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

IN RE ACTIQ SALES AND MARKETING PRACTICES LITIGATION	:	**CIVIL ACTION**
		NO. 07-4492

MEMORANDUM OPINION

Tucker, C. J. **March 23, 2015**

I. INTRODUCTION

Pennsylvania Turnpike Commission and Indiana Carpenters Welfare Fund (collectively, "Plaintiffs") bring this putative class action suit alleging that off-label prescription payments made by Plaintiffs to Defendant Cephalon, Inc. ("Cephalon") were excessive and constituted unjust enrichment. Plaintiffs are entities, called third party payors ("TPPs"), that are responsible for paying all or part of the costs of prescriptions for their members, employees, plan participants, beneficiaries, or insureds ("beneficiaries"). Cephalon is a Delaware corporation with its principal place of business in Frazer, Pennsylvania that is engaged in the business of manufacturing, selling, and distributing pharmaceutical drugs. Plaintiffs claim that Cephalon engaged in unlawful off-label marketing of Actiq, a drug approved by the U.S. Food and Drug Administration ("FDA") to manage breakthrough cancer pain in patients who are already receiving, and are tolerant to, opioid therapy. Plaintiffs argue that Cephalon's conduct caused Plaintiffs to make excessive off-label prescription payments for Actiq to treat conditions not approved by the FDA and for whom less expensive pain management drugs were appropriate

and less dangerous. This Court exercises jurisdiction over this matter pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d), because the amount in controversy exceeds $5,000,000 and at least one Plaintiff resides outside of Pennsylvania.

Presently before the Court is Plaintiffs' Motion for Class Certification. Plaintiffs seek certification of a class action under Fed. R. Civ. P. 23(a) and (b)(3) to recover economic damages for unjust enrichment. Cephalon vigorously opposes certification. Its primary contention is that Plaintiffs' claim is not fit for class treatment under Rule 23 because of the individualized inquiry required to prove the elements of unjust enrichment. Cephalon asserts that no common questions of fact exist, individualized factual issues will predominate, and the action would be unmanageable if certified.

Upon consideration of the parties' submissions, their arguments at a class certification hearing, and for the reasons that follow, the Court DENIES Plaintiffs' motion.

II. THE PROPOSED CLASS

Plaintiffs move for certification of one Nationwide Class defined as follows:

> All Third Party Payors ("TPP") in the United States who paid and/or reimbursed, in whole or in part, for the cost of Actiq prescribed for indications other than cancer and for consumption by their members, employees, plan participants, beneficiaries or insureds during the period from January 1, 2002 through December 31, 2006.

(Pls.' Mem. in Supp. of Mot. for Class Cert., 1.) In the first alternative, Plaintiffs move for two multi-state Alternative Classes, defined as follows:

> (1) *Unjust Enrichment (Restatement) Class:* All Third Party Payors ("TPP") in the United States who paid and/or reimbursed, in whole or in part, in Arkansas, Colorado, Connecticut, the District of Columbia, Hawaii, Illinois, Indiana, Iowa, New Hampshire, New York, Oklahoma and West Virginia, for the cost of Actiq prescribed for indications other than cancer and for consumption by their members, employees, plan participants, beneficiaries or insureds during the period from January 1, 2002 through December 31, 2006.

> (2) *Unjust Enrichment (Appreciation) Class:* All Third Party Payors ("TPP") in the United States who paid and/or reimbursed, in whole or in part, in Alaska, California, Florida, Georgia, Kansas, Kentucky, Maine, Maryland, Massachusetts, Missouri, Nevada, New Mexico, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Washington and Wisconsin, for the cost of Actiq prescribed for indications other than cancer and for consumption by their members, employees, plan participants, beneficiaries or insureds during the period from January 1, 2002 through December 31, 2006.

(*Id.* at 2-3.) In the second alternative, Plaintiffs move for two single-state classes to be certified under the laws of Indiana and Pennsylvania, which is where the Plaintiffs reside. (*Id.* at 3 n.4.)

"Third Party Payor," as used in the class definition, is defined as "a private or governmental entity that was or is at risk to pay all or part of the cost of Actiq, which was prescribed, provided or administered in the United States for individual members, employees, plan participants, beneficiaries or insureds of the TPP's prescription drug or health coverage." (*Id.* at 2 n.3.) TPP is not to include: (1) Cephalon, any entity in which Cephalon has a controlling interest, and Cephalon's legal representatives, predecessors, successors, assigns, and employees; (2) the U.S. Government and its agencies and departments, and all other governmental entities that made payments pursuant to any state's Medicaid program; (3) all federal, state, or local governmental entities, except for such governmental agencies or programs that made or incurred any obligations to make a reimbursement for Actiq as part of a health benefit plan for their employees, but only with respect to such payments; (4) the Court and any judge assigned to this case; and (5) class counsel. (*Id.*)

III. FACTUAL BACKGROUND[1]

A. Regulatory Landscape for Prescription Drugs

A pharmaceutical manufacturer may distribute a prescription drug only if the drug has been approved by the Food and Drug Administration ("FDA"), the federal agency that regulates the distribution of drugs in the United States. 21 U.S.C. § 355(a). In order to obtain the FDA's approval, a manufacturer must show that the drug is "safe for use under the conditions prescribed, recommended or suggested" on the drug's label. 21 U.S.C. § 355(d). Pursuant to the Food, Drug, and Cosmetic Act ("FDCA"), the FDA regulates both the advertising and labeling of all prescription drugs. *See* 21 C.F.R. § 202.1 (advertising); 21 C.F.R. §§ 201.1-201.327 (labeling). Those drugs that are out of compliance with the FDA's requirements are deemed misbranded and may not be distributed through interstate commerce. *See* 21 U.S.C. § 331. The U.S. government enforces the FDCA and no private cause of action is available. *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir. 1994).

For a small class of prescription drugs, the FDA will grant approval under the distribution regulations of 21 C.F.R. § 314.520 ("Subpart H"), which is reserved for drug products that are effective but carry significant safety risks. Such drugs are subject to post-marketing restrictions because the FDA has determined that the drug is safe only if its distribution and use is restricted. *Id.* § 314.520(a). The drug's manufacturer is to follow a Risk Management Program ("RMP" or

[1] This factual summary is compiled from the following documents: Amended Class Action Complaint (Doc. 22); Plaintiffs' Proffer of Facts in Support of Plaintiffs' Motion for Class Certification (Doc. 347); Declaration of Deborah B. Leiderman, M.D. (Doc. 343); Defendant's Response and Counter-Statement to Plaintiffs' Proffer of Facts in Support of Plaintiffs' Motion for Class Certification (Doc. 376); Plaintiffs' Rebuttal Proffer of Facts (Doc. 396); and Parties' Joint Notice of Record Supplements (Doc. 415). Plaintiffs' exhibits shall be in reference to the Kurowski Declaration; Cephalon's exhibits shall be in reference to the Menkowitz Declaration.

"RiskMAP"[2]), which is designed to ensure safe use of the product. *See* 21 U.S.C. § 355-1. RiskMAPs may incorporate a range of programs and tools that go beyond cautionary labeling, including registries or educational programs. (Leiderman Decl. ¶ 12.) RiskMAPs, however, are unusual. (Kurowski Decl. Ex. 100, Pyfer Dep. 27:21-28:6, Nov. 4, 2011; *see also id.* Ex. 101, Brennan Dep. 14:2-14, Nov. 16, 2009.)

B. The FDA Approved Actiq Under Subpart H

Actiq is a drug developed by Anesta Corporation, which merged with Cephalon in 2000. (Kurowski Decl. Ex. 103, DeRogatis Dep. 34:13-18, Sept. 17, 2009; Pyfer Dep. 38:14-39:8.) Cephalon also acquired U.S. marketing rights to Actiq from Abbott Laboratories at that time. (Menkowitz Decl. Ex. 49, Cephalon Form 10-K405, filed Mar. 30, 2001, at 31.) Actiq answered the unmet medical need for "relief of severe cancer pain not adequately controlled by other narcotic therapy." (Leiderman Decl. ¶ 21.) Its active ingredient is fentanyl citrate, a potent opioid painkiller many times stronger than morphine, oxycodone, or codeine. Fentanyl citrate causes respiratory depression, which carries a serious risk of death in vulnerable patients. (*Id.* ¶¶ 8-9; Kurowski Decl. Ex. 3, Package Insert.) Actiq is packaged as a lozenge, formulated so that patients can quickly absorb a sufficient dose of fentanyl citrate through their gums to ease their pain. (Package Insert.)

In November 1998, the FDA approved Actiq under Subpart H for "the management of breakthrough cancer pain[3] ["BTCP"] in patients with malignancies who are already receiving

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[2] These terms applied during the proposed class period. The current terminology used by the FDA is Risk Evaluation and Mitigation Strategies ("REMS"). *See* Food and Drug Administration Amendments Act of 2007, 21 U.S.C. § 355-1.

[3] Breakthrough pain is a "transitory flare of pain that occurs on a background of otherwise stable, persistent pain in patients receiving chronic opioid therapy." (Kurowski Decl. Ex. 104, Actiq 2002 Marketing Plan, at 22.)

and who are tolerant to opioid therapy for their underlying persistent cancer pain." (Kurowski Decl. Ex. 2, FDA Approval Letter, Nov. 4, 1998, at 1.) The FDA emphasized Actiq's limited approval:

> We have concluded that adequate information has now been presented to demonstrate that Actiq is safe and effective, when marketed in accordance with the terms of restricted distribution and use described in the Risk Management Program . . . and as recommended in the attached final labeling. . . . In addition, please note that this product has been approved **ONLY** for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

(*Id.* at 1, 5). Under the circumscriptions of Actiq's approved label, off-label[4] marketing is not permissible since most forms of off-label use were for contraindicated conditions. The label also specified that Actiq must not be used by patients who are not opioid tolerant because it is potentially life threatening. [5]

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[4] "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described on the drug's labeling. Such uses include treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified on the label, or treating a different patient population. (Proffer of Facts in Supp. of Pls.' Mot. for Class Certification ¶ 9.)

[5] Actiq's approved label reads:

> PHYSICIANS AND OTHER HEALTHCARE PROVIDERS MUST BECOME FAMILIAR WITH THE IMPORTANT WARNINGS IN THIS LABEL.
> *Actiq* is indicated only for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking at least 60 mg morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
> Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, *Actiq* is contraindicated in the management of acute or postoperative pain. This product **must not** be used in opioid non-tolerant patients.
> *Actiq* is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain . . . .
> CONTRAINDICATIONS
> Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, *Actiq* is contraindicated in the management of acute or postoperative pain. The risk of respiratory depression begins to increase with fentanyl plasma levels of 2.0 ng/mL in opioid non-tolerant individuals . . . This product **must not** be used in opioid non-tolerant patients.

(Package Insert).

Section 9.0 of the Actiq RiskMAP, entitled "Intervention," required Cephalon to monitor prescribing patterns and to intervene when off-label usage came to the company's attention. (Kurowski Decl. Ex. 102, 2001 RiskMAP at 27; *id.* Ex. 4, 1998 RiskMAP at 26.) As to individual prescribers, if Cephalon became aware of a problem of off-label usage, the Actiq RiskMAP required Cephalon to individually notify "all identified prescribers to emphasize the approved indication and appropriate patient selection." (2001 RiskMAP at 27; 1998 RiskMAP at 26; *see* Pyfer Dep. 300:11-16 (testifying that if Cephalon "became aware of a physician prescribing off label, according to the RMP, a letter was to be sent.").) Cephalon was also to monitor groups of prescribers:

> If groups of physicians (such as a particular specialty) are identified as having prescribed *Actiq* inappropriately, and these prescriptions represent potential off-label usage greater than 15% of total quarterly Actiq prescriptions, Cephalon, Inc. will contact the appropriate professional society (i.e. American College of Surgeons, American Society of Anesthesiologists). This letter will outline prescribing concerns and offer to implement an educational program in conjunction with the professional society in a national setting.
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> Prescribing patterns will be monitored for the physician groups in question and should the level continue to exceed 15% of total Actiq prescriptions for two additional quarters, an aggressive educational program will be initiated by mail clearly warning of the potential liabilities of prescribing Actiq to inappropriate patient populations.

(2001 RiskMAP at 27.)

C. Cephalon Launched a New Marketing Strategy for Actiq

In February 2001, when Cephalon acquired U.S. marketing rights for Actiq, it "repositioned" and "relaunched" Actiq. Prior to the relaunch, "the marketing directive had been to target oncologists, hematologists and pain specialists, with the emphasis being placed on oncology." (Kurowski Decl. Ex. 104, Actiq 2002 Marketing Plan at 8.) Cephalon's strategy was

to shift the target market from oncologists to other physicians.[6] (*See* Actiq 2002 Marketing Plan at 13.) Cephalon's 2002 marketing plan stated, "[w]hile oncologists obviously use ACTIQ to treat BTCP," anesthesiologists and pain specialists ("APMs") "may feel comfortable with ACTIQ's potential in other pain states regardless of the narrow BTCP indication."[7] (*Id.* at 11.) Cephalon cited Actiq's use for, among other things, lower back pain, adhesions, headache, osteoarthritis, fibromyalgia, rheumatoid arthritis, and lupus. (*Id.*)

In addition to targeting more physicians, Cephalon's campaign also focused on breakthrough pain ("BTP") instead of breakthrough cancer pain.[8] (Kurowski Decl. Ex. 113,

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[6] *See* Kurowski Decl. Ex. 105, E-mail from Nancy Shanfelt to Cephalon Sales Representatives (May 19, 2004, 16:11 EST) (regarding 2004 Actiq marketing targets, the Actiq Sales and Marketing Team noted that "over 7,000 new physicians" would be added to Cephalon's sales targets with a specialty breakdown of new targets being: "Anes/Pain- 13%," "Oncology- 11%," "PCP-60%," "Neuro-3%," "Psych-1%," and "Other-12%."); *cf.* 2001 RiskMAP at 16 ("The target physician audience for *Actiq* is a group of approximately 5,000 oncologists and pain specialists, their nurses, and office staff.").

[7] *See also* Kurowski Decl. Ex. 114, Makalusky Dep. 26:10-25, Jan. 7, 2010 (testifying that neurologists and pain care specialists "had the largest amount of narcotic prescriptions and the lowest use of Actiq," and that such physicians were the "target class" that sales representatives were "supposed to sell to.").

[8] In addition to the above quoted language, Plaintiffs direct the Court's attention to other excerpts from the Actiq 2002 Marketing Plan allegedly confirming Cephalon's decision to promote Actiq off-label. *See* Actiq 2002 Marketing Plan at 8 (discussing 2001 survey results confirming that APMs accounted for the vast majority of Actiq prescriptions and concluding that "anesthesiologists/pain specialists are more productive prescribers"); *id.* at 11 ("While oncologists obviously use ACTIQ to treat BTCP, the participating APMs cited ACTIQ usage in the following disease states illustrating a wide spectrum of application and opportunity"); *id.* at 24 ("Additionally, due to ACTIQ's rapid onset, it has a clear and distinct advantage over other products in the treatment of episodic or recurrent pain (e.g., sickle cell crisis, migraine headaches). This type of pain represents a substantial market opportunity."); *id.* at 43 ("The targeted patient populations will be both cancer patients and chronic non-malignant patients, as well as patients suffering from episodic pain such as migraine headaches and sickle cell disease."). Plaintiffs also point to presentations made within Cephalon to promote Actiq for treating conditions other than BTCP. *See* Kurowski Decl. Ex. 117, "Headache, Mid-Atlantic POA, June 5 & 6, 2002" at CEP_TPP 10026885 (directing sales representatives to discuss the use of Actiq for managing "episodic" headaches or "intractable or status migraines"); *id.* Ex. 118, "Use of Actiq in Procedures/Other, Mid-Atlantic POA, June 5-6, 2002" at CEP_TPP 10026890-91 (indicating that Actiq could be used for minor surgeries, bone marrow biopsies, post-operative pain, and wound dressing changes); *id*. Ex. 119, "Fibromyalgia Syndrome" at CEP_TPP 10026929 ("Although most authorities on FMS [fibromyalgia syndrome] treatment believe opioid analgesics and cortisone are ineffective and should be avoided, some favor considering them for occasional rescue doses when pain of 'flares' cannot be controlled by other means."); *id*. Ex. 120, "Osteoarthritis and DJD" at CEP_TPP 10026904, 09-10 (touting Actiq's fitness for treating osteoarthritis and degenerative joint disease because it provides "physical therapy pain reduction," "control of morning stiffness pain" and "[s]pine surgeons (dedicated) are usually few in numbers making targeting easier"). Years later, Cephalon reported that approximately 48% and 25% of Actiq patients had underlying

"2002 National Sales Meeting" at CEP_TPP 10035538; *id.* at CEP_TPP 10035560 ("Cephalon is successfully repositioning ACTIQ as a viable and uniquely effective BTP treatment option").) Cephalon trained its sales representatives to use a "Pain is Pain" sales pitch to promote Actiq. (*See* Kurowski Decl. Ex. 114, Makalusky Dep. 14:19-20, Jan. 7, 2010.) Cephalon also distributed coupons for free Actiq samples to doctors, some of whom passed them on to non-cancer patients. (*See id.* Ex. 7, John Carreyrou, *Narcotic 'Lollipop' is Big Seller Despite FDA Curbs*, Pittsburgh Post-Gazette, Nov. 3, 2006, http://www.post-gazette.com/news/health/2006/11/03/Narcotic-lollipop-is-big-seller-despite-FDA-curbs/stories/200611030261; Menkowitz Decl. Ex. 9, Hartman Dep. 36:9-37:1, Jan. 25, 2013; *id.* Ex. 11, Stoner Dep. 70:10-71:4, Mar. 6, 2013.)

Cephalon paid third party medical marketing firms and physicians to help promote Actiq. The marketing firms hosted seminars and events for doctors and Cephalon paid physicians to speak favorably about Actiq at medical education programs.[9] (*See* Actiq 2002 Marketing Plan at 3; Kurowski Decl. Ex. 150, "Actiq Launch 2001" at CEP_TPP10031956-59; Kurowski Decl. Ex. 195, "2004 Actiq Marketing Sales Training, July 2004" at CEPH-DR-00025469 (crediting Cephalon's success, in part, to "Lots o' MedEd").) The educational programs sponsored by Cephalon focused on expanding awareness of BTP and other forms of non-cancer pain.[10] (*See*

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conditions of back pain and headaches, respectively, and only 6% of Actiq patients had cancer. *Id.* Ex. 196, 2006 Actiq Marketing Sales Training, Dec. 13, 2005, at CEP_TPP10043547.

[9] Plaintiffs also allege that Cephalon paid physicians to publish journal articles and letters to the editor about the use of Actiq for treating pain not related to cancer. *See* Kurowski Decl. Ex. 152, "Actiq Publication Project Monthly Status Update," Aug. 2, 2004 (listing publications with topics including a comparison of oral transmucosal fentanyl citrate ("OTFC") and morphine and the use of OTFC for migraine headaches and musculoskeletal pain); *id.* Ex. 153, "Active Actiq Publication Projects" (listing publications with topics including sickle cell, migraine, and fibromyalgia as well as cancer).

[10] *See also* Kurowski Decl. Ex. 128, "2004 Actiq Marketing Regional Managers Meetings" at CEP_TPP_CTAG10048313 (listing topics for CME lectures to include management of chronic pain, breakthrough

Kurowski Decl. Ex. 124, 2003 Actiq Marketing Plan at 55; *see also* Kurowski Decl. Ex. 148, Actiq Consultants Meeting: Event Evaluation at CEP_TPP_CTAG10097161 (commenting in an evaluation survey after an Actiq consultants meeting, one physician participant wrote, "I feel less alone in using ACTIQ for non-cancer pain.").) Among other things, Cephalon trained speakers on how to support the use of Actiq to treat BTP in patients without cancer and how to justify the reimbursement costs of Actiq. (Kurowski Decl. Ex. 143, "Pharmaeconomics/Managed Care: Frequently Asked Questions" at 4-34.) Cephalon, however, did remind speakers to present on Actiq's FDA-approved indication and cautioned them to discuss off-label usage only in response to unsolicited questions from their audiences. (Kurowski Decl. Ex. 141, "Guidelines for Cephalon Speakers" at 4; *id.* Ex. 156, "Compliance Workshop: March 3, 2004" at 4-5.)

Another element of Cephalon's marketing plan was to ensure reimbursement and insurance coverage for Actiq prescriptions. In 2000, Cephalon launched Actiq "under the radar" of managed care by not aggressively promoting or discounting the product. (Kurowski Decl. Ex. 108, Actiq "Master Plan" at 18.) It created a reimbursement assistance program designed to help patients obtain insurance coverage for Actiq. (*Id.* at 18-19; *see also* Menkowitz Decl. Ex. 42, 2006 Activity Report for the Actiq Reimbursement Hotline at CEP_TPP11199605-06 (reporting that, for the month of September 2006, 93% of researched cases and all prior authorization requests coming through the reimbursement hotline were for conditions other than BTCP).)

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pain, musculoskeletal pain, neuropathic pain, migraines, and substance abuse); Makalusky Dep. 39:4-17 (testifying that during conferences, physicians who received honorariums from Cephalon did not promote or discuss Actiq's on-label indication); *id.* Dep. 41:9-11 ("We were instructed to talk to physicians about their use of Actiq and their success stories to other doctors, which was always off-label, yes."); *see also* Kurowski Decl. Ex. 137, Transcript of "Managing Chronic Pain with Opioids: A Consensus Meeting" at 82 (discussing, at a consensus meeting hosted by a third party contracted by Cephalon, various forms of pain management, including a comment by a paid physician panelist, "One of the way [sic] I use ACTIQ, which has been great in my practice, is migraine patients because they are not really tolerant to opioids, most of them and I notice, I keep track of them, they trip [sic] to the emergency room has decreased drastically with ACTIQ.")

Cephalon's healthcare systems department worked with managed care organizations, TPPs, and pharmacy benefit managers to maximize reimbursement or coverage for products like Actiq. (Menkowitz Decl. Ex. 38, Caminiti Dep. 8:13-9:18, Dec. 16, 2009.) By 2005, Cephalon reported that managed care organizations had increased restrictive measures on the reimbursement of Actiq, but "managed care has, for the most part, been relatively unsuccessful at slowing or stopping ACTIQ[.]" (Kurowski Decl. Ex. 107, Actiq 2005 Marketing Plan at 33.)

Since Cephalon's marketing "relaunch" of Actiq, sales grew significantly. U.S. sales revenue grew from $15 million in 2000 to $550 million in 2006. (Menkowitz Decl. Ex. 49, Cephalon Form10-K, filed Mar. 30, 2001, at 45; *id.* Ex. 54, Cephalon Form 10-K, filed Feb. 28, 2007, at 48.)

D. Cephalon's Internal Audit Revealed Non-Compliance with the Actiq RiskMAP

In March 2003, Cephalon tasked an internal compliance auditor, David Brennan, with conducting an audit of the Actiq RiskMAP. (Kurowski Decl. Ex. 101, Brennan Dep. 13:18-14:16; *id.* Ex. 157, RMP Audit Plan.) Regarding off-label usage, the audit plan sought to "verify that individual prescribing patterns are monitored," and, for groups of prescribers, to "verify that potential off-label use is evaluated" and "verify that potential off-label use does not exceed 15%." (RMP Audit Plan at CEP_TPP_BREN00000411.) Upon completion of the audit, Brennan concluded that Cephalon was not in compliance with the commitments of the Actiq RiskMAP. The violations cited included Cephalon's failure to monitor inappropriate patient selection and failure to calculate whether inappropriate patient selection accounted for greater than 15% of all Actiq prescriptions. Cephalon had also listed "Oncology," "Hematology," and "Pain Specialists" as categories exempt from the 15% requirement. (Kurowski Decl. Ex. 159,

Quality Assurance Memo at CEP_TPP_BREN 00000252-53.) Included in the exempt "Pain Specialists" category were pain medicine, anesthesiology, anesthesiology pain medicine, physical medicine and rehabilitation, and palliative medicine. (Kurowski Decl. Ex. 162, SOP-0426-J02 at 3.) The audit did not uncover any evidence of intervention activities, which would be required under the RiskMAP in the event that potential off-label usage of Actiq exceeded 15% of total quarterly prescriptions. (Quality Assurance Memo at CEP_TPP_BREN00000259.)

Cephalon responded to Brennan's audit by internal memorandum, explaining that standard operating procedure was to report inappropriate prescription levels only if prescriptions from any single inappropriate specialty exceeded 15% of total prescriptions. (Kurowski Decl. Ex. 161, Internal Mem., Mar. 22, 2004, at CEP_TPP_EDPA10170966; *id.* Ex. 162, SOP-0426-J02 at 3; *see also* Brennan Dep. 133:8-23.) Cephalon had identified 192 different specialty groups with no single specialty accounting for more than 20% of total Actiq prescriptions. (Kurowski Decl. Ex. 164, E-mail from Michael Richardson to Carol Marchione, et al. (May 13, 2004, 19:03 EST).) Thus, according to its measures, Cephalon did not need to implement any intervention because no inappropriate specialty accounted for more than 15% of Actiq's total quarterly prescriptions. (Internal Mem., Mar. 22, 2004 at CEP_TPP_EDPA10170966.)

E. Third Party Payors Paid for Actiq Prescriptions

Meanwhile, during the proposed class period, doctors and other health care providers wrote prescriptions for patients whom they felt would benefit from Actiq, including Plaintiffs' beneficiaries.[11] The conditions for which they prescribed Actiq were often outside the approved

[11] Defendant avers that each health care provider who prescribed Actiq off-label did so based on his or her independent medical judgment. As support, Defendant offers deposition testimony from nine doctors and one nurse practitioner, all of whom prescribed Actiq for one of Plaintiffs' beneficiaries, to show that each considered a variety of factors in making their prescribing decisions. Menkowitz Decl. Ex. 8, Magill Dep 22:3-24:23, Jan. 26, 2013; *id.* Ex. 9, Hartman Dep. 21:17-19, 68:3-9, 230:20-24, Jan. 25, 2013; *id.* Ex. 10, Mueller Dep. 26:13-27:23, Jan. 17,

indication of breakthrough cancer pain.[12] For many patients, Actiq proved effective for alleviating their pain.[13]

Prescribing physicians had varied exposure to Cephalon's marketing of Actiq: many were visited and detailed by Cephalon sales representatives;[14] some attended consultant meetings or medical education programs organized by Cephalon;[15] and some engaged with Cephalon as formal speakers or consultants to promote Actiq.[16] Meanwhile, Cephalon had individually

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2013; *id.* Ex. 11, Stoner Dep. 23:4-9, Mar. 6, 2013; *id.* Ex. 12, Cozza Dep. 25:15-26:20, Mar. 5, 2013; *id.* Ex. 13, Swonder Dep. 56:17-21, Jan. 29, 2013; *id.* Ex. 14, Washington Dep. 25:3-26:25, Jan. 28, 2013; *id.* Ex. 15, Tuley Dep. 25:24-28:18, Jan. 23, 2013; *id.* Ex. 16, Eoff Dep. 216:13-17, Feb. 25, 2013; *id.* Ex. 17, Green-Mack Dep. 39:3-5, 112:19-114:2, Mar. 4, 2013. All also testified that Cephalon's activities had no influence whatsoever on whether or not to prescribe Actiq. Magill Dep. 61:17-20, 153:6-10; Hartman Dep. 40:12-19, 216:18-218:16; Mueller Dep. 41:17-19, 44:7-11, 163:23-165:18; Stoner Dep. 74:2-12, 202:20-23; Cozza Dep. 48:22-49:6; Swonder Dep. 27:5-10, 39:8-11; Washington Dep. 27:1-28:23; Tuley Dep. 39:20-41:15, 59:7-23; Eoff Dep. 207:18-208:15; Green-Mack Dep. 108:25-109:7.

[12] *See* Magill Dep. 29:6-8, 32:8-20 (migraine headaches); Hartman Dep. 30:8-12 (sinus, neck, back, and knee problems), 31:11-13 (headaches); Mueller Dep. 40:23-41:3 (chronic headaches); Stoner Dep. 57:21-59:9 (knee surgery pain); Cozza Dep. 46:21-47:16 (severe foot pain); Swonder Dep. 17:19-22 (liver and bone marrow biopsies), 21:8-10 (non-opioid tolerant patients); Washington Dep. 41:11-14 (cutaneous lesions); Tuley Dep. 38:20-39:11 (back pain); Eoff Dep. 38:1-8 (headaches), 68:14-16 (back and knee pain). One doctor, however, testified that he would never use Actiq for non-cancer related headaches or migraines. Washington Dep. 118:21-24.

[13] *See* Magill Dep. 54:24-55:4; Stoner Dep. 62:3-21; Cozza Dep. 50:20-51:9; Swonder Dep. 27:20-25; Washington Dep. 69:2-6; Tuley Dep. 47:16-48:1, 60:10-12; Eoff Dep. 43:3-7, 49:1-6, 59:19-20; Green-Mack Dep. 38:22-39:2, 81:19-22.

[14] *See* Magill Dep. 17:22-18:23 (met with Cephalon representative and physician speaker); Hartman Dep. 50:12-15 (Cephalon representatives were in contact "throughout [physician's] career"); Mueller Dep. 146:21-147:22 (noting 34 visits from a Cephalon representative, 17 for which the representative brought lunch or dinner); Cozza Dep. 75:3-10 ("I do know that representatives came and talked about Actiq."); Swonder Dep. 36:12-37:5 (failing to recall any detail visits from a Cephalon representative); Tuley Dep. 141:6-9 (stating that the content of interactions with Cephalon sales representatives varied depending on who the representative was and when the detail occurred); Eoff Dep. 83:22-85:12, Green-Mack Dep. 106:2-17 (describing visits to Dr. Green-Mack's office from three different Cephalon representatives).

[15] *Compare* Mueller Dep. 176:7-18 (attending a Cephalon-sponsored meeting for Actiq), *and* Stoner Dep. 142:18-143:12 (attending a consultant meeting with Cephalon in San Francisco), *and* Eoff Dep. 94:7-95:11 (attending three or four Cephalon-sponsored conferences, one of which involved Actiq), *with* Swonder Dep. 27:11-16 (never attending a Cephalon-sponsored or continuing medical education program concerning Actiq), *and* Washington Dep. 28:14-20 (same), *and* Tuley Dep. 58:16-20 (same).

[16] *See* Hartman Dep. 89:12-15, 90:8-11; Mueller Dep. 44:12-17, 83:16-20; Stoner Dep. 107:1-11, 149:3-7; Green-Mack Dep. 150:22-25; *see also* Kurowski Decl. Ex. 178, Actiq National Speaker Training (listing Mary Jo Eoff as a participant at an Actiq speaker training session).

contacted some prescribers by letter, purportedly in response to their off-label prescribing of Actiq, to remind them of Actiq's indication and to direct them to educational support materials.[17]

Once prescriptions were written, TPPs were often responsible for paying all or part of the costs of Actiq for their beneficiaries. Plaintiff Indiana Carpenters Welfare Fund ("ICWF"), a TPP, is a welfare fund that provides health insurance benefits to its union members. (Am. Compl. ¶ 11.) During the proposed class period, ICWF paid for fifty-one Actiq prescriptions for seven beneficiaries, for a total of $170,342.27. (Kurowski Decl. Ex. 169, Newman Dep. 50:24-51:13, Mar. 26, 2010; *id.* Ex. 170, ICWF Payments.) ICWF worked with third party administrators including pharmacy benefit managers ("PBMs"), which handled the administration of prescription drug claims for ICWF members. (*See* Newman Dep. 62:19-64:23 (describing ICWF's relationship with Zenith, a third party administrator, and various PBMs).) With its first PBM, Rx America, ICWF had a formulary[18] allowing nearly all drugs, including Actiq, to be paid for under its insurance program. (Newman Dep. 156:18-157:8, 157:19-158:4.) ICWF did not require stricter measures such as prior authorization[19] or step therapy[20] in order for

[17] Hartman Dep. 50:16-53:10; Stoner Dep. 84:16-87:18; Green-Mack Dep. 110:3-111:24, Mar. 4, 2013; *see* Menkowitz Decl. Ex. 121, Actiq Off-Label Prescribers; *id.* Ex. 28, Actiq RMP Letter.

[18] PBMs and managed care organizations use formularies, which are lists of specific drugs for coverage, in administering a prescription drug benefits plan. (Menkowitz Decl. Ex. 23, Bradford Report ¶ 34.) Pharmacy and Therapeutics ("P&T") Committees, comprised of independent physicians, pharmacists, and health care professionals, develop formularies. (*Id.* ¶ 38.) Formularies can be open (all drugs are covered to some degree), incented (some drugs have financial incentives for prescription), or closed (prior authorization is required for non-listed drugs). (*Id.* ¶ 34.) Formularies may also be tiered such that co-payment amounts vary across tiers. (*Id.* ¶ 36.)

[19] Prior authorization is the pre-approval of a drug by a benefits administrator before a pharmacy can dispense it to a beneficiary. The authorization process typically asks the prescribing physician about a patient's diagnostic tests, symptoms, and other clinical measures to establish the propriety of the drug. Prior authorization is intended to lower costs and ensure appropriate drug utilization. (Menkowitz Decl. Ex. 39, Iz, Peri, Study of Pharmaceutical Benefit Management 81-82 (2001).)

[20] Step therapy is a restrictive measure employed by benefits administrators. It requires a patient to have tried one or more alternative medications without success before obtaining approval for a particular drug. (Bradford Report ¶ 37.)

Actiq to be covered. (Newman Dep. 165:13-23, 166:8-16, 171:2-19.) With its second PBM, Medco, ICWF also declined to take advantage of services designed to contain costs on expensive drugs. (Newman Dep. 198:23-201:24, 204:4-205:11.) It received quarterly reports from Medco, which included information on member drug usage and cost management. (Newman Dep. 202:19-203:10.) In 2007, when ICWF became aware that Actiq was being used by non-cancer patient members, it began requiring prior authorization for Actiq prescriptions. No Actiq prescriptions have been approved since. (Newman Dep. 217:1-16, 218:21-219:19, 222:13-223:17.)

Plaintiff Pennsylvania Turnpike Commission ("PTC"), a self-insured employer that provides group medical benefits, also paid for Actiq prescriptions as a TPP. (Am. Compl. ¶ 12.) During the proposed class period, PTC paid $153,823.10 for 179 Actiq prescriptions. (Kurowski Decl. Ex. 172, Pa. Turnpike Claims.) Like ICWF, PTC worked with multiple PBMs during the proposed class period to administer prescription drug claims. (Menkowitz Decl. Ex. 5, Schlegel Dep. 91:8-92:4, 226:6-10, Jan. 12, 2010.) As a product of union negotiations, PTC had its PBMs use an open formulary, which meant that all prescription drug costs were reimbursed under PTC's insurance coverage. (Schlegel Dep. 41:20-42:9, 109:17-23.) Though PTC eliminated certain drug classes from coverage, it never considered striking specific drugs. (Schlegel Dep. 116:3-17, 119:9-16.) It did, however, impose a step therapy restriction on Actiq in 2003. (Schlegel Dep. 97:23-98:19, 177:18-178:10.) And in 2008, on recommendation by its PBM, Aetna, PTC began requiring prior authorization for reimbursement on Actiq prescriptions. (Schlegel Dep. 230:20-231:21.)

F. Cephalon Pleaded Guilty to Off-Label Promotion of Actiq

At least as early as September 2004, the Office of the United States Attorney for the Eastern District of Pennsylvania was conducting an investigation into Cephalon's distribution of multiple prescriptions drugs including Actiq. (Joint Notice of Record Supplements, Ex. C, Cephalon Form 10-K, filed Mar. 13, 2006, at 111.) As a result, in September 2008, Cephalon agreed to plead guilty to the charge that it introduced "into interstate commerce . . . drugs that were misbranded through off-label promotion, . . . arising from Cephalon's off-label promotion of its drugs Provigil, Gabitril, and Actiq between January 2001 and October 1, 2001." (Kurowski Decl. Ex. 1, Guilty Plea Agreement ¶1.) In the plea agreement, Cephalon stipulated to the following:

> Between January 2001 and October 1, 2001, Cephalon promoted Actiq for uses not approved by the FDA, including non-cancer pain uses, such as injuries and migraines. Cephalon's promotion of Actiq for these additional intended uses violated 21 U.S.C. §352(f)(1), because Actiq's labeling did not bear adequate directions for each of the drug's intended uses . . . Between 2001 [sic] through October 1, 2001, Cephalon profited by misbranding Provigil, Gabitril and Actiq, and distributing these drugs in interstate commerce.

(*Id.* ¶ 6(A)(8)-(9).) While the government contended "that, as a matter of relevant conduct, the conduct which forms the basis for this plea agreement . . . continued past October 1, 2001," for purposes of the plea agreement, Cephalon did not admit that its conduct extended past this date. (*Id.* ¶ 6(B).)

IV. PROCEDURAL BACKGROUND

On October 25, 2007, Employers Mutual Casualty Company, EMCASCO Insurance Company, and Union Insurance Company (collectively, "EMC Insurance Companies") filed a Class Action Complaint against Defendant Cephalon, Inc. ("Cephalon") containing two counts: (1) violations of state consumer protection laws and (2) unjust enrichment. On April 24, 2008,

the Court consolidated this action with two others filed against Cephalon by the Indiana Carpenters Welfare Fund ("ICWF") and the Pennsylvania Turnpike Commission ("PTC"). *See Indiana Carpenters Welfare Fund v. Cephalon, Inc.*, Civ. No. 07-4775 (E.D. Pa.); *Pa. Turnpike Comm'n v. Cephalon, Inc.*, Civ. No. 07-5284 (E.D. Pa.). On May 19, 2008, Plaintiffs EMC Insurance Companies, ICWF, and PTC filed a First Amended Class Action Complaint, alleging two additional counts for violations of the Racketeer Influenced Corrupt Organizations Act, 18 U.S.C. § 1962 ("RICO"). Cephalon filed its Answer on June 30, 2008.

On May 22, 2009, the Court granted Cephalon's motion for judgment on the pleadings as to the RICO counts and accordingly dismissed them. The parties stipulated to the dismissal of the EMC Insurance Companies on June 22, 2010.[21] Cephalon filed motions for summary judgment against ICWF and PTC, both of which the Court denied on March 23, 2011. *See In re Actiq Sales and Marketing Practices Litigation*, 790 F. Supp. 2d 313, 331 (E.D. Pa. 2011). After a lengthy period of discovery, Plaintiffs ICWF and PTC moved for class certification solely on the unjust enrichment claim on October 26, 2012. Plaintiffs seek $698.9 million in damages, which they argue are Cephalon's profits conferred by TPPs as a result of off-label marketing of Actiq. On March 20, 2013, Cephalon filed a motion to exclude Dr. Meredith Rosenthal's declaration and testimony regarding calculated class-wide damages, which the Court denied on July 21, 2014. On July 24, 2013, this Court held a hearing on Plaintiffs' Motion for Class Certification.

[21] Other parties also appeared as Plaintiffs at various stages of this case: Iron Workers District Council Benefit Fund of Philadelphia and Vicinity ("Iron Workers"), American Federation of State, County and Municipal Employees, District Council 47 Health and Welfare Fund ("AFSCME"), and Philadelphia Firefighters Union Local No. 22 Health and Welfare Fund ("Firefighters"). On June 28, 2010, Iron Workers stipulated to dismissal of their claims in this matter. AFSCME and Firefighters remain Plaintiffs in this case, but they do not join ICWF and PTC in moving for class certification.

V. LEGAL STANDARD FOR CLASS CERTIFICATION

"The class action is 'an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only.'" *Comcast Corp. v. Behrend*, 133 S. Ct. 1426, 1432 (2013) (quoting *Califano v. Yamasaki*, 422 U.S. 682, 700-01 (1979)). Rule 23 of the Federal Rules of Civil Procedure governs class certification in federal courts. "Class certification is proper only 'if the trial court is satisfied, after a rigorous analysis, that the prerequisites' of Rule 23 are met." *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 309 (3d Cir. 2008) (quoting *Gen. Tel. Co. of Sw. v. Falcon*, 457 U.S. 147, 161 (1982)). Rule 23 contains two sets of requirements for class certification, both of which plaintiffs must meet to prevail on their motion. *Baby Neal for and by Kanter v. Casey*, 43 F.3d 48, 55 (3d Cir. 1994). Under Rule 23(a), the party seeking class certification must show that four prerequisites have been met: (1) the class is so numerous that joinder of all members is impracticable ("numerosity"); (2) there are questions of law or fact common to the class ("commonality"); (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class ("typicality"); and (4) the representative parties will fairly and adequately protect the interests of the class ("adequacy"). Fed. R. Civ. P. 23(a). "Rule 23(a) ensures that the named plaintiffs are appropriate representatives of the class whose claims they wish to litigate." *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 2541, 2550 (2011).

The plaintiffs must also show that the proposed class action fits into one of the three categories of class actions listed in Rule 23(b). Here, Plaintiffs seek damages under Rule 23(b)(3), which provides that an action may be maintained only if "the court finds that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly

and efficiently adjudicating the controversy." The requirements of Rule 23(b)(3) are known as predominance and superiority. *In re Hydrogen Peroxide*, 552 F.3d at 310. Together, the criteria of Rule 23(a) and (b) ensure "that a proposed class has sufficient unity so that absent class members can fairly be bound by decisions of class representatives." *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 621 (1997).

A decision to certify a class requires "findings by the court, not merely a 'threshold showing' by a party, that each requirement of Rule 23 is met." *In re Hydrogen Peroxide*, 552 F.3d at 306; *see Wal-Mart Stores, Inc.*, 131 S. Ct. at 2551. In conducting its analysis, a court is to resolve factual disputes by a preponderance of the evidence and to consider all relevant evidence and arguments by the parties. *In re Hydrogen Peroxide*, 552 F.3d at 306, 320. "Frequently [the court's] 'rigorous analysis' will entail some overlap with the merits of the plaintiff's underlying claim." *Wal-Mart Stores, Inc.*, 131 S. Ct. at 2551. "Merits questions may be considered to the extent—but only to the extent—that they are relevant to determining whether the Rule 23 prerequisites for class certification are satisfied." *Amgen Inc. v. Conn. Ret. Plans and Trust Funds*, 133 S. Ct. 1184, 1195 (2013). Plaintiffs' burden is not to prove the elements of their claim, but to show that those elements are capable of proof through evidence that is common to the class. *See In re Hydrogen Peroxide*, 552 F.3d at 311-12.

VI. DISCUSSION

Plaintiffs move for class certification on a claim of unjust enrichment against Cephalon. This Court will engage in a class certification inquiry after deciding the threshold issue of a conflict of laws.

A. Conflict of Laws

Because choice of law is relevant to a determination under Rule 23, the Court must determine what law applies to Plaintiffs' claim of unjust enrichment.[22] *Powers v. Lycoming Engines*, 328 F. App'x 121, 124 (3d Cir. 2009). Irreconcilable conflicts among state laws may defeat class certification. *Id.* Federal courts sitting in diversity are to use conflict of laws rules of the forum state to determine which substantive law applies. *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496-97 (1941); *Kaneff v. Del. Title Loans, Inc.*, 587 F.3d 616, 621 (3d Cir. 2009). This Court therefore uses Pennsylvania rules on conflict of laws.

In Pennsylvania, a conflict of laws analysis is two-step. The first is to determine if there is an actual conflict among the potentially applicable laws. *Hammersmith v. TIG Ins. Co.*, 480 F.3d 220, 230 (3d Cir. 2007). In other words, the court "must determine whether these states would actually treat this issue any differently." *Air Prods. and Chemicals, Inc. v. Eaton Metal Prods. Co.*, 272 F. Supp. 2d 482, 490 n.9 (3d Cir. 2003). If there is no difference, then Pennsylvania law applies. *Id.* If there is a difference, then the court is to consider the governmental policies underlying each law to determine whether a conflict is "true", "false", or "unprovided-for." *Hammersmith*, 480 F.3d at 230. Only if a true conflict exists should the court proceed to the second step of its analysis by examining which state has a greater interest in the application of its law. *Id.* at 231. Simply counting the contacts is not enough, so the court "must

[22] Plaintiffs argue that the law-of-the-case doctrine applies in that the Court previously ruled, in denying summary judgment, that no actual conflict existed amongst the unjust enrichment laws of the fifty states. *See In re Actiq Sales and Mktg. Practices Litig.*, 790 F. Supp. 2d 313, 322, 329 (E.D. Pa. 2011). "Under the law-of-the-case doctrine, 'once an issue has been decided, parties may not relitigate that issue in the same case.'" *Ogbudimkpa v. Ashcroft*, 342 F.3d 207, 210 n.7 (3d Cir. 2003) (quoting *Waldorf v. Shuta*, 142 F.3d 601, 616 n.4 (3d Cir. 1998)), *superseded by statute on other grounds*, REAL ID Act of 2005, Pub. L. No. 109-13, 119 Stat. 231. Without disturbing its prior decision, the Court nevertheless acknowledges that the issue at the summary judgment stage was whether a conflict existed between Pennsylvania and Indiana unjust enrichment laws. Cephalon therefore had no occasion to dispute whether a conflict of laws existed among all fifty states, which is the question presented here. The Court will therefore engage in a choice of law analysis anew, now that the parties have had an opportunity to brief the issue fully. *See id.* ("[C]ourts may refuse to infer decisions on issues that were barely presented . . . .").

weigh the contacts on a qualitative scale according to their relation to the policies and interests underlying the [particular] issue." *Id.* (quoting *Shields v. Consol. Rail Corp.*, 810 F.2d 397, 400 (3d Cir. 1987)).

The Court begins with a determination of whether an actual conflict exists among the unjust enrichment laws of the fifty states. It is presumed that putative class members will reside in every state, so the law of each is potentially applicable. In Pennsylvania, "[u]njust enrichment is the retention of a benefit conferred by another, without offering compensation, in circumstances where compensation is reasonably expected, and for which the beneficiary must make restitution." *Roethlein v. Portnoff Law Assocs., Ltd.*, 81 A.3d 816, 825 n.8 (Pa. 2013). Plaintiffs argue that no material difference distinguishes the states' common law on unjust enrichment. Indeed, some courts in this circuit have confronted this issue and found that no material conflict exists. *See In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. 46, 58 (D.N.J. 2009) ("While there are minor variations in the elements of unjust enrichment under the laws of the various states, those differences are not material and do not create an actual conflict."); *Agostino v. Quest Diagnostics Inc.*, 256 F.R.D. 437, 464 (D.N.J. 2009) (applying New Jersey's most significant relationship test, concluding that "there are no actual conflicts among the laws of unjust enrichment"); *Powers v. Lycoming Engines*, 245 F.R.D. 226, 231 (E.D. Pa. 2007) ("Although there are numerous permutations of the elements of the cause of action in the various states, there are few real differences."), *vacated*, 328 F. App'x 121 (3d Cir. 2009). Other courts, however, have reached a contrary conclusion. *See Mazza v. Am. Honda Motor Co., Inc.*, 666 F.3d 581, 591 (9th Cir. 2012) ("The elements necessary to establish a claim for unjust enrichment also vary materially from state to state."); *Yarger v. ING Bank, fsb*, 285 F.R.D. 308, 325 (D. Del. 2012) ("After reviewing the unjust enrichment laws of the sixteen states for which

Plaintiffs seek class certification, the Court concludes that these states' laws have material variations."); *Montich v. Miele USA, Inc.*, 849 F. Supp. 2d 439, 458-59 (D.N.J. 2012) (declining to rely on *In re Mercedes-Benz* and *Agostino* in conducting a choice of law analysis for unjust enrichment). "[U]njust enrichment is a tricky type of claim that can have varying interpretations even by courts within the same state, let alone amongst the fifty states." *In re Sears, Roebuck & Co. Tools Mktg. and Sales Practices Litig.*, Nos. 05 C 4742, 05 C 2623, 2006 WL 3754823, at *1 n.3 (N.D. Ill. Dec. 18, 2006).

Here, Cephalon has presented several bases upon which states' laws purportedly conflict. For example, states apply various statutes of limitations to unjust enrichment claims. *See, e.g.*, *Vichi v. Koninklijke Philips Elecs. N.V.*, Civ. Action No. 2578-VCP, 2009 WL 4345724, at *15 (Del. Ch. Dec. 1, 2009) (citing 10 Del. Code Ann. § 8106(a), applying a three year statute of limitations to an unjust enrichment claim); *Jacobson v. Bd. of Tr. of the Teachers Ret. Ass'n*, 627 N.W.2d 106, 110 (Minn. Ct. App. 2001) ("Appellants' claims alleging breach of contract, promissory estoppel, unjust enrichment, and impairment of contract all rest on the same facts, and all are governed by a six-year statute of limitations." (citing Minn. Stat. § 541.05, subd. 1(1) (2000)); *Elliott v. Qwest Commc'ns Corp.*, 25 A.D. 3d 897, 898 (N.Y. App. Div. 2006) (barring an unjust enrichment claim under New York's six-year statute of limitations); *Sevast v. Kakouras*, 915 A.2d 1147, 1153 (Pa. 2007) ("The cause of action which Appellee brought before the court is based upon a theory of unjust enrichment. According to statute, there is a four-year statute of limitations for such causes of action." (citing 42 Pa. Cons. Stat. § 5525(a)(4)) (footnote omitted)); *see also Sterenbuch v. Goss*, 266 P.3d 428, 436-37 (Colo. App. 2011) (recognizing that although unjust enrichment, an equitable claim, is technically subject to a defense of laches,

absent extraordinary circumstances, the court will apply the statute of limitations governing legal actions of similar character).

States also vary in how the applicable statute of limitations starts to accrue. *See, e.g.*, *Stratton v. Am. Med. Sec., Inc.*, No. CV-07-1491-PHX-SMM, 2008 WL 2039313, at *3 (D. Ariz. May 12, 2008) (stating that the statute of limitations for claims of unjust enrichment is four years and, under Arizona's discovery rule, a "plaintiff's cause of action does not accrue until the plaintiff knows or, in the exercise of reasonable diligence, should know the facts underlying the cause" (citing *Gust, Rosenfeld & Henderson v. Prudential Ins. Co. of Am.*, 898 P.2d 964, 966 (Ariz. 1995)); *GIV, LLC v. Int'l Bus. Machines Corp.*, Civ. Action No. 3:07CV067-HEH, 2007 WL 1231443, at *2 (E.D. Va. Apr. 24, 2007) ("An unjust enrichment action accrues when the unjust enrichment actually occurs, i.e., when the expected compensation is not paid, not when a party knew or should have known of the unjust enrichment."); *Sterenbuch*, 266 P.3d at 437 ("A claim of unjust enrichment accrues when a person discovers, or through the exercise of reasonable diligence should discover, that all elements of the claim are present."); *Winner Acceptance Corp. v. Return on Capital Corp.*, Civ. Action No. 3088-VCP, 2008 WL 5352063, at *14 (Del. Ch. Dec. 23, 2008) (unpublished opinion) (stating that "a cause of action [for unjust enrichment] accrues at the time of the wrongful act, even if the plaintiff is ignorant of the cause of action"); *Elliott*, 25 A.D.3d at 898 ("A cause of action for unjust enrichment accrues 'upon the occurrence of the wrongful act giving rise to a duty of restitution . . . .'").

These differences mean that Plaintiffs' claim for unjust enrichment can withstand a statute of limitations defense in some jurisdictions but not in others depending on the applicable law. A statute of limitations evidences a state's policy interest in preventing litigation of delayed claims and preventing injustice by affording a defendant a fair opportunity to defend. Those

states with shorter statutes of limitations have a greater interest in "promoting repose by giving security and stability to human affairs." *Hadidi v. Intracoastal Land Sales, Inc.*, Civ. Action No. 4:12-cv-535-RBH, 2014 WL 2881875, at *8, *10 (D.S.C. June 25, 2014) (internal quotation marks omitted) (discussing the policy interests of New Jersey and South Carolina regarding their statutes of limitations for tort-based claims of unjust enrichment). Here, Cephalon's guilty plea establishes that Cephalon engaged in off-label promotion of Actiq as early as 2001. The filing of this suit in October 2007 may or may not have been within a state's statute of limitations and it cannot be said that application of different statutes of limitations would yield the same result. Additional variances in states' unjust enrichment jurisprudence exists, including the availability of unjust enrichment as an independent cause of action,[23] the need to show an absence of an adequate remedy at law,[24] the requirement that a benefit be obtained at the direct expense of the

[23] *See, e.g.*, *Baxter v. PNC Bank Nat'l Ass'n*, 541 F. App'x 395, 397 n.2 (5th Cir. 2013) ("Texas courts have not recognized a claim for unjust enrichment as an independent cause of action"); *Blystra v. Fiber Tech Group, Inc.*, 407 F. Supp. 2d 636, 644 n.11 (D.N.J. 2005) (applying New Jersey law, concluding that "the Court will treat the Plaintiffs' unjust enrichment claim as subsumed by their other tort claims, not as an independent cause of action"); *Gen. Insulation Co. v. Eckman Constr.*, 992 A.2d 613, 621 (N.H. 2010) (dismissing a restitution suit based on unjust enrichment for failure to state a claim, but also noting that "unjust enrichment generally does not form an independent basis for a cause of action" (quoting 42 C.J.S. Implied Contracts § 10 (2007)); *Dellagrotta v. Dellagrotta*, 873 A.2d 101, 113 (R.I. 2005) ("Under Rhode Island law, unjust enrichment is not simply a remedy in contract and tort but can stand alone as a cause of action in its own right.").

[24] States differ on whether a claim for unjust enrichment, based in equity, can survive when there is an adequate remedy at law available. Some states, including Pennsylvania, bar an equitable remedy for unjust enrichment when a party has an adequate remedy at law. *See, e.g., Trustmark Ins. Co. v. Bank One, Ariz., NA*, 48 P.3d 485, 491 (Ariz. Ct. App. 2002); *Sean O'Kane A.I.A. Architect, P.C. v. Puljic*, 87 A.3d 1124, 1132 (Conn. App. Ct. 2014); *Porter v. Hu*, 169 P.3d 994, 1007-08 (Haw. Ct. App. 2007); *Santagate v. Tower*, 833 N.E.2d 171, 176 (Mass. App. Ct. 2005); *ServiceMaster of St. Cloud v. GAB Bus. Servs., Inc.*, 544 N.W.2d 302, 305 (Minn. 1996); *Harvell v. Goodyear Tire and Rubber Co.*, 164 P.3d 1028, 1035 (Okla. 2006); *Dunn v. Bd. of Prop. Assessment, Appeals and Review of Allegheny Cnty.*, 877 A.2d 504, 514 n.18 (Pa. Commw. Ct. 2005); *Seattle Prof'l Engineering Emps. Ass'n v. Boeing Co.*, 991 P.2d 1126, 1134 (Wash. 2000).

Other jurisdictions, however, have conflicting case law as to whether an unjust enrichment claim may stand. *Compare RC Aluminum Indus., Inc. v. Regions Bank*, 127 So.3d 881, 882 (Fla. Dist. Ct. App. 2013) (remanding a case that was dismissed by the trial court, in part because an adequate remedy at law does not bar a claim for unjust enrichment), *with Rushing v. Wells Fargo Bank, N.A.*, 752 F. Supp. 2d 1254, 1265 (M.D. Fla. 2010) (dismissing claim for unjust enrichment because an express contract covered the same subject matter); *compare In re Sears, Roebuck & Co. Tools*, 2006 WL 3754823, at *3 ("It is well settled that a party cannot seek equitable relief when he has an adequate legal remedy. Unjust enrichment, however, is a legal claim." (internal citations omitted)), *with Prignano v. Prignano*, 934 N.E.2d 89, 108 (Ill. App. Ct. 2010) (denying remedy under an unjust enrichment

plaintiff,[25] the level of misconduct a plaintiff must prove,[26] and the availability of defenses such as unclean hands and laches.[27] In light of these differences, some of which could result in differential treatment of Plaintiffs' claim among the fifty states, this Court concludes that a true conflict exists. *See Budget Rent-A-Car Sys., Inc. v. Chappell*, 407 F.3d 166, 170 (3d Cir. 2005)

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theory when a contract specifically governed the dispute and allowed for legal remedies). *See also Starko, Inc. v. Presbyterian Health Plan, Inc.*, 276 P.3d 252, 278 (N.M. Ct. App. 2011) ("[U]njust enrichment constitutes an independent basis for recovery in a civil-law action, analytically and historically distinct from the other two principal grounds for such liability, contract and tort." (quoting *Hydro Conduit Corp. v. Kemble*, 793 P.2d 855, 860 (N.M. 1990)), *rev'd on other grounds*, 333 P.3d 947 (N.M. 2014); *but see Abraham v. WPX Energy Prod., LLC*, 20 F. Supp. 3d 1244, 1276 (D.N.M. 2014) (concluding that a plaintiff may pursue an unjust enrichment claim even if it is the subject of a contract between the plaintiff and a third party, but only if something, such as bankruptcy or a statute, prohibits the plaintiff from pursuing the contract claim).

[25] Some states require that a benefit be directly conferred by the plaintiff to the defendant for an unjust enrichment claim to stand. *See, e.g., Arlandson v. Hartz Mountain Corp.*, 792 F. Supp. 2d 691, 711 (D.N.J. 2011) ("Since a plaintiff must confer a benefit on the defendant to support an unjust enrichment claim, this element has been interpreted by New Jersey courts as a requirement that the plaintiff allege a sufficiently direct relationship with the defendant to support the claim." (internal quotation marks omitted)); *BTA Oil Producers v. MDU Resources Grp., Inc.*, 642 N.W.2d 873, 882 (N.D. 2002) ("Unjust enrichment requires a showing of an enrichment, an impoverishment, and a connection between the two.").

Other states, however, do not have such a requirement. *See, e.g., Thompson v. Bayer Corp.*, No. 4:07CV00017, 2009 WL 362982, at *5 (E.D. Ark. Feb. 12, 2009) ("In Arkansas, although the enrichment to the defendant must be at the expense of the plaintiff, the enrichment need not come *directly* from the plaintiff. The enrichment may come from a third party."); *Muehlbauer v. Gen. Motors Corp.*, 431 F. Supp. 2d 847, 853 (N.D. Ill. 2006) ("[W]e see that an unjust enrichment claim may be premised on an indirect conferral of benefits."); *Freeman Indus., LLC v. Eastman Chem. Co.*, 172 S.W.3d 512, 525 (Tenn. 2005) ("In accordance with this underlying principle, we conclude that to recover for unjust enrichment, a plaintiff need not establish that the defendant received a direct benefit from the plaintiff.").

[26] *Compare Thompson*, 2009 WL 362982, at *4 ("Courts in Arkansas do not require a tortious, illegal or fraudulent act by the defendant to prove unjust enrichment."), *and Nelson v. Levy Home Entertainment, LLC*, No. 10 C 3954, 2012 WL 403974, at *12 (N.D. Ill. Feb. 8, 2012) ("A cause of action based upon unjust enrichment does not require fault or illegality on the part of the defendants . . . ." (quoting *Eighteen Invs. v. Nationscredit Fin. Servs. Corp.*, 876 N.E. 2d 1096, 1103 (Ill. App. Ct. 2007)), *with Mantiply v. Mantiply*, 951 So.2d 638, 654-55 (Ala. 2006) (requiring proof of mistake or misreliance by the conferring party or proof of wrongful conduct by the receiving party in order to prevail on unjust enrichment), *and Rhue v. Rhue*, 658 S.E.2d 52, 59 (N.C. Ct. App. 2008) ("Evidence of fraud is one way to establish an unjust enrichment claim but it may not be necessary. Evidence of fraud is unnecessary if the plaintiff establishes a 'breach of duty' or 'some other circumstance making it inequitable' for the defendant to retain his property interest.").

[27] Insofar as unjust enrichment is regarded as an equitable claim, states may entertain equitable defenses such as unclean hands and laches. *See, e.g., Sean O'Kane A.I.A. Architect, P.C.*, 87 A.3d at 1132 (articulating the standard for a defense of laches when a remedy for unjust enrichment is sought); *Sundance Homes, Inc. v. Cnty. of DuPage*, 746 N.E.2d 254, 263 (Ill. 2001) (noting "laches analysis is no longer mechanically applied to all actions denominated equitable" and allowing only a statute of limitations defense for particular equitable actions based on unjust enrichment); *see also Clay v. Am. Tobacco Co.*, 188 F.R.D. 483, 501 (S.D. Ill. 1999) ("Many states, but not all, permit an equitable defense of unclean hands. Those states that permit a defense of unclean hands vary significantly in the requirements necessary to establish the defense.").

("A true conflict exists 'when the governmental interests of [multiple] jurisdictions would be impaired if their law were not applied.'" (quoting *Lacey v. Cessna Aircraft Co.*, 932 F.2d 170, 187 n.15 (3d Cir. 1991)).

The Court now proceeds to the second step of its conflicts analysis to determine which state has the greatest interest in the application of its law. Courts engaging in a deeper analysis of true conflicts is to undertake "a combination of the approaches of both [the] Restatement II (contacts establishing significant relationships) and 'interests analysis' (qualitative appraisal of the relevant States' policies with respect to the controversy)." *Hammersmith*, 480 F.3d at 231 (internal quotation marks omitted). In weighing contacts, the court is to consider the following factors for unjust enrichment claims: (1) the place where the parties' relationship was centered; (2) the state where defendants received the alleged benefit or enrichment; (3) the location where the act bestowing the enrichment or benefit was done; (4) the parties' domicile, residence, place of business, and place of incorporation; and (5) if applicable, the jurisdiction where a physical thing, substantially related to the enrichment, was situated at the time of the enrichment. *Powers v. Lycoming Engines*, 328 F. App'x at 126 (adopting the contacts analysis of Restatement (Second) of Conflict of Laws § 221 (1971)).

The Court finds that the first factor weighs in favor of applying the law of putative class members' home states because the parties' relationship was centered there. Certainly, much of Cephalon's activities such as conducting market research, designing marketing plans, and making managerial decisions took place in Pennsylvania. The crux of the parties' relationship, however, was in the TPPs' home states because that is where Cephalon directed its sales efforts, where doctors made their prescribing decisions, where TPPs' beneficiaries transacted for Actiq, and where TPPs conferred payments to Cephalon for Actiq prescriptions. The second factor

weighs in favor of applying Pennsylvania law because Cephalon received Actiq payments here. This is balanced by the third factor because, as mentioned, payments for Actiq prescriptions originated in TPPs' home states. The fourth factor weighs slightly in favor of applying Pennsylvania law. Since it is likely that class members will reside in all U.S. jurisdictions, no single state has a greater relationship to the case than any other by virtue of its ties to a TPP. Pennsylvania, however, being the home of PTC, other TPPs, and Cephalon, is connected to both sides of the dispute. Finally, the fifth factor weighs in favor of TPPs' home states because the Actiq lozenges purchased by beneficiaries were located in those states. In sum, three of the five factors weigh in favor of applying the laws of TPPs' various home states, including the first factor, which is often given the greatest weight. *See* Restatement (Second) of Conflict of Laws § 221 cmt. d.

Policy considerations also lead to the same conclusion. Plaintiffs' home states have a regulatory interest in providing redress to its citizens for acts of wrongdoing. As discussed, a state with a shorter statute of limitations for unjust enrichment claims values stability over providing redress for stale claims. To apply Pennsylvania law, with a four-year statute of limitations, would impede on the interests of states with either shorter or longer statutes of limitations. TPPs' home states also have an interest in ensuring that corporations conducting business within their borders are doing so fairly. These interests outweigh Pennsylvania's interest in regulating a resident corporation. *Cf. Rapp v. Green Tree Servicing, LLC*, 302 F.R.D. 505, 518 (D. Minn. 2014) (weighing state interests in enforcing unjust enrichment laws to find that there is no reason why the laws of non-forum states could not "equally or more effectively" hold corporations accountable). Having conducted a full choice of law analysis, the Court concludes that the unjust enrichment laws of TPPs' home states apply to the present matter.

B. Rule 23(b)(3) Requirements

The Court now proceeds with its analysis for class certification under Rule 23. Plaintiffs must satisfy the requirements of both Rule 23(a) and (b) and failure to meet either part will defeat class certification. This Court begins by evaluating the predominance and superiority requirements of Rule 23(b)(3) and notes that doing so is not to adjudicate the case, but to determine the most suitable method for adjudication. *See Amgen Inc.*, 133 S. Ct. at 1191.

1. Predominance

Under Rule 23(b)(3), the court must find "that the questions of law or fact common to class members predominate over any questions affecting only individual members[.]" The focus of a Rule 23(b)(3) predominance inquiry is "whether proposed classes are sufficiently cohesive to warrant adjudication by representation." *Amchem Prods., Inc.*, 521 U.S. at 623. Rule 23(b)(3) does not require every element of a plaintiff's claim to be susceptible to class-wide proof, but it does require that common questions predominate over individual ones. *Amgen Inc.*, 133 S. Ct. at 1196. "[C]lass certification is unsuitable where 'proof of the essential elements of the cause of action requires individual treatment[.]'" *In re Ins. Brokerage Antitrust Litig.*, 579 F.3d 241, 266 (3d Cir. 2009) (quoting *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 172 (3d Cir. 2001)). A district court must make some prediction about how a trial will play out because the nature of the evidence presented as to specific issues will determine whether the issue is common or individual and whether common issues predominate. *See In re Hydrogen Peroxide*, 552 F.3d at 311.

The elements of Plaintiffs' unjust enrichment claim cannot be succinctly identified because, as discussed, the law of each TPP's home state will govern. For example, some states require five elements to prove a claim of unjust enrichment while others require three or four.

Compare Nat'l Credit Union Admin. v. Shel-Tec Ltd., LLC, No. CV-12-02500-PHX-NVW, 2013 WL 4231016, at *2 (D. Ariz. Aug. 15, 2013) ("To plead a claim for unjust enrichment [under Arizona law], [plaintiff] must allege facts showing (1) an enrichment, (2) an impoverishment, (3) a connection between the enrichment and the impoverishment, (4) absence of justification for the enrichment and the impoverishment, and (5) absence of a legal remedy."), *and Troxler v. Breaux*, 105 So. 3d 944, 948 (La. Ct. App. 2012) (same), *with Durst v. Milroy Gen. Contracting, Inc.*, 52 A.3d 357, 360 (Pa. Super. Ct. 2012) ("The elements necessary to prove unjust enrichment are: (1) benefits conferred on defendant by plaintiff; (2) appreciation of such benefits by defendant; and (3) acceptance and retention of such benefits under such circumstances that it would be inequitable for defendant to retain the benefit without payment of value."), *and Schlinger v. McGhee*, 268 P.3d 264, 272 (Wyo. 2012) ("In Wyoming, the elements of unjust enrichment are: 1) valuable services were rendered; 2) to the party to be charged; 3) which services were accepted, used and enjoyed by the charged party; and 4) under circumstances that reasonably notified the party being charged that the other party would expect payment for the services."). For the same reasons why an actual conflict exists among the unjust enrichment laws of the fifty states, individual issues of law predominate with regard to a nationwide class. In addition to proving different elements for all class members to establish unjust enrichment at trial, other individual issues that may predictably arise include the level of misconduct required to be proven and whether Cephalon may avail itself of particular defenses. *See* discussion *infra* and notes 26, 27; *In re Cmty. Bank of N. Va.*, 622 F.3d 275, 293-94 (3d Cir. 2010) (noting how statute of limitations issues may overlap with Rule 23 requirements including predominance); *see also* 1 McLaughlin on Class Actions § 5:60 (11th ed. 2014) ("Where certification of a

multistate unjust enrichment class is sought, variations in state law also have precluded class certification based on unjust enrichment theories." (footnote omitted)).

Variations in the law, however, do not conclusively foreclose class certification if grouping is possible. *See In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions*, 148 F.3d 283, 315 (3d Cir. 1998) (rejecting a defendant's argument that predominance is defeated because the laws of the fifty states are applicable to plaintiffs' claims); *see also* Larry Kramer, *Choice of Law in Complex Litigation*, 71 N.Y.U. L. Rev. 547, 583 (1996) ("[W]ith respect to . . . one or two issues, there will never be fifty different substantive rules, or even fifteen or ten. States tend to copy their laws from each other, and many use identical or virtually identical rules. In practice, the court will seldom have to deal with more than three or four formulations, and the choice will often be between two alternatives."). The Third Circuit has noted that, to fulfill the predominance requirement, "grouping, in general, may be a permissible approach to nationwide class action litigation[.]" *Grandalski v. Quest Diagnostics Inc.*, 767 F.3d 175, 183 (3d Cir. 2014); *see In re Prudential Ins. Co.*, 148 F.3d at 315 ("Courts have expressed a willingness to certify nationwide classes on the ground that relatively minor differences in state law could be overcome at trial by grouping similar state laws together and applying them as a unit."). When taking this approach, however, "plaintiffs face a significant burden to demonstrate that grouping is a workable solution." *Grandalski*, 767 F.3d at 183.

Plaintiffs contend that common issues of law predominate for an Unjust Enrichment (Restatement) Class and an Unjust Enrichment (Appreciation) Class, respectively. They have provided a comprehensive chart demonstrating how the fifty states and Washington, D.C. are grouped based on their treatment of unjust enrichment claims. (*See* Pls.' Mem. in Supp. of Mot. for Class Cert., 27-30.) Plaintiffs have identified which states have adopted one of four

definitions of unjust enrichment: (1) eighteen jurisdictions follow the Restatement (First) of Restitution's definition of unjust enrichment; (2) twenty-seven jurisdictions follow the Restatement (First) of Restitution's definition of unjust enrichment with the additional element that the defendant appreciate, realize, or know of the plaintiff's conferral of a benefit; (3) four jurisdictions require a direct connection between the impoverishment of a plaintiff and the enrichment of a defendant; and (4) two jurisdictions require that a plaintiff prove that a defendant had reasonable notice that the plaintiff would expect payment for the benefit conferred. (*Id.* at 28.) The first two groupings are those which Plaintiffs propose as multi-state classes.

Plaintiffs' notable grouping efforts, however, still do not account for individual fact issues such that common issues predominate. "The polestar of the unjust enrichment inquiry is whether the defendant has been *unjustly* enriched[.]" *Limbach Co., LLC v. City of Phila.*, 905 A.2d 567, 577 (Pa. Cmmw. Ct. 2006). Resolution to this question is, by nature, fact-sensitive. *Id.* Some common proof regarding equitable circumstances is present here. It is clear that Cephalon was enriched by monetary payments from putative class members who, by definition, paid for Actiq.[28] Plaintiffs offer ample evidence that Cephalon's marketing and distribution of Actiq was coordinated across the country and thus common to all class members. The Actiq RiskMAP, which delineates whether Cephalon's conduct was within the FDA's approval, is likewise common to all claims. So is evidence of Cephalon's internal audit revealing inconsistencies with the Actiq RiskMAP and Cephalon's 2008 guilty plea following the U.S. Department of Justice's investigation into Actiq marketing. Using common proof, Plaintiffs can

[28] Whether that conferral must have been direct depends on the applicable state law. *See* discussion *infra* note 25.

easily establish the facts of Cephalon's marketing and sales activities for Actiq and whether it complied with the Actiq RiskMAP.

Not as easy is Plaintiff's class-wide showing of whether Cephalon's enrichment was *unjust*. Under an unjust enrichment theory, all facts and circumstances are considered to determine whether, without a remedy, inequity would result or persist. *See Vega v. T-Mobile USA, Inc.*, 564 F.3d 1256, 1274 (11th Cir. 2009); *Hernandez v. Ashley Furniture Indus., Inc.*, Civ. Action No. 10-5459, 2013 WL 2245894, at *9 (E.D. Pa. May 22, 2013). According to the Actiq RiskMAP, if off-label usage exceeded 15% of total quarterly Actiq prescriptions, Cephalon must take interventional measures including sending explanatory letters and, if the off-label prescribing persists, instituting an educational program for physicians. (*See* 2001 RiskMAP at 26-27.) Plaintiffs assert that Cephalon violated the Actiq RiskMAP by failing to prevent off-label prescriptions.

Plaintiffs have not shown, however, how proving Cephalon's non-compliance with the RiskMAP by common evidence also proves that all payments for off-label prescriptions beyond 15% of total quarterly Actiq prescriptions are unjust.[29] Even if Cephalon did administer an educational campaign in accordance with the Actiq RiskMAP, off-label Actiq prescriptions may

[29] On a previous *Daubert* motion, this Court examined Plaintiffs' assumption that payment for all off-label Actiq prescriptions in excess of 15% of total quarterly prescriptions are the inequitable result of Cephalon's allegedly unlawful marketing. *In re Actiq Sales and Marketing Practices Litig.*, Civ. Action No. 07-4492, 2014 WL 3572932, at *13-16 (E.D. Pa. July 21, 2014). This assumption formed part of the basis upon which Dr. Meredith Rosenthal, Plaintiffs' expert, calculated class damages. *Id.* at *13; Menkowitz Decl. Ex. 19, Rosenthal Decl. ¶ 14. Cephalon challenged this assumption with expert opinions from Dr. Scott Gottlieb and Pradeep Chintagunta, who opined that off-label prescriptions are the product of individual physician decisions unrelated to the Actiq RiskMAP and that many factors in addition to pharmaceutical marketing influence these decisions. *In re Actiq*, 2014 WL 3572932, at *14-15; Menkowitz Decl. Ex. 26, Gottlieb Report ¶¶ 31-36; *id.* Ex. 24, Chintagunta Report ¶ 51. The Court found that Dr. Rosenthal's assumption was sufficiently grounded under a *Daubert* analysis. Presently, the Court revisits the issue under a Rule 23 "rigorous analysis" to determine whether Dr. Rosenthal's assumption, now framed as Plaintiffs' argument, can be established by common proof. *See In re Hydrogen Peroxide*, 552 F.3d at 323 ("Expert opinion with respect to class certification, like any matter relevant to a Rule 23 requirement, calls for rigorous analysis . . ." even when "the court holds the testimony should not be excluded").

have remained above 15%. Dr. Gottlieb, Cephalon's regulatory expert, opined that the FDA does not regulate the practice of medicine, even when approving a drug with a RiskMAP under Subpart H.[30] Therefore, it is a physician's prerogative whether to prescribe Actiq for any medical purpose, on-label or off. (Menkowitz Decl. Ex. 26, Gottlieb Report ¶¶ 23, 35.) *See* 21 U.S.C. § 396 (expressly stating that the FDCA shall not be construed "to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship"). Physicians may have accounted for a number of factors in making their Actiq prescriptions, including their experiences with patients and their experiences with prescribing Actiq. *See Ironworkers Local Union 68 v. AstraZeneca Pharm., LP*, 634 F.3d 1352, 1362 (11th Cir. 2011) ("Several considerations shape the physician's medical judgment, including both individual patient concerns and drug-specific information regarding the propriety of a drug's use for treatment of a patient's given condition . . . The physician learns about a drug through multiple sources, only one of which might be the drug manufacturer's promotions and literature." (citations omitted)). It is also uncontested that Actiq provided the benefit of effective pain relief to many who used it. If doctors would have written Actiq prescriptions even if Cephalon complied with the Actiq RiskMAP, then payment for prescriptions beyond the 15% limit would not be unjust.

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[30] Plaintiffs' expert, Dr. Deborah Leiderman, testified to the same:

> Q: But the FDA does not prohibit a doctor from writing an off-label prescription for Actiq. Correct? . . .
> A: During the class period, that's correct – does not prohibit, that's correct.

(Menkowitz Decl. Ex. 20, Leiderman Dep. 104:20-105:5, Feb. 20, 2013.)

Further, Plaintiffs made their own decisions regarding coverage for Actiq prescriptions, which must be considered in assessing equitable circumstances. The parties dispute the extent to which TPPs varied their administration of prescription drug benefits. Cephalon's expert, Dr. David Bradford,[31] found that TPPs had a variety of methods by which they could manage prescription costs of Actiq. (Menkowitz Decl. Ex. 23, Bradford Report ¶ 65-67.) Dr. Bradford's analysis shows that, during the proposed class period, TPPs implemented various measures for controlling Actiq prescriptions, with some requiring prior authorization or quantity limits and others imposing no restrictions at all. (*Id.* ¶¶ 76-83.) By contrast, Plaintiffs' expert, Dr. Thomas McGuire,[32] opines that TPP reimbursement policies for prescription drugs were substantially similar throughout the class period. According to Dr. McGuire, Actiq's unique indication nearly guaranteed its placement on PBM formularies, which led to reimbursement in virtually all plans. (Rebuttal Expert Report of Thomas McGuire ¶¶ 23, 25.) He avers that PBMs that contracted with TPPs did little to hinder physicians' ability to prescribe Actiq because their administrative focus was on treatments with a larger share of costs. (*Id.* ¶ 50.) Regarding those TPPs who opted to use formulary and cost management tools, Dr. McGuire concludes that they did so ineffectively, as evidenced by Actiq's relatively high reimbursement rate. (*Id.* ¶¶ 42-43.)

The Court finds that Dr. Bradford's opinion is more firmly supported by the record than Dr. McGuire's. Cephalon records and employee testimony show that TPPs treated claims for

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[31] Dr. Bradford is the Busbee Chair of Public Policy and Professor in the Department of Public Administration and Policy at the University of Georgia. He has previously served as Director of the Center for Health Economic and Policy Studies and Professor in the Department of Health Administration and Policy at the Medical University of South Carolina. For twenty years, Dr. Bradford has conducted research in the area of health economics. (Bradford Report ¶¶ 1-2.)

[32] Dr. McGuire is a Professor of Health Economics in the Department of Health Care Policy at Harvard Medical School. Over the past 35 years, he has conducted research on issues including the economics of managed care, health insurance and health care payment systems, and drug pricing and procurement. (Rebuttal Expert Report of Thomas McGuire ¶¶ 4, Doc. 398.)

Actiq reimbursement differently throughout the proposed class period. (*See* Menkowitz Decl. Exs. 128-29, 2003-2004 Formulary Grid Sheets and Summaries; *id.* Ex. 140, Caminiti Dep. 156:17-23, 157:14-24 (regarding prior authorization procedures, testifying, "As I said, it's a giant quagmire of different issues because every plan makes their own determination").) Though Actiq was regularly reimbursed by TPPs, it is still relevant to consider how TPPs varied, or could have varied, their coverage decisions. For example, those TPPs who approved payment after completing patient-specific prior authorization procedures cannot then claim that their payment resulted from inequity. Indeed, the record reflects that Plaintiffs eventually did, at various times, adopt practices to reduce or eliminate Actiq payments.[33] An inquiry into equitable circumstances cannot be undertaken by common proof since TPPs had varying degrees of control over prescription benefits and various cost-saving measures available to them.

In sum, whether TPPs' payments for Actiq prescriptions resulted in unjust enrichment is a question resolved by examination into the actions not only of Cephalon, but also of individual TPPs and prescribing doctors.[34] *See Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 611 (3d Cir. 2012) (reviewing a grant of class certification in a consumer fraud case and stating, "the District

[33] Though no longer a party here, EMC, a TPP, also had discretion to exclude particular drugs from coverage under its prescription drug insurance program. (Kurowski Decl. Ex. 198, Knutsen Dep. 221:13-24, Mar. 23, 2010.) Cephalon records indicate that other TPPs, which could be putative class members, also had concerns regarding payment for off-label Actiq prescriptions and implemented prior authorization requirements. (*See* Menkowitz Decl. Ex. 40, National Account Manager ("NAM") Reports.)

[34] In their Reply in Support of Class Certification, Plaintiffs rely on *In re Neurontin Marketing and Sales Practices Litigation*, 712 F.3d 21 (1st Cir. 2013), which found that off-label prescribing was causally affected by the defendant pharmaceutical's fraudulent marketing scheme, notwithstanding the individual decisions of prescribing physicians and TPP. *In re Neurontin* involved the RICO and unfair competition claims of a single TPP plaintiff. In finding the defendant liable, a jury and the court weighed plaintiff's aggregate evidence of causation against the defendant's individual physician testimony. *Id.* at 45-46. A decision for the plaintiff in *In re Neurontin*, however, does not mean that common issues predominated. Rather, it appears that the jury and court, in addition to plaintiff's aggregate causation evidence, also considered individual evidence of plaintiff's formulary decisions and defendant's direct misrepresentations to plaintiff. *See id.* at 28-29. This Court's denial of class certification would not preclude an outcome similar to *In re Neurontin*, but any such outcome must occur at an individual level, as *In re Neurontin* did.

Court should not have focused exclusively on [the defendants'] conduct, and should have made factual findings critical to the predominance analysis"); *see also Grandalski*, 767 F.3d at 185 (noting the various factual scenarios that could lead to overbilling a patient for clinical testing and concluding that individual inquiries are required to determine whether the alleged overbilling constituted unjust enrichment); *Hernandez*, 2013 WL 2245894, at *9 ("Whether the doctrine applies depends on the unique factual circumstances of each case. Thus, the unjust enrichment claim essentially *demands* an individualized inquiry[.]" (internal citations and quotation marks omitted)). What may be unjust for one TPP may not be unjust for another depending on individual facts. This individualized inquiry into equitable circumstances applies with regard to both Plaintiffs' proposed multi-state and single-state groupings. Thus, this Court concludes that common questions of law or fact do not predominate under Rule 23(b)(3).

In their arguments, Plaintiffs liken this case to *In re Pa. Baycol Third-Party Payor Litigation*, in which the Pennsylvania Court of Common Pleas certified a class of TPPs on their unjust enrichment claim based on prescription payments for Baycol, a drug manufactured by the defendant. No. 1874 SEPT. TERM 2001, 2005 WL 852135 (Pa. Com. Pl. Apr. 4, 2005). *Baycol*, however, is legally and factually dissimilar from the instant case. To start, the *Baycol* court granted class certification under Pa. R. Civ. P. 1702 and 1708. The Pennsylvania standard for class certification has criteria analogous to Rule 23, but it requires only a prima facie showing that the criteria are met, which plaintiffs can satisfy by substantial evidence. *See In re Pa. Baycol*, 2005 WL 852135, at *2-3. "[I]t is a strong and off-repeated [sic] policy of this Commonwealth that decisions applying the rules for class certification should be made liberally and in favor of maintaining a class action." *Id.* at *4. By contrast, "Rule 23 [of the Federal Rules of Civil Procedure] does not set forth a mere pleading standard. A party seeking class

certification must affirmatively demonstrate his compliance with the Rule[.]" *Wal-Mart Stores, Inc.*, 131 S. Ct. at 2551. Under Rule 23, this Court is to undertake a "rigorous analysis" at the class certification stage, making factual determinations by a preponderance of the evidence and ensuring "'actual, not presumed, conformance' with the Rule 23 requirements[.]" *In re Hydrogen Peroxide*, 552 F.3d at 326.

Further, *Baycol* is factually distinguishable in that the defendant drug manufacturer voluntarily stopped selling Baycol and advised all patients to cease use of the drug immediately. The defendant refunded co-pay costs of unused Baycol to individual patients, but not to TPPs who paid for the same unused Baycol. *In re Pa. Baycol*, 2005 WL 852135, at *1. The *Baycol* court, in a combined commonality and predominance inquiry, found that predominance was satisfied in part because the TPPs sought relief only to the extent that they paid for Baycol that the defendant subsequently urged consumers not to use. This was common proof of unjust enrichment. *Id.* at *7. Here, Cephalon neither urged patients to stop using Actiq nor refunded any portion of Actiq payments. Rather, Cephalon insists that its distribution of Actiq was proper throughout the proposed class period and that no unjust enrichment occurred in light of intervening physician and TPP decisions. Thus, *Baycol* does not have the persuasive force that Plaintiffs urge.

2. Superiority

The second inquiry under Rule 23(b)(3) is whether "a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." A court's consideration of superiority requires a "balance, in terms of fairness and efficiency, [of] the merits of a class action against those of 'alternative available methods' of adjudication." *Georgine v. Amchem Prods., Inc.*, 83 F.3d 610, 632 (3d Cir. 1996), *aff'd sub nom. Amchem*

Prods., Inc. v. Windsor, 521 U.S. 591 (1997). Together with predominance, the superiority criterion is designed to "achieve economies of time, effort, and expense, and promote . . . uniformity of decision as to persons similarly situated, without sacrificing procedural fairness or bringing about other undesirable results." *Amchem Prods., Inc.*, 521 U.S. at 615 (quoting Fed. R. Civ. P. 23 advisory committee's note).

The Court considers the factors enumerated in Rule 23(b)(3) for determining superiority:

> (A) the class members' interests in individually controlling the prosecution or defense of separate actions;
> (B) the extent and nature of any litigation concerning the controversy already begun by or against class members;
> (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and
> (D) the likely difficulties in managing a class action.

Here, the largest impediment to a finding of superiority is the difficulty of managing a class action in which the laws of TPPs' various home states apply and individual questions of fact predominate. *See Powers*, 328 F. App'x at 127 ("Attempting to apply the law of a multiplicity of jurisdictions can present problems of manageability for class certification under Rule 23(b)(3)."). Also, TPPs are sophisticated institutional entities with an interest in controlling litigation when relatively large amounts of money are at stake. *Cf. Amchem Prods., Inc.*, 521 U.S. at 617 ("The policy at the very core of the class action mechanism is to overcome the problem that small recoveries do not provide the incentive for any individual to bring a solo action prosecuting his or her rights." (quoting *Mace v. Van Ru Credit Corp.*, 109 F.3d 338, 344 (7th Cir. 1997)). Indeed, some TPPs have already filed suit based on Cephalon's distribution of Actiq. This Court's survey of cases reveals that TPPs have brought and lost individual suits against Cephalon alleging violations of RICO and state claims including consumer fraud, misrepresentation, and

unjust enrichment. *See Travelers Indem. Co. v. Cephalon, Inc.*, 32 F. Supp. 3d 538 (E.D. Pa. 2014); *Indiana/Kentucky/Ohio Reg'l Council of Carpenters Welfare Fund v. Cephalon, Inc.*, Civ. Action No. 13-7167, 2014 WL 2115498 (E.D. Pa. May 21, 2014); *Cent. Reg'l Emps. Ben. Fund v. Cephalon, Inc.*, Civ. Action No. 09-3418, 2009 WL 3245485 (D.N.J. Oct. 7, 2009). The Court acknowledges that failure to certify a class may result in numerous individual suits like these, but an interest in fairness in adjudicating individual issues outweighs the judicial burden of such suits. This Court therefore concludes that a class action is not a superior method for fair and efficient adjudication of this case.

Plaintiffs' failure to satisfy the criteria of Rule 23(b)(3) is dispositive in this Court's decision regarding class certification. This Court therefore declines to engage in further analysis under Rule 23(a).

VII. CONCLUSION

For the reasons explained herein, the Court concludes that this putative class action does not meet the predominance and superiority requirements of Rule 23(b)(3). Accordingly, Plaintiffs' Motion for Class Certification is DENIED. An appropriate order follows.