SEALED BY ORDER OF THE COURT

AO 91 (Rev. 11/11) Criminal Complaint

UNITED STATES DISTRICT COURT

for the

Northern District of California

United States of America
v.
MARK SCHENA

Defendant(s)

Case No. CR 20-70721-MAG

CRIMINAL COMPLAINT

I, the complainant in this case, state that the following is true to the best of my knowledge and belief.

On or about the date(s) of 2016 to present in the county of Santa Clara in the Northern District of California, the defendant(s) violated:

Code Section	*Offense Description*
Title 18 U.S.C. §§ 1349 and 1347 Title 15 U.S.C. §§ 78j, 78ff; 17 C.F.R. 240-10b.5	Count One: Conspiracy to Commit Health Care Fraud Count Two: Securities Fraud Max. penalties: Count One: Not more than 10 years imprisonment, not more than $250,000 fine, not more than 3 years supervised release and $100 assessment; Count Two: Not more than 20 years imprisonment, not more than $5,000,000 fine, not more than 3 years supervised release and $100 assessment.

This criminal complaint is based on these facts:

Please see the attached affidavit of USPIS Postal Inspector Anna Hallstrom.

☑ Continued on the attached sheet.

/s/ Anna Hallstrom by VKD w/permission
Complainant's signature

Approved as to form William Frentzen
AUSA William Frentzen

Anna Hallstrom, Postal Inspector, USPIS
Printed name and title

Sworn to before me and signed via telephone.

Date: June 8, 2020

Virginia K. DeMarchi
Judge's signature

City and state: San Jose, CA

Hon. Virginia K. DeMarchi, U.S. Magistrate Judge
Printed name and title

Print Save As... Attach Reset

AFFIDAVIT IN SUPPORT OF A CRIMINAL COMPLAINT

I, Anna Hallstrom, Inspector with the United States Postal Inspection Service, being duly sworn, do declare and state:

INTRODUCTION

1. I make this affidavit in support of a criminal complaint for MARK SCHENA, for one count of securities fraud, in violation of 15 U.S.C. §§ 78j & 78ff and 17 C.F.R. 240.10b-5, and one count of conspiracy to commit health care fraud, in violation of 18 U.S.C. § 1349.

2. I am a Postal Inspector employed by the U.S. Postal Inspection Service. I have been a Postal Inspector since July 2014. In addition, I have been a Certified Fraud Examiner since August 2008, which requires twenty continuing education hours per year. These education hours include additional training in white-collar and cybercrimes. As part of my current duties as a Postal Inspector, I investigate instances of fraud including, but not limited to, those involving the use of the United States Postal Service. I received my basic training as a criminal investigator at the U.S. Postal Inspection Service Academy in Potomac, Maryland. Over the years, I have received training in the areas of financial fraud and white-collar crime. I have been the case agent in numerous criminal investigations. I have authorized and sworn to numerous affidavits in support of federal search warrants and federal arrest warrants. I have personally participated in executing search warrants and seizing evidence, including computers and other electronic equipment, from both businesses and personal residences. As a Postal Inspector, I am an "investigative or law enforcement officer" of the United States within the meaning of 18 U.S.C. § 2510(7), in that I am empowered by law to conduct investigations and to make arrests for federal felony violations.

3. The facts in this affidavit come from my personal participation in this investigation, my training and experience, and information obtained from other agents and witnesses. Statements of individuals are set forth as summaries unless otherwise indicated. This affidavit is intended to show merely that there is sufficient probable cause for the requested complaint and does not set forth all of my knowledge about this matter.

4. As part of this investigation, SCHENA has spoken with me and other investigating agents on multiple occasions. Throughout this affidavit, his statements are presented in sum and substance.

5. Based on my training and experience and the facts set forth in this affidavit, there is probable cause to believe that SCHENA has committed securities fraud, in violation of 15 U.S.C. §§ 78j & 78ff and 17 C.F.R. § 240.10b-5, and conspiracy to commit health care fraud, in violation of 18 U.S.C. § 1349.

6. SCHENA is the President of Arrayit Corporation ("Arrayit"), a publicly traded medical technology company based in Sunnyvale, California. As part of the scheme, SCHENA and others submitted or caused the submission of false and fraudulent allergy test claims to the Medicare Program ("Medicare") that were procured by the payment of illegal kickbacks and bribes, medically unnecessary, and/or not provided as represented, while making numerous misrepresentations to potential investors about Arrayit's allergy test sales, financial condition, and its future prospects. Further, SCHENA and others at Arrayit transmitted email communications and marketing materials that misrepresented Arrayit's ability to provide accurate, fast, reliable, and cheap COVID-19 tests in compliance with applicable regulations, instructing its patient recruiters and medical clinics to add on or bundle Arrayit's much more lucrative allergy test with its COVID-19 test regardless of medical necessity, and made misrepresentations to potential

investors about its COVID-19 testing capability and Arrayit's future prospects for COVID-19 testing. In sum, Arrayit and SCHENA's statements surrounding COVID-19 fit within a pattern of false and misleading statements to investors and others about Arrayit and its allergy testing.

THE MEDICARE PROGRAM

7. Medicare was a federally funded program that provided free or below-cost health care benefits to certain individuals, primarily the elderly, blind, and disabled. Medicare was administered by the Centers for Medicare and Medicaid Services ("CMS"), a federal agency under the United States Department of Health and Human Services ("HHS"). Individuals who received benefits under Medicare were referred to as Medicare "beneficiaries." Medicare was divided into multiple parts with separate coverages: Part A covered hospital inpatient care; Part B covered physicians' services and outpatient care; Part C covered Medicare Advantage Plans; and Part D covered prescription drugs.

8. Physicians, clinics, and other health care providers, including laboratories, all of which provided services to Medicare beneficiaries, were able to apply for and obtain a "provider number." A health care provider that received a Medicare provider number was able to file claims with Medicare to obtain reimbursement for services provided to beneficiaries.

9. Medicare only paid for services that were medically necessary and reasonable, and which were actually provided as represented. Medicare did not pay claims that were procured based on the payment or receipt of kickbacks and bribes.

10. Medicare was a "Federal health care program" as defined in Title 42, United States Code, Section 1320a-7b(f), and a "health care benefit program" as defined in Title 18, United States Code, Section 24(b).

DIAGNOSTIC TESTING

11. Medicare Part B covered medical testing by clinical laboratories. Some examples of medical tests that fell within the purview of Medicare Part B included:

a. Allergy testing: Allergy refers to conditions in which immune responses to environmental antigens cause tissue inflammation and organ dysfunction. Allergy testing is performed to determine immunologic sensitivity or reaction to antigens for the purpose of identifying the cause of the allergic state.

b. COVID-19 testing: COVID-19 testing assessed whether an individual had the novel coronavirus disease 2019, commonly referred to as "COVID-19."

12. Medicare did not cover diagnostic testing that was "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Title 42, United States Code, Section 1395y(a)(1)(A). Medicare, through its contractors, set forth rules and regulations regarding the circumstances in which allergy testing was reasonable and necessary.

13. Allergy test can be conducted "in vivo", which correlates the performance and evaluation of selective cutaneous and mucous membrane tests (commonly referred to as "skin tests") with the patient's history, physical examination, and other observations. Allergy hypersensitivity may also be tested "in vitro" (commonly referred to as "blood tests") by measurement of allergen-specific serum IgE. Percutaneous skin testing remains the test of choice in most clinical situations where immediate hypersensitivity reactions are suspected. Overall, skin testing is quick, safe, and cost-effective.

14. Under certain limited conditions, in vitro testing is covered by Medicare Part B. Quantitative (measuring the amount of sensitivity) in vitro allergen specific IgE testing is covered

under conditions where skin testing is not possible or is not reliable. Examples of indications for in vitro testing include patients with severe dermatographism, ichthyosis or generalized eczema.

15. It would not be expected that all patients would receive the same tests or the same number of sensitivity tests. The number of tests performed must be judicious and related to the history, physical findings, and clinical judgment specific to each individual.

INDIVIDUALS AND ENTITIES

16. Arrayit is a Nevada corporation based in the Northern District of California. Arrayit describes itself as "a world leader in microarray technology empowering researchers and doctors in the life sciences, wellness and healthcare testing markets." Arrayit is a participating provider in the Medicare program and submitted claims to Medicare.

17. SCHENA is a 57-year-old scientist who describes himself as the "Father of Microarray Technology," and serves as Arrayit's President. SCHENA is a resident of the Northern District of California.

STATEMENT OF PROBABLE CAUSE

A. Introduction

18. Arrayit purports to employ "microarray technology" for allergy and COVID-19 testing that allows for laboratory testing based on a finger-prick drop of blood that is placed on a paper card and sent by mail to Arrayit's laboratory. Arrayit touts that it is the "only laboratory in the world that offers" this test and claims on the Arrayit Facebook page that the Arrayit microarray can use drops of blood "which are 250,000 times smaller than the volume of the Theranos nanotainer."

19. Arrayit's common stock is quoted on OTC Link LLC (previously Pink Sheets), operated by OTC Markets Group Inc., under the ticker symbol ARYC. Arrayit is often referred to

as a "penny stock," and it has consistently traded at prices below $0.20 a share over the last five years. Arrayit's low price reflects the fact that the stock is diluted; Arrayit has issued several billion shares of stock. Members of the investing public have been able to sell and purchase Arrayit securities, and I am aware of transactions that investors have conducted in Arrayit securities during the period discussed below.

20. The investigation revealed that Arrayit paid kickbacks and bribes to recruiters and doctors to promote its blood allergy test without regard to whether patients needed to be tested for 120 allergens (including things ranging from stinging insects to food allergens) and needed to be tested using a blood test as a result of a skin condition or other contraindication for a skin test. In addition to being conducted without regard to medical necessity, Arrayit's allergy test produced results that have little clinical relevance to the treatment of allergy symptoms. At the same time, SCHENA engaged in an aggressive promotional campaign, using Twitter and press releases to promote the allergy test offered by the company and boast about the company's growth without disclosing the material limits on billing the tests, while also touting purported partnerships with Fortune 500 companies, government agencies, and public institutions that were non-existent or materially misleading.

21. In early March 2020, Arrayit began promoting a test for COVID-19 through its website and attempted to exploit the pandemic by claiming that it could test dried blood samples for both allergens and COVID-19, and instructing its patient recruiters and clinics to add on or bundle Arrayit's allergy test and COVID-19 test regardless of medical necessity. Arrayit's stock price doubled in mid-March. Arrayit never disclosed that the FDA informed Arrayit on April 17 that its COVID-19 test was not at an acceptable level of performance. On April 13, 2020, the SEC suspended trading in Arrayit stock because of questions regarding the accuracy and adequacy of

publicly-available information concerning Arrayit's financial condition and COVID-19 blood test. The suspension lasted from April 13-27; Arrayit has resumed trading since, though at low prices and with low volume.

B. SCHENA's Communications with Investors

22. Since 2015, Arrayit has communicated with investors using a number of methods and means. Arrayit largely ceased filing formal quarterly reports (Form 10-Qs) with the SEC in 2015, but continued to communicate with investors using press releases, email, and Twitter.

23. Until mid-2019, Arrayit posted frequently on a Twitter account identified with the username @arrayit. There has been no posted tweets or other publicly visible activity from this account since on or about August 15, 2019.

24. SCHENA has provided contradictory information about his involvement with the Arrayit Twitter account. For example, in a voluntary interview on April 15, 2020, SCHENA explained that he was not involved with social media and he focused on Arrayit's lab. In a second interview on April 20, 2020, SCHENA stated that he was responsible for posting some of the content on the Twitter account, alongside several others. When asked who else posted on Twitter on behalf of @arrayit, SCHENA stated "I'm responsible for much of it."

25. Arrayit's tweets were often bunched together, so that Arrayit posted multiple tweets per day. Many tweets adopted a journalistic tone, noting that Arrayit sales teams are "report[ing]" on a topic of interest related to the company, and appear to have used stock photos, which I know from my experience are photos that are available on the Internet or for purchase.

26. On or about March 31, 2019, Arrayit posted to its Twitter account: "This summary of our regular bi-weekly press releases, reinforced with our daily Twitter feed and popular VIP shareholder tours, illustrates our commitment to providing shareholders with an exciting real-time

view of Arrayit Corporation." This indicates that Arrayit's Twitter feed was designed, at least in part, to provide information to shareholders.

27. Arrayit's tweets are often quoted by others on social media or on investor message boards, using the phrase $ARYC, which I know from my experience is a way that Twitter users can aggregate and collect tweets using a stock's ticker symbol. This may have the effect of amplifying Arrayit's tweets to ensure they are widely seen by investors and potential investors, thus affecting the stock price. I have seen message boards, including a message board known as Investors Hub ("IHub"), where these tweets, Arrayit press releases, and other Arrayit communications are discussed in relation to the current or anticipated future price of Arrayit stock.

C. SCHENA's Statements to Investors About Arrayit's Financial Status

28. Until August 2019, Arrayit was a public company required to file financial reports with the SEC. I know from my training and experience that these reports are often valuable to investors, who can use them to evaluate a company's financial strength or weakness and opportunity for growth.

29. SCHENA repeatedly issued tweets and press releases on Arrayit's behalf, stating that the financials were forthcoming shortly. These statements were false or misleading.

30. For example, on or about June 15, 2018, Arrayit's Twitter account stated: "Arrayit financial experts use Monte Carlo analysis to re-calculate derivatives as required for audit completion by our very stringent and thorough auditors. Becoming current with our financials remains a top corporate priority. Thanks for being patient!"

31. On or about October 31, 2018, Arrayit tweeted: "Arrayit provides an update to shareholders. We are currently is a quiet period regarding our financials. Our next financial

announcement will be the filing of our 10-K and 10-Q forms through 2018. Thanks everyone for your continued support and patience!"

32. I have interviewed individuals at a firm ("the Auditor") that was hired by Arrayit to audit its financial reports. These individuals communicated with SCHENA throughout the period from 2016 and 2019. According to one of these individuals, a final version of Arrayit's audited financials was never prepared because Arrayit failed to provide the Auditor with documents necessary to complete such an analysis.

33. At one point, an employee of the Auditor confronted SCHENA about one of Arrayit's tweets regarding the financials. SCHENA told the employee that it would not happen again, and acknowledged that Arrayit's failure to release the financials was Arrayit's fault, not the Auditor's.

34. On or about March 27, 2019, an investor asked SCHENA if "the financials will be released on schedule for Q1, 2019 per letter to shareholders." SCHENA responded that day: "We appreciate your support and feedback. We are reiterating Q1-2019 for the financials. Thanks, Mark." An employee of the Auditor informed me that during this period Arrayit was not providing the Auditor with financial documents that were necessary to prepare the filing. The Auditor eventually resigned from its position in part because of concerns that its association with Arrayit would tarnish the Auditor's reputation.

35. Late in the evening of Sunday, March 31, 2019 - at or about 11pm Eastern Time - Arrayit posted a 38-part thread to Twitter entitled "Financials Update." These tweets include discussion of the company's sales, and reiterate its commitment to its shareholders and to filing financial reports. For example, Arrayit posted that "Arrayit is fully committed to its shareholders,

to filing its financial reports as quickly as possible, to listing on a national exchange as soon as possible and to accelerating growth through deployment of our new healthcare products."

36. Arrayit has not, to date, filed financial statements for the aforementioned years with the SEC, nor are such statements available on Arrayit's website. On or about August 16, 2019, Arrayit deregistered as a filing entity, thus releasing it from its obligation under the Securities Exchange Act of 1934 to file such in the future.

C. Fraud Surrounding Arrayit's Allergy Testing

1. Evidence of Health Care Fraud Related to the Arrayit Allergy Test

37. In interviews with federal agents, SCHENA acknowledged that it was important to follow anti-kickback rules and medical necessity regulations. However, SCHENA also stated that Arrayit ran a quantitative test for 120 allergens every time for every patient. An Arrayit "allergy testing report" obtained in the investigation from a medical clinic confirmed that Arrayit tests for 120 allergens, including numerous molds and fungi; tree pollens; grasses; animals and insects; weed pollens; fruits and vegetables; grains; nuts and seeds; proteins; stinging insects; and others.

38. Physician #1 is a medical doctor who is licensed in the State of California and a participating provider with Medicare. Physician #1 has proffered with the government pursuant to a Kastigar agreement and has signed an agreement to plead guilty to one count of conspiracy to commit health care fraud, in violation of 18 U.S.C. § 1349.

39. Physician #1 stated that s/he conspired to commit health care fraud with SCHENA and others. Physician #1 stated it is not medically necessary to test every patient for 120 allergens using the Arrayit test. Physician #1 stated that SCHENA requested the NPI number of Physician #1 and that Physician #1 later discovered that Arrayit submitted claims to Medicare and private insurance plans using Physician #1's NPI to represent that Physician #1 had ordered allergy testing

for patients whom Physician #1 had never seen. Many of these patients were located outside of the State of California and never received treatment from Physician #1. Physician #1 stated that an executive of Arrayit (Executive #1) paid Physician #1 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. In addition, Physician #1 stated that SCHENA and others submitted false and fraudulent documentation to regulatory bodies in order to obtain regulatory approval to allow Arrayit to conduct laboratory testing.

40. The investigation has revealed that one of the principal tools for marketing the Arrayit test is the Arrayit "Client Services Manual." This affiant has reviewed numerous emails distributing the Client Services Manual to medical clinics that inquired about potentially using the Arrayit test. The Client Services Manual cites four published works that support the purported effectiveness and desirability of using the Arrayit allergy test, three authored by SCHENA about microarray technology generally and one authored by Medical Expert #1 regarding the use of microarray technology for allergy testing. In an interview with federal agents involved in this investigation, Medical Expert #1 stated that the published work did not support the testing conducted by Arrayit because the published work only examined microarray testing using blood serum (not dried blood samples that are collected remotely and sent via mail to a laboratory for testing by Arrayit). While the Client Services Manual states that Arrayit's technology is validated by ">6000 peer review scientific publications," Medical Expert #1 was not aware of any such publications or any other company that has successfully demonstrated an ability to conduct this testing using a dried blood sample. Medical Expert #1 also noted that the article cited in the Client Services Manual concluded that tests of the type offered by Arrayit were medically unnecessary except in limited circumstances. Medical Expert #1 stated that most patients will present with

symptoms that indicate only certain allergies and it's not necessary to test for other allergens. The Arrayit test also can lead to false positive results – it is known that sensitization and allergy are distinct, in that sensitization (in blood tests) do not necessarily imply that symptoms will occur upon exposure to that allergen. Medical Expert #1 stated that with quantitative in-vitro tests for 120 allergens, it is "almost inevitable that the test comes up with something that has no clinical relevance of that individual."

41. Agents involved in this investigation also interviewed individuals who were involved in recruiting and referring patients for quantitative in-vitro tests conducted by Arrayit. Consultant #1 stated that Arrayit paid patient recruiters a percentage of the amount that Arrayit was paid by private insurers for allergy testing and that percentage from private insurance also compensated the marketer for their efforts marketing Arrayit to Medicare providers. Consultant #2 stated that s/he received a percentage of the amount that private insurance paid Arrayit for each quantitative in-vitro tests that was ordered for patients who were recruited by Consultant #2. Consultant #2 stated that many doctors told her/him that the testing conducted by Arrayit was not medically necessary because Arrayit tested for many allergies that the patients were not suspected of having.

42. Agents involved in the investigation spoke with three Medicare beneficiaries. In regard to all three of the Medicare beneficiaries, Arrayit billed $5,216 for each test for each beneficiary and was paid $352.41 per test. None of the three Medicare beneficiaries had a skin condition or other contraindication for a skin test that would have made a blood test reasonable and medically necessary. While Physician #1 was listed as the ordering provider in the Medicare claims data, all three of the Medicare beneficiaries stated that they never had met or received treatment from Physician #1. Physician #1 confirmed that s/he did not treat the three beneficiaries,

43. Agents involved in the investigation also reviewed billing data submitted by Arrayit and medical clinics that used the Arrayit test to Medicare and private insurance plans. From 2018 to the Present, Arrayit submitted or caused the submission of over $5.9 million in claims to Medicare, and submitted or caused the submission of over $63 million in claims to private insurance plans, that were procured by the payment of kickbacks and bribes, medically unnecessary, and/or not provided as represented. As a result of these claims, Medicare paid $290,000, and private insurance plans paid in excess of $2 million, to Arrayit or other medical providers ordering the Arrayit test.

2. Misrepresentations to Investors Surrounding the Arrayit Allergy Test

44. For several years, SCHENA has used Arrayit tweets and press releases to issue statements about Arrayit's business opportunities and other developments. These tweets often discuss Arrayit's revenues, or refer to deals that Arrayit has made with large companies and government entities.

45. Some of these tweets were false or misleading. For example, on or about March 11, 2019, SCHENA tweeted that Arrayit "increases weekly guidance for medical billing associated with its physician-prescribed allergy testing services from $1,000,000 ($1 million) per week . . . to $2,000,000 ($2 million) per week." This implied not only that Arrayit's billings had doubled, but also that Arrayit's prior billings were greater than $50,000,000 per year.

46. In statements provided to law enforcement, SCHENA stated that this press release was an accurate statement and that it was to be "understood literally." SCHENA explained that this tweet was based on the billing data for the allergy services.

47. These statements were materially misleading because Arrayit was not billing $2,000,000 per week in allergy tests; in fact, Arrayit was broke and had taken to paying employees

and consultants in stock, and asking shareholders to help it with rent. In addition, SCHENA failed to disclose the material information that Medicare's rules and regulations limited the use of in-vitro blood testing and required the number of allergens tested for to be based off of individualized medical need.

48. The investigative team has reviewed billing data obtained from Arrayit's biller. The billing data indicates that Arrayit was billing nowhere near $1 million per week in allergy tests, much less $2 million. Records obtained from Arrayit's biller establish that Arrayit and other medical providers billing the Arrayit test billed $1.6 million for dates of service in January 2019, $1.9 million in February, and $2.7 million in March. Thus, at no time in the quarter did Arrayit bill $1 million per week ($4 million per month), much less $2 million per week ($8 million per month). The tweet also was materially misleading because Arrayit was paid a fraction of these amounts: approximately $74,000 (January), $80,000 (February), and $114,000 (March).

49. At least one investor has told the investigative team that he purchased Arrayit shares and felt that Arrayit's stock was undervalued due to the information in SCHENA's tweet about Arrayit's billing revenue.

50. SCHENA also disseminated statements, through press releases and tweets, about Arrayit business opportunities. Many of these tweets described partnerships and contracts with large companies, and included dollar figures that were false and misleading.

51. For example, on or about August 20, 2018, SCHENA tweeted that Arrayit's "CLIA clinical laboratory reports $2,490,000 clinical services sales request from the top government agency the United States Department of Veterans Affairs headquartered in Washington DC USA and providing premium healthcare." But Arrayit never entered into such a contract or provided

such services for the Veterans' Administration ("VA"); Arrayit appears to have seen a solicitation publicly posted by the VA and made an unsuccessful bid for the contract for only for $840,000.

52. The investigative team has interviewed a VA employee, who stated that it would be "inaccurate" to claim that a bid on the contract SCHENA referred to constituted a "$2,490,000" contract. The employee stated that the contract was a base year "pilot program" and would have been extended for additional years and amounts only if it was successful. Accordingly, even if Arrayit had received the contract—which it did not—its value would have been approximately one-third of what SCHENA claimed it to be.

53. Further, I have reviewed emails between an Arrayit employee and an employee of the VA. On the same day the tweet was issued, the Arrayit employee told the VA that Arrayit had "just found this solicitation" and asked about the possibility of a time extension for Arrayit to bid. This suggests that the VA did not approach Arrayit about a contract, as implied by SCHENA's tweet; rather, Arrayit found a publicly posted solicitation and inquired with the VA. This email between an Arrayit employee and the VA employee was forwarded to SCHENA one week later, on August 27, 2018.

54. SCHENA did not publish a correction or update to indicate that it had not received a contract from the VA.

55. On or about November 19, 2018, Arrayit released a press release stating that pursuant to "an allergy testing agreement," Arrayit "is providing its proprietary microarray-based finger stick allergy testing services to Sutter Health via doctors in the Sutter Health-affiliated Palo Alto Medical Foundation," Sutter Health, "one of the nation's largest healthcare networks," reports "total patient service revenues of $12,000,000,000 annually."

56. The investigative team has learned that Arrayit had no contractual relationship with Sutter Health or with Palo Alto Medical Foundation, a non-profit member of the Sutter Health Network. When the Palo Alto Medical Foundation became aware of Arrayit's press release, legal counsel for Sutter Health sent a cease-and-desist letter to Arrayit. In response to the cease and desist letter, Executive #1 responded to Sutter by email and agreed to cease and desist using the name of Sutter Health or Palo Alto Medical Foundation in any press releases, or postings on Twitter or other social media platforms under Arrayit's control. SCHENA never clarified the original press release or took it down.

57. On or about August 8, 2019, SCHENA posted from the Arrayit Twitter account that "Arrayit clinical team commences $240,000,000 test kit manufacturing run to build inventory for our rapidly expanding physician-ordered finger stick allergy testing services empowering clinic network doctors to identify, manage and treat allergy and asthma." This tweet was subsequently repeated elsewhere, including on social media and IHub.

58. SCHENA's August 8, 2019 tweet suggested that Arrayit had substantial means and demand for its allergy testing product, such that it could justify hundreds of millions of dollars in production. There is no evidence that this statement is true; in fact, at the time of this statement, Arrayit was broke, and SCHENA was soliciting investors to help Arrayit cover its rent. Arrayit never corrected this statement.

59. SCHENA's tweet was not the first time that SCHENA had posted false or misleading information about Arrayit's manufacturing and production capabilities. On or about May 8, 2019, SCHENA posted that "Arrayit microarray manufacturing team completes $27.9 million production run to build allergy testing services inventory for our rapidly expanded network of 700 healthcare clinics using our physician-ordered allergy and asthma tests for patient

wellness." There is no evidence of such a production run, and Arrayit's revenues do not approach the number mentioned in either tweet.

60. SCHENA has published many other similar tweets and press releases touting Arrayit's business relationships over the years.

D. COVID-19

1. Evidence of Health Care Fraud Surrounding COVID-19

61. The investigation has revealed that SCHENA 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. As described below, SCHENA offered an Arrayit COVID-19 test in order to obtain Medicare beneficiary information that then was used to submit false and fraudulent claims for an unrelated and far more expensive allergy test for 120 allergens. SCHENA and others transmitted false and fraudulent email communications and marketing materials about the Arrayit COVID-19 test and purported need to bundle the COVID-19 test with Arrayit's allergy test, while never disclosing that there were substantial questions about the accuracy of Arrayit's COVID-19 test.

62. In interviews with agents involved in this investigation, SCHENA stated that it was straightforward to use the Arrayit microarray allergy test process to also test for COVID-19, which he described as a "trivial" adaptation. Expert #1 stated to agents involved in this investigation that claiming that a microarray allergy test could easily be converted to a COVID-19 test is "great hype to get more investor money in . . . To make that claim is for the consumption of investors, not health care."

63. On March 17, 2020, SCHENA sent emails to medical clinics announcing that Arrayit had developed a COVID-19 test based "on advanced Silicon Valley technology and finger

stick blood collection." In reality, Arrayit had not developed, validated, or produced a test at that time; indeed, this affiant has reviewed emails and purchase orders indicating that SCHENA first ordered the COVID-19 antigens that would be necessary to attempt to develop a test on that same date. However, Arrayit's announcement generated substantial market interest in Arrayit's test kit (the same finger stick test kit that Arrayit used for its allergy test).

64. In addition, SCHENA and others also falsely represented the validity and results of the COVID-19 test in email communications and marketing materials that were transmitted to medical clinics and others. For example, SCHENA and others represented that Arrayit's test was accurate at a time when no Arrayit test existed, such as in an email sent by Arrayit's Vice President, copying SCHENA, that claimed that the accuracy of Arrayit's serological test "was comparable or better" than a COVID-19 PCR test. In addition, after SCHENA developed a purported test, SCHENA and others failed to disclose that it failed to satisfy FDA performance standards for obtaining an emergency use authorization, which is necessary for an unapproved medical device to be legally marketed and sold in the United States during the public health emergency related to COVID-19. An email obtained in this investigation that was transmitted by a representative of the FDA to Executive-1 at Arrayit on April 17, 2020 stated that Arrayit's emergency use authorization would be converted to a pre-emergency use authorization because it was missing key pieces of information that was necessary for FDA to conduct its review of the test. The email also stated that Arrayit's test sensitivity of 85.7% in detecting those with antibodies and specificity of 88.1% in detecting those without antibodies were not at an acceptable level of performance that was necessary to obtain emergency use authorization. However, SCHENA and others nonetheless continued to promote Arrayit's bundled COVID-19/allergy test without disclosing these facts.

65. Evidence obtained in this investigation indicates that the purpose of SCHENA's false representations was to increase revenue from Arrayit's expensive and medically unnecessary allergy test. As early as March 17, 2020, Arrayit began to distribute marketing material entitled "COVID-19 and Allergen Testing" that stated "COVID-19 compels allergy testing" and that the Arrayit COVID-19 test "is being combined with the Environmental Allergen Panel." In order to promote the test, Arrayit falsely represented that government agencies and prominent scientists endorsed the approach. Numerous emails that were sent by Arrayit employees to medical clinics and others, some of which copied SCHENA, falsely represented that Arrayit "was following CDC and NIAID directives in eliminating both allergies and the common flu whenever possible." Arrayit's marketing materials and pages on the Arrayit website (that subsequently have been deleted) suggested prominent public figures, such as Dr. Anthony S. Fauci, Director of Allergy and Infectious Disease, and/or White House Coronavirus Coordinator Dr. Deborah Birx were emphasizing the importance of a finger stick blood test for COVID-19 in order not to confuse allergy symptoms with those of COVID-19. These marketing efforts were amplified online by patient recruiters working on behalf of Arrayit, in posts on Facebook and other social media platforms. Agents involved in this investigation have spoken with medical experts and other witnesses who have stated that there is little medical basis for bundling COVID-19 and tests for 120 allergens. For example, allergies typically cause nasal symptoms such as a runny nose and sinus congestion but do not usually result in a fever, as is found with coronavirus or the flu.

66. In response to the bundling of the COVID-19 and allergy test, at least one clinic administrator responded by email with edits that eliminated the allergy references, writing to SCHENA on March 24 that "it is important to maintain as much clarity as possible in regard to COVID-19 in the current climate." Arrayit did not modify its requisition form in response to the

email. Consultant #2 told law enforcement that after Arrayit introduced the COVID-19 test, doctors who ordered the test told him/her that Arrayit also had conducted allergy tests that the doctors had not ordered and did not believe were necessary. Consultant #2 was concerned that Arrayit was billing for allergy testing that doctors had not ordered and sent an email about these concerns that subsequently was forwarded to SCHENA.

67. Physician #1 told agents that it was not medically necessary to test for both COVID-19 and 120 allergens. Physician #1 stated that SCHENA and others promoted Arrayit's COVID-19 test for use with patients despite the fact that the test returned "false positive" results, whereby it indicated that a patient was positive for antibodies for COVID-19, when in reality the positive results were due to past or present infection with non-COVID-19 coronavirus strains. In an interview with this affiant, SCHENA admitted that Arrayit did not include language in its test results that was required by the FDA to inform patients that positive results from serological tests may be due to antibodies for other coronavirus strains, as opposed to for COVID-19.

2. Misrepresentations to Investors Surrounding COVID-19

68. Beginning in early March 2020, SCHENA and Arrayit told investors, prospective investors, and other individuals that Arrayit had received substantial interest about its purported test for COVID-19. For example, on March 9 and 10, 2020, SCHENA told several Arrayit shareholders via email: "Confirming that we have a test for COVID-19. Thanks, Mark." Between in or about March 19 and in or about March 21, 2020, SCHENA sent an email to dozens of investors who had inquired about the COVID-19 test. SCHENA's email stated: "*Dear Valued Customer, We received more than 50,000 requests for our finger stick blood test for SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19). Our team is coordinating with local, state and federal agencies and with our distributors to make this test available to as many patients*

as possible on an expedited timeline. Please consult our website and press releases for updates. Best regards, Arrayit Corporation." These emails were subsequently reposted on IHub and SCHENA's statements were amplified by individuals who posted his statements on IHub, Twitter, and other media.

69. SCHENA has, in interviews with law enforcement, provided multiple and conflicting explanations for his "we have a test" email and the "50,000 requests" email. SCHENA told investigators that he was confident Arrayit would be able to develop a COVID-19 test on March 9 because the switch from testing for allergies to testing for COVID-19 was "like a pastry chef" who switches from selling "strawberry pies" to selling "rhubarb and strawberry pies," but admitted that Arrayit did not start running the test "until April of 2020." SCHENA later told law enforcement that his email was accurate because Arrayit was able to source COVID-19 tests from other suppliers. But, as discussed above, this affiant has reviewed emails and other documents where SCHENA promoted a proprietary Arrayit finger stick blood test for COVID-19 to investors beginning in early March and did not mention sourcing a test from third party suppliers. Agents involved in this investigation also have interviewed Arrayit employees and consultants, who stated that they were unaware of any plans to source COVID-19 tests from other suppliers.

70. SCHENA initially stated that the "50,000" number referred to the number of patients at Arrayit's partnered allergy clinics. Later, SCHENA stated that the "50,000" number referred to inquiries into availability of the test, and the number was based on a polling of the clinics done on "the back of the envelope." SCHENA then stated that the number was based on the number of units doctors had requested. SCHENA then said that the number was an estimate on the Arrayit side, and must have been based on feedback from clinics. Finally, SCHENA

explained that the number was "probably" based on a discussion with sales consultants, and that he did not recall if those contacts were over email, multiple phone calls, or another means.

71. Law enforcement has interviewed a marketer who has assisted Arrayit in its communications with doctors. This individual has told law enforcement that no doctors requested the COVID-19 test from Arrayit.

72. In regard to the statement regarding coordination with federal, state, and local regulators, SCHENA stated in an interview with federal agents that the federal regulators were the Food and Drug Administration (FDA) and Department of Health and Human Services (HHS).

73. The investigative team has reviewed correspondence between the FDA and Arrayit. As discussed above, the correspondence indicates that Arrayit did not notify FDA or submit an emergency use authorization until April 13, 2020, nearly a month after the March 19 emails by SCHENA.

74. As discussed above, in response to Arrayit's submission, the FDA informed Arrayit that its test was not at an acceptable level performance that would allow it to obtain emergency use authorization for marketing and sale in the United States. Arrayit did not disclose any of these setbacks to the market. SCHENA never updated or corrected statements to investors about the viability or availability of Arrayit's purported COVID-19 test.

75. Arrayit's stock price began rising in mid-March 2020, even as the stock market was crashing; it more than doubled in price by mid-March.

76. On April 14, 2020, the SEC instituted a two-week trading suspension on Arrayit due to fraud related to COVID-19, preventing individuals from buying or selling the stock. Since Arrayit has resumed trading, the stock has traded at lower price points.

77. In furtherance of the scheme, SCHENA used instrumentalities of interstate commerce, including but not limited to emails between California and other states.

CONCLUSION

78. Based on the above facts and based on my training and experience, I believe there is probable cause that MARK SCHENA engaged in securities fraud, in violation of 15 U.S.C. §§ 78j & 78ff and 17 C.F.R. 240.10b-5, and conspiracy to commit health care fraud, in violation of 18 U.S.C. § 1349.

79. I respectfully request that this Complaint, any warrant issued pursuant thereto, and any related records, be filed under seal until further order of the Court, as the investigation is ongoing. An application and sealing order are filed concurrently with this affidavit and criminal complaint. I declare under penalty of perjury that the above is true and correct to the best of my knowledge.

/s/ Anna Hallstrom by VKD w/permission
ANNA HALLSTROM
Postal Inspector
United States Postal Inspection Service

Sworn to before me over the telephone and signed by me this 8th day of June 2020.

Virginia K. DeMarchi
HON. VIRGINIA D. DEMARCHI
United States Magistrate Judge