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 REGARDING DISPOSITION
OF MONEY REMAINING IN THE CONSUMER SETTLEMENT POOL

May 19, 2009

STEARNS, D.J.

This class action involved a scheme in which TAP Pharmaceutical Products, Inc. (TAP), and two affiliated[1] co-defendants were alleged to have artificially inflated the price of the prostate cancer drug Lupron®.[2] Because of the number and similarity of the cases filed against defendants in various state and federal courts by patients, health care plans, and medical insurers, the Multi-District Litigation Panel consolidated the action in the District of Massachusetts for pretrial proceedings. After an extended period of litigation,[3] this court approved the certification of a national class consisting of

[a]ll persons or entities who paid for Lupron® at a price in whole or in part

[1]The co-defendants were Abbot Laboratories and Takeda Pharmaceutical Company Limited (f/k/a Takeda Chemical Industries, Ltd.).

[2]Lupron®, the trade name for leuprolide acetate, is also effective in the treatment of endometriosis, central precocious puberty, and uterine fibroid preoperative anemia.

[3]Decisions published by this court describe in detail the underlying litigation. See, e.g., In re Lupron Marketing and Sales Practices Litig., 345 F. Supp. 2d 135 (D. Mass. 2004) and In re Lupron Marketing and Sales Practices Litig., 245 F. Supp. 2d 280, 295-297 (D. Mass. 2003).

> calculated by reference to the AWP [average wholesale price] as published in national pharmaceutical publications such as the *Red Book* and First Data Bank . . . during the period from January 1, 1991, through September 30, 2001 . . . .

In re Lupron® Marketing and Sales Practices Litig., 228 F.R.D. 75, 81 (D. Mass. 2005). The Settlement Agreement approved by the court divided a $150 million Class Settlement Fund between a Third Party Payor (TPP) Settlement Pool and a Consumer Settlement Pool. The Agreement allocated $110 million to the TPPs, and $40 million to consumer claimants. A nationwide notice campaign was then conducted. By the end of the campaign, the TPP Pool was fully subscribed. Nearly 11,000 consumers also filed claims. The consumers were paid an average of 167 percent of their listed out-of-pocket expenses or insurance co-payments. After the payment of claims, fees, and expenses, an unexpended surplus of $11,400,000 remains in the Consumer Settlement Pool.

The Settlement Agreement included a provision addressing the possibility of a surplus. Under the terms of paragraph 17(b)(6)(ii) of the Agreement, "[a]ll unclaimed funds remaining in the Net Consumer Settlement Pool shall be distributed in the discretion of the Settlement Court as it deems appropriate." The *cy pres* ("near as possible") distribution of unclaimed funds in a common pool is well within the authority of a settlement court. See Six (6) Mexican Workers v. Arizona Citrus Growers, 904 F.2d 1301, 1306 (9th Cir. 1990); Masters v. Wilhelmina Model Agency, Inc., 473 F.3d 423, 436 (2d Cir. 2007). See also In re Folding Carton Antitrust Litig., 557 F. Supp. 1091, 1105 (N.D. Ill. 1983) ("[C]ourts have the power and the responsibility to exercise equitable discretion to achieve substantial justice in the distribution of the [residual] funds."). Cf. Zients v. LaMorte, 459 F.2d 628,

630 (2d Cir. 1972) ("Until the fund created by the settlement is actually distributed, the court retains its traditional equity powers."). As the Second Circuit has explained,

> [c]ourts have utilized Cy Pres distributions where class members are difficult to identify, or where they change constantly, or where there are unclaimed funds." Id. at § 10:16 n.1. In this connection, we take note of the recent Draft of the Principles of the Law of Aggregate Litigation by the American Law Institute. With respect to the approval of settlements providing for a Cy Pres remedy, the Draft proposes a rule limiting Cy Pres "to circumstances in which direct distribution to individual class members is not economically feasible, or where funds remain after class members are given a full opportunity to make a claim." Draft § 3.08, entitled "Cy Pres Settlements." This proposed rule is consonant with the observation of our sister circuit that "[f]ederal courts have frequently approved [the Cy Pres] remedy in the settlement of class actions where the proof of individual claims would be burdensome or distribution of damages costly."

Masters, 473 F.3d at 436, citing Six (6) Mexican Workers, 904 F.2d at 1305.

While affirming the court's discretion in the matter, case law provides little by way of practical guidance when it comes to a *cy pres* distribution. See e.g., In re Airline Ticket Comm'n Antitrust Litig., 307 F.3d 679, 684 (8th Cir. 2002) (the court is to distribute surplus funds to "recipient[s] [who] relate, as nearly as possible, to the original purposes of the class action and its settlement."). Consequently, the court invited suggestions from the parties before deciding how to proceed. The invitation generated a number of proposals including: (a) a renewed notice campaign using previously unavailable patient data from the Centers for Medicare and Medicaid Services in an effort to identify and locate additional potential consumer claimants; (b) the award of funds to nonprofit groups "advocating" on behalf of patients and consumer causes; (c) "brick and mortar" grants to hospitals and medical centers treating prostate cancer; (d) awards to "outreach" groups seeking to "educate" and "screen" prostate cancer patients; (e) the distribution of a

"dividend" to the 11,000 existing claimants (or their heirs); and (f) grants to researchers investigating the causes and cures of diseases or ailments treated by Lupron®. The court convened a hearing on January 13, 2009, to permit the parties to elaborate further upon the suggestions.[4]

After careful reflection and analysis, the court is inclined to adopt the research funding proposal presented by Dr. Kevin Loughlin, the Director of Urologic Research at Brigham and Women's Hospital.[5] In brief, Dr. Loughlin proposes that the money be used to fund cutting-edge research into the causes and cures of prostate cancer and other Lupron®-treated conditions.

The court will invite Dr. Loughlin to submit a formal proposal along the lines of his January 13, 2009 presentation. Of particular interest to the court are the following: (1) the protocol under which grant requests would be solicited and structured; (2) the average amount and duration of the awards contemplated; (3) the eligibility requirements for potential recipients; (4) the anticipated administrative expenses involved in selecting and monitoring the grant awards; (5) the means by which the grant opportunities would be

---

[4]There was very little dissent among the parties over the appropriateness of any one or all of the *cy pres* proposals submitted. The TAP interests opposed any distribution of funds to so-called "advocacy" groups, while the Intervenors strongly preferred that the money be divided among the existing consumer class members. All parties agreed that any further expenditure of settlement funds on attorneys' fees was neither necessary nor appropriate.

[5]Dr. Loughlin's participation came at the invitation of the Plaintiffs' Counsel Steering Committee. Three other physicians worked with Dr. Loughlin in developing the research proposal. They are Dr. Marc Garnick, an oncologist and prostate cancer researcher at Beth Israel-Deaconess Medical Center; Dr. Anthony Zietman, a radiation oncologist at Massachusetts General Hospital; and Dr. Michael Barry, the Chief of the General Medicine Unit at Massachusetts General Hospital.

advertised; (6) the anticipated division of research grants between the investigation of prostate cancer and other Lupron®-treated conditions (such as precocious puberty); (6) the measures that would be taken to avoid any real or perceived conflict of interest in the awarding of grants; (7) the restrictions that would be placed on overhead expenses paid to institutions with whom grantees are affiliated; (8) the appointment by the court of a member of the grant-awarding body to serve as the court's monitor; (9) the mechanism by which grant funds would be paid out and accounted for; (10) the procedures that would be followed in evaluating the progress of the funded research; (11) provisions for the disposition of any possible intellectual property issues arising from the funded research; and (12) the time-frame in which the court could expect all funds to be expended and a final accounting made.

ORDER

The court invites Dr. Loughlin to submit a formal proposal for the *cy pres* distribution of the excess settlement funds within sixty (60) days of today's date (if feasible), consistent with the preliminary proposal that he outlined at the hearing, and addressing the issues (among others), raised by the court in this Memorandum and Order.

SO ORDERED.

/s/ Richard G. Stearns

_____

UNITED STATES DISTRICT JUDGE