice of claim sent is attached herein further below in the document.

CNE the Costa Rican Emergency Commission:see correspondences

Ministryofforeignaffairs–seedocumentaryevidence

Office of the President Costa Rica- please see final resolutions not duly motivated and absolute nullities - breaches of duty etc..

WorldHealthOrganization-plaintiffsarestakeholdersinthepandemic preparedness and response at the WHO - please see non response and how it affects our organization to refuse to communicate with the international organizations

FDA - Stakeholders - please see documentasry evidence

CDC – See Documentary evidence

HHS OGA Health and human services Office of global affairs stakeholders in the World Health assembly Stakeholders

WEF-world economic forum – See documentary evidence

United Nations- processes See documentary evidence

process’s almost every single legislator in Costa Rica – See documentary evidence

Department of Defense USA - information requests the Secretary of Defense shall submit to the Committee on Armed Services of the Senate and the Committee on Armed Services of the House of Representatives of the United States Government – see documentary evidence

Plaintiffs submitted to the CIPA application for Costa Rica and the public participation mechanisms and they have failed to respond at all! See documentary evidence

And also have processes with the Fiscalia Anticorruption Unit Of the Costa Rican Governm – see documentary evidenceent

Plaintiffs cannot get anywhere with anyone in the world so far as we are silenced, lied to, disregarded and ultimately ignored in our efforts to speak about all of this. Plaintiffs are defenseless. The State relies on FDA and WHO for the safety and efficacy of the product but WHO will not even respond to 2 criminal charges presented through their Ethics department months ago & FDA director Peter Marks denies our citizens petitions in a way which is not duly motivated and not pertinent to the issues of FDA hiding 1223 deaths in the Pfizer trial and FDA authorizing Pfizer BioNtech for children the same day Maddie was in the hospital!

FDA, HHS, WHO, CONIS (regulators who defendants rely on) all flat refuse to address Plaintiffs serious issues and all are still inefficient, inactive, and continuing to execute the absolutely null acts and giving more baseless resolutions that are null which are not duly motivated or pertinent to the issues or facts raised.

On May 21, 2023 Plaintiffs sent a final "Notice Of Claim" To every single responsible party stated in this notice. Please see attached Final Notice of claim to the WHO, HHS OGA, Ministry of Foreign affairs Costa Rica, President of Costa Rica and all regulatory agencies FDA etc...

- CONIS is In violation of the WHO MEURI framework which is an advisory opinion

Main new fact or omissions that motivates it is regarding the CONIS headed by the Health Minister and serious undue experimentation:

INDEX

Introduction and brief of new facts

- The plaintiff files this process so that in a judgment the cessation of the accused inactivity is ordered, which corresponds to the facts

- **CONIS REPLY 1.**
    - Such resolutions as CONIS-0067-2023 are wholly irrelevant and not pertinent or consistent with what is requested by the administrator within the respective constitutive, declarative or recursive administrative procedure.
    - Defendants Constitutional Chamber 4 argument and plaintiffs reply
- **ABOUT THE CONIS REPLY 1**
    - Further More
    - Judicial Notice
        - CONIS is in charge of applying these mandatory compliance laws
        - CONIS omits to add evidence to prove the statement:

        - The lawsuit against the DOD, Operation Warp Speed and the COVID vaccines filed May 31, 2023
        - EUA Statement: This emergency use of the product has not been approved or licensed by FDA
        - This omission to provide adequate and truthful information or fulfilled justice to petitioners is causing an act in excess of law that CONIS is failing to properly resolve

- **CONIS Reply 2**
    - Regarding informed consent
    - **ABOUT CONIS REPLY 2**
        - The product is supposed to be regulated under 9234 and 39061-S
        - WHO document from 2022 - EMERGENCY USE OF UNPROVEN CLINICAL INTERVENTIONS OUTSIDE CLINICAL TRIALS: ETHICAL CONSIDERATIONS
        - The purpose of our petition for serious undue experimentation is precisely because the CONIS response failed to adequately address the points in our petition that the above laws are being disregarded and this is a violation of 9234 Article 78 and 79.
- **CONIS Reply 3**
    - studies to evaluate the effects of a medicine that has already been approved and are observational***; therefore
    - **About the CONIS REPLY 3**
        - They lied Pfizer is fully approved, but what about AstraZenica which is admittedly only under EUA?
        - CONIS CLAIMS: 3 and Biomedical research 9234 explanation and definitions
        - The resolution is not resolved according to strict legalities and definitions because CONIS is pretending apples are oranges and omitting to decide facts in the proper WHO ethical framework that applies
- **CONIS Reply 4**
    - Regarding your complaint, I must also inform you that Article No. 72 of Law 9234 indicates the characteristics
    - **ABOUT CONIS REPLY 4**
        - The documentary evidence from CNVE and the Health Minister January 24, 2022
        - Regarding point c) Plaintiffs forcefully reject this unmotivated unproven reason to deny our complaint
        - Regarding point e) The documentary evidence was attached in an email in the same email thread

- **CONIS Reply 5**
  - Due to all of the above (CONIS REPLY 1-5), your requests set forth in the document received cannot be complied with for the following reasons *
  - The noted resolution CONIS-0067-2023 from March 27, 2023 is not duly motivated and pertinent. The response from CONIS fails to resolve the administrative procedure
  - Conclusions and Judicial Notice*
  - Issues presumed true because the defendant has failed to address or refute each point*
    - CONIS omits to address or refute the fact that the covid vaccine is investigational and therefore had to be imported for the "exclusive use of biomedical research" and "in compliance with applicable laws
    - CONIS omits to address or refute the fact that on record they are studying the ADVERSE effects in interventional studies
    - CONIS is omitting their duty under the WHO's MEURI ethical framework to monitor the identified known risks such as VAED's or ADE (auto immune attack from self antigens) of the unproven intervention.
    - continued
    - Judicial Notice
      - The act of applying unproven medical interventions outside clinical trial by not applying the Biomedical Research laws
      - facts prove that CONIS facilitates to third parties WHO, EMA, FDA, Pfizer, AstraZenica, et al
      - CONIS is in breach of function by infringing, consenting, or facilitating to third parties infractions of the legal provisions, regulations, agreements of the Conis, CEC or bioethical principles that govern biomedical research
  - THE APPROPRIATE WHO ETHICAL AND LEGAL LIMITS ARE UNDER THE WHO ETHICAL MEURI FRAMEWORK THAT APPLIES TO "COVID-19 VACCINES"
  - Considering
    - According to the Organic Regulations of the National Health Research Council (CONIS) N° 40884 - S Organic Regulations of the National Health Research Council (CONIS) N° 40884 - S
    - The representation of CONIS as a body attached to the Ministry of Health is approved and the organization of said body is ***partially approved in accordance with the technical criteria described above***
  - Conclusions of Fact
    - CONIS is merely ***"partially approved" only so long as it acts "in accordance with the technical criteria described above".

- CONIS is omitting to apply the proper laws in order to commit manifestly illegal and immoral acts of undue experimentation and serious undue experimentation by omitting adequate and truthful information and informed consent
- CONIS response does not resolve the process. CONIS OMIITS adequate and truthful information, a right under Article 46 of the Constitution

The right that's considered, violated or threatened:

- The right to an efficient administration
- adequate and truthful information
- The right to Prompt and fulfilled administrative procedure
- Control the legality
- protect the public interest
- The right to defend human rights

The name of the public servant or body responsible for the threat or offense:

- The State of Costa Rica
  - Ministerio de salud
    - Organic Regulations of the National Health Research Council (CONIS)

CONIS Facilitated breaches and infractions of law 9234 to third parties

- Pfizer
- Astrazenica
- Costa Rica
- Costa Rica Ministry of Foreign Affairs
- Comptroller of Costa Rica
- PANI Childrens Fund
- President of Costa Rica
- FDA USA
- DoD (Department of defense USA)
- World Health Organization prequalification and emergency use listing programs (EUL)
- Given the rapid development of vaccines against COVID-19 as well as their early approval has raised concerns in some people about whether all the safety and efficacy standards of the vaccines were met, we want to clarify a little about the research phases of the vaccines. vaccines and a bit of the vaccine approval process by the FDA and EMA who are founding members of the International Council on Harmonization of Technical Requirements for Pharmaceutical Substances for

Human Use and meet the WHO definition of Strict Regulatory Authority (available at https:// www.who.int/ initiatives/ who listed-authority-reg-authorities/ SRAs).

And Evidence:

CONIS Complaints through email:

Administrative record complaint to CONIS

1. First complaint - March 15, 2023 IOJ wrote CONIS a complaint for serious undue experimentation

2. Second email of evidence - March 16, 2023 IOJ amplifies the complaint which was sent March 15, 2023 with evidence

3. March 27, 2023, CONIS responds with a notification of receipt stamped

4. Conis Response March 27 2023 CONIS-0067-2023. The foregoing March 27, 2023 CONIS resolution to continue to execute the act of applying unproven medical interventions outside clinical trial by not applying the Biomedical Research laws to the covid vaccines, facilitates to third parties WHO, EMA, FDA, Pfizer, AstraZenica, et al infractions of CR law CONIS law 9234 Article 20 breach of function, also violating penal code ARTICLE 339.- Breach of duties
   - CONIS Resolution is not duly motivated and pertinent
   - CONIS not regulating the sponsors interventional research registered as interventional in CONIS
   - says APPROVED but OMITS the evidence, therefore the claim covid vaccines are not biomedical research has not been duly motivated or proven.
   - CONIS omits their burden of proof to dismiss our petition to control the legality and stop the interventional serious undue experimentation that violates 9234 78 and 79
   - Facilitates breaches of law 9234 Articles 78 & 79 to third parties still OMITTING Informed consent for biomedical research, in violation of 9234 Article 78, 79
     * Pfizer
     * Astrazenica
     * Costa Rica
     * Costa Rica Ministry of Foreign Affairs
     * Comptroller of Costa Rica
     * PANI Childrens Fund
     * President of Costa Rica
     * FDA USA

* DoD (Department of defense USA)

* World Health Organization prequalification and emergency use listing programs (EUL)

* Given the rapid development of vaccines against COVID-19 as well as their early approval has raised concerns in some people about whether all the safety and efficacy standards of the vaccines were met, we want to clarify a little about the research phases of the vaccines. vaccines and a bit of the vaccine approval process by the FDA and EMA who are founding members of the International Council on Harmonization of Technical Requirements for Pharmaceutical Substances for Human Use and meet the WHO definition of Strict Regulatory Authority (available at https://www.who.int/initiatives/wholisted-authority-reg-authorities/SRAs).

* Resolution from CONIS not duly motivated and pertinent CONIS-0067-2023, 27 de Marzo de 2023

1. Overview Emergency use of unproven clinical interventions outside clinical trials: ethical considerations 12 April 2022 Technical document https://www.who.int/publications/i/item/9789240041745

2. CONIS and Health Ministry are omitting key systems needed for compliance and harmonization with WHO advisory opinion https://www.researchgate.net/publication/361334249_Research_ethics_systems_in_Latin_America_and_the_Caribbean_a_systemic_assessment_using_indicators

3. Indicator countries indicator to strengthen research compliance

4. Title called "Regulatory approvals for Pfizer-BioNTech's COVID-19 Vaccine:", with a list of dates and authorizations for Pfizer BioNTech and AstraZenica

5. Testimony in the record January 24, 2022 from Health Minister Daniel Salas and CNVE secretary Roberto Arroba Tijerino proving "covid-19 vaccines are investigational biomedical research products"

6. January 4th, 2022 cease and desist the covid non vaccine gene therapy bioweapon demand as URGENT and PERTINENT due to death being common from Pfizer BioNTech

7. Lancet article proving the PCR test is void creating all false positives "the PCR test is not the gold standard")

8. **The lawsuit against the DOD, Operation Warp Speed and the COVID vaccines filed May 31, 2023 explains the BioNTech and Corminarty bait and switch https://childrenshealthdefense.org/defender/george-watts-jr-pfizer-covid-vaccine-injury/ The family of a 24-year-old man who died from complications of COVID-19 vaccine-induced myocarditis

9. Pfizer-BioNTech COVID-19 Vaccine COMIRNATY® Receives Full U.S. FDA Approval for Individuals 16 Years and Older". https://www.pfizer.com/news/press-release/press-release-detail/pfizer-biontech-covid-19-vaccine-comirnatyr-receives-full

10. difference of the approved COMIRNATY and legally different EUA BioNTech https://www.fda.gov/media/150386/download
11. The FDA website currently says BioNTech is under EUA see: https://www.fda.gov/vaccines-blood-biologics/coronavirus-covid-19-cber-regulated-biologics/pfizer-biontech-covid-19-vaccines#additional
12. EUL Strict regulatory agencies https://extranet.who.int/pqweb/vaccines/covid-19-vaccines
13. 12 registered experiments of covid-19 vaccines. There are a few registered studies of Pfizer BioNTech
14. https://www.ministeriodesalud.go.cr/conis/index.php/servicios/investigaciones-registradas
15. https://www.ministeriodesalud.go.cr/conis/index.php/servicios/requisitos-de-importacion
16.https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-investigational-drug
17. The **investigational** drugs, biological products, or medical devices have **not yet been approved or cleared by the FDA https://www.fda.gov/news-events/public-health-focus/expanded-access
18. FDA requested that the Sponsor update their PVP to include missing information in pediatric participants less than 16 years of age. see pg 44 https://www.fda.gov/media/144245/download
19. ethical considerations ISBN 978-92-4-004174-5 (electronic version) https://www.who.int/publications/i/item/9789240041745
20. WHO issued a document December 2022 that says covid-19 vaccines are "unproven novel vaccine interventions outside clinical trials" that need to go by the WHO MEURI ethical framework
21. CONIS testified on March 27, 2023 that the CONIS is not regulating the experimental use of the covid vaccines at al

22. World Health Organization *Emergency use of unproven clinical interventions outside clinical trials: ethical considerations.pdf*

23. Carla_Saenz_PAHO_2022_ethics_docAguileraetal_ResearchethicsindicatorsLAC (2).pdf

Exact International instrument articles of treaties and bodies

* Memorandum of law

Contentious administrative procedural code 30 and more

* Treaties and National Laws

Siracusa Principles, medical morality law article 10 which includes nuremberg code articles 1,3,5,7-8 as well as the declaration of Helsinky and every law in article 10 which is intended to protect the health, life and safety involved in biomedical research.

ARTICLE 71.- Precautionary measures
During the processing of administrative procedures or investigations in court that question the legality of the activity of the investigator, the sponsor or the CEC, the OIC or the OAC and for the purpose of safeguarding the health and safety of the participants in an investigation , the competent body may impose the necessary precautionary measures. The investigations, the investigator or the approval of research projects may be temporarily or permanently, partially or totally suspended in the event that the administrative authority or the judicial authority considers it necessary. The competent body, through a well-founded resolution and after hearing the interested parties, must resolve whether to confirm, modify or revoke the measure adopted. To do this, you must apply the procedure established by the Contentious-Administrative Procedure Code.

legality is based on omissions of conduct which include lack of duly motivated resolutions, from the defendants who are all acting in concert together to violate Plaintiffs rights. Such resolutions are wholly irrelevant and not pertinent or consistent with what is requested by the administrator within the respective constitutive, declarative or recursive administrative procedure.

The plaintiff files this process so that in a judgment the cessation of the accused inactivity is ordered, which corresponds to the fact that from March 15, 2021 until today, Plaintiff presented administrative procedures to stop serious undue experimentation by CONIS, right to control the legality including the import and use of covid-19 non vaccine biological agents; which as of the filing date of this claim, the plaintiff indicates that it has not been resolved.

Brief:

The plaintiff files this process so that in a judgment the cessation of the accused inactivity is ordered, which corresponds to the fact that from March 15, 2023 until today as well as other extraordinary administrative and judicial processes from 2020 to 2023, he presented administrative procedure for the recognition, declaration and cessation of the use of unproven intervention covid-19 non vaccine biological agents outside a clinical trial in violation of 9234 Article 78 and 79 serious undue experimentation; which as of the filing date of this claim, the plaintiff indicates that it has not been resolved

5. Resolution from CONIS not duly motivated and pertinent CONIS-0067-2023, 27 de Marzo de 2023

2).- The representation of the defendant, in what is relevant to the specific case, rejected petition dated March 15, 2023 titled "Dear Friends" with a void resolution CONIS-0067-2023 27 de Marzo

de 2023 which is not duly motivated or pertinent to the issues of human research and experimentation including the import and use of investigational covid-19 non vaccine biological agents under health law Article 117 "for the exclusive purpose of human research" and other points as stated herein which are not duly motivated and pertinent.

The CONIS response to our serious petition was based on misinterpretations of the biomedical research law by CONIS that are causing our petition to not be promptly resolved in strict accordance with law, and causing breach of function and unfulfilled justice.

CONIS has failed to meet their burden of proof that the covid-19 vaccines are FULLY APPROVED and therefore not serious undue experimentation, in excess of 9234 Article 58, 78, 79 as alleged in the initial filing.

The CONIS, is not attending to the truth of the fact the covid-19 vaccines are properly regulated under 9234 and 39061-S as biomedical research.

The legality is for the right to control the legality, to an efficient Administration, prompt and fulfilled justice and adequate and truthful information which is systematically being denied to petitioners! It seems interpretations of law are required to get to the truth and justice.

The petitioners right to prompt and fulfilled justice cannot be truly fulfilled until the CONIS proves both of the covid-19 vaccines are approved and not investigational or interventional, or failing that impossible task, to have the law finally work right, which requires the court to prevent the investigational unproven interventions outside clinical trial, which constitute serious undue experimentation in violation of 9234 Article 78 and 79 and correct all omissions of the CONIS and members of Minesterio de Salud, CNVE, etc inside of CONIS.

Our petition to CONIS was denied contrary to law, based on false facts and should be approved so the manifestly illegal acts are stopped.

Furthermore the challenged conduct is based on prima facie **violations of the latest WHO advisory opinion in the Emergency use of unproven clinical interventions outside clinical trials: ethical considerations 12 April 2022 Technical document** outlined herein. Plaintiffs forcefully assert that under Emergency use of unproven clinical interventions outside clinical trials: ethical considerations 12 April 2022 Technical document, Costa Rica laws 9234 and 39061-3 the CONIS and all human research in Costa Rica must be suspended until the biomedical research laws and oversight of all human research is reformed to be in compliance with the latest WHO standards. See Overview Emergency use of unproven clinical interventions outside clinical trials: ethical considerations 12 April 2022 Technical document - https://www.who.int/publications/i/item/9789240041745 "This document is intended to provide

policy-makers, authorities in charge of the prevention and management of a public health emergency, such as ministries of health, national regulatory authorities and national disaster management agencies, health-care workers, ethics committees and others, with:
- an updated version of the ethical framework for use of unproven clinical interventions outside clinical trials during public health emergencies (the MEURI ethical framework),
- general and operational recommendations for implementing the framework and
- answers to questions that stakeholders may raise."

Plaintiffs point out the evidence attached shows the CONIS and Health Ministry are omitting key systems needed for compliance and harmonization with WHO advisory opinion: https://www.researchgate.net/publication/361334249_Research_ethics_systems_in_Latin_America_and_the_Caribbean_a_systemic_assessment_using_indicators

22 Latin America and the Caribbean countries were selected on the basis of population size (more than 1 million inhabitants), which is where more than 99% of research in the region is being done (appendix p 1): Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, Guatemala, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, Trinidad and Tobago, Uruguay, and Venezuela. Although this approach was devised for Latin America and the Caribbean, our recommendations are applicable in other low- middle- income and middle -income countries (LMICs) facing common challenges, such as scarce resources, inadequate research capacity and infrastructure, and weaker governance frameworks and institutions.6 We directly accessed national legal repositories and ministerial websites to retrieve legal documents (eg, laws, government decrees, and ministerial circulars)and other publicly available information. These were analysed and used to complete the indicators evaluation tool,7 which was successively discussed with health authorities— whom PAHO supports on an ongoing basis—and ethicists from the region who regularly collaborate with the Regional Program on Bioethics. Given the complexity of the landscape and to do justice to the diverse efforts taking place to strengthen research ethics, the preliminary results were further discussed in meetings with the research ethics community from Latin America and the Caribbean, which contributed to a better understanding of challenges and the way forward. The analysis was conducted between February, 2020, and June, 2021 (with a May, 2020, to March, 2021, pause due to the COVID-19 pandemic). Action (ie, legal documents, policy instruments, and establishment of entities) taken specifically to deal with the pandemic was not included in the analysis; that has been addressed in another study focusing on the region's research ethics response to COVID-19. Assessment!

To be a functional regulatory the elements would have to comply with the following, which are all omitted by the WHO, FDA, EMA, CONIS, HHS, DoD, et al:

- Latest 2022 WHO advisory opinion and guidance on covid-19 vaccines: "***Emergency use of unproven clinical interventions outside clinical trials: ethical considerations"*** (CONIS,

WHO, FDA, EMA, et al – all globally incorporated into the WHO prequalification program are all not applying this guidance to thecovid-19 vaccine, which is unethical and causes the invocation of the duty to impose restrictions and limits in strict accordance with law and this ethical framework. Precautionary measures to extend to the superiors are wholly appropriate and long overdue to fulfill legislative and WHO real intent in these documents. The application of this critical guidance is omitted and violated, therefore precaution in the interest of legality and ethics is appropriate to reconsider!

- Existence of the requirement of the prospective registration of clinical trials in accordance with WHO standards
- Existence of policies on the responsible conduct of research
- Existence of established procedures to do thorough accelerated ethics review of research during emergencies
- Existence of policies on the responsible conduct of research
- Existence of established procedures to do thorough accelerated ethics review of research during emergencies
- The following WHO advisory opinions for research standards from the PAHO document: "Research ethics systems in Latin America and the Caribbean: a systemic assessment using indicators **Article** *in* The Lancet Global Health · June 2022 DOI: 10.1016/S2214-109X(22)00128-0" are NOT in compliance in Costa Rica require precaution is appropriate to reconsider the request for prevention!

	Indicator	Achieved	In progress	Not initiated
1	Existence of legally binding instruments for health-related research with human participants in alignment with international guidelines	Argentina, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, Mexico, Panama, Peru, and Uruguay	Bolivia, El Salvador, Guatemala, Haiti, Honduras, Jamaica, Nicaragua, Paraguay, and Venezuela	Trinidad and Tobago
2	Existence of a national body responsible for the oversight of research ethics committees	Argentina, Brazil, Chile, Costa Rica, Cuba, Ecuador, El Salvador, Mexico, Panama, Paraguay, Peru, and Uruguay	Bolivia, Colombia, Dominican Republic, Guatemala, Haiti, Honduras, and Venezuela	Jamaica, Nicaragua, and Trinidad and Tobago
3	Existence of policies that support research ethics training for investigators and ethics review committees	Argentina, Colombia, Costa Rica, Cuba, Panama, Peru, and Venezuela	Bolivia, Brazil, Chile, Dominican Republic, Ecuador, El Salvador, Guatemala, Mexico, Paraguay, and Uruguay	Haiti, Honduras, Jamaica, Nicaragua, and Trinidad and Tobago
4	Existence of the requirement of the prospective registration of clinical trials in accordance with WHO standards	Cuba	Argentina, Brazil, Chile, Colombia, Costa Rica, Ecuador, Guatemala, Haiti, Mexico, Panama, Peru, and Uruguay	Bolivia, Dominican Republic, El Salvador, Honduras, Jamaica, Nicaragua, Paraguay, Trinidad and Tobago, and Venezuela
5	Existence of policies on the responsible conduct of research	Peru	Colombia and Panama	Argentina, Bolivia, Brazil, Chile, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, Guatemala, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Paraguay, Trinidad and Tobago, Uruguay, and Venezuela
6	Existence of established procedures to do thorough accelerated ethics review of research during emergencies	Panama	Brazil and Peru	Argentina, Bolivia, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, Guatemala, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Paraguay, Trinidad and Tobago, Uruguay, and Venezuela

Table 2: **Countries per indicator and its compliance**

The new fact, or omission that motivates this appeal

Such resolutions as CONIS-0067-2023 are wholly irrelevant and not pertinent or consistent with what is requested by the administrator within the respective constitutive, declarative or recursive administrative procedure.

CONIS REPLY 1.

*"According to what has been indicated by the Constitutional Chamber in different votes to indicated that it adopts what has been indicated by the health authorities on the fact that the vaccine against COVID-19 is not a vaccine that can be classified as experimental, an example of this is cited in accordance with vote number 2022000487 of 9:15 hours of January 7, 2022, which indicates: "V.- On the specific case. First of all, it should be emphasized that, as explained by the Minister and the Technical Secretary of the National Commission of Vaccination and Epidemiology of the Health Surveillance Directorate, both of the Ministry of Health, as well as the Executive President and the Medical Manager, both of the Costa Rican Social Security Fund (CCSS), **the vaccines applied in the country, against the COVID-19 coronavirus, are not drugs in experimental phase**. IX.- The appellant insisted that the mandatory vaccination should not be applied without an informed consent indicating to the patients that it is an experimental drug. In this regard, it should be noted that **the competent health authorities in the matter have rejected that it is an experimental drug, as stated above.**" It should be noted that the Constitutional Chamber itself has also made reference to the National Commission of Vaccination and Epidemiology as the body called to define the use of vaccines in the country."*

Plaintiff states that in order to prove it, there is a title called "Regulatory approvals for Pfizer-BioNTech's COVID-19 Vaccine:", with a list of dates and authorizations for Pfizer BioNTech and AstraZenica, none of which show any evidence of actually being approved, which the alleged approval is the basis of denying our petition for serious undue experimentation.

ABOUT THE CONIS REPLY 1. The main basis of denial which is "the alleged APPROVAL of both vaccines", which CONIS says "makes them not biomedical research products", is a false conclusory statement that is NOT duly motivated.

CONIS has failed to meet their burden of proof that the covid-19 vaccines are FULLY APPROVED and therefore not serious undue experimentation, in excess of 9234 Article 78, 79.

The following CONIS response is an unsubstantiated claim with no supporting evidence, in order for CONIS to get out of applying the applicable law:

CONIS unsubstantiated testimony March 27, 2023, *"August 23, 2021 FDA formally approves Pfizer-BioNTech's COVID-19 vaccine under the brand name Cominarty to prevent COVID-19 disease in people 16 years of age and older."*

It is worth mentioning there is no evidence to support this claim of CONIS, and there is mountains of evidence, including testimony in the record January 24, 2022 from Health Minister Daniel Salas

and CNVE secretary Roberto Arroba Tijerino proving "covid-19 vaccines are investigational biomedical research products" to dispute the CONIS claim above.

CONIS reply #1 provided a list of dates of Pfizer BioNtech and AstraZenica EUA authorizations under the title "Regulatory approvals for Pfizer-BioNTech's COVID-19 Vaccine:" All dates had links as evidence of the investigational nature. The deceit comes into play when CONIS finished the list of EUA authorizations for Pfizer BioNTech, with the already disproven claim that:

"August 23, 2021 FDA formally approves Pfizer-BioNTech's COVID-19 vaccine under the brand name Cominarty to prevent COVID-19 disease in people 16 years of age and older."

Notably, this one key critical piece of so called evidence that would indeed prove CONIS is innocent of serious undue experimentation has no link or reference to where CONIS dreamed up that Biontech Pfizer EUA product was approved on August 23, 2021.

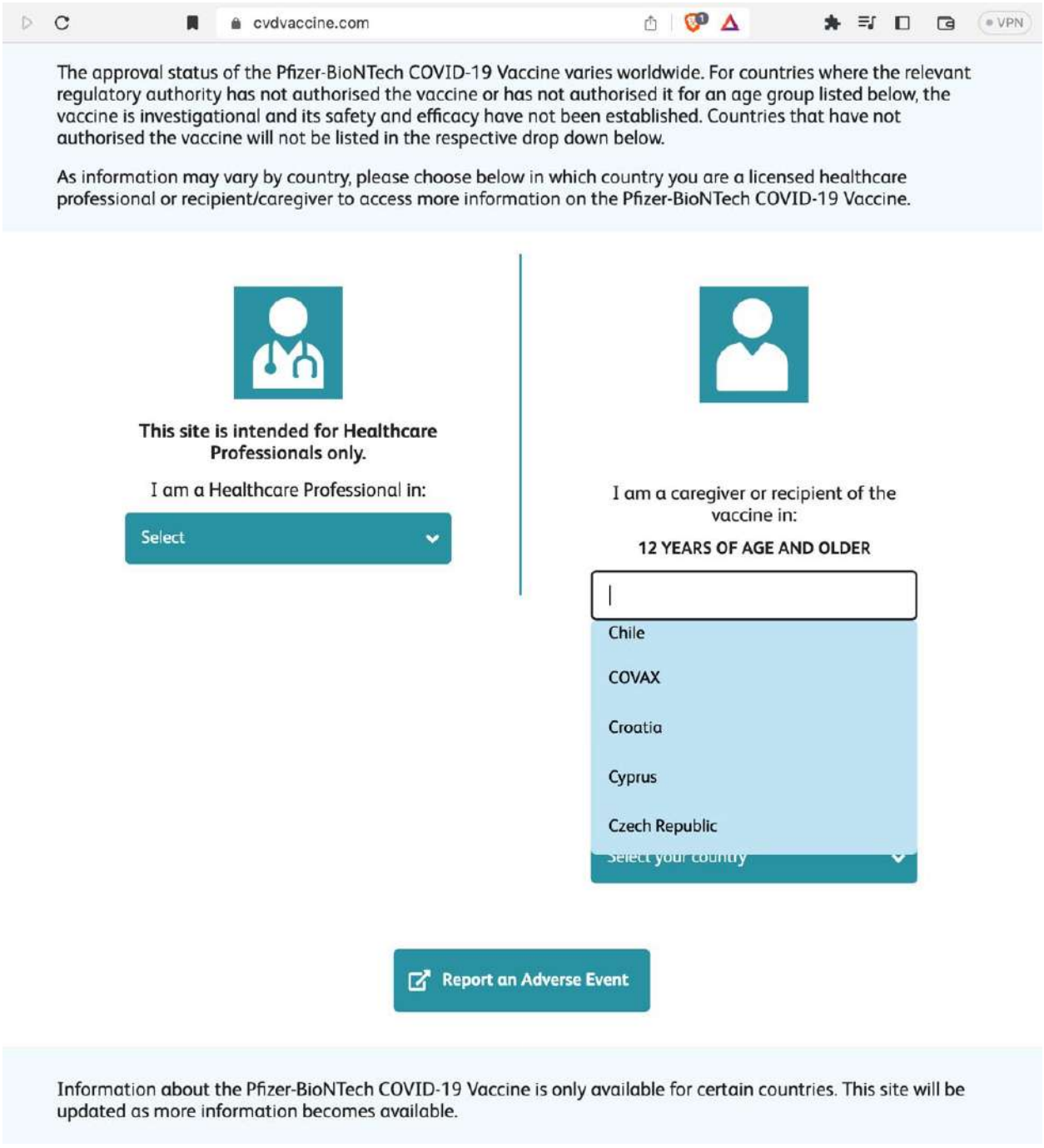
Remember, CNVE testified already the covid vaccines are imported under 117 health law "for the exclusive purpose of human research"

It seems to Plaintiffs that the other links for Pfizer and AstraZeneca EUA's provided by CONIS are irrelevant and the one piece of relevant "evidence" is missing - the proof that both brands are fully approved (Pfizer on August 23, 2021 and AstraZeneca who's approval date is not mentioned by CONIS), if it really exists, is required to be absolutely proven, because it is a lie that affects non derogable fundamental rights and freedoms to not be experimented upon without informed consent.

To date: no evidence exists anywhere on earth that Pfizer BioNtech or Astrazeneca is fully approved and therefore not subject to the biomedical research laws of Costa Rica.

Proof that it is NOT yet approved can be found on the official BioNTech website: see the official FDA & Pfizer fact sheet: https://www.cvdvaccine.com/ *"Global Information About Pfizer-BioNTech COVID-19 Vaccine (also known as BNT162b2 or as COMIRNATY) The approval status of the Pfizer-BioNTech COVID-19 Vaccine varies worldwide. For countries where the relevant regulatory authority has not authorised the vaccine or has not authorised it for an age group listed below, the vaccine is investigational and its safety and efficacy have not been established. Countries that have not authorised the vaccine will not be listed in the respective drop down below. As information may vary by country, please choose below in which country you are a licensed healthcare professional or recipient/caregiver to access more information on the Pfizer-BioNTech COVID-19 Vaccine. Information about the Pfizer-BioNTech COVID-19 Vaccine is only available for certain countries. This site will be updated as more information becomes available."*

The following screenshot is from July 20, 2023 in which Costa Rica is NOT on the dropdown menu which means Costa Rica has NOT authorized the vaccine.



The truth is the Pfizer BioNTech covid vaccine in use in the republic from day 1 until today is not approved on August 23, 2022. it is still under EUA, still investigational, a word meaning experimental and may never be approved according to Pfizers SEC filing for investors. CONIS does concede AstraZenica is merely authorized, not fully approved, however, insisting illogically that the unapproved AstraZenica covid vaccine is not experimental, which makes no sense. There is no motivation why they claim this in light of the evidence.

CNVE & the Health Minister must be lying when they testified the opposite by saying covid-19 vaccines are:
* Imported under 117 as an investigational product (a law which allows imports for exclusive purpose of biomedical research)

Furthermore,

Its important to notice the date of CONIS's so called evidence which is from Sala 4 on January 7, 2022. To prove the covid vaccine is not experimental CONIS refers us to a highly contentious and disputed Sala 4 ruling issued January 6, 2022, the very same day Minesterio de Salud stamped our January 4th, 2022 cease and desist the covid non vaccine gene therapy bioweapon demand as URGENT and PERTINENT due to death being common from Pfizer BioNTech in phase 4 RWE study using FDA and CDC public data aggregated and analyzed by ehealthme.com, a source for Lancet and other scientific publications which the Health Minister Daniel Salas testified is an acceptable scientific rigor that is documentary evidence. (even though he refused to acknowledge our Lancet article "the PCR test is not the gold standard" proving the PCR test is not the gold standard as he repeatedly testified) The Jan 6, 2022 is documentary evidence. (even though he refused to acknowledge our Lancet article proving the PCR test is void creating all false positives "the PCR test is not the gold standard")

Judicial notice:

It is important to notice that Sala 4 has referred Daniel Salas to the prosecutor three times in Plaintiffs ordeal of an ongoing record for false testimony to determine the falsity of the testimony such as the kind CONIS referred to lying its not experimental. Sala 4 essentially says they are a rubber stamp for administrative lies and they wrongly insist that until the prosecutor determines its false they must take whatever technical guidance the administration testifies as true. We prove its a lie over and over (our facts are not taken as true by any judge or administration, despite being factually correct). Sala 4 wont budge to recognize the experimental nature or false testimony, even though Plaintiffs repeatedly prove it before the rulings. The serious undue experimentations continued execution is only because the Prosecutor is inactive and inefficient and Sala 4 is not functional. Its very distressing, financially overly burdensome and time consuming causing Plaintiffs serious damage financially, morally and psychologically to watch harm to humanities genome, health and life be stolen by corrupt captured regulators and to see CONIS fail duty entirely leaving vulnerable people to be experimented upon in a way that absolutely causes harm and is creating a literal genocide by the strict definition of law and fact. On January 18, 2022 the corrupt and malicious Daniel Salas denied our January 4th cease and desist the non vaccine gene therapy experiment demand (stamped urgent & pertinent Jan 6 2022). The resolution was in error, not duly motivated or pertinent, based on false facts and contrary to law. The ongoing administrative record goes into great detail of facts and law which prove absolute nullity. In the resolution he insisted

"I reiterate the covid vaccine is not experimental". On January 24th, 2022 the CNVE had replied which was sent through Daniel Salas completely contradicting the prior weeks testimony of the Health Minister. Roberto Arroba Tijerino irrevocably testified and confessed the product is imported as investigational for exclusive research purposes and properly regulated under 9234 biomedical research laws which CONIS is in charge of applying these mandatory compliance laws.

There is no motivation why the Sala 4 ruling from January 6, 2022 would be relevant to the matter when we explained CNVE and Ministerio De Salud issued a resolution January 24, 2022 confessing the products are investigational and regulated as research under 9234 and other biomedical research laws, imported under 117 health law for the "exclusive purpose of human research"

CONIS omits to add evidence to prove the statement: "August 23, 2021 FDA formally approves Pfizer-BioNTech's COVID-19 vaccine under the brand name Cominarty to prevent COVID-19 disease in people 16 years of age and older.

CONIS did not give a link to the proof of their claim that "August 23, 2021 FDA formally approves Pfizer-BioNTech's COVID-19 vaccine under the brand name Cominarty" because the press release for the Corminarty approval on August 23, 2021 says BioNTech is merely under EUA and NOT approved like Corminarty is, it is legally different and under Emergency Use Authorization (EUA).

The lawsuit against the Department of Defense USA (DOD), Operation Warp Speed and the COVID vaccines filed May 31, 2023 explains the BioNTech and Corminarty bait and switch very well and why 9234 Article 58 insurance currently omitted by CONIS is required under law

https://childrenshealthdefense.org/defender/george-watts-jr-pfizer-covid-vaccine-injury/

The family of a 24-year-old man who died from complications of COVID-19 vaccine-induced myocarditis today filed a lawsuit against the U.S. Department of Defense (DOD), which oversaw the development and distribution of the drug under [Operation Warp Speed](https://childrenshealthdefense.org/defender/operation-warp-speed-big-payouts-pharma-execs/). On Oct. 27, 2021, at home with his mother, Watts began coughing up blood and then became unresponsive. His mother called 911 and administered CPR.

Watts was taken to the ER where he was found to be in cardiac arrest and subsequently died. He had no previous medical history that could explain his [sudden death](https://childrenshealthdefense.org/defender/cause-unknown-edward-dowd-sudden-deaths-covid-vaccines/). Watts also tested negative for COVID-19 in a post-mortem test.

The medical examiner ruled his cause of death to be "complications of COVID-19 vaccine-related myocarditis." His death certificate also listed COVID-19 vaccine-related myocarditis as the sole immediate cause of death.

An independent physician, Dr. Sanjay Verma, also attested the vaccine was the proximate cause of death as alleged in the complaint.

[Ray Flores](https://childrenshealthdefense.org/authors/ray-l-flores-ii-esq/), the attorney representing the estate of George Watts Jr. filed the [lawsuit](https://childrenshealthdefense.org/wp-content/uploads/Watts-v.-DOD-EDT.pdf) in the U.S. District Court for the District of Columbia against the DOD and [Lloyd Austin III](https://www.defense.gov/About/Biographies/Biography/article/2522687/lloyd-j-austin-iii/) in his official capacity as defense secretary.

The lawsuit alleges the DOD engaged in "willful misconduct" by continuing to exclusively allow distribution of the stockpiled version of the Pfizer-BioNTech vaccine that had been authorized for emergency use even after the U.S. Food and Drug Administration (FDA) granted full approval to a different vaccine, [Comirnaty](https://childrenshealthdefense.org/defender/steve-kirsch-alix-mayer-pfizer-approved-comirnaty-vaccine/).

According to the complaint, the DOD "capitalized on a quintessential '[bait and switch](https://childrenshealthdefense.org/defender/childrens-health-defense-sues-fda-pfizer-comirnaty-covid-vaccine/)' fraud," using the fact that Comirnaty was FDA-approved to bolster its claims that the vaccine authorized for emergency use was "safe and effective," in a move that intentionally misled millions of Americans.

The DOD did this despite being fully aware that drugs granted Emergency Use Authorization (EUA) cannot legally be marketed as "safe and effective" because the FDA standard for EUA is only that drugs "may be effective."

That means the DOD intentionally, without justification and with disregard for the risks, misrepresented an experimental vaccine as "safe and effective" when it could not legally use that terminology, the lawsuit states.

As a result, the lawsuit alleges, George Watts Jr. was misled into taking the investigational vaccine and he died as a result.

The [FDA approved](https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine) the Pfizer Comirnaty vaccine on Aug. 23, 2021, but the DOD didn't make it available.

In January 2020, then-Health Secretary Alex M. Azar of the U.S. Department of Health and Human Services declared a [public health emergency](https://aspr.hhs.gov/legal/PHE/Pages/2019-nCoV.aspx) for COVID-19.

The emergency declaration allowed the health secretary to make a [PREP Act declaration](https://childrenshealthdefense.org/defender/prep-act-covid-vaccine-injury-liability/) so the [FDA could issue an EUA](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities) for an unapproved vaccine or other "countermeasure" to address the emergency if the

following [emergency circumstances](https://childrenshealthdefense.org/wp-content/uploads/Watts-v.-DOD-EDT.pdf) exist:

"(1) the existence of a serious or life-threatening disease; (2) a product 'may be effective' in treating or preventing it; (3) there is 'no adequate, approved, and available alternative to the product for diagnosing, preventing or treating such disease or condition;' (4) a risk-benefit analysis that measures both the known and potential benefits of the product against the known and potential risks of the product is positive; and (5) that the patient's option to accept or decline the product is protected through informed consent."

On May 15, 2020, the Trump White House announced [Operation Warp Speed](https://web.archive.org/web/20201216233803/https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html) — a partnership between the White House and the DOD to accelerate the development, production and distribution of a COVID-19 vaccine.

Two months later, the [DOD signed a contract with Pfizer](https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf) to manufacture hundreds of millions of doses of its mRNA COVID-19 vaccine, guaranteeing that any vaccine produced under the contract would be protected under the PREP Act and therefore not subject to liability.

The FDA issued an EUA for the Pfizer-BioNTech COVID-19 vaccine on Dec. 11, 2020, and Army Gen. Gustave F. Perna, [Operation Warp Speed chief operating officer](https://www.defense.gov/News/News-Stories/Article/Article/2445137/operation-warp-speed-official-first-covid-19-vaccines-to-arrive-monday/), announced the vaccine would be rapidly distributed across the country.

Drugs fully approved by the FDA must be found to be "safe, pure, and potent," but EUA drugs are held to a lower standard — they are required only to demonstrate that they "may be effective," [according to the FDA](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities#relating). According to the lawsuit, the DOD blurred the line between the two legally distinct vaccines, promoting the idea that the COVID-19 vaccine was FDA-approved and therefore "safe and effective" — while administering the vaccine that was only "authorized," and therefore not legally allowed to be described as "safe."

The DOD knowingly blurred this line, the lawsuit alleges, because it had already been found liable for violating [informed consent](https://childrenshealthdefense.org/defender/informed-consent-covid-misinformation-law-california/) and of imposing an experimental vaccine. In the 2004 case of [Doe v. Rumsfeld, et al.](https://law.justia.com/cases/federal/appellate-courts/cadc/11-5209/11-5209-2012-06-15.html), a federal court ruled the DOD could not mandate the EUA [anthrax vaccine](https://childrenshealthdefense.org/defender/covid-vaccine-military-botched-anthrax /) for service members because forcing them to take an experimental vaccine violated their right to informed consent.

That [ruling](https://biotech.law.lsu.edu/cases/vaccines/Doe_v_Rumsfeld_I.htm) stated that absent informed consent or a presidential waiver, "The United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs."
The current lawsuit further alleges that the DOD knowingly deceived Watts and other Americans for the purpose of mass human experimentation, which violates protections provided by the [Nuremberg Code](https://childrenshealthdefense.org/defender/mary-holland-nuremberg-code-anniversary-speech/).
According to the complaint, the DOD committed "willful misconduct," having "deliberately misled Mr. Watts and the public at large by blurring the critical distinction between EUA and fully licensed vaccines," which would nullify the protections afforded the DOD under the PREP Act.
It concludes that Watts died because he believed he was receiving safe and effective vaccines, but in fact "received the deadly ones."
The lawsuit seeks "general, special, compensatory and punitive damages."
Commenting on the significance of the case, Kim Mack Rosenberg, acting outside general counsel for CHD, told The Defender:
"The PREP Act purports to provide an extraordinary liability shield to the government, manufacturers, distributors, and others, related to COVID-19 vaccines and other so-called countermeasures covered by the act. The Watts complaint is an important and unprecedented challenge to that liability shield.
"The complaint threads the act's needle by pointing the finger squarely at Operation Warp Speed leadership while raising critical legal challenges to the act's protection, particularly where, as is alleged in the Watts complaint, a defendant like the Department of Defense has engaged in willful misconduct.
"But the complaint does more than that. It will educate about the PREP Act's far reach, actions by the DOD during the 'state of emergency,' and the general lack of accountability for entities and individuals protected by the PREP Act.
"The public needs to understand that this act intentionally allows potentially bad actors to go unpunished. Here, a young man lost his life, and the government has remained silent, hiding behind a legal shield.
"That is not justice for George Watts or anyone else."

See more about how BioNTech is not approved and under EUA below:
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see official press release CONIS omitted:
"Pfizer-BioNTech COVID-19 Vaccine COMIRNATY® Receives Full U.S. FDA Approval for Individuals 16 Years and Older". Monday, August 23, 2021 - 11:57am https://www.pfizer.com/news/press-release/press-release-detail/pfizer-biontech-covid-19-vaccine-comirnatyr-receives-full
Indication & Authorized Use -

COMIRNATY® (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech.
- It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older
- It is also authorized under Emergency Use Authorization (EUA) to be administered for emergency use to:
  - prevent COVID-19 in individuals 12 through 15 years, and
  - provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to:
- prevent COVID-19 in individuals 12 years of age and older, and
- provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series. An individual may be offered either COMIRNATY® (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2.

Please see this **EUA Statement**:
This emergency use of the product has not been approved or licensed by FDA, but has been authorized by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older; and the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.**

Also see the difference of the approved COMIRNATY and legally different EUA BioNTech with dates here: https://www.fda.gov/media/150386/download On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 for individuals 16 years of age and older pursuant to Section 564 of the Act. FDA reissued the letter of authorization on: December 23, 2020 and, February 25, 2021 and, May 10, 2021 and, June 25, 2021, and August 12, 2021. On August 23, 2021, FDA approved COMIRNATY (COVID-19 Vaccine, mRNA) and reissued the letter in its entirety for both Pfizer-BioNTech COVID-19 Vaccine and certain uses of COMIRNATY (COVID-19 Vaccine, mRNA). Subsequently, FDA reissued the letter of authorization on September 22, 2021, October 20, 2021, October 29, 2021, 12 November 19, 2021, December 9, 2021, - footnotes: In the May 10, 2021 revision, FDA authorized Pfizer-BioNTech Vaccine for the prevention of COVID-19 in individuals 12 through 15 years of age, as well as for

individuals 16 years of age and older. In addition, FDA revised the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to include the following Warning: "Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting." In addition, the Fact Sheet for Recipients and Caregivers was revised to instruct vaccine recipients or their caregivers to tell the vaccination provider about fainting in association with a previous injection. In the June 25, 2021 revision, FDA clarified terms and conditions that relate to export of Pfizer-BioNTech COVID-19 Vaccine from the United States. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to include a Warning about myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine. The Fact Sheet for Recipients and Caregivers was updated to include information about myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine. In the August 12, 2021 revision, FDA authorized a third dose of the Pfizer-BioNTech COVID-19 Vaccine administered at least 28 days following the two dose series of this vaccine in individuals years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise. 8 COMIRNATY (COVID-19 Vaccine, mRNA) was approved for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. 9 In the August 23, 2021 revision, FDA clarified that, subsequent to the FDA approval of COMIRNATY (COVID-19 Vaccine, mRNA) for the prevention of COVID-19 for individuals 16 years of age and older, this EUA would remain in place for the Pfizer-BioNTech COVID-19 Vaccine for the previously-authorized indication and uses. It also authorized COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved biologics license application (BLA). In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to provide updates on expiration dating of the authorized Pfizer-BioNTech COVID19 Vaccine and updated language regarding warnings and precautions related to myocarditis and pericarditis. The Fact Sheet for Recipients and Caregivers was updated as the Vaccine Information Fact Sheet for Recipients and Caregivers, which comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA). 10 In the September 22, 2021 revision, FDA authorized the administration of a single booster dose of COMIRNATY (COVID-19 Vaccine, mRNA) or Pfizer-BioNTech COVID-19 Vaccine at least 6 months after completing the primary series of this vaccine in individuals: 65 years of age and older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 put them at high risk of serious complications of COVID-19 including severe COVID-19. 11 In the October 20, 2021 revision, FDA clarified eligibility for the booster dose of COMIRNATY (COVID-19 Vaccine, mRNA) or PfizerBioNTech COVID-19 Vaccine and authorized the administration of a single booster dose of Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA) was a heterologous booster dose following

completion of primary vaccination with another authorized COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous booster dose were the same as those authorized for a booster dose of the vaccine used for primary vaccination. 12 In the October 29, 2021 revision, FDA authorized: 1) the use of Pfizer-BioNTech COVID-19 Vaccine for children 5 through 11 years of age; and 2) a manufacturing change to include an additional formulation of the Pfizer-BioNTech COVID-19 Vaccine that uses tromethamine (Tris) buffer instead of phosphate buffered saline (PBS) used in the originally authorized Pfizer-BioNTech COVID-19 Vaccine. The formulation of the Pfizer-BioNTech COVID-19 Vaccine that uses Tris buffer was authorized in two presentations: 1) multiple dose vials, with gray caps and labels with a gray border, formulated to provide, without need for dilution, doses (each 0.3 mL dose containing 30 microgram (mcg) nucleosidemodified messenger RNA (modRNA)) for individuals 12 years of age and older; and 2) multiple dose vials, with orange caps and labels with an orange border, formulated to provide, after dilution, doses (each 0.2 mL dose containing 10 mcg modRNA) for individuals 5 through 11 years of age. The formulation that uses Tris buffer is the only formulation that is authorized for use in individuals 5 through 11 years of age. 13 In the November 19, 2021 revision, FDA authorized the use of COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine as a single booster dose in individuals 18 years of age or older at least 6 months after completing the primary series of this vaccine (i.e., as a homologous booster dose), and as a single booster dose following completion of primary vaccination with another authorized COVID-19 vaccine (i.e., as a heterologous booster dose) in individuals 18 years of age or older. The dosing interval for the heterologous booster dose was authorized to be the same as that authorized for a booster dose of the vaccine used for primary vaccination. 14 In the December 9, 2021 revision, FDA authorized the use of the vaccine as a single booster dose in individuals 16 and 17 years of age, at least 6 months after completing the primary series of this vaccine (i.e., as a homologous booster dose).

also see: See Doe v. Austin, 2021 WL 5816632, at 3 n.5. Compare Summary Basis of Regulatory Action, BLA 125742/0 at 9 (Aug. 23, 2021) ("August 23 Comirnaty SBRA") (listing 11 components, including .450 ml per vial of a redacted excipient) (**this document has been scrubbed from the FDA website, but was filed as an exhibit in the Doe v. Austin and Crosby v. Austin proceedings and can be filed with the Court if the amicus motion is granted),** with FDA BioNTech EUA Expansion Letter, supra, note 6 at 7 (listing 10 components, all of which also appear on the Comirnaty SBRA) and November 8 Comirnaty SBRA at 7-8 (listing 11 components, but removing .450 ml per vial of redacted excipient and replacing with unspecified amount of water as 11th component) **EUA and FDA Licensed Products do not have the "Same Formulation" and are not "Interchangeable" Notwithstanding any potential assertions to the contrary, the EUA and licensed versions of PfizerBioNTech do not have the "same formulation" as revealed by a simple inspection of the Pfizer Vaccine EUA letters and the Summary Basis for Regulatory Action (SBRA) for Comirnaty. Thus, they cannot be treated**

as "interchangeable," **<u>because there is no legal basis to administer an EUA product as if it were the FDA-licensed product. By definition, they are different.</u>**

CONIS entire basis for denial is "covid vaccines are approved" and "not biomedical research", but **CONIS has omitted duty to provide proof that BioNTech EUA in use in Costa Rica is the same legally as Corminarty which is fully approved but not available.** The imported versions are under EUA and investigational according to testimony in this case by CNVE January 24, 2022.

The FDA website currently says BioNTech is under EUA see:
https://www.fda.gov/vaccines-blood-biologics/coronavirus-covid-19-cber-regulated-biologics/pfizer-biontech-covid-19-vaccines#additional

According to the above FDA website there was a [Letter of Authorization](https://www.fda.gov/media/150386/download "Pfizer-BioNTech COVID-19 Vaccine EUA LOA reissued May 17, 2022") (Reissued)|April 28, 2023 to renew the EUA for Pfizer-BioNTech's COVID-19 vaccine. Nowhere in the letter does it say Pfizer-BioNTech's COVID-19 vaccine is approved under the brand name Cominarty. Also, The [monovalent Pfizer-BioNTech COVID-19 Vaccine](https://www.fda.gov/vaccines-blood-biologics/industry-biologics/coronavirus-covid-19-cber-regulated-biologics "Coronavirus (COVID-19) | CBER-Regulated Biologics") is no longer authorized for use in the United States.

To really see the CONIS resolved our petition in error based on the false presumption the covid-19 vaccine is fully registered and approved see:

Testimony from MS-DM-0318-2022 San José, 24 de enero del 2022 says "The vaccines used by the country against covid-19 are authorized by WHO and, in addition, they have approval to be used by Strict Regulatory Agencies, such as FDA and EMA." "The vaccines against COVID-19 **that are being applied to the Costa Rican population Pfizer- BioNTech Vaccine against COVID-19 and Vaccine against COVID-19 are vaccines authorized by the World Health Organization for inclusion in the Emergency Use List** (EUL, for its acronym in English) as can be verified on the website of this organization: https://extranet.who.int/pqweb/vaccines/covid-19-vaccines."
The WHO, for its part, has the mechanism of the Emergency Use List that we already mentioned above, where a committee of external experts convened by the WHO analyzes the results of clinical trials and recommends the vaccines that should be used and the way to use them. Subsequently, it is up to the authorities of each country to authorize or not, the use of each vaccine in their jurisdictions and develop policies to administer them, based on the recommendations of the WHO. In the case of Costa Rica, article 117 of the General Health Law indicates that: The Ministry of Health, the Costa Rican Social Security Fund and any other state entity, with public health or social security functions, may purchase medicines not registered, at any time or circumstance. In case of urgency or public necessity, that Ministry may authorize the importation of unregistered

medicines. Thus, by declaring, through Executive Decree No. 42227 - MP —S, of March 16, 2020, the state of national emergency throughout the territory of the Republic of Costa Rica, due to the health emergency situation caused by the disease caused by COVID-19, both the CCSS and any other state entity can import vaccines against COVID-19 without health registration.
Executive Decree No. 42571-S Regulation for the sanitary authorization for the clearance and acquisition of medicines not registered by state entities with public health or social security functions and for the authorization of clearance in case of public necessity, details the import requirements for medicines in cases of public necessity as in the case of vaccines against COVID-19.
Similarly, Executive Decree No. 38414-COMEX-MEIC-S Central American Technical Regulation 11.03.59:11 Pharmaceutical Products, Medicines for Human Use, Requirements for Sanitary Registration, applicable to the Sanitary Registration of Medicines, in article 13 it states that: The Regulatory Authority may authorize the importation and use of medicines without sanitary registration in the following cases: ... 13.2 National emergencies and officially declared public necessity.
However, since these are vaccines that would be used for the first time in humans, and to ensure rapid access to vaccines for the population and to safeguard the health of the Costa Rican population, the National Commission for Vaccination and Epidemiology made the decision to include within of its selection criteria for vaccines against COVID-19 that these will have the approval of a Strict Regulatory Authority or approved in the WHO Emergency Use List, so we make sure that the expert committees of these authorities that have a fairly strict regulation and robust regulatory processes, will review the information and give their recommendation and Costa Rica, would provide an authorization based on the recognition made by these Strict Regulatory Authorities as described in administrative resolutions DM- RM-7905-2020 of December 3, 2020 and DM-RC-0486- 2021 of February 22, 2021.

Based on the contradictory and more recent CNVE & Health Minister testimony above from January 24, 2022, it is evident the CONIS fails duty of substantiation and motivation for the claim they used to deny our claims: "August 23, 2021 FDA formally approves Pfizer-BioNTech's COVID-19 vaccine under the brand name Cominarty". - unmotivated! VOID.

This omission to provide adequate and truthful information or fulfilled justice to petitioners is causing an act in excess of law that CONIS is failing to properly resolve!

CONIS REPLY 2.

Regarding informed consent, it is relevant to mention what has been said by the Constitutional Chamber of the Supreme Court of Justice, through vote No. 2021018800 of 09:26 hours of August 24, 2021, stating the following: "Secondly, it should be noted that the recognition of the need for informed consent is based on the recognition of patients' rights to autonomy and information. That

is to say, on the basis of the information provided by the treating physician, a patient chooses to accept or refuse a medical service. In the specific case, as has been examined, there are sufficient provisions that legitimize the obligatory nature of the vaccine, so that autonomy, in such cases, is diminished in order to protect the general interest and welfare, namely public health (art. 21 of the Political Constitution, art. 1° of the General Health Law and the regulations on vaccination cited above).
This does not prevent to emphasize that in all cases the right to information of all persons who are subjected to this mandatory vaccination must be respected. In this regard, it is worth mentioning once again the Manual of Procedures for the execution of vaccination against COVID-19 in the health establishments of the Costa Rican Social Security Fund,

which requires precisely that to ensure the users' right to information and which provides as follows:...".

ABOUT CONIS REPLY 2:

The product is supposed to be regulated under 9234 and 39061-S which have a higher protection for users of biomedical research than approved vaccines. CONIS (and Sala 4) omits to apply the correct law referenced by CNVE (9234 and 39061-S) and instead applies the Manual of Procedures for the execution of vaccination against COVID-19 in the health establishments of the Costa Rican Social Security Fund, **which requires precisely that to ensure the users' right to information...

Its also an irrelevant and prior unmotivated ruling from August 24, 2021 in the CONIS reply. Sala 4 is in error when they say, *"there are sufficient provisions that legitimize the compulsory nature of the vaccine, so that autonomy, in such cases, is diminished in order to protect the general interest and welfare, namely public health (art. 21 of the Political Constitution, art. 1° of the General Health Law and the regulations on vaccination cited above).* It is a void ruling based on false facts and contrary to the same evidence we directly provided Sala 4 repeatedly.

Sala 4 ruled "there are sufficient provisions that legitimize the compulsory nature of the vaccine, so that autonomy, in such cases, is diminished in order to protect the general interest and welfare, namely public health (art. 21 of the Political Constitution, art. 1° of the General Health Law and the regulations on vaccination cited above)" Its not motivated or in context why Sala 4 says "there are sufficient provisions that legitimize the compulsory nature of the vaccine" to give petitioners due process to challenge the claim. It is worth mentioning that when Sala 4 issued this ruling they were willfully blind ignoring petitioners repeated cases with proof to the contrary and Sala 4 was sending the false testimony of "not experimental" to the inactive Prosecutor over and over while verifying the testimony of the administration, despite it not actually being proven.

If Sala 4 were told the right laws that regulate this product which CNVE did testify is 9234 and 39061-S, the court would not have ruled the same as quoted by CONIS above to deny our petition. There is so much evidence in the record to prove CONIS wrong. CONIS provided no evidence or motivation to adequately contradict the testimony of the Health Minister and CNVE Secretary January 24, 2022, who insist the covid vaccines are investigational interventions for which informed consent is required.

Informed consent under 9234 is entirely omitted, despite 9234 being the proper law according to CNVE & the Health Minister: ARTICLE 12.- Approval of informed consent The informed consent and any modification to it must be approved, numbered and stamped on all its pages by the Scientific Ethics Committee, prior to its presentation to the eventual participants. In the cases of observational research, the Scientific Ethics Committee, after an exhaustive analysis of the content and scope of the research, may waive the signing of the informed consent, when it considers that this does not affect the rights of the participants. ARTICLE 13.- Information quality Before any activity related to the research begins and before proceeding to sign the informed consent, the participating individual must be informed in their own language, in an appropriate and understandable language, about the nature of the research, the procedures , the risks and benefits, other therapeutic or diagnostic options, the confidentiality of the information collected and about your rights, so that you understand and make the decision to participate or not, freely, voluntarily and consciously, without coercion, coercion, threat , fraud, deception, manipulation or any other type of pressure. The informed consent information must be truthful, clear, precise and written, in a way that is not misleading, deceptive or coercive and that can be understood by the participants. For this purpose, it must be guaranteed that the procedure for signing the informed consent has the appropriate time and conditions so that people can correctly understand the information. *ARTICLE 9.- Informed consent The participation of an individual in an investigation regulated by this law will require the express, specific, written and signed consent or with the fingerprint, of this or his legal representative, on all pages. Informed consent is the process by which a person voluntarily confirms their desire to participate in biomedical research. The purpose of informed consent is to protect the participants, so it cannot become a mechanism to legally protect the researcher, the sponsor, the contract administration organization and the contract research organization.

ARTICLE 10.- Minimum content of the informed consent document The information in the informed consent document must be truthful, clear, precise and written in a way that can be understood by the participants and that is not misleading or coercive. It must contain at least:
a) Statement that the study involves research.
b) Identity of the professional responsible for the investigation and their collaborators.
c) Explanation of the objective and purpose of the investigation.
d) Source of funding for the research project.
i) Description of the risks or inconveniences that may arise with the investigation.

j) Measures to respond to eventual inconveniences or adverse events that arise.
k) Measures to ensure adequate compensation in the event that the participant suffers any damage as a result of the investigation.
l) Description of the expected benefits for the participant or for others.
ñ) Measures to access relevant information for the participant, arising from the investigation or its total results.
p) Indicate any potential future use of the research results.
r) Statement that participation is voluntary and that the person can withdraw from the research at any time without losing the benefits to which the person is otherwise entitled, or being punished in any way for their withdrawal.
t) List of people you can contact if you have questions about the study and your rights. The list must contain at least the telephone number or numbers, the email address, the office address and any other data suitable for locating them.
u) The name, signature, date, time and place where the participant is summoned to deliver the copy of the document and the place where it is signed and the identification number of the participant or his legal representative, of the person who explains the informed consent and the impartial witness who signs the consent and the date it is signed.
v) The others determined by the regulations of this law and those others that in the opinion of the respective scientific ethics committees are required.

Documentary evidence 1, Page 27 of the WHO document from 2022 - EMERGENCY USE OF UNPROVEN CLINICAL INTERVENTIONS OUTSIDE CLINICAL TRIALS: ETHICAL CONSIDERATIONS May health-care workers waive the informed consent process for use of unproven interventions outside clinical trials during a public health emergency? No. When health-care workers use unproven interventions, they should inform patients that the intervention may not benefit them and may even harm them (22). It is important to remember that consent, in clinical practice or research, is a process and is not equivalent to its documentation (e.g. signing a written document). Any consent process should enable informed consent of patients by ensuring their understanding and that a decision to enrol in a protocol for emergency use of unproven clinical interventions outside clinical trials is made voluntarily, with adequate understanding of the consequences of participation. When necessary, health-care workers should adapt the documentation of the consent process to the realities of the public health emergency (e.g. using alternatives to written consent). For patients who are unable to give informed consent, proxy consent should be obtained as appropriate, as in any other medical circumstances (22). Physicians and other health-care workers may have their own opinions about whether a particular unproven clinical intervention is more likely to be beneficial or harmful. A consent process for use of unproven clinical interventions that does not explicitly recognize the scientific community's uncertainty about the risk–benefit ratio would not, however, be ethically appropriate. Individual health-care workers and national health authorities must avoid overstating the evidence for

unproven interventions. Overstatement of evidence, whether for self-interest or to provide a putative benefit to patients, is contrary to the appropriate consent process for unproven clinical interventions. Hence, community engagement is necessary to prevent undue promotion of unproven interventions outside clinical trials and undue influence on public opinion and the equipoise of the medical community.

The purpose of our petition for serious undue experimentation is precisely because the CONIS response failed to adequately address the points in our petition that the above laws are being disregarded and this is a violation of 9234 Article 78 and 79. The inadequate CONIS reply solidifies we are correct, there is an act in excess of law due to the omission of informed consent of the investigational biomedical research of the covid-19 non vaccine interventions outside a clinical trial.

CONIS REPLY 3.

Regarding the studies that appear registered, the fact that protocols are developed for one or another medicine/vaccine or medical device does not make it experimental in itself; especially that these studies are not of an interventional nature on the development of the vaccine; but studies to evaluate the effects of a medicine that has already been approved and are observational; therefore, your criterion that the existence of registered research does not validate the fact that these studies turn the medicine into an experimental product.

About the CONIS REPLY 3:

They lied Pfizer is fully approved, but what about AstraZenica which is admittedly only under EUA? CONIS knows the laws but testified CONIS intentionally does not actually apply the informed consent law to Pfizer. By human presumption we presume CONIS is not informing AstraZenica users its dangers and investigational nature, although CONIS fully failed to address this question. CONIS clearly omits what is required to provide adequate and truthful information that CONIS is withholding either due to lack of due diligence or corruption regarding the experimental and dangerous nature of the unproven intervention outside clinical trials.

CONIS resolution claims, without reference to the 9234 law definitions or any evidence, that the studies are not of an interventional nature on the development of the vaccine, they are only to evaluate the effects of a medicine that has already been approved and are observational

CONIS reply shows a serious breach of international obligations owed erga omnes to prevent experimentation, by omitting to apply the correct biomedical research laws.

The CONIS resolution OMITS to provide definitions, but yet CONIS relies upon and misuses key words taken from 9234, such as "interventional, "observational", "biomedical research". 9234 is a biomedical research law which they quote from, but which they claim does not apply because they purport the covid vaccine is "not biomedical research". It is absurd CONIS quotes biomedical research law definitions, such as "observational" to describe their "studies", but at the same time they claim its not biomedical research!

The CONIS omitted to provide the legal definitions of key terms they relied upon, however they denied our petition based on a single term biomedical research: CONIS claims our arguments do not apply simply because they say covid vaccines are approved and not "biomedical research".

CONIS CLAIMS: 3. "*Regarding the studies that appear registered, the fact that protocols are developed for one or another medicine/vaccine or medical device does not make it experimental in itself; especially that these studies are not of an interventional nature on the development of the vaccine; but **studies to evaluate the effects of a medicine** that has already been approved and are observational; therefore, your criterion that the existence of registered research does not validate the fact that these studies turn the medicine into an experimental product.*

Petitioners point the court to the definition of biomedical research under 9234: **Biomedical research** : a type of activity designed to develop or contribute to generalizable knowledge regarding health in humans. It can be observational, epidemiological, or non-interventional or experimental, clinical or interventional. For the purposes of this law, any reference to research will be understood as biomedical research with human beings in health matters.

Under 39061-S we find more significant definitions omitted by CONIS when denying our petition. CNVE secretary referred us to this law to define investigational. see: jj) Product under investigation: Product of registered or unregistered health interest that is being tested or used as a reference or comparator in biomedical research. Included in this definition are pharmaceutical products, biomedical equipment and material, food and dietary or nutritional supplements, diagnostic tests, natural products, cosmetics and hygiene products. vs. ee) Medication: Any natural, synthetic or semi-synthetic substance or product and any mixture of these substances or products that are used for the **diagnosis, prevention or treatment and alleviation of diseases or abnormal physical states, or their symptoms. and for the establishment or modification of organic functions** in people.

Petitioners find CONIS is misinterpreting the law by twisting the definitions to suit their purpose of not regulating the experiments.

We also find the 9234 law itself to be contradictory, insufficient and in violation of superior law by not requiring informed consent under Article 7, which is the dirty trick CONIS and the Administration are using:

UNDER LAW 9234: ARTICLE 7.- Research in public health**

Observational research in public health will require the approval of the Scientific Ethics Committee, hereinafter CEC, ***except in the case of investigations that are part of the institutional work of the Ministry of Health or the Costa Rican Social Security Fund and refers to related investigations***. with:

a) Prevention and control of endemic and epidemic diseases that require the collection of relevant data for health decisions, such as outbreaks or epidemics.

b) Public health surveillance, which incorporates the collection of data in forms or electronic files that must be sent to the Ministry of Health to define, based on its epidemiological analysis, prevention and control actions.

c) Evaluation of social programs or evaluation of results and impact of public health interventions.

d) **Intensive pharmacovigilance of medicines and vaccines, so that actions related to their safety, warnings or marketing can be taken.**

To understand the above article 7 a), b), d) lets refer back to 9234 article 2 definitions:
Experimental, clinical or interventional biomedical research: any scientific research in the area of health in which a **preventive, diagnostic or therapeutic intervention is applied to human beings, in order to discover or verify the clinical, pharmacological or pharmacodynamic effects of an experimental product**, a medical device or a clinical or surgical procedure; or attempting to identify any adverse reaction to an experimental product, device, or procedure; or study the absorption, distribution, metabolism and excretion of an experimental product, i**n order to assess its safety and efficacy or assess the outcome of an unproven psychological intervention.** For the purposes of this law, any reference to clinical research shall be understood as experimental, clinical or interventional biomedical research in human beings in the field of health.

CONIS is misinterpreting the law and in reality, the law is terribly written, needing revision.

Covid-19 vaccines are obviously a preventive, diagnostic or therapeutic intervention which is being applied to human beings, in order to discover or verify the clinical, pharmacological or pharmacodynamic effects of an experimental product. This TRUTH contradicts CONIS who wildly claims the interventions are "merely observational" studies of approved medicines.

ARTICLE 2 9234 - definitions:
Observational, epidemiological or non-interventional biomedical research: research in which **no diagnostic or therapeutic intervention is carried out for experimental purposes**, nor is the

participating individuals subjected to conditions controlled by the researcher. For the purposes of this law, any reference to observational research shall be understood as observational, epidemiological, or non-interventional biomedical research in human beings in terms of health.

Biomedical research : a type of activity designed to develop or contribute to generalizable knowledge regarding health in humans. It can be observational, epidemiological, or non-interventional or experimental, clinical or interventional. For the purposes of this law, any reference to research will be understood as biomedical research with human beings in health matters.

Intervention: all actions of any kind, related to research with human beings, that may affect in whole or in part, individually or collectively, in one way or another, the dignity and identity, integrity and well-being of people. or any of your human rights and fundamental freedoms. This type of research differs from observational studies in which there is no intervention.

Adverse event or reaction that would be attributable to the experimentation: unfavorable occurrence that:
a) results in death,
b) threatens life,
c) requires hospitalization of the participant or prolongation of the existing hospitalization,
d) produces persistent or significant disability or disability, or produces a congenital anomaly or birth defect
Investigations typical of the institutional task will be considered those that the institution must carry out to fulfill the functions assigned to it and that are within its operational plan, or in cases of emergency.
The institutions that carry out this type of research must submit a report of the final results of the study to the CONIS.

It should be noted that CONIS has at least 12 registered experiments of covid-19 vaccines. There are a few registered studies of Pfizer BioNTech that very clearly say "**Interventional**", studying adverse effects of health workers being mandated the investigational product. Other studies do say "observational", but the reality is CONIS registered "interventional" studies of Pfizer BioNTech investigational EUA product, NOT approved yet and refuse to apply the 9234 limitations of this act of serious undue experimentation.
see:
https://www.ministeriodesalud.go.cr/conis/index.php/servicios/investigaciones-registradas

https://www.ministeriodesalud.go.cr/conis/index.php/servicios/requisitos-de-importacion

CONIS clearly quoted Sala 4 saying the covid vaccines need informed consent to respect right to information and autonomy. As a result, the claim "the studies are **not of an interventional nature on the development of the vaccine, they are only to evaluate the effects of a medicine that has already been approved and are observational***" is illogical and irrational as well as not duly motivated or pertinent to us raising this exact problem and not getting a valid answer with evidence to prove us wrong". Interventional research affects rights. CONIS makes no sense in their reply, exceeding legality.

CONIS is mischaracterizing words which is improper and unethical see: Emergency use of unproven clinical interventions outside clinical trials: ethical considerations ISBN 978-92-4-004174-5 (electronic version) https://www.who.int/publications/i/item/9789240041745 "*Health authorities, health-care workers, ethics committees and other stakeholders must avoid mischaracterization of emergency use outside clinical trials, including “off-label” use, as activities (e.g. “observational research”, “compassionate use”, “quality improvement”) to evade the requirements of justification, ethical and regulatory oversight, consent processes and contribution to evidence established in the MEURI ethical framework (22, 24).""* According to the WHO ethical framework Glossary of terms the covid-19 vaccine is an intervention:

Intervention (general definition): The terms “intervention” and “use of an intervention” refer to a specific action in a biomedical setting, including clinical care, research and public health. It is better defined as “intervention ensemble”.

Intervention ensemble (technical definition): Although we define interventions as specific actions in a biomedical setting, they are usually identified with their most noticeable material, such as drugs, biologicals (e.g. antibodies, vaccines), devices, procedures and behaviour. What truly identifies an intervention, however, is how a material is used. Hence, an aspirin taken for a headache and an aspirin taken to prevent a heart attack involve the same material but are used in two different interventions. Consequently, an intervention could be defined as a coordinated set of materials, operative dimensions (e.g. dose, schedule, route of administration, risk mitigation, end-point, duration, co-interventions) and constraints (e.g. target populations, contraindications, likely side-effects) (2). The term “intervention ensemble” – a set of coordinated materials, operative dimensions and constraints – is a reminder that an intervention has many dimensions other than its materials (2). This definition is also useful from a regulatory point of view (3, 4).

Clinical intervention (use and regulation): In this document, “clinical intervention” refers to the use or regula- tion by health-care workers and/or relevant national health authorities of an intervention intended to provide a clinical benefit. The term “clinical benefit” is typically used as a synonym for the well-being or best interests of the recipients of an intervention (5). Nevertheless, use of clinical interventions has other consequences for public health and society and can benefit or harm populations. Hence, an adequate ethical evaluation of and justification for the use and

regulation of clinical interventions must be broader than clinical benefit (4, 6). This document is based on a broader public health ethics evaluation of clinical interventions.

Research intervention: Clinical interventions should be distinguished from research interventions, which are use of an intervention primarily to generate knowledge for the public good (7). The fundamental distinction in ethics between clinical and research interventions is their primary aim or goal, sometimes referred to as their "intention", and not the material aspect of the intervention nor the preliminary support for scientific evidence of their use based on a favourable risk–benefit ratio. The aim or intention of any medical activity may be evaluated in the plan or written protocol for such activities.

Unproven intervention, completely unproven intervention, "off label" use (risk-benefit umbrella terms):

In this document, the term "unproven intervention" is defined as an intervention for which there is insufficient evidence of safety and/or efficacy for regular use in a health system. We also distinguish sub-groups of unproven interventions: "off-label" use, i.e. unproven modes of use of a proven intervention, and "completely unproven interventions", i.e. interventions for which there is no proven mode of use.2 Alternative definitions of "off- label" use are "use of licensed medicines for indications that have not been approved by a national medicines regulatory authority" (9) and "use of a pharmaceutical agent for an unapproved indication or in an unapproved age group, different dosage, duration or route of administration" (10). The terms "unproven intervention", "'off- label' intervention" and "completely unproven intervention" are umbrella terms that group a wide variety of unproven interventions with disparate preliminary evidence and risk–benefit profiles.

Other terms for unproven intervention: Other terms often used to refer to unproven interventions or sub- groups of unproven interventions in both ethics and regulatory documents are:
- Lack of sufficient evidence. This first group of terms refers to or implies lack of sufficient evidence for regular use of an intervention and includes the terms "unproven", "experimental", "investigational", "empirical", "untested", "unvalidated" and "non-validated".
- **Lack of full authorization.** A second group of terms refers to lack of full authorization by a relevant regulatory authority for regular use in a health system, such as "unregistered", "unlicensed", "unauthorized" and "unapproved".
- **Preauthorized. An important subgroup is preauthorized interventions, which have some form of partial authorization but have not been fully authorized.** (this is what CNVE testified is happening. Covid-19 vaccines are procured for Costa Rica under WHO EUL list - more information on WHO EUL below)

- Unauthorized modes of use. Another subgroup are unauthorized modes of use of authorized interventions,
such as “off-label”, “used in unapproved ways”, “repositioned” and “repurposed” (also known as
“repositioning”, “reprofiling”, “redirecting” or “rediscovering”) (11).

**- Novelty. A third group of terms associates unproven interventions with their novelty, such as “innovation”,
“innovative”, “novel”, “new non-validated” and “emergent**”.

- Desperate situation. A fourth group of terms refers to the desperate situations in which unproven interventions
are often used, such as “compassionate use”, “last chance”, “last ditch” and “rescue”.

The attributes of evidence, authorization, novelty and desperate situation are not logically equivalent, i.e. not all unproven interventions are unauthorized, novel or used in desperate situations. The same is true for the other possible combinations of attributes. Monitored emergency use of unregistered and experimental interventions (MEURI), monitored emergency use, emergency use outside clinical trials (designations): In this document, these terms are used synonymously. **They refer to a special purpose for using unproven interventions under the ethical criteria in the MEURI framework.** Table 1 is a non-systematic list of WHO emergency use designations, ordered by year, that are associated with the monitored emergency use designation. Below, we also discuss the origin and use of the term MEURI and the reasons for avoiding the designation “compassionate use”.

To illustrate further that CONIS is omitting to regulate the unlicensed covid-19 vaccines, which are unproven interventions by WHO definition, prequalified or pre-authorized, novelty, with lack of full authorization, unregistered, unapproved. We need to be clear that testimony pasted below from CNVE says all covid-19 vaccines are from the WHO EUL list.

pg 28 of EMERGENCY USE OF UNPROVEN CLINICAL INTERVENTIONS OUTSIDE CLINICAL TRIALS: ETHICAL CONSIDERATIONS

How is the MEURI ethical framework related to the WHO EUL procedure?

WHO’s EUL is a procedure for assessing emergency use of unauthorized interventions (vaccines, therapeutics and in-vitro diagnostics) while further data are collected and evaluated. It is thus complementary to the considerations of the MEURI ethical framework. WHO established the “emergency use assessment and listing” procedure in 2015 in response to the outbreak of EVD in West Africa (83) for systematic evaluation and listing of unlicensed medical products in order to

expedite the availability of those products. The procedure was updated and renamed the EUL procedure in 2020 (64) to aid United Nations procurement agencies and the national regulatory authorities of Member States in determining the acceptability of specific unlicensed medical products.

For an intervention to be included in an EUL, the following criteria must be met (43):

- The disease for which the product is intended is serious or immediately life-threatening and has the potential of causing an outbreak, epidemic or pandemic, and it is reasonable to consider the product for an EUL assessment, e.g. there are no licensed products for the indication or for a critical subpopulation (e.g. children).

- Existing products have not been successful in eradicating the disease or preventing outbreaks (in the case of vaccines and medicines).

- The product is manufactured in compliance with current good manufacturing practice in the case of medicines and vaccines and under a functional quality management system in the case of in-vitro diagnostics.

- The applicant undertakes to complete development of the product (validation and verification in the case of in-vitro diagnostics) and apply for WHO prequalification once the data are collected.

As stated in the EUL procedure document (43),

the EUL is not equivalent or an alternative to WHO prequalification, and should not be thought of as such. The EUL is a special procedure for unlicensed vaccines, medicines and in vitro diagnostics in the event of a PHE [public health emergency of international concern or other public health emergency authorized by the Director-General] when the community/public health authorities may be willing to tolerate less certainty about the efficacy and safety of products, given the morbidity and/or mortality of the disease and the lack or paucity of treatment, diagnosis/detection or prevention options. It is intended to provide a time-limited listing [...] for unlicensed products in an emergency context when limited data are available and the products are not yet ready for application for prequalification. As part of the EUL, it is expected that the manufacturer will complete the development of the product and submit for licensure and WHO prequalification.

The document also states that

WHO has developed the EUL process to expedite the availability of unlicensed medical products needed in public health emergency situations, to assist interested UN procurement

agencies and Member States in determining the acceptability of using specific products in the context of a public health emergency, based on an essential set of available quality, safety, and efficacy/immunogenicity/ performance data. The EUL is not intended to interfere with ongoing clinical trials. This means that the clinical development should proceed as planned after the initial submission and subsequent updates. WHO-Member States have the sole prerogative to use the EUL as the basis to authorize the use of an unlicensed vaccine/medicine/in-vitro diagnostics at the national level [original emphasis].

Testimony from MS-DM-0318-2022 San José, 24 de enero del 2022 says “The vaccines used by the country against covid-19 are authorized by WHO and, in addition, they have approval to be used by Strict Regulatory Agencies, such as FDA and EMA." "The vaccines against COVID-19 **that are being applied to the Costa Rican population Pfizer- BioNTech Vaccine against COVID-19 and Vaccine against COVID-19 are vaccines authorized by the World Health Organization for inclusion in the Emergency Use List** (EUL, for its acronym in English) as can be verified on the website of this organization: https://extranet.who.int/pqweb/vaccines/covid-19-vaccines."

As proven above by referencing the 2022 WHO document *EMERGENCY USE OF UNPROVEN CLINICAL INTERVENTIONS OUTSIDE CLINICAL TRIALS: ETHICAL CONSIDERATIONS*

by definition an EUL vaccine is defined as Lack of sufficient evidence. This first group of terms refers to or implies lack of sufficient evidence for regular use of an intervention and includes the terms “unproven”, “experimental”, “**investigational**”, “empirical”, “untested”, “unvalidated” and “non-validated”.

Further testimony from MS-DM-0318-2022 San José, 24 de enero del 2022 says:

It is important to clarify that while phase I, II and III studies are in progress, they are called "vaccine candidates", but that this type of vaccine after obtaining approval is either an authorization for emergency use, a conditional authorization, or even formal authorization, can continue in phase III and IV follow-up and post-marketing clinical studies, or even new phase III studies in new population groups, for what can always be referred to as “**investigational vaccines**” and is completely acceptable.

In accordance with Executive Decree No. 39061-S Regulation of the Biomedical Research Regulatory Law, an **investigational product** is defined as a product of **registered or unregistered health interest that is being tested or used as a reference or comparator in an investigation. biomedical**. Included in this definition are pharmaceutical products, biomedical equipment and material, food and dietary or nutritional supplements, diagnostic tests, natural products, cosmetics and hygiene products. Being a pharmaceutical product (a medicine) one used

for the treatment of diseases and medical conditions, as well as the prevention and diagnosis of diseases, vaccines are medicines.

-Facts: In testimony on January 24, 2022, we learned that non-vaccine covid-19 was imported under section 117 as "investigational," a word meaning experimental.
Understanding investigational drugs > An _**investigational drug**_ may also be called an experimental drug**_ and is being studied to see if your disease or medical condition improves while you take it. Scientists are trying to test it in clinical trials:

> - If the drug is safe and effective.
> - How the drug could be used in that disease. > - How much drug is needed.

> - Information about the possible benefits and risks of taking the drug.
>-
> Before you can be given an investigational drug, either through a clinical trial or expanded access, your healthcare professional _**must give you additional information about the potential risks and benefits of the drug**_.

> As promising as an investigational drug may seem. It is still being tested_ in clinical trials to determine if it can be used to treat a disease or medical condition.

> Finally, remember that _**approved drugs have completed extensive testing** in clinical trials and **there is scientific evidence that they are safe and effective**_ in treating the particular disease or medical condition studied. **Content updated as of:** 04/02/2019.
> **See: https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-investigational-drug.

also see:
Expanded access - The **investigational** drugs, biological products, or medical devices have **not yet been approved or cleared by the FDA and the FDA has not determined that these products are safe and effective** for their specific use. In addition, the investigational medical product may, or **may not, be effective** in treating the condition, **and use of the product may cause unexpected serious side effects.**" - **Current content as of:** 12/21/2022, and conspicuously NOT included in the fact sheet, contrary to international obligations owed by the U.S. regulatory agencies and the CEC, CONIS, CNVE, CCSS, Ministry of Health and Costa Rica.
> **See: https://www.fda.gov/news-events/public-health-focus/expanded-access

CONIS should have ruled differently and granted our petition to ensure the public safety, morality and interest as well as prompt and fulfilled justice to petitioners who should have their petition GRANTED for cessation of serious undue experimentation and omissions of insurance owed to the injured public by law.

The resolution is not resolved according to strict legalities and definitions because CONIS is pretending apples are oranges and omitting to decide facts in the proper WHO ethical framework that applies.

The CONIS are apparently undertrained or confused as to terms and their duties under WHO MEURI ethical framework for the EUL listed covid-19 vaccine unproven covid-19 vaccine interventions outside clinical trials. We still require prompt justice being withheld in order to prevent the unethical and illegal unproven covid-19 vaccine interventions outside clinical trials.

CONIS REPLY 4.

Regarding your complaint, I must also inform you that Article No. 72 of Law 9234 indicates the characteristics for submitting such complaints and their content, and therefore I hereby inform you that the document submitted does not fully comply with the regulations in accordance with the following: C) It does not provide the name or purpose of the research that is being denounced, since it indicates that the application of the COVID-19 vaccine is a study, but it has been demonstrated that this is not an experimental drug (mentioned earlier in this document) and ***therefore has not been presented to CONIS as biomedical research.***

ABOUT CONIS REPLY 4:

1. The documentary evidence from CNVE and the Health Minister January 24, 2022 says the covid-19 vaccines were always biomedical research. CONIS is headed by the Health Minister and CNVE officials are integrated, but here is CONIS saying no one presented the covid-19 vaccines as biomedical research. This makes no sense and we are left with no resolution to the legal violations we need to stop, and unresolved contradictory testimonies.

2. CONIS refers us to Article 72 of why they say our complaint is insufficient:

a) Plaintiffs are not aware of a law that says we need to give ID to complain, we did sign it as Interest of Justice. Aren't they supposed to write early to tell us to correct it in 3 days by adding ID if needed? This requirement seems to be a demand in excess of law which says: i. Name and surname of the complainant, ID card ***or any other identity document and place or means to attend the notifications.***

Regarding point b). The CEC is not known because CONIS isn't posting all the information. They know very well who is the CEC, or they just never assigned one by pretending it was always approved. Also, this requirement seems to be a demand in excess of law for us to psychically identify the CEC. CONIS should just inform us where we need to go to deal with this issue.

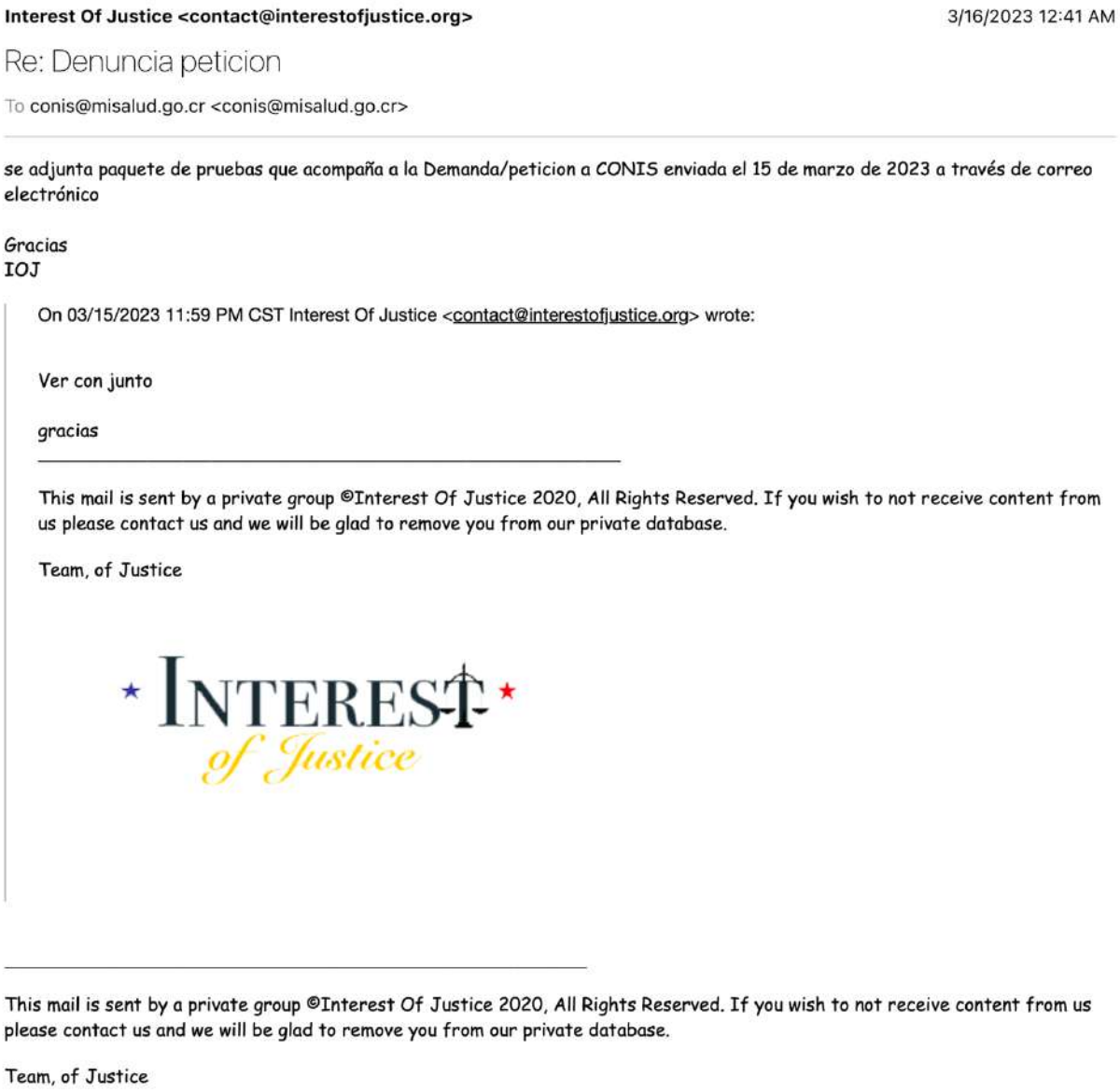
Regarding point c) Plaintiffs forcefully reject this unmotivated unproven reason to deny our complaint. It is absolutely not demonstrated whatsoever anywhere in the document that: " *it has been demonstrated that this is not an experimental drug (mentioned earlier in this document) and therefore has not been presented to CONIS as biomedical research."* The Sala 4 ruling that supposedly "demonstrates" the fact is not conclusive, it is evidence in criminal court now because we allege it was always a ruling based on false testimony. The ruling is also unmotivated because CONIS never explained how its pertinent, considering it was issued 2-3 weeks before the CNVE and Health Minister irrevocably confessed covid vaccines are indeed investigational biomedical research regulated under 9234 and 39061-S, contradicting the earlier ruling relied upon in error by CONIS. Its not motivated.

Regarding point d) some of the documents mentioned provide addresses and internet that lead to specific pages, and is conclusive public information and documentary evidence of what is denounced as serious undue experimentation in Costa Rica. CONIS claims: "Of the evidence indicated after your signature in the section "Consult the list of documentary evidence", none of the indicated evidence was provided in your e-mail." That is true, because the urgency we sent the Petition at 11: 59pm and had to stay up to assemble the remainder evidence which was attached in the email chain as a notice which cured in three days. The CONIS has all the evidence in the same email thread only 40 minutes later and never even wrote back to acknowledge the email with the evidence. This is another dirty trick to delay & deny truth and fulfilled justice.

Also, CONIS acts like we need to provide Costa Rica data to show death is common in Costa Rica, but the data we gave is from FDA and CDC analyzed by ehealthme.com to show death is common. There is no motivation why the evidence we gave would not be applicable in Costa Rica considering they claim they all use the same product authorized by FDA and CDC. CONIS is playing games with peoples lives. Death is common and apparently they want to find feeble excuses to not review that data by claiming it does not denounce experimentation in CR. The resolution is not motivated or pertinent on this point.

Regarding point e) The documentary evidence was attached in an email in the same email thread only 40 minutes later. "se adjunta paquete de pruebas que acompaña a la Demanda/peticion a CONIS enviada el 15 de marzo de 2023 a través de correo electrónico"

See attached screenshot evidence which proves CONIS was provided all evidence



Interest Of Justice <contact@interestofjustice.org> 3/16/2023 12:41 AM

Re: Denuncia peticion

To conis@misalud.go.cr <conis@misalud.go.cr>

se adjunta paquete de pruebas que acompaña a la Demanda/peticion a CONIS enviada el 15 de marzo de 2023 a través de correo electrónico

Gracias
IOJ

On 03/15/2023 11:59 PM CST Interest Of Justice <contact@interestofjustice.org> wrote:

Ver con junto

gracias

This mail is sent by a private group ©Interest Of Justice 2020, All Rights Reserved. If you wish to not receive content from us please contact us and we will be glad to remove you from our private database.

Team, of Justice

INTEREST of Justice

This mail is sent by a private group ©Interest Of Justice 2020, All Rights Reserved. If you wish to not receive content from us please contact us and we will be glad to remove you from our private database.

Team, of Justice

Gracias IOJThat email was never responded to by CONIS, but they got it according to plaintiffs sent folder.

CONIS REPLY 5.

On evidence provided and that are accessible through the Internet should be indicated:

Due to all of the above (CONIS REPLY 1-5), your requests set forth in the document received cannot be complied with for the following reasons:

1. No research being conducted without authorization from CONIS and CECs is clearly identified at this time directed at an experimental-type vaccine.

2. Regarding informed consent, since it is not a biomedical research, the technical body in charge of referring to its use is the National Commission on Vaccination and Epidemiology, to which your note is being sent.

3. As for VAED and VAR, since it is a drug approved for use in Costa Rica and not an experimental drug, this is the responsibility of the Dirección de Regulación de Productos de Interés Sanitario (DRPIS) of the Ministry of Health, to whom this note is also sent.

4. CONIS and the CECs are always attentive to ensure that sponsors of biomedical studies comply with their functions; however, in this specific case, since it is not biomedical research, it is not within the competence of CONIS to refer to this.

Therefore, your complaint is dismissed due to the **lack of substantiation and clarity of the facts denounced**; furthermore, your document contains accusations of a criminal nature, which CONIS will not
evaluate in any way.

The noted resolution CONIS-0067-2023 from March 27, 2023 is not duly motivated and pertinent.

The above response from CONIS fails to resolve the administrative procedure of stopping the violations of the biomedical research law 9234 Articles 58 Sponsor must have insurance for injuries, 78 and 79 serious undue experimentation, continuing the execution of the VOID acts in excess of legality!

Issues presumed true because the defendant has failed to address or refute each point:

CONIS FAILED TO ADRESS 9234 ARTICLE 58 VIOLATIONS BY CLAIMING THE COVID VACCINES ARE "APPROVED" AND "NOT BIOMEDICAL RESEARCH". This critical issue of absolute nullity of the use for violating Article 58 was evaded and not yet resolved: Plaintiffs fourth issue was not addressed:
Fourth, CONIS initiated the investigation before the Sponsors fulfilled their obligations to provide insurance in the contracts to protect the right of vulnerable people to compensation for damages.

Individuals are injured en masse by their grossly improper experimentation and as a matter of strict law Sponsors have an obligation to ensure that sponsors provide insurance for
damages. see CONIS law: ARTICLE 58.- Contract All biomedical research that has external sponsorship to the public or private entity, where such activity is conducted, must have a contract that regulates the rights and obligations of both the sponsor and the investigator conducting the research. This contract should indicate the payment agreed upon for carrying out the research and include a clause whereby the sponsor is responsible for short and long term adverse events arising from the research. The absence of such a clause does not exempt the sponsor from
liability. Such a contract should be signed by the sponsor's representative, the principal investigator and the representative of the public or private entity, and should be signed prior to the start of the investigation should be signed prior to the start of the investigation.

The whistleblowers found the registered covid-19 mRNA vaccine experiments on the CONIS website, which had to be registered to import covid-19 vaccines under Section 117, and the registered CONIS experiments are scandalously looking for adverse effects of the Pfizer vaccine in healthcare workers and other groups.

- CONIS omits to address or refute the fact that the covid vaccine is investigational and therefore had to be imported for the "exclusive use of biomedical research" and "in compliance with applicable laws", and the applicable laws are biomedical research laws 923 rand 39061-S.
- CONIS omits to address or refute the fact that on record they are studying the ADVERSE effects in interventional studies, precisely to find out what the unproven intervention outside a clinical trial does to humans.
- In particular CONIS aims to study the adverse effects, even the possibility of death and this truth is not being told to the public, CONIS obfuscates and is still omitting informed consent of the adverse effects such as VAED's.
- CONIS is omitting their duty under the WHO's MEURI ethical framework to monitor the identified known risks such as VAED's or ADE (auto immune attack from self antigens) of the unproven intervention.

The research for Pfizer and AstraZenica is started in violation of Article 58: see: CONIS law: ARTICLE 58.- Contract All biomedical research that has external sponsorship to the public or private entity, where such activity is carried out, must have a contract that regulates the rights and obligations of both the sponsor and the researcher who carries out the research. This contract must indicate the agreed payment for carrying out the research and ***include a clause whereby the sponsor is responsible for short-term and long-term adverse events resulting from the research. The absence of such clause does not relieve the sponsor of its responsibility.*** Said contract must be signed by the representative of the sponsor, the principal investigator and the representative of the public or private entity, and **must be signed prior to the start of the research**.

CONIS wrongly referred our issues of VAED to outside competencies by stating: *3. As for VAED and VAR, since it is a drug approved for use in Costa Rica and not an experimental drug, this is the responsibility of the Dirección de Regulación de Productos de Interés Sanitario (DRPIS) of the Ministry of Health, to whom this note is also sent.*

NO ONE from Dirección de Regulación de Productos de Interés Sanitario (DRPIS) of the Ministry of Health wrote back to confirm they have BioNTech registered as approved, or what is going on with the monitoring of VAED, which occurs even years after taking the experiment.

Plaintiffs complaint states 2 points about VAED's::

1. The FDA does not monitor the identified risk of **vaccine-associated enhanced disease including vaccine-associated enhanced respiratory disease**, instead leaving that task to Pfizer (*the habitual criminal sponsor who stands to gain billions of dollars by not telling people the product fails and is making things much worse)* 7. Pharmacovigilance Activities - Pfizer submitted a Pharmacovigilance Plan (PVP) to monitor safety concerns that could be associated with Pfizer-BioNTech COVID-19 Vaccine. ***The Sponsor identified vaccine-associated enhanced disease including vaccine-associated enhanced respiratory disease as an important potential risk***. Use in pregnancy and lactation and vaccine effectiveness are areas the Sponsor identified as missing information. In addition to the safety concerns specified by the Sponsor, FDA requested that the Sponsor update their PVP to include missing information in pediatric participants less than 16 years of age. see pg 44 - https://www.fda.gov/media/144245/download
2. Costa Rica has a huge increase of people and children overfilling the ICU units who are displaying all hallmark symptoms of completely unmonitored vaccine-associated enhanced disease including vaccine-associated enhanced respiratory disease from the serious undue experimentation. Plaintiffs have been warning the willfully blind malicious administration since March 2021 about the vaccine-associated enhanced disease including vaccine-associated enhanced respiratory disease. Even after winning Amparo in November 2021 after having to ask 3x in Sala 4, Plaintiffs questions about ADE/VAED/VARD and how many people in ICU took 1 or more doses (because we think they are in ICU with vaccine injuries & not covid) are met with total contempt, avoidance, inactivity and inefficiency, allowing the populations health, non derogable rights and international community's heritage of humanity, the human genome to be at risk from their serious undue experimentation and disinformation global Pharma terrorism vaccine peddler network directed and controlled by UN-WEF-WHO, U.S et al.

The above serious risk for humanity is ignored by CONIS passing the buck to Minesterio de Salud who is also inactive and allowing unmitigated harm to non derogable rights.

CONIS is clearly failing their duty to monitor the research for identified known risks because they are not regulating at all. This violates WHO MEURI ethical frameworkl. see: Emergency use of unproven clinical interventions outside clinical trials: ethical considerations ISBN 978-92-4-004174-5 (electronic version) https://www.who.int/publications/i/item/9789240041745 WHO recognizes that Member States and the international community have the ethical obligation to ensure that national public health laws assign sufficient responsibility and power to relevant health authorities, such as ministries of health, national regulatory authorities and national disaster management agencies, for the prevention and management of public health emergencies (16, 28). Lack or inadequate regulation of both research during public health emergencies and monitored emergency use outside clinical trials breach this ethical obligation. Ethical and regulatory oversight of emergency use of unproven clinical interventions outside clinical trials should be regarded by health-care workers and relevant health-care authorities as a public health intervention in itself to avoid harm to public health, which requires a sufficiently clear legal basis for government action, and also a system for oversight and review (see also section 3).8. also see pg 19 Currently, many low- and middle-income countries or contexts do not have an optimally functioning research ethics system, nor adequate pre-approval access regulations and have insufficient capacity and expertise to regulate even every day, non-emergency research. Hence, a research ethics system is necessary pg 23 As recognized by PAHO (22), a key challenge to ethically using unproven interventions outside of clinical trials during the COVID-19 pandemic is lack of or limited adherence to the MEURI ethics framework, for a number of reasons: first, unfamiliarity with the MEURI ethical framework, which was devised for the outbreak of EVD in 2014; and, secondly, the complex correlation of the MEURI ethical framework with different regulatory frameworks and pre-approval access designations (e.g. “off-label” use, expanded access, compassionate use, emergency use authorization), which are not globally harmonized and may not exist in some jurisdictions. **Failure to adhere to the MEURI ethical framework or its appropriate implementation has raised serious ethical concerns, which can be categorized according to the MEURI ethical categories, such as:**

Inadequate justification:

- use of unproven clinical interventions, such as those known to be toxic (e.g. chlorine dioxide, methanol), that is not justified by the available evidence and risk–benefit ratio and are thus expected to be more harmful than beneficial (37, 39, 40); and
- excessive assignment of limited resources to unproven clinical interventions with unknown risk–benefit profiles (22).

Inadequate ethical and regulatory oversight:

- undue interference with clinical trials or other necessary research activities (58);
- negligent or intentional mischaracterization by health-care workers, health authorities, ethics committee and other stakeholders of emergency use outside clinical trials, including “off-label” use, as activities

- (e.g. “observational research”, “compassionate use”, “quality improvement”) that evade or do not satisfy the justification, oversight, consent and monitoring established in the MEURI ethical framework (22, 24)15;**
- lack of appropriate coordination of use of unproven interventions within and outside clinical trials, including unfair distribution of and access to scarce unproven clinical interventions (58);
- undisclosed conflicts of interest of Member States’ authorities, prescribers and manufacturers (79);
- misuse of unproven interventions outside clinical trials for commercial gain (80);
- exploitation of desperate individuals willing to try any intervention offered, regardless of the expected risks or benefits (16); and
- **other harm to third parties due to use of unregulated or underregulated, unproven interventions,** including “off-label” uses (e.g. diffusion of unsafe or ineffective unproven interventions, unnecessary stockpiling, creation of shortages of approved medicines for other diseases) (9).

Inadequate consent process:
- invalid or no individual informed consent process when it is required (22);
- undue promotion of unproven clinical interventions outside clinical trials that interferes with appropriate consent (22); and
- irresponsible overstatement of the benefits and understatement of the risks and uncertainties of unproven clinical interventions by national authorities, health-care workers and the media that interferes with the consent process (81).

Inadequate contribution to the generation of evidence:
• failure to use unproven interventions outside clinical trials in a manner that contributes to the generation of evidence (22).

Judicial Notice:

The CONIS resolution outrageously allows Defendants (and 3rd parties Pfizer, WHO, FDA, et al) to continue to execute the act of applying unproven medical interventions outside clinical trial by not applying the Biomedical Research laws to the covid vaccines. Clearly the simple facts prove that CONIS facilitates to third parties WHO, EMA, FDA, Pfizer, AstraZenica, et al infractions of CR law and this means the CONIS is in breach of function by infringing, consenting, or facilitating to third parties infractions of the legal provisions, regulations, agreements of the Conis, CEC or bioethical principles that govern biomedical research and because any other breach of the duties imposed by the legality block or the bioethical principles that govern biomedical research is incurred. See: b) Breach of Functions: i. When_ violations of the legally assumed duties are incurred _by_ infringing, consenting, or facilitating to third parties infractions of the legal provisions, regulations, agreements of the Conis, CEC or bioethical principles that govern biomedical research. IV. _When any other breach of the duties imposed by the legality block or the bioethical principles that govern biomedical research is incurred.

THE APPROPRIATE WHO ETHICAL AND LEGAL LIMITS ARE UNDER THE WHO ETHICAL MEURI FRAMEWORK THAT APPLIES TO "COVID-19 VACCINES"

1. Contrary to what CONIS says about the covid vaccines being merely "observational" and NOT "interventional", the WHO issued a document December 2022 that says covid-19 vaccines are "unproven novel vaccine interventions outside clinical trials" that need to go by the WHO MEURI ethical framework. The word intervention is obvious and re-iterated by WHO. CONIS is not up to speed with the legalities and limits of the ethical use of this biomedical research product.
2. The CONIS is in violation of WHO ethical limits and by not regulating the product, which was imported under 117 for the exclusive purpose of human research.
3. The CONIS denied our petition in error based on misinterpretations of 9234 and 39061-S laws and definitions. Covid-19 vaccines are an "unproven intervention outside clinical trials" according to WHO and needs extra biomedical research protections for end users and consumers. CONIS should know the product is an unproven intervention.
4. The WHO document states that many Ministries of Health are not educated in the MEURI framework which applies to the product and therefore the MEURI framework may not be applied, which violates rights.
5. In this case the unregulated use of the "covid-19 unproven intervention outside a clinical trial" fails to consider recent WHO guidance, and as such the unregulated use of the investigational unproven intervention violates the limits of the legal system.

CONSIDERING:

According to the Organic Regulations of the National Health Research Council (CONIS) N° 40884 – S Organic Regulations of the National Health Research Council (CONIS)
N° 40884 - S THE PRESIDENT OF THE REPUBLIC AND THE MINISTER OF HEALTH
In use of the powers conferred by articles 50, 140, paragraphs 3) and 18) and 146 of the Political Constitution; 25 paragraph 1), 27 paragraph 1), 28 paragraph 2) subparagraph b) of Law No. 6227 of May 2, 1978 "General Law of the Public Administration", 2, 4 and 7 of Law No. 5395 of October 30, 1973, "General Law of Health"; 1, 2 and 6 of Law No.5412 of November 8, 1973, "General Law of Health"; 1, 2 and 6 of Law No.5412 of November 8, 1973, "General Law of the Public Administration"; 1, 2 and 6 of Law No.5412 of November 8, 1973, "General Law of Health". of November 8, 1973, "Organic Law of the Ministry of Health"; Law No. 9234 of April 22, 2014, "Regulatory Law of Biomedical Research"; and Executive Decree No. 39061-S of May 08, 2015, "Regulations to the Regulatory Law of Biomedical Research".
1.- That by means of Law No.9234 of April 22, 2014, "Ley Reguladora de Investigación Biomédica", published in La Gaceta No. 79 of April 25, 2014, Article 34 created the Consejo Nacional de Investigación en Salud, hereinafter CONIS, as an independent, multidisciplinary, ethical, technical and scientific body, attached to the Ministry of Health with a maximum degree

of deconcentration and with instrumental legal personality. The same article also states that CONIS shall have the administrative structure to be defined by regulation and shall have its own internal audit in accordance with Law No. 8292 of July 31, 2002, "General Law of Internal Control", and Law No. 7428 of September 7, 1994, "Organic Law of the Comptroller General of the Republic".
2.- As CONIS is a new, recently created body, ***it needs to be endowed with a structure, so that it can fulfill its objectives and perform the powers and competencies attributed by Law***. And this structure ***must be sufficiently suitable to fulfill the legal tasks within the requirements of reality.***
That in accordance with the provisions of the General Guidelines for Administrative Reorganizations (LGRA), of the Ministry of National Planning and Economic Policy MIDEPLAN, the proposed structure of CONIS, **with the description of the functions of each organizational unit, in accordance with the provisions of Law No. 9234** of April 22, 2014, "Regulatory Law of Biomedical Research", is proposed by the Ministry of Health through official letter No. DM-6818-2016, and is submitted for consideration of MIDEPLAN, for its approval.
That by means of official letter No. DM-067-17, the Ministry of National Planning and Economic Policy MIDEPLAN approves the structure of CONIS, with modifications to be taken into account, which are complied with by the Ministry of Health, indicating, among other things, the following: "By virtue of the above, it is concluded that the proposed changes are consistent with the functions and objectives of the National Health Research Council (CONIS) and the regulations in force, and therefore, the representation of CONIS as a body attached to the Ministry of Health is approved and the organization of said body **is partially approved in accordance with the technical criteria described above".**

CONCLUSION:

CONIS is merely **"partially approved"** only so long as it acts "in accordance with the technical criteria described above".

If the CONIS fails to act in accordance with the above technical criteria in 9234 the law says they must be declared in breach of function, and are obviously incapable of performing their obligations as a matter of law and ethics.

39061-S Article 4 - **Of the applicable regulations**. All biomedical research involving human beings must guarantee, respect and fulfill Human Rights. The National Health Research Council (CONIS), the Scientific Ethics Committees (CEC), the researchers, the technical team related to the research, the sponsors, the Contract Administration Organizations (OAC), the Contract Research Organizations (OIC) and the support personnel of these entities **must fulfill their functions and obligations in strict adherence to the Universal Declaration of Human Rights, the Inter-American Convention on Human Rights, the International Covenant on Civil and Political Rights, the Convention on the Rights of People with Disabilities,**

At this point, according to the facts in the record, and defendants testimonies, it is evident and manifest that CONIS is omitting to apply the proper laws in order to commit manifestly illegal and immoral acts of undue experimentation and serious undue experimentation by omitting adequate and truthful information and informed consent.

The issues which CONIS gives false representations about directly affect 97% of the populations non derogable rights to be free of experimentation without informed consent.

CONIS registered an interventional covid vaccine genomic experiment, approved it to allow entry of the experimental biological agent covid-19 vaccine into Costa Rica under Article 117 health law, for the exclusive use of human research, and CONIS allows the manifestly illegal act of undue experimentation to be administered, intentionally violating every participants right to adequate and true information.

CONIS is so new and obviously undertrained, with the CNVE Secretary (who is part of the structure) testifying to give us different applicable biomedical research laws and information than CONIS, it is evident and manifest that CONIS is not endowed with a structure, so that it can fulfill its objectives and perform the powers and competencies attributed by Law.

The current structure is not honorable **or informed enough by CNVE (who is part of the structure)** to be sufficiently suitable to fulfill the legal tasks within the requirements of reality. There is no way to explain this other than corruption.

CONIS response does not resolve the process. CONIS OMIITS adequate and truthful information, a right under Article 46 of the Constitution.

All members including the Health Minister Daniel Salas, then Joselyn Chacon have falsely testified about the experimental nature of the DoD biological agent, causing deception, disinformation and manipulation, elements of 9234 Article 78, 79 serious undue experimentation on humanity. There is an open penal case against the false testimony.

This omission of adequate and truthful information of the CNVE's testimony January 24, 2023 proving the covid vaccine is investigational, imported for the exclusive purpose of human research under Article 117, regulated under biomedical research laws 9234 and 39061-S, is why CONIS has denied our petition to cease and desist the serious undue experimentation.

In issuing the void resolution CONIS has failed to stop the violation of Article 78, 79, and is facilitating to many third parties violations of Costa Rican laws, including Siracusa Principles Articles 58 and 69b, which prevent serious undue experimentation.

FINDINGS OF FACTS CONCLUSIONS OF LAW.

CONIS claims the covid vaccines are not biomedical research, despite the evidence to the contrary which proves CONIS registered the imported investigational product defined in registered experimental "studies" as both investigational and observational research with assigned investigators and registration numbers per "study". Some studies are to find out the adverse effects of Pfizer BioNTech.

CONIS testified on March 27, 2023 that the CONIS is not regulating the experimental use of the covid vaccines at all because they mistakenly purport 9234, 39061-S doesn't apply to the allegedly approved covid vaccines. This position is ignoring the evidence that CNVE testified the applicable laws to govern covid-19 vaccines are import law 117 of the health law, Biomedical Research laws 9234 and 39061-S which defines investigational and experimental as the same.

CONIS is also willfully blind, ignoring public and notorious facts that there are two current precautionary measures in place due to the fact its still EUA, not approved.

By misinterpreting that the covid-19 vaccine is approved, CONIS has claimed the covid-19 vaccine is not biomedical research, when in reality is is biomedical research, therefore, the court finds a clear omission not addressed, insofar as CONIS has failed to apply 9234 article 58, 78 and 79. These articles are intended for the benefit of the public who are subjected to biomedical research and prevent this exact type of serious undue experimentation and provides insurance for injuries.

CONIS has shown prima facie willful intent, willful blindness or extreme gross negligence of documentary evidence of scientific rigor they must accept, contributing to third party violations of Biomedical Research mandatory compliance laws 9234, 39061-S, making immediate annulment mandatory as a prima facie constitutional guarantee of prompt justice in strict accordance with law:

REMEDY:

ALL MEDICAL AND SCIENTIFIC RESEARCH IN COSTA RICA SHALL BE SUSPENDED WITH A FULL MORATORIUM PENDING RESOLUTION OF HOW TO OVERSEE FUTURE APPLICATION OF 9234, 39061-S TO MAKE IT EFFECTIVE.

The right that's considered, violated or threatened:

* The right to an efficient administration
* adequate and truthful information
* The right to Prompt and fulfilled administrative procedure
* control the legality
* protect the public interest
* The right to defend human rights
* The right to informed consent

The name of the public servant or body responsible for the threat or offense

* The State of Costa Rica
    * Ministerio de salud
        * Organic Regulations of the National Health Research Council (CONIS)
* Facilitated third parties
    * Pfizer
    * Astrazenica
    * Costa Rica
    * Costa Rica Ministry of Foreign Affairs
    * Comptroller of Costa Rica
    * PANI Childrens Fund
    * President of Costa Rica
    * FDA USA
    * DoD (Department of defense USA)
    * World Health Organization

And Evidence:

* Resolution from CONIS not duly motivated and pertinent CONIS-0067-2023, 27 de Marzo de 2023

CONIS Complaints through email:

Administrative record complaint to CONIS

5. First complaint - March 15, 2023 IOJ wrote CONIS a complaint for serious undue experimentation

6. Second email of evidence - March 16, 2023 IOJ amplifies the complaint which was sent March 15, 2023 with evidence

7. March 27, 2023, CONIS responds with a notification of receipt stamped

8. Conis Response March 27 2023 CONIS-0067-2023 . The foregoing March 27, 2023 CONIS resolution to continue to execute the act of applying unproven medical interventions outside clinical trial by not applying the Biomedical Research laws to the covid vaccines, facilitates to third parties WHO, EMA, FDA, Pfizer, AstraZenica, et al infractions of CR law CONIS law 9234 Article 20 breach of function, also violating penal code ARTICLE 339.- Breach of dutiesF

    - CONIS Resolution is not duly motivated and pertinent
    - CONIS not regulating the sponsors interventional research registered as interventional in CONIS
    - says APPROVED but OMITS evidence, therefore the claim covid vaccines are not biomedical research has not been duly motivated or proven.
    - CONIS omits their burden of proof to dismiss our petition to control the legality and stop the interventional serious undue experimentation that violates 9234 78 and 79
    - Facilitates breaches of law 9234 Articles 78 & 79 to third parties still OMITTING Informed consent for biomedical research, in violation of 9234 Article 78, 79
        * Pfizer
        * Astrazenica
        * Costa Rica
        * Ministry of Foreign Affairs
        * Comptroller
        * PANI
        * President
        * CNE

1. All evidence listed in the initial precautionary measure
2. from https://registrelo.go.cr/ page 3
3. W.H.O.Chief Scientist, stating in a PSA November 28, 2019 that vaccines are safe and then 5 days later saying the opposite and that some countries are not adequately monitored at a summit. Do you trust the "experts"? Precaution is warranted because the WHO is on recording lying about vaccine safety and admitting the dangers are inadequately monitored for the EUL list! [

https://www.bitchute.com/video/gq6CDGgNcFRA/](https://www.bitchute.com/video/gq6CDGgNcFRA/)

4. · WHO Chief scientist stating they have zero evidence that the vaccines will even work https://www.bitchute.com/video/ILuQvyHbGVZP/

5.FDA extrajudicial irrevocable confession: Investigational drugs, biologics or medical devices have not yet been approved or cleared by FDA [https://www.fda.gov/news-events/public-health-focus/expanded-access-Content

6. the FDA and EMA who are founding members of the International Council on Harmonization of Technical Requirements for Pharmaceutical Substances for Human Use and meet the WHO definition of Strict Regulatory Authority (available at https://www.who.int/initiatives/wholisted-authority-reg-authorities/SRAs).

7. Overview Emergency use of unproven clinical interventions outside clinical trials: ethical considerations 12 April 2022 Technical document https://www.who.int/publications/i/item/9789240041745

8. CONIS and Health Ministry are omitting key systems needed for compliance and harmonization with WHO advisory opinion https://www.researchgate.net/publication/361334249_Research_ethics_systems_in_Latin_America_and_the_Caribbean_a_systemic_assessment_using_indicators

9. The lawsuit against the DOD, Operation Warp Speed and the COVID vaccines filed May 31, 2023 explains the BioNTech and Corminarty bait and switch. The family of a 24-year-old man who died from complications of COVID-19 vaccine[https://childrenshealthdefense.org/defender/george-watts-jr-pfizer-covid-vaccine-injury/

10. [Operation Warp Speed]([https://childrenshealthdefense.org/defender/operation-warp-speed-big-payouts-pharma-execs/] On Oct. 27, 2021, at home with his mother, Watts began coughing up blood and then became unresponsive. His mother called 911 and administered CPR.

11. He had no previous medical history that could explain his [sudden death]([https://childrenshealthdefense.org/defender/cause-unknown-edward-dowd-sudden-deaths-covid-vaccines/

12.[https://childrenshealthdefense.org/authors/ray-l-flores-ii-esq/ the attorney representing the estate of George Watts Jr.

13. https://childrenshealthdefense.org/wp-content/uploads/Watts-v.-DOD-EDT.pdf in the U.S. District Court for the District of Columbia against the DOD

14. Lloyd Austin III]([https://www.defense.gov/About/Biographies/Biography/article/2522687/lloyd-j-austin-

iii/](https://www.defense.gov/About/Biographies/Biography/article/2522687/lloyd-j-austin-iii/)) in his official capacity as defense secretary.

15. The lawsuit alleges the DOD engaged in "willful misconduct" by continuing to exclusively allow distribution of the stockpiled version of the Pfizer-BioNTech vaccine that had been authorized for emergency use even after the U.S. Food and Drug Administration (FDA) granted full approval to a different vaccine, [Comirnaty]([https://childrenshealthdefense.org/defender/steve-kirsch-alix-mayer-pfizer-approved-comirnaty-vaccine/

16. According to the complaint, the DOD "capitalized on a quintessential '[bait and switch](https://childrenshealthdefense.org/defender/childrens-health-defense-sues-fda-pfizer-comirnaty-covid-vaccine/](' fraud," using the fact that Comirnaty was FDA-approved to bolster its claims that the vaccine authorized for emergency use was "safe and effective," in a move that intentionally misled millions

17. FDA approved]([https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine] the Pfizer Comirnaty vaccine on Aug. 23, 2021, but the DOD didn't make it available

18. In January 2020, then-Health Secretary Alex M. Azar of the U.S. Department of Health and Human Services declared a [public health emergency]([https://aspr.hhs.gov/legal/PHE/Pages/2019-nCoV.aspx

19. The emergency declaration allowed the health secretary to make a [PREP Act declaration]([https://childrenshealthdefense.org/defender/prep-act-covid-vaccine-injury-liability/ 20. FDA could issue an EUA] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities)) for an unapproved vaccine or other "countermeasure"

21. "countermeasure" to address the emergency if the following [emergency circumstances]([https://childrenshealthdefense.org/wp-content/uploads/Watts-v.-DOD-EDT.pdf

22. On May 15, 2020, the Trump White House announced [Operation Warp Speed](https://web.archive.org/web/20201216233803/https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html]— a partnership between the White House and the DOD to accelerate the development, production and distribution of a COVID-19 vaccine

23. Two months later, the [DOD signed a contract with Pfizer] https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf to manufacture hundreds of millions of doses of its mRNA COVID-19 vaccine, guaranteeing that any vaccine produced under the contract would be protected

24. The FDA issued an EUA for the Pfizer-BioNTech COVID-19 vaccine on Dec. 11, 2020, and Army Gen. Gustave F. Perna, [Operation Warp Speed chief operating officer]([https://www.defense.gov/News/News-Stories/Article/Article/2445137/operation-warp-speed-

official-first-covid-19-vaccines-to-arrive-monday/](https://www.defense.gov/News/News-Stories/Article/Article/2445137/operation-warp-speed-official-first-covid-19-vaccines-to-arrive-monday/)

25. Drugs fully approved by the FDA must be found to be "safe, pure, and potent," but EUA drugs are held to a lower standard — they are required only to demonstrate that they "may be effective," [according to the FDA]([https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities#relating

26. The DOD knowingly blurred this line, the lawsuit alleges, because it had already been found liable for violating [informed consent]([https://childrenshealthdefense.org/defender/informed-consent-covid-misinformation-law-california and of imposing an experimental vaccine. In the 2004 case of [Doe v. Rumsfeld, et al. https://law.justia.com/cases/federal/appellate-courts/cadc/11-5209/11-5209-2012-06-15.html ,

27. a federal court ruled the DOD could not mandate the EUA [anthrax vaccine] https://childrenshealthdefense.org/defender/covid-vaccine-military-botched-anthrax for service members because forcing them to take an experimental vaccine violated their right to informed consent

28. DOD knowingly deceived Watts and other Americans for the purpose of mass human experimentation, which violates protections provided by the [Nuremberg Code]([https://childrenshealthdefense.org/defender/mary-holland-nuremberg-code-anniversary-speech/

29. see official press release CONIS omitted: "Pfizer-BioNTech COVID-19 Vaccine COMIRNATY® Receives Full U.S. FDA Approval for Individuals 16 Years and Older". Monday, August 23, 2021 - 11:57am https://www.pfizer.com/news/press-release/press-release-detail/pfizer-biontech-covid-19-vaccine-comirnatyr-receives-full 30. Also see the difference of the approved COMIRNATY and legally different EUA BioNTech with dates here: https://www.fda.gov/media/150386/download On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA)

31. The FDA website currently says BioNTech is under EUA see https://www.fda.gov/vaccines-blood-biologics/coronavirus-covid-19-cber-regulated-biologics/pfizer-biontech-covid-19-vaccines#additional

32. According to the above FDA website there was a [Letter of Authorization] https://www.fda.gov/media/150386/download

33. Nowhere in the letter does it say Pfizer-BioNTech's COVID-19 vaccine is approved under the brand name Cominarty. Also, The [monovalent Pfizer-BioNTech COVID-19 Vaccine] https://www.fda.gov/vaccines-blood-biologics/industry-biologics/coronavirus-covid-19-cber-regulated-biologics](https://www.fda.gov/vaccines-blood-biologics/industry-biologics/coronavirus-covid-19-cber-regulated-biologics "Coronavirus (COVID-19) | CBER-Regulated Biologics") is no longer authorized for use in the United States

34. (EUL, for its acronym in English) as can be verified on the website of this organization: https://extranet.who.int/pqweb/vaccines/covid-19-vaccines

35. CONIS registered "interventional" studies of Pfizer BioNTech investigational EUA product, NOT approved yet and refuse to apply the 9234 limitations of this act of serious undue experimentation. see https://www.ministeriodesalud.go.cr/conis/index.php/servicios/investigaciones-registradas https://www.ministeriodesalud.go.cr/conis/index.php/servicios/requisitos-de-importacion
36. U.S. regulatory agencies and the CEC, CONIS, CNVE, CCSS, Ministry of Health and Costa Rica.

**See:https://www.fda.gov/news-events/public-health-focus/expanded-access

37. The omission of WHO, EMA, FDA, CONIS, Minesterio De Salud, CCSS, et al to provide informed consent to the end users and consumers that the covid-19 vaccines are "investigational" a word meaning "experimental" that FDA accurately says is not found by FDA to be safe or effective, and which may cause serious side effects", but which they publicly proclaim the opposite see: https://www.fda.gov/news-events/public-health-focus/expanded-access and https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-investigational-drugs
38. “[biological agent] https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=18-USC-1937569830-323568840&term_occur=999&term_src=title:18:part:I:chapter:10:section:178 ” means any
39. (2)the term “[toxin] https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=18-USC-110553922-323568839&term_occur=999&term_src=title:18:part:I:chapter:10:section:178 ” means the toxic material or product of plants, animals, microorganisms (including, but not limited to,
40. “[delivery system] https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=18-USC-2021055525-323568838&term_occur=999&term_src=title:18:part:I:chapter:10:section:178 ” means

41. [biological agent]
https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=18-USC-1937569830-323568840&term_occur=999&term_src=title:18:part:I:chapter:10:section:178
42. [toxin,]
https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=18-USC-110553922-323568839&term_occur=999&term_src=title:18:part:I:chapter:10:section:178
43. [vector;]
https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=18-USC-820387517-323568837&term_occur=999&term_src=title:18:part:I:chapter:10:section:178 or(B)any
44. [vector]
https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=18-USC-820387517-323568837&term_occur=999&term_src=title:18:part:I:chapter:10:section:178 ;
45. (4)the term “[vector]
https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=18-USC-820387517-323568837&term_occur=999&term_src=title:18:part:I:chapter:10:section:178 ” means a living organism, or molecule, including a recombinant or synthesized molecule, capable of carrying a
46. [biological agent]
https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=18-USC-1937569830-323568840&term_occur=999&term_src=title:18:part:I:chapter:10:section:178 or

47. [toxin] https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=18-USC-110553922-323568839&term_occur=999&term_src=title:18:part:I:chapter:10:section:178 to a host;

1. Overview Emergency use of unproven clinical interventions outside clinical trials: ethical considerations 12 April 2022 Technical document https://www.who.int/publications/i/item/9789240041745
2. CONIS and Health Ministry are omitting key systems needed for compliance and harmonization with WHO advisory opinion https://www.researchgate.net/publication/361334249_Research_ethics_systems_in_Latin_America_and_the_Caribbean_a_systemic_assessment_using_indicators
3. Indicator countries indicator to strengthen research compliance Research ethics systems in Latin America and the Caribbean: a systemic assessment using indicators Article in The Lancet Global Health · June 2022 - Not following WHO technical or research standards!
4. Title called "Regulatory approvals for Pfizer-BioNTech's COVID-19 Vaccine:", with a list of dates and authorizations for Pfizer BioNTech and AstraZenica
5. Testimony in the record January 24, 2022 from Health Minister Daniel Salas and CNVE secretary Roberto Arroba Tijerino proving "covid-19 vaccines are investigational biomedical research products"
6. January 4th, 2022 cease and desist the covid non vaccine gene therapy bioweapon demand as URGENT and PERTINENT due to death being common from Pfizer BioNTech
7. Lancet article proving the PCR test is void creating all false positives "the PCR test is not the gold standard")
8. **The lawsuit against the DOD, Operation Warp Speed and the COVID vaccines filed May 31, 2023 explains the BioNTech and Corminarty bait and switch https://childrenshealthdefense.org/defender/george-watts-jr-pfizer-covid-vaccine-injury The family of a 24-year-old man who died from complications of COVID-19 vaccine-induced myocarditis

9. Pfizer-BioNTech COVID-19 Vaccine COMIRNATY® Receives Full U.S. FDA Approval for Individuals 16 Years and Older". https://www.pfizer.com/news/press-release/press-release-detail/pfizer-biontech-covid-19-vaccine-comirnatyr-receives-full
10. difference of the approved COMIRNATY and legally different EUA BioNTech https://www.fda.gov/media/150386/download
11. The FDA website currently says BioNTech is under EUA see: https://www.fda.gov/vaccines-blood-biologics/coronavirus-covid-19-cber-regulated-biologics/pfizer-biontech-covid-19-vaccines#additional
12. EUL Strict regulatory agencies https://extranet.who.int/pqweb/vaccines/covid-19-vaccines
13. 12 registered experiments of covid-19 vaccines. There are a few registered studies of Pfizer BioNTech
14. https://www.ministeriodesalud.go.cr/conis/index.php/servicios/investigaciones-registradas
15. https://www.ministeriodesalud.go.cr/conis/index.php/servicios/requisitos-de-importacion
16.https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-investigational-drug
17. The **investigational** drugs, biological products, or medical devices have **not yet been approved or cleared by the FDA https://www.fda.gov/news-events/public-health-focus/expanded-access
18. FDA requested that the Sponsor update their PVP to include missing information in pediatric participants less than 16 years of age. see pg 44 https://www.fda.gov/media/144245/download
19. ethical considerations ISBN 978-92-4-004174-5 (electronic version) https://www.who.int/publications/i/item/9789240041745
20. WHO issued a document December 2022 that says covid-19 vaccines are "unproven novel vaccine interventions outside clinical trials" that need to go by the WHO MEURI ethical framework
21. CONIS testified on March 27, 2023 that the CONIS is not regulating the experimental use of the covid vaccines at al

22. World Health Organization *Emergency use of unproven clinical interventions outside clinical trials: ethical considerations.pdf*

23. *Carla_Saenz_PAHO_2022_ethics_docAguileraetal_ResearchethicsindicatorsLAC (2).pdf*

24. FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT WHICH HAS EMERGENCY USE AUTHORIZATION (EUA) TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19).pdf

Exact International instrument articles of treaties and bodies

* Memorandum of law
Contentious admin procedure code Art. 127-128
Administrative contentious procedural code article 30
Article 10 med moral law
* Treaties and National Laws
Siracusa Principles articles 58 and 62b
ICCPR – International covenant on Civil and political rights
b) Breach of Functions under CONIS law No. 39061-S: i. When violations of the legally assumed duties are incurred by infringing, consenting, or facilitating to third parties infractions of the legal provisions, regulations, agreements of the CONIS, CEC or bioethical principles that govern biomedical research. IV. When any other breach of the duties imposed by the legality block or the bioethical principles that govern biomedical research is incurred.
* CONIS testified not regulating covid-19 vaccine at all because they purport "its approved", contrary to evidence and citing no evidence to support incorrect assertion!
* CONIS facilitates to 3rd parties breaches of biomedical research laws 9234 and 39061-S:
* Gross and systematic failure to perform obligations owed to Costa Rica and the International community to abide by national laws:
* c. Violating 9234 Article 58 - Insurance for injuries is mandatory to begin research!
No. 39061-S Regulations to the Biomedical Research Regulatory Law
* Allowed research to begin prior to contract ensuring insurance for injured users of the imported research product
- CONIS law: ARTICLE 58.- Contract All biomedical research that has external sponsorship to the public or private entity, where such activity is carried out, *must have a contract that regulates the rights and obligations of both the sponsor and the researcher who carries out the research. This contract must indicate the agreed payment for carrying out the research and include a clause whereby the sponsor is responsible for short-term and long-term adverse events resulting from the research. The absence of such clause does not relieve the sponsor of its responsibility. Said contract must be signed by the representative of the sponsor, the principal investigator and the representative of the public or private entity, and must be signed prior to the start of the research.

Judicial Notice:

The court failed to serve us the final resolution Ordered by the judge to dismiss the precautionary measure on March 2023. Until July 17, 2023, over 4 months after the judge ruled. In doing so, plaintiffs unknowingly entered in new facts on the record after the dated ruling, but without notice of the precautionary measure being denied. Thus the new facts were never considered. On June 7th 2023, plaintiffs entered in the new facts in the document titled "IN THE INTEREST OF

JUSTICE, MOTION FOR IMMEDIATE RULING AND UPDATE OF NEW FACTS NOT AVAILABLE AT THE TIME"

Subsequent to this appeal will be filed more evidence and expand this appeal to include more requests for precautionary measures based on the facts which were entered on June 7, 2023 which are appropriate and timely, yet still not taken into consideration, which plaintiffs wish for the judge to review in order to protect the public interest and petitioners' private interests as well

Request for remedy:

1. It is requested to issue an immediate precautionary measure to prevent the act of serious undue experimentation in Costa Rica using the unproven intervention of covid-19 vaccine biological agent. The court should prevent all mRNA and Viral vector biological agents outside clinical trials including vaccines, food, air or otherwise. The manifestly illegal act of serious undue experimentation is prevented by Nuremberg Code, Siracusa Principles biomedical research laws 9234 and 39061-S and currently caused by:

1. the manifestly illegal application of 8111 authorizing CNVE to approve the covid-19 vaccines, which are only defined by WHO as a vaccine, but which do not conform to the vaccine regulatory law 32722 article 1 section p, meaning the CNVE authority is in excess of law

2. The omission of WHO, EMA, FDA, CONIS, Minesterio De Salud, CCSS, et al to provide informed consent to the end users and consumers that the covid-19 vaccines are "investigational" a word meaning "experimental" that FDA accurately says is not found by FDA to be safe or effective, and which may cause serious side effects", but which they publicly proclaim the opposite see: https://www.fda.gov/news-events/public-health-focus/expanded-access and https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-investigational-drugs

3. The omission to provide informed consent to the end users and consumers that the covid-19 vaccines have identified risks of VAED's - vaccine associated enhanced disease which essentially destroys your immune system and gives you auto immune disease, and this identified risk, as well as death being common is not being monitored at all by any regulator on earth or explained in the fact sheets.

4. The omission of all strict regulators WHO, EMA, FDA, and CONIS, Minesterio De Salud, CCSS, et al to apply the MEURI framework outlined in the guidance "Emergency use of unproven clinical interventions outside clinical trials: ethical considerations ISBN 978-92-4-004174-5 (electronic version) ISBN 978-92-4-004175-2 (print version)"

5. The omission of CONIS to apply latest WHO technical and research standards for functional research - see: Research ethics systems in Latin America and the Caribbean: a systemic

assessment using indicators in Article in The Lancet Global Health · June 2022 DOI: 10.1016/S2214-109X(22)00128-0

6. The omission of HHS OGA and DoD to inform the fact sheet that the covid-19 vaccines (mRNA Pfizer BioNTech and viral vector AstraZenica) are a delivery system for a cytotoxic biological agent as defined in # 18 U.S. Code § 178 - Definitions As used in this chapter—(1)the term

"[biological agent] https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=18-USC-1937569830-323568840&term_occur=999&term_src=title:18:part:I:chapter:10:section:178 " means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance, capable of causing—

(A)death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;

(B)deterioration of food, water, equipment, supplies, or material of any kind; or

(C)deleterious alteration of the environment;

(2)the term "[toxin] https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=18-USC-110553922-323568839&term_occur=999&term_src=title:18:part:I:chapter:10:section:178 " means the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes—

(A)any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or

(B)any poisonous isomer or biological product, homolog, or derivative of such a substance;

(3)the term

"[delivery system] https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=18-USC-2021055525-323568838&term_occur=999&term_src=title:18:part:I:chapter:10:section:178 " means—(A)any apparatus, equipment, device, or means of delivery specifically designed to deliver or disseminate a

[biological agent]
https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=18-USC-1937569830-323568840&term_occur=999&term_src=title:18:part:I:chapter:10:section:178,

[toxin,]
https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=18-USC-110553922-323568839&term_occur=999&term_src=title:18:part:I:chapter:10:section:178 or

[vector;]
https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=18-USC-820387517-323568837&term_occur=999&term_src=title:18:part:I:chapter:10:section:178 or(B)any

[vector]
https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=18-USC-820387517-323568837&term_occur=999&term_src=title:18:part:I:chapter:10:section:178 ;

(4)the term "[vector]
https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=18-USC-820387517-323568837&term_occur=999&term_src=title:18:part:I:chapter:10:section:178 " means a living organism, or molecule, including a recombinant or synthesized molecule, capable of carrying a

[biological agent]
https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=18-USC-1937569830-323568840&term_occur=999&term_src=title:18:part:I:chapter:10:section:178 or

[toxin]
https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=18-USC-110553922-323568839&term_occur=999&term_src=title:18:part:I:chapter:10:section:178 to a host;

2.It is requested to issue the same protection globally to prevent the covid-19 vaccine WHO EUL emergency use listing for global use of the experimental biological agent, EMA "rolling review approval", FDA full approval and authorization and to prevent all international regulators involved in the WHO EUL program from authorizing or approving the covid-19 vaccine or other mRNA or Viral Vector biological agent research outside a clinical trial who this court has jurisdiction over under 9234, that are directly or indirectly involved in human research using covid-19 vaccines in Costa Rica. Plaintiffs request the covid-19 vaccines be declared biomedical research and prevented in both Costa Rica and also globally if possible, for not following the rules of 9234, which do apply to all regulators involved in authorizing the WHO EUL that Costa Rica relies on.

3. It is strongly requested to re-issue the full moratorium to once again prevent all human research in Costa Rica. The laws were created but there is no oversight to make them work. The moratorium on all research and to suspend all CONIS is very appropriate and necessary in the public interest. The legislators require the CONIS and all research to be stopped until the problems are resolved.

4. The new facts show CONIS started the research prior to the sponsor having insurance, a manifestly illegal act, and plaintiffs wish for the court to prevent further omissions of the State to provide the insurance owed by law under 9234 article 58. ARTICLE 58.- "*Contract All biomedical research that has external sponsorship to the public or private entity, where such activity is carried out, must have a contract that regulates the rights and obligations of both the sponsor and the researcher who carries out the research. This contract must indicate the agreed payment for carrying out the research and include a clause whereby the sponsor is responsible for short-term and long-term adverse events resulting from the research. The absence of such clause does not relieve the sponsor of its responsibility. Said contract must be signed by the representative of the sponsor, the principal investigator and the representative of the public or private entity, and must be signed prior to the start of the research.* As noted by the law, "The absence of such clause does not relieve the sponsor of its responsibility". Please issue the appropriate precautionary measure to ensure the law is given effect and people who need the insurance are able to apply and be informed of the procedure to apply for the required insurance owed by the Sponsor. Plaintiffs believe the sponsors are AstraZenica and BioNTech/Pfizer, but if they dispute they are the sponsors then a hearing should be ordered to immediately ascertain who the sponsor is that this law applies to and who is responsible for the serious omission to apply Article 58.

5. Plaintiffs strongly request the immediate suspension pending review in the main process of the following decrees that allow Costa Rica to provide an authorization based on the recognition made by these corrupt and non responsive Strict Regulatory Authorities as described in administrative resolutions DM- RM-7905-2020 of December 3, 2020 and DM-RC-0486- 2021 of February 22, 2021. It is important to note the WHO refuses to answer charges of serious undue experimentation and fraudulent science, and FDA refused our citizens petition to revoke the EUA with no motivation and not pertinent to issues of research misconduct explained herein, meaning there is a false rebutted presumption of CNVE in January 24, 2022 testimony: "since these are vaccines that would be used for the first time in humans, and to ensure rapid access to vaccines for the population and to safeguard the health of the Costa Rican population, the National Commission for Vaccination and Epidemiology made the decision to include within of its selection criteria for vaccines against COVID-19 that these will have the approval of a Strict Regulatory Authority or approved in the WHO Emergency Use List, so we make sure that the expert committees of these authorities that have a fairly strict regulation and robust regulatory processes". The robust review and regulation of WHO, EMA and FDA, et al is wholly illusory, Costa Rica cannot allow these reckless decrees to stand because this problem will continue.

Appellants affirm under the penalty of perjury the foregoing is true and correct according to law

Respectfully,

Lord Dustin Bryce [redacted] and Lady Xylie Desiree [redacted]

July 20, 2023

Lord Dustin Bryce [redacted]

Lady Xylie Desiree [redacted]

AUTENTICACIÓN

El suscrito Notario Adrián Ceciliano Altamirano, con oficina abierta en San José, Pérez Zeledón, San Isidro de El General, exactamente frente al costado oeste del parque central, Edificio Vargas Abogados, primer piso; hace constar la autenticidad de las firmas que anteceden realizadas por Lord Dustin Bryce Rosondich y Lady Xylie Desiree Eshleman, en el documento identificado como "Contencioso Administrativo de Tribunal de Apelación Expediente número 22-001917-1028-CA" el cual contiene ochenta y seis páginas, por haber sido puestas en mi presencia, de puño y letra por los firmantes, que son quienes dicen ser. De igual manera, el suscrito Notario hace constar que la firma que estampo corresponde a aquella debidamente registrada ante la Dirección Nacional de Notariado. San Isidro de El General, Pérez Zeledón, catorce horas cuarenta y ocho minutos del doce de setiembre del año dos mil veintitrés.

Autentica
Lic. Adrián Ceciliano Altamirano
Carné 21623

LIC. ADRIÁN CECILIANO ALTAMIRANO
NOTARIO PUBLICO
C. 21623
COSTA RICA

Banco de Costa Rica
Oficina:245 SAN ISIDRO DE EL GENERAL
Fecha:28/08/2023 Hora:11:20:04

Detalle de Tasacion
Tasacion:501602437 Entero:519003594

Pagado

TIMBRE COLEGIO DE ABOGADO	275.00

BCR SAN ISIDRO DE EL GENERAL

28 AGO 2023

JOSE CORDERO MORA
CAJERO

Moneda de Transaccion:	COLONES
Sub Tot Timbres:	275.00
Descuento:	16.50
Total Timbres:	258.50