Amtrak OIG supported investigation leads to 36-month prison sentence for manufacturer that distributed unapproved drug

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LOS ANGELES — The currently imprisoned founder and chief executive officer of a California-based company that marketed stem cell-based products linked to multiple hospitalizations was sentenced September 30, 2024, to 36 months in prison—consecutive to his current prison sentence—following his conviction under the Federal Food, Drug and Cosmetic Act, according to the U.S. Attorney's Office, Central District of California.

John Warrington Kosolcharoen, 53, most recently of Orange County, California, pleaded guilty August 27, 2024, to one count of introducing an unapproved new drug into interstate commerce with the intent to defraud and mislead. Kosolcharoen is currently in custody serving a sentence for a separate, unconnected conviction. Amtrak OIG provided support for this joint investigation at the request of the U.S. Attorney's Office.

According to court documents, beginning in 2016, Kosolcharoen created two companies, Liveyon LLC and Genetech Inc., to manufacture and distribute injectable stem cell products made from human umbilical cord blood. Liveyon marketed the products under different brand names, including "ReGen." Kosolcharoen admitted that he and others misrepresented ReGen as suitable for the treatment of a variety of conditions, such as lung and heart diseases, autoimmune disorders, Alzheimer's disease, Parkinson's disease, and others. Liveyon marketed the products throughout the United States until about April 2019 using advertising materials that contained multiple false and misleading statements about their purported safety and effectiveness. At sentencing, the government alleged that sales of Liveyon products generated approximately $21.6 million in revenue between 2017 and 2018.

In 2018, the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) received reports of patients in multiple states requiring hospitalization for bacterial infections after receiving Liveyon products. Kosolcharoen admitted that he and others fraudulently induced customers into purchasing stem cell-derived Liveyon products by, among other things, misleading the public about the cause and severity of adverse events suffered by Liveyon patients and falsely reporting and concealing material facts regarding the outcome of an FDA inspection of Genetech. The government alleged in court filings that an investigation by CDC, with the assistance of state and local health departments, found that the stem cell products were linked to the hospitalization of 19 patients in eight different states.

In recent years, the FDA has warned consumers that patients seeking cures and remedies for serious diseases and conditions may be misled about unapproved stem cell products that are illegally marketed, have not been shown to be safe or effective, and, in some cases, may have significant safety issues that put patients at risk. Stem cell products are regulated by FDA, and generally they must have FDA approval before being introduced into interstate commerce.

In addition to Amtrak OIG, the case was investigated by the FDA's Office of Criminal Investigations, FBI, Defense Criminal Investigative Service, Department of Health and Human

Services OIG, Department of Labor Employment Benefits Security Administration and California Department of Health Care Services. More information is available in the press release from the U.S. Attorney's Office: https://direc.to/mkFZ.

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