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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

In re DURA PHARMACEUTICALS, INC. SECURITIES LITIGATION	Master File No. 99-CV-0151-L(WMC)
	CLASS ACTION
This Document Relates To: ALL ACTIONS.	THIRD CONSOLIDATED AMENDED COMPLAINT FOR VIOLATION OF THE SECURITIES EXCHANGE ACT OF 1934

TABLE OF CONTENTS

THE FRAUDULENT SCHEME

1. Plaintiffs bring this action on behalf of purchasers of Dura Pharmaceuticals, Inc. ("Dura" or the "Company") securities between 4/15/97 and 2/24/98 (the "Class Period") including those purchasers who acquired their Dura securities during the Class Period and held such securities until after 9/23/98, 11/4/98 and 12/4/98. Dura became a publicly traded company in 1992, pursuing a business strategy of marketing niche pharmaceutical drugs. Typically Dura purchased the rights to market drugs developed by large pharmaceutical companies that were approaching the end of their profitability to those companies. This action is brought against Dura and the Company's senior officers, Cam L. Garner ("Garner"), James W. Newman ("Newman"), Charles W. Prettyman ("Prettyman"), Walter F. Spath ("Spath"), Mitchell R. Woodbury ("Woodbury"), Julia R. Brown ("Brown") and Joseph C. Cook, Jr. ("Cook"), who directed, approved of and profited from the fraud in violation of the Securities Exchange Act of 1934 ("1934 Act").

2. Dura did not have the resources or capability to develop drugs on its own. By 1995, however, it became obvious to Dura's management that, given the Company's size, it would be increasingly difficult to achieve continued revenue and earnings per share ("EPS") growth solely by acquiring marketing rights to niche drugs. Therefore, Dura insiders decided to embark on a risky and expensive diversification of its business, attempting to become a medical device development company and develop its own proprietary drug products.

3. In 1995, Dura began development of the Spiros drug delivery system for Albuterol ("Albuterol Spiros" or "Spiros drug delivery system"), a method of aerosolizing powders so that asthma medicines, including Albuterol, could be inhaled. According to Dura, its Spiros drug delivery system would be utilized first to deliver Albuterol and later other medications to persons with respiratory problems such as asthma. The system purportedly would have advantages over existing inhalers which were dependent upon the ability of the user to successfully coordinate the use

of the inhaler and inhalation of the medication, something some persons with respiratory distress (such as children) had difficulty doing. The Spiros drug delivery system supposedly utilized a mechanically driven dosing mechanism that provided uniform dosing regardless of the ability of the patient to coordinate the operation of the inhaler.

4. The Spiros drug delivery system was a software-driven device with software programmed to turn on a motor that activated an impeller inside the device. The impeller extracted the Albuterol drug compound from the storage cassette that fit inside the inhaler. The storage cassette contained 30 separate wells that each contained one dose of Albuterol dry power compound. Each time the inhaler opened and closed, one dose was released and the cassette advanced to the next well. With the software, the inhaler was programmed to allow the inhaler to dispense 1,500 doses, which was considered the optimal dose lifetime for each inhaler.

5. The millions of dollars of necessary research and development costs associated with developing, testing and obtaining approval for the Spiros drug delivery system had to be immediately expensed as a charge against current earnings under Generally Accepted Accounting Principles ("GAAP"). To avoid such a huge negative impact on its earnings, Dura's management created Spiros Development Corp. ("Spiros I") to incur Dura's costs of developing the Spiros drug delivery system. Dura performed the development work under contract to Spiros I and billed the expenses to Spiros I, plus a mark-up of 15%-25%. Through this "off balance sheet" arrangement with Spiros I, Dura recorded revenue and profits on the "expenses" it incurred for research and development of the Spiros drug delivery system. If Dura had expensed the research and development costs, it would have reduced Dura's profitability to a loss at a time when they had promised shareholders that they would be profitable.

6. Although this arrangement protected Dura's positive financial results, it exacerbated the pressure on Dura's insiders to keep Dura's stock at high levels. Dura ultimately would have to

use its stock to repurchase Spiros I when Spiros I ran out of funds. Spiros I had been funded in 12/95 through a $28 million private placement and $13 million from Dura. To induce investors to finance Spiros I, they were given warrants to purchase 2.2 million shares of Dura at $19.47 and Dura reserved the right to re-purchase Spiros I.

7. After reaching an all-time high of $47-7/8 on 12/31/96, Dura's stock declined sharply, falling to $27-7/8 on 4/14/97, due to concerns over the ability of Dura's existing drug lines to continue to drive Dura's EPS growth and the ability of Dura to successfully introduce the Spiros drug delivery system by late 1998 or early 1999. This decline created a dilemma for Dura's executives. The perception of weakness in Dura's drug sales was well-founded, as is described below.

8. More troubling for Dura executives were the significant problems plaguing the development of the Spiros drug delivery system since the fall of 1996. Because Dura executives desperately wanted to transform Dura into a drug device development company, they made the strategic decision to proceed to clinical trials in the fall of 1996 for the Spiros drug delivery system despite the fact that the system was merely a prototype that had not yet undergone sufficient development. Dura's executives, including defendants, put tremendous pressure on Dura's engineering department to develop a prototype. Although Dura's Product Development Department designed and manufactured the Spiros drug delivery system prototype and the Albuterol cassette extremely fast, Dura executives decided to proceed to Phase III clinical trials even though the Spiros drug delivery system was not reliable and the Albuterol cassette system was not stable.

9. In fact, Dura's top executives ignored the recommendations of Dura's engineers to ***not*** proceed with Phase III clinical trials and ***not*** proceed to file a New Drug Application ("NDA") until these problems were remedied. In 10/96, in an internal Dura engineering report, Robert Eisele, Dura's Vice President of Product Development, included a list of problems with the Spiros drug

delivery system and the Albuterol cassette. This list of problems, five to six pages long, compiled by Eisele who was the lead project manager on Albuterol Spiros, detailed items Dura's engineers considered critical before a NDA could be submitted. The "Eisele List" was distributed to senior management at Dura during the weekly executive management meeting held every Monday from 8:00-10:00 a.m., and attended by defendant Garner, Dura's President, Chief Executive and Operating Officer and Chairman, defendant Newman, Dura's Chief Financial Officer and Senior Vice President of Finance and Administration, defendant Prettyman, Senior Vice President of Development and Regulatory Affairs, defendant Spath, Senior Vice President of Sales and Marketing, defendant Brown, Senior Vice President of Business Development and Planning, defendant Woodbury, Senior Vice President and General Counsel to Dura, David S. Kabakoff, Chief Executive Officer of Spiros I, Robert Schultz, Senior Vice President of Product Development, Robert Eisele, Malcolm Hill, Vice President of Clinical Development and Chet Damecki, Vice President of Operations.

10. One of the seminal problems with the Spiros drug delivery system set forth in the Eisele List was its reliability. The delivery system was incapable of consistently delivering the required dose, was insufficiently robust in that it could not withstand normal use conditions, and was subject to an unacceptable rate of failure. Additionally, a critical problem with the device set forth in the Eisele List was the instability of the Albuterol cassette system. In the cassette system, doses of Albuterol were stored in a vacuum-sealed foil pouch ready for insertion into the Spiros delivery device. After removal from the foil pouch, it was unknown how long Albuterol would remain chemically stable under realistic use conditions. For example, because a patient might use the device erratically or under varying temperature and humidity conditions, the Albuterol would have to remain stable.

11. Because Albuterol stability was so important, before Phase III clinical trials began, Dura devised in-house testing of the system. Respirable dose amounts of Albuterol were subject to aging experiments at certain temperatures and humidity levels – 25 degrees centigrade and 75% relative humidity – for fixed periods of time according to industry testing procedures and FDA requirements. Following the temperature – humidity aging process, the sample dose was dispensed from the Spiros delivery device into a filter designed to simulate a human lung. FDA guidelines set forth standards regarding acceptable levels of reduced drug efficacy and changes in particle size not to exceed 10% in the specified time frame. Dura's in-house aging tests showed unacceptable levels of reduced efficacy. Basically, as the drug aged at fixed temperatures and humidity, the Albuterol particles clumped together allowing less to be absorbed into a patient's lungs. Senior management was kept apprised that Albuterol failed Dura's in-house aging tests via chemical stability test results and analytical reports that were circulated during weekly product development meetings. Albuterol chemical stability issues were also described in detail in minutes generated from the product development meetings and circulated to senior management.

12. By the time Dura commenced Phase III clinical trials for the Spiros delivery device with Albuterol, defendants were aware that the device had serious reliability and Albuterol stability problems that Dura's own engineering department recommended be remedied before commencing clinical trials. Defendants, however, who had predominately sales and marketing and not scientific backgrounds, pursued Phase III clinical trials, over the objections of Dura's own engineers, without an adequate scientific basis because they were desperate to transform Dura into a drug development company or at least led investors into believing they were doing so.

13. Not surprisingly, serious reliability problems manifested themselves during the Phase III clinical trials. To ensure the Spiros device's reliability, during clinical trials the Spiros device was subjected to "benign abuse conditions" designed to test the device's reliability under ordinary

types of abuse conditions. One example is dropping the device from various heights. During clinical trials, Dura experienced an over 30% failure rate of the devices. Because of this high failure rate, Dura experienced an extremely high early return rate, which measures the number of inhalers removed from the clinical studies before the 1,500 dose lifetime marker as compared to the total number of inhalers dispensed for clinical trials. Dura experienced an early return rate exceeding 30% due to the inhaler's unreliability. This early return rate experienced during clinical trials was much higher than the FDA would find acceptable. In fact, during the development of medical devices, the industry standard is to try to achieve an early return rate of 1% or less to avoid incurring expensive repairs once the device is on the open market.

14. The unacceptably high early return rate Dura experienced during the first study conducted in Phase III clinical trials (drug efficacy) was caused by reliability problems that kept the inhaler from functioning. The battery wires that powered the inhaler kept disconnecting from the battery because of faulty welds connecting the battery contacts to the wiring. Additionally, the routing and gauging of certain wires running from the battery to the inhaler's internal motor caused the inhaler to malfunction so that it would not open and close each time when it was dispensing a dose of Albuterol. When these failures occurred before the inhaler reached the 1,500 dose lifetime mark, an "end-of-life" response was triggered in the inhaler and it immediately stopped functioning. When the inhaler was functioning properly and ready to dispense a dose of Albuterol, a green light indicator was activated. Once the end-of-life response was triggered, or if the 1,500 dose lifetime was reached, a red-light indicator was activated. Once the red light was on, the inhaler stopped working altogether.

15. As a result of the inhaler's reliability problems during Phase III clinical trials, Dura began making modifications to the inhalers actually being used in the ongoing clinical trials to improve reliability. Dura included multiple versions of the inhaler in the Phase III clinical trials.

The modifications made to the inhaler during trials included using different shaped battery contacts that were welded to the battery to better secure the battery wires, re-routing certain wiring and using stronger gauge wire. Dura also modified the inhaler's lid to make it easier to see the remaining doses of Albuterol and ribbing was added to the outside of the device to make it easier to hold. Dura kept very careful track of the different versions of the inhaler used in clinical trials. The various configurations of the inhaler were given different "Rev" designations. For example, the configuration of the device first used in clinical trials was designated Rev D, while Rev G was a modified version added halfway through clinical trials to address reliability concerns. Rev H and Rev J were designations given to still later versions of the inhaler.

16. All modifications were well documented within the clinical trial results and reliability reports and each test run on each configuration was analyzed in a separate report. In each of the reports, the configuration number and the test type were referenced in the title of the report such as Rev G vibration or Rev G impeller test. More importantly, senior management at Dura, including defendant Prettyman as Senior Vice President of Regulatory Affairs, had to sign off on proposed modifications before they could be made. Other employees within the Regulatory Affairs department, Kathleen Heffernan, Director of Regulatory Affairs, and Darlene Rosario, Regulatory Affairs Manager, were also intimately familiar with the modifications being made to the inhaler and involved in approving the modifications.

17. Senior management at Dura, including defendants, were kept constantly informed of the problems affecting the inhaler's reliability via product reports prepared by Mike Ligotke, the Senior Product Engineer for the Spiros device and Linda Gieschen, the Spiros Project Leader. These same reports also constantly informed senior management of the different configurations of the inhaler, the different tests being performed and the results of those tests. These reports were prepared for and circulated in advance of and during weekly research and development meetings

attended by senior management. Research and development meeting minutes, that also detailed the inhaler's reliability problems and the different versions of the inhaler, were prepared and circulated to senior management following the meetings.

18. Making changes to a device in the middle of clinical trials rendered the trials invalid because the modifications cast doubt on whether the product tested would, in fact, be the final product described in the NDA. Senior executives at Dura were so concerned about the inhaler's reliability problems and the mid-clinical trial modifications that were made to the device, that the decision was made to contract with an outside testing facility, El Segundo, California-based Wyle Labs, to conduct highly accelerated life tests ("HALT") on the device. HALT are extreme condition tests designed to identify potential operational failures in a device. Dura contracted with Wyle Labs to conduct these tests while Phase III clinical trials were still ongoing. Ed Dusel, Senior Engineering Development Manager, supervised the Wyle Lab testing and Mike Ligotke, Senior Project Manager, analyzed the test results. Dura gave Wyle Labs inhaler configurations Revs D, G, H and J of the device. Dura used the HALT results from Wyle Labs in an 9/98 amendment to Dura's NDA to try to demonstrate that the different inhaler configurations tested in Phase III clinical trials as well as the concurrent HALT resulted in progressively improved operational reliability.

19. At the same time as the disastrous Phase III clinical trials were being completed, defendants were already taking steps to complete a major debt offering for Dura to obtain desperately needed working capital to acquire additional pharmaceutical products. They also knew that Spiros I would exhaust its financial resources during 1997, and Dura would have to exercise its option to repurchase Spiros I and finance a new follow-on Spiros Development Corp. II entity ("Spiros II") to continue to pay for the ongoing development of Albuterol Spiros.

20. In addition, the value of Dura's insiders' existing stock options to purchase thousands of shares of Dura stock at $29.63-$37.63 per share had been completely wiped out by the early 1997

stock decline, while the value of their other lower priced options had been severely diminished. Finally, the 1997 cash bonuses of Dura's top executives – which could amount to 100% of their base salaries – were dependent upon Dura meeting internally set 1997 EPS targets and Dura's stock price performance during 1997.

21. For all of these reasons, it was imperative to Dura's insiders that they drive Dura's stock higher during 1997 to enable Dura to accomplish a huge debt offering to raise desperately needed capital, to exercise its option to purchase Spiros I stock by issuing as few Dura shares as possible, to successfully complete a public offering of Spiros II securities, to restore the value of their stock options so that they could unload hundreds of thousands of shares of the Dura stock they owned, pocketing millions in insider-trading proceeds before the stock collapsed, and to achieve large cash bonuses based on Dura's 1997 EPS and a strong 1997 stock performance.

22. To accomplish their scheme, defendants commenced in a concerted campaign to falsely persuade investors that Dura's pharmaceutical sales were increasing and that Dura was successfully completing the development and clinical trials of the Spiros drug delivery system. To ensure their personal gain, the individual defendants in 4/97 re-priced hundreds of thousands of their $37.63 per share options lower – to just $25 per share. Then, on 4/15/97, Dura issued a press release announcing better-than-expected 1Q 1997 results, representing that "Dura continues to execute its strategy of developing its proprietary Spiros dry powder drug delivery technology" and has completed the design of its Albuterol Spiros drug system and the patient dosing studies necessary for filing a NDA with the FDA. The 4/15/97 press release also represented that Dura was making strong progress selling Ceclor CD and that the drug was being well received by prescribing physicians. In response to these positive representations and Dura's strong 1Q financial results, Dura's stock soared from $27-7/8 on 4/14/97 to $34 on 4/15/97. Following the release of Dura's 1Q 1997 results, defendants went to great lengths to convince securities analysts, during conference calls and in one-

on-one sessions, that the Spiros delivery device development was on track and Dura was executing its strategy to transform itself into a drug development company. Defendants' interactions with securities analysts had their desired effect as one analyst noted: "Without Spiros, Dura would be strictly a high-growth specialty marketing company, acting as a consolidator of niche respiratory product lines."

23. Contravening their public praise of the Spiros technology, defendants knew from the clinical trial data that the Spiros drug delivery system suffered from serious reliability problems forcing Dura to remove over 30% of the inhalers from clinical trials and the Albuterol cassette suffered from serious stability problems, all of which would prevent approval of Dura's NDA. Despite the fact that Dura modified the device, conducted in-house stability testing showing that Albuterol was not stable and even contracted an outside firm to test the device, defendants assured investors that Albuterol Spiros had successfully completed clinical trials, that the Company would file the NDA later in 1997 and commence marketing the device in 1998.

24. In addition to concealing these problems, defendants also concealed a pre-NDA filing meeting Dura conducted with the FDA in 5/97. By the time the pre-NDA filing meeting occurred with the FDA, Dura had completed clinical trials and 95% of the data from the trials concerning chemical in stability, doser reliability and failure rates had been received by Dura.

25. The pre-NDA meeting, which took place in the FDA's offices in the Washington, D.C. area, was attended by defendants Garner and Prettyman, and by Kathleen Heffernan, David Kabakoff and Chet Damecki. During that meeting, the FDA raised concerns about how mechanically reliable the doser was for consistently delivering Albuterol to the user's lungs in the right amount or at all. The FDA also questioned whether and how long Albuterol contained in the cassette would remain chemically stable after removal from the foil pouch.

26. In total, defendants were in possession of the following adverse facts:

- that Dura's engineers wanted to do further development of the Spiros device, that the Eisele List identified the inhaler's reliability and Albuterol's stability as necessary items to be fixed before a NDA could be successfully submitted;
- Albuterol had in fact failed Dura's in-house temperature-humidity age testing and Dura had failed to remedy Albuterol's stability problems;
- serious reliability problems caused over 30% of the Spiros inhalers to fail during clinical trials;
- Dura had been forced to retain Wyle Labs to conduct HALT; and
- Dura executives, including defendants Garner and Prettyman, attended the pre-filing meeting with the FDA which raised the same concerns identified by Dura's own engineers in the Eisele List and for which Dura had no satisfactory answer.

27. Armed with this knowledge, defendants re-priced their options, artificially drove up the price of Dura stock and then dumped their shares. Defendants embarked on a massive bailout of Dura stock selling 188,626 shares for over $7.3 million between 5/12/97 and 7/22/97. Defendants sold their stock at prices ranging from $36 to $42 beginning just one month after re-pricing these options from $37.63 to $25.00 in 4/97.

28. Defendants compounded their wrongdoing later in 1997 with additional, highly suspicious insider trading of Dura stock. Because the Spiros device was so unreliable and Dura had been forced to modify the device and could not adequately demonstrate the stability of Albuterol, certain Dura insiders were against filing the NDA. In fact, in late October or early November 1997, a meeting was held to discuss the NDA filing. Defendants Garner and Prettyman along with Kabakoff and Damecki attended the meeting during which Prettyman made it very clear that he did not want to file the NDA, for which his department, Regulatory Affairs, was responsible. Prettyman was against filing the NDA because based on his prior experience – Prettyman worked for the FDA for over ten years prior to working for Dura – he knew the NDA would not be approved by the FDA.

Despite this, defendant Garner and Kabakoff forced Prettyman to file the NDA. Shortly after the NDA was filed, defendants raised an additional $88 million, premised on Dura's artificially-inflated stock price, to fund Spiros II. Despite his non-public knowledge that the NDA would not pass due to Albuterol Spiros defects, defendant Prettyman sold 15,000 shares of Dura stock on 11/5/97 for proceeds exceeding $728,000. Other defendants similarly engaged in suspicious insider trading concurrent with the filing of the doomed NDA as defendants collectively dumped 197,607 shares for proceeds exceeding $9.2 million between 11/3/97 and 1/6/98.

29. In addition to concealing the problems plaguing the Spiros drug delivery system development, defendants also made false statements regarding purportedly strong sales of Dura's primary drug, Ceclor CD. Defendants falsely represented that certain of Dura's recently acquired niche pharmaceutical products were selling well to convince the securities markets that it was achieving strong revenues and earnings even as it completed development of the Spiros drug delivery system. Dura had acquired two prescription antibiotics, Ceclor CD and Keftab, on 8/22/96. Defendant Garner stated: "Keftab and Ceclor CD are ideally suited for Dura as they should provide strong revenue and earnings growth and support the expansion of our sales force to position Dura for an effective launch of our Spiros products."

30. Ceclor CD would become Dura's largest-selling product, however, contrary to defendants' representations, its sales were not growing during the Class Period, but were flat or declining. Ceclor CD is a slow-release form of Ceclor, a second generation cephalosporin generically known as cefaclor. It was developed by Eli Lilly ("Lilly") in the 1980's, which later sold the marketing rights to Dura. As it has significant side effects, including serum-sickness-like reactions and shock, its use decreased in the late 1990s as more powerful antibiotics with less significant side effects have been developed.

31. Also hurting Ceclor CD sales during the Class Period was the fact that the drug was not listed on most managed-care formularies and, therefore, would not be covered by most managed-care insurance. As a result of these factors, then undisclosed, Ceclor CD sales began to drop around March or April 1997, and significantly worsened during the summer of 1997. Actual sales were 25%-40% below Dura's projections. To bolster their false representations of strong Ceclor CD sales, Dura reported market share by comparing Ceclor CD not to the entire class of respiratory antibiotics, but only to sales of Lilly's generic Ceclor product. Defendants, therefore, knew that the market share increases reported during the Class Period were misleading when made and falsely suggested that Ceclor CD sales were strong and expanding. If Dura had properly compared its sales of Ceclor CD to all other drugs in the same class, namely, those drugs used to cure respiratory infections, Dura's reported sales of Ceclor CD would not have reflected any market share growth during the Class Period.

32. Moreover, Dura's sales force was inefficient, underpaid and suffered from an extremely high rate of turnover. Such deficiencies adversely affected sell through of Dura's products, including Ceclor CD. Compensation packages for Dura sales representatives were not competitive with the rest of the pharmaceutical industry. In early 1997, Dura attempted to reduce its salesperson turnover rate by increasing the base salary of its sales force. However, at the same time, Dura decreased commissions paid to salespersons, thereby failing to solve its turnover problem. Dura failed to distribute sales revenue figures of any kind to the sales force, thereby making them ill-equipped to deal with changes in the market. Dura frequently ignored its stated requirement that sales applicants have a minimum of two years of prior sales experience, thereby reducing the collective quality of the sales force.

33. Additionally, Dura's sales force was hampered by a non-operational software and sales force hand-held computer system during the Class Period. Dura had contracted with Walsh

International, Inc. to install the Precise System by 9/96. By 4/97, however, the system had just been installed and Dura had privately identified some 24 malfunctions that were severely hampering its sales force's performance. By 12/97, the malfunctions had worsened to the point where Dura was incapable of preparing necessary quarterly inventory reports or accurate FDA reporting.

34. Knowing that Dura was experiencing a decline in the demand for its drug lines, including Ceclor CD, Dura undertook a scheme to artificially inflate its revenues and earnings by shipping on the final few days of fiscal quarters excess amounts of product to wholesalers. When defendants realized that Dura would be unable to achieve analysts earnings expectations of the end of quarters during 1997, defendants Garner, Newman and Spath instructed Dura employees to conduct what were referred to as "load-ins" to ship excess product to the Company's wholesale distributors.

35. According to the former national accounts manager, in each quarter in 1997 about two or three weeks before a quarter's end when it became apparent that the Company's revenues were going to fall short of estimates, Dura's national accounts managers flew into San Diego to attend a sales meeting led by defendant Spath and Doug Weiherer aimed at strategizing on deals and terms that they could offer their respective third party distributors as incentives to get them to take on large quantities of Ceclor CD. These meetings usually occurred offsite at a hotel not far from Dura's headquarters or in a conference room in the San Diego headquarters, on the first floor, just to the left when entering the building. The national account managers flew into San Diego over the weekend, and then the meeting took place on Monday and all dreaded coming to San Diego for meetings because when they occurred, they knew they would be directed to participate in what was referred to as "load-ins." At these meetings, Spath first made some general statements indicating that he needed the sales reps to generate more revenue before the end of the quarter so Dura would meet its quarterly projections. Spath then left the meeting, and Doug Weiherer got into the details of how much in revenues the sales managers needed to generate in order for the Company to meet the quarterly projections. Weiherer then outlined specific discounts, payment extensions, and rights of

return that they should offer their respective customer accounts as incentives to accept large orders of Ceclor CD. They referred to this practice at Dura as "loading it in," a "load-in" or a "fire sale."

36. Weiherer received direction and approval to have the national account managers offer their customers the terms Dura used to stuff the channel in meetings with defendants Newman, Spath and Garner. These high-level meetings preceded the meetings Weiherer had with the national accounts managers. Examples of the terms that were typically offered were a 6% or 12% discount on the price depending on the volume of the order (higher volume orders received the higher percentage discount), payment terms of 60, 90 or 120 days rather than the standard 30-day term that Dura provided and allowance for returns anywhere from three months to three years after shipment for a full or half credit on the purchase price. Product quantities were sold by the case, and each case contained between 12 and 24 packs of Ceclor CD. A typical deal might include two dozen cases for a discounted price plus another two or three dozen cases for free with unlimited rights of return and no payment due for a year. The distributors were willing to accept these terms because it allowed them to take on the additional product and return whatever they could not sell before they even had to pay for any of the inventory.

37. When Weiherer received instructions from these executives to implement a "load-in" with distributors, Weiherer himself traveled to meet with customer reps at McKesson Drug Company ("McKesson"), Cardinal Health, Inc. ("Cardinal") and Bergen Brunswig Drug Company ("Bergen Brunswig"), even though these accounts technically were assigned, to the national account managers. According to the former national account manager, "for a VP to call on a specific accounts was unheard of in this industry" at the time, and it was well-known at Dura that Weiherer's involvement meant that the Company was seeking to place a large "load-in" order of Ceclor CD with these customers.

38. The terms used to complete the "load-ins" created problems for Dura's national account managers because other customers would hear about the generous terms Dura provided during drug wholesaler conferences. After these conferences, customers such as Bindley Western Drug Company ("Bindley Western"), would complain to the national account managers that McKesson got better prices, discounts, payment terms or return rights for the same products that had

been sold in the same quarter. This practice created a credibility issue for the national account managers and their customers.

39. According to the former national account manager, the quarter-end "load-ins" resulted in significant returns which impacted the national account managers' quarterly sales bonuses. "Bonuses were predicated on sales," and Dura issued these bonuses at the end of the quarter in which the sales were booked. However, when returns on sales came back in subsequent quarters, Dura deducted from that quarter's bonus whatever portion of a prior quarter's bonus was tied to the returned inventory. Despite that Dura would experience 75% returns of product sold subject to the "load-ins," Dura always booked 100% of the revenues in the quarter the deal was struck, and did not set aside any of the revenues as a reserve for returns.

40. Defendants accomplished the "load-ins" in varying ways. The Director of National Accounts, Doug Weiherer, pressured his subordinates to push extra product into the pharmacy chains in order to increase EPS. National Account Manager Jack Strathmeyer told his district sales manager several times that he had been ordered to push additional product into pharmacy chains in order to boost Dura's earnings numbers. This practice upset Strathmeyer because it strained sales relationships with pharmacy representatives.

41. In addition, defendant Spath and other upper management would contact the Company's larger wholesalers, such as McKesson, Cardinal, Bergen Brunswig and Bindley Western, to get an "additional buy" from them at quarter ends to complete the "load-ins." Dura's sales representatives were instructed to "load wholesalers to the max" with Ceclor CD, pressuring them to ship even more Ceclor CD near each quarter's end. Loading Dura's wholesalers with excess product had a tremendous impact on the Company's overall sales as Dura's four largest customers constituted up to 60% of sales. Dura offered wholesalers extended payment terms, 120 days or six months within which to pay for orders, rather than the standard 30 days, and told wholesalers that Dura would take back any returns or unsold product. Dura gave its distributors unlimited rights of

return for full or partial credit even up to three years later. The wholesalers took more product than they had orders for because Dura gave up to 6%-12% discounts from the wholesale purchase price, extended the payment date to give them time to move the product and let them return unsold product. As wholesalers operate on a narrow profit margin, these price reductions could increase their margins from 30%-100%. In 12/97, Dura offered a 6%-12% price reduction to wholesalers on purchases of Ceclor CD to induce its largest customers to take a one-year supply of the product instead of the usual 30-day supply.

42. In 4Q 1997, defendants were desperate to continue the illusion that Dura was achieving strong Ceclor CD sales because they knew they had to use Dura shares to buyout Spiros I shareholders and complete an offering to fund Spiros II. Defendants, however, were aware that the actual demand for Ceclor CD was insufficient to meet Dura's revenue and earnings expectations. For this reason, Dura's executives, including Garner and additional defendants, met at the end of November or early December 1997 to discuss the fact that Dura would not meet its inside sales numbers for 4Q 1997. Ultimately, it was decided at the meeting that to complete the massive "load-in" to close the earnings shortfall so the Company could achieve earnings estimates Dura would engage in a "fire sale" of its products and would urge wholesalers to buy more product than normal. Dura granted special discounts to wholesalers in order to convince them to buy a years worth of inventory at one time. McKesson, Cardinal and Bergen Brunswig, Dura's largest wholesalers, participated in the "fire sale" and agreed to purchase enough Ceclor CD in December 1997 to fill all their needs for 1998. By offering massive discounts and unlimited rights of return, Dura induced its largest customers McKesson and Cardinal to each purchase over $1.5 million in Ceclor CD and Bergen Brunswig to purchase over $1 million in December 1997. Later Dura's executives specifically discussed the impact of the "fire sale" and privately acknowledged that the Company could not "make the numbers" for 1Q 1998 because of the 1997 "load-ins."

43. Garner himself had to approve price reductions to wholesalers, so he knew in each instance when these practices occurred. As a result of these drastic, one-time measures, Dura product inventories in the distribution channel were greatly in excess of the normal one-month supply and Dura's primary Ceclor CD customers were sitting on an excess supply of Ceclor CD and had no need to make additional orders. Accordingly, the success of Dura's products was misrepresented and its sales were artificially inflated. Defendants knew that Dura was achieving strong Ceclor CD sales by giving massive incentives to wholesalers and not by experiencing strong sales generated by its sales force. For this reason, defendants knew that Dura was "robbing Peter to pay Paul" by "borrowing" millions of dollars of sales of Ceclor CD and from future periods, and that Dura's sales would fall sharply once this practice was stopped. Moreover, defendants were also aware that Dura would not only be unable to continue stuffing the channel without impacting future sales, but also that Dura would receive over 75% of "fire-sale" product back. By the Spring of 1998, defendants admitted to securities analysts that Dura's wholesale channels were clogged with as much as a five-month inventory of its products.

44. Defendants took advantage of their decision to complete massive load-ins by selling over 190,000 shares of Dura stock between 11/3/97 and 1/6/98 and pocketing $9.2 million in proceeds. Further, defendants closed the Spiros II offering by selling 5.5 million units raising $88 million.

45. On 2/24/98, after the close of trading, Dura shocked the market by revealing that it expected much lower than forecast 1998 revenues and 1998 EPS – at least $.50-$.55 lower than the $1.40-$1.45 being forecast – due to, *inter alia*, slower Ceclor CD sales and the immediate need to vastly increase the size of Dura's sales force from 270 to over 450 to try to boost sales of existing products. Investors were stunned as defendants had recently assured investors demand for Ceclor CD was strong and defendants announcement cast doubt on defendants' credibility. Even though the

Dow Jones average went up 87.7 points on 2/25/98, Dura's stock collapsed from $39.13 on 2/24 to $20.75 on 2/25 – an $18.38 per share, 47% one-day decline on unprecedented volume of 32 million shares. Analysts were both shocked and furious over having been lied to. Alex. Brown analyst Ryan wrote:

> ***Management credibility has been severely damaged by this announcement***, particularly in light of recent investor conference presentations exuding confidence on the Company's fundamentals . . . .
>
> * * *
>
> ***Our confidence in management and their credibility with us has been greatly diminished.*** As recently as one month ago, we reviewed our model with the Company line by line and were guided to higher Ceclor CD estimates.

46. The shocking disclosures continued throughout 1998. Months later, on 9/23/98, Dura revealed that it had submitted additional chemistry and manufacturing control data requested by the FDA in support of the original NDA – finally indicating the truth about the problems that had plagued Albuterol Spiros during and before the Phase III testing. Dura also announced that the purported launch date for the device had slipped to 2Q 1999. In response to the disclosures about the Spiros drug delivery system, Dura's stock price declined an additional 28%, on high volume, from $15.25 on 9/23/98 to $10.00 on 9/25/98.

47. Six weeks later, on 11/4/98, in another announcement, which came as no surprise to defendants, Dura acknowledged that the FDA had found that Albuterol Spiros was not approvable due to electro-mechanical reliability issues and chemistry, manufacturing and control concerns. In an effort to cushion the blow, defendants claimed that the FDA "raised no issues on the clinical data with the inhaler filed in the NDA demonstrating therapeutic comparability of Albuterol Spiros™ with Ventolin® (albuterol) MDI using standard lung function measures." Nevertheless, in response to this further disclosure on 11/4/98 of the long-standing problems with the Spiro's devise, Dura's stock price declined 21% from $12.50 to $9.34.

48. Just a few days later, however, on 11/6/98 the FDA issued a "notice of violation" to Dura stating that ***Dura's press release "'misleadingly minimizes the fact that Dura must conduct a completely new clinical data [study],'"*** and demanded that Dura immediately cease distribution of materials containing its previous claims. Dura was forced to immediately remove the offending press release from its Web site and subsequently admitted that Albuterol Spiros would be delayed by at least a year as completely new Phase III clinical trials were required. The FDA rejected the NDA for Albuterol Spiros because Dura changed the device during clinical trials, had not shown that the device was reliable and could not demonstrate Albuterol's device based on the same issues stability. In other words, the FDA rejected the Albuterol Spiros device based on the same issues delineated in the Eisele List in 10/96. The 11/6/98 letter of rebuke from the FDA was not publicly revealed to investors and the market until 12/4/98. On that day Dura's stock price further declined 13% from $12.56 to $10.50.

49. Dura's business performed miserably during 1998. In particular, sales of Ceclor CD fell sharply to only $30 million as Dura admitted the distribution channel was clogged with many months of excess inventory. Dura also admitted contrary to statements during the Class Period that its sales force was inadequate, which contributed to Dura's poor sales. By 9/98, forecasts of Dura's 1998 and 1999 EPS were cut to $.53 and $.71 – large declines from Dura's 1997 EPS of $.99. Moreover, defendant Garner finally admitted that there was excessive inventory of its top-selling antibiotic Ceclor CD to start the year, which took at least five months to work down.

50. Later still, Dura announced that it would abandon its efforts to seek FDA approval of the Spiros delivery device for use with Albuterol. Dura was unable to solve the Albuterol stability issues that were revealed during Dura's in-house stability testing conducted in 1996 before clinical trials even began.

51. Public investors, who purchased Dura stock at prices inflated by the false representations about the successful development of Albuterol Spiros, continuing strong sales of Dura's non-proprietary products, and very strong sales of Ceclor CD, and who, thus, paid as high as $53 per share for Dura's stock during the Class Period, suffered millions in damages when the artificial inflation left the stock price as detailed below in ¶¶183-198. Dura and Dura's insiders who knew the truth fared much better. Before the startling truth was revealed and Dura's stock price collapsed, Dura raised over $375 million in desperately needed new capital from note purchasers, and in total the individual defendants unloaded 386,233 shares of their Dura stock at artificially inflated prices as high as $49.31, pocketing over $16.6 million in illegal insider-trading proceeds. This illegal insider selling is detailed in ¶¶175-182.

52. The chart below shows how the defendants took advantage of their false and misleading statements, Dura's artificially inflated stock price and the Company's stock price decline when adverse news about its sales and drug-delivery system was disclosed to the market. The chart also shows that, when compared to an index of similar stocks, Dura's stock was inflated and declined due to company-specific events and not market or industry forces:

JURISDICTION AND VENUE

53. The claims asserted herein arise under §§10(b) and 20(a) of the 1934 Act and Rule 10b-5. Jurisdiction is conferred by §27 of the 1934 Act. Venue is proper pursuant to §27 of the 1934 Act.

THE PARTIES

Lead Plaintiffs

54. Michael Broudo ("Broudo") purchased 100 shares of Dura common stock on 2/24/98 at $38.94 per share and 2,000 shares on 2/24/98 at $38.88 per share. As a result of the defendants' conduct detailed herein, Broudo suffered damages in connection with his purchases of Dura securities.

55. Baldev S. Gill ("Gill") purchased 4,000 shares of Dura common stock on 2/9/98 at $39.88 per share; 2,000 shares on 2/13/98 at $38.72 per share; 1,000 shares on 2/17/98 at $37.64 per share; 2,000 shares on 2/19/98 at $37.53 per share; and 3,000 shares on 2/20/98 at $36.96 per share. As a result of the defendants' conduct detailed herein, Gill suffered damages in connection with his purchases of Dura securities.

56. Larry Morgan IRA ("Morgan") purchased 1,290 shares of Dura common stock on 1/28/98 at $39.13 per share. As a result of the defendants' conduct detailed herein, Morgan suffered damages in connection with his purchases of Dura securities.

57. Leonid S. Shvartsman ("Shvartsman") (for G&S Partnership) purchased 2,000 shares of Dura common stock on 2/17/98 at $38.25 per share. As a result of the defendants' conduct detailed herein, Shvartsman suffered damages in connection with his purchases of Dura securities.

58. Neil Siskind ("Siskind") purchased 15 of Dura's Convertible Subordinated Notes on 7/30/97 at $1,025.00 per note. As a result of the defendants' conduct detailed herein, Siskind suffered damages in connection with his purchases of Dura securities.

59. Roberta Speck ("Speck") purchased 50 of Dura's Convertible Subordinated Notes on 7/30/97 at $1,022.50 per note. As a result of the defendants' conduct detailed herein, Speck suffered damages in connection with her purchases of Dura securities.

60. Brent Vogt ("Vogt") purchased 500 shares of Dura common stock on 6/15/97 at $39.58 per share; 100 shares on 7/29/97 at $37.32 per share; 500 shares on 9/2/97 at $36.35 per share; 500 shares on 9/17/97 at $41.60 per share; and 500 shares on 10/29/97 at $45.35 per share. As a result of the defendants' conduct detailed herein, Vogt suffered damages in connection with his purchases of Dura securities.

Defendants

61. Dura was a San Diego-based developer and marketer of prescription pharmaceutical products for the treatment of allergies, asthma and related respiratory conditions. During the Class Period Dura represented that it pursued a two-step business strategy: (1) licensing, acquiring and developing late stage pharmaceuticals for marketing to high-prescribing respiratory physicians; and (2) developing Spiros, a proprietary dry powder drug delivery system for use with respiratory and non-respiratory drugs. During the Class Period, Dura's common stock traded in an efficient market on the Nasdaq National Market System. In November 2000, Dura was acquired by the Irish drug company Elan Corporation.

62. The following seven former officers of Dura are the "Individual Defendants":

(a) Cam L. Garner was President, Chief Executive and Operating Officer and Chairman of Dura during the Class Period. He sold 154,623 shares of his Dura stock based on inside information, pocketing over $6.4 million in illegal insider-trading proceeds – 67% of the Dura stock he actually owned.

(b) James W. Newman was Senior VP-Finance & Administration and Chief Financial Officer of Dura during the Class Period. He sold 52,227 shares of his Dura stock based on

inside information, pocketing over $2.3 million in illegal insider-trading proceeds – 78% of the Dura stock he actually owned.

(c) Charles W. Prettyman was Senior VP-Development and Regulatory Affairs of Dura during the Class Period. He sold 15,000 shares of his Dura stock based on inside information, pocketing over $728,000 in illegal insider-trading proceeds – 100% of the Dura stock he actually owned.

(d) Walter F. Spath was Senior VP-Sales & Marketing of Dura during the Class Period. He sold 50,000 shares of his Dura stock based on inside information, pocketing over $2 million in illegal insider-trading proceeds – 100% of the Dura stock he actually owned.

(e) Mitchell R. Woodbury was Senior VP/General Counsel of Dura during the Class Period. He sold 35,000 shares of his Dura stock based on inside information, pocketing over $1.6 million in illegal insider-trading proceeds – 100% of the Dura stock he actually owned.

(f) Julia R. Brown was Senior VP-Business Development and Planning of Dura during the Class Period. She sold 39,383 shares of her Dura stock based on inside information, pocketing over $1.5 million in illegal insider-trading proceeds – 100% of the Dura stock she actually owned.

(g) Joseph C. Cook, Jr. was a director of Dura during the Class Period. He sold 40,000 shares of his Dura stock based on inside information, pocketing over $1.7 million in illegal insider-trading proceeds – 43% of the Dura stock he actually owned.

63. Garner, Newman and Spath, by reason of their positions with Dura, were controlling persons of Dura and the other Individual Defendants. They are, therefore, liable under §20(a) of the 1934 Act.

BACKGROUND TO THE CLASS PERIOD

64. Both before and during the Class Period, defendants entered into a series of "off balance sheet transactions" with entities Dura created. The purpose of these transactions was to permit Dura to transfer its rights to the Spiros technology to these entities as a mechanism to enhance Dura's revenues by converting what would otherwise be recorded as development expenses into revenues for Dura. The millions of dollars of research and development costs associated with developing, testing and obtaining approval for the Spiros drug delivery system would normally have to be immediately expensed as a charge against current earnings under GAAP. But the use of these "off balance sheet" entities allowed Dura to avoid this huge negative impact to earnings. Critically, as set forth below, this scheme motivated defendants to maintain Dura stock at artificially inflated prices both because: (1) Dura's ability to raise money through initial offerings of these entities was directly dependant on the appearance of Dura's financial health and robust stock price; and (2) defendants needed to maintain Dura's stock price at artificially inflated levels so that Dura would be able to exercise its option to reacquire the rights to the Spiros technology from these off balance sheet entities as cheaply as possible by using Dura stock trading at artificially inflated prices.

65. In 1993 Dura created Dura Delivery Systems, Inc. ("DDSI"), a paper corporation with no employees of its own. Dura transferred its rights to the Spiros technology to DDSI and had DDSI issue callable shares of stock. DDSI granted Dura an option to purchase DDSI by calling in the callable shares from whoever owned them in return for paying those shareholders a specified per share price that varied depending upon when the option was exercised.

66. On 12/29/95, Dura exercised its option to call in and purchase all outstanding DDSI shares, paying shareholders $33.5 million for a company that had been worth $13 million two years before. The entire amount was paid in Dura stock.

67. On 12/22/96, Dura issued a press release entitled "Dura Pharmaceuticals Announces Acquisition of Ceclor (R) CD and Keftab(R) From Lilly." The release stated in pertinent part:

> Dura Pharmaceuticals, Inc. today announced that it has signed an agreement with Eli Lilly and Company to acquire exclusive U.S. marketing rights to the patented cephalosporin antibiotics Keftab(R) (cephalexin hydrochloride) and Ceclor(R) CD (cefaclor extended release tablets) for approximately $100 million plus additional contingent amounts. As part of the agreement, Lilly will manufacture the products for Dura. The transaction is expected to close next month, and is subject to review under the Hart-Scott-Rodino Act.
>
> The Company believes that the two products could generate combined annual sales of $100 million in the year 2000. The market for oral antibiotics in the U.S. was approximately $4.8 billion in 1995. Keftab has current annual sales of approximately $15 million. Currently, there are approximately four million prescriptions written annually in the United States for the solid form of Ceclor. Ceclor CD, for which Lilly received marketing approval from the FDA in June and which Dura expects to launch this fall, will offer the advantage of twice-a-day dosing.
>
> The addition of Ceclor CD and Keftab complements Dura's existing line of prescription products and is expected to have both strong strategic and positive financial impact. ***The products are not only expected to produce incremental earnings and continued strong sales growth, they will also enable Dura to grow its field sales force to effectively launch its first Spiros(TM) product (albuterol) expected in late 1998.*** Dura will immediately undertake expansion of its field sales force from approximately 140 to over 200 by the end of 1996, and expects to continue sales force growth in 1997.
>
> Dura will begin promoting Keftab to physicians immediately after the transaction closes and will launch and vigorously promote Ceclor CD in time for the upcoming respiratory season. Ceclor CD is expected to be heavily prescribed for bronchitis by Dura's current physician base.
>
> Commenting on the announcement, Dura's Chairman, President and Chief Executive Officer Cam L. Garner stated, "Keftab and Ceclor CD are ideally suited for Dura as they should provide ***strong revenue and earnings growth and support the expansion of our sales force to position Dura for an effective launch of our Spiros products.*** Keftab is a well-established product that has been shown to be very responsive to promotional efforts. Ceclor CD has exciting potential and will benefit from the strong brand recognition of Ceclor.
>
> "We will immediately begin investing in the launch of these products, including the expansion of the sales force," Garner said. "Earnings from these products should build significantly starting in 1997."

68. On the news that Dura would acquire exclusive US marketing rights from Lilly for Ceclor and Keftab, Dura shares shot up $5.75 or 21%, to $32.50.

69. On 10/14/96, Dura released its results for the 3Q 1996. The release entitled "Dura Pharmaceuticals' Earnings Triple as Revenues Almost Double During Third Quarter 1996," stated in pertinent part:

> Dura Pharmaceuticals, Inc. today reported record revenue and net income for the third quarter ended September 30, 1996. For the quarter, net income rose 229% to $5,806,000, as revenue grew 97% to $25,920,000, compared to net income of $1,767,000 on revenue of $13,189,000 in the same period last year. Per share earnings for the third quarter of 1996 were $0.14 on average shares outstanding of 42,266,000, compared to $0.06 per share on average shares outstanding of 30,114,000 in the third quarter of 1995. For the nine-month period ended September 30, 1996, Dura reported net income of $14,471,000, or $0.37 per share, on revenues of $63,307,000 compared to net income of $4,435,000, or $0.16 per share, on revenues of $35,695,000 in the same period last year. The 1995 per share numbers have been adjusted to reflect the two- for-one stock split by way of a 100% stock dividend effective July 1, 1996.
>
> Revenues from the sale of respiratory pharmaceuticals, including HealthScript sales, totaled $18,940,000 during the third quarter of 1996, up 82% from $10,423,000 in the third quarter of 1995. The increase in pharmaceutical sales was due to greater sales force productivity, as well as new product acquisitions and introductions. Total revenues for the third quarter of 1996 included $6,980,000 in contract revenues from various licensing and royalty agreements, compared to $2,766,000 in the same period last year.
>
> Commenting on the quarter, Dura Chairman, President and Chief Executive Officer Cam L. Garner stated, "We are pleased with the Company's performance in the third quarter of 1996 given the fact that the third quarter is typically the weakest in the respiratory business due to seasonal trends in the cough/cold market. Our results for the quarter benefited from sales of our Entex(R) line of prescription drugs, acquired in early July 1996 from Procter & Gamble Pharmaceuticals."
>
> In September 1996, the Company acquired two patent protected antibiotics from Eli Lilly and Company, Keftab(R) (cephalexin hydrochloride) and Ceclor(R) CD (cefaclor extended release tablets). The fourth quarter will be Dura's first full quarter marketing Keftab, which is expected to have annual sales of approximately $15 million in 1996. ***Ceclor CD is a significant new product for Dura, and stocking of the distribution channels began in early October. The Dura sales force will begin promoting Ceclor CD to physicians in late October, in time for the upcoming respiratory season.***
>
> "***Besides producing sales growth, the addition of products such as Ceclor CD and Keftab enable Dura to expand its sales force to effectively launch its first Spiros(TM) product (albuterol), expected in late 1998,***" noted Garner.

70. A 1/8/97, *PR Newswire* article, titled "Dura Pharmaceuticals Update at Hambrecht & Quist Conference," stated:

> Garner reported that Dura's newest product, Ceclor(R) CD (cefaclor extended release tablets), a patent protected respiratory antibiotic, has been well received by physicians. Market share has climbed steadily to 7.5% of cefaclor total prescriptions

since launch in late October, as physicians recognize Ceclor CD's advantage in treating bronchitis patients with a seven-day, two tablets-per-day course of therapy instead of the 10 day, three tablets-a-day treatment required with the original Ceclor(R) product. Ceclor CD is expected to be a significant contributor to sales and earnings in the coming years.

Dura also sees significant opportunity for its dry powder inhaler, Spiros, and expects to introduce three Spiros products for asthma and COPD (chronic obstructive pulmonary disease) by the year 2000. . . . Progress in Spiros development is continuing on schedule, with the company anticipating a NDA filing for its first asthma product, Spiros albuterol, in the second half of this year.

71. On 1/21/97, Dura announced its fourth quarter and fiscal 1996 results in a press release titled "Dura Pharmaceuticals Announces Record Revenues and Earnings For Fourth Quarter And Year-End 1996." The release stated in pertinent part:

"During the year we made several key product acquisitions, enabling us to exceed $100 million in annual revenue for the first time. Two of the most significant additions, Ceclor(R) CD (cefaclor extended release tablets) and Keftab(R) (cephalexin hydrochloride), contributed to revenues in the fourth quarter, as Ceclor CD was launched by Dura in late October. We are pleased with physician response to the promotion of Ceclor CD, which allowed us to achieve 7.5% share of total cefaclor prescriptions by the year end." Dura anticipates that Ceclor CD and Keftab could contribute $100 million in annual revenues by the year 2000.

"Our expeditious launch of Ceclor CD enabled us to bring the product to market in time for the start of the winter respiratory season and to make a strong impact, even though we were still building our marketing strength. In December we added 50 new sales representatives, expanding the sales force to 200. Their efforts will now be supported by a comprehensive marketing program and the implementation of our Ceclor CD managed care strategy. Ceclor CD represents an exceptional strategic opportunity for Dura, as it facilitates the sales force growth needed for the upcoming launch and promotion of Spiros and furthers our reach to the targeted respiratory physicians." Dura expects to market its first Spiros product, albuterol, in late 1998.

"Dura advanced Spiros development significantly this year," Garner noted. "In the albuterol program, the pivotal clinical trials remain on schedule for completion in the first quarter. We completed the first clinical trial for the beclomethasone product for Spiros Development Corporation and look forward to beginning pivotal trials in 1997. Through a collaboration with an independent clinical investigator, using the peptide hormone, calcitonin, we demonstrated potential applicability of the Spiros technology for systemic delivery. Additionally, we conducted several feasibility studies on a variety of types of drugs for other pharmaceutical companies, advanced our proprietary powder processing technology and expanded our manufacturing facilities.

72. On 2/24/97, as reported in a *Dow Jones News Service* article titled "Dura Pharma - 2:OpCo Sees Strong Demand For Ceclor CD," Oppenheimer & Co. analyst Steve Gerber upgraded

Dura to "buy from outperform, according to a source at the firm. The analyst upped his rating on the stock because of what he sees as strong demand for the company's Ceclor CD antibiotic."

73. On 3/6/97, Dura issued a press release titled "Dura Pharmaceuticals Announces Completion of Patient Dosing of Spiros™ Albuterol Clinical Trials." The release stated in pertinent part:

> Dura Pharmaceuticals, Inc. and Spiros Development Corporation (Spiros Corp.), a separate corporation, today announced completion of patient dosing of the Spiros(TM) albuterol pivotal clinical trials necessary for NDA (New Drug Application) submission. . . .
>
> Dura, on behalf of Spiros Corp., announced that it has completed dosing of all patients in both the pivotal 12-week and pivotal short-term safety and efficacy studies comparing albuterol delivered in the Spiros(TM) system to a leading branded albuterol metered dose inhaler (MDI) product. Data from the studies are currently being audited prior to unblinding and statistical analysis.
>
> "Assuming that the results meet our objectives of demonstrating comparability between Spiros(TM) and the MDI, we expect to file a NDA for Spiros(TM) albuterol in the second half of this year," stated Cam Garner, Dura's Chairman, President and CEO. "Given the expected timing of the NDA filing, we anticipate that FDA review and approval may allow us to launch the first Spiros(TM) product in the second half of 1998."
>
> * * *
>
> The current development timeline calls for NDA filings with the FDA for albuterol in the second half of 1997, noted above, beclomethasone in late 1998, and ipratropium, in late 1999. Approval and commercialization of these products is anticipated approximately one year after the respective NDA filings.

FALSE OR MISLEADING STATEMENTS

74. On 4/15/97, Dura issued its 1996 Annual Report. With respect to Dura's Spiros drug delivery technology, the 1996 Annual Report stated:

> The Spiros family of drug delivery systems advances the promise of pulmonary drug delivery by addressing the weaknesses of existing inhalation delivery systems. In contrast to existing systems, including nebulizers, metered dose inhalers (MDIs) and traditional dry powder inhalers (DPIs), Dura's Spiros system is designed to be easy for patients to use, is breath-actuated and free of CFC propellants. In addition, each Spiros system is compact, durable and reusable.
>
> Most important, however, is the fact that Spiros is designed to be "flow rate independent," which means it can deliver a consistent dose of a drug relatively independent of a patient's ability to inhale forcefully. It also means most patients receive an adequate dose with minimal inhalation effort – a key benefit to a patient who is suffering an asthma attack. The greater ease-of-use and convenience of

Spiros, combined with its effectiveness in delivering the intended dose to the patient, should translate into more regular and efficient use. . . .

CORE COMPETENCIES IN PLACE

Dura's current Spiros development capabilities include a newly constructed manufacturing facility designed to meet rigid GMP requirements, and dedicated to the production of dry powder formulations of various pharmaceutical compounds. The facility has been licensed by the State of California and clinical trial materials are now being manufactured on-site. As the Spiros program advances, the facility will have the capacity to produce commercial-scale quantities of material.

* * *

Dura's expert scientific team has developed precision technology for the formulation, blending, milling and filing of a variety of drugs for delivery in Spiros.

75. Also on 4/15/97, Dura announced in a press release better-than-expected 1Q 1997 results:

Dura Pharmaceuticals, Inc. today announced that revenues and net income for the first quarter more than doubled over the same period last year. Revenues for the quarter totaled $40.9 million and net income was $8.8 million. Revenue from the sale of pharmaceuticals increased 141% over the same period in the prior year, which primarily resulted from the increased size of the sales force and new product introductions. Dura's net income increased 117% . . . [and its EPS] for the quarter were $0.19, a 73% increase from $0.11 in first quarter 1996 . . . .

"We are very pleased with first quarter results," said Cam Garner, Dura's Chairman, President and Chief Executive Officer, "and we are happy with the strong progress made in selling our new respiratory antibiotic, Ceclor® CD." In the first quarter, Dura doubled the Ceclor® CD share of cefaclor weekly new prescriptions over fourth quarter 1996 to 15%, up from 7.5% at year end. Commenting on this increase, Garner noted "Since the product launch just 20 weeks ago, our sales representatives have been successfully delivering the message to high prescribing physicians of patient compliance advantages of Ceclor® CD over Ceclor® in the treatment of bronchitis.

* * *

Dura continues to execute its strategy of developing its proprietary Spiros™ dry powder drug delivery technology. . . . "Patient dosing was completed for clinical trials needed for NDA (new drug application) submission of Spiros™ albuterol, and U.S. clinical trials for Spiros™ beclomethasone were initiated. . . ."

"The year is off to a great start," commented Garner.

76. Dura's stock soared over 21% from $27.87 on 4/14/97 to $34 on 4/15/97 on heavy volume of over 1.3 million shares, as a result of these announcements.

77. Each of the statements made on 4/15/97 regarding Dura's sales and business performances were false or misleading when issued. The true but concealed facts were:

(a) Sales of Dura's major drug products were flat or declining, especially Ceclor CD, whose sales levels were dropping throughout the Class Period; and

(b) Dura was engaging in a subterfuge to artificially inflate its revenues and EPS by shipping excessive amounts of Ceclor CD and other products to wholesalers, who were enticed to take the product by price discounts, extended payment terms and/or other incentives. Dura's sales representatives conducted "load-ins" and were instructed to "load wholesalers to the max" with Ceclor CD, pressuring them to sell even more Ceclor CD near each quarter's end. Dura offered wholesalers 120 days or six months within which to pay for orders, rather than the standard 30 days, and told wholesalers that Dura will arrange to take back any returns or product that they did not sell. Sell-through from the wholesalers was adversely affected by Dura's insufficient sales force. As a result, Dura's Ceclor CD and other product inventories in the distribution channel were, accordingly, greatly in excess of the normal one-month supply. As a result of this practice, Dura's Ceclor CD sales were artificially inflated and Dura's insiders knew that as a result of "borrowing" millions of dollars of sales of Ceclor CD from future periods, Dura's sales of Ceclor CD would fall sharply once this practice stopped.

78. According to the former national accounts manager, in each quarter in 1997 about two or three weeks before a quarter's end when it became apparent that the Company's revenues were going to fall short of estimates, Dura's national accounts managers flew into San Diego to attend a sales meeting led by defendant Spath and Doug Weiherer aimed at strategizing on deals and terms that they could offer their respective third party distributors as incentives to get them to take on large quantities of Ceclor CD. These meetings usually occurred offsite at a hotel not far from Dura's headquarters or in a conference room in the San Diego headquarters, on the first floor, just to the left when entering the building. The national account managers flew into San Diego over the

weekend, and then the meeting took place on Monday and all dreaded coming to San Diego for meetings because when they occurred, they knew they would be directed to participate in what was referred to as "load-ins." At these meetings, Spath first made some general statements indicating that he needed the sales reps to generate more revenue before the end of the quarter so Dura would meet its quarterly projections. Spath then left the meeting, and Doug Weiherer got into the details of how much in revenues the sales managers needed to generate in order for the Company to meet the quarterly projections. Weiherer then outlined specific discounts, payment extensions, and rights of return that they should offer their respective customer accounts as incentives to accept large orders of Ceclor CD. They referred to this practice at Dura as "loading it in," a "load-in" or a "fire sale."

79. Weiherer received direction and approval to have the national account managers offer their customers the terms Dura used to stuff the channel in meetings with defendants Newman, Spath and Garner. These high-level meetings preceded the meetings Weiherer had with the national accounts managers. Examples of the terms that were typically offered were a 6% or 12% discount on the price depending on the volume of the order (higher volume orders received the higher percentage discount), payment terms of 60, 90 or 120 days rather than the standard 30-day term that Dura provided and allowance for returns anywhere from three months to three years after shipment for a full or half credit on the purchase price. Product quantities were sold by the case, and each case contained between 12 and 24 packs of Ceclor CD. A typical deal might include two dozen cases for a discounted price plus another two or three dozen cases for free with unlimited rights of return and no payment due for a year. The distributors were willing to accept these terms because it allowed them to take on the additional product and return whatever they could not sell before they even had to pay for any of the inventory.

80. When Weiherer received instructions from these executives to implement a "load-in" with distributors, Weiherer himself traveled to meet with customer reps at McKesson, Cardinal and Bergen Brunswig, even though these accounts technically were assigned, to the national account managers. According to the former national account manager, "for a VP to call on a specific accounts was unheard of in this industry" at the time, and it was well-known at Dura that Weiherer's

involvement meant that the Company was seeking to place a large "load-in" order of Ceclor CD with these customers.

81. The terms used to complete the "load-ins" created problems for Dura's national account managers because other customers would hear about the generous terms Dura provided during drug wholesaler conferences. After these conferences, customers such as Bindley Western, would complain to the national account managers that McKesson got better prices, discounts, payment terms or return rights for the same products that had been sold in the same quarter. This practice created a credibility issue for the national account managers and their customers.

82. According to the former national account manager, the quarter-end "load-ins" resulted in significant returns which impacted the national account managers' quarterly sales bonuses. "Bonuses were predicated on sales," and Dura issued these bonuses at the end of the quarter in which the sales were booked. However, when returns on sales came back in subsequent quarters, Dura deducted from that quarter's bonus whatever portion of a prior quarter's bonus was tied to the returned inventory. Despite that Dura would experience 75% returns of product sold subject to the "load-ins," Dura always booked 100% of the revenues in the quarter the deal was struck, and did not set aside any of the revenues as a reserve for returns.

83. Garner, Prettyman, Spath, Woodbury and Brown had knowledge of the false and misleading statements regarding Dura's 1Q 1997 results as they were the top executives of Dura. They ran Dura as "hands-on" managers, dealing with the important issues facing Dura's business, such as sales of its Ceclor CD product, the development of its new Albuterol Spiros product and the issuing of Dura's Securities and Exchange Commission ("SEC") filings, press releases and financial statements. Garner, Prettyman, Spath, Woodbury and Brown each attended the weekly executive management meetings from 8:00 to 10:00 a.m. every Monday.

84. Because increased sales of Ceclor CD, the successful development of and substantial sales of Dura's Albuterol Spiros product, and the continuing sales of Dura's core products were indispensable elements to Dura meeting its internally budgeted and publicly disseminated 1998 and

1999 revenue and EPS forecasts, defendants constantly monitored each of these key factors affecting Dura's business.

85. Each of the Individual Defendants, because of their top executive positions with Dura and involvement in the day-to-day management of its business, actually knew from internal corporate documents, detailed herein, and conversations with other corporate officers and employees and their attendance at management and Board meetings, the adverse non-public information about the poor sales of Dura's Ceclor CD, the serious problems in the development of Dura's Spiros drug delivery system and Dura's deteriorating revenue and EPS prospects.

86. Defendants closely monitored the performance of Dura's business via internal reports generated on a daily, weekly and monthly basis. Among the specialized reports prepared were drug-by-drug sales volume summaries, year-over-year sales volume comparisons of each Dura product, sales volume comparisons of Dura drugs to competitor drugs, sales revenue reports and daily, weekly and monthly reports on prescription volumes, competitor prescription volumes and market share. On a monthly basis, Dura's Information Technology Department, after receiving information from IMS, a service that tracks prescription drug sales, would prepare reports comparing actual versus planned sales of Dura's drug products. Through such reports, which were prepared for and disseminated by defendant Spath, defendants were kept apprised of Dura's drug sales and knew that such sales were below plan and insufficient for Dura to achieve continued growth in sales and earnings.

87. The monthly sales reports showed, for example, that Ceclor CD sales began dropping around March-April 1997, and significantly worsened during the summer of 1997. These reports showed that sales were 25%-40% below internal projections at that time. Monthly sales reports showed that Ceclor CD sales dropped from 47,288 in 3/97 to 39,808 in 5/97 to 24,797 in 7/97.

88. The Finance Department also distributed monthly financial reports comparing Dura's actual financial results to projected results. Thus, each defendant was apprised of the sales of every Dura product so that they knew where Dura stood in terms of the sale of and demand for its products as well as Dura's actual results compared to plan. Defendants were also constantly aware of the prescription rate for its products and knew that excess inventory was building up with distributors and that Dura was not recouping its investments in certain drugs.

89. Dura recognized revenue on the sale of a product when it shipped the product to drug wholesalers. These drug wholesalers in turn would resell the drug to pharmacies, drug chains or even individual physicians. Dura did not publicly disclose to analysts or investors sales of each of its various drug products, *i.e.*, shipments to wholesalers. Thus, analysts and investors were completely dependent upon what Dura told them regarding sales of these products, as shipment-to-wholesaler data was not publicly available. While the number of prescriptions written for a given drug was publicly available on a periodic basis, this information did not disclose the rate at which drugs are being shipped to wholesalers, as that information was not publicly available. Analysts and investors did not know that Dura was shipping amounts of Ceclor CD to wholesalers well in excess of the amount justified by or necessary to keep pace with current prescription levels and, thus, Dura had created vastly excessive amounts of inventory of Ceclor CD in the distribution channel. While Dura reported higher revenue and EPS during each of the quarters of 1997 from these shipments, these excessive inventory levels would eventually have to be worked off, causing sales and earnings to plummet.

90. Dura's statements regarding the Albuterol Spiros development were false and misleading when made. Telling investors that Dura had successfully completed clinical trials was highly misleading. As of April 1997, it was all but certain that Dura's NDA for Albuterol Spiros would be rejected by the FDA and Dura would be required to completely redo its Phase III clinical

human trials, and that the product would be delayed in reaching the market, if it ever reached the market. The configuration of the product Dura used to conduct clinical trials was unreliable and plagued by significant electro-mechanical problems. During clinical trials over 30% of the inhalers failed. One problem was that a light which came on to indicate that the medication dose had been successfully delivered operated erratically and did not consistently turn on due to a defect in a printed circuit board in the product. A second defect was that the small battery-operated motor in the product to drive a fan to push the medication dose into the patient did not reliably turn on upon inhalation as it was supposed to. Dura was unable to fix these problems prior to commencing Phase III clinical trials. As a result, Dura commenced its Phase III clinical trials with versions of Albuterol Spiros that had these defects and, in fact, changed the device during clinical trials. Dura knew this would invalidate the Phase III clinical trials.

91. Dura also discovered serious problems with the stability of Albuterol in 1996 even before Phase III clinical trials began. Once Albuterol was removed from its foil pouch container, as a dry powder it is subject to humidity and temperature problems and degradation. To address stability concerns, Dura conducted in-house temperature and humidity aging where Albuterol was aged for fixed intervals at 25 degrees Celsius and 75% relative humidity under industry and FDA guidelines. During this testing, Dura determined that Albuterol was unstable when aged and subject to clumping which reduced its efficacy when exposed to humidity.

92. Defendants knew, based on their prior experience with the FDA and the medical device industry, that the FDA would not approve a NDA for an unreliable product and unstable drug. For example, during clinical trials, Dura experienced an early return rate exceeding 30% for the Spiros device. Industry standards dictated that a NDA not be filed unless the early return rate was 1% or less. Defendants Garner, Prettyman, Spath, Woodbury and Brown were informed during executive management meeting held every Monday from 8:00 to 10:00 a.m. of the problems

encountered during the Phase III clinical trials and of Albuterol's stability problems. Furthermore, defendants Garner and Prettyman attended Research and Development meetings, also held weekly, during which the Spiros device development team presented Phase III clinical trial results and stability test results. Minutes were also generated from these meetings and circulated to senior management.

93. To address the reliability problems plaguing the Spiros device during clinical trials, Dura decided to modify the device while the trials were ongoing. All device modifications had to be approved by defendant Prettyman and others in his Regulatory Affairs Department. Dura also kept careful records of the different configurations of the Spiros device labeled Rev D or Rev G. All modifications were documented in the clinical trial results and each test on each configuration was analyzed independently in a separate report. The Senior Project Engineer, Mike Ligotke, and Project Leader, Linda Gieschen, were responsible for drafting these reports.

94. Defendants were also aware of the reliability problems plaguing the Spiros device and the Albuterol stability problems from the Eisele List presented to senior management during an executive management meeting in 10/96. Bob Eisele, Vice President of Product Development, prepared a list that was contained in a five to six page document which set forth necessary items to be addressed before a NDA could be properly submitted. In fact, through the Eisele List, Dura's engineers recommended that further development of the Spiros device be completed and the stability of Albuterol be established before the NDA was submitted. Thus, senior management, including defendants Garner, Prettyman, Spath, Woodbury and Brown, were informed of these problems even before they were revealed during clinical trials. Defendants ignored Dura's engineers and proceeded with clinical trials without fixing these issues.

95. On 4/15/97, Oppenheimer & Company, Inc. ("Oppenheimer"), Alex. Brown, Robertson Stephens & Co. ("Robertson Stephens) and William Blair & Co. ("William Blair"), issued

reports on Dura and the development of Spiros which were based on and repeated information provided in a 4/15/97 conference call with securities analysts in conjunction with the 1996 Annual Report and press release and in follow-up conversations with Garner or Newman. The Oppenheimer report stated:

> [T]he company's second business, that which is developing a proprietary drug delivery system for drugs administered by the inhalation route, moves ever closer to commercialization. Here, the company's Spiros dry powder, non-aerosol system will shortly be completing clinical trials using albuterol, the most widely used inhaled asthma medicine, leading to a filing for approval with the FDA late this year.

The Alex. Brown report stated:

> The Company's efforts to develop new products are on track for an FDA filing in 2H 1997 for the first Spiros product, a dry powder formulation of albuterol . . . .

The Robertson Stephens report stated:

> Dura announced on March 6, 1997 that it had completed patient dosing in its Spiros albuterol trials. . . . [W]e still expect a 4Q98 approval and launch. . . . Dura's Spiros manufacturing facilities appear to be close to commercial scale-up capacity.

The William Blair report stated:

> We still expect Spiros albuterol to be filed in the second half of this year for marketing approval in the United States. . . . The company expects to file NDAs for Spiros beclomethasone and Spiros ipratropium in 1998 and 1999, respectively, with sales following as early as one year after NDA filings.

96. On 4/25/97, Oppenheimer issued a report on Dura which was based on and repeated information concerning Dura's Spiros development provided in conversation with Garner and Newman. The report stated:

> [The] Spiros product [will] become commercialized late next year. . . .
>
> This program has now progressed to the point that the first Spiros product, inhaled albuterol without the need for a propellant, should be submitted to the FDA before the end of this year.

97. On 4/28/97, UBS Securities ("UBS") issued a report on Dura which was based on and repeated information concerning Dura's Spiros development provided in conversations with Dura executives, including defendants Garner or Newman. The report stated:

> ***Without Spiros, Dura would be strictly a high-growth specialty marketing company, acting as a consolidator of niche respiratory product lines. . . .***

> What differentiates Dura from a typical marketing company is its interests in becoming more "fully-integrated" mainly through developing its own platform technology, the Spiros dry powder inhaler. We believe that this technology will provide an important growth catalyst following the second half 1997 NDA filing and our expectations for approval in the U.S. in the second half of 1998. Based on our projections, Spiros revenues will add [] about $58 million to Dura's current sales base in 1999.

98. On 5/7/97-5/9/97, UBS, Vector Securities International ("Vector") and William Blair issued reports on Dura after discussions with Garner and Newman following the Roche Holding AG announcement which were based on and repeated information provided by them. The 5/7/97 UBS report stated:

> Dura expects to have 350 reps in place by the time of the launch of the first Spiros inhaler product (Spiros albuterol) in late-1998.

The 5/8/97 Vector report stated:

> Separately, the company is still on track to submit their first Spiros NDA filing in the second half of 1997 for the dry-powder delivery of albuterol. The addition of 50 sales people further prepares Dura for the first Spiros product launch, potentially in the second half of 1998.

The 5/9/97 William Blair report stated:

> Dura expects to have about 350 sales reps in time for the anticipated introduction of Spiros albuterol in late 1998.

99. On 5/30/97, Alex. Brown and Vector issued reports on Dura and the Spiros development after discussions with Dura executives, including Garner and Newman, which were based on and repeated information provided by them. The Alex. Brown report stated:

> DURA will file its first NDA for Spiros albuterol with the FDA in 2H 1997, which will compete in the sizable $670 million market for albuterol, and could add $100 million in revenues by 2000 . . . .

The Vector report stated:

> [W]e note that the company still appears on track to submit its first Spiros NDA filing in the second half of 1997 . . . .

100. On 6/5/97, Dura issued a release stating:

> Dura . . . announced the completion of the clinical trials necessary for a new drug application (NDA) submission for the Albuterol Spiros™ product. . . .
>
> "Our clinical trials for Albuterol Spiros™ were designed to demonstrate comparability of the Spiros™ delivery system with a leading branded metered dose

inhaler product," noted David S. Kabakoff, Dura's Executive Vice President and President and CEO of Spiros Corp. "We are pleased with the results to date and are preparing the NDA for filing in the latter half of this year."

101. Dura's 6/5/97 announcement that clinical trials had been completed and defendants' statements made to and repeated by securities analysts in 5/97 were false and misleading and made with scienter for the reasons set forth in ¶¶90-94. Further, reporting to investors that clinical trials had been successfully completed and that the Company was on track to file its NDA later in 1997 was also false and misleading because Dura representatives, including defendants Garner and Prettyman, attended a pre-filing meeting with the FDA in 5/97 in the FDA's offices in the Washington D.C. area. During that meeting, the FDA informed Dura that it was concerned with the Spiros device's reliability and with Albuterol's stability.

102. Defendants had scienter of the falsity of the statements regarding the completion of clinical trials for the reasons set forth in ¶¶91-94. Defendants' scienter is further demonstrated by the pre-filing meeting with the FDA attended by defendants Garner and Prettyman in 5/97. Furthermore, these defendants' scienter is also demonstrated through their regular attendance at the weekly Research and Development meetings to discuss the Spiros device. At one such meeting, shortly before the 5/97 pre-filing meeting with the FDA, defendant Garner specifically asked the Spiros development team about the inhaler's unreliability issues. During that meeting, the Spiros development team again informed defendants Garner and Prettyman that over 30% of the inhalers failed during clinical trials.

103. Between 6/24/97 and 6/26/97, defendant Newman appeared at the William Blair 1997 Investment Conference in Chicago. As reported by William Blair on 6/30/97, Newman told analysts, money and portfolio managers, institutional investors, brokers and stock traders in a formal presentation that:

- Overall, the Company was performing well in both the acquisition and Spiros product development fronts. Dura's recently acquired key product, Ceclor CD,

continued to gain market share – it had an approximate 17.9% share of the cefaclor market, versus 16.9% at the end of April and 7.5% at the end of 12/96. Dura still planned to file an Albuterol Spiros product by year's end.

- One of the main reasons Dura could capture additional licensing/co-promotion agreements was that it had a highly specialized sales force of about 250 reps that were focused on the respiratory prescription market. Although Dura's sales force was relatively small, it still could call on almost 45%-50% of the high respiratory prescription writers.

- The Company also was continuing to develop the Spiros product line aggressively. Albuterol Spiros NDA should be filed by the fall of 1997.

104. The statements made during the William Blair 1997 Investment Conference detailed above were false or misleading when issued and made with scienter for the reasons described in ¶¶90-94.

105. Defendants' false statements had their desired effect and, by 7/2/97, Dura stock had recovered to $44.87 from its 4/97 low of $22.75. As Dura's stock soared higher, despite their knowledge that Dura's own engineers thought it was premature to file a NDA, that over 30% of the Spiros inhalers failed during clinical trials, that Albuterol was unstable and that in 5/97 in a pre-filing meeting the FDA had raised the same issues Dura's own engineers warned about and for which Dura had no satisfactory clinical data, Garner, Spath, Cook, Brown and Newman quickly re-priced their own stock options from $37.63 to $25.00 and unloaded 188,626 shares of their Dura stock, pocketing $7,345,527 in illegal insider-trading proceeds. Many of the shares sold were option-related and the options ***would not have expired until at least the year 2000***. For example, defendant Garner, a filer since 1992, reduced his actionable holdings (exercisable options plus common shares) by 30% with his sale of 97,623 shares. Additionally, in his largest open-market sale since 1995, defendant Spath dumped 30,000 shares, a 23% decrease in his actionable holdings. Defendant Cook also completed his first open-market sale since initially filing in 1995, dumping 20,000 shares. This trade diminished Cook's actionable position by 13%.

106. On 7/15/97, Dura reported "Record Revenues" and better-than-expected 2Q 1997 results in a press release, stating:

> Dura Pharmaceuticals, Inc. today reported record revenues and record earnings for both the second quarter and six months year-to-date of 1997, compared to the same periods last year.
>
> Net income for the second quarter ended June 30, 1997 totaled $9.3 million, or $0.20 per share, on revenues of $43.6 million compared to net income of $4.6 million, or $0.12 per share, on revenues of $18.8 million in the second quarter ended June 30, 1996. . . .
>
> The increase in revenues was primarily the result of growth in sales of respiratory pharmaceuticals, which rose 174% to $35.4 million in the second quarter of 1997 compared to $12.9 million in the second quarter of 1996. Pharmaceutical sales growth is principally attributable to the impact of new product acquisitions and introductions, a larger sales force size, and growth in sales at Health Script. Total revenues for the second quarter also included $8.2 million in contract revenues from various development and royalty agreements, including revenues from Spiros Development Corporation (Spiros Corp.) for the development of three asthma medications for delivery in the Company's proprietary Spiros(TM) pulmonary drug delivery system.
>
> * * *
>
> Commenting on the results for the quarter, Dura Chairman, President and Chief Executive Officer Cam L. Garner stated, "We are pleased with Dura's performance in the second quarter of 1997. Ceclor® CD (cefaclor extended release tablets) and Keftab® (cephalexin HC1, USP) . . . have been well received by physicians, who are responding favorably to our promotional efforts. We are also benefiting from our more experienced and expanded sales force, which currently totals approximately 225 representatives. We plan to continue growing our sales force to approximately 300 representatives by the end of 1997.
>
> . . . We completed clinical trials necessary for NDA (new drug application) submission and are on track to file the Albuterol Spiros™ NDA on behalf of Spiros Corp. in the second half of 1997.

107. The statements regarding Dura's 2Q 1997 results were false and misleading when issued. The true but concealed facts were:

(a) Sales of Dura's major drug products were flat or declining, especially Ceclor CD, whose sales levels were dropping throughout the Class Period; and

(b) Dura was engaging in a subterfuge to artificially inflate its revenues and EPS by shipping excessive amounts of Ceclor CD and other products to wholesalers, who were enticed to take the product by price discounts, extended payment terms and/or other incentives. Dura's sales

representatives were instructed to "load wholesalers to the max" with Ceclor CD, pressuring them to sell even more Ceclor CD near each quarter's end. Dura offered wholesalers 120 days or six months within which to pay for orders, rather than the standard 30 days, and told wholesalers that Dura will arrange to take back any returns or product that they did not sell. Sell-through from the wholesalers was adversely affected by Dura's insufficient sales force as detailed above. Dura's Ceclor CD and other product inventories in the distribution channel were, accordingly, greatly in excess of the normal one-month supply. As a result of this practice, Dura's Ceclor CD sales were artificially inflated and Dura's insiders knew that as a result of "borrowing" millions of dollars of sales of Ceclor CD from future periods, Dura's sales of Ceclor CD would fall sharply once this practice stopped. Further details how defendants accomplished the "load-ins" to convince wholesalers to take a one-year supply of Ceclor CD are set forth in ¶¶78-89.

108. Defendants had scienter of the false and misleading 2Q 1997 results because Garner, Prettyman, Spath, Woodbury and Brown were the top executives of Dura. They ran Dura as "hands-on" managers, dealing with the important issues facing Dura's business, such as sales of its Ceclor CD product, the development of its new Albuterol Spiros product and the issuing of Dura's SEC filings, press releases and financial statements. Garner, Prettyman, Spath, Woodbury and Brown each attended the weekly executive management meetings from 8:00 to 10:00 a.m. every Monday.

109. Because increased sales of Ceclor CD, the successful development of and substantial sales of Dura's Albuterol Spiros product and the continuing sales of Dura's core products were indispensable elements to Dura meeting its internally budgeted and publicly disseminated 1998 and 1999 revenue and EPS forecasts, defendants constantly monitored each of these key factors affecting Dura's business.

110. Each of the Individual Defendants, because of their top executive positions with Dura and involvement in the day-to-day management of its business, actually knew from internal

corporate documents, detailed herein, and conversations with other corporate officers and employees and their attendance at management and Board meetings, the adverse non-public information about the poor sales of Dura's Ceclor CD, the serious problems in the development of Dura's Spiros drug delivery system, Dura's falsification of its reported 2Q 1997 EPS and Dura's deteriorating revenue and EPS prospects.

111. Defendants closely monitored the performance of Dura's business via internal reports generated on a daily, weekly and monthly basis. Among the specialized reports prepared were drug-by-drug sales volume summaries, year-over-year sales volume comparisons of each Dura product, sales volume comparisons of Dura drugs to competitor drugs, sales revenue reports and daily, weekly and monthly reports on prescription volumes, competitor prescription volumes, and market share. On a monthly basis, Dura's Information Technology Department, after receiving information from IMS, a service that tracks prescription drug sales, would prepare reports comparing actual versus planned sales of Dura's drug products. Through such reports, which were prepared for and disseminated by defendant Spath, defendants were kept apprised of Dura's drug sales and knew that such sales were below plan and insufficient for Dura to achieve continued growth in sales and earnings.

112. The monthly sales reports showed, for example, that Ceclor CD sales began dropping around March-April 1997, and significantly worsened during the summer of 1997. These reports showed that sales were 25%-40% below internal projections at that time. Monthly sales reports showed that Ceclor CD sales dropped from 47,288 in 3/97 to 39,808 in 5/97 to 24,797 in 7/97.

113. The Finance Department also distributed monthly financial reports comparing Dura's actual financial results to projected results. Thus, Defendant was apprised of the sales of every Dura product so that they knew where Dura stood in terms of the sale of and demand for its products as well as Dura's actual results compared to plan. Defendants were also constantly aware of the

prescription rate for its products and knew that excess inventory was building up with distributors and that Dura was not recouping its investments in certain drugs.

114. Dura recognized revenue on the sale of a product when it shipped the product to drug wholesalers. These drug wholesalers in turn would resell the drug to pharmacies, drug chains or even individual physicians. Dura did not publicly disclose to analysts or investors sales of each of its various drug products, *i.e.*, shipments to wholesalers. Thus, analysts and investors were completely dependent upon what Dura told them regarding sales of these products, as shipment-to-wholesaler data was not publicly available. While the number of prescriptions written for a given drug was publicly available on a periodic basis, this information did not disclose the rate at which drugs are being shipped to wholesalers, as that information was not publicly available. Analysts and investors did not know that Dura was shipping amounts of Ceclor CD to wholesalers well in excess of the amount justified by or necessary to keep pace with current prescription levels and, thus, Dura had created vastly excessive amounts of inventory of Ceclor CD in the distribution channel. While Dura reported higher revenue and EPS during each of the quarters of 1997 from these shipments, these excessive inventory levels would eventually have to be worked off, causing sales and earnings to plummet.

115. On 7/15/97, Vector, Alex. Brown, William Blair, Robertson Stephens and Oppenheimer issued reports on Dura which were based on and repeated information provided in a 7/15/97 conference call following the 2Q 1997 press release and in follow-up conversations concerning the Spiros development with Garner and Newman. The Vector report stated:

> The company also reiterated that it remains on track to file the Albuterol Spiros NDA (new drug application) in the second half 1997.

The Alex. Brown report stated:

> Spiros Is The Platform For Long-Term Growth

> ***Efforts to develop new products are on track***; Spiros albuterol . . . could be on the market in late 1998, with initial sales of $10 million growing to over $55 million by 2000 . . . .
>
> . . . [W]e believe ***upside could emanate from the launch of Spiros albuterol in mid-1998***.

The William Blair report stated:

> We still expect Spiros albuterol to be filed in the second half of this year for marketing approval in the United States. . . . The company expects to file NDAs for Spiros beclomethasone and Spiros ipratropium in 1998 and 1999, respectively, with sales following as early as one year after NDA filings. . . . These products should contribute significantly to Dura's long-term revenue and earnings growth.

The Robertson Stephens report stated:

> ***Spiros continue[s] on track or ahead of schedule.***

The Oppenheimer report stated:

> [T]he company's second business, that which is developing a proprietary drug delivery system for drugs administered by the inhalation route, moves ever closer to commercialization.

116. Dura's statement in its 7/15/97 press release and statements made during the conference call with securities analysts and repeated by securities analysts regarding the Spiros development were false and misleading when made.

117. Telling investors that Dura had successfully completed clinical trials was highly misleading. It was all but certain that Dura's NDA for Albuterol Spiros would be rejected by the FDA and Dura would be required to completely redo its Phase III clinical human trials, and that the product would be delayed in reaching the market, if it ever reached the market. The configuration of the product Dura used to conduct clinical trials was unreliable and plagued by significant electro-mechanical problems. During clinical trials, over 30% of the inhalers failed. One problem was that a light which came on to indicate that the medication dose had been successfully delivered operated erratically and did not consistently turn on due to a defect in a printed circuit board in the product. A second defect was that the small battery-operated motor in the product to drive a fan to push the medication dose into the patient did not reliably turn on upon inhalation as it was supposed to. Dura

was unable to fix these problems prior to commencing Phase III clinical trials. As a result, Dura commenced its Phase III clinical trials with versions of Albuterol Spiros that had these defects and, in fact, changed the device during clinical trials. Dura knew this would invalidate the Phase III clinical trials.

118. Dura also discovered serious problems with the stability of Albuterol in 1996 even before Phase III clinical trials began. Once Albuterol was removed from its foil pouch container, as a dry powder it is subject to humidity and temperature problems and degradation. To address stability concerns, Dura conducted in-house temperature and humidity aging where Albuterol was aged for fixed intervals at 25 degrees Celsius and 75% relative humidity under industry and FDA guidelines. During this testing, Dura determined that Albuterol was unstable when aged and subject to clumping which reduced its efficacy when exposed to humidity.

119. Defendants knew, based on their prior experience with the FDA and the medical device industry, that the FDA would not approve a NDA for an unreliable product and unstable drug. For example, during clinical trials, Dura experienced an early return rate exceeding 30% for the Spiros device. Industry standards dictated that a NDA not be filed unless the early return rate was 1% or less. Defendants Garner, Prettyman, Spath, Woodbury and Brown were informed during executive management meeting held every Monday from 8:00 to 10:00 a.m. of the problems encountered during the Phase III clinical trials and of Albuterol's stability problems. Furthermore, defendants Garner and Prettyman attended Research and Development meetings, also held weekly, during which the Spiros device development team presented Phase III clinical trial results and stability test results. Minutes were also generated from these meetings and circulated to senior management.

120. To address the reliability problems plaguing the Spiros device during clinical trials, Dura decided to modify the device while the trials were ongoing. All device modifications had to be

approved by defendant Prettyman and others in his Regulatory Affairs Department. Dura also kept careful records of the different configurations of the Spiros device labeled Rev D or Rev G. All modifications were documented in the clinical trial results and each test on each configuration was analyzed independently in a separate report. The Senior Project Engineer, Mike Ligotke, and Project Leader, Linda Gieschen, were responsible for drafting these reports.

121. Defendants were also aware of the reliability problems plaguing the Spiros device and the Albuterol stability problems from the Eisele List presented to senior management during an executive management meeting in 10/96. Bob Eisele, Vice President of Product Development, prepared a list that was contained in a five to six page document which set forth necessary items to be addressed before a NDA could be properly submitted. In fact, through the Eisele List, Dura's engineers recommended that further development of the Spiros device be completed and the stability of Albuterol be established before the NDA was submitted. Thus, senior management, including defendants Garner, Prettyman, Spath, Woodbury and Brown, were informed of these problems even before they were revealed during clinical trials. Defendants ignored Dura's engineers and proceeded with clinical trials without fixing these issues.

122. Furthermore, defendants Garner and Prettyman attended a pre-filing meeting with the FDA in 5/97 in the FDA's offices in the Washington D.C. area. During that meeting, the FDA informed defendants that it was concerned with the Spiros device's reliability and with Albuterol's stability. Defendants' scienter is also demonstrated through their regular attendance of the weekly Research and Development meeting to discuss the Spiros device. At one such meeting, shortly before the pre-filing meeting with the FDA, defendant Garner specifically asked the Spiros development team about the inhaler's unreliability issues. During that meeting, the Spiros development team again informed defendants Garner and Prettyman that over 30% of the inhalers failed during clinical trials.

123. On 7/25/97, Dura sold $287.5 million in convertible notes with the help of Merrill Lynch. This was the largest securities offering in Dura's history.

124. On 8/11/97, Vector issued a report on Dura after discussions with Garner and Newman during the 7/97 convertible debenture road show conferences and which was based on and repeated information provided by them. The report stated:

> We still do not believe that Spiros is totally factored into the current stock price. A NDA filing for the first Spiros product, for albuterol, should occur in the second half of this year ***with a market launch expected in the second half of 1998.***

125. On 8/19/97, Piper Jaffray issued a report on Dura after discussions with Garner and Newman which was based on and repeated information provided by them. The report stated:

- Spiros is on track for a late 1998 launch . . . .
- The convergence of these two arms of Dura's strategy upon the launch of Spiros ***will be a watershed event for the company, marking Dura as a leader in the respiratory pharmaceuticals market.***

* * *

> Spiros has outstanding potential as a drug inhalation device . . . . The Spiros system . . . ***possesses significant advantages over alternative inhalers currently marketed or in development***. We expect Dura to file a new drug application (NDA) relating to a Spiros formulation of albuterol (the most widely prescribed asthma drug) this fall and receive approval in the fall of 1998.

126. On 9/11/97 - 9/12/97, Piper Jaffray, Vector and Montgomery Securities issued reports on Dura after discussions with Garner and Newman, each of which was based and repeated information provided by them. The 9/11/97 Piper Jaffray report stated:

> Second, Spiros will likely begin to account for more of Dura's valuation as the filing of the Spiros albuterol NDA in the next couple of months brings Spiros into the limelight.

The 9/11/97 Vector report stated:

> We expect Spiros albuterol to be launched in the second half of 1998 when we estimate it will generate $20 million in sales.

The 9/12/97 Montgomery Securities report stated:

> Spiros albuterol is expected launch in 1998 with anticipated sales of nearly $50 million in 1999. We also anticipate launch of Spiros beclomethasone in 1999 and Spiros ipratropium in 2000.

127. On 10/8/97, Dura representatives appeared at the UBS Life Science Conference. The Company revealed that an upcoming NDA filing for its first Spiros respiratory product line was expected "'within days.'" As reported by UBS, Dura further "presented compelling market share data with respect to Ceclor CD's continuing progress in the U.S. cefaclor cephalosporin franchise. Moving into the flu season and reflecting increased promotional support behind the brand, Ceclor CD registered nearly a three-point sequential increase in market share between August to September."

128. That same day, UBS issued a report on Dura which was based on and repeated information provided at the UBS Life Science Conference and in conversations with Garner and Newman. The report stated:

> Dura Pharmaceuticals at the UBS Life Science Conference indicated that an upcoming NDA filing for its first Spiros respiratory product line . . . was expected "within days." This regulatory filing reinforces our confidence in a late-1998 commercialization of this new dry powder inhaler system, representing the first of three Spiros product lines scheduled for steady roll-out over the 1998-2000 period.

129. On these announcements, Dura's stock rose 7.7% to $52.25 – its then all-time high price. On 10/10/97, Dura announced that it was going to exercise its option to buy Spiros for $45.7 million and then take Spiros public. The public sale included one common share of a new company, Spiros II, as well a warrant to buy one-fourth of a share of Dura common stock. The initial public offering ("IPO") was expected to raise between $75 million and $86.25 million. Dura said it would contribute some technology and technology rights, as well as $75 million cash to Spiros II prior to the IPO.

130. Defendants' statement to securities analysts during conference calls, one-on-one sessions and analyst conferences and repeated by securities analysts between 8/11/97 and 10/8/97,

set forth in ¶¶124-128, regarding the imminent filing of the NDA for Albuterol Spiros and strong Ceclor CD sales were false and misleading for the reasons set forth in ¶¶107-114, 117-122.

131. On 10/14/97, Dura reported better-than-expected 3Q 1997 results via a press release headlined and stating:

DURA PHARMACEUTICALS REPORTS RECORD EARNINGS FOR THIRD QUARTER 1997

> Dura . . . today reported record earnings for both the third quarter and nine months year-to-date of 1997, compared to the same periods last year.
>
> Net income for the third quarter ended September 30, 1997 totaled $11.3 million, or $0.24 per share, on revenues of $43.3 million compared to net income of $5.8 million, or $0.14 per share, on revenues of $25.9 million for the third quarter ended September 30, 1996. . . .
>
> The increase in revenues was primarily the result of growth in sales of respiratory pharmaceuticals, which rose 91% to $36.1 million in the third quarter of 1997 compared to $18.9 million in the third quarter of 1996. Pharmaceutical sales growth is principally attributable to the impact of new product acquisitions and introductions, such as Ceclor® CD (cefaclor extended release tablets) and Nasarel® . . . and the expansion of the sales force.
>
> * * *
>
> "We are pleased with Dura's sales performance in the third quarter of 1997, particularly in light of the seasonal slow-down that we typically experience in the summer quarter," stated Cam L. Garner, Dura's Chairman, President and CEO.

132. In a follow-up conference call on 10/14/97, Dura management continued to support the false belief that it was experiencing strong sales. As reported by Vector on 10/15/97:

> Of note, during the conference call, management suggested that, excluding acquisitions, earnings for 1998 could run in the "low $1.40's range" . . . .
>
> * * *
>
> As for the sales force expansion, the company projects that it will have 300 sales reps by the end of the year and 350 reps at the point that Spiros Albuterol is launched.

133. On 10/14/97-10/15/97, defendants' statements and omissions pushed Dura's stock price to an all-time high of $53 per share.

134. The statements regarding Dura's 3Q 1997 results were false and misleading when issued. The true but concealed facts were:

(a) Sales of Dura's major drug products were flat or declining, especially Ceclor CD, whose sales levels were dropping throughout the Class Period; and

(b) Dura was engaging in a subterfuge to artificially inflate its revenues and EPS by shipping excessive amounts of Ceclor CD and other products to wholesalers, who were enticed to take the product by price discounts, extended payment terms and/or other incentives. Dura's sales representatives were instructed to "load wholesalers to the max" with Ceclor CD, pressuring them to sell even more Ceclor CD near each quarter's end. Dura offered wholesalers 120 days or six months within which to pay for orders, rather than the standard 30 days, and told wholesalers that Dura will arrange to take back any returns or product that they did not sell. Sell-through from the wholesalers was adversely affected by Dura's insufficient sales force as detailed above. Dura's Ceclor CD and other product inventories in the distribution channel were, accordingly, greatly in excess of the normal one-month supply. As a result of this practice, Dura's Ceclor CD sales were artificially inflated and Dura's insiders knew that as a result of "borrowing" millions of dollars of sales of Ceclor CD from future periods, Dura's sales of Ceclor CD would fall sharply once this practice stopped. Further details how defendants accomplished the "load-ins" to convince wholesalers to take a one-year supply of Ceclor CD are set forth in ¶¶78-89.

135. Defendants had scienter of the false and misleading 3Q 1997 results because Garner, Prettyman, Spath, Woodbury and Brown were the top executives of Dura. They ran Dura as "hands-on" managers, dealing with the important issues facing Dura's business, such as sales of its Ceclor CD, the development of its new Albuterol Spiros product, the issuing of Dura's SEC filings, and press releases and financial statements. Garner, Prettyman, Spath, Woodbury and Brown each attended the weekly executive management meetings from 8:00 to 10:00 a.m. every Monday.

136. Because increased sales of Ceclor CD, the successful development of and substantial sales of Dura's Albuterol Spiros product and the continuing sales of Dura's core products were

indispensable elements to Dura meeting its internally budgeted and publicly disseminated 1998 and 1999 revenue and EPS forecasts, defendants constantly monitored each of these key factors affecting Dura's business.

137. Each of the Individual Defendants, because of their top executive positions with Dura and involvement in the day-to-day management of its business, actually knew from internal corporate documents, detailed herein, and conversations with other corporate officers and employees and their attendance at management and Board meetings, the adverse non-public information about the poor sales of Dura's Ceclor CD, the serious problems in the development of Dura's Spiros drug development system, Dura's falsification of its reported 3Q 1997 EPS and Dura's deteriorating revenue and EPS prospects.

138. Defendants closely monitored the performance of Dura's business via internal reports generated on a daily, weekly and monthly basis. Among the specialized reports prepared were drug-by-drug sales volume summaries, year-over-year sales volume comparisons of each Dura product, sales volume comparisons of Dura drugs to competitor drugs, sales revenue reports and daily, weekly and monthly reports on prescription volumes, competitor prescription volumes and market share. On a monthly basis, Dura's Information Technology Department, after receiving information from IMS, a service that tracks prescription drug sales, would prepare reports comparing actual versus planned sales of Dura's drug products. Through such reports, which were prepared for and disseminated by defendant Spath, defendants were kept apprised of Dura's drug sales and knew that such sales were below plan and insufficient for Dura to achieve continued growth in sales and earnings.

139. The monthly sales reports showed, for example, that Ceclor CD sales began dropping around March-April 1997, and significantly worsened during the summer of 1997. These reports

showed that sales were 25%-40% below internal projections at that time. Monthly sales reports showed that Ceclor CD sales dropped from 47,288 in 3/97 to 39,808 in 5/97 to 24,797 in 7/97.

140. The Finance Department also distributed monthly financial reports comparing Dura's actual financial results to projected results. Thus, each defendant was apprised of the sales of every Dura product so that they knew where Dura stood in terms of the sale of and demand for its products as well as Dura's actual results compared to plan. Defendants were also constantly aware of the prescription rate for its products and knew that excess inventory was building up with distributors and that Dura was not recouping its investments in certain drugs.

141. Dura recognized revenue on the sale of a product when it shipped the product to drug wholesalers. These drug wholesalers in turn resell the drug to pharmacies, drug chains or even individual physicians. Dura did not publicly disclose to analysts or investors sales of each of its various drug products, *i.e.*, shipments to wholesalers. Thus, analysts and investors were completely dependent upon what Dura told them regarding sales of these products, as shipment-to-wholesaler data was not publicly available. While the number of prescriptions written for a given drug was publicly available on a periodic basis, this information did not disclose the rate at which drugs are being shipped to wholesalers, as that information was not publicly available. Analysts and investors did not know that Dura was shipping amounts of Ceclor CD to wholesalers well in excess of the amount justified by or necessary to keep pace with current prescription levels and, thus, Dura had created vastly excessive amounts of inventory of Ceclor CD in the distribution channel. While Dura reported higher revenue and EPS during each of the quarters of 1997 from these shipments, these excessive inventory levels would eventually have to be worked off, causing sales and earnings to plummet.

142. On 10/14/97-10/15/97, Oppenheimer, Alex. Brown, Vector and Hambrecht & Quist issued reports on Dura which were based on and repeated information provided in the 10/14/97

conference call and in follow-up conversations with Garner or Newman. The 10/14/97 Oppenheimer report stated:

> [T]he company's second business, developing a proprietary drug delivery system for drugs administered by the inhalation route, moves ever closer to commercialization. Here, the company's Spiros dry powder, non-aerosol system will shortly be submitting its first marketing applications to the FDA for albuterol, the most widely-used inhaled asthma medicine. The expected November filing keeps the company on track for initial commercial sales of this product at the end of 1998.

The 10/15/97 Alex. Brown report stated:

> The Company plans to file its first NDA for Spiros albuterol in November 1997, and it could be on the market in late 1998, with initial projected sales of $10 million expected to grow to over $55 million by 2000, further leveraging Dura's growing marketing infrastructure. A Phase III trial of Spiros beclomethasone, an inhaled steroid for the treatment of asthma, has just begun enrolling patients, and a NDA could be filed in late 1998.

The 10/15/97 Vector report stated:

> [W]e expect that the company will file a NDA for Spiros Albuterol in November of this year and launch the product in the second half of 1998. Dura's confidence in this product has been clearly communicated by the recent announcement that Dura will buy Spiros Development Corp. . . . Dura is targeting the second half of 1999 for approval of Spiros beclomethasone.

The 10/15/97 Hambrecht & Quist report stated:

> Spiros and Pipeline Update
>
> * * *
>
> ***Spiros albuterol has apparently performed well in clinical trials*** . . . . An NDA filing is expected before the end of 1997. We estimate approval in late 1998, with a launch in early 1999 . . . .

143. On 11/10/97, Dura announced in a press release that it had submitted a new drug application for Albuterol Spiros stating:

> Dura . . . today announced that it has submitted a new drug application (NDA) with the FDA for Albuterol Spiros™. . . . Three pivotal studies in addition to a number of dose finding and performance verification studies were conducted for the submission.
>
> * * *
>
> "Submission of the first Spiros™ NDA is an exciting milestone for Spiros Corp. and Dura," commented Cam L. Garner, Dura's Chairman, President and CEO. "It represents a significant advancement in the execution of our strategy to establish Dura as a leader in the respiratory marketplace."

144. On 12/17/97, Dura and Spiros II sold 5.5 million Spiros II units at $16 per unit, raising $88 million in needed new capital. Each unit sold consisted of one share of callable common stock of Spiros II and one warrant to purchase one-fourth of one share of Dura common stock.

145. Dura's announcements regarding the submission of the Spiros delivery device NDA to the FDA on 11/10/97 and statements made to and repeated by securities analysts regarding the NDA for Spiros on 10/14/97 and 10/15/97 were false and misleading and made with scienter for the reasons set forth in ¶¶117-122. The falsity of these statements and defendants' scienter thereof is also demonstrated by the internal dissension existing at Dura in 10/97 between defendants themselves about whether to even file the NDA for the Spiros device. In late October or early November 1997, a meeting was held to discuss the NDA filing. Defendants Garner and Prettyman along with Kabakoff and Damecki attended the meeting during which Prettyman made it very clear that he did not want to file the NDA, for which his department, Regulatory Affairs, was responsible. Prettyman was against filing the NDA because, based on his prior experience – Prettyman worked for the FDA for over ten years prior to working for Dura – he knew the NDA would not be approved by the FDA. Despite this, defendant Garner and Kabakoff overruled Prettyman and caused Dura to file the NDA. Shortly after this meeting, the NDA was submitted on 11/10/97.

146. Defendants' scienter of the serious problems plaguing the reliability of the Spiros device causing over 30% of the devices to fail and, thus, their scienter of the falsity of the NDA filing announcement and their statements to analysts is also demonstrated by the defendants' decision to retain Wyle Labs to conduct HALT. Senior executives at Dura were so concerned about the inhaler's reliability problems and the mid-clinical-trial modifications that were made to the device that the decision was made to contract with an outside testing facility, Wyle Labs, to conduct HALT. HALT are extreme condition tests designed to identify potential operational failures in a device. Dura contracted with Wyle Labs to conduct these tests while Phase III clinical trials were

still ongoing. Ed Dusel, Senior Engineering Development Manager, managed the Wyle Lab testing and Mike Ligotke, Senior Project Manager, analyzed the test results. Dura gave Wyle Labs inhaler configurations Revs D, G, H, and J of the device. Dura used the HALT results from Wyle Labs in a 9/98 amendment to Dura's NDA to try to demonstrate that the different inhaler configurations tested in Phase III clinical trials as well as the concurrent HALT resulted in progressively improved operational reliability. Thus, defendants knew that Dura's Phase III clinical trials, upon which the NDA was based, were inadequate to obtain FDA approval.

147. Defendants' scienter of the falsity of these statements is also demonstrated by the massive insider bailout of Dura stock immediately after defendant Prettyman lost the power struggle over whether to file the NDA to defendant Garner. On 11/5/97, defendant Prettyman sold 15,000 shares and pocketed over $728,000 – his only selling during the Class Period – despite his undisclosed knowledge that the Spiros device NDA would not be approved.

148. On December 30, 1997, in his first comments since the restriction was lifted, Donald Lufkin Jenrette ("DLJ") analyst Kent Blair said he expected fourth-quarter earnings of $0.36 a share, 57% more than the year-ago $0.23. He predicted fourth quarter revenues would be $52 million, compared to $41 million a year ago. DLJ, was an underwriter on Dura's and Spiros II's recent offering of stock-warrant units. Blair cited the inclusion of two recently-acquired hay fever medicines and the growth of the Company's Ceclor CD antibiotic as causes of the earnings and revenue growth in the quarter. On this positive report shares of Dura surged 6.9%, up $3 to $46.75 per share.

149. On 1/20/98, Dura reported better-than-expected Q4 1997 results via a release stating:

> Dura . . . today announced results for the fourth quarter and year ended December 31, 1997. Dura reported record revenues of $53.5 million and $181.3 million for the quarter and the full year, respectively . . . . If [] one-time charges were excluded, Dura would have reported record net income of $18.0 million, or $0.37 per share in the quarter, and $47.4 million, or $0.99 per share for the year, compared to a net income of $9.9 million, or $0.22 per share for the fourth quarter of 1996 and $24.3 million, or $0.60 per share for the full year 1996 . . . .

* * *

> Revenues from the sale of respiratory pharmaceuticals rose 89% to $150.5 million in 1997 compared to $79.6 million in 1996, due largely to product acquisitions and the increased productivity of the Company's expanded sales force. . . .
>
> Commenting on the results for the year, Dura Chairman, President and Chief Executive Officer Cam L. Garner stated, "During the past year we significantly strengthened both the pharmaceutical product marketing and the Spiros development arms of our business. . . . We have continued to demonstrate our capabilities as a respiratory marketing force as shown by the growth of our Ceclor(R) CD market share of the oral solid cefaclor market from 8% at the beginning of 1997 to 25% by year-end.

150. The statements regarding Dura's Q4 1997 results were false and misleading and made with scienter for the same reasons stated in ¶¶134-141. In addition, according to a confidential witness, a former National Account Manager responsible for wholesalers and managed care providers, when Dura realized it lacked sufficient pull – through demand for Ceclor CD, the Company artificially inflated its revenues and earnings by shipping on the final few days of fiscal quarters excess amounts of product to wholesalers. When defendants realized that Dura would be unable to achieve analysts earnings expectations of the end of quarters during 1997, defendant instructed Dura employees to conduct what were referred to as "load-ins" to ship excess product to the Company's wholesale distributors. Defendants accomplished this in varying ways. The Director of National Accounts, Doug Weiherer, pressured his subordinates to push extra product into the pharmacy chains in order to increase EPS. National Account Manager Jack Strathmeyer told his district sales manager several times that he had been ordered to push additional product into pharmacy chains in order to boost Dura's earnings numbers. This practice upset Strathmeyer because it strained sales relationships with pharmacy representatives.

151. In addition, according to the same national accounts manager, defendant Spath and other upper management would contact the Company's larger wholesalers, such as McKesson, Cardinal, Bergen Brunswig and Bindley Western, to get an "additional buy" from them at quarter-ends to complete the "load-ins." Dura's sales representatives were instructed to "load wholesalers to

the max" with Ceclor CD, pressuring them to ship even more Ceclor CD near each quarter's end. Dura offered wholesalers extended payment terms, 120 days or six months within which to pay for orders, rather than the standard 30 days, and told wholesalers that Dura would take back any returns or unsold product. Dura gave its distributors unlimited rights of return for full or partial credit even up to three years later. The wholesalers took more product than they had orders for because Dura gave up to 6%-12% discounts from the wholesale purchase price, extended the payment date to give them time to move the product and let them return unsold product. As wholesalers operate on a narrow profit margin, these price reductions could increase their margins from 30%-100%.

152. Moreover, a former Dura Regional Sales Director confirmed that Dura management, including Garner and additional defendants, met at the end of November or early December 1997 to discuss the fact that Dura was not going to make its 4Q 1997 numbers. Ultimately, it was decided and agreed upon at this meeting that in order to publicly hit its 4Q 1997 numbers, Dura would engage in a "fire sale" of its products and would urge wholesalers to buy more product than normal. Dura granted special discounts and terms to wholesales customers in order to convince them to buy a years worth of inventory at one time. For example, McKesson and Cardinal, Dura's largest wholesalers – accounting for 11% each of Dura's 1997 overall sales revenue, participated in the "fire sale" and bought a full years supply of Ceclor CD inventory in December, when typically these purchases would be made throughout the year. In 12/97, Dura offered these wholesalers 6%-12% price reductions on purchases of Ceclor CD to induce them to take a one-year supply of a product for which they normally only stocked a 30 day supply. Additionally, Dura's sales representatives gave these larger customers extended payment terms of 120 days or six months within which to pay for orders, rather than the standard 30 days, telling wholesalers that Dura would take back any returns or unsold product. In this manner, Dura induced McKesson and Cardinal to purchase $1.5 million of Ceclor CD product each in 12/97 so Dura could achieve analysts earnings estimates.

153. Garner himself had to approve price reductions to wholesalers, so he knew in each instance when these practices occurred. As a result of these drastic, one-time measures, Dura product inventories in the distribution channel were greatly in excess of the normal one-month supply and Dura's primary Ceclor CD customers were sitting on an excess supply of Ceclor CD and had no need to make additional orders. Accordingly, the success of Dura's products was misrepresented and its sales were artificially inflated. Defendants knew that, as a result of "borrowing" millions of dollars of sales of Ceclor CD and other products from future periods, Dura's sales would fall sharply once this practice was stopped. Moreover, defendants were also aware that Dura would not only be unable to continue stuffing the channel without impacting future sales, but also that Dura would receive over 75% of "fire-sale" product back. By the Spring of 1998, defendants admitted to securities analysts that Dura's wholesale channels were clogged with as much as a five-month inventory of its products.

154. Dura's management discussed the impact of the "fire sale" on Dura's ability to make 1Q 1998 numbers and knew that they could not make the numbers with the "fire sale." According to a former Regional Sales Director, the defendants knew ahead of time that because of the fire sale at the end of 1997, the next question was "[h]ow are we going to make 1Q 1998 numbers?" According to the witness, the defendants all knew that they could not make the 1Q 1998 numbers because they had pulled in all of Dura's anticipated 1Q 1998 during the fire sale. Further, according to the same witness, because the defendants knew they would have to disclose the fact that Dura was not going to make its 1Q 1998 numbers, when the first opportunity to sell their Dura stock came, they "all cashed out." "Everyone dumped" their shares.

155. As the former Regional Sales Director described, in late 1997 and early 1998, defendants unloaded their personal Dura holdings. In total, between 11/3/97 and 1/6/98, while Dura's stock continued to trade at artificially inflated prices near its all-time high, Garner,

Woodbury, Prettyman, Newman, Spath and Cook unloaded 197,607 shares of their Dura stock, pocketing $9.2 million in illegal insider-trading proceeds.

156. On 1/20/98-1/21/98, Vector, Merrill Lynch, Oppenheimer and Hambrecht & Quist issued reports on Dura which were based on and repeated information provided in a 1/20/98 conference call following the Q4 1997 press release and in follow-up conversations with Garner or Newman. The 1/20/98 Vector report stated:

> A late 1998/early 1999 time frame for a launch of ***Spiros albuterol***, now with the proposed trade name ***AlSpiros, was confirmed by the company***.

The 1/20/98 Merrill Lynch report stated:

> In the meantime, we expect steady progress with the FDA's review of the Spiros Dry Powder inhaler with albuterol, (AlSpiros) the most prescribed asthma drug. ***Final approval is likely by year end***.
>
> By 2002, we believe that Spiros based products could contribute up to 50% of corporate revenue.

The 1/20/98 Oppenheimer report stated:

> [T]he company's Spiros dry-powder, non-aerosol system will shortly be reviewed by [the] FDA following its acceptance of Dura's first marketing application to the FDA for albuterol, the most widely-used inhaled asthma medicine. The recent FDA acceptance of this filing keeps the company on track for the product's approval by the end of 1998.

The 1/21/98 Hambrecht & Quist report stated:

> Spiros albuterol (now called AlSpiros) is the front-runner, with a NDA filed in November, and an acceptance of that filing issued by the FDA last week, ***everything is on schedule (pending FDA approval) for an early 1999 launch*** . . . .

157. On 1/29/98, Merrill Lynch issued a report on Dura which was based on and repeated information provided in the 1/20/98 conference call and in follow-up conversations with Garner or Newman. The report stated:

> [W]e expect steady progress with the FDA's review of the Spiros Dry Powder inhaler with albuterol, (AlSpiros) the most prescribed asthma drug. ***Final approval is likely by year end.***

158. Each of defendants' statements made to securities analysts between 1/20/98 and 1/29/98 described above were false or misleading when issued. Assuring investors that approval of

the NDA was likely during 1998 was false and misleading as defendants knew that the clinical data submitted in support of the NDA showed that the inhaler had a 30% failure rate and that the data was inadequate to demonstrate Albuterol's stability. The falsity of these statements, and defendants' scienter thereof, is further demonstrated by the reasons set forth in ¶¶117-122, 145-146.

THE TRUTH ABOUT THE DURA FRAUD EMERGES

159. On 2/24/98, after the close of trading, Dura shocked the market by revealing that it was actually experiencing slower Ceclor CD sales. In a conference call with analysts, Dura admitted that both increased competition from other antibiotics, as well as a need for its sales force to increase physician calls and sampling rates, was adversely affecting Ceclor CD's sales. Dura hoped that its new, much larger sales force would be able to properly market Ceclor CD, and correct the sales decline. Investors were stunned by these revelations. Because defendants' revelations disclosed that their prior statements about strong Ceclor CD sales were false which also cast doubt on defendants' credibility, Dura's stock price collapsed over 37% on trading volume of over 32 million shares from $39.13 on 2/24 to $20.75 on 2/25. Analysts were furious over having been lied to. Alex. Brown analyst Ryan wrote:

> Management credibility has been severely damaged by this announcement, particularly in light of recent investor conference presentations exuding confidence on the Company's fundamentals . . . .
>
> * * *
>
> Our confidence in management and their credibility with us has been greatly diminished. As recently as one month ago, we reviewed our model with the Company line by line and were guided to higher Ceclor CD estimates. In our opinion, not too much could have changed between now and then, and we believe that this revenue shortfall is not new news to Dura, but frankly, comes as a surprise to us.

160. During the balance of 1998, Dura's business performed miserably. In a 4/16/98 conference call with analysts, ***defendant admitted*** that, at least by 12/97, the wholesale channels had been clogged with many months of excess Ceclor CD inventory. Dura also admitted its sales force

was inadequate and had been plagued by very high turnover and that this was contributing to the poor sales of its drug products. On 10/5/98, analyst Ryan wrote:

> There was excessive inventory buildup in Ceclor CD among wholesalers in late 1997, and the Company asserts that this hurt 1998 sales. Management believes that the buildup has decreased, with inventory levels now down to one month's supply (versus five months earlier in the year) . . . .

161. After revelations that the Company's Ceclor CD sales were slower than expected and the Class Period ended, defendants still misled investors regarding the true state of Albuterol Spiros. For example, Dura placed an advertisement in the April 1998 edition of ***Advance for Managers of Respiratory Care*** which stated:

> Albuterol Spiros™ by Dura Pharmaceuticals Inc. is a powder aerosol formulation of albuterol. It's delivered to the lungs in Dura's proprietary Spiros inhaler.
>
> Spiros is designed to deliver a relatively consistent dose of drug to the lungs, independent of the patient's ability to inhale forcefully. It uses no chlorofluorocarbon propellants and requires minimal patient coordination.

162. On 4/30/98, the FDA sent Dura a letter of rebuke stating that: "the journal ad is in violation of the Federal Food, Drug, and Cosmetic Act (the "Act") and its implementing regulations, because it promotes an unapproved drug by making claims of safety and efficiency that have not been demonstrated by substantial evidence (*i.e.* adequate and well-controlled studies)."

163. Later, on 9/23/98, Dura disclosed that it had submitted additional chemistry and manufacturing control information requested by the FDA in support of the time of the original NDA submission finally revealing the long-known problems with the device. Dura also conceded that the Albuterol Spiros launch date had slipped to second quarter 1999. In response to this announcement Dura's stock price declined 28% from $15.25 on 9/23/98 to $10.00 on 9/25/98.

164. On 11/4/98, Dura was forced to report that the FDA had rejected the Albuterol Spiros NDA because the Spiros device was not reliable because of its unacceptably high failure rate and because Dura had provided insufficient data to demonstrate Albuterol's stability. In other words, the

FDA rejected the Albuterol Spiros NDA for the same reasons set forth in the Eisele List in 10/96, revealed during Dura's in-house stability testing completed before clinical trials, revealed during clinical trials and identified by the FDA in the 5/97 pre-filing meeting, all of which prompted defendant Prettyman to urge that the NDA not be filed in the late 10/97, right before the NDA was actually submitted. The FDA requested additional clinical trials on the Spiros inhaler in order to ensure inhaler reliability and replicate the clinical outcomes of the initial trials. The FDA also requested the resolution of a number of chemistry, manufacturing and control issues. In an effort to soften the blow and obfuscate their earlier lies and omissions, defendants claimed that the FDA's letter raised no issues on the clinical data with the inhaler filed in the NDA demonstrating therapeutic comparability of Albuterol Spiros with Ventolin® (albuterol) MDI using standard lung function measures. Nevertheless, in response to this stunning disclosure the Company's stock price declined 21% from $12.50 to $9.34 on 11/3/98.

165. On 11/6/98 – just three days later – the FDA issued a "notice of violation" to Dura. "[T]he Division of Drug Marketing, Advertising and Communications (DDMAC) . . . found that Dura's press release sent a message that 'misleadingly minimizes the fact that Dura must conduct a completely new clinical data [study] . . . .'" Upon receiving the FDA letter, Dura removed the press release from its Web site. The 11/6/98 letter of rebuke from the FDA, however, was not publicly revealed until 12/4/98. When the FDA's rebuke was finally disclosed, Dura's stock price declined an additional 13% from $12.56 to $10.50. Ultimately, Dura completely abandoned the development of the Spiros device for use with Albuterol because Dura could never overcome the long known reliability and stability problems.

166. On or about December 23, 1998, defendant Garner admitted that:

> I think the truth is what we've disappointed shareholders this year in terms of earnings, as we underestimated the disruptive impact that our sales force reorganization and expansion had on the growth Ceclor CD and Nasarel during the year. However, we firmly believe that the investment we've made to accelerate the

success of Ceclor CD and Nasarel and to prepare for the launch of Spiros will serve us well as we seek to deliver long-term shareholder value.

DEFENDANTS' SCIENTER

167. Defendants knew, or recklessly disregarded, that their statements about the development of the Albuterol Spiros system and the strength of sales of Ceclor CD were misleading and false when made. Each defendant also knowingly participated in a scheme and course of business that operated as a fraud on purchasers of Dura stock and damaged class members and sold Dura stock while concealing material adverse information.

168. Prior to the Class Period, after reaching a then all-time high price of $47.87 on 12/31/96, Dura stock declined sharply, falling to $27.87 on 4/14/97. This decline was due to concern over the ability of Dura's new Ceclor CD/Keftab drugs to continue to drive Dura's EPS growth and the ability of Dura to successfully introduce Albuterol Spiros by late 1998 or early 1999. This decline created tremendous problems for Dura's executives. By early 1997, they were already taking steps to complete a major convertible debt offering for Dura. They also knew during 1997 that Spiros I would exhaust its existing resources and that Dura would have to exercise its option to repurchase Spiros I stock and finance a new follow-on Spiros II entity to continue to pay for the development of the Spiros drug delivery system. The creation of a new Spiros II entity would require a public offering of securities that included warrants to buy Dura stock. Also, the value of the Dura insiders' existing stock options to purchase Dura stock at $29.63-$37.63 per share had been completely wiped out by the 1997 stock decline, and the value of the insiders' other options was greatly reduced. Finally, the yearly cash bonuses of Dura's top executives – which could amount to 100% of their base salaries – were dependent upon Dura's reported EPS and stock price performance. For all of these reasons, it was imperative to Dura's insiders that they drive Dura's stock price higher to enable Dura to raise needed capital, to exercise Dura's option to purchase Spiros I's stock by issuing as few shares as possible, to successfully complete a public offering of

Spiros II securities, to restore the value of their stock options so that they could unload millions of dollars of the Dura stock they owned before the stock collapsed and to allow them to be paid large year-end 1997 cash bonuses based on Dura's 1997 EPS and a strong 1997 stock performance.

169. Thus, in 4/97 as Dura stock fell to as low as $27.87, the defendants re-priced thousands of their $37.63 per share options – to just $25 per share – as follows: Garner 150,000 options; Brown 40,000 options; Newman 40,000 options; Prettyman 35,000 options; Spath 40,000 options; and Woodbury 30,000 options. Defendants also commenced a concerted publicity campaign to persuade investors that Dura's Ceclor CD sales were doing better in the marketplace than had been anticipated and that Dura was successfully completing the development and clinical trials of its Albuterol Spiros product, such that it would likely result in that product reaching the market by late 1998/early 1999, generating millions of dollars of revenue and profits for Dura ¶¶74-75.

170. As detailed above, Albuterol Spiros and Ceclor CD were Dura's two most important products. The crippling defects with Albuterol Spiros and the dismal results of in-house and clinical tests (*e.g.*, 30% failure rate) were documented internally, communicated directly to Garner and Newman and discussed among the Individual Defendants and privately with the FDA. ¶¶90-94. As detailed above, the Individual Defendants reacted to reports from Dura's IT department, that showed sequentially declining sales, by contacting Dura's largest wholesale customers (*e.g.*, McKesson, Cardinal and Bergen Brunswig) at quarter-end and offering price reductions, extended payment terms and return rights in order to encourage the purchase of excess product – including the "fire sale" discussed during the meeting with Garner in early December 1997. ¶¶77-89. Finally, within just a month of their last false reports of strong Ceclor CD sales, defendants were forced to admit to artificially inflating sales by prematurely pushing product into the sales channel. ¶159.

171. Defendants' fraudulent scheme was a success – for them. The Individual Defendants sold 390,374 shares of their Dura stock at artificially inflated prices, pocketing $16.8 million in illegal insider-trading proceeds. *See* ¶¶175-182. According to a witness whose duties at the highest levels of Dura's finance department required the witness to working closely with Garner and Newman, Garner discussed with the witness even before the Class Period that he did not intend to stay at Dura longer than a couple of years, when he expected to cash out and do other things. Garner and Newman frequently talked openly in the area outside their offices of their plan to maximize the stock price so that they could "take the cash and run." They also discussed how they could make stock analysts "perceive" that Dura was doing better than it actually was. When employees questioned Newman on his tactics, his standard response was "let 'em catch us." Newman repeated this catch phrase so often that it became part of the Company vernacular.

172. Dura's executive compensation structure also provided an additional motive for the Individual Defendants to participate in the fraud. Defendants' 1996-1997 cash bonuses, based on achieving EPS growth targets, are shown below:

		Annual Compensation	
Name and Principal Position	Year	Salary	Cash Bonus
Cam L. Garner	1997	$396,519	$475,000
Chairman, President & CEO	1996	$347,654	$610,000
Walter F. Spath	1997	$210,808	$140,000
Senior VP-Sales & Marketing	1996	$201,538	$190,000
James W. Newman	1997	$200,769	$140,000
Senior VP-Finance & Administration & CFO	1996	$190,039	$190,000
Charles W. Prettyman	1997	$191,116	$140,000
Senior VP-Development & Regulatory Affairs	1996	$179,577	$190,000

173. The Individual Defendants, because of their positions as high-ranking officers and/or directors with the Company, possessed the power and authority to control the contents of Dura's

quarterly and annual reports, SEC filings, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. Each individual defendant participated in drafting and was provided with copies of the Company's reports, SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them but not to the public, each of these defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations which were being made were then materially false and misleading.

174. The undisclosed adverse information concealed by defendants during the Class Period is the type of information which, because of SEC regulations, regulations of the national stock exchanges and customary business practice, is expected by investors and securities analysts to be disclosed and is known by corporate officials and their legal and financial advisors to be the type of information which is expected to be and must be disclosed. The Individual Defendants are liable for the false statements pleaded in SEC filings and press releases, as those statements were each "group-published" information, the result of the collective action of the Individual Defendants.

DEFENDANTS' UNUSUAL AND SUSPICIOUS INSIDER STOCK SALES

175. During the Class Period, each of the Individual Defendants occupied a position as top Dura executives and was privy to non-public information concerning the Company. Each of them knew of the adverse facts specified herein and omitted to disclose these facts. Notwithstanding their duty to refrain from selling Dura stock or other securities while in possession of material, adverse, non-public information concerning the Company, these defendants sold hundreds of thousands of shares of Dura stock at grossly inflated prices improperly benefiting from their wrongful course of conduct and omissions.

176. Dura itself took advantage of the inflated stock price and the fraud to raise financing from investors. Following positive statements to the market, Dura on 7/25/97, sold $287 million to investors through the largest bond offering in Dura's history. Just months after raising nearly $300 million in its historic bond offering and with its stock price near its then all-time high, 12/17/98, with Dura's stock nears its then all-time high, Dura and Spiros II sold some 5.5 million Spiros II units raising $88 million.

177. While Dura's top insiders were issuing favorable statements about Dura, the Individual Defendants sold 386,233 shares of Dura stock, for more than $16.6 million – 82% of their collective holdings of Dura stock – to personally profit from the artificial inflation in Dura's stock price. Notwithstanding their access to material non-public information and their duty to disclose same before trading in Dura stock, they sold significant amounts of their Dura stock at artificially inflated prices at highly suspicious times. Defendants began dumping their shares just one month after re-pricing their options from $37.63 to $25.00 in April 1997 and immediately after the pre-filing meeting with the FDA in 5/97 when insiders sold 188,626 shares for proceeds exceeding $7.3 million between 5/12/97 and 7/22/97. Defendants' massive bailout continued at the same time Dura was filing the doomed Spiros device NDA, when the stock was at an all-time high, and defendants had conspired to meet 1997 earnings expectations only through the one-time massive "fire sale." Defendants sold another 197,607 shares for proceeds exceeding $9.2 million between 11/3/97 and 1/6/98. The later selling is highly suspicious given the internal disagreement between defendants themselves whether to even file the NDA. For example, after telling defendant Garner and other senior executives that he was against filing the NDA because there was insufficient data to obtain FDA approval, defendant Prettyman nonetheless sold 15,000 shares on 11/5/97 for $728,100 in proceeds.

178. This insider selling by the Individual Defendants was highly unusual, both in its timing and in its amount. The defendants who exercised options on Dura stock during the Class Period each sold 100% or close to 100% of the stock they acquired by option exercise. These sales came just after the purported successful introduction of major new product lines by Dura (Ceclor CD/Nasalide) that were supposed to push its earnings higher for several quarters, and while the market was expecting FDA approval of Dura's new Albuterol Spiros product in 1998. While the Individual Defendants also owned vested stock options which were not exercised, their stock sales were still significant in amount and unusual in timing, even considering their options holdings.

179. During the Class Period, the Individual Defendants pocketed proceeds of over $16 million. Defendants Spath, Prettyman, Woodbury and Brown each sold 100% of the Dura common stock they actually owned during the Class Period, at prices inflated by their fraud.

180. The table below summarizes defendants' insider selling comparing sales to stock actually owned and total holdings, including vested options:

Dura Pharmaceuticals, Inc.
Class Period: April 15, 1997 - February 24, 1998

Insider	Class Period Sales/ Distributions	Sales Proceeds	Percent of Stock Sold (1)	Percent of Total Holdings Sold (2)
Brown, Julia R	39,383	$1,583,590	***100%***	36%
Cook Jr., Joseph C.	40,000	$1,780,950	43%	29%
Garner, Cam L.	154,623	$6,456,801	67%	62%
Newman, James W.	52,227	$2,390,417	78%	34%
Prettyman, Charles W.	15,000	$728,100	***100%***	46%
Spath, Walter F.	50,000	$2,076,500	***100%***	32%
Woodbury, Mitchell	35,000	$1,603,280	***100%***	31%
Total:	386,233	$16,619,638		

(1) Includes common stock and options exercised and sold during the Class Period.
(2) Includes common stock, options and warrants exercisable.

181. Public investors, who purchased Dura stock at prices inflated by the false representations and omissions concerning the successful development of Albuterol Spiros and the

very strong sales of Ceclor CD, and who, thus, paid as high as $53 for Dura's stock during the Class Period, have suffered millions in damages. Dura and Dura's insiders who knew the truth fared much better. Before the startling truth was revealed and Dura's stock price collapsed, Dura raised over $375 million in desperately needed new capital from note purchasers, and in total the Individual Defendants unloaded 386,233 shares of their Dura stock at artificially inflated prices as high as $49.31, pocketing over $16.6 million in illegal insider-trading proceeds.

182. The chart at ¶52 demonstrates the price of Dura's stock during the Class Period as defendants attempted to keep Dura's stock price inflated while selling over 386,000 shares of their own common stock at prices as high as $49.31 per share.

PROXIMATE LOSS CAUSATION/ECONOMIC LOSS

183. During the Class Period, as detailed herein, defendants engaged in a scheme to deceive investors and the market and a course of conduct that artificially inflated Dura's stock price and operated as a fraud or deceit on Class Period purchasers of Dura stock by misrepresenting the state of the Company's successful development of and clinical trials for the Spiros drug-delivery system, Dura's pharmaceutical sales and its future business prospects. Defendants achieved this façade of successful development of Albuterol Spiros and strong Ceclor CD sales during the Class Period by assuring investors that Dura would receive FDA approval for the Spiros drug-delivery system and introduce the product in late 1998 or early 1999. Defendants also assured investors the Company was experiencing strong demand for its Ceclor CD drug.

184. At the same time, however, defendants knew that the Company had proceeded to Phase III clinical trials with a prototype that was not reliable and with a cassette system that was not stable. Dura's top executives ignored the recommendations of Dura's engineers to not proceed with Phase III clinical trials and not proceed to file a NDA until these problems were remedied. One big problem with the Spiros drug-delivery system set forth in the Eisele List was its reliability. Because

it was a mere prototype, the delivery system was incapable of consistently delivering the required dose, was insufficiently robust in that it could not withstand normal use conditions and was subject to an unacceptable rate of failure. Another huge problem with the device set forth in the Eisele List was the stability of the Albuterol cassette system. As a result of the inhaler's reliability problems during Phase III clinical trials, Dura began making modifications to the inhalers actually being used in the ongoing clinical trials to improve reliability. In addition, defendants knew that the Company was only achieving strong Ceclor CD sales by "stuffing the channel" by giving drug distributors risk free incentives to take more product than they could use by offering unlimited rights of return and engaging in end-of-year fire sales. Later, however, when defendants' prior misrepresentations and fraudulent conduct was disclosed and became apparent to the market, Dura stock fell precipitously as the prior artificial inflation came out of Dura's stock price. As a result of their purchases of Dura stock during the Class Period and the corrections removing the artificial inflation, lead plaintiffs and other members of the class suffered economic loss, *i.e.*, damages, under the federal securities laws.

185. Instead of truthfully disclosing during the Class Period that Dura's NDA for Albuterol Spiros was in serious jeopardy because of changes made to the device during Phase III clinical trials, defendants told investors that Spiros Albuterol would be released in late 1998 and early 1999. During the Class Period, defendants repeatedly emphasized the successful development of the Spiros drug delivery system, including:

> "We are pleased with the results to date and are preparing the NDA for filing in the latter half of this year." ¶100.
>
> * * *
>
> ***Spiros continue[s] on track or ahead of schedule***. ¶115.
>
> * * *
>
> Spiros is on track for a late 1998 launch . . . . ¶125.
>
> * * *

> Spiros has outstanding potential as a drug inhalation device . . . . The Spiros system . . . ***possesses significant advantages over alternative inhalers currently marketed or in development***. We expect Dura to file a new drug application (NDA) relating to a Spiros formulation of albuterol (the most widely prescribed asthma drug) this fall and receive approval in the fall of 1998. *Id.*
>
> * * *
>
> ***Spiros albuterol has apparently performed well in clinical trials***. . . . A NDA filing is expected before the end of 1997. We estimate approval in late 1998, with a launch in early 1999 . . . . ¶142.
>
> "Submission of the first Spiros™ NDA is an exciting milestone for Spiros Corp. and Dura," commented Cam L. Garner, Dura's Chairman, President and CEO. "It represents a significant advancement in the execution of our strategy to establish Dura as a leader in the respiratory marketplace." ¶143.
>
> * * *
>
> ***Final approval is likely by year end. . . .*** ¶156.

186. In addition, defendants constantly reiterated the purportedly strong growth rate for Dura's Ceclor CD drug sales:

> Ceclor® CD (cefaclor extended release tablets) and Keftab® (cephalexin HC1, USP) . . . have been well received by physicians, who are responding favorably to our promotional efforts. ¶106.
>
> The increase in revenues was primarily the result of growth in sales of respiratory pharmaceuticals, which rose 91% to $36.1 million in the third quarter of 1997 compared to $18.9 million in the third quarter of 1996. Pharmaceutical sales growth is principally attributable to the impact of new product acquisitions and introductions, such as Ceclor® CD (cefaclor extended release tablets) and Nasarel® . . . and the expansion of the sale force . . . . ¶131.
>
> * * *
>
> We have continued to demonstrate our capabilities as a respiratory marketing force as shown by the growth of our Ceclor(R) CD market share of the oral solid cefaclor market from 8% at the beginning of 1997 to 25% by year-end. ¶149.

187. Defendants' false and misleading statements about the Albuterol Spiros drug delivery system and strong Ceclor CD sales caused and maintained the artificial inflation in Dura's stock price throughout the Class Period and until the truth was revealed piece by piece, to the market. Defendants' false and misleading statements had the intended effect and caused Dura's stock to trade at artificially inflated levels up to $53.00 per share throughout the Class Period. *See* ¶52.

188. Beginning in February 1998 defendants were forced to publicly disclose that the Company's experiencing slower Ceclor CD sales. In a press release the Company announced "plans to begin expanding its sales force immediately from 270 representatives to over 450 by year-end in order to increase the market penetration of Ceclor® CD (cefaclor extended release tablets), to prepare for the launch of Albuterol Spiros™ and to support the growth of the companies other pharmaceutical products." In a conference call with analysts, Dura elaborated on the need for an increased sales force to increase physician calls and sampling rates because such were adversely affecting Ceclor CD sales. Dura could only offer that it hoped that its new, much larger sales force would now be able to properly market Ceclor CD, and correct the sales decline, as well as be in place for the launch of Albuterol Spiros. Investors were stunned by the revelations of poor Ceclor CD sales. Analysts were furious over having been lied to about the Company's fundamentals. Alex. Brown analyst Ryan wrote: ****

> *Management credibility has been severely damaged by this announcement, particularly in light of recent investor conference presentations exuding confidence on the Company's fundamentals . . . .
>
> * * *
>
> Our confidence in management and their credibility with us has been greatly diminished. As recently as one month ago, we reviewed our model with the Company line by line and were guided to higher Ceclor CD estimates. In our opinion, not too much could have changed between now and then, and we believe that this revenue shortfall is not new news to Dura, but frankly, comes as a surprise to us.

189. As a result of, these stunning revelations, Dura's stock price collapsed from $39.13 on 2/24/98 to $20.75 on 2/25/98. After the end of the Class Period, Dura admitted that, at least by 12/97, the wholesale channels had been clogged with many months of excess inventory. Dura further admitted its sales force was inadequate and had been plagued by very high turnover and that this was also contributing to the poor sales of its drug products. On 10/5/98, analyst Ryan wrote:

> There was excessive inventory buildup in Ceclor CD among wholesalers in late 1997, and the Company asserts that this hurt 1998 sales. Management believes

> that the buildup has decreased, with inventory levels now down to one month's supply (versus five months earlier in the year) . . . .

190. A significant portion of the late-February stock drop reflected legitimate concern about increasing costs for both Ceclor and Albuterol Spiros due to sale-force increases – increases Dura knew were necessary in the Fall of 1997 as Ceclor pull through was not happening. Defendants themselves had long tied the Spiros launch to existing product sales, with defendant Garner, for example, telling the market on 8/22/96 that "Keftab and Ceclor CD are ideally suited for Dura as they should provide strong revenue and earnings growth and support the expansion of our sales force to position Dura for an effective launch of our Spiros products." ¶67. Thus, the inflationary effect of false statements about the adequacy of the sales-force and the need for an increased sales-force for Ceclor and Albuterol Spiros were inextricably intertwined. And with the 2/24 disclosure of disappointing sales and an inadequate sales force, Dura's story about being able to effectively launch Albuterol Spiros – and investors' faith in it – began to fall apart, resulting in the tremendous stock drop on 2/25. Following Dura's admissions that sales were far weaker than earlier represented, and that Dura's sales force would have to be greatly expanded to reverse the decline and launch Albuterol Spiros, *Bloomberg News* warned that higher sales costs would impair profits when Dura was obliged to "boost its sales force to 450 from 270 this year as it prepares to start sales of its Spiros inhaler in 1999." Kerry Dooley, "Dura Shares Plunge on Profit Warning, Slow Drug Sales," Bloomberg News, Feb. 25, 1998. And a 3/4/98 *Pharma Marketletter* article titled "Analysts Losing Faith in Dura Pharma" tied the stock's decline to Dura's disclosure that it would have to "expand its sales force immediately . . . in a bid to increase market penetration of Ceclor . . . and to prepare for the launch of Albuterol Spiros." "Analysts Losing Faith in Dura Pharma," Pharma Marketletter, Mar. 4, 1998. In short, the dramatic collapse of Dura's stock clearly reflected, in some substantial part, investors' concern that the Company was losing its edge and that management was no longer credible.

191. After revelations that the Company's Ceclor CD sales were slower than expected defendants continued to mislead investors regarding the true state of Albuterol Spiros. For example, Dura placed an advertisement in the April 1998 edition of "Advance for Managers of Respiratory Care" which stated:

> Albuterol Spiros™ by Dura Pharmaceuticals Inc. is a powder aerosol formulation of albuterol. It's delivered to the lungs in Dura's proprietary Spiros inhaler.
>
> Spiros is designed to deliver a relatively consistent dose of drug to the lungs, independent of the patient's ability to inhale forcefully. It uses no chlorofluorocarbon propellants and requires minimal patient coordination.

192. On 4/30/98, the FDA sent Dura a letter of rebuke stating that: "the journal ad is in violation of the Federal Food, Drug, and Cosmetic Act (the "Act") and its implementing regulations, because it promotes an unapproved drug by making claims of safety and efficiency that have not been demonstrated by substantial evidence (*i.e.* adequate and well-controlled studies)."

193. During the late Summer, as the market continued to digest the increased costs of the sales-force, the impact of such on a successful launch of Albuterol Spiros and slumping sales of Ceclor CD, the stock dropped from $24.43 on 8/6/98 to $15.62 on 9/18/98. Later, on 9/23/98, Dura began revealing problems surrounding the Albuterol Spiros NDA, acknowledging that the Company had to submit additional information to the FDA that was not available at the time of the original submission. Continuing the façade, however, Dura also announced that the purported launch date had slipped to 2Q 1999. In response to this announcement Dura's stock price declined 28% from $15.25 on 9/23/98 to $10.00 on 9/25/98.

194. On 11/3/98, Dura disclosed that the FDA had rejected the Albuterol Spiros NDA because the Spiros device was not reliable because of its unacceptably high failure rate and because Dura had provided insufficient data to demonstrate Albuterol's stability. In other words, the FDA rejected the Albuterol Spiros NDA for the same reasons set forth in the Eisele List in 10/96, revealed during Dura's in-house stability testing completed before clinical trials, revealed during clinical trials

and identified by the FDA in the 5/97 pre-filing meeting, all of which prompted defendant Prettyman to urge that the NDA not be filed in the late 10/97, right before the NDA was actually submitted. The FDA requested additional clinical trials on the Spiros inhaler in order to ensure inhaler reliability and replicate the clinical outcomes of the initial trials. The FDA also requested the resolution of a number of chemistry, manufacturing and control issues. In an effort to soften the blow and obfuscate their earlier lies and omissions, defendants claimed that the FDA's letter raised no issues on the clinical data with the inhaler filed in the NDA demonstrating therapeutic comparability of Albuterol Spiros with Ventolin® (albuterol) MDI using standard lung function measures. Nevertheless, in response to this stunning disclosure the Company's stock price immediately declined 21% from $12.50 to $9.34.

195. On 11/6/98 – just three days later – the FDA issued a "notice of violation" to Dura. "[T]he Division of Drug Marketing, Advertising and Communications (DDMAC) . . . found that Dura's press release sent a message that 'misleadingly minimizes the fact that Dura must conduct a completely new clinical data [study] . . . .'" Upon receiving the FDA letter, Dura removed the press release from its Web site. The 11/6/98 letter of rebuke from the FDA, however, was not publicly revealed until 12/4/98 when the FDA rebuke was finally disclosed, Dura's stock price declined an additional 13% from $12.56 to $10.50.

196. As a direct result of defendants' forced admissions and the public revelations regarding the truth about Dura's Ceclor CD sales, the Company's ability to achieve strong product sell through with its existing sales force and management credibility being damaged, Dura's stock price plummeted from $39.12 on 2/24/98 to $20.75 on 2/25/98. Upon revelations that managements statements regarding the development of Albuterol Spiros were false, Dura's stock price drifted from $24.43 to $15.62 during August to late September and then fell 28%, from $15.25 to $10.50, on 9/23/98 when defendants disclosed the Company had to provide additional data to the FDA for the

Albuterol Spiros NDA. Dura's stock suffered an additional 21% decline on 11/4/98, falling from $12.50 to $9.34, when the Company revealed that the FDA had rejected the Company's NDA for Albuterol Spiros. Finally, Dura's stock price suffered another 13% decline on 12/4/98, falling from $12.56 to $10.50, when it was revealed that the Company received a letter of rebuke from the FDA on 11/6/98 critical of the Company's characterization of the NDA reject letter. These drops removed the inflation from Dura's stock price, causing economic loss to investors who had purchased the stock during the Class Period.

197. In sum, as the truth about defendants prior misstatements and fraudulent conduct regarding the Company's Ceclor CD sales and sales force adequacy for both Ceclor CD and the Spiros drug delivery device on 2/24/98, the artificial inflation came out of the stock and lead plaintiffs and other members of the class were damaged, suffering economic losses of up to $19.00 per share. Investors suffered additional losses in late Summer and early Fall 1998 as the market drifted from $24.43 to $15.62 as the market continued to digest bad information about costs and sales. Further, as the truth about defendants' prior misstatements and fraudulent conduct regarding Albuterol Spiros was revealed on 9/23/98, 11/4/98 and 12/4/98, more artificial inflation came out of the stock and lead plaintiffs and other members of the class who purchased or otherwise acquired Dura common stock and who held until after the 9/23/98, 11/4/98 and 12/4/98 disclosures were damaged and suffered economic losses of up to an additional $8.02 per share.

198. These stock price declines and the resulting damages to lead plaintiffs and members of the class who purchased stock during the Class Period were the result of Dura's Company-specific disclosures and not industry related or market forces.

SAFE HARBOR

199. The safe harbor provided for forward-looking statements ("FLS") does not apply to the false FLS pleaded. The safe harbor does not apply to Dura's allegedly false financial statements.

None of the FLS pleaded herein were identified as FLS when made, it was not stated that actual results "could differ materially from those projected," nor did meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the FLS accompany those FLS. 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.

CLASS ACTION ALLEGATIONS

200. This is a class action on behalf of those persons who purchased Dura securities between 4/15/97 and 2/24/98, including those purchasers who acquired their Dura securities during the Class Period and held such securities after 9/23/98, 11/4/98, and 12/4/98 and were harmed thereby. Class members are so numerous that joinder of them is impracticable.

201. Excluded from the class are: (i) defendants; (ii) members of the families of each individual defendant; (iii) any entity in which any defendant has a controlling interest; (iv) officers and directors of Dura and its subsidiaries and affiliates; and (v) the legal representatives, heirs, successors or assigns of any such excluded party.

202. Throughout the Class Period, shares of Dura common stock were actively traded on the Nasdaq National Market System, which is an efficient market. The members of the class, as purchasers on that market, are so numerous that joinder of all members is impracticable. As of 2/24/98, approximately 46 million shares of Dura common stock were outstanding.

203. Common questions of law and fact predominate and include whether defendants: (i) violated the 1934 Act; (ii) omitted and/or misrepresented material facts; (iii) knew or recklessly

disregarded that their statements were false; (iv) artificially inflated Dura's stock price; and (v) the extent of and appropriate measure of damages.

204. Lead plaintiffs' claims are typical of those of the class. Prosecution of individual actions would create a risk of inconsistent adjudications. Plaintiffs will adequately protect the interests of the class. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Because the damages suffered by individual class members may be relatively small, the expense and burden of individual litigation make it virtually impossible for class members individually to seek redress for the wrongful conduct alleged herein.

205. The names and addresses of the record owners of Dura securities purchased or acquired during the Class Period are available from the Company's transfer agent(s). Notice may be provided to such record owners via first class mail using techniques and a form of notice similar to those customarily used in class actions.

FIRST CLAIM FOR RELIEF

For Violation of Section 10(b) of the 1934 Act and Rule 10b-5 Against All Defendants

206. Plaintiffs incorporate and allege ¶¶1-205.

207. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 by:

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

(b) Making untrue statements of material facts and omitting to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and

(c) Engaging in acts, practices and a course of business that operated as a fraud or deceit upon the class in connection with their purchases of Dura securities.

208. Class members were damaged. In reliance on the integrity of the market, they paid artificially inflated prices for Dura securities and were damaged when the artificial inflation was removed from those securities.

SECOND CLAIM FOR RELIEF

For Violation of Section 20(a) of the 1934 Act Against Defendants Garner, Spath and Newman

209. Plaintiffs incorporate and allege ¶¶1-208. Plaintiffs assert this claim against Garner, Spath and Newman. These defendants acted as controlling persons of Dura and the other Individual Defendants within the meaning of §20 of the 1934 Act as alleged herein. By virtue of their executive and directorial positions, their knowledge and involvement in the day-to-day business of Dura, including its financial reporting and research and development, their stock ownership, and their power and ability to make public statements on behalf of Dura to shareholders, potential investors and the media, these defendants had the power and ability to control the actions of Dura and the other Individual Defendants.

210. By reasons of their wrongful conduct, defendants Garner, Spath and Newman are liable pursuant to §20(a) of the 1934 Act. As a direct and proximate result of these defendants' wrongful conduct, plaintiffs and the other members of the class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER

WHEREFORE, plaintiffs pray for judgment, declaring this action to be a proper class action; awarding damages, including interest; and such equitable/injunctive or other relief as the Court may deem proper.

JURY DEMAND

Plaintiffs demand a trial by jury.

DATED: August 26, 2005

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DECLARATION OF SERVICE BY MAIL

I, the undersigned, declare:

1. That declarant is and was, at all times herein mentioned, a citizen of the United States and a resident of the County of San Diego, over the age of 18 years, and not a party to or interested party in the within action; that declarant's business address is 401 B Street, Suite 1600, San Diego, California 92101.

2. That on August 26, 2005, declarant served the **THIRD CONSOLIDATED AMENDED COMPLAINT FOR VIOLATION OF THE SECURITIES EXCHANGE ACT OF 1934** by depositing a true copy thereof in a United States mailbox at San Diego, California in a sealed envelope with postage thereon fully prepaid and addressed to the parties listed on the attached Service List.

3. That there is a regular communication by mail between the place of mailing and the places so addressed.

I declare under penalty of perjury that the foregoing is true and correct. Executed on August 26, 2005, at San Diego, California.

/s/ Diana L. Houck
DIANA L. HOUCK