

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MDL NO. 1430

MASTER FILE NO. 01-CV-10861-RGS

IN RE: LUPRON® MARKETING AND
SALES PRACTICES LITIGATION

MEMORANDUM AND ORDER APPROVING
SETTLEMENT AND CERTIFYING THE CLASS

May 12, 2005

STEARNS, D.J.

This aspiring Multi-District Litigation (MDL) class action was brought by patients, health care plans, and insurers seeking damages incurred because of an alleged scheme orchestrated by TAP Pharmaceutical Products, Inc. (TAP) to inflate the retail price of the prescription drug Lupron®.¹ Plaintiffs' principal claims are based on the civil provisions of the Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. § 1962, and various state consumer protection statutes. On November 24, 2004, the court preliminarily certified a settlement class consisting of consumers and certain Third Party Payers (TPPs), and gave its preliminary approval to a proposed settlement agreement between TAP,

¹Lupron®, the trade name for leuprolide acetate, is principally used in the treatment of prostate cancer. It is also effective in the treatment of endometriosis, precocious puberty, and uterine fibroid preoperative anemia. Lupron® is administered by intramuscular injection, typically in the arm or buttocks, in daily or monthly doses. Consequently, most Lupron® is sold through doctors who administer the injections to their patients.

Abbott Laboratories (Abbott), and Takeda Pharmaceuticals Company Ltd. (Takeda),² and the universe of prospective litigants who claimed to have suffered economic damages as a result of TAP's Lupron®-related pricing practices.³ Under the terms of the settlement, TAP transferred \$150 million into an escrow account to satisfy the claims of consumers and TPPs who had made purchases of Lupron® between 1985 and 2005, and to pay the fees and expenses of plaintiffs' counsel. The parties now seek final approval of the settlement, permanent certification of the class, and entry of final judgment.

The court held a three-day Fairness Hearing beginning on April 13, 2005. Valerie Samsell and Milton Greene were permitted to intervene as objectors to the settlement. The Intervenor participants participated in the hearing through retained counsel, the Philadelphia-based firm of Kline & Specter. Having considered the evidence presented at the hearing, the objections, the arguments of counsel, and the full record of the case, the court will grant the motion for final certification of the class, confirm the appointment of class counsel, and approve the proposed settlement.

BACKGROUND

²TAP is a venture jointly owned by Abbott and Takeda. TAP, which is based in Waukegan, Illinois, has a corporate identity separate from its owners, that is, it has its own officers and board of directors.

³In the Settlement Agreement, the class is defined as “[a]ll individual persons or entities who, [between January 1, 1985, through March 15, 2005] made Lupron® Purchases. Excluded from the class are the Settling Health Plans; Defendants, their respective present and former, direct and indirect, parents, subsidiaries, divisions, partners and affiliates; and the United States government, its officers, agents, agencies and departments, and all other government entities’ claims, to the extent that they previously released their claims pursuant to the 2001 Settlement Agreement and Release resolving the matter of United States of America v. TAP Pharmaceutical Products, Inc. (D. Mass.) and related litigation.”

Procedural History

On October 16, 2001, TAP pled guilty in the federal district court to violations of the Prescription Drug Marketing Act, 21 U.S.C. §§ 331(t), 333(b).⁴ TAP admitted that it had encouraged doctors to fraudulently bill the federal Medicare program for free samples of Lupron® as part of a “brand loyalty” scheme. The intent was to provide incentives to doctors to prescribe Lupron® instead of cheaper, similarly effective drugs, such as Zoladex® (manufactured by AstraZeneca). Pursuant to a plea agreement with the United States government, TAP paid a \$290,000,000 criminal fine and \$559,483,560 in civil restitution and penalties, the largest beneficiary of which was the federal Medicare program, although \$25,516,440 was paid to the fifty States and the District of Columbia to compensate for overcharges absorbed by state Medicaid programs. TAP also executed a Corporate Integrity Agreement with the Inspector General of the Department of Health and Human Services (HHS) and the state Attorneys-General committing to changes in the supervision of its marketing and sales staff and agreeing to report to Medicare and Medicaid the true “Average Sales Price” (ASP) of its reimbursable drugs. Abbott and Takeda agreed to cooperate fully with any further government investigation of TAP in exchange for an agreement by the United States to forgo a prosecution alleging complicity by Abbott and Takeda in TAP’s wrongdoing.

³Following TAP’s plea, an indictment was unsealed against six present and former TAP employees and a Massachusetts urologist alleging a criminal conspiracy to defraud Medicare. Several other urologists pled guilty to criminal informations. Alan Mackenzie, W. Donald Meek, Donald Patton, and Eric Otterbein, the highest ranking TAP executives indicted in connection with the alleged scheme, were among a group of TAP employees who, after a lengthy trial, were acquitted on July 14, 2004, of any criminal wrongdoing. See U.S. v. MacKenzie, No. 01-CR-10350-DPW (D. Mass.).

At the heart of the scheme was TAP's overt or tacit encouragement of doctors to bill Medicare for Lupron® at an imaginary "Average Wholesale Price" (AWP) provided by TAP to the *Red Book*, an industry publication used by Medicare and other TPPs to establish payment schedules for reimbursable prescription drugs.⁵ "TAP knew that [it] could 'raise' the average wholesale price of Lupron® at any time by simply forwarding to the *Redbook* a new and higher average wholesale price. This allowed TAP, in effect, to control the maximum Medicare reimbursement paid to a doctor for [prescribing] Lupron®." Government's Sentencing Memorandum, at 12. The government acknowledged that its "global" settlement with TAP did not provide restitution to private insurers and co-paying patients who may have been overcharged for Lupron®, but noted that "some patients and health insurers have commenced litigation against TAP to recover overpayments caused by the criminal conduct and thus have a forum in which to demonstrate and obtain any appropriate damages." *Id.* at 4.

⁵While Medicare Part B does not generally reimburse the costs of self-administered drugs, it does pay providers for up to 80 percent of the "allowable cost" of physician-injected drugs like Lupron®. The remaining 20 percent is paid by the Medicare beneficiary as a "co-payment." "Allowable cost" was defined by HHS regulations from 1992 to 1998 as the lesser of a drug's estimated actual acquisition cost or its national average wholesale price (AWP). 42 C.F.R. § 405.517 (amended Nov. 2, 1998; Jan. 7, 2004; Nov. 15, 2004). Prior to 1992, Medicare reimbursements were based on the "reasonable charge method." From 1998 to 2004, "allowable cost" was defined as the lesser of a drug's estimated actual acquisition cost or 95 percent of AWP. 42 C.F.R. § 405.517. For 2004, reimbursement for Lupron® was set at the lesser of the actual charge on the bill or 81 percent of the April 1, 2003 AWP for Lupron®. 42 C.F.R. § 414.707. For 2005, reimbursement is based on the ASP. 42 C.F.R. § 414.904. The AWP was taken by HHS from the *Drug Topics Red Book (Red Book)*, a pharmaceutical industry publication compiling wholesale drug prices. The AWP for Lupron® published in the *Red Book* was supplied by TAP. No independent verification of the actual AWP was undertaken by HHS, Medicare, or the editors of the *Red Book*. The published AWP for Lupron® as reported by TAP ranged from \$418.75 in 1992 to \$623.79 in 2001.

In fact, a number of actions were brought in various state and federal courts against TAP, Abbott, and Takeda on behalf of co-paying patients, direct purchasers of Lupron®, private health care plans, and insurers that were not included in the government-negotiated civil settlement. The unifying themes of these civil claims are allegations that the defendants fraudulently manipulated the AWP for Lupron® and engaged in unscrupulous practices in the marketing of the drug. They are also mostly pled, as in this case, under the federal RICO law and state consumer protection statutes.⁶ According to plaintiffs, the AWP reported by TAP for Lupron® bore no resemblance to the actual prices being charged to doctors, nor did it bear any relationship to a reasonable interpretation of the terms “average” or “wholesale.” The AWP rather was inflated at plaintiffs’ expense to funnel hidden profits to doctors. As summarized in the Consolidated Amended Complaint:

[t]he improper marketing and sales practices include, *inter alia*: (a) deliberately overstating the published average wholesale price (“AWP”) for Lupron® – the rate upon which Medicare reimbursement (and Medicare beneficiaries['] co-payments) as well as many other insurers’ payments are set – so that Plaintiffs and the Class pay an artificially inflated amount of money for Lupron®; (b) providing free samples of Lupron® to medical providers and instructing them, with the intent, that they could and should unlawfully bill Medicare, private insurers and individual patients for the free samples; (c) providing other unlawful financial inducements and hidden price discounts; and (d) actively concealing, and causing others to conceal, information about the true price being charged for Lupron®.

Id. ¶ 4. TAP’s concession in its guilty plea that its sales representatives distributed \$31 million in “free” Lupron® samples between 1993 and 1999 figures prominently in most of the civil complaints. The complaints also mirror the government’s criminal case in reciting

⁶The factual allegations and legal theories underlying the Consolidated Amended Complaint are set out at length in In re: Lupron® Marketing and Sales Practices Litigation, 295 F. Supp. 2d 148 (D. Mass. 2003).

other irregular financial inducements offered by TAP to doctors to stimulate the sales of Lupron®, including volume discounts, rebates, “education” grants, junkets, off-invoice pricing, free goods, credit memos, supposed consulting fees, and debt forgiveness.

William Porter filed the first of two Lupron®-related class actions in the Massachusetts federal district court on May 18, 2001. Similar cases seeking class action status were filed in Alabama, Illinois, and Minnesota.⁷ On December 17, 2001, all pending federal class actions were consolidated by the MDL Panel (MDLP) in this district for pretrial proceedings. Two cases filed on behalf of Blue Cross and Blue Shield entities (Blues) in the District of Massachusetts were later joined with the MDL action as related cases.⁸

Several Lupron®/AWP cases were also filed as either state or nationwide class actions in state courts. Counsel in a number of these cases, including those in California (In re Lupron® Drug Cases, San Francisco Superior Court, JCCP No. 4238; Peralta v. Abbott Laboratories, Los Angeles County Superior Court, No. BC 259587); Texas (Benoit

⁷The lead plaintiffs in six of these cases are named as plaintiffs in the Consolidated Amended Complaint. The six cases are: Russano v. TAP Pharmaceutical Products, Inc. (N.D. Ill. C.A. No. 01-6982); Goetting v. TAP Pharmaceutical Products, Inc. (S.D. Ill. C.A. No. 01-703); Porter v. TAP Pharmaceutical Products, Inc. (D. Mass. C.A. No. 01-10861); Beacon Health Plans, Inc. v. TAP Pharmaceutical Products, Inc. (D. Mass. C.A. No. 01-10897); Brickey v. TAP Pharmaceutical Products, Inc. (N.D. Ala. C.A. No. 01-2770); and Twin Cities Bakery Workers Health and Welfare Fund v. TAP Pharmaceutical Products, Inc. (D. Minn. C.A. No. 01-2023).

⁸The Blues cases are Empire Healthchoice, Inc., d/b/a/ Empire Blue Cross and Blue Shield v. TAP Pharmaceutical Products, Inc. (D. Mass. C.A. 02-10015), and Blue Cross and Blue Shield of Florida, Inc. v. TAP Pharmaceutical Products, Inc. (D. Mass. C.A. 02-10139). On January 14, 2003, the court approved a stipulation adding Oxford Health Plans, Inc., and Horizon Healthcare Services, Inc., as parties to the Consolidated Amended Complaint.

v. Takeda Chemical Industries Ltd., et al., Jefferson County District Court, No. B166742); and Illinois (Clark v. TAP Pharmaceuticals, Inc. et al., Williamson County Circuit Court No. 01L132; Jarman v. TAP Pharmaceutical Products, Inc. et al., Madison County Circuit Court, No. 01L1019), agreed to coordinate discovery efforts with the counsel appointed by this court as the interim representatives of the interests of the MDL plaintiffs. However, Kline & Specter, which directly or through local counsel had brought class actions in Arizona, North Carolina, and New Jersey, refused to join in the cooperative effort.⁹ Kline & Specter instead embarked on a preemptive strategy to seize control of the litigation by using the state court proceedings to gain leverage over counsel cooperating with the MDL action.¹⁰

⁹On December 31, 2001, Kline & Specter filed a class action in the North Carolina Superior Court on behalf of lead plaintiff Harry Stetser. The complaint named the Lupron® defendants (TAP, Abbott and Takeda), as well as Johnson & Johnson, a distributor of Lupron®, and two wholly-owned Johnson & Johnson subsidiaries, Ethicon Endo-Surgery and Indigo Laser Corporation as defendants. On April 24, 2003, Superior Court Judge Paul Jones certified Stetser as a nationwide class action. On July 6, 2004, the Court of Appeals reversed the decision and decertified the nationwide class. On January 7, 2005, Judge Jones recertified Stetser as a North Carolina-only class action, retroactive to October 8, 2004. On October 9, 2001, Kline & Specter filed a class action against the Lupron® defendants in the New Jersey Superior Court on behalf of lead plaintiff Bernard Walker alleging unjust enrichment, fraud, civil conspiracy, and violations of the New Jersey consumer protection statute. On August 29, 2003, Superior Court Judge Joseph Visalli denied the request to certify a nationwide class of Lupron® purchasers, but certified a New Jersey-only Lupron® class. Judge Visalli is proceeding to trial on Walker's individual claims. On June 28, 2002, an Arizona law firm allied with Kline & Specter filed a class action in the Maricopa County Superior Court against the Lupron® defendants and other drug manufacturers that had also used AWP as a marketing tool. The complaint mirrors the causes of action set out in the Walker complaint. On March 10, 2005, Superior Court Judge Rebecca Albrecht stayed proceedings in Swanston pending a certification ruling in the MDL action.

¹⁰Bringing an end to unseemly attempts to exact advantage over class action defendants or lawyers representing competing plaintiffs' claims by exploiting the potential

On February 11, 2002, the court held a case management conference to establish a discovery and motions schedule. By that time, the defendants had assembled a central depository containing more than 300 boxes of case-related documents to which plaintiffs' counsel (including Kline & Specter) were given access. On March 15, 2002, the MDL plaintiffs filed a Consolidated Amended Complaint, and on June 7, 2002, a Corrected Consolidated Amended Complaint. Takeda, a Japanese company, challenged the Consolidated Amended Complaint on jurisdictional grounds. On January 24, 2003, the court denied Takeda's motion to dismiss in part, holding that while plaintiffs Goetting and Russano had failed to establish specific jurisdiction over Takeda, they had produced sufficient prima facie evidence to establish general jurisdiction under the "doing business" test of the Illinois Long-Arm Statute, 735 Ill. Comp. Stat. § 5/2-209(b)(4). See In re Lupron Mktg. & Sales Practices Litig., 245 F. Supp. 2d 280, 295-297 (D. Mass. 2003).

On November 25, 2003, after another heated exchange of briefs and arguments, the court issued a lengthy decision on defendants' Rule 12(b)(6) motion to dismiss, ultimately rejecting the (not inconsequential) arguments that political question considerations, statutes of limitations issues, and the "filed rate doctrine" operated to bar the litigation in its entirety. The court found the RICO claims as pled (alternatively identifying TAP as the enterprise and Takeda and Abbott as RICO "persons," or the three defendants as an "enterprise-in-fact" with each defendant acting as a RICO "person") sufficient to satisfy the requirements of Rule 9(b). The court also ruled that the state

for conflict inherent in a federal system of coordinate sovereigns was a principal argument advanced by advocates of the Class Action Fairness Act of 2005. The Act essentially consolidates all class actions with multi-state constituencies in the federal courts.

consumer protection act claims were not preempted by the Employment Retirement Income Security Act of 1974 (ERISA), § 514(a), 29 U.S.C. § 1144(a), or the Medicare Act. The court, however, agreed with defendants that plaintiffs had failed to plead a manageable RICO claim of an “association-in-fact” involving all doctors and clinics in the United States who had sold Lupron® at a price derived from AWP. Consequently, it dismissed the physician-related claims.

In February of 2004, the MDL plaintiffs, apparently content with the nucleus of the remaining state and federal claims, moved to certify a class consisting of

[a]ll persons or entities who paid for Lupron® at a price in whole or in part calculated by reference to the AWP as published in national pharmaceutical publications such as the *Red Book* and *First Data Bank* (the “Class”) during the period from January 1, 1991, through September 30, 2001 (the “Class Period”). Excluded from the Class are (a) Defendants and any entity in which any Defendant has a controlling interest, and their legal representatives, officer, directors, assignees and successors, and (b) any co-conspirators.

The impending hearing on the certification motion precipitated a flurry of discovery disputes as the parties maneuvered for position. See Orders dated March 1, 2004 (re: Motion to Compel Calculations); March 1, 2004 (re: Motion to Compel Individual Plaintiffs’ Releases); March 2, 2004 (re: Motion to Compel Individual Plaintiffs to Produce Documents); March 17, 2004 (re: Motion to Compel TAP to Produce Documents); April 5, 2004 (re: Temporary Stay); April 16, 2004 (re: Certification of Order for Appellate Review); April 23, 2004 (re: Production of Transcripts of Deposition of TAP Employees); June 14, 2004 (re: protective order); June 25, 2004 (re: motion for modification of schedule). On May 6, 2004, TAP filed an emergency petition with the First Circuit Court of Appeals

seeking an order of mandamus vacating the order of this court compelling the production of documents for which TAP had claimed attorney-client privilege and attorney work-product protection. On July 12, 2004, the First Circuit denied TAP's petition.

On January 22, 2004, the MDLP transferred to this court "tag-along" actions brought by Liberty National Life Insurance Company (Liberty) and United American Insurance Company (United) against TAP and Abbott. Liberty reimburses beneficiaries under a special cancer treatment policy for Lupron® injections. United reimburses beneficiaries who purchase a supplemental Medicare insurance policy for prescription drug co-payments including Lupron®. Both insurers based their reimbursement rates on the published AWP. On May 14, 2004, the court issued a decision denying motions by TAP and Abbott to dismiss both complaints. On August 4, 2004, the court denied a motion by TAP to dismiss a similar complaint brought by Aetna Health, Inc., alleging claims under RICO and the Pennsylvania insurance fraud statute, 18 PA. CONS. STAT. ANN. § 4117(a)(2) (West 2005).¹¹

On August 12, 2004, the court held an extended hearing on MDL plaintiffs' class certification motion, and took the matter under advisement. On October 11, 2004, as the court was completing the draft of its decision, the MDL parties notified the court that they had reached a settlement, which if approved, would eliminate the need to certify a litigation class. The MDL parties then moved for preliminary approval of the negotiated settlement.

¹¹On October 3, 2003, Aetna filed suit in the Eastern District of Pennsylvania. After the complaint was transferred by the MDLP to the District of Massachusetts, Aetna added by amendment three counts under RICO. At oral argument, Aetna waived three of its originally filed state law claims.

Immediately after the settlement was announced, Kline & Specter filed a motion to intervene on behalf of Valerie Samsell and Milton Greene.¹² The court allowed the motion “for the purpose of participating in the process established by the court for the evaluation of the proposed settlement.” On November 24, 2004, after a hearing in which counsel for the MDL parties and the Intervenor participants participated, the court gave preliminary approval to the proposed settlement and settlement class.¹³ MDL counsel were ordered to implement the Settlement Notice Plan and to establish an interactive website on which notice materials could be accessed and downloaded by prospective class members.

On December 10, 2004, less than three weeks after the court’s preliminary approval order, the MDL plaintiffs filed an emergency motion asking the court to enjoin Kline & Specter from

improper communication with members of the Lupron® Purchaser Class, dissemination of false, misleading and confusing information to members of the Lupron® Purchaser Class concerning both the MDL settlement and the status of other state court proceedings related to Lupron®, the improper solicitation of opt outs from the MDL settlement, and plans to conduct individual trials of Lupron® related claims in specific state court proceedings while the MDL settlement is pending review and approval by this court.

Defendants filed a similar motion of their own. The MDL parties directed the court to Kline

¹²Samsell and Greene object to the settlement as negotiated. Although Samsell and Greene are clients of Kline & Specter, neither appears to be a potential beneficiary of a pending Lupron® lawsuit other than the MDL action, including any lawsuit brought by Kline & Specter. Samsell believes (apparently mistakenly) that Kline & Specter represents her in a coverage dispute with an insurer who refused to reimburse her for Lupron® purchased on behalf of family members.

¹³On December 6, 2004, the Intervenor participants appealed the Preliminary Approval Order and asked the district court to stay its proceedings pending the outcome of the appeal. The district court declined to do so. See Rule 23(f). As of this date, no action has been taken by the Court of Appeals.

& Specter websites established under the domain names www.lupronlaw.com and www.lupronclass.com purporting to “welcome” potential members to “the class” and inviting Lupron® purchasers “to register for the Lupron® class action.” After reviewing the websites, the court issued a Memorandum and Order in which it found that the Kline & Specter websites were intended to mislead potential members of the MDL class. The court concluded that the typical registrant on a Kline & Specter website would not know that he or she was opting out as a participant in the MDL class by “registering” with Kline & Specter. Moreover, neither of the websites explained that a registrant who opted for inclusion “in litigation in the state courts” might (depending on his or her state of residence) be left with no means of recovery.¹⁴ The court acknowledged that while “[Kline & Specter] and attorney Haviland are perfectly free to criticize the proposed settlement agreement . . . they are not privileged to engage in deceptive conduct manipulating the very consumers they claim to protect.” Order dated December 21, 2004, at 3. The court ordered Kline & Specter to remove the purported “registration” form from the websites and to prominently display a banner stating that the websites had not been authorized by the MDL court, and directed that a complete list of all “registrants” be produced to the court (under seal) for inspection. Upon *in camera* review of the list, the court found that the great majority of those who had “registered” were not residents of New Jersey or North

¹⁴The websites appear to have originated as part of the notice plan undertaken in the later decertified North Carolina Stetser action, and to have been resuscitated by Kline & Specter as convenient fora for attacking the proposed MDL settlement.

Carolina, the states in which Kline & Specter had Lupron® actions pending.¹⁵

Immediately after the court ruled on the website issue, it learned that on December 29, 2004, attorney Haviland had addressed a “Dear Client” letter to every person who had registered on the Kline & Specter websites. The letter began by noting that the national class previously certified in North Carolina had “recently” been decertified (in fact, it had been decertified six months earlier) and reported (accurately) that nonresidents of North Carolina were “no longer included in and being protected by the North Carolina case.” The letter then advised registrants “to affirmatively protect their rights going forward” by opting out of the MDL settlement and by completing a Kline & Specter Retainer Agreement. The letter then presented a distorted picture of the MDL settlement, including the patently false statement that MDL claimants would be paid only 3 cents for each dollar of their actual damages. The letter was signed by attorney Haviland as “Co-Lead Counsel for State Court Plaintiffs and the State Court Classes,” without any disclosure of the fact that Kline & Specter was serving as lead counsel in pending Lupron® actions in only two states.

Having found the “Dear Client” letter to contain a number of deliberate misrepresentations and falsehoods, the court ordered that a curative notice be sent by Kline & Specter to all of the letter’s recipients.¹⁶ The notice highlighted misstatements in

¹⁵According to the list submitted by Kline & Specter, some 7,000 prospective class members had registered with Kline & Specter, of whom some 600 are residents of New Jersey and North Carolina.

¹⁶The curative notice was drafted by the court after soliciting suggestions from the MDL parties and comments from Kline & Specter.

the “Dear Client” letter, informed recipients living outside of North Carolina and New Jersey that Kline & Specter had not filed state lawsuits on their behalf, and warned that persons opting out of the MDL class might be required to bring a lawsuit personally to recover damages from the Lupron® defendants. The court advised recipients of the “Dear Client” letter desiring more information to contact the MDL Claims Administrator or to discuss with Kline & Specter their rights and obligations under any retainer agreement.¹⁷

After the mailing of the curative notice, the court sent Letters of Request to Judge Jones in North Carolina (dated February 2, 2004), and Judge Visalli in New Jersey (dated January 27, 2004), the presiding judges in the Stetser and Walker cases. The Letters noted the misinformation disseminated by Kline & Specter and the efforts undertaken by the court to provide prospective MDL class members with a full understanding of their rights and the opportunity to make an informed choice about participating in either the federal or (where available) state Lupron® litigation. As a matter of comity, the court asked Judge Jones and Judge Visalli to defer ruling on dispositive motions or proceeding with any potentially preclusive trials until this court could convene a hearing and rule on the fairness of the proposed MDL settlement.

Intervenors then moved to disqualify this judge from continuing to preside over the MDL proceedings, arguing that the federal court’s “unsolicited” communications with the state court judges gave “an objective appearance of partiality, if not actual partiality,” by demonstrating that “Judge Stearns has become fully engaged with the MDL litigants in

¹⁷The court allowed Kline & Specter’s request that for economic and client privacy reasons it rather than the MDL Claims Administrator be permitted to mail the curative notice to the list of registrants.

their efforts to deprive Walker, Stetser, Nelson and DeMontbrun of their timely day in court.” Intervenors’ Memorandum, at 5. The court denied the motion, noting the longstanding federal policy encouraging MDL judges to communicate directly with state court judges presiding over parallel cases in the interests of avoiding conflicts and conserving judicial resources. See Manual for Complex Litigation, Fourth, § 20.312 (Fed. Jud. Ctr. 2004) (Manual).

The court commenced a three-day Fairness Hearing on April 13, 2005. Prior to the hearing, the Intervenors filed seven boxes of exhibits, together with associated memoranda and affidavits. MDL plaintiffs and TAP also submitted substantial briefs and affidavits. The court provided the MDL parties and Intervenors each a total of four hours for the presentation of evidence, with an additional hour for argument. Objectors who requested to appear were allotted time to address the court, including several objectors affiliated with Kline & Specter.¹⁸ The court heard direct testimony from nine witnesses called by the MDL plaintiffs and the Intervenors, and received in deposition form the testimony of seven additional witnesses offered by Intervenors. The Intervenors submitted twenty-three exhibits at the hearing, the MDL plaintiffs eighteen, and the MDL defendants four. Three insurers appeared to express their support for the settlement.¹⁹

¹⁸Prior to the hearing, Paula Treskow withdrew her objection after reviewing with MDL counsel the reasons for the apportionment of the settlement funds between the consumer and TPP classes. Larry Crown (co-counsel with Kline & Specter in the Arizona AWP case) addressed the court on behalf of objector Swanston. Jennifer Koiles, Esq., explained that an objection filed on behalf of Rhonda Marcus on the mistaken belief that the settlement documents had been sealed by the court.

¹⁹Michael Hefter, Esq., addressed the court in support of the settlement on behalf of Empire Health Choice, Inc., Aetna, and Cobalt.

Notice

Notice to the class was disseminated by Hilsoft Notifications, a Pennsylvania company “specializing in designing, developing, analyzing and implementing large-scale, un-biased legal notification plans.” Hilsee Aff. ¶ 2. Todd B. Hilsee, the president of Hilsoft, has served as a notice expert in more than 175 class action cases, including In re Holocaust Victims Assets Litig., No. CV-96-4849 (E.D.N.Y.); In re Domestic Air Transp. Antitrust Litig., MDL 861 (N.D. Ga.); In re Dow Corning Corp., 95-20512-11 (Bankr. E.D. Mich.); In re Synthroid Mktg., MDL 1182 (N.D. Ill.); and In re Bridgestone/Firestone Tires Prods. Liab. Litig., MDL No. 1373 (S.D. Ind.). Hilsee was the only notice expert invited to testify before the Advisory Committee on Civil Rules on the amendment to Rule 23 requiring “clear, concise, plain language notices.” Hilsee was also asked by the Federal Judicial Center to design model notices to illustrate Rule 23 plain language “best practices.”

The notice plan approved by the court provided for individual notice where practicable as well as nationwide publication notice, the solicitation of public service radio announcements and mainstream news coverage, the posting of court-approved notices on Lupron®-related websites, the establishment of an interactive claims information website (www.lupronclaims.com), and a toll free telephone number to take questions from class members. The Notice Program was designed to

- (a) effectively reach approximately 80% or more of consumer Class members;
- (b) provide the consumer Class members reached with multiple opportunities to be exposed to the Notice – on average three or more times each;
- (c) provide a comprehensive and virtually complete reach of TPP Class members by way of mailed summary Notice;
- (d) use targeted notice

vehicles and state-of-art notice planning (i.e. media known to be used by Class members), with audiences that can be mathematically calculated; (e) provide thorough and fair geographic coverage of the United States; (f) design a program broadly targeting Class members without disadvantaging any potential Class member on the basis of geography (where they choose to live) or demographics (e.g. their age or socio-economic status); (g) develop a program consistent with other notice programs we have designed that have been court-approved and that we have implemented for large classes certified for purposes of settlement in federal courts, Massachusetts courts, and elsewhere; (h) use high quality notification vehicles and methods in order to convey the importance of the information affecting Class members' rights; (i) write and design Notices in plain language that will be "noticed" as well as simple, clear, easy to understand and act upon; (j) ensure that Class members who choose to participate can conveniently act on their right to claim a payment from the settlement through repetition, a variety of notice distribution methods, and notice design features; and (k) ensure an overall effective effort based on all relevant communication standards.

Hilsee Aff. ¶ 28. To enhance consumer exposure, Hilsoft studied the media habits of persons most likely to have received or procured Lupron® injections: men fifty years of age and older (prostate cancer); women ages 18 to 64 (endometriosis); parents of children likely to have been afflicted by precocious puberty; and African-American women ages 18 to 64 (the population group most susceptible to uterine fibroids).

The Claims Administrator, Complete Claim Solutions, Inc., reported that on January 7, 2005, it mailed a "TPP Notice Packet" to 235,480 potential TPP class members. TPP and Consumer Notice Packets were mailed to the Attorneys General of the fifty States (two packets were sent to the Office of the Attorney General in Pennsylvania – one to the then current Attorney General and one to the Attorney General-elect), Puerto Rico, and the Virgin Islands. As of April 4, 2005, 3,206 Consumer Notice Packets had been mailed to potential class members who contacted the Lupron® Hotline to request a claims package.

According to Hilsee, the plan exposed 80 percent of the members of the consumer class on three or more occasions to notice of the proposed settlement and the procedure for submitting claims. Specifically, Hilsee calculates that adults over 18 were reached an average of 3 times, 85 percent of living adults treated for prostate cancer were exposed an average of 3.7 times, 80.7 percent of all men over 50 were exposed an average of 3.1 times, 83.2 percent of women between the ages of 18 and 64 3.0 times, 80.8 percent of parents 3.1 times, and 86.2 percent of African American women between the ages of 18 and 64 an average of 3.2 times. Hilsee published notice in 947 newspapers, in Sunday newspaper supplements (Parade Magazine and USA Weekend), and in publications as diverse as *American Legion*, *Cosmopolitan*, *Ebony*, *Field & Stream*, *National Enquirer*, *Newsweek*, *Parents*, *People*, *Popular Mechanics*, *Reader's Digest*, *Time* and *VFW Magazine*. Hilsee testified that the notice was positioned opposite news articles and editorial features to increase the likelihood that it would be read.

Hilsee testified that additional exposure was achieved through public service announcements, the website, and free media coverage of the settlement. Hilsoft produced and distributed fifteen, thirty and sixty second public service announcements to 1,250 radio stations, including the top three to six adult stations in every major media market. Hilsoft also “selected the voice talent to help ensure that Class members would identify with the voice from the standpoint of demographic matching.” Hilsee Aff. ¶ 70. As of March 15, 2005, 127 radio stations in thirty-seven states had aired the announcement a total of 25,083 times (an average of 198 broadcasts per radio station). Hilsee estimates that this figure translates into an audience of 61,953,500 adults. The www.lupronclaims.com

website address was prominently displayed in all notice materials and website keywords were registered with hundreds of search engines, including Google, AOL, Ask Jeeves, Lycos, Yahoo!, WebCrawler, and AltaVista. Hilsee testified that as of April 15, 2005, 38,187 “hits” had been recorded at the website.²⁰ On January 7, 2005, a court-approved informational release was issued to established news wires reaching more than 450 health and medical publications, as well as 4,200 press outlets throughout the country. The informational release was also sent to sixty-eight support groups for the diseases treated by Lupron®.

At the Fairness Hearing, Hilsee testified that direct mail was not used to contact the consumer class because of privacy and practicality concerns. To compile an accurate mailing list would have required the obtaining of patient names and addresses from medical providers, insurers, and pharmacies that are for the most part forbidden from divulging patient information by federal and state privacy laws. Hilsee testified that in his experience with similar cases, including the Synthroid® and Paxil® drug litigations, “privacy concerns stood in the way of being able to consider giving individual notice to patients. . . . In this particular circumstance, it’s even more problematic, because these are very personal issues, prostate, infertility, [and] precocious puberty.” Fairness Hearing, April 14, 2005 Tr. at 154. Also, because the class period dates back to 1985, most of the older addresses (even if they could be obtained) would have no value for purposes of

²⁰A “hit” is an instance of a web page being loaded by an Internet user into his or her browser.

direct mail. Id., April 14, 2005 Tr. at 151.²¹

Hilsee explained that a “placard” program (advocated by Intervenor’s counsel) would have been ineffective for several reasons. Placard notice is usually positioned in pharmacies while almost all consumer class members received Lupron® injections directly from their physicians (who would be unlikely to display a potentially incriminating notice in their offices). According to Hilsee, placard notice is “a tool that [he] would [n]ever rely on nor has [he] ever [done so] in providing constitutionally-adequate notice under due process concerns.” Fairness Hearing, April 14, 2005 Tr. at 163. Hilsee pointed out that the Intervenor’s counsel did not utilize placard notice (or patient direct mail) in giving notice of a proposed settlement to the Stetser “national class.” In Hilsee’s opinion the Notice Plan “as implemented, fully satisfied the notice requirements of Federal Rule of Civil Procedure 23, including the new plain language requirements of Rule 23(c)(2).” Hilsee Aff. ¶ 81.

The Parties to the Settlement

The proposed settlement of this case involves two distinct agreements. The first is between the defendants and the Settling Health Plans (SHPs).²² The SHPs are a consortium of insurance companies and health plans that provide prescription drug benefits to an estimated 70 percent of the 197,869,000 persons in the United States who are covered by private medical insurance. The SHPs brought a separate complaint

²¹Hilsee also cited studies showing that 75 percent of direct mail is thrown away by the recipient or the recipient’s “gatekeeper” without being opened. Hilsee Aff. at 55 n.30.

²²The term SHPs is common to both agreements.

against the defendants. The SHPs are not associated as a class and have settled in their individual capacities with the defendants. The SHPs agreement is before the court for informational purposes only.

The second agreement, which has been presented for the court's approval, is between the defendants and the "Lupron® Purchaser Class." This class consists of consumer-purchasers and TPPs that are not part of the SHPs settlement. The class TPPs consist primarily of self-insured employers and Taft-Hartley benefit plans. The SHPs are explicitly excluded from the Lupron® Purchaser Class.

The Proposed Settlement

The total amount allocated between the two settlement agreements is \$150 million. Of this sum, \$40 million is earmarked for the claims of individual consumers, while \$55 million is initially allocated to the claims of the TPP class members, and an additional \$55 million to those of the SHPs. Attorneys' fees and expenses are subtracted from each pool, with the SHPs paying their own fees and costs, and the members of the Lupron® Purchaser Class paying the fees and costs of class counsel in proportion to the ultimate amounts awarded to consumer-purchasers and class TPPs. The first \$1 million in notice and claims expenses is to be borne by the class TPPs; thereafter the TPPs and the consumer-purchasers are to bear their respective costs in processing any remaining claims. Incentive payments to class representatives will be borne separately by each funding pool. Any unclaimed surplus in the consumer pool will not revert to TAP, but will

be distributed by the court at its discretion.²³ TAP is, however, entitled to a refund from the TPP pool in proportion to the value of the claims of those TPPs that opt out of the class settlement.

A mechanism is also provided to adjust the division of funds between the class TPPs and the SHPs depending on claims experience. To the extent that the SHPs group accounts for more than 50 percent of the eligible claims, it will receive a proportionate contribution from the class TPP pool, net of expenses, attorneys' fees, and the deduction for opt outs from the TPP class. Conversely, if the SHPs group accounts for less than 50 percent of the eligible claims, the TPPs will take a proportionate share of the SHPs pool, to a maximum of \$15 million.²⁴ By way of example, if 70 percent of the approved claims originate from the SHPs group, it will be entitled to an additional \$22 million (20 percent) of the \$110 million allocated between the SHPs and the class TPPs, net of fees, expenses, and opt out deductions.

Consumer-purchasers are entitled to recover 30 percent of their total out-of-pocket payments for Lupron®, or \$100, whichever is greater, unless the total amount of claims exceeds the amount allotted to the consumer pool. If the pool is depleted, pay-outs to consumers will be reduced on a pro rata basis. MDL counsel estimate that after payment of expenses and attorneys' fees, \$27.5 million will be available to the consumer-purchaser

²³If the court designates a charity as the recipient of any surplus funds, the Settlement Agreement permits TAP to take a corresponding tax deduction.

²⁴To insure payment of this \$15 million, the SHPs will initially distribute only \$40 million in claims, and will place the remaining \$15 million in escrow until the claims of all SHPs and class TPPs are processed.

class, an amount that MDL plaintiffs' counsel believe will be sufficient to pay all claims in full. On the other hand, because the TPP class may experience a higher claims rate, in the event its fund pool becomes oversubscribed the class through its representatives has agreed to share the funds available on a pro rata basis according to each TPP's purchase of Lupron® in 2000-2001. A representative sample method was chosen to avoid the expense involved in recreating twenty years of purchasing data.

According to the analysis of MDL plaintiff's expert, Dr. Raymond Hartman, the allocation of the settlement funds is deliberately weighted to favor the consumer-purchaser class over the SHPs and the class TPPs. (Hartman Decl., at 1-2). By Dr. Hartman's calculation, the average spread (AWP/ASP) was 182 percent between 1993 and 2000 (the years for which reliable data is available). (Hartman Decl. at 15.) Assuming that an AWP/ASP percentage spread of 125 percent (the "but-for spread") would be expected by the market, the difference between the actual and the but-for spread in the years analyzed by Dr. Hartman is 57 percent. This "unreasonable" 57 percent excess in the spread amounts to approximately 30 percent of the actual spread, explaining Dr. Hartman's opinion that a 30 percent of AWP recovery to consumers is reasonable.^{25, 26}

²⁵As an example, a 30 percent claims reimbursement pegged to an AWP of \$182 would result in a recovery of \$54.60 (roughly equivalent to the presumed overcharge of \$57).

²⁶Dr. Meredith Rosenthal, an MDL plaintiffs' expert who testified at the final approval hearing, points out that while consumer claims most likely account for 9 to 13 percent of the total overcharges (with extremes of 7 to 25 percent), consumers will receive 27 percent of the settlement. Dr. Rosenthal and Dr. Hartman believe that consumer damages over the period from 1991 to 2001 amounted to some \$166 million. Of this amount, \$150 million was borne by Medicare patients making out-of-pocket or coinsurance payments, and \$16 million was borne by consumers paying coinsurance in a private context. Both experts are

CLASS CERTIFICATION

Rule 23(a) sets out several prerequisites for a class action. A class may be certified only if:

(1) the class is so numerous that joinder of all members is impracticable; (2) there are questions of law or fact common to the class; (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and (4) the representatives will fairly and adequately protect the interests of the class.

Fed. R. Civ. P. 23(a).

Plaintiffs seek to certify a class pursuant to Rule 23(b)(3). This section provides that a class action may be maintained only if, in addition to the prerequisite of Rule 23(a):

the court finds that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy. The matters pertinent to the findings include: (A) the interest of members of the class in individually controlling the prosecution or defense of separate actions; (B) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class; (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; (D) the difficulties likely to be encountered in the management of a class action.

Fed. R. Civ. P. 23(b)(3).

“A district court must conduct a rigorous analysis of the prerequisites established

of the opinion that the overcharge for private consumers was around 30 percent, whereas for Medicare patients it was around 45 percent, because of the difference in what they consider to be the baseline. The but-for price for Medicare (that is, what Medicare patients would have paid absent the inflation) they set at the ASP, whereas the but-for price in the private context they set at 80 percent of the AWP. Both experts, however, consider a 30 percent recovery to be a reasonable approximation of the economic damages to the class members.

by Rule 23 before certifying a class.” Smilow v. Southwestern Bell Mobile Sys., Inc., 323 F.3d 32, 38 (1st Cir. 2003). In “determinating the propriety of a class action, the question is not whether the plaintiff or plaintiffs have stated a cause of action or will prevail on the merits, but rather whether the requirements of Rule 23 are met.” Waste Mgt. Holdings, Inc. v. Mowbray, 208 F.3d 288, 298 (1st Cir. 2000) (quoting Eisen v. Carlisle & Jacquelin, 417 U.S. 156, 178 (1974) (internal citation omitted)). In the settlement context, however, there is an important refinement to the Rule 23 analysis: the court “need not inquire whether the case, if tried, would present intractable management problems.” Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 620 (1997). When a settlement class is proposed, it is incumbent on the district court to give heightened scrutiny to the requirements of Rule 23 in order to protect absent class members.²⁷ Amchem, 521 U.S. at 620. This cautionary approach notwithstanding, the law favors class action settlements. City P’ship Co. v. Atl. Acquisition Ltd. P’ship, 100 F.3d 1041, 1043 (1st Cir. 1996).

(a) Numerosity

The class easily meets the Rule 23(a) requirement that “the class [be] so numerous that joinder of all members is impracticable.” While the mortality rate associated with prostate cancer, coupled with the extended class period, makes it impossible to predict the size of the class to any degree of mathematical certainty, the class includes thousands of

²⁷The heightened scrutiny rule is a byproduct of the controversy over the concept of a settlement class, a litigation device that was initially viewed with deep suspicion by courts and commentators who feared (not without justification) that it invited collusion between defendants and fee-hungry lawyers. Judge Becker summarizes the arguments for and against settlement classes in his seminal decision on the subject, In re General Motors Corp. Pickup Truck Fuel Tank Prods. Liab. Litig., 55 F.3d 768, 787-792 (3d Cir. 1995).

TPPs and tens if not hundreds of thousands of consumer-purchasers or their estates.

(b) Commonality

While at least one common issue of fact or law at the core of the action must shape the class, Rule 23(a) does not require that every class member share every factual and legal predicate of the action. In re General Motors Trucks, 55 F.3d at 817. “The threshold of ‘commonality,’ is not high. Aimed in part at ‘determining whether there is a need for combined treatment and a benefit to be derived therefrom,’ the rule requires only that resolution of the common questions affect all or a substantial number of the class members.” Jenkins v. Raymark Indus., Inc., 782 F.2d 468, 472 (5th Cir. 1986) (citation omitted). In this case, there are a number of common issues of fact and law that the class members would be required to establish to prove the defendants’ liability, as well as their entitlement to damages. All class members would need to establish that (1) they purchased Lupron® (2) at a price derived from a fraudulently inflated AWP (3) published by defendants as part of a concerted marketing scheme involving, inter alia, the provision of “free” samples, rebates, debt forgiveness, junkets, and “education grants” (4) that was intended to funnel hidden profits to doctors (5) as an inducement to prescribe Lupron® instead of less expensive alternatives like Zoladex®. The class would also be required to prove scienter on defendants’ part, as well as complicity on the part of physicians and clinics who billed members directly or through their insurers at a price derived from the inflated AWP. The civil RICO statute (the mainstay of the Consolidated Amended Complaint) would require the class to prove as a matter of fact and law that defendants (1) conducted (2) an enterprise (either a legal entity or an association in fact) (3) through a

pattern (at least two related acts) (4) of racketeering activity.²⁸ Sedima, S.P.R.L. v. Imrex Co., Inc., 473 U.S. 479, 496 (1985). In short, the commonality requirement is easily satisfied.²⁹

(c) Typicality

“A sufficient nexus is established [to show typicality] if the claims or defenses of the class and the class representative arise from the same event or pattern or practice and are based on the same legal theory.” In re Terazosin Hydrochloride Antitrust Litig., 220 F.R.D. 672, 686 (S.D. Fla. 2004) (finding that representatives were typical of plaintiffs subject to an overcharge for a prescription drug despite the fact that class members paid for the overcharge in different ways) (quoting Kornberg v. Carnival Cruise Lines, Inc., 741 F.2d 1332, 1337 (11th Cir. 1984)). “Although [the plaintiffs] may not have suffered identical damages, that is of little consequence to the typicality determination when the common issue of liability is shared.” In re Lorazepam & Clorazepate Antitrust Litig., 202 F.R.D. 12, 28 (D.D.C. 2001) (finding representatives’ claims typical despite the fact that some class

²⁸The predicate acts alleged by plaintiffs to constitute racketeering activity on the part of the defendants are mostly mailings and electronic communications plead as violations of the mail and wire fraud statutes. See Neder v. United States, 527 U.S. 1, 20 (1999).

²⁹While the Intervenor suggests that some Lupron® purchasers might not have been charged an AWP-based price or might not have paid for Lupron® distributed to doctors as “free” samples, plaintiffs’ evidence credibly demonstrates that virtually every purchase of Lupron® during the class period was influenced to one degree or another by the defendants’ manipulation of the published AWP. Given the needle and haystack problems that would be associated with any attempt to cull out the minuscule number of purchasers (if they in fact exist) who did not pay for Lupron® based on AWP or who did not receive a bill for a free sample, the inclusion of all purchasers of Lupron® in the class is an expeditious means of insuring that all purchasers who were affected by the scheme receive relief.

members bought prescription drugs directly while others bought from agents or wholesalers at various rates) (quoting Lewis v. Nat'l Football League, 146 F.R.D. 5, 9 (D.D.C. 1992)). Typicality is not a demanding test. Forbush v. J.C. Penney Co., Inc., 994 F.2d 1101, 1106 (5th Cir. 1993).

Intervenors challenge the typicality of the claims of the class representatives, relying on the briefs filed by the defendants prior to the hearing on the certification of a litigation class asserting that no class representative actually paid for Lupron® at the AWP.³⁰ The challenge is without merit. The court is satisfied, based on the affidavits presented by the MDL plaintiffs, that the Lupron® purchases of the class representatives were impacted by TAP's publication of an inflated AWP for Lupron®. The class representatives, in common with all other class members, claim to have been damaged by the defendants' price manipulation scheme. They claim to have been unaware of the fraudulent conduct in which the defendants were engaged. They seek to recover the maximum amount of damages possible, as would any member of the class, and they seek

³⁰Intervenors additionally assert that the class representatives are not typical of class members who have claims based on the diversion theory pressed by Intervenors' counsel in the North Carolina state court action in that no class representative claims to have been victimized by this alleged scheme. The complaint filed in North Carolina alleges that the Johnson & Johnson companies are liable for conspiring with TAP to sell excess Lupron® to doctors in North Carolina, a "Least Costly Alternative" (LCA) state, at a discount. The defendants then allegedly allowed or encouraged doctors to resell the surplus Lupron® in non-LCA states at a profit, as a means of preserving Lupron®'s market share at a time when doctors were switching their patients to Zoladex® because of LCA programs. Assuming that these allegations are true, they simply represent a variant in the overall marketing scheme resulting in the same generic injury – economic damages – suffered by the class representatives. See In re Prudential Ins. Co. of Am. Sales Practices Litig., 148 F.3d 283, 311-312 (3d Cir. 1998) (rejecting the argument that to satisfy the typicality requirement, the class representatives must share every form of injury suffered by the class); City P'ship, 100 F.3d. at 1044 (same).

to do so under the civil RICO statute and state consumer protection laws, as would most of the members of the class. In sum, I find that the claims of the class representatives are typical of those of the members of the class.

(d) Adequacy

“The [adequacy] rule has two parts. The moving party must show first that the interests of the representative party will not conflict with the interests of any of the class members, and second, that counsel chosen by the representative party is qualified, experienced, and able to vigorously conduct the proposed litigation.” Andrews v. Bechtel Power Co., 780 F.2d 124, 130 (1st Cir. 1985). “In complex actions such as this one, named plaintiffs are not required to ‘have expert knowledge of all details of the case, . . . and a great deal of reliance on the expertise of counsel is to be expected.’” County of Suffolk v. Long Island Lighting Co., 710 F. Supp. 1407, 1416 (E.D.N.Y. 1989) (citation omitted).

Intervenors challenge the adequacy of the class representatives, but the challenge is lacking in analysis, and for the most part appears to be the product of sloppy investigation.³¹ The Intervenors first accuse the TPP representatives, Twin Cities Bakeries

³¹With respect to the second component of the adequacy of representation prerequisite, the Intervenors make a rhetorical attack on the competence of MDL plaintiffs’ counsel, accusing them of being “feeble,” “disarmed,” “ineffectual,” and interested only in their fees, but without citing anything by way of evidentiary support for these insults (other than reckless claims of conflicts of interest that were exposed at the Fairness Hearing as false). The court has previously found MDL counsel to be highly competent and zealous in their pursuit of the interests of the class. Nothing said in the Intervenors’ brief or adduced at the Fairness Hearing would cause the court to revise that finding.

and Beacon Health Plans, of being “professional plaintiffs.” Even if the accusation is true (no evidence suggests that it is), it has no relevance to the competence of these TPPs to act as representatives of the TPP class. If anything, experience with prior similar litigation and knowledge of the legal issues involved enhances their role as class representatives. Intervenor also complain that the consumer representatives are reluctant role players who lack knowledge of allocation issues, the scope of the releases granted to the defendants, and the settlement in general. These allegations are not borne out by the record. Mrs. Brickey, in her capacity as the executor of the estate of William Brickey, submitted to a seven hour deposition at the defendants’ request. There is nothing surprising in the fact that Mrs. Brickey and Mrs. Goetting, the widows of the original class representatives, are unschooled in the intricacies of the legal process or the complexities of prescription drug pricing. They are, however, fully aware of the circumstances in which their husbands purchased Lupron®. During the Fairness Hearing, consumer class representative William Porter (who is 78 years old) gave a telephone deposition in which he demonstrated a full understanding of the settlement and the consequences of the release being offered to the defendants. Intervenor also argue that a number of potential conflicts exist among class members. Those that are identified are illogical. Individual differences in damages suffered do not create a class conflict when recovery varies in direct proportion to the amount of individual damages incurred. The fact that a SHP may be able to pull into the SHPs group benefit plans that it has a contractual right to represent does not create a conflict by allowing a SHP to “steal” from the TPP class. There is nothing untoward about contracts for representation, and the only likely effect of a SHP’s exercise of the right to

appropriate a claim is the revenue-neutral shift of a payment that would be made in any event from one pool to the other. Also, unlike the situation in In re General Motors Trucks, 148 F.3d at 800-801, where the class representatives were individual truck owners whose interests were in conflict with unrepresented fleet owners who received a less generous settlement, the Lupron® class representatives include both TPPs and consumer-purchasers. No objector has complained of any disparity in the benefits negotiated on behalf of consumer-purchasers and TPPs giving rise to an intra-class conflict. Nor are there any potential disparities in possible recoveries under state law of a significant enough magnitude to warrant separate state proceedings.³² In sum, I find the representation to be adequate.

(e) Predominance

“The Rule 23(b)(3) predominance inquiry tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation.” Amchem, 521 U.S. at 623. “Predominance is a test readily met in certain cases alleging consumer or securities fraud or violations of antitrust laws.” Id. at 625. “Where . . . common questions predominate regarding liability, then courts generally find the predominance requirement to be satisfied even if individual damages issues remain,” for “[t]he individuation of damages in consumer class actions is rarely determinative under Rule 23(b)(3).” Smilow, 323 F.3d at 40. See

³²Intervenors claim that certain MDL plaintiffs’ counsel face ethical conflicts because of their involvement in other drug pricing cases. Intervenors, for example, assert that the lead class counsel represents the State of Nevada in a suit involving similar Lupron® claims. In fact, the Nevada lawsuit does not involve Lupron®, but other drugs. A similar accusation that one of the class counsel represented doctors suing certain SHPs who were also plaintiffs in the MDL action proved equally untrue.

also Tardiff v. Knox County, 365 F.3d 1, 6-7 (1st Cir. 2004) (the certification of a litigation class of individuals subjected to illegal strip searches was not improper despite the fact that individual damages would inevitably vary depending upon each individual's claims of emotional distress, lost wages, and medical bills). Similarly, "where common issues otherwise predominated, courts have usually certified Rule 23(b)(3) classes even though individual issues were present in one or more affirmative defenses," for "[i]f . . . evidence later shows that an affirmative defense is likely to bar claims against at least some class members, then a court has available adequate procedural mechanisms." Smilow, 323 F.3d at 39-40. See also Waste Mgt., 208 F.3d at 296 ("Although a necessity for individualized statute-of-limitations determinations invariably weighs against class certification under Rule 23(b)(3), we reject any per se rule that treats the presence of such issues as an automatic disqualifier."); Tardiff, 365 F.3d at 5 (noting that the probability that some members of the class were lawfully strip searched did not defeat class certification, since class members could be grouped by the seriousness of the crime for which they were arrested); Carnegie v. Household Int'l, Inc., 376 F.3d 656, 660-63 (7th Cir. 2004) (Posner, J.) (affirming a RICO class certification and suggesting procedural mechanisms that at a later stage in the proceedings could be used to address the issues of whether particular class members were defrauded and the extent of any corresponding damages).

Courts dealing with allegations of pricing fraud in an analogous antitrust context have generally found common issues to predominate despite individual differences in amounts paid, the method of payment, and potential knowledge of the fraud. See, e.g., In re Linerboard Antitrust Litig., 305 F.3d 145, 163 (3d Cir. 2002) ("Key questions will not

revolve around whether Appellees knew that the prices paid were higher than they should have been or whether Appellees knew of the alleged conspiracy among Appellants. Instead, the critical inquiry will be whether ‘defendants successfully concealed the existence of the alleged conspiracy, which proof will be common among the class members in each class.’”) (citation omitted); In re Cardizem CD Antitrust Litig., 200 F.R.D. 326, 345 (E.D. Mich. 2001) (“The courts have routinely rejected similar arguments, despite differences in prices paid by class members, where the plaintiffs show that the ‘minimum baseline for beginning negotiations, or the range of prices which resulted from negotiations, was artificially raised (or slowed in its descent) by the collusive actions of the defendants.’”) (quoting In re Commercial Tissue Prods., 183 F.R.D. 589, 595 (N.D. Fla. 1998) (internal citations omitted)); Terazosin, 220 F.R.D. at 694-700 (finding plaintiff purchasers of drugs showed predominance of common issues in a suit alleging increased prices from antitrust conspiracy to prevent generic competition). But see Lienhart v. Dryvit Sys., Inc., 255 F.3d 138, 147-49 (4th Cir. 2001) (decertifying class in part because of the possible contributory negligence of contractors who may have failed to follow instructions in installing defendant’s house siding product); Markarian v. Conn. Mutual Life Ins. Co., 202 F.R.D. 60, 63-70 (D. Mass. 2001) (denying certification in part because despite evidence that company may have encouraged salespersons to use a misleading sales pitch, determination of whether it was actually used in particular cases would require individual inquiry).

Here, issues common to the class predominate over those that are personal to class members. The core factual issues involve the manner in which the defendants marketed

Lupron® to physicians; the methodology of the Medicare and private-payor reimbursement systems; the effect of competition from Zoladex® on Lupron®'s market share; and the impact of the defendant's marketing scheme on the actual price of the drug. As previously observed, the need to establish the elements of a civil RICO claim – the conduct of an enterprise through a pattern of racketeering activity – poses mixed issues of fact and law common to the class. Individual issues, on the other hand, primarily involve the amount of damages to be awarded to individual class members, a factor disfavored in determining predominance. While the extent to which individual class members were aware of the defendants' marketing scheme might weigh against certification, particularly in the case of the larger insurers that were arguably aware that the AWP for Lupron® was an artificial number, these entities are part of the SHPs group that has settled outside of the class.³³

Thus, this issue does not create individual predominance.

(f) Superiority

Rule 23(b)(3) requires a class action to be “superior to other available methods for the fair and efficient adjudication of the controversy.”

The matters pertinent to the findings include: (A) the interest of members of the class in individually controlling the prosecution or defense of separate

³³Intervenors finally note some differences in the state consumer protection laws plead by various members of the class. These differences, however, do not pose a serious obstacle to certification. See In re Prudential Ins. Litig., 148 F.3d at 315 (“Courts have expressed a willingness to certify nationwide classes on the ground that relatively minor differences in state law could be overcome at trial by grouping similar state laws together and applying them as a unit.”); Mowbray, 208 F.3d at 292, 296-297 (variations in twenty states' laws concerning reliance, waiver, and statutes of limitations did not cause individual issues to predominate). In any event, the issue is one of manageability, which is not a consideration in the certification of a settlement class. See Amchem, 521 U.S. at 620.

actions; (B) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class; (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; (D) the difficulties likely to be encountered in the management of a class action.

Id. “In adding ‘predominance’ and ‘superiority’ to the qualification-for-certification list, the Advisory Committee sought to cover cases ‘in which a class action would achieve economies of time, effort, and expense, and promote . . . uniformity of decision as to persons similarly situated, without sacrificing procedural fairness or bringing about other undesirable results.’” Amchem, 521 U.S. at 615. “[A] class action has to be unwieldy indeed before it can be pronounced an inferior alternative – no matter how massive the fraud or other wrongdoing that will go unpunished if class treatment is denied – to no litigation at all.” Carnegie, 376 F.3d at 661.

The superiority analysis dovetails with the predominance analysis. The issue here is one that lies at the very heart of the invention of the class action as a litigation vehicle: few, if any, members of the settlement class have incurred damages in an amount sufficient to justify the costs of pursuing an individual action. That fact alone makes a class action the only means by which most class members can obtain redress. Even if the claims could be prosecuted individually, their sheer number would make it unlikely that any significant number would be resolved during the lifetimes of the consumer class members. The court finds that under the circumstances, a class action is superior to any other mechanism for adjudicating this case (including joinder).³⁴

³⁴In the court’s experience, joinder of parties for trial in numbers above two dozen is unworkable.

(g) Ascertainability of the Class

“The proposed class must be precisely defined and its members must be ascertainable through the application of ‘stable and objective factors’ so that a court can decide, among other things, ‘who will receive notice, who will share in any recovery, and who will be bound by the judgment.’” Van West v. Midland Nat’l Life Ins. Co., 199 F.R.D. 448, 451 (D.R.I. 2001) (finding insufficiently definite a class of persons harmed by the unspecified “wrongful conduct” of defendant’s sales agents, whose practices differed from transaction to transaction). Compare Crosby v. Soc. Sec. Admin., 796 F.2d 576, 580 (1st Cir. 1986) (finding that a class of disability benefits claimants who did not receive a hearing “within a reasonable time” was impossible to ascertain in any objective fashion); In re Copper Antitrust Litig., 196 F.R.D. 348, 358-360 (W.D. Wis. 2000) (finding that the class was unascertainable where indirect purchasers had no means of knowing if they had been harmed) with Lorazepam, 202 F.R.D. at 22-25 (finding that the complexities of the pharmaceutical market did not make purchasers of drugs unascertainable, and collecting cases certifying classes of direct purchasers in complex markets) .

Intervenors make three challenges to ascertainability. First, they argue that self-funded plans might not know if they are members of the class. Second, they argue that the class period post-dates the notice, so that some persons who purchase Lupron® after the notice period may not know that they are in the class. Even if these persons learn of the class, Intervenors argue, they may do so after the March 15 deadline for objections and with a limited opportunity to opt out. Third, they argue that the class is “sprawling,” making it difficult to ascertain the appropriate time frame and to differentiate included from

excluded entities.

The first argument is without merit. A self-funded plan may determine whether it has the right to file a claim in its own name, or whether the right belongs to the SHP that administers claims on its behalf, by simply reviewing its contract with the SHP. The second argument has no relevance to ascertainability, but is rather concerns the sufficiency of the notice given to members of the class. The third argument is entirely unsupported by analysis, and is on its face unpersuasive. The inclusion of “all purchasers” rather than purchasers who paid in reference to AWP makes purchasers easier, not harder, to ascertain, while the opening and closing dates of the class could not be set out any more clearly than they are in the class definition.

FAIRNESS DETERMINATION

General Considerations

While the factors to be considered in making a fairness determination pursuant to Rule 23(e) often overlap with the class certification requirements of Rule 23(a) and (b), a court is required to analyze fairness as a separate and distinct issue. Rule 23(e) “was designed to function as an additional requirement, not a superseding direction, for the ‘class action’ to which Rule 23(e) refers is one qualified for certification under Rule 23(a) and (b).” Amchem, 521 U.S. at 621. While settlement and compromise are favored by the law, the court has a fiduciary duty to absent members of the class in light of the potential for conflicts of interest among class representatives and class counsel and the absent

members. “Rule 23(e) imposes on the trial judge the duty of protecting absentees, which is executed by the court’s assuring the settlement represents adequate compensation for the release of the class claims.” In re General Motors Trucks, 55 F.3d at 805. Approval is to be given if a settlement is untainted by collusion and is fair, adequate, and reasonable. “When sufficient discovery has been provided and the parties have bargained at arms-length, there is a presumption in favor of the settlement.” City P’ship, 100 F.3d at 1043. While the First Circuit has not established a formal protocol for assessing the fairness of a settlement, other circuits have identified factors deemed appropriate for consideration. The most commonly referenced factors were identified by the Second Circuit in City of Detroit v. Grinnell Corp., 495 F.2d 448 (2d Cir. 1974), overruled on other grounds by Missouri v. Jenkins, 491 U.S. 274 (1989):

(1) the complexity, expense and likely duration of the litigation; (2) the reaction of the class to the settlement; (3) the stage of the proceedings and the amount of discovery completed; (4) the risks of establishing liability; (5) the risks of establishing damages; (6) the risks of maintaining the class action through the trial; (7) the ability of the defendants to withstand a greater judgment; (8) the range of reasonableness of the settlement fund in light of the best possible recovery; (9) the range of reasonableness of the settlement fund to a possible recovery in light of all the attendant risks of litigation.

Id. at 463 (citations omitted). As a prelude to consideration of each of each of these factors, the court will briefly describe the negotiations that produced the proposed settlement and the principal objections tabled by the Intervenor, and principally the allegation that this is a collusive settlement.

The storm warnings indicative of collusion are a “lack of significant discovery and [an] extremely expedited settlement of questionable value accompanied by an enormous

legal fee.” In re General Motors Trucks, 55 F.3d at 801. The successful negotiations that led to this settlement were consummated relatively quickly (they appear to have been concluded in one or two days). However, the negotiations must be viewed in the context of the litigation as a whole.³⁵ The successful negotiation built on an earlier, three-month attempt to reach a settlement in 2003. The negotiations were not bilateral. MDL counsel wisely chose to secure separate and independent representation for the two distinct subclasses, the consumer-purchasers and the TPPs. At the Fairness Hearing, the court heard the testimony of Gregory Cox, the lead counsel in the Texas Lupron® action, and Stephen Rosenfeld, an attorney with extensive experience in pharmaceutical litigation (who is not affiliated with the MDL steering committee). Cox and Rosenfeld were designated to represent consumers in the negotiations. Operating on the assumption that the consumer share of the damages might amount to at most 15 percent of the total damages, Rosenfeld testified that his (and Cox’s) primary objective was to maximize their percentage recovery from the settlement fund. The achievement of that objective over the resistance of the more powerful SHPs group is strong evidence of the arms-length nature of the negotiations. A secondary objective of the consumer representatives, insuring that any unclaimed funds did not revert to TAP, was also achieved.

Intervenors’ criticism is directed less at the percentage of the allocation of the fund to consumers than at the size of the fund itself, which they contend would be larger but for

³⁵One of the concerns with so-called “drive by” class actions is that the court called upon to certify the class and approve the settlement is presented with a *fait accompli* and has no independent means of verifying the lawyers’ representations. Here, several years of hotly contested litigation has educated the court in the factual and legal intricacies of the case and the relative strengths and weaknesses of the parties’ respective positions.

a “reverse auction” orchestrated by the defendants. The only support offered for this allegation is the affidavit of Geoffrey Miller, a New York University law professor, which while instructive on the theory of reverse auctions, disavows any familiarity with the negotiations in this case. Intervenors’ stronger argument is that the impetus to settle on defendants’ part arose from the impending Walker trial in New Jersey (where attorney Haviland serves as lead counsel), and that the defendants found the MDL steering committee to be a more pliant negotiating partner than Kline & Specter as the latter would have insisted on a larger settlement fund in exchange for a release. This would be a persuasive argument if it were true. I credit defendants’ representation that the global peace that they desired could never have been negotiated with Kline & Specter. The firm represents less than 5 percent of the national pool of consumer-purchasers and more critically, almost none of the TPPs, the entities with claims of 90 percent of the damages. As a consequence, a settlement with Kline & Specter was never considered a realistic alternative, and hence no global negotiations were ever undertaken with the firm.

Intervenors’ final substantive objection is that the release agreed to by MDL counsel is broader than warranted by the size of the settlement. Intervenors offered two witnesses on the subject, Ms. Samsell, who is involved in a dispute with her insurer over coverage for Lupron®, and Steven Rowan, a prostate cancer patient who appears to have been the victim of fraudulent billing by his treating clinic. Both witnesses had been told by Kline & Specter that the release would extinguish their claims. An attorney appearing for Robert Swanston, the class representative in the Arizona action, argued that the release given to TAP might conceivably be interpreted as immunizing other pharmaceutical companies

which Swanston alleges conspired with TAP in the manipulation of the AWP of other drugs. As to the first two issues, MDL counsel agree that the only claims extinguished by the release are those related to defendants' marketing, pricing, and sale of Lupron®.³⁶ The release would have no affect on insurance coverage disputes or on overcharging claims unrelated to TAP's conduct. Insofar as Swanston is concerned, the release of TAP would have no affect on the liability of any alleged coconspirator. It has always been the law that a legally immune party may be part of an actionable conspiracy.³⁷ See, e.g., Standefer v. United States, 447 U.S. 10, 15-21 (1980). While the issue of the release of physicians who prescribed Lupron® was not a subject of testimony at the Fairness Hearing, it is touched upon in the Intervenor's brief. However, as MDL counsel point out, their RICO enterprise theories involving physicians were dismissed by the court as either failing the RICO tests of association, organization and control, or if brought individually against 10,000 urologist enterprises as totally impracticable and unmanageable. In re Lupron® Litig., 295 F. Supp. 2d at 173-174 & n.27. Consequently, MDL plaintiffs' counsel state, and correctly so, that in releasing the claims against the urologists, they gave up

³⁶I agree with Intervenor's that as written the release does not make the point as clearly as did MDL counsel at the Fairness Hearing that it is intended to cover only conduct related to defendants' alleged fraudulent activity in marketing Lupron®. I will ask that the Proposed Final Judgment clarify the scope of the release in this respect.

³⁷Intervenor's also complain of the absence of prospective injunctive relief barring TAP from engaging in similar overpricing in the future. I agree with the MDL parties that the Corporate Integrity Agreements entered by TAP with the United States Government and the State Attorneys General make any such relief redundant.

little of consequence.³⁸

The Grinnell Factors³⁹

(a) the complexity, expense and likely duration of the litigation

The continued litigation of the case would be noxiously burdensome to all involved, given the twenty year duration of the alleged RICO conspiracy, the involvement of a foreign party (Takeda), and the differing orders of proof required to establish (or defeat) the claims of the consumer and TPP subclasses. MDL plaintiffs' counsel report having incurred over \$14 million in fees and over \$1 million in costs to date. I have to assume that the costs incurred in defending the case are of a similar magnitude and are compounded by the rearguard skirmishes being fought with Kline & Specter. These costs and fees would escalate precipitously if the case were to be litigated through certification of a litigation class, summary judgment and the two or four trials (depending on the bifurcation of liability and damages as between the two subclasses) that would be required to achieve a comprehensive verdict. This process would reasonably take another two to three years to complete, and at least another year to resolve on appeal. Given the fact that many in the consumer claimant class are elderly and/or ill, it is in the interest of this subclass to bring the litigation to a closure, particularly one that allows a distribution of damages, as expeditiously as possible.

³⁸MDL counsel also note that neither Intervenors' counsel nor anyone else has actually brought a direct claim against a urologist.

³⁹I have not considered one of the traditional Grinnell factors, the risks of maintaining the suit as a class action through trial. As Judge Scirica observed in In re Prudential Ins. Litig., 148 F.3d at 321, this factor is largely irrelevant in settlement-only cases as Amchem does not require a manageability inquiry in a settlement context.

(b) the reaction of the class to the settlement

Absent polling data, which is not available to the court, this factor can be analyzed only by comparing the number of objectors and opt outs with the number of claimants, and by assessing the extent to which notice effectively reached absent class members. As of May 9, 2005, 10,614 consumer claims had been filed with the Claims Administrator. To date 7,123 of these claims have been processed for a total claimed amount of \$15,320,831.81. The only significant number of opt outs are persons who have been excluded from the settlement by Kline & Specter.⁴⁰ Most of these persons are residents of states in which the firm has no Lupron® action pending. Only forty-nine persons unaffiliated with Kline & Specter have opted out of the settlement on their own initiative and only ten persons submitted objections (several of whom are associated with Kline & Specter).⁴¹ See In re Prudential Ins. Litig., 148 F.3d at 318 (in assessing the weight of the objections, the district court properly considered the fact that the most

⁴⁰The Claims Administrator has received several letters from attorney Haviland purporting to exercise blanket opt outs on behalf of 783 (or as many as 978) consumers who are said to be clients of Kline & Specter. (The exact number is difficult to ascertain as the lists submitted by attorney Haviland are inconsistent. See Supplemental Decl. of Thomas R. Glenn. Some of the consumers on various of the lists have independently filed claims with the MDL Claims Administrator. The MDL parties have asked that the court either strike the Haviland opt outs and give each person affected an opportunity to decide personally whether or not to join the MDL class, or at a minimum, that the court require Kline & Specter to submit proof that attorney Haviland has the authority to exercise the exclusions on each individual's behalf.

⁴¹As previously noted, the objection of Paula Treskow was withdrawn prior to the Fairness Hearing. After hearing the uncontradicted statements of MDL counsel that no consideration was given in exchange for withdrawal of the objection, and that the objection was withdrawn on the merits after Treskow and her attorney had the opportunity to review the settlement documents in depth, the court will give its approval for the withdrawal as required by Rule 23(e)(4)(B).

vociferous objectors were persons enlisted by counsel competing with MDL counsel for control of the litigation). As previously indicated, the SHPs, the parties with the largest claim to damages, but also the group most vulnerable to defendants' affirmative defenses, have settled separately with defendants. Of the TPP class members, 880 have submitted claims, of which 286 have been processed for a total claimed amount of \$39,160,604.89. None of the TPPs has objected to the settlement, and of the some 235,000 TPPs who received mail notice, only fourteen have elected to opt out. Finally, six state Attorneys General purported to exercise opt outs on behalf of the citizens of their states who are otherwise qualified as members of the consumer-purchaser class.⁴² With respect to the effectiveness of notice, in the absence of any evidence to the contrary, I accept the testimony of Todd Hilsee that the plan he designed achieved its objective of exposing 80 percent of the members of the consumer class on three or more occasions to notice of the proposed settlement and the procedure for submitting claims, and of providing direct written notice to all TPPs that might be affected by the settlement. I have examined the materials that were used to publicize the settlement, and I agree with Hilsee's opinion that they complied in all respects with the "plain, easily understood language" requirement of Rule 23(c). In sum, I find that the notice given meets the requirements of due process.

(c) stage of the proceedings and the amount of discovery completed

As the procedural history of the case outlined earlier makes clear, the case was in

⁴²This matter is in the process of being separately briefed after the court questioned the authority of the Attorneys General to act on behalf of private citizens without their express consent. It would appear now that at least some of the Attorneys General have come to the view that the court's scepticism is well-taken.

litigation for nearly four years before the settlement was reached. Some 500 boxes of documents totaling over a million pages had been produced by the defendants for review. Twenty-six depositions had been taken, including depositions of TAP's senior management. Discovery has been sufficient to give counsel an informed view of the strengths and weaknesses of plaintiffs' case. More impressive, however, than the sheer volume of documents reviewed and depositions taken is the skillful use that MDL plaintiffs' counsel have made of that discovery in fending off aggressive and equally skillful motions brought by defendants, several of which had the potential of collapsing the plaintiffs' case.

(d) the risks of establishing liability and damages

As any experienced lawyer knows, a significant element of risk adheres to any litigation taken to binary adjudication. With respect to establishing liability, plaintiffs' principal risks arise from: (1) the complexity of the case; (2) the difficulty of establishing any uniform practice in the actual use of the AWP in marketing Lupron®, particularly Lupron® sold through TPPs pursuant to negotiated contracts; (3) the difficulty of deflecting defenses based on imputed knowledge that the AWP was subject to manipulation by the defendants, as well as apparent government ratification of the defendants' conduct; and (4) related statutes of limitations defenses.⁴³ The plaintiffs face formidable, albeit not insurmountable obstacles in presenting to a lay jury a clear, and yet legally sufficient,

⁴³In noting the risks, the court is not passing judgment on the ultimate outcome. A settlement court reviewing the fairness of a compromise does not "decide the merits of the case or resolve unsettled legal questions." Carson v. Am. Brands, Inc., 450 U.S. 79, 88 n.14 (1981).

narrative of the evidence,⁴⁴ while defendants have a powerful argument that the AWP was known to Congress and large insurers to be an artificial benchmark with no real market significance.⁴⁵ Proving damages represents two significant risks to the consumer class: (1) a number of consumers (or their estates) would likely no longer have records available to prove the extent of their Lupron® purchases; while (2) those consumers who made flat co-payments for prescription drugs might be found to have suffered no damages at all, as a co-payment is a fixed fee that does not vary with the price of the drug in question. The TPPs, on the other hand, which account for the lion's share of the damages, were the most likely to have been aware of the manipulation of AWP by TAP and therefore the most vulnerable to TAP's knowledge defense.

(e) ability of the defendants to withstand a greater judgment

This defendant-oriented factor is largely neutral as there seems little doubt that TAP and its venture partners (Takeda and Abbott) are defendants with classic deep pockets.

(f) the amount of the settlement fund in contrast to the best possible recovery

In applying this test of reasonableness, "the present value of the damages plaintiffs would likely recover if successful, appropriately discounted for the risk of not prevailing, should be compared with the amount of the proposed settlement." In re General Motors

⁴⁴While the standard of proof in a criminal case is much higher than in a civil one, it cannot go unremarked that the government failed to win a single conviction in its trial of some dozen TAP executives and employees who were indicted for their roles in the marketing of Lupron®.

⁴⁵This consideration appears to have led the government to abandon an AWP-based criminal prosecution of TAP and to substitute instead the allegations of "free sample" fraud to which TAP pled guilty.

Trucks, 55 F.3d at 806 (quoting Manual § 30.44). Measured against the civil recovery from TAP obtained by the government under the threat of debarment, the proposed settlement is roughly commensurate in size. More importantly, the sufficiency of the allotment to the consumer fund, which was initially difficult to judge because of the lack of claims experience and uncertainty as to the size of the ultimate claimant pool, now appears more than adequate to fully compensate all consumer claimants and to perhaps pay a dividend. While it is possible to hypothesize about larger amounts that might have been recovered,⁴⁶ as do Intervenor, Judge Becker counsels: “[t]he evaluating court must . . . guard against demanding too large a settlement based on its view of the merits of the litigation; after all, settlement is a compromise, a yielding of the highest hopes in exchange for certainty and resolution.” In re General Motors Trucks, 55 F.3d at 806. Based on Dr. Hartman’s and Dr. Rosenthal’s analysis of the likely damages, the opinions of experienced MDL counsel, and my own determination that the risks plaintiffs face in establishing a viable litigation class outweigh any potential benefit to be gained by further litigation, I find that the proposed settlement lies within the range of reasonableness.

ATTORNEYS’ FEES AND COSTS

Under the terms of the Settlement Agreement, and subject to the court’s approval, class counsel may seek reasonable attorneys’ fees not to exceed 30 percent of the \$95,000,000 settlement fund (after deducting any amount that might be rebated to TAP

⁴⁶Intervenors’ counsel are consistently inconsistent in their evaluation of what might optimally be recovered, ranging from \$300 million with a 50 percent chance of an adverse result to literally billions of dollars with no risk whatsoever.

because of TPP exclusions).⁴⁷ MDL class counsel have petitioned the court for an award of attorneys' fees in the amount of \$23,750,000 and for reimbursement of \$1,822,754.71 in costs.⁴⁸ The court finds the fee request to be within the range of reasonableness, given the duration and intensity of the litigation, and the results achieved.⁴⁹ It will, however, defer making specific findings until all outstanding motions are resolved and final judgment is entered. The award of attorneys' fees will in any event not exceed 25 percent of the settlement fund, and should the court award less, it will order any surplus to be paid into the appropriate pool. Class counsel also request that the court approve modest incentive awards totaling \$100,000, including \$5,000 to be paid to each named consumer plaintiff who was deposed, \$2,500 to be paid to each named consumer plaintiff who was not deposed, and \$25,000 to be paid to each of the named TPP plaintiffs. Incentive awards are recognized as serving an important function in promoting class action settlements, particularly where as here, the named plaintiffs participated actively in the litigation. Denney v. Jenkins & Gilchrist, 2005 WL 388562, at *31 (S.D.N.Y. Feb. 18, 2005). Consequently, I will approve the awards as requested.

⁴⁷Despite the terms of the Settlement Agreement, class counsel have agreed that the collective request for fees will not exceed 25 percent of the settlement fund.

⁴⁸The lodestar as of the date the petition was filed, April 6, 2005, amounted to \$14,503,055.50, meaning that class counsel were seeking an award at a multiplier of 1.64, a number that will shrink as additional hours are expended implementing the settlement. The court takes no position for present purposes as to the appropriateness of the requested multiplier.

⁴⁹At the Fairness Hearing, MDL counsel and TAP suggested that any excess funds in the consumer pool be used to increase the percentage of the recovery allocated to consumer-purchasers, to provide for additional notice and further distribution to absent class members, or to fund a *cy pres* award to benefit the consumer class as a whole.

ORDER

For the foregoing reasons, the court will:

- (1) OVERRULE the objections to the settlement class and the proposed settlement;
- (2) APPROVE the withdrawal of the Treskow and Marcus objections pursuant to Rule 23(e)(4)(b);
- (3) CERTIFY the proposed class, the court having found that the class satisfies the prerequisites of Rules 23(a) and (b);
- (4) APPROVE the proposed settlement as fair, reasonable, and adequate for purposes of Rule 23(e);
- (5) APPOINT interim class counsel as permanent class counsel pursuant to Rule 23(g)(1)(A);
- (6) APPROVE the award of incentive fees to the named class plaintiffs;
- (7) DEFER acting on the petitions for attorneys' fees and costs until all outstanding motions are resolved, including any involving disputes over the allocation of an attorneys' fee award; and
- (8) ORDER MDL counsel to submit a joint proposed form of final judgment within thirty (30) days of the court's resolution of all outstanding motions other than those concerning the award of attorneys' fees and costs.

SO ORDERED.

/s/ Richard G. Stearns

UNITED STATES DISTRICT JUDGE

