To The Ecuadorean Ministry of Public Health and The National Health Agency for Regulation, Control, and Oversight. For review and consideration when formulating a public health policy around a COVID-19 vaccine.

Due to the rapid roll out of a vaccine for COVID-19, concerns have arisen regarding the safety and bioethical nature of the vaccine, and administration of the vaccine in violation of individual civil rights. Under International and Ecuadorean Law, consideration must be given to whether the current public health policies to deliver a potentially unsafe vaccine conforms with an individual's rights in relation to personal health. In doing so, the Government of Ecuador must balance the competing need to protect the public interest with the need to protect human rights, in this case, an individual's right to make informed health decisions for his/herself; freely opting out of a vaccine program, the right to be free from discriminatory punitive measures for not participating in the vaccine program, the right to be protected from and compensated for potential harm caused by the vaccine, and the right to safe and bioethical vaccines.

Our mission is to highlight and remind the Ministry of Public Health its legal obligations and limitations under the Ecuadorean Constitution. We are concerned that individual civil liberties are being violated and also that the Ecuadorean government is opening itself up to legal claims based on its recent actions and current policies. Our hope is that the Ministry considers our recommendations and aligns its policies with stipulations of the Constitution and international laws.

The Government of Ecuador and its agencies have an obligation to protect human rights.

Ecuador's Constitution of 2008 incorporates obligations and protections set forth in international law and specifically addresses human rights, both social and civil. Title I, Chapter 1, Article 3 lays out as one of the State's prime duties *"Guaranteeing without any discrimination whatsoever the true possession of the rights set forth in the Constitution and in international instruments, especially the rights to education, health, food, social security and water for its inhabitants."* Title II, Chapter 1, Article 10 further adds that *"Persons, communities, peoples, nations and communities are bearers of rights guaranteed to them in the Constitution and in international instruments."* Government responsibility is confirmed again in Article 11, Subsection 1*, "Rights can be exercised, promoted, and enforced individually or collectively before competent authorities, these authorities shall guarantee their enforcement."* Title II, Chapter 1, Article 11, Subsection 3, "*The*

rights and guarantees set forth in the Constitution and in international human rights instruments shall be directly and immediately enforced by and before any civil, administrative or judicial servant, either by virtue of their office or at the request of the party. For the exercise of rights and constitutional guarantees, no conditions or requirements shall be established other than those set forth in the Constitution or by law."

Ecuador has an obligation to protect an individual's right to informed consent.

The 1966 International Covenant on Civil and Political Rights (ICCPR) is the instrument which provides protections of individual civil liberties and guarantees the right to self-determination. Inherent in the concept of self-determination is the right to make one's own health decisions. The United Nations High Commissioner for Human Rights Right to Health Fact Sheet #31 (Fact Sheet 31) defines freedoms and entitlements under the right to health, one of which is the right to be free from non-consensual medical treatment. In the UNESCO 2005 Universal Declaration on Bioethics and Human Rights (UNESCO Bioethics Declaration), Article 6 Section 1 states there must be ***"prior, free and informed consent".*** Necessarily implied in a right to consent is the right to non-consent or, in other words, the right to denial. When formulating a vaccine mandate a provision for an individual's right of denial (Opt-Out) must be provided.

This is affirmed by Ecuador's Constitution, Title II, Chapter 6, Section 10 also guarantees *"The right to take free, responsible and informed decisions about one's health…"* and Section 12 articulates that individuals have "***The right to conscientious objection,*** *which shall not undermine other rights or cause harm to persons or nature," a*nd Title VII, Chapter 1, Section 2, Article 362, *"Healthcare services…shall guarantee informed consent…".*

Ecuador has an obligation to protect the right to Opt-Out even during times of an epidemic.

The right to health was first articulated in the 1946 Constitution of the World Health Organization (WHO) whose preamble defines health as *"a state of complete physical, mental and social well-being and not merely the absence of disease."* The United Nations has rejected this definition and has adopted a modified version of this. The Office of the United Nations High Commissioner for Human Rights, in Fact Sheet 31, has outlined the United Nations official position on the Right to

Health and defines it as "*the right to the enjoyment of the highest attainable standard of physical and mental health."* The 1966 International Covenant on Economic, Social and Cultural Rights (ICESCR) is widely considered as the central instrument of protection for the right to health. Article 12 of the ICESCR outlines the issue of health and provides stipulations for governments to follow. The ICESCR Article 12.2 (c) obligates governmental action in the prevention of epidemics. However, Fact Sheet 31 also emphasizes the relationship between the right to health and other human rights. Therefore, when issuing a vaccine mandate provisions of other human rights instruments such as the ICCCPR need to be considered. Tension may arise between these two concepts of rights, on the one hand the social right requiring governments to provide *"the highest degree of health attainable for society"* and the civil right to protect an individual from government impeding an individual's decisions regarding his/her own health.

However, efforts have been made and initiatives and proposals put forward by UN agencies and treaty monitoring bodies to clarify and in effect harmonize these rights. Provisions of The UNESCO Bioethics Declaration Article 6, Section 3 provides that ***"community consent is not to override individual consent."*** These modifications have the effect of incorporating and safeguarding an individual's right of consent based in the civil rights enshrined in the ICCPR and in effect harmonize this right with obligations set forth in the ICESCR. Ecuador's Constitution also stresses the need to consider other human rights. Title II, Chapter 2, Section 7, Article 32 *Health is a right guaranteed by the State and whose fulfillment is linked to the exercise of other rights…"*

Ecuador's Constitution, Title II, Chapter 1, Article 11, Subsection 4 also establishes the permanence of these rights even under unusual or emergent times *"No legal regulation can restrict the contents of rights or constitutional guarantees."* Subsection 6 provides that *"All principles and rights are unalienable, obligatory, indivisible, interdependent and of equal importance."* Therefore, any governmental agency formulating public policy and issuing mandates needs to address and assimilate principles of individual civil liberties enshrined in the Ecuadorean Constitution and international human rights instruments. Title IX, Chapter 1, Article 424 of Ecuador's 2008 Constitution states *"The Constitution is the supreme law of the land and prevails over any other legal regulatory framework. The standards and acts of public power must be upheld in conformity with the provisions of the Constitution: otherwise they shall not be legally binding. The Constitution and international human rights treaties ratified by the State that recognize rights that are more favorable than those enshrined in the Constitution shall prevail over any other legal regulatory system or action by public power."* Again, these articles stress the inalienability of rights articulated in Ecuador's Constitution (and in the international covenants pertaining to human rights that Ecuador has ratified), and

therefore, when dealing with an emergent situation such as an epidemic, individual civil rights, particularly the right to make one's own health decisions to participate in a vaccine program or mandate must be respected in the creation of a public health response.

Additionally, Ecuador's Constitution Title III, Chapter 2, Article 85, Subsection 2 *"Without detriment to the prevalence of public welfare over individual well-being, when the impacts of the implementation of public policies or the provision of public goods and services undermine or threaten to undermine constitutional rights, the policy or provision must be reformulated or alternative measures shall be adopted to reconcile the conflicting rights."* Under Ecuador's Constitution, provisions must be made for an individual's Opt-Out of a vaccine mandate. This is even further articulated in Title II, Chapter 6, Article 66, Section 10 which guarantees *"The right to take free, responsible and informed decisions about one's health…"* and Section 12 "*The right to conscientious objection, which shall not undermine other rights or cause harm to persons or nature."*

Ecuador has an obligation to protect individuals from discriminatory measures based on health status.

Even though the ICESCR may obligate governments to take action to protect overall public health it is also concerned with equality. It is argued that providing punishment for individuals refusing a vaccine is discriminatory. After all, it is generally accepted that the rights articulated in the ICCPR are inalienable and cannot be waived by an individual, in this case by refusing a vaccine. Punitive action against individuals who resist inoculation therefore does not stand up under either convention. Ecuador's Constitution also disallows discriminatory practices based on health. Title II, Chapter 1, Article 11, Subsection 2 further adds that "*No one shall be discriminated against for reasons of…**health status**…whether personal or collective, temporary or permanent, which might be aimed at or result in the diminishment or annulment of recognition, enjoyment or exercise of rights."* Under this provision, individuals cannot be discriminated against based on health status. Inoculated and non-inoculated are health statuses and therefore individuals cannot be treated differently based on their decision to decline a vaccine. Again, Title I, Chapter 1, Article 3 lays out as one of the State's prime duties *"Guaranteeing without any discrimination whatsoever the true possession of the rights set forth in the Constitution and in international instruments, especially the rights to education, health, food, social security and water for its inhabitants."* This is particularly relevant in the case of children under the age of 18. In the 1989 Convention on the Rights of the Child, Part 1, Article 28, recognizes education as a right of the child, making access to education an obligation of governments. Part

1, Article 2 addresses non-discrimination. Section 2 provides that *"State Parties shall take all appropriate measures to ensure that the child is protected against all forms of discrimination or punishment on the basis of status, activities, expressed opinions, or beliefs of the child's parents, legal guardians, or family members."* Because inoculation is a health status and choice by parents, non-inoculated children must be permitted to attend school.

Ecuador has an obligation to provide safe vaccines.

Guidelines for Government responsibility in relation to safety are emphasized at the international level. The Office of the United Nations High Commissioner for Human Rights states in Fact Sheet 31, Section III, subsection B, that the right to health includes an *"obligation of States to refrain from marketing unsafe drugs."*

Ecuador's Constitution stipulates safety as a requirement of health services too. Title VII, Chapter 1, Section 2, Article 362 states *"…Healthcare services shall be safe, of high quality, and humane…"*. Title VII, Chapter 1, Section 2, Article 363, Subsection 7 *"The State shall be responsible for…Guaranteeing the availability and access to quality, safe and effective medicines, regulating their marketing, and promoting the national production and use of generic drugs that meet the epidemiological needs of the population. With respect to access to medicine, public health interests shall prevail over economic and commercial interests."*

The question of COVID-19 vaccine safety is a legitimate concern. This year there has been an extreme push to get a vaccine to the public, fast-tracking clinical trials to a point of possible inadequacy. Normal clinical trials pass through internationally accepted phases. The Pre-Cinical Stage is normally 1-2 years of tissue and animal testing. Phase 1, in which a small number of human volunteers receive an antigen and reactions to it are studied. Phase 2, in which a larger number (on average 200) of human volunteers receive the antigen while a control group receives a placebo. Phase 2 normally takes years of monitoring results before success is achieved. When the volunteers are free of side effects trials move on to Phase 3. Phase 3 involves random, blind tests, in which tens of thousands of volunteers receive the vaccine which is then tested again against a placebo-receiving control group. Efficacy of the vaccine is tested at this stage, in other words, does the vaccine prevent disease? Does it prevent infection with a pathogen? Does it lead to production of antibodies? Once completed the vaccine is normally licensed. At this stage it passes into a Phase 4 which includes a Post Licensing Monitoring Phase, which is an alert for adverse effects after release of the vaccine.

As part of Phase 4 clinical trials, post-licensing monitoring is still occurring. Reactions by recipients will be monitored after the release of the vaccines for COVID-19, therefore standard principles of research are incomplete. Research that

is still ongoing precipitates another analysis under the Nuremberg Code of 1947 in regards to clinical trials, particularly Code 6 which states ***"the risks are not to exceed the benefits".*** Has the vaccine been proven to be safe? Is the vaccine effective? What are the risks? At this time these questions remain inadequately answered.

The Declaration of Helsinki developed by the World Medical Association in 1964 is another major international document providing guidelines for clinical research on humans. Under Section B, Article 11 also requires an assessment of research risks versus benefits; along with Article 15 that requires use of approved protocols, subject to independent ethical review and oversight by a properly convened committee. Unfortunately, Article 15 has been ignored. Independent review has not been allowed and when outside researchers provide analysis this analysis has been censored. Also of note under Section B, participants must know the source of funding for the study, potential conflicts of interest, and researcher affiliations. To date, these recommendations have not been met, especially in regards to potential conflicts of interest as an integrated international web of pharmaceutical companies, vaccine promoters, and public policy makers is now being exposed. The Vancouver Group, another internationally respected watchdog group, in its Uniform Requirements, under Section 2 "Ethical Considerations in the Conduct and Reporting of Research," addresses conflicts of interest in funding which may cast suspicion on results which indicate a potential for bias. In emphasis, The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, Guidelines for Good Clinical Practices acknowledges that what constitutes "good clinical practices" should be based on the principles outlined in the Declaration of Helsinki. It also notes that approval of a new drug should consider safety, quality and efficacy. The findings and recommendations of this conference are now considered basics in international testing standards. All of these international standards have been overlooked in the push by the pharmaceutical companies and their adherents to get a vaccine to market.

In the U.S., the Pre-Clinical trial phase has been shortened to 2-3 months. Phases 1 and 2 of standard clinical trials have been collapsed, and testing has only been done on healthy individuals. Results for humans in a more volatile condition have not been conducted. In Europe, researchers are now using "rolling reviews", instead of waiting for trial conclusion before proceeding to the next phase, early data is examined while later phase testing continues without previous conclusive evaluation. Normal timelines for evaluating effectiveness and safety of vaccines is around 10-15 years. Clinical trials lasting only one year are highly suspect, and therefore, extra precaution is warranted before general distribution occurs.

In evidence heard by the International Tribunal on Natural Justice, it was found that 20 years of testing on corona virus vaccines have not been able to produce a safe vaccine. In tests done on animals, paradoxical immune responses occurred, killing the hosts. Recent tests on the COVID-19 vaccine, specifically those by Astra

Zeneka in September of 2020, have also resulted in participants exhibiting negative reactions within the body's auto-immune system at the end of an abbreviated Phase 2 trial. Additionally, between 50%-100% of participants in the Pfizer and Moderna clinical trials have experienced uncomfortable to violent reactions, including death, after receiving the vaccines.

Licensing after abbreviated clinical trials remains suspect. Conclusive studies have not been finalized. Therefore, it is extremely difficult to determine a risk/benefit analysis when it has not yet even been proven whether the vaccine is effective, and if it is, how effective it will be, especially against the more volatile strain of COVID. Nor has the vaccine been shown to be safe, as adverse reactions are still occurring.

In light of the remaining questions and doubts it is upon the Ecuadorean government to test the vaccines for safety and efficacy before distributing to the general populace.

Ecuador has an obligation to protect against and compensate for harm caused by vaccines.

Individual government's actions within their own borders have strong persuasive effect in international law and may be used by other countries as a point of reference when formulating public health policy initiatives. Policies of the world's individual governments are the enactments of the international recommendations and provide the international norms of best policy practices and are considered as part of international law. Even in countries mandating vaccines, Opt-Outs are almost universally allowed. Additionally, vaccine mandates are monitored and are held in check and supplemented by a number of programs, namely: requiring reporting of vaccine-related adverse effects, and requiring the establishment of fully-funded vaccine injury compensation programs. Ecuador's Constitution does address these duties and practices in Title VII, Chapter 1, Section 2, Article 359. *"The national health system shall be comprised of institutions, programs, policies, resources, actions, and players in health; it shall encompass all the dimensions of the right to health; it shall guarantee the promotion, prevention, recovery and rehabilitation of all levels; and it shall encourage public participation and social monitoring"* and in Article 361 "*The State shall exercise leadership of the system through the national health authorities, shall be responsible for national health policymaking, and shall set standards for, regulate and monitor all health-related activities, as well as the functioning of sector entities."* And Title VII, Chapter 1, Section 2, Article 363, Subsection 7 "*The State shall be responsible for…Guaranteeing the availability and access to quality, safe and effective medicines, regulating their marketing, and promoting the national production and use of generic drugs that meet the epidemiological needs of the population. With respect to access to medicine, public health interests shall prevail over eco nomic*

and commercial interests". Continuing, Article 366 provides, *"Public funding for health shall be timely, regular and sufficient and must come from ongoing sources of the General Budget of the State. Government resources shall be distributed on the basis of population criteria and health needs. The State shall fund state health, shall be able to financially support autonomous and private institutions as long as they are not for profit; guarantee services free of charge, comply with public policies, and ensure quality, security, and respect for rights. These institutions shall be subject to State monitoring and regulation."*

Some countries have banned liability lawsuits against vaccine manufacturers, however, Ecuador's Constitution does not allow for blanket immunity to entities providing goods and services. Title II, Chapter 3, Section 9, Article 52 protects users and consumers and provides that *"Persons have the right to have goods and services of the highest quality and to choose them freely, as well as to accurate information that is not misleading with respect to their contents and characteristics. The law provides for quality control mechanisms and consumer defense procedures, as well as penalties for the infringement of these rights, reparation and compensation for defects, damages or poor quality of goods and services and for the interruption of public services not caused by acts of God or force majeure situations".*

Many nations have public health policies addressing difficulties and impediments (such as arduous court battles against giant pharmaceutical companies, and access to affordable representation, etc.), that can arise for individuals seeking reparations for injuries caused by vaccines, such as government compensation programs. Ecuador's Constitution stipulates additional liability on the provider and administrator of the vaccine, in this case the Government of Ecuador. Title II, Chapter 3, Section 9, Article 53 adds "*Companies, institutions and organizations that provide public services must incorporate systems to measure user and consumer satisfaction and put into practice assistance and reparation systems. The State shall be held liable for civil damages caused to persons for negligence and carelessness in the provision of public services under its charge and for the deficiency of services that have been paid."* This provision more than suggests liability on the Government to establish quality control mechanisms, and consumer defense procedures, a reporting system for vaccine-related injuries and to provide a fully-funded government compensation program for individuals harmed by the vaccine. To further emphasize the point Title II, Chapter 3, Section 9, Article 54 adds *"Persons or entities that provide public services or produce or market consumer goods shall be held liable both civilly and criminally for the inadequate provision of the services, for poor quality of the product or when its conditions are not consistent with the advertising that was made or with the description provided.*

Persons shall be held liable for any malpractice in the exercise of their profession, craft or trade, especially practices that endanger the integrity or life of persons"

Ecuador has an obligation to ensure that a vaccine it administers is bioethical.

A major concern regarding vaccines in general and, specifically a COVID-19 vaccine, is the issue of bioethics. In question is the bioethical nature of nanoparticles and genetic material in the vaccines.

Ecuador's Constitution, Title II, Chapter 2, Section 7, Article 32 states that *"Health is a right guaranteed by the State and whose fulfillment is linked to the exercise of other rights…"* also "*The provision of healthcare services shall be governed by the principles of…bioethics…"* Title II, Chapter 7, Article 73 has a provision that states ***"The introduction of organisms and organic and inorganic material that might definitively alter the nation's genetic assets is forbidden."*** Additionally, Title II, Chapter 6, Article 66 outlines the rights to freedom. Section 3 defines "*the right to well-being which includes a. Bodily, psychological, moral and sexual safety. d.* ***Prohibition of the use of genetic material*** *and scientific experimentation that undermines human rights."*

Concern is also expressed at the international level. A growing number of scientific practices have extended beyond national borders and the necessity of setting universal ethical guidelines covering all issues raised in the field of bioethics and the need to promote the emergence of shared values have increasingly been a feature of the international debate. In response UNESCO, in 2005, released the Universal Declaration on Bioethics and Human Rights (UNESCO Bioethics Declaration). The UNESCO Bioethics Declaration stresses the respect for individual human rights and emphasizes the need to regard the impact of life sciences on future generations, including their genetic constitution.

In regards to nanoparticle inclusion in the vaccine, a 2017 study of 44 types of 15 traditional vaccines, manufactured by leading pharmaceutical companies, found a heavy contamination of nanoparticles, many of which were metal. The study, which was reported in the International Journal of Vaccines and Vaccination, Volume 4, Issue 1, 23 January, 2017 "New Quality-Control Investigations on Vaccines: Micro- and Nanocontamination", the scientists found non-biocompatible and bio-persistent foreign bodies **undeclared by the producers of the vaccines**. The contaminants were found to be inorganic, non-biocompatible and non-biodegradable. They were found to cause inflammation at the injection site and throughout the body. Because they are non-biodegradable they are considered bio-persistent, remaining in the body, and can also cause further and long-term harm; for instance, harm may occur when metals can corrode in the

body and cause toxicity affecting tissue. Other non-metal nanoparticles, such as hydrogels, remain problematic in that they are still bio-persistent and long-term effects, particularly on genetics, have not been fully studied yet.

In addition to physical harm are more far-reaching concerns of what the nanoparticles are also capable of doing in the human body and what misuses may arise from this. Nanoparticles are capable of brain-machine interface (proven in tests being conducted in the United States by DARPA). They can output electrical signals of brain activity or receive input of electrical stimuli to moderate brain activity in concert with external machines, specifically computers, which suggests monitoring and/or modulation of the brain remotely. These factors leave the individual vulnerable to external manipulation. Also, as to monitoring, storing and use of medical information acquired in this way this may leave individuals open to abuse and thus violates guidelines of The Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks (The Declaration of Taipei). In its preamble The Declaration of Taipei states "*In analyzing the scenarios that already exist for the use (and misuse) of health data and biobanks, we came to the conclusion that the major risk scenarios may not result from science, but from the commercial, administrative or political use of such data. Limiting our guidelines to research only would have left us blind to the imminent risk of abuse from outside the field of medicine: commercialization, cost-cutting and potential political abuse."*

In the past, vaccines were produced that did not require the use of nanoparticles as a delivery platform. Nanoparticles are not essential to producing antibodies that actually fight the disease.

Another major, and perhaps the most concerning bioethical issue that may arise for recipients of a vaccine is the inclusion of genetic material, and impact on the human genome. The corona vaccines are vector-based. These vaccines encapsulate virus mRNA into a second, genetically modified non-infectious virus, which is then injected as a vaccine. The foreign mRNA gets a foothold in the human body by attaching or combining into DNA and causes DNA to begin to produce proteins of the original virus. These proteins are the antigens that invoke an immune response. At this time, because no other mRNA-based product has ever been approved or used, it is not known with any certainty how long it stays in the system, how pervasively it integrates into the human genome, or if it is passed on to offspring. Because vector based vaccines, specifically mRNA vaccines, such as the corona vaccines, have the **potential of altering the functioning of DNA** in humans, this raises concerns for Ecuador's genetic assets, possibly the greatest asset being the people of Ecuador themselves.

Another inclusion in most vaccines is Medical Research Council cell strain 5 (MRC-5) which is a diploid human cell culture line originally developed from research deriving from lung tissue of a 14-week old aborted fetus. Not only is this genetic material being introduced into the human system, but in a country with a vastly Catholic population, questions of religious-based morality and ethical code arise surrounding the use of aborted fetuses in medical research and products deriving from it.

Based on constitutional restrictions and international guidelines, Ecuador cannot purchase or administer a vaccine which contains nanoparticles, nor genetic material. The Ecuadorean government therefore has a duty to ensure that any vaccine it administers be clean and free of these substances.

In summary,

Under International and Ecuadorean Law, the Government of Ecuador, when formulating a public health policy around a COVID-19 vaccine, must take into consideration whether a potentially unsafe vaccine conforms with an individual's rights. In doing so, the Government of Ecuador must balance the competing need to protect the public interest with the need to protect human rights, in this case, an individual's right to make informed health decisions for his/herself; the right to opt-out of a government-mandated vaccine program, the right to be free from discriminatory punitive measures for not participating in the vaccine program, the right to be protected from and compensated for potential harm caused by the vaccine, and the right to safe and bioethical vaccines.

Mandated vaccines during epidemics are not irregular, however this does not mean that there are not safeguards in place to protect individual civil rights and these are argued to the fullest extent. It is upon the governments of the world, in this case, specifically Ecuador, to uphold the principles enshrined in the ICCPR and other international documents, along with its own Constitution, to ensure that individuals are protected and still have determination over their medical lives, especially during health crises. Generally, it is held that human rights are natural rights and cannot be waived or abolished; social and cultural rights should not take priority over natural rights but be considered in unison with them.