**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| **BLUE CROSS BLUE SHIELD ASSOCIATION, *et al.*,**<br><br>**Plaintiffs,**<br><br>**vs.**<br><br>**GLAXOSMITHKLINE LLC,**<br><br>**Defendant.** | **Civil Action No. 2:13-cv-4663-JS** |

**PLAINTIFFS' BRIEF IN OPPOSITION TO**
**DEFENDANT'S MOTION TO DISMISS THE COMPLAINT**

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Contrary to the arguments made by GlaxoSmithKline ("GSK"), Plaintiffs' claims adequately allege injury (Point I), are timely (Point II), and are unaffected by a prior, irrelevant settlement (Point III). GSK's motion to dismiss should be denied.

**Background**

Plaintiffs are 41 insurers that collectively supply more than 60% of the U.S. market for private health insurance. GSK is one of the world's largest pharmaceutical manufacturers. From at least 1997 through 2006, GSK illegally sold huge quantities of adulterated drugs throughout the United States. GSK lied to the FDA and to the public that the drugs were properly manufactured and thus were reliable, safe, and effective. Plaintiffs paid billions of dollars for the drugs on behalf of individuals covered by their health benefit plans. Plaintiffs seek recovery of those payments and related relief.

GSK manufactured the adulterated drugs at a plant in Cidra, Puerto Rico -- GSK's largest plant in the world and the sole source of many of GSK's most lucrative drugs, including Paxil and Avandia. (Compl. ¶ 78.) GSK derived as much as $5.5 billion in annual revenue from the drugs produced at Cidra. (*Id.*) GSK operated the plant through a wholly-owned subsidiary, SB Pharmco Puerto Rico, Inc. ("SB Pharmco"). (*Id.* ¶ 58.)[1]

The plant was shut down in 2009. (Compl. ¶ 59.) In 2010, SB Pharmco pled guilty to the federal crime of shipping adulterated drugs manufactured at Cidra, with intent to defraud and mislead, in violation of the Food, Drug and Cosmetic Act (the "FDC Act"), 21 U.S.C. §§ 331(a), 333(a)(2), 351(a)(2)(B). (Compl. ¶ 5.) GSK paid a $150 million fine for the felony admitted in the guilty plea. In addition, GSK paid $600 million to settle a related civil whistleblower case brought on behalf of federal and state

[1] The drugs in issue are Paxil, Paxil OS, Avandia, Avandamet, Coreg, Bactroban, Kytril, Compazine, Denavir, Dyazide, Dibenzyline, Thorazine, Stelazine, Relafen, Factive, Dyrenium, and Albenza (collectively referred to in the Complaint as the "At-Issue Drugs"). (Compl. ¶ 3.)

healthcare programs, which had purchased a wide range of the adulterated drugs produced at Cidra.[2]

As admitted in the guilty plea, GSK's misconduct included: release of drugs intended for vulnerable patient populations, such as cancer patients and infants, that were contaminated with micro-organisms; release of a diabetes drug that was chronically super-potent or sub-potent; repeated product mix-ups (different drugs or potencies found in the same container); repeated interference with quality assurance personnel by Cidra's Site Director; and GSK's active concealment from the FDA of serious product defects.

The FDC Act prohibits the sale of any "adulterated" drug. *Id.* § 331(a). A drug is adulterated if it has not been made "in conformity with current good manufacturing practice to assure that such drug meets the requirements of [the FDC Act] as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess." *Id.* § 351(a)(2)(B). The statute thus incorporates mandatory minimum standards, known as "current good manufacturing practices" or "cGMPs," promulgated by the FDA. *See* 21 C.F.R. Parts 210 & 211.

GSK asks the Court to believe that its violations at Cidra were merely technical infractions of cGMPs that affected only a few batches of finished product, with no material impact on Cidra's output generally. (GSK Br. at 2-3, 4-9.) GSK thus seeks to rewrite and dispute the Complaint's factual allegations, which it cannot do on a motion to dismiss. As specifically alleged in the Complaint, the Cidra plant was riddled with fundamental and chronic violations for years before it was finally shut down. All of the plant's basic systems were broken, including air, water, production, laboratory, facilities

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[2] See http://www.justice.gov/opa/pr/2010/October/10-civ-1205.html. The charges admitted in the guilty plea are attached to the Complaint, and reattached here, as Ex. A.

and equipment, packaging and labeling, materials, and quality assurance. (Compl. ¶¶ 77, 81-82, 104, 111-74.) These violations negated GSK's assurances -- made to Plaintiffs and the general public in literally millions of package inserts, advertisements, clinical materials, and other communications -- that the drugs produced at Cidra conformed to their represented safety, identity, strength, quality, and purity. As a direct result, Plaintiffs were fraudulently induced to pay for adulterated drugs that they would not otherwise have paid for. (Compl. ¶¶ 4-11, 183-85.)

The nature and extent of GSK's misconduct remained unknown to the public until 2010, when the U.S. Department of Justice announced the guilty plea and civil settlement noted above. The civil case was a *qui tam* whistleblower suit filed under seal in 2004 by Cheryl Eckard, suing as relator on behalf of government healthcare programs.[3] Ms. Eckard was a GSK Quality Assurance Manager who reported Cidra's problems to GSK management and was fired shortly thereafter. The suit was unsealed in 2007 but remained unpublicized until announcement of the criminal plea and civil settlement in 2010.

Plaintiffs' collective payments for Cidra's products exceed the amounts obtained in the *Eckard* case. There government healthcare programs recovered $600 million under the federal False Claims Act and counterpart state laws. Here the proper vehicles for Plaintiffs' recovery are the RICO statute and pendent state law claims. The arguments made in GSK's motion to dismiss demonstrate GSK's refusal to acknowledge and take responsibility for its misconduct, which inflicted economic injury not only on the government but also on private parties that paid for Cidra's adulterated products. GSK

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[3] *United States ex rel. Eckard v. SmithKline Beecham Corp., d/b/a/ GlaxoSmithKline, et al.*, No. 04-CV-10375-JLT (D. Mass.)

engaged in fraudulent conduct that undermined the reliability of the nation's drug delivery systems, yet it now seeks to avoid a full accounting for its actions. GSK attempts to achieve that goal by misreading RICO's requirement of injury to "business or property," which the Complaint amply satisfies; and by asserting a statute of limitations defense that ignores GSK's successful concealment of its misconduct over many years, which denied Plaintiffs notice of their claims until the misconduct was revealed by the government in 2010. Plaintiffs' claims are properly stated and should be allowed to proceed.

**Argument**

On a motion to dismiss, a complaint's factual allegations must be accepted as true, and all logical inferences must be drawn in the plaintiff's favor. *ALA, Inc. v. CCAIR, Inc.*, 29 F.3d 855, 859 (3d Cir. 1994). A complaint cannot be dismissed if it presents a "plausible" basis for recovery "under *some* viable legal theory." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 562, 570 (2007) (internal quotation marks omitted, emphasis in original); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). This test simply requires "enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element." *West Penn Allegheny Health Sys. v. UPMC*, 627 F.3d 85, 98 (3d Cir. 2010) (internal quotation marks omitted). "Legal questions that depend upon a developed factual record are not properly the subject of a motion to dismiss." *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 2013 WL 5761202, at *4 (E.D. Pa. Oct. 23, 2013).

As the movant, GSK bears the burden of satisfying these standards. *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005). GSK has failed to carry its burden.

## I. GSK Has Failed To Carry Its Burden Of Proving That Plaintiffs' Injury Allegations Are Insufficient

GSK asserts that absent proof that its adulterated drugs were "unsafe or ineffective" or caused "physical harm" to particular patients, Plaintiffs' allegations of egregious manufacturing violations are insufficient to support economic injury claims by anyone who paid for the drugs, under any circumstances. (See GSK Br. at 2-3, 12-14.) GSK's argument fails both legally and factually. This is not a personal injury case, which requires proof of physical harm. Nor is it a case in which Plaintiffs must prove that ***properly manufactured*** drugs were unsafe or ineffective for a particular use. Instead, Plaintiffs allege that the abysmal conditions at Cidra establish that GSK's drugs were ***not*** properly manufactured, GSK knew that fact, and consequently GSK's assurances regarding the drugs -- assurances that the drugs conformed to their represented attributes and therefore were reliable, safe, and effective -- were fraudulent. (See, e.g., Compl. ¶¶ 6-9.) If Plaintiffs had known the truth, they would have removed the drugs from their approved formularies and would not have paid for them. These allegations state claims of economic injury and entitle Plaintiffs to develop the factual record concerning the conditions at Cidra and the fraudulent nature of GSK's assurances.

GSK's attempts to minimize the significance of its violations are unavailing. For example, GSK characterizes the term "adulterated" as "simply a regulatory designation" and quotes a statement on the FDA's website that cGMP violations do not "necessarily" mean that a drug is defective. (GSK Br. at 2.) But GSK omits the FDA's further statement: "The impact of cGMP violations depends on ***the nature of those violations***

and on the specific drugs involved."[4] Plaintiffs are entitled to prove that the nature of GSK's violations had a material impact on the drugs they paid for.

Moreover, GSK's subsequent actions contradict any notion that its violations were insignificant. GSK negotiated a felony guilty plea and a $150 million fine for its misconduct at Cidra, which involved an admitted "intent to defraud and mislead." GSK also paid $600 million to settle civil claims by government healthcare programs that paid for Cidra's products. Plaintiffs here paid for the same products -- in much greater amounts -- and are entitled to make corresponding claims.

GSK also attempts to minimize its violations by arguing that "only four of the cGMP issues alleged in the Complaint relate directly to the quality or packaging of the finished drug products themselves," and that Plaintiffs have not "specifically" alleged payment for those particular drugs. (GSK Br. at 4.) The four "issues" GSK tries to dismiss are: mixed-up drugs; microbial contamination in drugs for cancer patients and infants; super-potent and sub-potent diabetes drugs; and metal shavings, punch lubricant, and iron oxide embedded in various drugs. (GSK Br. at 4-8.) GSK's argument misses the point. The cited examples are illustrative, not exclusive. They demonstrate the egregious nature of the violations GSK committed and concealed, which, as alleged in detail in the Complaint, go far beyond those examples. (E.g., Compl. ¶¶ 77, 111-74.)[5]

As GSK knows, compliance with cGMPs is not an after-the-fact determination based on whether patients were affected by improperly manufactured drugs. The basic purpose of cGMPs is to impose on drug makers the legal duty "to assure that [each] drug

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[4] http://www.fda.gov/drugs/developmentapprovalprocess/manufacturing/ucm169105.htm (emphasis added).

[5] GSK falsely suggests, for instance, that only one "potentially" contaminated Bactroban lot was released to the market. (GSK Br. at 6, citing only Compl. ¶ 132.) In fact, GSK released numerous lots of ***actually*** contaminated Bactroban. (See Compl. ¶¶ 81-82, 127-32.)

meets the requirements of [the FDC Act] as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess."[6] As already noted, GSK cites an FDA document but omits essential language. The same document states, under the heading "Why are cGMPs so important?":

> A consumer usually cannot detect (through smell, touch, or sight) that a drug product is safe or if it will work. While cGMPs require testing, testing alone is not adequate to ensure quality. In most instances testing is done on a small sample of a batch (for example, a drug manufacturer may test 100 tablets from a batch that contains 2 million tablets), so that most of the batch can be used for patients rather than destroyed by testing. Therefore, it is important that drugs are manufactured under conditions and practices required by the cGMP regulations to assure that quality is built into the design and manufacturing process at every step.[7]

Thus, a dismissal of this case on the ground that the "finished drug products themselves" are no longer available for examination would set exactly the wrong precedent for the drug industry. It would tell manufacturers that they can escape liability by concealing fundamental cGMP violations and allowing adulterated products to be consumed and thus rendered unavailable for analysis. Such a precedent, in effect, would encourage manufacturers to spoliate evidence through fraudulent acts and deception of the public. Nothing in the law justifies that result.[8]

Indeed, the law requires just the opposite result. RICO comprehensively defines economic harm as injury to "business" or "property." 18 U.S.C. § 1964(c). Congress has

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[6] 21 U.S.C. § 351(a)(2)(B).

[7] http://www.fda.gov/drugs/developmentapprovalprocess/manufacturing/ucm169105.htm.

[8] Similarly, Plaintiffs are entitled to assert economic injury claims without the need to demonstrate consumers' personal injuries. Any contrary doctrine would be improper for two reasons. First, bacterial contamination, sub-potency, and other types of adulteration involved here can easily cause serious adverse effects in consumers while remaining untraceable to the adulterated drugs -- if the effects are detected at all. Second, such a doctrine would encourage manufacturers to play Russian roulette with consumers' health and safety. Manufacturers would have the incentive to gamble that any personal injury damages would be less than the legal and business liabilities that would result from fully disclosing the adulteration, recalling the drugs in question, and refunding the purchase price to everyone who paid for them.

directed courts to read RICO's provisions "liberally." Pub. L. No. 91-452, § 904(a), 84 Stat. 922, 947 (1970) ("The provisions of [RICO] shall be liberally construed to effectuate its remedial purposes."); *see also id.* at 923 (RICO's purpose is to provide "enhanced sanctions and new remedies"). The liberal construction clause applies especially to RICO's civil remedy provisions. *See, e.g., Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 491 n.10 (1985) ("if Congress' liberal-construction mandate is to be applied anywhere, it is in § 1964, where RICO's remedial purposes are most evident"). GSK's narrow interpretation of economic injury is unsupported by the statute's express language or its legislative history. RICO's injury provision, modeled on antitrust law, broadly encompasses any situation in which "property is diminished by the payment of money wrongfully induced." *Chattanooga Foundry & Pipe Works v. Atlanta*, 203 U.S. 390, 396 (1906) (Holmes, J.) (antitrust injury).[9]

That is precisely the situation here. GSK wrongfully induced Plaintiffs to pay for drugs that GSK misrepresented as compliant with the FDA's mandatory manufacturing standards. Plaintiffs would not have paid for the drugs if they had known the truth. GSK is not entitled to keep the money paid. RICO provides Plaintiffs with a remedy.

**A. GSK's Position Is Contradicted By Third Circuit Law**

GSK argues that, to establish injury, Plaintiffs must show that GSK's drugs were "ineffective for the prescribed use or caused physical harm to a patient." (GSK Br. at 14.) GSK's position contradicts Third Circuit precedent. In *In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 531 (3d Cir. 2004), the Court recognized that healthcare insurers may assert claims for "business or property" injury against drug manufacturers

[9] Properly understood, RICO's "property" concept is as broad as the concepts applied to its various predicate offenses. *See, e.g., Pasquantino v. United States*, 544 U.S. 349, 356 (2005) (foreign government's entitlement to unpaid taxes was "property" within the wire fraud statute).

***regardless*** of whether individual patients were harmed by the drugs in issue. The Court did so by adopting the holding in *Desiano v. Warner-Lambert Co.*, 339 F.3d 326 (2d Cir. 2003), which upheld healthcare insurers' claims concerning the fraudulent marketing of Rezulin, a diabetes drug. *Desiano* stated:

> [The insurers] allege an injury directly to themselves; an injury, moreover, that is ***unaffected by whether any given patient who ingested Rezulin became ill.*** Plaintiffs' claim is that the Defendants' wrongful action was their misrepresentation of Rezulin's safety, and that this fraud directly caused economic loss to them as purchasers . . . .

*Id.* at 349 (emphasis added); *see Warfarin*, 391 F.3d at 531. Similarly, *Desiano* held that the insurers' claims could proceed even "if Rezulin had been effective in all diabetic patients." *Desiano*, 339 F.3d at 349-50.

In *Warfarin*, the Third Circuit adopted *Desiano*'s analysis in approving a class action settlement where healthcare insurers and consumers alleged that a manufacturer had disseminated false information about its drug and generic alternatives. The Court rejected the argument that the insurers' claims were improperly derivative of consumers' injuries. The Third Circuit distinguished the insurers' claims from product liability suits and held that the insurers had properly asserted direct economic injury. It then quoted *Desiano*'s holding that insurers could assert claims when they "allege an injury directly to themselves" that is "in no way derivative of damages to a third-party." 391 F.3d at 531 (quoting *Desiano*, 339 F.3d at 349) (internal quotation marks omitted).

Most recently, this Court properly applied *Warfarin*, *Desiano*, and other precedents in a case strikingly similar to this one. In *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 2013 WL 5761202 (E.D. Pa. Oct. 23, 2013), insurers brought RICO and state law claims against GSK for fraudulently concealing heart attack

risks and other dangers linked to its diabetes drug, Avandia. (Avandia is also one of the drugs in issue here.) The insurers sought to recover their payments for the drug on the ground that GSK's fraudulent statements to the public induced the insurers to place Avandia on their approved formularies -- a direct analogue of Plaintiffs' allegations here. (See Compl. ¶¶ 183-85.) Judge Rufe held that the insurers' allegations established a "concrete economic injury" ***regardless*** of whether "any given patient who ingested Avandia became ill." *Id.* at *5. The Court denied GSK's Rule 12(b)(6) motion, ruling that "Plaintiffs' claims sufficiently allege an economic injury at this pleading stage of the litigation"; GSK's arguments regarding proof of injury and "the calculation of damages" were premature. *Id.* at *5 & nn.25-26 (citing *Warfarin*, *Desiano*, and other cases).[10]

Moreover, the only Third Circuit decision cited by GSK on this issue, *Maio v. Aetna, Inc.*, 221 F.3d 472 (3d Cir. 2000) (GSK Br. at 14-15), confirms Plaintiffs' position, not GSK's. *Maio* held that claims regarding intangible "contractual rights" failed to establish "business or property" injury, as opposed to claims regarding tangible objects such as "a plot of land or a diamond necklace." *Id.* at 488-90. That distinction supports Plaintiffs' claims here, which are based on GSK's fraudulent representations concerning its physical drug products. In *Maio*, the plaintiffs alleged that the defendant HMO's general policies and practices constituted "inferior" healthcare coverage, for which the plaintiffs had been overcharged. *Id.* at 484. The Court held that HMO coverage was not a physical object with an easily determined value, but rather a set of intangible "contractual rights" that could be considered inferior only if and when the HMO delivered substandard medical treatment to particular individuals. *Id.* at 494-95.

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[10] *See also In re Bextra & Celebrex Mktg., Sales Practices & Prod. Liab. Litig.*, 2007 WL 2028408, at *5-7, 9 (N.D. Cal. July 10, 2007).

Here, by contrast, tangible property is involved. GSK misrepresented its physical products as satisfying the FDA's mandatory manufacturing standards while knowing that the conditions at Cidra falsified its representations. Consequently, this case fits squarely within *Maio*'s holding that RICO claims may be based on "external conditions or the occurrence of events which cause the value of the real or personal property to be reduced." *Id.* at 489. Plaintiffs allege just such "external conditions" or "events." *See also Mathews v. Kidder, Peabody & Co.*, 260 F.3d 239, 248-49 (3d Cir. 2001) (reiterating *Maio*'s distinction between "contractual rights" and "tangible property").

**B. GSK's Position Is Unsupported By Other Case Law**

GSK's other case citations are equally unavailing. GSK's leading case is *Ironworkers Local Union 68 v. AstraZeneca Pharmaceuticals, LP*, 634 F.3d 1352 (11th Cir. 2011) (GSK Br. at 14), where insurers alleged that AstraZeneca had fraudulently promoted its drug to doctors through "off-label marketing" for unapproved uses. The Eleventh Circuit held that the insurers' claims failed because they alleged only "indirect" injury -- injury that stemmed from individual doctors' decisions to prescribe AstraZeneca's drug rather than an alternative. In principle, such decisions are left to doctors' judgments regarding the needs of their individual patients. To overcome that principle, the court held, insurers must allege that individual doctors' judgments were medically unsound, i.e., that choosing AstraZeneca's drug over an alternative was "medically unnecessary or inappropriate" for individual patients. *Id.* at 1360, 1363-64.

That holding cannot help GSK here. The Complaint alleges that GSK made affirmative misrepresentations ***directly*** to Plaintiffs and others who paid for the drugs, not just to doctors. (E.g., Compl. ¶¶ 10, 183-85.) Plaintiffs' injury does not depend on proof

that individual doctors' prescription decisions were medically "inappropriate." Thus, there is no need to trace causation here through doctors' prescription decisions. As alleged in the Complaint, if GSK had disclosed the situation at Cidra, Plaintiffs would have removed the drugs from their formularies and avoided paying for the drugs, whether or not individual doctors continued to prescribe them. (E.g., Compl. ¶¶ 178, 183-85.)

GSK's other cases similarly fail to support its position:

- In *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 2009 WL 2043604 (D.N.J. July 10, 2009) (GSK Br. at 15), the court held that the defendant's "off-label marketing" was "directed at physicians" rather than insurers, did not involve fraudulent representations, and had no bearing on the drugs' reliability, safety, or efficacy. *Id.* at *18-19. Here, however, GSK made fraudulent representations concerning its drugs' reliability, safety, and efficacy directly to Plaintiffs and others.

- In *District 1199 Health & Welfare Plan v. Janssen, L.P.*, 2008 WL 5413105 (D.N.J. Dec. 23, 2008) (GSK Br. at 15-16), insurers sued to recover overpayments for the defendant's drugs on the ground that alternative drugs were more "cost-effective." The court held that the allegations were "conclusory" and thus failed to establish "a concrete financial loss." *Id.* at *8. Again, this case is different. Plaintiffs allege that specific conditions at Cidra negated GSK's assurances that the drugs conformed to their specified formulas and attributes and therefore were reliable, safe, and effective.

- In *In re McNeil Consumer Healthcare, et al., Mktg. & Sales Practices Litig.*, 877 F. Supp. 2d 254 (E.D. Pa. 2012), consumers alleged that they had overpaid for drugs produced at a plant with cGMP violations. The manufacturer recalled many of the plant's product lines and offered purchasers full refunds, while other product lines were

not recalled. As to products that were not recalled, the Court emphasized that the plaintiffs made conclusory allegations that relied on "experiences of other individuals" who incurred adverse effects, and on the manufacturer's recall of other products from the same plant. *Id.* at 272-73. By contrast, Plaintiffs here do not rely on "experiences of other individuals" or on product recalls, but rather on detailed allegations concerning specific conditions at Cidra that violated the most basic manufacturing standards. Plaintiffs are entitled to present evidence in support of those allegations, including, for example, the testimony of fact witnesses with personal knowledge of GSK's violations, the testimony of expert witnesses, and GSK's audit reports and other internal documents.

- *Myers-Armstrong v. Actavis Totowa, LLC*, 2009 WL 1082026 (N.D. Cal. April 22, 2009), *aff'd*, 382 Fed. Appx. 545 (9th Cir. 2010) (GSK Br. at 17-18), involved consumer claims under California law concerning drugs recalled by the manufacturer from retailers, without offering refunds to consumers. Relying on two California state court decisions, the *Myers-Armstrong* court rejected the plaintiff's claim because she had consumed only one brand of drug (out of many in issue) and alleged no adverse effects. At the same time, however, the court inconsistently stated: "If the pills had not been consumed, the consumer might possibly have a claim for a refund." 2009 WL 1082026, at *4. It cannot be the case that the right of recovery depends on whether a drug is consumed. In any event, insurers do not, and cannot, "consume" any drugs. They still have the right to recover payments for drugs they were fraudulently induced to pay for.

- In *Polk v. KV Pharmaceutical Co.*, 2011 WL 6257466 (E.D. Mo. Dec. 15, 2011) (GSK Br. at 18), the court held that a "conclusory allegation that the Medication was adulterated and therefore worthless" had no "factual support," where the allegation

was based solely on an FDA consent decree in which the defendant disclaimed any admissions or liability. *Id.* at *6. Here the Complaint provides detailed factual allegations regarding the pervasive cGMP violations at Cidra, key aspects of which are expressly admitted by a felony guilty plea GSK negotiated with the government.

- Finally, *In re Digitek Prods. Liab. Litig.*, 821 F. Supp. 2d 822 (S.D. W. Va. 2011) (GSK Br. at 17), addressed wrongful death claims and thus is irrelevant on its face. Such cases require individualized proof of physical injury and have no bearing on Plaintiffs' economic injury claims. Moreover, the discovery record in *Digitek* showed that only one defective pill out of millions reached the market. Here, by contrast, Plaintiffs allege chronic and pervasive manufacturing violations. At the very least, Plaintiffs have the right to develop the record concerning the effect of those violations.

In sum, the Complaint alleges economic injury resulting from misrepresentations made directly to Plaintiffs and others who paid for GSK's drugs. GSK has failed to carry its burden of showing that Plaintiffs cannot prove their injury under any circumstances. Plaintiffs are not required to present at trial particular tablets or vials (which no longer exist) to prove that they were unsafe or ineffective, nor are Plaintiffs required to present individual patients and their doctors to prove that the drugs caused physical injuries. Plaintiffs are entitled to present evidence that the alleged conditions at Cidra rendered fraudulent GSK's assurances concerning the drugs' reliability, safety, and efficacy, and that, but for those fraudulent assurances, Plaintiffs would not have paid for the drugs.[11]

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[11] The Complaint's allegations establish actionable injury under state law as well as RICO. GSK does not suggest that different injury standards govern Plaintiffs' state law claims. Indeed, GSK's only additional argument is that Plaintiffs' unjust enrichment claim fails to qualify as "an independent cause of action under Pennsylvania law." (GSK Br. at 14 n.26.) GSK's argument is mistaken. *See, e.g., In re Actiq Sales & Mktg. Practices Litig.*, 790 F. Supp. 2d 313, 329-30 (E.D. Pa. 2011) (upholding insurers' unjust enrichment claim against drug manufacturer).

## II. GSK Has Failed To Carry Its Burden Of Proving That Plaintiffs' Claims Are Time-Barred

Plaintiffs filed this case on July 15, 2011. GSK argues that certain events gave Plaintiffs notice of their claims more than four years before that date, i.e., before July 15, 2007, and thus the claims are time-barred. The cited events start in 2002 and end "no later than March 2005." (GSK Br. at 22.) GSK's arguments fail, for three basic reasons.

***First***, GSK bears the burden of proof with regard to the statute of limitations. The burden is a "heavy" one. *Van Buskirk v. Carey Canadian Mines, Ltd.*, 760 F.2d 481, 498 (3d Cir. 1985). In particular, GSK must show that Plaintiffs had "inquiry notice" regarding the "probability" -- not just the possibility -- of the alleged injury. *Cetel v. Kirwan Fin. Group, Inc.*, 460 F.3d 494, 506-07 (3d Cir. 2006). GSK has failed to carry its burden. As discussed in Point I above, the injury alleged in this case stems from the plant-wide breakdown of manufacturing and quality systems at Cidra, thus rendering fraudulent GSK's guarantees regarding the drugs produced there. During GSK's asserted "inquiry notice" period, from 2002 to 2005, nothing in the public record indicated the "probability" of that type of injury. On the contrary, everything in the public record indicated that Cidra's manufacturing issues were isolated and confined to particular products and batches. The FDA allowed the plant to continue operating, and GSK continued releasing to the market the overwhelming majority of Cidra's output. At the same time, GSK repeatedly assured the public that it was cooperating fully with the FDA and resolving promptly the issues that had been identified. During the asserted "inquiry notice" period, Plaintiffs had no reason to suspect that GSK's assurances were false.

***Second***, even if the FDA's actions from 2002 to 2005 were sufficient to put Plaintiffs on "inquiry notice," the inquiry would have been fruitless. GSK makes the

conclusory assertion that "[b]y early 2005" Plaintiffs were in a position to investigate and "could have discovered their alleged injuries and connected them to GSK." (GSK Br. at 25.) GSK thus ignores the detailed allegations in the Complaint, which describe GSK's systematic, and successful, efforts to conceal and misrepresent the conditions at Cidra, despite the FDA's regulatory oversight. Those allegations must be taken as true for purposes of GSK's Rule 12(b)(6) motion. It is preposterous to argue that Plaintiffs, with none of the FDA's investigatory powers, and with the right to rely on the FDA's oversight, should have discovered independently that Cidra was irreparably broken. Alternatively, and at the very least, the question whether additional inquiry would have been fruitful should be deemed an unresolved factual issue and left for further discovery.

***Third,*** GSK's fraudulent concealment of the conditions at Cidra tolled the limitations period. Again, the Complaint contains detailed allegations of GSK's concealment, which must be taken as true for present purposes. Moreover, GSK's public statements -- many of which are included in GSK's own exhibits -- confirm that it engaged in a deliberate cover-up of what was actually occurring at Cidra.

**A. GSK's Narrative Of Events Fails To Establish "Inquiry Notice"**

As noted above, GSK cites events during a period starting in 2002 or 2003 and ending "no later than March 2005."[12] (GSK Br. at 22.) GSK misstates those events and fails to show that during the specified period Plaintiffs had reason to suspect the true state of affairs at Cidra and the "probability" that Plaintiffs were being defrauded. Indeed, GSK's narrative proves just the opposite. The cited events, including GSK's public assurances, consistently created the appearance that any problems at Cidra were limited,

[12] GSK makes inconsistent statements regarding the period's start: "2002 and 2003" (GSK Br. at 3); "February 2002" (*id.* at 9); "as early as 2003" (*id.* at 22); "2002 and 2003" (*id.*).

and that GSK was cooperating fully with the FDA to correct the problems promptly and fully. GSK created that appearance by concealing for years the appalling conditions at Cidra from everyone, including the FDA. The outside world had no notice of the truth until it was revealed by the announcement of GSK's global settlement of the government's civil proceedings in *Eckard* and its criminal case in October 2010.[13]

We address in chronological order each of the events cited by GSK.

**2002: Bactroban recall and FDA warning letter.** GSK refers to a limited Bactroban recall in 2002. (GSK Br. at 9, 22.) Product recalls are frequent and routine. GSK itself confirms that fact by exhibiting a newsletter that lists no less than five product recalls, by five different manufacturers, during a four-week period. (GSK Ex. 7.)

Following the Bactroban recall, the FDA issued a "warning letter" to GSK. (GSK Ex. 8.) The letter took no regulatory action and noted only product-specific issues. Nothing in the letter indicated that the problems at Cidra were fundamental or plant-wide.[14] The letter was not even mentioned in GSK's 2002 Annual Report.[15] Moreover, GSK's finance director publicly dismissed the entire matter in 2003 by announcing: "The issues raised were fully resolved and closed up." (GSK Ex. 9.)

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[13] *Eckard* was filed under seal in 2004 and unsealed on July 16, 2007. The present case was filed on July 15, 2011, less than four years after the unsealing. Thus, ***even if*** the unsealing provided Plaintiffs with "inquiry notice," this action is timely. Furthermore, the *Eckard* case remained unpublicized until 2010, except for brief, one-sentence references in GSK's 2007 and subsequent Annual Reports. The references failed to identify the case by name or docket number, and never suggested that the allegations in the case went significantly beyond the limited cGMP issues previously identified by the FDA. (See, e.g., Ex. B attached, at p. 157.) In any event, Plaintiffs had no reason to notice the *Eckard* case until the announcement of GSK's global settlement in 2010. *See In re Neurontin Mktg. & Sales Practices Litig.*, 2011 WL 3852254, at *51 (D. Mass. Aug. 31, 2011) ("The unsealing of a case in Massachusetts, unaccompanied by extensive press coverage, cannot be viewed as sufficient notice, particularly to a California [healthcare organization]."). Thus, state law claims subject to a two-year limitations period are timely as well. *See, e.g., Wise v. Mortgage Lenders Network USA, Inc.*, 420 F. Supp. 2d 389, 395-96 (E.D. Pa. 2006) (discovery rule applied to two-year statute for "fraud or deceit" claims).

[14] The warning letter referred only to Bactroban, Paxil OS, and Thorazine. (GSK Ex. 8.)

[15] http://www.gsk.com/content/dam/gsk/globals/documents/pdf/annual-report-2002.pdf.

Like product recalls, FDA warning letters are frequent and routine. For example, during the year in question (2002), the FDA issued 724 warning letters, at an average rate of about two letters per calendar day, a rate that continues to the present.[16] The FDA has stated: "A Warning Letter is informal and advisory. It communicates the agency's position on a matter, but it does not commit FDA to taking enforcement action."[17] Courts recognize that such letters do not provide prospective plaintiffs with notice of their claims. *See, e.g., Schering-Plough*, 2009 WL 2043604, at *22 ("the FDA warning letter, public filings and newspaper articles reporting the Government's investigation" failed to provide notice to plaintiffs of their RICO claims). (See also Point II.D below.)

**2003: Unspecified FDA investigation and Forms 483.** The FDA continued to investigate issues at Cidra in 2003, but the only publicly available information indicated that the FDA's activity remained limited and routine. Nothing in the public record suggested what was actually occurring: in October 2003, federal prosecutors opened a criminal investigation, executed a search warrant, and seized records at the plant. GSK repeatedly misstates the record on this point by asserting that news articles in October 2003 "widely publicized" and "documented" the commencement of a "***criminal***" investigation. (GSK Br. at 9, 23, emphasis added.) GSK's assertions are incorrect. The criminal investigation was not disclosed until 2008, more than four years later, when GSK issued its 2007 Annual Report.[18]

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[16] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2002/default.htm. Similarly, in 2012, the FDA issued 752 warning letters. http:/www.fda.gov/ICECI/Enforcement ActionsWarningLetters/2012/default.htm.

[17] http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ ucm176870.htm#SUB4-1.

[18] See Ex. B attached, at p. 157. GSK's exhibits include excerpts of its 2003 to 2006 Annual Reports (GSK Exs. 13-16) but omit its 2007 Report.

Indeed, from 2003 to at least 2008, GSK's disclosures concerning Cidra were consistently uninformative. In October 2003, GSK's finance director disclaimed knowledge regarding the nature of any ongoing investigation: "The FDA are now back. They are being quite coy about exactly what they are looking for." (GSK Ex. 9.) Similarly, GSK's lack of disclosure is demonstrated by the other articles exhibited by GSK. (GSK Exs. 10-12.) They contain nothing specific about the situation at Cidra. The most detailed article reported that the FDA was investigating unspecified "manufacturing issues" at Cidra and had "asked for records related to manufacturing in 2001 and 2002." (GSK Ex. 10.) (This illustrates what GSK knew and failed to disclose: the government had begun a criminal investigation and seized, not merely "asked for," Cidra's records.) The article also reported GSK's statement that any ongoing investigation "would not interrupt the supply" of drugs from Cidra, a clear assurance that the plant had no serious problems. (*Id.*) GSK's two other articles are even less informative. One simply stated that the FDA had "launched a probe" at Cidra, "but it remains unclear precisely what the FDA is investigating." (GSK Ex. 11.) The other referred to the fact that the FDA "was investigating a Glaxo factory in Puerto Rico," with no further information about the investigation. (GSK Ex. 12.)

In addition to citing these uninformative news articles containing GSK's misleading assurances, GSK argues that it "disclosed the investigation" in its 2003 Annual Report, issued in March 2004. (GSK Br. at 9.) By that time, the FDA had issued two "Forms 483" in connection with its ongoing oversight. The Forms were issued in December 2003 and merely stated a set of "observations," without taking any regulatory action. The FDA emphasizes on its website that a Form 483 "does not constitute a final

Agency determination of whether any condition is in violation of the [Food, Drug & Cosmetic Act] or any of its relevant regulations."[19] Like FDA warning letters, Forms 483 are routine. Hundreds typically are issued each year.[20] During the period in question, the FDA did not post the two Forms 483 on its website or otherwise publicize their contents.

The following statement constituted GSK's ***entire*** disclosure in its 2003 Annual Report regarding the FDA's investigation and Forms 483:

> In October 2003 the FDA began an investigation of the Group's manufacturing facility in Cidra, Puerto Rico. The Cidra site is engaged in tableting and packaging for a range of GlaxoSmithKline products -- primarily for the US market -- including Paxil, Paxil CR, Coreg, Avandia and Avandamet. ***Subsequently, the FDA has issued two Forms 483 ('observations' of possible deficiencies in manufacturing practices) to the Group.***
>
> The FDA observations relate to certain aspects of production controls, process validation and laboratory investigations primarily in respect of activities that occurred between 2001 and 2003. ***The Group has responded to the observations contained in the Forms 483, but to date the FDA has not advised the Group as to whether any further action is indicated.*** The Group continues to work closely with the FDA to address any concerns and implement any changes required by the agency arising from the Forms 483 or the FDA investigation. ***The Group has received no indication that ongoing supply from the site will be affected.***

(GSK Ex. 13, emphasis added.) Nothing in this statement suggested the true nature of the problems at Cidra. Moreover, the statement reiterated GSK's announcement to the press in October 2003, quoted above, that there was no reason to expect an interruption of supply, thus confirming that any issues at Cidra were limited, not chronic or plant-wide.

**2004: Two additional Forms 483.** In 2004, the FDA conducted a follow-up inspection at Cidra and issued two more Forms 483. (See GSK Br. at 10, 23.) GSK's 2004 Annual Report (issued in March 2005) again failed to disclose the true state of

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19 http://www.fda.gov/ICECI/EnforcementActions/ucm256377.htm.

20 http://www.fda.gov/ICECI/EnforcementActions/ucm255532.htm.

affairs at Cidra and made only a brief, cryptic reference to the additional Forms 483. It merely stated that the FDA had "carried out a further inspection in November 2004 and subsequently issued two further Forms 483," in which the FDA made "observations" that "relate to certain aspects of production controls, process validation and laboratory investigations." (GSK Ex. 14.) Again, during the period in question, the FDA did not post the Forms 483 on its website or otherwise publicize their contents.

**2005: Seizure of stocks of Avandamet and Paxil CR, and related consent decree.** In March 2005, the government filed *in rem* civil forfeiture proceedings that allowed the FDA to seize stocks of two drugs produced at Cidra, Avandamet and Paxil CR. (GSK Br. at 10-11, 23-25.) Although the seizure was widely reported in the press, the FDA did ***not*** assert -- and GSK certainly did not disclose -- that the problems at Cidra extended in any way beyond the stocks in question. On the contrary, GSK repeatedly emphasized the limited nature of the FDA's action. Nothing in the FDA's or GSK's statements suggested the existence of broader, more fundamental problems.[21]

Indeed, the Court need look no further than GSK's own brief for confirmation that the FDA's activities in 2005 served as reassurances rather than red flags. GSK's brief emphasizes "what the FDA did ***not*** do when it seized certain lots of Paxil CR and Avandamet": "The agency did ***not*** require that GSK shut down the Cidra facility or cease manufacturing processes for any other drugs produced at the facility." (GSK Br. at

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[21] GSK's 2005 Annual Report discussed the civil forfeiture proceedings but continued to omit any disclosure of the criminal nature of the investigation launched in 2003. The 2005 Annual Report merely referred to a "subpoena" issued in "April 2005" (not the search warrant executed in 2003) "requesting production of records regarding manufacturing at the Cidra site covering the same type of information as that collected by the US government in Puerto Rico in 2003." (GSK Ex. 15.) GSK thus carefully avoided disclosing that the information "collected" in 2003 was actually seized by the government pursuant to a search warrant. GSK used the same evasive language in its 2006 Annual Report (issued in March 2007). (GSK Ex. 16.)

8, both emphases in original.) That makes Plaintiffs' point precisely. Because the FDA did not force a shutdown, consumers and insurers who continued to pay for "any other drugs produced at the facility" had no reason to suspect that the plant as a whole was broken, and they were entitled to rely on GSK's continuing assurances of quality.

The limited scope of the FDA's action is also confirmed by all of the civil forfeiture materials accompanying GSK's brief, including the consent decree filed in the Spring of 2005. (GSK Exs. 4, 26-34.) The consent decree did not disclose problems regarding the plant as a whole. Rather, it required GSK to hire an "outside expert" to determine "***whether***" there were broader issues. (GSK Ex. 4, ¶¶ 7, 21, emphasis added.) (To this day, the outside expert's report has not been published.)[22]

At the same time, GSK continued to trumpet the integrity of the plant as a whole and its continued operation. Even as the consent decree was being filed, GSK announced that it would resume production of both Paxil CR and Avandamet by midyear, far sooner than expected. (GSK Ex. 36.) GSK's global chief of pharmaceuticals told the press that the company "was able to resolve the issue quickly because of its strong relationship with the F.D.A." (*Id.*) The same executive went on to assure the public that the FDA "has 'respect for us and our manufacturing' process." (*Id.*) GSK's statements also emphasized that the FDA had not imposed a fine. (GSK Exs. 15, 36-37.)

In sum, the FDA's actions and all of GSK's statements pointed to one and only one conclusion: limited problems regarding stocks of two products had been identified

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[22] GSK mischaracterizes the affidavits filed in the forfeiture proceedings. GSK states that the affidavits referred to "issues related specifically to Paxil CR and Avandamet, ***as well as issues related to the facility more generally***." (GSK Br. at 12, emphasis added.) In fact, the affidavits made no reference to drugs produced at Cidra other than the two named products. As noted above, GSK concedes that the FDA made no attempt to shut down the plant or to stop "manufacturing processes for any other drugs produced at the facility." (GSK Br. at 8.)

and promptly corrected. GSK quickly resumed producing both Paxil CR and Avandamet, no fine was imposed, and there was ***still*** no disclosure that GSK was the subject of a criminal investigation of pervasive violations and a comprehensive cover-up at Cidra.

GSK's notice argument ends with the events, just described, in 2005. GSK does not, and cannot, argue that any subsequent events provided additional notice.

### B. Even If GSK Could Establish "Inquiry Notice," Further Inquiry Would Have Been Fruitless

GSK's failure to carry its burden of proving "inquiry notice" eliminates any need for further analysis: Plaintiffs' action must be deemed timely. But even if the Court were to find that GSK had established such notice, GSK's argument still fails. Further investigation by Plaintiffs would not have revealed the information necessary to assert their claims within four years after the supposed notice.

Undisputed facts amply demonstrate this point. Despite the FDA's regulatory oversight, GSK continued releasing to the market the vast majority of Cidra's output throughout the period in question. As private parties, Plaintiffs had none of the FDA's powers of oversight and investigation. Yet according to GSK, Plaintiffs somehow should have discovered facts that would support allegations far beyond what the FDA alleged in its forfeiture action. That proposition is meritless on its face and should be rejected as a matter of law. *See generally Gabelli v. SEC*, 133 S. Ct. 1216, 1222 (2013) (contrasting private parties' ability to discover fraud with the government's far greater abilities, and holding that the discovery rule could be invoked only by private parties). Alternatively, at the very least, the Court should leave for discovery and trial the question whether Plaintiffs could have made further, and successful, inquiries. As this Court has stated: "Unless there is a clear basis for the court to determine when plaintiff knew or should

have known of the existence of her cause of action, the issue of whether the plaintiff had a reasonable opportunity to discover the violation is a question to be resolved by a jury." *Stafford Investments LLC v. Vito*, 2008 WL 5062136, at *3 (E.D. Pa. Dec. 1, 2008) (Sánchez, J.) (internal quotation marks omitted).

Moreover, it must be noted that if GSK's position were accepted, the legal and practical consequences would be unprecedented and effectively disrupt the basic functioning of the nation's healthcare system. As soon as the FDA issued a warning letter, Form 483, or seizure order, every insurer -- indeed, every person -- who paid for the drug or medical device in question would be required to begin demanding further information from the FDA and the manufacturer, or else face the risk that potential claims would be time-barred. The result would be regulatory and commercial chaos. If the FDA were forced to consider and respond to thousands of demands for information in connection with each of its enforcement actions, the agency would grind to a halt. Furthermore, each insurer's drug formulary lists literally thousands of drugs. Insurers cannot launch their own investigations each time the FDA undertakes a routine action with respect to a listed drug -- or some other drug produced at the same plant.

Plaintiffs reasonably relied on the FDA's oversight and GSK's assurances regarding Cidra's continued output until October 2010, when the truth about the plant was finally revealed. Plaintiffs sued less than one year thereafter. This action is timely.

### C. In Addition, GSK's Fraudulent Concealment Tolled The Limitations Period

GSK's limitations argument must be rejected for another reason as well. GSK actively engaged in fraudulent concealment of the problems at Cidra, thus tolling the limitations period until the truth was disclosed in 2010. The Complaint's detailed

allegations regarding GSK's concealment must be accepted as true. Moreover, GSK negotiated a felony guilty plea that ***admitted*** the distribution of adulterated drugs "with intent to defraud and mislead." (Compl. Ex. A, also attached here as Ex. A.)

Fraudulent concealment requires three elements: (1) the defendant actively misled the plaintiffs; (2) as a result, the plaintiffs failed to recognize their claims within the limitations period; and (3) the plaintiffs are not chargeable with a lack of due diligence. *Cetel*, 460 F.3d at 509. These requirements are satisfied here. GSK actively concealed Cidra's conditions from both the FDA and the public, as alleged in detail in the Complaint. (E.g., Compl. ¶¶ 7, 113-19, 177-78.) In addition, as shown by GSK's own exhibits, GSK falsely assured the public that Cidra's problems were limited and were promptly resolved in cooperation with the FDA. Finally, GSK's deception of the FDA demonstrates that further investigation by private parties such as Plaintiffs was futile.

The Third Circuit has stated that fraudulent concealment, a form of equitable tolling, "is not generally amenable to resolution on a Rule 12(b)(6) motion" because it "generally requires consideration of evidence beyond the pleadings." *In re Community Bank of N. Va.*, 622 F.3d 275, 301-02 (3d Cir. 2010); *see also Stafford Investments*, 2008 WL 5062136, at *4-5 (due diligence is a factual determination and should ordinarily be resolved by a jury). GSK seeks to evade that principle by declaring in a footnote that Plaintiffs' allegations of fraudulent concealment are "unsupported and conclusory" under Fed. R. Civ. P. 9(b), and are "implausible in the face of the [sic] GSK's public statements and the vast publicity" surrounding the events discussed above. (GSK Br. at 22 n.30.) GSK's footnote is inadequate on its face. *See, e.g., Johnson v. MetLife Bank, N.A.*, 883 F. Supp. 2d 542, 550 n.4 (E.D. Pa. 2012) (arguments asserted only in a footnote are waived).

GSK has ***not*** moved for dismissal under Rule 9(b), and its statement that Plaintiffs' allegations are "implausible" cannot overcome two sets of facts: (1) GSK repeatedly concealed conditions at the plant from the FDA; and (2) GSK repeatedly concealed, and affirmatively misrepresented, conditions at the plant in its statements to the world at large.

The Complaint alleges in detail the first set of facts -- GSK's concealments from the FDA -- which suffice by themselves to establish fraudulent concealment. These are hardly "conclusory" allegations. The Complaint alleges, for example:

- GSK "lied to the FDA in its Field Alert filings [in 2002] by stating that the [product] mix-ups must have occurred outside of Cidra's control." (Compl. ¶ 89(a).) The filings with the FDA were "knowingly false." (*Id.* ¶ 113; see also ¶¶ 115, 117.)

- Cidra's Site Director repeatedly concealed product mix-ups. SB Pharmco's guilty plea admitted the concealments. (*Id.* ¶ 119 & Ex. A.)

- In 2003, GSK executives -- including the President of SB Pharmco and Cidra's General Manager -- met with the FDA to discuss an FDA warning letter. The executives "misrepresented to the FDA the true status of" GSK's response to the warning letter. (*Id.* ¶ 100; see also ¶¶ 86-87.)

- GSK executives told the FDA that internal laboratory investigations had been fully reviewed by an outside consultant. This assurance to the FDA was knowingly false: "more than 30 investigations were still outstanding." (*Id.* ¶¶ 140-41.)

- GSK executives told the FDA that GSK "had reviewed all process validation reports to assure compliance with current guidelines. In fact, many elements of this review were incomplete." (*Id.* ¶ 144.) Cidra executives also told the FDA that a plan for correcting Cidra's instrument calibrations -- a critical function in drug manufacture and quality control -- was on schedule. The assurance was false. (*Id.* ¶ 147; see also ¶ 160.)

- In 2002, an internal audit report identified an improper tank filling practice as having caused the contamination of Bactroban with micro-organisms. "GSK advised the FDA that this contaminating practice had been discontinued. If it was, it was re-instituted shortly thereafter." SB Pharmco admitted this conduct in its guilty plea. (*Id.* ¶¶ 129-30.)

The second set of facts -- GSK's statements to the public -- reinforces the first set. At the same time it was concealing serious violations from the FDA, GSK falsely reassured the world that any issues at Cidra were minor and GSK was cooperating fully with the FDA to resolve them. The news articles and other public communications contained in GSK's own exhibits, discussed above, amply prove the point.

Other instances of public deception by GSK are available as well. For example, GSK deliberately misled the press about product mix-ups at Cidra. In 2005, GSK was quoted as telling a Canadian news agency: "[T]he FDA said there was a potential risk for tablet mix, but there was never a tablet in a prescription bottle, it ***never*** ended up in a prescription bottle (or bulk packaging), ***never***." (Ex. C attached here, emphasis added.) Those assertions were untrue. By 2003, GSK knew that serious product mix-ups were occurring at Cidra. SB Pharmco's guilty plea acknowledges that fact. (See Compl. Ex. A, also attached here as Ex. A.)

GSK cannot sweep aside all of these facts with a footnote. At a minimum, the issue of fraudulent concealment requires further discovery and cannot be resolved on a motion to dismiss. *Community Bank of N. Va.*, 622 F.3d at 301-02.[23]

**D. GSK's Own Case Citations Contradict Its Position**

GSK's efforts to show that Plaintiffs' claims are time-barred are contradicted even by its own cited cases. For example, as discussed in Point I above, GSK mistakenly cites *Schering-Plough* in arguing that Plaintiffs lack an actionable injury. In addition, GSK ignores what *Schering-Plough* says about the statute of limitations in a RICO case:

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[23] GSK argues that the discovery rule is inapplicable to Plaintiffs' warranty claims. (GSK Br. at 25-26.) GSK overlooks the fact that fraudulent concealment equitably tolls the limitations period for warranty claims in the same manner as other claims. *See, e.g., In re Ford Motor Co. E-350 Van Prods. Liab. Litig.*, 2008 WL 4126264, at *18-19 (D.N.J. Sept. 2, 2008); *Connaught Labs., Inc. v. Lewis*, 557 A.2d 40, 43-44 (Pa. Commw. Ct. 1989).

> Defendants bear the burden of proving that plaintiffs have failed to comply with the relevant limitations period. [Citation omitted.] Moreover, because the applicability of the statute of limitations usually involves questions of fact for the jury, defendants bear a heavy burden in seeking to establish that there is no genuine issue of material fact and that as a matter of law the [RICO] claims are barred.

2009 WL 2043604, at *22 (internal quotation marks omitted).[24]

Issues regarding the statute of limitations typically are decided on a fully developed factual record, on motions for summary judgment or at trial, not on threshold motions to dismiss. GSK's own brief illustrates the point: all of the cases cited by GSK with respect to the discovery rule are summary judgment decisions, except for one case that is factually and legally inapposite.[25]

Moreover, although GSK cites various cases for general propositions of law regarding the discovery rule, none of them addressed facts analogous to those involved here. Indeed, GSK cites only one case that even remotely concerned the question of notice based on a product seizure or recall: *In re Diet Drugs (Phentermine/Fenfluramine/ Dexfenfluarmine) Prods. Liab. Litig.*, 352 F. Supp. 2d 533 (E.D. Pa. 2004) (GSK Br. at 25). But both the facts and the holding in that case undermine GSK's argument. The case involved a suit under Kentucky law for personal injuries allegedly caused by defective "phen/fen" diet drugs. The court pointed to the plaintiff's effective ***admission***

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[24] GSK states that "Plaintiffs have the burden to show that the discovery rule applies to save their claims." (GSK Br. at 21.) GSK's statement is inaccurate. Under settled Third Circuit law, ***GSK*** bears the burden of proving that Plaintiffs had "inquiry notice" of their claims more than four years before filing suit. *Cetel*, 460 F.3d at 507. If and only if GSK carries that burden, Plaintiffs have the burden (at most) of showing that further inquiry was stymied or futile. GSK's failure to carry its burden on the first issue relieves Plaintiffs of any burden on the second. Furthermore, even if GSK were to prove "inquiry notice," Plaintiffs need only identify a factual issue that cannot be decided on a motion to dismiss. As shown above, the futility of any further inquiry must be resolved in Plaintiffs' favor as a matter of law or left for further discovery.

[25] The one exception, *Yates v. Commercial Index Bureau, Inc.*, 861 F. Supp. 2d 546 (E.D. Pa. 2012) (GSK Br. at 21), held that the discovery rule was inapplicable to trespass and invasion of privacy claims where the plaintiff opened his front door and saw immediately that defendants had entered his property without permission. *Id.* at 551. That holding is plainly irrelevant here.

of inquiry notice in her deposition: she testified that she "'knew she had some kind of problem'" potentially related to the drugs. *Id.* at 538. Thus, *Diet Drugs* illustrates the need for appropriate discovery before claims can be adjudicated as time-barred.

GSK's cited case law undermines its position in other ways as well. *Schering-Plough*, for example, specifically addressed FDA warning letters and publicity surrounding an FDA investigation in relation to the discovery rule:

> [T]aking the allegations in the Complaint as true, it is not at all clear that the FDA warning letter, public filings and newspaper articles reporting the Government's investigation of Schering's off-label marketing of the Subject Drugs provided warnings sufficient to put Plaintiffs on notice of their purported RICO claims as early as 2002 as alleged by Defendants.

2009 WL 2043604, at *22. The court concluded that the plaintiffs received "actual or inquiry notice of facts underlying the alleged frauds" only when the defendant "ultimately settled federal criminal and civil charges in August 2006." *Id.* That is exactly analogous to the case here: Plaintiffs received "actual or inquiry notice" only when GSK settled the government's criminal and civil proceedings in October 2010. *See also In re Merck & Co., Inc. Securities, Derivative & "ERISA" Litig.*, 543 F.3d 150, 166-67 (3d Cir. 2008) (FDA warning letter and product liability claims failed to provide drug company investors with inquiry notice concerning possible securities violations), *aff'd sub nom. Merck & Co. v. Reynolds*, 130 S. Ct. 1784 (2010).

*Schering-Plough* also supports Plaintiffs' position regarding GSK's acts of fraudulent concealment. After holding that FDA warning letters and related publicity were insufficient to establish "inquiry notice," the court went on to hold:

> In addition, Plaintiffs' allegation that Defendants concealed their illegal conduct raises the possibility that the applicable statutory periods should be tolled . . . . Because there are legitimate questions of fact as to whether the Plaintiffs were on inquiry notice of the conduct and injury underlying

> their claims and of the alleged concealment by Defendants of their illegal conduct, the Defendants' motion to dismiss Plaintiffs' RICO and NJRICO claims as barred by the applicable statutes of limitations will be denied.

2009 WL 2043604, at *22.

In sum, GSK has failed to carry its "heavy burden" of establishing a statute of limitations defense. Plaintiffs' claims are timely.[26]

## III. GSK's Argument Regarding "Paxil CR" Is Irrelevant

GSK argues that claims regarding "Paxil CR" are "barred by the settlement agreement and judgment" in *Simonet v. GlaxoSmithKline*, No. 06-1230 (D.P.R.). (GSK Br. at 26-27.) GSK's argument is irrelevant. Plaintiffs make no claims regarding Paxil CR. The only Paxil-related drugs in issue are Paxil and Paxil OS. (Compl. ¶ 3.)

## Conclusion

GSK's motion to dismiss should be denied.

Respectfully submitted,

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[26] The same principles regarding the discovery rule and fraudulent concealment apply to Plaintiffs' pendent state law claims. *See, e.g., Sadtler v. Jackson-Cross Co.*, 587 A.2d 727, 732 (Pa. Super. 1991) (notice "is generally an issue of fact to be determined by the jury"; it can be determined as a matter of law only if "the facts are so clear that reasonable minds cannot differ").

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# EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

| | | |
|---|---|---|
| UNITED STATES OF AMERICA | ) | Crim. No. |
| | ) | |
| v. | ) | Violation: |
| | ) | |
| SB PHARMCO PUERTO RICO, INC. | ) | 21 U.S.C. §§ 331(a), 333(a)(2), and |
| | ) | 351(a)(2)(B) Interstate Shipment |
| Defendant | ) | of Adulterated Drugs |
| | ) | |

**INFORMATION**

The United States Attorney charges that:

## I. GENERAL ALLEGATIONS

At all times material to this Information:

### The Defendant

1. **SB PHARMCO PUERTO RICO, INC. ("SB PHARMCO")**, was a corporation organized under the laws of the Commonwealth of Puerto Rico with a principal place of business in Cidra, Puerto Rico. **SB PHARMCO** was an indirect subsidiary of GlaxoSmithKline, plc ("GSK"), a British corporation with a principal place of business in Brentford, Middlesex, England, with publicly traded shares on the London Stock Exchange (ticker symbol: GSK) and the New York Stock Exchange (ticker symbol: GSK).

2. **SB PHARMCO** was engaged in, among other things, the manufacture and interstate distribution of prescription drugs intended for human use throughout the United States, including the District of Massachusetts. **SB PHARMCO** owned and operated manufacturing and packaging facilities in Cidra, Puerto Rico.

3. SB PHARMCO was dissolved effective July 3, 2008, but continues to exist under operation of law for three years for purposes of litigation, prosecution, and settlement of its affairs.

The FDA and the FDCA

4. The United States Food and Drug Administration ("FDA") was the federal agency responsible for protecting the health and safety of the public by enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA") and ensuring, among other things, that drugs intended for use in humans were safe and effective for their intended uses and that the labeling of such drugs bore true and accurate information. Pursuant to such responsibility, FDA published and administered regulations relating to the approval, manufacture, and distribution of drugs.

5. The FDCA defined drugs as, among other things, articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man, and articles (other than food) intended to affect the structure of any function of the body of man. 21 U.S.C. §§ 321(g)(1)(B) and (C).

6. Prescription drugs under the FDCA were drugs intended for use in humans which, because of their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary to their use, were not safe for use except under the supervision of a practitioner licensed by law to administer such drugs, 21 U.S.C. § 353(b)(1)(A), or drugs limited by the terms of FDA approval to use under the professional supervision of a practitioner licensed by law to administer such drugs, 21 U.S.C. § 353(b)(1)(B).

7. The FDCA prohibited causing the introduction or delivery for introduction into interstate commerce of any drug that was adulterated. 21 U.S.C. § 331(a).

8. Under the FDCA, a drug was deemed adulterated if the methods used in, or the facilities or controls used for, its manufacturing, processing, packing or holding did not conform to or were not operated or administered in conformity with current good manufacturing practice ("cGMP") to assure that such drug met the requirements as to safety and had the identity and strength, and met the quality and purity characteristics, which it purported or was represented to possess. 21 U.S.C. § 351(a)(2)(B).

9. Implementing regulations under the FDCA further defined cGMP required for finished pharmaceuticals, and included, among other specific requirements, the following:

a. *Quality Control Unit.* Drug manufacturers were required to maintain a quality control unit with the responsibility and authority to approve or reject all components, drugs product containers, closures, in-process materials, packaging, material, labeling and drug products and the authority to review production records to assure that no errors had occurred or, if errors had occurred, that they were fully investigated. 21 C.F.R. § 211.22(a) (2003). The quality control unit was to have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product. 21 C.F.R. § 211.22(c) (2003).

b. *Contamination and Product Mix-ups.* Separate or defined areas or such other control systems were required for the firm's operations as necessary to prevent contamination or mixups during the course of packaging and aseptic processing. 21 C.F.R. §§ 211.42(c)(6) and (10) (2003). Packaging and labeling facilities were required to be inspected immediately before use to assure that all drug products were removed from previous operations,

and results of such inspections were required to be documented in the batch records. 21 C.F.R. § 211.130(e) (2003).

c. *Equipment.* Automatic, mechanical or electronic equipment or other types of equipment used in the manufacture, processing, packing or holding of a drug product was required to be of appropriate design to facilitate operations for its intended use. 21 C.F.R. § 211.63 (2003). Equipment was required to be routinely calibrated, inspected, or checked according to a written program designed to assure proper performance. 21 C.F.R. § 211.68(a) (2003).

d. *In-Process Testing.* In-process materials were required to be tested for identity, strength, quality and purity as appropriate, and approved or rejected by the quality control unit during the production process, e.g. at commencement or completion of significant phases or after storage for long periods. 21 C.F.R. § 211.110(c) (2003).

e. *Drug Product Testing.* Drug products failing to meet established standards or specifications and any other relevant quality control criteria were required to be rejected, unless satisfactorily reprocessed. 21 C.F.R. § 211.165(f) (2003).

f. *Production and control records.* Drug manufacturers were required to prepare drug product production and control records, and to have those records reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures, before a batch was released or distributed. 21 C.F.R. §§ 211.188 and 192 (2003). Any unexplained discrepancy or the failure of a batch or any of its components to meet any of its specifications were required to be thoroughly investigated whether or not the batch was already distributed, and the investigation was required to extend to other batches of the same

drug product and other drug products that may have been associated with the specific failure or discrepancy. 21 C.F.R. § 211.192 (2003).

10. As part of its mission to enforce the FDCA and protect the public health, the FDA had the authority to enter and inspect, at reasonable times and within reasonable limits and in a reasonable manner, all establishments where drugs were manufactured, processed, packed or held for introduction into interstate commerce or after shipment in interstate commerce. 21 U.S.C. § 374(a)(1). Upon conclusion of the inspection, the FDA had various options, including among others:

a. *Form 483.* A "Form 483," otherwise known as a "Notice of Inspectional Observations," was issued by the FDA to summarize the cGMP deficiencies observed by the FDA inspectors during a particular inspection.

b. *Warning Letter.* A "Warning Letter" was issued by the FDA to document the agency's conclusion that certain manufactured products were adulterated, and to provide notice that unless sufficient corrective actions were implemented, further regulatory action would be taken without notice.

11. Drug manufacturers had certain duties and responsibilities to notify the FDA of information that might impact on the safety or efficacy of the drugs it manufactured, including among others, the following:

a. *Field Alert Reports.* The manufacturer of a drug subject to an approved new drug application was required to notify FDA in a "Field Alert Report" within three working days of receiving information if the information concerned any bacteriological contamination, or any significant chemical, physical or other change or deterioration in the distributed drug

product, or any failure of one or more distributed batches of the drug product to meet the specification established for it under the drug's approved new drug application. 21 C.F.R. § 314.81(b)(1)(ii).

b. *Annual Reports*. The manufacturer of a drug subject to an approved new drug application was required to submit to FDA an annual report with the following information, among other information: (1) a brief summary of significant new information from the previous year that might effect safety, effectiveness or labeling of the drug product, 21 C.F.R. § 314.81(b)(2)(i) (2003); (2) reports of experiences, investigations, studies or tests involving chemical or physical properties, or any other properties of the drug that might affect the FDA's previous conclusions about the safety or effectiveness of the drug product, 21 C.F.R. § 314.81(b)(2)(iv)(a) (2003); and a full description of the manufacturing and controls changes not requiring a supplemental application, listed by date in the order in which they were implemented, 21 C.F.R. § 314.81(b)(2)(iv)(b) (2003).

**The Cidra Manufacturing Facility**

12. In or about January 2001, following the merger between Glaxo Wellcome and SmithKline Beecham pharmaceutical companies, the SB PHARMCO Cidra manufacturing site ("Cidra") became one of GSK's largest manufacturing facilities worldwide and a major supplier of prescription drugs to the United States market. Cidra was a SmithKline Beecham site prior to the merger. Cidra was responsible for making a complex portfolio of drugs, including pills, creams, ointments, and injectables. In addition, GSK designated Cidra to be a new product introduction site for solid dose form products, responsible for moving new compounds from development to commercial production, a technically challenging process.

13. Among other drugs manufactured at Cidra, SB PHARMCO made the following drugs for distribution to the United States, including in the District of Massachusetts: Kytril (a sterile injectable anti-nausea medication), Bactroban (a topical anti-infection ointment commonly used to treat skin infections in adults and children), Paxil CR (the controlled release formulation of the popular antidepressant drug, Paxil), and Avandamet (a combination Type II diabetes drug).

14. On or about April 1, 2003, GSK retained a new Site Director for Cidra. In or about July 2003, certain key managers at Cidra resigned as a result of the new Site Director's lack of leadership skills and poor management style. Those managers included, among others, a Quality Assurance Director, the Director of Solids Manufacturing and Packaging, a Manufacturing and Packaging Director, and the Human Resources Director.

15. From in or about April 2003 through September 2004, the Cidra Site Director interfered with the functioning of Cidra's Quality Unit by, for example: ordering all investigative results to be recorded in Spanish to make the results more difficult for GSK Corporate Quality Auditors to review, directing that no investigations into possible process deficiencies be opened without her prior approval, challenging the content of investigative reports prepared by the Quality Unit, and otherwise engaging in inappropriate actions to interfere with the Quality Unit at Cidra.

16. From in or about July 2003 through September 2004, additional managers and other employees at Cidra resigned as a result of the Site Director's interference and management style. Those managers and others employees included, among others, the Packaging Engineering Leader, Validation Manager, Laboratory Manager, Equipment Validation Scientists, Facilities

Validation Scientist, and Computer Validation Scientist. During this time frame, various managers and other employees also complained about the Site Director's interference and management style, including the Director of Quality Assurance and Quality Control, the Director of Compliance, a Quality Manager, and the Human Resource Director. In or about October 2004, the Site Director was removed.

**Contaminants in Kytril**

17. Kytril was a terminally sterilized injectable anti-nausea medication that was primarily used to treat cancer patients receiving chemotherapy or radiation, and post-surgical patients who experienced nausea. Kytril injection was manufactured at Cidra in the sterile suite. Kytril was manufactured in a Single Dose Vial of 1 ml, and a Multi Dose Vial of 4 ml from which four 1 ml doses could be extracted.

18. As part of the merger between SmithKline Beecham and Glaxo Wellcome, Kytril was divested to another pharmaceutical manufacturer. Under the divestiture agreement, SB PHARMCO was required to continue to manufacture Kytril at Cidra until an sNDA to transfer the product was approved.

19. SB PHARMCO manufactured Kytril until in or about December 2003, when production was transferred to the acquiring entity.

20. In or about January 2001, following the merger, GSK performed a compliance risk assessment of Cidra and found, among other "high priority" findings, that "[a]wareness needs to be heightened for current and future sterile expectations" and that "[a]septic filling areas had no barrier technology to protect components and point of fill" from contamination. One of the conclusions of the report was that "the aseptic filling area has not been updated with barrier

technology nor has the operation progressed technologically beyond its initial, dated design (circa 1980's)."

21. In or about December 2001, a GSK expert reviewed the Cidra sterile suite and informed **SB PHARMCO** and others that "[f]or the introduction of new or transferring sterile products, the current areas are not appropriate. Detailed improvements will be required which would require a capital project." The expert noted that "[p]resent areas and ways of working would not meet major regulators' (e.g. MCA [European regulators]/FDA) current expectations."

22. On or about July 1, 2002, the FDA issued a Warning Letter to **SB PHARMCO** stating that certain other drug products manufactured at Cidra were adulterated because, among other reasons, **SB PHARMCO** failed to "conduct investigations in a timely manner and to take corrective actions to prevent recurrence." FDA cited as examples delayed investigations involving the water sampling and media fill vials.

23. A follow-up FDA inspection was undertaken in the fall of 2002, and on or about October 9, 2002, the FDA issued a Form 483 observation to **SB PHARMCO** that: "[p]rocedures designed to prevent microbiological contamination of drug products purporting to be sterile were not followed. Specifically, the quality control unit did not assure that adequate systems and controls were in place to monitor sterile areas used to manufacture sterile drug products."

24. On or about April 2, 2003, GSK Global Quality Assurance ("GQA") reviewed regulatory risks at Cidra and identified nine areas of risk required to be controlled to avoid future regulatory enforcement activities. One of the identified risk areas was "sterile manufacturing facility activities and documentation including Kytril Injection." Another identified risk area was

"isolation of objectionable organisms in the water system" and "out of specification events for environmental monitoring of clean equipment."

25. On or about June 13, 2003, **SB PHARMCO** concluded a trend investigation regarding microbial growth in bulk solution in 15 of the 19 Kytril lots manufactured in the first campaign of 2003 at Cidra. The cause was determined to be a bottom outlet flange assembly of glass lined holding tanks that was not disassembled and cleaned, causing microbial growth "TNTC" (too numerous to count). The types of microbial growth included *bacillus cereus, staphylococcus sp., burkholderia cepacia, comamonas testosterone, and stenotrophomonas maltophilia.*

26. From on or about June 23, 2003 until on or about June 27, 2003, GSK GQA audited Cidra against its Quality Management System ("QMS") and found a major deficiency in the sterile manufacturing of Kytril injectable, noting that "[o]perations do not comply with current QMS expectations and a recent campaign has resulted in rejected batches due to high bioburden of bulk solution." QMS auditors concluded that "[c]apital expenditure is necessary to improve current conditions or sterile operations should be discontinued with a sense of urgency."

27. Between in or about April 29, 2003 and May 28, 2003, **SB PHARMCO** released to the company that acquired Kytril for distribution in interstate commerce, including in the District of Massachusetts, certain lots of Kytril that were deemed adulterated because the manufacturing processes and laboratory testing were insufficient to assure the Kytril was of the quality and purity that Kytril was represented to possess.

**Contaminants in Bactroban**

28. Bactroban was a topical antibiotic primarily used to treat skin infections such as impetigo, in adults and children. Bactroban was manufactured at Cidra both as an ointment and a cream.

29. On or about June 1, 2001, **SB PHARMCO** released Bactroban Ointment Lot 50-1B25 for distribution in interstate commerce even though it was contaminated with *"pseudomonas fluorescens."*

30. On or about November 1, 2001, **SB PHARMCO** issued a Field Alert Report to notify the FDA of the release of the contaminated Bactroban Ointment Lot 50-1B25.

31. On or about February 27, 2002, after additional communications with the FDA regarding the possible health risks of the contaminated Bactroban, **SB PHARMCO** conducted a voluntary recall for Lot 50-1B25.

32. From on or about February 7, 2002 through on or about April 10, 2002, the FDA inspected Cidra.

33. On or about April 10, 2002, the FDA issued a Form 483 to **SB PHARMCO** that noted, among other deficiencies, the following:

> Your Quality Control Unit (QCU) failed to reject drug products not meeting established specifications and quality control criteria. Specifically, your QCU failed to properly review batch records and laboratory analysis reports for Bactroban Ointment lot 50-1B25. Consequently, this batch that was contaminated with *Pseudomonas fluorescens*, an objectionable organism, was released into the market on June 1, 2001. . . .
>
> This oversight was not noticed until Investigation 01-207 was initiated six months later in November 2001 to investigate continuous problems with microbial contamination in Bactroban lots. . . .

> Your firm failed to recognize and evaluate the possible risk of this contamination in a product used to treat impetigo in small children. Your firm did not recall this lot until this issue was brought up during the inspection and a conference call was held with CDER [Center for Drug Evaluation and Research at the FDA].
>
> Your firm failed to investigate and evaluate the reason for recurrent contamination with the organism CDC Group IV e-2 (*Ralstonia paticula*) in Bactroban Ointment and its impact that it might have on the safety and efficacy of Bactroban Ointment. Lots 2901B25, 62-1B25, 84-1B25, 94-1B25 and 105-1B25 were contaminated with this organism and were released and distributed in the market. . . .
>
> Your procedures and actions designed to prevent objectionable microorganisms in drug products not required to be sterile were not effective. . . .

34. In early April 2002, GSK performed a recall investigation at **SB PHARMCO** to determine the root cause of the improper release of the contaminated Bactroban Lot 50-1B25 to market. The audit found that "the final portion of batches were filled as manufacturing operators opened the tank and hand scraped the tank and hopper walls facilitating the filling of the final portion but potentially introducing objectionable organisms as a result of this human intervention," and that a likely cause of the contamination of the Bactroban was that manufacturing operators "could inadvertently introduce the contaminated water into the end of the batch while performing the tank/hopper scrape down." The audit noted that "the practices of disconnecting the chilled water hose from the tank and scraping the tank have been discontinued."

35. On April 23, 2002, GSK responded to the FDA's Form 483 observations and represented in part that **SB PHARMCO** had discontinued "human intervention with holding tanks during filling; the practice of manually scraping the holding tanks during filling; and the practice of disconnecting the hoses supplying the water to the jacket of the holding tanks."

36. In May 2002, as a result of further communications with the FDA, SB PHARMCO extended the voluntary recall to five additional lots of Bactroban Ointment that were contaminated with gram-positive organisms that were potentially objectionable.

37. On or about July 1, 2002, the FDA issued a Warning Letter to SB PHARMCO stating that certain drug products, including Bactroban Ointment, were adulterated because of the following cGMP violations, among others: (a) failure of the quality control unit to exert its responsibility and authority as required by 21 C.F.R. § 211.22 to reject all drug product that failed to meet the established specifications; and (b) failure to have in place procedures to prevent microbial contamination of products as required by 21 C.F.R. § 211.113, that resulted in release of certain lots of Bactroban to market contaminated with *Pseudomonas fluorescens* and questionable gram-positive organisms.

38. After a new Cidra Site Director was appointed in April 2003, the practice of manually scraping the Bactroban tanks was re-instituted to increase yield of Bactroban ointment, with projected 2003 cost savings of $128,074.

39. In June 2003, the Cidra Site Director's new Director of Manufacturing congratulated the "Semisolids Unit" for salvaging Bactroban that was "being wasted" by the failure to scrape the tanks and hopper, resulting in a reduction of waste from 84 kg to 1.25 kg per lot, an increase in production of 3,343 units, and an increase in output from 88% to 97.7%.

40. On or about October 24, 2003, SB PHARMCO released Lot 71-3B25 of Bactroban Ointment for distribution in interstate commerce, including in the District of Massachusetts, despite the fact that the potentially objectionable gram positive organism "*staph spp. not aureus or intermedius*" was identified on equipment used to manufacture the lot.

41. Lot 71-3B25 of Bactroban Ointment was deemed adulterated because the manufacturing processes and laboratory testing procedures were insufficient to assure that the Bactroban was of the strength, identity, quality, and purity that was represented to possess.

**Split Tablets in Paxil CR**

42. Paxil was a drug used to treat depression, anxiety, and pre-menstrual dysphoric disorder. The controlled release formulation of the drug, Paxil CR, controlled the rate of dissolution and absorption of the active ingredient, Paroxetine, in the body. **SB PHARMCO** manufactured Paxil CR in varying strengths including 12.5 mg, 25 mg, and 37.5 mg strengths.

43. Paxil CR had two layers, one containing the active ingredient ("active layer"), and one containing no active ingredient ("barrier layer").

44. During the manufacturing process, first the active layer was compressed and then the barrier layer was added to the active layer for compression into the final bi layer tablet. In development at GSK's Crawley plant in the United Kingdom, GSK used a triple-layer press machine to perform these functions.

45. In or about February 2002, **SB PHARMCO** began commercial manufacture of the Paxil CR tablet, the first and only bi-layer tablet manufactured at Cidra. Cidra used three modified single-layer Hata press machines to perform the compression function. The three Hata compression machines used by Cidra were less sensitive in their ability to measure the compression force than the triple-layer press machine GSK used in development.

46. In or about late March and early April 2002, shortly after commercial production began, **SB PHARMCO** observed during packaging that some of the Paxil CR tablets separated between the active layer and the barrier layer. Split tablets contained either only the active layer,

which was absorbed in the body more quickly because of the absence of the controlled release function provided by the barrier layer, or only the barrier layer, which had no active ingredient and no therapeutic benefit for the patient.

47. SB PHARMCO classified the split tablet as a "critical defect" which was defined by SB PHARMCO as a defect with "a high probability of causing adverse consequences to the patient or consumer, [or] may result in significant deviations in the safety, identity, strength or purity of the product. . . ."

48. On or about April 5, 2002, SB PHARMCO completed an investigation of split tablets observed in five different lots of Paxil CR 25 mg and concluded that the most probable cause of the splits was that the compression forces on the active layer in commercial production were slightly higher than the compression forces applied during validation, which could result in the barrier layer not adhering to the active layer. After concluding the investigation, SB PHARMCO performed 100 percent visual inspection in an attempt to remove the split tablets, and distributed the five lots.

49. In or about April 2002, SB PHARMCO implemented 100 percent visual inspection of all Paxil CR tablets in an attempt to remove split tablets prior to packaging and release of the product to market. As SB PHARMCO knew, visual inspection of millions of tablets by human operators was subject to error as a result of the quality of the operator's depth perception, speed of the conveyor belt, and other environmental and human conditions.

50. From in or about December 2002 to February 2003, SB PHARMCO conducted a Design of Experiment ("DOE") to determine the cause of the split tablets. The DOE report concluded that "the splitting of CR tablets occurred because the active layer in side A was

compressed using a high pressure, which did not allow a good adhesion of the active layer to the barrier layer." The DOE report recommended, among other things, that **SB PHARMCO** "use lower pressures in the active layer compression process, combined with a load cell that could read those pressures." A load cell was a pressure sensor that detected variations in compression force, and the DOE report concluded that a "load cell of 50 KGF is required to allow the Hata [to] read the low pressures required to control the split situation."

51. Despite its own classification of the split tablet defect as a critical defect, **SB PHARMCO** failed to report the defect or findings of the DOE to the FDA in its 2003 Annual Report, instead informing the FDA that "[n]o significant new information was obtained during this reporting period that might affect the safety, effectiveness, or labeling of Paxil (paroxetine hydrochloride) CR."

52. In or about February 2004, following a series of studies, **SB PHARMCO** instituted manufacturing changes to lower the compression force and to monitor tablet weight, thickness, and hardness during production of the active layer of the 12.5 mg and 25 mg Paxil CR. **SB PHARMCO** did not install the more sensitive load cells on the Hata tablet presses that were necessary to allow the Hata presses to read the lower pressures.

53. After instituting the manufacturing changes, **SB PHARMCO** eliminated visual inspection of the coated 12.5 mg and 25 mg Paxil CR tablets for splits, and substituted statistical inspection. The 37.5 mg tablets continued to undergo 100 percent visual inspection. Statistical inspection involved examination of a sample of 1000 tablets in a batch of approximately 1.5 to 2 million tablets. If no split tablets were found in the sample, the lot was released for packaging and distribution; if splits were found, the lot was 100 percent visually inspected.

54. The change from 100 percent visual to statistical inspection of Paxil CR was a significant change in the manufacturing process, requiring progression and documentation through SB PHARMCO's change control process, which included approval by Cidra's Quality Unit. SB PHARMCO did not follow the change control process for the implementation of the statistical inspection protocol.

55. Following the change from visual to statistical inspection, SB PHARMCO continued to find split tablets of Paxil CR 12.5 mg and 25 mg during packaging, both at Cidra and at GSK's packaging facility in Zebulon, North Carolina, which also packaged Paxil CR for Cidra. Five separate investigations of eight different lots were initiated between April and August 2004 relating to the occurrence of splits in 12.5 and 25 mg tablets after compression. SB PHARMCO performed 100 percent visual inspection in an attempt to remove the split tablets and distributed these lots

56. From on or about September 7, 2004 through on or about November 5, 2004, the FDA conducted another inspection of Cidra. The FDA issued a Form 483 to SB PHARMCO with the following observation:

> Your firm failed to take adequate corrective and preventive actions to prevent the split tablet defect, classified by your firm as critical defect, in distributed Paxil CR product. Although your process controls include an inspection after the coating process to detect the defect, the defect has been found during the packaging operation of Paxil CR 12.5 tablets and Paxil CR 25 tablets, in approximately 12% and 25% of the batches manufactured/packaged during 2004.
>
> Furthermore, this defect has been found in distributed products and non-distributed products outside GSK-Cidra premises . . . . [providing five examples].

57. During the FDA inspection, on or about September 15, 2004, SB PHARMCO re-instituted 100 percent visual inspection of 12.5 and 25 mg Paxil CR tablets.

58. In or about November 2004, **SB PHARMCO** purchased sorting machines to conduct 100 percent automated inspection of the thickness of Paxil CR tablets.

59. Between on or about February 20, 2004 and September 15, 2004, **SB PHARMCO** released certain lots of Paxil CR 12.5 mg and 25 mg tablets for distribution in interstate commerce, including in the District of Massachusetts, that were deemed adulterated because the equipment on which Paxil CR was manufactured was insufficient to ensure that the proper compression force was used on the active layer, and the process controls could not assure that Paxil CR released to market was of the strength, identity, quality and purity that the drug was represented to possess.

**Content Uniformity Failures in Avandamet**

60. Avandamet was a drug used to treat diabetes. Avandamet was a tablet comprised of two substances blended together in specific amounts. Those substances were rosiglitazone and metformin. Avandamet was made of a small amount of rosiglitazone and a large amount of metformin (e.g. one strength of Avandamet was 1 mg of rosiglitazone and 500 mg of metformin, known as the "1/500 mg" strength).

61. To properly manufacture Avandamet, a homogenous blend of rosiglitazone and metformin was required to ensure all tablets were comprised of the proper blend of the two substances, referred to as "content uniformity." To achieve content uniformity, the rosiglitazone and the metformin were subjected to a granulation process (much like sifting flour to make a cake). Cidra used a wet granulation process that involved adding liquid solution to the powders to achieve the correct density so that a homogenous blend of the two drug substances could be obtained.

62. Commercial production of the 1/500 mg, 2/500 mg and 4/500 mg strengths of Avandamet commenced at Cidra in October 2002. Avandamet was manufactured, in part, in granulation areas known as the Niro 200 suite and the Niro 300 suite at Cidra.

63. In the first few months of production, certain batches of Avandamet failed content uniformity tests. A failed content uniformity test related to rosiglitazone meant that the batch was out-of-specification ("OOS") and contained sub-potent or super-potent tablets.

64. In or about February 2003, one of the GSK GQA auditors commented in connection with a proposed internal mock pre-approval inspection for production of the 2/1000 and 4/1000 mg strengths of Avandamet that "there are many investigations now for content of the 1/500 mg tablet."

65. In or about April 2003, GSK GQA performed the mock pre-approval inspection for the 2/1000 and 4/1000 mg tablets and observed one "Priority 1" finding, which was a finding that "may result in the regulatory agency not having sufficient confidence in process/facility/quality systems/people to allow them to approve the facility as a manufacturer." The Priority 1 finding was "[t]he Niro Fluid Bed Dryer malfunctioned allowing inconsistent drying of the granulation used in Avandamet 1-gram qualification batch, commercial Avandamet 500 mg tablets and commercial Avandia tablets."

66. In or about November 2003, **SB PHARMCO's** sister site in Aranda, Spain complained of defects in tablets received from Cidra, including out-of-specification [i.e. content uniformity failures] tablets.

67. From in or about October 2003 to December 2003, the FDA conducted an inspection of Cidra, and issued Form 483 findings to **SB PHARMCO** that observed the following deficiencies, among others:

a. *Failure to question process.* "The following investigations related to OOS (assay/content uniformity and/or dissolution) obtained for Avandamet have not been questioned in terms of the adequacy of the process for Avandamet tablets . . ."

b. *Failure to take corrective action:* "Failure to take appropriate action against all lots that may be affected by a conclusion included as the assignable cause of a failing result . . . . Although your conclusion assigns as the most probable cause the use of common Rosiglitazone concentrate . . . not all lots using this same granulation concentration were rejected . . . . Furthermore, no action has been taken against any batch that may have been released to the market for distribution."

c. *Inadequate investigations:* "Your 2003 OOS manufacturing investigations related to assay, content uniformity and/or dissolution OOS, obtained for batches of Avandamet . . . are inadequate in that none of these investigations have questioned the adequacy of the process validation used to determine that your manufacturing process is robust and reproducible. Furthermore, your investigations related to these and other failures are not completed in a timely manner . . . ."

68. The FDA conducted another inspection of Cidra from on or about September 7, 2004 through November 15, 2004, and observed continuing deficiencies regarding the Avandamet manufacturing process:

> Since July 2004, your firm has obtained about nine (9) out-of-specification (OOS) results in the content uniformity test for Avandamet as follows [listing lots]. As of November 5, 2004, your firm had not determined the root cause for the failures; if all the OOS results were related to each other; and how to correct the problem. . . . The impact in other lots that used the same in-process materials and obtained passing finished testing results has not been determined. . . .
>
> Investigations of an unexplained discrepancy and a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product. Specifically, lot #323-4A67 was recommended for rejection on 9/28/04 due to OOS results for content uniformity test for the Rosiglitazone

> active ingredient. At the closing of the investigation, your firm had not determined the assignable cause for the failure. Twenty seven (27) other lots of Avandamet were manufactured using one or more of this lot's granulations and blends. . . . These lots were not included in the investigation and twenty six (26) of them were released and distributed. There is no assurance that the other lots manufactured under the same manufacturing conditions of the failing lots will have the strength, quality and purity they represent to possess.

69. In early 2005, GSK sent above-site experts to Cidra to determine the root cause of the content uniformity failures regarding Avandamet. Those experts concluded that: (a) a humidity sensor in a Fluid Bed Dryer in the Niro 200 suite had been improperly calibrated for an unknown amount of time, resulting in inappropriate drying times and a shift in granulation moisture content that resulted in poor blending of the metformin; and (b) a spacer or washer had been inserted in the milling machine in the Niro 200 suite that was used to produce rosiglitazone granules, resulting in some over-sized granules of rosiglitazone being used in the final product.

70. Between in or about March 2003 and October 2004, SB PHARMCO released certain lots of Avandamet for distribution in interstate commerce, including in the District of Massachusetts, that were deemed adulterated because the manufacturing processes and laboratory testing procedures were insufficient to assure that the Avandamet was of the strength, identity, quality and purity that Avandamet was represented to possess.

**Product Mix-Ups**

71. During 2002, eight Field Alert Reports were filed with the FDA regarding complaints of product commingling from patients, pharmacies, and hospitals, and nine internal investigations were initiated based on line clearance problems that raised concerns of possible product mix-ups at Cidra.

72. On or about April 2, 2003, a GSK GQA auditor summarized the compliance risks at Cidra against QMS and informed SB PHARMCO and others that one of the areas of high risk was product mix-ups and commingling of product.

73. On or about December 2, 2003, the FDA informed SB PHARMCO in Form 483 observations:

> Your firm fails to have appropriate procedures and controls in place to prevent mix-ups and/or adverse effects to product from occurring during the manufacturing/packaging process. Furthermore, batches are released by your Quality Unit for distribution although you are aware of findings of mix-ups prior to these batches being released to market.
>
> Product mix-up incidents have been repeatedly occurred [sic] since year 2001 through 2003. Products mentioned in the above examples were approved and released for distribution. Furthermore, complaints related to product mix-ups have been received since year 2001-2003 (period covered during the EI). Nevertheless, you have informed the FDA through FARs [Field Alert Reports] and previous and the current inspection that all incidents are isolated and not related to your manufacturing operation.

74. From in or about at least January 2004 until in or about October 2004, the Cidra Site Director collected rogue tablets from the manufacturing areas and packaging lines, kept them in a gowning hat in her office, and failed to alert site and above-site quality personnel.

75. On or about November 20, 2004, the FDA informed SB PHARMCO in Form 483 observations that:

> Procedures for the cleaning and maintenance of equipment are deficient regarding inspection of the equipment for cleanliness immediately before use. Specifically, line clearance's procedures and controls are not appropriate to prevent mix-ups during the manufacturing/packaging processes. The following line clearance's related incidents occurred at the firm during the period of January-August 2004 in products that were released . . . [listing eight separate instances].
>
> About three (3) complaints related to product packaging/mix-ups have been received since 12/2003 that could be related to batches manufactured/packaged within the same period of time and/or the same area of the complaint's lots.

> However, your firm relied on the adequacy of cleaning and line clearance's controls to conclude that it was unlikely that the situation was originated within the packaging area at GSK-Cidra. There is no assurance that adequate controls are in place as to prevent mix-ups during your manufacturing operations . . . .
>
> The responsibilities and procedures applicable to the quality control unit are not fully followed. Specifically, your Quality Unit failed to conduct a thorough investigation of all the events associated with line clearance to prevent mix-ups during the manufacturing/packaging process according to your written procedures. . . . [citing two examples in 10/2004].

76. In or about August 2003, **SB PHARMCO** released Lot 161-3P07 of Paxil CR which contained commingled dosages of Paxil CR for distribution in interstate commerce, including in the District of Massachusetts, which was adulterated because the manufacturing and packing processes were insufficient to assure that the Paxil CR was of the strength, identity, quality and purity that it was represented to possess.

## COUNT 1

**(21 U.S.C. §§ 331(a), 333(a)(2), 351(a)(2)(B) - Interstate Shipment of Adulterated Drugs)**

77. The allegations of paragraphs 1 through 76 are realleged and incorporated herein by reference.

78. Between in or about March 2003 and in or about October 2004, in the District of Massachusetts and elsewhere,

**SB PHARMCO PUERTO RICO, INC.**

defendant herein, did, with intent to defraud and mislead, cause to be introduced and delivered for introduction into interstate commerce quantities of drugs – to wit Kytril, Bactroban, Paxil CR and Avandamet – that were adulterated in that the methods used in, and the controls used for, drug manufacturing, processing, packing and holding did not conform to and were not operated and administered in conformity with current good manufacturing practices.

All in violation of Title 21, United States Code, Sections 331(a), 333(a)(2) and 351(a)(2)(B).

## FORFEITURE ALLEGATIONS

1. Upon conviction of a violation of Title 21, United States Code, Section 331(a),

**SB PHARMCO PUERTO RICO, INC.**

shall forfeit to the United States pursuant to Title 21, United States Code, Section 334 and Title 28, United States Code, Section 2461(c) any quantities of Paxil CR, Avandamet, Kytril and Bactroban which were introduced into interstate commerce in violation of Title 21, United States Code, Section 331 and/or 351(a)(2)(b);

2. If any of the property subject to forfeiture, as a result of any act or omission of the defendant:

(a) cannot be located upon the exercise of due diligence;

(b) has been transferred or sold to, or deposited with, a third party;

(c) has been placed beyond the jurisdiction of the Court;

(d) has been substantially diminished in value; or

(e) has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), incorporated by reference in Title 28, United States Code, Section 2461(c), to seek forfeiture of any other property of the defendant up to the value of the property subject to forfeiture.

All pursuant to Title 21, United States Code, Sections 334 and 853 and Title 28, United States Code, Section 2461(c), and Rule 32.2 of the Federal Rules of Criminal Procedure.

CARMEN M. ORTIZ
UNITED STATES ATTORNEY

TONY WEST
ASSISTANT ATTORNEY GENERAL
CIVIL DIVISION
U.S. DEPARTMENT OF JUSTICE

By: [redacted]
SUSAN G. WINKLER
SHANNON T. KELLEY
ASSISTANT U.S. ATTORNEYS

[redacted]
MARK L. JOSEPHS
TRIAL ATTORNEY
OFFICE OF CONSUMER LITIGATION

# EXHIBIT B

# Answering the Questions that mAtter

Annual Report 2007


GlaxoSmithKline

Do more, feel better, live longer

## 44 Legal proceedings continued

*Paxil/Seroxat*

Following announcement of the New York State Attorney General's office about the state's lawsuit, subsequently settled in August 2004, alleging failure to disclose data on the use of *Paxil* in children and adolescents, similar cases, some of which purport to be class actions, were filed in state and federal and Canadian courts by private plaintiffs seeking to recover amounts paid for *Paxil* purchased for use by patients under age 18. The Canadian litigation has been dismissed. The Group reached a class settlement agreement in an Illinois state court action that includes all persons in the USA who bought *Paxil* for someone under age 18. The Group denies any liability. The agreement relates only to the cost of purchasing *Paxil* for use by paediatric patients and does not include any personal injury claims. The settlement was approved by the court in April 2007. Remaining are four lawsuits seeking recovery on behalf of insurance companies and other third-party payers for payments for prescriptions of *Paxil* to children and adolescents. The Group was granted partial summary judgement dismissing class claims in one of those cases. Discovery is underway in a state court action in California pending a hearing on class certification.

In the UK an investigation remains pending by the UK Medicines and Healthcare products Regulatory Agency (MHRA) to determine whether the Group has complied with its pharmacovigilance obligations in reporting data from clinical trials for *Seroxat/Paxil* in children and adolescents.

Cidra, Puerto Rico manufacturing site

Following FDA inspections in October 2003 and November 2004 which resulted in observations of possible deficiencies in manufacturing practices at the Group's manufacturing facility in Cidra, Puerto Rico, in March 2005 the FDA seized certain lots of *Paxil CR* and *Avandamet* due to manufacturing issues. The FDA observations related to certain aspects of production controls, process validation and laboratory investigations.

In April 2005 the Group reached agreement with the FDA on a Consent Decree. The Consent Decree provides for an independent expert to review manufacturing processes at the site for compliance with FDA Good Manufacturing Practice (GMP) requirements. As provided in the Consent Decree, in September 2005 the Group provided a report to the FDA on the deficiencies identified in this review, setting out a corrective plan and timetable for completion. The Group anticipates completion of the work identified in that plan by mid-2008. In March 2007, the FDA completed a general GMP inspection which resulted in four inspectional observations. The Group has been advised by the FDA that the Group's response to the inspectional observations is satisfactory.

In October 2007 the Group announced plans to cease operations at the Cidra site but expects to continue production of *Paxil CR* at the site until that production can be transferred to another facility which the Group currently expects to take place in 2009. Production of all other products at the site was discontinued by the end of 2007.

In October 2003, the US federal government executed a search warrant at the Cidra facility and seized records relating to the manufacturing operations at the site.

In April 2005, the Group received a subpoena from the US Attorney's Office in Boston requesting production of records regarding manufacturing at the Cidra site, covering information that is similar to that seized by the US government in Puerto Rico in 2003. Subsequently, in August 2007 and January 2008, the Group received two additional subpoenas from the government related to the Cidra facility. The Group is co-operating with the US Attorney's Office and producing the records responsive to the subpoenas. In addition, in July 2007, the Group learned that the US District Court for the District of Massachusetts had unsealed a complaint brought by a former employee under the federal False Claims Act claiming monetary damages as a result of the alleged failure of the Cidra facility to comply with GMP in the manufacture of various products.

The Group is also named in two purported consumer fraud class action lawsuits – one filed in California state court and the other in the US District Court for the District of Puerto Rico – alleging that *Paxil* products were not manufactured according to GMP. Plaintiffs seek economic, statutory and punitive damages, along with a request for injunctive relief. There has not yet been any determination whether either case will be permitted to proceed as a class action.

Anti-trust

*Paxil/Seroxat*

In the paroxetine patent infringement actions brought by the Group as described under 'Intellectual property' above, Apotex and certain other companies filed anti-trust and unfair competition counterclaims against the Group in the US District Court for the Eastern District of Pennsylvania. These were based on allegations that the Group monopolised a 'market' for *Paxil* by bringing allegedly sham patent litigation and allegedly abusing the regulatory procedures for the listing of patents in the FDA Orange Book. Whilst the Apotex matter remains in the discovery stage, the matters with the other companies have been resolved.

In November 2000, the FTC staff advised the Group that they were conducting a non-public investigation to determine whether the Group was violating Section 5 of the Federal Trade Commission Act by 'monopolising or attempting to monopolise' the 'market' for paroxetine hydrochloride by preventing generic competition to *Paxil* and requested the Group to submit certain information in connection with that investigation. In October 2003, the FTC closed its investigation on the basis of its finding that no further action was warranted. Following public reference to the FTC investigation regarding *Paxil*, a number of governmental and private civil actions and claims were initiated in the USA. All have been resolved with the exception of a private indirect purchaser opt-out lawsuit brought in the Minnesota courts. That matter is in the discovery phase. Additionally, class actions have been filed in provincial courts in Canada on behalf of direct and indirect purchasers. Those cases are in their early stages.

In October 2005, the Competition Directorate of the European Commission initiated an inspection concerning allegations that the Group has abused a dominant position in the marketplace concerning enforcement of its intellectual property rights, litigation surrounding regulatory approvals and marketing of *Seroxat* in Europe. In October 2006, the Commission made a formal request for further information. The Group responded to this request by the end of 2006.

# EXHIBIT C

# Risk of stray pill of wrong drug in prescription 'very remote': manufacturer

Canadian Press

*April 25, 2005*

TORONTO (CP) - The chance of consumers finding a stray tablet of the wrong medication in their prescriptions because of packaging problems at one GlaxoSmithKline pharmaceutical plant is virtually nil, the company said Friday.

Health Canada issued an advisory Thursday that consumers taking certain drugs marketed by GlaxoSmithKline and Ratiopharm should check to make sure their pill bottles or blister packs contain only their prescribed medication.

The warning applies to six medications made by GlaxoSmithKline - Avandamet, Avandia, Coreg, Paxil, Paxil CR and Relafen - and ratio-Paroxetine, the generic version of the antidepressant Paxil marketed by Ratiopharm Canada of Mississauga, Ont.

Avandamet and Avandia are used to treat Type 2 diabetes, Coreg is a treatment for congestive heart failure and Relafen is an arthritis drug.

The chance of an incorrect pill ending up in someone's prescription is "extremely remote. This represents a very low risk for patients," Marie-Christine Beauchemin, a spokeswoman for GlaxoSmithKline, said Friday from Montreal.

The potential packaging problem at the company's Puerto Rico plant was pointed out by U.S. Food and Drug Administration inspectors. Beauchemin insisted the company has rectified the problem and the advisory to consumers was strictly a precaution.

"During an inspection at the GSK plant in Puerto Rico, the FDA identified a potential for tablet mix-up and that was possibly during the cleaning and the preparation of the manufacturing line between batches," she said.

"For example, it's like finding a single tablet in a difficult place to reach in the machine or finding a tablet which kind of wandered off in the packaging suite. So it's basically finding a tablet which did not belong where it should have been.

"Based on this observation, the FDA said there was a potential risk for tablet mix, but there was never a tablet in a prescription bottle, it never ended up in a prescription bottle (or bulk packaging), never."

There have been no incidents reported in Canada of incorrect pills being dispensed, but "there is a theoretical risk that this could occur," a Health Canada spokeswoman has said. Blister packs of Paxil and ratio-Paroxetine are not affected.

Should a consumer ingest a non-prescribed pill, any adverse reactions would be mild, with the exception of an asthmatic taking Coreg, which could cause severe broncospasm, the company said.

The drug maker has alerted pharmacists across Canada to keep an eye out for stray pills by dispensing them manually, rather than by machine, said Beauchemin, adding that consumers should not stop taking their medication.

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

| | |
|---|---|
| **BLUE CROSS BLUE SHIELD ASSOCIATION, *et al.*,**<br><br>**Plaintiffs,**<br><br>**vs.**<br><br>**GLAXOSMITHKLINE LLC,**<br><br>**Defendant.** | **Civil Action No. 2:13-cv-4663-JS** |

**[PROPOSED] ORDER**

And now this ____day of _____, 201_, upon consideration of GlaxoSmithKline LLC.'s submissions in support of its motion to dismiss the Complaint and Plaintiffs' opposition thereto, it is hereby **ORDERED** and **DECREED** that the motion is **DENIED**.

DATED: _____

_____
HONORABLE JUAN R. SÁNCHEZ
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

| | |
|---|---|
| **BLUE CROSS BLUE SHIELD ASSOCIATION, *et al.*,**<br><br>**Plaintiffs,**<br><br>**vs.**<br><br>**GLAXOSMITHKLINE LLC,**<br><br>**Defendant.** | **Civil Action No. 2:13-cv-4663-JS** |

**CERTIFICATE OF SERVICE**

I declare under penalty of perjury that a copy of Plaintiffs' Brief in Opposition to Defendant's Motion to Dismiss the Complaint was served today on all counsel by ECF.

Dated: White Plains, N.Y.
December 6, 2013

LOWEY DANNENBERG COHEN & HART, P.C.

By: s/ Peter D. St. Phillip, Jr.