

The Convergence: Feds Level First Hybrid Healthcare- and Securities-fraud Charges Arising from COVID-19 Marketing and Sales

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In what may be the beginning of a wave of enforcement actions, the Justice Department charged an organization and its leadership with dual healthcare and securities fraud charges. The prosecution underscores the risks facing many organizations seeking to sell into the lucrative healthcare and government markets. The case is notable because it is the first COVID-19 case featuring claims of securities act and health care fraud, and demonstrates the government's efforts to press investigations when alleged misconduct involves fraud related to the pandemic.

As law enforcement agencies across the country crack down on COVID-19 related fraud, their enforcement efforts took a new turn this past week: filing charges against Mark Schena, the president of a California-based medical technology company called Arrayit Corporation, for alleged securities act violations and health care fraud. *United States v. Schena*, No. CR-20-70721-MAG (N.D. Cal.). The health care charges result from an alleged scheme to submit to the Government over \$69 million in false and fraudulent claims for the company's allergy and COVID-19 test kits; the Securities Act charges result from an alleged related scheme to prop up Arrayit's stock price based on false and misleading statements about its testing capabilities.

According to the [criminal complaint](#) filed June 8, and recently unsealed, Arrayit is a medical technology company that purports to employ "microarray technology" for allergy and COVID-19 testing based on a finger-prick drop of blood placed on a paper card and mailed to Arrayit's laboratory. Arrayit is described as a publicly traded "penny stock" company, and a participating provider in the Medicare program.

The complaint details allegations that Arrayit, for years before the pandemic, submitted millions of dollars in fraudulent claims for its allergy testing kits because such tests were medically unnecessary (the kits tested every patient for 120 allergens regardless of patient needs) and tainted by illegal kickbacks and bribes to referring physicians and recruiters to promote the comprehensive tests. Of particular note, the complaint describes incriminating statements from several cooperating witnesses, including

Related People

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Related Capabilities

- Government Enforcement & Corporate Investigations
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- Healthcare & Life Sciences

“Physician #1,” who proffered with the government pursuant to a *Kastigar* agreement and has, according to the complaint, already signed a plea agreement to one count of conspiring to commit health care fraud with Schena and others. Physician #1, for example, stated it is not medically necessary to test every patient for 120 allergens and that s/he received illegal kickbacks in the form of insurance reimbursement checks in exchange for Arrayit's ordering of allergy testing for patients whom Physician #1 had never seen. The complaint also alleges that Arrayit's allergy tests produced results that had little clinical relevance to the treatment of allergy symptoms, and that Arrayit and Schena engaged in aggressive promotional campaigns using social media and press releases to misrepresent the efficacy of its tests and Arrayit's financial condition. Arrayit is alleged to have additionally touted in false and misleading ways purported partnerships with Fortune 500 companies, government agencies such as the U.S. Department of Veterans Affairs, and public institutions.

While the complaint describes alleged misconduct that dates back several years based on Arrayit's provision and marketing of its allergen tests, the impetus for the filing of the complaint in June appears to be its allegations that Arrayit began selling and promoting COVID-19 tests in March 2020. The complaint alleges that Arrayit exploited the pandemic by claiming it could test dried blood samples for both allergens and COVID-19, and instructed its patient recruiters and clinics to bundle Arrayit's allergy test with a COVID-19 test regardless of whether the tests were medically necessary. Arrayit also failed, the complaint alleges, to disclose substantial questions about the accuracy of its COVID-19 tests, including that its COVID-19 tests failed to satisfy FDA performance standards for obtaining emergency use authorization. Such authorizations are required for an unapproved medical device to be legally marketed and sold in the United States during a public health emergency such as the COVID-19 pandemic. During the pandemic, the complaint alleges that Arrayit and Schena also made several affirmative misleading and exaggerated statements about its COVID-19 tests, including statements in March 2020 it had COVID-19 test kits available when they were unavailable until April (and never approved by the FDA even after that). Schena, in interviews with law enforcement as described, stated he was confident in his representations about Arrayit's COVID-19 testing because it was analogous to “a pastry chef” who switches from selling “strawberry pies” to selling “rhubarb and strawberry pies.” Investors apparently believed the same, as Arrayit's stock price doubled during the pandemic, before the SEC suspended trading in the stock based on questions of the accuracy and adequacy of publicly available information about Arrayit's financial condition and COVID-19 testing.

The Takeaways

As the government's complaint shows, there is much more at stake here than medically unnecessary tests or tests with false positives. The convergence of an energized and lucrative market for COVID-19 products and services, coupled with significant incentives to hit numbers and an active law enforcement community, is cause for organizations to carefully vet claims to the Government, representations to the public and investors, and regulatory compliance. Schena faces up to 20 years imprisonment and a \$5 million fine for his alleged fraud, in which Arrayit is alleged to have received over \$2 million in

payments from Medicare and private insurance for its \$69 million in fraudulent submissions. Schena has also been released on a \$2 million unsecured bond and faces a hearing on June 17 to review his release from custody. The Northern District of California's complaint demonstrates urgency as well—the government was apparently unwilling to wait until its next grand jury (which, according to the United States District Court for the Northern District of California's latest May 21 COVID-19 Order No. 72-3, were to "resume in June on a date and in a manner to be determined"), but instead filed a detailed 24-page complaint supporting the charges on June 8. Schena will presumably be indicted before his preliminary hearing scheduled for July 2. Finally, the case also demonstrates that the federal government is bringing all agencies to bear on investigating COVID-19 fraud, including the United States Postal Inspection Service on Securities Act and health care fraud, whose Postal Inspector authored the affidavit supporting the complaint.