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 lowering statin drugs* (February 28, 2012),
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Food and Drug Administration,
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Loretta Planavsky *et al.*, Cleveland Clinic,
Statin Medications and Heart Disease,
[http://my.clevelandclinic.org/heart/prevention/cholesterol/statin-medications-and-
 heart-disease.aspx](http://my.clevelandclinic.org/heart/prevention/cholesterol/statin-medications-and-heart-disease.aspx) 4

The Silverstein Group,
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Defendant Pfizer Inc. (“Pfizer”) submits this response in opposition to the motion by Plaintiff Dianne Christopher to establish a multidistrict litigation proceeding for the 62 actions identified in her motion.¹

PRELIMINARY STATEMENT

Less than three months ago, this Panel denied a motion by other plaintiffs to establish a Lipitor MDL, even though it found that “the number of actions pending in this litigation might, in other circumstances, be sufficient to justify centralization.” *In re: Lipitor (Atorvastatin Calcium) Mktg., Sales Practices and Prods. Liab. Litig.*, MDL No. 2459, 2013 WL 4048505, at *1 (J.P.M.L. Aug. 8, 2013). Arguments in the second MDL petition aside, there has been no significant change in circumstances that would warrant a different result. The same factors that this Panel identified in denying the first MDL petition apply with equal force to the second petition and warrant its denial.

For one, the number of case filings remains low, particularly considering that over the last 16 years, more than 29 million patients in the United States have taken Lipitor and the label change on which plaintiffs rely in support of their claims occurred nearly two years ago. Since the Panel’s denial of plaintiffs’ first petition, various plaintiffs’ firms have expended substantial sums on advertising for new cases, including at least \$1.5 million for August 2013 alone.² Yet, only around 100 new federal cases have been filed.

In addition, the cases are proceeding expeditiously: Discovery and other pretrial activities are well underway and trial dates are set for late 2014 and early 2015 in more than

¹ Since the filing of Plaintiff’s motion, approximately 62 other cases have been identified as related.

² See The Silverstein Group, *Products Liability Attorney Advertising, August 2013*, at <http://www.silversteingroup.net/august-2013-attorney-advertising-report.html> (last visited October 31, 2013).

seven jurisdictions. These cases are thus poised for prompt merits decisions, including on core science issues, which will shape the litigation nationwide and conserve significant party and judicial resources. The creation of an MDL could substantially delay these merits resolutions. Moreover, the creation of an MDL is likely to artificially inflate the number of case filings and thereby actually increase, rather than reduce, the burden on the federal court system. Diabetes, the injury alleged in these cases, is a common medical condition that has many known risk factors. A products liability MDL involving one of the most widely-prescribed medicines in U.S. history and an alleged injury that is a common condition in the patient population at issue has the potential to generate massive filings of cases with questionable merit that would not otherwise be filed in the absence of an MDL. Management and administration of such an MDL would require substantial resources, and there would likely still be a need for courts around the country to expend resources on case-specific discovery and trial after remand of cases from an MDL. Those expenditures would dwarf those that will be required to allow the parties and courts to adjudicate the much smaller number of cases that are likely to proceed to completion in the absence of an MDL.

The creation of an MDL could have other adverse consequences. The medical community widely views Lipitor and other statin medications as important therapies that have provided essential treatment to millions of patients at risk for heart attacks, strokes, and death. The Food and Drug Administration (“FDA”) has expressly observed that the “benefit [of statins] is indisputable,”³ and that “the cardiovascular benefits of statins outweigh [the] small increased

³ Food and Drug Administration, *FDA Expands Advice on Statin Risks* (February 27, 2012), <http://www.fda.gov/forconsumers/consumerupdates/ucm293330.htm>.

risk[]” of elevated blood sugar levels, on which plaintiffs base their claims.⁴ Yet, many of the lawyer advertisements for Lipitor cases include statements that directly contradict the FDA’s findings and guidance. (See excerpts below.) The creation of an MDL would likely increase these firms’ advertising efforts, at the risk of both generating numerous new cases with little screening and scaring patients from taking statins.

“The Panel has often stated that centralization under Section 1407 ‘should be the last solution after considered review of all other options.’” *In re: Gerber Probiotic Prods. Mktg. & Sales Practices Litig.*, 899 F. Supp. 2d 1378, 1380 (J.P.M.L. 2012) (quoting *In re Best Buy Co., Inc., California Song–Beverly Credit Card Act Litig.*, 804 F. Supp. 2d 1376, 1378 (J.P.M.L. 2011)). Here, continuing coordination within and across federal district courts will better promote the interests of judicial economy and efficiency than would creating an MDL. By proceeding in the jurisdictions in which plaintiffs have filed and by continuing to coordinate where it is appropriate, the parties will be able to more quickly and effectively reach the merits. The benefits include both significant savings to the judicial system and the parties and an earlier opportunity to achieve clarity on a public health issue as to which plaintiffs’ claims are at odds both with FDA-approved labeling and clear statements by the FDA about that labeling.

Pfizer respectfully requests that the Panel deny the motion to transfer and permit the parties to continue their efficient coordination and litigation of these cases.

⁴ Food and Drug Administration, *FDA Drug Safety Communication: Important safety label changes to cholesterol-lowering statin drugs* (February 28, 2012), <http://www.fda.gov/Drugs/DrugSafety/ucm293101.htm>.

FACTUAL BACKGROUND

A. Lipitor and Plaintiffs' Claims

Lipitor, Pfizer's cholesterol-lowering medication, was approved by the FDA in 1996 and is one of a class of medicines commonly known as statins. Among other approved uses, Lipitor is approved to reduce the risk of heart attack, stroke, and certain kinds of heart surgeries in patients with multiple risk factors for coronary heart disease. Lipitor is one of the most well-studied prescription medicines ever approved, and it has been prescribed to over 29 million patients in the United States alone.⁵ Generic versions of Lipitor began to be sold in 2011. Lipitor and other statins are considered highly valuable, "first-line" treatment options for millions of patients at risk for heart disease and related events, including fatal heart attacks and strokes.⁶

Plaintiffs allege that Lipitor caused them to develop type 2 diabetes, and they cite language that was added to the warning sections of the labels for Lipitor and other statins in early 2012, stating that increases in blood sugar levels have been reported with use of statins, including Lipitor. Pfizer submits, however, that available scientific and epidemiological data do

⁵ See "About Lipitor," at <http://lipitor.com/aboutLipitor.aspx> (last visited October 31, 2013).

⁶ See, e.g., Loretta Planavsky *et al.*, Cleveland Clinic, *Statins Medications and Heart Disease*, <http://my.clevelandclinic.org/heart/prevention/cholesterol/statin-medications-and-heart-disease.aspx> (last visited October 31, 2013) (noting that "[s]tatins help prevent coronary heart disease in patients without a history of CVD (primary prevention) and those who are at very high risk of developing CVD," and that "[s]tatins are the first-line treatment of choice for patients with high cholesterol and those diagnosed with coronary heart disease"); Cholesterol Treatment Trialists' Collaborators, *Efficacy and safety of cholesterol-lowering treatment: prospective meta-analysis of data from 90,056 participants in 14 randomised trials of statins*, 366 *The Lancet* 1267, 1267 (2005) (reporting results of large meta-analysis of statin clinical trials, finding that statin therapy can reduce the incidence of major coronary events and stroke, and concluding that, "[t]hese findings reinforce the need to consider prolonged statin treatment with substantial LDL cholesterol reduction in all patients at high risk of any type of major vascular event").

not show that Lipitor causes diabetes or that Pfizer failed to adequately warn of a potential risk. Pfizer specifically disagrees with statements set forth in the Interested Party Response filed by the Richardson Patrick firm [Dkt. 29], which purport to summarize various Pfizer and FDA documents and published literature. As plaintiffs themselves acknowledge in that filing, their effort to argue the merits of their claims before this Panel is not appropriate and Pfizer will not respond here to each of their statements. Pfizer notes briefly, however, that plaintiffs' counsel has mischaracterized the documents they cite.⁷ And, importantly, they have provided no credible reason for why, if their allegations are correct, the "numerous additional filings" they anticipate

⁷ As just one example, plaintiffs assert, in their Interested Party Response, that "[t]he clinical trial data that was submitted in support of the NDA [for Lipitor] demonstrated a statistically significant 3-fold increased incidence of blood glucose more than 1.25 times the upper limit of normal in subjects who used Lipitor/atorvastatin; a level that is diagnostic for diabetes." Interested Party Response [Dkt. 29] at 4. In support of that statement, Plaintiffs cite to and attach as Exhibit A to their filing *one page* of the FDA Medical Officer's 1996 Review of the Lipitor NDA. The very next page of the FDA Medical Officer's Review, which is available online (and thus plainly not information that has been hidden from the FDA or the public), includes the following paragraphs specifically addressing the blood glucose laboratory values:

Specific laboratory abnormalities

Plasma glucose elevations

The increased incidence of glucose elevations in the atorvastatin-treated patients bears comment. In the placebo-controlled data grouping, of the 37 atorvastatin patients with glucose elevations, 36/37 had elevated glucose at baseline, and in 25 of those 36, elevations were > 1.25 X ULN [upper limit of normal]. In addition, 7/37 had a history of diabetes and 2/37 had a history of glucose intolerance.

Similarly, in the all-completed studies grouping, of 185 atorvastatin patients with glucose elevations, 115/185 had a history of NIDDM [noninsulin-dependent diabetes mellitus]. 174/18 had baseline values > ULN.

In sum, there is little evidence for an effect of atorvastatin on glucose metabolism.

FDA Medical Officer's Review, at 106 (1996), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/pre96/020702_s000.pdf.

and cite as support for creating an MDL [Dkt. 29 at 3] have not taken place despite aggressive plaintiff firm advertising and nearly two years after a labeling change related to this issue.

Type 2 diabetes is the most common form of diabetes. It affects millions of Americans, amounting to more than 12% of the U.S. population aged 45 to 64 and over 20% of the population aged 65 to 74,⁸ and it has numerous risk factors and potential causes. Significantly, there is an overlap among the risk factors for developing type 2 diabetes (such as obesity and elevated cholesterol) and the risk factors for developing coronary heart disease. As a result, diabetes is often a “comorbidity,” or a concurrent medical condition, in patients for whom statins are prescribed.

In addition, the FDA has expressly advised, with respect to the potential risk of an increase in elevated blood sugar levels with statin use, that, “FDA continues to believe that **the cardiovascular benefits of statins outweigh these small increased risks.**”⁹ Indeed, in reporting to consumers in February 2012 that “[a] small increased risk of raised blood sugar levels and the development of Type 2 diabetes have been reported with the use of statins,” the FDA unequivocally advised patients: “Clearly we think that **the heart benefit of statins**

⁸ See Centers for Disease Control and Prevention, *Percentage of Civilian, Noninstitutionalized Population with Diagnosed Diabetes, by Age, United States, 1980–2011*, <http://www.cdc.gov/diabetes/statistics/prev/national/figbyage.htm> (last visited October 31, 2013).

⁹ Food and Drug Administration, *FDA Drug Safety Communication: Important safety label changes to cholesterol-lowering statin drugs* (February 28, 2012), <http://www.fda.gov/Drugs/DrugSafety/ucm293101.htm> (emphasis added).

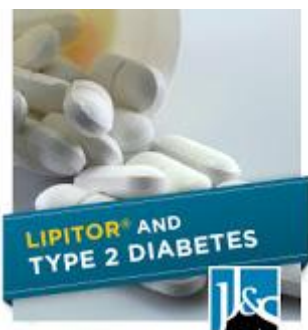
outweighs this small increased risk.”¹⁰ The same consumer update emphasized: “This new information should not scare people off statins.”¹¹

Yet contrary to the FDA’s statements and advice to physicians and patients, plaintiffs’ counsel around the country have launched television, Internet, and print advertising campaigns designed to amass new cases through statements and images that misrepresent the available science and FDA-approved labeling for Lipitor.¹² In many cases, these ads blatantly exaggerate what the FDA has described – based on its review of available data – as a potential small increased risk of elevated blood sugar levels with use of statins. Such ads have the potential to do exactly what the FDA urged against: “scare people off statins.” Scaring people from taking a medication prescribed to prevent potentially life-threatening cardiovascular events or conditions could have dire consequences. The following ads provide just a few examples of such messages:

¹⁰ Food and Drug Administration, *FDA Expands Advice on Statin Risks* (February 27, 2012), at <http://www.fda.gov/forconsumers/consumerupdates/ucm293330.htm> (emphasis added).

¹¹ *Id.* (emphasis added).

¹² Advertising appears to have increased dramatically following the denial of the MDL petition in August. See The Silverstein Group, *Products Liability Attorney Advertising, June/July 2013*, at <http://www.silversteingroup.net/junejuly-2013-attorney-advertising-report.html> (last visited November 1, 2013) (reporting Lipitor advertising in July 2013 of \$726,000, compared to \$1.5 million in August 2013 (*see supra* n. 2)).



Cholesterol-lowering drugs known as statins, including the brand name **LIPITOR**, have been linked to a **HIGH RISK OF TYPE 2 DIABETES**, especially in middle-aged and older women.

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¹³ At <http://myadvocates.com/lipitor-diabetes-lawsuit>.

¹⁴ At <http://www.ispot.tv/ad/7Zwx/janet-jenner-and-suggs-lipitor>.

¹⁵ At <http://www.youtube.com/watch?v=hvjTyEKFX6E>.



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B. Coordination of Pending Actions

As Pfizer set forth in its opposition to plaintiffs' first Lipitor MDL petition, personal injury actions involving Lipitor have been efficiently managed over the last 10 years as individual actions, with appropriate coordination where claims have shared similar issues. There continues to be no need to change that course now. The overlapping discovery of Pfizer that has already been sought and is expected to continue to be requested across the pending cases has been, and can continue to be, readily coordinated – through, among other things, cross-noticed depositions, shared document discovery, and cooperative conversations among counsel – without the need to transfer cases. The moving Plaintiff has not made any showing that such coordination is or will be inadequate to accomplish the objectives of justice and efficiency in

¹⁶ At <http://www.youtube.com/watch?v=E7etuEKVkfG>.

¹⁷ At <http://www.youtube.com/watch?v=eoTbvaNUunY>.

these proceedings. And although Plaintiff asserts that “there are now twenty-six (26) different sets of Plaintiffs’ counsel involved” (Pl.’s Mem. at 2), the reality is that the vast majority of the cases involve one or more of the same group of approximately six different firms who have filed cases around the country. Indeed, 80 percent of the federal cases involve one or more of the same four plaintiffs’ firms (including the firm who filed the first petition for an MDL and firms who supported it): Richardson Patrick (with over 80 cases on its own), Pendley Baudin, Lopez McHugh, and the Simmons Law Firm. The 26 firms that Plaintiff references include the various local counsel in those cases, but the majority of those counsel are affiliated with one of the four primary firms. Indeed, counsel from those primary plaintiffs’ firms are already coordinating with one another and participating in coordinated meet and confer calls about discovery matters with Pfizer’s counsel. The undersigned counsel represents Pfizer in all of the pending actions.

In two of the jurisdictions in which multiple cases are pending, the District of South Carolina and the Southern District of Illinois, the parties and courts in each district have agreed to coordinate all pending actions and pretrial discovery activities before a single judge (Judge Richard Gergel in South Carolina and Judge Michael Reagan in Illinois). As a result of these efforts, the parties have been able to achieve the entry of a protective order, discovery orders, and scheduling orders. In the coordinated cases in both the District of South Carolina and the Southern District of Illinois, as well as in several cases pending in other districts (including *Taylor* in the Southern District of Mississippi, *Pauley* in the Southern District of West Virginia, *Holbrook* in the Eastern District of Kentucky, *Jefferson* in the Eastern District of Pennsylvania, and *Calamese* in the Northern District of Mississippi), there are expert disclosure deadlines beginning in Spring and Summer 2014 and trial dates starting in Fall 2014 and Winter 2015. The schedules in many of the cases provide for briefing and hearings on core science and merits

issues within the next year to 16 months. Among the recently filed cases, there are also opportunities to seek coordination before a single judge within a district. No party or judge has opposed or denied such a request in this litigation.

The 14 cases coordinated before Judge Gergel in the District of South Carolina are most advanced. Pfizer has begun an extensive document production pursuant to an agreed protective order, and the collection of plaintiffs' medical records and documents is underway. Pfizer will make its production available in other jurisdictions pursuant to a similar appropriate protective order. Pfizer has also served interrogatories and requests for production in the South Carolina and Illinois cases and other actions, and responses are due shortly. Judge Gergel has adopted a discovery schedule providing for case-specific discovery, including depositions, in each of the first 14 actions filed in South Carolina, to be completed by November 2014.

Further, after this Panel denied the first motion for a Lipitor MDL, several of the plaintiffs' firms who had brought or supported that motion subsequently filed large multi-plaintiff actions in various state courts – including a 70-plaintiff action in Missouri (filed by the Simmons Law Firm),¹⁸ a complaint purporting to join 40 unrelated plaintiffs in West Virginia (filed by the Richardson Patrick firm), and several multi-plaintiff actions in California (filed by the Heard Robins firm), where plaintiffs have moved for a coordinated state court proceeding. Each of these actions includes one or more parties intended to destroy federal diversity jurisdiction. The existence of these numerous state court litigations, involving virtually the same or a potentially greater number of plaintiffs than in federal court, would limit the ability of a federal MDL court to achieve efficiencies and serve as a focal point for the litigation.

¹⁸ This action was remanded to state court from the Eastern District of Missouri after Plaintiff filed her motion with this Panel.

ARGUMENT

I. TRANSFER WILL NOT PROMOTE THE JUST AND EFFICIENT CONDUCT OF THESE PROCEEDINGS

As this Panel has explained,

The “just and efficient conduct” of the actions is the most important of the statutory criteria [under Section 1407]. And, as the statute and congressional reports emphasize, the existence of a common fact is not enough to justify transfer of litigation to a single district; there must be a showing that the transfer will produce “significant economy and efficiency of judicial administration.”

In re Equity Funding Corp. of Am. Sec. Litig., 375 F. Supp. 1378, 1393-94 (J.P.M.L. 1973) (Wisdom, J., dissenting).¹⁹

Just as the existence of a common fact does not, by itself, mandate transfer, transfer is not inevitable simply because a number of related actions have been filed. *See, e.g., In re Rely Tampon Prods. Liab. Litig.*, 533 F. Supp. 1346 (J.P.M.L. 1982) (denying transfer of 92 actions); *In re Ambulatory Pain Pump-Chondrolysis Prods. Liab. Litig.*, 709 F. Supp. 2d 1375, 1378 (J.P.M.L. 2010) (denying transfer of over 100 actions accompanied by more than 70 related actions). Nor is transfer automatic simply because the number of actions has increased since an earlier denial of a motion to transfer by this panel. In *In re Ambulatory Pain Pump*, for instance, this Panel denied the plaintiffs’ renewed motion to transfer, even though the number of related

¹⁹ *See also* 15 CHARLES ALAN WRIGHT, ARTHUR MILLER & EDWARD COOPER, FEDERAL PRACTICE AND PROCEDURE § 3863 at 413-15 (3d ed. 2007) (“The third and, in the minds of many courts, the most important prerequisite to obtaining a transfer and consolidation for pretrial purposes under Section 1407 is a showing that the just and efficient conduct of the actions will be served thereby. Indeed, it has been argued that the crucial issue in determining whether to grant pretrial consolidation is not whether there are common questions or whether the parties will be inconvenienced, but whether ‘the economies of transfer outweigh the resulting inconvenience to the parties.’ Read broadly, which the open-ended and embracing character of the statutory language permits, of course, this third requirement really subsumes the other two.”) (citations omitted).

actions had grown from 13 to over 100, because the same considerations that had previously militated against transfer remained. *See* 709 F. Supp. 2d at 1377-78. Among other factors, which also exist here, the litigation still involved highly individualized personal injury claims and discovery was already underway in various actions. *See id.* The Panel also discounted the movants' argument that an MDL was necessary to prevent discovery delays, since several actions had advanced productively without the assistance of MDL proceedings. *Id.* at 1378.

Regardless of the number of constituent actions or the expansion of litigation, the party seeking a transfer must still show that a transfer would "promote the just and efficient conduct of such actions." 28 U.S.C. § 1407. Plaintiff here has failed to meet this burden.

A. Continuing Coordination Across the Cases is Both Appropriate and Feasible

Plaintiff has failed to show that the formal and informal methods of coordination that are already well underway in this litigation are insufficient. This Panel has repeatedly indicated its support for such methods, where feasible, over the creation of an MDL. *See In re Qwest Commc'ns Int'l, Inc., Sec. & "Erisa" Litig.*, 395 F. Supp. 2d 1360, 1361 (J.P.M.L. 2005) (denying motion to transfer 23 actions, in part because "alternatives to transfer exist that can minimize whatever possibilities there might be of duplicative discovery and/or inconsistent pretrial rulings"); *see also In re Eli Lilly & Co. (Cephalexin Monohydrate) Patent Litig.*, 446 F. Supp. 242, 244 (J.P.M.L. 1978) (describing, with approval, alternative methods of coordination among parties and courts).

As set forth above, Pfizer has supported the formal coordination of Lipitor dockets in two district courts already (before Judge Gergel in the District of South Carolina and Judge Reagan in the Southern District of Illinois), and it expects coordination before a single judge to be possible and appropriate in other districts in which multiple cases have been or may be filed. These efforts conserve the courts' resources while allowing the cases to proceed in their home

jurisdictions and on schedules that are not unnecessarily prolonged based on the existence of other cases in other jurisdictions. In addition, Pfizer has been committed from the start of this litigation to coordinating discovery (including document productions and depositions), scheduling, and other pretrial activities across the cases, and it has already been working in a cooperative and coordinated manner with a number of plaintiffs' firms with cases filed in various jurisdictions. Because informal coordination across the cases has already been successful in achieving efficiencies, and should continue to be feasible here, this Panel's precedent supports denial of Plaintiff's motion.

For these reasons too, the request by certain plaintiffs for this Panel to reschedule Plaintiff's motion to be heard on the Panel's earlier hearing date, on December 5, 2013, should be denied. *See* Interested Party Response [Dkt. 27]. As established above, there is no "need for immediate transfer" (*id.* at 9), and maintaining the anticipated hearing date in January will allow the Panel to address the motion at a time when it will have more clarity and information about the status of the litigation.

B. An MDL Would Delay and Inflate the Proceedings

The potential disadvantages to creating an MDL in this litigation also outweigh any potential added efficiencies that might be gained. First, establishing an MDL would inevitably delay the discovery and trial schedules already underway in a number of the actions. Based on experience with other pharmaceutical MDLs, the necessary processes of transferring all cases to an MDL court, selecting a Plaintiffs' Steering Committee, conducting initial conferences, and adopting case management and scheduling orders can take many months. Discovery activities would need to be suspended in the interim, and the potential to achieve resolution of science and merits issues by late 2014 or early 2015 – which is anticipated by the current schedules and appears highly likely at this time – would be lost. The moving Plaintiff offers no sound reason

to derail these schedules and delay the opportunity for plaintiffs in those cases already set for trial and for Pfizer to reach prompt resolution of the claims and key science issues.

The creation of an MDL would also reduce, rather than enhance, judicial efficiency by spurring the filing of potentially hundreds to thousands of cases with questionable merit that would otherwise never be filed. Particularly because Lipitor is one of the most-prescribed medications in history, with nearly two decades of use, and the claims at issue involve a medical condition that is highly prevalent in the statin patient population, the risk that an MDL will increase, not alleviate, the burdens of this litigation on the judicial system is significant. These considerations include both the burden on the system of a large MDL, which itself could consume many years and substantial court resources, but also the burden on courts around the country of handling hundreds of cases after pretrial proceedings are completed and cases are remanded or transferred back to transferor or other appropriate district courts for case-specific proceedings and trial. These are likely to include numerous pro se cases that remain after counsel withdraw from cases during or at the conclusion of the MDL.

Further, as noted above, the same plaintiffs' firms who previously requested an MDL and are expected to support the request again have also been filing large multi-plaintiff state court actions with combinations of parties that are intended to defeat Pfizer's ability to remove diverse plaintiffs' actions to federal court. (When the same plaintiffs' firms file Lipitor cases in federal court, they never join unrelated plaintiffs in a single action or add a local pharmaceutical distributor as a defendant.) Those firms' efforts to create competing state court proceedings not only raise questions about their commitment to a coordinated federal litigation but also compromise the ability of an MDL court to manage and control the litigation on a national basis and thereby significantly undermine the objective of creating an MDL in the first place.

C. The Cases on Which Plaintiff Relies Do Not Support Creation of an MDL

The cases on which Plaintiff relies do not support the creation of a Lipitor MDL. Many of the cases involved putative consumer or employer class actions. *See, e.g., In re Glaceau VitaminWater Mktg. and Sales Practices Litig. (No. II)*, 764 F. Supp. 2d 1349, 1350 (J.P.M.L. 2011); *In re Foot Locker, Inc., Fair Labor Standards Act (FLSA) & Wage & Hour Litig.*, 787 F. Supp. 2d 1364, 1365 (J.P.M.L. 2011); *In re Lawnmower Engine Horsepower Mktg. and Sales Practices Litig. (No. II)*, 588 F. Supp. 2d 1379, 1380 (J.P.M.L. 2008); *In re FedEx Ground Package Sys., Inc., Employment Practices Litig. (No. II)*, 381 F. Supp. 2d 1380, 1381 (J.P.M.L. 2005). This Panel has recognized that such cases may be appropriate for centralization with a relatively small number of cases. *See, e.g., In re Canon U.S.A., Inc., Digital Cameras Prods. Liab. Litig.*, 416 F. Supp. 2d 1369, 1370-71 (J.P.M.L. 2006) (coordinating two putative class actions and one potential tag-along class action). In addition, none of the product liability cases Plaintiff cites involved a pharmaceutical product with the patient population of Lipitor, the high prevalence of the injury alleged, or the unique situation of a litigation being virtually manufactured nearly two years after the label change on which plaintiffs base their claims.

This Panel's order granting a motion to centralize various cases involving Plavix is also distinguishable because the defendant manufacturers there were the parties seeking centralization and they had demonstrated "a significant change in circumstances" in the landscape of the litigation during the year after the Panel's denial of the first motion for an MDL. *In re: Plavix Mktg., Sales Practices & Prods. Liab. Litig. (No. II)*, 923 F. Supp. 2d 1376, 1378 (J.P.M.L. 2013). As set forth above, there has not been such a change in circumstances here, and this Panel should follow its earlier analysis and decision declining to establish a Lipitor MDL. This Panel can best promote the underlying purposes of Section 1407 by allowing the parties to continue with the coordination of discovery and other pretrial activities that has already

advanced the litigation efficiently and can continue to serve the interests of justice and conservation of resources.

CONCLUSION

For the foregoing reasons, Pfizer respectfully requests that the Panel deny Plaintiff's Motion for Transfer.

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