

United States Court of Appeals For the First Circuit

Nos. 10-2494; 11-1329

IN RE: LUPRON MARKETING AND
SALES PRACTICES LITIGATION

AUDREY ROHN, individually and as executrix of the estate of
Dennis Rohn; BARBARA SENSING; VALERIE SAMSELL,

Plaintiffs, Appellants,

MILTON GREENE; CROSSROADS ACQUISITION CORP.; WILLIAM M. PORTER;
LIBERTY NATIONAL LIFE INSURANCE COMPANY; UNITED AMERICAN
INSURANCE COMPANY; COBALT CORPORATION; AETNA, INC.,

Plaintiffs,

WILLIAM M. PORTER,

Plaintiff, Appellee,

v.

TAP PHARMACEUTICAL PRODUCTS, INC.; ABBOTT LABORATORIES; TAKEDA
PHARMACEUTICAL COMPANY, LIMITED,

Defendants,

DANA FARBER/HARVARD CANCER CENTER,

Interested Party, Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Richard G. Stearns, U.S. District Judge]

Before

Lynch, Chief Judge,
Souter, Associate Justice,*
and Lipez, Circuit Judge.

Donald E. Haviland, Jr., with whom Michael J. Lorusso and Haviland Hughes, LLC were on brief, for appellants.

Thomas M. Sobol, with whom Edward Notargiacomo, Hagens Berman Sobol Shaprio LLP, Jeffrey L. Kodroff, John A. Macoretta, Specter Roseman & Kodroff, P.C., David S. Stelling, Daniel R. Leathers, Lieff Cabraser Heimann & Bernstein, LLP, Lisa M. Mezzetti, and Cohen Milstein Sellers & Toll PLLC were on brief, for appellee William M. Porter.

Martin M. Fantozzi, with whom Mariana Korsunsky and Goulston & Storrs, P.C. were on brief, for appellee Dana Farber/Harvard Cancer Center.

April 24, 2012

* The Hon. David H. Souter, Associate Justice (Ret.) of the Supreme Court of the United States, sitting by designation.

LYNCH, Chief Judge. Appellants, a small dissident group ("the Samsell plaintiffs"), are within a larger class of medical patient consumers in a case alleging fraud in overcharging for the medication Lupron. These plaintiffs, along with insurers and private health care providers, have achieved a major settlement agreement which was approved by the district court. The total amount of the settlement was \$150 million, of which \$40 million was allocated to consumers. That agreement provided that if there were unclaimed monies from the \$40 million consumer settlement pool even after full recovery to consumer plaintiffs, all unclaimed funds would go into a cy pres fund to be distributed at the discretion of the trial judge.

The Samsell plaintiffs appeal from the district court's distribution of the \$11.4 million cy pres fund to the Dana Farber/Harvard Cancer Center and the Prostate Cancer Foundation ("DF/HCC") for work on the treatment of the diseases for which Lupron is prescribed. The Samsell plaintiffs make a series of subordinate attacks, all designed to increase the sums paid to them, though they have already recovered more than 100% of their actual damages. The award is defended by the plaintiff class and, naturally, by the recipient DF/HCC. The defendant manufacturer of Lupron, having settled the case, has not filed a brief with us.

We address for the first time the procedural and substantive standards for distribution of cy pres funds; in doing

so, we express our unease with federal judges being put in the role of distributing cy pres funds at their discretion.

Finding no error, we affirm.

I.

In 2001, the Department of Justice initiated criminal proceedings against TAP Pharmaceutical Products, Inc., ("TAP")¹ for violation of the Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293, 102 Stat. 95. TAP admitted that from 1991 to 2001 it had encouraged doctors to improperly bill Medicare for free samples of its cancer drug Lupron so that they would continue to prescribe Lupron instead of less expensive, similarly effective drugs. Lupron is prescribed for prostate cancer in men, endometriosis and infertility in women, central precocious puberty in children, and preoperative treatment of patients with anemia caused by uterine fibroids. TAP encouraged physicians to bill Medicare for Lupron at an inflated Average Wholesale Price ("AWP") that TAP provided to an industry publication used by Medicare and insurance plans to establish reimbursement schedules for prescription drugs including Lupron. TAP pled guilty and paid a criminal fine of \$290 million as well as civil restitution of nearly \$600 million to Medicare and Medicaid and \$25.5 million to the fifty states and the District of Columbia.

¹ TAP is a wholly owned joint venture of defendants Abbott Laboratories and Takeda Pharmaceutical Company, Ltd.

On the heels of TAP's guilty plea, three groups -- individual consumer purchasers of Lupron, private health care plans, and insurers -- brought nine putative class action lawsuits against TAP to recover overpayment incurred as a result of TAP's practices. See In re: Lupron Mktg. & Sales Practices Litig., 245 F. Supp. 2d 280, 285 (D. Mass. 2003). Private insurers and health care plans had used the inflated AWP, as had Medicare and Medicaid, to determine their reimbursement payments to doctors for Lupron. The inflated AWP also resulted in higher out-of-pocket payments for patients on any portions of Lupron payments that were not covered by their insurance.

The Multi-District Litigation Panel consolidated all nine actions in the District of Massachusetts for pretrial proceedings. Id. The consolidated class action was brought under the civil provisions of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962, as well as under state consumer protection statutes and theories of common-law fraud and unjust enrichment.

The district court dismissed the conspiracy claims involving physicians under RICO because the complaint neither named a single doctor as a defendant nor alleged that the doctors who benefitted from the discounted purchases or free samples of Lupron were even aware of one another's existence as participants in a purported scheme to defraud. That dismissal is important for

reasons stated later. The district court allowed the remaining conspiracy claims under RICO to proceed.

On October 11, 2004, the MDL parties informed the district court that they had reached a settlement as to all groups of plaintiffs and moved for preliminary approval of the negotiated agreement. On November 4, 2004, appellant Valerie Samsell, a consumer, filed a motion to intervene. The district court allowed Samsell to intervene "for the purpose of participating in the process established by the court for the evaluation of the proposed settlement." In re: Lupron Mktg. & Sales Practices Litig., No. 01-CV-10861 (D. Mass. Nov. 17, 2004). On November 24, 2004, the district court issued an order preliminarily approving the proposed settlement and settlement class. In re: Lupron Mktg. & Sales Practices Litig., 345 F. Supp. 2d 135, 138-39 (D. Mass. 2004).

In April 2005, the district court held a three-day fairness hearing on the proposed settlement. See In re Lupron Mktg. & Sales Practices Litig., 228 F.R.D. 75, 78 (D. Mass. 2005). Samsell called witnesses to testify, submitted seven depositions of additional witnesses, and presented twenty-three exhibits. Id. at 83-84. In addition, Samsell filed several objections to the settlement, including an objection that the amount of the settlement allocated to the class of consumer purchasers of Lupron was inadequate. On May 12, 2005, having found that the settlement was fair, reasonable and adequate, the district court issued a

memorandum and order approving the settlement and certifying the class. Id. at 78, 98.

The approved settlement agreement allocated \$40 million of the \$150 million total settlement to consumer purchasers of Lupron. Id. at 86. It allowed these consumers to recover 30% of their total out-of-pocket payments for Lupron, or \$100, whichever sum was greater. Id. at 87. Although the district court could not determine the size of the consumer class with certainty, given the high mortality rate associated with prostate cancer and the extended class period of more than twenty years, the district court found that the class likely included tens if not hundreds of thousands of consumer purchasers of Lupron or their estates. Id. at 88.

The district court's decision to approve the settlement agreement rested in part on an analysis of the likely damages suffered by the class plaintiffs, as presented by expert witnesses. Plaintiffs' two experts, Dr. Hartman and Dr. Rosenthal, testified that the allocation of the settlement funds was deliberately weighted to favor the consumer members of the class. Id. at 87 & n.26. Consumers were allocated approximately 27% of the total settlement, even though the consumer claims most likely accounted for 9% to 13% of the total overcharges. Id. at 87 n.26. The experts also testified that approximately 30% of the consumers' out-of-pocket expenses for Lupron represented a reasonable estimate

of the actual overcharge that consumers suffered as a result of the inflated AWP. Id. at 87 & n.26. The settlement agreement was designed to pay consumers 100% of this estimated overcharge.

Significantly, the settlement agreement expressly anticipated the possibility of either a shortage or a surplus in the portion of the settlement funds allocated to consumers. In the case of a shortage, the settlement agreement provided that payments to consumers would be reduced on a pro rata basis. In the case of a surplus, the agreement provided:

All unclaimed funds remaining in the Net Consumer Settlement Pool shall be distributed in the discretion of the Settlement Court as it deems appropriate. If all or part of any unclaimed funds is distributed to one or more charitable organizations, TAP reserves whatever right it may have to claim any appropriate tax deductions for any such charitable donation(s), and no member of the Consumer Class or the TPP [Third Party Payers] Class or the SHP [Settling Health Plans] Group shall have a claim to any such deductions.

Following the district court's approval of the settlement agreement, the Samsell plaintiffs said they would pursue appeals of the settlement agreement unless they received more. As a result, all of the parties, including the Samsell plaintiffs, negotiated and executed an "implementation agreement." The implementation agreement provided an increase in the payments to the consumer class from 30% to 50% of their out-of-pocket expenses for Lupron. This meant that consumers would receive 167% of the damages the district court had found they had suffered. In return, the Samsell

plaintiffs and other objectors agreed to withdraw their pending appeals and other objections to the settlement, to rescind their opt-out requests, to participate in the claims process, and to waive their right to appeal from the final judgment approving the settlement. The implementation agreement also awarded incentive payments to certain objectors, including Samsell, and permitted her attorneys to seek an award of their fees. On August 26, 2005, the district court entered its final order approving the settlement agreement as modified by the implementation agreement. In re: Lupron Mktg. & Sales Practices Litig., No. 01-CV-10861 (D. Mass. Aug. 26, 2005).

The parties initiated a national notice campaign designed to expose 80% of the members of the consumer class on three or more occasions to notice of the proposed settlement and the procedure for submitting claims. Notice was published in 947 newspapers, as well as through public service announcements, Lupron-related websites, and media coverage of the settlement. An interactive claims information website and a toll-free telephone number to take questions from class members were established. Consumer Notice Packets were mailed to the attorneys general of the fifty states, Puerto Rico, and the Virgin Islands. Direct mail was not used because of privacy and practicality concerns.

Consumers were allowed more than four years to file their claims. Despite these efforts, only about 11,000 individuals -- a

fraction of the estimated tens or hundreds of thousands of members of the consumer class -- filed claims, given the high mortality rate among members of the class. At the conclusion of the claims administration process, approximately \$11.4 million remained unclaimed.

The plaintiffs requested that the district court determine a plan for distribution of the \$11.4 million in unclaimed funds. On January 13, 2009, during a hearing regarding the proposed disposition of the unclaimed funds, the district court stated its intention to "ensure that any distribution, whatever is done, is done both with the highest benefit of the class, present and absent in mind; that the money is distributed and spent responsibly; and, that it serves the highest purpose that was intended by the litigation and the ultimate settlement." After hearing the plaintiffs' alternative proposals, the district court narrowed its choice to three options: (1) awarding the unclaimed funds as additional compensation to the members of the consumer class who had already made claims and been paid in full under the settlement agreement; (2) conducting a supplemental claims process with a goal of identifying absent class members; and (3) making a cy pres award of the unclaimed funds for research addressing the medical conditions treated by Lupron for the benefit of the present and future patients suffering from these afflictions.

In response to a proposal to distribute some of the residual funds to a program created by a group of four doctors affiliated with Brigham and Women's Hospital ("the Loughlin Group"), the district judge disclosed that for nearly twelve years he had served as an uncompensated trustee on the board of Vincent Memorial Hospital, which is affiliated with the Massachusetts General Hospital. The judge said he was considering whether this posed any issues. The Samsell plaintiffs, who were present at the hearing, did not, either then or later, raise any objection regarding the judge's position on the board at Vincent or his continued involvement in the proceedings.

On May 19, 2009, the district court issued a memorandum and order stating its intention to make a cy pres award and distribute the residual funds for the purpose of funding research into the causes and treatments of Lupron-related conditions. In re: Lupron Mktg. & Sales Practices Litig., No. 01-CV-10861, 2009 WL 1395411 (D. Mass. May 19, 2009). The district court stated that it was inclined to distribute the funds to the Loughlin Group and invited the Loughlin Group to submit a formal proposal for the court's review. Id. at *2. The Samsell plaintiffs appealed this order to this court; we concluded that we lacked jurisdiction to review a non-final order and dismissed the appeal. See Samsell v. TAP Pharm. Prods., No. 09-1887 (1st Cir. Jan. 7, 2010).

Having learned about the residual funds from the May 19, 2009 order, a different group, DF/HCC, petitioned the district court to consider its proposal with respect to the unclaimed funds. The district court granted the request. On May 25, 2010, the district court invited the public to comment on the proposals advanced both by the Loughlin Group and by DF/HCC.

On August 6, 2010, the court issued a memorandum and order stating that it had decided to make a cy pres award of all of the unclaimed settlement funds to DF/HCC, to be made in three installments. In re: Lupron Mktg. & Sales Practices Litig., 729 F. Supp. 2d 492 (D. Mass. 2010). The court explained that it had rejected the option of a supplemental claims process because it would be "exorbitantly expensive (estimated at upwards of \$1.74 million), time-consuming, and would likely recruit few new claimants given the high mortality rate among members of the class." Id. at 494 n.4. No attack is made on that finding in this appeal. The court further explained that its decision to award the funds to DF/HCC was influenced by four principal considerations. First, DF/HCC is an established organization "with experience in managing grant programs." Id. at 497. Second, its proposal "leverage[d] existing institutional infrastructure, funding mechanisms, and . . . relationships," which would reduce start-up and administrative costs. Id. Third, the proposal was designed to have "a broad national outreach to attract large-scale research

collaborations, innovative pilot projects, promising young investigators, and talented graduate students." Id. Finally, DF/HCC "propose[d] to dedicate an appropriate portion of the funds to research involving cures for . . . Lupron-treated diseases and conditions" other than prostate cancer. Id.

The district court also crafted an oversight plan which required DF/HCC to submit regular reports to account for the grant awards and expenditures. Id. at 497-98. The award would be paid to DF/HCC in three installments as explicitly authorized by the district court. Id. at 498. The first installment was ordered disbursed to DF/HCC on November 16, 2010. The Samsell plaintiffs have not sought a stay of the disbursements.

On December 16, 2010, Valerie Samsell and Audrey Rohn filed a Notice of Appeal from the November 16, 2010 Order. On January 5, 2011, Samsell filed an Amended Notice of Appeal to add Barbara Sensing as an appellant.

II.

Procedural Objections

Appellees attempt to short stop this appeal on several procedural grounds. We dispose of these procedural objections quickly.

First, appellee William Porter, who represents the certified consumer class, argues that the appeals are untimely because they were not filed within 30 days of the August 6, 2010

order, which he asserts was a final decision. Appellee DF/HCC argues that appellants Rohn and Samsell timely filed their appeals within 30 days of the November 16, 2010 order disbursing initial payment to DF/HCC, which they consider the pertinent order. But they say that appellant Sensing's appeal is still untimely because it was not filed within 30 days of any order.

The relevant "order" which starts our analysis is the August 6, 2010 order awarding the cy pres distribution to DF/HCC. The later November 16, 2010 disbursement order was a mere ministerial order. See, e.g., Am. Ironworks & Erectors Inc. v. N. Am. Constr. Corp., 248 F.3d 892, 898 (9th Cir. 2001) ("A mere ministerial order, such as . . . an order to disburse funds from the court registry, is not a final appealable order.").

Not all orders qualify as appealable orders. A notice of appeal in a civil case "must be filed with the district clerk within 30 days after entry of the judgment or order appealed from." Fed. R. App. P. 4(a)(1)(A). A judgment or order is "entered" for Rule 4(a) purposes "when the judgment or order is entered in the civil docket . . . [and] set forth on a separate document, or 150 days have run from entry of the judgment or order in the civil docket." Fed. R. App. P. 4(a)(7)(A)(ii). If an order is not set forth on a separate document, it is not considered "entered" and is not itself appealable until 150 days after entry in the civil

docket. Colón-Santiago v. Rosario, 438 F.3d 101, 108 (1st Cir. 2006).

Here, the August 6, 2010 order was not set forth on a separate document, but set forth on pages seven through nine of a nine-page memorandum containing the court's reasoning. It fails the "separate document" requirement. See Nunez-Soto v. Alvarado, 956 F.2d 1, 2 (1st Cir. 1992) (explaining that the Federal Rules of Civil Procedure require "that a judgment be set forth on a separate document and not simply tacked on to a memorandum or opinion").

The order was not "entered" for purposes of appeal until January 3, 2011, 150 days after August 6, 2010. The 30-day period for appealing from that order expired 30 days later, on February 2, 2011. Because all of the appellants filed before February 2, 2011, their appeals are timely.

Next, appellees argue that the Samsell plaintiffs lack standing because they are unnamed, nonparty class members who have never objected to the settlement agreement under which they have accepted full payment for their losses.² Only parties to a civil action may appeal from a final judgment. Devlin v. Scardelletti,

² This issue does not implicate the jurisdiction of the courts under Article III of the Constitution. The Samsell plaintiffs clearly have an interest in the residual funds that creates a "case or controversy" sufficient to satisfy the constitutional requirements of injury, causation, and redressability. See Lujan v. Defenders of Wildlife, 504 U.S. 555 (1992). Rather, the question is whether the Samsell plaintiffs should be considered "parties" for the purposes of appealing the cy pres distribution.

536 U.S. 1, 7 (2002). The Supreme Court has applied this rule strictly, and has generally rejected attempts to craft exceptions to the rule. Microsystems Software, Inc. v. Scandinavia Online AB, 226 F.3d 35, 39-40 (1st Cir. 2000).

Those who intervene in the district court properly become parties and may appeal a final judgment. Id. at 39. Of course, a nonparty may appeal from the denial of a motion to intervene. Id. at 40. However, courts are generally "powerless to extend a right of appeal to a nonparty who abjures intervention." Id. The Supreme Court has recognized only one exception to this rule: that "nonnamed class members . . . who have objected in a timely manner to approval of the settlement at the fairness hearing have the power to bring an appeal without first intervening." Devlin, 536 U.S. at 14.

Appellant Valerie Samsell clearly has standing to appeal because she was allowed to intervene in the trial court.³ See

³ Appellees argue that Valerie Samsell's intervenor status has expired. Samsell was granted intervenor status in 2004 "for the purpose of participating in the process established by the court for the evaluation of the proposed settlement." In re: Lupron Mktg. & Sales Practices Litig., No. 01-CV-10861 (D. Mass. Nov. 17, 2004). However, the court continued to treat Samsell as an intervenor well after the settlement was approved, conferring her continued intervenor status. See Microsystems Software, Inc. v. Scandinavia Online AB, 226 F.3d 35, 39 (1st Cir. 2000); accord In re E. Sugar Antitrust Litig., 697 F.2d 524, 527-28 (3d Cir. 1982). The district court referred to Samsell as an intervenor during the cy pres selection process, and most recently, did so again in its August 6, 2010 order.

Stringfellow v. Concerned Neighbors in Action, 480 U.S. 370, 375-76 (1987).

The status of appellants Audrey Rohn and Barbara Sensing is less clear. Neither Rohn nor Sensing were named parties in the district court proceedings and neither moved to intervene. Nor did either object to the final settlement agreement. See Devlin, 536 U.S. at 14. Both, however, appear to have objected to the court's cy pres distribution of unclaimed monies without first distributing additional funds to class claimants. Dennis Rohn, Audrey Rohn's deceased husband, appears to have advocated from the outset of the cy pres selection process that the court give any extra unclaimed funds to consumers who made claims. Barbara Sensing appears to have joined Samsell and Rohn in echoing that argument later on, when the court requested public comment on the proposal submitted by DF/HCC. The question then becomes whether Devlin, which created an exception for unnamed class members who have objected to settlement agreements, extends to this situation in which unnamed class members have objected to a cy pres distribution. For present purposes, we need not decide this question because Rohn's and Sensing's interests are represented on appeal by Samsell, who clearly has standing to appeal.

III.

Challenge to the Cy Pres Distribution

When class actions are resolved by settlement, unclaimed money may remain in the settlement fund after initial distributions to class members because some class members cannot be located, some decline to file a claim, or some have died. Settlement agreements often dispose of these unclaimed monies by providing for "cy pres" distributions. Cy pres is an equitable doctrine that has been imported into the very different class-action context from the field of trusts and estates law:

In trusts and estates law, cy pres, taken from the Norman French expression cy pres comme possible ("as near as possible"), "save[s] testamentary gifts that otherwise would fail" because their intended use is no longer possible. Courts permit the gift to be used for another purpose as close as possible to the gift's intended purpose In class actions, courts have approved creating cy pres funds, to be used for a charitable purpose related to the class plaintiffs' injury, when it is difficult for all class members to receive individual shares of the recovery and, as a result, some or all of the recovery remains.

In re Pharm. Indus. Average Wholesale Price Litig., 588 F.3d 24, 33 (1st Cir. 2009) (citations omitted) (quoting In re: Airline Ticket Comm'n Antitrust Litig., 307 F.3d 679, 682 (8th Cir. 2002)).

In In re Pharmaceutical Industry Average Wholesale Price Litigation, we recognized for the first time in this circuit that settlement agreements may establish cy pres funds for the distribution of residual unclaimed funds. Id. at 33-36. There, this court affirmed the approval of a cy pres fund where it was

part of a settlement agreement that was negotiated at arm's length by the parties; was not court mandated; some class members would not otherwise receive recovery; more than actual damages were paid out to class members; the creation of the cy pres fund facilitated the settlement of a hard-fought complex action; and the cy pres fund was meant to benefit absent and non-claimant class members. We rejected the argument that claimants are entitled to receive any unclaimed residual money, in preference to a cy pres distribution, regardless of whether they have already been compensated for their losses. Id. at 35. We held that the district court did not abuse its discretion in approving the cy pres part of the settlement because the settlement agreement met the American Law Institute's benchmark of "100 percent recovery" for all class members before any money would be distributed through cy pres. Id. at 35-36 (citing Am. Law Inst., Principles of the Law of Aggregate Litigation § 3.07 cmt. b (Apr. 1, 2009) (proposed final draft)). This case involves an agreement with these same characteristics. In our earlier case we did not address questions concerning the distributions from cy pres funds. We do so for the first time here.

We review a district court's approval of a proposed class action settlement for abuse of discretion. Id. at 32-33. The abuse of discretion standard is highly deferential and "not appellant-friendly." Texaco P.R., Inc. v. Dep't of Consumer

Affairs, 60 F.3d 867, 875 (1st Cir. 1995) (quoting Lussier v. Runyon, 50 F.3d 1103, 1111 (1st Cir. 1995)) (internal quotation marks omitted). Of course, a material error of law is an abuse of discretion. Spooner v. EEN, Inc., 644 F.3d 62, 66 (1st Cir. 2011). Ordinarily, however, an abuse of discretion will not be found unless "the record provides strong evidence that the trial judge indulged a serious lapse in judgment," Texaco P.R., 60 F.3d at 875, such as if the decision "ignores a material factor deserving significant weight, relies upon an improper factor, or assesses only the proper mix of factors but makes a serious mistake in evaluating them," Downey v. Bob's Disc. Furniture Holdings, Inc., 633 F.3d 1, 5 (1st Cir. 2011) (quoting Gomez v. Rivera Rodriguez, 344 F.3d 103, 112 (1st Cir. 2003)) (internal quotation mark omitted). We apply the same abuse of discretion standard to questions regarding a court's approval of distribution from a cy pres fund as part of a settlement agreement.

The Samsell plaintiffs frame some of their challenges as attacks on the underlying consent decree, but they gave up that challenge to the agreement when they executed the implementation agreement. They have waived any right to object to the agreement on appeal; indeed they received consideration for that waiver. After extended negotiations resulting in a 67% increase in their full damages awards, the Samsell plaintiffs entered into the implementation agreement in which they agreed to be bound by all

terms and provisions of the settlement agreement and agreed not to appeal from a final judgment. They also agreed to accept the roughly 167% of their damages as "fair and reasonable" compensation.⁴

The settlement agreement, which appellants are not free to attack, explicitly anticipated that there could be unclaimed funds after the distribution to claimants, and expressly granted the district court broad discretion to make awards from the cy pres fund.⁵ The agreement anticipated that a distribution might be made to appropriate charitable institutions. It granted TAP tax deduction rights if "all or part of any unclaimed funds is distributed to one or more charitable organizations."

We turn to the issue of whether the district court abused its discretion, under the evolving law of cy pres distributions in class action settlement agreements, in either the process utilized

⁴ Those who sought treble damages were given an opportunity to opt out of the settlement. Many plaintiffs did opt out and filed their own individual claims in state court. See, e.g., Walker v. TAP Pharm. Prods., Inc., No. CPM-L-682-01 (N.J. Super. Ct.); Stetser v. TAP Pharm. Prods., Inc., No. 01-CVS-5268 (N.C. Super. Ct.).

⁵ This is not a situation in which the primary purpose of the cy pres fund is to assure a settlement fund large enough to guarantee substantial attorney's fees or to make the bringing of the class action worthwhile, a danger pointed out by commentators. See Martin H. Redish, Peter Julian, & Samantha Zyontz, Cy Pres Relief and the Pathologies of the Modern Class Action: A Normative and Empirical Analysis, 62 Fla. L. Rev. 617 (2010).

or in the decision to make a cy pres award of the unclaimed consumer settlement proceeds to DF/HCC.

Here, the district court considered a supplemental consumer claims process designed to reach more consumers using previously unavailable patient data from the Centers for Medicare and Medicaid Services. The district court was concerned, however, that only 11,000 individuals out of the estimated tens or hundreds of thousands of class consumers filed claims despite extensive notice procedures. The district court appropriately decided that a supplemental consumer claims process would be prohibitively expensive, time-consuming, and, given the high mortality rate among members of the class, would likely recruit few new claimants.

The Samsell plaintiffs clarified at oral argument that they are no longer appealing the district court's choice to arrange a cy pres distribution rather than to recruit more claims by absent class members. In any event, there was no abuse of discretion in the district court's choice to forego a direct notice mailing given that the administrative burden of doing so appeared to outweigh the small potential for increased claims.

Instead, the Samsell plaintiffs make several categories of arguments, which are essentially these:

1. That they were entitled to greater distributions in preference to distributions for the benefit of absent class members because they have not received treble damages.

2. That the process used was flawed, including on the grounds that the judge should have recused himself.

3. That no award can be made to DF/HCC because:

a) its doctors are precluded from being recipients of awards by the terms of the agreement; and

b) the principles of cy pres are violated in that this is not a "next best" award to absent national class members because DF/HCC is located in Massachusetts and the research will be primarily focused on prostate cancer.

Many of these assertions are factually untrue.

We turn to the law on distribution of cy pres funds. To the extent the American Law Institute's Principles of the Law of Aggregate Litigation ("ALI Principles") provides guidance, it does not support a claim of abuse of discretion. The ALI Principles set forth proposed rules for the use of a cy pres distribution in class action settlements. See Am. Law Inst., Principles of the Law of Aggregate Litigation § 3.07 (2010) [hereinafter "ALI Principles"]. The ALI Principles express a policy preference⁶ that unclaimed funds be redistributed to ensure class members recover their full

⁶ The ALI Principles state: "If the settlement involves individual distributions to class members and funds remain after distributions (because some class members could not be identified or chose not to participate), the settlement should presumptively provide for further distributions to participating class members unless the amounts involved are too small to make individual distributions economically viable or other specific reasons exist that would make such further distributions impossible or unfair." Am. Law Inst., Principles of the Law of Aggregate Litigation § 3.07(b) (2010) [hereinafter "ALI Principles"].

losses. This policy preference was motivated by a concern that "few settlements award 100 percent of a class member's losses, and thus it is unlikely in most cases that further distributions to class members would result in more than 100 percent recovery." In re Pharm. Indus., 588 F.3d at 24 (quoting Am. Law Inst., Principles of the Law of Aggregate Litigation § 3.07 cmt. b (Apr. 1, 2009) (proposed final draft)). Where class members have been fully compensated for their losses, this presumption does not apply.

The ALI Principles also reject the presumption, suggested by a concurring opinion in Klier v. Elf Atochem North America, Inc., 658 F.3d 468 (5th Cir. 2011), that any residual funds must be returned to the defendant. Id. at 482 (Jones, J., concurring). The ALI Principles explain that returning unclaimed funds to the defendant "would undermine the deterrence function of class actions and the underlying substantive-law basis of the recovery by rewarding the alleged wrongdoer simply because distribution to the class would not be viable." ALI Principles, § 3.07 cmt. b. Courts have generally agreed with the ALI Principles. See 3 Newberg on Class Actions § 10:17 (4th ed. 2011). The ALI Principles also reject escheat to the state as a more preferable option. See ALI Principles, § 3.07 cmt. b.

Instead, ALI Principles § 3.07(c) sets up an order of preference: when feasible, the recipients should be those "whose interests reasonably approximate those being pursued by the class."

Id. If no recipients "whose interests reasonably approximate those being pursued by the class can be identified after thorough investigation and analysis, a court may approve a recipient that does not reasonably approximate the interests being pursued by the class." Id.

Both case law and the ALI Principles support our adoption of the "reasonable approximation" test. As to whether distributions reasonably approximate the interests of the class members, we consider a number of factors, which are not exclusive. These include the purposes of the underlying statutes claimed to have been violated, the nature of the injury to the class members, the characteristics and interests of the class members, the geographical scope of the class, the reasons why the settlement funds have gone unclaimed, and the closeness of the fit between the

class and the cy pres recipient.⁷ Failure to meet the reasonable approximation test can lead to reversal.⁸

For example, in In re Airline Ticket Commission Antitrust Litigation, 268 F.3d 619 (8th Cir. 2001), a national antitrust class action against airlines concerning caps on ticket commissions earned by travel agencies, the Eighth Circuit held that a cy pres distribution of unclaimed funds to Minnesota law schools and charities was invalid. Id. at 625-26. On remand, the district court ordered the funds distributed to the National Association for Public Interest Law, "to support attorneys providing legal services to low income clients by paying the interest on grant recipients'

⁷ As Judge Posner has pointed out, the cy pres doctrine under the trust law "is based on the idea that the settlor would have preferred a modest alteration in the terms of the trust to having the corpus revert to his residuary legatees. So there is an indirect benefit to the settlor." Mirfasihi v. Fleet Mortg. Corp. 356 F.3d 781, 784 (7th Cir. 2004). He contrasts this with a different rationale in the class action context:

[T]he reason for appealing to cy pres is to prevent the defendant from walking away from the litigation scot-free because of the infeasibility of distributing the proceeds of the settlement . . . to the class members. There is no indirect benefit to the class from the defendant's giving the money to someone else. In such a case the 'cy pres' remedy [is] . . . badly misnamed.

Id. That is another reason to require the cy pres fund to provide some benefit to class members, even if indirect.

⁸ One commentary has suggested that abandonment of "next best" relief intended to be an alternate means of indirectly compensating victims who could not feasibly be compensated directly would create issues of constitutional dimension. See Redish at 641-51.

outstanding student loans." In re: Airline Ticket Comm'n, 307 F.3d at 682. The Eighth Circuit reversed again, explaining that the "next best" recipients were not public interest organizations, but rather the travel agencies in Puerto Rico and the U.S. Virgin Islands who suffered from the same allegedly unlawful caps. Id. at 683-84. The court remanded the case, ordering that the cy pres fund be distributed on a proportional basis to those travel agencies. Id. at 684.

Other courts have similarly applied the reasonable approximation test. See, e.g., Nachshin v. AOL, LLC, 663 F.3d 1034, 1040 (9th Cir. 2011) (rejecting, in a nationwide privacy class action, a cy pres distribution to local Los Angeles charities because it did not "account for the broad geographic distribution of the class," did not "have anything to do with the objectives of the underlying statutes," and would not clearly "benefit the plaintiff class"); Six Mexican Workers v. Ariz. Citrus Growers, 904 F.2d 1301, 1311-12 (9th Cir. 1990) (invalidating a cy pres distribution to the Inter-American Fund for "indirect distribution in Mexico," id. at 1304, in a class action brought by undocumented Mexican workers regarding violations of the Farm Labor Contractor Registration Act, because the distribution was "inadequate to serve the goals of the statute and protect the interests of the silent class members," id. at 1312); Houck v. Folding Carton Admin. Comm., 881 F.2d 494, 502 (7th Cir. 1989) (invalidating settlement

agreement, in a national antitrust class action, that made a cy pres distribution to local law schools, and directing the district court to "consider to some degree a broader nationwide use of its cy pres discretion"; In re Folding Carton Antitrust Litig., 744 F.2d 1252, 1253-54 (7th Cir. 1984) (invalidating, in a national antitrust class action, a cy pres distribution that would establish a private antitrust research foundation on the basis that "[t]here has already been voluminous research" on the subject). As these cases make clear, the mere fact that a recipient is a charitable or public interest organization does not itself justify its receipt of a cy pres award.

Against these criteria we turn to the Samsell plaintiffs' arguments. They first argue that the residual funds should have been used first to pay the claimants their "full out-of-pocket expenses." That is not the measure of their damages. Only a portion of the sum charged for Lupron was an overcharge. The Samsell plaintiffs have already received their full damages, and more. Their damages are not the full price they paid for Lupron; rather, their damages are the money they paid above the market value of the drug as a result of the inflated price. The district court found that 30% of the price the class paid for Lupron was a reasonable estimate of the class's full damages. The implementation agreement paid the class 50% of the price they paid for Lupron, which amounts to 167% of their damages.

The Samsell plaintiffs argue that even though they have received their full damages, the district court abused its discretion by choosing to make a cy pres distribution instead of using the residual funds to award treble damages to the claimants.⁹ We disagree. The 11,000 claimants have already received an enhanced payment beyond single damages. Because the consumer fund was established for the benefit of all consumer purchasers of Lupron, not just the 11,000 who filed claims, the court appropriately determined that the "next best" relief would be a cy pres distribution which would benefit the potentially large number of absent class members.¹⁰ Such relief may yield tangible benefits for class members in the form of lower prices for existing drugs, more effective or more cost-efficient versions of current drugs, or even new cures altogether. Such benefits would accrue both to the claimant class members and to the living absent class members, most of whom would enjoy the advantages of less expensive or more

⁹ At oral argument, the Samsell plaintiffs also argued that because this is a consumer fraud case, the cy pres funds should go to entities that would combat consumer fraud. This argument, made for the first time at oral argument, is waived. In any event, we reject the argument. RICO and the state consumer fraud statutes at issue in this case were meant to protect vulnerable consumers like the victims in this case. The cy pres distribution in this case honors that objective by distributing funds to benefit the absent class members who have not yet been compensated.

¹⁰ This is not a "fluid class recovery" case in which the court attempts to direct residual funds "to those who will be impacted by the defendant in the future, in an effort to roughly approximate the category of those who were injured in the past." See Redish at 620.

effective drugs that combat the multitude of conditions the class faces, which this research may produce. Moreover, the parties themselves contemplated such use of any unclaimed funds: the tax provisions of the settlement agreement clearly provided for the possibility that unclaimed funds would go to a charity to benefit silent class members.

In In re Pharmaceutical Industry Average Wholesale Price Litigation, we voiced a concern about overcompensating claimant class members at the expense of absent class members. 588 F.3d at 34-36. There, we rejected the argument that claimants are entitled to receive a windfall of any unclaimed residual money regardless of whether they have already been compensated for their losses. Id. at 35. It is well accepted that protesting class members are not entitled to windfalls in preference to cy pres distributions. The Fifth Circuit, for example, has recently stated that "[w]here it is still logistically feasible and economically viable to make additional pro rata distributions to class members, the district court should do so, except where an additional distribution would provide a windfall to class members with liquidated-damages claims that were 100 percent satisfied by the initial distribution." Klier, 658 F.3d at 475 (footnote omitted).¹¹

¹¹ In Klier v. Elf Atochem North America, Inc., the court reversed a district court order imposing a cy pres fund for residual unspent monies which had not been provided for in the settlement agreement. 658 F.3d 468, 480 (5th Cir. 2011). While the defendant had proposed seven cy pres beneficiaries, the plaintiff opposed and sought additional distributions to a subclass

Commentators have agreed that distributing residual funds to claimants who have already recovered their losses "necessarily results in an undeserved windfall for those plaintiffs, who have already been compensated for the harm they have suffered." Martin H. Redish, Peter Julian, & Samantha Zyontz, Cy Pres Relief and the Pathologies of the Modern Class Action: A Normative and Empirical Analysis, 62 Fla. L. Rev. 617, 639 (2010); see also 2 McLaughlin on Class Actions § 8:15 (8th ed. 2011); Susan Beth Farmer, More Lessons From The Laboratories: Cy Pres Distributions in Parens Patriae Antitrust Actions Brought By State Attorneys General, 68 Fordham L. Rev. 361, 393 (1999).

We agree that allowance of such windfalls "could create a perverse incentive among victims to bring suits where large numbers of absent class members were unlikely to make claims. It might also create an incentive for the represented class members to keep information from the absent class members." Redish at 632; see also Mirfasihi v. Fleet Mortg. Corp., 356 F.3d 781, 785 (7th Cir. 2004); Van Gemert v. Boeing Co., 553 F.2d 812, 816 (2d Cir. 1977) (explaining that such windfalls may "encourage the bringing of class actions likely to result in large uncollected damage pools").

or alternatively to a different cy pres recipient. Id. at 473. The court found no support in the settlement documents for the creation of a cy pres fund, in contrast to our case. Id. at 476-78. It ordered the district court to reallocate the funds among the subclasses of the class that generated the settlement. Id. at 480.

The Samsell plaintiffs argue next that in any event DF/HCC is not a proper recipient for several reasons. The initial argument is that DF/HCC "profited from the fraudulent scheme and conspiracy alleged in this case" through its for-profit members. This claim has no basis in the record. DF/HCC is a not-for-profit corporation organized under Massachusetts law; it is not a defendant and the conspiracy claims under RICO against doctors were dismissed early on. Nor do the Samsell plaintiffs point to any DF/HCC employee or affiliate who participated in the fraudulent Lupron scheme. Further, during the cy pres selection process, Samsell herself recommended that half of the cy pres funds go to DF/HCC.¹²

The Samsell plaintiffs lodge several attacks against the cy pres selection process itself. First, the Samsell plaintiffs argue that the "next best" requirement is not met because the cy pres recipient, DF/HCC, is in Boston while the injuries are to a national class. This objection fails. It is not the location of the recipient which is key; it is whether the projects funded will provide "next best" relief to the class. DF/HCC is required to do work which will have benefits well beyond Boston. The DF/HCC proposal uses a venture capital model to invest in high-impact,

¹² Dennis Rohn joined Samsell in asking the court to give the other half of the cy pres funds, or at least some portion, to claimant consumers. Barbara Sensing was not yet involved in the cy pres selection process.

high-risk research projects across the globe, with the expectation that promising results will attract grants from more traditional funding sources. DF/HCC says it intends to be a catalyst for large-scale research collaboration by providing incentives to teams of researchers to join forces at the national and international levels. Moreover, the grants will be awarded by an Oversight Board composed of nationwide leaders in prostate cancer research.

Additionally, the claim that only prostate cancer research is being funded is false. The DF/HCC proposal is specific that "[t]he central and overarching goal of [the DF/HCC] program is to directly impact the treatment of prostate cancer and other Lupron-treatable diseases and conditions" including "endometriosis, uterine fibroids, and/or central precocious puberty." Indeed, Samsell recommended to the district court that half of the cy pres funds be distributed to DF/HCC precisely because it would "support[] research in the treatment of infertility, endometriosis, ovarian and breast cancer, and precocious puberty," unlike the alternative Loughlin proposal which focused only on prostate cancer.

The Samsell plaintiffs also argue that the district court judge erred by failing to recuse himself from participation in the cy pres distribution on account of his service as an uncompensated trustee on the board of the Vincent Memorial Hospital, which is affiliated with the Massachusetts General Hospital (MGH). MGH, in

turn, is affiliated with both Brigham & Women's Hospital and Harvard Medical School. MGH, Brigham & Women's, and Harvard Medical School are all member institutions of DF/HCC.

This recusal claim is without merit. Recusal is only required by a state of mind "so resistant to fair and dispassionate inquiry as to cause a party, the public, or a reviewing court to have reasonable grounds to question the neutral and objective character of a judge's rulings or findings." In re United States, 158 F.3d 26, 34 (1st Cir. 1998). That test is not met here. More than that, no question is raised here that the selection of the recipients was made on any basis other than the merits. See ALI Principles § 3.07.

This recusal claim has also been waived by being raised only on appeal, which is another indication of its invalidity. Litigants must raise a claim for disqualification of a district court judge after learning of the grounds for disqualification, and certainly may not wait and see how the court rules before acting. Giannetta v. Boucher, No. 92-1488, 1992 WL 379416, at *6 (1st Cir. Dec. 22, 1992) (per curiam) (holding that the appellant waived his claim of recusal under 28 U.S.C. § 455(a) because he failed to raise it in the district court); In re Abijoe Realty Corp., 943 F.2d 121, 126 (1st Cir. 1991) (holding that a party knowing of a ground for requesting disqualification may not wait to raise the

issue until after the judge issues a ruling that the party dislikes).

Samsell was aware of the judge's service on the board of Vincent; was aware of the indirect affiliation of Vincent through MGH to DF/HCC; was aware DF/HCC was a potential recipient; and yet never raised a word of concern. The district court judge disclosed his affiliation with Vincent Memorial Hospital at the January 13, 2009 hearing to discuss cy pres award proposals.¹³ The Samsell plaintiffs were present at the hearing and did not object upon hearing the disclosure to the judge's continued participation in the case.

There is a double waiver. In 2010, when the judge submitted the final candidate proposals for public comment, Samsell expressly acknowledged the judge's participation on the Vincent board, and yet nonetheless recommended that half of the funds be distributed to DF/HCC. It is only now, for the first time on

¹³ The judge stated:

I am on the board at Vincent Memorial Hospital, which is a board at Mass. General Hospital. We are part of the Partners system. So the question is whether that is a conflict of interest I want everyone to understand that I am not, obviously, a compensated trustee, but I have been affiliated through Vincent with Mass. General for almost 12 years now and would not want anyone to think that I have favored, if this was the direction I would choose to go, a Mass. General or, for that matter, a Brigham-affiliated group because of my own personal involvement at the hospital.

appeal, that the Samsell plaintiffs have raised an objection to the judge's participation in the cy pres selection process.

In a related attack, the Samsell plaintiffs argue that the district court improperly appointed Dr. Jonathan L. Tilly, a Harvard Medical School professor, as the court's representative to a committee overseeing DF/HCC's use of the cy pres funds. As the district court disclosed in its August 6, 2010 order, Dr. Tilly "has served as a special law clerk to the court," and is Chief of the Division of Research at the Vincent Center for Reproductive Biology at MGH. Dr. Tilly is also Chair of the Trustee Committee at the Vincent Memorial Hospital. We reject this argument for the same reasons articulated above.

The Samsell plaintiffs also argue that the cy pres selection process was tainted because class counsel simultaneously represented one of the proposed, but not successful, cy pres recipients, Community Catalyst/PAL. This is a nonissue since class counsel's proposed cy pres recipient was not chosen by the district court. Nor was DF/HCC on the list of candidates selected by class counsel (in fact, class counsel objected to the court's consideration of DF/HCC).

There was no abuse of discretion in the process used or as to selection of the recipient.

Although we find no abuse of discretion in this case, and indeed the process followed was admirable, we express our concerns

that district courts are given discretion by parties to decide on the distribution of cy pres funds. Our concerns are also stated in the ALI Principles, which stress in § 3.07(c) that "the court, when feasible, should require the parties to identify a recipient whose interests reasonably approximate those being pursued by the class." (emphasis added). In the commentary, the ALI Principles also note that the court should give weight to the parties' choice of recipient as demonstrated by the settlement agreement. ALI Principles § 3.07 cmt. b.

It is true that the court attempted to compensate for the parties' failure to designate recipients in the agreement by taking proposals from the parties and fully involving them in the selection process. But the choice would have been better made by the parties initially and then tested by the court, against the principles we have identified.

It is one thing for the district court to exercise its traditional judicial function to approve class action settlement agreements. See Fed. R. Civ. P. 23(e). It is quite another for the parties to abandon the task of agreement over the assignment of residual funds and just hand that task to the court. The parties expressly contemplated that significant sums might remain here, and indeed \$11.4 million out of \$40 million remained. The amounts involved also raise concerns. We recognize, as class counsel candidly articulated, that there are imperfections in all methods

of handling the issue of disposition of residual funds. But the adversary process is better suited to the parties making the decisions and leaving less to the discretion of the judges.

Distribution of funds at the discretion of the court is not a traditional Article III function, as many courts have recognized:

Federal judges are not generally equipped to be charitable foundations: we are not accountable to boards or members for funding decisions we make; we are not accustomed to deciding whether certain nonprofit entities are more "deserving" of limited funds than others; and we do not have the institutional resources and competencies to monitor that "grantees" abide by the conditions we or the settlement agreements set.

In re Compact Disc Minimum Advertised Price Antitrust Litig., 236 F.R.D. 48, 53 (D. Me. 2006); see also Redish at 642.

Moreover, having judges decide how to distribute cy pres awards both taxes judicial resources and risks creating the appearance of judicial impropriety. A growing number of scholars and courts have observed that "the specter of judges and outside entities dealing in the distribution and solicitation of settlement money may create the appearance of impropriety." Nachshin, 663 F.3d at 1039; see also SEC v. Bear, Stearns & Co., 626 F. Supp. 2d 402, 415 (S.D.N.Y. 2009). These concerns have been noted in the media. See George Krueger & Judd Serotta, Op-Ed., Our Class-Action System is Unconstitutional, Wall St. J., Aug. 6, 2008, at A13; Editorial, When Judges Get Generous, Wash. Post, Dec. 17, 2007, at

A20; Adam Liptak, Doling out Other People's Money, N.Y. Times, Nov. 26, 2007, at A14.

With that cautionary note, we affirm the cy pres distribution, with one adjustment to the August 6, 2010 order. We add an explicit requirement that the district court must receive an annual audit at the expense of DF/HCC, in addition to the annual and semi-annual accountings to be submitted by DF/HCC to the court. This will ensure that the cy pres fund is distributed in a way that is both financially sound and comports with the interests of the class and that the auditing function will not fall on the district court. We believe that was intended by the court and is implicit in its orders. The district court's November 16, 2010 order, in which it references a "required accounting of accrued expenditures," suggests it intended to include such an audit requirement in the August 6, 2010 order.

So ordered.