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VIVERA PHARMACEUTICALS, INC.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

VIVERA PHARMACEUTICALS, INC., a Delaware corporation, Plaintiff, vs. GANNETT CO., INC., a Delaware corporation; GANNETT MEDIA CORP., a Delaware corporation; GANNETT SATELLITE INFORMATION NETWORK, LLC, d/b/a USA TODAY, a Delaware limited liability company; DAVID HEATH, an individual; KEVIN MCCOY, an individual; MICHAEL REED, an individual; PAUL BASCOBERT, an individual; DONOVAN SLACK, an individual; KEN ALLTUCKER, an individual; MARIBEL WADSWORTH, an individual; THOMAS CURLEY, an individual; and DOES 1 through 20, inclusive, Defendants.	Case No.: **PLAINTIFF VIVERA PHARMACEUTICALS, INC.'S COMPLAINT FOR DAMAGES FOR:** **(1) DEFAMATION** **(2) TRADE LIBEL** **(3) INTENTIONAL INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE** **(4) NEGLIGENT INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE** **DEMAND FOR JURY TRIAL**

Plaintiff VIVERA PHARMACEUTICALS, INC. ("Plaintiff" or "Vivera"), complains and alleges as follows in this Complaint against Defendants GANNETT CO., INC. ("Gannett"), GANNETT MEDIA CORP. ("Gannett Media"),

GANNETT SATELLITE INFORMATION NETWORK, LLC d/b/a USA TODAY ("USA Today"), DAVID HEATH ("Heath"), KEVIN MCCOY ("McCoy"), MICHAEL REED ("Reed"), PAUL BASCOBERT ("Bascobert"), DONOVAN SLACK ("Slack"), KEN ALLTUCKER ("Alltucker"), MARIBEL WADSWORTH ("Wadsworth"), THOMAS CURLEY ("Curley"), and Does 1 through 20 (collectively "Defendants"), as follows:

INTRODUCTION

1. This case involves a news publication with a waning subscriber base and its attempt to manufacture a story relating to the coronavirus and purportedly faulty antibody tests to "cash in" on the global pandemic. To that end, Defendants attacked Vivera by focusing on years-old, false allegations made against its CEO Paul Edalat ("Edalat") by Edalat's former business partner and his agents as part of their public disparagement campaign against Edalat that they initiated in 2016 during a federal court case, as well as resulting publications that were later retracted. By doing so, Defendants acted more like opposing parties in litigation with Edalat, instead of investigative reporters. Notably, although Defendants' article purportedly criticizes antibody tests, Defendants do not directly attack the quality of Vivera's tests. Indeed, as explained below, Vivera's antibody tests are highly accurate and validated, having undergone analytical and clinical testing prior to submission to the Food and Drug Administration ("FDA"). Despite being presented with the true facts about Vivera and its antibody tests, Defendants refused to retract or correct the article. As a result, Vivera has been harmed in excess of $500 million.

THE PARTIES

2. Plaintiff 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.

3. Plaintiff is informed and believes, and on that basis alleges, that Defendant Gannett is, and at all times relevant hereto was, a Delaware corporation,

with its principal place of business in the state of Virginia, and that regularly conducts business within the state of California.

4. Plaintiff is informed and believes, and on that basis alleges, that Defendant Gannett Media is, and at all times relevant hereto was, a Delaware corporation, with its principal place of business in the state of Virginia and that regularly conducts business within the state of California. Upon information and belief, Gannett Media is the corporate parent of USA Today and is a wholly-owned subsidiary of Gannett.

5. Plaintiff is informed and believes, and on that basis alleges, that Defendant USA Today is, and at all times relevant hereto was, a Delaware limited liability company, with its principal place of business in the state of Virginia and that regularly conducts business within the state of California, that has offices in California, and that publishes content on its website, www.usatoday.com and on social media accounts, such as Twitter. Upon information and belief, Gannett is the managing member of USA Today.

6. Plaintiff is informed and believes, and on that basis alleges, that Defendant Heath is, and at all relevant times was, a reporter for Gannett, Gannett Media and USA Today.

7. Plaintiff is informed and believes, and on that basis alleges, that, at all relevant times, Defendant McCoy is, and at all relevant times was, a reporter for Gannett, Gannett Media and USA Today.

8. Plaintiff is informed and believes, and on that basis alleges, that Defendant Reed is, and at all relevant times was, the President, Chief Executive Officer and Board member of Gannett.

9. Plaintiff is informed and believes, and on that basis alleges, that Defendant Bascobert was, at all relevant times, the President, Chief Executive Officer and Board member of Gannett Media.

10. Plaintiff is informed and believes, and on that basis alleges, that Defendant Slack is, and at all relevant times was, a reporter for Gannett, Gannett Media and USA Today.

11. Plaintiff is informed and believes, and on that basis alleges, that Defendant Alltucker is, and at all relevant times was, a reporter for Gannett, Gannett Media and USA Today.

12. Plaintiff is informed and believes, and on that basis alleges, that Defendant Wadsworth is, and at all relevant times was, President of News and Publisher of USA Today.

13. Plaintiff is informed and believes, and on that basis alleges, that Defendant Curley is, and at all relevant times was, associate General Counsel for Gannett, Gannett Media and USA Today.

14. Plaintiff is ignorant of the true names and capacities of defendants, sued herein as DOES 1 through 20, inclusive, and therefore sues these defendants by such fictitious names. Plaintiff will amend this complaint to allege their true names and capacities when ascertained. Plaintiff is informed and believes and thereon alleges that each of these fictitiously named defendants is responsible in some manner for the occurrences herein alleged and/or that Plaintiff's damages as herein alleged were proximately caused by their conduct. Defendants Gannett, Gannett Media, USA Today, Heath, McCoy, Reed, Bascobert, Slack, Alltucker, Wadsworth, and Curley and DOES 1-20 shall collectively be referred to hereafter as "Defendants."

15. Plaintiff is informed and believes and thereupon alleges that, at all times herein material, Defendants, and each of them, was, were and are the agents, representatives, servants, alter egos or employees of the other Defendants, and each of them conspired with the remaining Defendants in doing the wrongful conduct herein alleged and were acting within the course and scope of said agency and/or employment or conspiracy, with the knowledge and consent of each other Defendant and all of them jointly.

JURISDICTION AND VENUE

16. Jurisdiction in this court, pursuant to 28 U.S.C. § 1332, as the action is between citizens of different states and the matter in controversy exceeds $75,000.00.

17. Venue is proper in this court, pursuant to 28 U.S.C. § 1391(b)(2), as a substantial part of the events or omissions giving rise to the claim occurred in this district.

GENERAL ALLEGATIONS

Vivera's US-Manufactured COVID Antibody Test

18. With over 28 years of experience developing products and brands in the nutraceutical and pharmaceutical industries, Edalat formed Vivera in April 2018 and is currently its Founder, CEO and Chairman. Vivera is an innovative, science-driven pharmaceutical company that is focused on developing novel therapies utilizing its patented and provisionally patented, pharmaceutical sublingual delivery system, pharmaceuticals, and medical devices. Vivera works with internationally renowned Contract Research Organization ("CRO") Parexel to conduct its clinical trials.

19. In response to and in an effort to address the COVID-19 global pandemic, Vivera brought to market two SARS-CoV-2 antibody screening tests. Antibody tests detect the body's immune response to infection. Such tests are easy to administer, requiring no complex equipment or specialized training, and produce rapid results.

20. In late March 2020, Vivera filed the first of its Emergency Use Authorization ("EUA") packages with the FDA for its German-sourced COVID-19 Rapid Test kits ("Rapid Test kit"). Vivera worked, and continues to work, closely with the FDA in review of the submission and validation data. Each submission package contains comprehensive validation as required by the FDA.

21. In May 2020, Vivera began nationwide delivery of its Rapid Test kits for use by qualified CLIA laboratories under the FDA and EUA guidelines. Vivera posts on its website the test specification data for the COVID-19 Rapid Test and makes its validation and technical data information readily available upon request.

22. In May 2020, Vivera filed two patents with the United States Patent and Trademark Office ("USPTO") for its line of antibody tests.

23. On June 4, 2020, Vivera filed its second EUA package with the FDA for its "Made in the USA" serology antibody test. This second test, COVx-RT, is manufactured completely in the United States, and Vivera has submitted clinical studies for Point of Care Authorization from the FDA. Again, Vivera's team works closely with the FDA to ensure complete compliance with the Guidelines set forth for Emergency Use Authorizations.

24. Additionally, Vivera voluntarily took part in the National Cancer Institute ("NCI") backed validation studies, submitting both its COVID-19 Rapid Test and COVx-RT rapid test products for validation testing in May and June, 2020, respectively, as soon as the pathway was made available to Vivera. The results from this FDA/NCI partnership are publicly posted on the FDA's website.

25. With the capacity to manufacture millions of tests per week, Vivera is ready to widely distribute its antibody test kits upon FDA-authorization. As a non-Chinese, Made in the USA test that has analytical and clinical validation, and is pending validation via NCI, Vivera's antibody tests have had tremendous interest from numerous third parties, including high-level government agencies and the Tribal Nations. Yet, due to the false and misleading statements about Vivera that Defendants published, as described below, Vivera is facing losses in excess of $500 million.

Defendants Initiate a Meritless Attack on Vivera

26. On June 2, 2020, Defendants published an article on the www.usatoday.com website, entitled "'You could see the train wreck coming':

Inexperienced, dubious companies, among many aiming to cash in on coronavirus antibody tests" (the "Article"). A copy of the Article is attached as **Exhibit A**. That same day, Defendants included a link to the Article on Twitter through Alltucker's account and his over 2,300 followers, with this misquote from the Article attributed to Vivera's chief medical officer Stephen McColgan: "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." Defendants Heath, McCoy, Slack and Alltucker of USA Today are identified as the reporters for this Article. Upon information and belief, each of the individual defendants, including but not limited to Reed, Bascobert and Curley, had supervisory authority over Gannett's and USA Today's reporting and editorial staff, and each of the Defendants had a responsible role in writing, reporting and publishing the false and misleading statements about Vivera. As explained below, Defendants' Article contains numerous false and misleading statements about Vivera, its antibody tests and its CEO Mr. Edalat.

27. Although the Article purportedly reports on "inexperienced, dubious companies," Defendants centered its attack on Vivera on false and misleading statements about its CEO Edalat. For example:

a. Defendants' Article states that "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." This is false and misleading.

The true fact is that Vivera has never issued a press release depicting Mr. Edalat as a jet-setting chief executive.

Moreover, by making these statements together, Defendants are implying that Edalat chose advisory board members to support his image. Defendants make no mention of the PhD's, scientists, medical

doctors and other professionals on Vivera's executive staff and advisory board.

b. In the Article, Defendants state that: "Paul 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 "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." These statements are false and misleading.

None of these statements are in reference to Vivera or its antibody tests. Instead, the statements are rehashed allegations of one-sided accusations made by Edalat's former partner Bruce Cahill ("Cahill"), his Boston-based lawyer, John Markham II ("Markham") and their public relations firm Denterlein Worldwide, Inc. ("Denterlein"), as part of their public disparagement campaign against Edalat that began in 2016 during Cahill's federal court litigation with Edalat.

Notably, many of the statements in Defendants' Article, including the allegations about Edalat's watch and cars, his personal bankruptcy, Edalat's social media accounts, and the alleged bar from selling dietary supplements, come from this disparagement campaign against Edalat. For example, they were contained in a pitch letter, drafted in 2016 by Cahill, Markham and attorneys in his firm, and Denterlein and were repeated in an article and press releases in 2016

and 2017, all of which were retracted before Defendants published the Article. The pitch letter itself was an attack piece against Edalat that called him a "snake oil" salesman. While Cahill hired Denterlein to pursue a public disparagement campaign against Edalat both during and after his federal court litigation with Edalat, the pitch letter went beyond that lawsuit, sought to portray Edalat in a way that would generate media interest, and was sent to numerous publications. Defendants' use of these one-sided portrayals about Edalat, in order to harm Vivera, was actionable, reckless and malicious.

Defendants' statements imply that Cahill was completely vindicated by the jury verdict, which is not true. Had Defendants fully investigated the jury verdict, they would have learned that Edalat obtained a $250,000 award against Cahill for breach of fiduciary duty and fraud. Defendants' mischaracterization about the verdict mirrors statements in a Denterlein press release, dated September 18, 2017, titled "Markham & Read Announces Total $880,000 Federal Jury Award to Orange County Businessman Bruce Cahill and Co-Defendants Following Verdict of Fraud and Libel Against Paul P. Edalat." This press release, however, has been retracted.

According to public records that were available to Defendants prior to publishing their Article, Denterlein agreed to retract the press releases it published during its public disparagement campaign against Edalat, including the September 18, 2017 press release, and paid a settlement in excess of $450,000.00 to Edalat in or about October 2019. By doing so, Denterlein acknowledged the falsity of its statements about Edalat. Defendants should have been aware of these retractions, as well as the retraction of the 2016 article in the New Hampshire

Union Leader, before publishing false and misleading statements about Edalat that repeated the previously retracted allegations.

c. Defendants' Article states that "The Food and Drug Administration barred him from selling dietary supplements after his company failed a string of inspections." This statement is false. Notably, the same false allegation - that Edalat is barred from doing business in the nutritional supplement industry - appears in the 2016 pitch letter.

The true fact is that Mr. Edalat has not been "barred" from selling dietary supplements. He 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.

d. Defendants' Article continues by stating that "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." This statement is false.

These false allegations are made by Alternate Health, who is represented by the same Boston-based lawyer who represents Cahill in his litigation with Edalat, John Markham, who has been in litigation with Edalat since August 2019, in a case entitled *Paul Edalat v. John J.E. Markham, II, et al.* (Los Angeles Superior Court case no. 19NWCV00652). Accordingly, this is not a credible or reliable source for Defendants' statements.

Further, as explained above, Mr. Edalat was not barred from selling dietary supplements.

e. In the Article, Defendants state that "even companies led by CEOs with a history of legal entanglements… can sell tests." Defendants' statement refers to Edalat, who is the only CEO referenced in Defendants' article with a history of "legal entanglements."

This statement is false and misleading by implying that, because an opposing party in litigation made false and misleading accusations about Edalat and accused Edalat of fraud, there must be something wrong with Vivera's antibody tests.

28. In Defendants' Article, in addition to harming Vivera through its statements that rehash old accusations made by a litigant to disparage Edalat, Defendants made false and misleading statements about Vivera. For example:

a. Defendants' Article states that "The FDA now requires all companies to reveal the results of validation testes to the agency. Many companies post accuracy numbers on their website. Vivera does not – and when asked about the test's accuracy, McColgan was reluctant to answer." This is false.

The true facts are that Vivera's website posts accuracy numbers, Vivera has revealed all validation testing to the FDA and works closely with the FDA, and Vivera is voluntarily participating in the independent validation NCI pathway.

b. Defendants' Article 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." This is false.

The true fact is that Vivera does not make a claim on its website that its antibody tests can be used to diagnose active COVID-19. Had the Defendants simply looked at the FDA's own website for COVID-19

related medical devices, they would clearly see that the FDA refers to all medical devices of this nature as *In vitro* **diagnostics** ("IVD"). Vivera's website uses language set forth by the FDA in March 4, 2020 and subsequently in May 11, 2020 guidance.

c. Defendants' Article states that "Like Vivera Pharmaceuticals, some have ties to the world of dietary and health supplements." This is false.

The true fact is that Vivera has never manufactured, sold or distributed any dietary or health supplements.

d. Defendants quoted Mr. Edalat as saying that "the FDA looks at [Vivera] more as the manufacturer" because Vivera adds "small" devices to the box. This is misleading.

In fact, Mr. Edalat confirmed to the reporter that, under 21 C.F.R. § 820.3, Vivera is appropriately listed as the manufacturer of the devices. Moreover, Vivera contributes far more than the lancet, including the test kit's external controls as required by FDA, and Vivera conducted additional clinical validation tests required by the FDA, all of which could have been verified by Defendants.

e. In the Article and in Alltucker's tweet, Defendants' misquoted Dr. McColgan, stating that "It's all FDA Confidential. We have a great test, that's all I can say." In conjunction with the caption "FDA confidential," Defendants' misquote of Dr. McColgan and use of a screenshot of an unrelated page on Vivera's website are misleading and make it appear that Vivera is attempting to conceal information that should have been disclosed.

The true fact is that the communications between an applicant, like Vivera, and the FDA remain confidential. Contrary to Defendants' statements, however, Dr. McColgan did not refuse to disclose the

clinical performance of Vivera's antibody tests, and Defendants never requested performance or technical information for the antibody tests. Moreover, Vivera has two separate COVID-19 test kits and maintains two websites for these tests, which Defendants could have but did not link or imbed to their article.

29. On June 3, 2020, one day after Defendants published the Article, Vivera, through its counsel, delivered a letter to Wadsworth and 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 dissemination of the Article, that USA Today immediately retract the Article, remove any reference to Vivera or Mr. 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."

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

31. Since receiving Vivera's retraction request letter, Defendants updated the Article, including editing the Article to change the title. However, Defendants did not retract or correct the false and misleading statements about Vivera.

32. Vivera was and continues to be damaged by Defendants' false and misleading statements. As a result of the Article, Vivera's business reputation and business prospects have been damaged, and Vivera has lost investors, customers and a Board Member, among other things, amounting to damages in excess of $500 million.

33. Plaintiff is still in the process of discovering the full extent of Defendants' malfeasance.

FIRST CAUSE OF ACTION

FOR DAMAGES FOR DEFAMATION

(Against Defendants Gannett, Gannett Media, USA Today, Heath, McCoy, Reed, Bascobert, Slack, Alltucker, Wadsworth, Curley and Does 1 through 20)

34. Plaintiff repeats and realleges the allegations contained in Paragraphs 1 through 33, above, and incorporates them herein by reference as though set forth in full.

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

36. Defendants published the false and defamatory statements negligently and with actual malice, common law malice, and constitutional malice. Defendants knew that these statements were false and/or acted with reckless disregard of the truth of these statements. The statements also were made with a high degree of awareness of their probable falsity.

37. Vivera is entitled to general damages for its loss or reputation in accordance with proof at trial.

38. Vivera also is entitled to special damages for the harm done to its property, 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.

39. Defendants acted with reckless, willful or callous disregard for Vivera's rights and with malice, fraud or oppression toward Vivera, entitling Plaintiff to an award of punitive damages.

SECOND CAUSE OF ACTION

FOR DAMAGES FOR TRADE LIBEL

(Against Defendants Gannett, Gannett Media, USA Today, Heath, McCoy, Reed, Bascobert, Slack, Alltucker, Wadsworth, Curley and Does 1 through 20)

40. Plaintiff repeats and realleges the allegations contained in Paragraphs 1 through 39, above, and incorporates them herein by reference as though set forth in full.

41. Defendants published the false statements set forth above in unprivileged context which contained, directly or by clear implication, factual statements about Vivera's antibody tests that were false and defamatory.

42. Defendants published the false and defamatory statements with the knowledge that these statements were false and/or acted recklessly in making these statements, with actual malice, common law malice, and constitutional malice.

43. Vivera is entitled to general damages for its loss or reputation in accordance with proof at trial.

44. Vivera also is entitled to special damages for the harm done to its property, 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.

45. Defendants acted with reckless, willful or callous disregard for Vivera's rights and with malice, fraud or oppression toward Vivera, entitling Plaintiff to an award of punitive damages.

THIRD CAUSE OF ACTION

FOR DAMAGES FOR INTENTIONAL INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE

(Against Defendants Gannett, Gannett Media, USA Today, Heath, McCoy, Reed, Bascobert, Slack, Alltucker, Wadsworth, Curley and Does 1 through 20)

46. Plaintiff repeats and realleges the allegations contained in Paragraphs 1 through 45, above, and incorporates them herein by reference as though set forth in full.

47. As described above, Vivera has engaged in business relationships with third parties, including high-level government agencies, the Tribal Nations and other investors, clients and partners, which would result in probable future economic benefit or advantage to Vivera. Upon information and belief, Defendants' wrongful conduct constitutes tortious interference with contractual relationships, among other things. Based upon publicly available information and/or, upon information and belief, wrongfully obtained confidential information, Defendants were aware of these economic relationships and of their importance to Vivera.

48. Nevertheless, Defendants engaged in the misconduct described above with the intent to disrupt and interfere with Vivera's economic relationships with these third parties. As described above, such third-party relationships were disrupted. Defendants knew or should have known that its actions would interfere with, damage and/or deprive Vivera of the benefit of these relationships and the related prospective economic advantage.

49. As a proximate result of Defendants' interference with Vivera's economic relationships, Vivera has been damaged believed to be in excess of $500 million, and the exact amount of which is according to proof.

50. The foregoing conduct of Defendants constitutes fraud, oppression and malice within the meaning of California Civil Code § 3294. As such, Vivera is

entitled to obtain punitive damages in an amount sufficient to punish and deter Defendants from such wrongful acts in the future.

FOURTH CAUSE OF ACTION

FOR DAMAGES FOR NEGLIGENT INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE

(Against Defendants Gannett, Gannett Media, USA Today, Heath, McCoy, Reed, Bascobert, Slack, Alltucker, Wadsworth, Curley and Does 1 through 20)

51. Plaintiff repeats and realleges the allegations contained in Paragraphs 1 through 45, above, and incorporates them herein by reference as though set forth in full.

52. As described above, Vivera has engaged in business relationships with third parties, including high-level government agencies, the Tribal Nations and other investors, clients and partners, which would result in probable future economic benefit or advantage to Vivera. Upon information and belief, Defendants' wrongful conduct constitutes tortious interference with contractual relationships, among other things. Based upon publicly available information and/or, upon information and belief, wrongfully obtained confidential information, Defendants were aware of these ongoing economic relationships and of their importance to Vivera.

53. Nevertheless, Defendants recklessly and/or with negligent disregard for the consequences of their conduct engaged in the wrongful conduct described above that disrupted and interfered with Vivera's economic relationships with these third parties. As described above, such third-party relationships were disrupted. Defendants knew or should have known that its actions would interfere with, damage and/or deprive Vivera of the benefit of these relationships and the related prospective economic advantage.

54. As a proximate result of Defendants' interference with Vivera's economic relationships, Vivera has been damaged in an amount believed to be in excess of $500 million, the exact amount of which is according to proof.

PRAYER

WHEREFORE, Plaintiff prays for entry of judgment against Defendants, jointly and severally, as follows:

1. For actual, compensatory, economic, special, general, statutory and consequential damages in amounts to be determined at the time of trial for all causes of action but believed to be in excess of $500 million;

2. For exemplary and punitive damages in an amount to be determined by the trier of fact on the first, second, and third causes of action;

3. For a retraction of the subject article and other equitable relief as this Court deems appropriate;

4. For prejudgment interest and post-judgment interest at the highest rate allowed by law;

5. For costs of suit; and

6. For such other and further relief as the Court considers just and proper.

Dated: June 30, 2020

LKP GLOBAL LAW, LLP

By: /s/ Albert T. Liou
ALBERT T. LIOU
Attorneys for Plaintiff
VIVERA PHARMACEUTICALS, INC.

DEMAND FOR JURY TRIAL

Plaintiff VIVERA PHARMACEUTICALS, INC. hereby demands a trial by jury of all issues in this action triable of right before a jury.

Dated: June 30, 2020

LKP GLOBAL LAW, LLP

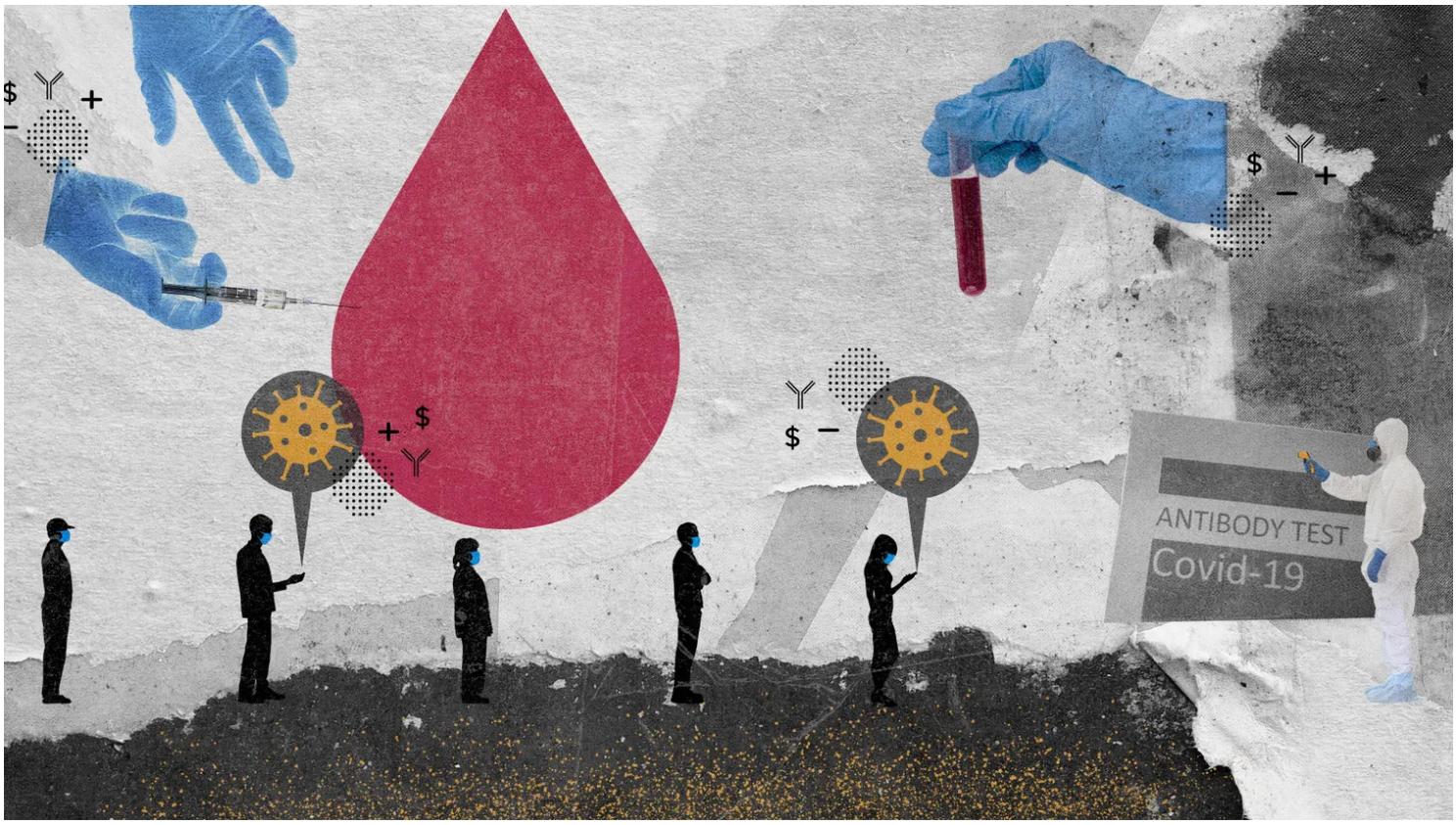
By: /s/ Albert T. Liou
ALBERT T. LIOU
Attorneys for Plaintiff
VIVERA PHARMACEUTICALS, INC.

CERTIFICATE OF SERVICE

I hereby certify that a copy of **PLAINTIFF VIVERA PHARMACEUTICALS, INC.'S COMPLAINT FOR DAMAGES FOR: (1) DEFAMATION; (2) TRADE LIBEL; (3) INTENTIONAL INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE; (4) NEGLIGENT INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE; DEMAND FOR JURY TRIAL** was filed electronically with the Clerk of the Court this 30th day of June, 2020 and will be served electronically to designated CM/ECF participant counsel through the court's electronic filing system.

/s/ Fran Castro

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."

> **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

"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.

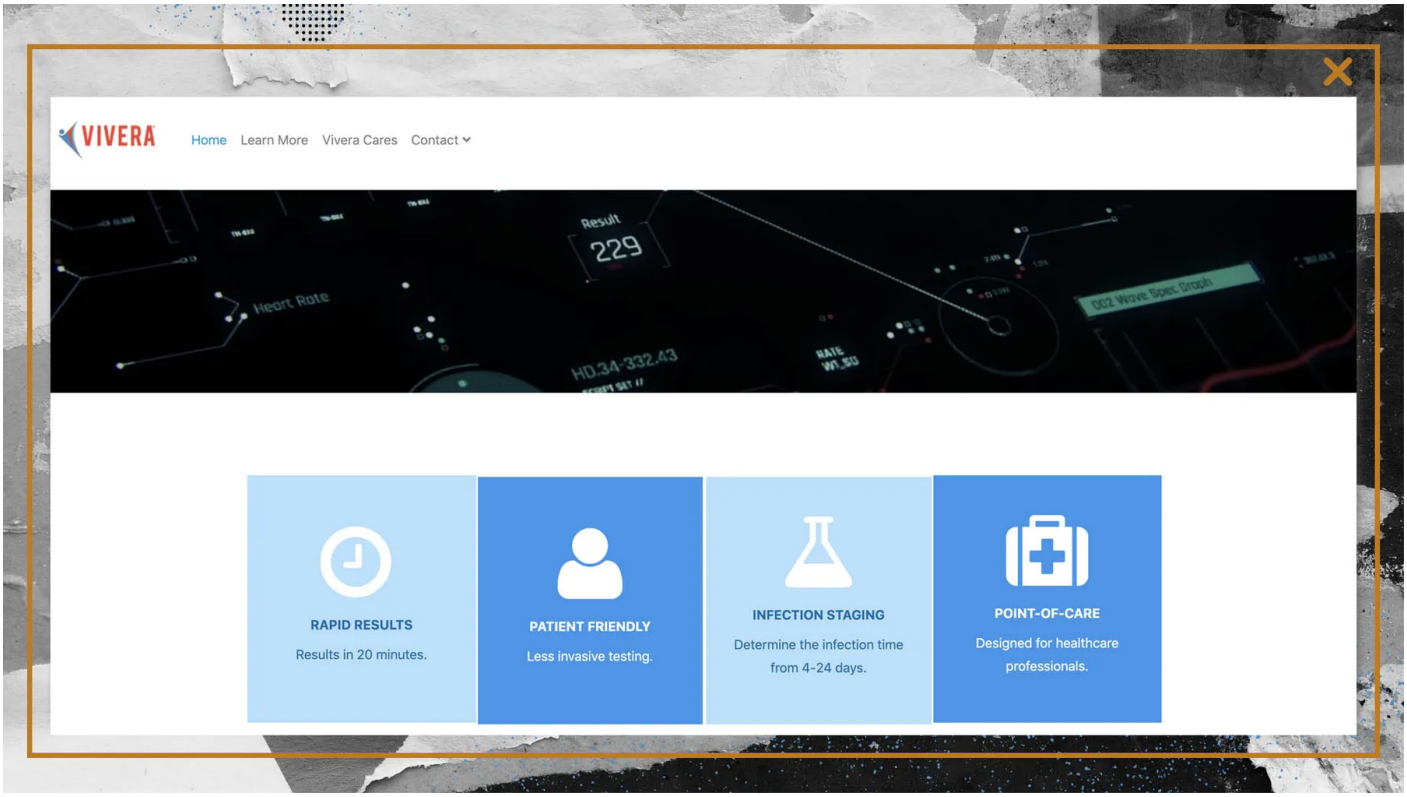
The FDA now requires all companies to reveal the results of validation tests to the agency. Many companies post accuracy numbers on their websites. Vivera does not – and when asked about the test's accuracy, McColgan was reluctant to answer.

> **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.

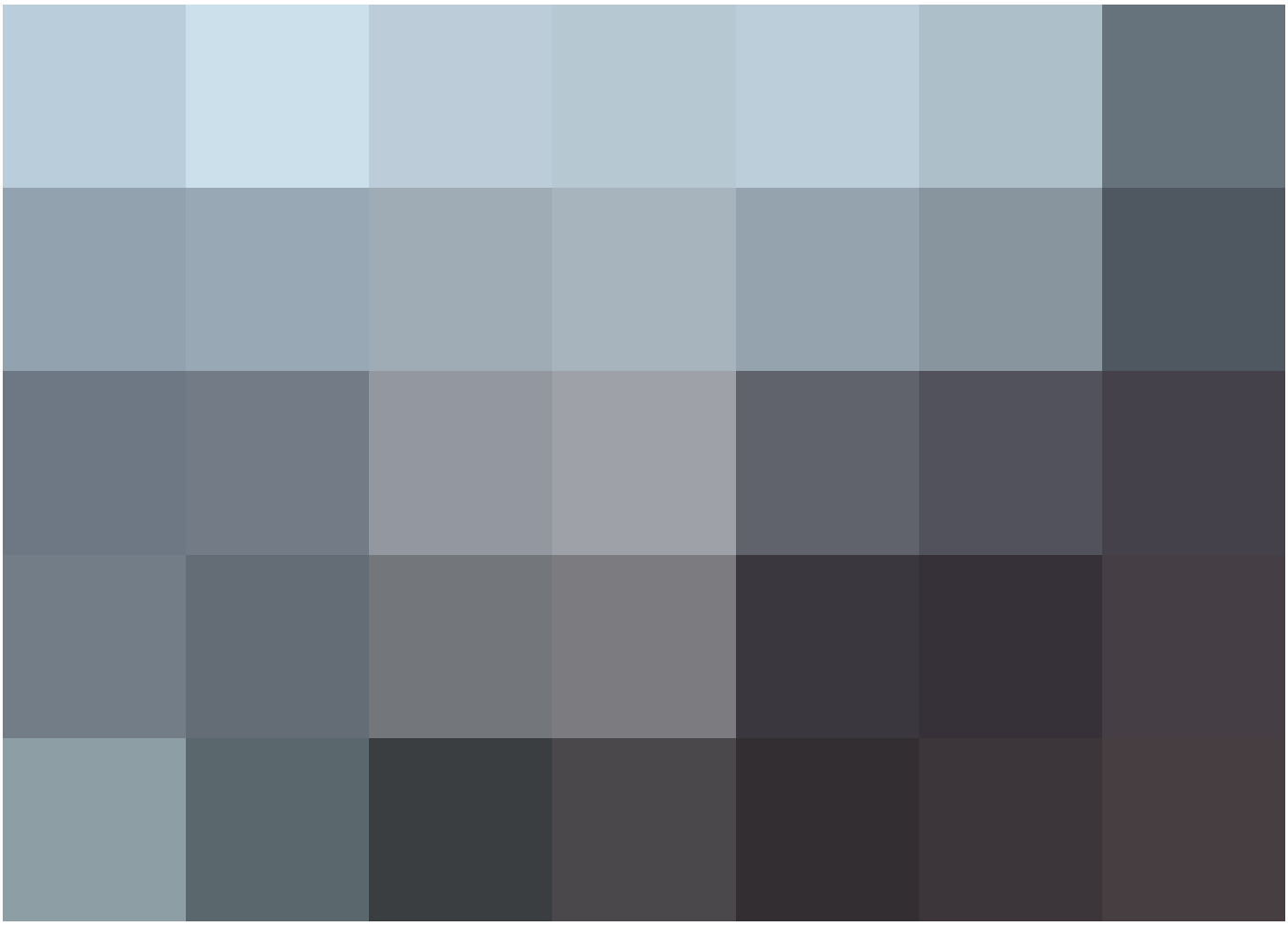
Edalat added that he now suspects there was foul play in the FDA's inspections of his previous company and he is "investigating the investigators."

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.”

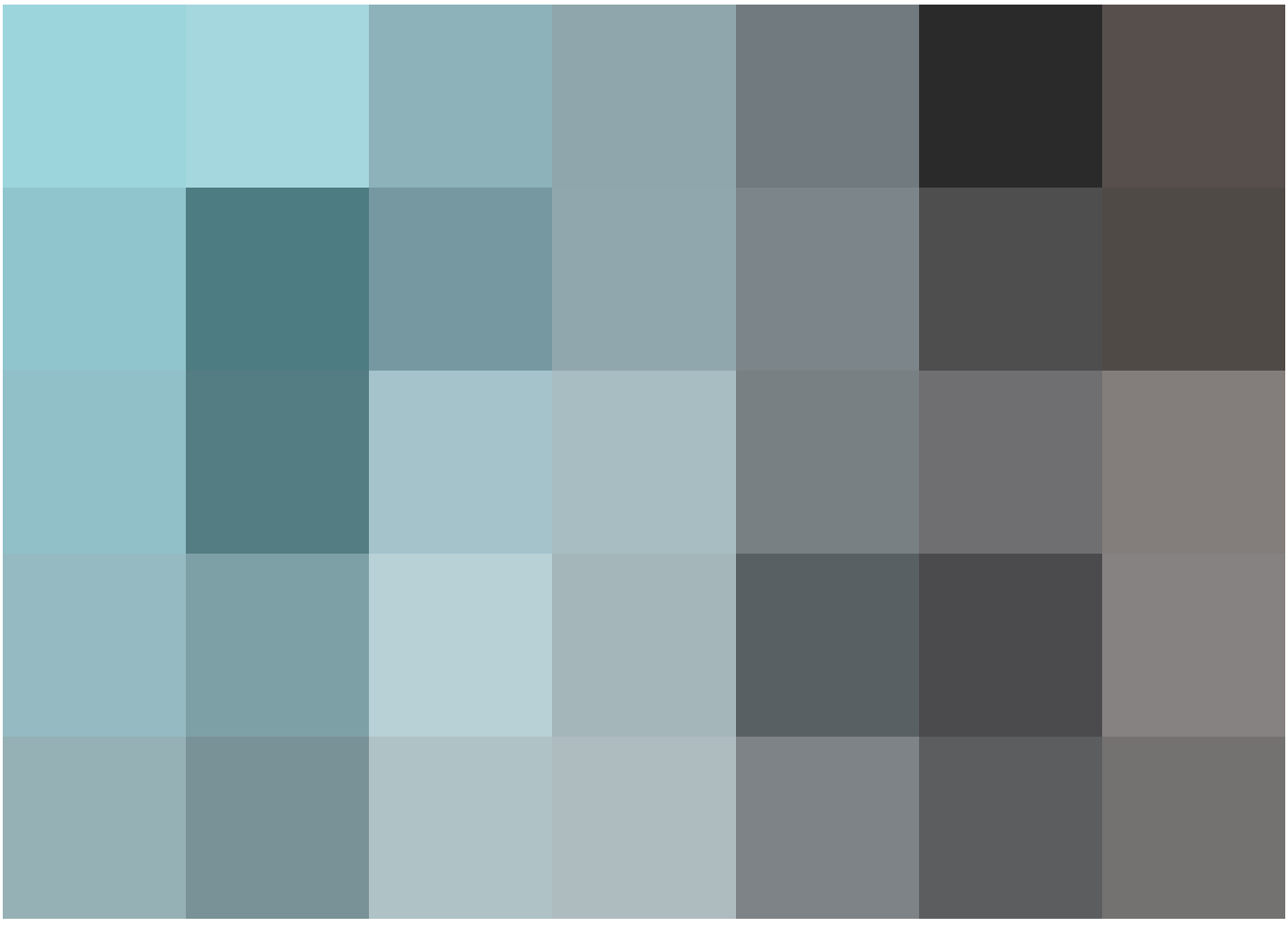
After USA TODAY contacted Xu, a new section appeared on his company’s home page featuring smiling employees in white coats and scrubs alongside placeholder text that reads: “position/role.” The images actually are stock photos, some of them available for sale online.

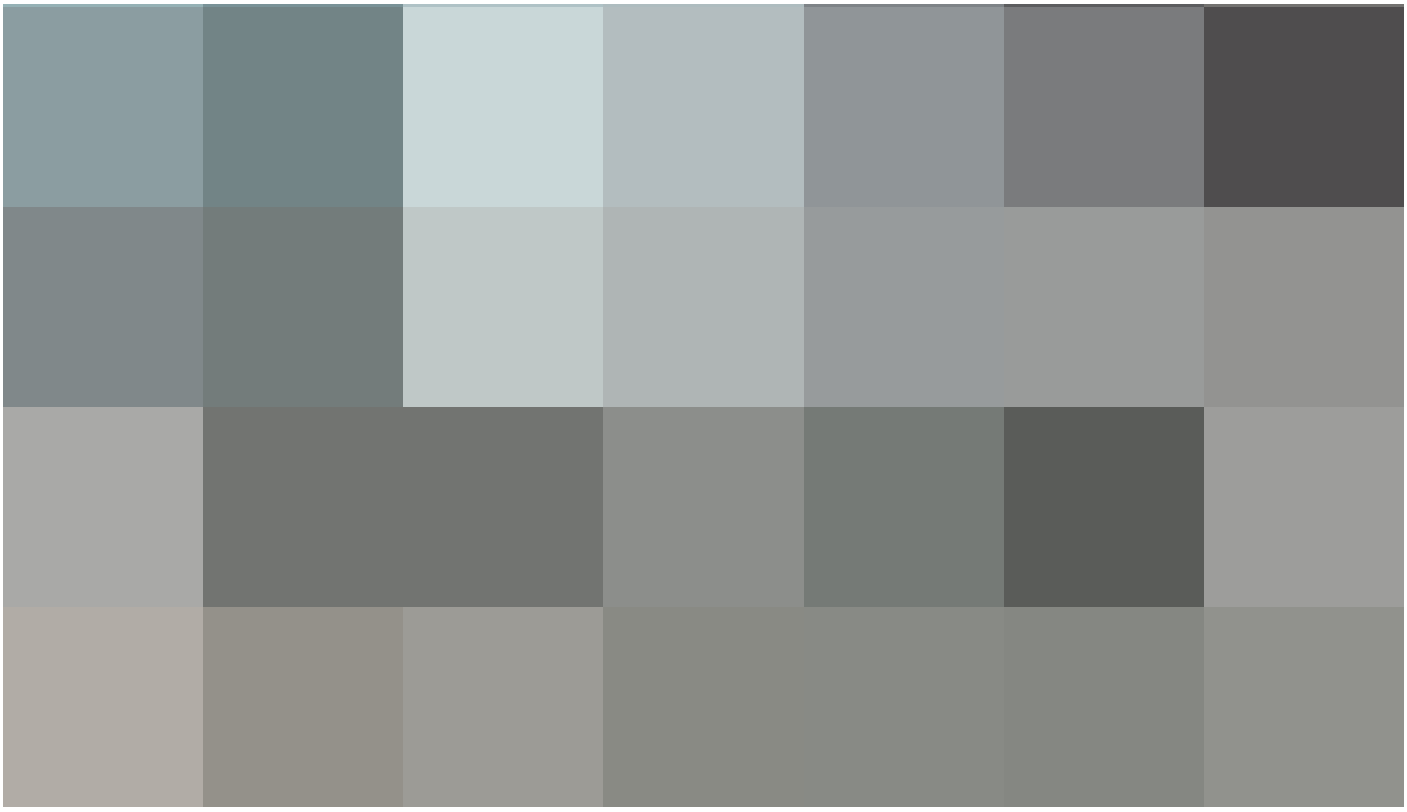
Pacific Connect Group LLC, based in Hong Kong, is run by a physical therapist for the Chinese Olympic Committee. He teamed up with a recent graduate of Rice University who worked briefly for a hardware design company and started a business to automate airport baggage checking.

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.

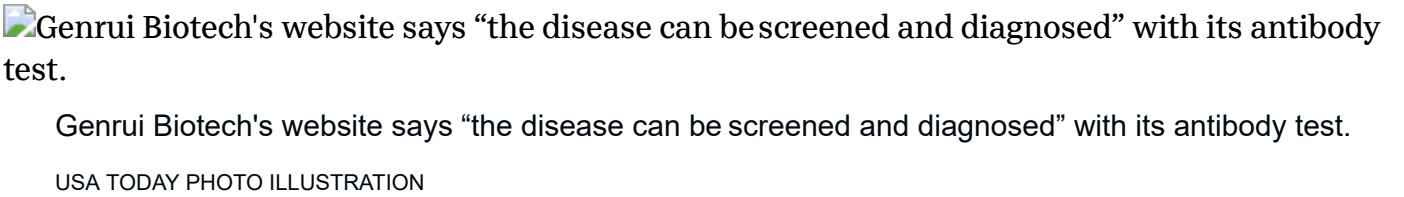
Witherspoon's biography on the website of an organization called the African American Business Foundation says he's a serial entrepreneur and "technology evangelist" whose ventures have included FaithPhone Wireless and the digital NuGospel Network. He did not respond to messages left with a Telepoint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

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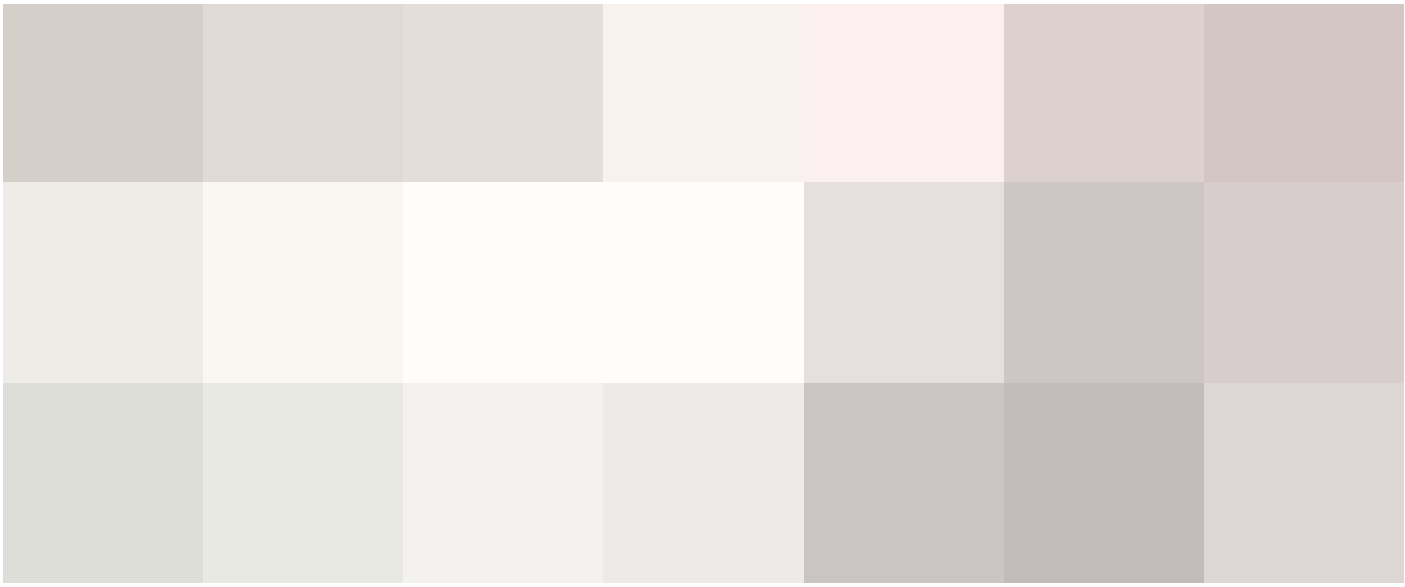
USA TODAY PHOTO ILLUSTRATION

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

Share on Facebook

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.

Eryring 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."

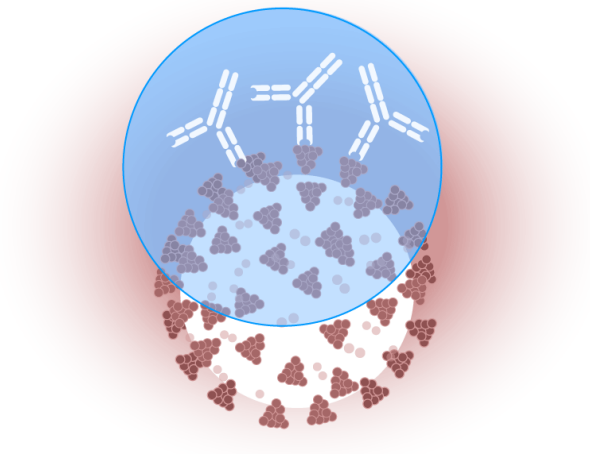
The attorney general separately investigated Eyring for a series of investment schemes. One involved a $37,000 loan he received from a former patient to help him renew his medical license. Instead, Eyring used the funds for personal expenses, state investigators allege.

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. →

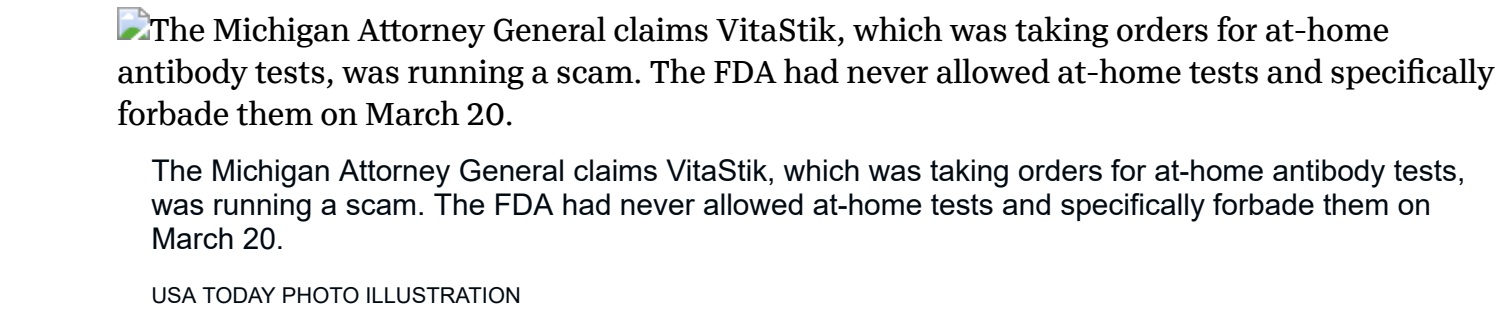
Unproven tests. Inaccurate results. Public health labs worry 'bad data' could taint US recovery from coronavirus crisis. →

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."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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.

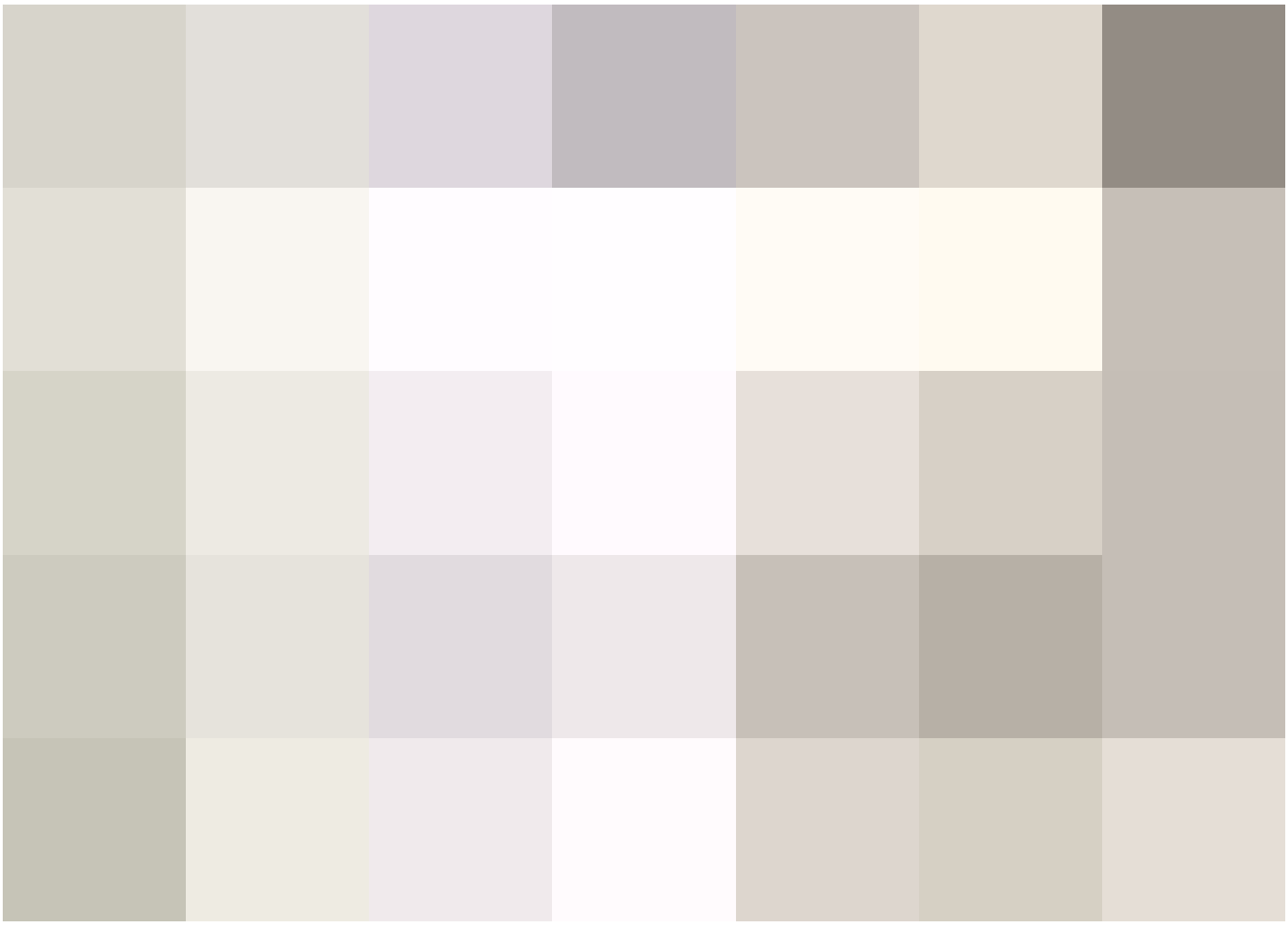
On April 1, VitaStik – which specializes in vaping devices for vitamins and essential oils – was ordered to stop.

"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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