

## Report on Research Compliance Volume 17, Number 1. January 01, 2020

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By Theresa Defino

◆ A man from Richland, Washington, is facing life in prison after being convicted of 47 counts of fraud for staging clinical trials that purportedly enrolled dozens of subjects, and paid him and his two firms more than \$5 million, William Hyslop, the U.S. Attorney for the Eastern District of Washington, recently announced. From 2013 to 2018, Sami Anwar, 42, “headed a conspiracy to have his companies fraudulently pose as legitimate human clinical research trial sites and provided mountains of false clinical research trial data regarding drug safety and drug efficacy to dozens of drug companies and, through them, the Food and Drug Administration [FDA],” Hyslop’s office announced Nov. 25. “The false clinical research data that Sami Anwar injected into the public health system included safety data on dozens of different drugs and medicines designed to treat a wide variety of diseases and conditions including, but not limited to, heart disease, diabetes, asthma, pediatric illnesses, adolescent smoking, cirrhosis, scabies, depression, and opioid addiction to name just a few, according to the evidence presented at trial.”

Based on the 97-count indictment that *RRC* reviewed, it does not appear that Anwar received any government funding. Although a number of clinical research organizations and drug firms were said to have been duped, only two are identified by name—Medpace Inc., of Cincinnati, and Braeburn Pharmaceuticals Inc., of Princeton, New Jersey, respectively. Anwar’s firms served as a trial site as part of an FDA-approved trial sponsored by Braeburn to test slow-release injections of buprenorphine to treat moderate-to-severe opioid addiction. He was found guilty on Nov. 22 following a three-week trial. More than a dozen former employees testified that Anwar “directly instructed them to assist him in committing the fraud including falsifying medical records and data to admit dozens of ineligible research subjects; falsifying research data including electrocardiograms and vital signs; obtaining blood specimens from Sami Anwar’s employees or stealing them from unwitting medical patients of his medical center; disposing of study medications by shooting them down the drain and then falsely recording them as having been properly injected as required; dangerously hoarding opioids intended to be dispensed to study subjects; and fabricating required subject diary entries,” the announcement states.

He was also alleged to have “filed false police reports, made false allegations to the Washington State Department of Health, the FDA, threatened [employees] at their homes, at their places of work, slashed their tires, and stalked them in order to prevent them from cooperating with the authorities.” Sentencing is scheduled for March 11; each fraud count could bring a jail sentence of 20 years. (12/12/19)

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