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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

_____, Individually and on behalf of all others similarly situated, Plaintiff, v. ESTABLISHMENT LABS HOLDINGS INC., JUAN JOSE CHACON QUIROS, and RENEE M. GAETA, Defendants.	Case No. **CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

Plaintiff _____ ("Plaintiff"), individually and on behalf of all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants (defined below), alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, inter alia, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the defendants' public documents, conference calls and announcements made by defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Establishment Labs Holdings Inc. ("Establishment Labs" or the "Company"), analysts' reports and advisories about

the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants who purchased or otherwise acquired the securities of Establishment Labs between July 19, 2018 and April 9, 2019, both dates inclusive (the "Class Period"). Plaintiff seeks to recover compensable damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act").

JURISDICTION AND VENUE

2. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and §78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

3. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §1331 and §27 of the Exchange Act.

4. Venue is proper in this judicial district pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b) as the Company conducts business within this judicial district.

5. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

6. Plaintiff, as set forth in the accompanying Certification, purchased the Company's shares at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosure.

7. Defendant Establishment Labs manufactures and markets medical devices for aesthetic plastic surgery and reconstructive plastic surgery. Establishment Labs is headquartered in Alajuela, Costa Rica and incorporated in the British Virgin Islands. Establishment Labs's shares trade on the NASDAQ under the ticker "ESTA."

8. Defendant Juan Jose Chacon Quiros ("Quiros") is the Company's Chief Executive Officer ("CEO") and member of the board of directors and has been throughout the Class Period.

9. Defendant Renee M. Gaeta ("Gaeta") is the Company's Chief Financial Officer and has been throughout the entire Class Period.

10. Defendants Quiros and Gaeta are sometimes referred to herein as the "Individual Defendants."

11. Each of the Individual Defendants:

(a) directly participated in the management of the Company;

(b) was directly involved in the day-to-day operations of the Company at the highest levels;

(c) was privy to confidential proprietary information concerning the Company and its business and operations;

(d) was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;

(e) was directly or indirectly involved in the oversight or implementation of the Company's internal controls;

(f) was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or

(g) approved or ratified these statements in violation of the federal securities laws.

12. The Company is liable for the acts of the Individual Defendants and its employees under the doctrine of *respondeat superior* and common law principles of agency because all of the wrongful acts complained of herein were carried out within the scope of their employment.

13. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to the Company under *respondeat superior* and agency principles.

14. The Company and the Individual Defendants are referred to herein, collectively, as the "Defendants."

SUBSTANTIVE ALLEGATIONS

Materially False and Misleading Statements

15. On July 17, 2018, Establishment Labs filed with the SEC a Form F-1/A Registration Statement (the "Registration Statement") for the IPO. The Registration Statement was signed by Defendants Quiros and Gaeta and declared effective by the SEC on July 18, 2018.

16. On July 20, 2018, Establishment Labs filed with the SEC a prospectus (the "Prospectus") for the IPO, which forms part of the Registration Statement, offering to sell to the public 3,715,277 common shares at the price of $18.00 per share. The Registration Statement touted an independent study by Dr. Marcos Sforza conducted between April 2013 and April 203 (the "Sforza Study), which purports to show the superior safety of Establishment Labs' implants:

Third-Party Retrospective Data

> ***An independent study by Sforza et al., published in the peer-reviewed* Aesthetic Surgery Journal *in 2017, conducted at a single center, the Hospital Group Ltd.'s Dolan Park Clinic, or Dolan Park, in Bromsgrove, England, between April 2013 and April 2016, reported 5,813 consecutive cases of breast augmentation with Motiva Implants. This independent study was commissioned by Dolan Park's medical director, Dr. Sforza, who is also a member of our medical advisory board and receives compensation from us in such capacity***. The study, conducted by a group of 16 plastic surgeons at Dolan Park, reported overall rates of complication and reoperation of 0.76% over an interval of three years. We have also entered into a long-term supply agreement for our products with Dolan Park. There were no serious adverse events and no cases of implant rupture for device failure, capsular contracture (Baker III/IV) in primary cases, double capsules, or late seromas. The authors presented consistent real-world data and believe that their free, three year aftercare system is a strong method for patient retention and follow-up by eliminating any financial limitations for patients to return for follow-up consultations if any issues occur. Anecdotally, the same group of surgeons utilizing the same aftercare system for the last seven years reported substantially different results utilizing other types of silicone breast implants (i.e, non-Motiva Implants). The overall revision rate for this group from 2010 to 2013 utilizing a different, macro-textured, FDA approved implant (N > 10,000) was 8.43%, which is more than 10 times higher than the rate for Motiva Implants reported in this analysis.
>
> (Emphasis added.)

17. On March 20, 2019, Establishment Labs filed a Form 10-K with the SEC, which provided its financial results and position for the fiscal year ended December 31, 2018 (the "2018 10-K"). The 2018 10-K was signed by Defendants Quiros and Gaeta. The 2018 10-K contained signed SOX certifications by Defendants Quiros and Gaeta attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal control over financial reporting and the disclosure of all fraud."

18. The 2018 10-K stated the following regarding the Sforza Study:

> **Independent Clinical Experience**
>
> ***An independent study by Sforza et al., published in the peer-reviewed Aesthetic Surgery Journal in 2017, conducted at a single center, the Hospital Group Ltd.'s Dolan Park Clinic, or Dolan Park, in Bromsgrove, England, between April 2013 and April 2016, reported 5,813 consecutive cases of breast augmentation with Motiva Implants. This independent study was commissioned***

> ***by Dolan Park's medical director, Dr. Sforza, who is also a member of our medical advisory board and receives compensation from us in such capacity.*** The study, conducted by a group of 16 plastic surgeons at Dolan Park, reported overall rates of complication and reoperation of 0.76% over an interval of three years. We have also entered into a long-term supply agreement for our products with Dolan Park. There were no serious adverse events and no cases of implant rupture for device failure, capsular contracture (Baker III/IV) in primary cases, double capsules, or late seromas. The authors presented consistent real-world data and believe that their free, three year aftercare system is a strong method for patient retention and follow-up by eliminating any financial limitations for patients to return for follow-up consultations if any issues occur. Anecdotally, the same group of surgeons utilizing the same aftercare system for the last seven years reported substantially different results utilizing other types of silicone breast implants (i.e., non-Motiva Implants). The overall revision rate for this group from 2010 to 2013 utilizing a different, macro-textured, FDA approved implant (N > 10,000) was 8.43%, which is more than 10 times higher than the rate for Motiva Implants reported in this analysis.

(Emphasis added.)

19. The statements referenced in ¶¶ 15-19 above were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company's business, operational and financial results, which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) the Sforza Study was not independent; and (2) as a result, Defendants' statements about Establishment Lab's business, operations, and prospects were materially false and misleading at all relevant times.

The Truth Emerges

20. On April 10, 2019, before the market opened, Cannell Capital LLC published an article on *Seeking Alpha* entitled "*Establishment Labs: Troubling Conflicts and Financial Red Flags*." The report alleged that Establishment Labs provided "misleading information to the SEC and investors in its July 17, 2018 IPO and/or the Aesthetic Surgery Journal" regarding the

independence of the Sforza Study, detailing the extensive relationship between the Company and Dr. Sforza:

> The Dolan Park Clinic ("Dolan Park") in Bromsgrove, England conducted an "independent" study of the safety of ESTA's Motiva implants from April 2013 to April 2016 (*Sforza et al.)* culminating in a peer-reviewed article in the *Aesthetic Surgery Journal* on September 14, 2017. It appears that this study is the only peer-reviewed and "independent" study on the safety of ESTA's implants and is therefore deeply important to the company. The result of this "independent" single site three-year study showed "overall rates of complication and reoperation of 0.76% over an interval of three years" versus three-year reoperation rates of approximately 8.4% for ESTA's FDA-approved competitors. Dr. Marcos Sforza serves as the Medical Director of the Dolan Park Clinic and was the lead author for the study. The *Aesthetic Surgery Journal* article in question states:
>
> > *"**During the study period, Prof. Sforza declared no potential conflicts of interest** with respect to the research, authorship, and publication of this article**. In 2017 (after the study was completed and was submitted to this journal), Prof. Sforza accepted a position at Establishment Lab's Medical Advisory Board.**"*
> >
> > Source
>
> However, according to an August 16, 2018 correspondence letter with the SEC, ESTA discloses "Dr. Sforza also **received an option grant in September 2016** for 36,953 Class A Ordinary Shares." This would seem to directly contradict Dr. Sforza's peer-reviewed article stating that he accepted a position **in 2017** and declared "no potential conflict of interest." This quantity of shares is worth nearly $900,000 today.
>
> According to the editors of the *Aesthetic Surgery Journal*, Dr. Sforza submitted the article for publishing on December 17, 2016. Therefore, Dr. Sforza had already received compensation from ESTA when he chose to submit the article for publishing. A July 2016 supply agreement filed in ESTA's original S-1 makes mention of a "proprietary Sforza Bulb Side-Port Injector designed by" the Company. Could it be a coincidence that ESTA "designed" a "proprietary" medical tool and happened to apply the Sforza name to it? If he was involved, was Dr. Sforza paid for this work? ESTA CEO Juan José Chacón-Quirós' Instagram account and the Facebook page of ESTA is a treasure trove of proof that **Dr. Sforza was deeply involved with ESTA dating back into the Dolan Park Study's study period (April 2013 to April 2016)** for which he declared "no potential conflicts of interest." Chacón-Quirós posted a photo on October 30, 2015 (during the study period) captioned "Tehran loves Motiva!" showing himself (center) and Dr. Sforza (right) together at an event in Iran.

[Image omitted]

On December 2, 2015 (during the study period), Dr. Sforza gave a speech in Germany promoting Motiva. A video of the speech posted to YouTube by former ESTA distributor Menke Med GmbH ("Menke Med") includes Dr. Sforza saying that the Dolan Park Clinic's former breast implant supplier was AGN who threatened him with "legal actions" and "recently asked my hospital to fire me." These remarks occur around the 31-minute mark. Furthermore, according to ESTA's Facebook page, Dr. Sforza gave a "training course" at a February 24, 2016 Motiva product launch in Almaty, Kazakhstan during the study period.

[Image omitted.]

Dr. Sforza spoke at a Motiva EDGE Symposium on March 10, 2016 (again during the study period) in Uruguay according to the Company's Facebook page.

Pictured: Dr. Sforza (left) and CEO Chacón-Quirós (center) at the Uruguay symposium on March 10, 2016:

[Image omitted.]

It would be highly unusual if Dr. Sforza was *not* paid to travel as far and wide as Uruguay, Iran and Kazakhstan to give "training courses" on the Motiva product all during the study period. Why would this accomplished surgeon fly around the world promoting a product without compensation or the promise of compensation? One surgeon we spoke with said this level of engagement without compensation is "unthinkable" in the industry. In the aforementioned August 16, 2018, correspondence with the SEC, ESTA claims they "did not commission the study and that **it was an independent academic study** conducted and published by Dr. Sforza and his institution." This statement would appear to be at odds with Dr. Sforza's extensive involvement with ESTA during the study period. Furthermore, the study itself states "This article was supported by Establishment Labs (Alajuela, Costa Rica), who co-funded the development of this supplement." Today, Dr. Sforza serves as "coordinator of the Company's medical advisory board" receiving $10,000 to $15,000 per month in cash compensation on top of the 36,953-share option grant package received in September 2016 and a 68,233-share grant provided in April 2018. The market value of these shares is ~$2.5 million. The Dolan Park study clearly does not meet the smell test for "independence" and is filled with conflicts. **It appears ESTA may have provided misleading information to the SEC and investors in its July 17, 2018 IPO and/or the Aesthetic Surgery Journal about the nature of the "independent" study conducted by Dr. Sforza.** If this is the case, then ESTA could face legal and regulatory consequences.

21. On this news, shares of Establishment Labs fell $3.28 per share or over 14% over the new two trading days to close at $21.17 on April 11, 2019.

22. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's shares, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

23. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased Establishment Labs shares during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosure. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

24. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, the Company's shares were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by the Company or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

25. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

26. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

27. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether Defendants' acts as alleged violated the federal securities laws;

(b) whether Defendants' statements to the investing public during the Class Period misrepresented material facts about the financial condition, business, operations, and management of the Company;

(c) whether Defendants' statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) whether the Individual Defendants caused the Company to issue false and misleading SEC filings and public statements during the Class Period;

(e) whether Defendants acted knowingly or recklessly in issuing false and misleading SEC filings and public statements during the Class Period;

(f) whether the prices of the Company's shares during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

(g) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

28. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as

the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

29. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) the omissions and misrepresentations were material;

(c) the Company's shares are traded in efficient markets;

(d) the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;

(e) the Company traded on the NASDAQ, and was covered by multiple analysts;

(f) the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's shares; Plaintiff and members of the Class purchased and/or sold the Company's shares between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts; and

(g) Unexpected material news about the Company was rapidly reflected in and incorporated into the Company's stock price during the Class Period.

30. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

31. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I
Violation of Section 10(b) of The Exchange Act and Rule 10b-5
Against All Defendants

32. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

33. This Count is asserted against the Company and the Individual Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

34. During the Class Period, the Company and the Individual Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

35. The Company and the Individual Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they: employed devices, schemes and artifices to defraud; made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of the Company's shares during the Class Period.

36. The Company and the Individual Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These defendants by virtue of their receipt of information reflecting the true facts of the Company, their control over, and/or receipt and/or modification of the Company's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning the Company, participated in the fraudulent scheme alleged herein.

37. Individual Defendants, who are the senior officers and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiff and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other personnel of the Company to members of the investing public, including Plaintiff and the Class.

38. As a result of the foregoing, the market price of the Company's shares was artificially inflated during the Class Period. In ignorance of the falsity of the Company's and the Individual Defendants' statements, Plaintiff and the other members of the Class relied on the statements described above and/or the integrity of the market price of the Company's shares during the Class Period in purchasing the Company's shares at prices that were artificially inflated as a result of the Company's and the Individual Defendants' false and misleading statements.

39. Had Plaintiff and the other members of the Class been aware that the market price of the Company's shares had been artificially and falsely inflated by the Company's and the Individual Defendants' misleading statements and by the material adverse information which the Company's and the Individual Defendants did not disclose, they would not have purchased the Company's shares at the artificially inflated prices that they did, or at all.

40. As a result of the wrongful conduct alleged herein, Plaintiff and other members of the Class have suffered damages in an amount to be established at trial.

41. By reason of the foregoing, the Company and the Individual Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the Plaintiff and the other members of the Class for substantial damages which they suffered in connection with their purchases of the Company's shares during the Class Period.

COUNT II
Violation of Section 20(a) of The Exchange Act
Against The Individual Defendants

42. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

43. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information regarding the Company's business practices.

44. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to the Company's financial condition and results of operations, and to correct promptly any public statements issued by the Company which had become materially false or misleading.

45. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which the Company disseminated in the marketplace during the Class Period. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause the Company to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of the Company's shares.

46. Each of the Individual Defendants, therefore, acted as a controlling person of the Company. By reason of their senior management positions and/or being directors of the Company, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, the Company to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of the Company and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

47. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: May , 2019

Respectfully submitted,

THE ROSEN LAW FIRM, P.A.

By:_____

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