May 11, 2022

To:

Brazilian Health Regulatory Agency (ANVISA)

Ministry of Health

From:

Tholos Foundation

722 12th Street NW

Washington, DC, USA

**Introduction:**

On behalf of the Tholos Foundation, a non-profit organization which advocates in the interests of taxpayers and consumers across the globe, we offer these comments on the ANVISA consultation on the prohibition or regulation of e-cigarettes (*Dispositivos Eletrônicos para Fumar*) referred to in this document as e-cigarettes, vapes, or ENDS.

**The Tholos Foundation strongly encourages ANVISA to end the prohibition of e-cigarettes so that adult consumers in Brazil can have legal access to these lifesaving products**. There is overwhelming scientific consensus in support of e-cigarettes as smoking cessation devices. Encouraging Brazilian cigarette smokers to make the switch to e-cigarettes will drastically improve health outcomes across the country and help decrease socioeconomic disparities. These reduced-risk alternatives to traditional cigarettes have produced outstanding results in many countries.

All evidence presented in this submission is entirely based on scientific studies and analysis from the world’s top researchers. We urge Brazil to accept this science, legalize e-cigarettes, and encourage adult consumers to transition to safer products.

**E-Cigarettes are Significantly Less Harmful than Traditional Cigarettes:**

Contrary to popular belief, e-cigarettes are not a product invented by tobacco companies. In 2001, a Chinese man called Hon Lik, a cigarette smoker himself, created the world’s first e-cigarette after his father succumbed to lung cancer caused by deadly cigarettes. The major difference between e-cigarettes and traditional cigarettes is how the “smoke” is created. In cigarettes, a combustion process creates smoke. This process is what produces many of the harmful chemicals that cause cigarette smokers, and innocent bystanders, to be subject to significant damage to their health.

**E-cigarettes do not have a combustion process, and therefore lack many of the dangerous chemicals that are present in combustible cigarettes.** As a result, e-cigarettes have become a significantly less harmful way of consuming nicotine. According to a study from Public Health England**, e-cigarettes are at least 95% less harmful than traditional cigarettes.** A separate, comprehensive analysis of the harm of different nicotine products estimated that e-cigarettes contain just 4% of the harm of cigarettes.

It is important to note that it is the combustion, not the nicotine, that causes disease and cancer among cigarette users. Nicotine is a relatively benign substance like caffeine that “does not result in [clinically significant](https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction) short- or long-term harms”. Nicotine replacement therapies, like gums or patches, have been available for decades but often fail in their mission of helping smokers quit. E-cigarettes mimic the habitual nature of smoking while creating vapor, rather than harmful smoke, to remove the deadly carcinogens in tobacco.

As such, **statements in support of e-cigarettes have been released by over 100 public health organizations across the globe**. This list includes the British Medical Association, New Zealand Ministry of Health, Royal College of Physicians, French National Academy of Medicine, the American Heart Association, and many more.

**Evidence Shows E-Cigarettes Improve Public Health:**

**E-cigarettes are products with lifesaving capabilities**. According to a [study](https://newsroom.heart.org/news/vaping-combined-with-smoking-is-likely-as-harmful-as-smoking-cigarettes-alone) by the American Heart Association, **switching from smoking to nicotine vaping lowers the risk of stroke by 84%.** The same study found that the heart health biomarkers of e-cigarette users are similar to, or indistinguishable from, people who had never smoked a cigarette. The United States National Academies of Sciences, Engineering, and Medicine [stated](https://www.nap.edu/resource/24952/012318ecigaretteConclusionsbyEvidence.pdf) “there is *conclusive evidence* that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users’ exposure to numerous toxicants and carcinogens present in combustible cigarettes”.

According to a large-scale analysis from Georgetown University Medical Center, an estimated 6.6 million American lives would be saved if a majority of cigarette smokers made the switch to e-cigarettes. Extrapolating this data, we estimate that **the legalization of e-cigarettes in Brazil could save over 4,250,000 lives.** The smoking rate in Brazil ([16.5%](Brazil%20Smoking%20Rate%202007-2022%20%7C%20MacroTrendshttps%3A/www.macrotrends.net%20%E2%80%BA%20BRA%20%E2%80%BA%20smoking-rate-statistics) as of 2018) is significantly higher than the United States ([12.5%](Current%20Cigarette%20Smoking%20Among%20Adults%20in%20the%20United%20Stateshttps%3A/www.cdc.gov%20%E2%80%BA%20tobacco%20%E2%80%BA%20fact_sheets%20%E2%80%BA%20adult_data) as of 2020). It can therefore be expected that Brazilian access to e-cigarettes could save many more than four million lives.

There is ample evidence to suggest that cigarette smokers will be willing to make the lifesaving switch to e-cigarettes. A recent study found that **a smokers who attempts to quit with an e-cigarette has an estimated 323% higher chance of achieving complete cessation compared to someone using a traditional nicotine replacement therapy like patches, gum, or oral spray**.

E-cigarettes have a demonstrated ability to reduce smoking. In the United States, the adult smoking rate was 21.6 when e-cigarettes entered the market in 2003. **Due to increased access to vaping, the U.S. adult smoking** [**rate**](https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5420a3.htm#:~:text=In%202003%2C%20an%20estimated%2021.6,8.6%20million)%20smoked%20some%20days.) **has plummeted to 13.7% as of 2018**. In the United Kingdom, a new [analysis](https://www.gov.uk/government/publications/vaping-in-england-evidence-update-february-2021/vaping-in-england-2021-evidence-update-summary) from 2021 by Public Health England demonstrated just how effective vaping is in helping people quit smoking, noting that in just one year, over 50,000 British smokers, who would have continued smoking otherwise, quit smoking with vaping.

The current prohibition on e-cigarettes in Brazil takes away people’s ability to use the best available products to end their deadly habit of smoking

**E-Cigarettes as a Tool of Reducing Socioeconomic Disparities in Brazil:**

Scientific studies have shown that **e-cigarette use will “reduce health disparities”.** The reason for this is smoking rates are historically highest among those with lower income and less education. This will “translate directly into lower medical costs” and would produce “an improved quality of life” for these disadvantaged populations.

This is quite relevant to Brazil, as a [study](https://pubmed.ncbi.nlm.nih.gov/26816162/) from 2016 published in the National Library of Medicine found that **many Brazilians who spend money on tobacco products “are older, earn low salaries and have less schooling”** than someone who is not a tobacco user. Continuing to prohibit e-cigarettes will fail to decrease socioeconomic disparities.

Additionally, there is scientific evidence that **nicotine-containing e-cigarettes dramatically help people with mental health issues quit smoking**, even when they have no desire to quit. For people who suffer from schizophrenia, vaping has a demonstrated ability to better their mood, make them feel more awake, less irritable, and have improved concentration. These communities smoke at rates three to four times higher than average. Efforts to increase smoking cessation among people with mental health issues must be a major priority.

A [study](https://scielosp.org/pdf/rsp/2020.v54/04/en) from Brazilian researchers at Centro Universitário do Paraná and Universidade Federal do Espírito Santo found that **low socioeconomic status and limited access to education increases the prevalence of mental health issues among Brazilian adolescents**. These conditions place Brazilian children at risk for picking up the deadly habit of traditional cigarettes.

The legalization of vaping in Brazil will offer underserved communities a method of decreasing the harm they are subjected to by cigarette smoking. This will reap benefits for public health throughout the country.

**Demonstrated Dangers of Brazil’s Unregulated, Illicit Market:**

Prohibitions, like Brazil’s current prohibition on e-cigarettes, promote illicit markets for these products that can have deadly consequences. **Tobacco and nicotine-product smuggling is largely run by highly organized, international crime syndicates. These organizations use their smuggling profits to fund more nefarious activities including human trafficking, money laundering, and terrorism.** Because of this, the U.S. State Department has explicitly labelled tobacco smuggling a “[threat to national security](https://2009-2017.state.gov/documents/organization/250513.pdf)”.

Brazil already has a well-documented issue with nicotine smuggling among organized crime groups. In February 2022, Brazilian Police successfully arrested dozens of gang members who were suspected of engaging in illegal cigarette smuggling, arms trafficking, drug peddling, and money laundering. According to the [Asociación Latinoamericana Anticontrabando](https://insightcrime.org/news/brief/illegal-cigarettes-southern-cone-brazil-fuel-tax-losses-criminal-groups/), **contraband cigarettes represent more than half the cigarettes for sale in Brazil**. It is [estimated](https://www.jb.com.br/economia/2019/06/1005605-mercado-ilegal-chega-a-54--no-brasil-e-rio-de-janeiro-perde-r--372-milhoes-so-com-a-venda-ilegal-de-cigarros.html) that Brazil lost approximately 11.5 billion reais in 2018 due to illicit sales. This lost tax revenue is more than the actual amount that Brazil collected in cigarette taxes.

**Tobacco smuggling in Brazil is also shown to exploit slave labor**. In November 2021, Brazilian authorities rescued 18 people from an [underground cigarette factory](https://insightcrime.org/news/illegal-cigarettes-produced-with-slave-labor-in-brazil/) in the town of Triunfo in Rio Grande do Sul. These poor victims had been subject to horrific living conditions. They had not seen sunlight in over 8 months and were only fed once every two days. It was estimated that the factory they were working in was providing criminal gangs with as much as $50 million reais in profit each month.

Illicit products also lack the regulation and safety standards of legal products. ANVISA has an opportunity to legalize and properly regulate e-cigarettes in Brazil. This will provide the Brazilian government with demonstrated decreases in health costs as well as increased tax revenue which **will offer Brazil increased flexibility regarding fiscal decisions**. E-cigarette legalization also be expected to lessen the influence of criminal smugglers and gangs who profit from these products.

**Conclusion:**

For the reasons above, the Tholos Foundation strongly encourages ANVISA to end the prohibition on e-cigarettes and embrace e-cigarette use as a method of smoking cessation. **All decisions concerning public health must be based upon scientific evidence and proven facts**. The science is clear, vaping offers people who smoke the greatest chance of quitting cigarettes while exposing them to significantly less harm than traditional cigarettes.

In the interests of public health, improving the Brazilian economy, and reducing socioeconomic disparities, **we call upon ANVISA to legalize e-cigarettes in Brazil. Millions of Brazilian lives quite literally depend upon it.**

Sincerely,

Tim Andrews

Director of Consumer Issues

Tholos Foundation