The Department of Justice (DOJ) has announced its first criminal securities fraud prosecution related to COVID-19, and it involves health care fraud as well. Mark Schena, president of Arrayit Corporation, a publicly traded medical technology company, faces criminal charges in connection with false and fraudulent claims submitted for allergy and COVID-19 testing. The complaint charges Schena with one count of securities fraud and one count of conspiracy to commit health care fraud.

From 2018 to present, Arrayit, under Schena’s direction, allegedly submitted or caused the submission of over $5.9 million in Medicare claims and over $63 million in private insurance claims for allergy and COVID-19 tests that were not medically
necessary, were not provided as claimed, or were tainted by the payment of kickbacks and bribes.

The government’s investigation initially focused on Arrayit’s promotion of an allergy test panel that is run on a finger-prick drop of blood placed on a paper card and sent by mail to Arrayit’s laboratory. Arrayit allegedly ran a full test panel of 120 allergens every time for every patient without regard to medical necessity requirements imposed by Medicare and private insurers. In addition, DOJ claims that Arrayit paid a physician (who has agreed to plead guilty to conspiracy to commit health care fraud) illegal kickbacks in exchange for the physician providing his or her NPI number to Arrayit, which then used that NPI number to submit claims for testing provided to patients that the physician had never seen.

Adding fuel to the fire, Schena then allegedly “used the COVID-19 pandemic as an opportunity to expand the pre-existing allergy test scheme and to capitalize on a national emergency for his own financial gain.” According to DOJ, Schena offered COVID-19 testing to obtain Medicare beneficiary information used to submit claims for Arrayit’s allergy test panel, which was far more lucrative than COVID-19 testing. Arrayit promoted the ordering of its allergy test panel with every COVID-19 test despite the fact that it is not medically necessary to do so. Further, Arrayit’s COVID-19 test kit allegedly failed to satisfy FDA performance standards for obtaining an emergency use authorization, which is required for an unapproved COVID-19 test kit to be legally marketed and sold in the United States during the COVID-19 public health emergency. Much like the questionable finger-prick testing technology promoted by the now-defunct Theranos, the test kits allegedly returned “false positive” results.

In addition to conspiracy to commit health care fraud, Schena is also accused of securities fraud because, among other things, he and others allegedly made misrepresentations to investors about a variety of issues and concealed information regarding the accuracy of Arrayit’s COVID-19 testing.

This case comes as no surprise given that Attorney General William Bar made clear in a March 16th memorandum that investigating and prosecuting wrongdoing related to the COVID-19 pandemic is an ongoing priority for DOJ. In addition, DOJ typically takes cases involving patient harm (e.g., false positive test results) very seriously. While the Schena prosecution is DOJ’s first criminal securities fraud prosecution related to COVID-19, DOJ has previously announced an enforcement action against a fraudulent website claiming to offer COVID-19 vaccines; successfully sought an injunction halting the sale of silver products fraudulently touted as cures for COVID-19; and arrested a man accused of participating in a kickback scheme in return for referring patients for COVID-19 testing. We expect that enforcement activity related to COVID-19 will continue even as the national public health crisis begins to ease.

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