IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

THE COUNTY OF SANTA CLARA, on behalf of itself and all others similarly situated,

Plaintiffs,

v.

ASTRA USA, INC., ASTRA ZENECA PHARMACEUTICALS LP, EVENTS PHARMACEUTICALS, INC., BAYER CORPORATION, BRISTOL-MYERS SQUIBB COMPANY, PFIZER, INC., SCHERING-PLOUGH CORPORATION TAP PHARMACEUTICAL PRODUCTS, INC., ZENECCA, INC., ZLB BEHRING LLC, SMITHKLINE BEECHAM CORPORATION, SMITHKLINE BEECHAM CORPORATION d/b/a GLAXO SMITHKLINE, WYETH, INC., WYETH PHARMACEUTICALS, INC.,

Defendants.
_____/

No. C 05-03740 WHA

ORDER REGARDING MOTION FOR CORRECTIVE ACTION REGARDING BRISTOL-MYERS SQUIBB'S COMMUNICATIONS WITH PUTATIVE CLASS MEMBERS AND ATTEMPT TO OBTAIN ACCORD AND SATISFACTION

INTRODUCTION

This action arises out of a dispute between two California counties that allege defendant pharmaceutical companies overcharged them by charging a price for their drugs greater than the ceiling prices imposed by Section 340B of the Public Health Service Act of 1992. In April 2010, Bristol-Meyers Squibb Co. ("BMS"), one of the defendants, sent checks to its customers nationwide, including putative class members in California. The accompanying letter explained that these payments were a refund for overcharged drugs, and that acceptance of these refunds

constituted accord and satisfaction, and a release of future claims. Plaintiffs contend that this communication did not provide a full, fair, and accurate explanation of putative class members' rights, and it was not made in good faith. Plaintiffs move for corrective action. For the reasons that follow, plaintiffs' motion is **GRANTED**.

STATEMENT

Plaintiff County of Santa Clara owns and operates Santa Clara Valley Health and Hospital System; plaintiff County of Santa Cruz owns and operates the Santa Cruz County Health Agency. Plaintiffs allege that defendant pharmaceutical manufacturers breached contractual duties owed to them as third-party beneficiaries of agreements between the manufacturers and the Secretary of the Health and Human Services, called the Pharmaceutical Pricing Agreements ("PPAs"). PPAs carry out statutory obligations that arise under Section 340B of the Public Health Service Act of 1992. 42 U.S.C. 256b. Congress passed Section 340B to provide discounts on outpatient drugs to certain federally funded hospitals and clinics. Under this agreement, the manufacturers may not charge any 340B entities over the so-called "ceiling price" created by the statute. Plaintiffs contend that these defendants violated their obligations under the PPA by charging a price exceeding the ceiling price defined in Section 340B and the PPA, based on miscalculations of the components of the ceiling price, the average manufacturer price ("AMP") and the best price ("BP"). The case is currently in the discovery stage.

As part of its submission for a motion for a protective order and partial judgement, which was denied, BMS filed the Larkin Declaration on February 4, 2010. The Larkin Declaration explained that in 2004 BMS began a review of its methodology for calculating the AMP and BP components of ceiling drug prices (Larkin Decl. ¶ 6). From that review, BMS filed restated prices to adjust Medicaid rebate payments (*id.* at ¶ 9). It also stated that it "intends in the near future to offer refunds to those 340B participants who in the above periods paid net ceiling prices in excess of those calculated with the restated AMPs and BPs" (*ibid.*).

All agree that following a hearing on March 18, 2010, in the hallway outside the courtroom, BMS's counsel orally confirmed that BMS intended to send refund payments to its

340B customers within the next few weeks, and also informed plaintiffs that these repayments would be characterized as "accord and satisfaction" of claims regarding the ceiling price calculations (Br. 2–3; Opp. 4). Plaintiffs' counsel then indicated they had questions about the legal propriety of sending the letters, and requested to review a draft of the letter before it was sent (Party Exh. 2 at 1). Over three weeks later on Friday, April 16, 2010, BMS emailed a sample letter to counsel; in response to counsel's inquiry, BMS's counsel stated that the letters would be "going out very soon, probably next week" (Party Exh. 3 at 1–2). Plaintiffs' counsel reviewed and responded to the letter by the next business day (Party Exh. 6 at 1). Yet on that day they were informed that BMS had already sent the checks and letters to all putative class members (not including named plaintiffs), and those going to Santa Cruz and Santa Clara were going out on that day (*ibid.*). BMS's counsel claims he was unaware that BMS was already in the process of mailing the letters when he sent the draft letter to plaintiffs (*ibid.*).

The letters to BMS 340B customers nationwide explained that BMS "has recalculated the 340B ceiling prices based on restated AMPs and BPs for the applicable period (1Q98 through 1Q10 and 3Q02 though 2Q05) and relevant products" (Baig Decl. Exh. 7 at 1). The letter also stated:

> According to calculations performed using BMS chargeback records, the net aggregate payment to your entity is [REDACTED]. Enclosed is a check in this amount. Please note that this check is tendered in, and *your acceptance will constitute, full and final satisfaction of any actual or potential claim* by you related to prices charged by BMS or paid by you under the 340B program for BMS products during the applicable quarters described above (1Q98 through 1Q10 and 3Q02 though 2Q05).
>
> If you have any questions regarding this payment, please contact the BMS Government & Public Program Operations group by phone at 609-897-5421 or via email at govt.programs@bms.com.

(*ibid.*) (emphasis added). Additionally, those letters that were sent to putative class members in California had the following paragraph inserted between the previous two quoted paragraphs:

> In this latter regard, we hereby inform you of a lawsuit entitled *County of Santa Clara et ano. v. Astra USA, et al.*, No. CV 05-03740-WHA pending in the United States District Court for the Northern District of California (the "Santa Clara Action"). Plaintiffs in the Santa Clara Action seek to certify a class of all 340B Entities in the State of California pursuant to a complaint that alleges that several drug manufacturers, including but not

> limited to BMS, breached contracts under which they calculate and offer 340B ceiling prices. The Court in the Santa Clara Action denied the plaintiffs' first request for class certification, but without prejudice to a renewed motion at a later time. The claims in the Santa Clara Action include but are not limited to the 3Q02 through 2Q05 period covered by this letter and the enclosed check. In the event a class is certified, BMS will maintain that any California 340B Entity that has cashed a check provided hereunder has fully and finally compromised any claim that it may have under the Santa Clara Action for the period 3Q02 through 2Q05. You may obtain documents filed in the Santa Clara Action through the Clerk's office in the United States District Court for the Northern District of California by referencing the above case number.

(Party Exh. 1 at 4). The letter did not include a copy of the complaint, contact information for plaintiffs' counsel, or information about the current status of the case.

ANALYSIS

1. APPLICABLE LEGAL STANDARDS.

Until 2003, Rule 23(e) stated, "A class action shall not be dismissed or compromised without the approval of the court, and notice of the proposed dismissal or compromise shall be given to all members of the class in such a manner as the court directs." This served to curb the many abuses of a class action that could occur before certification, such as a plaintiff threatening a class action for a higher settlement offer or a defendant offering the putative class members very low offers to waive any claims before their strength is determined. In 2003, Rule 23(e) was revised to state: "The claims, issues, or defenses *of a certified class* may be settled, voluntarily dismissed, or compromised only with the court's approval," and then continues with detailed procedures for approval. FRCP 23(e) (emphasis added). The amendment notes explain that the purpose of the amendment was to "strengthen the process of reviewing proposed class-action settlements." FRCP 23 Notes of Advisory Committee on 2003 Amendments. But with the addition of the phrase "certified class," the new rule does not address the requirements for settlement if the class has not yet been certified, and leaves open the question of whether in appropriate circumstances judicial approval is warranted or necessary. The Ninth Circuit has not yet clarified this issue. The parties have not addressed this question, but instead have briefed the motion as if this were an issue of improper communications with the putative class and a lack of good faith. Therefore, it shall be addressed in that manner.

The Supreme Court in *Gulf Oil Co. v. Bernard* stated that "[b]ecause of the potential for abuse [of the class action process], a district court has both *the duty and the broad authority* to exercise control over a class action and to enter appropriate orders governing the conduct of counsel and parties." 452 U.S. 89, 100 (1981) (emphasis added). The order must be based on "a clear record and specific findings that reflect a weighing of the need for a limitation and the potential interference with the rights of the parties," and thus further the policies embodied in Rule 23. *Id.* at 101-02. Furthermore, any such order issued must be "a carefully drawn order that limits speech as little as possible, consistent with the rights of the parties under the circumstances." *Id.* at 102. In *Gulf Oil*, the Court overturned the district court's restraint on communication between the plaintiffs' counsel and putative class members because the restraint was "sweeping" in scope and the district court made neither factual findings nor legal arguments.

Settlements are usually to be encouraged. Settlements, however, cannot come "at the expense of the class action mechanism itself to the detriment of putative class members." *Keystone Tobacco Co. v. United States Tobacco Co.*, 238 F. Supp 2d 151, 154 (2002). A business entity has the right to communicate with its customers over the normal course of business, including discussing offers to settle. But it may not give "false, misleading, or intimidating information, conceal material information, or attempt to influence the decision about whether to request exclusion from a class certified under Rule 23(b)(3)." *Manual for Complex Lit.* § 21.12. Examples of communications that may warrant restraint include efforts by a defendant to encourage potential class members not to participate in the class action, thereby reducing potential liability. *Kleiner v. First Nat'l Bank of Atlanta*, 751 F.2d 1193, 1201–03 (11th Cir. 1985). Courts also have limited communications to putative class members when those communications are shown to contain misleading information. *See In re McKesson HBOC, Inc. Secs. Litig.*, 126 F. Supp. 2d 1239, 1244 (N.D. Cal. 2000); *Burford v. Cargill, Inc.*, 2007 U.S. Dist. LEXIS 1679 at *5 (W.D. La. Jan. 19, 2007) (finding that sending settlement offer without also notifying potential class members of pending class action was misleading).

The Ninth Circuit and the Manual for Complex Litigation have not yet adopted a specific test to determine what constitutes false or misleading offers to settle. But surely that test is

concomitant with the with potential for abuse in the communications, including being misled about the strength and extent of their claims. *In re General Motors Corp. Engine Interchange Litig*, 594 F.2d 1106, 1139 (7th Cir. 1979). The putative class members can be misled though omissions and failure to provide enough information, which can include the failure to append the plaintiffs' complaint to a settlement offer. In *Eshelman v. OrthoClear Holdings, Inc.*, Judge Jeffery White found that no corrective action was necessary when the offers for settlement (1) apprised the putative class about the pending lawsuit, (2) contained contact information for the plaintiffs' counsel, and (3) included the second amended complaint. No. C 07-01429 JSW, 2007 WL 2572349, *3 (N.D. Cal. Sept 4, 2007).

2. LIMITED INTERVENTION IS WARRANTED TO PROTECT THE PUTATIVE PLAINTIFF CLASS FROM MISLEADING INFORMATION.

While there were not any alleged misstatements in the letter, it was inadequate to inform the putative class. Not only did the letter omit a summary of the plaintiffs' complaint, it did not even provide an explanation of the claims of the plaintiffs, the plaintiffs' counsel's contact information, or the current status of the case, all of which were found in *Eshelman*. Nor did it include the important statement that the court of appeals had already vetted and approved the theory of the case, an important factor in examining the strength of a claim. BMS asserts that the letter included all that was required, including the name of the case and the explanation that it was a putative class action. This is erroneous. BMS should not have concealed material information. It was required to provide enough information so that the recipients would not be misled about the strength or extent of the claims and the purpose of Rule 23 was not frustrated. To this end, BMS at a minimum should have explained the specific claims that plaintiffs allege against BMS, precisely how the new components were calculated, and how closely the new calculations aligned with plaintiffs' allegations. While there is no strict requirement to include a complaint or the Ninth Circuit opinion, the putative class must have been given the necessary information to choose whether to accept the settlement checks.

Plaintiffs also allege that the letter was factually misleading for several reasons. *First*, although the letter explained that plaintiffs alleged BMS "breached contracts" concerning

the 340B prices, it did not explain how these breaches were alleged to have occurred, which involved the determination of AMP and BP (Party Exh. 1 at 4).

Second, the letter indicated that BMS undertook the recalculations of its own volition (*id.* at 3). This was misleading because during the time of the review there were four *qui tam* cases pending that ended in a settlement that included a Corporate Integrity Agreement and required IRO reviews (Party Exh. 2 at 1-2). The letter also failed to mention that these recalculations resulted in BMS gaining "tens of millions of dollars" from Medicaid (Larkin Decl. at ¶ 15).

Third, the letter misled the putative plaintiffs about the status of the case. The letter only mentioned that the class certification was denied, but could be renewed (Party Exh. 1 at 4). However, this occurred over a year ago, and now discovery is underway that will allow ascertainment of precisely how the AMP and BP figures were calculated and whether a class should be certified. The letter also neglected to advise the putative plaintiff class that the Ninth Circuit had blessed plaintiffs' legal theory.

Fourth, and more importantly, the letter was unclear and misleading about the actual effects of the "aggregate net basis" methodology for determining payments (*id.* at 3). For example, the 340B requirements are merely price ceilings, but a 340B entity could actually have negotiated a lower price in return for other benefits like a minimum market share (Br. 11–12; Party Exh. 9 at 2). The letter did not state that the aggregate net basis methodology makes an exception for these types of discounts (Party Exh. 1 at 3–4). If the aggregate net basis did not make this exception, then BMS misled the putative class into believing that only the changes based on the recalculated components would be factored into their repayments, and they would not be penalized for contracting for lower prices. BMS asserts that there is no law that disallows its aggregate net basis methodology, and a disagreement in payment calculation methodology is allowable when offering a settlement. However, the putative plaintiff class must still have been fully informed to be able to decide whether to accept the settlement offer. In this case, because the aggregate net basis did not explain how contractual discounts were calculated into the repayment, and because the letter only discussed recalculations based on the new BP and

AMP components, it misled the putative plaintiffs into believing that the aggregate net basis made an exception for contracted discounts. Thus, their repayment checks could actually have been much less than what they would have received if the contractual discounts were not included, yet this was never explained to the putative plaintiffs.

Finally, the letter made it seem as though the repayments had final approval from the Centers for Medicaid and Medicare Services ("CMS") because the components had CMS's approval and the recalculations were based on the approved component calculations (Party Exh. 1 at 3). However, this veneer of official approval was misleading. The letter from CMS specifically indicated that its approval of the calculations is limited only to that case and "has no applicability to a different set of facts" (and so would not apply to the 340B customers), does not supercede any subsequent investigations, and that the CMS approval "is not a release of liability" (Party Exh. 11 at 2). BMS's protestation that the discussion of the CMS approval and the 340B repayments were in different paragraphs rings false; the fact that one immediately proceeded the other and stated that the recalculated prices were "based on *these* restated AMPs and BPs " (referring to the CMS approved BPs and AMPs) inextricably links the 340B repayments with the CMS recalculations, although CMS explicitly stated that its approval of the components does not extend to any other situation. Thus, in all of these instances, the letter significantly misled the putative plaintiff class about the strength and extent of the plaintiffs' claims, and they were unable to make an informed choice about whether to accept the settlement payment.

BMS asserts that it had a First Amendment right to contact its own customers, citing *Gulf Oil* (Opp. 1, 6–7). Even so, BMS had no First Amendment right to extract a release. Its First Amendment right was limited by considerations for protecting the putative plaintiff class. BMS also claims that the putative plaintiff class could find the necessary information though a Google search of the case name (Opp. 2). However, none of the cases that plaintiffs or BMS cited support the proposition that an accord and satisfaction offer contains sufficient information if further documents can be found though an online search.

3. GOOD FAITH.

Turning to an issue extensively briefed by the parties, the California Uniform Commercial Code § 3311 establishes the following components for a valid accord and satisfaction agreement: "(1) that person *in good faith* tendered an instrument to the claimant as full satisfaction of the claim, (2) the amount of the claim was unliquidated or subject to a bona fide dispute, and (3) the claimant obtained payment of the instrument, the following subdivisions apply" (emphasis added). Good faith is defined as "not only honesty in fact, but the observance of reasonable commercial standards of fair dealing," with the meaning of fair dealing "depend[ing] upon the facts in the particular case." Cal. Com. Code § 3311 (2010), cmt. 4 (citing Cal. Com. Code § 3103(a)(4)). The trier of fact must determine whether there was a meeting of minds as to the subject matter of the new agreement and an intention to reach a genuine compromise. *Milgard Tempering, Inc. v. Selas Corp. of America*, 902 F.2d 703, 712 (9th Cir, 1990). An example of a lack of good faith resulting in an invalid accord and satisfaction agreement is if an insurer takes advantage of a claimant by issuing a small check to a necessitous claimant with a larger claim. Cal. Com. Code § 3311 (2010), cmt. 4.

If the refunds had been sent prior to this investigation, a jury question would be presented as to the good faith of the settlement. Given that it was sent *after* the litigation arose — and while BMS knew good and well that a Rule 23 certification was still on the table — this tactic cannot be allowed under Rule 23, for to rule otherwise would allow defendants to shift control of one proceeding from the district judge to the defense counsel. Therefore, the recipients are entitled to cash the checks and receive back their money — money BMS admits should never have been extracted in the first place – without prejudice to seeking even greater in this or separate lawsuits. In other words, the release is invalid in California.

CONCLUSION

The duty and authority to protect the putative plaintiff class and uphold the policies of Rule 23 extends to the limited ruling in this case. BMS has omitted material information and misled the putative plaintiff class: the letter did not contain the complaint or Ninth Circuit opinion, did not describe the claims, did not contain the current status of the case, did not

provide contact information for the plaintiffs' attorneys, did not explain how the aggregate net basis methodology can actually decrease the payment amount, and tried to establish a veneer of CMS authorization that was clearly not accurate. Indeed, misleading the putative plaintiffs, offering a potentially much decreased settlement, and not cooperating with the plaintiffs all show a lack of good faith. Thus, the plaintiffs' motion for corrective action is **GRANTED**. The accord and satisfaction release is invalid in California. Any checks cashed will be deducted from any recovery obtained herein (or presumably elsewhere) by the recipients. It is not necessary for BMS to make any corrective communications.

IT IS SO ORDERED.

Dated: July 8, 2010.

WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE