

THE ROSEN LAW FIRM, P.A.

Laurence M. Rosen, Esq.
609 W. South Orange Avenue, Suite 2P
South Orange, NJ 07079
Tel: (973) 313-1887
Fax: (973) 833-0399
Email: lrosen@rosenlegal.com

Counsel for Plaintiff

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

_____, Individually and on behalf of
all others similarly situated,

Plaintiff,

v.

PHILIP MORRIS INTERNATIONAL INC.,
ANDRÉ CALANTZOPOULOS, and JACEK
OLCZAK,

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 Philip Morris International Inc. (“Philip Morris” 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 publicly traded securities of Philip Morris from July 26, 2016 through December 20, 2017, 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”) and Rule 10b-5 promulgated thereunder.

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 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 and a significant portion of the Defendants’ actions, and the subsequent damages, took place within this 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 Philip Morris securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosure.

7. Defendant Philip Morris is a Virginia corporation with its principal executive offices located at 120 Park Avenue, New York, New York. Philip Morris, through its subsidiaries, manufactures and sells cigarettes, other tobacco products, and other nicotine-containing products. The Company trades on the New York Stock Exchange (“NYSE”) under the ticker symbol “PM.”

8. Defendant André Calantzopoulos (“Calantzopoulos”) has been the Chief Executive Officer (“CEO”) of Philip Morris since May 8, 2013.

9. Defendant Jacek Olczak (“Olczak”) has been the Chief Financial Officer (“CFO”) of Philip Morris since August 1, 2012.

10. Defendants Calantzopoulos and Olczak 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."

Background

15. Philip Morris is currently developing a portfolio of Reduced-Risk Products ("RRP). RRP does not burn tobacco and produces significantly lower levels of harmful or potentially harmful compounds than found in smoke.

16. Phillip Morris has four RRP platforms in various stages of development and commercialization readiness.

17. Platform 1 uses a precisely controlled heating device that Philip Morris is commercializing under the IQOS brand name, into which a specially designed and proprietary consumable tobacco product ("IQOS Consumables") is inserted and heated to generate an aerosol.

SUBSTANTIVE ALLEGATIONS

18. On July 26, 2016, the Company filed a Form 10-Q for the quarter ended June 30, 2016 (the “2Q 2016 10-Q”) with the SEC, which provided the Company’s second quarter 2016 financial results and position. The 2Q 2016 10-Q stated that the Company’s disclosure controls and procedures were effective as of June 30, 2016, and that “[t]here have been no changes in PMI’s internal control over financial reporting during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, PMI’s internal control over financial reporting.” The 2Q 2016 10-Q was signed by Defendant Olczak. The 2Q 2016 10-Q contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 (“SOX”) by Defendants Calantzopoulos and Olczak attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company’s internal controls over financial reporting, and the disclosure of all fraud.

19. The 2Q 2016 10-Q discussed IQOS and stated that the Company’s “assessment approach and the studies conducted to date reflect the rigorous evidentiary package contemplated in the FDA’s Draft Guidance for Modified Risk Tobacco Product Applications (2012),” stating in pertinent part:

Reduced-Risk Products: We use the term RRP to refer to products with the potential to reduce individual risk and population harm in comparison to smoking cigarettes. Our RRPs are in various stages of development and commercialization, and we are conducting extensive and rigorous scientific studies to determine whether we can support claims for such products of reduced exposure to harmful and potentially harmful constituents in smoke and, ultimately, claims of reduced disease risk when compared to smoking cigarettes. Before making any such claims, we will rigorously evaluate the full set of data from the relevant scientific studies to determine whether they substantiate reduced exposure or risk. Any such claims may also be subject to government review and authorization, as is the case in certain markets today. We draw upon a team of world-class scientists and engineers from a broad spectrum of scientific disciplines, and our efforts are guided by the following three key objectives:

- to develop RRP platforms that provide adult smokers the taste, sensory experience, nicotine delivery profile and ritual characteristics that are similar to those currently provided by cigarettes;
- to substantiate the reduction of risk for the individual adult smoker and the reduction of harm to the population as a whole, based on robust scientific evidence derived from well-established assessment processes; and
- to advocate for the development of science-based regulatory frameworks for the development and commercialization of RRP platforms, including the communication to adult smokers of scientifically substantiated reduced exposure or reduced risk claims.

Our product development is based on the elimination of combustion via tobacco heating and other innovative systems for aerosol generation, which we believe is the most promising path to reduce risk.

Our approach to individual risk assessment is to use cessation as the benchmark, because the short-term and long-term effects of smoking cessation on risk reduction are well known.

Four RRP platforms are in various stages of development and commercialization readiness:

- *Platform 1* uses a precisely controlled heating device that we are commercializing under the *iQOS* brand name, into which a specially designed tobacco product under the *Marlboro*, *Parliament*, *Heets* and *HeatSticks* brand names is inserted and heated to generate an aerosol. Six short-term clinical studies have been completed. The study results show a substantial reduction in relevant biomarkers of exposure to harmful or potentially harmful constituents (“HPHCs”) in adult consumers who switched to *iQOS* compared to adult consumers who continued to smoke cigarettes over a five-day period. The final report of a three-month clinical reduced-exposure study conducted in Japan has been issued, and the final report for a three-month clinical reduced-exposure study conducted in the U.S. will be issued shortly. In these studies, we observed reduction in all 15 biomarkers of exposure to corresponding HPHCs measured in those who switched to *iQOS* compared to those who continued to smoke cigarettes. Furthermore, the reductions measured in those who switched to *iQOS* approached those that were observed in study participants who quit smoking for the duration of the study. We also initiated a 6+6 month exposure response study in

December 2014, and expect the results regarding the first six-month term in the first quarter of 2017.

* * *

We are also developing other potential product platforms.

We are proceeding with the commercialization of RRP. In January 2014, we announced an investment of up to €500 million over three years in our first manufacturing facility in the European Union and an associated pilot plant near Bologna, Italy, to produce our RRP. The Bologna factory, which will initially manufacture Platform 1 tobacco sticks (*HeatSticks*), started commercial production in the first quarter of 2016 and is planned to reach production of 30 billion units by the end of 2017. We anticipate capacity limitations through the first quarter of 2017. Additional investments are planned at the Bologna site as well as the conversion of some of our existing manufacturing facilities in the European Union for RRP production.

In the United States of America, an established regulatory framework for assessing “Modified Risk Tobacco Products” exists under the jurisdiction of the Food and Drug Administration (“FDA”) by virtue of a 2009 statute. We expect that future FDA actions are likely to influence the regulatory approach of other interested governments. Our assessment approach and the studies conducted to date reflect the rigorous evidentiary package contemplated in the FDA’s Draft Guidance for Modified Risk Tobacco Product Applications (2012). We have shared our approach and studies with the FDA’s Center for Tobacco Products. We plan to submit a Modified Risk Tobacco Product Application as well as a Premarket Tobacco Application for Platform 1 in 2016.

20. On February 14, 2017, the Company filed a Form 10-K for the fiscal year ended December 31, 2016 (the “2016 10-K”) with the SEC, which provided the Company’s year-end financial results and position and stated that the Company’s internal control over financial reporting and disclosure controls and procedures were effective as of December 31, 2016. The 2016 10-K was signed by Defendants Calantzopoulos and Olczak. The 2016 10-K also contained SOX signed certifications by Defendants Calantzopoulos and Olczak attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company’s internal controls over financial reporting, and the disclosure of all fraud.

21. The 2016 10-K discussed IQOS, stating in pertinent part:

Reduced-Risk Products

Our Approach to RRPs: We recognize that smoking cigarettes causes serious diseases and that the best way to avoid the harms of smoking is never to start or to quit. Nevertheless, it is predicted that over the next decade the number of smokers will remain largely unchanged from the current estimate of 1.1 billion, despite the considerable efforts to discourage smoking.

Cigarettes burn tobacco, which produces smoke. As a result of the combustion process, the smoker inhales various toxic substances. In contrast, Reduced-Risk Products do not burn tobacco and produce significantly lower levels of harmful or potentially harmful compounds than found in smoke.

For smokers who would otherwise continue to smoke, we believe that RRPs offer a much better choice. Accordingly, our key strategic priorities are: to develop and commercialize products that present less risk of harm to adult smokers who switch to those products versus continued smoking; and to convince current adult smokers who would otherwise continue to smoke to switch to those Reduced-Risk Products.

We recognize that this transformation from cigarettes to RRPs will take time and that the speed of transformation will depend in part upon factors beyond our control, such as the willingness of governments, regulators and other policy groups to embrace RRPs as a desired solution to the smoking problem. We also recognize that the transformation must be funded from our existing cigarette business. For so long as a significant number continues to smoke, it is critical that the industry be led by responsible and ethical manufacturers. Therefore, during the transformation, we intend to remain the leading international cigarette manufacturer.

We have a range of RRPs in various stages of development, scientific assessment and commercialization. We conduct rigorous scientific assessment of our RRP platforms to establish that they reduce exposure to harmful and potentially harmful constituents in smoke and, ultimately, that these products present, are likely to present, or have the potential to present less risk of harm to adult smokers who switch to them versus continued smoking. We draw upon a team of expert scientists and engineers from a broad spectrum of scientific disciplines and our extensive learnings of consumer preferences to develop and assess our RRPs. Our efforts are guided by the following key objectives:

- to develop RRPs that adult smokers who would otherwise continue to smoke find to be satisfying alternatives to smoking;

- for those adult smokers, our goal is to offer RRPs with a scientifically substantiated risk reduction profile that approaches as closely as possible that associated with smoking cessation;
- to substantiate the reduction of risk for the individual adult smoker and the reduction of harm to the population as a whole, based on scientific evidence of the highest standard that is made available for scrutiny and review by external independent scientists and relevant regulatory bodies; and
- to advocate for the development of science-based regulatory frameworks for the development and commercialization of RRPs, including the communication of scientifically substantiated information to enable adult consumers to make better health choices.

Our RRP Platforms: Our product development is based on the elimination of combustion via tobacco heating and other innovative systems for aerosol generation, which we believe is the most promising path to providing a better choice for those who would otherwise continue to smoke. We recognize that no single product will appeal to all adult smokers. Therefore, we are developing a portfolio of products intended to appeal to a variety of distinct tastes.

Four RRP platforms are in various stages of development and commercialization readiness:

Platform 1 uses a precisely controlled heating device that we are commercializing under the *IQOS* brand name, into which a specially designed and proprietary consumable tobacco product (“*IQOS* Consumables”) is inserted and heated to generate an aerosol. Eight clinical studies have been completed (including two with the duration of three months). The study results show a substantial reduction in relevant biomarkers of exposure to harmful or potentially harmful constituents (“HPHCs”) in those adult smokers who switched to *IQOS* compared to those who continued to smoke cigarettes for the duration of the study. The reductions measured in those who switched to *IQOS* approached those that were observed in study participants who quit smoking for the duration of the study. While these reduced exposure clinical studies were primarily designed to focus on biomarkers of exposure, in our three-month studies, we also measured six clinical risk markers. These clinical risk markers are associated with disease mechanisms known to be affected by smoking and to reverse upon cessation. The results are generally consistent with the expected direction of change and indicate that switching completely to *IQOS* led to an overall improvement of clinical risk markers affected by smoking after only three months. We also initiated a 6+6 month exposure response study in December 2014 and expect the results regarding the first six-month term in the third quarter of 2017. We have developed a new version of *IQOS* to further improve the

consumer experience and plan to introduce this new version in the second quarter of 2017.

* * *

In the United States, an established regulatory framework for assessing “Modified Risk Tobacco Products” and “New Tobacco Products” exists under the jurisdiction of the Food and Drug Administration (“FDA”). Future FDA actions may influence the regulatory approach of other interested governments. In December 2016, we submitted a Modified Risk Tobacco Product Application for Platform 1 to the FDA. We plan to submit a Premarket Tobacco Application in the first quarter of 2017 for Platform 1.

22. The statements referenced in ¶¶18-21 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) there were irregularities in the clinical experiments that underpin Philip Morris’ application to the FDA for approval of its iQOS smoking device; and (2) as a result, Defendants’ statements about the Company’s business, operations and prospects were materially false and misleading and/or lacked a reasonable bases at all relevant times.

The Truth Emerges

23. On December 20, 2017, *Reuters* published a report stating that “[f]ormer employees and contractors [of Phillip Morris] have detailed irregularities in the clinical experiments that underpin Philip Morris International’s application to the FDA for approval of its iQOS smoking device,” stating in pertinent part:

PART 3

Scientists describe problems in Philip Morris e-cigarette experiments

Part 3: Former employees and contractors have detailed irregularities in the clinical experiments that underpin Philip Morris International's application to the FDA for approval of its iQOS smoking device. The agency is expected to decide by next year on whether the tobacco giant can sell its new product in the U.S.

By TOM LASSETER, PARITOSH BANSAL, THOMAS WILSON, AMI MIYAZAKI, DUFF WILSON and ADITYA KALRA

Filed Dec. 20, 2017, noon GMT

TOKYO/NEUCHATEL, Switzerland – The U.S. Food and Drug Administration is weighing whether to approve a potentially path-breaking smoking device by Philip Morris International Inc. With a decision expected next year, former employees and contractors have described to Reuters a number of irregularities involving clinical trials that underpin the tobacco giant’s application to the agency.

By heating tobacco instead of burning it, the company says the device, known as iQOS, avoids subjecting smokers to the same levels of carcinogens and other toxic substances found in a regular cigarette. The company has spent more than \$3 billion developing new smoking platforms like iQOS. As part of that initiative, Philip Morris has published extensive scientific findings, based in part on clinical studies.

Tamara Koval, who worked at the company from 2012 to 2014 and helped coordinate clinical trials for the device, questioned the quality of some of the researchers and sites contracted to carry out those experiments. Koval was a co-author of the company’s protocol used to run the studies globally. When she highlighted an irregularity in one of the studies, Koval said, Philip Morris excluded her from meetings.

Reuters also found irregularities during interviews with some of the principal investigators contracted to conduct the trials for the company. One principal investigator said he knew nothing about tobacco. Philip Morris had to jettison the experiment that investigator performed after it emerged he hadn’t followed a basic procedure for obtaining informed consent from participants during clinical trials.

A second investigator submitted urine samples that exceeded what a human being is capable of, according to two former company employees, and then initially refused to acknowledge there was a problem. A third said he doesn’t hold such company-sponsored clinical trials in high regard, describing them as “dirty” because their purpose is more commercial than scientific.

After reviewing Reuters’ findings, Philip Morris said in a statement that “all studies were conducted by suitably qualified and trained Principal Investigators.” The company said it understands that “FDA inspectors have already audited some

facilities” involved in the trials. Philip Morris also said it had taken steps to address “any reported irregularity in our studies.”

* * *

In addition to former Philip Morris employees involved with the iQOS program, Reuters interviewed six of the 11 principal investigators who were responsible for five of eight clinical trials the company submitted to the FDA. Reuters also reviewed hundreds of pages of publicly available Philip Morris study reports and FDA filings.

That reporting identified shortcomings in the training and professionalism of some of the lead investigators, as well as their knowledge of the study results.

A group of tobacco research and policy experts reviewed detailed summaries of Reuters’ reporting and Philip Morris’ response. The experts, including a former head of the FDA and two former scientific advisers for the agency, said those findings raise concerns about Philip Morris’ clinical trial program.

“Taken as a whole, it’s clear they do not have the sophistication to carry out adequate and well-controlled clinical trials,” said David Kessler, the FDA’s commissioner from 1990 to 1997, referring to the company. “I am not inferring any malicious intent here, just that they lack sophistication, because this is not their bread and butter.”

If the FDA has already audited some of the trial sites used by Philip Morris, the agency **“should carefully review its audits and possibly expand them,”** said Kessler, a former dean of the medical school at Yale University.

Tom Eissenberg, who served on the FDA’s tobacco products scientific advisory committee until earlier this year, said: **“The FDA should audit.”**

* * *

The new insights into the company’s clinical trial program for iQOS come at a crucial time for Philip Morris. The world’s largest publicly traded tobacco company by market value and maker of Marlboro cigarettes has applied to the U.S. FDA to be able to sell iQOS in America, and also for permission to market it as a modified-risk tobacco product. That designation could mean that Philip Morris is allowed to market iQOS as presenting less harm or risk of disease to users than traditional tobacco.

For now, the FDA is evaluating the company’s studies. Reuters outlined its findings about the iQOS trials to the agency. The FDA said it cannot comment on a pending application.

* * *

Internal Philip Morris documents reviewed by Reuters show the significance of iQOS goes beyond its profit potential. The device is now sold in more than two dozen nations after it was first launched in Japan and Italy during late 2014.

The company has a 10-year plan for what it calls “normalization” of the tobacco industry, according to a 2014 strategy document. The industry has been shunned over the past two decades for producing and marketing products that kill people and previously lying about it. Under a section on “strategies and actions” to achieve that goal, the document lists, among other things, new smoking devices such as iQOS and the scientific research involved in developing them.

[Emphasis added]

24. Specifically, the *Reuters* article details the doubts of one of the Company’s principal investigators as to the honesty of the study’s participants, stating in pertinent part:

The eight clinical experiments that Philip Morris submitted to the FDA were conducted between 2013 and 2015. For one study, scientists in Texas and Florida did not respond to messages left by Reuters. Other scientists, in Belfast and Tokyo, declined to talk. Half of the eight studies were done in Japan.

FDA guidelines for conducting clinical studies say a trial should adhere to standards such as Good Clinical Practice. That best-practices document says investigators “should be qualified by training and experience and should have adequate resources” to properly conduct a trial.

Masayuki Sugimoto, the principal investigator who oversaw testing at one facility used by Philip Morris to conduct a trial, said his Tokyo clinic is “heavily in the red.”

Sugimoto said he generally has little confidence that all the participants in experiments like the one he ran for Philip Morris on nicotine tell the truth about their smoking history – that is, whether they smoke.

Speaking about the final study report from the Philip Morris trial, Sugimoto said in an interview that he generally doesn’t have time to read such things in detail. He said he probably signed a document indicating he had received the final report. **Sugimoto gestured with his thumb and forefinger to indicate a thick document: “I just don’t read them.”**

* * *

The Japanese company hired to monitor studies in the country, CMIC Holdings Co Ltd, said in a statement that researchers confirmed that trial participants were smokers by using urine tests.

Asked about the tests, Sugimoto said he thought they would prevent non-smokers from joining the trial but added, “I don’t know whether they were done that rigorously.”

Told of Sugimoto’s doubts about the honesty of study participants, Eissenberg, who served on the FDA’s tobacco products scientific advisory committee from 2011 to 2017, said “it raises a great deal of concern.”

A principal investigator “is required to make sure that the participants meet the inclusion-exclusion criteria that are in the protocol,” said Eissenberg. He was referring to the fact that clinical trial subjects’ backgrounds – such as whether they are smokers – should meet the parameters of the experiment for the data to be valid. **“And a PI should have confidence in that,” he said.**

[Emphasis added].

25. The *Reuters* article also highlights questions about the competency of one of its principal investigators, stating in pertinent part:

At another laboratory in Japan, issues with how the study was carried out were so acute that data from 56 participants was thrown out, raising questions about the competence of the principal investigator. Philip Morris halted the study at that location.

In the company’s study documentation released by the FDA, Philip Morris recorded the reason for discarding the data as non-compliance with good clinical practices, specifically “failure of the site to meet sample collection procedures and data recording procedures.”

Kishor Lad, who was Philip Morris’ data manager on the study, said the site crossed a line of what’s allowed during such trials: It collected samples before getting informed consent forms signed by the volunteers. “Completely a no-no in the GCP world,” Lad said, using the acronym for good clinical practice.

Philip Morris confirmed to Reuters that “informed consent was not obtained prior to execution of a study procedure” – specifically, the collection of urine samples. The problem was identified by CMIC, the contract research group, during a routine monitoring visit, Philip Morris said. A subsequent round of audits, it added, “led to prompt discontinuation of the study at the Seishukai Clinic.” The incident, the company said, was properly logged in the study report and the submission to the FDA.

“It suggests the investigator had no idea, did not understand or just didn’t care what his responsibilities were in conducting the study,” said Greg Koski, a former director of the U.S. federal Office for Human Research Protections, which advocates for research subjects. “This is such a flagrant violation, that investigator shouldn’t be doing clinical studies.”

Mamoru Oki was the principal investigator at the time at the facility, the Seishukai Clinic in Tokyo. Reached by phone, Oki said: “My specialty is urology and I don’t know anything about tobacco, so I cannot talk.”

Told of that remark, Philip Morris said: “Dr. Oki was qualified and trained specifically on the product.”

Dorothy Hatsukami, a member of the FDA’s tobacco products scientific advisory committee from 2010 to 2013, said a principal investigator’s professed lack of knowledge about tobacco is not ideal.

“For any tobacco-related clinical trial, an investigator with a background in tobacco product research would have better qualifications to evaluate the study results than a novice,” she said.

The study continued at a parallel site, the Tokyo Heart Center.

During an interview at the center, principal investigator Masahiro Endo said repeatedly that he had no idea what the results were from his study.

“We did medically safe and accurate blood samples, but were not told the results. So even if we are asked questions, we won’t be able to answer,” he said. “We were paid, it ended there.”

But in a statement signed last year and submitted by Philip Morris to the FDA, Endo said he had read the clinical study report from the company and confirmed “that to the best of my knowledge it accurately describes the conduct and results of the study.” Principal investigators in all of the Philip Morris clinical trials signed the same statement.

A day after speaking with Reuters, Endo sent an email clarifying that after checking his records he saw that he’d signed a receipt saying he received a report on the results and acknowledging that he’d be listed as the principal investigator. He had spoken during the interview “with a fuzzy memory,” Endo said.

Clinical trial experts interviewed by Reuters said it’s not uncommon for principal investigators to be unaware of test results sent to a third party specialty laboratory for analysis. But they also emphasized that if companies want better science, they need the investigators to be more involved with all aspects of a study.

“It seems like the investigator here is in the role of a technician, not as a principal investigator,” said Kessler, the former FDA commissioner.

Kessler said it’s hard to understand how such investigators could have signed off on the clinical study report “when they clearly were not versed in the study results.”

[Emphasis added].

26. The *Reuters* article also revealed that some of the researchers are not fluent in

English, stating in pertinent part:

As part of her job coordinating between Philip Morris and those contracted to run its clinical trials, Koval, the former company scientist, conducted medical safety training across the world for principal investigators and others involved with the iQOS studies.

During one study training session in Tokyo, Koval said, she realized some of the researchers could not speak English well and she was unable to communicate with them. Koval said she does not speak Japanese and there was no interpreter present.

“I was like, Jesus, what are we doing here?” she said. At dinner later, Koval said, she saw two of the men, and they were unable to describe in English what their jobs were.

When asked about Koval’s session, Philip Morris said it was a meeting with its contract research organization and others. It added that “all PIs and team members with active roles in the study were fluent in English.”

But Sugimoto, one of the Japanese principal investigators, told Reuters in an interview, “I can’t speak English.”

And Endo, another of the lead researchers, said that when Philip Morris executives visited his site someone was present who helped translate “questions like whether to cut the crusts off bread” when giving food to study subjects.

* * *

Koval said that after she raised concerns about the Polish study with Philip Morris executives in Switzerland she was excluded from meetings.

Philip Morris said in a statement that Koval was “part of the team” that followed up on the urine samples. In fact, the company said, she was “an

active member” of the group that finalized the data set from the studies for further analysis.

Koval confirmed that she was part of the team and involved with the data set. But she stood by her account that she was shut out of conversations and meetings about the urine samples.

In 2014, Philip Morris terminated her contract, Koval said. She said she returned to the pharmaceutical industry a few months later and now works for Swiss drugs giant Novartis AG.

After leaving Philip Morris, Koval was given a certificate of service that said, “Tamara drove clinical program development activities.” It said she had demonstrated “professionalism” and “unwavering commitment” in her work.

[Emphasis added].

27. On this news, shares of Philip Morris fell \$3.75 per share or approximately 3.5% from its previous closing price to close at \$104.37 per share on December 20, 2017, damaging investors.

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

CLASS ACTION ALLEGATIONS

29. 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 or otherwise acquired the publicly traded securities of Philip Morris 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.

30. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, the Company's securities were actively traded on the NYSE. 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.

31. 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.

32. 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.

33. 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 securities 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.

34. 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.

35. 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 securities are traded in efficient markets;

- d. the Company's securities were liquid and traded with moderate to heavy volume during the Class Period;
- e. the Company traded on the NYSE, 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 securities;
- g. Plaintiff and members of the Class purchased and/or sold the Company's securities 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
- h. Unexpected material news about the Company was rapidly reflected in and incorporated into the Company's stock price during the Class Period.

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

37. 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

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

39. 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.

40. 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.

41. 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; 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 securities during the Class Period.

42. 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.

43. 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.

44. As a result of the foregoing, the market price of the Company's securities were 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 securities during the Class Period in purchasing the Company's securities at prices that were artificially inflated as a result of the Company's and the Individual Defendants' false and misleading statements.

45. Had Plaintiff and the other members of the Class been aware that the market price of the Company's securities 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 and the Individual Defendants did not disclose, they would not have purchased the Company's securities at the artificially inflated prices that they did, or at all.

46. 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.

47. 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 securities during the Class Period.

COUNT II

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

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

49. 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.

50. 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.

51. 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 securities.

52. 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 complaint.

53. 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: December __, 2017

Respectfully submitted,

THE ROSEN LAW FIRM, P.A.

By: _____

Laurence M. Rosen
609 W. South Orange Avenue, Suite 2P
South Orange, NJ 07079
Tel: (973) 313-1887
Fax: (973) 833-0399
Email: lrosen@rosenlegal.com

Counsel for Plaintiff