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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

IN RE SCHERING-PLOUGH  
CORPORATION / ENHANCE  
SECURITIES LITIGATION

This Document Relates to:

ALL ACTIONS.

Lead Case No. 2:08-397 (DMC) (MF)  
(Securities Class Action)

**ORAL ARGUMENT REQUESTED**

**LEAD PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION  
TO THE EXCHANGE ACT DEFENDANTS' MOTION TO STRIKE  
ALLEGATIONS DERIVED FROM ANONYMOUS SOURCES  
PURSUANT TO FED. R. CIV. P. 12(f)**

**TABLE OF CONTENTS**

	<b>Page</b>
I. INTRODUCTION .....	1
II. ARGUMENT.....	6
A. The CaféPharma Posts In The Complaint Are Material And Pertinent ..	6
1. The CaféPharma Posts Help Support A Strong Inference Of Scienter At The Pleading Stage.....	7
2. Congress Recognized That The CaféPharma Posts Are Material To Scienter.....	12
3. None Of The CaféPharma Posts Cited In The Complaint Is Scandalous .....	13
B. The Confidential Witness Statements Are Pleaded With Sufficient Particularity And Corroborated By Additional Facts .....	20
III. CONCLUSION.....	27

**TABLE OF AUTHORITIES**

	<b>Page(s)</b>
<b>CASES</b>	
<i>Abrams v. Lightolier</i> , 702 F. Supp. 509 (D.N.J. 1988).....	17, 18
<i>Biovail Corp. Int’l v. Hoechst Aktiengesellschaft</i> , 49 F. Supp. 2d 750 (D.N.J. 1999).....	17
<i>California. Pub. Employees’ Ret. Sys. v. Chubb Corp.</i> , 394 F.3d 126 (3d Cir. 2004) .....	21, 26
<i>Cryofab, Inc. v. Precision Med., Inc.</i> , No. 08-1236, 2008 U.S. Dist. LEXIS 51758 (D.N.J. July 8, 2008) .....	6, 16, 18
<i>D.E.&amp;J Ltd. P’ship v. Conaway</i> , 284 F. Supp. 2d 719 (E.D. Mich. 2003) .....	16
<i>Flammer v. County of Morris</i> , No. 05-5039, 2006 U.S. Dist. LEXIS 23509 (D.N.J. Apr. 25, 2006).....	17, 18
<i>Gaigiulo v. Isolagen, Inc.</i> , 527 F. Supp. 2d 384 (E.D. Pa. 2007).....	21
<i>Gateway Bottling, Inc. v. Dad’s Rootbeer Co.</i> , 53 F.R.D. 585 (W.D. Pa. 1971) .....	13, 14
<i>Higginbotham v. Baxter Int’l, Inc.</i> , 495 F.3d 753 (7th Cir. 2007) .....	21
<i>In re Am. Italian Pasta Co. Sec. Litig.</i> , No. 05-0725, 2006 U.S. Dist. LEXIS 40548 (W.D. Mo. June 19, 2006).....	20
<i>In re Carlson v. Xerox Corp.</i> , 392 F. Supp. 2d 267 (D. Conn. 2005).....	20

*In re CIGNA Corp. Sec. Litig.*,  
 No. 02-8088,  
 2005 U.S. Dist. LEXIS 35524 (E.D. Pa. Dec. 23, 2005).....17

*In re Intelligroup Sec. Litig.*,  
 527 F. Supp. 2d 262 (D.N.J. 2007).....19

*In re Levi Strauss & Co. Sec. Litig.*,  
 527 F. Supp. 2d 965 (N.D. Cal. 2007).....22

*In re McKesson HBOC, Inc. Sec. Litig.*,  
 126 F. Supp. 2d 1248 (N.D. Cal. 2000).....17

*In re Nat’l Century Fin. Enters., Inc. Inv. Litig.*,  
 541 F. Supp. 2d 986 (S.D. Ohio 2007).....20

*In re Pfizer, Inc. Sec. Litig.*,  
 538 F. Supp. 2d 621 (S.D.N.Y. 2008) .....19

*In re Scottish Re Group Sec. Litig.*,  
 524 F. Supp. 2d 370 (S.D.N.Y. 2007) .....22

*In re Xethanol Corp. Sec. Litig.*,  
 No. 06-10234,  
 2007 U.S. Dist. LEXIS 65935 (S.D.N.Y. Sept. 7, 2007) .....22

*Makor Issues & Rights, Ltd. v. Tellabs Inc.*,  
 513 F.3d 702 (7th Cir. 2008) .....21

*Miller v. Dyadic Int’l, Inc.*,  
 No. 07-80948,  
 2008 U.S. Dist. LEXIS 95934 (S.D. Fla. Nov. 25, 2008) .....20

*Ratvasky v. Citizens Nat’l Bank*,  
 No. 05-1056,  
 2005 U.S. Dist. LEXIS 40474 (W.D. Pa. Dec. 5, 2005) .....18

*Tellabs, Inc. v. Makor Issues & Rights, Ltd.*,  
 127 S. Ct. 2499 (2007).....passim

*Wieland v. Stone Energy Corp.*,  
 No. 05-2088,  
 2007 U.S. Dist. LEXIS 76636 (W.D. La. Aug. 17, 2007).....22

**STATUTES AND RULES**

Fed. R. Civ. P. 12(f).....passim

**OTHER AUTHORITIES**

5C CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FED. PRACTICE &  
PROCEDURE § 1382 (3d ed. 2008).....13, 16

Plaintiffs respectfully submit this memorandum of law in opposition to the Exchange Act Defendants' Motion to Strike Allegations Derived from Anonymous Sources Pursuant to Fed. R. Civ. P. 12(f).<sup>1</sup>

## I. INTRODUCTION

In accordance with the PSLRA's requirements for pleading scienter, the Complaint contains detailed factual allegations collectively giving rise to a strong inference that the Exchange Act Defendants knowingly or recklessly concealed from investors the fact that Schering's critical clinical trial, "Ezetimibe and Simvastatin in Hypercholesterolemia Enhances Atherosclerosis Regression" (commonly known as "ENHANCE"), failed to yield any statistically significant positive results on the study's primary endpoint.

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<sup>1</sup> In this action, Plaintiffs assert claims for violations of the Securities Act of 1933 against Defendant Schering-Plough Corporation ("Schering" or the "Company"), four members of the Company's senior management, eleven of the Company's current directors, one former director, and each of the eighteen underwriters that participated in an August 2007 public offering of the Company's common and preferred stock. Defendants Schering, Fred Hassan ("Hassan"), Carrie S. Cox, Robert J. Bertolini, Steven H. Koehler and Merck/Schering-Plough Pharmaceuticals ("M/SP"), a joint venture between Schering and Merck & Co, Inc. (collectively, "the Exchange Act Defendants"), are also sued for violations of the Securities Exchange Act of 1934 (the "Exchange Act"). Plaintiffs' allegations are set forth in a 230-page Consolidated Class Action Complaint (the "Complaint") that includes detailed allegations of fact as mandated by the Federal Rules of Civil Procedure and the Private Securities Litigation Reform Act of 1995 ("PSLRA"). These factual allegations are summarized in the Statement of Facts of the Lead Plaintiffs' Memorandum of Law in Opposition to the Exchange Act Defendants' Motion to Dismiss the Consolidated Complaint, filed herewith and incorporated herein by reference. "¶\_\_" refers to paragraphs in the Complaint.

Schering and its investors had hoped that ENHANCE would show, through the study's primary outcome measure, that the Company's blockbuster drug VYTORIN (which consists of Schering's ZETIA plus a statin) is more effective at fighting atherosclerosis than the statin alone. However, when the ENHANCE results were belatedly released to the public in January 2008 (partial release) and March 2008 (full release), they revealed that there was no statistically significant difference between ZETIA plus simvastatin (a generic statin) and simvastatin alone with respect to the primary endpoint, which measured the mean change in the intima-medial thickness ("IMT") of the carotid artery in three places. Additional adverse facts became public thereafter, including as a result of a Congressional investigation.

The Complaint alleges that the Exchange Act Defendants knowingly or recklessly failed to inform investors of the ENHANCE results for over one year. Among the facts alleged in the Complaint collectively giving rise to a strong inference of scienter are allegations that: (1) Schering failed to disclose the negative ENHANCE results until 2008, even though a January 2007 report by independent consultant Dr. Michiel L. Bots (the "Bots Report") concluded that the ENHANCE data was "fine," finding no reasons to justify delaying disclosure of the ENHANCE results based on purported data problems; (2) Schering CEO Hassan made statements in April 2007 suspiciously downplaying the importance of

ENHANCE; (3) ENHANCE's Principal Investigator Dr. John Kastelein expressed shock to Schering personnel in July 2007 (when the Company advised him it would not be releasing the ENHANCE results in November 2007, as it had previously planned), and advised Schering that there was no good reason to delay publishing the results; and (4) in November 2007, Schering suspiciously attempted to change ENHANCE's primary endpoint to manipulate its results and publicly misrepresented that a panel of outside experts had recommended the proposed change when they did not.

In addition to these and other facts collectively demonstrating a strong inference of scienter, the Complaint alleges that: (1) anonymous individuals posted detailed and what now are known to be remarkably accurate entries about the ENHANCE results on CaféPharma, a pharmaceutical industry website, beginning in March 2007, which strongly suggests that ENHANCE results were known within Schering long before they were made public; and (2) six former Schering employees confidentially provided additional corroborating facts, that: (a) by the Summer of 2006 (the start of the Class Period), it was clear to Schering insiders based on a quality control assessment of ENHANCE that it was unlikely that Schering would obtain any positive results from ENHANCE; (b) the delayed release of ENHANCE results was not justified by any data quality issues; and (c)

Schering employees and senior managers were familiar with and regularly visited the CaféPharma site.

The Exchange Act Defendants, who have moved separately to dismiss the Complaint, move under Federal Rule of Civil Procedure 12(f) to strike the CaféPharma posts and confidential witness statements from the Complaint, contending that they are “scandalous, immaterial, and impertinent.” But whatever “scandal” has been introduced in this case comes from Defendants’ filing, which soils the record with offensive and repulsive materials that have nothing to do with the CaféPharma posts cited in the Complaint (the “Cited Posts”) let alone with this securities case. The Exchange Act Defendants’ motion is utterly without basis. None of the material that Defendants inflict on the Court with their filing was cited in the Complaint.

Unlike the posts cited by Defendants, the eight CaféPharma posts quoted in the Complaint, which appeared between March and November of 2007, have ample indicia of reliability. The Cited Posts – none of which is remotely scandalous – evince a level of access consistent with knowledgeable persons because, among other things, they include specific details that were not public at the time, but which were subsequently confirmed when the ENHANCE results were finally made public in 2008. The now confirmed and detailed nature of these posts includes, for example, reported “higher liver problems” and “arguing back

and forth” between Schering and the Principal Investigator for ENHANCE “about how/when to release the info” – which, as public investors later learned in 2008, was actually occurring at the time of the posts. Indeed, one telling indication of the materiality and pertinence of the Cited Posts is that Congress considered them highly relevant to its investigation of Schering and noted the “obvious[]” significance of the CaféPharma posts to “the question of whether anyone within Merck or Schering-Plough knew the results of the ENHANCE trial prior to the official release of data.” Letter to Fred Hassan and Richard Clark from U.S. Representatives Dingell and Stupak (Feb. 11, 2008) (the “February 11, 2008 Letter”), attached as Exhibit 1 to the Declaration of James E. Cecchi, submitted herewith (“Cecchi Decl.”). Nor is there any requirement that the person or persons responsible for the CaféPharma posts be identified and testify at trial for the Court to consider them at the pleading stage.

Defendants are also off-base regarding the facts provided by former Schering employees who agreed to discuss on a confidential basis what they had witnessed inside the Company. The vast majority of courts have allowed securities plaintiffs to rely on confidential witness statements at the pleading stage to support a strong inference of scienter. The Cited Posts and confidential witness statements should not be stricken because they properly support a strong inference at the pleading stage, collectively with all of the other facts alleged, that Defendants were

aware of the ENHANCE results more than a year before the results were publicly released. Accordingly, Defendants' motion to strike should be denied.

## **II. ARGUMENT**

Rule 12(f) permits material in a pleading to be stricken only if it is redundant, scandalous, immaterial, or impertinent. Striking factual allegations in a pleading is a "drastic" remedy to be used "sparingly." *Cryofab, Inc. v. Precision Med., Inc.*, No. 08-1236, 2008 U.S. Dist. LEXIS 51758, at \*2 (D.N.J. July 8, 2008). Motions to strike are "not favored and usually will be denied unless the allegations have *no possible relation to the controversy* and may cause prejudice to one of the parties, or if the allegations confuse the issues." *Id.*<sup>2</sup>

A motion to strike is unavailing here because the CaféPharma posts and confidential witness statements are material and pertinent to the issue of scienter and (unlike Defendants' motion papers) are not scandalous. Moreover, the Complaint is pleaded with sufficient detail and includes sufficient corroborating facts that the CaféPharma posts and confidential witness statements should be given full consideration on the motion to dismiss.

### **A. The CaféPharma Posts In The Complaint Are Material And Pertinent**

All of the CaféPharma posts included in the Complaint relate to the critical question of when Defendants knew the ENHANCE results were unfavorable. *See*

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<sup>2</sup> All emphasis is added unless otherwise indicated.

¶¶ 120-21, 124-25, 131-34. The materiality of the Cited Posts was also recognized by Congressmen John D. Dingell and Bart Stupak of the House Subcommittee on Oversight and Investigations, who noted the “obvious[]” significance of the CaféPharma posts to “the question of whether anyone within Merck or Schering-Plough knew the results of the ENHANCE trial prior to the official release of data.” Cecchi Decl. Ex. 1. *See also* ¶ 191. Because these posts are highly relevant to scienter, a key issue in this case, they are material and pertinent under Rule 12(f) and should not be stricken from the Complaint.

**1. The CaféPharma Posts Help Support A Strong Inference Of Scienter At The Pleading Stage**

The now obvious high degree of accuracy with which CaféPharma posts in the spring, summer, and fall of 2007 described ENHANCE results and other related facts that were not publicly released until 2008 strongly suggests that the ENHANCE results were known as early as March 2007, months before the study was purportedly unblinded and released to the public. And while the accuracy of these posts could not have been known to the public at the time they were made, the Cited Posts have been subsequently corroborated in every important respect by the release of the ENHANCE results and additional non-public information made public as a result of the Congressional investigations. This is specifically demonstrated in the Complaint as follows:

- On March 13, 2007, a CaféPharma post responding to a question about the status of the ENHANCE study stated: “have a buddy at SPRI. *He says that the study is a bust. Adding Zetia to already maxed-out statin is useless.*” ¶ 121. This post correctly identifies several facts about ENHANCE that were not then publicly known, including the eventual top-line results disclosed one year later. *Id.*

- On June 3, 2007, a CaféPharma post captioned “Re: What happened to ENHANCE?” also correctly described the study’s yet unreleased results: “Still not released! Heard it crashed and burned!” ¶ 124. A response posted on June 4, 2007 stated: “*NO difference in the primary endpoint (change in CIMT from baseline) between simva+zetia and simva+placebo, and there were higher rates of liver problems in the simva+zetia group.*” *Id.* These posts collectively help show a strong inference of scienter by both accurately describing the ENHANCE results months before they were purportedly unblinded and released and correctly noting that patients receiving VYTORIN had “*higher rates of liver problems,*” a fact that was not publicly disclosed until March 2008. ¶ 125.

- On July 19, 2007, a CaféPharma post captioned “ENHANCE-Zetia 10-Simva 80 NOT better than simva 80/placebo!!!” described ENHANCE as “the first trial with a clinically meaningful end[p]oint (carotid IMT)” and correctly stated that the study “*shows that adding Zetia to high dose GENERIC statin*

*provides no real benefit. By inference, it suggests that Vytorin is really no better than the simva component alone, too.” ¶ 131. The post also correctly noted that, “[e]conomically-speaking, generic simva is so cheap now (and getting cheaper) that adding Zetia or using Vytorin will have to provide a wide margin of benefit in order to make up for cost differences. ENHANCE shows us that there is and will be no wide margin of benefit.” Id. This post further supports a strong inference of scienter by correctly describing the not-yet-public ENHANCE results as well as a key concern about the results, namely that the high cost of ZETIA and VYTORIN would not be justified if those drugs did not provide significant cardiovascular advantages. Id.*

- On July 24, 2007, a response to the above post on CaféPharma also confirmed that the ENHANCE results were negative, and provided a strikingly detailed roadmap of Schering’s subsequent attempts to hide and spin the ENHANCE results:

I think the time delay is because they are stalling in order to do 2 things: 1) datamine the trial to try to find some secondary or tertiary endpoint analysis that looks positive to some degree to offset the primary endpoint not being met, and 2) develop a counter-strategy to spin the results and/or discredit/disavow the trial (i.e. point out limitations in study design, the endpoint, etc). By itself, this trial won’t torpedo the whole thing because there are too many people who think that carotid IMT isn’t an ideal endpoint, and they’ll come out with some BS about “having to wait until the results of IMPROVE-IT before we have the definitive answer”.

¶ 132. This post is strongly corroborated by other factual allegations concerning Schering's public attempts to change the ENHANCE endpoint based on the most favorable trial data (*i.e.*, "data mining") and to disavow the ENHANCE trial by minimizing its significance in favor of IMPROVE-IT. *Id.*

- On September 20, 2007, a CaféPharma post provided detailed results of the purportedly blinded ENHANCE study while summarizing a conflict between the Principal Investigator and Schering that was not publicly known until *over six months later*:

One of my docs is a very good friend of the study PI [principal investigator] overseas. *I'm told that the study IS negative in that there is absolutely no difference in carotid IMT between simva 80+placebo vs simva 80+Zetia 10. Although Zetia did lower LDL-C as expected, it did nothing else of any value.* So much for "lower is better"! *Apparently, the PI and the company have been arguing back and forth about how/when to release the info. PI wants to report, but company keeps blocking/delaying.* We're pretty well-screwed if what is essentially max dose Vytorin is no better than max dose generic simva!!

¶ 133. Similar to, and collectively with the other CaféPharama posts set forth above, this post helps support a strong inference of scienter by demonstrating that the ENHANCE results were known for months before they were purportedly unblinded, and its accuracy is further demonstrated by the fact that it correctly summarized the conflict with Principal Investigator Dr. John Kastelein. *Id.* Only in April 2008, as a result of the Congressional investigations was a heated internal

e-mail exchange between Principal Investigator Dr. Kastelein and Dr. John Strony at Schering in July 2007 made public. *Id.* In that exchange, Dr. Kastelein wrote:

If this is true [that Schering decided not to present at the AHA conference], SP must have taken this decision without even the semblance of decency to consult me as PI of the study. I can tell you that if this is the case, our collaboration is over and I will take the appropriate steps to get in touch with the editors of major Journals as well as with the FDA. ***This starts smelling like extending the publication for no other than [sic] political reasons and I cannot live with that.***

¶¶ 126-28.<sup>3</sup>

- Finally, on November 14, 2007, a CaféPharma post stated (once again *before* the ENHANCE data was purportedly unblinded) that “***word of mouth from investigators involved in running the trial is that it is a negative study.***” ¶ 134.

The post’s author noted that:

We and Merck both talked up this study publicly a bunch before the results were known internally, now both are stone cold silent. The study was first supposed to be presented at AHA 2006, then ACC 2007, and now both ESC and AHA are passed this year with not a peep. You do the math.

*Id.*

When read together, and in light of the Company’s subsequent disclosures, these posts from the CaféPharma website help support a strong inference of scienter – that Schering insiders knew of the belatedly-reported ENHANCE results

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<sup>3</sup> Dr. Kastelein also warned Schering in his email exchange: “***you will be seen as a company that tries to hide something and I will be perceived as being in bed with you!***” *Id.*

for months before they were purportedly unblinded and publicly released – because they contain detailed information about the ENHANCE results and other non-public contemporaneous facts that were ultimately confirmed when the results finally were made public in 2008. Given the high degree of accuracy of these posts, the most cogent and compelling conclusion at the pleading stage is that the ENHANCE results were known or recklessly disregarded within the Company at the time these posts appeared on CaféPharma and, thus, well before they were made public. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499, 2510 (2007) (“A complaint will survive, we hold, only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.”).<sup>4</sup>

## **2. Congress Recognized That The CaféPharma Posts Are Material To Scienter**

Another telling indication of the materiality and pertinence of the CaféPharma posts is that Congress considered them highly relevant to its investigation of Schering. *See* February 11, 2008 Letter. Specifically, Congressmen Dingell and Stupak of the House Committee on Energy and

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<sup>4</sup> The Exchange Act Defendants’ argument that the CaféPharma postings placed an efficient market on notice of the ENHANCE results at the time they were first posted (Def. Mem. at 30) ignores the Complaint’s additional allegations that it was only after the actual ENHANCE results were released in 2008 that the CaféPharma postings were confirmed and, thus, became highly relevant to the issue of scienter. *See, e.g.*, ¶ 119.

Commerce and its Subcommittee on Oversight and Investigations cited five CaféPharma postings that were also quoted in the Complaint and noted the “*obvious*” relevance of these posts to the question of whether Schering withheld ENHANCE study results. *Id.* Representatives Dingell and Stupak specifically noted that, in the CaféPharma posts, “anonymous posters *apparently reveal knowledge of ENHANCE trial results as early as March 13, 2007*, nine months before Merck/Schering-Plough (M/SP) released the unblinded data.” *Id.* According to the Congressional investigators, the CaféPharma posts “are *obviously troubling* and *raise again the question of whether anyone within Merck or Schering-Plough knew the results of the ENHANCE trial prior to the official release of data* in the January 14, 2008 press release.” *Id.* Because of their relevance, Congress requested detailed information about the CaféPharma posts and about when Defendants first became aware of them. *Id.*

### **3. None Of The CaféPharma Posts Cited In The Complaint Is Scandalous**

The Exchange Act Defendants contend that the CaféPharma statements should be stricken as “scandalous” under Rule 12(f). As Defendants acknowledge, scandalous material “is that which improperly casts a derogatory light on someone.” 5C C. ALAN WRIGHT & A. R. MILLER, FED. PRACTICE & PROCEDURE § 1382 (3d ed. 2008). For material to be stricken as scandalous, “it must be obviously false and unrelated to the subject matter of the action.” *Gateway*

*Bottling, Inc. v. Dad's Rootbeer Co.*, 53 F.R.D. 585, 588 (W.D. Pa. 1971). Not a single CaféPharma post cited in the Complaint contains material that could be considered scandalous under this or any other definition of the term. To the contrary, the posts – most of which are recited in their entirety above – speak directly and powerfully to an important subject of this action, the question of scienter. It is these cogent and compelling facts which make them highly relevant to scienter.

The Exchange Act Defendants do not – indeed cannot – attack the statements that actually appear in the Complaint. So instead they introduce numerous patently offensive – and irrelevant – posts from the CaféPharma website that are wholly unrelated to the facts at issue in this case. Without any legal support, the Exchange Act Defendants take the bizarre position that the statements about drug studies cited *in* the Complaint are somehow rendered scandalous by entirely distinct and highly offensive statements that were *not* cited in the Complaint. The posts invoked by Defendants merely confirm the unfortunate, and unremarkable, fact that one can find profanity, invective, *ad hominem* attacks, and despicable racist and sexist comments on the Internet. Certainly, most of the statements enumerated by the Exchange Act Defendants are repellant to all thoughtful readers. But they have nothing to do with this case or the Complaint

and it is unfortunate that the Exchange Act Defendants saw fit to infect the record in this case with so many despicable comments.

Moreover, Rule 12(f) only permits courts to strike scandalous material “from a pleading,” and none of these repellant materials is included in the Complaint. As Defendants acknowledge, the statements were cherry-picked from CaféPharma’s “scores of message boards,” which are “categorized by topics” and broken down into “threads” consisting of one or more individual posts. Def. Mem. at 5. The majority of the offensive posts come from threads entirely unrelated to ENHANCE, or even Schering generally (*e.g.*, threads with sexually explicit or offensive headings, threads devoted to other pharmaceutical companies, and threads devoted to “political discussions”). By contrast, all of the CaféPharma posts quoted in the Complaint (and cited by Congress) contain statements that relate directly to the central question of when the ENHANCE results were known within Schering. The Exchange Act Defendants have pointed to no authority for the strange proposition that these uncontroversial materials can somehow be rendered “scandalous” by statements that did not appear in the pleading.

Because the CaféPharma posts help support a strong inference of scienter, they are material and pertinent under Rule 12(f). Generally, motions to strike are “viewed with disfavor,” and Rule 12(f) motions will “be denied unless the allegations have no possible relation to the controversy *and* may cause prejudice to

one of the parties, or if the allegations confuse the issues.” *Cryofab*, 2008 U.S. Dist. LEXIS 51758, at \*2. Thus, this Court “construe[s] [such motions] strictly against striking portions of the pleading on grounds of immateriality.” *Id.*

As in all securities fraud cases under the PSLRA, scienter is a critical issue in this case. This is particularly true here because Defendants specifically challenge the adequacy of Plaintiffs’ scienter allegations. *See* Brief of Exchange Act Defendants, at 13-19, 30-35. The discussion above demonstrates that the CaféPharma posts included in the Complaint directly relate to the issue of scienter because they raise a strong inference that Schering knew the negative ENHANCE results long before they were purportedly unblinded and made public. Such materials clearly “pertain to” and have an “essential relationship to” the securities fraud claims at issue in this case. 5C C. ALAN WRIGHT & A. R. MILLER, FED. PRACTICE & PROCEDURE § 1382 (3d ed. 2008) (impertinent matter “consists of statements that do not pertain, and are not necessary, to the issues in question” and immaterial matter “has no essential or important relationship to the claim for relief or the defense being pleaded”). Because these materials focus squarely on the legal issues in dispute in this case, they are material and pertinent. *See, e.g., D.E.&J Ltd. P’ship v. Conaway*, 284 F. Supp. 2d 719, 737 n.20 (E.D. Mich. 2003) (denying Rule 12(f) motion to strike “anonymous” letters relied upon by plaintiffs to show a strong inference of scienter).

Contrary to the Exchange Act Defendants' assertions, Rule 12(f) does not require statements made in pleadings to be admissible at trial. Admissibility determinations are not appropriate at the pleading stage, even under the heightened pleading standards of the PSLRA. *See Biovail Corp. Int'l v. Hoechst Aktiengesellschaft*, 49 F. Supp. 2d 750, 771-72 (D.N.J. 1999) ("This is not a motion for summary judgment and any contention that only admissible evidence can be considered on a motion to dismiss is ludicrous."). *See also In re CIGNA Corp. Sec. Litig.*, No. 02-8088, 2005 U.S. Dist. LEXIS 35524, at \*41 (E.D. Pa. Dec. 23, 2005) ("In all the rulings made above, the Court is not necessarily determining that any specific piece of evidence is either admissible or not admissible in the presentation of dispositive motions or at trial."); *In re McKesson HBOC, Inc. Sec. Litig.*, 126 F. Supp. 2d 1248, 1272 (N.D. Cal. 2000) ("all pleadings on information and belief are hearsay . . . [e]ven under the [PSLRA], plaintiffs are only required to plead facts, not to produce admissible evidence.").

Rule 12(f) does not change this analysis to require all statements made in a pleading to be admissible. *See Flammer v. County of Morris*, No. 05-5039, 2006 U.S. Dist. LEXIS 23509, at \*5 (D.N.J. Apr. 25, 2006) (denying Rule 12(f) motion to strike while noting that "nothing prevents [defendant] from attacking [] admissibility . . . at a later, more appropriate stage of the proceedings"); *Abrams v. Lightolier*, 702 F. Supp. 509, 511-12 (D.N.J. 1988) (denying Rule 12(f) motion

without reaching admissibility); *Ratvasky v. Citizens Nat'l Bank*, No. 05-1056, 2005 U.S. Dist. LEXIS 40474, at \*5 (W.D. Pa. Dec. 5, 2005) (denying Rule 12(f) motion without reaching admissibility). Rule 12(f) merely permits courts to strike statements that will confuse the issues or that “have no possible relation to the controversy and may cause prejudice to one of the parties.” *Cryofab*, 2008 U.S. Dist. LEXIS 51758, at \*2. Hearsay and other inadmissible statements may be included in a pleading so long as the statements are not redundant, immaterial, impertinent, or scandalous. *See Flammer*, 2006 U.S. Dist. LEXIS 23509, at \*5; *Abrams*, 702 F. Supp. at 509; and *Ratvasky*, 2005 U.S. Dist. LEXIS 40474, at \*5.

In this case, the Cited Posts speak directly to the question of when Defendants knew the ENHANCE results and, thus, are material and pertinent. It is of no moment that CaféPharma does not keep records revealing the identity of those who posted this information on its website, because that information may be discovered later with other evidence residing within Schering's own electronic data. Finally, even if the identity of the person or persons posting this information on CaféPharma is never confirmed through discovery or admissible at trial, that does not mean that the Court cannot rely on these highly specific and later corroborated postings at the pleading stage in assessing all of the facts that collectively given rise to a strong inference of scienter. The very fact that *someone* knew the details about the ENHANCE results discussed above many months

before the study was supposedly unblinded strongly supports the inference of scienter by cogently and compellingly demonstrating that the ENHANCE results were known for months before Defendants purportedly unblinded them and, collectively with all of the other facts alleged, give rise to a strong inference of scienter as to the Exchange Act Defendants.

The Exchange Act Defendants' motion cited in vain to *In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 369-70 (D.N.J. 2007) (anonymous internet postings *undercut* plaintiffs' allegations by asserting that the alleged undisclosed problems occurred only after defendants' challenged statements were made), and *In re Pfizer, Inc. Sec. Litig.*, 538 F. Supp. 2d 621, 630-31 (S.D.N.Y. 2008) (rejecting allegation that was "based entirely on an anonymous blog post"). Unlike the anonymous messages posted in those cases, the facts in this case include that the CaféPharma messages *pre-dated* Schering's eventual adverse disclosures for months and contained details which are remarkably consistent with the results eventually disclosed by Schering. Because of these meaningful differences, the CaféPharma postings should be considered by the Court (as they were by Congress) among the facts that contribute to a strong inference of scienter. Moreover, to the extent those district courts determined that internet postings must be subject to a more demanding standard of proof before the information is considered, they did so prior to the Supreme Court's decision in *Tellabs*, 127 S. Ct.

at 2509 (“The inquiry, as several Courts of Appeals have recognized, is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.”) (emphasis in original).<sup>5</sup>

**B. The Confidential Witness Statements Are Pleaded With Sufficient Particularity And Corroborated By Additional Facts**

Defendants also contend that all statements from the six confidential witnesses cited in the Complaint should be disregarded or highly discounted. Def. Mem. at 19-20. But, as the Third Circuit has recognized, “[s]o long as plaintiffs supply sufficient facts to support their allegations, there is no reason to inflict the obligation of naming confidential sources.” *Cal. Pub. Employees’ Ret. Sys. v.*

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<sup>5</sup> See also *Miller v. Dyadic Int’l, Inc.*, No. 07-80948, 2008 U.S. Dist. LEXIS 95934, \*10-11, \*37-41 (S.D. Fla. Nov. 25, 2008) (considering anonymous whistleblower e-mails as relevant to defendant’s scienter post-*Tellabs* and finding that “[w]hile the Amended Complaint does not list any specific communication that would give [defendant] that specific knowledge . . . [t]o have not put two and two together under these facts would have been an ‘extreme departure from the ordinary standards of care’ [from which] one may easily infer [defendant’s] knowledge of the fraud.”); *In re Am. Italian Pasta Co. Sec. Litig.*, No. 05-0725, 2006 U.S. Dist. LEXIS 40548, \*25-26 (W.D. Mo. June 19, 2006) (denying motion to dismiss on securities fraud claim against accounting firm where the firm failed to investigate or inform auditing committee after receiving anonymous letters detailing improprieties); *In re Nat’l Century Fin. Enters., Inc. Inv. Litig.*, 541 F. Supp. 2d 986, 1001-04 (S.D. Ohio 2007) (an anonymous letter was one of several “red flags” supporting strong inference of scienter); *In re Carlson v. Xerox Corp.*, 392 F. Supp. 2d 267, 290-91 (D. Conn. 2005) (considering an anonymous note as part of the factual allegations that, taken as a whole, supported a strong inference of scienter).

*Chubb Corp.*, 394 F.3d 126, 147 (3d Cir. 2004). *Chubb* looks at several factors in deciding whether to fully credit testimony from confidential witnesses, including the witnesses' basis for knowledge, the corroborative nature of other facts, the plausibility of the allegations, and similar indicia. *Id.* As set forth below, the confidential witnesses here satisfy the *Chubb* analysis because their testimony is plausible and corroborated and because their basis of knowledge is adequately pleaded.

Defendants cite *Tellabs* and *Higginbotham v. Baxter Int'l, Inc.*, 495 F.3d 753, 757 (7th Cir. 2007), to support their contention that the statements of confidential witnesses should be stricken. In doing so they misconstrue *Tellabs* – which subsequently limited *Higginbotham* to its unique facts in its opinion – and overlook that numerous courts have continued to credit well-pleaded and corroborated information from confidential witnesses, including the Seventh Circuit itself on the *Tellabs* remand. *See Makor Issues & Rights, Ltd. v. Tellabs Inc.*, 513 F.3d 702, 711-12 (7th Cir. 2008) (discussing *Tellabs* and *Higginbotham* and holding that “the absence of proper names does not invalidate the drawing of a strong inference from informants' assertions”) (Posner, J). *See also Gaigiulo v. Isolagen, Inc.*, 527 F. Supp. 2d 384, 390 (E.D. Pa. 2007) (finding, post-*Tellabs*, that plaintiffs established strong inference of scienter through the use of confidential witnesses, identified in the complaint only as UK physicians); *In re*

*Scottish Re Group Sec. Litig.*, 524 F. Supp. 2d 370, 392-93 (S.D.N.Y. 2007) (finding, post-*Tellabs*, that unnamed former employees provided an adequate basis for strongly inferring defendants' statements were false where the complaint identified the positions occupied by the former employees that "would have allowed for relevant hands-on experience in various parts of the Company"); *In re Levi Strauss & Co. Sec. Litig.*, 527 F. Supp. 2d 965, 973, 988-89 (N.D. Cal. 2007) (considering, post-*Tellabs*, the testimony of two unnamed ex-employees who were identified by their position and tenure within the defendant company); *In re Xethanol Corp. Sec. Litig.*, No. 06-10234, 2007 U.S. Dist. LEXIS 65935, \*9-10 & n.3 (S.D.N.Y. Sept. 7, 2007) (same); *Wieland v. Stone Energy Corp.*, No. 05-2088, 2007 U.S. Dist. LEXIS 76636, at \*18-19 (W.D. La. Aug. 17, 2007) (same).

In this case, Plaintiffs have provided a sufficient description of the six confidential witnesses cited in the Complaint, including their positions, dates of employment, and bases of knowledge, as well as corroborative facts and documentary evidence. In addition to corroborating one another, the confidential witness statements are corroborated by documentary evidence such as e-mails, the Bots Report, the March 24, 2008 *Wall Street Journal* article, and the ENHANCE results themselves. As a result, these facts should be considered by the Court as it assesses the adequacy of the scienter allegations and not stricken from the Complaint. These facts are summarized as follows:

- CW 1 was a Senior Medical Director in charge of Schering's Cardiovascular Therapeutics from November 2004 until September 2006. ¶¶ 102-03. CW 1 interacted with Schering's Brand Team on a daily basis regarding ZETIA and VYTORIN, including those members most involved with and familiar with the ENHANCE study. *Id.* Consistent with a March 24, 2008 *Wall Street Journal* article quoted in the Complaint (¶¶ 96-101), CW 1 states that there was a quality control assessment of ENHANCE data in late 2005 to 2006, and that Schering knew, as early as the summer of 2006, that there were real problems with ENHANCE and "that they were not going to get any good news" from ENHANCE. ¶ 103. CW 1 reports that as a result of this information and because it was unlikely that Schering was going to obtain any meaningful results from ENHANCE, the Brand Team held meetings in the summer of 2006 to discuss what they would do if the ENHANCE results were negative. *Id.* Importantly, these facts are also consistent with the unexpectedly low levels of arterial plaque found at the outset of the ENHANCE study (but reported only at the end of the Class Period) that made it more difficult to detect the between-group differences that ENHANCE was powered to determine. ¶ 101.

- CW 2 was a consultant for Schering on ENHANCE who worked directly with researchers in Amsterdam for approximately four to five years regarding quality control of the ultrasound imaging. ¶¶ 130, 142. CW 2 primarily

spoke to the people directly responsible for the ultrasound and image readings at the center in the Netherlands and frequently e-mailed and participated in conference calls with Schering's Dr. Strony. *Id.* CW 2 states that the quality control data in ENHANCE were equal to that in almost every other study and that great care was taken to ensure that the ENHANCE data were valid and reproducible. *Id.* This fact is corroborated by, *inter alia*, the Bots Report in the Complaint. ¶¶ 104-11. Also consistent with other allegations of the Complaint, CW 2 reports that Schering manipulated the data presented to an expert panel convened after the Bots Report by choosing the 74 most "discrepant" images for the panel's review. *See, e.g.*, ¶¶ 144-45.

- CW 3 is a doctor who worked in Schering's Department for Medical Service Liaisons ("MSLs") from 2002 to early 2007. ¶¶ 156, 212. The role of MSLs was to educate doctors that are treating patients about ongoing studies to which the sales people did not have access. *Id.* CW 3 was personally involved in the preparation of materials for Schering's cholesterol franchise Brand Team's monthly meetings. *Id.* According to CW 3, ENHANCE, its progress, and results, were regularly discussed by Schering's Drs. Veltri and Strony at the meetings. *Id.* Consistent with numerous other facts set forth in the Complaint, CW 3 reports that the doctors in charge of ENHANCE seemed "a bit worried" and told him "[t]hey

did not like the kind of results they were seeing and they had to take another look at something” when he asked them about the ENHANCE results “years ago.” *Id.*

- The statements of CW 4, CW 5 and CW 6 corroborate the CaféPharma posts by showing that Schering employees, including management, were aware of the CaféPharma website and regularly visited it. ¶ 117. CW 4, a district sales manager with Schering from before 2002 until early 2007, was aware of and visited CaféPharma and believes that senior management, at least at a director or national sales director level, visited the site as well. CW 4 specifically recalls the national sales director saying, “You should have seen what was posted on CaféPharma today.” *Id.* CW 5, a Schering sales representative from March 2004 to early 2007 who was responsible for selling ZETIA and VYTORIN, was familiar with CaféPharma and visited it to find background information on pharmaceutical sales. *Id.* CW 6, a regional Sales Director at Schering from 2004 to early 2008, states that 95% of the people whom he respected most in the pharmaceutical business used CaféPharma for information. *Id.* This included CW 6’s mentors and management at Schering. *Id.* By showing that Schering employees at all levels were aware of the CaféPharma website and used it for information, these confidential witness statements further support a strong inference of scienter.

All of these former employees may be relied upon by the Court in assessing scienter, as the Complaint specifically alleges their bases of knowledge and the information they provide is corroborated by other alleged facts.<sup>6</sup> *Chubb*, 394 F.3d at 147. Moreover, in assessing the plausibility of these accounts, it is important to note that none of these individuals is alleged to have made any conclusory assertions beyond his or her scope of knowledge or experience. *Id.* In fact, each former employee provides information limited to his or her direct knowledge and experience at the Company, which is well corroborated by other facts evidenced through several other independent sources of information. Indeed, it is the cumulative impact of the information presented in the Complaint that gives rise to a strong inference of scienter. *Tellabs*, 127 S. Ct. 2509. Accordingly, the Court should not strike these accounts, but consider them collectively with all other well-pleaded facts in assessing scienter at the pleading stage.

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<sup>6</sup> Even the Exchange Act Defendants appear to agree that the statement of CW 1 and CW 3 are “fully consistent” with data quality problems announced to investors only at the end of the Class Period. *See* Def. Mem. at 16.

### III. CONCLUSION

For the reasons above, the Exchange Act Defendants' Motion to Strike should be denied.

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/s/ James E. Cecchi

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