VIRGINIA: IN THE CIRCUIT COURT FOR THE COUNTY OF FAIRFAX

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CLERK OF CIRCUIT COURT
FAIRFAX, VA

VIVERA PHARMACEUTICALS, INC.,	JURY TRIAL DEMANDED
Plaintiff,	Case No.: 2023 8320
v.	
GANNETT SATELLITE INFORMATION NETWORK, LLC, d/b/a USA TODAY, DAVID HEATH, KEVIN MCCOY, and DONOVAN SLACK,	
Defendants.	

COMPLAINT

COMES NOW, VIVERA PHARMACEUTICALS, INC., the Plaintiff ("Plaintiff" or "Vivera"), by and through its undersigned counsel, and sues Defendants GANNETT SATELLITE INFORMATION NETWORK, LLC d/b/a USA TODAY ("USA Today"), DAVID HEATH ("Heath"), KEVIN MCCOY ("McCoy"), and DONOVAN SLACK ("Slack"), and in support hereof alleges as follows:

NATURE OF ACTION

This is a civil action against Defendants for defamation by implication and defamation.

INTRODUCTION

This case arises from Defendants' brazen efforts to falsely paint Vivera—one of the first companies to develop a COVID-19 test in response to the global COVID-19 coronavirus pandemic—as an opportunistic enterprise looking to "cash-in" in a June 2, 2020 article published on USA Today's website. As one of the article's lead editors, Amy Pyle, conceded, Defendants targeted companies, like Vivera, that were producing COVID-19 tests looking for so-called "red flags" to feature in their story. When Defendants could not find any negative information about Vivera, however, they knowingly and intentionally resorted to personal attacks against Vivera's CEO, Paul Edalat, drawing on false claims and anecdotes about Edalat' s past, which have nothing to do with the safety or efficacy of Vivera's COVID-19 tests.

Defendants' lead reporter, David Heath, admitted under oath in a related proceeding that USA Today had virtually zero information regarding the validity of Vivera's COVID-19 tests.[1] Nevertheless, Defendants forged ahead: falsely depicting Mr. Edalat as an unscrupulous and dishonest businessman—creating the equally false impression that his company, Vivera, was unethical and that its products could not be trusted. Defendants then went further and falsely implied that Vivera withheld information about its COVID-19 tests from the public and

[1] Vivera raised similar allegations regarding the Article in a prior lawsuit it filed against Defendants in the Circuit Court for the County of Fairfax, Case No: 2020-14458 (the "Related Litigation").

government regulators. Again, this was untrue.

As a result, Vivera has been harmed in excess of $500 million due to the immediate loss of business expectancies and contractual opportunities, including at least one key contract with the U.S. Government, developed through Vivera's contacts with high level officials in the White House, including Dr. Dr. Peter Navarro. Vivera now sues Defendants for defamation and defamation by implication.

PARTIES

1. Vivera is a Delaware corporation, authorized to do business in the State of California, with its principal place of business in Los Angeles County, California.

2. Defendant USA Today is a Delaware limited liability company, with its principal place of business in the Commonwealth of Virginia. USA Today regularly conducts business within Fairfax County, has its headquarters in McLean, Virginia and publishes content on its internet website, www.usatoday.com and on social media accounts, such as Twitter.

3. Defendant Heath was, at all relevant times, a reporter for USA Today.

4. Defendant McCoy was, at all relevant times, a reporter for USA Today.

5. Defendant Slack was, at all relevant times, a reporter for USA Today.

JURISDICTION

6. This Court has jurisdiction over USA Today, as its headquarters office is located in Fairfax County, Virginia, at 7950 Jones Branch Drive, McLean, Virginia, 22102.

7. The defamatory statements were published in Fairfax County, Virginia. Accordingly, the torts committed by the Defendants were committed in Fairfax County, Virginia.

8. Thus, Defendants are subject to the personal jurisdiction of this Court under Va. Code § 8.01-328.l(A)(l), (3) and/or (4).

9. The amount in controversy exceeds the jurisdictional minimum for this Court.

VENUE

10. The Defendants' actions at issue here, which caused the Plaintiff's damages, took place in Fairfax County, Virginia.

11. The Defendants reside or have their principal place of business located in Fairfax County, Virginia.

12. The Defendants regularly conduct substantial business activity in Fairfax County, Virginia.

13. Thus, venue for Plaintiff's claims is proper under Va. Code § 8.01-262(1), (3) and (4).

VIVERA'S COVID-19 TESTS WERE SUBJECTED TO RIGOROUS TESTING AND GENERATED GREAT INTEREST FROM THE GOVERNMENT AND BUSINESS COMMUNITY

14. In 2020, Vivera was a pharmaceutical company focused on developing novel therapies utilizing its patented and provisionally patented pharmaceutical sublingual delivery system, pharmaceuticals, and other medical devices.

15. As of June 2, 2020, Vivera was not a public figure and has never pressed itself into any public controversy.

16. As of June 2, 2020, Vivera had never sought to influence the outcome of any public controversy, including any controversy relating to the COVID-19 coronavirus pandemic.

17. In response to the outbreak of the global COVID-19 coronavirus pandemic in the Spring of 2020, Vivera was one of the first companies working to develop two American-made COVID-19 tests: 1) a COVID-19 rapid test ("Rapid Test"); and 2) a serology antibody test ("Antibody Test") (the Rapid Test and Antibody Tests, together, the "Tests"), both of which Tests detected the body's immune response to a COVID-19 infection.

18. In May 2020, Vivera began nationwide delivery of its Rapid Tests

for use by qualified CLIA laboratories under the FDA and Emergency Use Authorization guidelines.

19. Vivera posted on its website the test specification data for the Rapid Test.

20. Vivera made its validation and technical data information readily available upon request.

21. On June 4, 2020, Vivera filed a second Emergency Use Authorization package with the FDA for its Antibody Test.

22. In support of this application, Vivera submitted clinical studies for Point of Care Authorization to the FDA.

23. In addition, Vivera voluntarily took part in the National Cancer Institute ("NCI") backed validation studies, submitting both the Rapid Test and Antibody Test for validation testing in May and June 2020, respectively.

24. Aware that Vivera had the capacity to manufacture millions of Tests per week, senior officials in the White House approached Vivera to discuss distribution of Vivera's Tests.

25. Supplying American made, domestically sourced COVID-19 tests to the American public was a high priority for the White House in 2020, to preserve the country's testing supply inventory.

26. Discussions with White House staff, including Dr. Peter Navarro,

who served as the Director of the Office of Trade and Manufacturing Policy, continued through May and portions of June of 2020.

27. By early summer of 2020, Vivera was on the cusp of obtaining a contract to manufacture and distribute the Tests with the U.S. Government.

28. The Antibody Test generated tremendous interest not only from the White House, but from numerous third parties, including corporations, and local and state governments, among others.

DEFENDANTS' ARTICLE FALSELY IMPLIED THAT VIVERA WAS NOT QUALIFIED TO DEVELOP COVID-19 TESTS BECAUSE OF ITS CEO'S CHARACTER

29. On June 2, 2020, Defendants published an article on the www.usatoday.com website (the "Article"), titled "'You could see the train wreck coming': Inexperienced, dubious companies, among many aiming to cash in on coronavirus antibody tests." A true and correct copy of the Article is attached hereto as **Exhibit A.**

30. The publication of the Article was approved by editors, Amy Pyle and Steve Meyers.

31. Pyle and Meyers had the authority to prevent publication of the Article.

32. Pyle and Meyers oversaw the drafting of the Article and were both directly involved in drafting the language used in the Article.

33. Although the Article purports to focus on "inexperienced, dubious companies" "cashing in on coronavirus antibody tests," Defendants did not publish any evidence that Vivera's Tests were unreliable—instead, Defendants resorted to making inflammatory and false statements about the reputation of Vivera's CEO, Paul Edalat ("Edalat"), to draw the entirely false conclusion that Vivera was not qualified to develop COVID-19 tests.

34. The Article states that "[o]n social media and in company news releases, Edalat portrays himself as a jet-setting chief executive officer. He has appointed former professional athletes to the advisory board of Vivera Pharmaceuticals."

35. Vivera has never issued a press release depicting Edalat as a jet-setting chief executive.

36. Nor does the Article mention any of the Ph.D.'s, scientists, medical doctors and other highly qualified medical and science professionals on Vivera's executive staff and advisory board.

37. In the Article, Defendants also state that: "[Edalat] is a fraud." "Investors accused [Edalat] in court of deceiving them by driving a Rolls-Royce and wearing a gold Rolex to hide his bankruptcy . . ." "[Edalat] tried to fool investors with his extravagant lifestyle: staying in luxury suites, 'wearing a diamond-studded gold Rolex watch which he brags that he purchased for more

than $50,000' and 'driving fancy cars, including two Rolls-Royces, three Lamborghinis, a Land Rover, a BMW, a Ferrari, and a Hummer, among others,'" and that "[t]he suit went before a federal jury, which found that Edalat defrauded and libeled some of the investors. He was ordered to pay them $880,000."

38. The statements quoted in paragraph 37 above were made as part of a public disparagement campaign against Edalat that began in 2016 during federal court litigation between Edalat and a former business partner (the "2016 Federal Litigation").

39. The 2016 Federal Litigation had nothing to do with Vivera—which was not even in existence in 2016—much less its qualifications to develop effective and accurate COVID-19 tests.

40. The Article also falsely states that "[t]he Food and Drug Administration *barred* [Edalat] from selling dietary supplements after his company failed a string of inspections." (Emphasis added).

41. Edalat was never "barred" by the Food and Drug Administration from selling dietary supplements.

42. Edalat voluntarily agreed to a procedure by which he would inform the FDA if he elected to resume manufacturing of dietary supplements and follow certain procedures thereafter.

43. Defendants' statement quoted in paragraph 40 above also falsely implied that because Edalat was supposedly "barred" from selling dietary supplements, Vivera should not be permitted to develop COVID-19 tests.

44. The FDA has never prevented Vivera from developing COVID-19 tests.

45. The Article continues by falsely stating that "[i]n a case still awaiting trial, Alternate Health Inc. alleges Edalat told a series of lies to ink a 2017 agreement worth $4.2 million to sell a cannabis supplement."

46. Alternate Health—who sued Edalat in 2019—falsely alleged that "Edalat said he could mass produce the product and didn't reveal he was barred from doing so."

47. Defendants state in the Article that "even companies led by CEOs with a history of legal entanglements . . . can sell tests," which is clearly a reference to Edalat, who is the only CEO specifically named in the Article.

48. The Article failed to mention that Vivera was never a party to any of the above-mentioned lawsuits and disputes.

49. As acknowledged by Defendant Heath, the lead reporter for USA Today, in his sworn deposition testimony in the Related Litigation, Defendants intended that a reasonable reader would conclude that because of Edalat's reputation, Vivera was questionable as a seller of COVID-19 tests.

THE ARTICLE FALSELY IMPLIED THAT PLAINTIFF WITTHELD INFORMATION FROM THE PUBLIC AND GOVERNMENT REGULATORS ABOUT ITS COVID-19 TESTS

50. In addition to falsely implying that Vivera was not qualified to develop COVID-19 tests, the Article also falsely implied that Vivera had wrongfully withheld information about the Tests from the public.

51. Defendants' Article states that "The FDA now requires all companies to reveal the results of validation tests to the agency. Many companies post accuracy numbers on their website. Vivera does not- and when asked about the test's accuracy, McColgan [the Chief Medical Officer for Vivera] was reluctant to answer."

52. In truth, Vivera's website posted accurate numbers, Vivera revealed all validation testing to the FDA, worked closely with the FDA, and voluntarily participated in the independent validation NCI pathway study.

53. Defendants' statement quoted in paragraph 51 above falsely implied that Vivera was refusing to be transparent with the public as well as regulators.

54. Defendants' Article further states that "Boston BioPharma also describes its test as being for diagnostic use. After USA TODAY pointed out the language, a spokesman said the company would revise its wording. Vivera Pharmaceuticals makes the claim, too, although it does include the FDA disclaimer on its site."

55. Vivera did not make a claim on its website that the Antibody Test could be used to diagnose active COVID-19 infections.

56. The Article stated that "[l]ike Vivera Pharmaceuticals, some have ties to the world of dietary and health supplements."

57. Vivera has never manufactured, sold, or distributed any dietary or health supplements.

58. Defendants quoted Edalat as saying that "the FDA looks at [Vivera] more as the manufacturer" because Vivera adds "small" devices to the box.

59. Defendants' statement quoted in paragraph 58 above is misleading, as under 21 C.F.R. § 820.3, Vivera is appropriately listed as the manufacturer of the devices.

60. Moreover, Vivera contributed far more than "small devices," including the Rapid Test Kit's external controls as required by FDA, final quality control release, and conducted additional clinical validation tests required by the FDA, all of which could have been verified by Defendants.

61. In the Article, Defendants misquoted Dr. McColgan, stating that "[i]t's all FDA Confidential. We have a great test, that's all I can say."

62. Defendants' selective quotation of Dr. McColgan falsely suggested that Vivera was attempting to conceal information about the Tests from the

public.

63. The communications between an applicant, like Vivera, and the FDA were confidential, and, contrary to Defendants' statements, Dr. McColgan did not refuse to disclose the clinical performance of the Antibody Tests.

64. Defendants never requested performance or technical information for the Antibody Test from Vivera.

65. A reasonable person reading the Article would draw the false conclusion that Vivera was withholding information about the Tests from the public and government.

DEFENDANTS PUBLISHED THE ARTICLE INTENDING TO DAMAGE VIVERA'S REPUTATION

66. As the Article's lead editor, Amy Pyle, put it, Defendants' intent was to identify "red flags" that would cause them to look further into companies selling COVID-19 tests. (Pyle Depo., 50:19-51:5).[2]

67. The so-called "red-flags" Defendants were searching for had little to do with test reliability.

68. In the case of Vivera, Pyle testified the "red flag" was Edalat's past that drove Defendants to feature Vivera in the Article:

[2] References to the Deposition of Amy Pyle in the Related Litigation, which was taken on November 18, 2022, shall be as follows: (Pyle Depo, Pg. [Page: Line Number(s)]).

Q. What was it that made Vivera, the Vivera story, one of the crazy stories that should be featured?

A. I think -- I don't think that I said the companies were crazy. I think I was talking about craziest examples, but maybe I did. Anyway, I think one of the things that caused Vivera to become of interest to us was in particular that they had been in trouble with the FDA before.

Q. Vivera? I'm sorry, go ahead.

A. Paul Edalat had been --

MR. BOWMAN: Let the witness finish her answers. Let the witness finish her answer.

THE WITNESS: That Paul Edalat had been in trouble with the FDA before and that he was deeply involved with this company. That's the main thing that caused Vivera to come to our attention.

> And as we looked into it, there certainly were plenty of details.
>
> There were a lot of -- there was a lot of litigation by past investors and other things that also made it seem like one that we might want to feature.

(Pyle Depo, 84:6-85:6).

69. Defendants intended their readers to draw the conclusion that Vivera should not be producing COVID-19 tests based on false allegations surrounding the character of its CEO and false implications that Vivera deliberately withheld information surrounding the Tests.

70. In an email to the reporters, editor Steve Myers instructed reporters Heath, McCoy and Slack that the Article should: "cite the craziest stuff,". . . "male enhancement to vape pens," . . . "make the examples work to prove the point of that section," . . . "[w]e realize the risk of painting with too broad a brush, but we should use terms that describe people: serial entrepreneurs, opportunists, certainly newcomers to the field of medical testing, people working out of their homes."

71. Heath, the lead reporter on the Article, testified under oath at his deposition in the Related Litigation that the only negative information Defendants had on Vivera was that Edalat was its CEO:

Q And you didn't have anything negative on Vivera, the company, right?
A Well, we had -- we knew that Paul -- Paul Edalat was the CEO.
Q Outside of that, what negative information did you have about Vivera, the company?
A Well, at that time, well, nothing specifically.

(Heath Depo, pg. 66:11-18). [3]

72. Heath ultimately conceded that his "use of the negative information about [Edalat]," as the CEO of Vivera, "was intended to hold up Vivera in this position as an example of a company that had no business" developing COVID-19 tests:

Q So, is it then fair to say that your use of the negative information about Paul Edalat, because he was the CEO of Vivera, was intended to hold up Vivera in this position as an example of a company that had no business in this space that the FDA was allowing?
A Yeah. I think the reader could draw that conclusion.

[3] References to the Deposition of David Heath in the Related Litigation, which was taken on September 20, 2022, shall be as follows: (Heath Depo, Pg. [Page: Line Number(s)]).

Q Was that the intended conclusion?
A I think the fact that he was -- that the CEO of the company was barred from selling supplements by the FDA raised questions about the integrity of the CEO of Vivera, so that made Vivera questionable as a seller of antibody tests.
Q Was it the intended conclusion, sir?
A I just answered that question.
Q You did not. It's a yes or no question.
A Yeah. I -- yes. I think the reader could draw that inference.

(Heath Depo, Pg. 100:7-24).

73. Heath further conceded that he intended for a reasonable reader to draw the same conclusion:

Q -- hang -- hang on one second. That's a question only you can answer. I'm not asking how many readers concluded the same way you did, how many concluded differently. I'm asking what the author's intent was when he wrote it. And that's a question only you can answer. So again, was it your intent when you wrote that that the reader draw the same conclusion you did?
A I think a -- I think a reasonable reader would draw the same conclusion that I did.

Q And that was your intent that they reached that conclusion?
A It was -- it would be my intent that a reasonable reader would draw the same conclusion.
Q So you intended for readers to reach the same conclusion based on what you put in the story?
A I think that's a reasonable conclusion.

(Heath Depo, Pg. 104:7-23).

74. Heath's former colleague, McCoy, similarly acknowledged that he intended for readers to conclude that references to Edalat's conduct prior to his involvement with Vivera should be imputed to Vivera:

Q Why focus on the CEO of the company and his prior -- well, you acknowledge that the references in the opening paragraph are references to alleged conduct of Mr. Edalat prior to his involvement with Vivera, right?
A Yes.
Q Why include that information in the opening paragraph rather than information about the company itself?
A Because what he did in another company may

16 well have relevance to what he did or doesn't do with
17 Vivera.
18 Q. And you're, in fact, hoping the reader draws
19 that conclusion, right?
20 A. I think that we were trying to point that out,
21 yes.

(McCoy Depo, Pg. 66:6-21).[4]

75. Defendants' testimony shows they knew that the statements they made about Edalat in the Article falsely implied Vivera was an unethical company that should not be producing COVID-19 Tests.

76. At minimum, Defendants acted with reckless disregard to whether their statements about Edalat falsely implied that Vivera was an unethical company that should not be producing COVID-19 Tests.

WHEN CONFRONTED WITH THEIR FALSE AND MISLEADING STATEMENTS DEFENDANTS REFUSED TO WITHDRAW THE ARTICLE

77. On June 3, 2020, one day after Defendants published the Article, Vivera, through its counsel, delivered a letter to USA Today, specifying the false and misleading statements in the Article and demanding that USA Today "immediately cease and desist from any further publication, release or

[4] References to the Deposition of Kevin McCoy in the Related Litigation, which was taken on September 22, 2022, shall be as follows: (McCoy Depo, Pg. [Page: Line Number(s)]).

dissemination of the Article, that USA Today immediately retract the Article, remove any reference to Vivera or Edalat in the Article, or correct the Article to remove the false and misleading facts specified herein, and that USA Today issue a retraction of the statements cited herein."

78. On June 10, 2020, USA Today responded to Vivera's retraction request, refusing to retract the Article and to remove or correct the false and misleading statements about Vivera.

79. As of the filing of this Complaint, the statements about Edalat and Vivera remain available on USA Today's website.

80. Defendants achieved their intended effect of having Edalat's reputation reflect poorly on Vivera.

81. The same day the Article was published, on June 2, 2020, a senior FDA official, Timothy Stenzel, informed a Vivera representative, Bret Healy, via email that the FDA was opening an investigation into Vivera due to the Article's accusations and included a link to the Article as justification.

82. Communications with the White House senior officials ceased shortly after Defendants' publication of the Article.

83. Almost immediately upon publication of the Article, Vivera received customer inquiries about the veracity of the Defendants' statements and claims concerning Edalat's and Vivera's business practices and integrity,

resulting in the loss of significant business opportunities.

84. In particular, Vivera lost a Board member who resigned due to the Article's statements about the company.

85. As a result of the Article, Vivera's business reputation and business prospects have been damaged, amounting to damages in excess of $500 million.

COUNT I - DEFAMATION BY IMPLICATION

86. Plaintiff repeats and realleges the allegations contained in paragraphs 1 through 85 above, as though fully set forth herein.

87. Defendants published statements about Edalat intending to harm Vivera's reputation, lower Vivera's reputation in the estimation of the community, and to deter third parties from dealing with Vivera.

88. Defendants Heath and McCoy, in their capacity as reporters for USA Today, admitted under oath that they intended the readers to impute to Vivera any alleged misgivings about Edalat's character.

89. Defendant Heath further admitted that he intended for the readers to draw the conclusion that Vivera was unethical and should not be trusted because Edalat was its CEO.

90. Defendants could not find any negative information about Vivera, so they included the statements about Edalat to reflect poorly on Vivera and suggest that Vivera was managed by an unscrupulous individual and was

therefore unethical.

91. Even if the statements about Edalat were facially true, they were certainly not true as to Vivera, and were designed and intended by the Defendants to imply a defamatory meaning as to Vivera, by implication or through innuendo.

92. At least some of the injury arising from Defendants' statements was not a result only of what was said about Vivera, but also what was implied about Vivera because of statements made by Defendants regarding Edalat.

93. Defendants achieved their intended effect of having Edalat's reputation reflect poorly on Vivera and place Vivera's credibility into question.

94. In light of the circumstances prevailing at the time the statements were made by Defendants in the Article, the statements conveyed such defamatory implication to those who read them.

95. As a result of the Article, Vivera's business reputation and business prospects have been damaged, causing Vivera to lose investors, customers and a Board Member, among other things.

96. Vivera is entitled to damages for injury to its reputation.

97. Vivera is also entitled to special damages for the harm done to its business, trade and profession, including lost business opportunities and amounts of money Vivera expended as a result of the defamatory statements.

98. Defendants acted with reckless, wanton, willful, or callous disregard for Vivera's rights and with actual and constitutional malice toward Vivera, entitling Vivera to an award of punitive damages of not less than $350,000.

99. Defendants' testimony shows they knew that the statements they made about Edalat in the Article falsely implied Vivera was an unethical company that should not be producing COVID-19 Tests.

100. At minimum, Defendants acted with reckless disregard to whether their statements about Edalat falsely implied that Vivera was an unethical company that should not be producing COVID-19 Tests.

COUNT II - DEFAMATION

101. Plaintiff repeats and realleges the allegations contained in paragraphs 1 through 85 above, as though fully set forth herein.

102. Defendants published false, defamatory statements about Vivera, claiming that Vivera had withheld or concealed information about its Tests from the public and government regulators, which tended to harm Vivera's reputation, lower Vivera's reputation in the estimation of the community, and to deter third persons from dealing with Vivera.

103. Defendants also falsely published a statement claiming that Vivera had indicated on its website that its Antibody Test could be used to diagnose

active COVID-19 infections.

104. Defendants published the false statements set forth above in an unprivileged context which contained, directly or by clear implication, factual statements about Vivera that were false and defamatory.

105. Defendants published the false and defamatory statements negligently and with actual malice, common law malice, and constitutional malice.

106. Defendants knew that these statements were false and/or acted with reckless disregard for the truth of these statements.

107. The statements were made with a high degree of awareness of their probable falsity since they were informed prior to publication that their sources were unreliable.

108. As a result of the Article, Vivera's business reputation and business prospects have been damaged, causing Vivera to lose investors, customers and a Board Member, among other things, amounting to damages in excess of $500 million.

109. Vivera is entitled to general damages for its loss or reputation.

110. Vivera is also entitled to special damages for the harm done to its business, trade and profession, including lost business opportunities and amounts of money Vivera expended as a result of the defamatory statements in

accordance with proof at trial.

111. Defendants acted with reckless, wanton, willful, or callous disregard for Vivera's rights and with actual and constitutional malice toward Vivera, entitling Vivera to an award of punitive damages of not less than $350,000.

JURY TRIAL DEMAND

Plaintiff demands a trial by jury for all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, **VIVERA PHARMACEUTICALS, INC.,** requests that this Court enter judgment against Defendants, jointly and severally:

1. Awarding Plaintiff compensatory damages;

2. Awarding Plaintiff statutory maximum in punitive damages;

3. Awarding Plaintiff pre- and post-judgment interest;

4. Requiring retraction of the Article by Defendant;

5. Awarding Plaintiff its reasonable attorney fees and costs of this action; and

6. Granting Plaintiff such other and further relief as this Court deems just and proper under the circumstances.

Dated: June 2, 2023

Respectfully submitted,

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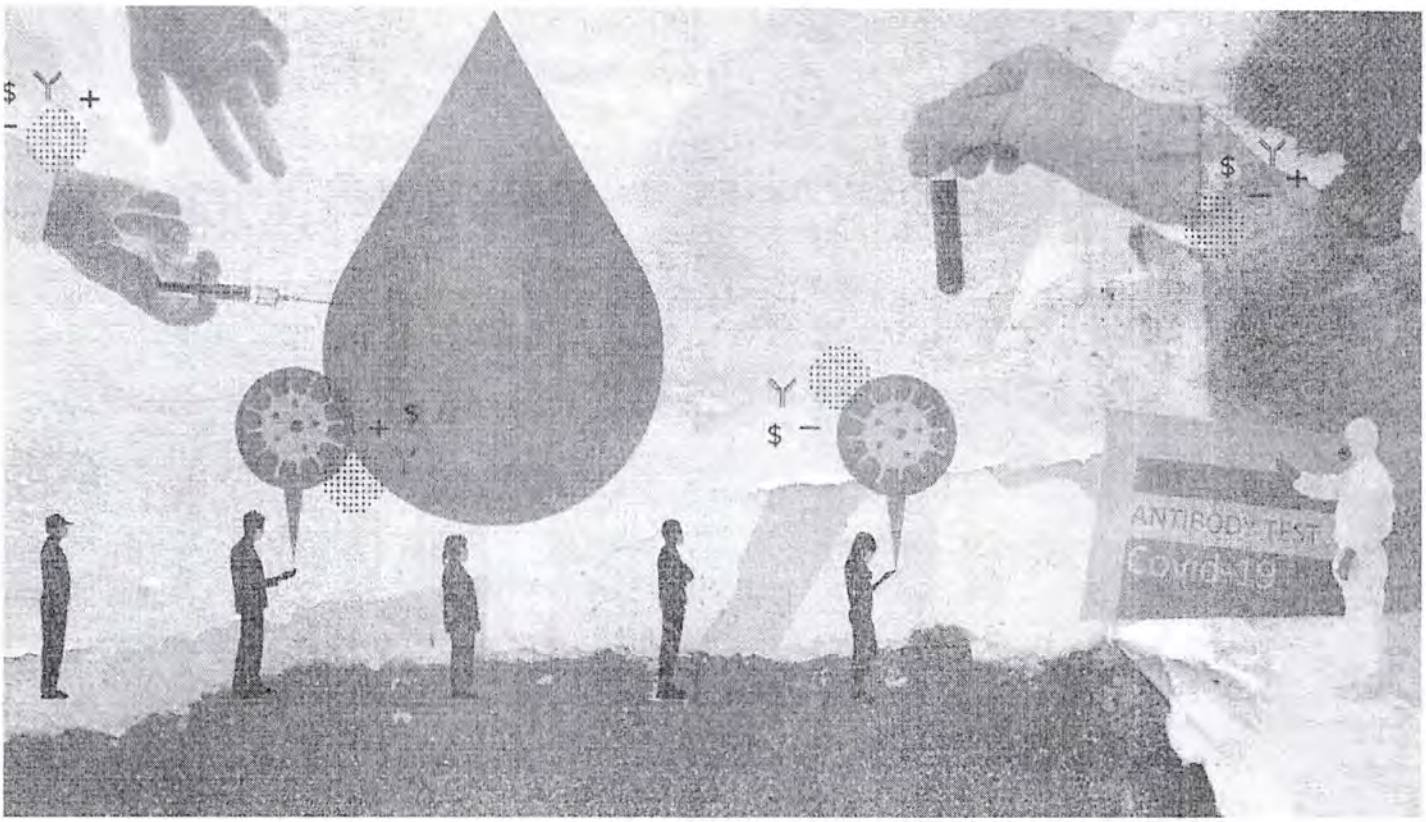
EXHIBIT “A”



'You could see the train wreck coming': Inexperienced, dubious companies among many aiming to cash in on coronavirus antibody tests

David Heath, Donovan Slack, and Kevin McCoy, USA TODAY

Investors accused him in court of deceiving them by driving a Rolls-Royce and wearing a gold Rolex to hide his bankruptcy. The Food and Drug Administration barred him from selling dietary supplements after his company failed a string of inspections.

Yet Paul Edalat's company, Vivera Pharmaceuticals, is one of more than 150 with the FDA's blessing to sell coronavirus antibody tests – tests that could become vital gatekeepers to reopening America.

For nine critical weeks during the pandemic, the agency exercised little of its power to decide which companies could sell blood tests aimed at detecting whether someone was previously infected. In that vacuum of oversight, USA TODAY — in the most thorough independent review to date — found a nascent industry with inexperienced or dubious companies jockeying to cash in.

For now, public health experts say antibody tests are valuable only for research and identifying plasma donors who could help those who are sick. But if scientists establish that having the virus leads to immunity, the tests could help people decide whether to return to work, socialize or travel. Relying on inaccurate tests poses grave risks.

The FDA's list of tests has included those from companies with little to no background in medical testing, including one that sells vape pens and one headed by a self-proclaimed technology evangelist. Like Vivera Pharmaceuticals, some have ties to the world of dietary and health supplements; one advertises a male enhancement powder.

At least five companies have claimed that their tests can be used to diagnose COVID-19, a violation of FDA guidelines. Another offers a do-it-yourself option.

"It could be easier than you think to build a COVID-19 test kit," it says.

Facing withering criticism, the FDA recently tightened its restrictions, requiring companies to submit data on their test's accuracy and how it will be marketed. In recent days, about 30 tests have been dropped from the FDA list, some of them voluntarily.

Coronavirus testing: How antibody tests work and why they are needed

The FDA's new rules spell out a process for evaluating the tests, but but not the manufacturers. As a result, even companies led by CEOs with a history of legal entanglements – including at least one with a criminal past – can sell tests.

Responding to USA TODAY's findings, the FDA said in a written statement that it takes fraud seriously and "continually monitors and conducts surveillance for fraudulent and inappropriately marketed medical products, including tests."

> **66**
>
> **We unfortunately have seen unscrupulous actors marketing fraudulent medical products, including drugs and test kits, using the pandemic as an opportunity to take advantage of Americans' anxiety**

> take advantage of Americans' anxiety.
>
> The Food and Drug Administration in a written statement

TWEET SHARE

"We unfortunately have seen unscrupulous actors marketing fraudulent medical products, including drugs and test kits, using the pandemic as an opportunity to take advantage of Americans' anxiety," the agency said.

Scott Becker, CEO of the Association of Public Health Laboratories, said lab representatives were on a conference call with the FDA in March. As the agency outlined its initial plans to allow virtually all comers to sell antibody tests, he said, "You could see the train wreck coming."

'FDA confidential'

On social media and in company news releases, Paul Edalat portrays himself as a jet-setting chief executive officer. He has appointed former professional athletes to the advisory board of Vivera Pharmaceuticals.

Currently, the only other products Vivera sells are gel pads to relieve scarring. On March 22, the company applied with the FDA for an emergency-use authorization to sell antibody tests. That approval is far less rigorous than the normal FDA review of new medical products, an approach the agency chose to speed up testing in the pandemic.

Vivera's chief medical officer, Stephen McColgan, told USA TODAY he expects approval soon.

The FDA now requires all companies to reveal the results of validation tests to the agency. Many companies post accuracy numbers on their websites. Vivera does not – and when asked about the test's accuracy, McColgan was reluctant to answer.

> **It's all FDA confidential. We have a great test, that's all I can say. There's no reason your readers need to hear this because they don't have the level of knowledge to understand.**
>
> Stephen McColgan, Vivera's chief medical officer

"It's all FDA confidential," he said. "We have a great test, that's all I can say. There's no reason your readers need to hear this because they don't have the level of knowledge to understand."

Later McColgan offered rough estimates of the test's accuracy, describing it as "very high."

Vivera's antibody test is made by a German company Edalat identified as PharmACT. That company has not applied with the FDA. But because Vivera adds small devices to the test box, including lancets to prick fingers, Edalat contended "the FDA looks at us more as the manufacturer."

A screenshot of Vivera's website.

USA TODAY PHOTO ILLUSTRATION

The FDA declined to discuss specific companies but said manufacturers should be the ones applying for emergency-use authorization, naming their distributors in their application.

Edalat has a history with the FDA. In 2014, the agency went to court to stop his company, SciLabs Nutraceuticals, from selling dietary supplements, alleging the products had not been tested to ensure they contained only dietary ingredients. At the time, Edalat said: "We would rather work with the FDA than fight them; they play a critical role in consumer safety."

Just before the Justice Department issued a permanent injunction on behalf of the FDA, SciLabs went under and Edalat declared Chapter 7 bankruptcy. Months later, four investors allege Edalat persuaded them to put $2 million into a company called Pharma Pak Inc., whose products included the controversial hemp product CBD oil.

The investors filed suit, saying they didn't know Edalat was not allowed to sell supplements.

"Defendant Paul Edalat is a fraud," the investor lawsuit alleges. It contends he tried to fool investors with his extravagant lifestyle: staying in luxury suites, "wearing a diamond-studded gold Rolex watch which he brags that he purchased for more than $50,000," and "driving fancy cars, including two Rolls-Royces, three Lamborghinis, a Land Rover, a BMW, a Ferrari, and a Hummer, among others."

The suit went before a federal jury, which found that Edalat defrauded and libeled some of the investors. He was ordered to pay them $880,000.

In a case still awaiting trial, Alternate Health Inc. alleges Edalat told a series of lies to ink a 2017 agreement worth $4.2 million to sell a cannabis supplement. The Canadian company claims Edalat said he could mass produce the product and didn't reveal he was barred from doing so.

Edalat is pursuing counterclaims against some of the plaintiffs who sued him in the Pharma Pak case, federal court records show. An appeal in that case also is pending. Edalat similarly filed a counterclaim in the Canadian company case, which court records show is awaiting a scheduled Sept. 29 trial date.

When USA TODAY asked Edalat if the FDA had expressed concern about his history, he said, "No, not at all." The ongoing agency injunction, he said, involved a different branch of the FDA: Supplements are considered food, while antibody tests are medical products.

The FDA declined to say whether such an injunction would prohibit a company from selling an antibody test, stating it would depend on the terms of the enforcement action.

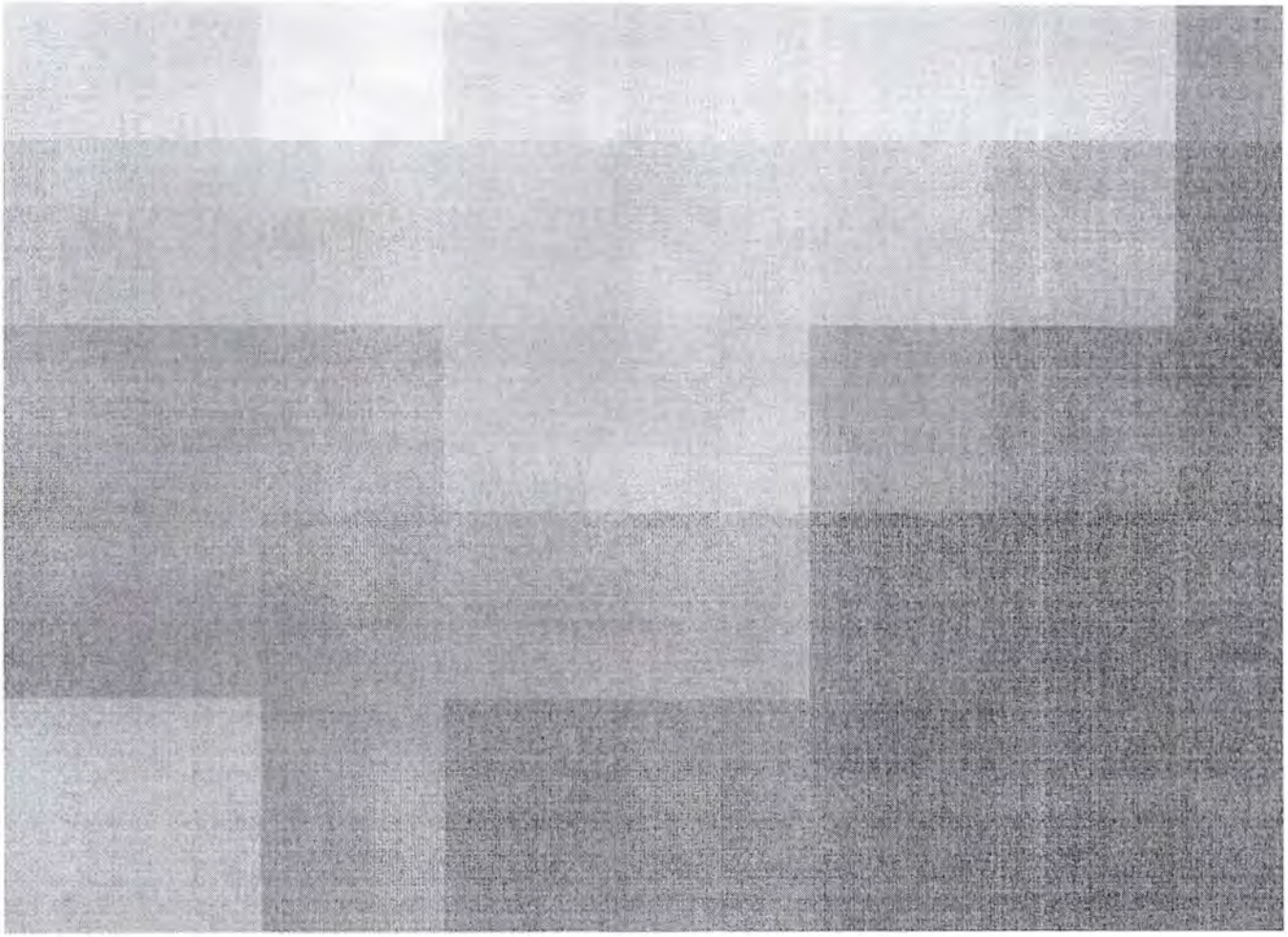
Edalat added that he now suspects there was foul play in the FDA's inspections of his previous company and he is "investigating the investigators."

Vivera is distributing samples of its test to places like nursing homes and hospitals, Edalat said. On its website, the company links to a local TV newscast of a firefighter in Hillside, New Jersey, being tested that includes a closeup of a Vivera test box. The doctor who administered that test told USA TODAY Vivera was one of 10 companies that sent him antibody tests to try out.

'We are businessmen. We see a need.'

Experience in medical testing is not a prerequisite to dive into that world today, thanks to the lax FDA rules for antibody tests.

On its website, Jiangsu Eubo Biotechnology Co. offers male enhancement powders, human growth hormones, anti-hair loss powders, steroids and, until the FDA dropped it from the authorized list on May 21, rapid COVID-19 tests. The company's website features an illustration of barely dressed male and female fitness models. An email sent to the Chinese company bounced back.



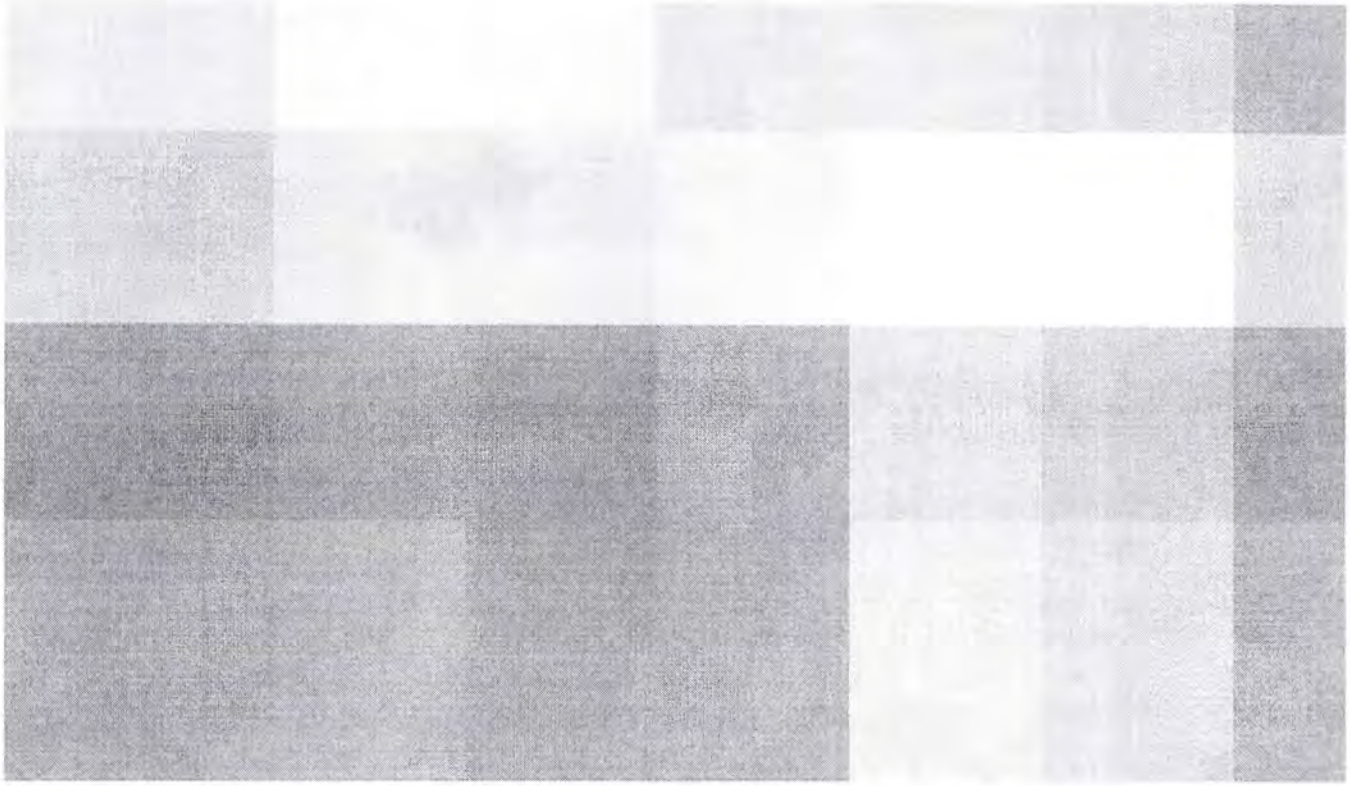
A screenshot of Jiangsu Eubo Biotechnology Co.'s website, where it offers male enhancement powders, human growth hormones, anti-hair loss powders, steroids and, until the FDA dropped it from the authorized list on May 21, rapid COVID-19 tests.

USA TODAY PHOTO ILLUSTRATION

In February, another company, Naturitious, sprang up in California. Owner Danny Xu said he had previously manufactured dietary supplements along with test strips to detect ketosis for low-carb dieters. Producing antibody test kits, he told USA TODAY, is a "pretty similar" process.

Xu said his company has manufactured and shipped 200,000 test kits so far, mostly overseas. The Naturitious website cautions that they are for "professional use only by clinical laboratories and healthcare workers." It offers an option for customers to buy parts and build their own kits.

Xu said he got into the antibody test business because he wanted to "do something helpful in this pandemic." But, he said, it's too complicated for a long-term commitment.



A screenshot of the Naturitious website, which offers an option for customers to buy parts and build their own antibody test kits.

USA TODAY PHOTO ILLUSTRATION

"Working with FDA is hard," he said. "Dealing with customers is also hard."

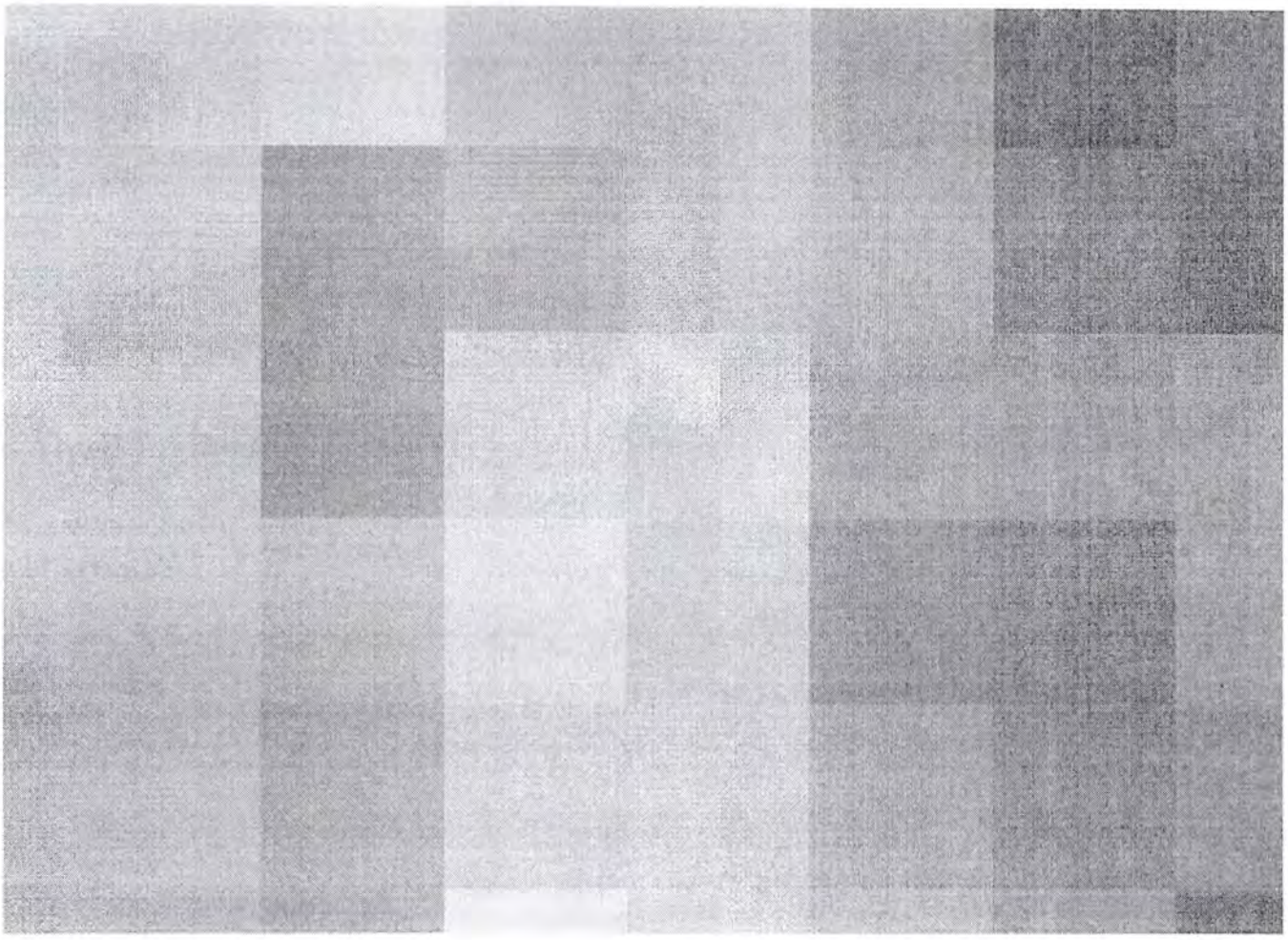
After USA TODAY contacted Xu, a new section appeared on his company's home page featuring smiling employees in white coats and scrubs alongside placeholder text that reads: "position/role." The images actually are stock photos, some of them available for sale online.

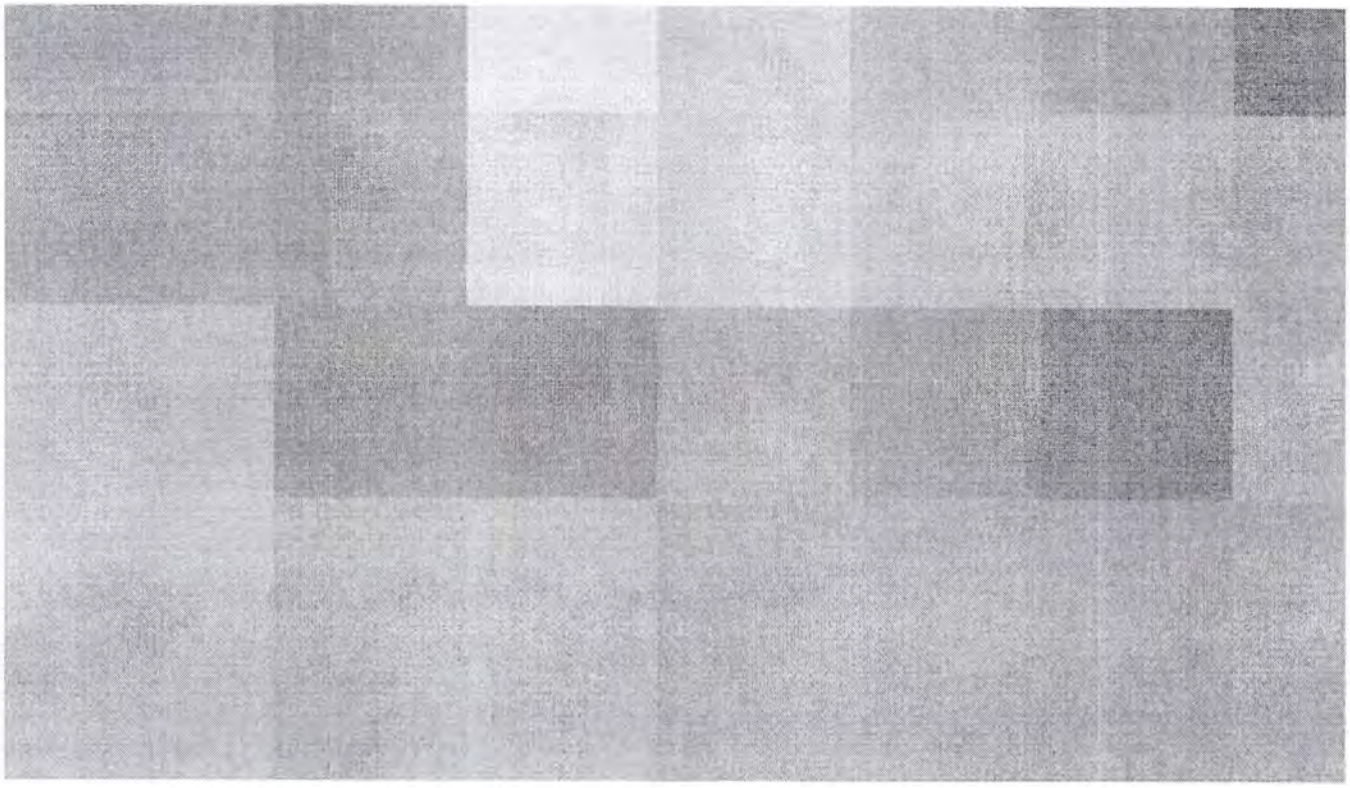
Pacific Connect Group LLC, based in Hong Kong, is run by a physical therapist for the Chinese Olympic Committee. He teamed up with a recent graduate of Rice University who worked briefly for a hardware design company and started a business to automate airport baggage checking.

Company president Jason Wong and Zach Bielak, his vice president of operations, are now selling N95 and surgical masks.

"We are not doctors. We are not medical specialists. We are businessmen. We see a need," Bielak said.

The duo pledged not to sell their tests unless they get the FDA's emergency-use authorization.





A screenshot of a Telepoint testing booth.

USA TODAY PHOTO ILLUSTRATION

The Arizona registration of a new company, Telepoint Medical Services LLC, was approved Dec. 31, the day the World Health Organization was notified about pneumonia cases of unknown cause in Wuhan, China.

Telepoint's website offers N95 masks, a rapid coronavirus diagnostic test kit, walk-up testing booths and instructions for using its coronavirus antibody test. It gives no information on the test's accuracy or performance.

Telepoint is run out of a shopping center in Phoenix, according to registration documents filed in Arizona. Larry Witherspoon, listed as the company's agent, is identified on Telepoint's website as its owner and managing partner.

Witherspoon's biography on the website of an organization called the African American Business Foundation says he's a serial entrepreneur and "technology evangelist" whose ventures have included FaithPhone Wireless and the digital NuGospel Network. He did not respond to messages left with a Telepoint sales employee.

Not a test to diagnose COVID-19

The FDA requires manufacturers to make it clear that antibody tests should not be used to diagnose active COVID-19, the disease caused by the coronavirus. But at least five companies with antibody tests still on the FDA list say their tests can be used that way. Two corrected their claims after being contacted by USA TODAY last week.

Antibodies don't show up in the blood immediately when a person is infected. So a test that typically uses a nasal swab to gather mucous is used to diagnose COVID-19.

The FDA says when it becomes aware of fraudulent claims regarding antibody tests, it will "take appropriate action, including criminal or civil action." The agency requires disclaimers by companies, including, "Results from antibody testing should not be used to diagnose or exclude acute SARS-CoV-2 infection."

Genrui Biotech's website says "the disease can be screened and diagnosed" with its antibody test.

Genrui Biotech's website says "the disease can be screened and diagnosed" with its antibody test.

USA TODAY PHOTO ILLUSTRATION

Genrui Biotech Inc. of China says on its website that "the disease can be screened and diagnosed" with its antibody test. Another Chinese company, H-Guard Co., says its test for one antibody "is used as a marker for acute infectious diagnosis."

Boston BioPharma also describes its test as being for diagnostic use. After USA TODAY pointed out the language, a spokesman said the company would revise its wording. Vivera Pharmaceuticals makes the claim, too, although it does include the FDA disclaimer on its site.

Singapore-based Sensing Self presents its test as a pre-screening tool – a finger-prick blood test individuals can administer themselves before deciding if a lab test is warranted. The site blares in a pop-up message that the company has the "world's first COVID-19 Pre-screening test," with results in 10 minutes.

On its product page, Sensing Self also said its test is for diagnostic use, and detecting antibodies "is an effective method for the rapid diagnosis of COVID-19 infection." It adds: "No lab visits, no doctors Just one finger prick of blood."

A screenshot of Sensing Self's COVID-19 antibody test kit.

USA TODAY PHOTO ILLUSTRATION

Company co-founder and CEO Shripal Gandhi said Sensing Self has sold a "pretty significant quantity across the world" but declined to say how many or where. He said the company has focused on Europe and Asia and now is working with prominent U.S. universities.

Following inquiries from USA TODAY, the company changed the language on its product page.

"We thank you for alerting us," Gandhi said, "and we have updated the word 'diagnostics' to 'screening.'"

Know someone who plans to take an antibody test? Share this story

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Company backgrounds not obvious to customers

CoronaCide LLC registered as a company on March 23 in Utah and weeks later in Florida, offering 10-minute antibody tests. Its website says demand is so high that the company accepts only bulk orders.

What potential customers wouldn't find there is company creator Edward Joseph Eyring II's past.

Once a colorectal surgeon, Eyring agreed to be barred from renewing his medical license in 2012, about five years after Utah's professional licensing division investigated him for patient treatment, state records show. Anton Hopen, an attorney representing CoronaCide in a lawsuit against a competitor, said Eyring allowed his medical license to expire.

In one case, rectal and colon surgery for a 37-year-old man was interrupted for emergency repair of a vein lacerated during the operation, the records show. The man underwent two more surgeries by Eyring and died after the third procedure.

Eyring admitted to the state that during those two years he "engaged in unprofessional conduct … when he violated generally accepted professional and ethical standards … by making clinical procedural errors and by providing inadequate medical documentation."

The attorney general separately investigated Eyring for a series of investment schemes. One involved a $37,000 loan he received from a former patient to help him renew his medical license. Instead, Eyring used the funds for personal expenses, state investigators allege.

In August 2018, Eyring entered a guilty plea to a pattern of unlawful activity, a felony. His prison term was suspended, and he agreed to pay a fine and interest totaling nearly $20,000.

Although CoronaCide is included on the FDA's list of antibody test manufacturers, Hopen said in an email it's actually a distributor. He said CoronaCide had registered as a distributor "for complete transparency."

In some cases, the websites of companies on the FDA list offer clues to customers only because the information they provide is so sparse.

The website for Carlsbad, California-based Axium Bioresearch says it is a leading provider for toxicology, women's health and health prevention testing. Last month, its website said nothing about a coronavirus antibody test.

Antibody tests remain unproven

Antibody tests shouldn't determine who can return to work, warns CDC →

Coronavirus antibody tests are available around the country. Here's why they may provide a false sense of security. →

FDA tightens oversight of blood tests used to detect coronavirus antibodies →

Antibody tests were supposed to help guide reopening plans. They've brought more confusion than clarity. →

Unproven tests. Inaccurate results. Public health labs worry 'bad data' could taint US recovery from coronavirus crisis. →

After a USA TODAY reporter asked about the
omission, the company updated its website to feature a microscopic image of the coronavirus and a link to inquire how much the test costs. Friday, around the time of a USA TODAY interview with company president Sergius Albert Salvatore, access to the website changed again and required a password.

Salvatore said he learned about medical tests by working with research labs in China. His small company receives antibody test components from partners there, he said.

Axium adds other components to create rapid-result testing kits for sale through distributors to hospitals and medical facilities in Latin America, Salvatore said, but the customers won't buy unless the tests have FDA approval.

"In no way do I say I'm a scientist," he said. "I have scientists who are on board in China."

The Michigan Attorney General claims VitaStik, which was taking orders for at-home antibody tests, was running a scam. The FDA had never allowed at-home tests and specifically forbade them on March 20.

The Michigan Attorney General claims VitaStik, which was taking orders for at-home antibody tests, was running a scam. The FDA had never allowed at-home tests and specifically forbade them on March 20.

USA TODAY PHOTO ILLUSTRATION

In Michigan, the state attorney general says VitaStik, which was taking orders for at-home antibody tests, was running a scam. The FDA had never allowed at-home tests and specifically forbade them on March 20.

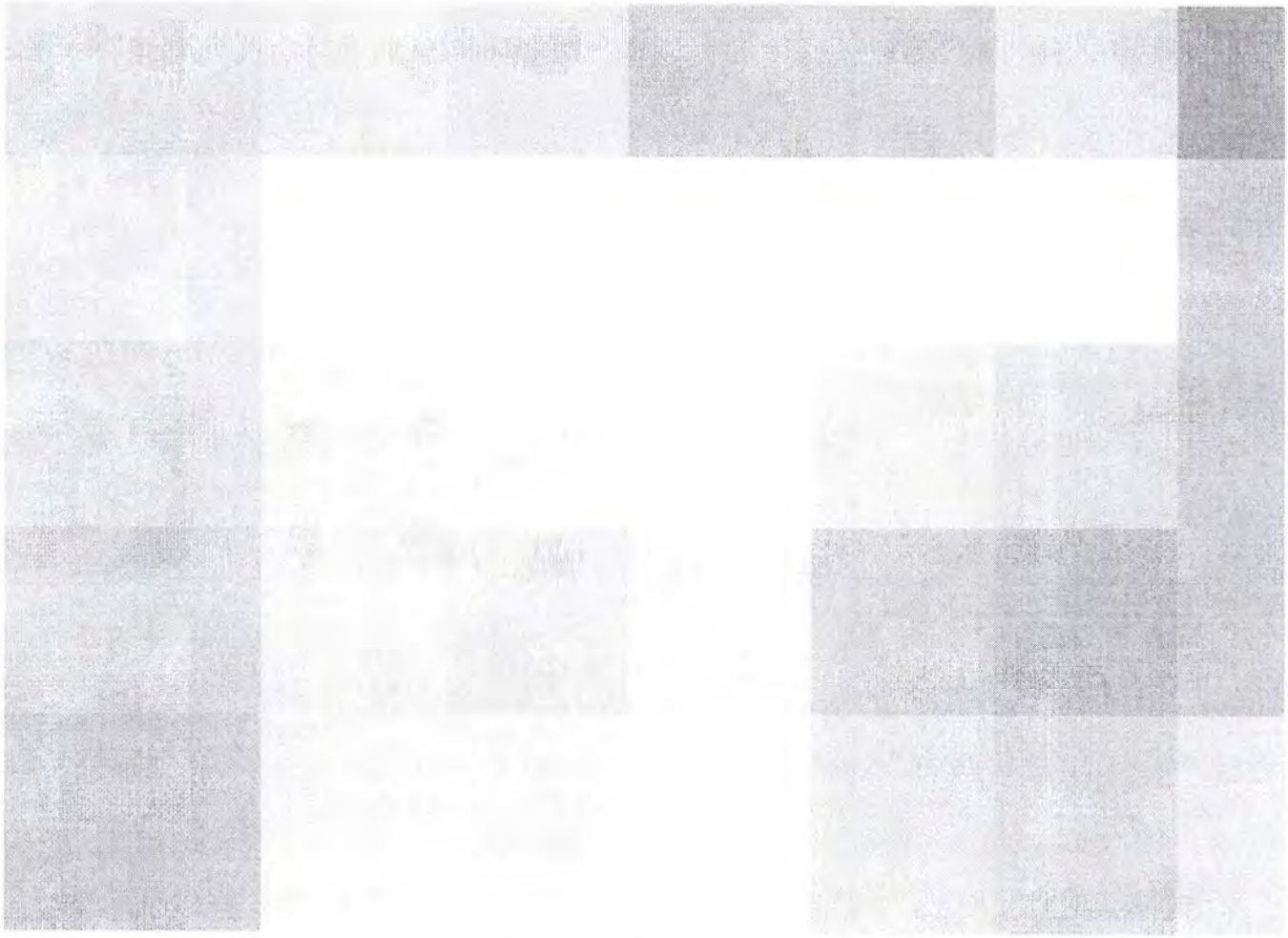
On April 1, VitaStik – which specializes in vaping devices for vitamins and essential oils – was ordered to stop.

"False reliance on whatever test strips you are selling could have deadly consequences for both those who buy them and their loved ones," Michigan Assistant Attorney General Darrin Fowler wrote.

Ten days after the attorney general's order, VitaStik's owner set up a new company, Vita Testing, to sell rapid antibody tests. The FDA added it to the list of companies that could sell in the U.S.

Vita Testing's website offered 100 tests for $3,500. It warned they could be sold only to labs certified to perform complex testing and associated medical providers, but it offered to notify people when at-home tests are available.

"We are listed on the FDA.gov website, and so is our test," the company assured.



A screenshot of Vita Testing's website, offering rapid antibody tests.

USA TODAY PHOTO ILLUSTRATION

Vita Testing was among those dropped from the FDA list on May 21. The next day its website went offline.

In an email to USA TODAY, company owner Alfred Santos didn't explain why he created the new company after Michigan ordered his previous one to stop selling tests there. But he said none of the tests sold in Michigan was shipped and the money was refunded.

A spokesman for the Michigan Attorney General's Office, Ryan Jarvi, said: "The purchase our special agent had made under a different name was refunded," and the office planned no further action, aside from sharing information with "other law enforcement agencies that have expressed interest in this target."

Santos wrote in his email that he is "ACTIVELY working" with the FDA and still hopes to get emergency-use authorization for his antibody tests to be used in labs, health care settings and, one day, homes.

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