BEFORE THE
UNITED STATES JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

IN RE: BYETTA THYROID CANCER PRODUCTS LIABILITY LITIGATION	§ § § § § § §	MDL - _____

BRIEF IN SUPPORT PLAINTIFF'S MOTION FOR TRANSFER OF ACTIONS PURSUANT TO 28 U.S.C. § 1407

MAY IT PLEASE THE COURT:

Pursuant to 28 USC § 1407 and Rule 7.2(a) of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, Plaintiff, Elizabeth Childress, submits this memorandum of law in support of Plaintiffs' motion for transfer of all currently filed cases identified in the included Schedule of Actions ("Actions"), as well as any cases subsequently filed involving similar facts or claims ("tag-along cases"), to the United States District Court for the Southern District of California, and to consolidate and coordinate all cases for pretrial proceedings before the Honorable Anthony J. Battaglia, United States District Judge, Southern District of California. Presently, there are at least **36** substantially similar actions pending in **3** different judicial districts in the United States alleging similar wrongful conduct on the part of Defendants.

Movants represent the Plaintiffs in **7** of the **36** cases that have been filed to date. All related actions, including those actions filed by Movants, by other Plaintiffs, and by future Plaintiffs, involve common questions of law and fact and arise from Plaintiffs' development of thyroid cancer from ingestion of Byetta (exenatide synthetic), which at all times relevant hereto, was manufactured, designed, tested, packaged, labeled, marketed, advertised, distributed, and sold by Defendants Amylin Pharmaceuticals, LLC f/k/a Amylin Pharmaceuticals, Inc. and Eli Lilly and Company (collectively, the

"Defendants").

In addition to issues of causation, common issues also include whether the Defendants knew of the thyroid cancer risk associated with Byetta and failed to disclose it to the medical community and/or consumers. All related actions seek damages for personal injury and/or economic damages on behalf of individuals exposed to Byetta, asserting various state law claims, such as negligence, products liability, breach of warranty, negligent misrepresentation, and/or fraud regarding the risks of ingestion of Byetta. Movant respectfully requests an Order transferring these related actions and future-filed actions to the Southern District of California as the most appropriate and convenient forum. Such consolidation is particularly appropriate as Judge Anthony J. Battaglia is currently presiding over *In re: Incretin-Based Therapies Products Liability Litigation* (MDL 2452), which includes Byetta-related pancreatic cancer cases. As discussed further herein, these Actions will have substantial overlap in discovery and experts with the Byetta-related discovery and experts already being developed before Judge Battaglia in MDL 2452.

Likewise, because of the scope of Defendants' conduct, it is likely that hundreds of additional actions will be filed in jurisdictions throughout the United States of America. Plaintiff's counsel herein is aware of hundreds of related cases that are under contract with various law firms across the United States of America. Transfer for consolidation and coordination is proper because each of the Actions and tag-along cases arise out of the same or similar nucleus of operative facts, arise out of the same or similar alleged wrongful conduct, will involve resolution of the same or similar questions of fact and law, will involve the same or similar scientific / medical evidence, and discovery will be substantially similar and will involve the same documents and witnesses.

I. Background

A. The Basis of Litigation

According to the American Diabetes Association, "Type 2 diabetes is the most common form of diabetes. Millions of Americans have been diagnosed with type 2 diabetes."[1] Type 2 diabetes mellitus is a chronic disease, characterized by insulin resistance and deficient insulin secretion leading to high blood sugar levels (or hyperglycemia), which is the hallmark of the condition. Diabetes remains the most frequent cause of blindness, amputations, and dialysis worldwide.[2] With the current estimate of more than 350 million patients worldwide[3] it is considered to be one of the major health challenges of the 21st century.

Byetta is a glucagon-like peptide-1 (GLP-1) receptor agonist and is a member of the incretin-based therapies class of drugs. Byetta is currently involved in MDL 2452 pending before the Honorable Anthony J. Battaglia in the Southern District of California, along with other Incretin-based therapies, related to its propensity to cause pancreatic cancer.

Byetta "work[s] by mimicking the incretin hormones that the body usually produces naturally to stimulate the release of insulin in response to a meal. [It is] used along with diet and exercise to lower blood sugar in adults with type 2 diabetes."[4] Byetta, like the other incretin-based therapies involved in MDL 2452, is supposed to help prevent diabetic complications.

Byetta was approved by the FDA in April of 2005 and was marketed to the medical community and general public shortly thereafter. In January 2010, the FDA

[1] http://www.diabetes.org/diabetes-basics/type-2/?loc=DropDownDB-type2
[2] Id.
[3] IDF Diabetes Atlas, http://www.idf.org/diabetesatlas/5e/diabetes.
[4] http://www.fda.gov/Drugs/DrugSafety/ucm343187.htm

approved Victoza, another member of the GLP-1 subclass of incretin-based therapies. As members of the same subclass, Byetta and Victoza act similarly in the human body and have similar side effects.

Victoza was approved with several post-marketing requirements under the Food and Drug Administration Amendments Act (FDAAA) to ensure that the manufacturer would conduct studies to provide additional information on safety. The FDA acknowledged the need for these post-marketing requirements based on concerns over animal studies demonstrating an association between Victoza and thyroid cancer.[5]

Victoza's approval by the FDA also came with a "black box" warning explaining that Victoza "causes thyroid C-cell tumors at clinically relevant exposures in rodents." Victoza's GLP-1 counterpart, Byetta, fails to make even this meager disclosure regarding thyroid cancer in the warning section of its label.[6]

In February 2011, the journal Gastroenterology published on-line the work of Elashoff et al[7] titled, "*Pancreatitis, pancreatic, and thyroid cancer with glucagon-like peptide-1-based therapies.*" These researchers used the FDA Adverse Event Reporting System (AERS) with the primary goal of their analysis being to assess the association between treatment with Byetta (and similar drugs) and an adverse event report of pancreatitis, where the drug was listed as the primary suspect associated with a pancreatitis report. A secondary goal was to examine the FDA AERS database for reported pancreatic or thyroid cancer associated with use of Byetta (and similar drugs), with various other

[5] http://www.fda.gov/downloads/AdvisoryCommittees/Committees%20MeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/UCM151129.pdf

[6] http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021773s029s030lbl.pdf at 20.

[7] Elashoff M, Matveyenko AV, Gier B, Elashoff R & Butler PC *Pancreatitis, pancreatic, and thyroid cancer with glucagon-like peptide-1-based therapies*. Gastroenterology (2011) 141:150-156.

anti-diabetic drugs used as controls.

Because thyroid tumors were reported to be increased in rodents treated with Victoza in a filing to the FDA, Elashoff et al evaluated the reported rates of thyroid cancer with Byetta and Januvia, another anti-diabetic incretin-based therapy[8], compared to control events relative to Avandia (rosiglitazone). The reported event rate for thyroid cancer was 4.73-fold greater in patients treated with Byetta compared to other therapies. Byetta's association with thyroid cancer was statistically significant.

In January 2012, Defendant Amylin Pharmaceuticals also gained FDA approval for Bydureon. Through its website, Amylin touts its Byetta and Bydureon drugs as the same, and notes that Bydureon is merely a longer-lasting version of Byetta, "BYDUREON is a long-acting form of the medication in BYETTA®[…]"[9]

By Defendant's own admission their medications are the same, but shockingly, only the label for Bydureon contains a "black box" warning (or any warning) for thyroid cancer. Indeed, in bold letters, the Bydureon label warns that it, "[…] causes thyroid C-cell tumors at clinically relevant exposures in rats. It is unknown whether BYDUREON causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as human relevance could not be determined by clinical or nonclinical studies."[10] While admitting Bydureon and Byetta are the same, Defendants have nevertheless been indifferent to the health and safety of Byetta users, having wholly failed to provide any warning related to its link to thyroid cancer.

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[8] Januvia is a dipeptidyl peptidase-4 (DPP-4) inhibitor. Byetta, discussed supra, is a glucagon-like peptide-1 (GLP-1) receptor agonist. GLP-1s and DPP-4s are subclasses of drugs subsumed in the larger incretin-based therapies family of drugs. While highly similar, including both subclasses tendency to cause pancreatitis and pancreatic cancer, the GLP-1s and DPP-4s have disparate impacts on the thyroid, with only the GLP-1s being linked to thyroid cancer.

[9] http://www.bydureon.com/

[10] http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022200Orig1s000lbledt.pdf

Due to the flawed formulation of Byetta, it increases the risk of thyroid cancer in those diabetic patients to whom it is prescribed. Defendants are indifferent to this fact and instead are focused on a singular, material consideration – their profits. In 2010, the worldwide sales of Byetta reached $0.710 billion and sales are predicted to reach $1.00 billion by 2015.[11]

Defendants' zeal for blindly manufacturing, marketing, and promoting Byetta, putting corporate profit over patient safety, has left a horrific trail of thyroid cancers, and too often, resulted in the excruciating suffering and or death of those who ingested this deadly drug. Plaintiffs seek to consolidate the Actions to assist in holding the Defendants accountable for their bad acts and to promote the efficient prosecution and resolution of the claims.

ARGUMENT

II. Transfer and Consolidation or Coordination of All Actions Is Appropriate Under 28 U.S.C. § 1407

A. The Purpose of Multidistrict Litigation

The purpose of the multidistrict litigation process is to "eliminate the potential for contemporaneous pretrial rulings by coordinating district and appellate courts in multidistrict related civil actions." *In re Multidistrict Private Civ. Treble Damages Litig.*, 298 F. Supp. 484, 491-92 (J.P.M.L. 1968).

Transfer of related actions to a single district for pretrial proceedings avoids conflicting pretrial discovery and ensures uniform and expeditious treatment in the pretrial procedures. *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 460 F.3d 1217, 1230 (9th Cir. 2006). Moreover, the Panel "considers that eliminating duplicate discovery in similar cases, avoiding conflicting judicial rulings, and conserving valuable

11 www.pipelinereview.com/store/toc/sample_pages_vg0151.pdf

judicial resources are sound reasons for centralizing pretrial proceedings." Hon. John G. Heyburn II, A View from the Panel: Part of the Solution, 82 Tul. L. Rev. 2225, 2236 (2008).

Accordingly, pursuant to 28 U.S.C. § 1407, transfer of actions to one district for coordinated or consolidated pretrial proceedings is appropriate where: (1) actions pending in different districts involve one or more common questions of fact, and (2) the transfer of such actions will be for the convenience of the parties and witnesses and will promote the just and efficient conduct of such actions. 28 U.S.C. § 1407(a). Consolidation is especially important in multidistrict litigations where "the potential for conflicting, disorderly, chaotic" action is greatest. *Id.* at 493.

B. Common Fact Issues Require Transfer, Coordination, and Consolidation

Here, transfer, coordination, and consolidation are appropriate because many common questions of fact exist, including, but not limited to:

- Whether Byetta was (and is) defective;
- Whether Defendants conducted adequate testing of Byetta;
- Whether Defendants breached their duty of care to Plaintiffs;
- Whether Defendants had knowledge regarding the existence of a defect in Byetta;
- Whether Defendants failed to warn about their product as alleged in the various Actions;
- Whether Defendants beached any warranty, express or implied, related to their sale of Byetta;
- Whether Byetta caused the thyroid cancer and related injuries of the Plaintiffs in the Actions;
- Whether Plaintiffs relied on Defendants' claims as to the safety and efficacy provided by Byetta; and
- Whether Plaintiffs are entitled to compensatory and exemplary damages.

Determination of these and other common issues in a single district will benefit the parties and witnesses and serve to promote the efficient prosecution and resolution

of these Actions. Notably, this Panel has routinely ordered the transfer and consolidation of multidistrict product liability actions involving drug products, often over the objections of one or more parties. *See, e.g., In re Bextra and Celebrex Prods. Liab. Litig.*, 391 F. Supp. 2d 1377 (J.P.M.L. 2005); *In re Vioxx Prods. Liab. Litig.*, 360 F. Supp. 2d 1352 (J.P.M.L. 2005); *In re Accutane Prods. Liab. Litig.*, 343 F. Supp. 2d 1382 (J.P.M.L. 2004); *In re Zyprexa Prods. Liab. Litig.*, 314 F. Supp. 2d 1380 (J.P.M.L. 2004); *In re Paxil Prods. Liab. Litig.*, 296 F. Supp. 2d 1374 (J.P.M.L. 2003); *In re Prempro Prods. Liab. Litig.*, 254 F. Supp. 2d 1366 (J.P.M.L. 2003); *In re Meridia Prods. Liab. Litig.*, 217 F. Supp. 2d 1377 (J.P.M.L. 2002); *In re Serzone Prods. Liab. Litig.*, 217 F. Supp. 2d 1372 (J.P.M.L. 2002); *In re Phenylpropanolamine Prods. Liab. Litig.*, 173 F. Supp. 2d 1377 (J.P.M.L. 2001); *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, 990 F. Supp. 834 (J.P.M.L. 1998); *In re the UpJohn Co. Antibiotic "Cleocin" Prods. Liab. Litig.*, 450 F. Supp. 1168 (J.P.M.L. 1978).

C. Byetta Thyroid Cancer Actions Should be Coordinated

Without transfer, coordination, and consolidation of these Actions and tag-along cases to the Honorable Anthony J. Battaglia in the Southern District of California, there exists a real and significant hazard of inconsistent rulings, in addition to judicial inefficiency, overlapping discovery, and unnecessary expense to all parties.

Indeed, many of the scientific studies and medical research relevant to the Actions consists of results and findings not just relevant to Byetta, but more broadly, relating to the incretin mimetic drug class as a whole, and involve a core issue of common fact – the incretins relationship to the formation of cancer (namely, pancreatic and thyroid cancer) in those patients who ingest these drugs. As noted by Dr. Wolfe, "it is clear that all of the drugs in this family are associated with an increased risk of

pancreatic cancer."[12] As a result, it would be an unnecessary expense and burden to have expert witnesses vetted in different federal district courts on highly similar injuries that require analysis of the same studies, evidence, documents, and opinions. Moreover, the prospect of inconsistent rulings and the potential for conflicting, disorderly, and chaotic litigation would be immense absent consolidation of the Actions in a distinct MDL assigned to the same judge presiding over the actions in MDL 2452.

Counsel for Eli Lilly, Matt Hamilton, also recognized the potential need to consolidate Byetta thyroid cancer cases alongside the actions included in MDL 2452 during argument before the Panel on Plaintiff's motion to consolidate pancreatic cancer cases related to the incretin-based therapies. Mr. Hamilton informed the panel during argument that his client, "[…] would like to reserve our rights to brief more fully for the Panel what [other cancers] should be included in the MDL for consideration now on the basis that the mechanism of action and assigning [sic] people is essentially the same, and the witnesses and the companies will be the same, and there will be some efficiencies there."

The consolidation of all Actions before Judge Battaglia in a new, distinct MDL ensures the pivotal common issues of fact with the proceedings in MDL 2452 will proceed in an orderly, consistent, and efficient manner. Moreover, transfer, coordination, and consolidation are especially appropriate here because no formal discovery has commenced in any Action outside the Southern District of California, and no responsive pleadings have been filed in any Action outside of the Southern District of California. Accordingly, transfer, coordination, and consolidation of the Actions and tag-along cases to a single district are appropriate for the just and efficient prosecution

[12] http://www.citizen.org/pressroom/pressroomredirect.cfm?ID=3850

of the Actions and convenience of the parties and witnesses.

III. The Southern District of California Is the Most Appropriate Forum for Transfer and Consolidation for Coordination.

Currently, there are 34 (of 36 total) Byetta thyroid cancer cases filed in the Southern District of California. The district courthouse is located in San Diego, California; in close proximtiy to mass transit, numerous hotels, and is only minutes away from an international airport. Furthermore, Counsel for the Byetta Defendants previously agreed in MDL 2452 the Southern District of California is an acceptable and appropriate forum for actions in that matter.

Moreover, Los Angeles County, California is home to the only other consolidated proceeding related to Byetta and claims of thyroid cancer. Indeed, *In re: Byetta Cases* JCCP 4574 contains what is believed to be dozens of thyroid cancer cases related to the ingestion of Byetta. As such, the geographic proximity of the Southern District of California to the Los Angeles JCCP actions is likely to allow for easy coordination and cooperation. Indeed, Judge William Highberger, who is presiding over the California JCCP, and Judge Battaglia, presiding over the Federal Incretins-Based Therapies MDL, have already demonstrated an ability and willingness to utilize a degree of coordination and cooperation – a trend Plaintiffs expect will continue if the Panel grants this motion and assigns Judge Battaglia In re: Byetta Thyroid Cancer Products Liability Litigation.

Further, in previously ordering the consolidation and coordination of the Incretin-Based Therapies actions, this Panel recognized the importance of many of the factors discussed herein; "[the Southern District of California] also enjoys the support of all responding plaintiffs and defendants, including defendant Amylin, which developed Byetta in this district and has company offices there. Further, centralization in this district will foster the coordination of this federal court litigation with the

pending state court coordinated proceedings in California state court."[13]

For these and other reasons further detailed below, the Actions and tag-along cases should be transferred and consolidated before the Honorable Anthony J. Battaglia in the Southern District of California, who is currently presiding over all Byetta thyroid cancer cases filed in the Southern District of California, and further, is presiding over all federal court Byetta-related pancreatic cancer cases pending nationwide.

A. San Diego Is a Convenient Location for Consolidated Proceedings

The Southern District of California courthouse is centrally located in San Diego, California, a large metropolitan area easily accessible for all parties and witnesses. The Court's location is particularly convenient in light of the fact that this litigation will unquestionably involve parties and witnesses located in a variety of areas throughout the United States. Moreover, Defendant Amylin Pharmaceuticals LLC is headquartered in San Diego, California, and as such, the Southern District of California is unquestionably convenient to this Defendant.

B. The Southern District of California Is Well-Equipped to Manage a Multi-District Litigation.

The Southern District of California provides an ideal venue for managing this litigation in the most efficient and expeditious manner. The Southern District of California is currently handling numerous other multi-district litigations. The staff and Clerk's office of the Southern District of California, therefore, are well equipped and have the experience to provide the necessary support services for managing this litigation.

[13] MDL No. 2452, *In re: Incretin-Based Therapies Products Liability Litigation*, Doc. No. 71.

C. Judge Anthony J. Battaglia Is Amply Qualified to Manage Multi-District Litigation.

With nearly two decades of federal judicial experience in the Southern District of California, Judge Battaglia is an excellent choice for managing this complex litigation. Judge Battaglia served the Southern District with distinction for many years as a magistrate judge prior to his appointment as a United States District Judge in 2011.

Judge Battaglia has significant experience in managing complex litigation, as well as consolidated, mass tort litigation in an efficient manner. Further, Judge Battaglia is already presiding over the federal court Byetta-related pancreatic cancer cases in an efficient and expiditious manner. Judge Battaglia is an appropriate choice for managing this MDL in a manner that will facilitate this litigation for the benefit of all parties. Moreover, Judge Battaglia has an experienced and talented staff and law clerks that have managed his current caseload and MDL 2452 with great care and efficiency.

IV. Conclusion

For the reasons discussed above, Plaintiff respectfully requests that the Panel transfer the above-mentioned actions and all subsequently filed tag-along cases for coordinated and consolidated pretrial proceedings before the Southern District of California, and assign the matter to Judge Anthony J. Battaglia.

Dated this 28th day of January, 2014

Respectfully submitted,

s/ Ryan L. Thompson

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ATTORNEYS FOR PLAINTIFFS IN THE FOLLOWING ACTIONS:

Case No. 3:13-cv-01114; *Elizabeth Childress v. Amylin Pharmaceuticals LLC, Eli Lilly and Company, and Does 1-100*; In the United States District Court for the Southern District of California, San Diego Division

Case No. 3:13-cv-01736; *Dorothy Diego v. Amylin Pharmaceutical LLC, Eli Lilly and Company, and Does 1-100*; In the United States District Court for the Southern District of California, San Diego Division

Case No. 3:13-cv-01861; *Geneva Edwards v. Amylin Pharmaceutical LLC, Eli Lilly and Company, and Does 1-100*; In the United States District Court for the Southern District of California, San Diego Division

Case No. 3:13-cv-02631; *Ivona Glovick v. Amylin Pharmaceuticals LLC f/k/a Amylin Pharmaceuticals, Inc., Eli Lilly and Company, and Does 1-100*; In the United States District Court for the Southern District of California, San Diego Division

Case No. 2:14-cv-00084; *Rosie Hernandez v. Amylin Pharmaceuticals LLC f/k/a Amylin Pharmaceuticals, Inc., Eli Lilly and Company, and Does 1-100*; In the United States District Court for the District of Arizona

Case No. 1:14-cv-00130; *Lorie Savinar v. Amylin Pharmaceuticals LLC f/k/a Amylin Pharmaceuticals, Inc., Eli Lilly and Company, and Does 1-100*; In the United States District Court for the District of Colorado

Case No. 3:13-cv-01865; *Albert Turner v. Amylin Pharmaceuticals LLC, Eli Lilly and Company, and Does 1-100*; In the United States District Court for the Southern District of California, San Diego Division