UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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In re SCHERING-PLOUGH CORP.	**:**	**Master File No. 2:06-cv-05774**
Intron/Temodar Consumer Class Action	**:**	**JURY TRIAL DEMANDED**

AMENDED CONSOLIDATED CLASS ACTION COMPLAINT

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The Named Plaintiffs[1] bring this Amended Consolidated Class Action Complaint against Schering-Plough Corporation ("Schering" or the "Company") and other defendants (collectively, the "Defendants"),[2] on behalf of a proposed Class of health and welfare funds and other third-party payors (collectively, the "TPPs") who paid any portion of the purchase price for Intron Franchise Drugs (which include Intron-A, PEG-Intron, and Rebetol when sold individually or in combination), and/or Temodar (collectively, the "Subject Drugs") marketed and sold by Defendants, from on or about January 1, 1999 to at least December 31, 2003 (the "Class Period"). Named Plaintiffs assert claims against Defendants on behalf of a nationwide Class under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1961 et seq.; NJ RICO, N.J. Stat. Ann. § 2C:41-1 et seq.; under the common law for intentional interference with contractual relations; and in equity for unjust enrichment.

I. NATURE OF DEFENDANTS' CONDUCT

1. Defendants indisputably made false and misleading statements in their illegal off-label marketing (*i.e.* marketing for uses not approved by the FDA)

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[1] The Named Plaintiffs are International Brotherhood of Teamsters Local No. 331 Health & Welfare Trust Fund ("Local 331"); Heavy and General Laborers' Local Union 472/172 Welfare Fund ("Local 472"), United American Insurance Company ("UAI"), and Blue Cross Blue Shield of Alabama ("BCBSAL").

[2] The Defendants are Schering; the following Schering subsidiaries: Integrated Therapeutics Group, Inc. ("ITGI"), Schering Corporation ("Schering Corp."), and Schering Sales Corporation ("Schering Sales"); and the following Schering executives: Richard J. Kogan ("Kogan"); William K. Heiden ("Heiden"); and Mary Naughton ("Naughton").

campaign promoting the Subject Drugs during the Class Period.

2. Defendants' illegal off-label marketing scheme was massive in scope. Defendants spent tens of millions of dollars annually to push the Subject Drugs off-label. Defendants targeted doctors, other medical professionals and quasi-professionals, pharmacy benefits managers (PBMs), third party payors (TPPs) and individual patients through a variety of sophisticated marketing tactics and gimmicks that were designed to mislead.

3. Schering knew its off-label marketing push for the Subject Drugs was about profits, not patient care. According to one sales representative who took notes during an off-label training session (Temodar use for brain metastasis), dying brain cancer patients were "perceived" by Schering as "the last bit of water circling before it goes down the drain." Treating them with Schering drugs was like "rearranging the deck chairs on the Titanic." (SPNJ 0236203). Temodar was ineffective on brain metastasis, Schering knew it, but Schering pushed the drugs for this indication anyway by making false and misleading claims about the drugs' safety and efficacy.

4. False and misleading statements were a centerpiece of Schering's illegal marketing efforts. Such statements, moreover, were not false and misleading because the FDA said so, or *ipso facto* because the indications were not "on-label." They were false and misleading because Schering had no factual

support for the statements that Schering touted as scientific fact. A Schering Senior Product Manager for the Mid-Atlantic region (Jorge Diaz) in charge of Temodar, for example, told government investigators that "[h]e knew there was off-label promotion of Temodar going on" and he **"agreed that the statement [made in writing to the FDA] concerning Temodar crossing the Blood Brain Barrier was a false statement."** (HHS-OIG 00291). Diaz further admitted that when marketing Temodar for brain metastases, a purpose for which Temodar was not approved, **"the push for Temodar was quality of life and crossing the blood brain barrier even though the studies did not support these claims…."** *Id.* Schering's false "crosses the blood-brain barrier" claim was crucial to increasing Temodar sales. Brain cancer is notoriously difficult to treat. The brain's superb self-protection, preserving cerebral homeostasis impedes anti-cancer drugs from working in the brain. Treating brain cancer turns largely on the ability of drugs to cross the blood-brain barrier.

5. Schering also knew that Temodar was not effective to treat brain metastases, and even possessed data (Study 086) showing that Temodar was not an effective treatment for brain metastases. Undeterred in its quest for illicit profits, Schering acknowledged privately that "[n]othing works for brain mets," suppressed the data showing that Temodar did not work (even from doctors participating in Study 086) (SPNJ 0125070), and falsely touted Temodar as a safe

and effective treatment for brain metastases throughout the Class Period. *See* Temodar 2000 Plan. Schering not only concealed the fact that there was little or no proof to support Temodar's use in patients with brain metastases, but affirmatively trained its sales force to mislead medical professionals by stating that there was "[e]ncouraging preliminary data" showing that Temodar "[s]ignificantly improves response" in brain metastases patients with a "[t]rend toward improvement in survival." These marketing claims were false and misleading when made during the Class Period because Temodar was not effective to treat brain metastases and Schering knew it.

6. Schering knew that Temodar's off-label use to treat metastatic melanoma had "[m]arginal if any efficacy advantage over DTIC," a low cost generic drug that was the standard treatment with an "equal" safety profile to Temodar. Despite knowing that Temodar provided marginal to no efficacy or safety advantage over DTIC and despite the fact of DTIC's much lower price, Schering instructed its sales representatives to induce doctors to replace DTIC with Temodar in treating metastatic melanoma by falsely stressing that Temodar had efficacy advantages over DTIC. *See* Temodar 2000 Plan.

7. Schering's off-label promotion of Intron A in bladder cancer is another example of Schering's false and misleading marketing. During the Class Period, a senior Schering sales executive, Rich Zahn, gave a presentation regarding

the off-label use of Intron A in bladder cancer highlighting the results of clinical trials set up and funded by Schering. Zahn dubbed the presentation "Sales through Science" but internally referred to it as "**Sales *not* Science**." (HHS-OIG 00296) (emphasis added).

8. These are but a few examples of the falsity of Schering's off-label marketing message, and Schering's knowledge of that falsity. As set forth in detail below, Schering, intending that Plaintiffs pick up the tab, bombarded every rung of the health care ladder, from doctors to nurses to staff and even patients themselves, with these, and other, false and misleading statements and claims relating to non-effective or unsafe off-label uses for the Subject Drugs.

9. Throughout the Class Period, Schering's sales force was actively trained to tout the science of the Subject Drugs in off-label indications while knowing full-well that many of the cited "studies" were flawed, insignificant, nonexistent or biased as a result of Schering funding and/or bribes paid to doctors to prescribe the Subject Drugs and to influence other medical professionals to do the same. Schering knew that many of the scientific claims it touted to support off-label use of the Subject Drugs were false and misleading because they were "bought" by Schering. But, Schering sales representatives, and others paid to speak on behalf of Schering, promoted off-label uses as based on "good science" when they plainly were not.

10. Each of the marketing tactics employed by Defendants during the Class Period (and described in further detail below) facilitated the dissemination of Schering's false and misleading statements regarding the efficacy, safety, and cost-effectiveness of the Subject Drugs. Schering's false and misleading statements drove off-label sales of the Subject Drugs in New Jersey and Alabama (the home states of Named Plaintiffs) in the same manner as they were used to drive off-label sales elsewhere throughout the country during the Class Period.

11. Where Schering's panoply of marketing tactics and gimmicks were deemed insufficient in disseminating Defendants' false and misleading statements about the Subject Drugs, Schering's aggressive sales force directly contacted prescribing physicians. Upon information and belief, numerous false and misleading statements regarding the efficacy, safety and cost-effectiveness of the Subject Drugs were drilled into physicians during the thousands of private meetings between Schering sales representatives and medical professionals.

12. For example, Schering repeatedly used the medically crucial, but false, statement that Temodar "readily crosses the blood brain barrier" as part of its off-label marketing for Temodar during the Class Period. (*See* SPNJ115516-519). On October 22, 2002, for example, Schering sales representative Diane Dorn called on Dr. Aron Bick, and noted:

> had lung to brain met pt but used arrisa [competitor drug] instead of [Temodar]. said didn't think [Temodar] had activity in primary lung;

> tried to discuss adonizio but he didnt want to have a discussion; definitely a know-it-all; asked him if arrisa crosses blood brain barrier he said

As this truncated note clearly shows, doctors were being privately detailed with the same false and misleading statements about Temodar's ability to cross the blood-brain barrier that Schering was training its sales representatives to repeat.

13. The doctors who were the most likely to write off-label prescriptions of the Subject Drugs were, not coincidentally, the doctors Schering most lavishly bribed. Those doctors who became regular recipients of Schering bribes became "thought leaders" in off-label indications. Schering would parade these doctors around to tout Schering's false and misleading off-label marketing messages while at the same time filling their pockets with money and other gifts. These doctors would do Schering's bidding not only by writing off-label scripts, but also by disseminating Schering's false and misleading off-label marketing messages to wider audiences of medical professionals.

14. While numerous doctors were blind to Schering's illegal marketing tactics and gimmicks and were thus fooled by Schering's false and misleading statements regarding the Subject Drugs, others discovered that Schering's off-label marketing blitz of the Subject Drugs was a sham premised on false and misleading statements and fuzzy or non-existent science that was "paid for" by Schering. Regardless of which group a doctor fell into, the result was the same. Doctors

were either blind to the true facts or content to turn a blind-eye as long as they received fishing trips, golf outings, dinners, vacations and/or (in most cases) large cash payments from Schering as a *quid pro quo* for writing off-label scripts for the Subject Drugs.

15. Dr. Barrears, an oncologist in Florida, provides a good example. He was skeptical of Schering's claims that Temodar could be used to treat brain metastases because any data supporting such a use was so weak. Schering sales representative Jay Stafford falsely assured Dr. Barrears that a published study was coming showing that Temodar was effective to treat brain metastases. Dr. Barrears remained skeptical right up until the time that he enjoyed a tuna fishing excursion with Stafford, whereupon Dr. Barrears "changed his mind" and put 20 patients on Temodar. About six months later, when Stafford checked in with Dr. Barrears, the doctor reported that Temodar was not at all effective in his brain metastases patients. "[E]very patient progressed the way he though [sic] they would, every patient died when he thought they would." Regardless, having been greased with Schering bribes, Dr. Barrears continued to write prescriptions for Temodar, generating $157,000 in business for Schering in 2001. (HHS-OIG Report of Interview, Jay Stafford, Feb. 12, 2002, at 5 (HHS-OIG 000318)).

16. Numerous doctors just took cash as a *quid pro quo* for writing off-label scripts of the Subject Drugs without doing anything but writing off-label

scripts. Schering's Atlanta Sales Representative Michelle Milhoff gave melanoma cancer researchers (the Georgia Cancer Institute) a $25,000 "unrestricted educational grant" to host a large melanoma conference during which the use of Intron A as a treatment was to be explored. Those doctors did not host any conference, and just pocketed the funds with Schering's approval to "encourage them to keep using Intron A for melanoma." [HHS-OIG 000580]. Schering Sales representative Douglas Hay stated that Dr. Gupta of Broward County "just wanted to make money . . . was looking for inducements and wanted to do any trial that would pay him money." When Hay arranged for a free physician assistant for Gupta, the physician "started accruing and treating 25 new patients on the protocol [for PEG-Intron]." (HHS-OIG 000298).

17. Dr. Henry Friedman was equally brazen. He was one of Schering's "thought leaders," which meant that whatever he demanded he usually got regardless of budget constraints, business reasons or its legality. In 2000, for example, Dr. Friedman was taking his family on vacation to Disney and told Schering he wanted to set up a program to speak at an Orlando Florida hospital on off-label drug issues. Some Schering sales representatives, including Tracy Stein, questioned the usefulness of such a program, and originally denied Dr. Friedman's request (and the typical $2,500 honorarium that Dr. Friedman would collect from Schering for such a speaking program). District sales managers quickly reversed

that decision and made sure that Dr. Friedman got paid. According to sales representative Tracy Stein, who followed up with the Florida hospital, Dr. Friedman scheduled no program and no program occurred. Dr. Friedman merely visited the hospital, walked around with one doctor for 20-30 minutes, and left, presumably back to vacation with his family, with an extra $2,500 in his pocket.

18. Dr. Gupta of Broward County Florida also preferred the "cash for nothing" bribe in exchange for his writing off-label scripts of Intron A. Schering sales representative Douglas Hay reported to government investigators that Dr. Gupta "always had his hand out," and that Schering invited Dr. Gupta to speak at phony dinner programs (three or four times at $750 per event) where the only attendees were Dr. Gupta, his family, and Hay. But this was common practice at Schering for someone like Dr. Gupta, who wrote numerous off-label prescriptions for Intron-A in bladder cancer and, upon information and belief, other off-label indications.

19. It is indisputable that Named Plaintiffs were harmed by the false and misleading statements and widespread bribery employed by Defendants to support Schering's illegal off-label marketing scheme. BCBSAL and UAI alone had thousands of members prescribed the Subject Drugs during the Class Period. BCBSAL alone spent $41,320,753.18 for the Subject Drugs during the Class Period.

20. Several members of Named Plaintiff Local 472 were prescribed Temodar from 2002 through 2003, which were paid for in large part by Local 472. For example, [redacted] was prescribed Temodar on five separate occasions between January and May of 2002 (specifically, 1/24/2002, 2/12/2002, 3/12/2002, 4/11/2002, 5/15/2002); [redacted] was prescribed Temodar on three different occasions between March and June 2003 (specifically, 3/26/2003, 5/15/2003, 6/12/2003); and, [redacted] was prescribed Temodar on six different occasions between June 2003 and December 2003 (6/23/2003, 7/26/2003, 8/16/2003, 10/28/2003, 11/24/2003, 12/15/2003). Dozens of prescriptions (for [redacted] were written and filled for Intron Franchise Drugs between January 2002 and December 2003 which were again in large part paid for by Local 472. Upon information and belief, each of these prescriptions were written for off-label uses by physicians improperly influenced by the false and misleading statements, bribes, and other dishonest inducements brought to bear by Defendants' illegal off-label marketing scheme.

21. Named Plaintiff Local 331 was similarly harmed by Schering's illegal marketing scheme. [redacted] were both prescribed Rebetol during the Class Period which were paid for in large part by Local 331. Upon information and belief, these prescriptions were written for off-label uses by

physicians improperly influenced by the false and misleading statements, bribes, and other dishonest inducements brought to bear by Defendants' illegal off-label marketing scheme.

22. Since eighty-five to ninety-five percent (85-95%) of Temodar scripts written during the Class Period for Temodar and over thirty percent (30%) of Intron Franchise Drugs scripts written were for off-label indications, it is reasonable to infer, and unreasonable not to infer, that at least some of the hundreds of thousands of patients and hundreds of thousands of prescriptions written for Named Plaintiffs' members relating to the Subject Drugs were written off-label by physicians improperly influenced b Defendants' false and misleading marketing claims or corrupted by Defendants' bribes.

II. NATURE OF DEFENDANTS' SCHEME

23. During the Class Period, Defendants carried out an unlawful sales and marketing scheme to increase the sales of the Subject Drugs. The scheme was centered around various false and misleading statements and omissions, including (a) false and misleading information about the efficacy, safety, and cost-effectiveness of the Subject Drugs, and (b) promotion of the Subject Drugs based not on facts and efficacy, but on improper bribes, kickbacks and other forms of illegal remuneration and inducements to health care providers, and others involved

in the decision-making regarding whether to prescribe and pay for prescription medication.

24. Using U.S. mail, interstate wire facilities, and travel in interstate commerce in order to increase Schering's revenues, Defendants promoted the Subject Drugs with false promises of proven superiority where, in fact, cheaper and equally or more effective alternative drugs existed (*e.g.*, DTIC vs. Temodar [metastatic melanoma]; Bacillus Calmette-Guerim ("BCG") vs. Intron A [bladder cancer]) or where the Subject Drugs had no benefit whatsoever (*i.e.*, was completely ineffective and like "rearranging the deck chairs on the Titanic") in treating an off-label condition (*e.g.*, Temodar's use on brain metastases).

25. Because Defendants recognized that off-label sales of the Subject Drugs would vastly increase their revenues and profits, and knew also that they could not legally market the Subject Drugs for these uses, Defendants resorted to illegal tactics, including false and misleading statements and the blatant payment of bribes and kickbacks to influence physicians to prescribe the Subject Drugs when they otherwise would not have done so.

26. Temodar, for example, was approved for treatment of a relatively rare brain cancer, with only about 3 to 4,000 patients needing the drug in an average year. Not satisfied with selling Temodar to treat such a limited population, Schering expanded the market by illegally marketing Temodar as a first-line

treatment for use by patients with brain tumors, brain metastasis, and other cancers. These uses for Temodar were not just off-label during the Class Period. Schering, despite its false statements and promotional claims to the contrary, did not have evidence at the time that Temodar was effective for treating these cancers.

27. At a minimum, Defendants misled doctors and other medical professionals regarding the efficacy of the Subject Drugs. Schering never disclosed that most of the clinical studies it relied upon were sponsored by Schering, and the results of these studies were often tainted by large bribes paid to the doctors supposedly conducting the research.

28. Schering knew, for instance, it could dramatically grow sales for Intron A by marketing this drug to doctors for the treatment of superficial bladder cancer, even though an Intron A was not approved for this purpose and an effective, inexpensive, FDA-approved competing drug was on the market. Schering created incentives to encourage doctors to use Intron A, including bribes, kickbacks, and instructions on how to overbill and defraud health insurance providers, TPPs, Medicare and Medicaid. Schering concocted a vast array of ways, detailed below, to funnel gifts and bribes to doctors in exchange for prescribing Intron A for bladder cancer.

29. A significant portion of these Intron A / bladder cancer bribes, for example, went to Dr. Michael O'Donnell. O'Donnell ran a large, Schering-funded,

investigational trial involving off-label use of Intron A in treating superficial bladder cancer. Schering paid O'Donnell large amounts of money for his various forms of support in promoting off-label use of Intron A. Underscoring the falsity at the heart of Schering's off-label campaign, the evidence gathered to date reflects that O'Donnell's supposedly independent study was actually ghost-written by Schering's own marketing consultants Projects-in-Knowledge and, therefore, by Schering itself. For Schering to promote O'Donnell's work, as it did extensively throughout the Class Period, as independent, based upon good science, and supporting Intron A as the "new standard-of-care" in treating superficial bladder cancer is affirmatively misleading.

30. During the Class Period, Defendants paid improper bribes, kickbacks and other illegal remuneration and inducements to physicians in at least the following ways to facilitate the dissemination of Schering's false and misleading marketing statements: (a) paying money, purportedly for speaking at functions such as a dinner lecture, when in reality this money was given as a reward for prescribing the Subject Drugs; (b) paying amounts ranging from $500 to $1,000, ostensibly for teaching Schering sales representatives about technical aspects of their own medical practices; (c) sending $10,000 checks in exchange for signing a so-called "consulting agreement" with Schering; (d) disguising improper and unlawful payments to for prescribing Intron A by falsely stating that such

compensation was being given to conduct phony "clinical trials"; (e) providing free samples of Intron A to induce prescription-writing, whereupon the physicians then charged patients and/or third-party payors $500 for each of these "free samples" that they prescribed; (f) paying physicians, whom it called "investigators," to give speeches about off-label uses of Temodar and Intron Franchise drugs to other physicians; (g) giving so-called "grants" to physicians, physician groups and medical facilities, ostensibly for an educational program or research program; (h) paying physicians to participate in "advisory boards" for the ostensible purpose of obtaining their feedback about drug performance and how physicians treat diseases; (i) rewarding physicians who prescribed Rebetron for Hepatitis C, by providing them with a free physician's assistant for one year; and (h) providing free nursing services to physicians through Defendants' in-house "Patient Care Consultants."

31. Schering's marketing scheme was nationwide and massive, targeting and corrupting doctors with sophisticated precision, as well as all other medical professionals and quasi-professionals who might come into contact with a patient who might use Schering drugs. With respect to each aspect of its illegal sales and marketing scheme, Defendant Schering would "profile" doctors using third-party services to obtain data on physicians writing prescriptions for patients with particular diseases. Many of those doctors who met Schering's "profile" were

educated on the off-label uses of Schering drugs and were lavished with illegal bribes and kickbacks in the form of grants, honoraria and other financial inducements to become "advisors," "investigators," or "speakers" promoting the off-label uses of Schering drugs.

32. Neuro-oncologists, for example, were singled-out as "initial targets" for Schering's Temodar marketing efforts because they "see 8 times as many pts. as oncologists [and are] early adapters [who] will overwhelmingly try new therapy before FDA approval." (SPNJ0322052). With respect to off-label Intron A marketing, Schering would obtain data on doctors who were prescribing BCG, a competitor's drug to treat superficial bladder cancer, and then it would specifically target those doctors with a barrage of off-label marketing techniques promoting Schering's drug.

33. Schering also engaged in off-label marketing that was aimed directly at patients. An agenda and slide presentation for Schering business planning during the Class Period states that "Key issue priorities" include "increase patient education effort for Temodar, especially in off-label indications." (SPNJ 0332041). To purportedly increase patient "education" Schering pumped its off-label message over the internet so that searches for certain off-label indications would drive unsuspecting patients to, for example, brain tumor websites that purported to provide independent information. The unsuspecting patients, many of

whom were gravely ill and desperate, had no idea that Schering had actually given large grants to these websites to carry and tout Schering's false and misleading off-label marketing messages. In this way, the patients were encouraged to request treatment with the Subject Drugs despite the fact that Schering knew at the time the data supporting such use was non-existent, inconclusive, weak, and (in most cases) corrupted by large Schering bribes.

34. Schering knew its multimillion dollar per-year off-label marketing efforts, based on false and misleading statements such as Temodar's crossing the blood-brain barrier, and Intron's therapeutic superiority were effective and resulted in increased profits. Schering specifically budgeted for off-label promotion of the Subject Drugs and kept track of how its off-label marketing translated into increased sales. An "action plan" for Intron, for example, contains a chart demonstrating that Schering budgeted $600,000 for a bladder cancer speakers' bureau targeted at urologists and that as a "measurable result" Schering reaped the benefits of "300 new patients" and $1.9 million based on "prescribing habits before and after [the seminar]." (SPNJ 0333362).

35. Schering encouraged its sales force to promote off-label uses for the Subject Drugs by offering huge compensation incentives for increased sales. A document describing Schering stock option incentives states that "Schering offers

truly unmatched opportunities for accumulating significant wealth." (SPNJ 0329195).

36. In addition to incentivizing its sales force, Schering also bribed physicians with kickbacks and gifts expressly intended to increase prescriptions. A description for a Schering field sales position blatantly describes the duties of a Schering sales representative as "optimiz[ing] utilization of samples, promotional items, and Travel & Entertainment in accordance with physicians' needs/potential to generate maximum market share and Return on Investment." (SPNJ 0330645). Schering expected its sales representatives to "influence[] prescribing habits and reinforce[] the endorsement of priority products by staff physicians." (SPNJ 0330661) The wide variety of means by which Schering trained its sales force to drive off-label sales is described in detail below. Schering knew all of these methods were illegal, based on false and misleading claims of therapeutic benefit, and on a false portrait of the underlying "science" and studies. Schering intended these false and misleading messages to generate off-label prescriptions for the Subject Drugs.

37. Because of its illegal sales and marketing scheme based on the wide dissemination of false and misleading information about the purported safety and efficacy of the Subject Drugs in treating off-label indications, Defendants caused the number of prescriptions of Subject Drugs to skyrocket throughout the Class

Period resulting in excess of $3.4 billion in revenues, representing ill-gotten gains to which Schering was not entitled.

III. PARTIES

38. Plaintiff, Heavy and General Laborers' Local Union 472/172 Welfare Fund ("Local 472/172 Fund"), is a Taft-Hartley welfare fund created pursuant to the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1001 *et seq.* Local 472/172 Fund is funded by contributions of participating employers and provides health and welfare benefits to covered employees and retirees. Local 472/172 Fund's principal place of business is located at 700 Raymond Boulevard, Newark, New Jersey. Local 472/172 Fund's health care coverage to eligible participants includes paying for medically necessary uses of prescription drugs. During the Class Period, Local 472/172 Fund paid for the Subject Drugs sold by Defendants as a result of Defendants' illegal and false sales and marketing scheme on behalf of persons participating in Local 472/172 Fund's healthcare plan. When Local 472/172 made payments for the Subject Drugs it was unaware of Defendants' illegal sales and marketing scheme, or the false representations contained therein.

39. Plaintiff, International Brotherhood of Teamsters Local No. 331 Health & Welfare Trust Fund ("Local 331 Fund"), is a joint union-employer Taft-Hartley trust fund, organized and operating in the State of New Jersey. Local 331

Fund's principal place of business is located at 117 West Washington Avenue, Pleasantville, New Jersey. Local 331 Fund's health care coverage for eligible participants includes paying for medically necessary uses of prescription drugs. During the Class Period, Local 331 Fund paid for the Subject Drugs sold by Defendants as a result of Defendants' illegal and false sales and marketing scheme on behalf of persons participating in Local 331 Fund's healthcare plan. When Local 331 Fund made payments for the Subject Drugs it was unaware of Defendants' illegal sales and marketing scheme, or the false representations contained therein.

40. Plaintiff, United American Insurance Company ("UAI"), an insurance company organized under the laws of the State of Delaware, is headquartered in Texas, and is licensed to do and is doing business in multiple states across the nation. UAI provides health care coverage, including coverage of medically necessary prescription drugs, to its members through the issuance of supplemental Medicare insurance policies. Pursuant to its policies, UAI's payments for the Subject Drugs are controlled by the amounts paid and allowed by Medicare. During the Class Period, UAI paid for the Subject Drugs sold by Defendants on behalf of its members as a result of Defendants' illegal and false sales and marketing scheme, and these payments were made by UAI throughout the United States, including the State of New Jersey. When UAI made payments pursuant to

its supplemental Medicare insurance policies, it was unaware of Defendants' illegal sales and marketing scheme, or the false representations contained therein.

41. Plaintiff, Blue Cross and Blue Shield of Alabama is a not-for-profit health care services corporation organized under the laws of the State of Alabama with its principal place of business located at 450 Riverchase Parkway East, Birmingham, Alabama. Blue Cross and Blue Shield of Alabama and its wholly-owned subsidiary, Cahaba Benefit Administrators (collectively "BCBSAL") provide health care coverage to its members, including medically necessary prescription drug coverage, through a variety of arrangements, including health indemnity coverage, managed care coverage, the issuance of Medicare supplemental policies and ERISA plan administration. During the Class Period, BCBSAL paid for the Subject Drugs on behalf of its members sold by Defendants as a result of Defendants' illegal and false sales and marketing scheme, and these payments were made throughout the United States, including New Jersey. When BCBSAL made payment for the Subject Drugs it was unaware of Defendants' illegal sales and marketing scheme, or the false representations contained therein.

42. Defendant, Schering, is a New Jersey corporation with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey. On August 7, 2009, shareholders of Schering approved a merger with Merck &Co., another pharmaceutical manufacturer. Merck & Co. shareholders have also

approved the deal, which is expected to close in the fourth quarter of 2009. Schering engages in the research, development, manufacture and marketing of prescription medicines and other therapeutic products. In 2005, Schering reported over $9.5 billion in sales, of which $1.96 billion – ***nearly 21% of the total*** – was attributable to sales of Temodar and Intron Franchise drugs.

43. During the relevant time period and up to April 2003, Defendant Kogan served as Schering's Chairman and Chief Executive Officer.

44. During the relevant time period and up to May 2002, Defendant Heiden served as Schering's Vice President for Marketing and Sales in the oncology and biotechnology business unit ("OBBU").

45. During the relevant time period, Defendant Naughton served as Schering's Senior Product Manager.

46. During the relevant time period, Defendants Kogan, Heiden and Naughton, assisted by other officers, senior managers and employees of Schering, devised and carried out the illegal sales and marketing scheme alleged herein.

47. Defendant, Schering Corp., is a New Jersey corporation with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey. Schering Corp. is a wholly-owned subsidiary of Schering. Upon information and belief, at all times relevant hereto, Schering Corp. directed, engaged, or otherwise assisted in the manufacture, distribution, sale, promotion and/or marketing of

Schering's prescription pharmaceuticals and, specifically, in the illegal and false sales and marketing scheme with respect to the Subject Drugs that is alleged herein.

48. Defendant, Schering Sales, is a wholly-owned subsidiary of Schering Corp. Schering Sales is a Delaware corporation with its principal place of business located in Kenilworth, New Jersey. During the Class Period, Schering Sales marketed and sold the Subject Drugs through a nationwide sales force that was divided among business units, one of which was the oncology and biotechnology business unit ("OBBU"). The OBBU sold and marketed the Subject Drugs, including Temodar and Intron A, directly to physicians across the country. As alleged herein, Defendant Schering Sales pled guilty to a federal criminal charge arising out of the illegal sales and marketing scheme alleged in this Consolidated Complaint, and made false statements to the FDA and to the targets of its marketing efforts in connection with that scheme.

49. Defendant ITGI is a wholly-owned subsidiary of Schering with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey. During the Class Period, ITGI played a critical role in the illegal marketing of Schering's Subject Drugs because it entered into contracts with and wrote checks to physicians and third-party service providers to facilitate and support many facets of Defendants' illegal and false sales and marketing scheme.

50. Defendants ABC Corporations 1-10, whose present identities are unknown, are business entities that participated in or assisted Defendants in the illegal and false sales and marketing scheme alleged herein. Named Plaintiffs will seek leave to amend this Complaint once Named Plaintiffs learn the identities of these corporations through further investigation and/or discovery.

51. Defendants John Does 1-10 and Jane Does 1-10, whose present identities are unknown, are individuals, including physicians and officers, senior managers and employees of Schering, who participated in or assisted Defendants in the illegal and false sales and marketing scheme alleged herein. Named Plaintiffs will seek leave to amend this Complaint once Named Plaintiffs ascertain the identities of these individuals through further investigation and/or discovery.

52. Defendants ABC Corporations and Jane and John Does, acted by and through their employees, agents and servants, actual or ostensible, who then and there were acting within the course and scope of their duties, agency, employment and/or authority in conspiring, participating, assisting and otherwise acted in concert with Defendants in the illegal and false sales and marketing scheme alleged herein. The wrongful conduct complained of herein was uniformly adopted and carried out by Defendants, who were acting in concert with John and Jane Does and ABC Corporations. Named Plaintiffs will seek leave to amend this

document once Named Plaintiffs have ascertained the identities of these institutions and/or persons through further investigation and/or discovery.

53. The acts alleged herein to have been committed by each of the Defendants were authorized, ordered, done and/or ratified by their respective officers, directors, agents, employees and/or representatives while engaged in the management, direction, control and/or transaction of their respective business affairs. Various persons and/or firms not named as Defendants herein have participated as co-conspirators in the violations and wrongful acts alleged herein and have performed acts and made statements or omissions in furtherance thereof.

54. The research, design, marketing and advertising for the Subject Drugs was centralized in Schering's New Jersey offices, and Defendants' illegal and false sales and marketing scheme was designed, agreed upon and carried out from Schering's corporate headquarters. Accordingly, the wrongful acts and omissions complained of herein emanated from the State of New Jersey.

IV. JURISDICTION AND VENUE

55. This Court has subject matter jurisdiction over this class action pursuant to the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d), because members of the nationwide Class are citizens from a state different from Defendants' corporate residence of New Jersey and the aggregate amount in controversy exceeds $5,000,000. This Court has personal jurisdiction over the

parties because Named Plaintiffs are located and operating in this State or otherwise submit to the jurisdiction of this Court, and Defendants are headquartered in this State and systematically and continuously conduct business in this State, including marketing, advertising and selling drugs, such as the Subject Drugs, to residents in this State.

56. Venue is proper in this District under 28 U.S.C. § 1391 because Defendants engaged in substantial conduct relevant to Named Plaintiffs' claims within this District and caused harm to Named Plaintiffs and Class members residing within this District.

57. Venue is also proper in this District pursuant to transfer orders issued by the Judicial Panel on Multidistrict Litigation.

V. FACTUAL BACKGROUND

A. State And Federal Laws Prohibit Defendants From Making Payment To Doctors To Write Prescriptions

58. Schering's scheme to bribe and provide other inducements to doctors to write prescriptions for the Subject Drugs violated the following state and federal laws:

1. The New Jersey Commercial Bribery Statute

59. During the Class Period, by paying physicians to prescribe certain Subject Drugs, Defendants violated applicable state commercial bribery laws, including the New Jersey Commercial Bribery Statute, N.J.S.A. § 2C:21-10.

Section 2C:21-10 states: "A person commits a crime if he solicits, accepts or agrees to accept any benefit as consideration for knowingly violating or agreeing to violate a duty of fidelity to which he is subject as . . . [a] physician." Further, the statute provides: "A person commits a crime if he confers, or offers or agrees to confer, any benefit the acceptance of which would be criminal under this section." N.J.S.A. § 2C:21-10(c).

60. Each separate violation of the New Jersey Commercial Bribery Statute committed and/or aided and abetted by Defendants constitutes an act of "racketeering activity," as that term is defined by RICO, 18 U.S.C. § 1961(1)(A) (defining "racketeering activity" to "mean[] … any act … involving … bribery … which is chargeable under State law and punishable by imprisonment for more than one year"), and NJ RICO, N.J. Stat. Ann. § 2C:41-1(a)(1)(g) & (a)(2) (defining "racketeering activity" to "mean[] … bribery" and "any conduct defined as 'racketeering activity' under" 18 U.S.C. § 1961(1)(A)"). Upon information and belief, Defendants traveled in interstate or foreign commerce or used the U.S. mail or any facility in interstate commerce with intent to promote, manage, establish, carry on, or facilitate the promotion, management, establishment, or carrying on of any "unlawful activity," namely, bribery, and such acts constitute a violation of the Travel Act, 18 U.S.C. § 1952, which is also a predicate act of "racketeering" activity under the above-referenced provisions of RICO and NJ RICO.

2. The Federal Medicare Anti-Kickback Statute

61. The Medicare Anti-Kickback Statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for federally-funded medical service, including services provided under the Medicare and Medicaid. In particular part, the statute states:

> Whoever knowingly and willfully offers or pays [or solicits or receives] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal Health care program, or to purchase, lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony.

42 U.S.C. § 1320(a)-7b(b).

62. During the Class Period, Schering bribed physicians to prescribe certain Subject Drugs, in violation of the Medicare Anti-Kickback Statute. Upon information and belief, the payment of such bribes was carried out by Defendants using the U.S. Mail and/or interstate wire facilities, and each separate violation of the Medicare Anti-Kickback Statute committed and/or aided and abetted by Defendants constitutes a violation of the federal mail and/or wire fraud statutes, 18 U.S.C. §§ 1341 & 1343, which is also a predicate act of "racketeering" activity under the above-referenced provisions of RICO and NJ RICO.

B. The FDA's Regulation Of Drug Manufacturers

63. Schering's off-label marketing scheme violated federal laws and regulations governing how prescription drug manufacturers may promote drugs.

1. Prescription Drugs Must Be Approved By The FDA

64. No drug may be sold in interstate commerce unless it is approved by the FDA. *See* 21 U.S.C. § 355(a). In order for the FDA to approve a drug, the manufacturer must show that a drug is "safe for use" for all "conditions prescribed, recommended, or suggested" on a drug's label. Therefore, when the FDA approves a drug, it does not approve that drug for illness in general, but only for specific uses listed on the drug's label.

65. To demonstrate to the FDA that drugs are safe and effective, drug manufacturers, such as Schering, must generally undertake expensive clinical trials that test the drug's risks and benefits. *See* 21 C.F.R. § 312.21 (describing three phases of clinical trials that drugs generally undergo to receive FDA approval).

66. For certain drugs that show promise in treating serious or life-threatening illnesses, the FDA will expedite approval based on less exhaustive clinical trials. *See* 21 C.F.R. §§ 314.500-510. Drug manufacturers, however, are obligated to continue to investigate such drugs to confirm that they provide a clinical benefit to patients and submit all promotional materials to the FDA for

review. *Id.* If the additional studies confirm the initial benefits, the FDA may approve the drug under traditional procedures. *See* 21 C.F.R. § 314.560.

67. Although the FDA approves drugs only for certain uses, doctors may prescribe drugs approved by the FDA for any purpose.

2. Under Applicable Federal Law, Drug Manufacturers May Not Market Drugs For Off-Label Use

68. Where a drug company promotes a drug for uses not indicated on the drug's label, such drugs are misbranded and may not be distributed in interstate commerce. *See* 21 U.S.C. § 331(a) & (d). A drug may be misbranded if the manufacturer directly advertises a drug for off-label use or employs a third party to promote a drug for off-label uses. As alleged herein, during the Class Period Schering employed both direct and indirect methods to advertise the Subject Drugs for off-label purposes.

69. A drug is considered misbranded if its label does not contain, *inter alia*, "[s]tatements of all conditions, purposes, or uses for which such drug is intended." 21 C.F.R. § 201.5. The applicable regulation states that the term "intended," as used in 21 C.F.R. § 201.5, refers to "the objective intent of the persons legally responsible for the labeling of drugs [*e.g.*, the manufacturer]." 21 C.F.R. § 201.128.

70. When a drug manufacturer directly advertises a drug for a particular use, that use is considered an "intended" use and must be described on the drug's

label. *See* 21 C.F.R. § 201.128 ("[I]ntent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by . . . [manufacturers] or their representatives.").

71. When a drug manufacturer promotes off-label use indirectly using third parties – for example, by sponsoring continuing medical education ("CME") courses that promote off-label use – such off-label use may be considered an "intended" use if the manufacturer is not sufficiently independent from the third party. *See* 21 C.F.R. § 201.128 ("It may be shown by the circumstances that the article is, with the knowledge of . . . [the manufacturer] or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.").

72. Under federal law, a drug manufacturer may directly distribute information about the off-label use of approved drugs in only three circumstances: (a) in response to an "unsolicited request from a healthcare practitioner;" (b) where a study has been relied upon by the FDA in approving a drug but contains information at variance with the label, the manufacturer may distribute articles that report on the study where, *inter alia*, the articles deal principally with the on-label indication and the manufacturer discloses how effectiveness rates, data, analyses, uses, regimens, or other information discussed in the article differ from the label; and (c) where a textbook has off-label information, a manufacturer may distribute the textbook if it was not written, edited, or significantly influenced by

the manufacturer and was distributed through conventional channels, not just by the manufacturer. Additionally, the materials must be submitted in an unabridged form and may not be false or misleading.

C. Prohibition Against Causing False Statements To Be Made To The United States Government

73. Schering's promotion of drugs for non-medically accepted indications through false and misleading claims violated The False Claims Act ("FCA"), 31 U.S.C. § 3729, which creates civil liability for any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid
>
> ***
>
> [in the amount of] not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person . . .

74. As set forth below, during the Class Period, Defendants' illegal and false sales and marketing campaign caused doctors to seek inappropriate reimbursement from Medicare and Medicaid in violation of the FCA.

1. Medicare

75. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare Program, to pay for the costs of certain health care

services. Entitlement to Medicare is based on age, disability, or affliction with certain diseases. *See* 42 U.S.C. § 1395-1395ccc. Under the Medicare program, eligible persons may enroll in Medicare Part B to obtain benefits, such as physician services, durable medical equipment and certain pharmaceuticals including certain Subject Drugs such as Intron A and Temodar. 42 U.S.C. § 1395k(a)(2)(B). When Medicare Part B covers a drug, it only reimburses medical providers 80% of the allowed amount. The remaining 20% that is owed by the Medicare beneficiary is called the "co-payment" amount. Medicare beneficiaries may purchase Medicare supplemental policies, such as those provided by Named Plaintiffs UAI and BCBSAL, to cover the co-payment amount. These policies are sometimes referred to as "Medigap" insurance policies.

76. The Medicare statute, 42 U.S.C. § 1395y(a)(1)(A), prohibits Medicare from paying for any item or service not reasonable and necessary for the diagnosis and treatment of an illness or injury. Medicare has specific requirements that must be met before it will pay for an off-label use of an anti-cancer drug. The coverage policy is articulated in Section 2049.4f of the MEDICARE CARRIERS MANUAL ("MCM"):

> FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. In the case of drugs used in anti-cancer chemotherapeutic regimen, unlabeled uses

> are covered for a medically accepted indication as defined as §2049.4.C.
>
> Section 2049.C of the MCM provides, in part:
>
> > Contractors must not deny coverage based solely on the absence of FDA approved labeling for the use, if the use is supported by one of the following and the use is not listed as "not indicated" in any of the three compendia ...American Hospital Formulary Service Drug Information ... American Medical Association Drug Evaluations ... United States Pharmacopoeia Drug Information (USPDI), ... or "use supported by clinical research that appears in peer reviewed medical literature."

77. By misleading, bribing and otherwise inducing physicians to prescribe Subject Drugs for off-label uses and thereby causing physicians to seek inappropriate reimbursements from Medicare, during the Class Period, Schering caused Medicare to pay for an increased number of Subject Drugs in violation of the FCA. Upon information and belief, because such reimbursement requests and the reimbursements themselves involved the use of the U.S. Mail and/or interstate wire facilities, each such request and/or reimbursement constitutes a violation of the federal mail and/or wire fraud statutes, 18 U.S.C. §§ 1341 & 1343, and constitutes an act of "racketeering activity," as that term is defined by RICO, 18 U.S.C. § 1961(1), and NJ RICO, N.J. Stat. Ann. § 2C:41-1(a)(1)(g) & (a)(2).

2. Medicaid

78. Medicaid is an entitlement program jointly funded by the State of New Jersey and other states and the U.S. Government that pays medical costs for

the poor. Under federal law, the Medicaid program cannot cover the cost of prescription drugs unless the drug is identified as a "covered outpatient drug[]." 42 U.S.C. § 1396b(i)(10). The definition of covered outpatient drugs excludes any drug not used for a "medically accepted indication." 42 U.S.C. § 1396r-8(k)(2)-(3) ("[A covered outpatient drug] does not include any such . . . drug or biological used for a medical indication which is not a medically accepted indication"). A "medically accepted indication" in turn is defined as a "use for a covered outpatient drug which is approved under the Federal Food, Drug & Cosmetic Act [21 U.S.C. § 301 *et seq.*]" or a use which is "supported by one or more citations included or approved for inclusion in any of the compendia" listed in the statute. *See* 42 U.S.C. § 1396r-8(k)(6); *see also* 42 U.S.C. § 1396r-8(g)(1)(B)(i) (identifying compendia as consisting of: American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information and the DRUGDEX Information System).

D. The Subject Drugs

1. <u>Temodar</u>

79. Defendants manufactured, distributed, promoted, marketed and sold Temodar, a brand name prescription drug generically known as temozolomide.

(a) Approval History

80. In or about 1998, Defendants submitted to the FDA a New Drug Application ("NDA") for approval of Temodar for use in treatment of three forms

of brain cancer: (a) refractory anaplastic astrocytoma (an aggressive form of brain cancer that does not respond to other drug therapies such as nitrosurea and procarbazine); (b) recurrent glioblastoma multiforme (an aggressive form of brain cancer that has returned after a period in which it could not be detected); and (c) metastatic malignant melanoma (melanoma that has spread to other parts of the body). At the time, Temodar was a "new drug" within the meaning of 21 U.S.C. § 321(p) and 21 C.F.R. § 310.3(h)(4) & (5). The FDA considered Temodar under its accelerated approval procedures for new drugs for serious or life-threatening illnesses. *See* 21 C.F.R. § 314.510.

81. Both anaplastic astrocytoma and recurrent glioblastoma multiforme are gliomas, or primary tumors that originate in the brain. Metastases, such as metastatic malignant melanoma, start in another part of the body and spread to the brain.

82. In or about August 1999, Temodar was approved by the FDA on an accelerated basis under 21 C.F.R. §§ 314.510 to treat only "adult patients with refractory anaplastic astrocytoma, *i.e.*, patients who have experienced disease progression on a drug regimen containing nitrosurea and procarbazine."

83. In March 2005, the FDA approved a broader indication for Temodar. First, the FDA approved Temodar to treat "adult patients with newly diagnosed glioblastoma multiforme concomitantly with radiotherapy and then as maintenance

treatment." Second, the FDA approved Temodar for the treatment of "adult patients with refractory anaplastic astrocytoma, *i.e.*, patients who have experienced disease progression on a drug regimen containing nitrosurea and procarbazine," under traditional FDA procedures. Previously, the FDA only approved this indication on an accelerated basis.

84. The FDA did not then or thereafter approve Temodar for treatment of any other gliomas such as newly diagnosed anaplastic astrocytomas. Further, the FDA never approved Temodar for ***any*** brain metastases.

(b) Temodar's Dangerous Side Effects

85. Although Temodar has been shown to benefit some patients with certain types of brain tumors, it can cause certain serious side effects, including nausea, vomiting, anorexia, alopecia (hair loss), headache, fatigue, constipation, convulsions, weakness, and thrombocytopenia (low blood platelets).

2. Intron Franchise Drugs

86. Defendants manufactured, distributed, promoted, marketed and sold: (a) Intron A, a brand name prescription drug generically known as interferon alfa-2b, recombinant; (b) PEG-Intron a brand name prescription drug generically known as Peginterferon alfa-2b; (c) Rebetol; a brand name prescription antiviral drug generically known as ribavirin; and (d) Rebetron, a brand name for Rebetol and Intron A sold in combination.

(a) Approval History

87. The FDA first approved Intron A in 1986 to treat hairy cell leukemia. Following numerous clinical trials, the FDA approved Intron A:

a. as adjuvant to surgical treatment in patients 18 years of age or older with malignant melanoma who are free of disease but at high risk for systemic recurrence, within 56 days of surgery;

b. for follicular Non-Hodgkin's Lymphoma;

c. for condylomata acuminate [genital warts];

d. for AIDS-Related Kaposi's Sarcoma;

e. for the treatment of chronic hepatitis C in patients 18 years of age or older with compensated liver disease [where the liver is damaged but continues to function] who have a history of blood or blood-product exposure and/or are HCV antibody positive; and

f. for the treatment of chronic hepatitis B in patients 1 year of age or older with compensated liver disease.

88. In 1998, the FDA approved Rebetron, a combination therapy consisting of Rebetol and Intron A packaged together to treat Hepatitis C in patients with compensated liver disease.

89. In 2001, the FDA approved Peg-Intron, a longer lasting form of Intron A, for patients with compensated liver disease. Also, in 2001 the FDA approved a stand alone package for Rebetol and approved the use of Rebetol with Peg-Intron to treat Hepatitis C.

90. The FDA has ***not*** approved Intron A to treat superficial bladder cancer, renal cell carcinoma, chronic myelogenous leukemia, myeloma, metastatic

melanoma, and Peyronie's disease -- uses for which Schering heavily marketed the drug during the Class Period.

91. Further, the FDA never approved any Intron Franchise Drug for Hepatitis C patients with normal liver enzymes. Abnormal liver enzymes may be an indication of an unhealthy liver. Additionally, the FDA never approved the use of a high-dose Intron A or Peg-Intron where Hepatitis C patients did not respond to Rebetron. Nevertheless, during the Class Period, Schering heavily marketed the drugs for these indications.

(b) Intron Franchise Drugs Used To Treat Hepatitis C

92. Intron Franchise Drugs are often not helpful in treating Hepatitis C, a largely asymptomatic disease that may cause harm to the liver after a latency period that can last decades. Many people die of other causes well before they feel the effects of Hepatitis C.

93. Further, Intron Franchise Drugs only provide limited benefits in treating Hepatitis C for persons without evidence of liver disease. Hepatitis C is considered eradicated where there is a sustained virologic response (SVR), meaning that tests can no longer detect Hepatitis C RNA in the blood. Depending on what strain of Hepatitis C a person has, Intron Franchise Drugs may not be effective in over one-half of Hepatitis C patients. Dorris B. Strader, *Diagnosis,*

Management, and Treatment of Hepatitis C, 36 HEPATOLOGY 1147, 1153 (April 2004) (the "Guidelines").

94. Because of the limited efficacy of Intron Franchise Drugs and the slow developing or non-existent risks of Hepatitis C, not all patients should be prescribed drugs to treat the disease. The Guidelines state: "Treatment decisions should be individualized based on the severity of liver disease, the potential of serious side effects, the likelihood of treatment response and the presence of co-morbid conditions." Physicians must weigh numerous factors before deciding to prescribe Intron Franchise Drugs, including the presence of liver damage, history of depression, presence of other conditions making drug side effects more likely or harmful, history of alcohol and drug use, and a patient's attitude towards treatment.

95. Indeed, Kathleen Hurtado, the former U.S. Vice President of Oncology/Biotech for Schering, who preceded Heiden in the position, stated that she wanted to narrow the population of potential Intron patients, but that her colleagues at Schering did not want to limit their sales potential, and instead wanted to market Intron to all potential patients. (HHS-OIG Report of Interview, Kathleen Hurtado, June 26, 2003, at 2 (HHS-OIG 000307)).

96. For many patients, lifestyle changes – such as avoiding alcohol and maintaining a healthy weight – and monitoring for any progression of Hepatitis C may be a better treatment alternative than using Intron Franchise Drugs.

97. Despite the drugs' dangerous side effects and limited benefits, during the Class Period, Schering attempted to tip the scales in favor of treatment by paying physicians to prescribe Intron Franchise drugs for Hepatitis C.

(c) Dangerous Side Effects

98. Both Intron A and PEG-Intron cause serious side effects and both have a "black box" warning on their label, which is the most serious warning the FDA can require. Both "black box" warnings state that "[the drug] may cause or aggravate fatal or life-threatening neuropsychiatric, autoimmune, ischemic [inadequate blood flow to part of the body], and infectious disorders. Patients should be monitored closely with periodic clinical and laboratory evaluations. Patients with persistently severe or worsening signs or symptoms of these conditions should be withdrawn from therapy." The life-threatening neuropsychiatric disorders include, but are not limited to, suicidal and homicidal thoughts, hallucinations, and bipolar disorders.

99. In addition, Intron A and/or PEG-Intron can cause a laundry list of other side effects including, but not limited to, heart attack, respiratory failure, pneumonia, loss of vision, pancreatitis, hypothyroidism, hyperthyroidism, colitis, and bone marrow toxicity.

100. Rebetol also has very serious side effects including, but not limited to, causing severe birth defects and hemolytic anemia (an inadequate number of red

blood cells causing fatigue, shortness of breath, dark urine, enlarged spleen and rapid heart rate).

E. Schering Sales Pleads Guilty To A Federal Crime And Schering Settles The Government's Civil Claims

101. On August 29, 2006, the U.S. Government announced that Defendant Schering Sales had agreed to plead guilty of one charge of conspiracy to make false statements to the federal government relating to concealing the off-label marketing of Temodar and Intron A. On the same day, Schering agreed, without admitting wrongdoing, to settle civil claims brought on behalf of, *inter alia*, the Medicare and Medicaid programs for damages caused by Schering's illegal sales and marketing scheme to inflate sales of Temodar and Intron A through off-label marketing. In total, Schering agreed to pay $255 million to resolve civil liability and Schering Sales paid a $180 million criminal fine.

1. Schering Sales Pleads Guilty

102. Judge Patti B. Saris of the District of Massachusetts accepted Schering Sales' criminal plea of guilt on or about January 17, 2007. In accepting that guilty plea, Judge Saris made clear her disdain for Defendants' criminal actions, stating in relevant part:

> [I]t's been upsetting to me how many of the big pharmaceutical companies have engaged in what I view as clearly illegal behavior in terms of off-label marketing. . . . [I]t is against the law to market if it's not an FDA-approved indication. I do not accept that there is a First Amendment right to market something that does not get FDA

> approval. . . . But if it's ever been unclear to Schering or anyone else, you cannot market for indications that the FDA has not approved or has rejected. . . . *The thing that was so upsetting to me is, it wasn't just the Claritin, but it was people with brain cancer and serious illnesses.* And this isn't the only company. It just almost seems as if the pharmaceutical companies said "Yeah, yeah, and yeah" to the FDA and then went and did it anyway. . . . [Y]ou can't thumb your nose at the FDA . . . [and] at the end of the day you can't market off-label. So I don't know how further to send this message if other people from the industry are listening and watching, but it's wrong.
>
> (emphasis added).

103. As alleged in the Criminal Information, Schering made false statements to the FDA in response to a June 28, 2001 letter sent by the FDA's Division of Drug Marketing, Advertising, & Communications ("DDMAC") notifying the Company that the FDA had identified promotional activity that provided false or misleading information about the drug Temodar (the "FDA Letter"). Specifically, the FDA Letter cited Schering for conducting off-label marketing of Temodar at the 37th American Society of Clinical Oncology Annual Meeting ("ASCO Meeting") held in San Francisco, California, in May 2001. (SPNJ 0331349).

104. At a Schering exhibit at the ASCO Meeting, the FDA witnessed a Schering representative stating to attendees that Schering had "tons of data on first line use" of Temodar, meaning that the drug could be used as an initial treatment for brain tumors, even though that statement was false. (SPNJ 0331349). In truth, at the time, Temodar was only indicated for "the treatment of adult patients with

refractory anaplastic astrocytoma, *i.e.*, patients at first relapse who have experienced disease progression on a drug regimen containing a nitrosourea and procarbazine." Schering's promotional claims that "tons of data" supported first line use of Temodar for brain tumors was false and misleading. The data Schering had was either non-existent, inconclusive, weak, and/or "bought" and corrupted by Schering's illegal bribes and kickbacks.

105. Additionally, during the ASCO Meeting, a Schering sales representative stated that Temodar's survival results were compared to a placebo in a particular study. (SPNJ 0331349). However, the study in question did not compare Temodar to a placebo. Rather, it was a single-arm study, which does not compare a drug's efficacy to that of a placebo. Thus, in this instance, Schering made specific false statements about Temodar's efficacy.

106. The FDA Letter stated that Schering had disseminated "false or misleading information about Temodar"; that Defendant Schering "promoted Temodar for the unapproved use in first line therapy of anaplastic astrocytoma"; and demanded that Schering "immediately cease making such violative statements and any other promotional activities or materials for Temodar that make the same or similar claims or presentations."

107. At the time of receipt of the FDA Letter, according to the Criminal Information filed by the U.S. Government, Schering Sales and its co-conspirators

knew that Schering's sales force, at the direction of the corporate home office in New Jersey and under the direct supervision and instigation of Defendants Kogan, Heiden and Naughton, was engaged in the widespread unlawful off-label marketing of Intron A for superficial bladder cancer, and widespread unlawful off-label marketing of Temodar for conditions other than refractory anaplastic astrocytoma.

108. According to the Criminal Information, Schering "aggressively" trained the OBBU sales force to market Temodar and Intron A for off-label use through "training classes, ride alongs with managers, district meetings, teleconferences, and sales meetings." Further, according to the U.S. Government, Schering's marketing department "provided the sales force a plan of action that targeted off-label sales." Further, according to the Information, Schering's headquarters provided to sales representatives "clean copies of 'for your information only' scientific articles and abstracts" to use with physicians. The Information stated that Schering's sales representatives were provided with "substantial budgets for advisory boards, speakers, entertainment, and preceptorships to assist in obtaining off-label sales."

109. In the letter to the FDA, Schering further represented that an electronic message (e-mail) was that day being sent to all Schering Temodar sales representatives regarding the "importance of appropriate and accurate promotion"

and that the sales force was being "reminded that they may only discuss the approved indication for this product."

110. At that time, Schering Sales and its co-conspirators knew that the e–mail was was not designed or intended to deter off-label promotion because it would be substantially overridden by the training, incentives, and support, carried out under the supervision of Defendants Kogan, Heiden and Naughton, to promote off-label uses of the drug. Upon information and belief, the dissemination of that e-mail constituted a violation of the federal wire fraud statute, 18 U.S.C. § 1343.

111. Schering successfully concealed its illegal and fraudulent marketing practices from the FDA and, on or about August 2, 2001, the FDA sent a letter informing Schering that, based upon Schering's representations, the FDA considered the matter closed. Nevertheless, Schering continued its illegal and false sales and marketing scheme.

112. In the above-referenced criminal and civil proceedings before Judge Saris, the U.S. Government and Schering agreed that Schering had been enriched by $94,687,000 in before-tax profit as a result of its off-label promotion of Temodar, and by $29,492,000 in before-tax profit as a result of its off-label promotion of Intron A between July 2001, when it gave the FDA false assurances about its sales and marketing scheme, and December 2003. Thus, Schering

acknowledged that during that 29-month period alone, it was enriched by over $123 million in before-tax profits.

113. To calculate gain from off-label sales of Intron A and Temodar due to the off-label marketing in the above-referenced court proceedings, the U.S. Government took the gross sales of the Subject Drugs and then used internal Schering estimates to determine the percentage of such drugs that were prescribed off-label. Once the Government attributed a dollar amount to Schering's off-label sales, it applied a causation factor to determine the percentage of off-label sales due to illegal marketing, as opposed to independent physician decisions. This causation factor took into account, *inter alia*, the following variables: evidence of off-label promotion activities and existence of clinical studies supporting off-label use of the drug.

2. Schering Settles the U.S. Government's Civil Claims Relating To The Illegal Promotion of Temodar and Intron Franchise Drugs

114. On August 29, 2006, Schering agreed to settle civil claims that it defrauded U.S. Government health benefit programs, including the prescription benefit programs of Medicare, Medicaid, the Veteran's Administration, the Department of Defense, and FEHBP.

115. The U.S. Government settled civil claims against Schering for the following actions involving, *inter alia*, violations of the False Claims Act and Anti-Kickback Statute:

a. Paying illegal remunerations to induce physicians to start patients on PEG-Intron, Rebetron, and PEG-Intron Combination Therapy for patients with Hepatitis C from January 1999 to December 2002.

b. Paying illegal remunerations to physicians to induce physicians to prescribe Temodar for brain tumors and brain metastases from September 1999 through December 2003.

c. Marketing Temodar for off-label uses between September 1999 and December 2003 for non-medically accepted indications.

d. Paying doctors illegal remunerations for prescribing Intron A for superficial bladder cancer and illegally marketing Intron A to treat superficial bladder cancer.

116. Schering agreed to settle these claims without admitting or denying wrongdoing.

F. During The Class Period, Schering's Illegal Sales And Marketing Scheme Caused Financial Harm To Third-Party Payors

117. Named Plaintiffs and Class members are TPPs who pay part or all of the purchase price of medications such as the Subject Drugs.

118. Some TPPs utilize pharmacy benefit managers ("PBMs") to instruct and/or inform them on which prescription drugs to provide their members and/or approve for coverage.

119. PBMs prepare a list of approved-for-coverage drugs known as a "*formulary*." To get on the formulary, a drug is assessed by the PBM for clinical

safety, efficacy and cost-effectiveness. These facts are well known to drug manufacturers such as Schering and, in fact, pharmaceutical companies including Schering carefully track formulary status of their products with TPPs.

120. Due to the large number of drugs purchased by TPPs, it is vital for a drug manufacturer's economic interests to have its product listed on as many of the TPP Class members' formularies as possible.

121. However, once a drug is on a formulary, as a general rule, TPPs do not check for off-label uses of medications, which are left instead to physicians to determine if a prescription is medically necessary, safe and effective.

122. Schering expended vast sums of marketing money during the Class Period to ensure that the Subject Drugs were placed on formularies and to ensure that PBMs (and, in turn, TPPs) bought into their false and misleading off-label marketing messages. Schering intended that its false and misleading off-label marketing messages reached PBMs (and, in turn, TPPs) and knew that TPPs, like Named Plaintiffs, were foreseeable victims of Schering's illegal, off-label marketing campaign.

123. Defendants' wrongful activities harmed TPPs by causing them to place Temodar and Intron Franchise Drugs on their formularies, and then engaging in an illegal and false sales and marketing scheme to cause TPPs to pay for drugs

in cases where the drugs were ineffective, unsafe, and/or when they were more expensive than more or equally effective treatments.

124. During the Class Period, Schering's illegal and false sales and marketing scheme harmed all TPPs – even those that do not have formularies – because Schering's scheme caused physicians to write prescriptions for certain Subject Drugs when the drugs were ineffective, unsafe or when they were more expensive than more or equally effective treatments.

125. Schering's false marketing scheme was aimed at all levels of the pharmaceutical prescription chain. This included, among others, the FDA, TPPs, PBMs, all medical professionals and quasi-professionals, and individual patients. Schering knows TPPs pay for the Subject Drugs. Schering intended that Named Plaintiffs receive and rely upon the false and misleading statements that Schering put forth to market and sell the Subject Drugs. It was more than reasonably foreseeable that Named Plaintiffs would receive and rely upon Schering's false and misleading statements.

126. All channels of reliable medical information had been thoroughly corrupted by Schering's multimillion-dollar-a-year, illegal marketing scheme. This was the intended result of Defendants' scheme.

127. During the Class Period, the Named Plaintiffs purchased the Subject Drugs for ineffective or unsafe off-label uses on account of Schering's

promulgation of false and misleading information in its massive off-label marketing campaign, causing Named Plaintiffs to suffer damages.

128. Named Plaintiff BCBSAL paid over $41 million for the Subject Drugs during the Class Period, representing hundreds of thousands of prescriptions written for its members. Named Plaintiff UAI paid millions more for the Subject Drugs during the Class Period, representing thousands of prescriptions written for its members. Named Plaintiff Local 472/172 Fund had at least 15 patients use Intron Franchise Drugs (totaling 190 prescriptions) and at least 3 patients use Temodar therapy (42 prescriptions). Named Plaintiff Local 331 Fund had at least 2 patients who were prescribed the Intron Franchise Drugs.

129. It is reasonable to infer, and unreasonable not to infer, that at least some of the hundreds of thousands of patients and hundreds of thousands of prescriptions written for Named Plaintiffs' members relating to the Subject Drugs were written off-label as a result of Schering's false claims that, *e.g.*, Temodar crossed the blood-brain barrier. ***Eighty-five to ninety-five percent of Temodar's annual sales during the Class Period was off-label.*** (FDA-OCI 0000266). Over thirty percent (30%) of Intron's annual sales during the Class Period was also driven by prescriptions in off-label indications.

130. Accordingly, each of the Named Plaintiffs suffered damages because they were forced to pay for Temodar and Intron Franchise Drugs for off-label uses

that were ineffective and unsafe, and/or inferior to alternative, lower-priced medications that were equally or more effective than the Subject Drugs.

131. As a result of Schering's illegal and false sales and marketing scheme, and the foreseeable consequences thereof, Named Plaintiffs and Class Members sustained economic loss any or all of the following ways:

a. the price differential between the price of the Subject Drugs and cheaper available alternatives that were equal to or better than the Subject Drugs;

b. the full amounts paid for off-label prescriptions resulting from Schering's false and misleading claims and falsely touted "science-based" marketing;

c. the percentage of the Subject Drugs' costs attributable to Defendants' illegal, false and misleading sales and marketing scheme; and

d. the 20% of Medicare supplemental policies' reimbursements for Schering's unlawfully marketed drugs.

VI. SCHERING'S SCHEME TO DEFRAUD PLAINTIFFS AND CLASS MEMBERS

A. Schering Made False And Misleading Statements In Promoting The Subject Drugs For Off-Label Use

132. Using false and misleading statements, Schering marketed the Subject Drugs for off-label use to ensure company revenues continued to grow, even though the Subject Drugs were either less safe and less effective or cost more than equally (or more) effective competing treatments. Schering carefully identified areas of expansion and doctors willing to be influenced. Schering's illegal sales and marketing scheme was so pervasive that a Schering sales representative stated

that he would be done with a week's worth of work "at noon on Monday" if he did not market certain of the Subject Drugs for off-label use. As described, false and misleading statements were central to Schering's push to expand the Subject Drugs' market into off-label uses.

133. For example, in 2003, Schering identified brain metastases, primary central nervous system cancers, and metastatic melanoma as "potential areas of opportunity and future growth." (SPNJ 0120388). Temodar is approved to treat none of these illnesses.

134. Schering rolled the dice and chose to break the law rather than enter into the costly FDA-approval process. As a former Schering sales representative Tracy Stein reported, Defendant Kogan stated that there was no reason to "buy the cow when the milk is free." (Email from former Schering sales representative Tracy Stein, dated Friday, April 28, 2006). In other words, because Defendant Schering was marketing – and successfully selling – the Subject Drugs for unapproved uses, no reason existed to spend time and money to seek additional approved indications from the FDA.

135. During the Class Period, using the U.S. Mail, interstate wire facilities and interstate travel, Schering employed a wide array of devices to fraudulently promote off-label uses of Temodar and Intron Franchise Drugs, even though the Subject Drugs were less effective, less safe and/or more costly than equally safe

and effective competing drugs. Specifically, Schering used the following methods (among others) to disseminate false and misleading off-label information about Temodar and Intron Franchise Drugs:

- Continuing medical education programs ("CME's"), which, while dressed up as "independent," were not independent but were devised, directed and controlled by Schering's sales representatives, under the direct supervision of Defendants Heiden and Naughton to promote off-label uses of Temodar and Intron Franchise drugs.
- The Consulting Care Network, a program where physicians could call Schering-paid physicians who promoted Schering drugs for off-label use.
- National/Regional/District Advisory Board meetings, where Schering marketed drugs off-label to physicians.
- Speaker Training Meetings, where Schering-paid physicians trained Schering speakers to discuss Temodar and Intron Franchise Drugs off-label using company-approved language and themes.
- Investigatory Meetings, where Schering-paid doctors marketed drugs off-label to physicians.
- In person detailing meetings with physicians and their staff.

1. Schering Made False and Misleading Statements In Illegally Marketing Temodar For Off-Label Use

136. Schering's marketing plans were never even remotely related to the relatively small population of cancer patients that the drug was approved to treat. Upon Temodar's launch, Heiden sent a blast voicemail to the entire oncology sales force stating: "I want every CML ["Chronic myelogenous leukemia"], bladder and melanoma patient possible treated with Intron A and ultimately with Temodar."

Schering's strategy in marketing Temodar was not based on the drug's usefulness or efficacy but on Schering's leveraging its relationships with doctors prescribing Intron A to induce them to prescribe Temodar. (HHS-OIG 000353).

137. As part of their illegal sales and marketing scheme, Schering illegally marketed Temodar for, *inter alia*, newly-diagnosed anaplastic astrocytoma ["AA"], newly diagnosed glioblastoma multiforme ["GBM"], refractory glioblastoma multiforme, meningiomas, oligodendrogliomas, brain metastasis from primary tumors, malignant melanoma ["MM"], all other types of brain tumors, extended therapy uses, combination therapy usage with radiation, and combination therapy usage with other chemotherapy agents. For some of these uses, Temodar was not effective. For example, Jorge Diaz Senior Product Manager for Schering, admitted to the HHS Office of Inspector General that "studies did not support" the claim that Temodar improved "quality of life" for patients with brain metastasis. (HHS-OIG 00291). Additionally, a consultant to Schering, Richard Tinsley of Putnam Associates, Inc., stated that "publish[ing] sufficient data to validate the off-label use [of Temodar] in . . . recurrent GBM, new AA as well as MM" would be a "significant challenge." (SPNJ 0218521-218528).

138. Heiden later bragged about success of the scheme to market Temodar drugs off-label. In a motivational blast voicemail sent to the entire oncology sales force, he stated: "[O]ne rep had 12 patient starts in one territory alone, only one of

those patients being an on-label indication, so getting a lot of early off-label utilization." (HHS-OIG 000354).

139. To achieve its sales goal in the year 2000, Schering budgeted $5 million to drive its Temodar marketing efforts, which was more than the total combined ***sales*** of the drug in 1999. To recoup these extravagant marketing expenses, Schering's "Temodar 2000 Plan," an internal Schering document that outlined Schering's marketing scheme for the drug (and which was disseminated to Schering's district sales managers and sales representatives via U.S. Mail and/or interstate wire facilities), called for, among other things, pushing Temodar in off-label indications where Schering had no proof of efficacy.

140. Two out of four "key issues" listed in Schering's "Temodar 2000 Plan" were squarely targeted at increasing the marketing and sales of off-label uses of Temodar, regardless of the drug's efficacy. "Key Issue 2," for instance, questioned: "How do we educate patients so that they request Temodar treatment from their physicians, especially in off-label indications?" (SPNJ 0117103). The "strategy" and "tactics" to address this issue included the payment of "grants" and "sponsorships" to brain tumor foundations, "feed[ing] data to brain tumors [web]sites," and updating "foundation disease brochures on off label topics to include TEMODAR: gbm, AA, brain mets, adult and pediatric treatment options," among others. (*See* SPNJ 0117104).

141. Schering's lack of and disregard for data to back up their aggressive marketing of Temodar is highlighted by "Key Issue 3" of the Temodar 2000 Plan, which stated that "[d]ata in high potential tumors is either off label (GBM/MM) ***or not yet available (brain mets/other cancers)***. With an approved labeling in refractory AA only, how due [sic] we gain use of TEMODAR in non approved indications?" (SPNJ 0117105). Schering knew it had no basis for its Temodar claims, but falsey promoted Temodar as therapeutically superior for its ability to cross the blood-brain barrier. To flog this false statement, Schering and its sales representatives, under the supervision of Defendants Heiden and Naughton, unleashed its full panoply of marketing gimmicks including, but not limited to: (a) disseminating of off-label "reprints" by its sales representatives; (b) paying grants for speaker programs and dinner meetings; (c) paying national and Regional grants; (d) conducting regional "advisory boards" in GBM, MM and brain mets; (e) convention booths at major oncological conferences; (f) updating "investigators" with new data; (g) utilizing the "Consultant Care Network" to discuss off-label topics; (h) educating physicians on Temodar's GBM data; (i) media relations; (j) developing new data in off-label indications by guiding research directions; (k) continuing to support supposed "clinical trials" being conducted by key influential doctors; (l) developing and supporting new clinical trials; (m) expanding use to include other more prevalent solid tumors,

such as brain mets, breast, and lung where Temodar has potential activity; and (n) speeding clinical trials to publish data on off-label indications. (SPNJ 0117105-6).

142. Schering targeted all health care professionals involved in the decision-making on whether to prescribe and/or pay for a Subject Drug to achieve its aims, including brain tumor centers, neurologists, neurosurgeons, radiation oncologists, neuro-oncologists, brain tumor foundations, nurses, and patients. *See* Temodar 2000 Plan. A May 3, 2000 Schering "Strategy Brief" directly described Schering's intention and strategy to increase Temodar sales by promoting off-label use: "I am actively pursuing avenues of greatest sales potential, including the Duke Brain Tumor Center (Henry Friedman, MD) and community oncologists who see potential for off-label Temodar use." (SPNJ 0074258).

143. Besides expanding Temodar's market far beyond its limited indication, Schering also marketed Temodar for unapproved doses, falsely and misleadingly concealing key information that led to harm to those taking the drug. A blast voicemail from Denise Stevens advised Temodar Coordinators to market a new, unapproved dosage of Temodar: 6 weeks on Temodar at 75mg/m^2 per day and 4 weeks off. At the time, this dosage was only in the initial stages of testing. Incredibly, Stevens advocated this dosage even though she was receiving negative reports of patients getting extremely ill when taking Temodar on this schedule. She stated: "We have had a couple of incidences of numerous symptoms occurring,

and most of that is just because if you are giving Temodar a lot on the 6 week schedule, you are causing neutropenia [a potentially life threatening condition characterized by low white blood cells]." (HHS-OIG 000367).

144. Since Temodar was only proven safe and effective to treat refractory AA, which affects about 3,000 to 4,000 Americans yearly, Schering illegally marketed it as an effective treatment for ***all*** gliomas and metastases, even though it did not have clinical data to back up such claims. In contrast to the small percentage of patients who could be treated with Temodar with proven potential efficacy, there are over 17,000 gliomas and 100,000 brain metastases diagnosed yearly.

145. Chasing ever-increasing revenues, Schering made calculated plans to increase prescriptions despite lacking clinical data to justify Temodar's use in these types of cancers. Schering's sales and marketing goal was to increase sales of Temodar from $4.1 million as of October 1999 to over $22 million in 2000, according to the "Temodar 2000 Plan." Schering was well aware that "[l]ess than 5,000 patients have AA." Accordingly, Schering's marketing plan specifically stated that "[s]uccess of TEMODAR lies outside of AA indication in other diseases such as GBM, Melanoma, Brain mets and other more prevalent solid tumors." Schering falsely said Temodar crossed the blood-brain barrier in seeking this illegal "success."

146. A February 11, 1999 "Temodar Sales Force Strategy Recommendation" from Richard Tinsley of Putnam Associates, Inc. to Schering employees Kathy Hurtado and Denise Stevens clearly revealed the cause and effect relationship between Schering's market analyses and illegal promotional activities: "From our earlier analysis, we anticipate that Temodar market potential at launch is between $25-$30 million based on use as a primary mono-therapy in the AA /GBM/MM market segments. With an indication expected only in recurrent AA, many challenges must be met even to achieve that potential. A significant challenge is to quickly publish sufficient data to validate the off-label use in the remaining core markets of new and recurrent GBM, new AA as well as MM." (SPNJ 0218521-218528). This last sentence reveals Schering's known lack of any legitimate scientific basis for its claims of Temodar's superiority and safety in those off-label uses.

147. Kathy Hurtado confirmed to government investigators that her recommendation was to market Temodar initially only for refractory AA, which would mean selling only to the major cancer centers such as Memorial Sloan Kettering. She recounted how she fought with her bosses, Rich Zahn and Raul Cesan, who wanted a more aggressive marketing strategy. Hurtado confessed that she even overstated the sales potential of Temodar – inflating her actual projection of $17-$18 million to roughly $30 million – because she knew senior management

did not want to hear the truth about its limited potential. In fact, Zahn and Cesan told her she would be more effective if she were more greedy. (*See* HHS-OIG Report of Interview, Kathleen Hurtado, June 26, 2003, at (HHS-OIG 000308)).

148. Soon after the internal discord surrounding the Temodar launch, Hurtado was transferred to Schering's Managed Care division. While Hurtado thought the transfer was not punishment for her resistance to off-label marketing of Temodar, she conceded that management may have had mixed motives. Hurtado said Schering seemed to want a more aggressive manager in that position. A few months after Hurtado was transferred, her replacement was then replaced. Defendant Heiden then took the reins, and pushed the fraud-based off-label Temodar marketing strategy to the depths described herein. (*See* HHS-OIG Report of Interview, Kathleen Hurtado, June 26, 2003, at 4-5 (HHS-OIG 000308-09)).

149. According to Schering's own internal documents, during the Class Period there was little, if any, data supporting the efficacy of Temodar for many of the off-label uses for which Schering promoted it. Despite the lack of valid scientific support, Schering heavily targeted three specific brain cancers not indicated on Temodar's label: GBM (a type of glioma), brain metastases (BM), and metastatic melanoma (MM).

150. Most of the off-label uses for which Temodar was marketed were not supported by the compendia used by Medicare and Medicaid and other TPPs to

determine what constitutes a medically accepted use of a drug. For example, the compendia did not support the use of Temodar to treat BM or other gliomas besides GBM.

151. Although the compendia did support the use of Temodar to treat MM and GBM, Schering believed there was little evidence that Temodar worked better than cheaper alternative drugs used to treat these cancers. Thus, Schering's marketing of these drugs in those off-label indications based upon statements of superior efficacy remained false and misleading.

152. Efficacy aside, Schering was also willing to put patients at serious risk in order to sell more Temodar. Outside consultants hired by Schering identified opportunities to expand the drug's limited market. One such opportunity, "combination therapy," was limited by "the lack of any data validating its safety and dosing." Further, the "key differentiating characteristics" of Temodar "become less important" in combination therapy. Worse, "the favorable side effect profile of Temodar is negated when used in combination with more punishing drugs. Combination therapy also presents some risk of reduced dosing." Putnam Associates, Inc.'s February 11, 1999 "Temodar Sales Force Strategy Recommendation." Schering did not disclose these lacks, risks and side effects when pushing Temodar.

153. The cataloguing of Temodar's fundamental medical and safety problems illustrate that Schering's goal was to make more money by wrongly expanding the market in spite of the consequences: "In spite of these challenges, while combination use will not turn Temodar into a blockbuster chemotherapeutic drug, it will propel its market potential beyond the initial forecast of $30 million."

154. Schering's sales force was exhorted to reach the larger brain metastases market with internal communiqués, such as ones closing with the following message: "Remember: Temodar Sales Growth is achieved by Creating New Treaters and Expanding the Use Into the Brain Met Market." As part of this goal, Schering's sales force profiled hospitals within their territory that used Temodar, listing the number of gliomas and metastatic melanomas per year, the staff that treated these diseases, and any notes on trials the institution or medical staff had been involved with.

155. Schering's sales representatives were also armed with "check lists" to use in Temodar sales pitches. These "check lists," which were disseminated to the sales representatives via the U.S. Mail and/or interstate wire facilities, instructed sales representatives to focus on brain metastasis, including newly diagnosed conditions, and to push the misleading and incomplete message that "Encouraging Preliminary Data … Significantly improves response … Trend toward improvement in survival." (SPNJ 003923).

156. Schering's Temodar sales "check–lists" also instructed its sales representatives to illegally push the subject of putting patients on Temodar for off-label uses by posing "Probing Questions in Brain Metastasis," to physicians, such as:

> Whether targeted doctors see patients with new brain metastasis;
>
> The targeted doctors' thoughts regarding Schering's Temodar information; and
>
> Directing the sales personnel to ask: "Let us talk about specific patients in your practice that you think can benefit from Temodar?"

(SPNJ 0003924).

157. To reach sales target goals, sales representatives were instructed without regard to whether Temodar was effective, to "[e]xpand usage of Temodar outside of brain tumors and melanoma" and to "expand brain met usage" according to yearly performance reviews. Schering sales representatives responded to these directions to market drugs off label by "fitting Temodar in to the Oncologists treatments for Brain Mets," according to one Schering sales representative's list of 2002 accomplishments.

158. At least one Schering sales representative wrote in the Executive Summary of a *2001 Marketing Plan for the Growth of Temodar and Intron*, that "brain mets and expanding my treater base will be the main focus of Temodar. This will be ***achieved through speaker programs*** and influence ***to make the use of Temodar for brain mets more widely acceptable***." (emphasis added). (SPNJ

0057532). This, Schering did, by claiming efficacy for Temodar that Schering had no basis to claim.

159. By early 2002, at regional POA meetings, for example in Atlanta, Georgia on January 13-16 2002, Schering sales representatives were specifically trained in "off label selling of Temodar in Brain Mets." ("BM").

160. Schering was not looking to help patients with BM, an often deadly form of cancer. Rather, according to handwritten notes on a Schering slide presentation purporting to provide scientific support for Temodar's use for BM, Schering viewed these patients like "the last bit of water before circling and go[ing] down the drain." Treating BM with Schering drugs was, according to the handwritten notes, akin to "rearranging deck chairs on the Titanic." Schering was merely trying to turn a profit on these patients. (SPNJ 0236198-205).

161. Schering's marketing team also sought to ensure that Temodar could become "***the standard of care*** in gliomas [GBM is a type of glioma] and melanoma," despite the fact that Schering was aware that Temodar carried a high price compared to alternative drugs and, ***in Schering's own words***, demonstrated "limited efficacy" in treating these diseases. *See* Temodar Plan 2000 Executive Summary. (Emphasis added.) (SPNJ 0117086).

2. Schering Fraudulently Marketed Intron Franchise Drugs For Off-Label Use

162. Upon information and belief, during the Class Period, Defendant Schering fraudulently marketed Intron A for the following off-label uses: renal cell carcinoma, chronic myelogenous leukemia, myeloma, metastatic melanoma, and Peyronie's disease. Schering also marketed Intron A to treat superficial bladder cancer, although a less expensive and equally effective treatment existed.

163. As with Temodar, Schering's illegal off-label sales and marketing campaign relating to the Intron Franchise Drugs included, upon information and belief, the dissemination of false and misleading statements about the efficacy and cost-effectiveness of Intron Franchise Drugs when compared to alternative, many times cheaper and equally effective, treatments. In addition, Schering's illegal off-label sales and marketing campaign relating to the Intron Franchise Drugs included paying illegal remunerations to physicians to prescribe the drugs off-label.

164. Schering conducted its unlawful and false Intron off-label sales and marketing scheme in order to increase revenues and profits, as evinced by Schering's Oncology/Biotech division's "Total Projected Sales for Targeted Cancers" for the year 2002. Those projections anticipated that 2002 would witness a 66% jump in Intron A sales for the treatment of bladder cancer – an off-label use.

165. At least one Schering sales representative wrote in a "Schering Oncology/Biotech Business Plan" that "[m]y largest success has been my bladder

business," and that in order to expand growth of Intron A sales, "I will continue to emphasize that high dose Intron A is the only dose that provides a survival benefit in high risk melanoma. Coupled with ***continued emphasis on superficial bladder cancer***." (SPNJ 0057505). Schering's emphasis on superficial bladder cancer included "naïve" − previously untreated − superficial bladder cancer. Upon information and belief, Schering had no basis to claim Intron A was safer or otherwise superior to BCG, the much less expensive standard of care. But Schering did so.

166. Schering also developed standardized forms, such as a "Sample Intron A Appeal – Denied Drug for Bladder Cancer Diagnosis," for physicians to appeal denials of coverage by TPPs for the use of Intron A for these off-label uses even though the drug was not safer or superior to BCG. (SPNJ 0256326).

167. Additionally, Schering promoted Intron Franchise Drugs to treat people with normal liver enzymes. Intron Franchise Drugs were only approved to treat persons with elevated liver enzymes, a sign of liver disease. Further, Schering promoted high doses of Intron A, when Rebetron alone failed at treating Hepatitis C, an indication not supported by Intron A's label or, upon information and belief, the then-current state of science.

168. Schering further exhorted its sales representatives to market Intron A off-label for ailments unsupported by clinical data, upon information and belief,

with internal communiqués announcing contingent incentive plan bonuses of $20,000 – labeled by Schering as the "Intron A Turbo Charge Kicker" – that could be earned in two months by sales representatives who utilize new data to "turbo charge our bladder business." Such communications were disseminated by Schering to its sales representatives by use of the U.S. Mail and/or interstate wire facilities.

169. Schering's relentless focus was on the sales, not the science, of Intron A, despite what uses the drug was effective for. In a blast voicemail from Heiden to the oncology sales force, Heiden stated: "Keep focused on driving Intron A using melanoma and bladder cancer. At the end of the year, when the dust settles, those who do successfully will find themselves well compensated." (HHS-OIG 000387).

(a) Schering's False and Misleading Marketing of Intron A For Superficial Bladder Cancer

170. At no time during the Class Period was Intron A approved to treat superficial bladder cancer. BCG, the inexpensive standard-of-care drug, was much less costly. According to an internal Schering training document, a six-week course of treatment with BCG costs $157, compared to $683.16 for Intron A. (HHS-OIG 00082).

171. Schering's sales representatives marketed Intron A for superficial bladder cancer in at least three different ways, depending on the time period:

- Until 1999, Defendants' sales representatives attempted to cause physicians to prescribe Intron A alone (when BCG failed), without combining it with BCG;

- Beginning in the mid to late 1990s, Defendants funded studies which, according to their paid physician/study authors, suggested that Intron A is synergistically beneficial for bladder cancer patients when combined with BCG. As a result, and beginning in 1999, Defendants' sales representatives pitched Intron A to be used in conjunction with BCG (as opposed to alone) when BCG initially failed; and

- In or after 2000, sales representatives pushed physicians to prescribe Intron A for patients who have not yet failed, called "naive" patients.

172. For example, one Schering sales representative stated in their plan to promote Intron A for the second half of 2001: "[G]oal – [E]ducate urologists that Intron/BCG should be next step for BCG failures every time . . . expand business by introducing the higher dose of Intron as 2nd and 3rd line and BCG/Intron for first line use." (SPNJ 0229524).

173. Schering's May 3, 2000 "Strategy Brief" described Schering's illegal marketing of Intron A even more directly: "Market share is approximately 90%, therefore business expansion will have to come from new growth vs. taking competitive share….Concentration on Intron use for bladder cancer in key urology accounts and redirection of melanoma business (away from Siegler/DUMC) will increase high-volume usage…off-study use of Intron in community-based urology practices has steadily increased this year to include 15 urology practices. Personal

target is 20% growth for 2000." This directly involved promoting Intron A for naive superficial bladder cancer despite Schering's known lack of support for such use.

174. A Schering Intron presentation from 2002 makes clear that Schering's focus lay in increasing Intron A prescriptions regardless of efficacy. It listed "key issues" facing Intron A in 2002 as: "#1 – Leverage Melanoma "Body of Evidence" Data to Expand Melanoma Business…. #2 Focus on Dermatologists, Surgeons and Pathologists to Increase Referrals…. #3 Increase Dose and Duration of INTRON A delivered in Melanoma…. #4 Maximize Bladder Cancer Opportunity." (TS2 000003).

175. During the Class Period, Defendant Schering carried out its illegal sales and marketing scheme through a sales force whose training materials for the marketing of Intron A for off-label uses included "key issues" such as how to, in Schering's own words, "Maximize Bladder Cancer Opportunity." Such training materials were disseminated by Schering to its sales representatives by use of the U.S. Mail and/or interstate wire facilities. According to a 2002 performance review of a Schering sales representative, the Company's representatives were evaluated on their ability to "greatly expand[] the use of INTRON for bladder cancer" a condition that, upon information and belief, Schering did not have sufficient clinical data to support.

176. Schering even provided sample "role play" scripts to its sales representatives to sell Intron A for bladder cancer. The script instructs sales representatives *to initiate* conversation with the doctors and ask them point-blank whether they had seen studies using Interferon (Intron A) in superficial bladder cancer. The sales representative then pitches Intron A for bladder cancer. (US 01615-1617).

177. Similarly, Schering regularly updated its sales force with voicemail tips designed to violate the spirit but not the letter of the law concerning Schering's ethical obligations concerning off-label marketing; noting in one message that while sales representatives could not physically give doctors a Schering produced CD-ROM on Intron A and bladder cancer, they could ask if doctors had received it and open a dialogue about using the drug for that condition. (HHS-OIG 000221).

(b) Schering Illegally Marketed Intron A To Treat Metastatic Melanoma

178. During the Class Period, Intron A was only approved to treat persons with malignant melanoma who are free of disease. Defendant Schering, however, illegally marketed the drug to treat metastatic melanoma, or melanoma that has spread to other parts of the body despite the fact that it was not as effective as other treatments, upon information and belief.

179. Schering instructed its sales representatives through training materials to "Leverage Melanoma 'Body of Evidence Data' to expand the melanoma

business, including increasing the dose and duration of Intron A as a melanoma treatment.

(c) Evidence Does Not Support Schering's Claims Of Efficacy For Certain Off-Label Uses Of Intron Franchise Drugs

180. Upon information and belief, Defendant Schering did not have evidence to support its claims that Intron Franchise drugs were effective for some of their marketed off-label uses.

181. For example, Intron A is not listed in the compendia used by Medicare, Medicaid and other TPPs to define medically accepted indications to treat Peyronie's disease or Hepatitis C patients with normal liver enzymes. Further, high doses of Intron A are not listed in the compendia to treat Rebetron non-responders.

182. Schering's off-label marketing of Intron Franchise Drugs also involved deception. Schering developed techniques to actively confuse doctors where studies showed no benefits from Intron-A when used for off-label purposes. Three studies investigating whether Intron A could help patients who had surgery to remove renal cancer concluded that Intron A did not prevent an occurrence of renal cancer and did not prolong life in patients. In response to these studies, Schering set up an internet chat room which instructed the sales force misleadingly

to tell doctors that Intron-A "wasn't given at a high enough dose or for long enough" in those studies. (HHS-OIG 000383).

183. Evidence also suggests that certain supposedly independent scientific publications were actually ghostwritten by, or at the direction of, Schering, even though they were purportedly authored by a respected physician who also happened to be a frequent recipient of Schering bribes and other inducements.

B. Schering's False and Misleading Statements Regarding the Subject Drugs

184. Numerous and specific examples exist of Schering's false and misleading statements in illegally promoting the Subject Drugs. For example:

1. Temodar False and Misleading Statements

185. As alleged in the Criminal Information, and fully acknowledged by Schering by its guilty plea, Schering made false and misleading statements concerning Temodar at the 37th American Society of Clinical Oncology Annual Meeting ("ASCO Meeting") held in San Francisco, California, in May 2001. Schering representatives at the ASCO Meeting falsely stated to attendees (primarily cancer doctors) that the Company had "tons of data on first line use" of Temodar even though at the time that statement was not true. (SPNJ 0331349).

186. At the same ASCO Meeting, Schering falsely told attendees that Temodar's survival results in patients compared favorably to a placebo in a particular study, even though that study did not compare Temodar to a placebo in

the study at all. The study in question was a single arm multicenter study that did not compare Temodar survival rates to a placebo. Schering's false and misleading statements at the ASCO Meeting related directly to the "efficacy" of Temodar. [FDA-OCI 000027].

187. Schering's false statements regarding Temodar's survival rates compared to placebo related to a Temodar brochure produced by Schering entitled "Measurable Survival Results." Temodar's label at the time stated: "[N]o results [are] available from randomized placebo controlled trials in recurrent anaplastic astrocytoma that demonstrate a clinical benefit resulting from treatment, such as improvement in disease related symptoms, delayed disease progression, or improved survival."

188. These false and misleading statements were known to be false when Schering made them yet were widely disseminated to cancer doctors across the country at this event. Annual ASCO meetings are widely-attended and extremely influential. According to ASCO's website, the "main objective" of the ASCO meeting "is to advance the education of physicians and other professionals in the care of patients with cancer." According to the ASCO's 2002-2003 Annual Report, there were 25,000 oncologists and other cancer treatment professionals in attendance at the 2001 ASCO Meeting from across the country. Thus, thousands of cancer patient prescribers were lied to by Schering at this one event.

189. Schering also admits that Temodar was not only worth less than what patients paid for it during the Class Period, but that Temodar was worthless in indications like brain metastases because it had no efficacy, (SPNJ 0236202-203) (it was like "rearranging deck chairs on titanic" because these patients were like "the last bit of water circling before going down the drain"). (SPNJ 0236203).

190. Schering knew its marketing claims that Temodar was efficacious in brain metastases were false and misleading because Schering itself did the study showing that proved Temodar **did not work** in brain metastases. Study 086 was by Schering's own admission a "high profile" and "important trial" watched closely by oncologists and other cancer physicians. (SPNJ 0125070). It closed in August 1996 for previously treated patients, and in January 1997 for untreated or naive patients. *Id.* The results were negative: Temodar was not effective in treating brain metastases. Rather than disclosing these results, Schering simply suppressed them, and did not release them even to the physician investigators participating in the study, many of whom suspected "Schering is hiding the data." *Id.* Schering's Denise Stevens wrote to Schering's Kathleen Hurtado that Schering needed to "finish cleaning" the study (SPNJ 0125069), but at the same time acknowledged fully that "**Nothing works for melanoma brain mets**" including Temodar as shown in Study 086.

191. Schering also knew, for example, that Temodar was wildly overpriced in off-label indications like metastatic melanoma, where generic DTIC was equally effective, better supported by clinical data and then-current science, and available at a fraction of the price. *See* Temodar 2000 Plan.

192. During the Class Period, Defendant Schering also made false statements about Temodar's ability to cross the blood-brain barrier. On April 12, 2001, after reviewing Schering's promotional material, the FDA informed Schering that its claims that Temodar crossed the blood brain barrier were misleading because the claims "overwhelmingly suggest that Temodar's pharmacokinetic profile confers a clinical benefit to patients when this has not been demonstrated by substantial evidence." The blood-brain barrier is a membrane that preserves the brain's homeostatis by keeping certain molecules in a patient's bloodstream from crossing into a patient's brain. The blood-brain barrier can inhibit the efficacy of drugs intended to treat brain tissue diseases, including cancer. Medications that cross this barrier are perceived as having additional clinical benefits.

193. Well after the FDA's admonition in April of 2001, Schering continued to misleadingly promote Temodar as a drug that could cross the blood-brain barrier. Schering brazenly directed its sales representatives to inform doctors that Temodar "crossed the brain barrier well" and shows "promising efficacy" in

treating brain metastases. *See* Temodar Plan of Action, June 2001. In the second half of 2001, Schering instructed Temodar sales reps to focus on brain metastasis and metastatic melanoma and deliver the message that Temodar "[c]rosses blood brain barrier well." "Temodar 2nd Half 2001 POA" (TS2 000171-72; *see also* TS2 000195).

194. Similarly, minutes from a Schering Oncology Conference Call held June 11, 2001 indicate a new detail aid for Temodar that "mentions that Tem[odar] crosses BBB [blood brain barrier]." (TS2 000158). Schering even integrated the point into their role-playing scripts used to train sales representatives. (TS2 000211). Yet Schering was well aware of Temodar's problems, stating in an internal memo from Schering's Sales and Marketing Teams (TS 000085-91) "We cannot make claims that TEMODAR crosses the blood-brain barrier" and "Cannot use 'favorable effects profile.' This minimizes the risks associated with TEMODAR." (TS 000091).

195. Other internal Schering documents reveal that Schering knew they could not "make claims that TEMODAR crosses the blood-brain barrier. This is because a decision has been made that the extent and duration of TEMODAR's penetration of the blood-brain barrier is not adequately understood and the references on this data do not demonstrate substantial evidence." (TEMODAR Approved Promotional Key Messages, faxed Apr. 10, 2003 (TS 000091)). But

Schering continued to falsely make the claim that Temodar crossed the blood-brain barrier.

196. In an interview conducted by the HHS-OIG and U.S. Attorney, Jorge Diaz, a Senior Product Manager for Temodar, admitted to the government investigators that Schering's statements were false, that the studies did not support the claims regarding crossing the blood brain barrier, and that such claims were not endorsed by the FDA. (*See* HHS-OIG Report of Interview, Jorge Diaz, Sept. 25, 2003, at 1 (HHS-OIG 000291)).

197. Even through 2003, the unsubstantiated claim that Temodar crossed the blood brain barrier was the centerpiece of Schering's marketing campaign. Temodar 2003 contained Schering's marketing message: "Expand New Marketing Campaign – position as novel, oral 2nd generation alkylating agent that crosses the BBB (provides "CNS [central nervous system] coverage") and has the unique ability to be easily combined with commonly used chemotherapy agents as well as radiation." (SPNJ 0120378).

198. Schering's false and misleading statements were not an isolated incident, but part of Schering's ongoing illegal sales and marketing scheme premised on misrepresentation and deception. Schering was obviously willing to make these false and misleading statements in an effort to off-label market Temodar in a public forum, like the annual ASCO meeting, with so many

prominent oncologists (and, to Schering's chagrin, the FDA) present. Schering was surely even more willing to make these false statements (and others) in the thousands of meetings, CMEs, dinner meetings, and detailing sessions it conducted in private.

199. In such private meetings, Schering used false and misleading statements to advance off-label sales because that is what they were trained to do. Salespeople were told to inform doctors, for instance, that there was "encouraging preliminary data" showing that Temodar "significantly improves response" in patients with brain metastasis (an off-label indication) showing a "trend toward improvement in survival." At the time these statements were made, Schering knew they were false. In truth, no "encouraging" data then showed that Temodar "significantly improves response" or "survival" of brain metastasis patients. As one Schering sales representative coldly put it, treating these patients was akin to "rearranging deck chairs on the Titanic" because these patients were like "the last bit of water circling before going down the drain." (SPNJ 0236203).

200. Even where the medical compendia did support the use of Temodar to treat MM and GBM, Schering boosted its marketing and sales efforts with false and misleading claims of superior efficacy even though Schering itself believed little evidence existed showing that Temodar worked better than cheaper alternative drugs used to treat these cancers.

201. With respect to GBM, for example, Schering's marketing of Temodar during the Class Period based upon statements of superior efficacy were still false and misleading, because, as Schering privately admitted to its sales representatives, there was a "low level of published data available to support use" of Temodar for GBM and at least "some neuro-oncologists" did not advocate its use. (SPNJ 0117094).

202. Schering also admitted in internal documents that Temodar had only a "marginal if any efficacy advantage" over cheap alternative therapies used to treat GBM, such that "[d]r.'s may question value." (SPNJ 0117100). This problem was particularly acute because, according to the "Temodar 2000 Plan" that was disseminated to sales representatives, the competition was "traditional chemotherapies…[that] are generic with low pricing…." (SPNJ 0117091).

203. Also during the Class Period, the FDA sent Schering a non-approval letter for use of Temodar to treat GBM, after the Oncologic Drug Advisory Committee ("ODAC"), a panel of oncology experts convened by the FDA, unanimously concluded on January 12, 1999, that the results of Phase II trials of Temodar did not support Temodar's use to treat recurrent GBM and voted not to approve the drug for that indication. On March 23, 1999, the ODAC considered and concluded unanimously, with one abstention, that the study presented did not provide sufficient evidence that Temodar was effective for treatment of the

condition. (SPNJ 0117100). Schering ignored the non-approval letter, and, upon information and belief, touted the study in question as supporting off-label use of Temodar to treat recurrent GBM because of Temodar's proven, superior efficacy.

204. Despite Temodar's admitted "weaknesses" resulting from its lack of proven efficacy, Schering's "Temodar 2000 Plan" still urged its sales representatives to find "opportunities" to illegally off-label market Temodar to treat GBM. According to Schering, a "window of opportunity exists to become standard of care as nothing else works." Thus, Schering and its sales representatives took advantage of a desperate group of very sick patients, offering a snake-oil-like treatment when it simply did not have the studies to back up Schering's claims of efficacy.

205. Schering's use of false and misleading statements to support the off-label marketing of Temodar to treat MM was even worse. The main MM competition identified by Schering (a drug called DTIC) was "available as a low cost generic, $265/cycle in comparison to TEMODAR $1500/cycle," according to the Temodar 2000 Plan (SPNJ 0117099). Temodar's price rapidly escalated during the Class Period, and by 2003 it cost between $1,970 to $2,727 per cycle, or 10 times as much as DTIC, according to Schering's Temodar 2003 Plan. (SPNJ 0120386).

206. Despite the astronomically higher price, according to Schering the safety of Temodar was "equal to DTIC" but there was "[m]arginal if any efficacy advantage over DTIC." In other words, Temodar had ***no*** efficacy advantage. As a result, according the Schering, "Dr.'s may question value," particularly given the "[h]igher cost of therapy in comparison to traditional therapies." (SPNJ 0117100).

207. Sales Representatives were specifically instructed in their annual performance review to target doctors in their region and induce them to "[r]eplace the use of DTIC with Temodar in Met. Melanoma." Consequently, sales persons consistently "reinforce[ed] . . . the benefit of using Temo[dar] over DTIC," even though Schering itself did not believe any such "benefit" existed and even though Schering itself believed that Temodar's much higher price was a significant disadvantage when compared to DTIC.

2. <u>Intron Franchise Drugs False and Misleading Statements</u>

208. Upon information and belief, consistent with its pattern and practice of illegal and deceptive behavior detailed herein, Schering's illegal off-label marketing of the Intron Franchise Drugs included the use of false of misleading statements.

209. Upon information and belief, consistent with its pattern and practice of illegal and deceptive behavior detailed herein, Intron A was falsely touted by

Defendants as having superior safety and efficacy than equally or more effective treatments available at a fraction of the price.

3. Schering Shielded Additional False And Misleading Statements From Discovery

210. Upon information and belief, Defendants and third-parties exclusively possess thousands of other specific examples and instances of Defendants' dishonesty, corruption, and false and misleading statements. Plaintiffs requested such documents in discovery from Defendants and third parties and diligently pursued such discovery. However, by Court order, Plaintiffs have been provided with only limited discovery relating exclusively to class certification (as interpreted by Defendants), despite the Third Circuit's December 30, 2008 *In re Hydrogen Peroxide Antitrust Litigation*, No. 07-1689 ruling, 552 F.3d 305, that courts are not just permitted to but should make merits inquiries at class certification, and despite the elusive and often impossible to draw distinction between class certification discovery (*e.g.* of a common overarching scheme of deception by Defendants) and merits discovery (*e.g.* of Defendants' deceptions of Plaintiffs, including through a common overarching scheme).

211. With respect to the limited discovery that has been provided, Defendants have interpreted the class vs. merits distinction in their favor to refuse to produce documents. Upon information and belief, Defendants have also contacted third parties from whom Plaintiffs requested discovery, and imposed

their self-serving interpretation of what can and cannot be discovered upon such third parties, informing them that providing Plaintiffs with the materials requested would violate Court orders, even though at least one of these third parties Projects In Knowledge had assembled and was prepared to produce over 120,000 pages of responsive documents Plaintiffs requested.

212. In addition, Defendant Schering has destroyed evidence of its dishonesty, corruption and false statements. In connection with the investigation of Schering's off-label sales practices conducted by the U.S. Dept. of Health and Human Services, Office of Inspector General, "evidence" was obtained (as of 2/25/2003) that at least "one District Sales Manager recently sent out a voice mail instructing employees to destroy documents … and told several sales representative to destroy information that was not approved by the Company for marketing purposes" despite the fact that this "information may have been the subject of [governmental] subpoenas issued in November [2002]." [HHS-OIG 000274]. Subsequent government interviews with Schering employees separately confirmed that this document destruction was not limited to "one" district sales manager, but might have been Company policy. At least three former Schering Oncology sales representatives recalled that two Oncology District Sales Manager (Jeff Pfister and Janet Gusmerotti) issued directives "about getting rid of [marketing] materials in [their] car and storage unit" despite (or perhaps because

of) the existence of government subpoenas. [HHS-OIG 000576]; *see also*, [SPNJ324276; SPNJ326835] (instructing sales reps to destroy sales materials and physician detailing aids). Thus, additional examples and instances of Defendants' dishonesty, corruption, and false and misleading statements remain shielded from discovery, or were improperly destroyed.

213. Former Schering sales representative Tracy Stein, one of the original relators in the Government's investigation of Schering, claimed to have eighteen to twenty (18-20) file boxes of documents relating to Schering's illegal activity that he took from Schering during the course of his employment. See Stein Dep. Tr. at 25:17-19; 27:11-12 (May 16, 2008). However, by the time the documents were finally produced to Plaintiffs on August 20, 2008, the documents amounted to 454 pages − a mere redweld's worth.

C. During The Class Period, Schering Offered Improper Bribes, Kickbacks And Other Illegal Remunerations and Inducements To Prescribe The Subject Drugs

214. During the Class Period, Defendants' false and misleading statements regarding the Subject Drugs were disseminated through a variety of marketing tactics through which Schering offered improper bribes, kickbacks and other illegal remunerations and inducements to physicians to prescribe the Subject Drugs where the physicians otherwise would not have written such scripts. The nature of these bribes varied, from "[h]igh quality medically related gifts (brain model, reflex

hammer)" (SPNJ 0120378) to more brazen cash payments of tens of thousands of dollars.

215. These bribes and payments were illegal because they caused physicians to breach their fiduciary duties of loyalty, care and full disclosure to patients, in violation of New Jersey's Commercial Bribery Statute and other statutes and regulations and, further, caused providers to prescribe the Subject Drugs to patients. Because the U.S. Government paid the purchase price for some of these drugs, Defendants' conduct violated the Anti-Kickback Statute.

216. To increase the sales of the Subject Drugs Schering paid improper bribes, kickbacks and other remunerations to physicians in at least the following ways:

1. Phony Speaker Events

217. During the Class Period, Schering paid money to physicians, purportedly for speaking at functions such as a dinner lecture. In reality, this money was given as a reward for prescribing Intron Franchise Drugs and Temodar. Schering also made illegal payments to cover the cost of travel so that the physician's spouse or companion could attend the event and be reimbursed for these and other "expenses." As to each type of payment, Defendants issued Internal Revenue Service Form 1099s to each physician; however, many

physicians who received such payments from Defendants never actually spoke at a formal event.

218. For example, Dr. Gupta of Broward County, Florida, was retained as a preceptor through Schering sales representative Douglas Hay. Hay ostensibly engaged Dr. Gupta to speak at dinner meetings. But, as Hay reported to government investigators, Dr. Gupta "spoke" at three or four sham dinners where the assembled audience consisted of Dr. Gupta's family and Hay. Dr. Gupta received $750 per dinner for his "services." Dr. Gupta, and other such physicians, had no reservations about being paid to do nothing. (*See* HHS-OIG Report of Interview, Douglas Hay, Feb. 12, 2002, at 3 (HHS-OIG 000299)).

219. Similarly, Hay set up 22 so-called education initiatives, paying doctors $5,000 to $10,000 per dinner. In 2001, Hay gave away roughly a half-million dollars through these efforts. (*See* HHS-OIG Report of Interview, Douglas Hay, Feb. 12, 2002, at 3-4 (HHS-OIG 000299-300)).

220. Similarly, sales representative Jay Stafford explained to government investigators how Schering had hosted four meetings on Intron at Turnberry Isle in Aventura, Florida. Schering invited physicians to stay at the resort for two nights but only asked them to attend a one one-hour session. According to the HHS OIG's Report of Interview of Jay Stafford, prepared by Special Agent David Furtado, Stafford's boss, Don Brown, instructed Stafford to let the physicians "do

anything they want – fish, use the spa, etc. The doctors and guests were allowed to use any of the facilities at no expense. Schering-Plough spent about $200,000 on these trips." (HHS-OIG Report of Interview, Jay Stafford, Dec. 18, 2001, at 3 (HHS-OIG 000322)).

221. Illustrating Schering's efforts to co-opt these physicians into uncritical acceptance of Schering's false and misleading claims, an internal Schering document, bearing a fax heading date of September 14, 1998, describes Fayetteville, North Carolina as "a largely untapped resource for HCV research," in terms revealing Schering's "pay for play" approach to doctors: "Dr. Poulos is a hepatologist who has expressed strong interest in doing research for us. He worked with Schering on the ribavirin trials in the Boston area, and he is a strong supporter. He knows we hold the purse strings and wants our help with getting his name known…I am putting him on our speaker's list." Referring to another physician in the same practice, the document states: "Dr. Vorder Bruegge…has just started treating HCV, but he wants to grow his practice. He has asked us to set up his clinic to handle a large number of HCV patients. He wants to be on our speakers list."

222. An example of a Schering "investigator/speaker list" includes information about the physician such as his/her affiliation, office address, whether they were a speaker, their specialty and disease of interest. Schering collected this

information nationally; an example of a Temodar investigator/speaker list contains names of physicians culled from all over the country. (TS2 000080-83), (TS2 000125-146). Of those physicians that actually gave talks on Schering's behalf, the program was clearly geared towards increasing Schering's revenues.

2. Phony Preceptorships

223. During the Class Period, Schering paid amounts ranging between $500 and $1,000 to physicians, ostensibly for teaching Schering sales representatives about technical aspects of their own medical practices. One sales representative described the program as "following the doctor around for the day watching him/her treat patients or watching the doctor in the operating room." (HHS-OIG Report of Interview, Jay Stafford, Dec. 18, 2001, at 2 (HHS-OIG 000321)). In reality, however, Schering sales representatives used this money to influence the physicians' prescribing decisions.

224. In fact, Schering made these improper payments to physicians, no matter how little time they spent with Schering's sales representatives. Sales representative Jay Stafford admitted to government investigators that he sometimes did not show up for his "training," yet paid the physician anyway. (HHS-OIG Report of Interview, Jay Stafford, Dec. 18, 2001, at 2 (HHS-OIG 000321)). This conduct continued until at least April 2003, when Schering sent a policy update memo suspending "all HCP preceptorship activity until further notice." Schering

stated that check requests for pending or completed preceptorships had to be processed by April 15, 2003, and that after that point, the "preceptorship" expense type would be taken out of the system. (TS 000084).

225. Another tool for manipulating the preceptorship program was to conduct this "training" in settings other than the doctor's office or a hospital. For example, Dr. Mark Lewis, an oncologist practicing at Memorial Hospital in Hollywood, Florida, held his preceptorship at the Emerald Hills Golf Course in Hollywood. Stafford paid Dr. Lewis's preceptorship fee, as well as his green's fees. (HHS-OIG Report of Interview, Jay Stafford, Dec. 18, 2001, at 2 (HHS-OIG 000321)).

226. As part of Schering's illegal sales and marketing scheme, sales representatives could give each physician multiple preceptorship payments. Further, Schering sales representatives did not need to get pre-approval before paying a preceptor, but rather were instructed by Schering management to use the money to illegally influence physicians' prescribing decisions.

227. Dr. Gupta, who was paid to speak at dinners to educate his family and Schering's Douglas Hay was also a beneficiary of the preceptorship largesse, receiving several payments for sessions that did not occur. Gupta was just one of 30 physicians with whom Hay had preceptorships in the first part of 2001, before having his funding cut for budget reasons. (*See* HHS-OIG Report of Interview,

Douglas Hay, Feb. 12, 2002, at 3 (HHS-OIG 000299)). Douglas Hay compiled a list of the physicians who received the most benefits from him in 2001, in the form of purported preceptorship fees or honorariums. (US01219-37).

228. A sample of these Field Check Requests submitted by Hay to Schering management shows the extent of Schering's use of bribes and meals to improperly influence physicians to accept Schering's false marketing claims:

- Check Request No. 347275, $300.00 for [redacted] for Rebetron "Hep C Update Presentation" at "Meal Meeting." (TS 000127).
- Check Request No. 347279, $500.00 for [redacted] for Rebetron Preceptorship. (TS 000128).
- Check Request No. 345844, $300.00 for [redacted] for Rebetron "Hep C Update Presentation" at "Meal Meeting." (TS 000129).
- Check Request, $750.00 for [redacted] for Rebetron "Hep Update Presentation" at "PCP Hep." (TS 000130).
- Check Request No. 347263, $500.00 for [redacted] for Rebetron Preceptorship. (TS 000131).
- Check Request No. 333093, $750.00 for [redacted] for Rebetron Preceptorship. (TS 000132).
- Check Request No. 407647, $300.00 for [redacted] for Rebetron Hep C update talk. (form bears handwritten notation "$13,300 question 4") (TS 000176).
- Check Request No. 407634, $300.00 for [redacted] for Rebetron Hep C update talk. (TS 000177).
- Check Request No. 407631, $300.00 for [redacted] for Rebetron Hep C update talk. (TS 000178)

- Check Request No. 347273, $300.00 for [redacted] for Rebetron Hep C update meal meeting. (TS 000179).
- Check Request No. 347270, $300.00 for [redacted] for Rebetron Hep C update talk. (TS 000180).
- Check Request No. 347285, $500.00 for [redacted] for Rebetron Preceptorship. (TS 000133).
- Check Request No. 347284, $750.00 for [redacted] for Rebetron Preceptorship. (TS 000134).
- Check Request No. 347278, $750.00 for [redacted] for Rebetron Preceptorship. (TS 000135).
- Check Request No. 407626, $750.00 for [redacted] for Rebetron Hep C update meeting. (TS 000181).
- Check Request No. 407643, $750.00 for [redacted] for Rebetron "Hep C Update Presentation" at "Meal Meeting." (TS 000136).
- Check Request No. 336102, $750.00 for [redacted] for Rebetron "Hep C Update Presentation" at "Meal Meeting." (TS 000175).

3. Phony Consultant Agreements

229. During the Class Period, Schering mailed $10,000 checks to numerous physicians in exchange for their signing a so-called "consulting agreement" with Schering. *See* Gardiner Harris, *Treatment by Incentive; As Doctors Write Prescriptions, Drug Company Writes Check*, N.Y. TIMES, June 27, 2004, at 11.

230. From the program's inception, the consultant agreement was meaningless because there was no expectation that the physician would do anything. Before creating these bogus "Consultant Agreements," Schering used to

paid physicians an honorarium with no written agreement at all. Schering eventually realized that giving cash to physicians for no apparent reason might raise suspicions. Only then did Schering require physicians to sign an agreement stating that they would perform consulting services. (HHS-OIG 000415).

231. As reported by *The New York Times,* one physician received such a check from Schering in exchange for services to be provided per an attached "Schedule A." However, when the physician referred to "Schedule A," it was entirely blank. *Treatment by Incentive*, N.Y. TIMES, June 27, 2004, at 11.

232. Referring to Schering's "consulting agreements" with liver specialists, Dr. Chris Pappas, director of clinical research for St. Luke's Texas Liver Institute, stated: "These were very high-value consulting agreements with selected opinion leaders that looked like payments of money with no clear agreements on what was supposed to be executed." *Treatment by Incentive*, N.Y. TIMES, June 27, 2004, at 11. During the Class Period, Schering made these payments with the intent and result that physicians increase prescription of the Subject Drugs.

233. Internal Schering documents reflect that the phony consultant agreements were an intentional effort to evade Schering's ethical obligations. An email forwarded by DM Janet Gusmerotti to Schering sales representative Tracy Stein and other representatives instructs them that the "Honorarium" type of expense was deleted from Schering's internal accounting system "in an effort to

properly implement the new Fraud and Abuse." This ironic (apparently unintentionally) email instructs sales representatives that the replacement expense type will be "speaker/consultant meeting." (US 01470).

234. One apparent glitch is that after Schering began using written consulting agreements, some unwritten promises of compensation to physicians was still unpaid and were rejected by a low-level Schering employee because the doctors had not signed anything. Naughton stated, in a voicemail to another Schering employee, that one doctor called a Schering sales representative "kind of looking for her check." At that time, Naughton realized that there were doctors who attended two investigator meetings that did not receive promised compensation. In the voicemail Naughton stated: "Bill is working with the lawyers to try to have them grandfather these two meetings in and make these exceptions, so we don't need to go get anything else signed, which, you know, at this point would be embarrassing. . . They will get paid – I promise you that." (HHS-OIG 000415).

4. Phony "Clinical Trials"

235. During the Class Period, Schering also disguised improper and unlawful payments to physicians by falsely stating that such compensation was being given to conduct "clinical trials" to study various diseases and treatment regimens. Internal Schering documents make clear that the purpose of these trials

was not research, but rather to boost sales of Temodar by creating a false and misleading appearance of science-based selling.

236. Such phony "clinical trials" often began with Schering's sales representative(s) negotiating with the physician about compensation for conducting a "clinical trial." Generally Schering paid physicians a set fee for each patients who allegedly participated in the sham clinical trial. However, if a physician demanded or requested additional money, sales representatives had a budget of marketing money to increase payments to the physicians. A "clinical study" might include 10 to 50 patients, running 8 to 16 weeks, paying the doctors anywhere from $1,000 to $3,000 per patient. (*See* U.S. HHS-OIG Report of Interview, Douglas Wickliffe Hay, Dec. 18, 2001, at 3 (HHS-OIG 000304).

237. After the sales representative negotiated compensation with the physician, Schering's so-called "project manager" met with the physician and set up the "clinical study." Sales representatives and "project managers" continued to work in tandem throughout the entire "clinical trial." Schering's "sales representatives" and "sales managers," acting under the direct supervision of Defendants Heiden and Naughton, had knowledge of all aspects of the trials and regularly made joint calls with project managers to physicians. Further, sales representatives and "project managers" helped physicians fill out clinical trial forms, such as the FDA Form 1572, the Statement of Investigator, which was to be

signed by the investigator overseeing a clinical trial. (*See* HHS-OIG Report of Interview, Kathleen Hurtado, June 26, 2003, at 6 (HHS-OIG 000310)).

238. Additionally, the sales representatives regularly consulted with the "project managers" to check on the status of the clinical trial's patient accrual, which correlates with additional sales of the Subject Drugs.

239. The line between "project manager" and sales representative was blurry at best, with Schering sometimes designating a sales representatives as a "project managers." Regardless, "project managers" have admitted that their primary role is to generate sales for the sales representatives, not produce legitimate results from legitimate clinical trials. Further, in 2001 and 2002, "project managers" benefited from a dual bonus system that rewarded them on the basis of patient accrual and corresponding increases in sales of the Subject Drugs. "Project managers" took credit for sales representatives' success in generating sales dollars through these sham clinical trials.

240. For example, David Deneroff of Defendant ITGI told Douglas Hay that he had engineered a turn-around in sales for Hay's colleague Scott Boden, whose sales had been lagging. After Deneroff assisted Boden in setting up a "clinical trial," Boden's sales jumped, putting him among the top representatives for that year. (*See* U.S. HHS-OIG Report of Interview, Douglas Wickliffe Hay, Dec. 18, 2001, at 3 (HHS-OIG 000304)).

241. Demonstrating the falsity of its supposedly science-based promotion, Schering did not care whether it received any data from physicians who ran the supposed "clinical trials." Schering paid physicians for each patient placed on the Subject Drugs, even if the physician submitted incomplete data from the "clinical trial." One liver specialist referred to the fake Intron A clinical trials as "purely marketing gimmicks." If physicians who were conducting "clinical trials" for Schering prescribed competitors' drugs or attempted other clinical trials using competitors' drugs, Schering would no longer provide this funding to them.

242. Further, unlike conventional clinical trials, in Schering's so-called "clinical trials" the patients were not provided with the Subject Drugs for free; rather, they and/or their insurer had to pay the complete purchase price for therapy, which costs thousands of dollars. Therefore, the illegal bribes and kickbacks paid to physicians did not cut into Schering's profits during the Class Period but, rather, enhanced Schering's profits because of the price of the drugs used in the "study." The physicians, in turn, enhanced their own profits as they were paid both by their patients for the privilege of entering the Schering study, and by Schering, for enrolling patients in the study.

243. Additionally, during the Class Period, the phony "clinical trials" did not meet FDA criteria to be used in the approval process. In fact, Schering withdrew its application to get Intron A approved by the FDA for superficial

bladder cancer in the early 1990's. Despite this decision, during the Class Period, Schering set up various phony clinical trials, although it was not attempting to get approval for this indication. (*See* HHS-OIG Report of Interview, Jay Stafford, Dec. 18, 2001, at 3 (HHS-OIG 000322)).

244. These phony "clinical trials" were so successful in inducing physicians to write additional prescriptions that Schering's sales representatives lobbied Schering management to have the maximum number of "clinical trials" conducted in their respective sales district to help them meet their sales quotas. [need cite] They also felt they were at a disadvantage if they did not have clinical trials in their territory. (*See* HHS-OIG Report of Interview, Kathleen Hurtado, June 26, 2003, at 6 (HHS-OIG 000310)).

245. One such trial was referred to as the "Start Protocol." Deneroff (of Defendant ITGI) set up this trial to promote use of Rebetron while Peg-Intron (the next generation treatment) was awaiting FDA approval. Deneroff indicated to Douglas Hay that the trial was a way to keep patients on Schering's Rebetron, rather than having these patients receive no treatment until Peg-Intron hit the market. The program was set up to allow sales representatives to sign up as many patients as they wanted and to choose the study sites. Unsurprisingly, both Hay and Deneroff referred to the Start Protocol as a ***marketing*** trial. (*See* U.S. HHS-OIG Report of Interview, Douglas Hay, Feb. 12, 2002, at 1-2 (HHS-OIG 000297-

98)). And, in fact, Defendant Heiden directed employees to calculate the return on investment on certain studies, to determine whether the resulting added sales were worth the cost of the trials. (*See* U.S. HHS-OIG Report of Interview, Kathleen Hurtado, June 26, 2003, at 6 (HHS-OIG 000310)).

246. Physicians could earn several thousand dollars per patient through the Start Protocol. Physicians eager to earn such extra cash (or to receive other incentives) readily signed up patients. The same Dr. Gupta of Broward County, Florida, who accepted payment for speaking at phony dinner meetings and fake preceptorships also received numerous inducements to participate in this so-called trial. Schering provided Dr. Gupta's free clinic with a free physician's assistant fellow for one year, and treated him to dinner outings. In exchange, Dr. Gupta signed up approximately 25 patients in the Start Protocol. (*See* HHS-OIG Report of Interview, Douglas Hay, Feb. 12, 2002, at 2 (HHS-OIG 000298)).

247. Another willing physician, Dr. Banks of Boca Raton, Florida, signed up 10 to 15 patients. Hay encouraged Dr. Banks' nurse, Judy, to have Dr. Banks enroll in the Start Protocol. Her willingness to help out was tied to the practice of "get[ting] the nurses involved financially because they were the ones who treated the patients and filled out the forms." (HHS-OIG Report of Interview, Douglas Hay, Feb. 12, 2002, at 2 (HHS-OIG 000298)).

248. Other physicians came to similar arrangements with Schering. One

sales representative wrote in November of 1999 to his supervisor about one such arrangement: "The situation with Dr. Hodge has been resolved in terms of a special financial arrangement (Gleyndon Kenerly) for his O'Donnell Trial Pts. (No Further Action Needed)." (TS 000018).

249. Another sham clinical trial was the Recap program, also to promote sales of Rebetron. In theory, the program was meant to study why patients were non-compliant with their medication regime. In reality, the program was a pretext to pay physicians for prescribing the drug.

250. Brian Brothen, a Schering sales representative who left Schering because of its unethical practices, estimated that only 15% of Hepatitis C patients need immediate treatment. However, he stated that physicians were motivated to prescribe Rebetron because they received $500 for every patient that they enrolled in a study purporting to test the efficacy of the drug. (FDA-OCI 0000127-8).

251. According to Brothren, the study was questionable because treatment with Rebetron was suboptimal; most Hepatitis C patients could wait until Schering's new drug PEG-Intron was introduced to start therapy. Indeed many physicians had qualms about prescribing Rebetron. Some enrolled their patients in Recap without prescribing Rebetron. One physician, Dr. Godofsky, involved his patients in the study but then pulled out because he felt that it was wrong. (FDA-OCI 0000128).

252. Defendant Heiden discussed with Hay's colleague and fellow Schering sales representative Keith McCormick that $500 was a large enough sum to induce physicians to sign up their patients for the program. Ultimately, Hay paid out approximately $90,000 to roughly 15 physicians to participate in the Recap program, with the top five or six receiving most of the money. Among Hay's participating physicians was Dr. Gupta, who also participated in the Start Protocol. Dr. Gupta signed up 50 patients for the Recap program, at $500 per patient, a $25,000 reward. According to Hay, the patients signed up are patients whom the physician would otherwise not have treated. (*See* HHS-OIG Report of Interview, Douglas Hay, Feb. 12, 2002, at 2-3 (HHS-OIG 000298-99)).

253. Even members of Schering's sales force, including Defendant Naughton and District Manager Mark Manzo, did not believe the program would generate any results of scientific value. Nonetheless, as Jorge Diaz reported, Greg Divis pushed district managers to "make their numbers" on the Recap program. (*See* HHS-OIG Report of Interview, Jorge Diaz, Sept. 25, 2003, at 5 (HHS-OIG 000295)).

254. Indeed, when Schering's new drug PEG-Intron was introduced, Schering announced the study had problems and said that they were not going to use the data. (FDA-OCI 0000128).

255. Schering also organized phony clinical trials to push sales of Temodar. For example, in 2001, Schering budgeted $4.8 million to conduct "clinical trials" on off-label uses of Temodar, such as to treat brain metastasis, lung cancer, and breast cancer. In 2002, Schering planned 99 clinical trials of Temodar, with a projected patient accrual of 4,294 patients.

256. However, internal Schering documents demonstrate that the purpose of these clinical trials was not research, but to boost sales of Temodar for off-label use where Schering had no basis to believe it was either effective or safe. One internal document states: "We propose pursuing 39 additional (above 2001 operating plan) Temodar ECAP studies in new areas and with the new dosing schedules that will expand the market for Temodar. The anticipated accrual is approximately 2,100 patients with the majority of these in lung, breast, melanoma and brain mets . . . The estimated total grant costs of these 39 unfunded trials is $4.8 [million] and they are expected to yield us approximately [$33.4 million] in sales - a 7 to 1 return on investment."

257. During the Class Period, at least one Schering sales representative expressed reservations about these practices. The concerned employee wrote the following in a letter sent to the FDA: "I work in the Oncology/Biotech Sales force, and am concerned with recent proposed changes in our group, which I believe are intended to circumvent the rules designed to protect patients from fraudulent

research." (SPNJ 0214574). The sales representative's letter stated that physicians have "research protocols which are really thinly veiled attempts to pay for prescriptions." The sales representative further stated: "There are small amounts of research going on, but many of these studies have no real goal beyond promoting the off-label use of Schering products."

258. The letter further stated that Schering was moving its sales representatives into research groups and designating some of them as "medical liaisons or project managers." These moves "expand[ed] the reach of these pseudo-protocols," which were being "placed in physician offices that have no staff for research, and are not equipped to truly do the research required by the protocol." Additionally, the letter stated that the "intent of this expansion of phony research protocols . . . is to do an end run around FDA requirements for promotional activity." (SPNJ 0214574).

259. The letter also stated that the Schering representative felt uncomfortable with his level of participation in these "clinical trials": "[A]s a sales representative, I feel vulnerable, as I have no clinical background, and that I'm being placed at risk in this position, and misrepresenting myself and these protocols to my physicians. The biggest example of this would be in the area of bladder cancer, where offices are solicited to do trials without having the time or staff to do them." (SPNJ 0214574).

260. The letter also admitted that such "clinical trials" being conducted by Schering-paid physicians are not "fair to patients, or to the physicians, who rely on the sales representatives for information, to promote these fake studies." (SPNJ 0214574).

5. Free and Discounted Drugs For Physicians

261. To further induce physicians to prescribe the Subject Drugs when they otherwise would not, Schering also provided free samples or supplied the Subject Drugs at discounted prices. Physcians then charged patients and/or TPPs full price for each of these samples. As a result, physicians were further incentivized to prescribe the Subject Drugs regardless of whether those drugs were the best treatment. The so-called free samples indeed generated significant revenue. For example, free samples of Intron A accounted for 10 to 12% of all sales of that drug.

262. Throughout the Class Period, Schering explained to physicians how they could profit by charging the insurer the ***full*** price for Intron, yet pay Schering a ***discounted*** price, yielding extra profit. For example, although Medicare would reimburse the physician $683.16 for 50 MIU of Intron A, Schering would only charge the physician $534.74, at its special "Priority Acquisition Cost." Thus, for each 50 MIU installation, the physician could earn an ***extra*** $148.42 of profit – at the expense of Medicare (or the TPP or patient).

263. Schering further induced physicians to prescribe Intron A through a scheme allowing physicians to bill for more Intron A than they actually purchased and at a higher price than they paid. For example, physicians were permitted to purchase three vials of Intron A, each labeled as containing 25 MIU of the drug. These vials were intentionally overfilled by Schering and actually contained 32 MIU of Intron A. Schering sales representatives told doctors that they could purchase three vials of Intron A and bill insurers, TPPs, and/or patients for ***four*** vials because 96 MIU was close enough to 100 MIU, *i.e.*, a common dosage. (TS 000184).

264. Schering used this scheme heavily when it was promoting a 100 MIU dose of Intron A for bladder cancer. Using the U.S. Mail and/or interstate wire facilities, Schering sent written memoranda instructing its sales representatives to execute this aspect of the scheme. These instructions and directives were reiterated during district, regional and national "Plan of Action" meetings attended by sales representatives.

265. Schering sales representative Tracy Stein spent approximately $70,000 in providing free samples of Intron A to physicians over a three year period for a portion of Stein's melanoma and bladder cancer business; Stein believed he was "average to below average in sampling." (US 01165-1203). Stein

also compiled a list of the physicians who were the largest users of Intron A in his territory for both on- and off-label uses. (US 01204-11).

266. In attempt to conceal its scheme, Schering marked the free Intron A samples by designating them for "indigent use." Thus, from the labeling, it did not appear that physicians would get reimbursed for the drugs. However, Schering sales representatives understood that the marking was applied only so physicians could protect themselves if questioned. (FDA-OCI 0000141).

267. In one instance, Schering instructed physicians to set up a direct purchase account with a particular supplier, and set out an itemized tally of how the scheme would work, as follows:

Billing Information

First 12 weeks, Intron A 100 miu weekly

Net Direct Price (3, 25 miu multidose vials)	$ 720.49	
Reimbursement (J9214 code) $11.06 per miu (96 miu, includes overfill)	$ 1061.76	
Total Savings Installation (47.5 Net Margin)	$ 341.27	
12 Installations 1 per Week		$4095.24

(Intron A (IFN a-2b) for Superficial Bladder Carcinoma Handout (HHS-OIG 000075)).

268. The document explains that the physician would then earn another $4,095.24 for the patient's next 12 installations, to be paid once per month for the

next year, for a grand total of "revenue back to the office" of $8,190.48. Not only did the physician bill for more of the drug than purchased, but he also billed at a higher price than what he paid, since he paid approximately $9.60 per MIU, yet received reimbursement at $11.06 per MIU – cheating the insurance provider, TPP and/or patient in two ways, not just one. (Intron A (IFN a-2b) for Superficial Bladder Carcinoma Handout (HHS-OIG 000075)).

269. In or about 1999, Schering suggested a new dosage to be used with a new regimen, referred to as "combination" therapy. The new dosage, based on a protocol developed and studied by Dr. Michael O'Donnell, was 50 MIU Intron A, combined with "one third" 1/3 (strength) BCG. As a result, Schering deployed new illegal sales and marketing tactics, even before Dr. O'Donnell's results were published in 2001.

270. Under the first approach, the Schering sales representative offered the physician one free 50 MIU vial, for which he could bill the patient's insurer (or the patient) $500. The physician then had to purchase the next 5 doses to complete the initial course of 6 treatments. (HHS-OIG Report of Interview, Jay Stafford, Dec. 18, 2001, at 2 (HHS-OIG 000321)).

271. This method was not always effective. Thus, Schering tried another approach. Sales representatives explained to physicians that instead of wasting the other two-thirds of the BCG vial, they should use it for three separate patients at

the same time. The stratagem was referred to by Schering as "rack 'em and stack 'em." As part of the scheme, physicians scheduled three or more patients at one time to administer the doses of BCG. Physicians profited because they could charge Medicare and/or patients and/or TPPs for one full vial of BCG for each patient, thereby charging Medicare and/or patients and/or TPPs for the same vial, ***three times***. Put another way, the physician charged for two vials that were not used**.** This approach provided the physician with $4,000 per patient. (HHS-OIG Report of Interview, Jay Stafford, Dec. 18, 2001, at 2 (HHS-OIG 000321)).

272. Additionally, to promote Intron A to treat melanoma, Schering devised the "Melanoma First Start Program," in which a physician was given one free 50 MIU vial of Intron A for each new melanoma patient that a physician started on Intron A. Intron A is indicated for patients who had surgery to remove melanoma to prevent recurrence. The label states that persons with melanoma should initially take 20 MIU of Intron A daily for four weeks and continue taking 10 MIU of the drug weekly for 48 weeks. Thus, Schering was incentivizing physicians to begin Intron A for treatment of melanoma because once started on the drug, patients had to undergo almost a year of therapy.

273. During the Class Period, Schering's sales representatives were armed with computer spreadsheets explicitly illustrating to the physicians how much profit could be made by billing the free samples to patients and/or their TPP. The

sales representatives shared such information with the physicians to induce them to participate in the illegal sales and marketing scheme.

274. Schering also tried to maintain its business by giving discounts to physicians through contracts in which an institution agreed to utilize specific Schering drugs. In exchange Schering discounted one of the drugs listed. (TS 000017). One example was the "Schering Oncology/Hepatitis Committed Member Progam." (TS 000010-12, TS 000082-83). In one instance, Orlando Regional Healthcare System promised to utilize the Intron A/Rebetron combination at a level of 90% in exchange for a 14 percent discount off the net direct price of the Intron component. (TS 000014) This discount was not passed on to consumers or to Medicare. These contracts were used to maintain Schering business. In addition to using these contracts, Schering sales representatives provided free samples (in the case of the M.D. Anderson Cancer Center of Orlando, FL, ten free vials of Schering drugs in December of 1999) and discussed using "unrestricted educational grants" to make up the difference in cost between Schering's Rebetol, which was not discounted under the contract, and Roeferon, a competitor's lower-cost alternative. (TS 000017, TS 000018, TS 000019).

275. A letter from a Schering employee to a sales representatives in the Florida District states: "One interesting selling point I have found to be very influential to physicians is how much profit they can make from Intron vs. Bcg."

(Letter from Michael Planas to Florida District, Aug. 22, 1997, HHS-OIG 000069; US 01293, US 01456).

276. Upon information and belief, during the Class Period for every eight to ten vials of Intron A that were sold, one vial was given away free. Schering necessarily documented the exact amount of free vials given to physicians because such documentation is required by federal law.

277. Requests for samples submitted by Schering sales representative Tracy Stein demonstrate the extent to which Schering used free samples to improperly influence physicians and defraud Medicare:

- Sample Request Form No. 005876, 2 sample 25 MIU vials of Intron A to [redacted] (TS 000140).
- Sample Request Form No. 005881, 2 sample 25 MIU multidose vials of Intron A to [redacted] (TS 000141).
- Sample Request Form No. [illegible], 10 sample 25 MIU multidose vials of Intron A to [redacted] (TS 000150).
- Sample Request Form No. 005877, 2 sample 25 MIU multidose vials of Intron A to [redacted] (TS 000142).
- Sample Request Form No. 0039677, 10 sample 25 MIU multidose vials of Intron A to [redacted] (TS 000143).
- Sample Request Form No. 0039698, 10 sample 25 MIU multidose vials of Intron A to [redacted] (TS 000145).
- Sample Request Form No. 0039608, 10 sample 25 MIU multidose vials of Intron A to [redacted] (TS 000167).
- Sample Request Form No. [illegible], 6 sample 50 MIU Powder of Intron A to [redacted] (TS 000163).

- Sample Request Form No. [illegible], 1 sample 50 MIU Powder of Intron A to [redacted](TS 000144).
- Sample Request Form No. [illegible], 1 sample 25 MIU multidose vial of Intron A to [redacted](TS 000155).
- Sample Request Form No. [illegible], 4 sample 50 MIU Powder of Intron A to [redacted](TS 000146).
- Sample Request Form No. [illegible], 4 sample 50 MIU Powder of Intron A to [redacted](TS 000147).
- Sample Request Form No. [illegible], 4 sample 50 MIU Powder of Intron A to [redacted](TS 000149).
- Sample Request Form No. [illegible], 4 sample 50 MIU Powder of Intron A to [redacted](TS 000148).
- Sample Request Form No. [illegible], 3 sample 18 MIU Powder of Intron A to [redacted](TS 000151).

6. Phony Investigator Meetings

278. During the Class Period, Schering paid physicians, whom Schering called "investigators," to give speeches about Temodar and Intron Franchise Drugs to other physicians. The funds to pay such physician-promoters came directly from Schering's home office, and sales representatives were instructed to spend lavishly on physicians who either spoke at or attended attendees such meetings. These speeches, which lasted about two hours on average, were held at exclusive resorts and luxury hotels. Schering paid for physicians to travel to these locations and often paid for golf outings, spa treatments, fishing trips and expensive gifts, including satellite television dishes. These various forms of unlawful

compensation were designed to incentivize physicians to prescribe Intron Franchise Drugs and Temodar in instances where doctors would not otherwise prescribe the drugs. For example, on January 21, 2002, Schering held its Temodar Investigators Meeting at the Four Seasons Aviara, in Carlesbad, California. 142 "investigators" (physician-promoters) attended. (TS 000201).

279. Additionally, each sales representative also had the discretion to spend money on physicians for entertainment and gift-giving purposes, and often exercised this discretion during these meetings. These expenditures included fishing trips, hunting trips, wine tastings, tickets to theater productions, tickets to sporting events, spa services ("Spa Dash"), gift certificates to Home Depot ("Home Depot Dash"), Christmas trees ("Christmas Tree Dash"), satellite TV dish systems, and video cassette recorders.

7. Phony Grants

280. During the Class Period, Schering sales representatives were allowed (and, indeed, encouraged) to give so-called "grants" to physicians, physician groups and medical facilities, ostensibly for an educational program or research program.

281. Upon information and belief, Schering sales representatives were encouraged to give such "grants" to physicians, groups and companies in their sales territory. The representatives told health care providers to do whatever they

wanted with the "grant" money in return for giving their business to Schering. Often such "grants" were used to pay for physicians' spouses or companions to travel to the above-referenced "speaker" meetings at fancy resorts, to buy television sets for physicians' office waiting rooms, or to meet other so-called "physician needs."

282. Indeed, during one stretch of the year 2000, Schering spent nearly $1.4 million on such unrestricted grants in order to promote its Intron A drug, and openly defined such spending and carried such amounts on its books as "promotional spending" for that drug. For example internal Schering documents from July 1999 demonstrate that Schering made one such promotional grant to a physician for $17,800.

283. Brothren stated that Schering would regularly give grants of $10,000 if a physician switched a prescription to a Schering drug, and that Schering also gave money for phony preceptorships. Schering spent this money to make more physicians into "Schering guy[s]" (FDA-OCI 0000129).

284. Grants were also used as part of a *quid pro quo* to induce facilities to add the Subject Drugs to the list of products purchased by their pharmacies, or to maintain the Subject Drugs on such lists. For example, the Orlando Regional Health Care System ("Orlando Regional") indicated it was planning to switch from Intron A to Roeferon, a less expensive competing drug. To induce Orlando

Regional not to make the switch, Schering made grants totaling $5,000 to sponsor a program to educate nurses on melanoma treatment. Orlando Regional also managed to convince Schering to reduce its prices and to give them 10 to 15 free vials. (HHS-OIG Report of Interview, Tracy Stein, Dec. 18, 2001, at 2-3 (HHS-OIG 000324-25)).

8. Phony "Advisory Board" Meetings

285. During the Class Period, Schering paid physicians to participate in "advisory boards" for the ostensible purpose providing feedback about drug performance and treatment. In reality, however, the "advisory board" meetings were just another way for Schering to pay physicians and induce them to prescribe Temodar and Intron Franchise Drugs. For attending such "advisory board" meetings, physicians received honorariums, lavish entertainment and travel expenses.

286. For example, in February 2002 Schering entered into a contract with "Dr. A" of Miami, Florida, whereby "Dr. A" agreed to serve on Schering's "advisory board" relating to the treatment of superficial bladder cancer. "Dr. A" agreed to attend at least one meeting of the "advisory board" and further agreed to answer questions that "Schering may reasonably ask you, up to a maximum of 3 hours." In exchange, Schering paid an honorarium to "Dr. A" in the amount of

$500, and further agreed to reimburse his out-of-pocket expenses for attending the "advisory board" meeting.

287. Additionally, advisory boards were an opportunity to market certain Subject Drugs off-label to physicians. Pursuant to Schering's Temodar 2003 plan, Schering held a Brain Mets Advisory Board to "assist in [the] development of [a] launch plan for [the] Brain Mets indication." (SPNJ 0120378). Schering's "launch plan" was a pretext to market Temodar for ineffective uses. Six years after its "launch plan," the FDA still has not approved Temodar for treatment of brain metastasis.

288. In addition, Schering had an advisory panel specifically to promote Temodar to treat metastatic melanoma. Schering advocated using Temodar as a monotherapy, combined with Thalidomide, or combined with other melanoma agents. (SPNJ 0120378).

289. In 2000, Schering organized an advisory board of brain metastasis experts to promote the ineffective uses of Temodar. One such advisory board meeting for superficial bladder cancer took place in Aventura, Florida, on January 18, 2003. Participants were paid $500 for attending the event, which was billed as an clinical information sharing opportunity that would assist Schering "in the development of our clinical trials program." (TS2 000151). Minutes of a Schering Oncology conference call for sales representatives dated June 11, 2001 indicate

that a Saturday social event was attended by 800 oncologists, that the Temodar meeting was Sunday, and that Schering decided "Next year one meeting for both." (TS2 000156). Nowhere did Schering, apparently, disclose the lack of scientific bases for these Temodar uses.

9. Free Physician Assistants for Doctors

290. To reward Physicians who prescribed Rebetron for Hepatitis C, during the Class Period, Schering provided a free physician assistant ("PA") for one year. While the ostensible purpose of the program was to train PAs to treat Hepatitis C, in fact, Schering gave the PAs to physicians as a reward for frequently prescribing Rebetron. Dr. Gupta was one such recipient of a free PA. *See* HHS-OIG Report of Interview, Douglas Hay, Feb. 12, 2002, at 2 (HHS-OIG 000298)).

10. Free Nursing Services To Physicians Through Defendants' In-House "Patient Care Consultants"

291. Patient Care Consultants (PCCs) were Schering's in-house nurses. Schering's sales representatives directed these nurses to physicians' offices that were in need of patient side effect management, injection training and any other services that the physician's nurse would normally perform with patients. Approximately 30 to 35 PCCs were employed by Schering at any one time, each one being assigned to a particular state. PCCs attended sales meetings and worked with Schering's sales representatives to maximize sales at "targeted" locations.

11. Straightforward Kickbacks

292. In some instances where physicians were persuaded to prescribe Intron or Temodar after being entertained at the expense of Schering, Schering's payments amounted to little more than a bribe.

293. Dr. Barrears, an oncologist in Florida, was initially skeptical of Schering's claims that Temodar could be used to treat brain metastasis. Sales representative Jay Stafford worked for over a year to persuade Dr. Barrears that a published study would be forthcoming and, misleadingly, that Temodar was indeed effective. Dr. Barrears responded by criticizing the data as weak. However, after hearing the misleading efficacy claims and after enjoying a fishing excursion with Stafford, Dr. Barrears changed his mind, and put 20 patients on Temodar. About six months later, when Stafford checked in with Dr. Barrears, the doctor reported: "[E]very patient progressed the way he though [sic] they would, every patient died when he thought they would." Regardless, Dr. Barrears continued to write prescriptions for Temodar, generating $157,000 in business in 2001. (HHS-OIG Report of Interview, Jay Stafford, Feb. 12, 2002, at 5 (HHS-OIG 000318)).

294. The kickbacks did not always stop with the physicians in the office. In an internal Schering email from June 12, 2000, a Schering sales rep offered the following tip when marketing Intron A for bladder cancer accounts: "Reward the instillation nurses – a little thank you gift is a small token for someone who can

identify thousands of $$$ of new business for you." (Email from Anthony Lombardo to various Schering sales staff including Relator Stein, dated June 12, 2000 (US01299)).

295. Despite the rampant bribery and kickback scheme that Schering management orchestrated, at least as far back as April 1998, Schering had in place "Corporate Policies and Procedures concerning Fraud and Abuse." (US01307-12). The memo clearly prohibits using educational grants for anything other than "bona fide medically-related educational or informational purposes." (US01307). It also prohibits Schering from making direct payments to health care professionals to defray the cost of attending an educational conference. These policies, despite good intentions, were openly ignored throughout the Class Period.

12. Symbiotic Relationships With Influential Physicians

296. For certain influential physicians, Schering provided incentives to promote and prescribe the Subject Drugs through a combination of various benefits described above. From these physicians, Schering received more than added sales. Recommendations for Schering's products from an influential physician were valuable in persuading other physicians to prescribe the drugs as well.

297. Dr. Henry S. Friedman, the James B. Powell, Jr. Professor of Neuro-Oncology at Duke University Medical Center, and Deputy Director of the Preston Robert Tisch Brain Tumor Center at Duke, was one such practitioner. Temodar

Senior Project Manager Jorge Diaz explained that Dr. Friedman was "heavily funded" by Schering. Such funding was not limited to funding of research by Schering's research unit, the Schering-Plough Research Institute ("SPRI") – a relationship that would not be unusual. According to Diaz, Dr. Friedman "received money from the district managers, the PJMs [project managers], local sales force, SPRI, and the marketing group. [He] used them in a methodical way. . ." (HHS-OIG Report of Interview, Jorge Diaz, Sept. 25, 2003, at 2 (HHS-000292)). Diaz also reported that at Friedman's request, Heiden committed to giving unrestricted grants to an internet initiative at Duke. (HHS-OIG Report of Interview, Jorge Diaz, Aug. 26, 2003, at 7 (HHS-OIG 000290)).

298. Similarly, Dr. Michael O'Donnell, whose research established the efficacy of the Intron/BCG combination, was a key player for Schering. The relationship between Dr. O'Donnell and Schering, as with Dr. Friedman, extended beyond the researcher-sponsor relationship that is typical between academics and pharmaceutical companies. Dr. O'Donnell's first clinical trial, a retrospective study with 40 subjects, did not meet FDA standards for establishing efficacy, and thus was not well-received by SPRI personnel. However, according to Jorge Diaz, Dr. O'Donnell developed a relationship with the project management group, through which he received most of his support. Dr. O'Donnell also gave CME presentations and served on Schering's advisory board, both of which provided

him additional compensation. (HHS-OIG Report of Interview, Jorge Diaz, Sept. 25, 2003, at 3 (HHS-OIG 000293)). For example, in a Schering handout dated March of 2002, O'Donnell is one of the study authors listed under the bladder cancer heading for Intron A and Temodar papers/articles. (TS 000044).

D. Schering Paid PBMs To Place The Subject Drugs On Formularies

299. Schering paid "grants" to PBMs, ostensibly for research or educational purposes, but in reality to get the Subject Drugs placed on formularies. For example, Schering gave PBMs money for the stated purpose of studying medication compliance, chronic disease management and preventative health care. In reality, these payments were designed to incentivize PBMs to place Temodar and Intron Franchise Drugs on TPP formularies.

300. Generally, formularies are designed to incentivize patients to choose cost effective treatments. Rather than weighing the costs and benefits of Schering drugs for TPPs and their beneficiaries, PBMs were improperly influenced by bribes and kickbacks paid by Schering.

301. TPPs depend on pharmaceutical companies, including in this case Schering, to act honestly, to deal fairly, and to comply with federal rules and regulations. Schering in this case did not. To the contrary, as evidenced herein, Schering, through bribes and wide dissemination of false and misleading

statements, corrupted the drug delivery and payment processes, influencing the PBMs' formulary decisions to include Subject Drugs and damaging the Plaintiffs.

E. Schering's Scheme Inflated The Number Of Prescriptions For Temodar And The Intron Franchise Drugs.

302. As a result of Schering's scheme, sales of Temodar increased almost ten-fold during the Class Period, even though the drug was only approved for use by approximately 2,000 to 3,000 people nationwide:

Year	Sales of Temodar in Millions of Dollars
1999	$38
2000	$121
2001	$180
2002	$278
2003	$324

303. Of these Temodar sales, about 85% to 95% of Temodar usage and sales during the Class Period was for off-label uses. In fact, had Temodar been prescribed only on label to ***all*** persons in the U.S. with refractory anaplastic astrocytoma, the drug would have ***only*** generated $25 million in sales.

304. Similarly, sales of drugs in the Intron Franchise grew exponentially during the Class Period as a direct result of Schering's scheme:

Year	Sales of Intron Franchise Drugs in Billions of Dollars
1999	$1.119
2000	$1.36
2001	$1.447
2002	$2.736

305. During 2003, Pegasys and Copegus, competing Hepatitis C drugs manufactured by Hoffmann-La Roche Inc., came on the market and were priced significantly lower than comparable Intron Franchise drugs. As a result, sales of Intron Franchise drugs declined to $1.851 billion. But for Schering's scheme, sales of Intron Franchise drugs would have declined more precipitously.

F. The Increase In Temodar And Intron Franchise Drug Sales Was Caused By Schering's Illegal Marketing Campaign

306. The increases in sales was due primarily to Schering's fraudulent marketing campaign.

307. Schering recognized that many doctors did not independently verify whether the information from Schering was supported by medical literature. One survey of doctors conducted by Schering's marketing team found that 35-40% of physicians "would use PEG Intron without any published data." (SPNJ 0120682).

308. Feedback from doctors confirmed that many were not independently consulting medical literature after Schering fraudulently marketed the Subject

Drugs to them. For example, days after an advisory board meeting attended by Dr. Olsen promoting Temodar to treat brain metastasis, a Schering sales person stated in a voicemail to a colleague that he received a call from a concerned colleague of Dr. Olson: "I just got a call on my cell phone from Fred Schnell . . . [H]e said . . . I need you to run a query for me because I'm having a dispute with Dr. Olsen. I sent one of my patients up to see him and he sent her back with a prescription for Temodar, unless there's something I just don't know about . . . I am not sure that she should be on Temodar. She has breast cancer with brain mets. That would be the very first time that Dr. Olson has ever[] recommended Temodar for metastatic breast cancer brain mets."

309. The call illustrates the extent to which doctors relied on presentations by Schering sales persons in making prescribing decision. Dr. Olsen prescribed Temodar off-label after hearing a presentation from Schering. Another doctor concerned about the prescription did not independently consult studies, but rather called a Schering sales representative for more information. (HHS-OIG 000407).

310. Schering carefully monitored its fraudulent marketing activities by tracking each and every phone call made to doctors and carefully monitoring the uses for which the Subject Drugs were prescribed. (HHS-OIG 000379).

311. Because performance reviews were based in part on the number of calls a salesperson made to physicians, each and every such call was logged into a

database named Prism. In a blast voicemail to his sales force, Heiden warned: "[N]othing take[s] precedence over calling on the customer with the required frequency." (HHS-OIG 000379).

312. Furthermore, Schering's Business Information Center precisely estimated the percentage of drug sales that were a result of doctor's prescribing the drugs for off-label uses. In one blast voicemail to the oncology sales force, Heiden stated that the Business Information center was doing a "Herculean job" in indentifying how much Intron A was being prescribed for oncology and how much was being prescribed for Hepatitis C. (HHS-OIG 000386).

313. A small number of doctors were responsible for prescribing a majority of Temodar, making tracking the uses for which doctors prescribed the drug easier for Schering. Schering estimated that in 2003, 408 doctors would prescribed 60% of all Temdor sold; 2,374 doctors would prescribe an additional 34% of all Temodar sold; and 917 doctors would prescribe the remaining 7% Temodar sold.

314. Schering was able to estimate, down to the exact number of patients, how much Temodar was prescribed for off-label and on-label indications. Below is a chart from Temodar 2003 showing expected sales of Temodar.

	2003 Patients	2003 Sales ($)	% or 2003 Sales
New AA	1,606	$25,172	17%
Recurrent AA	1,398	$13,694	9%
New GBM	2,309	$20,671	14%
Recurrent GBM	2,489	$19,500	13%
Low Grade Gliomas	782	$10,499	7%

Melanoma	1,115	$23,584	16%
Brain Mets	5,236	$34,106	23%
ECAP Trials (Misc.) (outside 3 major areas)	370	$4,025	3%
Total	**15,305**	**$151,252**	100%

Thus, Brain mets, for which Temodar is not effective, made up 23% of Temodar sales. (SPNJ 0120364).

G. Defendant Schering Used Third Parties To Assist It In Carrying Out The Illegal Sales And Marketing Scheme

315. During the Class Period, because Defendant Schering was prohibited from marketing Intron Franchise drugs and Temodar for off-label use, Schering set up an illegal, parallel marketing operation, using at least the following third-party entities to market Intron Franchise drugs and Temodar for off-label uses: ProEd Communications, Inc. ("ProEd"), which developed content for CME programs and promoted and conducted such programs; OCC North America, Inc. ("OCC"), which arranged and conducted so-called "advisory group" meetings; Bucom International ("Bucom"), an event planner that helped to plan meetings with physicians; and Projects in Knowledge, Inc. ("PIK"), which drafted and edited manuscripts for publications (collectively, the "Marketing Firms").

316. Although ProEd, OCC, Bucom and PIK were supposedly independent companies, in reality their activities were controlled and directed by Defendant Schering, in accordance with contractual agreements executed by Schering with each of these entities. During the Class Period, as alleged in this Amended

Consolidated Complaint, Defendant Schering formed a separate, ongoing unit with each of the Marketing Firms. In each instance, Defendant Schering and a third-party entity (ProEd, OCC, Bucom and PIK) formulated tactical plans to promote the off-label usage of the Subject Drugs and, to carry out such tactical plans, and there was regular communication, via U.S. Mail and interstate wire facilities, between Schering, and its employees, and each of the Marketing Firms, and their employees. There were also financial ties between each of the Marketing Firms and Schering because Schering paid each of the Marketing Firms, and Schering funneled payments through each of the Marketing Firms to physicians for making speeches, attending meetings, and preparing and/or signing articles to be published.

317. Furthermore, Schering told CME speakers what to say. When Steve Cohen gave a CME promoting Intron A to treat bladder cancer, Schering employee Cheryl Kaufman bragged: "I trained him very well" (HHS-OIG 000398).

1. ProEd

318. During the Class Period, as an essential part of its illegal sales and marketing scheme in at least 2001, Defendant Schering entered into a contract with ProEd to promote and conduct CME courses that touted the benefits of off-label uses of Temodar and Intron A. In these programs, doctors who had been chosen as "speakers" by Schering "educated" their peers about the supposed benefits of the off-label uses of Temodar and Intron A.

319. All aspects of the CME programs conducted by ProEd were designed and implemented by the Company. Schering designed, reviewed and approved all of the content in Powerpoint presentations used by CME "speakers," and Schering trained the "speakers" to communicate the off-label prescription "message" that Schering sought to promote. Additionally, Schering provided funding for the CME programs conducted by ProEd.

320. Schering use of ProEd successfully garnered off-label sales of Subject Drugs. For example, according to an email by one Schering sales representative, a doctor who attended a 2001 ProEd CME, stated that he would start five of his superficial bladder cancer patients on Intron A.

321. In addition to promoting off-label uses of Temodar and Intron A, Schering funneled money to ProEd that ProEd paid to both physician-"speakers" and physician-attendees at the CME conferences. Physician "speakers" received compensation from Schering (paid through ProEd) for all expenses associated with speaking, including payment of so-called honorariums. Physician attendees had their travel expenses reimbursed by Schering (paid through ProEd) in the form of phony preceptorships, honorariums, and grant money.

322. Furthermore, the sales force used CME materials discussing the off label use of drugs when marketing to doctors. Denise Stevens, a Temodar Product Manager, in a blast voicemail to the oncology field force, instructed the sales force

to distribute documents to doctors from Pro-Ed discussing the off-label use of Temodar. (HHS-OIG 000384).

2. OCC

323. During the Class Period, as an essential part of its illegal sales and marketing scheme, in May 2002 Defendant Schering entered into a contract, which was negotiated by Defendant Naughton and approved by Defendant Heiden, with OCC to conduct "advisory board" meetings that touted the benefits of off-label uses of Temodar. All aspects of the "advisory board" meetings scheduled and conducted by OCC were designed and implemented by the Company. The above-referenced contract specified that the purpose of such "advisory board" meetings was "[t]o build awareness in the use of Temodar in the treatment of anaplastic astrocytoma, glioblastoma, metastatic melanoma, and brain metastases." Temodar was not effective to treat metastatic melanoma or brain metastases.

3. Bucom

324. During the Class Period, as an essential part of its illegal sales and marketing scheme, in November 2001 and January 2002 Defendant Schering entered into contracts, which were approved by Defendant Heiden, with Bucom to conduct the "2002 Temodar Investigators' Meeting," to be held in February 2002 at the Four Seasons Aviara Resort in Carlsbad, California. This meeting, which was held at a lavish resort, featured a "Themed Gala Dinner at Del Mar Country

Club," cocktail receptions and dinners, an outing to the San Diego Zoo, and a shopping expedition in exclusive La Jolla, California. In addition to paying all lodging and travel expenses for the physicians who attended, Defendant Schering provided an undisclosed "amenity item" to each attendee.

4. PIK

325. During the Class Period, as an essential part of the illegal sales and marketing scheme, in at least 2001 and 2002 Defendant Schering entered into contracts with PIK to promote and conduct CME programs that touted the benefits of off-label uses of Intron A. Schering provided funding for the CME programs conducted by PIK.

326. According to Defendant Schering's own internal documents, PIK was retained as a vendor without a bid because "vendor [PIK] has ***unique experience with the product's off-label use in the treatment of bladder cancer*** . . ."

327. In these programs, doctors who had been chosen as "speakers" by Schering "educated" their peers about the supposed benefits of the off-label uses of Intron A.

328. All aspects of the CME programs conducted by PIK were designed and implemented by Schering. Schering designed, reviewed and approved all of the content used by CME "speakers," to communicate the off-label prescription "message" that Schering sought to promote.

329. According to a contract between PIK and Schering: "Projects In Knowledge will prepare a manuscript on the overview of current clinical practice for the management of Superficial Bladder Cancer (SBC). The paper will establish the clinical need for a therapeutic solution with superior effect to that of bacillus calmette-guerin (BCG) alone in the setting of one failure on intravesical BCG. Projects In Knowledge will provide editorial assistance to the principle author, Dr. Michael O'Donnell from the University of Iowa, Department of Urology."

330. Further, the contract listed the following services to be provided by PIK: (1) "full editorial services for the development of the publication;" (2) "preliminary and final drafts including all text, figures, tables, and references (up to 3000 words);" (3) "Author review and revisions;" (4) "Client review and revisions and journal placement in The Journal of Urology, or like publication."

331. In essence, to give the illusion that off-label content was produced independent of Schering, the Company (1) retained PIK to write medical literature − which was reviewed, revised, and approved by Schering − touting the use of Intron A for off-label purposes and (2) paid doctors $3,000 to place their names on the pre-written medical literature as if they had written it themselves.

332. In addition to promoting off-label uses of Temodar and Intron A, Schering funneled money to PIK that PIK paid to both physician-"speakers" and physician-attendees at the CME conferences. Physician "speakers" received

compensation from Schering (paid through PIK) for all expenses associated with speaking, including payment of so-called honorariums. Physician attendees had their travel expenses reimbursed by Schering (paid through PIK) in the form of phony preceptorships, honorariums, and grant money.

H. Defendant Schering's Illegal Sales And Marketing Scheme Was Devised, Coordinated And Implemented At The Company's New Jersey Headquarters

333. From the Company's headquarters in New Jersey, Schering's top management, including Defendants Kogan and Heiden, devised and implemented Schering's multifaceted illegal sales and marketing scheme. In its guilty plea to federal criminal violations, Schering Sales admitted that its vast off-label campaign was orchestrated from the Company's home offices in New Jersey. Information, ¶ 37. During the Class Period, the message from Schering's top management to its sales representatives was this: Engage in off-label marketing, touting the Subject Drugs as treatments despite the lack of proof of efficacy or the existence of more cost-effective treatments, but "be smart" so that the Company would not be caught in engaging in illegal activity.

334. The following activities vital to this scheme were directed by Schering's management from New Jersey:

335. First, the Company's top management, including Defendants Kogan and Heiden, incentivized Schering's sales force to market Intron Franchise drugs

and Temodar for off-label use, paying sales representatives based on the amount of off-label sales that they could generate. Also, sales representatives were paid incentives based on their ability to generate schemes to meet goals for promoting Temodar and Intron Franchise drugs for off-label use.

336. On November 3, 2000, Greg Divis announced an incentive plan to Schering's sales force, offering up to $20,000 for the persons who sold the most Intron A. He stated: "Big money ladies and gentlemen, but we need big results. Your patients started on melanoma and bladder cancer therapy today and every day during the next 60 days." (HHS-OIG000348).

337. Schering specifically hired persons to manage the off-label marketing of Intron A. In mid-to-late November of 2000, Charles Brown at Schering sent a blast voicemail to Schering's sales force advertising an opening at Schering's headquarters, stating: "This position will be responsible for implementing the strategic marketing plans for Intron A. We are looking for someone with at least 2 years of oncology sales experience, a good understanding of marketing dynamics of Intron A oncology, especially as they relate to melanoma and bladder cancer, and strong technical skills." (HHS-OIG 000365).

338. Second, the Company's top management, including Defendants Kogan and Heiden, ensured that Schering's sales representatives were well educated in how to market Temodar and Intron Franchise drugs to treat conditions

for which these drugs had not been proven effective or superior to less costly alternatives. Sales representatives were instructed by Schering's management to engage in a marketing campaign via training classes, "ride-alongs" with managers, district meetings, teleconferences and sales meetings.

339. Third, using the U.S. Mail and/or interstate wire facilities, the Company's New Jersey corporate headquarters disseminated to Schering's sales representatives copies of scientific articles and abstracts that discussed the benefits of off-label use of Temodar and Intron Franchise drugs and were meant to encourage doctors to prescribe Temodar and Intron Franchise drugs for both on-label and off-label use – even though Schering knew it lacked evidence to support its claims of efficacy and that the Subject Drugs were more expensive than competing drugs.

340. Fourth, the scheme to pay bribes and kickbacks to doctors was devised at the Company's headquarters in New Jersey by the Company's top management, including Defendants Kogan and Heiden, who ensured that funds were made available to illegally pay doctors to prescribe Temodar and Intron Franchise drugs.

I. Defendant Schering's Illegal Activity Harmed Patients And Third-Party Payors, Including Named Plaintiffs And Class Members

341. TPPs footed the bill during the Class Period because doctors influenced and defrauded by Defendant Schering's illegal sales and marketing scheme prescribed an increasing number of the Subject Drugs where they were ineffective, less effective, or equally effective to cheaper alternative therapies. Unaware of Schering's illegal sales and marketing scheme, Named Plaintiffs and class members paid billions of dollars that they otherwise would not have paid, absent Schering's illegal and fraudulent scheme. As a result of Schering's illegal sales and marketing scheme, Named Plaintiffs and class members suffered an ascertainable loss by Defendants' (a) causing TPPs to pay for drugs that were not effective for the uses advertised; (b) causing TPPs to pay for the Subject Drugs where there were cheaper alternative medications; (c) causing TPPs, including Medicare supplemental insurers, to pay for non-covered drugs; and (d) causing TPPs, including Medicare supplemental insurers, to pay physicians for quantities of the Subject Drugs that physicians did not actually purchase.

1. Named Plaintiffs And Class Members Suffered Ascertainable Loss Because Schering's Off-Label Marketing and Illegal Remunerations Caused Doctors To Prescribe Drugs Where They Had Little Or No Efficacy

342. During the Class Period, Schering's illegal and fraudulent marketing scheme, which involved, among other things, paying bribes to doctors and

marketing Temodar and Intron Franchise drugs for off-label use, caused doctors to prescribe Temodar and Intron Franchise in instances where they were not effective. As the Government alleged in its briefing concerning Schering Sales' criminal guilty plea: "Schering behaved no differently than a traveling salesman hawking tonic water as a cure for arthritis." United States' Response to Defendant's Motion For a Status Conference To Address Restitution Issues, United States v. Schering Sales, 06-10250 at 10 (D. Mass. Oct. 31, 2006).

343. Specifically, Schering fraudulently marketed Temodar as a safe and effective treatment for gliomas other than anaplastic astrocytomas and glioblastoma multiforme (GBM); and for brain metastases, and made fraudulent claims about Temodar's ability to cross the blood-brain barrier. During the Class Period, clinical data had not demonstrated that Temodar was effective in treating these cancers, and the FDA specifically cautioned Defendant Schering about falsely representing that Temodar could cross the blood-brain barrier. Nevertheless, as detailed above, Schering fraudulently marketed Temodar for these uses and paid doctors remunerations to prescribe Temodar to treat these cancers, thereby influencing doctors to prescribe Temodar where clinical data had not established its efficacy. This scheme, in turn, caused third party payors to pay for an increased amount of medication that did not benefit their members, or that cost more than cheaper, equally effective therapies.

344. Upon information and belief, there are additional examples in which these types of losses were incurred with respect to the Subject Drugs.

2. Named Plaintiffs And Class Members Suffered Ascertainable Loss Where Schering's Scheme Caused Doctors To Prescribe Schering Drugs Over Cheaper, Equivalent or Superior Alternatives.

345. Schering illegally marketed its drugs where there were lower cost alternative treatments, causing Named Plaintiffs and Class members to suffer ascertainable loss in the amount of the difference between the cost of Schering's drugs and the less expensive alternatives.

346. Named Plaintiffs suffered ascertainable loss where Schering induced doctors, through fraudulent marketing and illegal remunerations, to prescribe Intron Franchise Drugs over lower-priced, equally effective competing Hepatitis C drugs manufactured by Hoffmann-La Roche, Inc. *See* BUSINESSWEEK ONLINE, *Schering-Plough Rating Lowered*, Dec. 17, 2003. TPPs suffered ascertainable loss where Schering's fraudulent scheme caused doctors to prescribe Intron Franchise Drugs over Pegasys and Copegus, Hoffmann-La Roche's cheaper Hepatitis C drugs, in the amount of the price differential between the two therapies.

347. Named Plaintiffs suffered ascertainable loss where Schering induced doctors, through fraudulent marketing and illegal remunerations, to prescribe Intron A, along with BCG, to patients who had not yet tried BCG alone to treat superficial bladder cancer. Schering's scheme caused TPPs to suffer ascertainable

loss in the amount paid for Intron A to treat patients for whom BCG alone would have worked just as well.

348. Named Plaintiffs suffered ascertainable loss where Schering induced doctors, through fraudulent marketing and illegal remunerations, to prescribe Temodar for metastatic melanoma because there were cheaper, equally effective medications available. Schering admits, in its internal documents, that Temodar has marginal, if any efficacy advantages over DTIC, a less expensive drug used to treat metastatic melanoma. According to Schering's own internal documents, during the Class Period, DTIC cost $265 per cycle, compared with $1,970-$2,627 per cycle for Temodar (SPNJ0120386).

349. TPPs suffered ascertainable loss where Schering's fraudulent scheme caused doctors to prescribe Temodar over DTIC to treat metastatic melanoma in the amount of the price differential between Temodar and DTIC.

350. Upon information and belief, there are additional examples in which these types of losses were incurred with respect to the Subject Drugs.

3. Named Plaintiffs And Class Members Suffered Ascertainable Loss Because Schering's Scheme Caused TPPs, Including Medicare Supplemental Insurers, To Pay For Non-Covered Drugs.

351. Many Medicare beneficiaries purchase private Medicare supplemental insurance ("Medigap policies") from TPPs like Named Plaintiff UAI, which require UAI to pay all or part of the 20% patient co-payment for Medicare Part B

drugs. Because of the acts of the Defendants, payments were made by UAI and other TPP Class Members pursuant to these Medigap policies, and other policies which based benefit payments on Medicare-allowed charges, that otherwise would not have been paid as the Subject Drugs would not have been prescribed at all, or paid in lesser amounts due to the fact that other, cheaper drugs would have been prescribed by doctors instead of the Subject Drugs.

352. Medigap policies mandate reimbursement by the Medigap insurer whenever Medicare pays for a drug – thus, the Medicare program's coverage determination of the drug is controlling on the Medigap insurer. Many other TPPs, in addition to Medigap insurers, use Medicare guidelines and rules in setting coverage and reimbursement rules for various services, including prescription drugs.

353. Intron A was not eligible for Medicare, Medicaid or Tricare ("Government Program") reimbursement when prescribed for the following off-label uses promoted by Schering: (1) metastatic melanoma; and (2) Peyronie's disease. Such off-label uses were not included in one of the compendia or other literature specified by 42 U.S.C. §1396r-8(g)(1)(B)(I) (Medicaid) or 32 C.F.R. §1992 (Tricare), or 42 U.S.C. §1395y(a)(1)(A), as specified by Medicare Carriers Manual Section 2049.4 (Medicare). Claims for Intron A, when prescribed for these uses, were not covered under any Government Program, Medigap policies,

and TPP programs, policies and plans modeled on those of Government Programs, and therefore all claims submitted in this regard are false claims.

354. Temodar was not eligible for Government Program reimbursement when prescribed for the following off-label uses during the Class Period: (1) newly diagnosed anaplastic astrocytoma (AA); (2) newly diagnosed glioblastoma multiforme (GBM); (3) refractory glioblastoma multiforme (GBM); (4) meningiomas; (5) oligodendrogliomas; (6) brain metastasis from primary tumors (colon, breast, and lung cancer); (7) malignant melanoma; (8) extended therapy usage; (9) combination therapy usage with radiation; (10) combination therapy usage with various other chemotherapy agents; and (11) all other known brain tumor types. Such off-label uses were not included in one of the compendia or other literature specified by 42 U.S.C. §1396r-8(g)(1)(B)(I) (Medicaid) or 32 C.F.R. §1992 (Tricare), or 42 U.S.C. §1395y(a)(1)(A), as specified by Medicare Carriers Manual Section 2049.4 (Medicare). Claims for Temodar, when prescribed for these uses, were not covered under any Government Program, Medigap policies, and TPP programs, policies and plans modeled on those of Government Programs, and therefore all claims submitted in this regard are false claims.

355. Upon information and belief, Rebetron was not eligible for Government Program reimbursement when prescribed for (1) Hepatitis C patients with normal liver enzymes; and (2) Rebetron non-responders by adding high-dose

Intron A or high-dose PEG-Intron. Such off-label uses were not included in one of the compendia or other literature specified by 42 U.S.C. §1395y(a)(1)(A), as specified by Medicare Carriers Manual Section 2049.4. Claims for Rebetol/combination therapy, when prescribed for these uses, were not covered by any Government Program, Medigap policies, and TPP programs, policies and plans modeled on those of Government Programs and therefore all claims submitted in this regard are false claims.

4. Named Plaintiffs And Class Members Suffered Ascertainable Loss Because Schering's Scheme Caused TPPs, Including Medicare Supplemental Insurers, To Pay For Quantities Of The Subject Drugs Not Purchased

356. Schering illegally induced physicians to prescribe Intron A by facilitating a scheme by which the physicians billed the insurers (including Medicare) for more Intron A than was actually purchased, causing Named Plaintiffs and Class members to suffer ascertainable loss for fictitious purchases that should not have been reimbursed.

357. As described in more detail above, *see supra* at ¶ 221, Schering devised several schemes to assist doctors in overbilling Medicare and other insurers for Intron A. Schering provided physicians with free samples, for which these doctors then charged the insurers. Schering also developed the practice of selling physicians 25 MIU vials that actually contained 32 MIU, enabling the doctors to charge for more product than was purchased, since the 100 MIU

treatment regimen would have required purchasing four vials. Last, Schering suggested that physicians use the same vial of BCG for three patients treated in succession (with the Intron-BCG combination), use only one-third of the vial for each patient, yet charge each patient (or the patient's insurer) for the full vial, referred as "rack 'em stack 'em."

358. TPPs, including Medigap insurers, suffered ascertainable loss in the amount that they paid for fictitious quantities of drugs allegedly used in treating their members, which were improperly reimbursed as a result of Schering's fraudulent scheme.

J. Defendant Schering Used Its Wholly-Owned Subsidiary, Schering Sales, To Escape The Consequences Of Its Own Illegal And Fraudulent Activity

359. Brent Saunders, Schering's senior vice president of global compliance and business practices, publicly stated that "[Schering Sales] is an entity whose sole purpose is to plead guilty in these matters." Silvia Pagan Westphal, *Schering-Plough Settles Charges for $435 Million*, WALL ST. J., Aug. 30, 2006, p. A2.

360. Similarly, Schering Sales pleaded guilty to illegally paying a health maintenance organization ("HMO") a kickback in order to keep its drug Claritin on the HMO's formulary.

361. As a result of its federal criminal guilty plea in the U.S. District Court for the District of Massachusetts on August 29, 2006, Schering Sales was excluded

permanently from participation in any government healthcare programs. *See* Press Release, *Schering To Pay $435 Million For The Improper Marketing Of Drugs And Medicaid Fraud*, U.S. Attorney's Office for the District of Massachusetts, Aug. 26, 2006.

362. However, the federal criminal conviction of Schering Sales did not negatively impact Defendant Schering's ability to sell drugs to the U.S. Government. Although Schering Sales was excluded from doing business with the federal government, "its marketing functions have been taken over by other parts of [Schering], which are permitted to continue doing business with Medicare and Medicaid." Silvia Pagan Westphal, *Schering-Plough Settles Charges for $435 Million*, WALL ST. J., Aug. 30, 2006, p. A2.

363. As part of the federal criminal guilty plea, Schering Sales also agreed to pay a $180 million fine.

K. Schering's Fraudulent Concealment And Tolling Of Limitations

364. Defendants have concealed from Named Plaintiffs, Class members and the members of the general public the details of their underlying fraudulent and other illegal conduct, not only during the time that they engaged in that conduct so as to avoid detection and cessation of their ill-gotten profits, but even to this day to avoid public scrutiny, any concomitant negative perception of their business, and liabilities to Named Plaintiff and Class members resulting from civil

litigation. Defendants still have not provided the public with the details of their conduct, notwithstanding the fact that the U.S. Attorney for the District of Massachusetts first served Defendants with subpoenas relating to the wrongful and illegal conduct alleged in this Consolidated Complaint at least as early as November 2002.

365. Indeed, as part of Schering's cover up, it intended to destroy all "call notes," which sales representatives write to summarize their discussions with doctors, after the United States served Schering with a subpoena on November 4, 2002 requesting the documents. (FDA-OCI 0000134). It is unclear whether Schering carried out this plan. Such call notes as Defendants produced to Plaintiffs were produced in a scrubbed fashion, containing the bare minimum of fields and a lack of description in the note fields themselves.

366. Joan McPhee, one of the lawyers for Defendant Schering in both the criminal prosecution and the related civil cases, described civil litigation brought by the victims of Schering's crimes, like this class action, as "a clean slate." She also stated that "the false statement [made by Schering] to the FDA does not establish anything with respect to the allegation being brought" by Schering's victims, including Named Plaintiffs and Class members. Further, she stated that "the allegations about kickbacks have not been tested to [sic], admitted or proved." Indeed, she told the press that Schering disagreed with the Government's view that

off-label sales are illegal, and, despite Schering's federal criminal guilty plea and civil settlement, she claims that Defendant Schering's statements about off-label use of the Subject Drugs were truthful and not misleading and had strong scientific support. She further claimed, on behalf of Defendant Schering, that off-label usages are common, appropriate and sometimes life-saving.

367. These public statements, made by Schering's legal representative, demonstrate an ongoing denial by Defendant Schering of its falsehoods and other wrongdoing, for which it was prosecuted criminally and pled guilty. These statements demonstrate that Defendant Schering continues to suppress and conceal the truth of its unlawful and fraudulent conduct, as alleged in this Amended Consolidated Complaint.

368. Defendant Schering's 2003 Annual Report indicates that it set aside hundreds of millions of dollars in litigation reserves for the U.S. Attorney's investigation in the District of Massachusetts, as well as certain other federal and state investigations of Schering. Schering's 2005 Annual Report states that such litigation reserves had been increased by $250 million, resulting in a total reserve of $500 million, "representing the Company's current estimate to resolve the [federal] Massachusetts investigation," as well as certain other federal and state investigations. Having paid out $435 million to settle the federal criminal and civil *qui tam* (whistleblower) cases, Schering maintains a reserve balance of at least $65

million to compensate its victims in this civil litigation. Yet, despite the length of the U.S. Government investigation, the prior anticipation of having to pay hundreds of millions of dollars, and now the agreement to pay those dollars to resolve the federal criminal charges, Defendants still have not come clean with the actual details of their illegal and fraudulent conduct.

369. Named Plaintiffs had no knowledge of Defendants' illegal fraudulent scheme, illegal off-label promotional activities, illegal sales and marketing programs and conduct, payment of bribes, kickbacks, or other forms of illegal remuneration, conspiracies and concerted activities, or other unlawful conduct alleged herein, or of any facts that might have led to the discovery thereof in the exercise of reasonable diligence, until the earliest date of August 29, 2006 when the U.S. Government filed its Criminal Information setting forth the charge of conspiracy to make false statements to the FDA and the U.S. Attorney for the District of Massachusetts issued a press release reporting on the resolution of that charge and certain associated civil liabilities.

370. Named Plaintiffs and Class members could not have discovered the illegal and fraudulent conduct alleged herein at an earlier date by the exercise of due diligence because of the deceptive practices and techniques of secrecy employed by Defendants and their co-conspirators to avoid detection of, and to conceal, their unlawful conduct and conspiracies. These techniques of secrecy

included, but were not limited to, secret meetings and communications, the making of false and fraudulent statements about their conduct to governmental authorities and the public, creation of fraudulent studies regarding the usefulness and effectiveness of their drugs, secret payments of bribes and kickbacks to physicians and the creation of secret programs to effectuate those bribes and kickbacks, and other conduct alleged herein, all intentionally designed to avoid detection of their illegal schemes and activities. To this day, Defendants continue to conceal the details of their conduct from the public, including Named Plaintiffs and the Class members.

371. By reason of the foregoing facts and circumstances, the claims of Named Plaintiffs and Class members are timely under any applicable statute of limitations (as tolled by the filing of this Amended Consolidated Complaint) pursuant to the discovery rule and the doctrine of fraudulent concealment.

372. Defendants have been aware of their unlawful conduct and conspiracies since the inception of such conduct. To this day, however, despite Defendants' awareness of their unlawful conduct, their knowledge of the U.S. Government's investigation of relevant conduct and their setting of litigation reserves in the hundreds of millions of dollars relating to the investigation, and now their resolution of federal criminal and civil charges brought by the U.S.

Government, Defendants continue to conceal from the public, including Named Plaintiffs and Class members, the full details of their unlawful conduct.

373. Defendants' failure to properly disclose their unlawful conduct and conspiracies, and other acts and omissions as alleged herein, was and is willful, wanton, malicious, outrageous, and was and continues to be undertaken in deliberate disregard of, or with reckless indifference to, the rights and interests of Named Plaintiffs and Class members.

VII. CLASS ACTION ALLEGATIONS

374. Named Plaintiffs bring this action as a class action pursuant to Fed. R. Civ. P. 23(a), (b)(2) and (b)(3) on behalf of a Nationwide Class comprised of the following sub-classes:

a. All Taft-Hartley funds in the United States and its territories that, for purposes other than resale, purchased, reimbursed, and/or paid for Temodar, Intron A, Rebetol/ Intron A Combination Therapy, Rebetol/ PEG-Intron Combination Therapy, and PEG-Intron from January 1, 1995, at least until December 31, 2003. For purposes of this Class definition, members "purchased" the aforementioned drugs if they paid all or part of the purchase price.

b. All non Taft-Hartley funds, insurance companies, third party administrators, and other entities in the United States and its territories that, for purposes other than resale purchased, reimbursed, and/or paid for Temodar, Intron A, Rebetol/ Intron A Combination Therapy, Rebetol/ PEG-Intron Combination Therapy, and PEG-Intron from January 1, 1995, at least until December 31, 2003. For purposes of this Class definition, members "purchased" the aforementioned drugs if they paid all or part of the purchase price.

375. Specifically excluded from the Class are (a) Defendants and any entities in which any of the Defendants has a controlling interest, and their legal representatives, officers, directors, assignees and successors; and (b) any co-conspirators.

376. Named Plaintiffs seek class certification under Fed. R. Civ. P. 23(b)(2) as to declaratory and equitable relief sought herein, and under Fed. R. Civ. P. 23(b)(3) as to the damages sought herein. The Named Plaintiffs assert claims under RICO, NJ RICO, and common-law claims for intentional interference with contractual relations..

377. Upon information and belief, thousands of members of the Class were induced to pay for the Subject Drugs by reason of Defendant Schering's illegal sales and marketing scheme, which unlawfully promoted the Subject Drugs for off-label use and bribed doctors to prescribe the drugs. The members of the Class are so numerous and dispersed throughout the United States and the State of New Jersey that joinder of all members is impracticable. The Class members can be identified by, *inter alia*, records maintained by Defendant Schering, pharmacies and PBMs.

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

a. whether Defendants engaged in a fraudulent and/or unfair and deceptive scheme of improperly marketing, promoting, and selling the Subject Drugs to treat conditions for which said drugs were not economically or medically efficacious, effective, useful, or safe;

b. whether Defendants engaged in a fraudulent and/or unfair and deceptive scheme of improperly marketing, promoting, and selling the Subject Drugs for durations of use, or dosages, that exceeded or were otherwise outside the scope of the FDA approval, or that were not economically or medically efficacious, effective, useful, or safe;

c. whether Defendants misrepresented the efficacy and/or cost effectiveness and/or economic efficiency of the Subject Drugs, to the financial detriment of Named Plaintiffs and the Class;

d. whether Defendants prepared, funded, and published studies and other materials which contained false information and misrepresentations regarding the off-label uses, or the validity of or propriety of or scientific or other support for, off-label uses of the Subject Drugs;

e. whether Defendants utilized others and/or engaged in conspiracies to assist in the publication and dissemination of false or misleading statements or studies to physicians, concerning the off-label uses of the Subject Drugs;

f. whether Defendants used bribes, kickbacks, and/or other payments or illegal remuneration or inducements to induce physicians to prescribe, administer, or otherwise treat patients with the Subject Drugs for medical conditions not approved by the FDA;

g. whether Defendants engaged in the illegal and fraudulent marketing and sales scheme and conspiracy alleged herein;

h. whether the conspiracy was implemented;

i. whether Defendants engaged in a pattern and practice with the intent of deceiving and defrauding Named Plaintiffs and the Class and with the intent of suppressing the unlawful conduct and conspiracy;

j. whether the acts and omissions of Defendant Schering violated RICO and/or NJ RICO;

k. whether Defendant Schering made material misrepresentations of fact, or omitted to state material facts to Named Plaintiffs and the Class regarding the off-label marketing, promoting, and advertising of the Subject Drugs, which material misrepresentations or omissions operated as a fraud and deceit upon Named Plaintiffs and the Class;

l. whether Defendants engaged in a pattern and practice that directly and proximately caused Named Plaintiffs and the Class to pay for the Subject Drugs for non-medically necessary uses, for non-covered uses under the terms of the Medicare program or otherwise, for uses not approved by the FDA, or in doses or for durations beyond the scope of FDA approval or medical necessity;

m. whether Defendants' bribes, kickbacks, payments of illegal remuneration and/or other illegal inducements provided to physicians and other medical providers directly and proximately caused Named Plaintiffs and the Class to pay for the Subject Drugs, or to pay more than they otherwise would have paid either for the Subject Drugs or an alternative drug or treatment, whether or not the Subject Drugs for which Named Plaintiffs and the Class paid were for FDA-approved uses;

n. whether Named Plaintiffs and members of the Nationwide Class sustained damages and losses thereby;

o. the scope, extent, and measure of damages and equitable relief that should be awarded to Named Plaintiffs and the Class;

p. whether the Defendants' acts and omissions were sufficiently wrongful so as to entitle Named Plaintiffs and the Class to recover attorneys' fees, prejudgment interest, and costs of suit; and

q. whether the Defendants' acts and omissions were sufficiently wrongful to entitle Named Plaintiffs and the Class to recover punitive damages.

379. Named Plaintiffs' claims against Defendant Schering are typical of the claims of the members of the Class because all members sustained damages arising out of the Company's wrongful conduct as detailed herein. Specifically, Named Plaintiffs' claims and Class members' claims arise from Defendant

Schering's illegal sales and marketing scheme to illegally inflate the number of prescriptions for the Subject drugs during the Class Period.

380. Named Plaintiffs will fairly and adequately protect the interests of the Class and have retained counsel competent and experienced in class action lawsuits. Named Plaintiffs have no interests antagonistic to or in conflict with those of the Class and therefore should be adequate as representatives for the Class.

381. A class action is superior to other available methods for the fair and efficient adjudication of this controversy since joinder of all members of the Class is impracticable. Furthermore, because the damages suffered by individual members of the Class may in some instances be relatively small, the expense and burden of individual litigation make it impossible for such Class members individually to redress the wrongs done to them. Also, the adjudication of this controversy through a class action will avoid the possibility of inconsistent and possibly conflicting adjudications of the claims asserted herein. There will be no difficulty in the management of this action as a class action.

382. Plaintiffs contend that this suit is properly maintainable as a class action pursuant to Rules 23(b)(1), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure.

VIII. CAUSES OF ACTION

COUNT I
(Violations Of RICO)

383. Named Plaintiffs repeat and reallege the allegations contained in each of the foregoing paragraphs as if fully set forth herein. This cause of action, which arises under 18 U.S.C. § 1964(c), asserts claims against Defendants Schering, Kogan, Heiden and Naughton for violations of 18 U.S.C. § 1962(c) for conducting the affairs of various "enterprises," as described herein, through a "pattern of racketeering activity."

384. During the Class Period, Defendants Schering, Kogan, Heiden and Naughton, Named Plaintiffs and the members of the Nationwide Class were and are each a "person," as that term is defined in 18 U.S.C. § 1961(3).

385. During the Class Period, as alleged above, pursuant to their contractual agreements and courses of dealing, there existed separate "associations-in-fact" between Schering and each of the Marketing Firms, namely, (a) Schering and ProEd, (b) Schering and OCC, (c) Schering and Bucom, and (d) Schering and PIK; each one of these "associations-in-fact" between Schering and each of the Marketing Firms constituted a separate "enterprise," as that term is defined in 18 U.S.C. § 1961(4). During the Class Period, Defendants Kogan, Heiden and Naughton violated 18 U.S.C. § 1962(c) by conducting the affairs of Schering, a RICO "enterprise," through a "pattern of racketeering activity," as that

term is defined in 18 U.S.C. § 1961(1)(A)-(B) & (5). In the alternative, during the Class Period, Defendant Schering violated 18 U.S.C. § 1962(c) by conducting the affairs of each of the following separate RICO enterprises through a "pattern of racketeering activity," as that term is defined in 18 U.S.C. § 1961(1)(A)-(B) & (5): the Schering-ProEd Enterprise; the Schering-OCC Enterprise; the Schering-Bucom Enterprise; and the the Schering-PIK Enterprise.

386. During the Class Period, as alleged herein, Defendants Schering, Kogan, Heiden and Naughton committed, engaged in and/or aided and abetted a "pattern of racketeering activity," as that term is defined in 18 U.S.C. § 1961(1) & (5), involving multiple violations of the following federal and state statutes:

a. violations of the New Jersey Commercial Bribery Statute, N.J. Stat. Ann. § 2C:41-10, by paying doctors to prescribe Temodar and Intron Franchise drugs, whether their patients needed the drugs or did not need them; inducing doctors to prescribe the Subject Drugs for off-label uses by paying doctors improper and unlawful remuneration through marketing programs, improper preceptorships, sham "advisory boards," lavish entertainment, and improper placement of "clinical trials"; these bribes and other forms of improper and unlawful payment were intended to and did cause doctors to breach their duty of fidelity to their patients;

b. violations of the federal mail and wire fraud statutes, 18 U.S.C. §§ 1341 & 1343, by, among other things, sending a false and misleading letter to the FDA in response to the 2001 FDA Letter; sending a false and misleading message, via electronic mail, to its sales representatives concerning Schering's purported compliance with the FDA's directives; transmitting and receiving contracts and payments to doctors; disseminating scientific articles and abstracts to physicians; representing to TPPs that Defendant Schering was only marketing Temodar and Intron Franchise drugs for on-label use; misrepresenting

to doctors that Temodar was a safe and effective treatment for tumors other than refractory anaplastic astrocytoma and that Intron A was a safe and effective treatment for superficial bladder cancer;

c. violations of the Travel Act, 18 U.S.C. § 1952, when Schering's employees or agents traveled in interstate commerce, or caused others (such as physicians, their spouses and/or their "guests") to travel in interstate and/or Schering's employees or agents used the U.S. mail or any facility in interstate commerce to promote, manage, establish, carry on, or facilitate the promotion, management, establishment, or carrying on of "unlawful activity," namely, bribery; and

d. violations of the National Stolen Property Act, 18 U.S.C. § 2314, when Defendants, having devised the illegal and fraudulent marketing scheme, transported or caused to be transported, or induced physicians and/or other persons to travel in, or to be transported in interstate commerce in the execution or concealment of that scheme.

387. Defendant Schering's, Kogan's, Heiden's and Naughton's violations of these state and federal statutes, as described herein constituted a "pattern of racketeering activity" because such predicate acts were related to each other in that they were committed as part of the illegal and fraudulent marketing scheme, and they amounted to or pose a threat of continued criminal activity.

388. Many of the precise dates and times of Defendant Schering's, Kogan's, Heiden's and Naughton's violations of the above-referenced New Jersey and federal criminal statutes are not known. Indeed, an essential part of the successful operation of the illegal sales and marketing scheme alleged herein depended upon secrecy and each of these Defendants took deliberate steps to conceal their wrongdoing. However, given the massive scope of the illegal and

fraudulent scheme, these Defendants likely committed thousands of predicate acts of "racketeering activity."

Schering-OCC Enterprise

389. During the Class Period, Defendant Schering participated in the conduct of an "enterprise," namely, an association-in-fact enterprise consisting of itself and OCC, through a "pattern of racketeering activity."

390. Pursuant to their contractual agreement, Defendant Schering controlled OCC by virtue of the fact that Schering designed the structure and created the content of "advisory group" meetings conducted by OCC. Defendants Schering, Kogan, Heiden and Naughton ensured that OCC would carry out Schering's instructions to market Schering's drugs for off-label uses, and further ensured that OCC would pay illegal remunerations to doctors through payments funneled by Schering through OCC.

Schering-Bucon Enterprise

391. During the Class Period, Defendant Schering participated in the conduct of an "enterprise," namely, an association-in-fact enterprise consisting of itself and Bucom, through a "pattern of racketeering activity."

392. Pursuant to their contractual agreement, Defendant Schering controlled Bucom by virtue of the fact that Schering designed the structure and created the content of the "2000 Temodar Global Investigators' Meeting" with

physicians planned by Bucom. Defendants Schering, Kogan, Heiden and Naughton ensured that Bucom would carry out Schering's instructions to market Schering's drugs for off-label uses, and further ensured that Bucom would pay illegal remunerations to doctors through payments funneled by Schering through Bucom.

Schering-PIK Enterprise

393. During the Class Period, Defendant Schering participated in the conduct of an "enterprise," namely, an association-in-fact enterprise consisting of itself and PIK, through a "pattern of racketeering activity."

394. Pursuant to their contractual agreement, Defendant Schering controlled PIK by virtue of the fact that Schering directed PIK's activities in drafting and editing manuscripts for publication. Defendants Schering, Kogan, Heiden and Naughton ensured that PIK would carry out Schering's instructions to market Schering's drugs for off-label uses, and further ensured that PIK would pay illegal remunerations to doctors through payments funneled by Schering through PIK.

Schering's Illegal And Fraudulent Scheme Caused Named Plaintiffs' And Class Members' Injuries

395. Named Plaintiffs and Class members were injured in their business or property by reason of Defendants Schering's, Kogan's, Heiden's and Naughton's above-referenced violations of 18 U.S.C. § 1962(c). Named Plaintiffs and the

members of the Class have standing to sue Defendants Schering, Kogan, Heiden and Naughton under 18 U.S.C. § 1964(c) and to recover compensatory damages, treble damages, and the costs of suit, including reasonable attorneys' fees. In addition, Named Plaintiffs and Class members are entitled to declaratory and injunctive relief, pursuant to 18 U.S.C. § 1964(a), to remedy and prevent Defendants Schering, Kogan, Heiden and Naughton from engaging in further violations of New Jersey and federal law.

COUNT II
(Violations Of NJ RICO)

396. Named Plaintiffs repeat and reallege the allegations contained in each of the foregoing paragraphs as if fully set forth herein. This cause of action, which arises under N.J. Stat. Ann. § 2C:41-4(c), asserts claims against Defendants Schering, Kogan, Heiden and Naughton for violations of N.J. Stat. Ann. § 2C:41-2(c) for conducting the affairs of various "enterprises," as described herein, through a "pattern of racketeering activity," as described herein.

397. During the Class Period, Defendants Schering, Kogan, Heiden and Naughton, Named Plaintiffs and the members of the Class are each a "person," as that term is defined in N.J.S.A. 2C:41-1(b).

398. During the Class Period and pursuant to their contractual agreements, there existed separate "associations-in-fact" between Schering and each of the Marketing Firms, namely, (a) Schering and ProEd, (b) Schering and OCC, (c)

Schering and Bucom, and (d) Schering and PIK; each of these "associations-in-fact" constituted a separate "enterprise," as that term is defined in N.J. Stat. Ann. § 2C:41-1(c).

399. During the Class Period, Defendants Schering, Kogan, Heiden and Naughton violated N.J. Stat. Ann. § 2C:41-2(c) by conducting the affairs of Schering, an "enterprise," through a "pattern of racketeering activity," as that term is defined in N.J. Stat. Ann. § 2C:41-1(a)(1)(g) & (a)(2). In the alternative, during the Class Period, Defendant Schering violated N.J. Stat. Ann. § 2C:41-2(c) by conducting the affairs of each of the following separate "enterprises" through a "pattern of racketeering activity," as that term is defined in N.J. Stat. Ann. § 2C:41-1(a)(1)(g) & (a)(2): The Schering-ProEd Enterprise; the Schering-OCC Enterprise; and Schering-Bucom Enterprise; and the Schering-PIK Enterprise.

400. During the Class Period, Defendants Schering, Kogan, Heiden and Naughton engaged in and/or aided and abetted a "pattern of racketeering activity" involving multiple violations of the following federal and state statutes:

a. violations of the New Jersey Commercial Bribery Statute, N.J. Stat. Ann. § 2C:41-10, by paying doctors to prescribe Temodar and Intron Franchise drugs, whether their patients needed the drugs or did not need them; inducing doctors to prescribe the Subject Drugs for off-label uses by paying doctors improper and unlawful remuneration through marketing programs, improper preceptorships, sham "advisory boards," lavish entertainment, and improper placement of "clinical trials"; these bribes and other forms of improper and unlawful payment

were intended to and did cause doctors to breach their duty of fidelity to their patients;

b. violations of the federal mail and wire fraud statutes, 18 U.S.C. §§ 1341 & 1343, by, among other things, sending a false and misleading letter to the FDA in response to the 2001 FDA Letter; sending a false and misleading message, via electronic mail, to its sales representatives concerning Schering's purported compliance with the FDA's directives; transmitting and receiving contracts and payments to doctors; disseminating scientific articles and abstracts to physicians; representing to TPPs that Defendant Schering was only marketing Temodar and Intron Franchise drugs for on-label use; misrepresenting to doctors that Temodar was a safe and effective treatment for tumors other than refractory anaplastic astrocytoma and that Intron A was a safe and effective treatment for superficial bladder cancer;

c. violations of the Travel Act, 18 U.S.C. § 1952, when Schering's employees or agents traveled in interstate commerce, or caused others (such as physicians, their spouses and/or their guests) to travel in interstate commerce and/or Schering's employees or agents used the U.S. mail or any facility in interstate commerce to promote, manage, establish, carry on, or facilitate the promotion, management, establishment, or carrying on of "unlawful activity," namely, bribery; and

d. violations of the National Stolen Property Act, 18 U.S.C. § 2314, when Defendants, having devised the illegal and fraudulent marketing scheme, transported or caused to be transported, or induced physicians to travel in, or to be transported in interstate commerce in the execution or concealment of that scheme.

401. Defendants' violations of these state and federal statutes, as described herein constituted a "pattern of racketeering activity," as defined in N.J. Stat. Ann. § 2C:41-1(d)(1)-(2), because they engaged in at least two incidents of racketeering conduct, one of which occurred after June 15, 1981 and the last of which occurred within 10 years after a prior incident of racketeering activity, and the incidents of

racketeering activity embraced criminal conduct that had either the same or similar purposes, results, participants, or victims, or methods of commission, or are otherwise interrelated by distinguishing characteristics and are not isolated incidents.

402. Many of the precise dates and times of Defendants Schering's, Kogan's, Heiden's and Naughton's violations of the above-referenced New Jersey and federal statutes are not known. Indeed, an essential part of the successful operation of the illegal and fraudulent marketing scheme alleged herein depended upon secrecy and Defendants took deliberate steps to conceal their wrongdoing. However, given the massive scope of the illegal and fraudulent scheme, Defendants likely committed thousands of predicate acts of "racketeering activity."

403. Named Plaintiffs and Class members were injured in their business or property by reason of Defendants Schering's, Kogan's, Heiden's and Naughton's violations of N.J. Stat. Ann. § 2C:41-2(c). Named Plaintiffs and the members of the Class have standing to sue Defendants Schering, Kogan, Heiden and Naughton under N.J. Stat. Ann. § 2C:41-4(c) and to recover compensatory damages, treble damages, and the costs of investigation and litigation, including reasonable attorneys' fees. In addition, Named Plaintiffs and Class members are entitled to declaratory and injunctive relief, pursuant to N.J. Stat. Ann. § 2C:41-4(a), to

remedy and prevent Defendants Schering, Kogan, Heiden and Naughton from engaging in further violations of New Jersey and federal law.

COUNT III
(Intentional Interference With Contractual Relations)

404. Named Plaintiffs repeat and reallege the allegations contained in each of the foregoing paragraphs as if fully set forth herein.

405. The patients who were treated with the Subject Drugs during the Class Period have contractual relationships with their treating physicians and the Named Plaintiffs and other TPPs that insure them.

406. As part of these contractual relationships, among other things, the physicians provide health care services to the patients, and the patients cause the physicians to receive compensation because (1) the patients are affiliated and insured by a TPP; (2) the patients cause claims to be submitted to a TPP; and/or (3) the patients pay any out-of-pocket difference directly to the physicians.

407. Physicians contract to treat patients with the knowledge or expectation that their patients, in most circumstances, are covered by a TPP, and that the prescriptions that the physicians write for the patients will be paid, in large part, by the TPP.

408. Defendants are aware that patients who are prescribed the Subject Drugs have a contractual relationship with their physicians through which the physician writes prescriptions for his/her patients, and are further aware that

patients have a contractual relationship with their TPPs to pay for some or all of the drugs, including the Subject Drugs, prescribed by the physician.

409. The Named Plaintiffs and other TPPs are a foreseeable party to the contractual relationship between patient and physician because it is foreseeable to Defendants (and generally known) that a TPP will often pay all or part of the remuneration that flows from the patient directly to the physician, and that a TPP will often pay all or part of the amount charged for drugs prescribed by the physician.

410. Defendants' off-label marketing efforts described herein interfered with the contractual relationships existing between the patient and physician and the patient and the TPP because Defendants intentionally sought to and did interject false and misleading off-label marketing claims relating to the Subject Drugs to both physicians and to patients that affected the nature of treatment, the writing and filling of prescriptions, and, ultimately, the amount of money paid by the TPP on behalf of the patient.

411. Defendants' conduct was injurious and transgressive of generally accepted standards of common morality and violative of the law because Defendants engaged in off-label marketing that included the dissemination of false and misleading information intended to deceive physicians, patients and TPPs (among others).

412. Defendants also improperly and intentionally interfered with these contractual relationships by paying bribes and kickbacks to physicians, and foisting lavish gifts and other economic inducements upon physicians to corrupt and interfere with the faithful performance of the physicians' contractual duties owed to patients.

413. Defendants' actions as described herein were intentional, criminal, and were specifically designed to increase off-label use of the Subject Drugs so Defendants could earn greater profits.

414. All of the Named Plaintiffs are TPPs who paid claims on behalf of patients who were treated by a physician, and were prescribed one or more of the Subject Drugs by that physician, under the circumstances detailed above where that physician's medical judgment, independence and loyalty to the patient was improperly influenced through Defendants' fraudulent statements or corrupted by bribes.

415. Named Plaintiffs and other TPPs suffered damages because they paid for ineffective drugs, or paid excessive prices for the Subject Drugs when equally or more effective drugs were available at cheaper prices, as a result of Defendants' interference with the contractual relationships between the patient and physician and between the patient and the TPP.

COUNT IV
(Unjust Enrichment)

416. Named Plaintiffs repeat and reallege the allegations contained in each of the foregoing paragraphs as if fully set forth herein.

417. Defendant Schering's scheme to market the Subject Drugs for off-label purposes through the use of false and misleading statements and bribes, as set forth in greater detail above, was dishonest, fraudulent, criminal, illegal and immoral.

418. Defendant Schering raked in vast profits (approx. $3.4 billion) as a direct results of its engaging in this dishonest, fraudulent, criminal, illegal and immoral behavior.

419. Most of the illicit profits Defendant Schering raked in during the Class Period were paid by TPPs (members of the putative Class) who were deceived into paying for the Subject Drugs at times when they were not effective, or where there existed equally or more effective competing treatments available at a fraction of the cost.

420. But for Schering's dishonest, fraudulent, criminal, illegal and immoral conduct, TPPs would not have paid and Schering would not have raked in more than a billion dollars in illicit proceeds. Had TPPs known that Schering was fraudulently marketing its drugs, fraudulently misleading doctors about the efficacy of the Subject Drugs, and fraudulently bribing doctors to increase

prescriptions of the Subject Drugs, even in areas where there was no proven efficacy, TPPs would not have paid Schering for them.

421. Schering's dishonest, fraudulent, criminal, illegal and immoral conduct materially and directly increased the off-label sales of the Subject Drugs, and Schering's own documents tracked exactly the extent to which its multimillion dollar marketing scheme represented a good return of investment.

422. It would be unjust for Schering to retain these illicit profits at the expense and to the detriment of the TPPs.

423. Accordingly, Defendant Schering should be ordered to return any funds obtained through its dishonest, fraudulent, criminal, illegal and immoral conduct to the Class.

PRAYER FOR RELIEF

WHEREFORE, Named Plaintiffs demand judgment on behalf of themselves and the Class as follows:

A. Awarding Named Plaintiffs and the Class compensatory damages against Schering in an amount to be determined at trial, together with prejudgment interest at the maximum rate allowable by law;

B. Awarding Named Plaintiffs and the Class punitive or exemplary damages in an appropriate amount to be determined at trial;

C. Awarding Named Plaintiffs and the Class all statutorily available damages under the RICO and NJ RICO;

D. Awarding Named Plaintiffs and the Class attorneys' fees, and all other costs of suit, including witness fees, exhibit costs and all other costs and disbursements of this action;

E. Awarding Named Plaintiffs and the Class such other and further relief as this Court may deem just and proper.

JURY DEMAND

The Named Plaintiffs demand a trial by jury of all facts, issues and claims so triable.

DATED: September 9, 2009

Respectfully Submitted,

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