

# CLNMUN V



## Organización Mundial de la Salud OMS

# **Colegio los Nogales**

## **CLNMUN V**

### **Organización Mundial de la Salud**

**Tema A:** Opioids Crisis and the Access of Medicinal Drugs in the Industry

**Tema B:** The Transparency of the Medicinal Industry regarding the Insulin Business

#### **Mesa:**

	President	President
Name	Martina Peña	Juan Jose Abril
Email	mar-penal@nogales.edu.co	juanjoseabril0216@gmail.com
Cell Phone number	3107683831	3156689196

## **1. Welcoming Letter:**

Welcome delegates to the V edition of CLNMUN, we are Juan José Abril and Martina Peña, the presidents of OMS this 2023. Personally, the debates of the United Nations have always been part of our development as citizens and we want to share that passion through our committee. We are very happy to guide you this year during the three days of the model, creating a totally dynamic space for dialogue along with the topics that we will present, looking for possible solutions to some problems in the medicine world. As your presidents, we want you to be able to develop dialogue skills during the debate in order to create a fluent committee. Besides, as your presidents, we want to create dialogue spaces that aren't completely academic. We also seek to achieve a space of integration and fun among all the present. As presidents we would like to create a dialogue space where we can focus to seek for possible solutions regarding the Opioid crisis, as well as analyze the transparency of the medical industry. It is important to take into account that both problems go against what the WHO is looking for in human life conditions, disrupting the idea of a healthy world.

## **2. Committee Introduction:**

The World Health Organization (WHO) is one of the traditional UN branches. Its mission is to connect all the world in order to achieve better health for everyone. The WHO was founded in 1948 in order to challenge the world's health problems that keep people from better life conditions. Diseases, pandemics, viruses, among others are the constant problems people have to face. In order to keep the value of life and sanity as priorities, the WHO has developed different projects to create global solutions to global problems.

The WHO helps acknowledge some sanitary and health problems that sometimes seem as far from reality; but, taking into account they are medical circumstances, these are closer than what it seems.

The way the WHO serves the world and deliberates decisions and new projects are with

the cooperation of the World Health Assembly, who is the main deliberative body of the World Health Organization. It is composed of 194 member states. Each year, WHO member states meet to agree on the priorities and policies of the organization. The World Health Assembly sets new goals, strategies, and tasks to achieve the objectives.

UN Delegations discuss and provide guidance on policies, while the World Health Assembly can make recommendations and propose courses of action, especially in times of unprecedented global health risk. Finally, each government that took part in the deliberation of ideas, determines its position and consequently acts.

*As a recommendation, it is important to stay in the role of the assigned delegations since each of the critical approaches of the committee that are going to be in debate are specifically determined.*

### **3. Topic A: Opioids Crisis and the access to medicinal drugs in the industry**

#### *a. Historical Context:*

The opioids crisis started around the 1800s with the lack of possibilities and resources to control pain after surgeries, changing from an era where pain was a sign of the patient's energy to an era where pain needed to be regulated prioritizing the personal experience of each patient. This, consequently led to the development of anesthetics for surgeries proposed by the Scottish Obstetrician, James Young Simpson. Germany developed the first industrialization of morphines in 1820; then, in 1830, the United States developed morphines based on opium, a narcotic substance obtained from plants. This created a great debate between the medical global departments; from one side, there was the approval of this anesthetics taking into account this helped to stay longer periods of times in surgery and to realize more complex ones. On the other side, some surgeons were against it because it harmed the process of cicatrization.

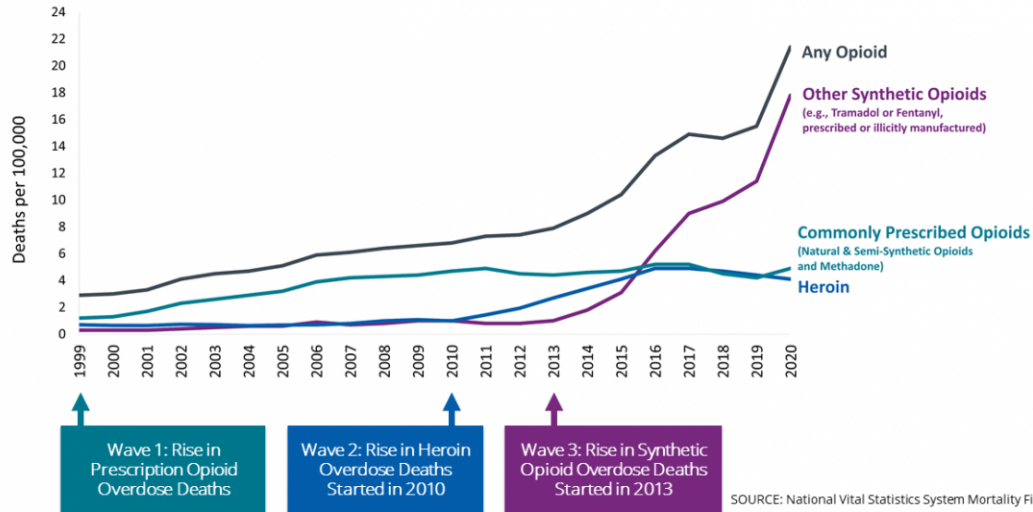


In 1870, the German multinational pharmaceutical company, Bayer, started to develop a new treatment less addictive than morphine but equally effective on surgeries, called “Heroin”, since medical departments judged the usage of the morphines made by Opium because it demonstrated some addictive behaviors on patients. The problem started in 1910 when the United States started to report some illicit marketing of a more compressed heroin, leading to the first Opioid pandemic. Later, the first morphine law for regulation was created, the Harrison Narcotic Control Act.

The Harrison Act’s main objective was to regulate the usage of morphines in medicine, limiting its purposes just for extreme cases like patients that had chronic diseases and, according to some surgeons, patients that had their days of life already counted.

Between 1986 and 1990, the Opioids Crisis had prominence in some European countries, after the mortality rate caused by morphine addiction increased severely. Countries such as Spain, Germany, Italy and Netherlands started to report an increase of 170% of the deaths caused by Opioids (Zenz). This great period of the Opioids Crisis was different from others. The increase of the mortality rate was not related with the increase of morphine development and instead was caused by the amount of illicit morphine cases of marketing and the no prescription of Opioids.

## Three Waves of Opioid Overdose Deaths



[https://www.cdc.gov/drugoverdose/images/3Wave\\_OverdoesDeathRates\\_LineGraph\\_2020-large.png](https://www.cdc.gov/drugoverdose/images/3Wave_OverdoesDeathRates_LineGraph_2020-large.png)

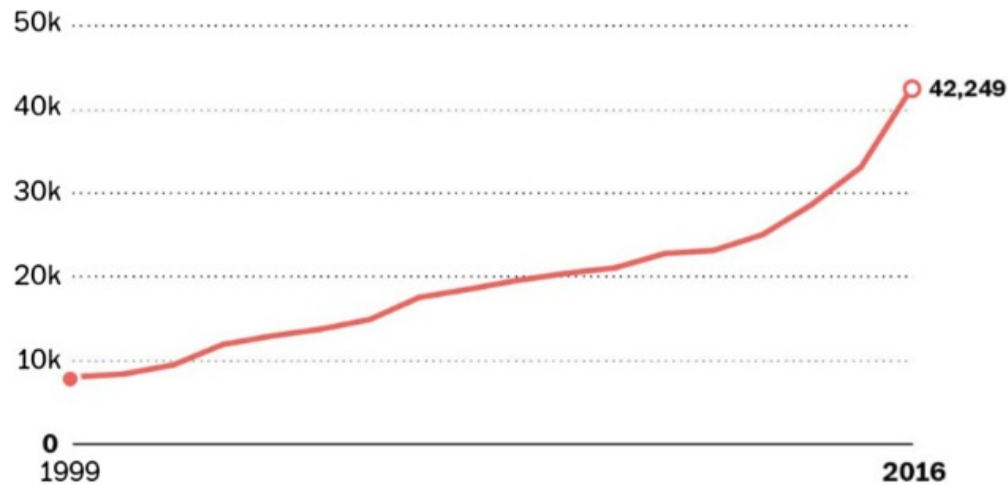
From 1991 to the late 2010s, medical departments started a process of morphine legalization just for extreme cases, such as patients with cancer, but the problem of addiction just kept rising.

### *b. Actual Situation:*

Nowadays, the Opioids Crisis was declared by the United States as an epidemic and a public health emergency. According to the NASPER (National All Schedules Prescription Electronic Reporting Act) the mortality rate by drug addiction keeps increasing compared to recent years. In 2016, over 64,000 people died from drug addiction and around 42,000 of those were from Opioids addiction, representing about a rise of 20% regarding the deaths from 2015 (Mattson CL).

## Opioid deaths surge in 2016

Number of opioid overdose deaths, 1999 to 2016



WAPO.ST/WONKBLOG

Source: CDC

[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5993682/bin/40122\\_2018\\_97\\_Fig2\\_HTML.jpg](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5993682/bin/40122_2018_97_Fig2_HTML.jpg)

The problematic of today's opioids epidemic is the incapacity to control the two sides of the morphine usage, the prescribed and medical purposes and their illegal market. In 2017, some hospitals decided to record information regarding patients that were hospitalized because of the consumption of illicit substances. 76% of patients declared to use or consume illicit substances in the past 12 months, 30% declared to have consumed Opioids illegally. (Simopoulos, 2017)

In November 2017, ex-president of the United States Donald Trump published "*The president's commission on combating drug addiction and the opioid crisis*". This document describes 6 of the main causes of the Opioid epidemic that was tormenting the United States and some European countries.

These causes are:

1. Production and distribution of purer, more powerful, oral and addictive opioids
2. Generalization of the availability of cheap illicit heroin

3. Influx of highly potent fentanyl and fentanyl analogues
4. Transitioning opioid prescription abusers to heroin and fentanyl use
5. Production of illicit opioid pills with deadly fentanyl forms or formats
6. Fentanyl use affects a wide age range, economic status, both rural and non-rural areas, all races and religions.

(Trump, 2017)

Taking into account these 6 principal factors for the amount of Opioid addiction cases, the U.S. government decided to design a new law regime by the Food and Drug Administration where 3 principal factors were going to be controlled in order to establish a complete regulation of the Opioid usage.

These factors are:

- Improve prescription control and prescription data collection at the extra-hospital level.
- Improve the application of treatment guidelines at the intra-hospital level, especially in post-surgery.
- Avoid any financial incentives in Medicare or Medicaid reimbursement plans that may result in an economic benefit to your doctor from prescribing an opioid versus other analgesia options.

(Food and Drug Administration, 2017)

Nowadays in 2022 the Opioids Crisis has not stopped, the first trimester of the year countries such as Canada reported about 1883 deaths by Opioids addiction, approximately 21 deaths per day and about 1350 hospitalized patients were intoxicated by consumption of Opioids, 15 hospitalized per day. In 2016, the deaths per day caused by the consumption of Opioids was approximately 8, taking into account between 2016 and 2017 the second great period of the Opioids Crisis started, the mortality rate has not decreased. According to the federal administration of Canada, about 3 of 4 consumers of Opioids that are either hospitalized or already dead are men. (Trudeau, 2022)

Even though through the years different types of organizations and government directives have tried to eradicate the Opioids epidemic with different laws and solutions, the amount of



death cases and addiction reports keep appearing demonstrating the conflict continues in today's society and health services.

The WHO responsibility is to seek for human health, looking for solutions in order to stop addiction or death cases around the world. It's important to remember that the WHO was founded in order to challenge the world's health problems that keep people from better life conditions. Opioid's Crisis have threatened humans since the 1800s until today, and the mortality rate has also increased.

This crisis is now objective to solve for the WHO, how each delegation could answer regarding this problem, even though in some other factors such as the economy, Opioids Crisis is an opportunity for growth.

*c. Glossary of terms*

**Opioids:** Several synthetic compounds, as methadone, having effects similar to natural opium alkaloids and their derivatives

**Anesthetics:** Substance that produces anesthesia

**Anesthesia:** Loss of sensation in the whole body or in certain areas caused by substances that drowse the body

**Morphine:** A drug made from opium and used chiefly in medicine as a pain reliever.

**Addiction:** The state of being enslaved to a habit or practice or to something that is psychologically or physically habit-forming, as narcotics, to such an extent that its cessation causes severe trauma.

**Mortality Rate:** The frequency of deaths in a certain population or death rate

**Heroin:** a white, crystalline, narcotic powder ( $C_{21}H_{23}NO_5$ ), derived from morphine, formerly used as an analgesic and sedative.

**Harrison Narcotic Control Act:** Law that provided the orderly marketing of opium, morphine, heroin, and cocaine. Federal prosecutors later decreed that what had purported to be a licensing law was a prohibition law.

**Surgeon:** A physician who specializes in surgery.

**FDA:** The United States Food and Drug Administration is a federal agency of the Department of Health and Human Services.

*d. QARMAS:*

1. Does your delegation support the Opioid different usages (medicinal and recreational)?
2. What has your country done in order to eradicate the Opioids Crisis?
3. In case of another great period of the Opioid Crisis, what type of actions your delegation would take?
4. How many death cases caused by Opioids consumption have been reported in your delegation?

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#### **4. TEMA B: Transparency in the medical industry as in the case of Insulin**

##### *a. Historical Context:*

Oskar Minkowski and Joseph von Mering, two German researchers, discovered in 1889 that when the pancreas gland was removed from dogs, the animals developed diabetes symptoms and died soon after. This gave rise to the notion that the pancreas was the site of production of

"pancreatic substances." Later researchers focused their efforts on the Langerhans islets. Sir Edward Albert Sharpey-Shafer proposed in 1910 that diabetes patients' pancreas lacked only one chemical. He chose the name insulin, which is derived from the Latin word insula, which means "island." In 1921, a young surgeon named Frederick Banting and his assistant Charles Best discovered how to extract insulin from the pancreas of a dog. With this success, the researchers went one step further with the assistance of colleagues J.B. Collip and John Macleod. A more refined and pure form of insulin was created, this time from cattle pancreases.

Leonard Thompson, a 14-year-old boy dying of diabetes in a Toronto hospital, became the first person to receive an insulin injection in January 1922. Leonard's dangerously high blood glucose levels had dropped to near-normal levels

The news about insulin spread like wildfire around the world. It wasn't long before there was enough insulin to supply the entire continent of North America. In the decades since, manufacturers have developed a variety of slower-acting insulins, the first of which was introduced in 1936 by Novo Nordisk Pharmaceuticals, Inc.

For many years, insulin derived from cattle and pigs was used to treat diabetes and saved millions of lives, but it wasn't perfect, as it caused allergic reactions in many patients. In 1978, *E. coli* bacteria were used to produce the first genetically engineered, synthetic "human" insulin. Under the brand name Humulin, Eli Lilly sold the first commercially available biosynthetic human insulin in 1982.

#### *b. Actual Situation:*

The World Health Organization (WHO) has issued a statement calling for the disclosure of clinical trial results for medical products, regardless of their outcome, so that decisions about the safety and efficacy of vaccines, drugs, and medical devices for public use are supported by the best available data. "Our intention is to encourage the exchange of scientific knowledge to



improve public health, thereby supporting the primary goal of medical research: to serve humanity and improve it" In one study of large-scale clinical trials registered on Clinicaltrials.gov and completed up to 2009, for example, 23% of the results, involving nearly 300,000 participants, were never reported. Only 29% of clinical trials of vaccines against five diseases registered in various databases between 2006 and 2012 were published in a peer-reviewed journal within the period recommended by the WHO, i.e. within 24 months of publication. (WHO, 2009)

This WHO call includes the release of old clinical trials whose results have never been made public, despite the fact that they may have significant implications for current scientific research. WHO also reiterates the importance of all clinical trials being inventoried in a WHO primary registry and accessible via the International Clinical Trials Registry Platform. This way, it will be clear which clinical trials were conducted and it will be possible to verify compliance with the disclosure requirements.

On the occasion of World Diabetes Day, The World Health Organization has issued a warning about the "alarming situation" in global insulin access. According to the WHO report, "the main obstacles to universal access"(WHO) are high insulin prices, low insulin availability, the fact that a few producers dominate the insulin market, and weak health systems.

Insulin is critical for more than 60 million people with type 2 diabetes to reduce the risk of kidney failure, blindness, and limb amputation. However, one in every two people with type 2 diabetes who require insulin do not receive it. Diabetes is on the rise in low- and middle-income countries, but insulin consumption has not kept pace with the disease's growing burden. Diabetes is on the rise in low- and middle-income countries, but insulin consumption has not kept pace with the disease's growing burden. imposition of "an unsustainable financial burden on low-income countries" "In general, human insulin is as effective as analogues," they argue, "but they are at least 1.5 times more expensive than human insulins, and in some countries three times more." They also noted that three multinational corporations control more than 90% of the insulin market, leaving little room for smaller companies to compete for insulin sales.

The World Health Assembly approved a resolution that points to the transparency of the price of medicines for diabetes and especially insulin, which constitutes a market monopolized by three multinationals. The resolution was approved after several European countries and the United States eliminated their opposition to the text that obliges the World Health Organization to develop objectives to expand diabetes treatment, as well as measures that encourage greater price transparency in the market. of insulin. "Importantly, the resolution calls for the establishment of a database to improve transparency around the price of diabetes medicines, including insulin," said Tonje Borch, Senior Adviser at the Department of Public Health at the Ministry of Health. from Norway. (Lilly, 2019)

Norway, precisely, was one of the countries that promoted the resolution with the greatest emphasis and even tried to insert more forceful paragraphs on market transparency. The public's trust in our healthcare systems is being eroded by a lack of transparency. Greater transparency is possible and beneficial in the case of Covid-19 vaccines. The pandemic prompt to consider the business models and collaborations that have emerged as a result of the pandemic. "Now is the time," Borch said during his World Health Assembly speech. In addition, the resolution recognizes "the importance of international cooperation in support of national, regional, and global plans...including to increase access to treatments such as insulin.(Borch)" Norway pressed for a stronger language, but supported the "compromise" adopted at the recent 74th World Health Assembly, while civil society provided a strong push for the resolution's approval.

Doctor Helen Bygrave, chronic diseases advisor for the Médecins Sans Frontières, said she was "enchanted" to see countries like Canada, Brazil, and Chile join the other 19 to support the resolution, which was led by the Russian Federation and Norway. "Insulin is one of the most expensive products in diabetes care, and there is an urgent need to increase access to affordable insulin through price transparency, as well as to support the harmonization of insulin regulatory requirements."

"Quality-assured insulins, including biosimilars," the Medecins Sans Frontieres or Doctors without borders representative emphasized. The draft resolution's overarching goals include

promoting access to quality, safe, efficacious, affordable, and essential diagnostics and medicines, including insulin, oral hypoglycemic agents, and other diabetes-related medicines and health technologies for all people living with diabetes, in accordance with national context and priorities. (Médecins Sans Frontières)

Tonje Borch of Norway, speaking at the World Health Assembly's opening session, supported the resolution but suggested that her government would have liked to go even further: "We also strongly support a global insulin price information mechanism. More transparency is clearly required, and lower prices will save lives." Dag-Inge Ulstein, Norway's Minister for International Development, told Health Policy Watch that "One of the main reasons for the high number of diabetes deaths today is the high cost of insulin. We strongly support a global insulin pricing reporting mechanism; clearly, more transparency is required." (Ulstein)

As a result, "we know that large-scale global efforts to combat diabetes and other NCDs could save millions of lives, contribute to a healthier population, and economic growth," Ulstein explained. "It is hoped that a mechanism will contribute to price reductions." (Ulstein)

The WHO is aware that the retail price can be ten times the production cost. People with diabetes in Norway can live well with their disease because they have access to affordable insulin. This may not be the case for a poor Malawian family with a type 1 diabetic son who is unable to provide life-saving insulin; or having to choose between life-saving insulin for one child and food for the other," emphasized the Norwegian minister. However, even in developed countries such as the United States, the high cost of insulin means that many people who require it either do not get it or travel all the way to Canada to get it at a lower cost.

As a result, Democratic Senator Elizabeth Warren, who published an investigation into the "inaccessible" price of insulin in her country in December 2019, celebrated the World Health Assembly resolution on Twitter. To make matters worse, several European countries banned the export of insulin in April 2020, at the height of the first wave of the COVID-19 pandemic, fearing that the lockdowns would lead to increased insulin demand and shortages, as well as possibly disrupting supply chains in other areas.

The resolution also requests that the General Director make "recommendations for the prevention and treatment of obesity throughout the life course, including consideration of the potential development of targets in this regard, and to present these recommendations to the 75th World Assembly of Obesity." Health issues to consider in 2022 ». Diabetes patients are also at a higher risk of becoming seriously ill or dying from COVID-19, making them among the most vulnerable to the pandemic.

Nina Renshaw, NCD Alliance's Director of Policy and Advocacy, praised the resolution as evidence of significant progress: "It's been through lengthy negotiations for quite some time," she said. He did, however, express reservations: "the resolution's mandate for WHO to develop targets to combat diabetes does not specifically call for the development of an insulin access target, which I hope changes." «It is a step forward in the conversation. "We hope that ambitious insulin goals will be developed in due course," he stated.

*c. Glossary of terms*

**Insulin:** a hormone produced in the pancreas by the islets of Langerhans, which regulates the amount of glucose in the blood. The lack of insulin causes a form of diabetes.

*d. QARMAS:*

1. How does your country react to the idea of free healthcare? Free medicine?
2. How does your country manage the idea of transparency in the prices of health care?
3. How does your delegation react to the idea of clinical trials and their results?

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