FDA BAN ON JUUL VAPING DEVICES: COMPANY APPEALS FDA DECISION

Vaping company Juul Labs, Inc., has recently requested an extension on the temporary stay placed by the Food and Drug Administration (FDA) regarding the ban on its e-cigarettes and flavored pods. The FDA had previously stated that Juul's application for market approval lacked adequate and consistent data regarding the potential risks associated with its products. The agency expressed concerns about the possibility of "potentially harmful chemicals" leaching from the e-liquid pods. Consequently, the FDA issued an order to halt the sale of Juul's vaping devices and tobacco- and menthol-flavored pods.

Dr. Nino Paichadze, an assistant research professor at George Washington University's Milken Institute School of Public Health, commended the FDA's decision, emphasizing its significance for public health. E-cigarettes have been shown to cause harm among youth and adolescents, with potential long-term health consequences into adulthood. Therefore, the ban was viewed as an important step in safeguarding public well-being.

However, the ban was short-lived due to a federal appeals court for the District of Columbia Circuit temporarily blocking the FDA's decision. This occurred after Juul filed an emergency motion seeking relief while it appealed the agency's ruling. Following this development, Juul submitted a motion to the same court requesting an extension of the stay. In its filing, the company claimed that the FDA had overlooked 6,000 pages of data related to the aerosols produced when the liquid in the pods is heated by the vaping device.

FDA Turns to Science to Regulate E-cigarettes

The FDA's ban on Juul products is part of the agency's broader efforts to regulate the multibillion-dollar vaping industry based on scientific evidence, adopting a similar approach to the regulation of the pharmaceutical and medical device industries. To maintain their products on the market, vaping companies must demonstrate that the benefits to the public outweigh the risks.

E-cigarettes have been considered as potential tools for helping cigarette smokers quit or transition to a less harmful alternative. Vaping can reduce the health risks associated with traditional tobacco use. The vapor generated by e-cigarettes contains fewer toxic chemicals compared to the more than 7,000 chemicals present in regular cigarette smoke. However, it is important to note that e-cigarette vapor is not entirely harmless.

According to the Centers for Disease Control and Prevention (CDC), e-cigarette vapor may contain potentially harmful substances such as nicotine, lead, other heavy metals, organic compounds, and carcinogenic chemicals. Furthermore, researchers have expressed concerns about the potential inflammation and lung damage caused by the particles present in e-cigarette vapor.

One of the significant risks associated with e-cigarettes is the potential for children and adolescents to develop addiction. Dr. Adnan Hyder, a professor of global health at George Washington University's Milken Institute School of Public Health, highlighted that these products not only pose immediate health risks to individuals but also increase the likelihood of addiction to substances like tobacco and nicotine, particularly among youth and adolescents. Studies suggest that e-cigarette use among adolescents may also elevate the risk of future cigarette smoking in adulthood, making it a concern for long-term public health.

Targeting Kids with Marketing and Flavors

Experts argue that vaping companies have actively targeted young people through kid-friendly marketing strategies and a wide range of appealing vape flavors, including fruit and dessert flavors. The intention behind creating flavors such as cotton candy and gummy bear is perceived as an attempt to entice young children and get them hooked on these products.

Responding to these concerns, the FDA implemented a ban in 2020 on the sale of flavored cartridge-based e-cigarettes, excluding menthol and tobacco flavors. However, prior to this ban, Juul utilized candy and fruit flavors along with their sleek design and high-nicotine e-liquid to capture a significant share of the U.S. vaping market, including the youth segment.

A study published in the journal Pediatrics on May 30, conducted by researchers from the University of California San Diego, revealed a 40 percent increase in e-cigarette sales in the United States in 2017, largely driven by Juul's products. Consequently, a substantial portion of new users were youth, with a 64.6 percent increase among 14- to 17-year-olds. The study estimated that in 2019, approximately 600,000 individuals under the age of 21 were using Juul products daily, surpassing the rate among 25- to 34-year-olds by 2.5 times.

Study author John Pierce, PhD, a distinguished emeritus professor at the UC San Diego Herbert Wertheim School of Public Health and Human Longevity Science, highlighted the lack of evidence supporting the use of Juul as a smoking cessation aid. Conversely, there was substantial evidence indicating addiction among 14- to 17-year-olds. He emphasized the potential long-term health consequences associated with e-cigarettes, comparing the situation to the identification of smoking as a cause of lung cancer, which took over 20 years to establish.

FDA Reviews E-cigarettes on a Case-by-Case Basis

Since the FDA began reviewing premarket applications for e-cigarettes, it has granted permission to two other companies, R.J. Reynolds and Logic, to market their e-cigarettes in the United States. However, the agency clarifies that such approval does not guarantee the safety of these products.

According to Pierce, e-cigarette companies have not proven that their products are harmless. On the contrary, as more data becomes available, concerns about future health consequences continue to grow. Studies conducted by other researchers at UC San Diego have suggested that e-cigarettes can cause inflammation and lung damage, with flavored e-cigarettes further exacerbating these risks.

Considering the evidence currently available, it is evident that a significant burden of disease may emerge in the future as a consequence of e-cigarette use. It is important to note that the FDA's allowance for two e-cigarette companies to sell their products in the United States could be reevaluated if new data indicates a higher level of harm associated with vaping.

Tobacco control experts stress the necessity of robust scientific evidence to not only demonstrate the risks of vaping but also provide accurate information to the public. It is crucial that reliable research emanates from the public health community to counterbalance industry-funded studies aimed at influencing consumers and regulatory decision-making.