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Liaison Counsel for the Lead Plaintiff and the Proposed Class

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE DR. REDDY'S LABORATORIES LIMITED SECURITIES LITIGATION	)	Case No. 3:17-cv-06436-PGS-DEA

AMENDED CONSOLIDATED CLASS ACTION COMPLAINT

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Glossary

ANDA	Abbreviated new drug application
APIs	Active Pharmaceutical Ingredients; the principal ingredients for finished pharmaceutical products that produce the desired effects of a given medicine.
BSE	Bombay Stock Exchange Ltd.; an Indian stock exchange, which Dr. Reddy's equity shares are listed on (as opposed to its American Depository Shares that are listed on the NYSE).
CAPA	Corrective and Preventative Action plans.
cGMP (or GMP)	Current good manufacturing practice; sets the minimum industry and regulatory standards governing drug manufacturing.
EIR	Establishment Investigation Report; internal FDA document that contains a more complete narration than the FDA Form 483 of an FDA inspection of a pharmaceutical manufacturing facility.
FD&C Act	Federal Food, Drug and Cosmetic Act
FDA Form 483	FDA Form 483 Notice of Inspectional Observations; issued by the FDA after an inspection to make the company's senior management aware of any objectionable conditions observed by the inspector.
HPLC	High performance liquid chromatography; a test performed during QC.
ICH Q7	International Conference on Harmonization guideline Q7. ICH Q7 sets forth industry cGMP standards for APIs, which generally conforms to the cGMP requirements as laid out in 21 C.F.R. Parts 210 and 211.
Lachman Consultants	Third-party consulting firm hired by Defendants to provide compliance and remediation support for assuring robust implementation and verification of its CAPA plan.
NAI	No Action Indicated; a post-inspection designation given by the FDA only when no objectionable items were found.
NDA	New drug application
OAI	Official Action Indicated; a post-inspection designation given by the FDA when objectionable items were found and further regulatory actions should be recommended.

PSAI	Pharmaceutical Services and Active Ingredients; Dr. Reddy's PSAI segment manufactures and markets APIs and intermediates; PSAI is responsible for approximately 15% of Dr. Reddy's total revenue.
QA	Quality assurance; the Quality Unit's QA organization ensures that all procedures were followed properly, including ensuring that the QC functions properly documented its analysis.
QC	Quality control; the Quality Unit's QC procedures focus both on what must occur during the drug manufacturing process and what results from it.
QMS	Quality Management System at Dr. Reddy's.
Quality Unit	Quality Units have specifically delineated responsibilities to oversee manufacturing operations and ensure compliance with cGMP and other regulations as well as the company's SOPs.
SOP	Standard Operating Procedures; SOP define the process by which the company's facilities manufacture pharmaceuticals and comply with cGMP.
Unit V	Dr. Reddy's API manufacturing facility at Miryalaguda, Telangana; cited in the Warning Letter.
Unit VI	Dr. Reddy's API manufacturing facility at Srikakulam, Andhra Pradesh; cited in the Warning Letter.
Unit VII	Oncology formulation manufacturing facility at Duvvada, Visakhapatnam, Andhra Pradesh; cited in the Warning Letter.
VAI	Voluntary Action Indicated; a post-inspection designation given by the FDA when objectionable items were found, but the FDA does not require further action from the company.
Warning Letter	A FDA enforcement action issued when the FDA determines that either (a) its observations are significant enough or (b) the company failed to adequately remedy the observations; Warning Letters outline the FDA's position concerning certain observations and mandates that the company correct the problem. All references to "Warning Letter," unless otherwise indicated, are referring to the November 5, 2015 Warning Letter the FDA issued Dr. Reddy's concerning Units V, VI, and VII.

Court-appointed Lead Plaintiff the Public Employees' Retirement System of Mississippi ("Mississippi PERS" or "Lead Plaintiff"), by its counsel, brings this federal securities class action pursuant to Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (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, on behalf of itself and other entities who purchased or otherwise acquired the publicly traded securities of Dr. Reddy's Laboratories, Ltd. (defined below as "DRL," and, together with its affiliates and subsidiaries, referred to herein as "Dr. Reddy's" or the "Company") from November 27, 2014 through September 15, 2017, inclusive (the "Class Period"), and were damaged thereby.

The allegations in this Consolidated Class Action Complaint, other than those allegations concerning Lead Plaintiff and its own acts, are based on Lead Plaintiff's information and belief. The allegations are based on facts obtained through Lead Plaintiff's investigation, which included, *inter alia*: (a) review and analysis of relevant filings made by Dr. Reddy's with the United States Securities and Exchange Commission (the "SEC") and the Bombay Stock Exchange ("BSE"); (b) review and analysis of Dr. Reddy's public documents, conference calls and press releases; (c) review and analysis of securities analysts' reports and advisories concerning the Company; (d) data and other information concerning Dr. Reddy's securities and the regulations under which Dr. Reddy's operates; (e) other publicly available information concerning the Company and the Individual Defendants; (f) an investigation conducted by and through Lead Plaintiff's attorneys and their investigators, including but not limited to interviews and discussions with former Dr. Reddy's employees; and (g) consultation with an industry expert, Mr. David Chesney, an expert and consultant in pharmaceutical manufacturing and FDA regulatory compliance. *See* Ex. 1.

Lead Plaintiff believes that further substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. INTRODUCTION – PRELIMINARY STATEMENT

1. Dr. Reddy's Laboratories Limited is an Indian pharmaceutical manufacturer which falsely misrepresented that it was compliant with mandatory manufacturing quality standards, when it was not. The U.S. Federal Food, Drug and Cosmetic Act ("FD&C Act") prohibits the import of "adulterated" drugs. 21 U.S.C. § 331(a). The Food and Drug Administration is charged with enforcing the FD&C Act, and under the statute a drug is adulterated if "the methods used in, or the facilities or controls used for, its manufacture . . . do not conform to or are not operated or administered in conformity with current good manufacturing practice." 21 U.S.C. § 351(a)(2)(B).

2. Current good manufacturing practice ("cGMP") effectively sets minimum standards for safely manufacturing drugs by outlining general rules for all aspects of drug manufacture including facilities, personnel, equipment, drug components and containers, production, packaging, labeling, and record-keeping. cGMP regulations require that companies follow highly-regimented processes and controls to prevent errors and ensure the manufacture of consistent and safe drugs for human use.

3. Questions swirled around Dr. Reddy's compliance with cGMP after investors learned that the FDA observed nine potential violations at Dr. Reddy's manufacturing facility Unit VI, one of its largest facilities, in November 2014. But Dr. Reddy's and certain corporate executives falsely assuaged the market's fears, downplaying any potential impact on

manufacturing and stating that "[a]ll of the [Dr. Reddy's] facilities are designed in accordance with and ***are compliant with current Good Manufacturing Practice requirements***."[1]

4. The fraud began to unravel in November 2015 when the FDA publicly issued a Warning Letter (the "Warning Letter") that described three of Dr. Reddy's manufacturing facilities as suffering from "recurrent" and "long-standing failures," with some violations dating back to 2008. The Warning Letter questioned Dr. Reddy's ability "to achieve overall compliance with CGMP" and concluded that "[***i***]***t is apparent that [Defendants] have not implemented a robust quality system at [Dr. Reddy's] sites***." The FDA "strongly recommend[ed]" that Defendants "evaluate global manufacturing operations to ***ensure compliance with CGMP regulations and requirements, comprehensively and immediately***."

5. Immediately following the receipt of the Warning Letter, Defendants continued to fraudulently downplay the impact that their purported efforts to get back into compliance would have on ongoing manufacturing. However, in February and July of 2016, Defendants disclosed that production had been slowed as a result of the remediation.

6. In the aftermath of the Warning Letter, Defendants also falsely touted that they had "done [their] part of it in terms of completing all the remediation activities." But in early 2017, the FDA re-inspected the three facilities under the Warning Letter and again found problems at all three facilities subject to the Warning Letter. One facility, Unit VII, was particularly problematic; the FDA "found that ***numerous items had not been corrected***" and during the inspection "***repeated instances of employees providing false or misleading statements [were] discussed with firm management***."

[1] Unless otherwise indicated, all emphasis is added.

7. During the summer of 2017, a string of disclosures revealed just how little Dr. Reddy's had actually accomplished in its purportedly "network wide" remediation. In August 2017, the German equivalent of the FDA rescinded Dr. Reddy's compliance certificate for a whole new facility, Unit II, which had not even been implicated by the Warning Letter. Similarly, in September 2017, the FDA found more observations of potential non-compliance at a facility based in the United Kingdom. As a result of these disclosures that revealed Defendants' fraud, the price of ***Defendants' U.S.-traded securities dropped over 50%*** from their pre-Warning Letter Class Period high.

8. Investors were damaged by Defendants' materially false and misleading statements throughout the Class Period (November 27, 2014 through September 15, 2017, inclusive) concerning: (i) Dr. Reddy's compliance with manufacturing quality regulations, including cGMP; (ii) the scope and severity of the FDA's observations of non-compliance; (iii) the Company's purported progress getting back into compliance; and (iv) the extent to which getting back into compliance would impact ongoing production.

A. Dr. Reddy's Manufacturing Process Must Comply with Strict FDA Regulations

9. Dr. Reddy's, like all pharmaceutical manufacturers, has a non-delegable duty to ensure that the drugs and pharmaceutical ingredients it produces are safe, effective, and in compliance with the regulations in the jurisdictions in which they are sold. For drugs sold in the U.S., the regulatory regime is premised on minimum manufacturing standards called cGMP, which are promulgated by the FDA. cGMP standards for the manufacture of finished pharmaceuticals are codified in the Code of Federal Regulations (21 C.F.R. Parts 210 and 211).

10. Dr. Reddy's routinely violated fundamental precepts of cGMP. For example, cGMP requires that when errors or discrepancies in the manufacture of a drug are discovered

during the quality control testing phase, such as the accidental production of batch of a super- or sub-potent drugs, the manufacturer must "thoroughly" investigate and identify the cause of the error (*see* 21 C.F.R. § 211.192). The FDA found numerous instances where Dr. Reddy's management knew about deviations and errors in the production of drugs at three of its largest and most important facilities, yet took no action to investigate the cause of the error nor to correct it.

11. Despite these blatant lapses, Defendants affirmatively touted the Company's compliance with cGMP throughout the Class Period. Indeed, much was riding on Dr. Reddy's continued compliance. If a manufacturing facility does not comply with these minimum requirements, the FDA can take a series of increasingly onerous enforcement actions, including banning the import of drugs from that facility and postponing the approval of critical new drug applications.

B. At the Start of the Class Period, the FDA Uncovered Flagrant Violations of cGMP at Three of Dr. Reddy's Manufacturing Facilities

12. Starting in 2012 through the start of the Class Period, Dr. Reddy's management oversaw a dramatic increase in the volume of production at the Company's manufacturing facilities, including those at the center of this action. At the time, Dr. Reddy's management described the increase in production as a "phenomenal growth story driven by significant . . . new [product] launches . . . and strong recovery of customer order[s]." However, a well-placed confidential witness and former Dr. Reddy's employee, CW 1, who had firsthand information of Dr. Reddy's manufacturing facilities in India, stated that the ramp up in production output led to increased quality problems and delays. As a result, significant pressure was put on the quality teams to cut corners and release batches of products from the review cycle without performing adequate quality assurance or control.

13. Ultimately, the FDA caught Dr. Reddy's shirking on its responsibility to follow cGMP and other mandatory regulations used to ensure drug safety. Just before the start of the Class Period, in November 2014, the FDA performed an unannounced on-site inspection of one of Dr. Reddy's largest manufacturing facilities ("Unit VI") and communicated that they observed nine objectionable instances of potential non-compliance. For example, one observation was that Dr. Reddy's had manipulated and deleted quality control testing data through the use of a quality control laboratory that it had not disclosed to the FDA. Dr. Reddy's had used the undisclosed lab to test and retest batches of pharmaceutical products that had failed quality control until they successfully passed muster. The FDA privately communicated these observations to Defendants in a FDA Form 483 Notices of Inspectional Observations ("FDA Form 483").

C. Defendants Misled Investors About the Company's Non-Compliance and the Impact It Would Have on the Company Going Forward

14. At the start of the Class Period, on November 27, 2014, investors got wind of the observations of potential non-compliance at Unit VI through news reports published that day. Nevertheless, Defendants immediately issued a "clarification," in which they acknowledged receipt of the FDA Form 483, but then misleadingly assuaged investors' fears, claiming "there is no implication on manufacturing," and that they were "confident it won't lead to any further enforcement."

15. Defendants' misstatements had their intended effect. Analysts covering Dr. Reddy's did not believe the FDA Form 483 would adversely affect the Company. One analyst noted: "DRRD has clarified that these observation[s] would not have any material impact on company's operation or consolidated results . . . We find non-stoppage of production from facility under observation to be positive for DRRD as it implies DRRD following norms to comply with USFDA regulation."

16. Dr. Reddy's went on to privately receive at least two more FDA Form 483s for two other manufacturing facilities in India in January and March 2015. Together, the ***thirty-three*** observations at three different facilities depicted a pervasive pattern of: (1) neither recording nor maintaining quality control testing data; (2) failing to investigate the cause of failing quality control test results; and (3) failing to mitigate the risks of microbiological contamination.

17. Despite receiving these two additional FDA Form 483s, Defendants affirmatively mislead investors by claiming that they were in full compliance with cGMP, despite knowing it to be false. For example, on June 17, 2015, Defendants claimed in their annual report for the year ended March 31, 2015, that "***[a]ll of the facilities are designed in accordance with and are compliant with current Good Manufacturing Practice ("cGMP") requirements*** . . . ."

18. Further, on July 30, 2015, Defendants falsely claimed that their compliance issues were "***pretty much a one site specific issue***" and that they had "***comprehensively addressed almost all the observations raised***" despite having received two additional FDA Form 483s for two separate facilities and, according to the FDA, having proposed woefully inadequate corrective actions.

D. The Truth Was Partially Revealed When the FDA Escalated Its Enforcement Action

19. In stark contrast to their public statements, Defendants utterly failed to fix the problems at their manufacturing facilities and the FDA escalated its enforcement by issuing a warning letter to Defendant Chairman of the Board, Satish Reddy on November 5, 2015 (the "Warning Letter"). The Warning Letter revealed that Dr. Reddy's manufacturing quality problems were not an isolated "one site specific issue," but rather, a pattern of cross-facility, persistent violations. Multiple violations dating back to 2008 and multiple observations from the FDA Form 483s remained uncorrected.

20. Furthermore, the Warning Letter memorialized portions of Defendants' responses to the FDA following their receipt of the three FDA Form 483s. The FDA's descriptions of these responses show that Defendants ***knew about specific non-compliant conditions at the same time they were claiming that all of their manufacturing facilities "are compliant with current Good Manufacturing Practice***."

21. For instance, in a December 15, 2014 letter responding to the FDA Form 483 issued to Unit VI in November 2014, Defendants attempted to justify their use of an undisclosed quality control lab to test and retest products until they passed, while only recording passing results. According to the FDA, Defendants' response "acknowledged that [their] analysts failed to document and start investigating [out-of-specification] results" in the undisclosed quality control lab. However, the Warning Letter concluded that eleven months later, Defendants still had "not assessed how [their] reliance on the incomplete and inaccurate data generated by the CQC [custom quality control] laboratory" affected the quality of the facility's products. Defendants' late 2014 and early 2015 acknowledgments in their responses to the FDA establish that Defendants knew that their statements were false and misleading before they were made.

22. Based on these observations and others, the Warning Letter concluded: "***Several violations are recurrent or represent long-standing failures to adequately resolve significant manufacturing quality problems. It is apparent that you have not implemented a robust quality system at your sites***."

23. Wall Street analysts covering Dr. Reddy's were surprised by the Warning Letter. Morgan Stanley stated that "[h]itherto, only one site, which is located at Srikakulam [*i.e.*, Unit VI], was perceived to be under FDA risk; warning letters to two additional sites is disappointing." Equirus echoed the surprise: "While we knew about the Srikakulam facility

issues, we never knew about the seriousness of observations at the other plants – mainly as management commentary was very optimistic in the quarterly calls. This clearly is significantly against our expectations . . . ."

24. The market learned on November 6, 2015 that Dr. Reddy's had received a Warning Letter, and Dr. Reddy's American Depositary Shares ("ADSs") dropped ***18%***. On November 27, 2015, Dr. Reddy's ADSs dropped an additional ***5.6%*** after the market realized that the Warning Letter had been published on the FDA's website.

E. Defendants Continued to Fraudulently Mislead Investors by Falsely Downplaying the Impact of the Warning Letter

25. Nevertheless, instead of acknowledging the significant impact that an "organization-wide" "revamp [of] our quality systems and processes" to "fully comply with the cGMP quality standards across all of our facilities" would have on production, Defendants claimed on November 9, 2015 that they had "de-risked" the three facilities subject to the Warning Letter and there would be minimal impact on manufacturing.

26. As part of the remediation, Defendants promised to engage an outside consultant to perform a "third party assessment of our quality systems and evaluate our global manufacturing operations to ensure compliance with CGMP regulations" as required by the FDA. Defendants engaged Lachman Consultants Services, Inc. ("Lachman Consultants" or "Lachman"), a consulting firm that specializes in responding to FDA warning letters.

27. According to CW 1, Lachman Consultants came in after Dr. Reddy's received the Warning Letter; due to Dr. Reddy's extended review process and Lachman's subsequent review, ***Dr. Reddy's batch releases slowed down by as much as 66%***, and management was fully aware of this slow down.

F. Investors Were Damaged as the Market Learned Remediation had Slowed Production and Remediation Had Not been Completed

28. Just three months after receiving the Warning Letter, on February 9, 2016, Defendants had to admit, contrary to their earlier public statements, that Dr. Reddy's was indeed experiencing manufacturing delays due to the remediation. In reaction, the price of Dr. Reddy's ADSs dropped almost ***6%***.

29. Defendants then falsely claimed these delays were essentially a one-time blip and manufacturing was "back on track." However, on July 26, 2016, Dr. Reddy's revealed that the Company's remediation efforts had once again substantially delayed production at the impacted facilities. As a result of this news on July 26, 2016, the price of Dr. Reddy's ADSs dropped an ***additional 15%***.

30. In addition to misleading the market about production delays caused by the remediation, Defendants misled the market about their progress in remediating the Company's non-compliance. On May 12, 2016, Defendants claimed that they believed "most of our commitments to the [FDA] will be over by the end of [May 2016]." Similarly, Defendants claimed on July 26, 2016, that they had completed up to 98% of their commitments to the FDA. However, at the time of these statements, Defendants knew they had not corrected the problems at the three facilities under the Warning Letter, nor had they completed a network wide revamp of the Company's compliance processes.

31. On March 8, 2017, the market further learned the true state of Dr. Reddy's purported "system wide" remediation efforts when news broke that Dr. Reddy's had spectacularly failed the FDA's re-inspection of Unit VII, receiving ***thirteen*** FDA observations. This news revealed the falsity of Defendants' claims that, since July 2016, they had basically

addressed all of the FDA concerns and were merely awaiting re-inspection. Based on the news, the price of Dr. Reddy's ADSs fell once again, this time by ***more than 5%*** over two days.

32. Thirteen days after that, on March 21, 2017, additional information about the failed re-inspection came to light following an economic news channel's report that "US FDA finds ***repeat observations from 2015 warning letter***. Failed to maintain complete data to ensure compliance." The news of five repeat observations from the Warning Letter continued to reveal the falsity of Defendants' claims that they had fully addressed the FDA's concerns. Additionally, the subsequently-released Unit VII inspection report made clear that management knowingly took no action concerning, amongst other things, more than 1,200 documentation errors from May 2016 to October 2016 in violation of cGMP. Consequently, the price of Dr. Reddy's ADSs took another hit, ***falling more than 6%***.

33. Finally, a string of disclosures during the summer of 2017 fully revealed just how little Dr. Reddy's had actually accomplished in its purportedly "network wide" remediation. On August 10, 2017, the Company revealed that a German regulator would not renew a cGMP compliance certificate for a manufacturing facility that was entirely separate from the facilities under the Warning Letter. After investors learned about the revocation of a compliance certificate at the new facility, the price of Dr. Reddy's ADSs ***fell almost 6%*** from its previous close. Similarly, on September 15, 2017, Dr. Reddy's disclosed that the Company had been advised of new FDA observations of potential non-compliance at a United Kingdom manufacturing facility.

34. When all of the truth was fully and finally revealed on September 15, 2017, the value of Dr. Reddy's ADSs had dropped to $33.78. From its Class Period high just before the issuance of the Warning Letter, Dr. Reddy's ADSs had fallen a staggering ***50.17%*** in value.

II. JURISDICTION AND VENUE

35. The claims asserted herein arise under and pursuant to Sections 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.

36. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

37. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b), as the Company has its principal U.S. executive offices located in this District and a significant portion of its business, actions, and the subsequent damages, took place within this District.

38. 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 exchanges.

39. Specifically, Dr. Reddy's uses the means and instrumentalities of interstate commerce to sell pharmaceutical products directly to U.S. customers and to U.S. drug manufacturers. U.S. sales make up approximately 50% of Dr. Reddy's total revenue.

40. Dr. Reddy's and Defendants have established manufacturing and corporate offices in the United States, including a U.S. headquarters in Princeton, New Jersey. In fact, Srinivasa Rao, VP and Head, Regulatory Affairs-North America was listed as the firm's US agent. He has offices located in, and works out of, Princeton, New Jersey.

41. At least one of Dr. Reddy's global research and development facilities is located in Princeton, New Jersey, and upon information and belief, Dr. Reddy's conducts systemic and continuous business in the State of New Jersey. Dr. Reddy's also often issues press releases

from Hyderabad, India and Princeton, New Jersey. Furthermore, Defendants' corporate officers have participated in conference calls from the United States.

42. In addition, Dr. Reddy's December 15, 2014 response to the FDA concerning the November 2014 Form 483 was sent by Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's USA"), which is Dr. Reddy's Laboratories Limited's authorized U.S. agent. Dr. Reddy's USA is located at 107 College Road East, Princeton, New Jersey, 08540. Moreover, the December 15, 2014 response to the FDA was sent from Srivivasa Rao, Dr. Reddy's Senior Director and Head of Regulatory Affairs for North America.

A. Dr. Reddy's Sought U.S. Investment Through Its ADS Program

43. In April 2001, Defendants chose to deepen their connections to the U.S. by registering American Depositary Shares ("ADS") on the New York Stock Exchange under the ticker "RDY" to garner direct U.S. investment in Dr. Reddy's.

44. On April 10, 2001, Dr. Reddy's entered into a deposit agreement with Morgan Guaranty Trust Company of New York (which was acquired by JPMorgan Chase Bank, N.A. on November 10, 2001) as depositary. Dr. Reddy's sold approximately 13.2 million ADSs, representing a half equity share of Dr. Reddy's Laboratories Limited, for $10.04 each through underwriters led by Merrill Lynch & Co. in New York, NY.

45. In November 2006, Dr. Reddy's issued additional ADSs in a secondary offering, with JPMorgan Chase Bank, N.A. ("JPMorgan")[2] as the depositary bank. Dr. Reddy's filed a Form F-6 registration statement (the "Registration Statement") with the SEC and included, among other things, a copy of the depositary agreement. Dr. Reddy's also filed a shelf registration statement on Form F-3 which included a prospectus and supplemental prospectus.

[2] As the Deposit Agreement provides, JPMorgan Chase's office is located at 4 New York Plaza, New York, New York 10004.

Dr. Reddy's also issued two press releases advertising a total issuance of an additional 14.3 million ADSs at $16. The November 2006 secondary offering increased the total number of ADSs outstanding to approximately 27.5 million.

46. The Registration Statement, which included a copy of the depositary agreement, was signed on October 27, 2006. The deposit agreement outlines obligations that Defendants willingly assumed under U.S. law, including agreeing to abide by "periodic reporting requirements of the Securities Exchange Act of 1934 and [filing of] certain reports with the United States Securities and Exchange Commission." Defendants also agreed to New York State choice of law clauses.

47. Moreover, the Registration Statement was signed by Defendants Reddy, Prasad, and Chakraborty, as well as Viswanatha Bonthu, Dr. Reddy's Authorized Representative in the United States—located at 200 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

48. Throughout the Class Period, Defendants knowingly used the means and instrumentalities of a U.S. national exchange to facilitate direct U.S. investment in Dr. Reddy's. Furthermore, Defendants knowingly assumed the responsibility of complying with U.S. securities laws, including the antifraud provisions of the Securities Exchange Act of 1934.

III. PARTIES

A. Lead Plaintiff

49. Lead Plaintiff Public Employees' Retirement System of Mississippi ("Mississippi PERS") was established in 1952 and provides retirement and related benefits for Mississippi state and public education employees, officers of the Mississippi Highway Safety Patrol, and certain elected officials, among others. As of June 30, 2017, Mississippi PERS oversaw approximately $27.1 billion on behalf of more than 324,000 members and their beneficiaries. As set forth in its Lead Plaintiff motion (ECF No. 12-3), Mississippi PERS purchased Dr. Reddy's

securities at artificially inflated prices during the Class Period and was damaged upon revelation of the alleged corrective disclosures.

B. The Defendants

50. Defendant Dr. Reddy's Laboratories Limited ("DRL") is a pharmaceutical manufacturing company which produces drugs and drug ingredients. The Company is incorporated and headquartered at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500 034, India and maintains a U.S. headquarters at 107 College Road East, Princeton, New Jersey 08540. Dr. Reddy's has two more locations in New Jersey and three more in the wider United States. The Company's ADS securities have traded on the NYSE since 2001 under the ticker "RDY." Furthermore, Dr. Reddy's often does not differentiate between its corporate entities, and blurs the line between those entities, operating as an integrated global company; for example, Dr. Reddy's itself states within its Form 20-Fs that "'Dr. Reddy's' or the 'Company' shall mean Dr. Reddy's Laboratories Limited ***and its subsidiaries***," including Defendant Dr. Reddy's Laboratories, Inc.

51. Defendant Dr. Reddy's Laboratories, Inc., ("Dr. Reddy's USA") was founded in 1984 and is DRL's wholly-owned U.S. subsidiary. Dr. Reddy's USA is DRL's registered agent in the United States, and it is located at 107 College Road East, Princeton, New Jersey 08540. Dr. Reddy's USA is primarily engaged in developing, manufacturing, and marketing generic pharmaceuticals and APIs in the United States. In the fiscal year ending March 31, 2014, Dr. Reddy's USA generated after tax profits of 484 million Indian rupees equating to approximately 2.25% of Dr. Reddy's total after tax profits; in fiscal year ending March 31, 2015, it generated 1.4 trillion Indian rupees equating to approximately 6.3% of Dr. Reddy's total after tax profits; and in fiscal year ending March 31, 2016, it generated 2.3 trillion Indian rupees—equating to approximately 11.5% of Dr. Reddy's total after tax profits. Dr. Reddy's USA is

DRL's authorized U.S. agent for communicating with the FDA, including the submission of responses to regulatory actions.

52. Defendant G.V. Prasad ("Prasad") was the Chief Executive Officer ("CEO") and Co-Chairman of the Company throughout the Class Period. Prasad signed, among other documents, each Form 20-F throughout the Class Period and the November 2006 registration statement for the secondary offering of Dr. Reddy's ADS on the NYSE. Prasad also participated in the November 2015 conference call, and subsequent other investor relation calls throughout the Class Period, in an effort to clarify analyst and investor questions concerning the FDA Warning Letter issued to Dr. Reddy's.

53. In addition to managing the Company as the CEO and Co-Chairman, by affirmatively participating in various calls and the approval process of the Company's Form 20-Fs—where he repeatedly made false and misleading statements concerning Defendants' quality management system, the impact of the Warning Letter, and their remediation efforts—Prasad had actual power and influence over Dr. Reddy's and the statements made by Dr. Reddy's.

54. Defendant Saumen Chakraborty ("Chakraborty") was the Chief Financial Officer and President of Dr. Reddy's throughout the Class Period. Chakraborty signed, among other documents, each Form 20-F throughout the Class Period and the November 2006 registration statement for the secondary offering of Dr. Reddy's ADSs on the NYSE. Chakraborty also participated in all earning calls during the Class Period, as well as the November 2015 conference call to clarify questions concerning the Warning Letter.

55. In addition to managing the Company as the CFO and President, by affirmatively participating in various calls and the approval process of the Company's Form 20-Fs—where he repeatedly made false and misleading statements concerning Defendants' quality management

system, the impact of the Warning Letter, and their remediation efforts—Chakraborty had actual power and influence over Dr. Reddy's and the statements made by Dr. Reddy's.

56. Defendant Abhijit Mukherjee ("Mukherjee") was the Chief Operating Officer ("COO") throughout the Class Period. As COO, Mukherjee was responsible for manufacturing, sales, and marketing operations at Dr. Reddy's, with a focus on the United States, India, Russia, Germany, and the UK. Mukherjee signed, among other documents, the November 2006 shelf registration regarding the sale of ADSs in the United States, in his capacity as President of Developing Business at the time. Mukherjee also participated in all earning calls during the Class Period, as well as the November 2015 conference call to clarify questions concerning the Warning Letter.

57. In addition to managing the Company as the COO, by affirmatively participating in various calls and signing the November 2006 Shelf Registration Statement—where he repeatedly made false and misleading statements concerning Defendants' quality management system, the impact of the Warning Letter, and their remediation efforts—Mukherjee had actual power and influence over Dr. Reddy's and the statements made by Dr. Reddy's.

58. Defendant Satish Reddy ("Reddy") was the Co-Chairman of the Company throughout the Class Period. Reddy signed, among other documents, each Annual Report throughout the Class Period, as well as the November 2006 shelf registration regarding the sale of ADSs in the United States. Reddy was also the recipient of the FDA's November 5, 2015 Warning Letter, and Reddy participated in the November 9, 2015 conference call to clarify questions concerning the Warning Letter. Reddy, by being responsible in part for the Annual Reports, contributed to the fraudulent misrepresentations regarding Defendants' quality management system, the impact of the Warning Letter, and their remediation efforts.

59. In addition to managing the Company as the Co-Chairman, by affirmatively participating in a November 9, 2015 conference call regarding the Warning Letter, and by affirmatively participating in the approval process of the Company's Annual Reports—where he repeatedly made false and misleading statements concerning Defendants' quality management system, the impact of the Warning Letter, and their remediation efforts—Reddy had actual power and influence over Dr. Reddy's and the statements made by Dr. Reddy's.

60. Defendants Prasad, Chakraborty, Mukherjee, and Reddy are collectively referred to as the "Individual Defendants." Dr. Reddy's and the Individual Defendants together are collectively referred to as "Defendants."

C. Relevant Non-Parties

61. Lachman Consultants Services Inc. ("Lachman Consultants" or "Lachman"), founded in 1978, is a leading U.S.-based consulting firm which "provides expert compliance, regulatory affairs, and technical services to clients around the world," including resolving FDA compliance issues. Dr. Reddy's hired Lachman Consultants as third-party consultants immediately after receiving a Warning Letter from the FDA on November 5, 2015. Lachman Consultants assisted Dr. Reddy's in its remediation process and implementation of a Corrective and Preventative Action ("CAPA") plan. Lachman Consultants is headquartered in Westbury, New York.

62. CW 1 was employed by Dr. Reddy's from 2008 to December 2016. During this period, CW 1 worked in both Hyderabad, India and Princeton, New Jersey. CW 1 was a member of the Bulk Active Group throughout this period and reported to the group's senior management.

63. CW 1's responsibilities included handling existing clients and products, and developing new customers. CW 1 regularly interacted with large pharmaceutical companies which were customers of Dr. Reddy's. During the course of CW 1's work, CW 1 would see the

audit reports for products that were sent to their customers. During CW 1's time working for Dr. Reddy's in Hyderabad, India, CW 1 worked out of a corporate office in the same city as Dr. Reddy's Unit V and Unit VI facilities and was responsible for Dr. Reddy's product portfolio. CW 1 stated that Dr. Reddy's Global Heads of Quality in the U.S. and India had access to all of the important quality documents from the facilities. One category of important quality documents were validation reports, which discussed the facilities' process robustness. Process robustness measures the replicability and consistency of a product's production as the company increases scale. CW 1 typically visited manufacturing facilities once a month.

IV. RELEVANT COMPANY AND INDUSTRY BACKGROUND

A. Nature of Dr. Reddy's Business

64. Founded in 1984, Dr. Reddy's Laboratories Limited ("Dr. Reddy's") is a global pharmaceutical company based in Hyderabad, Telangana, India. Dr. Reddy's manufactures and markets a wide range of pharmaceutical products in India and abroad, including active pharmaceutical ingredients and finished pharmaceutical products.

65. Active pharmaceutical ingredients ("APIs") are the principal ingredients which produce desired health effects in final pharmaceutical products. Final pharmaceutical products are what we commonly think of as medicinal drugs; they can come in the form of a tablet, capsule, or solution. Typically, APIs and inactive ingredients are assembled into drugs in a process called "formulation."

66. Dr. Reddy's manufactures pharmaceuticals and their ingredients through three business units: (1) Global Generics; (2) Pharmaceutical Services and Active Ingredients ("PSAI"); and (3) Proprietary Products. Most relevant in this action are the Global Generics and PSAI segments which account for approximately 97% of Dr. Reddy's revenue.

67. The Global Generics segment manufactures and markets prescription and over-the-counter drugs. Dr. Reddy's Global Generics has focused on producing branded and unbranded generic drugs, as well as biologics. Global Generics is responsible for approximately 82% of Dr. Reddy's total revenue.

68. Dr. Reddy's Global Generics segment offers more than 200 generic versions of drugs to over 80 countries. During the Class Period, North America (the U.S. and Canada) accounted for approximately 60% of Defendants' total Global Generic revenue.

69. Dr. Reddy's PSAI segment manufactures and markets APIs and intermediates. Dr. Reddy's PSAI segment produces and markets more than 100 different APIs, and exports to more than 80 countries. The United States, Canada, and Europe are the PSAI segment's principal overseas markets. Dr. Reddy's APIs and intermediates are both (i) used internally to formulate Dr. Reddy's drugs and (ii) sold externally to Dr. Reddy's pharmaceutical company customers for inclusion in the customers' drug formulations. PSAI is responsible for approximately 15% of Dr. Reddy's total revenue.

70. Given that Dr. Reddy's is vertically integrated, Dr. Reddy's API and intermediate manufacturing facilities are used by both the Global Generics and PSAI segments. Therefore, problems at API manufacturing facilities directly impact both the Global Generics and PSAI segments. In fact, Dr. Reddy's Form 20-Fs during the Class Period categorize all but one API manufacturing facility as primarily used by both the Global Generics and PSAI segments.

71. Dr. Reddy's has over twenty facilities located in India, including API manufacturing facilities, branded drug or "formulations" manufacturing facilities, and research and development facilities; Dr. Reddy's also has approximately ten facilities outside of India. Dr.

Reddy's has multiple facilities in the United States, including an API manufacturing plant in Middleburgh, New York and its U.S. headquarters in Princeton, New Jersey.

72. Highly relevant to this action are two API manufacturing facilities at Srikakulam, Andhra Pradesh ("Unit VI") and Miryalaguda, Telangana ("Unit V"), and an oncology formulation manufacturing facility at Duvvada, Visakhapatnam, Andhra Pradesh ("Unit VII"). Unit VI is Dr. Reddy's second largest manufacturing facility and Unit V is its third largest.

B. The Importance of Quality Control, Quality Assurance, and Internal Audit in Drug Manufacturing

73. Dr. Reddy's produces and markets more than 200 generics and 100 APIs to over 80 countries around the world. But to enjoy this global presence, Dr. Reddy's must comply with safety and quality requirements for each country or jurisdiction in which it sells pharmaceutical products. If Dr. Reddy's does not comply with a jurisdiction's regulations, it can be forbidden from selling products there. The FDA can restrict the entry of drug shipments at a port of entry into the U.S. by issuing an "Import Alert" or detaining and possibly refusing admission.

74. To ensure that the manufacturing process complies with regulations, pharmaceutical companies, including Dr. Reddy's, develop formulaic Standard Operating Procedures ("SOP") which explicitly define the processes their facilities use to manufacture pharmaceuticals. The creation of SOPs for manufacturing facilities is mandated by U.S. cGMP regulations.

75. Companies also establish a Quality Unit group in each manufacturing facility (the "Quality Unit"). Quality Units have specifically delineated responsibilities under cGMP to oversee manufacturing operations and ensure compliance with regulations and SOPs. Regulations require that the Quality Unit has available to it the services of a quality control ("QC") laboratory in order to perform tests on manufactured products. This testing informs the

Quality Unit's decision-making regarding whether to release a batch of medicine for human consumption.

76. The Quality Unit's QC procedures focus both on what must occur during the drug manufacturing process and what results from it. Specifically, QC processes (i) assess the suitability of incoming components, containers, closures, labeling, in-process materials, and the finished products; (ii) evaluate the performance of the manufacturing process to ensure adherence to proper specifications and limits; and (iii) determine the acceptability of each batch of manufactured product for release.

77. Quality Unit's QC procedures are highly regimented and must be faithfully documented in real-time. It is a violation of cGMP if "[t]he responsibilities and procedures applicable to the quality control unit" are not in writing or fully followed. 21 C.F.R. § 211.22(d).

78. After the Manufacturing Operations Unit has deemed a batch of manufactured product acceptable, and after the Quality Unit's QC processes have confirmed the assessment, the Quality Assurance ("QA") organization within the Quality Unit ensures that all procedures were followed properly, including ensuring that the QC function properly documented its analysis. Specifically, QA primarily involves (1) review and approval of all procedures related to production and maintenance, (2) review of associated records, and (3) periodically auditing and performing/evaluating trend analyses. In effect, QA double checks that the manufacturing process followed the SOP, that the manufactured products are within the defined specifications, that everything was documented, and that no errors or contamination occurred.

79. Onsite QC and QA is the first step in ensuring that pharmaceuticals are safe and effective for consumers. In addition to onsite QC and QA, large drug manufacturers like Dr. Reddy's typically rely on corporate internal audit teams that are independent from the

manufacturing facilities. Internal audit verifies that the company's QC and QA procedures are followed and that the data generated in these processes is maintained properly. Internal audit departments nearly universally report directly to senior management.

80. Industry standards for QC and QA are set forth in the FDA's "Guidance for Industry" reports and the International Conference on Harmonization's Pharmaceutical Quality System Q10 standard (the "ICH Q10 Standard"). The ICH Q10 Standard provides, among other things, that a company's Pharmaceutical Quality System shall: (1) establish and maintain a State of Control; (2) facilitate continual improvement; (3) facilitate effective knowledge transfer and management; and (4) facilitate implementation and effective utilization of Quality by Design (Q8) and Risk Management (Q9). ICH standards are guidance documents, but are the result of international collaboration in their creation and they have been adopted as persuasive guidance by most pharmaceutical regulatory authorities in the world. Core members of the ICH are the United States, the European Union, and Japan, with several other countries as non-core participants.

81. According to Dr. Reddy's 2013–2015 Sustainability Report, Dr. Reddy's implemented a "[t]hree-tier quality management review process" at the site level, business unit level, and senior management level. The report also provided that Dr. Reddy's conducted "[f]orensic internal audits (unannounced and floor operations focused)."

82. Dr. Reddy's affirmatively stated throughout the Class Period that it had implemented these basic processes overseeing drug manufacturing, including implementing effective QC, QA, and internal audit teams. According to Dr. Reddy's website, it has a "rigorously implemented Quality Management System (QMS)," where it "focuses on continual improvement aimed at optimizing processes and eliminating non-value-adding efforts in

production." Defendants claimed they had "robust quality processes and systems in place at [their] developmental and manufacturing facilities to ensure that every product is safe and of high quality" and that they have "integrated 'Quality by Design' to build quality into all processes and use quality tools to minimize process risks."

83. Despite Defendants' breezy assurances of compliance with these rigid standards, throughout the Class Period they failed to create effective Quality Units at multiple manufacturing facilities in India. Dr. Reddy's deficient Quality Units even failed to take action when specific production problems and deviations from the SOP were identified. *See infra* Section V.D.

C. The FDA's Regulatory Framework

84. One of the most important sets of standards and regulations for Dr. Reddy's business were those promulgated by the FDA. As one analyst from ICICI Securities put it in an analyst report dated November 10, 2015, "US revenues are the key driver for the company, contributing ~47% to its overall revenues." Therefore, it was of paramount importance to Defendants that they ensure compliance with the FDA's standards and regulations.

85. The FDA is charged with ensuring that the manufacturing of drugs and their component ingredients meets a minimum quality standard so they are safe and effective for U.S. consumers. The FDA enforces the FD&C Act, which prohibits, among other things, "the introduction or delivery for introduction into interstate commerce of any … drug… that is ***adulterated***." 21 U.S.C. §331(a). Under the FD&C Act, a drug is adulterated if:

> [T]he methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered ***in conformity with cGMP*** to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

21 U.S.C. § 351(a)(2)(B).

1. Current Good Manufacturing Practice

86. As the FDA explains, for pharmaceuticals produced for humans "[t]he main regulatory standard for ensuring pharmaceutical quality is" cGMP. cGMP effectively sets minimum standards. The FDA promulgates regulations defining cGMP for final drugs in the Code of Federal Regulations. *See generally* 21 C.F.R. § 210 (Current Good Manufacturing Practice in Manufacturing Processing, Packing, or Holding of Drugs; General) and 21 C.F.R. § 211 (Current Good Manufacturing Practice for Finished Pharmaceuticals). For Active Pharmaceutical Ingredients, the established standard is the International Conference on Harmonization guideline Q7 ("ICH Q7"), which generally conforms to the cGMP requirements as laid out in 21 C.F.R. §§ 210 and 211.

87. It is solely a pharmaceutical company's responsibility to proactively ensure that its manufacturing processes are performed in compliance with cGMP and FDA regulations. However, while it is the company's duty alone, the FDA is charged with enforcing compliance when drug manufacturers violate cGMP and other regulations.

88. The FDA's cGMP regulations were designed to, among other things, prevent super- and sub-potency, deviations, contamination, mislabeling and other errors in the manufacture of drugs. cGMP regulations outline general rules for all aspects of drug manufacture including buildings and facilities, personnel, equipment, drug components and containers, production, packaging and labeling, and record-keeping.

89. One of the basic tenets of cGMP is that manufacturing errors will occur from time to time. For example, one common error during production occurs when a batch of medicine or API has a greater amount of an active chemical than it should. When this happens, that batch is labeled "out-of-specification" or OOS.

90. Given this ever-present risk, cGMP requires that drug manufacturers test every stage of manufacturing, from the raw materials to the final product. Specifically, the Code of Federal Regulations states that, "[e]xamination and testing of samples shall assure that the drug product and in-process material conform to specifications." 21 C.F.R § 211.110(b); *see also* ICH Q7 § 11.20. Furthermore, "[i]n-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process." 21 C.F.R. § 211.110(c); *see also* ICH Q7 § 11.18.

91. Quality control testing of the final manufactured product is especially important because it is how a company "assure[s]" itself that the manufacturing processes worked properly and the drugs "conform to specifications." 21 C.F.R. § 211.110(b); *see also* ICH Q7 § 11.20. Quality control testing therefore lies at the heart of a drug manufacturer's successful operation.

92. cGMP mandates that all results of all of these quality control tests be contemporaneously recorded and preserved. *See* 21 C.F.R. § 211.194(a) ("Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays, as follows: . . . (6) A statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested.") *See also* ICH Q7 § 6.60.

93. Manufacturers must submit their laboratory records and quality control testing data to the FDA when applying to produce a new drug at that facility. The FDA also reviews this data when inspecting a manufacturing facility. The proper preservation of data and testing results allows the FDA to retrospectively evaluate the quality of the products being produced at a certain facility and evaluate its compliance with cGMP. The FDA's review of a manufacturer's

records and data is one of its key methods for protecting U.S. consumers from dangerous pharmaceuticals that could risk American lives.

94. Due to the important role that this data plays, cGMP established data integrity protections, requiring that "[a]ppropriate controls shall be exercised over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel." 21 C.F.R. § 211.68(b); *see also* ICH Q7 § 5.43. A failure to maintain all data derived from all laboratory tests, a failure to record activities at the time they were performed, and a failure to prevent unauthorized access or changes to data are all data integrity issues that are serious violations of cGMP and, when in the form of electronic records or employing the use of electronic signatures, the FDA's omnibus rule at 21 C.F.R. § 11.[3]

95. In addition, cGMP also requires that drug manufacturers' Quality Unit review and approve "[a]ll drug product production and control records," in order "to determine compliance with all established, approved written procedures before a batch is released or distributed." 21 C.F.R. § 211.192; *see also* ICH Q7 § 2.21.

96. Finally, cGMP requires that drug manufacturers establish and follow "[a]ppropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile." 21 C.F.R. § 211.113; *see also* ICH Q7 § 11.13. Failure to comply with cGMP regulations renders any resulting drug "adulterated" under the FD&C Act and the drug and its producer subject to regulatory action by the FDA. 21 C.F.R. § 210.1(b).

[3] 21 C.F.R. § 11 concerns itself with controls necessary to assure the integrity of electronic records and the use of electronic signatures. 21 C.F.R. § 11 is separate from the cGMP regulation and applies to all FDA regulated operations across all industries that use electronic records and signatures.

97. As discussed in greater depth below, Dr. Reddy's repeatedly claimed throughout the Class Period that it was in full compliance with regulations at their manufacturing facilities. *Compare infra* Section V.B-C *with* VI.B. However, Dr. Reddy's violated cGMP regulations and ICH Q7 standards by, among other things, manipulating and deleting laboratory records (21 C.F.R. § 211.194; ICH Q7 § 6.60), failing to maintain quality control testing records (21 C.F.R. § 211.192; ICH Q7 §§ 2.15, 6.12), and failing to mitigate the known risk of microbiological contamination (21 C.F.R. § 211.113; ICH Q7 § 11.13).

2. What Is Required When Quality Control Testing Reveals Manufacturing Errors

98. When Dr. Reddy's Quality Unit tests a batch of products and the test results show it does not meet the production parameters, the batch is termed "out-of-specification" or OOS. Out-of-specification results obtained in the laboratory are classified as one of three general categories of errors: (1) laboratory error; (2) nonprocess-related or operator error, also known as human error; and (3) process-related or manufacturing error.

99. cGMP requires that when errors or discrepancies are identified during testing, the manufacturer must "thoroughly" investigate and identify the cause of the error by performing a root cause analysis. 21 C.F.R. § 211.192 ("Any unexplained discrepancy . . . or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated."); *see also* ICH Q7 §§ 2.17, 11.15. A manufacturer may not release a batch for distribution until the error has been fully investigated and the root cause has been determined and corrected. These investigations must be contemporaneously recorded and preserved. 21 C.F.R. § 211.192 (a "written record of the investigation shall be made and shall include the conclusions and follow up"); *see also* ICH Q7 § 2.15.

100. Systemic issues must be further investigated to determine the scope of the impact, including determining whether the root cause impacted distributed or undistributed products. Manufacturers must conduct thorough investigations into the causes of any deviations, out-of-specification findings, or failing quality test results to understand what products have been impacted and prevent the release of unsafe or inconsistent pharmaceutical products.

101. In addition to claiming full compliance with cGMP, Defendants repeatedly assured investors that observations by the FDA in November 2014 were not significant and would not impact any activity at their manufacturing facilities. *Compare infra* Section V.B-E with VI.A. As discussed in greater depth below, Dr. Reddy's violated cGMP regulations and ICH Q7 standards by, amongst other things, failing to "thoroughly investigate[]" out-of-specification QC testing results at multiple manufacturing facilities over many years (21 C.F.R. § 211.192; ICH Q7 § 11.15).

3. FDA Inspections

102. The FDA's Office of Regulatory Affairs enforces drug manufacturers' compliance with U.S. rules and regulations for pharmaceutical safety. The FDA's Office of Regulatory Affairs performs on-site inspections of a manufacturer's facilities to evaluate their compliance with cGMP and regulations governing data integrity. FDA investigators conduct both pre-approval and general cGMP compliance inspections. Pre-approval inspections are conducted in advance of the FDA's decision on new drug applications where the product would be made in whole or in part at that facility. cGMP compliance investigations are of a more ad hoc nature and are used to check the manufacturer's ongoing cGMP compliance. Some inspections are comprehensive in scope, while others are limited.

103. After an investigation, inspectors may issue a FDA Form 483 Notice of Inspectional Observations ("FDA Form 483") for the express purpose of informing the

company's senior management of the objectionable conditions. The FDA encourages management to respond in writing within 15 days with a Corrective and Preventative Action plan ("CAPA").

104. A FDA Form 483 does not represent a final agency determination regarding the company's compliance. Rather, it means that in the judgment of the FDA inspection team the listed observations may, after further review by others in FDA, be considered to constitute violations of the cGMP regulations or other requirements. FDA Form 483s are not intended to be all-inclusive and are limited by the scope of the inspection.

105. If the FDA determines after further review that some observations are significant enough or if the company fails to adequately remedy the observations, the FDA may issue a warning letter. A FDA warning letter outlines the FDA's position concerning certain observations and mandates that the company correct the problem. The receipt of a Warning Letter usually means that a drug manufacturer's pending new drug applications will not be approved until the non-compliance is remedied. Warning Letters typically provide directions and a timeframe for the company to inform the FDA of its plans for remediation.

106. The FDA reviews the company's remediation plans and ensures they are sufficient to resolve the enumerated observations. After the company implements its remediation plans, the FDA conducts follow-up inspections to assess whether the company corrected all observations, and if it has, the FDA issues a close-out letter. However, if the problems persist, the FDA may take further enforcement action, including refusing to admit certain pharmaceutical products into the U.S through an Import Alert.

107. The FDA investigators also write Establishment Inspection Reports ("EIR") after inspections. EIRs expand upon the observations noted on the FDA Form 483, provide further

evidentiary details, and communicate general information about the company and its management to internal FDA agency reviewers to aid in their enforcement decision-making. EIRs are internal FDA documents that are usually not shared with the drug manufacturer whose facility is in trouble until such time as the matter is resolved and the investigatory file is closed.

108. An EIR contains the entire narration of the FDA investigator's inspection. The EIR is examined by officials at a District Office of the FDA who determine whether the facility meets the criteria for No Action Indicated ("NAI"), Voluntary Action Indicated ("VAI"), or Official Action Indicated ("OAI"). NAI is only appropriate when no objectionable items are found; VAI indicates that objectionable items were found, but the FDA does plan to take further regulatory action against the company based on the report; and OAI means objectionable items were found and further regulatory actions should be recommended, such as the issuance of a warning letter. When a company is under an OAI classification, the FDA typically halts further approval of pending New Drug or Abbreviated New Drug Applications until the agency is satisfied that the observations have been properly addressed.

V. DEFENDANTS' FRAUDULENT SCHEME

A. Prior to the Start of the Class Period, Dr. Reddy's Ramped Up Production, Putting Pressure on its Quality Team to Release Products

109. Beginning in 2012, Dr. Reddy's dramatically increased the number and volume of pharmaceutical products produced at its facilities. Specifically, CW 1, who had firsthand information concerning Dr. Reddy's facilities in India, recalled a sharp increase in the number and volume of products produced at Unit VI between 2011 and 2012, which put extreme pressure on the personnel and manufacturing resources.

110. Indeed, because of the increase in production from 2012 to 2014, Dr. Reddy's total revenue increased by approximately 77%. During that period, Dr. Reddy's Global Generics revenue grew by 97%, and the PSAI segment revenue increased by 22%.

111. Moreover, from 2011 to 2014, the Company announced key approvals of new drugs, and the resulting product launches were a primary driver of Dr. Reddy's growth prior to the Class Period. According to the Company's annual reports, in fiscal year 2011, Dr. Reddy's launched approximately 59 new products; in fiscal year 2012, it launched 30 new products; in fiscal year 2013, it launched 104 new products; and in fiscal year 2014, it launched 54 new products.

112. Although good for Dr. Reddy's bottom line in the short run, the dramatic increase in the number and volume of products produced at its plants created significant manufacturing risk because it pushed Dr. Reddy's production beyond its capacity for safe manufacturing. According to CW 1, there were a number of reasons that Dr. Reddy's was limited in how much it could safely scale up production at its manufacturing facilities. Lead Plaintiff's expert consultant confirmed that, based on his experience and knowledge of industry norms, the ramping up of production output at a facility necessarily affects the capacity for safe manufacturing.

113. First, pharmaceutical manufacturing plants have a finite amount of floor space that must be divided into manufacturing areas known as "production bays," which are usually dedicated to a single product. Products are segregated into separate production bays for safety and quality reasons—mainly to avoid contamination. Dr. Reddy's plants were no exception, and according to CW 1, the Company typically produced products in separate bays. However, because Dr. Reddy's rapidly expanded the number of products at its facilities, the Company increased the number of products manufactured in the same bay, increasing the risk of errors.

114. Second, the size of each bay and the capacity of the equipment in the bays limit the amount of product that a manufacturer can safely produce in a given production. According to CW 1, Dr. Reddy's facilities were not built for the increase in production and, in particular, large orders between 2011 and 2014 "jammed the facility" at Unit VI. As a result, there were production problems and delays because orders were processed on infrastructure that was woefully inadequate to meet the production schedule.

115. CW 1 said that a major factor in Unit VI's subsequent FDA violations was the overload of production at the facility. Indeed, CW 1 specifically identified a 200 kilogram order for Ezetimibe, a cholesterol lowering drug, produced on a bay that was mapped for less than 20 kilograms. A similar problem occurred when a 100 kilogram order for Eszopiclone, a treatment for insomnia, was processed on a bay that was built for less than 15 kilograms of production. The same logjam occurred for an order for Valgancilovir, an anti-HIV medication, which was a problem "from the word go" and it had issues with meeting the purity specifications. In addition, CW 1 recalled that orders for Valsartan (hypertension) and Vilazodone (depression) also overwhelmed Dr. Reddy's production facilities. CW 1 stated that this was not normal in the industry, and that a company would be expected to ramp up production in stages.

116. Third, Dr. Reddy's was limited in its ability to safely increase production, because it had to ensure that sufficient resources were dedicated to quality control and quality assurance, so that those programs could keep pace with the overall increase in production. For instance, according to CW 1, for a batch of product to be released, tests must be performed to ensure the product's consistency and quality. Generally speaking, individuals must be trained and qualified to perform those highly technical tests and, indeed, according to CW 1, these tests include gas chromatography and high-performance liquid chromatography.

117. CW 1 stated that during the ramp up in production, there was a lot of pressure on the quality teams to cut corners and release batches of products from the review cycle. CW 1 explained that in the span of seven months, two successive heads of quality for Unit VI quit because of the pressure. These heads of quality were asked to release batches in a short timeframe because of the delays in the extended review which had resulted in a drop in the monthly sales from Unit VI. CW 1 stated that these quality heads were unwilling to keep quickly releasing batches beyond a certain point and quit. CW 1 also confirmed that he/she was aware at the time of the quality teams' practice of retesting products that had failed quality tests, and the teams were worried that they were going to get caught releasing batches they should not have released.

118. CW 1 further explained that Dr. Reddy's monitored its ability to increase production through a metric called "process robustness," which measures the replicability and consistency of a product as the Company's production output increases. According to CW 1, Dr. Reddy's created "validation reports" to memorialize its facilities' process robustness as they increased the facilities' outputs. According to CW 1, Dr. Reddy's senior management, including Defendant Prasad and the Heads of Quality in the U.S. and India, had access to all important quality documents, including these validation reports.

119. Lead Plaintiff's expert consultant confirmed that process validation is a mandatory aspect of cGMP. Before validating a process, a drug manufacturer must ensure that all the equipment to be used has been qualified. This qualification process is subdivided into Installation Qualification ("IQ"), which assures the equipment is installed correctly; Operational Qualification ("OQ"), which demonstrates that the equipment will operate correctly throughout its anticipated operating range, and Performance Qualification ("PQ"), which shows it will run

correctly at the parameters to be used in the process. Process validation is a formalized exercise, done against a pre-approved protocol, which provides a high degree of assurance that the process will consistently produce a product meeting its pre-approved specifications and quality attributes. Most drug companies run three consecutive batches to establish process validation. If the batches pass QC controls for safety and effectiveness, the process is said to be robust. After the initial validation, drug manufacturers continue to monitor and evaluate process robustness. Thus, according to Lead Plaintiff's expert consultant, the quality problems at Dr. Reddy's due to the increased production should have been captured in the Company's validation reports, which CW 1 stated were accessible by Dr. Reddy's senior management.

B. The FDA Inspected Dr. Reddy's Manufacturing Facilities and Uncovered Serious and Wide-Spread Deficiencies in the Company's Quality Management Systems

1. The November 2014 FDA Form 483 Inspection Report

120. On November 21, 2014, Defendants received an FDA Form 483 Inspection Report (the "November Form 483") citing nine observations of potential non-compliance at Dr. Reddy's Srikakulam facility, Unit VI. *See* Ex. 2.[4] The November Form 483 was addressed to KVSN Raju, the "Senior Director – Works, Location Head" for Unit VI. As with all FDA Form 483s, the November Form 483 was issued to Dr. Reddy's in order to inform senior management of the observations found. S*ee supra* Section IV.C.3.

121. The Srikakulam facility, Unit VI, was a key manufacturing plant for Dr. Reddy's because the Company relied on it to produce a significant number of its most complex and material products. Additionally, many of the Company's abbreviated new drug applications submitted to the FDA hinged on the facility's compliance with cGMP for FDA approval,

[4] While the FDA Form 483s are not public documents, Lead Plaintiff has received multiple FDA Form 483s through Freedom of Information Act request. The FDA Form 483s that Lead Plaintiff received are attached as Exhibits to this Complaint.

including a generic version of Nexium, one of the Company's flagship products. Shortly after receipt of the Warning Letter, Defendant Chakraborty estimated in media interviews that Unit VI contributed "anywhere between 10–12%" to Dr. Reddy's top line. As Axis Capital would put it on November 6, 2015, "Srikakulam [Unit VI] is the main API facility (most advanced facility with complex filings) from where most critical products are filed (including gCopaxone, in our view)."

122. Unit VI manufactured API and intermediates that were (i) sold externally to Dr. Reddy's customers for inclusion in final pharmaceutical formulations, and (ii) used internally to manufacture Dr. Reddy's final pharmaceutical products. Dr. Reddy's SEC filings note that Unit VI was part of both its Global Generics and PSAI segments.

Observations Regarding Data Integrity

123. The November Form 483 included numerous observations that implicated data integrity and computer security concerns. Most alarming, the FDA observed that Defendants had created and used an undisclosed, unreported "[c]ustom QC [quality control] laboratory." Because this quality control laboratory was effectively hidden from FDA oversight, it allowed Dr. Reddy's to test and retest batches of manufactured products and record only positive, passing test results. The failure to disclose a quality control laboratory, by itself, is a gross violation of cGMP. 21 C.F.R. § 211.194 ("Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards."); *see also* ICH Q7 § 6.60.

124. The FDA inspector discovered the undisclosed laboratory only after inspecting the audit trail for particular batches of products. The FDA inspector described the discovery

stating that "[n]o explanation was provided regarding the failure to facilitate the review of cGMP data collected within this 'CQC' [custom quality control] laboratory."

125. After discovering the undisclosed laboratory, the FDA conducted a "subsequent limited review" of the tests performed there from January to February 2012. The FDA found at least five instances in that short timeframe where "written procedures regarding the raising of laboratory incidents . . . and/or out-of-specification (OOS) inspections . . . were not followed." The November Form 483, addressed to the Senior Director of the Unit VI facility, notified Defendants that because they had not documented, reported, or investigated prior test results for batches of drug products and that the products were out-of-specification and therefore were "adulterated" under the FD&C Act. Dr. Reddy's failure to record all of its testing and validation data at this undisclosed laboratory magnified the severity of the FDA's discovery.

126. Dr. Reddy's use of an undisclosed quality control laboratory that selectively reported passing results should have raised significant concerns amongst management and the Defendants regarding the Company's data integrity. Dr. Reddy's data integrity problems at Unit VI created a significant risk that Dr. Reddy's would recklessly sell "adulterated" pharmaceutical products for U.S. consumption in violation of the FD&C Act.

127. Beyond the use of the undisclosed lab, the FDA noted other serious, facility-wide data integrity problems. The November Form 483 noted that Defendants' computerized systems at Unit VI did not have sufficient controls to prevent unauthorized access or changes to data. (Observation 2). Specifically, the FDA stated that "[o]ur random review of one HPLC [high performance liquid chromatography test, one of a battery of quality control tests] (#AD021) hard drive uncovered evidence that ***analytical raw data had been collected throughout the month of November 2014 and had been deleted***." When the FDA investigator confronted the responsible

analyst, the analyst claimed that "another individual had logged into the system using his credentials and had performed injections and deletion without his knowledge."

128. Indeed, the inspection revealed that no passwords were required during log-in, including the use of the software Administrator privileges, meaning anyone could access and manipulate or delete data critical for assuring the quality and safety of Dr. Reddy's products. The lack of individual passwords also makes it impossible to later determine who made changes to data in the records, because anyone with access could have done so.

129. By any measure, these were serious violations of cGMP and FDA regulations. 21 C.F.R. § 211.194 ("Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards"); 21 C.F.R. § 211.68 ("Appropriate controls shall be exercised over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel."); *see also* 21 C.F.R. § 11, ICH Q7 §§ 5.43, 6.60.

130. One component of ensuring data integrity and computer security is appropriate preservation of quality control testing data and appropriate limitations of employees' permissions for recording data. The failure to maintain data integrity and computer security impairs the ability of a drug manufacturer to detect and prevent harm to end consumers of pharmaceuticals because cGMP decisions, including decisions that a product is safe and effective enough to administer to patients, depend upon the accuracy of the associated records. When the accuracy of the records is called into doubt, proper decisions cannot be made.

131. More troublingly, when the FDA discovers data integrity problems and inappropriate manipulation of quality control testing data by deleting negative results, the FDA becomes skeptical of the manufacturer's self-reported results. Moreover, given the FDA's then

focus on data integrity issues in India (*see infra* Section VII.C), Defendants knew or were reckless in not knowing that the FDA's observations concerning data integrity were serious issues of non-compliance and there was a substantial likelihood the Company would incur future enforcement actions and its manufacturing capabilities would be adversely impacted.

Observations Regarding a Failure to Investigate

132. The FDA also observed that Defendants' "[i]nvestigations into critical deviations or the failure of a batch of intermediate or API to meet specifications do not include justifications or follow-up. Specifically, laboratory investigations are inadequate as your firm fails to document adequate scientific justifications for your root cause determinations." (Observation 7). The FDA informed Defendants that when the quality control employees at Unit VI identified "critical deviations" or an out-of-specification result during their testing, they did not inquire into the cause of the problem as required by cGMP. The FDA noted that for one record it reviewed, "[y]our investigation documented that no laboratory error . . . occurred, but nonetheless your conclusion attributed the most probable cause to an unfounded laboratory error." Dr. Reddy's failure to institute a practice of properly determining the root cause of drug manufacturing errors violated one of the most important aspects of cGMP and risked the health and welfare of all customers who unwittingly consume "adulterated" drugs.

133. Notably, the FDA found that out-of-specification results at Unit VI languished uninvestigated for almost a year, most likely due to the increased pressure quality teams were under to release batches from the review cycle. Specifically, the FDA found that a batch of intermediate tested on December 11, 2013, "failed to meet the single unknown impurity specification" and with regard to the mandatory root cause analysis under cGMP the FDA noted, "[a]s of November 17, 2014, this investigation had not been completed." Rather than determine

the cause of the out-of-specification result, Dr. Reddy's ***retested the product five times*** and ***reported only the final, fifth retest***. "The investigation remains open, unsigned by the QC [quality control] unit, and has yet to be assessed by the QA [quality assurance] unit." cGMP standards, which Defendants claimed they followed, make clear that manufacturers may not bypass an investigation by repeatedly retesting product until it passes quality tests.

134. Rather, whenever Dr. Reddy's generated an out-out-specification result during quality control testing, the Company should have determined what caused the result and remedied the error. 21 C.F.R. § 211.192 ("Any unexplained discrepancy . . . or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated."); *see also* ICH Q7 §§ 2.17; 11.15. The seriousness of the observation is manifest. If an out-of-specification result was caused by a manufacturing error and Dr. Reddy's failed to resolve it in a timely manner, then the root cause of the deviation is ongoing and other batches are being manufactured with potentially harmful quality variations which may or may not be detected.

135. Additionally, despite cGMP and FDA regulations that mandate that all validation and quality control test results be maintained (21 C.F.R. § 211.194; ICH Q7 § 6.60), the FDA observed that Defendants' records at Unit VI "do not include complete data derived from all tests conducted to ensure compliance with established specifications and standards, including examinations and assays." (Observation 1). The FDA observed that Dr. Reddy's was not preserving the results of all quality, consistency, and purity tests.

Observations Regarding Microbiological Contamination

136. The FDA also noted the potential for microbiological contamination at Unit VI. cGMP requires that drug manufacturers establish and follow "[a]ppropriate written procedures,

designed to prevent microbiological contamination of drug products purporting to be sterile." 21 C.F.R. § 211.113; *see also* ICH Q7 § 11.13.

137. The FDA observed that the "[w]ater used in the manufacture of APIs has not been demonstrated to be suitable for its intended use." (Observation 5). The FDA found multiple incubated plates with "significant growth of both bacteria and mold, and appeared to be TNTC [too numerous to count]." Despite the visible bacterial growth and mold, Dr. Reddy's employees failed to make note of it, and the FDA noted that "during our review of your [REDACTED] trending data, no significant growth of bacteria and/or mold was noted." Dr. Reddy's Unit VI was not properly evaluating its manufacturing and testing facilities for the potential for biological contamination.

138. In sum, the non-public observations listed in the November Form 483 were extremely troublesome. Furthermore, Dr. Reddy's use of a hidden quality control laboratory raised alarm bells at the FDA and undermined the FDA's trust in Dr. Reddy's submissions and quality data reports.

2. The January 2015 FDA Form 483 Inspection Report

139. After issuing the November Form 483, the FDA continued to inspect Dr. Reddy's manufacturing facilities. Specifically, the FDA performed an inspection of a manufacturing facility located at Miryalaguda, Telangana ("Unit V") from January 27 to January 31, 2015. Unit V is an API manufacturing facility, much like Unit VI.

140. After completing the inspection of Unit V, on January 31, 2015, the FDA sent Defendants a second FDA Form 483 inspection report (the "January 2015 Form 483") noting four observations of potential non-compliance with cGMP for Unit V. The January 2015 Form 483 was addressed to K.V.S. Ramrao, a Senior Vice President at Dr. Reddy's. *See* Ex. 3.

141. Much as it was the case at Unit VI, two observations at Unit V concerned data integrity and computer security issues. (Observations 1 & 2). The FDA found that Defendants' computerized systems at Unit V did not have sufficient controls to prevent unauthorized access of data or unauthorized release of final products. *See* 21 C.F.R. § 211.68; *see also* ICH Q7 § 5.43. Additionally, the FDA observed that "[q]uality related documents are not maintained appropriately." *See* 21 C.F.R. § 211.194; *see also* ICH Q7 § 6.60.

142. Another common theme between the observations at Unit VI and Unit V was Defendants' failure to investigate out-of-specification results or to implement appropriate corrective actions. *See* 21 C.F.R. § 211.192; *see also* ICH Q7 §§ 2.17; 11.15. The FDA noted that five batches of products between November 18, 2013 and August 25, 2014 failed an optical purity test. The FDA observed that "[Dr. Reddy's] failed to investigate reoccurring non-conformances from occurring."

3. The March 2015 FDA Form 483 Inspection Report

143. The FDA performed an inspection of a manufacturing facility located at Duvvada, Visakhapatnam, Andhra Pradesh ("Unit VII") from February 26 to March 6, 2015. Unit VII is an oncology formulation facility with two manufacturing units, FTO Unit – 7 and FTO Unit – 9.

144. Based on the inspection of Unit VII, on March 6, 2015, Defendants received the third FDA Form 483 (the "March 2015 Form 483") noting ***twenty*** observations of potential non-compliance with cGMP for Unit VII. The March 2015 Form 483 was addressed to Ram Rajendra Kapratwar, Senior Director, Site Head. *See* Ex. 4. Again, the FDA observed data integrity, computer security issues, and inadequate investigations into deviations and out-of-specification results.

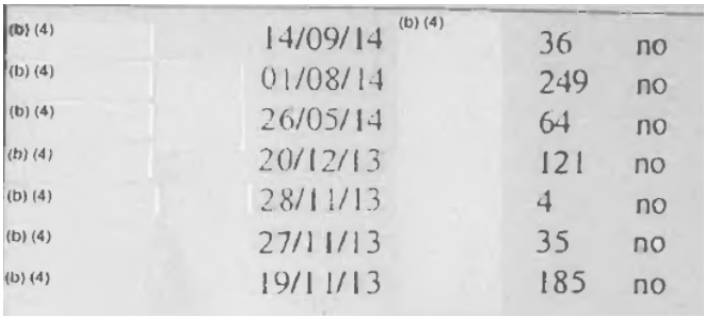
145. The FDA noted that Unit VII was missing certain raw data (21 C.F.R. § 211.194 and ICH Q7 § 6.60) and that numerous individuals who no longer worked for the company had

"operator access with password authorization." *See* 21 C.F.R. § 211.68; *see also* ICH Q7 § 5.43. Additionally, there was "no protocol or document to describe the manner with which the integrity test parameters were developed and established." (Observations 4 and 9).

146. The FDA noted that investigations into deviations were woefully inadequate in comparison to Dr. Reddy's own Validation Master Plan. "The media fill acceptance criteria [in the Validation Master Plan is] 'When filling fewer than 5000 units, no contaminated units should be detected. One (1) contaminated unit is considered cause for revalidation, following an investigation.'" When filling 5,000 to 10,000 units, according to Dr. Reddy's Validation Master Plan, "[o]ne (1) contaminated unit is considered cause for an investigation based on which a [redacted] revalidated run can be planned. Two (2) contaminated units are considered cause for revalidation, following investigation."

147. Despite the requirements in Dr. Reddy's Validation Master Plan, the FDA pointed out that Dr. Reddy's did not determine assignable cause for numerous batches with high numbers of rejected units, well beyond the threshold of one or two rejected units per media fill. Based on a review of a sampling of Dr. Reddy's batch manufacturing records ("BMR") during the inspection, the FDA provided a table highlighting numerous instances when Unit VII failed to determine an assignable cause for rejects from November 2013 until October 2014:

Batch #	Date	Filled Units	Reject Units	Assignable Cause for rejects
(b) (4)	30/10/14	(b) (4)	81	no
(b) (4)	27/10/14	(b) (4)	21	no



(b) (4)	14/09/14	(b) (4)	36	no
(b) (4)	01/08/14		249	no
(b) (4)	26/05/14		64	no
(b) (4)	20/12/13		121	no
(b) (4)	28/11/13		4	no
(b) (4)	27/11/13		35	no
(b) (4)	19/11/13		185	no

148. The FDA commented that:

> Regarding the above media fill batches, the Team Leader Production confirmed that there is no assignable cause for the rejection of the filled units. . . Rejecting the media filled vials without an assignable cause and not incubating the media filled units precludes the company from successfully achieving the media fill acceptance criteria.

149. Additionally, the FDA noted that the "[BMR] lists a number of routine and non-routine interventions" and "[a] Team Member of Production confirmed that the[re] is no rationale that established the media fill interventions."

150. In another observation, Unit VII, like Unit VI, failed to follow appropriate written procedures designed to prevent microbiological contamination of drug products purporting to be sterile. *See* 21 C.F.R. § 211.113; *see also* ICH Q7 § 11.13. The FDA noted that "[t]he firm's data does not support their current environmental monitoring program." (Observation 17). The FDA noted that "the firm does not have data to support their current practice" for microbial monitoring of surfaces.

151. Disturbingly, the FDA also stated that "[a]fter notifying Associate Director of Quality Assurance, Resource Manager of Quality Assurance, and Associate Director and Head Operations of the issues wit[h] [redacted] mechanism, management failed to intervene and allowed the filling process to continue uninterrupted." Even after specifically notifying

management of the issue, "[n]o incident report was initiated to evaluate the quality impact of the equipment malfunctions observed."

152. The FDA noted that while Dr. Reddy's "Quality Manual Annexure" claimed that the Unit VII "site Quality Assurance Department will operate in accordance with the requirements outline[d] in 21 C.F.R. 210 and 211 and EC guide to Good manufacturing practices," "***the aforementioned objectionable conditions document that the Quality Assurance department has not assured that they can meet their own Quality Objectives and Quality Program established by the 'Quality Manual***.'"

153. The FDA even witnessed one of Defendants' analysts mark a test positive when, in reality, the test had failed according to the regulations. (Observation 16).

154. In sum, among other serious observations, the three FDA Form 483 inspection Reports issued to Dr. Reddy's from November 2014 to March 2015 demonstrated a pattern of data integrity breaches, and inadequate investigations of out-of-specification findings, and documentation failures at all three sites. Furthermore, at Units VI and VII, Dr. Reddy's had not taken sufficient precautions to avoid microbiological contamination of the products they were manufacturing.

155. If Dr. Reddy's management had not been previously aware of these conditions and practices prior to the FDA inspections—even though the facts indicate that they were—they were certainly made aware of them via the issuance of the November, January, and March Form 483s.

156. Defendants provided formal responses to the November, January, and March Form 483s on December 15, 2014, February 19, 2015, and March 27, 2015, respectively. They

also provided updates to the FDA on January 31, April 9, May 13, May 21, July 14, and September 14, 2015.

C. Defendants Misled Investors About the Severity and Likely Impact of the FDA's Observations of Non-Compliance in the November, January, and March Form 483s

157. Through a series of affirmative misstatements throughout the Class Period, Defendants downplayed the significance of the observations in the November Form 483 and misled investors about similar problems existing at their other manufacturing facilities. Further, Defendants assured investors that they had "comprehensively responded" to the observations and that they would have no impact on the Company's manufacturing facilities and would not lead to additional regulatory actions.

158. At the start of the Class Period, on November 27, 2014, the media first reported that Defendants had received the November Form 483 concerning Unit VI. In response to those reports, Defendants immediately issued a press release and "Clarification" (the "November 27, 2014 Clarification"). Far from clarifying the observations, however, Dr. Reddy's provided no detail or explanation, and averred falsely that "***[a]t this stage, [the November Form 483] has no implication on any activity at the plant***. Hence, these are not expected to be material to the Company's operations or consolidated results."

159. That same day, Dr. Reddy's spokesperson Shilpi Lathia stated to industry analysts that, "[t]he observations were largely related ***to procedural and other compliances*** of the plant system," and "there is ***no implication on manufacturing*** and at this stage production continues as normal." Shilpi added that Dr. Reddy's is "***confident it won't lead to any further enforcement***" such as additional observations or a warning letter.

160. Defendants continued to reassure the market by downplaying the November Form 483's significance and telling the market they had addressed the FDA's concerns. On a January

29, 2015 earnings call—in the midst of the FDA's inspection of Unit V—(the "Q3 FY 2015 Earnings Call"), Defendant Mukherjee stated that "***[Dr. Reddy's] ha[s] responded comprehensively to the nine [observations]***." When asked by analysts who had obtained a copy of the November Form 483 whether the observations implicated data integrity, Defendant Mukherjee dodged the question and implied that the Company's responses addressed the FDA's concerns: "What you do not have access[] to are the rationale and the reasoning and the answers on this. . . . [W]e have answered fairly comprehensively on most of these. . . . ***Plus, if you read the observations, [it] doesn't give you the full story***."

161. Then, after Dr. Reddy's received the FDA's January and March 2015 Form 483s, and were put on notice that observations similar to those raised in the November Form 483 plagued two additional facilities, Defendants repeatedly and falsely maintained that ***all*** of their facilities complied with applicable safety and quality standards. For instance, in Dr. Reddy's Form 20-F for fiscal year 2015, filed with the SEC on June 17, 2015 ("2015 Form 20-F"), Defendants falsely assured the market that "[a]ll of the facilities are designed in accordance with and ***are compliant with current Good Manufacturing Practice ("cGMP") requirements***." The 2015 Form 20-F was signed by Defendants Prasad and Chakraborty.

162. A month later, on a July 30, 2015 earnings call with analysts to discuss the financial results for Q1 FY 2016 (the "Q1 FY 2016 Earnings Call"), Defendant Mukherjee flat out denied that there were compliance issues at facilities other than Unit VI. In response to an analyst's question about whether there were issues at other facilities that would impact ANDAs, Mukherjee said "[b]y no means. ***This is pretty much a one site specific issue***." This statement was knowingly false when made, since Dr. Reddy's had previously received the January and

March 2015 Form 483s for Unit V and Unit VII, which had contained observations similar to those that affected Unit VI.

163. These misstatements were unquestionably material to investors. According to a MoneyControl article published on March 8, 2017, Units V, VI, and VII "put together were contributing about 10-12 percent of total sales [for Dr. Reddy's], in addition to several key generic and Drug Master Filings in US." Defendants' misstatements affirmatively concealed a pattern of non-compliance across Dr. Reddy's manufacturing facilities, a condition that would have altered the total mix of information because the market was unaware that Dr. Reddy's had to undertake extensive remediation measures, which if not done correctly would likely lead to further regulatory action and impact Dr. Reddy's ability to manufacture drugs and sell them in the United States. *See supra* Section IV.B.

D. Dr. Reddy's Received an FDA Warning Letter but Continued to Issue Materially False Statements About the Impact to the Company's Manufacturing Capabilities and the Company's Remediation Efforts

164. Despite Defendants' multitude of prior statements— *e.g.*, they did not expect further enforcement—or they had "comprehensively" responded—or all of their facilities complied with cGMP—or the observations were a "one site specific issue," *etc.*—on November 5, 2015, the FDA issued a Warning Letter finding "significant" deviations and violations of cGMP at all three facilities, Units V-VII, in violation of 21 C.F.R. Parts 210 and 211 and Section 501(a)(2)(B) of the FD&C Act. 21 U.S.C. § 351(a)(2)(b).

165. The Warning Letter was addressed to Defendant Satish Reddy, Dr. Reddy's Co-Chairman, and was issued by Thomas Cosgrove, then a Director in the FDA's Office of Manufacturing Quality and Compliance at the Center for Drug Evaluation and Research.

166. Germane to the allegations herein, the Warning Letter catalogued a series of admissions by Defendants that show that (1) they were previously aware of significant violations

of cGMP that existed at their manufacturing facilities, and that (2) their responses to the FDA were inadequate.

167. Indeed, the Warning Letter demonstrated that Dr. Reddy's management had previously known of significant violations of cGMP concerning a lack of data integrity and computer security, insufficient investigations of failing results on quality control tests, and failures to mitigate risks of microbiological contamination. These admissions belie Defendants' false and misleading statements prior to their receipt of the Warning Letter. In the FDA's non-exhaustive analysis, the Warning Letter highlighted four deviations of "regulatory significance" at Unit VI, four such deviations at Unit V, and three such violations at Unit VII.[5]

1. Known Violations and Inadequate Responses Regarding Unit VI

168. The first significant deviation of cGMP at Unit VI, the FDA cited Defendants' "[f]ailure to maintain complete data derived from all laboratory tests conducted to ensure compliance with established specifications and standards." The deviation stemmed from Dr. Reddy's use of an "uncontrolled custom QC laboratory," which the FDA stressed had not previously been disclosed to the FDA, and which the inspectors discovered one day before the end of the November 2014 inspection of Unit VI. Based on a limited review of the lab equipment records, the FDA highlighted four instances where Dr. Reddy's appeared to manipulate quality control data to obtain desired results. Specifically, the Warning Letter found:

> Your laboratory records did not contain all raw data generated during each test for API batches manufactured at your firm. The investigator found that ***batch samples were routinely re-tested following failing or atypical results until acceptable results were obtained, and that failing or atypical results were not investigated or included in the official laboratory control records***.

[5] The FDA describes non-compliance of cGMP at API facilities as "deviations" because cGMP standards for API, unlike formulations, have not been codified in the C.F.R. However, deviations of cGMP at API facilities are violations of Section 501(a)(2)(B) of the FD&C Act.

169. The practice of retesting failing or atypical results until acceptable results are generated creates an unacceptable risk for end users and is in direct contravention of cGMP. 21 C.F.R § 211.110(b) ("Examination and testing of samples shall assure that the drug product and in-process material conform to specifications."); *see also* ICH Q7 § 11.20. The practice violates other fundamental precepts of cGMP. *See* 21 C.F.R. § 211.194 ("Laboratory records shall include complete data derived from all tests. . . ."); ICH Q7 § 6.60; 21 C.F.R. § 211.192 ("Any unexplained discrepancy . . . or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated."); ICH Q7 §§ 2.17; 11.15.

170. Critically, the FDA stated that at the time of the inspection, "[the Company's] QC Associate Director acknowledged that the CQC laboratory was involved in CGMP analysis of APIs intended for export to the United States through 2012."

171. Importantly, the FDA also explained the deficiencies in Defendants' December 15, 2014 response to the November Form 483. The FDA explained that:

> None of these explanations justify your failure to maintain complete records, nor do they support your practice of substituting repeat tests after failing results. ***You acknowledged that your analysts failed to document and start investigating OOS results***, as required by your SOP 01-045/03 "Handling of Incidents" and SOP 08-004/12 "Laboratory Investigation of Out of Specification Results." ***However, you have not assessed how your reliance on the incomplete and inaccurate data generated by the CQC laboratory, which was operational until April 2012, may have affected the quality of your APIs***.

172. Thus, the Warning Letter revealed that twelve months after Dr. Reddy's learned the FDA had discovered the existence of its undisclosed custom quality control laboratory, Defendants still had not determined whether their employees' practice of failing to record and investigate out-of-specification results impacted the safety and effectiveness of their APIs. According to the FDA, Defendants also had not adequately explained what steps they would take

to ensure future test results would be recorded, and that all out-of-specification results would be properly investigated.

173. The second significant deviation of cGMP at Unit VI also implicated data integrity. The FDA cited Dr. Reddy's "[f]ailure to prevent unauthorized access or changes to data, and to provide adequate controls for the omission of data." *See* 21 C.F.R. § 211.68; *see also* ICH Q7 § 5.43. During the November 2014 inspection, the FDA found uncontrolled access to electronic testing systems in Dr. Reddy's Product Development ("PD") laboratory. Specifically, the PD laboratory equipment did not require passwords or have adequate audit functions to prevent manipulation or deletion of data.

174. Indeed, the Warning Letter established that at the time of the inspection "neither [the Company's] quality unit nor [its] laboratory staff could demonstrate that HPLC records included complete and unaltered data." This, too, violated a fundamental feature of cGMP and made it easier and more likely that testing data would be manipulated. 21 C.F.R. § 211.194; ICH Q7 § 6.60.

175. Furthermore, the risk of someone altering or deleting critical quality testing data was not merely hypothetical. A Dr. Reddy's analyst mentioned to the FDA that an "unknown individual had logged into the system using the analyst's credentials. ***This unknown individual performed injections and deletions without the analyst's knowledge***."

176. The Warning Letter also documented the deficiencies in Defendants' "inadequate" December 15, 2014 response, which claimed the PD lab was merely used for "extended" investigation of non-cGMP activities. The FDA found Defendants' response to be inadequate because the PD lab activities were subject to cGMP, and Defendants had based "final disposition decisions" on activities in the PD lab. According to the FDA, Defendants had also

failed to explain how all analyses in support of cGMP activities would be overseen by the quality unit, and they failed to provide particular steps taken to prevent unauthorized access to electronic data and ensure data integrity.

177. The FDA found a third significant deviation at Unit VI, namely that Defendants had failed to ensure that QC personnel made contemporaneous recordings of quality data and recorded data on controlled sheets of paper. 21 C.F.R. § 211.194; ICH Q7 § 6.60. The FDA noted that Dr. Reddy's "staff told us that they write on sheets of paper ***to make management aware of missing data*** in the batch record." Thus, at the time of the inspection, management was manifestly aware of this lapse in cGMP.

178. Again, Dr. Reddy's December 15, 2014 justifications and responses following the FDA Form 483 being issued to Unit VI were insufficient. The FDA concluded that:

> These explanations do not justify your use of uncontrolled paper for documenting CGMP-relevant data, nor do they justify your failure to document events and information contemporaneously. For example, ***it is unacceptable to use uncontrolled sheets of paper to document deviations from the manufacturing process***, regardless of whether such deviations are critical or non-critical. ***Even non-critical deviations from established procedures should be documented and explained, and reviewed and approved by your quality unit prior to the release of your intermediates or APIs.***

179. In the fourth significant deviation, the FDA found that Defendants failed to implement adequate document control, and the Warning Letter documented that Defendants admitted that "[t]here was a lapse in document control system. . . ." The FDA further found that Defendants' December 15, 2014 response to this observation was inadequate because:

> [R]evising your SOP [Standard Operating Procedure] and re-training staff do not provide a comprehensive assessment of the extent of your practice of placing controlled records in the waste area, outside of the document control system. You also have not evaluated all records of products that remain within a retesting

> period to determine whether any records related to such products were discarded without quality unit approval.

2. Known Violations and Inadequate Responses Regarding Unit V

180. The text of the Warning Letter also highlighted four significant deviations from cGMP standards concerning Unit V in Miryalaguda. Three of the four deviations concerned data integrity problems or a failure to investigate out-of-specification results.

181. The first significant deviation of cGMP for Unit V related to Dr. Reddy's "[f]ailure to adequately investigate out-of-specification results and implement appropriate corrective actions." *See* 21 C.F.R. § 211.192 ("Any unexplained discrepancy . . . or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated"); *see also* ICH Q7 §§ 2.17; 11.15.

182. The FDA's investigator documented five batches of an intermediate product that failed the optical purity test using High Performance Liquid Chromatography (HPLC). With respect to Dr. Reddy's February 19, 2015 response to the January 2015 Form 483 issued to Unit V, the FDA stated, "[Dr. Reddy's] acknowledged that, since 2012, 11 batches had failed the optical purity test, and that [Dr. Reddy's] had been unable to determine a root cause for such failures."

183. Similarly, the Warning Letter stated:

> [The FDA's] investigator documented 13 instances of out of specification results for a single impurity found in [Dr. Reddy's] [redacted] intermediate for [redacted]. In [its] February 19, 2015 response, [Dr. Reddy's] indicate that, since 2012, 65 batches of this intermediate failed to meet the single impurity specification. This represents [redacted] of [the Company's] entire production of this intermediate, ***a failure rate [Dr. Reddy's] acknowledged as high***.

184. Demonstrating that Defendants' response was deficient, the FDA stated that "you have yet to find a process solution to minimize the formation of this impurity, and propose continuing to reprocess these batches that do not meet the established specifications."

185. The FDA's second significant deviation concerned the "[f]ailure to maintain all quality-related documents appropriately." *See* 21 C.F.R. § 211.192; *see also* ICH Q7 § 2.15. This again implicated data integrity concerns because Dr. Reddy's was photocopying labels for pharmaceutical products in an uncontrolled manner.

186. The FDA's third significant deviation concerned the "[f]ailure to prevent unauthorized access or changes to data." *See* 21 C.F.R. §§ 11, 211.68; *see also* ICH Q7 § 5.43. The FDA noted Dr. Reddy's allowed its quality control analysts to release product, but also found that:

> Release or rejection of finished product is a non-delegable responsibility of the quality unit, and cannot be shared with laboratory analysts or other personnel. However, [the Company's] SAP system permitted QC laboratory analysts to release intermediates from one process to the next process, as well as to release finished product into the market ***without requiring quality unit oversight***.

187. According to the FDA, in Defendants' response to the observation, Defendants "claimed that QC did not ***actually*** release finished API for commercial distribution using SAP because [its] quality unit is bound by SOP #01-021, 'QA Release,' which provides for quality unit oversight." However, the Warning Letter points out that, "[o]n May 21, 2015, [Dr. Reddy's] reported that three batches of an API (not identified in [its] correspondence) ***were*** released for commercial distribution by a QC analyst in 2013." According to the FDA, Defendants' remediation was so sloppy that Defendants claimed that their "review of the release process over two years indicated that 'the process operated as intended with no deviations,' even though

[Defendants] had just reported such a deviation to the FDA in [their] May 2015 correspondence."

3. Known Violations and Inadequate Responses Regarding Unit VII

188. The Warning Letter also highlighted three significant violations of cGMP standards for Unit VII in Duvvada. All concerned inadequate investigations into out-of-specification results and the risk of microbiological contamination.

189. The FDA's first significant violation found that "***[Dr. Reddy's] failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed***. (21 C.F.R. 211.192)." This failure was particularly concerning to the FDA because Defendants were not evaluating the problems with their products, regardless of whether those products were in customers' hands and mouths.

190. Additionally, at the time of the investigation in March 2015, an FDA investigator observed a mechanism malfunction and "notified [the Company's] Associate Director of Quality Assurance, [] Resource Manager of Quality Assurance, and [] Associate Director and Head Operations about the [redacted] mechanism failure. However, contrary to [the Company's] SOP FTCQA011-08, 'Reporting, Investigating and Disposition of Incidents,' ***[Dr. Reddy's] management failed to intervene, and allowed the filling process to continue uninterrupted***." Thus, even when management was directly told of a manufacturing problem by an FDA investigator who was on site performing an inspection, management failed to act.

191. Furthermore, the investigator observed repeated human interventions during the manufacturing process. The Warning Letter stated that:

> Each of these manual interventions risks compromising the sterility of the product and is a deviation from your SOP. . . . You did not simulate these critical manual interventions during media fills, ***so***

> ***you have no basis to know whether they may compromise the sterility of your product*** ***Even though your senior management was notified of the failure, you did not initiate an incident report to investigate the equipment malfunction or determine the effects of this discrepancy on the quality of the product*** until we concluded our inspection and issued a Form 483.

The FDA "note[d] that the lack of adequate investigations is a ***repeat violation from [its] February 2008 inspection***." For six years, Defendants knew about and did not correct an unacceptable risk of microbiological contamination.

192. The FDA's second significant violation for Unit VII was that "[Dr. Reddy's] failed to follow appropriate written procedures designed to prevent microbiological contamination of drug products purporting to be sterile, and that include[s] validation of all aseptic and sterilization processes (21 C.F.R. 211.113(b))."

193. In this violation, the FDA noted that Dr. Reddy's had deemed nine media fills as acceptable between November 2013 to October 2014 despite there being a number of rejected units that vastly exceeded Dr. Reddy's prescribed acceptance criteria. Media fills are used to assess whether aseptic filling procedures (normally for solutions) are working properly and are sterile. In a media fill, the manufacturer sets up and runs a production line just like it would to normally fill a product, but instead of filling the product medium the manufacturer fills a Petri dish. If the filled media does not show microbiological growth later, then the procedure is sterile. However, Dr. Reddy's marked nine media fills results acceptable despite failing results. Dr. Reddy's rejected the negative results and provided no written justification, thereby violating cGMP. The FDA noted that "[t]he lack of appropriate written procedures designed to prevent microbiological contamination of drug products purporting to be sterile is a ***repeat observation from our February 2008 inspection***."

194. After addressing the significant deviations and violations of cGMP at all three facilities, in the Warning Letter's conclusion the FDA warned Defendants that "[u]ntil you complete all corrections and FDA confirms your compliance with CGMP, ***FDA may withhold approval of any new applications or supplements listing your firm as a drug product or API manufacturer***. If you fail to correct these violations, under Section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3), ***FDA may also refuse admission of articles into the United States*** manufactured at" the three facilities, Units V-VII. "Under Section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3), articles may be refused admission because manufacturing methods and controls do not appear to conform to CGMP within the meaning of Section 501 (a)(2)(B) of the FD&C Act, 21 U.S.C. 351 (a)(2)(B)."

195. The Warning Letter further concluded, stating:

> ***These items, as well as other deficiencies our investigators found, lead us to question the effectiveness of your current corporate quality system to achieve overall compliance with CGMP***.
>
> ***Several violations are recurrent or represent long-standing failures to adequately resolve significant manufacturing quality problems. It is apparent that you have not implemented a robust quality system at your sites***.
>
> Dr. Reddy's corporate management is responsible for ensuring the quality, safety, and integrity of all drugs you manufacture. ***FDA strongly recommends that you evaluate global manufacturing operations to ensure compliance with CGMP regulations and requirements, comprehensively and immediately***.

196. The existence of the Warning Letter, as well as the fact that Units V and VII had also received observations of non-compliance, was revealed to the market the next day on November 6, 2015, and caused the price of Dr. Reddy's ADS to plummet ***more than 18%***. The Warning Letter's contents and the full scope and severity of the observations were revealed

weeks later, and on November 27, 2015, caused the price of Dr. Reddy's ADS to slide down another ***5.6%***.

E. Defendants Continued Their Fraudulent Scheme to Mislead Investors About the Company's Remediation Efforts and any Impact on Manufacturing

197. As soon as the Warning Letter became public, Defendants continued their fraudulent scheme by giving investors the false impression that production from the Units would not be affected by the Warning Letter and the necessary remediation. Defendants also misled investors about their "comprehensive" and "global" plan to revamp their quality systems, and to use an outside consultant to achieve that end.

198. Indeed, on November 6, 2015, in the same press release announcing Dr. Reddy's receipt of the Warning Letter, Defendant Prasad promised investors that Dr. Reddy's would respond to the FDA with a "comprehensive plan" and assured that they had "***embarked on an initiative to revamp our quality systems and processes, as an organization-wide priority***."

199. On a call with analysts the following Monday, November 9, 2015, Defendant Prasad stressed, *inter alia*, that "there is no directive from the FDA to stop the manufacturing activity or shipment of any products from these sites." He also stated that the Company had already instituted corrective actions to address the Form 483 observations and, in addition, as required by the FDA, Dr. Reddy's would hire an outside consultant to perform a "***detailed third party assessment of our quality systems and evaluate our global manufacturing operations to ensure compliance with CGMP regulations***."

200. Defendant Prasad also assured investors that the Company had taken steps to minimize the impact that the Warning Letter would have on manufacturing output by "de-risk[ing] supply by transferring select products to alternate sites." During the Q&A, he assured

investors that "our first priority today is remediation, risk assessment and ensuring products are available what we're producing in the marketplace."

201. On February 9, 2016, Defendants continued to mislead investors when the Company announced results for the third quarter of fiscal year 2016. On the earnings call, Defendant Mukherjee told investors that the Company had engaged Lachman Consultants to assure a ***"robust implementation and verification of the CAPA [corrective and preventive action] plan***." Defendant Mukherjee also said the plan was "comprehensive" and "manufacturing network-wide."

202. When analysts asked whether there would be continued delays in production given the ongoing remediation efforts and the need to have third-party validation, Defendant Mukherjee assured investors that they were "back on track." But these statements were false because Defendants knew that Lachman Consultants' engagement led to massive delays in production.

203. Unknown to analysts and the wider market, the Company could not have possibly "de-risked" the production from the three facilities or have arrived "back on track" in production by February 9, 2016, as management claimed. Within days of receiving the Warning Letter, and as alluded to by management on the November 9, 2015 investor call regarding the Warning Letter, Dr. Reddy's engaged Lachman Consultants to assist in implementing the Company's corrective plan of action and its remediation efforts.

204. A former employee of Dr. Reddy's, CW 1, stated that releases of batches of products at the impacted facilities drastically slowed down right after Dr. Reddy's received the Warning Letter. According to CW 1, the remedial efforts to respond to the Warning Letter impacted the time it took to complete review cycles, which is the time it took the Company to

properly test and release a batch of product. A review cycle of three days before the Warning Letter increased to a fifteen-day review after the letter due to extended Dr. Reddy's review and Lachman's review. CW 1 said that the increase in time to complete the review cycle at Unit VI caused the Company to go from releasing $30 million, in the cumulative value of products, to less than $10 million—***a decrease in production of more than 66% percent***.

205. CW 1 also confirmed that management was undoubtedly aware of these issues. After the FDA inspections, two types of regular calls between management in the U.S. and India took place. One call involved the sales, quality, and production teams, which was overseen by the business team. CW 1 also believed that a second regular call occurred between the overall heads of quality and business in the U.S. and India, as well as the Defendant CFO Chakraborty. When the Warning Letter was issued, CW 1 said that "a big part of the U.S. business got hit" and Dr. Reddy's lost customers for future business. The U.S. business alone lost out on $40-50 million in business as a result of the Warning Letter.

1. Defendants Falsely Claimed They Had Completed All Commitments to the FDA

206. Despite their promise to engage Lachman Consultants to perform a "robust implementation and verification" of the Company's remediation plan, starting in May of 2016 and continuing through the end of the Class Period, Defendants made sweeping claims that they had completed or nearly completed all of their remediation efforts. The FDA's subsequent re-inspections in early 2017 revealed, however, that at the time Defendants made these misstatements, they were nowhere near completing the revamping of the Company's quality systems as the FDA had required them to do.

207. Specifically, on May 12, 2016, the Company announced its fourth quarter results for fiscal year 2016, and during the earnings call with analysts, Defendant Mukherjee stated that

"we believe most of our commitments to the agency will be over by the end of this quarter [*i.e.*, by the end of June 2016] and post which we will request the agency for re-inspection." Analysts universally interpreted these statements as a positive development, and Credit Suisse, on the same day, for example, called it a "[p]ositive surprise- faster-than-expected remediation."

208. Then, on July 27, 2016, Dr. Reddy's management continued to mislead investors about the state of their remediation plan. During the Q1 FY 2017 Earnings Call, Defendant Mukherjee conversed with an analyst about the status of the remediation and touted that "***[Defendants] have completed most of the commitments***." And when asked point blank what percentage of the remediation measures are completed, Chakraborty responded, "***[v]ery high, closer to 97%, 98%***." Defendants repeated similar claims on October 25, 2016 and February 4, 2017.

209. Of course, and undisclosed to the investing public, none of these statements were true at the time they were made. Based on a review of the Company's own internal documents, upon re-inspection the FDA found that Defendants had been aware of hundreds of deviations in cGMP, and instead of investigating and addressing the problems, Defendants simply ignored them.

2. Regulators' Further Inspections of Dr. Reddy's Facilities Showed That Defendants' Prior Statements Concerning Remediation Were Knowingly False

210. When the FDA finally conducted their re-inspections of Units V-VII in February and March of 2017, it was a disaster for Defendants. The agency observed numerous instances of repeat non-compliance at all three facilities, and particularly hard-hit was Unit VII, which received thirteen observations of potential non-compliance. The FDA's internal Establishment Inspection Report ("EIR") for the February 27-March 8, 2017 inspection of Unit VII, like the

Warning Letter, catalogued numerous instances in which Dr. Reddy's quality systems failed to conduct adequate investigations following out-of-specification results.

211. Shockingly, the EIR established that ***Dr. Reddy's management previously knew*** of more than ***1,200*** documentation errors from May 2016 through October 2016. Despite receiving monthly reports starting in May 2016 detailing hundreds of errors each month, management made no attempt to ascertain why the errors were occurring and what steps should be taken to prevent them. As documented in the EIR, instead of properly investigating the problems as is required by cGMP, in November of 2016 Defendants simply stopped counting them.

212. When the market learned of Dr. Reddy's re-inspection fiasco through two partial disclosures on March 8 and March 21, 2017, the price of the Company's ADSs fell by 5% over a two-day window and 6%, respectively.

213. Defendants' scheme came to a whimpering close beginning in the summer of 2017, when regulators conducted three more inspections of Dr. Reddy's manufacturing facilities on August 10, September 8, and September 15, 2017. This time regulators found that not only had the problems persisted in Unit VII, but similar problems were discovered in two other facilities that had not been previously the subject of the Warning Letter. Based on these findings, it is evident that Defendants had not instituted a "global" "comprehensive" "network-wide" revamping of their Quality Management Systems throughout their entire manufacturing network.

VI. FALSE AND MISLEADING STATEMENTS

A. False and Misleading Statements About the Significance and Scope of the November 2014, January 2015, and March 2015 Form 483s and the Warning Letter

Misstatement 1:

214. On November 27, 2014, weeks after Dr. Reddy's received the November Form 483 regarding Unit VI, Shilpi Lathia—an official Dr. Reddy's spokesperson—commented in an article published by online industry publisher In-Pharmatechnologist.com, titled "Dr. Reddy's API Plant Receives USFDA Form 483 with Nine Observations" ("November 27, 2014 News Article"). In the November 27, 2014 News Article, Lathia stated that "[t]he observations were ***largely related to procedural and other compliances of the plant system***" and "***there is no implication on manufacturing and at this stage production continues as normal***."

215. With respect to what Dr. Reddy's was doing to address the issues, Lathia further said she was "***confident it won't lead to any further enforcement***."

Misstatement 2:

216. That same day, Defendants posted a Clarification on BSE's website—accessible to U.S. investors—which clarified a news article referencing Dr. Reddy's receiving Form 483 after FDA inspections ("November 27, 2014 Clarification"). Without qualification or caution, the November 27, 2014 Clarification stated:

> The Company clarified stating that the company had received some inspectional observations from the US FDA after their visit to their API manufacturing facility in Srikakulam district of Andhra Pradesh. The company is committed to respond to the agency within stipulated timelines with their remedial plans and start implementing the necessary measures immediately. ***At this stage, it has no implication on any activity at the plant. Hence, these are not expected to be material to the Company[']s operations or consolidated results***.

217. Misstatements 1 and 2 were materially false and misleading because at the time they were made, and unknown to investors, Dr. Reddy's management oversaw a years-long campaign to ramp up manufacturing production at the expense of adequate quality control and quality assurance systems. Indeed, CW 1 stated that the increase in production "jammed the facility" at Unit VI, and there was enormous pressure on the QC teams to release batches. Thus, Defendants' statements that the observations had "no implication on any activity at the plant" and had "no implication on manufacturing" were demonstrably false. Moreover, the FDA's observations had an implication regarding the adequacy of Defendants' Quality Management System and Quality Unit at Unit VI. Indeed, after assessing Dr. Reddy's quality management systems—which Defendants had access to—the FDA concluded: "Several violations are recurrent or represent long-standing failures to adequately resolve significant manufacturing quality problems. ***It is apparent that you have not implemented a robust quality system at your sites***."

218. For example, at the time of the misstatements, the FDA had already notified Defendants of significant cGMP violations and data integrity problems, including the discovery of (1) an undisclosed testing facility where employees repeatedly retested batches until they got a desired result; (2) significant growth of both bacteria and mold on incubated plates; (3) inadequate investigations of deviations and out-of-specification findings, including failing to determine the root cause for such errors; (4) the unauthorized deletion of analytical raw data since there were insufficient controls to prevent unauthorized access or changes to data; and (5) failures to correct known violations of cGMP.

219. For these reasons, management's assessment that the FDA's observations were merely "procedural and other compliances" was a misstatement, intended to give investors the

false impression that the observed violations were of little importance and would quickly be corrected by the Company.

220. Also for these reasons, Defendants had no rational basis to believe the observations "won't lead to any further enforcement" and "are not expected to be material to the company[']s operations" because those supposed expectations did not fairly align with Defendants' knowledge of the severity of the observations, which at minimum indicated there was a substantially heightened risk that the FDA would issue a Warning Letter, implement an import ban, delay ANDA approval or take some other action that would impair the Company's operations.

Analysts and Investors Were Misled by Misstatements 1 & 2

221. Analysts tracking Dr. Reddy's securities understood Defendants' November 27, 2014 statements to mean that Defendants were ***actually in compliance*** with FDA regulations and cGMP. For example, on November 28, 2014, IndiaNivesh[6] issued a report noting: "DRRD has clarified that these observation[s] would not have any material impact on company's operation or consolidated results . . . We find non-stoppage of production from facility under observation to be positive [sic] for DRRD as it implies DRRD following norms to comply with USFDA regulation."

222. Similarly, in a December 3, 2014 report, Morgan Stanley—which had obtained a copy of the November Form 483—could not come to an independent conclusion about the severity of the observations because, unlike Dr. Reddy's, it did not have the full "context" in which the observations were issued. While Morgan Stanley noted that two of the observations ***could*** be more serious than others, the analyst was swayed by Dr. Reddy's misstatements noting,

[6] IndiaNivesh analyst reports were also available on Bloomberg INNS, Thomson First Call, Reuters and Factiva INDNIV.

"[a]ccording to DRL, these observations relate to routine operational improvement rather than fundamental alteration to design or SOP. The company doesn't believe that there is any risk to product quality or safety, and there are no data integrity issues." Ultimately, Morgan Stanley concluded that "[w]e do not expect these observations to hurt commercially," and it maintained its "overweight" recommendation.

223. The same day, a Nomura analyst similarly stated the same day that "[t]here is as such no direct indication of data-integrity violations."

224. Journalists also believed the Company's false assurances that the issues the FDA identified would not impact ongoing manufacturing. For example, the Deccan Chronicle published an article on November 27, 2014 entitled "US FDA Discovers Lapses at DRL's Srikakulam Plant," which quoted a vice-president at Angel Broking stating that "[a]ccording to the company, 483 observations are unlikely to affect the production of the company and therefore, it will continue as per normal routine."

Misstatement 3:

225. On January 29, 2015, Defendants held an earnings call with analysts to discuss the financial results for Q3 FY 2015 (the "Q3 FY 2015 Earnings Call"). Earnings calls were made available to U.S. investors via a live webcast and the call's transcripts are posted on Dr. Reddy's website soon after the call. During the Q3 FY 2015 Earnings Call, Defendant Mukherjee downplayed the seriousness of the Form 483:

> **Analyst:** A quick question on Srikakulam. My understanding has been that over the last few years, FDA generally does not stop product approvals with the 483s. It requires a warning letter, so why is it that for you FDA has taken that stance?
>
> **Abhijit Mukherjee:** . . . [I]f your question is a direct question that whether we will be [getting a] warning letter, I do not know. That is not our expectation. ***We have responded comprehensively to the***

> ***nine observations*** [re: Srikakulam]. We are sending an update as we speak and let us see how that pans out.
>
> * * *
>
> **Analyst:** So just a personal thought and since it is very important for everyone, so therefore I am just pressing on that. Sir observations such as readings falling out of specifications being recorded as falling within the specifications, does it not really border on the lines of data integrated [*sic*] issues, what is really our internal assessment on observation such as these?
>
> **Abhijit Mukherjee:** So what is available and you read are the observations by FDA. ***What you do not have accesses to are the rationale and the reasoning and the answers on this***. ***So what I am telling you is that we have answered fairly comprehensively on most of these***. Are not there insights and learning? - Yes there are insights and learning but ***we have answered fairly comprehensively to most of the observations***. Per se if you read the observations it does not give you the full story.

226. Misstatement 3 was materially false and misleading because at the time it was made, and based on the contemporaneous facts and admissions memorialized in the Warning Letter, Defendants' responses to at least four of the nine observations for Unit VI were inadequate in that they failed to address issues raised by the FDA. For example, according to the FDA, Defendants had not determined whether their employees' practice of failing to record and investigate out-of-specification results impacted the safety and effectiveness of their APIs. According to the FDA, Defendants had also not explained what steps they would take to ensure future test results would be recorded, and that all out-of-specification results would be properly investigated. Thus, the statement "[w]e have responded comprehensively to the nine observations," is demonstrably false. For the same reasons, Defendants did not have any reasonable basis to believe that they had "answered fairly comprehensively to most" because that supposed response did not fairly align with the fact that Defendants had failed to conduct

adequate investigations and responses into at least four of the observations, as documented by contemporaneous facts and admissions reflected in the Warning Letter.

227. In addition, Defendant Mukherjee's suggestion in response to the analyst question regarding data integrity that there were no data integrity—or at least no serious data integrity—problems, was false since several of the observations were directly related to significant deviations of cGMP related to data integrity, such as the discovery of an undisclosed QC lab, unauthorized deletion of data, and insufficient access controls.

Misstatement 4:

228. On July 30, 2015, Defendants held an earnings call with analysts to discuss the financial results for Q1 FY 2016 (the "Q1 FY 2016 Earnings Call"). During the Q1 FY 2016 Earnings Call, Defendant Mukherjee downplayed the seriousness of the FDA observations by assuring investors that the observations were limited to just one facility. For example, the following exchange between Defendant Mukherjee and an analyst took place:

> **Analyst**: So per se, the 483 issue does not like really stop you from getting review on the other ANDAs, right?
>
> **Mukherjee**: ***By no means. This is pretty much one site specific issue***. A huge amount of organizational effort is standing for us everywhere where we are. Taking this is a drive to see how else we could more train, more do IT backup etc.

229. Misstatement 4 was materially false and misleading because at the time it was made, and unknown to investors, Dr. Reddy's had received two undisclosed Form 483s at two other manufacturing facilities as the result of inspections in January and March 2015, which evidenced a pattern of significant violations and deviations from cGMP including serious data integrity and contamination issues. Because Defendants had actual knowledge that serious cGMP violations were present in three sites at the time they made this statement, Defendant

Mukherjee's statement that "[t]his is pretty much one site specific issue" was demonstrably and knowingly false.

B. False and Misleading Statements About Dr. Reddy's Compliance with USFDA Regulations and Current Good Manufacturing Guidelines

Misstatement 5:

230. On December 26, 2014, in response to a report that Canada had placed an import restriction on Dr. Reddy's API facility in Srikakulam (Unit VI), Defendants posted a Clarification on BSE ("December 26, 2014 Clarification") that stated:

> The Exchange had sought clarification from Dr Reddys Laboratories Ltd with respect to news article appearing in Asian Age on December 26, 2014 titled "DRL under health Canada Scanner"
>
> …***Our products continue to meet intended quality standards, and we believe that, our APIs and Finished drug products manufactured using these APIs pose no risk to the health and safety of the Canadian people***. The Company is working with the agency for a satisfactory resolution of the matter. ***At this stage, it has no implication on any activity at the plant and hence, these are not expected to be material to the Company's operations or consolidated results***.

Misstatement 6:

231. On May 12, 2015, Defendants issued an Annual Report (the "2014-2015 Annual Report"), which was signed by Defendant Reddy. In discussing the PSAI segment, and APIs specifically, Defendants stated that their "focus on innovation-led affordability gives our customers access to the most complex active ingredients, ***while maintaining a consistent global quality standard***."

Misstatement 7:

232. On June 17, 2015, Defendants filed a Form 20-F for the year ended March 31, 2015 ("2015 Form 20-F"). The 2015 Form 20-F was signed by Defendants Prasad and

Chakraborty. In the 2015 Form 20-F, Defendants discussed the Company's investment in quality:

> Quality. ***We are fully dedicated to quality and have robust quality processes and systems in place at our developmental and manufacturing facilities to ensure that every product is safe and of high quality***. In addition, we have integrated "Quality by Design" to build quality into all processes and use quality tools to minimize process risks.

Misstatement 8:

233. Similarly, the 2015 Form 20-F stated:

> Manufacturing for our Global Generics segment entails converting active pharmaceutical ingredients ("API") into finished dosages. As of March 31, 2015, we had thirteen manufacturing facilities within this segment. Eleven of these facilities are located in India and two are located in the United States (Shreveport, Louisiana; and Bristol, Tennessee). In addition, we also have one packaging facility in the United Kingdom. ***All of the facilities are designed in accordance with and are compliant with current Good Manufacturing Practice ("cGMP") requirements*** and are used for the manufacture of tablets, hard gelatin capsules, injections, liquids and creams for sale in India as well as other markets. ***All of our manufacturing sites' laboratories and facilities are designed and maintained to meet increasingly stringent requirements of safety and quality***.

234. Misstatements 5–8 were materially false and misleading because at the time they were made, and unknown to investors, Dr. Reddy's had engaged in years-long campaign to ramp up manufacturing production at the expense of adequate quality control and quality assurance systems. Management's statements that "products continue to meet intended quality standards," there is "no implication on any activity at the plant," they are "maintaining a consistent global quality standard," they "have robust quality processes and systems in place," and "[a]ll of the facilities are designed in accordance with and are compliant with cGMP requirements," are demonstrably false. The severity of the Form 483 observations that they had already received at the time these statements were made indicated there were severe cGMP deviations. The FDA,

after looking through Dr. Reddy's quality management systems, concluded: "Several violations are recurrent or represent long-standing failures to adequately resolve significant manufacturing quality problems. It is apparent that you have not implemented a robust quality system at your sites."

235. For example, at the time of the misstatements, the FDA had already notified Defendants of significant cGMP violations and data integrity problems, including the discovery of (1) an undisclosed testing facility; (2) significant growth of both bacteria and mold on incubated plates; (3) inadequate investigations of deviations and out-of-specification findings, including failing to determine the root cause for such errors; (4) the unauthorized deletion of analytical raw data since there were insufficient controls to prevent unauthorized access or changes to data; and (5) failures to correct known violations of cGMP.

236. In addition, misstatements 5–8 were materially false and misleading because at the time they were made, and unknown to investors, Dr. Reddy's had received two undisclosed 483s at two other manufacturing facilities as the result of inspections in January and March 2015, which evidenced a pattern of significant violations and deviations from cGMP including serious data integrity and contamination issues.

237. For these reasons, Defendants had no rational basis to believe that their "APIs and Finished drug products manufactured using these APIs pose no risk to . . . health and safety" and the observations were "not expected to be material to the Company's operations" because those beliefs and expectations did not fairly align with Defendants' knowledge of the severity of the violations that were continuously occurring within their manufacturing facilities at the time the statements were made.

Misstatement 9:

238. On June 23, 2016, Defendants filed a Form 20-F for the year ended March 31, 2016 (the "2016 Form 20-F"). The 2016 Form 20-F was signed by Defendants Prasad and Chakraborty. In the 2016 Form 20-F, Defendants discussed the Company's investment in quality:

> Quality. ***We are fully dedicated to quality and have robust quality processes and systems in place at our developmental and manufacturing facilities to ensure that every product is safe and of high quality***. In addition, we have integrated "Quality by Design" to build quality into all processes and use quality tools to minimize process risks.

Misstatement 10:

239. In the 2016 Form 20-F, Defendants also stated:

> Manufacturing for our Global Generics segment entails converting active pharmaceutical ingredients ("API") into finished dosages. As of March 31, 2016, we had thirteen manufacturing facilities within this segment. Eleven of these facilities are located in India and two are located in the United States (Shreveport, Louisiana; and Bristol, Tennessee). In addition, we also have one packaging facility in the United Kingdom. ***All of the facilities are designed in accordance with and are compliant with current Good Manufacturing Practice ("cGMP") requirements*** and are used for the manufacture of tablets, hard gelatin capsules, injections, liquids and creams for sale in India as well as other markets. ***All of our manufacturing sites' laboratories and facilities are designed and maintained to meet increasingly stringent requirements of safety and quality***. All of our sites outside of India are approved by the respective regulatory bodies in the jurisdictions where they are located.

Misstatement 11:

240. Defendants issued an annual report each year explaining to shareholders that the best way for Defendants to communicate with investors is through its corporate website. For example, in Defendants' annual report for the year 2014–2015, dated May 12, 2015, Defendants told investors that the "primary source of information regarding the operations of the Company is the corporate website: www.drreddys.com."

241. During the Class Period, Defendants' website repeated the notion that all of the Company's manufacturing facilities operated in accordance with cGMP regulations. For example, at least since July 2016, Defendants' corporate website stated that: "Dr. Reddy's custom manufacturing operates in India, Mexico and the UK. ***These facilities have been built and are operated in accordance with the latest cGMP regulatory guidelines. Health and safety compliance is of the highest priority*** . . ."

242. During that same time, Defendants also stated on their corporate website that they not only meet cGMP, but that they exceed cGMP: "Our expertise in intellectual property and ***regulatory issues helps us consistently deliver the highest quality APIs that meet or exceed regulatory standards***."

243. Similarly, Defendants again touted the Company's compliance with cGMP on their corporate website:

> CPS' API manufacturing operates across nine cGMP facilities: seven in India; one in Mexico; and one in the UK. ***These facilities have been built and are operated in accordance with the latest cGMP regulatory guidelines***. All of our facilities have been inspected by the USFDA and numerous other international regulatory agencies for all major products. Health and safety compliance is of the highest priority across all aspects of CPS, including plant installation, equipment, systems, and trained personnel.

Misstatement 12:

244. On June 17, 2016, Defendants issued an Annual Report (the "2015-2016 Annual Report"), signed by Defendant Reddy. In discussing the PSAI segment, and APIs specifically, Defendants stated that their "focus on innovation-led affordability gives our customers access to the most complex active ingredients, ***while maintaining a consistent global quality standard***."

245. Misstatements 9–12 were materially false and misleading because at the time they were made, and unknown to investors, Dr. Reddy's had engaged in years-long campaign to ramp

up manufacturing production at the expense of adequate quality control and quality assurance systems. Management's statements that they "have robust quality processes and systems in place," "[a]ll of the facilities are designed in accordance with and are compliant with current Good Manufacturing Practice ("cGMP") requirements," their "facilities have been built and are operated in accordance with the latest cGMP regulatory guidelines," they "consistently deliver the highest quality APIs that meet or exceed regulatory standards," and they "maintain[] a consistent global quality standard" are demonstrably false.

246. Misstatements 9–12 are false because—in addition to the reasons misstatements 5–8 are false (as explained in ¶¶ 245-48)—upon re-inspection of Defendants' Unit VII facility alone, the FDA discovered that Defendants (1) still suffered from data integrity problems (for example, Dr. Reddy's had recently deleted quality control testing data that should have been retained); (2) still did not properly investigate failing quality control results in violation of Dr. Reddy's own internal policies; and (3) still had not mitigated the risk of biological contamination by "objectionable organisms" that can cause pneumonia, bloodstream infections, meningitis, acute gastroenteritis, flesh-eating necrosis, and staph infections.

247. Indeed, at the time Defendants made these statements, management had been aware since May 2016 of more than 1,200 errors in its Batch Manufacturing Records, as noted in the FDA's Unit VII EIR, yet Defendants allowed these errors to repeat month after month without ever identifying root causes for these errors or addressing any additional corrective actions.

C. False and Misleading Statements About Dr. Reddy's Corrective Plan of Action and the Progress of those Remediation Efforts

Misstatement 13:

248. On November 6, 2015, Dr. Reddy's issued a press release disclosing its receipt of the Warning Letter the prior day (the "November 6, 2015 Press Release"). In the November 6, 2015 Press Release, Defendant Prasad commented, "[w]e take quality and compliance matters seriously and ***stand by our commitment to fully comply with the cGMP quality standards across all of our facilities***. . ." He went on to say that Dr. Reddy's would respond to the FDA with a "comprehensive plan" and assured investors that Defendants had "***embarked on an initiative to revamp our quality systems and processes, as an organization-wide priority***."

Misstatement 14:

249. On November 9, 2015, Defendants held a conference call to clarify concerns over the warning letter (the "November 9, 2015 Warning Letter Conference Call"). During the November 9, 2015 Warning Letter Conference Call, Defendant Prasad explained:

> [W]e plan to do a comprehensive assessment of any risk to the quality of our products.
>
> * * *
>
> This recent letter underscores the need for us to re-evaluate the work done in light of the observations received, and continue to implement the CAPAs fully, assist the impact of FDA's observation on our products as well as enhance our overall quality management system. ***We'd also need to perform additional detailed third party assessment of our quality systems and evaluate our global manufacturing operations to ensure compliance with CGMP regulations***.

250. Defendant Prasad also repeated his promise that the Company took quality and compliance "seriously" and added that they would "remain focused on the remedial measures." Defendant Prasad again told investors that ***"[w]e have embarked on an initiative to revamp or quality systems and processes as a top organizational priority***," and stated that the Company

would "***not compromise on making any required investments in terms of investments, training, consultancy as well as other areas as may be required to bring us back into compliance***."

Misstatement 15:

251. On February 9, 2016, Defendants held an earnings call with analysts to discuss the financial results for Q3 FY 2016 (the "Q3 FY 2016 Earnings Call"). During the Q3 FY 2016 Earnings Call, Defendant Mukherjee provided the following update on the remediation:

> Post receipt of the warning letter from US FDA in early November 2015 for three of our sites, we submitted on December 7, 2015, a comprehensive, corrective and preventive action plan, which in short is called CAPA to address all the issues raised. ***The CAPA plan includes site-specific CAPA, manufacturing network-wide CAPA*** and CAPA to sustain and enhance our quality and compliance performance on an ongoing basis.
>
> As of January 31, 2016, all the CAPA which were due for completion have been completed. We have submitted a status update to the warning letter response on January 28, 2016, ***stating our progress on accelerated remediation efforts towards sustainable compliance***. As part of this quality journey, ***we have engaged well-respected third-party consultants, US-based Lachman [C]onsultants to provide necessary compliance and remediation support for assuring robust implementation and verification of the CAPA plan***.

252. Misstatements 13–15 were materially false and misleading because at the time they were made, and unknown to investors, a litany of cGMP violations continued to take place at Defendants' facilities. Defendants' statements that they would "not compromise on making any required investments in terms of investments, training, consultancy," that their plan included "manufacturing network-wide CAPA," that they made progress "towards sustainable compliance," and that they hired Lachman Consultants "to provide necessary compliance and remediation support for assuring robust implementation and verification of the CAPA plan" were false when made. At the time each of these statements was made, Defendants had no intention

of adequately addressing the violations of cGMP detailed in the Warning Letter, because they knowingly failed to implement the FDA's corrective plan of action.

253. For instance, Defendants were required to hire an expert third party consultant to support a global, network-wide review and assessment of the Company's quality systems, which they repeatedly promised to do. Not coincidentally, after Lachman's engagement ended on or around May 2016, the FDA documented many hundreds of instances wherein Dr. Reddy's ignored known deviations from cGMP, and failed to investigate or follow up in any way.

254. Moreover, Defendants had no reasonable basis to believe that they were "commit[ted] to fully comply with the cGMP quality standards across all of our facilities," nor had they "embarked on an initiative to revamp our quality systems and processes, as an organization-wide priority," nor had they "remain[ed] focused on the remedial measures." Those expressed beliefs did not fairly align with Defendants' knowledge that violations continued to exist at their facilities.

255. For instance, upon re-inspection of their Units V, VI, and VII facilities, the FDA determined that serious cGMP violations still existed and in fact "found that numerous items had not been corrected."

256. Within the Defendants' Unit VII facility alone, the FDA discovered that Defendants: (1) still suffered from data integrity problems, for example, Dr. Reddy's had recently deleted quality control testing data that should have been retained; (2) still did not properly investigate failing quality control results in violation of Dr. Reddy's own internal policies; and (3) still had not mitigated the risk of biological contamination by "objectionable organisms" that can cause pneumonia, bloodstream infections, meningitis, acute gastroenteritis, flesh-eating necrosis, and staph infections.

Misstatement 16:

257. On May 12, 2016, the Company held an earnings call with analysts to discuss its fourth quarter results for fiscal year 2016 ("Q4 FY 2016 Earnings Call"), and continued to mislead investors about the progress of remediation efforts. On the Q4 FY 2016 Earnings Call, Defendant Mukherjee stated that:

> [W]e submitted or first update to the FDA on January 28, followed by a second update on March 30 this year, ***stating our progress toward sustainable compliance***. We believe ***most of our commitments to the agency will be over by the end of this quarter*** and post which we will request the agency for re-inspection.

Misstatement 17:

258. On July 26, 2016, Defendants held an earnings call with analysts to discuss the financial results for Q1 FY 2017 (the "Q1 FY 2017 Earnings Call"). During the Q1 FY 2017 Earnings Call, Defendant Mukherjee conversed with an analyst about the status of the remediation and touted that "***[Defendants] have completed most of the commitments***."

259. Specifically, when asked during the Q1 FY 2017 Earnings Call point blank what percentage of the remediation measures are completed, Defendant Chakraborty responded, "***[v]ery high, closer to 97%, 98%***."

260. Immediately following Defendant Chakraborty's comments, Defendant Mukherjee stated, "***[w]e're almost done, and percentage will not give the right -- so essentially, everything whatever is committed has been done***. The institutionalization of activities, which are ongoing which will always continue. Right. So we are about to send out the letter with a request for re-inspection very soon."

261. Furthermore, during the Q1 FY 2017 Earnings Call, Defendant Chakraborty explained that "all of the remediation cost" is "pretty much done":

> **Analyst**: The first, is it correct that all of the remediation cost is pretty much done in this quarter as you're close to completion of the remediation and what was that amount?
>
> **Chakraborty**: ***It is pretty much done***. So far, we would have spent altogether around $36 million and I think it could be couple of million more in future.

262. Within the presentation that went along with the call, Defendants again touted that "***[p]rogress on quality management processes [was] in line with expectations [and they] [s]ubstantially completed the commitments on the CAPAs***."

Misstatement 18:

263. The next quarter on October 25, 2016, Defendants held an earnings call with analysts to discuss the financial results for Q2 FY 2017 (the "Q2 FY 2017 Earnings Call"). During the Q2 FY 17 Earnings Call, Defendant Mukherjee told investors that Defendants "***have done [their] part of it in terms of completing all the remediation activities***."

264. Within the presentation that went along with the call, Defendants' business highlight included that there was "***[c]onsiderable progress in [their] remediation efforts***."

Misstatement 19:

265. Also on October 25, 2016, Defendants issued a Form 6-K (the "October 25, 2016 Form 6-K"). In discussing key highlights, Defendants reiterated in the October 25, 2016 Form 6-K:

> Co-chairman and CEO, G V Prasad said "All our major businesses have shown sequential improvement over the previous quarter with revenues growing by 11% and EBITDA by 61%. ***We have made considerable progress in our remediation efforts*** and continue to work on addressing the concerns of the regulators. Looking ahead we will continue to focus on launching new products in our generics business, improving productivity and strengthening our quality management systems."

Misstatement 20:

266. On February 4, 2017, Defendants held an earnings call with analysts to discuss the financial results for Q3 FY 2017 (the "Q3 FY 2017 Earnings Call"). During the Q3 FY 2017 Earnings Call, Defendant Mukherjee touted the "significant progress" Defendants made in improving their quality control and quality assurance. Specifically, he stated:

> On the quality front as communicated earlier, our warning with the impacted sites are scheduled to get reaudited during the month of February and March. ***A substantial remediation work has been put in place from our side***. Our application of corrective and preventive actions or CAPAs were not just site specific, but they were also network wide and incorporated third-party review and assessments. We believe we have prepared ourselves well for the audit. In the process of implementing the CAPAs, ***we have made significant progress in enhancing our quality systems*** and infilling the consumer quality and [continuous] improvement.

267. Misstatements 16–20 were materially false and misleading because at the time these statements were made, a litany of cGMP violations continued to take place at Defendants' facilities. Defendants' statements that they made "progress toward sustainable compliance," were "98%" done with remediation, "[s]ubstantially completed the commitments on the CAPAs," "have done [their] part of it in terms of completing all the remediation activities," they made "[c]onsiderable progress in [their] remediation efforts," and that they "made significant progress in enhancing [their] quality systems" were demonstrably false because upon re-inspection of their Units V, VI, and VII facilities, the FDA determined that serious cGMP violations still existed and in fact "found that numerous items had not been corrected."

268. For example, within the Defendants' Unit VII facility alone, the FDA discovered that Defendants: (1) still suffered from data integrity problems (for example, Dr. Reddy's had recently deleted quality control testing data that should have been retained); (2) still did not properly investigate failing quality control results in violation of Dr. Reddy's own internal

policies; and (3) still had not mitigated the risk of biological contamination by "objectionable organisms" that can cause pneumonia, bloodstream infections, meningitis, acute gastroenteritis, flesh-eating necrosis, and staph infections.

269. Further, Defendants failed to adequately address the violations of cGMP detailed in the Warning Letter, because they knowingly failed to implement the FDA's corrective plan of action. For instance, Defendants were required to hire an expert third party consultant to do a global, network-wide review and assessment of the Company's quality systems, which they repeatedly promised to do. Not coincidentally, after Lachman's engagement ended on or around May 2016, the FDA documented many hundreds of instances wherein Dr. Reddy's ignored known deviations from cGMP, and failed to investigate or follow up in any way.

270. For these reasons, Defendants had no rational basis to believe on May 12, 2016, that "most of [their] commitments to the agency will be over by the end of [the] quarter" because that belief does not fairly align with Defendants' knowledge of the ongoing violations and deviations at their facilities.

Wall Street Analysts and Investors Were Misled by Misstatements 16–20

271. Analysts universally interpreted Defendants claims during the Class Period that they had completed remediation as a positive development. For instance in a May 12, 2016 report, Credit Suisse described the news as "Positive surprise—faster-than-expected remediation" and stated, "[Dr. Reddy's] expects large part of the remediation to be complete by May-16 and thereafter [the Company] will seek for re-inspection."

272. An analyst report issued by ICICI on May 13, 2016, similarly understood Defendants' statements to be positive news. For example, the report provided that although Q4 FY 16's performance was, in part, "largely impacted by one-offs on account of remedial

expanses," ICICI regained faith in Dr. Reddy's by "expect[ing] US revenues to normalise from H2FY17 either by successful resolution of warning letter or site transfers."

273. That same day, JPMorgan issued a particularly sunny report, saying the "timeline associated with completion of remediation and pickup in launches in 2H are positive drivers for earning recovery." JPMorgan continued: "We are currently assuming full resolution of the Warning Letter in early FY18 and an early resolution does provide upside." Furthermore, regarding future remedial costs, JPMorgan interpreted Defendants' statements to also mean that "the completion of the remediation process by end of the quarter implies these costs [will] taper[] off." Finally, JPMorgan was led to believe that although "PSAI revenue has been impacted by a delay in supplies due to ongoing remediation, [it] should also normalize as the company completes the process over the next few quarters."

274. Nomura, also on May 13, 2016, issued an analyst report retaining its "buy" rating, echoing the same understanding: "Management commentary of progress on remediation measures at the warning letter impacted site and pickup in approval are two key positives, in our view."

275. Analysts further understood Defendants' positive statements to mean that "most of the remediation measures are complete []," as a Nomura analyst report stated on July 27, 2016. That same day, a Karvy analyst report understood Defendants' positive statements to mean that Dr. Reddy's "has completed the major part of the remediation process and is expected to invite the USFDA for inspection in this quarter." Similarly, on July 27, 2016, a Jefferies analyst report interpreted the fact that "[m]anagement indicated that they have completed most of the remediation work for the warning letter [and] they expect to invite the FDA for a re-inspection in the current quarter" as a positive factor in its estimate.

276. Furthermore, analysts interpreted Defendants' misstatements to mean that because Dr. Reddy's essentially fixed all of the FDA's concerns, any material impact on future approvals would be unlikely. For example, on July 28, 2016, a Nomura analyst report provided the following:

> [W]e expect any delay in the resolution of warning letters is unlikely to have any material impact on new approvals. ***As per management, most of the remediation measures required for resolution of the warning letter are completed***. The company intends to seek a meeting with the USFDA in 2QFY17 and request re-inspection.

277. Analysts further interpreted Defendants' statements to mean that they had completed their remediation and the plants were ready to be inspected by the FDA. For example, on October 25, 2016, Credit Suisse issued a report with key takeaways from the Q2 FY 2017 Earnings Call, including: "Warning Letter: remediation is done and DRL is awaiting a face to face meeting with FDA." An October 25, 2016 Deutsche Bank analyst report likewise understood that Defendants "invited US FDA for reinspection" and that "all remediation activities are complete." That same day, an Elara analyst report understood that "DRL has completed remediation measures and have called FDA for a re-inspection."

D. False and Misleading Statements About Delays in Continued Production

Misstatement 21:

278. On November 9, 2015, Defendants Chakraborty, Reddy, and Mukherjee (who participated from the United States) conducted a conference call with analysts to discuss the recent announcement that Dr. Reddy's had received the Warning Letter. During his opening remarks, Defendant Prasad assured investors that:

> The issues cited in the letter are GMP violations relating primarily to documentation practices and control, laboratory testing procedures, incident investigation practices as well as some standard operating procedures. ***At this time, we feel confident in***

> ***the safety and efficacy of our products***. However, we plan to do a comprehensive assessment of any risk to the quality of our products. And this time, ***there is no directive from the FDA to stop the manufacturing activity or shipment of any products from these sites***.
>
> As we respond to the agency, it is imperative for us to continue to strengthen our quality management systems and processes, and enhance the infrastructure for training and development of our staff on the current GMP practices. ***We have instituted corrective actions to address the 483 observations*** received earlier in each of these sites, which formed part of the updates shared with the agency.

279. In addition, Prasad assured investors that the Company had taken steps to minimize the impact that the Warning Letter would have on manufacturing output by "***de-risk[ing] supply by transferring select products to alternate sites***." He further stated that the Company had already taken steps to implement the transfers and that there was a team dedicated to this activity.

280. During the Q&A, Defendants Prasad and Mukherjee also quelled analyst concerns about production by stating that in addition to undertaking site transfers for key products, the Company was outsourcing API and had "***various strategies to address the issue***." When asked whether it would be physically possible for the company to transfer up to seven products, Defendant Prasad stated that "our first priority today is products in the market, ensuring thereof they will meet all requirements and ensure there is no risk to entertain. That is our primary focus . . . . ***[O]ur first priority today is*** remediation, risk assessment and ***ensuring products are available what we're producing in the marketplace***."

Misstatement 22:

281. On February 9, 2016, Defendants held an earnings call with analysts to discuss the financial results for Q3 FY 2016 (the "Q3 FY 2016 Earnings Call"). During the Q3 FY 2016

Earnings Call, Defendant Mukherjee convinced investors that manufacturing is "back on track" and delays in PSAI was "largely behind" them:

> **Analyst**: On the USFDA again, just trying and understanding after having assessed the warning letter and having consulted your third party, if there is any supply disruption in order to have third-party validation of goods or delay in shipments or because US run rate seem to be very much on track. Do you anticipate that happening or any disruption in supply or any delay in shipments?
>
> **Mukherjee**: As we had mentioned earlier that PSAI business had some impact of batch releases. We are closely in touch with the shortage loop if there is anything. But there is nothing major to be reported at this juncture from the existing set of products. For future – we do not want to comment, but currently there is nothing meaningful. ***PSAI part also is largely behind us, it is now back on track***.
>
> **Analyst**: Just a clarification here on PSAI; the decline is largely due to one off impact, because warning letter you were clearly supplying and there is no issue as such for the upcoming quarters?
>
> **Chakraborty**: No, we mentioned that because of the remediation thing there were some delays in dispatches of API from these facilities.
>
> **Analyst**: But you are back on track?
>
> **Chakraborty**: ***Yes***.

282. Misstatements 21 and 22 were materially false and misleading because at the time these were made Defendants knew or should have known that their remediation efforts, as inadequate as they were, would cause significant delays in production. Defendants' statements that they have "instituted corrective actions to address the 483 observations," they "de-risk[ed] supply by transferring select products to alternate sites," they had "various strategies to address the [production] issue," their "first priority today is . . . ensuring products are available what we're producing in the marketplace," the PSAI issues were "largely behind [them]," and they were "back on track," all gave investors the false impression that Defendants' remediation efforts

would not cause delays. Yet, Defendants knew, or were reckless in not knowing, that Lachman's quality control testing and investigations of out-of-specification results caused substantial delays in approving products for dispatch. CW 1 confirmed that after the Warning Letter was received, Dr. Reddy's experienced drastic slowdowns in product releases, reducing output by up to 66%. At a minimum, Defendants had a duty to update investors once they learned that Lachman's engagement had caused substantial delays in production.

Wall Street Analysts and Investors Were Misled by Misstatements 21 and 22

283. Despite the mostly bad news on the November 9, 2015 conference call, analysts also picked up on the Company's assurances that the three affected facilities would continue to supply product and disruptions would be mitigated by site transfers and outsourcing.

284. In two reports issued on November 6 and November 9, 2015, JPMorgan stated that the impact from supply disruption and remedial costs "remains unclear." Further, JPMorgan noted that the Company had indicated that transfers of new and existing critical products were underway, and that Dr. Reddy's had "other facilities that can continue supplies to the US or work as alternate facilities for site transfer." It also pointed out that the key injectables produced at Unit VII were outsourced from third-party suppliers.

285. Macquarie Research stated that "existing sales do not get impacted as DRRD could continue to supply from these facilities into the US market," and added that "DRRD may look to site-transfer few important products near-term as an alternative strategy."

286. Morgan Stanley reported that according to management, the Warning Letter would not have a significant impact on current injectables since they were largely outsourced, and that key products had been "de-risked" from the Srikakulam facility.

287. Nomura reported on November 9, 2015 that "[w]hile the warning letter delays new approvals for products linked to these facilities, the production and sales for approved

products can continue. Therefore, if the regulatory actions are not further escalated, we would expect very limited impact on the financials near term." Nomura concluded, based on management's statements, that "[i]mmediate impact likely to be marginal" because there were few ANDAs impacted in the near term, the Company had working plans to shift important products to unaffected facilities, and a significant part of the remediation measures had already been implemented.

288. Analysts further understood Defendants' positive statements to mean that PSAI business and supply disruption issues are "back on track." For example, on February 9, 2016, Nomura described Defendants' statements as a "mixed bag," taking refuge in the fact that Defendants' positive statements indicated that (1) "[m]anagement expects a pickup in [ANDAs/NDAs] approvals in FY17F," (2) the "company is undertaking site transfer of products that were affected . . . by the FDA warning letter," (3) "[p]er management, most of the pending ANDAs are not linked to the facilities affected by the warning letter," and most influential, (4) although PSAI business was affected by remediation efforts, "[s]upplies are now back on track, per management."

289. On February 9, 2016, analyst Edelweiss' doubts likewise were in part alleviated following its belief that remedial measures had been "accelerated" by Defendants' hiring consultants. On February 10, 2016, analyst Equirus was similarly buoyed by management's false assurances that there were no delays in production and stated that: "as per the company, now it is back on the track. Management mentioned that 79 ANDAs awaiting approval, few products are related to the sites which are under warning letter issue." That same day, analyst Credit Suisse found that the "positive in the quarter was the confidence management gave in getting new approvals from non-affected US plants." Analyst HDFC, on February 10, 2016, also

interpreted Defendants' news to mean that although "PSAI sales declined because of supply disruption caused by the remediation measures[,] [i]t is back on track now."

VII. THE TRUTH EMERGED THROUGH A SERIES OF PARTIAL DISCLOSURES

A. Partial Disclosures Related to the Warning Letter

290. Investors learned the truth about the severity and scope of Dr. Reddy's non-compliance with cGMP that led to the Warning Letter through three corrective disclosures: (1) Defendants issued a press release announcing receipt of the Warning Letter, then (2) Defendants conducted an investor conference call to discuss the Warning Letter, and last (3) the FDA published the full Warning Letter on its website.

1. Dr. Reddy's Announced Receipt of the Warning Letter

291. Defendants received the FDA's Warning Letter for Units V-VII on November 5, 2015. The next day, Defendants issued a press release publicly acknowledging that Dr. Reddy's had been issued a Warning Letter (the "November 6, 2015 Press Release"), and stated for the first time that Units V and VII were implicated by the FDA's inspections. The Press Release stated:

> Today [Dr. Reddy's] issued a statement acknowledging that it has received a warning letter issued by the US FDA dated November 5, 2015 relating to its API manufacturing facilities at Srikakulam, Andra Pradesh, ***and Miryalaguda, Telangana, as well as Oncology Formulation manufacturing facility at Duvvada, Visakhapatnam, Andhra Pradesh***. This action follows the earlier inspections of these sites by the agency in November 2014, January 2015 and February 2015 respectively.

292. The same day, during a well-publicized interview about the Warning Letter with Indian television program ET Now, Defendant Chakraborty revealed for the first time that Defendants had received FDA Form 483s for Unit V and Unit VII in early 2015 prior to receiving the Warning Letter. Defendant Chakraborty stated that the Warning Letter "had some

observations related to some of the QC testing which used to get done, how data used to get recorded, [and] the kind of analysis which were happening." Defendant Chakraborty conceded that the FDA cited some data integrity problems as well but did not comment further. Finally, ET Now asked: "Srikakulam[,] people knew about this thing but the other two plants, the oncology plant and the Telangana plant comes out of the blue, did you receive a form 483 in these plants or just a direct warning letter was given to you?" Defendant Chakraborty responded "No[,] form 483 was there long back."

293. Following the interview, Business Insider published an article titled, "One of India's largest drugmakers is crashing after the FDA revealed it 'significantly violated' US regulations." An article by the Economic Times Bureau stated that Chakraborty "indicated that the FDA's observations on the Srikakulam site related to handling of records in analytical labs and sharing of passwords for systems used in manufacturing programmes. He did not divulge specific details in the warnings about the other two facilities."

294. Wall Street analysts covering Dr. Reddy's securities were surprised by the Company's receipt of a Warning Letter and noted that the market reacted negatively to the news. From the start of the Class Period in November 2014 until November 2015, Defendants' false and misleading statements had actively concealed the severity and scope of the problems at key manufacturing facilities.

295. Until November 6, 2015, analysts and the investing public remained unaware that the FDA had identified a pattern of non-compliance at two additional facilities in addition to Unit VI. Upon learning this, Barclays downgraded to equal weight "as the ***regulatory risk has escalated materially*** following the FDA Warning Letter (WL) of Nov 5th… Key highlights: 1) Nov-2014's FDA Form 483 on Srikakulam has escalated into a Warning Letter. 2) ***Surprisingly,***

two other facilities have also received WLs." Nomura wrote, "the warning letter for the formulation plant [Unit VII] is a negative surprise." Similarly, Morgan Stanley stated that "***[h]itherto, only one site, which is located at Srikakulam, was perceived to be under FDA risk; warning letters to two additional sites is disappointing***, in our view." Equirus echoed the surprise: "While we knew about the Srikakulam facility issues, ***we never knew about the seriousness of observations at the other plants – mainly as management commentary was very optimistic in the quarterly calls. This clearly is significantly against our expectations***…."

296. Morgan Stanley also noted the potential impact of an import alert for the three facilities at issue in the Warning Letter. "[I]f the situation were to worsen to an Import Alert at these three sites, we believe that the revenue loss could be under US$100m (driven by third-party API sales), which at a 60% gross margin would translate into 10-12% EBITDA erosion, we estimate."

297. On November 6, 2015, in response to this news, the price of ***Dr. Reddy's ADSs fell over 18%***, or $11.75 per share, from its previous closing price of $65.25.

2. Defendants Conducted a Conference Call with Investors Regarding the Warning Letter

298. The following Monday (at approximately 10:30 GMT), on the November 9, 2015 Conference Call, Defendants provided some additional details about the nature of the observations across the three facilities, which related to "documentation practices and control, laboratory testing procedures, incident investigation practices as well as some standard operating procedures." Moreover, Defendant Prasad revealed that in addition to completing the remedial plans for the three facilities affected by the Warning Letter, the FDA required the Company to hire an outside consultant to conduct an exhaustive assessment of Dr. Reddy's quality

management systems and evaluation of Dr. Reddy's global manufacturing operations to ensure compliance with CGMP regulations.

299. Analysts saw this as a negative development. On November 9, 2015, Morgan Stanley reported that ***the Warning Letter was "triggered by the FDA's rejection of DRL's remediation plan*** (and not its execution, re-inspection, etc). According to the company, this will require significant effort and time to resolve, since it requires corrective actions across its manufacturing facilities (such as third-party verification and validation)." Morgan Stanley concluded that "[o]verall, the company has ***roughly $250m revenue exposure from these three sites***…."

300. That same day, JPMorgan wrote following the November 9 call that "[w]hile DRRD has been implementing corrective action to address the observations raised in the Form 483s, management indicated that ***the Warning Letter asks for additional third-party evaluation of quality systems, verification of the steps taken so far and third-party evaluation of all its facilities***." The FDA's distrust of Dr. Reddy's due to its data integrity problems, despite Dr. Reddy's proposed corrective and preventive action plans, surprised investors and analysts and increased expected remediation costs.

301. Credit Suisse noted that one of its key takeaways from the call was that there were "***common observations across three plants*** on document control, computer control and investigation process." However, the "details of warning letter should be available shortly and that should help to determine the extent of remediation efforts. This will also help in assessing [the] possibility of an import alert."

302. The next trading day, the market reacted negatively to the news and the analyst coverage, and on November 10, 2015, the price of Dr. Reddy's ADS fell ***7.18%*** to a close of $49.01 on November 10, 2015.

3. The FDA Published the Warning Letter

303. On Wednesday, November 25, 2015, the day before Thanksgiving, analysts started to report that the FDA published the Warning Letter issued to Dr. Reddy's on its website. *See* Ex. 5. The market first learned the true scope and severity of the problems at some of Dr. Reddy's facilities after reading the contents of the Warning Letter.

304. The release of the text of the Warning Letter revealed to the market that Defendants' assertion in their Form 20-F that "[a]ll of the facilities are designed in accordance with and are compliant with current Good Manufacturing Practice ('GMP') requirements" was false. The FDA unambiguously said in the Warning Letter that "[i]t is apparent that you have not implemented a robust quality system at your sites."

305. In the wake of the FDA publishing the Warning Letter, analysts that covered Dr. Reddy's realized for the first time the full nature and seriousness of the violations, and noted the market's negative reaction to the news. On November 26, 2015, Thanksgiving Day, IDFC Securities published a report downgrading the stock to neutral and stating that "[t]he warning letter has highlighted some serious deviations related to data integrity / management (especially in Srikakulam API facility) and faulty quality management process across the three locations." The analyst noted that:

> Given the seriousness of the issues highlighted and the FDA's dissatisfaction with the corrective steps undertaken by the [Dr. Reddy's] management so far . . . Resolution could be a time consuming process for [the Company] and more worryingly, based on these observations, the FDA has raised doubts on [Dr. Reddy's] corporate quality management process meeting required CGMP standards.

306. The IDFC analyst report highlighted and quoted the Warning Letter stating that "[s]everal violations are recurrent or represent long-standing failures to adequately resolve significant manufacturing quality problems. It is apparent that you have not implemented a robust quality system at your sites." The IDFC report concluded that "[t]hese observations in the FDA warning letter are a negative surprise in terms of the seriousness of the issues highlighted by the FDA. Further, FDA's concerns on the potential status of compliance with quality norms across [Dr. Reddy's] manufacturing network make it worse. This was unexpected from a company of [Dr. Reddy's] scale and stature."

307. The same day, Phillip Capital issued a report downgrading the stock to neutral, and found that the particular "data-integrity related observations" set out in the Warning Letter "turned up as a key negative surprise for us." In a report published on December 2, 2015, online publication LiveMint noted that the Company's stock dropped 28.5% in November 2015, "its steepest monthly fall in 20 years." As the cause, the report cited the Warning Letter and the revelations of "serious charges against the company" including the existence of an "unknown" laboratory, "repeated violation of good manufacturing practices," and illegitimate testing and record keeping practices.

308. When the NYSE reopened for a half day of trading on Friday, November 27, 2015 following the Thanksgiving holiday, the price of Dr. Reddy's ADSs fell $2.80 to a close of $46.94, ***a half-day decline of more than 5.6%***.

309. Although the Warning Letter disclosed the extent and seriousness of the FDA's findings of non-compliance with cGMP that led up to the Warning Letter, it did not fully correct Defendants' misstatements that the violations and corresponding remediation plans would have "no implication on manufacturing." Nor did it correct Defendants' misstatement that they had

sufficiently "de-risked" the facilities that were subject to the Warning Letter or its later misstatement that production was "back on track."

310. Moreover, the release of the Warning Letter did not correct Defendants' misstatements in November 2015, that they had "embarked on an initiative to revamp our quality systems and processes, as an organization-wide priority," or their later misstatements that they had hired Lachman to do a "robust" implementation and verification of the CAPA plans, or that they had substantially completed their commitments to the FDA. Thus, the full truth had not been revealed and investors continued to be misled.

B. Partial Disclosures Related to Production Delays

311. On February 9, 2016, the Company announced earnings and results for the third quarter of fiscal year 2016. The same day, Defendant held an earnings call with investors to discuss the result, which were mixed. Although the Company's consolidated revenue grew marginally by three percent to $599 million, notably Defendant CFO Chakraborty announced that "[r]evenues from our PSAI segment of $77 million had declined year-on-year by 17%." Surprisingly, given the Company's assurances on the November 9, 2015 that production from the three affected facilities (Units V-VII) had been "de-risked," Defendant Chakraborty announced that the decline in revenue from the PSAI segment "reflects in part, the impact of delay in dispatches on account of the ongoing remediation activities related to the US FDA's observation."

312. Analysts reacted negatively to the news that sales were adversely affected due to remediation-related issues. For example, on February 9, 2016, Analyst Nomura described the results as a "mixed bag" and stated that they missed estimates in part because "remediation-related impact on sales and costs were negatives." Analyst Edelweiss, on February 9, 2016,

likewise reacted negatively as to Defendants' news that the PSAI business had been impacted due to remedial measures in the plant.

313. On February 10, 2016, Equirus stated that the forward outlook was "subdued" citing an extended estimated time for the Company to resolve the Warning Letter. In a section titled "Warning letter resolution to take another 3 to 6 months," Equirus stated:

> Company has appointed Lachman consultants and will take another 3-6 months to implement CAPA. Warning letter has deferred approval of gXeloda and gAbilify, which they were expecting anytime. Due to the ongoing remediation process, PSAI sales were impacted and declined by ~14% yoy.

314. In response to this negative development, on February 9, 2016, the price of Dr. Reddy's ADSs fell $2.66 per share or approximately ***6.0%***, to close at $41.92 per share, damaging investors.

315. However, the February 9, 2016 news was only partially corrective of Defendants' misstatement regarding production, because on the same day Defendants' continued to mislead the market by claiming they were "back on track." Similarly, in discussing the following quarter's results on May 12, 2016, Dr. Reddy's announced continued delays due to remediation. But this, too, was not corrective because at the same time Defendants continued the fraud by claiming that all of the required remediation would be complete by the end of May. Had the full truth emerged, Dr. Reddy's ADS price would have fallen lower than it had. Because it had not, however, investors continued to be misled about the ongoing delays due to the remediation efforts.

316. Despite Defendants' claim that production was "back on track" and that they had completed their remediation plan by the end of May 2016, the following quarter the Company announced disappointing results due, in part, to continued production delays stemming from the ongoing remediation efforts.

317. Indeed, on July 26, 2016, the Company announced first quarter results for fiscal year 2017 and the market learned that remediation efforts were still impacting production. Dr. Reddy's financial results for the quarter were abysmal; the Company announced consolidated revenue of $479 million, ***a fourteen percent year-over-year decline***. Defendant Chakraborty blamed the decline, in part, on lower API business revenues, explaining that "the PSAI performance impacted by delay in dispatches on account of the quality improvement issues." Defendant Mukherjee said much the same, stating that the "PSAI business posted revenues of $71 million and declined 21% year-on-year. This decline is primarily attributable to the delayed dispatches on account of ongoing remediation activities coupled with some amount of moderation in the off-take of key customers."

318. Analysts were not impressed with the Company's performance and noted that production problems were driving the Company's securities' prices lower.

319. In response to this negative development, on July 26, 2016, the price of Dr. Reddy's ADSs fell $7.99 per share or approximately ***15.3%***, to close at $44.11 per share, damaging investors.

C. Partial Disclosures Related to Dr. Reddy's Inadequate Remediation Efforts

1. The FDA's Observations Concerning Ongoing Problems at Unit VII

320. When the FDA conducted their re-inspections of Units V-VII in the spring of 2017, the agency observed numerous instances of repeat non-compliance at all three facilities, Unit V-VII. *See* Exs. 6, 7, and 8. Unit VII was particularly hard-hit in that it received thirteen observations of potential non-compliance. The thirteen observations in the March 2017 Form 483 for Unit VII revealed that many of the same problems that had been identified in March 2015 and were repeated in the Warning Letter, continued to exist at Unit VII despite two years of purported remediation.

321. The FDA's internal Establishment Inspection Report ("EIR") for the February 27-March 8, 2017 inspection of Unit VII, like the Warning Letter, catalogued numerous instances in which Dr. Reddy's quality systems failed to conduct adequate investigations following out-of-specification results. See Ex. 9. In fact, the subsequently-released EIR for Unit VII made clear that "[c]orrective actions for the previously cited observations [from the March 2015 Form 483] were evaluated during the current inspection. It was found that ***numerous items had not been corrected***." The EIR, which provided a narrative of the February and March 2017 inspection of Unit VII, commented that "***repeated instances of employees providing false or misleading statements was discussed with firm management***." The EIR included commentary on the "REFUSALS" experienced during the investigation, stating that:

> Over multiple days in multiple departments we were provided false and misleading answers to questions that we asked employees. We repeatedly expressed our concerned directly to the most responsible personnel present, Mr. Shukla, Vice President of Operations, and Mr. Choube, Vice President of Quality, at the time of these instances. We also expressed our concerns at the start of the day on numerous days. ***However, the pattern of providing false and misleading statements persisted throughout the inspection***.

322. According to the EIR, the FDA investigator identified recent deletions of Word and Excel documents on a computer in the quality control laboratory (including deletions of documents created in the last 24 hours). After which, the investigator explained to Mr. Choube, Dr. Reddy's VP of Quality of Injectables, that an "employee had provided me what appeared to be false, misleading, and incomplete answers about the deletion of these files. I explained that this was unacceptable and asked him to ensure all of the employees answer my questions directly and honestly." The next day, February 28, 2017, the FDA investigator "repeated [their] concerns prior to starting the inspection to all of the gathered upper management, that the employee appeared to have provided me false and misleading information."

323. Following the investigator's separate admonishments of Mr. Choube and Dr. Reddy's "upper management," Dr. Reddy's employees again lied to the investigator about deletions. After finding more evidence of Dr. Reddy's employees inappropriately deleting files, the investigator "spoke to Mr. Choube and explained that the false and misleading information that these employees had provided us was unacceptable and that it had caused delays in our ability to conduct our inspection. The following morning, [March 1, 2017], I repeated this statement to the upper management team prior to starting the inspection for the day." Importantly, under authority added to the FD&C Act by the FDA Safety and Innovation Act (FDASIA), delaying, limiting or obstructing an inspection renders products made at the facility where such actions took place to be adulterated, *see* 21 U.S.C. § 351(j).

324. Despite the false and misleading statements Dr. Reddy's employees gave, the FDA still identified thirteen observations for Unit VII during the February and March 2017 inspection. These thirteen observations made clear that Unit VII (i) still suffered from data integrity and computer security issues, (ii) still did not properly investigate out-of-specification and failing quality results, and (iii) still had not mitigated the risk of biological contamination.

325. First, continuing data integrity and computer security issues were identified in four of the thirteen observations:

(a) Unit VII failed "to maintain complete data to ensure compliance with established specifications and standards," and the FDA noted that "[t]he corporate FDA Warning Letter issued to Dr. Reddy's on 05 November 2015 identified similar data integrity concerns at another site. Investigation and retrospective review for data integrity was not extended to the Chromeleon chromatography data generated at this site." (Observation 3);

(b) "Production records do not contain complete and accurate information," (Observation 4);

(c) "Appropriate controls are not exercised over computer or related systems to assure that changes to master production records and control records or

other records are instituted only by authorized personnel," (Observation 8); and

(d) "Data is not documented contemporaneously," (Observation 9), which was explicitly cited as "a REPEAT OBSERVATION from the 06 March 2015 FDA 483."

These conditions at Unit VII violated cGMP. *See* 21 C.F.R. § 211.194 ("Laboratory records shall include complete data derived from all tests"); 21 C.F.R. § 211.68; ICH Q7 §§ 5.43, 6.60.

326. In the EIR for the inspection of Unit VII, the FDA documented Dr. Reddy's employees' false and misleading answers when asked about data integrity issues. The EIR stated:

> During the inspection recent files were observed to have been deleted off these [quality testing] computers, the computer "Recycle Bins" were emptied, and in some cases the personnel had deleted the "Recent" document list in programs such as Microsoft Word and Excel. Further, when asked about these activities during the inspection, an employee from the chemistry laboratory, two employees from the microbiology laboratory, and two employees from the production department provided repeated false and misleading statements before later admitting they had recently deleted files from the computers.

Lying to the FDA during an inspection is a violation of 18 U.S.C. § 1001.

327. Second, the March 2017 Form 483 observed a continuing failure to perform adequate investigations of out-of-specification and failing quality testing results. 21 C.F.R. § 211.192 ("Any unexplained discrepancy . . . or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated"); 21 C.F.R. § 211.192; *see also* ICH Q7 §§ 2.15; 2.17; 11.15. In an observation with seven subparts spanning seven pages of text, the FDA noted that "[t]here is a failure to thoroughly review any unexplained discrepancy whether or not the batch has already been distributed." (Observation 1).

328. This continuing failure to perform adequate investigations mirrored an observation in the Warning Letter, stating that "[f]ailure to perform thorough investigations is a

REPEAT OBSERVATION from the [November 5, 2015] FDA WARNING LETTER."[7] Unit VII had now been cited for inadequate investigations of out-of-specification and failing quality tests in March 2015, November 2015, and now again in March 2017, despite the purported success of the remediation.

329. As part of this observation concerning inadequate investigations, the March 2017 Form 483 stated that "[t]horough investigations with scientifically justifiable conclusions to incidents of out-of-specification (OOS) were not performed and/or failed to implement corrective actions for the root cause determination." (Observation 1, subpart 6). The Unit VII EIR explained that on March 2, 2017, the FDA investigator reviewed out-of-specification investigations and "observed repeated OOS results, which were attributed to analyst errors . . . I explained to the firm management that it appeared the root cause is not being identified; therefore proper corrective actions have not been implemented to prevent reoccurrence."

330. Separately and still concerning the failure to perform adequate investigations, the FDA Form 483 identified over 1,200 documentation errors (including violations of good documentation practices, calculation errors, missing signatures, and incomplete documentation) had occurred from May to October 2016. However, "[n]o evaluation was performed to determine root causes or evaluation why localized training of the affected personnel was ineffective in eliminating errors."

331. The Unit VII EIR expounded upon management's role in this continuing failure in the "Supporting Evidence and Relevance" section. The FDA wrote that it had confronted

[7] The Warning Letter stated that "[y]our firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of specifications, whether or not the batch has already been distributed" concerning Unit VII. The Warning Letter went on to note that "the lack of adequate investigations is a repeat violation from our February 2008 inspection."

management with these documentation errors and no action was taken to correct the problem. "In May of 2016, management began trending the frequencies of these types of [documentation] errors" and when the FDA confronted Dr. Reddy's with the errors identified in May 2016, "Mr. Choube [the Head of Global Quality for Injectable Operations and Microbiology across all sites] confirmed there was no critical evaluation of this data to identify root causes for these errors or address any additional corrective actions." The FDA investigator continued: "These errors repeated in subsequent months" with over 900 new errors identified in real time. The investigator continued, stating that "[e]ach month this data was presented to management."

332. However, Defendants' solution was not to get to the root cause of the problem and remedy it. Rather, the EIR documented that:

> Beginning in November 2016, [Dr. Reddy's] started only counting errors found during the final review for release. [However, this] does not represent the numbers of errors that are actually occurring and what number of corrections need to be made at a later time. This new way of trending made it appear corrections were made without addressing the root cause of the errors and making corrections.

In effect, Defendants sought to identify fewer errors rather than fix them.

333. Third and finally, the March 2017 Form 483 presented multiple observations identifying an ongoing risk of microbiological contamination at Unit VII. 21 C.F.R. § 211.113; *see also* ICH Q7 § 11.13. The FDA observed that:

(a) "Investigations into observations of objectionable organisms in the [redacted] system were not thorough." (Observation 1, subpart 3).

(b) "Written procedures designed to prevent microbiological contamination of drug products purported to be sterile are not followed, including validation of all aseptic process." (Observation 5).

(c) "Aseptic processing areas are deficient regarding the system for monitoring environment conditions." (Observation 6).

334. The March 2017 Form 483 specified five instances in which Dr. Reddy's identified "objectionable organisms," including *Burkholderia cepacia*, *Acinetobacter baumanii*, and *Vibrio vulnificus*, and *Staphylococcus aureus*. (Observation 1, subparts 3 and 4). These objectionable organisms are opportunistic pathogens that can cause pneumonia, bloodstream infections, meningitis, acute gastroenteritis, flesh-eating necrosis, and staph infections. In all five instances, Dr. Reddy's failed to adequately investigate and correct the problem.

335. In one instance, Dr. Reddy's sanitized the infected system four times and still found objectionable organisms. After the fourth sterilization, "[f]ollow-up sampling again identified the objectionable organisms [on September 7, 2015]… from a sample collected 28 August 2015." However, the "system had already been cleared for use on [September 4, 2015]. This is prior to implementation of corrective actions identified in the investigation. No additional actions were specified after the additional finding on [September 7, 2015]."

336. The EIR for Unit VII expanded upon the March 2017 Form 483 observations concerning Dr. Reddy's failures to adequately investigate, stating that "these investigations were not thorough to identify root causes and address them in a timely manner to prevent recurrences. As a result the [redacted] identifications continued to identify the same objectionable organisms."

337. The FDA's thirteen observations detailed significant continuing deviations from cGMP that were still not remediated at Unit VII. While the market was concerned by the number of observations at Unit VII, they wouldn't know the true scope and severity of the FDA's findings until the FDA's Form 483 for the re-inspection was released on March 21, 2017.

2. On March 9, 2017, Dr. Reddy's Acknowledges that the FDA Had Thirteen Observations Following the Re-inspection of Unit VII

338. Two years had passed since the FDA made twenty observations concerning Unit VII in 2015 and the market was expecting significantly fewer observations after the re-inspection. On March 8, 2017, LiveMint published an article entitled "Dr. Reddy's gets 13 observations from USFDA for Visakhapatnam plant." The article stated that Defendants "did not give details on the nature of the observations."

339. The LiveMint article quoted one analyst commenting that "[t]his is a negative development as the number of observations is high despite the remedial measures taken by Dr. Reddy's after receiving the warning letter I believe that remediation process will take at least one to one-and-a-half years and this will impact future product filings and approvals in the US."

340. On March 9, 2017, Defendants issued a press release (dated March 8, 2017) through the Bombay Stock Exchange which informed the market that "[w]e have been issued a Form 483 with 13 observations" for Dr. Reddy's Unit VII, a "formulation manufacturing facility at Duvvada, Visakhapatnam." The March 2017 Form 483 for the re-inspection was limited in scope and only evaluated one of Unit VII's two manufacturing units at the Duvvada facility and was addressed to Vikramkumar B Shukla, Vice President Operations.

341. Wall Street analysts covering Dr. Reddy's reacted immediately and negatively. IIFL Institutional Equities issued a report on March 9, 2017, stating that:

> As per management, it's an all-or-none scenario for Dr. Reddy's wherein all the sites under [the] warning letter have to come out clean for the warning letter to be lifted. We haven't seen the contents of the [FDA Form 483] letter and therefore leave our numbers and rating unchanged for now. However, the risks in the stock have substantially increased after the large quantum of observations at Duvvada.
>
> . . . .

> The company stated that it has received 13 observations post-inspection. While the content of the observation letter is unknown, the fact that such a high number of observations have been issued enhances the risk profile. The management has stated that all 3 impacted facilities have to come out clean in order for the warning letter to be lifted. We will wait for contents of the observation letter before taking a call on Dr. Reddy's earnings. As of now, we leave Dr. Reddy's earnings estimates unchanged.

342. Similarly, AMBIT noted that:

> On Duvvada [Unit VII], the company has received 13 observations and we await Form 483 from the US FDA to judge whether the issues are serious and whether remediation will be prolonged. However, we remain concerned about the quantum of observations raised by the US FDA… Though the Duvvada facility does not contribute materially to US revenues, it is a critical facility from the perspective of oncology filings.

343. Nomura also noted that:

> We await the details of the observations. The large number of observations and track record of the inspector issuing warning letters in the past for sterile facilities is a matter of concern . . . While we await the details of the inspection observations, we find the number of observations to be high. This is particularly so given that the site is under warning letter and significant remediation and upgradation efforts were undertaken by the company.

Nomura further noted that "[t]hree critical products are currently manufactured at the site – gDacogen, gVidaza and gRapamune . . . . We estimate that the approximate sales for these products from Duvaada [sic] site at ~USD50mn in FY18F. Therefore, in case of an escalation into an import alert at Duvaada [sic], the sales at risk are ~USD50mn."

344. In response to this negative development, the price of Dr. Reddy's ADSs fell $2.21 per share or approximately ***5%*** over the following two trading sessions, to close at $40.23 per share on March 9, 2017, damaging investors.

3. The Market Learned Additional Details About Dr. Reddy's Failed Re-Inspections

345. On March 21, 2017, the March 2017 Form 483 for Unit VII went public for the first time. The Indian economic news channel ET Now ran a segment on the revelations. In the segment, the ET Now anchor stated that:

> Dr. Reddy's, the Company had already indicated that there were thirteen observations on the Duvvada facility . . . Thirteen was a little too much. ***Today, they got public***. ***If I went through the Form 483, which we have***, there were indications of data integrity that actually were retained, destruction of some media trials, so that is that. But, overall, main issue will be where as far as the Duvvada facility is concerned there, the observations look very, very serious.

346. On the same day an article by Money Control commented that "[i]t has now emerged that the thirteen observations it received from the US Food and Drug Administration on March 18 [*sic*] ***contained repeats from a 2015 warning letter***." The article quoted Amey Chalke, an analyst tracking pharmaceutical manufacturers' securities at HDFC Securities, who stated that "the critical products that will likely get held up owing to potential delays at Duvvada [Unit VII] are Gleevec and Melphalan."

347. On March 21, 2017, Dr. Reddy's issued a clarification on the Bombay Stock Exchange with the subject line: "Clarification on news item appear on ET NOW dated March 21, 2017 captioned 'US FDA finds repeat observations from 2015 warning letter. Failed to maintain complete data to ensure compliance.'" Dr. Reddy's clarification went on to state that "the Company is preparing a comprehensive response and will submit it to the US FDA within the stipulated time."

348. The next day, on March 22, 2017, Nomura wrote that "[t]he inspection observation Form 483 is now in the public domain . . . Five observations are classified as Repeat Observations."

349. The price of Dr. Reddy's ADSs immediately and negatively reacted to the revelation of the severity of the thirteen observations and the fact that five of the observations were repeat observations from the Warning Letter. On March 21, 2017, the price of Dr. Reddy's ADSs closed at $39.05, which is a loss of $2.66 from the previous close or ***6.4%***.

4. The Market Learned That Dr. Reddy's Failed to Implement the Corrective and Preventive Action Plans Across all of Its Facilities

350. On August 10, 2017, Dr. Reddy's announced that its German subsidiary betapharm Arzneimittel GmbH received a letter from a regulatory authority of Bavaria, Germany (the Regierung von Oberbayern, which is the Central Authority for Supervision of Medicinal Products in Bavaria of the Upper Bavarian government) (the "German Regulator"). The German Regulator did not renew the cGMP compliance certificate for the Company's formulations manufacturing facility at Bachupally, Hyderabad ("Unit II") because of deviations identified during an inspection of the facility. The news revealed that Dr. Reddy's had not adequately implemented a "network-wide" CAPA plans that incorporated third party review and assessments, as the Company had claimed.

351. Specifically, as support for pulling Unit II's compliance certificate, the German Regulator viewed the following as "critical": "In hundreds of cases, OOS results were systematically invalidated without traceable or scientifically based root-cause-analysis; the only reason given was 'staff-errors.'" The German Regulator further found that "[d]eviation and OOS management including protocols-, review- and reporting-systems were designed and executed in such a way that all deviations, incidents and unusual events were ***systematically not documented***." Moreover, the German Regulator discovered that the "cleaning of rooms and direct-product-contact equipment had verifiably not been performed."

352. Thus, the German Regulator revealed to the public that Defendants not only continued such practice, but they continued it throughout other facilities—making it a network-wide pattern of non-compliance. Consequently, Unit II, which contributed to 20% of the European generics sales, was not permitted to export products to the European Union until satisfactory resolution of the issues identified in the inspection and renewal of the facility's cGMP compliance certificate. Thus, the public learned that Defendants had not adequately implemented a CAPA plan in Unit II, despite being told to do so throughout all of its facilities, and notwithstanding their own representations that they were doing so.

353. Dr. Reddy's ADS price subsequently took another hit, closing that day at $30.33 per share, down ***6%*** from the prior day close of $32.25 per share.

354. The truth was further revealed on September 8, 2017, when Hindu Business Line reported that the German Regulator concluded an audit of Dr. Reddy's Unit VII facility and issued a Warning Letter finding six major observations. In fact, the German Regulator found that the severity of the observations "has raised doubts regarding the extent of remedial measures undertaken by Dr. Reddy's after the US FDA pointed out several serious deviations in compliance to good manufacturing practices (CGMP) . . ."

355. At the moment the German Regulator issued these additional observations, Unit VII had 15–18 pending ANDAs. Analysts expressed concern that since the drug "Gleevec is the key launch due from this facility," and "if the Duvvada facility does not come back on track, Gleevec approval may get pushed further."

356. Dr. Reddy's ADS price subsequently took another hit, closing that day at $33.36 per share, down ***3.2%*** from the prior day close of $34.46 per share.

357. Finally, on September 15, 2017, Dr. Reddy's disclosed that the U.S. FDA had issued the Company a Form 483 with three observations after inspecting its API Mirfield plant, located in the United Kingdom.

358. The FDA found that Defendants again engaged in cGMP violations concerning data integrity, as well as other violations. For instance, the observations related to: (1) failing to follow procedures to file a report for noticed manufacturing issues, for the discontinued use and removal of laboratory equipment previously used, for failing to correctly label raw materials, and for failing to document the shutdown of HVAC during manufacturing of API; (2) failing to follow cleaning procedures (or lacking cleaning procedures in the first instance); and (3) failing to properly separate managed materials in the warehouse during storage.

359. Dr. Reddy's ADS price subsequently took another hit, closing that day at $33.78 per share, down ***3.5%*** from the prior day close of $35.02 per share.

360. Accordingly, it was revealed to investors for the first time in August and September 2017, that Defendants in reality had never implemented an adequate CAPA plans at all of their facilities, despite being required to do so and repeatedly touting that such appropriate CAPA plans had been implemented "network-wide."

VIII. ADDITIONAL INDICIA OF SCIENTER

A. Defendants' Purported Quality Management Review Process Supports Scienter

361. Throughout the Class Period, Defendants claimed to have established a "rigorously implemented Quality Management System," in which Dr. Reddy's implemented the proper quality control, quality assurance, and internal audit procedures to comply with FDA regulations. Specifically, Dr. Reddy's internal audit team evaluates the manufacturing facilities' compliance with cGMP. The internal audit team provided a regular and systematic update to Dr.

Reddy's senior management that included objective information about how the quality management system was functioning at its manufacturing facilities.

362. As part of this Quality Management System, Defendants purported to have a "three-tier quality management review process," including three levels of review. The final level of review was conducted by senior management. By virtue of the executive Defendants' participation in the three-tier quality management review process, Defendants knew, or had access to information that would show, that their public statements were false and misleading.

363. All of the non-complaint conditions observed by the FDA were, or should have been, observed by Dr. Reddy's internal audit team and reported to management.

364. Furthermore, Defendants personally involved themselves in the remediation. This personal involvement gave Defendants direct knowledge of the ongoing non-compliance at their manufacturing facilities and they were, or should have been, aware of the state of the remediation efforts. As a March 8, 2017 Money Control article put it, according to a source, Defendant Prasad "spearhead[ed] the entire remediation exercise. Since the last two years Prasad spent a third of his leadership time on addressing quality and compliance issues." Therefore, Defendant Prasad was personally involved in remediating the FDA's observations of potential non-compliance starting in March 2015, just after the issuance of the third FDA Form 483 at the start of the Class Period. Defendant Prasad's extensive personal involvement in the remediation bolsters the inference that Defendants' statements, which he controlled, were issued with scienter.

B. The Alleged Misrepresentations Concerned Defendants' Core Operations

365. A core operation for a pharmaceutical manufacturer is ensuring compliance with safety and manufacturing quality standards for each jurisdiction in which they sell products. If a pharmaceutical manufacturer fails to comply with these standards, the entire revenue stream

derived from sales within that jurisdiction will be threatened and potentially eliminated. For example, failing FDA inspections could result in the receipt of an FDA Form 483 or Warning Letter, withholding of new product and ANDA approvals, delays in production, and even the FDA refusing admission of products manufactured at the non-compliant facilities into the U.S.

366. Defendants even acknowledged in Class Period filings that Dr. Reddy's "must follow the cGMP regulations at all times during the manufacture of [their] products." Dr. Reddy's further claimed that the Company spent "significant time, money and effort in the areas of production and quality testing to help ensure full compliance with cGMP regulations."

367. As such, Defendants' statements concerning their manufacturing facilities' compliance with mandatory manufacturing and safety standards and their statements about the success of the Company's remediation concerned Dr. Reddy's core operations.

368. Compliance with the FDA's regulations, including cGMP, was of particular concern to Dr. Reddy's. According to one Dr. Reddy's securities analyst: "US revenues are the key driver for the company, contributing ~47% to its overall revenues." More granularly, for the fiscal year ending March 31, 2016, Dr. Reddy's Global Generics segment accounted for 83% of Dr. Reddy's total revenue and the PSAI segment accounted for 14% of total revenue. Global Generic's revenue generated from North America (the U.S. and Canada) accounted for 59% of Global Generic revenue and 48.7% of Dr. Reddy's total revenue. Similarly, PSAI's revenue generated from North America accounted for approximately 15% of the PSAI segment's revenue. Together,[8] the Global Generics and PSAI revenue generated from sales to North

[8] Dr. Reddy's business was vertically integrated and, according to the Company's SEC filings, Unit V and Unit VI produced pharmaceuticals for both segments. Unit VII produced pharmaceuticals for the Global Generics segment.

America accounted for ***50.7% of Dr. Reddy's total revenue*** in fiscal year ending March 31, 2016.

369. As Defendant Chakraborty admitted on November 6, 2014, the problematic plant Unit VI in Srikakulam alone contributed 10–12% of the Company's total revenue.

370. Defendants' repeated false and misleading statements about their compliance with manufacturing quality and safety standards and statements about the remediation efforts concerned a core operation of Dr. Reddy's pharmaceutical manufacturing business. Therefore, Defendants either knew Dr. Reddy's true state of non-compliance and remediation efforts or were reckless in not knowing about it before speaking.

C. The FDA's Recent Focus on Data Integrity Issues in India Put Defendants on Notice

371. In recent years, the FDA has focused on stamping out a trend of data integrity violations by Indian drug manufacturers. This FDA enforcement trend was widely known in the industry and Dr. Reddy's specifically mentioned it in their Form 20-F, stating: "There has been an increasing trend by the U.S. FDA and governmental regulators in other developed countries towards Indian manufacturing site audits."

372. The FDA's increased attention on Indian drug manufacturing facilities' data integrity began 10 years ago after the FDA discovered that Indian manufacturer Ranbaxy Laboratories had deceptively reported its drug validation and verification testing data. The FDA subsequently targeted other drug manufacturing companies for data integrity issues such as Novartis, Mylan, and India's largest drug maker, Sun Pharmaceutical Industries.

373. Following the findings at Ranbaxy Laboratories and other Indian drug manufacturers, the FDA increased the number of warning letters it issued to Indian manufacturers for data integrity issues. Many of these data integrity issues related to (1) lack of

control over access to computerized systems; (2) non-contemporaneous record-keeping; and (3) the deletion, falsification, alteration, or other manipulation of data—the very same violations in which Dr. Reddy's engaged.

374. As a result of this well-known trend that FDA enforcement was focusing on Indian manufacturers' data integrity, Defendants knew or were reckless in not knowing that they needed to verify the truth of their statements about complying with FDA regulations and data integrity regulations.

D. Dr. Reddy's History of Non-Compliance with FDA Regulations

375. FDA inspections and enforcement actions were not new phenomena for Defendants. In fact, Defendants' manufacturing facilities had a long history of being out of compliance with FDA regulations.

376. Indeed, the November 2015 Warning Letter was not the first warning letter that Defendant CEO G.V. Prasad had received from the FDA. Following November 8-11, 2010 inspections of Dr. Reddy's Mexican manufacturing facility, the FDA issued Warning Letter 320-11-014 on June 3, 2011. The June 2011 Warning Letter was addressed to Defendant Prasad and identified "significant deviations from Current Good Manufacturing Practice (GMP) for the manufacture of APIs. These deviations cause your APIs to be adulterated . . . in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, GMP."

377. More specifically, the FDA observed that:

(a) "Your firm did not validate analytical methods used to test APIs."

(b) "Your firm's cleaning validation was incomplete for non-dedicated manufacturing equipment."

(c) "Your firm's out-of-specification (OOS) investigations did not include analysis of all available data."

(d) "Your firm's quality unit did not exercise its responsibility to ensure the APIs manufactured were in compliance with cGMP, and met intended specifications for quality and purity."

378. In the June 2011 warning letter, the FDA concluded that "your quality unit has not overseen the controls required under cGMP to properly produce APIs . . . A quality unit is a basic requirement to ensure that quality APIs are produced at your facility." The FDA continued, "[***i***]***f you wish to continue to ship APIs to the United States, it is the responsibility of your firm to ensure compliance with all U.S. standards for cGMP and all applicable U.S. laws and regulations***."

379. The FDA reminded Dr. Reddy's about the importance of compliance with cGMP, stating that:

> Until all corrections have been completed and FDA has confirmed corrections of the deviations and your firm's compliance with cGMP, FDA may withhold approval of any new applications or supplements listing your firm as an API manufacturer. In addition, failure to correct these deviations may result in FDA refusing admission of articles manufactured at Industrias Quimicas Falcon de Mexico, S.A. de C.V. (also known as Dr. Reddy's Mexico) into the United States.

380. According to FiercePharma:

> The agency made sure Prasad would understand the seriousness of the violations: "Your quality unit has not overseen the controls required under cGMP to properly produce APIs. Your December 1 response stated that you will assess your firm's quality needs by April 30, 2011. A quality unit is a basic requirement to ensure that quality APIs are produced at your facility. Please provide a detailed current assessment of this deficiency."

381. Given Dr. Reddy's historical failings in meeting its non-delegable duty to ensure pharmaceutical products compliance with manufacturing quality and safety standards, Defendants were on notice that they needed to verify the accuracy of their statements concerning the Company's compliance with cGMP and other mandatory regulations. Defendants either

knew the true state of the non-compliance at their manufacturing facilities and they disseminated knowingly false statements or they were reckless in not ensuring that they were in compliance before speaking about their compliance to the markets.

E. Defendants' Statements Themselves Support a Strong Inference of Scienter

382. As discussed above, during the Class Period, Defendants spoke at length about how the observations from the Form 483s were mostly "procedural" and "one site specific."

383. These false and misleading statements, and others like it, provide a strong inference that Defendants knew they intentionally misled the market. At all points during the Class Period, Defendants had an informational advantage over the market as they directly received all of the FDA Form 483s and were aware of the true severity of the observations, as well as the fact that their problems were identified at multiple facilities. Accordingly, Defendants either knew their statements were false and/or misleading when made, or were reckless in not knowing, because unlike investors they had all of the FDA Form 483s.

384. Defendants similarly touted during the Class Period that their "facilities have been built and are operated in accordance with the latest cGMP regulatory guidelines" and that "[h]ealth and safety compliance is of the highest priority." However, Defendants had the full text of all of the FDA Form 483s which made clear that all of their facilities were not, in fact, "operated in accordance with the latest cGMP regulatory guidelines."

385. This false and misleading statement, and others like it, provides a strong inference that Defendants knew of, or at the very least, were reckless in not knowing that their facilities were not in full compliance with cGMP regulations.

F. Other Indicia of Scienter

386. Defendants' deceptive acts provide support for a strong inference of scienter. Defendants built, installed, and operated an undisclosed and unreported "[c]ustom QC [quality

control] laboratory" that they concealed from the FDA. Defendants' QC Associate Director even conceded that the secret laboratory was used for cGMP analysis of APIs intended for export to the United States through 2012. This undisclosed quality control laboratory allowed Dr. Reddy's to test and retest batches of manufactured products and only record positive, passing test results. The failure to disclose a quality control laboratory, by itself, is a gross violation of cGMP.

387. This undisclosed laboratory did not appear out of nowhere. Defendants had to purchase expensive laboratory testing equipment, devote finite floor space in the jam-packed Unit VI to the laboratory, and assign highly-trained personnel to it. None of these decisions were made by low-level employees; rather, they required the consent and sign off of senior management.

388. Defendants' decision to create an undisclosed laboratory to test and retest products until they passed quality control tests and Defendants' failure to log failing results evidences an intent to deceive the FDA and supports a finding of a strong inference of scienter.

389. The use of an undisclosed quality control laboratory is not the only evidence that Defendants intended to mislead the FDA. The FDA investigators' Establishment Inspection Report for their re-inspection of Unit VII in 2017 stated that Dr. Reddy's employees deleted quality control files from their computers just prior to the FDA's inspection and misled the FDA investigators, in the presence of Dr. Reddy's senior management.

390. Furthermore, the EIR stated that an "employee had provided [him] what appeared to be false, misleading, and incomplete answers about the deletion of these files." Moreover, when asked about it, "an employee from the chemistry laboratory, two employees from the microbiology laboratory, and two employees from the production department provided repeated false and misleading statements before later admitting they had recently deleted files from the

computers." The fact that Dr. Reddy's employees were misleading the FDA, even after the issuance of a Warning Letter and with senior management at the site during the inspection, provides further support for the finding of a strong inference of scienter and, more specifically, an intent to deceive the FDA.

391. The FDA's findings that Dr. Reddy's employees were providing false and misleading answers was particularly troubling because Defendants' employees continued to give the false and misleading answers even ***after*** the FDA investigators specifically informed "upper management" of the unacceptable behavior.

392. These false and misleading statements by Dr. Reddy's employees, after specific warnings to "upper management," slowed down the FDA's inspection. Delaying, limiting, or obstructing an FDA inspection renders products made at that facility "adulterated," under authority added to the FD&C Act by the FDA Safety and Innovation Act (FDASIA). *See* 21 USC § 351(j). Additionally, providing a false statement to the U.S. government is a violation of 18 U.S.C. § 1001.

IX. LOSS CAUSATION AND ECONOMIC LOSS

393. During the Class Period, Defendants repeatedly made materially false and misleading statements regarding the quality of the Company's manufacturing process. Defendants continuously and unequivocally committed to fully comply with cGMP quality standards for the manufacture of APIs and finished pharmaceuticals, as required by the FDA. Dr. Reddy's, however, consistently ignored those very principles. Moreover, the failure to comply with cGMP quality standards was either well-known or recklessly disregarded by Dr. Reddy's management, including the Individual Defendants.

394. Dr. Reddy's material misstatements regarding the quality of its manufacturing processes as well as compliance with applicable regulatory standards created a false impression

of Dr. Reddy's business, prospects, and operations, thereby causing the price of the Company's securities to be artificially inflated or maintained during the Class Period. As Defendants' fraudulent conduct was revealed to the market, the price of Dr. Reddy's securities fell precipitously. Defendants' materially false and misleading statements, therefore, directly caused Lead Plaintiff and other Class members economic loss, *i.e.*, damages.

A. Dr. Reddy's Stock Price Dropped after the Quality Manufacturing Issues Were Uncovered

395. Defendants' fraud on the market was first exposed to investors on November 6, 2015, when Dr. Reddy's disclosed in a press release issued at 5:35 a.m. Eastern Standard Time that the FDA had issued a Warning Letter for three of its manufacturing facilities in India: active ingredient plants in Srikakulam (Unit VI) and Miryalaguda (Unit V), and an Oncology Formulation manufacturing facility in Duvvada (Unit VII).

396. The immediate reaction from the market was negative. On November 6, Barclays released an analyst report predicting the Warning Letter would negatively impact Company earnings by 10 to 15% in FY 2016 to 2018 with further downside of 15% if risks worsen. The price of Dr. Reddy's stock also tumbled due to the disclosures. Indeed, the day prior to the FDA Warning Letter disclosure, Dr. Reddy's ADS traded at $65.25 per share. However, by the time the United States markets opened on November 6 at 9:30 a.m. Eastern Standard Time, the ADS's price had already dropped by $10.54—to $54.71 per share. Dr. Reddy's ADS price continued to plummet throughout the day on heavier than usual trading volume, closing at $53.50 per share (or down 18%).

397. A few days later, on November 9, 2015, Dr. Reddy's held a call with investors to discuss the Warning Letter and the Company's response. During the call, Defendants revealed some specifics about the findings of non-compliance, saying that they were related to

"documentation practices and control, laboratory testing procedures, incident investigation practices as well as some standard operating procedures."

398. The following day, November 10, 2015, Reliance Securities announced it was downgrading Dr. Reddy's valuation because "[g]rowth hinges on few products in US, which are now contingent to USFDA resolution." Reliance Securities also commented that the major areas of concern highlighted by the Warning Letter including: "inadequate lab testing procedures (repeat testing of API batches for impurity)"; "[standard operating procedures] on storage for intermediates were not followed"; "improper documentation of electronic chromatography data"; and "data manipulation, lack of systems to prevent unauthorized data access." Dr. Reddy's ADS price fell again that day, closing at $49.01 per share, down more than 7% from the prior day close of $52.80 per share on unusually high trading volumes of 2.27 million shares.

399. Over the November 26, 2015 Thanksgiving holiday period, it became widely publicized that the FDA published the Warning Letter issued to Dr. Reddy's on its website, making the full text available to the public for the first time while the NYSE was closed. In the Warning Letter, the FDA explained that the deviations cited therein did not represent an "all-inclusive" list. The FDA also explained in the Warning Letter that it was issued because "***[s]everal violations [were] recurrent or represent long-standing failures to adequately resolve significant manufacturing quality problems***," and because "***[i]t is apparent that [Dr. Reddy's had] not implemented a robust quality system at [its] sites***" following prior FDA Form 483 observations issued in late 2014 and early 2015. Finally, the Warning Letter admonished Dr. Reddy's for using an undisclosed laboratory to test APIs for impurities and only recorded those results that passed while failing to record failing quality control results.

400. Dr. Reddy's ADS price subsequently dropped almost 6% on November 27, 2015, the first day the NYSE was open following the publication of the Warning Letter's text. On the prior day of trading, November 25, 2015, Dr. Reddy's ADS price closed at $49.74 per share. However, by the end of trading on November 27, the closing price of Dr. Reddy's ADS had declined to $46.94 per share.

B. Dr. Reddy's ADS Price Continued to Fall Due to the Long-Term Impact of Defendants' False and Misleading Statements

401. In the wake of the FDA's Warning Letter, the long-term impact of Defendants' materially false and misleading statements (and omissions) crystalized. The artificially inflated price of Dr. Reddy's securities continued to drop as the market became aware of Defendants' endemic quality failures and the length of time (and cost) needed to make Defendants' facilities compliant with cGMP standards. The November 2015 price drops, however, were mitigated by the Company's assurances to the market that it was taking all necessary steps to promptly address and fully remedy the manufacturing quality issues outlined in the Warning Letter.

402. On February 9, 2016, the Company announced earnings and results for the third quarter of fiscal year 2016. On the earnings call, Defendant CFO Chakraborty announced that "[r]evenues from our PSAI segment of $77 million had declined year-on-year by 17%." Surprisingly, given the Company's assurances on the November 9, 2015 call that production from the three facilities identified in the Warning Letter was "de-risked," Chakraborty announced that the decline in revenue from the PSAI segment "reflects in part, the impact of delay in dispatches on account of the ongoing remediation activities related to the FDA's observation."

403. The market reacted negatively to the revelation that the Warning Letter and the Company's ongoing response had slowed down production. Analysts at Nomura noted that the

Company had missed estimates, in part, because "remediation-related impact on sales and costs were negatives." As a result of the news on February 9, 2016, Dr. Reddy's ADS price fell from its previous close of $44.58 to $41.92, a nearly 6% decline.

404. On July 26, 2016, Dr. Reddy's issued a press release at 1:03 p.m. Eastern Standard Time in conjunction with its Q1 FY 2017 Earnings Call, which was held on the same day. The press release announced that Dr. Reddy's year-over-year revenue had declined 14%. The press release also included a quotation from Dr. Reddy's CEO, Defendant Prasad, in which he stated that the declining revenue was due in part to "delayed launches as a result of the warning letter, which significantly impacted our earnings."

405. In the subsequent Earnings Call, Defendant Chakraborty explained that the Company's PSAI "performance continues to be impacted by delays in dispatches on account of the ongoing quality improvement initiatives," declining 21% year-on-year. Defendant Chakraborty also fielded a question during that Earnings Call regarding Warning Letter remediation costs, in which Defendant Chakraborty reported that Dr. Reddy's had already spent $36 million on remediation efforts and expected to spend "couple of million more in the future," which was consistent with Defendant Mukherjee's statement that Dr. Reddy's "believe[d] most of the commitments made by us to the agency have been duly addressed."

406. That same day, Reliance Securities released an analyst report, predicting Dr. Reddy's "EBITDA margin almost halved to 12.1% in Q1FY17 from vs. 26% in Q1FY16 due to price erosion in US product portfolio, higher remediation cost (pending warning letter to three plants) and higher R&D cost . . . ." Reliance Securities also expected Dr. Reddy's ADS to "remain range bound in the near-term due to pending USFDA warning letter on its three plants (Srikakulam, Mriyalguda, & Duvvada) and further concentration risk in the US market."

407. Consequently, on July 26, 2016, Dr. Reddy's artificially inflated ADS price again plunged on a day of particularly high trading. Indeed, on July 25, Dr. Reddy's ADS price closed at $52.10 per share, but by market close on July 26, a day where trading volume hit an unusually high 5 million shares, Dr. Reddy's ADS price fell more than 15% to $44.11 per share. Dr. Reddy's ADS price fell almost another full percent the following day, July 27, to $43.82 per share.

C. Dr. Reddy's ADS Price Continued to Fall as the Market Learned that the Company had not Implemented Remediation Efforts

408. From May 2016 through February 2017, Defendants repeatedly falsely informed investors that the Company had addressed all FDA concerns outlined in the Warning Letter and was ready for re-inspection by the FDA.

409. However, on March 8, 2017, LiveMint reported that Dr. Reddy's had disclosed in an exchange filing that the FDA had completed its re-inspection of Dr. Reddy's oncology site in Duvvada, Unit VII. The audit, which took place between February 27 and March 8, 2017, resulted in another FDA Form 483 that set forth 13 observations. LiveMint further reported that Dr. Reddy's did not give any details on the nature of the observations at that time. Finally, LiveMint commented that, following this news, brokerage firm Kotak Institutional Equities sent a note to its investors that the brokerage has given a "Sell" rating to the ADS because it did not expect Dr. Reddy's to get FDA clearance for this facility until FY2019, which would result in "delays to a few important products to [*sic*] FY2018."

410. Similarly, Nomura Securities commented in a March 9, 2017 analyst report, that the number of observations at the Unit VII was particularly concerning "given that the site is under warning letter and significant remediation and upgradation efforts were undertaken by the

company." As a result of the disclosures, Dr. Reddy's ADS price fell to close that day at $40.23 per share, down approximately 5.2% from the a close of $42.44 per share on March 7, 2017.

411. On March 21, 2017, additional information from the Duvvada inspection came to light following ET Now's report that "US FDA finds repeat observations from 2015 warning letter. Failed to maintain complete data to ensure compliance." That same day, Morgan Stanley issued an analyst report that classified the 13 FDA observations from the Duvvada site into 3 categories: repeat observations from the November 2015 Warning Letter, which were "more critical in nature"; repeat observations from the March 2015 Form 483 that were "technical in nature"; and new observations, which are technical in nature. Morgan Stanley then predicted the 2017 Unit VII observations would "delay remediation by a few quarters, in our view, and may result in escalation."

412. Likewise, on March 21, Macquarie Research issued an analyst report in which it lowered its projected earnings and target price for Dr. Reddy's in FY 18 and FY 19 "by 15% and 6% respectively to factor in likely delay in new launches. Owing to uncertainty around FDA timelines post the recent setback, we also cut our FY19 PER [price-earnings ratio] target multiple from 20x to 18x." Consequently, Dr. Reddy's ADS price took another hit, falling more than 6% from its prior day close of $41.71 per share to close on March 21, 2017, at $39.05 per share.

413. On August 10, 2017, Dr. Reddy's wholly-owned subsidiary Betapharm Arzneimittel issued a statement that, following an audit by the Regulatory Authority of Germany (Regierung von Oberbayern) at one of its formulations manufacturing units in Hyderabad, India, it was notified that the facilities cGMP compliance certificate would not be renewed. Without a cGMP compliance certificate, Dr. Reddy's was prohibited from exporting drugs manufactured at

that plant to the European Union. Dr. Reddy's ADS price subsequently took another hit, closing that day at $30.33 per share, down 6% from the prior day close of $32.25 per share.

414. The truth was further revealed on September 8, 2017, when Hindu Business Line reported that the German Regulator concluded an audit of Dr. Reddy's Unit VII facility and issued a Warning Letter finding six major observations. In fact, the German Regulator found that the severity of the observations "has raised doubts regarding the extent of remedial measures undertaken by Dr. Reddy's after the US FDA pointed out several serious deviations in compliance to good manufacturing practices (CGMP) . . ."

415. Dr. Reddy's ADS price subsequently took another hit, closing that day at $33.36 per share, down 3.19% from the prior day close of $34.46 per share.

416. Finally, on September 15, 2017, Dr. Reddy's disclosed that the FDA had issued the Company a Form 483 with three observations after inspecting its API Mirfield plant, located in the United Kingdom. This further revealed that Company had failed to implement its remediation plan on "company-wide" or "global" basis.

417. Dr. Reddy's ADS price subsequently took another hit, closing that day at $33.78 per share, down 3.54% from the prior day close of $35.02 per share.

418. Each decline in the price of Dr. Reddy's ADS price, as detailed above, was directly or proximately related to Defendants' fraud. Defendants' material misstatements regarding its commitment to fully comply with the cGMP quality standards across all facilities had the cause and effect of creating an unrealistically positive assessment of the Company's business, prospects, and operations. Meanwhile, Dr. Reddy's manufacturing operations, which were well-known or recklessly disregarded by Defendants, resulted in significant quality

problems that blatantly contradicted Defendants' representations concerning the Company's compliance with basic cGMP principles.

419. The timing and magnitude of each decline in the price of Dr. Reddy's ADS negates any inference that the loss suffered by Lead Plaintiff and other Class members was caused by changed market conditions, macroeconomics, industry factors, or Company-specific facts unrelated to Defendants' fraudulent conduct. The economic loss, *i.e.*, damages suffered by Lead Plaintiff and other members of the Class, was a proximate result of Defendants' material representations, which caused artificial inflation of the Company's ADS price and the subsequent significant declines in the price of Dr. Reddy's ADS were the result of the truth being revealed. Lead Plaintiff and Class members were, therefore, harmed by Defendants' materially false and misleading statements.

X. PRESUMPTION OF RELIANCE: FRAUD-ON-THE-MARKET

420. Lead Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

(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 ADS traded in an efficient market;

(d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's ADS; and

(e) Lead Plaintiff and other members of the Class purchased Dr. Reddy's common ADS between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

421. At all relevant times, the market for Dr. Reddy's shares was efficient for the following reasons, among others:

(a) Dr. Reddy's ADS met the requirements for listing, and was listed and actively traded on the NYSE, a highly efficient and automated market;

(b) As a regulated issuer, Dr. Reddy's filed periodic public reports with the SEC and the NYSE;

(c) Dr. Reddy's regularly communicated with public investors via established market communication mechanisms, including through investor conference calls, SEC filings, annual reports, and the regular dissemination of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services; and

(d) Dr. Reddy's was followed by numerous securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales forces and certain customers of their respective brokerage firms. Each of those reports was publicly available and entered the public marketplace.

422. As a result of the foregoing, the market for Dr. Reddy's common ADS promptly digested current information regarding Dr. Reddy's from publicly available sources and reflected such information in Dr. Reddy's ADS price. Under these circumstances, all purchasers of Dr. Reddy's common ADS during the Class Period suffered injuries through their purchases of common ADS at artificially inflated prices and a presumption of reliance applies.

423. Lead Plaintiff and the members of the Class are also entitled to a presumption of reliance under the Supreme Court's decision in *Affiliated Ute Citizens of Utah v. U.S.*, 406 U.S. 128 (1972), and its progeny, as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information as detailed above.

XI. NO SAFE HARBOR; BESPEAKS CAUTION IS NOT APPLICABLE

424. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the material misrepresentations and omissions alleged in this Complaint.

425. To the extent certain of the statements alleged to be misleading or inaccurate may be characterized as forward-looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

426. Defendants are also liable for any false or misleading "forward-looking statements" pleaded because, at the time each "forward-looking statement" was made, the speaker knew the "forward-looking statement" was false or misleading and the "forward-looking statement" was authorized and/or approved by an executive officer of Dr. Reddy's who knew that the "forward-looking statement" was false. Alternatively, none of the historic or present-tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by Defendants expressly related to or stated to be dependent on those historic or present-tense statements when made.

XII. CLASS ACTION ALLEGATIONS

427. Lead Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all persons and entities that, during the period from November 27, 2014 through September 15, 2017, inclusive (the "Class Period"), purchased or otherwise acquired Dr. Reddy's publicly traded securities on the New York Stock Exchange, and were damaged thereby (the "Class"). Excluded from the Class are: (i) Defendants; (ii) the officers and directors of the Company during the Class Period; (iii) the Company's affiliates and subsidiaries; (iv) members of the immediate family of any excluded person; (v) any entity in which any excluded person or entity has or had a controlling interest; and (vi) the legal representatives, heirs, successors or assigns and any excluded person or entity.

428. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Dr. Reddy's securities were actively traded on the NYSE. While the exact number of Class members is unknown to Lead Plaintiff at this time and can be ascertained only through appropriate discovery, Lead 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.

429. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class that predominate over questions which may affect individual Class members include:

(a) whether the Exchange Act was violated by Defendants;

(b) whether Defendants omitted and/or misrepresented material facts;

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

(d) whether Defendants knew or deliberately disregarded that their statements were false and misleading;

(e) whether the price of Dr. Reddy's ADSs was artificially inflated; and

(f) the extent of damage sustained by Class members and the appropriate measure of damages.

430. Lead Plaintiff's claims are typical of those of the Class because Lead Plaintiff and the Class sustained damages from Defendants' wrongful conduct.

431. Lead Plaintiff will adequately protect the interests of the Class and has retained counsel who is experienced in class action securities litigation. Lead Plaintiff has no interests which conflict with those of the Class.

432. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

XIII. CAUSES OF ACTION

COUNT I

Violation of Section 10(b) of The Exchange Act and Rule 10b-5 Against Defendants DRL, Prasad, Chakraborty, Mukherjee, and Reddy (together, the "§10(b) Defendants")

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

434. This Count is asserted against the §10(b) 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.

435. During the Class Period, the §10(b) 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.

436. The §10(b) Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

(a) employed devices, schemes and artifices to defraud;

(b) 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

(c) engaged in acts, practices and a course of business that operated as a fraud or deceit upon Lead Plaintiff and others similarly situated in connection with their purchases of Dr. Reddy's securities during the Class Period.

437. The §10(b) 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. The §10(b) 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.

438. Defendants Prasad, Chakraborty, Mukherjee, and Reddy, who are senior officers and/or directors of the Company, and Defendant DRL had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Lead 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 Lead Plaintiff and the Class.

439. As a result of the foregoing, the market price of Dr. Reddy's securities was artificially inflated during the Class Period. In ignorance of the falsity of the §10(b) Defendants statements, Lead Plaintiff and the other members of the Class relied on the statements described above and/or the integrity of the market price of Dr. Reddy's securities during the Class Period in purchasing Dr. Reddy's securities at prices that were artificially inflated as a result of the §10(b) Defendants' false and misleading statements.

440. Had Lead Plaintiff and the other members of the Class been aware that the market price of Dr. Reddy's securities had been artificially and falsely inflated by the §10(b) Defendants' misleading statements and by the material adverse information which the §10(b) Defendants failed to disclose, they would not have purchased Dr. Reddy's securities at the artificially inflated prices that they did, or at all.

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

442. By reason of the foregoing, the §10(b) Defendants have violated Section 10(b) of the 1934 Securities Exchange Act and Rule 10b-5 promulgated thereunder and are liable to the Lead Plaintiff and the other members of the Class for substantial damages which they suffered in connection with their purchases of Dr. Reddy's securities during the Class Period.

COUNT II

Violation of Section 20(a) of the Exchange Act
Against The Individual Defendants and Dr. Reddy's USA
(together, the "20(a) Defendants")

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

444. By reason of the foregoing, the Company violated Section 20(a) of the 1934 Act and Rule 10b-5 promulgated thereunder.

445. During the Class Period, the 20(a) 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 the Individual Defendants' senior positions, they knew the adverse non-public information regarding the Company's business practices. At all relevant times, Dr. Reddy's USA was the authorized agent for DRL and oversaw and submitted at least one response to the FDA concerning the known significant violations of cGMP at Unit VI.

446. As officers and/or directors of a Dr. Reddy's, which included the Company's wholly owned subsidiary Dr. Reddy's USA, the 20(a) 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.

447. Because of their positions of control and authority as senior officers, and authorized agent, the 20(a) 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 20(a) Defendants exercised their power and authority to cause the Company to engage in the wrongful acts complained of herein. The 20(a) 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 Dr. Reddy's securities.

448. Each of the 20(a) Defendants, therefore, acted as a controlling person of the Company. By reason of their senior management positions and/or being directors of the Company, or by acting as an authorized agent for DRL for the purpose of communicating with the FDA, each of the 20(a) 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 20(a) 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 Lead Plaintiff and the other members of the Class complain.

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

XIV. PRAYER FOR RELIEF

WHEREFORE, Lead 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 Lead Plaintiff as the Class representative;

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

C. Awarding Lead 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.

XV. DEMAND FOR TRIAL BY JURY

Lead Plaintiff hereby demands a trial by jury.

Dated: March 5, 2018

Respectfully submitted,

/s/ *Joel B. Strauss*
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Lead Counsel for Public Employees' Retirement System of Mississippi and Lead Counsel for the Proposed Class

CERTIFICATE OF SERVICE

I hereby certify that on March 5, 2018, I caused the Amended Consolidated Class Action Complaint and exhibits thereto to be electronically filed using the Court's CM/ECF system. A true and correct copy will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

Dated: March 5, 2018

/s/ Joel B. Strauss
Joel B. Strauss