CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

Plaintiffs, by and through their attorneys, allege the following upon personal knowledge, including, among other things, the investigation of their attorneys, including without limitation: (a) review and analysis of public filings made by Columbia Laboratories Inc. ("Columbia," or the "Company"), with the Securities and Exchange Commission (the "SEC"); (b) review and analysis of securities analysts' reports concerning Columbia; (c) review and analysis of press releases and other publications disseminated by defendants; (d) other publicly available information about Columbia; and (e) contact with factual sources.

I.

NATURE OF THE ACTION

1. This is a class action on behalf of all purchasers of the securities of Columbia between November 8, 1999 and June 9, 2000 inclusive, (the "Class Period"), seeking to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act"). During the Class Period, defendants made a series of false and misleading statements regarding Columbia's business and prospects in connection with its marketing of two products; Crinone, a female fertility drug, and "Advantage-S", a spermicide which Columbia led the market to believe
was on its way to approval by the Food and Drug Administration ("FDA") to prevent the spread of Acquired Immune Deficiency Syndrome, or "AIDS".

2. Prior to the start of the Class Period, defendants sponsored a "Phase III" study on female prostitutes in Africa. A "Phase III" study is the final step in seeking FDA approval for the sale of a new drug. Half the women in the study were given a placebo, and the other half were given Advantage-S. The study was "double-blinded" which meant that neither the women nor the study administrators knew which group was taking Advantage-S. As defendants well knew, previous studies done on Advantage-S showed that the product was safe to use, at maximum, four times per day for 14 days, or a dosage of 210 milligrams per day. Higher and more frequent doses of the product were shown to cause fragility in the skin, which could actually place a woman at significantly greater risk of contracting HIV.

3. Defendants repeatedly emphasized the likelihood of success of the study in proving Advantage-S effective against the transmission of HIV and went so far as to continuously describe Advantage-S as an "AIDS-fighting" spermicide. For example, defendants made numerous false and misleading statements regarding the efficacy and imminent marketing of Advantage-S, such as:

- On March 3, 2000, defendant Bologna, the Company's Chief Executive Officer stated in an interview that one of the things Columbia had done "is develop a product to prevent the transmission of the HIV virus, of the AIDS virus, in women". ¶ 64;

- On March 16, 2000, Bologna publicly announced that the impact of the Phase III study "is immense, with the world-wide market for such products exceeding $1 billion." ¶ 66;

- On March 20, 2000, defendants again described Advantage-S as an "AIDS-fighting spermicide" and described the product as "empowering women in the fight against AIDS." ¶ 73;
During a March 20, 2000 conference call, Bologna assured investors that Advantage-S would generate "serious profits" and that positive results from the study were, as one analyst described, "a done deal." ¶ 77.

On May 9, 2000, defendants preliminarily announced positive results for the Phase III study, and stated: "[u]nder current FDA regulations, the Company believes it will receive a priority review which should lead to [FDA] approval within six months of submission." Defendants represented that Advantage-S would help "stem the tide of AIDS in Africa." ¶ 86.

4. In response to defendants' repeated statements concerning its products and the sales prospects for Crinone and Advantage-S, the price of Columbia stock soared from $6 per share in November, 1999, to over $17 per share on March 10, 2000. Indeed, Columbia investors were led to believe that they were investing in a Company that had proprietary rights to the first "AIDS-fighting spermicide", as well as a Company which repeatedly emphasized the benefits of its product for "mankind" and "poor women in Africa."

5. Defendants knew at the time they made the statements alleged herein, however, that the Phase III tests were flawed because test subjects were using the Advantage-S spermicide in doses far in excess of the amounts the Company knew to be safe. In fact, defendants knew that the test women subjects could use Advantage-S an unlimited number of times per day--an amount that was not only toxic, but which could cause local vaginal lesions that could increase the incidence of AIDS infection.

6. Because defendants knew the Advantage-S Phase III tests were being administered improperly, there was no basis for defendants' confidence in the tests, nor any basis for defendants statements that the test results were a "done deal", or that the tests could lead to an NDA filing (as described below) or FDA approval. Defendants failed to disclose in any public filing or any press release that the Phase III tests were flawed. Instead, defendants claimed on
May 9, 2000 that the Phase III tests were capable of leading to FDA approval "within six
months." ¶ 86.

6. On March 20, 2000, defendants disclosed that its marketing of Crinone, the female fertility drug defendants emphasized early on as a key to the Company's profitability, would not contribute as significantly to the Company's profitability as investors had been led to believe, until, at the earliest, the second half of fiscal year 2000, due to a previously undisclosed inventory backlog.

7. On June 12, 2000, defendants shocked the market by revealing that, contrary to the Company's misleading Class Period representations, Advantage-S was not a viable product to stop the transmission of AIDS. Defendants were forced to admit that the Phase III study showed that Advantage-S actually increased the transmission of HIV.

8. In response to the devastating news that Advantage-S was not, as defendants had repeatedly represented, an "AIDS-fighting spermicide", the price of Columbia stock lost over 50% of its value, dropping from nearly $13 per share on June 9, 2000, to 6 and 1/8 on June 12, 2000. An investor quoted in a June 13, 2000 Miami Herald article described the unexpected disclosure as "a neutron bomb."

9. Columbia insiders did not suffer the same losses. During the Class Period, defendants and other insiders sold thousands of Columbia shares at artificially inflated prices, reaping proceeds in excess of $3 million before the truth regarding the dismal sales of Crinone and the failed Phase III study were revealed to the public. Indeed, the market for Columbia securities has not recovered - - on October 17, 2000, the stock traded at only 4 5/8 - - a far cry from the Class Period high of nearly $18 per share.
10. On July 12, 2000, defendants shocked the investment community even further by disclosing that the Phase III study was "faultily designed and administered" and was conducted in a "grossly negligent" and "unethical" manner. Despite the fact that defendants knew the product was only proven safe at four doses a day for two weeks, the women in the study used Advantage-S up to twenty times per day for 18 to 36 months -- and contracted HIV at higher rates than the women using a placebo.

11. Indeed, defendants concede that material problems in the design and implementation of the study, caused women to dose themselves to toxic levels -- actually increasing the incidence of HIV transmission. Defendants admitted that the protocol for the study -- a written plan submitted to the FDA prior to the start of the Phase III study -- did not include an upper limit on dosing. Defendants also admitted that investigators actively encouraged the female sex workers to use Advantage-S after each sex act.

12. In an effort to escape liability for their false and misleading statements, defendants seek to lay blame on other organizations involved in the study such as the United Nations who co-sponsored the study -- despite the fact that the Phase III trial was conducted on Columbia's benefit in order to file for FDA approval of the product, and despite the fact defendants could not have been ignorant of the way the study was conducted absent severe recklessness, as detailed below.
II.

JURISDICTION AND VENUE

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1337 and 1367 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

14. This action arises under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. § § 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5).

15. Venue is proper in this District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b) and (c). Substantial acts in furtherance of the alleged fraud and/or its effects have occurred within this District and Columbia maintains its principal executive offices in this District.

16. In connection with the acts and omissions alleged in this complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

III.

PARTIES

17. The Court appointed Marc Werner, Carlos Enriquez, and Gary and Nancy DiCresce as Lead Plaintiffs pursuant to an order dated August 29, 2000. Lead Plaintiffs purchased Columbia securities during the Class Period, as set forth in the accompanying certification which is incorporated herein by reference, and were damaged thereby.

18. Defendant Columbia is incorporated in the State of Delaware, and maintains its principal place of business at 2875 Northeast 191st Street, Suite 400, Aventura, Florida. According to the Company's annual report on Form 10-K filed on March 30, 2000,
Columbia is in the business of developing "unique pharmaceutical products that treat female specific diseases and conditions including infertility, hormonal deficiencies ...and the treatment of sexually transmitted diseases."

19. The individual defendants, at all times relevant to this action, served in the capacities listed below and received substantial compensation:

<table>
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<tr>
<th>Name</th>
<th>Position</th>
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<tbody>
<tr>
<td>William J. Bologna (&quot;Bologna&quot;)</td>
<td>Director of the Company since its inception in 1986, and Chief Executive Officer since January, 2000.</td>
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<tr>
<td>David L. Weinberg (&quot;Weinberg&quot;)</td>
<td>Chief Financial Officer since 1997.</td>
</tr>
<tr>
<td>Norman M. Meier (&quot;Meier&quot;)</td>
<td>Director since 1986, President and Chief Executive Officer until January, 2000.</td>
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20. The Individual Defendants, as senior officers and/or directors of Columbia were controlling persons of the Company. Each exercised his power and influence to cause Columbia to engage in the fraudulent practices complained of herein.

21. Each of the defendants is liable as a participant in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Columbia securities, by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme: (i) deceived the investing public regarding Columbia's business, its finances and the intrinsic value of Columbia securities; and (ii) caused Plaintiffs and other members of the Class to purchase Columbia securities at artificially inflated prices.
IV.

PLAINTIFFS' CLASS ACTION ALLEGATIONS

22. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all persons who purchased or otherwise acquired Columbia securities between November 8, 1999 and June 9, 2000, inclusive (the "Class Period"), and who were damaged thereby. Excluded from the Class are defendants, members of the immediate family of each of the Individual Defendants, any subsidiary or affiliate of Columbia and the directors, officers and employees of Columbia or its subsidiaries or affiliates, or any entity in which any excluded person has a controlling interest, and the legal representatives, heirs, successors and assigns of any excluded person.

23. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are thousands of members of the Class located throughout the United States. As of May 1, 2000, there were reportedly more than 33 million shares of Columbia securities outstanding. Throughout the Class Period, Columbia securities was actively traded on the American Stock Exchange under the symbol "COB." Record owners and other members of the Class may be identified from records maintained by Columbia and/or its transfer agents and may be notified of the pendency of this action by mail, using a form of notice similar to that customarily used in securities class actions.

24. Plaintiffs' claims are typical of the claims of the other members of the Class as all members of the Class were similarly affected by defendants' wrongful conduct in violation of federal law as alleged herein.
25. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

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

1) whether the federal securities laws were violated by defendants' acts and omissions as alleged herein;

2) whether defendants participated in and pursued the common course of conduct complained of herein;

3) whether documents, press releases, and other statements disseminated to the investing public and the Company's shareholders during the Class Period misrepresented material facts about the business, products, financial condition and prospects of Columbia;

4) whether statements made by defendants to the investing public during the Class Period misrepresented and/or omitted to disclose material facts about the business, finances, value, performance, products and prospects of Columbia;

5) whether the market price of Columbia securities during the Class Period was artificially inflated due to the material misrepresentations and omissions complained of herein; and

6) the extent to which the members of the Class have sustained damages and the proper measure of damages.
27. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this suit as a class action.

V.

SUBSTANTIVE ALLEGATIONS

A. Background To The Class Period -- Columbia Struggles To Gain Market Recognition And Financial Stability

28. Columbia, like many growth stocks, is valued by the market on its future prospects, and the prospects of its products, rather than its reported financial results. As recognized in a May 23, 2000 analyst report issued by Ryan Beck, Inc., Columbia, like most emerging drug companies, "has never been an earnings story...shares of [Columbia] move on news flow rather than earnings." (Emphasis added). Thus, as defendants knew, investors were extraordinarily reliant on the Company's public disclosures regarding its products. For pharmaceutical companies such as Columbia engaged in experimentation and the formulation of new products, the efficacy and successful marketing of new products coupled with market demand for those products was viewed as the key to the Company's valuation by investors and by Wall Street analysts.

29. Columbia went public in mid-1988 via an offering of 2.7 million shares at $1.50 each, by several former managers, including defendant Meier and Bologna, of a Miami-based company, Key Pharmaceuticals. The Company's initial revenues were generated primarily
through the sale of appetite suppressants, including an “Extra Strength Grapefruit Diet Plan” acquired from the purchase of a Michigan pharmaceutical company, O’Connor Products Co. See, Barron’s “A Little Start-Up Gets A Warm Speculative Greeting” Sept. 18, 1989 (Savitz, E.). Due to the sluggishness of the appetite suppressant market, Columbia pinned its hopes on a specific “delivery” system for medications - - the “mucoadhesive delivery system.” Id. The “system” under development by Columbia purportedly allowed drugs to be absorbed through the mucous membranes. Id. It was this system that Columbia touted as enabling the Company to release a next generation of products, primarily in the lucrative field of women’s health care.

30. Despite its grandiose plans, Columbia lacked funding, and struggled to obtain financing through a series of private placements. Defendant Weinberg assured investors that the Company would not have to raise additional money once its first over the counter product, Replens, a vaginal moisturizer for post-menopausal women was introduced to the market. Id.

31. At the same time Columbia began to develop women’s health care products, the prevalence of the AIDS virus generated significant attention in the medical community - - spawning a myriad of AIDS related research in the hope that a preventive medication could be discovered1 As early as 1993, Columbia sought to capitalize on what could be a highly profitable AIDS-related market. For example, a February 9, 1993 article in the Miami Review, noted that: “investors are drawn [to Columbia] . . . by its prospects of bringing

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1 The advent of the AIDS virus also generated a slew of fraudulent products. As noted in an October, 1987 article published by the U.S. Department of Health and Human Services entitled “Defrauding the Desperate”, . . . “AIDS is a quack’s dream come true; an incurable, fatal disease surrounded by fear and ignorance is tailor-made for the enterprising huckster who will stir up a cauldron of deceit to turn a quick profit. And, if the experts are right in their predictions, more and more of these profiteers will be on the scene selling their wares.”
two new medical products to the market — one of them a spermicide that may help prevent the transmission of the virus that causes AIDS.” The same article cited Wall Street’s “inattention” to Columbia due to the company’s lack of profitability, noting that Columbia’s visibility would increase once it posted profits. *Id.*

32. Defendants issued a series of public statements emphasizing one "blockbuster" product after another. Defendants' first emphasized Replens, a vaginal dryness product, as the key to Columbia's turn-around from a company posting repeated quarterly losses to a profitable one. Once Replens failed to generate significant sales, defendants began to emphasize Crinone, a fertility drug, as the next profit-maker, and as a possible avenue for the company's sale. After Crinone failed to generate the anticipated profitability, defendants' hype reached a new level. Defendants began to tout an existing spermicidal product, Advantage-S (formerly known as Advantage 24) as its new "AIDS-Fighting Spermicide." Advantage-S was already being sold as a contraceptive spermicide; designed to prevent pregnancy by killing sperm before fertilization *in utero* can occur. Accordingly, at the beginning of the class period, defendants seemed to be the forerunner among many companies developing HIV preventive products — poised to capture a lucrative market in women's healthcare.

33. Defendants began to tout Columbia's new “flagship” products early on, hoping to attract market interest. A June 9, 1994 press release quoted defendant Bologna as stating: “... the World Health Organization has recently completed an extensive trial of Advantage-24, (now referred to as “Advantage-S”) which confirmed its safety. Advantage-24 is the company's patented spermicide that is designed to prevent the spread of sexually transmitted diseases such as Chlamydia and AIDS.”
34. On February 21, 1997, an article published in the *South Florida Business Journal* announced Columbia’s soon expected “first profit.” Defendant Bologna announced that Columbia had received FDA approval to start testing Crinone — a hormone replacement therapy — in 35 major medical centers around the world. In May of 1996, Columbia signed a licensing agreement with the Wyeth-Ayerst division of American Home Products to market Crinone. Bologna now touted Crinone as the key to Columbia’s profitability, stating, “[a]s soon as the revenues [from Crinone] start flowing in, we expect to be profitable and have excess cash.” Bologna also expressed his view that Columbia may become a takeover target by American Home, noting “[i]f they make us rich enough, then we will be attractive.”

35. In an April 6, 1998 article entitled “A Lab Pregnant With Possibility” published by *Business Week*, Crinone was referred to by Columbia insiders as “one blockbuster product.” Bologna characterized the women’s health care market at $6 billion, increasing to $10 billion by 2000 and Crinone as Columbia’s “highlight.” Bologna described the market for Crinone as $1.5 billion, noting “[w]e expect to take some 2% of the Crinone . . . market this year and then ramp it up next year.” Despite the repeated endorsements of Crinone, one analyst, Evan Sturza, publisher of a Medical Investment Letter, issued a “sell” recommendation for Columbia stock, as revealed in an August 8, 1997 article published on *TheStreet.com*. Sturza noted that although American Home Products stated Crinone was not going to be one of its big products, Bologna repeatedly overstated the opportunity for Crinone. Sturza characterized the Company’s statements as part of a “now all-too-familiar-pattern” stating: “Crinone has yet to be launched in the United States, although the product received FDA approval three months ago.” *Id.*
36. The August 8, 1997 article in *TheStreet.com* stated:

"The 'pattern' Sturza refers to is the reason many analysts and investors shy away from Columbia, whose management is widely viewed as promotional. In the early 90's, investors got burned when the Company's Replens, for vaginal dryness, was put on the market to great fanfare but bombed. In the first half of 1996, Columbia got about a half a million dollars from Replens."

B. *The "Pattern" Continues - The UNAIDS Study Begins And Defendants Continue to Tout Anticipated Sales of Crinone*

1. *The Initiation Of The UNAIDS Study*

37. In May 1996, Columbia and the United Nations Global Program on HIV/AIDS (UNAIDS) announced the initiation of an international Phase III clinical study (the "Phase III study") of Columbia Laboratories' product, Advantage 24, for the prevention of the heterosexual transmission of HIV and sexually transmitted diseases in approximately 2,000 women. According to a July 10, 1996 press release in the *Business Wire*, the study was designed to assess the efficacy of Advantage 24, which "utilizes Columbia Laboratories' patented Bioadhesive Delivery System to deliver nonoxynol-9\(^2\), the most widely-used spermicide available without a prescription."

38. The large-scale efficacy trial was sponsored jointly by UNAIDS and Columbia Laboratories. The study was conducted as a double-blind multicenter trial among female prostitutes. Women were chosen at random from volunteers at test sites in Benin and Cote d'Ivoire, (Africa), Thailand and South Africa. The main objective of the study was to

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Nonoxynol-9 is a spermicidal agent used in contraceptive spermicide products, and constitutes the active ingredient in Advantage-S. Microbicides are chemical substances, in the form of gel, cream, suppository or film, which kill viruses and bacteria when applied vaginally before sexual intercourse.
determine whether there was a statistically significant difference in the incidence of HIV infection between women who received a placebo, and women who used Columbia's microbicidal product, Advantage-S. The trial coordinator from UNAIDS was Dr. Lut Van Damme of the Institute of Tropical Medicine in Antwerp, Belgium. Howard Levine, Columbia's Vice President of Research and Development, was charged with supervision of the clinical trials from Columbia's side. According to the protocol (as defined below) filed with the FDA prior to commencement of the Phase III trial, the women would receive dosages of 52.5 milligrams of Advantage-S (containing N-9), or the placebo, Replens, after each time the women had sex.

According to the protocol, the "end-point" or time for stopping the study, was 100 - meaning once 100 women became HIV-infected, the study would conclude and the data would be analyzed. If the results were successful, defendants agreed to sell the product through UNAIDS in poor nations at a lower but "significant" profit, and to sell the product elsewhere at any price defendants chose.

39. In the July 10, 1996 article, Defendant Bologna characterized the jointly-sponsored study as "undoubtedly the most advanced effort underway to develop an effective method for women to prevent HIV transmission." Defendants further noted:

"Under the supervision of UNAIDS, Advantage 24 has been tested for safety in more than 600 women in Europe and Thailand. These studies showed that Advantage 24, unlike many other such products that were tested by UNAIDS, is safe even when administered four times a day. Because of its favorable safety profile, Advantage 24 is the only product that has been selected for further testing."
40. Although defendants emphasized the "favorable safety profile" of Advantage 24, the testing in the studies cited by defendants had not exceeded usage of four times a day. Indeed, a wealth of information existed prior to the Phase III study, which revealed the danger of excessive usage or dosage of Nonoxynol-9 ("N-9"). For example:

- In 1990, the British Columbia Center for Disease Control reported that genital inflammation and irritation was common among prostitutes who used N-9;

- In 1989, a team sponsored by the University of Washington found that N-9 was associated with a high incidence of vaginal lesions, which could serve as a pathway to HIV transmission; Id.

- An AIDS alert published by American Health Consultants in March, 1996, reported that N-9 causes genital irritation, which in turn may enhance HIV transmission. The alert cited to studies which found that HIV transmission rates were higher among N-9 users, possibly caused by N-9's irritating effect, which could make the epithelial surface more susceptible to HIV penetration. The alert noted that "different types of N-9 products vary significantly in their formulations, . . . and that lower doses may be safer than higher ones. . . . if you are using [N-9] on a mucosal surface like the vagina, it could be that more is worse because it might actually break the epithelium;

- The AIDS alert also noted that N-9 used once or twice weekly is safe, but that even with relatively low dosages, daily use seems to cause changes in the surface of the epithelium;

- A UNAIDS release from 1996 entitled "Recommendations for the development of vaginal microbicides" noted that "safety studies are necessary because irritation of vaginal and cervical mucous has been recently associated with spermicide use and those lesions might increase HIV transmission";

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A 1991 trial found that N-9, in high doses, caused genital tract ulcers, possibly increasing the risk of HIV transmission. ⁴

41. Based on the widely-known incidence of lesions caused by N-9, a key ingredient of Advantage-S, it was crucial that defendants' FDA protocol for conducting the clinical trials include specified information and criteria for limiting the dosages of Advantage-S delivered to the study participants, in this case, prostitutes engaged in multiple daily acts of intercourse and using Advantage-S several times a day. As noted in a 1998 abstract published by the Center for Drug Evaluation and Research entitled "Considerations in the Development of Vaginal Products Intended to Prevent the Sexual Transmission of HIV":

"Commercial sex workers and patients in STD clinics at high risk for acquiring HIV infection are likely to differ from more low risk populations in a number of important respects. The frequency of product use, and thus, the potential for related toxicity . . . may facilitate HIV transmission, and compliance may differ substantially between these cohorts. Each of these factors, can in turn, affect product efficacy." (Emphasis added).

2. Overview of Relevant FDA Procedures

42. Before a biological product, such as Advantage-S, may be marketed in the United States, it must undergo an extensive regulatory approval process established by the FDA. The steps required before a biological product may be sold in the United States include: the conduct of preclinical studies, the filing of an Investigational New Drug Application (an "IND") with the FDA for the conduct of clinical studies, the performance of controlled clinical studies, and the submission of an FDA approved Product License Application ("PLA") containing the

⁴ See, UNAIDS technical update, April 1998, "Microbicides for HIV Prevention."
results of clinical studies which demonstrate, to the FDA’s satisfaction, the safety and efficacy of the product.

43. Preclinical studies are conducted on animals to evaluate the safety and potential efficacy of a therapeutic product. The results of preclinical studies are submitted to the FDA as part of the IND application. Human clinical trials may not begin until the IND application has become effective pursuant to FDA regulations.

44. In the case of vaginal products seeking approval for use in prevention of HIV transmission, preclinical activity and toxicity data are typically generated very early in the drug development process. This information then serves as the basis for a preliminary risk/benefit assessment to determine product suitability for further clinical testing.

45. The clinical investigation of a new biological product ordinarily is conducted in several sequential phases pursuant to a written protocol, which is submitted to the FDA as part of the IND application. The protocol sets forth, among other things, procedures for the clinical trials and the manner of data analysis to be employed during the various phases of testing. Indeed, Title 21 of the Code of Federal Regulations, § 312.23 sets forth detailed information which must be included in an IND application. In Phase II and III studies, detailed protocols describing all aspects of the study should be submitted, which include: the number of patients involved, a description of safety exclusion, and a description of the dosing plan including duration, dose, or method to be used in determining dose - - and should specify in detail elements of the study that are critical to safety. 21 CFR § 312.23 (6)(i) and (ii). A protocol is also required by federal regulation, to include: a description of the observations and measurements to be made to fulfill the objectives of the study; and the proposed duration of the investigation, and the dosage form. 21 CFR § 312.23 (7)(i).
46. Federal regulations also mandate that once an IND is in effect, a sponsor shall amend it as needed to ensure that the clinical investigations are conducted according to protocols included in the application. If the dosage level administered to the study participants in the Phase III study were changed -- including in frequency of use -- defendants were required to submit a protocol amendment to the FDA before its implementation. 21 CFR § 312.30(b)(ii).

47. The initial clinical evaluation, Phase I, consists of testing the product for its safety, tolerable dosage, and pharmacokinetic properties in a relatively small number of human subjects. Phase I testing also serves to establish a preliminary side-effect profile of the product. The results of the Phase I studies are used to design well-controlled, scientifically valid trials of the safety and efficacy of the product in larger populations.

48. Phase II clinical studies involve larger trials at several dosage levels. During Phase II testing, researchers continue to evaluate the safety and tolerable dosage of the product and begin to assess the effectiveness of the product in humans having the disease and other medical conditions for which the product appears useful. Phase II trials also are used to identify possible short-term side effects and risks associated with the product. Phase II studies typically are well-controlled and closely monitored.

49. The cumulative data base obtained from preclinical and clinical Phase I and II activity and toxicity studies is used to design Phase III confirmatory studies in humans. These "pivotal" trials are intended to demonstrate product efficacy in a large number of subjects. Phase III studies consist of additional testing to establish clinical safety and effectiveness in an expanded patient population at geographically dispersed test sites, to evaluate the overall benefit-risk relationship in administering the product, and to provide an adequate basis for physician labeling. A fundamental aspect of a Phase III trial is the assurance that the subjects, in this case
the female sex workers, receive strictly controlled and limited dosages of the product being tested. After completion of Phase III studies, the results of the clinical trials of a biological product are submitted to the FDA in the form of a PLA for approval of commercial sales, which is followed closely by the filing of a New Drug Application (an "NDA"), assuming that all prior steps have been successfully completed.

3. **Defendants Announce “Finalization” of the Crinone License Transfer**

50. Given the failure of Replens to transform Columbia into a profit-generating corporation, as detailed above, defendants began heavily emphasizing Crinone in an effort to convince investors and Wall Street that Columbia did in fact have "blockbuster" products capable of turning a profit. These statements, detailed below remained alive and uncorrected until well into the Class Period. For example, in a January 28, 1999 press release, defendants announced that Columbia raised over $6 million through the series of preferred stock and warrants through a private placement - - forced to seek capital from the investing community rather than from the sale of Replens. Defendant Bologna commented on the year ahead, stating, "[g]iven the prospects for Crinone . . . - - our natural progesterone vaginal gel - - and the availability of new capital to advance other strategies and development efforts, we believe Columbia is very-well positioned for a successful and profitable year." It was now Crinone rather than Replens which defendants stated "should return Columbia to profitability", as announced in a March 23, 1999 press release.
51. In a March 23, 1999 press release, defendants touted a "surge" in Crinone 8% prescriptions. Due to this "surge", defendant Weinberg stated:

"the Wyeth-Ayerst division of American Home Products [placed] orders to date for approximately $2.4 million in the first quarter, $4.8 million in the second quarter and $1.6 million in July, 1999. Filling these incoming orders, by itself, will be sufficient to restore the Company to profitability by the second quarter of 1999."

52. On June 10, 1999, defendants issued a press release announcing a "new strategic worldwide marketing partner for Crinone." Defendants revealed that Ares-Serono, "the world leader in reproductive health" signed an agreement to acquire the exclusive marketing rights for Crinone. Defendant Bologna described the agreement, stating: "with the synergy between Columbia and Ares-Serono, the full market potential of Crinone should be realized in the infertility market." Under the terms of the agreement, Columbia would supply Crinone to Ares-Serono under the same terms it previously enjoyed in its contract with American Home Products.

53. On July 8, 1999, in a press release published over the Business Wire, defendants reported "the finalization last Friday, July 2, 1999 of the previously announced arrangement between Ares-Serono and American Home Products under which Ares-Serono, the world leader in reproductive health, acquired the license originally granted to American Home Products Corporation by Columbia for Crinone. . ." Defendants further revealed that Ares-Serono "assumes immediate marketing responsibility." (Emphasis added).

54. On July 28, 1999, defendants issued a press release touting Ares-Serono's marketing efforts, announcing that "the fourth quarter will see the launch of Crinone in several new countries in Europe and Latin America, and a significant step-up in marketing efforts in countries where Crinone is already available for sale." Analysts reacted to the news of increased
marketing efforts as a positive indicator that a viable purchaser for the Company could be found. For example, a July 29, 1999 analyst report issued by Andrew S. Forman of Warburg Dillon Read noted: "[i]n our view, continued profitability, positive sales of Crinone 8%, and a new marketing partner increase the likelihood that Columbia could be acquired."

55. In a Form 8-K filed a few days before the commencement of the Class Period, defendants stated: "Since the 1st of October Ares-Serono has been actively marketing Crinone in the United States and we believe we will begin to see the results of their intensive efforts over the next few months."

56. Accordingly, as detailed above, at the start of the Class Period, although American Home Products was no longer considered a viable buyer for the Company, defendants continued to position Columbia as an acquisition candidate - - an outcome which would generate significant personal benefit for the defendants, as detailed below in ¶123. Once Replens, and then Crinone failed to generate the profitability promised, defendants hyped Advantage-S as the next "blockbuster", and as an "AIDS fighting" product. Unbeknownst to the investing public, Defendants knew at the time they made the statements alleged herein, however, that the Phase III tests were flawed because test subjects were using the Advantage-S spermicide in doses far in excess of the amounts the Company knew to be safe. In fact, defendants knew that the test women subjects could use unlimited doses of Advantage-S which in turn increased HIV transmission rates.
VI.

DEFENDANTS' FALSE AND MISLEADING STATEMENTS
DURING THE CLASS PERIOD

57. On November 8, 1999, the commencement of the Class Period, defendants reported third quarter results for the third quarter of fiscal year 1999. Defendants reported a net loss of $930,183 or $.03 per share on net sales of $4,504,390 for the three months ended September 30, 1999. For the nine months ended September 30, 1999, net income was $385,421 or $.00 per share on net sales of $17,129,968. With respect to Crinone, defendants announced:

As previously announced, Ares-Serono, the world leader in reproductive health, acquired the license and distribution rights to Crinone from American Home Products in July, 1999. Ares-Serono disclosed on November 2, 1999, that it had paid $68 million of these rights. Under the terms of the agreement, Ares-Serono assumed the same financial obligations to Columbia. New data on the efficacy of Crinone was presented at the American Society for Reproductive Medicine in September as Ares-Serono prepared to launch the product. Ares-Serono is currently selling Crinone in eight countries and anticipates selling Crinone in twenty countries by the end of next year.

58. On November 12, 1999, Columbia filed its quarterly report on Form 10-Q for the period ending September 31, 1999, signed by defendant Weinberg. The report repeated the financial results announced on November 8, 1999. With respect to sales, the report represented that net sales for the quarter increased by approximately $9.4 million to $17.1 million. Defendants attributed $8.2 million of the increase to sales of Crinone.

59. The price of Columbia stock, which traded at approximately $6 per share in early November, 1999, rose in response to the Company's positive announcements, reaching $8 per share on November 29, 1999. On March 10, 2000, Columbia stock rose even higher, closing at $17.6 per share after nearly reaching $19 that day.
60. Defendants statements in ¶¶ 57 and 58 above were materially false and misleading because:

(a) As disclosed in a Columbia press release dated March 20, 2000, in marked contrast to the statements in ¶ 50 attributing the increase in sales in large part to sales of Crinone, the transfer of the Crinone license to Ares-Serono was taking significantly longer than previously announced, and Ares-Serono did not even have a finalized license to market Crinone — contrary to defendants' statements detailed above in ¶ 46, that the deal was "finalized" on July 2, 1999;

(b) Due to inventory backlogs, defendants would not recognize additional profitability from Crinone sales for until at least, the second half of fiscal year 2000;

(c) As Defendant Bologna admitted during the June 12, 2000 conference call, Ares-Serono did not even start marketing the product with its entire sales staff until early June of 2000.

61. Defendants failed to disclose these material adverse facts to investors when they issued statements regarding Crinone's entry into new markets around the world, and the impact of Crinone on Columbia's business and financial condition.

62. On January 18, 2000, defendants issued a press release announcing a "senior management restructure." Specifically, former Chairman Bologna was appointed CEO and Vice Chairman James Apostolakis was appointed President. Former President and CEO, Norman Meier, was appointed Chairman Emeritus of the Board of Directors. Defendants also announced Columbia’s plan to divest its over-the-counter business. Commenting on the planned divestiture, defendant Bologna stated: “[f]unds from this transaction will ensure we have the resources to speed development of innovative Rx products and to bring these products to market in a timely fashion.”
63. In response to the Company’s corporate restructurings and the positive news regarding Crinone sales through Columbia’s new marketing partner, analyst Sharon di Stefano of Ryan Beck issued a “Strong Buy” rating for the Company, with an 18 month price target of $16, in a report issued January 19, 2000.

64. On March 3, 2000, defendant Bologna gave an interview which was published in *The Wall Street Transcript*. Defendant Bologna admitted that Columbia had a “weakness of resources” and needed to “bring more cash into the company.” Bologna also complained of the lack of investor and Wall Street interest, stating:

“... [R]elative to other companies who seem to have a lot less, we have we have a low valuation. I guess you can only compare yourself to other drug delivery system-type companies. Relative to those companies, our valuation is actually relatively low. So that means either they’re overvalued or we’re undervalued, one or the other.”

65. During the interview, defendant Bologna was asked whether there were any other specific achievements that would characterize the next three or four years as an investment period. Bologna stated:

“Oh, absolutely. Let me start in the very short run. *As we’ve announced to the world, and most people know, with our technology, one of the things that we’ve done is develop a product to prevent the transmission of the HIV virus, of the AIDS virus, in women.* We’ve been running studies for the last six years, and we will complete by mid-year our Phase III studies. We believe we will have the only product that a woman can use to prevent the transmission of HIV.”

66. On or about March 16, 2000, defendants included a Letter to Shareholders in the 1999 Annual Report to Shareholders, signed by defendant Bologna. With respect to Advantage-S, Bologna stated:
"The Company is optimistic that the results of the Phase III study will find that Advantage-S offers a statistically significant reduction in the transmission of the HIV-virus and other sexually transmitted organisms, thus providing a powerful tool in the fight against the spread of AIDS. **The impact of these results on Advantage-S is immense, with the world-wide market for such products exceeding $1 billion.** We are very excited about the impact this study will have on Columbia's future.

67. Bologna's statements in the Annual Report to Shareholders were materially false and misleading. In a conference call held on June 12, 2000, after public disclosure that Advantage-S was a failure, defendant Bologna, attempted to explain the unexpected news regarding the impotency of the product against the transmission of AIDS, stating: "[t]his study [the UNAIDS study] was blinded so no one could know the results until the end." Accordingly, defendants had no basis for representing, as they did in the 1999 Letter to Shareholders in the Annual Report, prior to receiving confirmed test results, that Advantage-S "offers a statistically significant reduction in the transmission of the HIV-virus and other sexually transmitted organisms." Moreover, defendants' statements characterizing the impact of the studies as "immense" with a "world-wide market for such products exceeding $1 billion" was also contradicted by defendant Bologna in the June 12, 2000 conference call, where he attempted to downplay the Company's fraud by stating that the product's failure "has no financial impact on the Company."

68. Defendants' statements detailed in ¶¶ 65 and 66 above, that Columbia had developed "a product to prevent the transmission of the HIV virus, of the AIDS virus, in women" as well as the statement characterizing the impact of the studies as "immense" were also false and misleading for the following reasons, among others:
(a) defendants knew or recklessly disregarded that the Company failed to provide proper organizational safeguards necessary to ensure that any negative results that were, or should have been obvious from reasonable testing procedures would be known to the Company and reported to the investment community, such that these adverse results would have been disclosed at an early stage of testing;

(b) defendants' statements regarding Advantage-S were materially false and misleading because defendants knew or recklessly disregarded that the Company failed to design clinical trials limiting the dosage of N-9, which had been previously proven safe at a maximum of four uses per day or 210 milligrams;

(c) notwithstanding the known danger of excessive usage of N-9 and the correlation between over-use and higher transmission of HIV, defendants knowingly or recklessly failed to take steps to ensure that the subjects were limited in their use of Advantage-S, causing the women who used the product to contract AIDS at a higher percent than the women using Replens. Consequently the entire Phase III trial was fundamentally flawed from its inception;

(d) According to the Director of the Alliance of Microbicide Development in Takoma Park, Maryland, defendants "certainly" knew the dosage being given to the sex workers in the Phase III study because the doses were outlined in the trial's protocol. According to the Director, some women used N-9 over seventy times per week, and it was well known that the sex workers had sexual intercourse numerous times per day;

(e) the trial's protocol stated that the participants used "either 52.5 milligrams of N-9 or a placebo every time they had sex for 18 to 36 months", which resulted in daily dosages of as much as 1050 milligrams per day -- five times higher than the maximum dosage tested for safety. The safety trial conducted on N-9 in 1997 concluded that the product showed minimal toxicity when applied in a dosage of 52.5 milligrams once daily for fourteen days, but in no cases should the amount have exceeded four times per day;

(f) according to the director of a microbicide advocacy group, the trial was being conducted on Columbia's behalf, and defendants knew the amount of N-9 being administered to the sex workers because Columbia supplied both the N-9 and the placebo, Replens;
(g) Defendants also knew or recklessly disregarded the women's overuse of the product - and the resulting increase in HIV transmission rates - because the subjects kept daily diaries of their product usage which were reviewed by the study administrators;

(h) Because defendants knew that Advantage-S Phase III tests were being administered improperly, there was no basis for defendants' confidence in the tests, nor any basis for their statements that Columbia had developed a product to prevent AIDS. Defendants failed to disclose in the press release and Letter to Shareholders detailed above, that the Phase III tests were flawed, instead characterizing the impact of the studies as "immense."

69. In response to the news touting the anticipated positive results of the Phase III study, the stock traded at $15.75 per share on March 20, 2000 - significantly higher than the stock would have traded had the truth about the flawed design and implementation of the Advantage-S Phase III study been known.

70. In the March 20, 2000 press release detailed above, defendants also announced financial results for the fourth quarter of fiscal year 1999. Defendants reported a net loss of $0.09 per share in the fourth quarter of 1999 compared to a net loss of $0.18 per share in the fourth quarter of 1998. For the year ended December 31, 1999, Columbia reported a net loss of $0.09 per share compared to a net loss of $0.48 per share for 1998. Net revenues for the full-year 1999 increased to $18,921,074, compared to $10,017,644 for the full-year 1998.

71. With respect to Crinone, defendants repudiated their earlier statements touting increased sales prospects for the product and expansion into new countries, stating:

The number of months it took for the finalization of the Crinone license transfer from American Home Products to Ares-Serono and for the new licensee to begin marketing Crinone as well as the high inventory levels transferred impacted on 1999 sales. Because of the delayed timing and the large inventory transferred, Columbia will not see the full benefit of the Serono marketing effort until the second half of 2000.
72. Defendants' earlier misrepresentations regarding Crinone were significant because, as disclosed in the Company's annual report on Form 10-K filed on March 30, 2000, Crinone accounted for 25% of the Company's sales in 1998, and 56% of the Company's sales in 1999.

73. In a second press release issued on March 20, 2000, entitled "Columbia Laboratories Announces the Reacquisition of the U.S. Rights to its Aids-Fighting Spermicide, Advantage-S" defendants announced that they had acquired all the U.S. rights to Advantage-S. The Company touted both the market potential for the product, as well as the efficacy of the product, stating:

In 1999, there were 14.8 million women with AIDS, worldwide, and their number is growing by more than 2 million each year. The development of safe and effective microbicides capable of preventing the transmission of HIV and other sexually transmitted organisms in the vagina has been Columbia's priority. We believe that Advantage-S widens the range of safe sex choices available to sexually active people and most importantly, empowers women in the fight against AIDS. The development of a polycarboxyl based bioadhesive vaginal gel permits the reduction of the dose of nonoxynol-9, thereby increasing the safety margin and simultaneously increasing the efficiency of virucidal activity.

* * *

"The UN Global Program on AIDS (UNAIDS) has been studying the safety and efficacy of Advantage-S for the past six years. UNAIDS previously published ...a randomized placebo-controlled safety study of this bioadhesive vaginal gel among 534 healthy volunteers. The product was administered once a day for 14 days. Overall epithelial disruption occurred in 3.5% of the active group and 3.4% of placebo users. The conclusion of the study was that Advantage-S was safe and associated with minimal toxicity when used once daily."
74. In the March 20, 2000, press release, Defendants also conceded the correlation between dosage and higher risk of HIV transmission, stating: "Previous attempts to protect against HIV infection with a higher dose of noxynol-9 products failed to show a protective effect. The investigators concluded that this might be due to the high incidence of genital mucosal lesions, because at least in theory, they could enhance transmission of HIV."

75. Defendants reiterated the anticipated positive results of the study, stating:

"UNAIDS will complete the multi-center, randomized placebo controlled double blind study of women at high risk of HIV infection within 90 days. The Company is optimistic that this study conducted in Africa and Asia will demonstrate that results in a statistically significant reduction in the transmission of the HIV virus and other sexually transmitted diseases such as Chlamydia."

76. Defendants' statements detailed above in ¶ 73 and 75, were materially false and misleading. The statements in ¶ 73 that Advantage-S "empowers women in the fight against AIDS" and that the product was found safe when used once a day for 14 days were intended to, and did, convey the impression that Advantage-S was safe and effective. However, as defendants knew or recklessly disregarded:

(a) the Phase III study had little or no chance of yielding positive results because the protocol – which was submitted in conjunction with Columbia's IND – did not place an upper limit on dosage;

(b) defendants knew that excessive use of N-9 could cause vaginal lesions, resulting in increased HIV infection rates;

(c) the sex workers participating in the study were encouraged to use the product after each sex act – which amounted to as much as twenty times per day, far in excess of the "once a day for 14 days" or even four times a day previously tested;

(d) defendants knew or recklessly disregarded that women were over-using the product because, inter alia: they supplied the quantity of Advantage-S and Replens to be used for the duration of the study; the women kept diaries detailing their product use; and the study was "run" by Howard
Levine. Columbia's Director of Research and Development – who reported
to defendant Bologna;

(e) Because defendants knew that Advantage-S Phase III tests were being
administered improperly, there was no basis for defendants’ confidence in
the tests, nor any basis for their statements that Advantage-S "empowers
women in the fight against AIDS." Defendants failed to disclose in the
public statements detailed above, that the Phase III tests were flawed,
instead conveying the impression that Advantage-S was following
previous studies which administered the product "once a day for fourteen
days" - - therefore ensuring the safety of the participants and a properly
conducted efficacy study.

77. On March 20, 2000, defendants held a conference call for analysts as well
as the investing public. Defendant Bologna emphasized that all data from the study would be in
and analyzed over the next three months, with HIV transmission as the primary end point which
had been analyzed “all along.” Bologna also touted a contract with UNAIDS for the sale of “tens
of million of tubes” of Advantage-S as though the product were market-ready. Defendant
Bologna stated that Advantage-S would sell for $9 a tube in the United States, with a much lower
price to the U.N., - - which would still generate “serious” profits. Defendants assured investors
that the product would also be effective against chlamydia. and that a claim of efficacy with the
FDA for sexually transmitted diseases would be straightforward.

78. Bologna intended to, and did, convey the impression that Advantage-S
was ready for sale, stating that it would be sold as a “stand alone product” and that it also could
be packaged with condoms after study. Bologna stated that while defendants did not know the
size of the U.N. budget for purchasing Advantage-S, “Ambassador Holbrook has recommended
that the fight against AIDS in the third world be raised to the level of war.” When asked if
Columbia had the capacity to manufacture millions of tubes of Advantage-S, Bologna stated “we
can make anything they want.”
79. Defendants also characterized Columbia as the leader in AIDS fighting products, stating that competing trials of other products containing N-9 would need to include treatment with Advantage-S and that competing trials were "years away." Bologna added that Columbia would like more firms to cover the Company, and added that Columbia had generated additional market interest.

80. Less than two weeks prior to the announcement detailing the benefits and prospects of Advantage-S, Dominique DeZiegler, the Company's Director in charge of pharmaceutical development, exercised 50,000 options at an average of $5.44 per share on March 9, 2000, which he sold on the same day at $15 per share -- near the stock's Class Period high -- generating proceeds of $478,000. Similarly, Howard Levine, the Company's Vice President in charge of pharmaceutical development, exercised options at $8.06 per share which he sold for $12.50 per share on March 23, 2000 generating over $100,000 -- only three days after the announcement emphasizing the prospects of Advantage-S. Defendant Meier sold over 70,000 Columbia shares between March 22, 2000 and March 28, 2000, at prices close to Columbia's Class Period high, resulting in proceeds of over $1 million.

81. Defendants' positive statements during the conference call led investors to believe, as noted below in ¶ 100, that successful completion of the study was a "done deal." Defendant Bologna's characterization of the profit per tube, Columbia's capacity for mass-quantity manufacturing and sales through the U.N. -- which had decreed that the fight against AIDS would be raised to the "level of war," were false and misleading. As detailed in ¶¶ 68(a)-(h) and 76(a)-(3), defendants had no basis for representing the near-term marketability of Advantage-S -- let alone on such a grandiose scale. Despite knowledge of the maximum dosage of N-9 which had previously been tested for safety, the fact that the protocol did not limit usage
in the subject population, and that investigators were actively encouraging women to exceed safe levels, Columbia proceeded with the Phase III study, representing that defendants expected statistically meaningful – if not highly positive – data to emerge from it.

82. On March 30, 2000, defendants filed an annual report on Form 10-K for the year ended December 31, 1999, signed by defendant Weinberg and Bologna. The report repeated the fourth quarter 1999 and year-end results previously announced. Defendants revealed that Columbia received a letter of intent from a prospective purchaser for its over the counter products, who was in the process of completing due diligence procedures. In the 10-K, defendants stated with respect to Advantage-S:

During 1997, the Company was granted a United States patent covering the technology used in its product, Advantage-S, which potentiates the activity of nonoxynol-9 against various organisms that can cause sexually transmitted diseases, including gonorrhea, chlamydia, trichomonial infections, syphilis and genital herpes.

83. For the reasons detailed above, defendants had no basis for representing that Advantage-S "potentiates the activity of nonoxynol-9 . . . against AIDS". Indeed, by defendants' own July 12, 2000 admission, the Phase III study which defendants relied on for proving that Advantage-S "potentiates" against AIDS" was "faultily designed and administered" and conducted in a "grossly negligent and highly unethical" manner.

84. On April 20, 2000, defendants issued a press release announcing the divestiture of its over the counter division through a series of agreements with Lil' Drugstore Products, which would end Columbia's involvement in the sale of Replens, Legatrin (a product marketed to alleviate nighttime leg cramping), Vaporizer in a Bottle (a portable cough suppressant) and other products. Defendants were quick to assure investors that Advantage-S
was still a Columbia product, stating: "Columbia retains rights to its ethical over the counter AIDS fighting spermicide Advantage-S".

85. Defendants' repeated representations such as the statement detailed in ¶ 77, above, that Advantage-S was an "AIDS-fighting spermicide" were materially false and misleading because, as set forth herein, defendants knew or recklessly disregarded the lack of safeguards and failure to adequately design the Phase III study. Moreover, as defendants tried to persuade investors, the study was double-blinded so no one was supposed to know the results of the trial, and defendants had no basis for the claim that Advantage-S as "AIDS-fighting." Defendants were also motivated to conceal the truth about the flawed Phase III study and perpetrate the image that Columbia had a pipeline of "blockbuster" products because Lil' Drugstore Products was in the midst of conducting a due diligence investigation on Columbia's business and operations in connection with the agreements detailed in ¶ 77.

86. On May 9, 2000, defendants issued a press release via the Business Wire entitled "Columbia Laboratories' Announces the Conclusion of its Multicenter Phase III Study for its AIDS Fighting Spermicide, Advantage-S." Defendants announced that results of the Phase III testing would be presented at the International AIDS conference on July 10, 2000. Specifically, defendants stated:

Columbia Laboratories today announced that patient enrollment had been completed and final patient visits initiated in the phase III, multi-center, randomized, placebo controlled double blind study of Advantage-S in women at high risk of HIV infection...Advantage-S is currently being sold in the United States, Canada and China as a spermicide. Assuming successful completion of the study, Columbia plans to submit an NDA later this year in the United States to amend its labeling to include a claim that Advantage-S helps prevent the transmission of HIV and other sexually transmitted diseases. A similar file will be submitted to EMEA in Europe as soon as the data is fully analyzed.
Under current FDA regulations, the Company believes it will receive a priority review which should lead to approval within six months of submission. Columbia is also working to ensure that Advantage-S is made available, as soon as possible, to women in Africa and Asia in order to help stem the tide of the AIDS epidemic and prevent the transmission of HIV to women, their offspring, and partners.

87. The May 9, 200 press release also stated:

"In 1999 there were 14.8 million women with AIDS and their number is growing by more than 2 million each year. The development of safe and effective microbicides capable of preventing the transmission of HIV (the AIDS virus) and other sexually transmitted organisms in the vagina has been Columbia's priority. Columbia has been working for the past six years to demonstrate that only with our patented bioadhesive delivery system can nonoxynol-9 reduce the transmission of HIV."

88. The Company also touted the product's safety, stating:

"The activity of nonoxynol is based on the disruption of cell membranes, of both sperm and microorganisms. Nonoxynol-9, particularly at high doses, can cause disruption of vaginal epithelial cells that can lead to irritation. The use of the bioadhesive technology to lower the dose helps minimize this problem. The bioadhesive polymer maintains greater contact between the anti-STD agent and the infectant for a much greater period of time, enabling a lower concentration to act longer on the infectant, when compared to currently available commercial applications containing N-9. Such delivery will enable a safe and non-irritating decrease in the risk of infections with STD's including HIV."

89. The press release cited previous studies to emphasize the safety of Advantage-S, stating:

"A previously published randomized placebo-controlled safety study... Of this bioadhesive vaginal gel among 534 healthy volunteers demonstrated its safety. The product was administered once a day for 14 days... The conclusion of the study was that
Advantage-S was safe and associated with minimal toxicity when used once daily."

90. On May 9, 2000, Columbia stock traded at $9.50 per share, and increased to $10.43 on May 17, 2000, after news of defendants' announced "priority review" for Advantage-S was disseminated to the market.

91. Defendants' statements detailed in ¶¶ 86-89, above, were materially false and misleading. Defendants' statements created the false impression that FDA approval would be likely in six months, and that the Company was poised to capture the rapidly growing market of nearly 15 million HIV-positive women --- a market worth over $1 billion to the Company. In fact, the description of Advantage-S as an "AIDS fighting spermicide" is in itself a misleading characterization, since Advantage-S had not and would not be proven useful in the prevention of AIDS, and defendants had no basis for marketing it as such.

92. Moreover, defendants' statements in ¶¶ 86-89 were intended to, and did, convey the false message that Advantage-S was soon to be approved, and that the tests were a formality. Defendants' statements misled the investing public by leading investors to believe that Advantage-S was the new "miracle drug" which could "stem the tide of the AIDS epidemic" in Africa and Asia. In fact, as later revealed, defendants had no basis for making the statements detailed above with regard to Advantage-S's use to prevent sexually transmitted diseases. As defendant Bologna admitted, "no one knows the results of a blind study until the end."

Nonetheless, Bologna preliminarily released positive results because, according to a June 16, 2000 Wall Street Journal article, Bologna stated, "we felt obliged to say something."
93. As defendant knew or recklessly disregarded, there was little to no chance of a "priority review" from the FDA or "submission to EMEA as soon as the data [was] fully analyzed." Similarly, defendants' statements regarding the "safe and non-irritating decrease in the risk of infections ... including HIV" from use of Advantage-S were materially false and misleading because, inter alia:

(a) Advantage-S had been tested for safety at one dose per day for fourteen days, or at maximum, four times per day. As defendants knew or recklessly disregarded, the Phase III study protocol stated that participants used either 52.5 milligrams of Advantage-S or a placebo after each sex act, for 18 to 36 months;

(b) as defendants conceded on July 12, 2000, the dosage the study participants received – as much as 1050 milligrams per day – causes local lesions which can increase the rates of HIV transmissions;

(c) at the dosage actually administered to the women in the study, Advantage-S was far from "safe and non-irritating." In fact, the group of women using Advantage-S had a higher incidence of HIV infection compared to the group using Replens. Of the 100 women constituting the "endpoint" of the study, the group using Advantage-S had 59 HIV-infected women, while the group using Replens had 41;

(d) as defendants later admitted, the investigators encouraged women to dose themselves to known toxic levels;

(e) defendant Bologna admitted on July 12, 2000 that "by no means" should women have received more than 210 milligrams of N-9 per day due to the likelihood of lesions which disrupt the epithelial layer and facilitate HIV-transmission; and

(f) defendants cannot claim ignorance of the study's administration because, as defendant Bologna admitted during a June 12, 2000 conference call, "the people in the study talked to their friends" and "we were getting calls in our offices".
94. On May 11, and May 15, 2000, defendants announced financial results for the period ended March 31, 2000, and filed Columbia's quarterly report on Form 10-Q, respectively. Defendants reported a net loss of $0.05 per share for the three months ended March 31, 2000, compared to a net income of $.00 per share for the comparable 1999 period.

95. On May 26, 2000, defendants issued a prospectus on Form S-3 to register 53,933 shares of securities owned by selling stockholders, and 100,000 shares of securities underlying warrants owned by selling stockholders. The prospectus revealed that Columbia had entered into various agreements with the "selling stockholders" which required defendants to "bear certain fees and expenses incurred in connection with the registration of shares of securities." The prospectus revealed that Columbia and the selling stockholders had agreed to indemnify each other against certain civil liabilities, "including certain liabilities arising under the Securities and Exchange Act."

96. The prospectus revealed that the "selling stockholders" included, among others, Sharon diStefano of Ryan Beck & Co., the analyst who repeatedly issued "strong buy" ratings for Columbia stock and whose reports issued in First Call failed to reveal that she herself owned shares in Columbia. Amazingly, the prospectus revealed that the analysts registered all of their shares for sale to the public despite the issuance of the positive statements regarding Advantage-S and its "immense" impact on the Company only weeks before. Other significant insiders such as James Apostalokis, Columbia's President, registered 75,000 shares for sale. The selling stockholders included:
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<th>Number of Shares Covered By Prospectus</th>
<th>Beneficial Ownership After Offering (Number of Shares)</th>
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The fact that these many of these selling stockholders included all of their shares in this prospectus, *only eleven days prior to the issuance of the news regarding the failure of Advantage-S*, is highly indicative that: (a) defendants engaged in "selective disclosure" of material information without simultaneously disclosing that information to the public; and (b) defendants acted with severe recklessness in that they knew or recklessly disregarded the material flaws in the administration and design of the Phase III study and its resulting failure to fight the transmission of AIDS - - and chose to impart that information to a select few of the Company's supporters and insiders so they could attempt to divest themselves of Columbia shares.
VII.

THE TRUTH EMERGES

98. On June 12, 2000, defendants shocked the market by announcing that Advantage-S, the drug previously represented as being ready to "stem the tide" of the AIDS virus in Asia and Africa, failed to prevent the transmission of the HIV virus. An article published in the June 13, 2000 edition of the Sun-Sentinel reported that the gel with the active ingredient did not perform any better than the placebo containing inert ingredients. Defendants could only state "we don't know why it happened" in connection with Advantage-S's failure to prevent the transmission of AIDS.

99. In a conference call held on June 12, 2000, defendants were questioned concerning the positive reported interim results and the unexpected final results. Defendant Bologna's response was that the results were "unexplainable" and that "the [UNAIDS] study was blinded so no one could know the results until the end" - - a far cry from defendants' false and misleading statements representing the likelihood of success of Advantage-S and their product claim as Advantage-S as the "AIDS-fighting spermicide." A June 16, 2000 article in the Wall Street Journal revealed that women who received Advantage-S were not prevented from contracting HIV, on the contrary, they had higher rates of HIV infection than the placebo group. Defendant Bologna admitted that he made the preliminary announcement in March 2000, concerning the product's efficacy because "we felt obliged to say something" and "everyone assumed it was the active group taking Advantage-S that showed the lower transmission rate." In truth, Bologna's expression of an obligation to "say something" was merely a desire to take advantage of an opportunity to artificially inflate the price of Columbia's stock.
100. During the June 12, 2000, conference call, defendant Bologna recoiled from his earlier characterization of the impact of Advantage-S's success as "immense" stating that "[t]his would have been if it worked out a bonus." During the call, analyst Tom McPhil of Morgan Cabot questioned Bologna about the misleading earlier statements regarding Advantage-S, stating:

"... I'm asking you a question pertaining to a conference call we had a couple of months ago with you, talking about the company. Talking about Advantage-S, numerous other things... I spoke to quite a few of my peers today. The bottom line was, that conference call we had a couple of months ago left no doubt in my mind that Advantage-S was a done deal in Phase III. It was a DONE DEAL. Granted, maybe I misinterpreted what you were saying, but everybody else feels the same way. And I want to know what, you guys are the experts, you have people out there following these tests, why did this all come out today, why didn't it come out a couple of months ago, that there was a possibility that this was not going to work out. Because the reason why the market is showing what it's showing today, is because we were told one thing, and in fact we have something else happening."

101. In response, Defendant Bologna attempted to shift the blame, first to the co-sponsor, UNAIDS, and then to the Drug Safety Monitoring Board. McPhil noted "[y]ou're 100% correct as far as the poor people in Africa, but we also have a lot of clients that have just lost a staggering amount of money."

102. During the conference call, the following exchange occurred between Dr. Howard Liebowitz, a Columbia investor, and defendant Bologna:

Howard Liebowitz: "I'm an investor, and I'm also a doctor, and I'm very interested in why, if you're conducting a double-blind study, and you really don't know anything about what the products are doing that are being used in the study, why you would release interim information at some point, when you really don't know what's going on in the study?"
William Bologna: "The answer is that unfortunately, a great number of people knew the interim data. For reasons that are hard to explain, the people involved in the study talked to their friends on a confidential basis and unfortunately the word leaked out. Everyone was, we were getting calls in our offices. Howard Levine, who was running the study for Columbia was getting congratulatory calls from AIDS researchers. That's the only reason that we released the information, and we were concerned that that information would be limited to a few people, and so whatever information there was, we provided to the general public."

103. Indeed, defendant Bologna contradicted himself again during the conference call, when he was asked by an analyst if the code used in the clinical studies was totally secret. Bologna replied, in direct contrast to his earlier statement, "[n]obody knew anything."

104. On June 12, 2000, the Company's stock fell $7.18, or 55%, to $5.75 per share, its 52-week low, making Columbia the top percentage loser on the American Stock Exchange. According to analyst Jerry Treppel of Banc of America Securities, quoted in a June 13, 2000 Miami Herald article, the damage was "self-inflicted...[t]he Company led people to believe that they expected positive results, and that's not what they got."

VIII.

EVENTS SUBSEQUENT TO THE CLASS PERIOD

105. On June 28, 2000, defendants issued a press release announcing that due to the continued decline of Columbia's stock price, the Company would again be looking to be acquired, or for other "strategic options for enhancing shareholder value."

106. On July 12, 2000, defendants issued a press release entitled "Columbia Laboratories Comments on UNAIDS condemnation of Nonoxynol-9 Products, Including Advantage-S, as Microbicides is Premature and Results From a Faultily Designed and Administered Study." The press release stated:
Columbia Laboratories today commented in response to a press release issued by UNAIDS that Advantage-S is a sustained and controlled release formulation containing 52.5 MG of N9 per dose initially designed to be used once daily. WHO/UNAIDS conducted and published a study demonstrating it was safe to use at that dose (citation omitted). Subsequently, a safety trial was conducted by UNAIDS administering the product four times per day in female sex workers and it again was judged to be safe. In the UNAIDS Phase III clinical trial no upper limit was put on dosing. In fact, the protocol encouraged women to use the product after each act of intercourse, which ranged from 0-20 per day. Women who used the product per-protocol may have used 10 or even 20 doses in a day. At this dose, previous studies have shown that N9 causes local lesions and is probably unsuitable as a microbicide. Advantage-S was designed to avoid this problem and by not limiting the dose to that which was tested and shown to be safe, the study encouraged women to dose themselves to a toxic level.” (Emphasis added).

107. Defendants continued to shift the blame towards anyone but themselves, as evidenced by defendant Bologna’s statement in the July 12, 2000 press release that:

"The maximum tolerated dose that was studied in this population was four times per day. Under no circumstances should this dose have been exceeded. Despite this the investigators allowed and even encouraged women to dose themselves to known toxic levels. The most disturbing aspect of this study is that the statistical design was two tailed. This means that its was anticipated from previous studies that a toxic dose of N9 could be reached and thus, when a difference was seen in the interim analysis, the Drug Safety Monitoring Board (DSMB) was obliged to ensure that it was the active group and not the placebo group that had a lower incidence of transmission. Their failure to do so is unpardonable and unethical. UNAIDS and the DSMB they appointed may have been grossly negligent in the manner in which they designed and monitored this study.” (Emphasis added).
IX.

DEFENDANTS ACTED WITH SEVERE RECKLESSNESS

108. As alleged herein, defendants acted with scienter in that defendants knew that the public documents and statements, issued or disseminated by or in the name of the Company were materially false and misleading; knew or recklessly disregarded that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violators of the federal securities laws. As set forth elsewhere herein in detail, defendants, by virtue of their receipt of information reflecting the true facts regarding Columbia and its business practices, their control over and/or receipt of Columbia's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Columbia were active and culpable participants in the fraudulent scheme alleged herein. Defendants knew and/or recklessly disregarded the falsity and misleading nature of the information which they caused to be disseminated to the investing public. This case does not involve allegations of false forward-looking statements or projections but instead involves false statements concerning the Company's business, finances and operations. The ongoing fraudulent scheme described in this complaint could not have been perpetrated over a substantial period of time, as has occurred, without the knowledge and complicity of the personnel at the highest level of the Company, including the Individual Defendants.
109. By defendants' own admission, the Advantage-S Phase III study was faultily designed and administered. The study's protocol failed to include a maximum dosage of N-9 despite known risks of excessive use including increased HIV transmission. In addition to the fundamental design flaws, defendants admitted that the study investigators encouraged women to use the product after each act of intercourse, sometimes as much as 20 times per day. As a result, the study had no reasonable chance of proving Advantage-S's efficacy, and increased the number of women contracting HIV. Defendants' admissions indicate that either (a) they knew the study's design and implementation problems or (b) they knew nothing whatsoever about the Phase III study but touted the efficacy and near-term marketability of the product nonetheless. Either way, defendants acted with severe recklessness.

A. **Defendants had significant control over the Phase III study and knew or recklessly disregarded its faulty administration and design**

110. The following factors support a strong inference of severe recklessness:

(a) As the top-ranking officers at the Company, defendants were ultimately involved in creating, reviewing and approving the protocol establishing how the Phase III trial would be constructed, the criteria for selecting on-site investigators, and the maximum dosage of the product administered. As a result, they knew that the study regime – either as drafted or implemented – encouraged blatant misuses of N-9;

(b) Defendants were aware of the lack of an upper limit on dosage of N-9 for the study participants because defendants supplied the entire supply of Advantage-S and the placebo, Replens, to be used for the entire duration of the study.

(c) According to a director of a microbicide research group, defendants were well aware of the dosage being administered to the sex workers because the protocol described a dosage of 52.5 milligrams of N-9 per usage with no upper limit.
(d) The study was conducted on Columbia's behalf, and defendants intended to use the results of the study to file an NDA application with the FDA – the final step in approval of a drug. Howard Levine, Columbia's Vice President of Research and Development who reported to defendant Bologna, was "running the study for Columbia" – by Bologna's own admission during the June 12, 2000 conference call.

(e) The sex workers were required to keep a daily diary of their usage of either N-9 or the placebo. Accordingly, defendants recklessly disregarded that many of the women were, by Bologna's own admission, "dosing themselves to toxicity" by failing to maintain minimal safeguards on the implementation of the study. Defendants' were aware of the safety levels of the product, by virtue of the prior AIDS study, and knew or recklessly disregarded that this dosage level was regularly being exceeded – making defendants' statements regarding the imminent marketing of Advantage-S false and misleading.

111. Defendants' scienter is also demonstrated by the federal regulations they were required to comply with, by virtue of the FDA regulatory process, as detailed above in ¶¶ 42-49. For example:

- Defendants were required to, and did file an IND with the FDA for the conduct of clinical studies;

- a written protocol is submitted for the conduct of clinical investigations as part of the IND. For Phase III studies the protocol must contain great detail regarding the implementation and design of the study;

- pursuant to 21 CFR § 312.23, the dosage form must be included in the protocol;

- if the dosage for the study changed, defendants were required to submit a protocol amendment to the FDA prior to any change being implemented.

112. Defendants' control of, and reckless disregard for the plan and implementation of the Phase III study is also evidenced by defendants' statements in Columbia's annual report on Form 10-K filed on March 30, 2000. In the 10-K, defendants stated:
The Company expended $6.7 million in 1999... on research and development activities. The expenditures are primarily the results of costs associated with contracting for, **supervising and administering the clinical studies on the Company's Crinone, Advantage-S, Chronodyne and Testosterone... products. These studies are coordinated from the Company's New York and Paris offices.**

113. Defendants' scienter is further illustrated by defendants' own admissions. Indeed, defendants' July 12, 2000 press release revealed that:

(a) no upper limit was placed on dosing;

(b) the protocol encouraged women to use the product after each act of intercourse;

(c) women used the product as much as twenty times a day;

(d) at excessive doses, previous studies have shown that N-9 causes local lesions which would result in a higher HIV transmission rate;

(e) the study encouraged women to dose themselves to a toxic level;

(f) under no circumstances should the women have received more than four doses of N-9 per day;

(g) it was anticipated from previous studies that a toxic dose of N-9 could be reached.

**B. Defendants Possessed Substantial Motives To Conceal The Truth About The Flawed Phase II Study And Its Failure To Yield Positive Results**

1. **Insider Selling**

114. Defendants were motivated to participate in the fraud alleged herein by the insider trading in which they engaged during the Class Period. By concealing the troubled state of Columbia's Phase III study and its flawed design and implementation, defendants and other
Columbia insiders were able to sell 255,600 shares of securities during the Class Period at prices between $12 per share and $16.33 per share, thereby generating proceeds of over $3,066,067.

115. These sales were suspicious in both timing and amount. For example, defendant Meier sold 100,000 shares at prices ranging from $12 to $12.63 from March 22 to March 28, generating proceeds of $1,236,145. David Knott, a Columbia insider and significant shareholder, sold 78,600 shares between March 2, 2000 and March 8, 2000, at prices ranging from $14.69 to $16.31 per share, generating proceeds of $1,240,922.5 Knott was followed by Dominique de Ziegler, a Director and Vice President of Pharmaceutical Development, who sold 50,000 shares at $15 a share after exercising options at an average price of $5.44 each on March 9, 2000, generating proceeds of $478,000. Vice President of Research and Development, Howard Levine -- who supervised the Phase III study for Columbia -- sold 25,000 shares at $12.50, on March 23, 2000, generating proceeds of $111,000. Levine also filed a Form 144 to sell an additional 50,000 shares on March 23, 2000, with estimated proceeds of an additional $625,000. The suspicious timing of these stock sales was noted in an April 26, 2000 article in The Broward Daily Business Review. The article noted:

Prior to late February, it had been almost two years since Aventura-based Columbia Laboratories Inc.’s stock traded in double digits. But during a three-week span that began February 22, the drug company’s stock more than doubled in value to a high of $18.75. The stock’s rarified air proved a short one... [i]t was trading this week at around $9.25. Nonetheless, some Columbia

The sales by Knott are particularly significant because of his inside knowledge of Columbia’s operations. Indeed, Knott led a "dissident" group of investors to oust Meier as Chief Executive Officer due to "waste", "inefficiency", and "indefensible practices" which caused Columbia’s stock to be "one of the 10-worst performing public stocks", according to a October 21, 1998 article in the Broward Daily Business Review.
insiders cashed in part of their holdings while the stock was flying high.

116. The article further noted that:

The company is still running in the red. It posted a $2.2 million loss on $18.9 million in revenue last year, compared with a $13.9 million loss on $10 million in revenue in 1998. Last year's loss helped the company crack the $100 million mark in combined losses. Thus, the run-up in Columbia's stock seemed an opportune time to sell. (emphasis added).

117. Moreover, the sales all took place between March 2, 2000 through March 28, 2000. At that point, defendants had made the following statements which caused the Company's stock to trade at artificially inflated prices:

- In a March 3, 2000 interview with the Wall Street Transcript, defendant Bologna stated that "one of the things that we've done is to develop a product to prevent the transmission of the HIV virus";

- In a March 16, 2000 letter to shareholders, Bologna characterized the potential for Advantage-S as "immense, with the world-wide market for such products exceeding $1 billion";

- In a March 20, 2000 conference call, defendant Bologna talked about the Phase III trial in a way which an analyst later described as "a done deal" for the company. Bologna described the profit to be generated, the number of tubes to be sold, and characterized the claim of efficacy with the FDA for sexually transmitted diseases as "straightforward."

118. Indeed, as a result of defendants' false and misleading statements, the closing price on March 10, 2000, during the midst of the insider selling, $17.625 -- the stock's Class Period high.
2. The Terms of Defendants' Compensation Packages Provided Them With Additional Incentive to Mislead Investors

119. The compensation packages of defendants Meier, Bologna and Weinberg provided them with additional motive to conceal the true state of the Company's products and the Phase III study. According to the Company's proxy statement on Form 14-A filed on May 10, 2000 defendants Meier and Bologna received salaries of $350,000 in 1999, and $400,000 in 1998. Defendant Weinberg received a salary of $189,000 in 1999, and $182,000 in 1998. During 1999, defendant Meier and Bologna are granted 10,000 options to purchase Columbia shares, at $5.75 per share; and 10,000 options to purchase shares at $8.25 per share, with present value of $82,091.

120. Defendant Weinberg was awarded 15,000 options to purchase shares at $5.75 per share, and 10,000 options to purchase shares at $8.25, with a present value of $98,949. Pursuant to the company's 1993 Annual Incentive Compensation Plan, the Company agreed to set aside an aggregate of 5% of the Company's pretax earnings as additional compensation. As a result of the net loss in 1999, no amounts were awarded under the Plan. Accordingly, defendants were motivated to "turn a profit" in order to maintain their significant compensation and increase their earnings under the Company's Compensation Plan. Defendants Meier and Bologna had additional interest in maintaining Columbia's inflated stock price because they had borrowed $80,000 and $110,350, respectively, from the Company in 1993 – totaling $128,667 and $178,017 at April 20, 2000 at which time the loans were still outstanding. Accordingly, defendants were strongly motivated to keep Columbia's sock price inflated, increasing the
opportunities for defendants to exercise valuable options and repay their long-standing indebtedness.

3. **Defendants Were Motivated To Mislead Investors Concerning The Company's Operations And Prospects By Columbia's Need To Attract Additional Investment Capital And A Buyer**

121. Defendants' motivation to maintain the artificially inflated price of Columbia stock, to conceal the fundamental flaws in the Phase III study and to create the illusion that Columbia was a company with "blockbuster" products, such Advantage-S, in the pipeline was necessary in order to find a purchase for Columbia, and attract additional investment capital to the Company.

122. Even prior to the commencement of the Class Period, defendants expressed a desire to sell the Company. As noted above, defendants initially looked to the Crinone deal with the Wyeth-Ayerst division of American Home Products as a stepping stone to the sale of Columbia to American Home Products – a prospect which did not materialize.

123. A sale would have resulted in significant personal benefit for the Individual Defendants. The Proxy Statement filed may 10, 2000 revealed that if a "change in control", including a sale or merger of the Company occurred, any outstanding awards including outstanding and unexercised options, stock appreciation rights and restricted stock, shall become immediately and fully exercisable. As revealed in the proxy statement, a sale of the Company would have resulted in the vesting of 80,000 options which were unexercizeable as of December 31, 1999 for defendants Bologna and Meier, and the vesting of 25,000 unexerciseable options for defendant Weinberg.
124. At the same time defendants positioned the Company as an acquisition candidate, defendants were faced with material cash flow problems. While Columbia made many spectacular claims regarding the quality of its clinical data and the efficacy of its drugs and drug pipeline, Columbia failed to generate significant profitability from the sale of its products. As noted above, defendants posted quarter after quarter of losses, despite touting imminent profitability. Accordingly, as conceded by defendant Bologna on March 3, 2000, Columbia had a "weakness of resources" and needed to "bring more cash into the company."

125. According to defendants' 10-Q, filed on May 15, 2000 the Company anticipated spending $8.2 million on research and development in 2000. At the same time, defendants' reported a loss for 1999 of over $2.2 million. To raise capital for the significant research and development expenditures as well as the continued operations and significant executive compensation, defendants were strongly motivated to maintain Columbia's inflated stock price to generate increased investor and Wall Street attention, as noted above. Defendants were also motivated to conceal the truth from the public in order to sell, on a continuous basis, additional shares of Columbia stock with a proposed maximum aggregate offering price of $75,000,000 as revealed in defendants' Form S-3 filed on May 31, 2000.

126. Similarly, defendants' desire to perpetuate the image of Columbia as a successful product developer and financially stable company was also necessary to enable Columbia to divest itself of its over-the-counter products division. As detailed in the Company's 10-Q filed on May 15, 2000, defendants sold the U.S. rights for Replens for $4.5 million, and licensed several other products to a third-party on May 5, 2000 after a due-diligence investigation into Columbia's operations was concluded. Had the serious flaws in the design of
the clinical studies been known at that time this divestiture either would not have occurred or would have occurred under less favorable terms for Columbia.

127. Defendants' scienter is also demonstrated by their selective disclosure of adverse material facts to "a select few," including analysts who repeatedly issued "strong buy" ratings for the company as detailed above in ¶¶ 95-97.

128. Defendants cannot claim they had no knowledge of the way the study was being conducted. According to defendant Bologna's admission during the June 12, 2000 conference call, "a great number of people knew the interim data", "the people involved in the study talked to their friends" and "we were getting calls in our offices." Defendants' attempt to now distance themselves from any knowledge whatsoever regarding the implementation and design of the Phase III study is not credible. Because of defendants' failure to properly design and administer the study, defendants had no basis for repeatedly emphasizing the "immense" impact of Advantage-S for Columbia and the profitability to be generated through the United Nations contact and around the world.

X.

APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD-ON-THE-MARKET DOCTRINE

129. At all relevant times, the market for Columbia securities was an efficient market for the following reasons, among others:

(i) Columbia securities met the requirements for listing, and was listed and actively traded, on the AMEX stock exchange, a highly efficient market;
(ii) As a regulated issuer, Columbia filed periodic public reports with the SEC and the NASD;

(iii) Columbia stock was followed by securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

(iv) Columbia regularly issued press releases which were carried by national newswires. Each of these releases was publicly available and entered the public marketplace.

130. As a result, the market for Columbia securities promptly digested current information with respect to Columbia from all publicly-available sources and reflected such information in Columbia's stock price. Under these circumstances, all purchasers of Columbia securities during the Class Period suffered similar injury through their purchase of stock at artificially inflated prices and a presumption of reliance applies.

XI.

NO SAFE HARBOR.

131. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this complaint. The specific statements pleaded herein were not identified as "forward-looking statements" when made. Nor was it stated with respect to any of the statements forming the basis of this complaint that actual results "could differ materially from those projected." To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor
does apply to any forward-looking statements pleaded herein, defendants are liable for those false forward-looking statements because at the time each of those forward-looking was made the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Columbia who knew that those statements were false when made.

132. Defendants also knew at the time of issuance of the statements detailed herein that the Phase III test had no upper limit on dosing, and failed to disclose that excessive use of N-9 could result in vaginal lesions -- thereby increasing the risk of HIV transmission. Accordingly, at the time the statements were made, defendants misrepresented existing facts regarding the Phase III study, and had no basis for the positive statements they issued regarding the near-term marketing of Columbia's "AIDS-fighting spermicide."

**FIRST CLAIM**

*(Violations Of Section 10(b) Of The Exchange Act And Rule 10b-5 Promulgated Thereunder Against All Defendants)*

133. Plaintiffs repeat and reallege each and every allegation contained above.

134. Each of the defendants: (a) knew or recklessly disregarded material adverse non-public information about Columbia's financial results and then existing business conditions, which was not disclosed; and (b) participated in drafting, reviewing and/or approving the misleading statements, releases, reports and other public representations of and about Columbia.

135. During the Class Period, defendants, with knowledge of or reckless disregard for the truth, disseminated or approved the false statements specified above, which were misleading in that they contained misrepresentations and failed to disclose material facts
necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

136. Defendants have violated § 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder in that they: (a) employed devices, schemes and artifices to defraud; (b) made untrue statements of material facts or omitted to state material facts necessary in order to make statements made, in light of the circumstances under which they were made, not misleading; or (c) engaged in acts, practices and a course of business that operated as a fraud or deceit upon the purchasers of Columbia stock during the Class Period.

137. Plaintiffs and the Class have suffered damage in that, in reliance on the integrity of the market, they paid artificially inflated prices for Columbia stock. Plaintiffs and the Class would not have purchased Columbia stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' false and misleading statements.

SECOND CLAIM

(Violation Of Section 20(a) Of The Exchange Act Against Individuals Defendants)

138. Plaintiffs repeat and reallege each and every allegation contained above.

139. The Individual Defendants acted as controlling persons of Columbia within the meaning of Section 20(a) of the Exchange Act. By reason of their senior executive and/or Board positions they had the power and authority to cause Columbia to engage in the wrongful conduct complained of herein.
140. By reason of such wrongful conduct, Columbia and the Individual Defendants are liable pursuant to §20(a) of the Exchange 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 Columbia stock during the Class Period.

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

1) Determining that this action is a proper class action and certifying Plaintiffs as a class representative under Rule 23 of the Federal Rules of Civil Procedure;

2) Awarding compensatory damages in favor of Plaintiffs and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

3) Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

4) Such other and further relief as the Court may deem just and proper.
JURY TRIAL DEMANDED

Plaintiffs hereby demands a trial by jury.


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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been forwarded via Federal Express to all counsel listed below this 20th day of October, 2000.

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