12-4208-cv(L)

12-4348-cv(XAP), 12-4624-cv(XAP)

IN THE

United States Court of Appeals

FOR THE SECOND CIRCUIT

JAMES R. HOLLON,

Plaintiff-Appellee-Cross-Appellant,

SHIRLEY BOLES,

Plaintiff,

—against—

MERCK & CO., INC.,

Defendant-Appellant-Cross-Appellee,

—against—

GARY J. DOUGLAS,

Appellant.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

FINAL BRIEF FOR
DEFENDANT-APPELLANT-CROSS-APPELLEE MERCK & CO., INC.

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and to enable the Judges of the Court to evaluate possible disqualifications or recusal, the undersigned attorneys of record for Defendant Merck Sharp & Dohme Corp. (formerly known as Merck & Co. Inc.) ("Merck"), certify that Merck is a wholly owned subsidiary of the entity formerly known as Schering Plough Corporation, which has been renamed Merck & Co., Inc. Merck is not aware of any publicly held company that owns 10% or more of Merck's stock.

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JURISDICTIONAL STATEMENT

The district court had subject-matter jurisdiction because Plaintiff and Merck were citizens of different states – Plaintiff resided in Florida, and Merck is incorporated and has its principal place of business in New Jersey – and the amount in controversy exceeded $75,000. 28 U.S.C. § 1332(a). [*See* A-111.] This Court has appellate jurisdiction because Merck appeals from a final judgment that disposes of all the parties' claims. 28 U.S.C. § 1291. Merck's appeal is timely because it noticed the appeal on October 18, 2012 [A-1230], which was within 30 days of the district court's entry of judgment on September 27, 2012 [SPA-154]. Fed. R. App. P. 4(a)(1)(A).

INTRODUCTION

This appeal is about Fosamax, a prescription drug approved by the FDA and used by millions of women for the treatment and prevention of osteoporosis, a condition that results in two million fractures in the United States per year. Plaintiff's theory below was that Fosamax is defectively designed – i.e., that its *risks* outweigh its *benefits* – because in "rare" cases it can cause osteonecrosis of the jaw (dead jaw bone, or "ONJ") and because its efficacy in women (like her) with higher bone mineral density is ostensibly unproven. The jury accepted Plaintiff's theory, but it did so in the face of insufficient evidence regarding risk,

an improper jury instruction regarding benefit, and "outrageous" misconduct by Plaintiff's counsel.

First, the jury had no basis to conclude that Fosamax posed a foreseeable *risk* of ONJ, as required under Florida law. The question whether a drug's alleged risk was foreseeable is a complex matter that can be proven only through expert testimony. Plaintiff did not proffer any expert testimony that ONJ was a foreseeable risk of Fosamax before Plaintiff's injury; to the contrary, her principal causation expert affirmatively testified that such a risk was *not* foreseeable at that time. The district court nevertheless refused to enter judgment for Merck, citing evidence that it believed could support a conclusion that the risk was foreseeable, even though no expert so testified at trial. That ruling was erroneous.

Second, the jury's verdict was the product of an erroneous jury instruction regarding the Florida standard for determining the *benefits* of a prescription drug. Throughout trial, Plaintiff's counsel conceded that Fosamax was a beneficial drug for some populations, but argued that Fosamax did not benefit Plaintiff. Merck thus sought a jury instruction that incorporated the right standard for determining benefits under Florida law: did Fosamax carry a benefit *for the population as a whole*? The district court refused to so instruct the jury, apparently based on its mistaken belief that Merck was arguing for a change in Florida law. Notably, the district court has since had a change of heart; in subsequent Fosamax trials, also

involving Florida law, the court *did* adopt Merck's requested instruction – and this Court recently held that the subsequent instruction was proper, in *Secrest v. Merck, Sharp & Dohme Corp.*, No. 11-4358-cv.

Third, the jury's analysis of benefit was also tainted by inadmissible hearsay evidence. Specifically, the trial court allowed Plaintiff to introduce a highly prejudicial unsigned report found in the FDA's files suggesting that Fosamax offered no benefit to women like her, even though that view was rejected by the FDA, which subsequently found that Fosamax is effective for Plaintiff's patient population.

Finally, the conduct of Plaintiff's counsel added an "outrageous" exclamation point to these errors. Both in examining witnesses and in his summation, Plaintiff's counsel engaged in *ad hominem* attacks on Merck and its witnesses, improperly referred to other Fosamax litigation, mocked witnesses, and repeatedly called on the jury to punish Merck for making profits even though punitive damages were off the table. The jury plainly responded to these antics, returning an $8 million verdict in approximately three hours, after a three-week long trial in which even Plaintiff's counsel had asked for a verdict of only $5 million. The district court sanctioned Plaintiff's counsel but did not grant Merck's motion for a new trial, based in part on its misplaced belief that jurors could not have been swayed by counsel's theatrics.

STATEMENT OF THE ISSUES

1. Was Merck entitled to judgment as a matter of law on Plaintiff's design-defect claims where the only expert she proffered on the question whether Fosamax posed a foreseeable risk of injury denied that the alleged risk was foreseeable before Plaintiff's injury?

2. Did the district court err in refusing to instruct the jury that, in deciding whether Fosamax was defectively designed, it had to consider the benefits of the drug as to the population as a whole, rather than solely as to Plaintiff or others like her?

3. Did the district court abuse its discretion in allowing Plaintiff to use hearsay evidence in the form of a report that was written by a single statistician at the FDA, was never formally adopted by the FDA, and was effectively rejected by the FDA's decision that Fosamax is effective for individuals like Plaintiff?

4. Did the district court abuse its discretion in refusing to grant Merck a new trial where Plaintiff's counsel engaged in repeated misconduct throughout trial, culminating in an "outrageous" summation that produced an immediate and excessive jury verdict for the Plaintiff?

STATEMENT OF THE CASE

Plaintiff Shirley Boles alleged that she developed ONJ as a result of taking Merck's prescription osteoporosis medication, Fosamax.[1] The gravamen of Plaintiff's case was that Fosamax was defectively designed because it presented a foreseeable risk of ONJ that outweighed its benefits by September 2003 (the month by which she allegedly developed ONJ).[2]

Plaintiff's case was first tried over three weeks in 2009. After five days of jury deliberations, the district court declared a mistrial (at Plaintiff's request) because the jury was hopelessly deadlocked, with seven jurors in favor of Merck and only one juror in favor of Plaintiff. [A-224-26, *Boles I* Tr. 2653-63; A-227-31.]

The case was then retried over three weeks in 2010.[3] The district court commented that "[t]he evidence introduced at the second trial was largely comparable to that in the first trial." [SPA-104.] However, after Plaintiff's counsel gave what the district court described as the most "outrageous summation" the court had heard in its 50-plus years in the legal profession [A-454-55, Tr. 1756-

[1] Plaintiff filed her complaint in the Northern District of Florida. The Judicial Panel on Multidistrict Litigation transferred the case to the Southern District of New York as part of the Fosamax MDL.

[2] Plaintiff conceded in her pre-trial briefing that her ONJ had developed by September 2003. [SPA-28-31.]

[3] After the first trial, the district court granted judgment for Merck on Plaintiff's failure-to-warn claims, leaving only the design-defect claims. [SPA-63-69.]

57], the jury deliberated approximately three hours and returned an $8 million verdict for Plaintiff [A-452-55, Tr. 1747, 1757-58].

Merck subsequently moved for judgment as a matter of law, arguing that Plaintiff had not presented sufficient evidence upon which a reasonable jury could conclude that Fosamax presented a foreseeable risk of ONJ in September 2003. [SPA-100.] Merck also moved for a new trial based on the "outrageous summation" and other misconduct by Plaintiff's counsel. [SPA-100.]

The district court (Keenan, J.) denied both motions [SPA-100-48],[4] but found the verdict excessive and offered Plaintiff the option of a remittitur to $1.5 million or a retrial on damages, [SPA-148-52]. Plaintiff chose the latter option [A-1194], but in lieu of the retrial, the parties later agreed to a sealed joint stipulation on the amount of Plaintiff's damages, while preserving the parties' right to appeal the district court's final judgment in the case. [SPA-154.][5] The district court subsequently entered a judgment for Plaintiff in the amount set forth in the stipulation. [*Id.*] This appeal followed.[6]

[4] The district court's opinion is reported at *In re Fosamax Prods. Liab. Litig.*, 742 F. Supp. 2d 460 (S.D.N.Y. 2010).
[5] The joint stipulation is filed under seal in the district court at ECF No. 381.
[6] Plaintiff died in September 2011. Her adult son, James Hollon, is pursuing this case as the executor of Plaintiff's estate. [A-1225, A-1229.]

STATEMENT OF FACTS

A. The Benefits of Fosamax

Fosamax (also called alendronate) is an oral bisphosphonate. The FDA has approved Fosamax as "safe and effective" for the treatment and prevention of osteoporosis in postmenopausal women [A-548, A-563], as well as three other indications.[7]

Osteoporosis is a disease of decreased bone mass and weakened bones that can result in fractures, including fractures in the hip, spine, and wrist. [A-367-68, A-373, A-371, Tr. 1071-75, 1102-03, 1096.] Bone mass is often measured by a bone mineral density ("BMD") score, also referred to as a "T-score." A T-score of -2.0 means that the patient's bone mineral density is two standard deviations below the mean for premenopausal women. [A-531.] There "have been several definitions of osteoporosis promulgated over time by different medical organizations." [SPA-57.] Some such definitions have included patients with a T-score below -2.0 (e.g., -2.1, -2.2, etc.), while others include patients with a T-score below -2.5 (e.g., -2.6, -2.7, etc.). [A-323, Tr. 752; SPA-14 n.5.] In 1995, the FDA suggested to Merck that the Indications section of the original Fosamax label define osteoporosis as a T-score of -2.0 or below. [A-531.]

[7] Those indications are treatment of Paget's Disease, treatment of glucocorticoid-induced osteoporosis in men and women, and treatment to increase bone mass in men with osteoporosis. [A-548, A-605, A-727.]

Plaintiff's counsel told the jury that Fosamax is a "great drug" [A-437, Tr. 1692] that "should be on the market for women who need it" [A-437, Tr. 1691].[8] Plaintiff claimed, however, that she was not one of the women who needed Fosamax because her T-score was -2.1. She alleged that data from a Merck clinical trial of Fosamax called "FIT" showed that Fosamax prevented fractures only in patients with a T-score below -2.5. [SPA-105; A-437, Tr. 1691-92.] In sum, as her counsel told the jury, her theory of liability was that Fosamax "is defectively designed for women who have her T-scores." [A-433, Tr. 1678.]

The FDA disagrees with Plaintiff's allegation that FIT showed fracture reduction efficacy only in patients below -2.5. In November 1999, based on its review of the FIT data, the FDA approved a revised Fosamax label stating that the FIT data showed Fosamax was effective in preventing fractures in patients at -2.0 or below. [A-702, A-705; A-330-31, Tr. 789-93.][9] The FDA has also found that Fosamax is effective in preventing the development of osteoporosis by maintaining

[8] [*See also* A-245, Tr. 103 (Plaintiff's counsel telling the jury: "Fosamax is a good drug.").]

[9] This new label stated that osteoporotic patients were defined as those with a "[b]aseline femoral neck BMD at least 2 [standard deviations] below the mean for young adult women," and that in those patients, Fosamax demonstrated a 22% relative reduction in fracture risk for "[a]ny clinical (symptomatic) fracture" and a 48% relative reduction in fracture risk for "[v]ertebral fractures (diagnosed by X-ray)." [A-711.]

bone mass in postmenopausal women who have risk factors for osteoporosis, including bone mass that is "moderately low" but still better than -2.0. [A-715.][10]

In addition, the scientists who conducted the FIT trial, including scientists from outside of Merck, published their results in the Journal of the American Medical Association ("JAMA") in 1998, stating that the FIT data showed "a 22% lower risk of clinical fractures in those whose T-scores were more than 2.0 [standard deviations] below the normal mean," and that "Alendronate treatment reduces the risk of clinical fractures among women with osteoporosis but not among those with hip or spine scores of -2.0 or more." S. Cummings et al., *Effect of Alendronate on Risk of Fracture in Women With Low Bone Density but Without Vertebral Fractures*, 280 J. AMERICAN MED. ASS'N 2077, 2080, 2082 (1998) [A-784, A-786; A-335-36, Tr. 803-10.] Other researchers have published similar conclusions in peer-reviewed medical journals.[11]

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[10] Women with low bone mass who do not meet the definition of osteoporosis are sometimes referred to as having "osteopenia." [A-399, Tr. 1265.]

[11] *See* S. Quandt et al., *Effect of Alendronate on Vertebral Fracture Risk in Women With Bone Mineral Density T Scores of -1.6 to -2.5 at the Femoral Neck: The Fracture Intervention Trial*, 80 MAYO CLIN. PROC. 343 (2005) ("In women with low bone mass who do not meet the bone mineral density criterion for osteoporosis, alendronate is effective in reducing the risk of vertebral fractures.") [A-798; A-339, Tr. 819-21]; S. Papapoulos, *Meta-analysis of the efficacy of alendronate for the prevention of hip fractures in postmenopausal women*, 16 OSTEOPOROSIS INT'L. 468 (2005) ("In patients with a T-score of less than or equal to -2.0, or with a vertebral fracture, the effect on hip fracture consistently favored patients receiving alendronate therapy, with an overall reduction in risk of hip fractures of 45%.") [A-805; A-340, Tr. 824-26].

In an effort to refute the FDA's conclusions and the published medical literature about Fosamax's proven fracture reduction efficacy, Plaintiff presented testimony by Dr. Curt Furberg, a professor at the Wake Forest University School of Medicine. Dr. Furberg showed the jury the "Mucci report," a statistical analysis conducted by an FDA employee in 1998. The document states that the FIT data showed Fosamax to be "effective in osteoporotic patients with no prevalent vertebral fracture only if osteoporosis is defined" as a T-score of -2.5, as opposed to -2.0. [A-598.][12]

Plaintiff did not present any evidence that the document represented a final FDA finding or that the FDA adopted Mucci's conclusions. Nor could she, since, as noted above, the FDA's review of the FIT data culminated in its approval of new labeling language stating that the FIT data showed Fosamax was effective in preventing fractures in patients at -2.0 or below. Indeed, Dr. Furberg conceded that his opinion was that the FDA simply "got it wrong" in not adopting Mucci's conclusions. [A-328, Tr. 772-73.]

Dr. Furberg also conceded that "the researchers who conducted the FIT trial" and authored the JAMA article "were some of the best in the country" [A-

[12] In reality, Dr. Mucci's analysis was based on a fundamental misunderstanding of the composition of the patient population in the FIT study. Dr. Mucci concluded that Fosamax only showed efficacy in the "osteoporotic cohort" of the FIT study [A-598], and that this cohort included only patients with a T-score of -2.5 or below [*id.*]. That belief was mistaken, as the cohort included patients with T-scores at or below -2.0. [A-208-14, *Boles I* Tr. 2126-52; A-926; A-981-82.]

338, Tr. 817-18], and that JAMA is "the leading medical journal in the world" [A-319, Tr. 736]. However, he accused the authors of being "deceptive" in their conclusion that Fosamax prevented fractures in patients with T-scores below -2.0. [A-344, Tr. 851.] According to Dr. Furberg, table 3 in the article, which stratified the study's results into three different subgroups based on T-score, showed that patients with a T-score between -2.5 and -2.0 did not benefit from Fosamax. [A-319-20, Tr. 736-740; A-785.] Dr. Furberg nonetheless conceded that the FDA had all of the information in the JAMA article when it approved the 1999 label change stating that FIT showed Fosamax prevented fractures in patients with T-scores below -2.0. [A-327-28, Tr. 767-73.][13]

Plaintiff also claimed, through Dr. Furberg, that the FIT data showed that even in patients with a T-score below -2.5, Fosamax stops preventing fractures after three years of use. [A-318, Tr. 733.][14] Dr. Furberg relied for this proposition on a statement in the Mucci report, as well as his own interpretation of a graph (figure 3) in the JAMA article regarding FIT. [A-321-26, Tr. 743-62; A-598, A-784.] But he offered no evidence that the FIT authors interpreted the data that

[13] Merck also presented expert testimony that FIT was not sufficiently powered (meaning not large enough) to detect statistically significant evidence of fracture reduction in each of the subgroups, and that the study's overall finding regarding fracture risk reduction should therefore be applied to each of the subgroups. [A-375-76, A-412, Tr. 1111-15, 1464-65.]

[14] Plaintiff had been using Fosamax for more than three years at the time of her injury.

way, and he conceded that the FDA did not interpret the data that way, as was evident from the fact that the 1999 FDA-approved label did not recommend discontinuation of use after three years. [A-328, Tr. 770-73.] In any event, Merck demonstrated that additional clinical trial data became available after 1998 showing that Fosamax continues to increase bone mineral density at both the hip and spine with longer-term use. [A-377, Tr. 1118.]

B. Fosamax and ONJ

ONJ is a condition "characterized clinically by an area of dead jaw bone that becomes exposed to the oral cavity." *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 170 (S.D.N.Y. 2009). While the parties disputed whether the scientific evidence establishes that Fosamax causes ONJ, it is undisputed that the risk of ONJ in patients who take Fosamax is small. Indeed, the district court has stated that "[b]y all estimates, the risk of developing ONJ while taking an oral bisphosphonate for osteoporosis is very small." *Id.* at 171.

Plaintiff's expert witness on ONJ was Dr. Robert Marx – the chairman of the department of oral and maxillofacial surgery at the University of Miami School of Medicine. [A-260, Tr. 196-97.] Plaintiff told the jury that Dr. Marx is one of the world's "best researchers" on ONJ and was "at the very frontline" of research on bisphosphonates and ONJ in 2003. [A-243-44, Tr. 96-97.] Notably, Dr. Marx did not testify that a risk of ONJ from Fosamax was foreseeable in September 2003.

To the contrary, although he had seen a "few" cases of Fosamax patients with ONJ as early as 2001 [A-273, A-279, Tr. 248, 275], he told the medical community in September 2003, in a letter to the editor of a medical journal, that oral bisphosphonates used for the treatment of osteoporosis had not been associated with ONJ [A-279, Tr. 276-77; A-795]. Dr. Marx also published an oral pathology textbook in 2003 in which he wrote "the most common bisphosphonates used for osteoporosis such as Fosamax are without serious bone necrosis complications." [A-277-78, Tr. 269-71; A-794.] Dr. Marx told the jury that when he published these statements to the medical community, there "was no literature out there" indicating that Fosamax might cause ONJ [A-267, Tr. 223], and that his 2003 statements accurately reflected the state of scientific knowledge on ONJ at the time:

> Q: You said [in 2003] that intravenous [bisphosphonates] had a bone death problem and Fosamax did not, right?
>
> A: Yes. At that time it was – that was the state of our knowledge at that time. And I'll stand by that.

[A-278, Tr. 273.][15]

[15] In addition to oral bisphosphonates that treat and prevent osteoporosis, the FDA has approved intravenous bisphosphonates for the treatment of cancer-related bone diseases. *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d at 170. Intravenous "bisphosphonates are prescribed in higher doses and are more potent than the ones taken orally for osteoporosis." *Id.*

It was not until after September 2003, when Dr. Marx observed additional Fosamax patients with ONJ, that he concluded that Fosamax causes ONJ. [A-260-64, Tr. 197-98, 202, 207, 210.] In reaching this conclusion, Dr. Marx theorized a "plausible mechanism" by which such causation occurs. [A-269, A-281, Tr. 233, 331.] In short, Dr. Marx claimed that Fosamax's known action of suppressing bone turnover, while "therapeutic" in other bones, can result in osteonecrosis in the jaw because the jawbone requires a greater rate of turnover in order to heal from traumatic events, such as tooth extractions or infections. [A-262, A-266, A-269, Tr. 203-04, 218-21, 233.] But Dr. Marx never testified that even this "plausible mechanism" was foreseeable in September 2003; nor could he, given his own admission about the state of scientific knowledge at that time.

C. Plaintiff's Counsel's Improper Conduct

As the district court noted, the trial was also marked by Plaintiff's counsel's "outlandish" behavior, including "the disparaging and insulting manner in which [he] treated defense witnesses and his outrageous behavior and accusations in summation." [SPA-133, SPA-137.] In the words of the district court, counsel was "rude" to defense witnesses and treated them "with scorn and derision." [SPA-137.] In addition, despite repeated warnings throughout the trial that his conduct was inappropriate, counsel went on to deliver what Judge Keenan described as the most "outrageous" summation that he had seen in his 50-year career. [A-454-55,

Tr. 1756-57; *see also id.* ("I don't put statements like that on the record loosely.").] According to the district court, counsel "created a sideshow of conspiracy theories, joked at the expense of defense witnesses, and was admittedly 'fooling around' and 'making fun,'" all as part of a "theatric" closing argument that "crossed the line between zealous advocacy and inappropriate behavior." [SPA-138-39.] The district court noted the following examples:

- Counsel attacked Merck's specific-causation expert, Dr. Robert Glickman, as "the so-called 'guy who knows nothing about bisphosphonate-related ONJ.' Rather than solely focusing on the substance of the expert's testimony," counsel "made fun of the manner in which it was conveyed, referring to Dr. Glickman's use of slides during direct testimony as a 'dog and pony show' in which he 'read[] from the board' using 'his fancy flashcards,' and telling the jury that he would 'bet dollars to doughnuts that Dr. Glickman didn't read those medical records." [SPA-139; A-432, Tr. 1671-72.]

- Counsel "also mocked the testimony of Dr. Anne de Papp, a Merck doctor." [SPA-139.] During her direct examination, Dr. de Papp "commented as an aside that she recently had observed an elderly woman on the local commuter train who she believed suffered from osteoporosis based on the woman's hunched posture." [*Id.*] Counsel "attack[ed] this insignificant background testimony," asking the jury sarcastically, "But she can diagnose fractures riding the subway. Is it the A train? Or is it the number 4 train? Is it going uptown? Or is it going downtown? Is it in Russia? Do you have to have your coat on? Don't you have to take your coat off?" [*Id*; A-436, Tr. 1688.]

- Counsel also "vilified Dr. [John] Bilezikian," Merck's expert witness on osteoporosis, as part of an alleged "conspiracy to scare people into believing that they will die from osteoporosis unless they take Fosamax." [SPA-142-43.] Counsel "called Dr. Bilezikian an 'industry mouthpiece' that 'travels the world' as part of a 'dog and pony show' to 'sell more pills.' He theorized that Dr. Bilezikian could benefit from a 'theme song,' singing: 'Fosamax, Fosamax, every day. Take one every day and

keep your brittle bones away." [SPA-143; A-435, Tr. 1683.]

- Counsel mocked Merck's conduct as synonymous with membership in the "Flat Earth Society," and he used a demonstrative exhibit on-screen during his closing argument that contained a single word "**HYPOCRISY**" in bold, capitalized letters. [A-433-35, Tr. 1678-79, 1682, 1684; SPA-140.] The district court called counsel's "Flat Earth Society" reference "[h]is most gratuitous gag." [SPA-140.] And the court described the "HYPOCRISY" demonstrative as "a superfluous visual aid for his slant on the conduct of Merck and defense counsel." [*Id.*]

- Counsel described Merck's relationship with the FDA as "incestuous" and suggested that Merck and other drug companies essentially bribe the FDA to approve their products. [SPA-140-41 (noting statements that FDA "gives cursory reviews and expedited approvals of new drug applications 'in exchange' for funding"); A-434-35, Tr. 1680-82, 1686.]

- Counsel emphasized Merck's economic condition, creating "a baseless conspiracy theory to the effect that Merck knew that Fosamax provides no benefit to osteopenic users, but sought to convince that class of patients that treatment was necessary in order to sell more pills and, in turn, make more money." [SPA-142.] Indeed, Mr. Douglas used some variation of the phrase "sell more pills" eleven times in summation. [A-430, A-432-33, A-435-36, A-440, Tr. 1663, 1664, 1666, 1674, 1678, 1683, 1688, 1705.]

- Counsel referred to other matters not supported by the evidence, including a slide suggesting that Merck employee Dr. Kimmel knew of a report of ONJ as early as 1999 despite the fact that "there was no [such] testimony." [SPA-141.]

- Counsel "insidiously sought to inject" punitive-damages issues into his closing argument despite their exclusion from trial. [SPA-89.] He referred to Merck's conduct as "reprehensible" and "disgusting," [SPA-91-92; A-440, Tr. 1704] and asked the jury rhetorically: "Makes your blood boil, huh?" [A-435, Tr. 1685.]

After the trial, Judge Keenan issued a four-page order to show cause listing nine separate categories of improper trial conduct, and he ultimately sanctioned Plaintiff's counsel for his conduct, explaining that counsel's summation improperly raised the issue of punitive damages. [SPA-89-94, SPA-98.] Nonetheless, the district court denied Merck's motion for a new trial, finding that: (1) counsel's misconduct did not directly bear upon "key evidence," which was sufficient to support the verdict; (2) counsel's conduct was so palpably outrageous that it would have been "difficult [for the jury] to take him seriously"; and (3) the court's curative instructions diminished any prejudice. [SPA-145, SPA-147.]

SUMMARY OF THE ARGUMENT

1. The district court erred in denying Merck judgment as a matter of law. Under Florida law, Merck could not be held liable in design defect unless Plaintiff proved, with expert evidence, that the alleged risk of harm was foreseeable at the time of the Plaintiff's injury. Plaintiff did not do so. To the contrary, Plaintiff's own expert affirmatively testified that the risk of ONJ was not yet foreseeable by the time Plaintiff developed her injury. And the district court's identification of other evidence in the record as supposed support for the jury's verdict could not stand in lieu of the necessary expert testimony.

2. The district court erred in refusing to instruct the jury that it should consider the benefits of Fosamax to the population as a whole, as opposed to

Plaintiff or some subset of Fosamax patients. As this Court recently held in *Secrest v. Merck, Sharp & Dohme Corp.*, Florida law is clear that the risk-utility test is an objective one. Here, an instruction to that effect was necessary in light of Plaintiff's counsel's repeated assertions that Fosamax was defective because it offered no benefit to Plaintiff specifically. Indeed, the district court has recognized as much in subsequent Fosamax trials also applying Florida law.

3. The district court abused its discretion in allowing Plaintiff to use the Mucci document because it was hearsay and did not qualify for the public-records exception to the hearsay rule. The district court's conclusion that the document was a final FDA statement was clearly erroneous, particularly in light of the fact that the FDA-approved labeling for Fosamax contradicted the document's conclusions. The erroneous admission of the document greatly prejudiced Merck because it enabled Plaintiff to claim (falsely) that the FDA supported her view that Fosamax offered no benefit to patients like her.

4. The district court also abused its discretion in refusing to grant a new trial despite the conduct of Plaintiff's counsel – conduct that the district court itself acknowledged was both "outrageous" and sanctionable. The repeated and extreme nature of counsel's conduct – coupled with the circumstances of the swift and excessive verdict after a long and closely contested trial – establish the prejudicial and incurable nature of the conduct and necessitate a new trial.

STANDARDS OF REVIEW

A district court's denial of a motion for judgment as a matter of law is reviewed *de novo*. *Sanders v. NY City Human Res. Admin.*, 361 F.3d 749, 755 (2d Cir. 2004). A defendant is entitled to judgment as a matter of law if "no reasonable juror could have returned a verdict for the plaintiff" based on the evidence presented at trial. *Zeno v. Pine Plains Cent. School Dist.*, __ F.3d __, 2012 WL 5992147, at *6 (2d Cir. Dec. 3, 2012). Although the evidence is reviewed in the light most favorable to the opposing party, a jury's verdict cannot stand if it could have been based on nothing more than "sheer surmise," *Bucalo v Shelter Island Union Free Sch. Dist*, 691 F.3d 119, 127-28 (2d Cir. 2012) (internal quotation marks and citation omitted), or "pure guess-work," *Doctor's Assocs., Inc. v. Weible*, 92 F.3d 108, 112 (2d Cir. 1996), *cert. denied*, 519 U.S. 1091 (1997).

A district court's jury instructions are reviewed *de novo*. *Sanders*, 361 F.3d at 758. Any error in instructing the jury warrants a new trial if the error left the jury with "a misleading impression or inadequate understanding of the law." *Fidelity & Guar. Ins. Underwriters, Inc. v. Jasam Realty Corp.*, 540 F.3d 133, 139 (2d Cir. 2008) (citation omitted).

A "district court's evidentiary rulings are reviewed for abuse of discretion." *Ret. Plan of UNITE HERE Nat'l Ret. Fund v. Kombassan Holding A.S.*, 629 F.3d 282, 287 (2d Cir. 2010). A "[d]istrict court necessarily abuses its discretion when

its decision rests on an error of law," *Somoza v. New York City Dep't of Educ.*, 538 F.3d 106, 112 (2d Cir. 2008), or "cannot be located within the range of permissible decisions." *Bryant v. New York State Educ. Dep't*, 692 F.3d 202, 210 (2d Cir. 2012) (internal quotation marks and citation omitted). Erroneously admitted evidence is not "harmless" unless the reviewing court can conclude that "the evidence was unimportant in relation to everything else the jury considered on the issue in question" and "did not substantially influence the jury." *Cameron v. City of New York*, 598 F.3d 50, 61 (2d Cir. 2010).

Similarly, "the district court's determination as to whether counsel's improper conduct caused prejudice is reviewed under the traditional abuse of discretion standard." *Pappas v. Middle Earth Condo. Ass'n*, 963 F.2d 534, 540 (2d Cir. 1992).

ARGUMENT

I. MERCK WAS ENTITLED TO JUDGMENT AS A MATTER OF LAW BECAUSE PLAINTIFF DID NOT PRESENT SUFFICIENT EVIDENCE FROM WHICH A REASONABLE JURY COULD HAVE CONCLUDED THAT FOSAMAX PRESENTED A FORESEEABLE RISK OF ONJ IN SEPTEMBER 2003.

First, the district court erred in denying Merck judgment as a matter of law. Plaintiff had the burden of proving that it was foreseeable by the date of her injury in September 2003 that Fosamax can cause ONJ. Despite the fact that such a showing necessarily entailed a complex medical analysis well beyond the capacity

of a lay jury, Plaintiff offered no expert testimony that such a link was foreseeable by September 2003. To the contrary, her proffered ONJ expert, Dr. Marx, affirmatively testified that the "state of our knowledge" in September 2003 was that Fosamax did not cause ONJ. [A-278, Tr. 273.] This conclusion was unsurprising: as of September 2003, Fosamax had been studied clinically in 17,000 patients without a single confirmed report of exposed, dead bone in the jaw or any other indication that Fosamax caused jaw bone to die. [A-380, A-382, Tr. 1134-35, 1144-45.] Further, by September 2003 Fosamax had been taken by millions of women worldwide with no reports of ONJ. [A-352, A-357, Tr. 969, 988-89.] Thus, Dr. Marx's statement stood undisputed by any other expert, and the jury was left with but one reasonable conclusion to reach: ONJ was not a foreseeable risk of Fosamax at the time of Plaintiff's claimed injury, and Merck was entitled to a verdict in its favor.

The jury did not reach that conclusion, however, and the district court did nothing to correct its error. Instead, the district court held that the jury's foreseeability finding could have rested on fragmentary facts that no expert had opined were sufficient to make a risk of ONJ foreseeable to Merck (or anyone else) in 2003. That holding was wrong.

Foreseeability is an essential component of both negligence- and strict-liability-based design-defect claims under Florida law. As the district court

acknowledged, Plaintiff had to prove that injury was foreseeable in order to show that Fosamax was a proximate cause of her injury for purposes of her negligence claim. [SPA-120-21.] The same is true with respect to Plaintiff's strict-liability claim. Florida courts have been clear that strict liability will lie only as to "those risks which are discoverable in light of the '*generally recognized and prevailing best*' knowledge available." *Ferayorni v. Hyundai Motor Co.*, 711 So. 2d 1167, 1172 (Fla. Dist. Ct. App. 1998) (emphasis in original).[16]

Importantly, Plaintiff was required to prove "foreseeability" with expert testimony. *See, e.g.*, *Benedict v. Zimmer, Inc.*, 405 F. Supp. 2d 1026, 1033 (N.D. Iowa 2005) ("Whether the device had a design defect, whether the foreseeable risks of harm the device posed could have been reduced or avoided by the adoption of a reasonable alternative design and whether the omission of such design rendered the device not reasonably safe are technical, scientific issues that cannot be fully understood by the average juror without some expert assistance."). This is so because prescription medications are "complex" products, "esoteric in formula and varied in effect." *Plummer v. Lederle Labs.*, 819 F.2d 349, 356 (2d Cir. 1987) (internal quotation marks and citation omitted). Accordingly, "[w]hat a drug

[16] *Ferayorni* addressed failure-to-warn claims, but the same reasoning would apply to design-defect claims, even though the district court found that Florida law is "not particularly clear" on this point. [SPA-122.] Any other rule would "reduce[] [manufacturers] to insurers," *Ferayorni*, 711 So. 2d at 1172, faced with potential liability for all unforeseeable risks of pharmaceutical products.

manufacturer knew or should have known . . . must [be] establish[ed] by expert testimony." *Giles v. Wyeth, Inc.*, 500 F. Supp. 2d 1063, 1067 n.4 (S.D. Ill. 2007); *see also, e.g.*, *Ins. Co. of the West v. Island Dream Homes, Inc.*, 679 F.3d 1295, 1298 (11th Cir. 2012) (Florida law requires expert testimony for matters "beyond the understanding of the average juror"); *Olivier v. Robert L. Yeager Mental Health Ctr.*, 398 F.3d 183, 190 (2d Cir. 2005) ("without expert assistance a jury will often have no understanding of what constitutes reasonable behavior in a complex and technical profession such as medicine") (internal quotation marks and citation omitted).[17] Otherwise, a jury would be "force[d] . . . to engage in speculation and conjecture on issues of defect and causation." *Hughes v. Stryker Sales Corp.*, 2010 WL 1961051, at *5 (S.D. Ala. May 13, 2010), *aff'd*, 423 F. App'x 878 (11th Cir. 2011).

That is exactly what happened here. The only relevant expert testimony proffered by Plaintiff rejected the notion that the alleged risks of Fosamax were foreseeable in September 2003. Dr. Marx stated *twice* in 2003 that oral bisphosphonates like Fosamax are not associated with ONJ and bone

[17] *See also, e.g.*, *Wilson v. Taser Int'l., Inc*., 303 F. App'x 708, 715 (11th Cir. 2008) ("the inference that a shock by a TASER can and did cause compression fractures in David Wilson's spine is not a natural inference that a juror could make through human experience . . . [so] medical expert testimony is essential to prove causation in this case"); *Allison v. McGhan Med. Corp*., 184 F.3d 1300, 1320 (11th Cir. 1990) ("That breast implants can and did cause systemic disease in Allison is not a natural inference that a juror could make through human experience[,] . . . [so] medical expert testimony was essential to prove causation in this case.").

complications [A-277-79, Tr. 269-277], and he reaffirmed these statements at trial, testifying that they were based on "the state of our knowledge at the time," and that he would "stand by" them [A-278, Tr. 273]. Although he later testified about a "plausible mechanism" by which Fosamax could cause ONJ, he never suggested that this "plausible mechanism" was foreseeable in 2003 or contradicted his prior statements about the state of scientific knowledge at the time. Thus, Plaintiff failed to present evidence that Merck should – or even could – have known before 2003 that Fosamax could cause ONJ based on the state of scientific knowledge.[18] On that basis, notwithstanding the district court's observation that foreseeability is usually a jury question [A-1216], Merck was entitled to judgment as a matter of law, *see, e.g.*, *Satchwell v. LaQuinta Motor Inns, Inc.*, 532 So. 2d 1348, 1350 (Fla.

[18] For this reason, the district court would have still erred even if it were correct in intimating that Merck bore the burden of proof on foreseeability as to Plaintiff's strict-liability claim. [*See* A-1215-18.] After all, the only expert evidence on foreseeability was that ONJ was not a foreseeable risk of Fosamax at the time of Plaintiff's injury. The jury was not free to disregard such unrebutted evidence, particularly since the contrary conclusion – that a risk *was* foreseeable – would be a complex matter of science that is not within a lay jury's province to determine without the assistance of an expert. *See, e.g.*, *Cruz-Vargas v. R.J. Reynolds Tobacco Co.*, 348 F.3d 271, 277 (1st Cir. 2003) (jury is not free to disregard evidence that is "neither improbable nor contradicted," particularly when it is expert testimony that bears on complex issues "beyond the competence of lay determination") (internal quotation marks and citation omitted), *cert. denied*, 543 U.S. 959 (2004); *cf. Tolbert v. Queens College*, 242 F.3d 58, 70-71 (2d Cir. 2001) (on a Rule 50 motion, "the court should give credence to the evidence favoring the nonmovant as well as that evidence supporting the moving party that is uncontradicted and unimpeached, at least to the extent that that evidence comes from disinterested witnesses") (citation omitted).

Dist. Ct. App. 1988) (affirming directed verdict where the plaintiff failed to proffer any expert evidence on foreseeability and failed to demonstrate how prior incidents were sufficient to give the defendant constructive knowledge of the risk; where "the basic underlying facts" on foreseeability are undisputed and "those facts point to but one possible conclusion, . . . the issue of foreseeability may be decided by the court as a matter of law").

In denying Merck's motion for judgment as a matter of law, the district court scoured the record for other potential evidence of foreseeability and pointed to: (1) the observation by FDA officers in 1999 that Fosamax suppresses bone turnover; (2) a 2006 internal Merck email theorizing that Fosamax may impede healing in the jaw; (3) Merck's receipt of adverse event reports referring to complications *other* than ONJ; and (4) a 1981 study documenting the development of ONJ in rats. But none of this constitutes the requisite expert evidence needed to prove foreseeability – particularly in the face of Dr. Marx's express statement that a risk of ONJ was not foreseeable.

The district court first cited the observation of FDA officers in 1999 that biopsy data showed that Fosamax "suppress[es] bone turnover in patients by 94%, and by 98% when combined with estrogen therapy." [SPA-122.][19] But Plaintiff

[19] Bone turnover is the process by which old bone is removed ("resorbed") and replaced by new bone. [A-552.] Osteoporosis "is most common among women following the menopause, when bone turnover increases and the rate of bone

offered no evidence that mere knowledge of the fact that Fosamax suppressed bone turnover made it foreseeable as a scientific matter that Fosamax could cause ONJ. Indeed, Dr. Marx expressly testified that the "state of our knowledge" in 2003 was that Fosamax *does not* cause ONJ [A-278, Tr. 273] – notwithstanding the facts that Fosamax's label has *always* stated that Fosamax suppresses bone turnover and that the biopsy data had been discussed in Fosamax's label and in the literature by 1999 [A-379, A-390, A-397, Tr. 1132, 1186, 1189, 1247; A-552, A-712-13, A-717, A-787].[20] In other words, Fosamax's effect on bone turnover had been known to the entire scientific community for years by 2003, but no one – not Dr. Marx or anyone else – had viewed that link as portending an as-yet undiscovered risk of ONJ by then. As other courts have explained in similar circumstances, a faint hint of risk does not make that risk foreseeable when "the generally accepted view on the part of the relevant scientific communities was that" no such risk exists. *Coley v. Commonwealth Edison Co.*, 768 F. Supp. 625, 629-30 (N.D. Ill. 1991) (risks of radiation were not foreseeable despite the fact that "accepted theories were or are being drawn into question by a few controversial scientists and theorists").

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resorption exceeds that of bone formation," resulting "in progressive bone loss." [*Id.*; *see also* A-367-69, Tr. 1072-79.]

[20] The 1999 Fosamax label stated that, "[c]ompared to placebo, there was a 98% suppression of bone turnover (as assessed by mineralizing surface) after 18 months of combined treatment with FOSAMAX and HRT, 94% on FOSAMAX alone, and 78% on HRT alone." [A-713.]

The district court relatedly claimed that "Merck's own employee, Dr. Kimmel, a bone biologist, theorized that Fosamax's effect of reducing bone turnover could reduce the jaw's ability to heal," citing a 2006 e-mail that supposedly reflected earlier knowledge. [SPA-123.] According to the court, Dr. Kimmel "acknowledged" that Merck and "the scientific community" had sufficient information to make a "connection between Fosamax and ONJ" before September 2003. [*Id.*] But this conclusion simply restates the court's view that knowledge of Fosamax's effect on bone turnover was itself sufficient to make ONJ a foreseeable consequence of Fosamax use. As just explained, no expert evidence in the record supports this leap. Certainly Dr. Kimmel never testified to this effect [*see generally* A-482-526 (setting forth the portion of Dr. Kimmel's deposition that was played at trial)]; and the only reasonable reading of Dr. Marx's testimony is that he would reject such a conclusion as well.

The district court next suggested that ONJ was a foreseeable risk of Fosamax by September 2003 because by that time, Merck had received a handful of adverse event reports ("AERs") regarding Fosamax patients experiencing oral or dental complications, such as "exostosis," "torus," and "xerostomia." [SPA-123-24; A-346, 357, 561, 566, 578, 603, 723-25; A-279-38, Tr. 919, 987-88.] But there were no AERs by September 2003 that mentioned ONJ specifically [A-357, Tr. 988-89], and the record is once again bereft of any expert testimony embracing the

conclusion that an AER reporting exostosis or other complications made the risk of ONJ foreseeable. Indeed, Plaintiff's designated ONJ expert, Dr. Marx, did not even mention AERs. Her "regulatory expert," Dr. Parisian, did, but she did not testify that the AERs made a risk of ONJ foreseeable. Instead, she testified that the terms "exostosis" and "torus" mean "bone growth," not "bone death," and that such growths occur "commonly" in the human mouth. [A-352-54, Tr. 970-75.][21] None of this sufficed. As one court has explained, AERs that report about one risk do not make another potentially related risk foreseeable unless expert testimony supplies the missing link. *See Staub v. Breg, Inc.*, 2012 WL 1078335, at *7-9 (D. Ariz. Mar. 30, 2012) (AERs alone did not establish foreseeability where they only mentioned a different type of injury that the plaintiff claimed could be "equate[d]" to her injury in the absence of "expert testimony to support" this claim).

The district court believed that such expert testimony was unnecessary here because a Merck scientist, Dr. Goldberg, testified at a 2008 deposition that based on the symptoms described in *one* of the exostosis AERs, that AER "could" have been a case of ONJ. [SPA-124, A-478.] But Dr. Goldberg was testifying based on his knowledge as of 2008, not 2003, and neither he nor anyone else testified that

[21] *See also* B. Neville, *Oral and Maxillofacial Pathology* 19 (3d ed. 2009) ("Exostoses are localized protuberances that arise from the cortical plate. These benign growths frequently affect the jaws."); *Davis v. Astrue*, 2008 WL 4589754, at *2 n.2 (S.D. Tex. Oct. 14, 2008) ("An 'exostosis' is a 'benign bony growth projecting outward from the surface of a bone.'") (quoting *Dorland's Illustrated Medical Dictionary* 634 (29th ed. 2000)).

the single exostosis AER made it foreseeable in 2003 that Fosamax presented a risk of ONJ. Again, the record demands the opposite conclusion. After all, Dr. Marx had seen not mere exostosis but true ONJ in a "few" Fosamax patients by September 2003 [A-273, A-279, Tr. 248, 275], but he nonetheless told the medical community that oral bisphosphonates had not been linked with ONJ [A-277-79, Tr. 269-71, 276-77]. If one of the "best researchers in the country," who was "at the very frontline" of research on bisphosphonates and ONJ [A-243-44, Tr. 96-97] did not foresee a link between Fosamax and ONJ even after seeing a few Fosamax patients with *actual ONJ*, no reasonable lay jury could have found that a single report of exostosis made it foreseeable that Fosamax presented a risk of ONJ.

The district court finally stated that the jury could have concluded that Fosamax presented a foreseeable risk of ONJ before September 2003 because a 1981 study in the Journal of Periodontal Research found that rats with periodontal disease developed ONJ when given high doses of clodronate, a first-generation bisphosphonate. [SPA-124.] But a lay jury is incapable of extrapolating the findings of animal studies to humans without the assistance of expert testimony, *see, e.g.*, *Toni's Alpacas, Inc. v. Evans*, 2010 WL 3730382, at *4 (D. Colo. Sept. 16, 2010) ("[e]xtrapolation from existing animal studies to other species or to humans" requires "evidence that the proposed extrapolation is warranted scientifically"), and Plaintiff presented no expert testimony that the 1981 rat study

showed that clodronate, let alone Fosamax, presented a foreseeable risk of ONJ in humans. To the contrary, the jury heard that clodronate "works by a very different mechanism than Fosamax" because it does not contain nitrogen [A-403, Tr. 1287-88], and Dr. Marx testified that he thinks it is the nitrogen-containing bisphosphonates, such as Fosamax, that cause ONJ [A-261, Tr. 198].

In sum, none of the evidence the district court cited in denying Merck's motion for judgment as a matter of law provided a reasonable basis for the jury's conclusion that Fosamax presented a foreseeable risk of ONJ in September 2003. As a result, Merck is entitled to judgment as a matter of law on Plaintiff's design-defect claims.

II. ALTERNATIVELY, MERCK IS ENTITLED TO A NEW TRIAL.

Even if the district court properly rejected Merck's motion for judgment as a matter of law, Merck would be entitled to a new trial on three independent grounds: (1) the jury was improperly instructed on Plaintiff's design-defect claims; (2) the court should have excluded inadmissible hearsay evidence that played a prominent role in Plaintiff's case; and (3) Merck was entitled to a new trial based on the "outrageous" misconduct of Plaintiff's counsel.

A. The District Court Erred In Refusing To Instruct The Jury To Consider Fosamax's Benefits To All Patients.

The district court improperly instructed the jury regarding Florida's risk-benefit test because it failed to specify, as requested by Merck, that the jury should

consider the benefits of Fosamax to the population as a whole. Notably, in later Fosamax trials involving Florida plaintiffs, the district court *did* adopt Merck's proposed instruction, thus implicitly recognizing its error here. And this Court recently held that the district court's subsequent instruction was proper under Florida law. *Secrest v. Merck, Sharp & Dohme Corp.*, 2013 WL 335987, at *1-2 (2d Cir. Jan. 30, 2013) (per curiam) (summ. order) (upholding verdict for Merck and rejecting plaintiff's challenge to jury instructions; the court's instruction properly clarified that Florida "employ[s] an 'objective' standard for the risk-benefit test").[22] Particularly given the focus of Plaintiff's case, this error was significant and almost certainly affected the verdict.

Throughout the trial, Plaintiff's primary theory of liability was that Fosamax "is defectively designed for women who have her T-scores." [A-433, Tr. 1678.] Consistent with that theory, Plaintiff and her counsel repeatedly suggested that the

[22] The *Secrest* ruling is a summary order and thus generally does not have precedential effect. *See* 2d Cir. R. 32.1.1(a). But as this Court has explained, the rationale for Rule 32.1.1 is that summary orders "frequently do not set out the factual background of the case in enough detail to disclose whether its facts are sufficiently similar to those of a subsequent unrelated case to make our summary ruling applicable to the new case." *Jackler v. Byrne*, 658 F.3d 225, 244 (2d Cir. 2011). That concern is not present here. This case and *Secrest* arise from the same underlying multidistrict litigation and involve identical claims of design defect under the same state's law, against the same defendant, and with respect to the same drug. In other words, this is not a "subsequent *unrelated* case," and the Court should treat *Secrest* as binding, particularly since a contrary holding in this case would send conflicting signals to the district court concerning the conduct of future Fosamax trials.

jury should consider only the risks and benefits to persons exactly like Plaintiff, not the risks and benefits to other patients generally. [A-245, A-318, A-433, A-437, Tr. 103, 730-31, 733, 1678, 1691-92.] In light of this repeated misstatement, Merck asked the district court to instruct the jury that Florida's risk-benefit test "consider[s] not only the benefits to the Plaintiff, but also the overall usefulness and benefits to the public as a whole." [A-991.] The district court refused Merck's request [A-419, A-451-52, Tr. 1619, 1744-45] and instead instructed the jury only that a "drug is unreasonably dangerous if the risks of the drug outweigh its benefits." [A-448, Tr. 1732.] This instruction was erroneous because it left the jury with the false impression that Merck was liable for design defect if the risks of Fosamax to Plaintiff outweighed the benefits that the drug provided to her specifically.

Under Florida's risk-benefit test, the plaintiff has the burden of proving "that the risk of danger in the [product's] design outweighs its benefits." *See, e.g.*, *Martin v. JLG Indus., Inc.*, 2007 WL 2320593, at *3 (M.D. Fla. Aug. 10, 2007). As a matter of Florida law, the risk-benefit test is an "objective" one, meaning that the question whether a product's benefits outweigh its risks should be answered with respect "to the public as a whole," rather than just the plaintiff. *Secrest*, 2013 WL 335987, at *2 (citing *Jennings v. BIC Corp.*, 181 F.3d 1250, 1255 (11th Cir. 1999) (the "defectiveness of a design is determined based on an objective standard,

not from the viewpoint of any specific user"), and *Liggett Grp., Inc. v. Davis*, 973 So. 2d 467, 475 (Fla. Dist. Ct. App. 2007) (same)).

In its post-trial order, the district court indicated that it had rejected Merck's proposed jury instruction out of concern that Merck was "urg[ing]" application of the risk-benefit test adopted in the Restatement (Third) of Torts: Products Liability § 6(c). [SPA-116-18.] According to the district court, Florida courts have "shown no apparent interest in adopting" the Restatement (Third) standard and instead generally follow the Restatement (Second) test. [*Id*.] In fact, however, Merck's proposed instruction was consistent with the Restatement (Second) standard, which considers the utility of a product to the public as a whole, not just to the plaintiff. *See Secrest*, 2013 WL 335987, at *1 (rejecting argument that Merck's requested instruction adopted "the approach in the Restatement (Third) of Torts").

By contrast, under the Third Restatement, a prescription drug or medical device is defectively designed only if the product's risks so outweigh its benefits that a reasonable physician, knowing of the risks and benefits, "would not prescribe the drug or medical device *for any class of patients*." RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c) (emphasis added). In other words, the Third Restatement standard "presents a narrower scope of tort liability for prescription drug manufacturers than the objective standard urged by Merck," as the district court later recognized, since the Third Restatement "approach would

permit a drug manufacturer to avoid liability on a defective-design claim *even if the overall* risks of a drug outweigh the benefits of that drug, so long as there is *some* class of patients for whom the benefits outweigh the risks." [A-1212 (emphasis added).] As set forth above, that is not the approach Merck advocated. Instead, Merck's proposed instruction directed the jury to consider Fosamax's "overall risks and benefits to the public as a whole."

Even the district court appears to recognize that it erred in refusing to adopt Merck's proposed jury instruction. The district court subsequently oversaw two more Fosamax trials involving Florida plaintiffs – *Graves* and *Secrest*. At the conclusion of both trials, Merck requested – and the district court gave – the following jury charge on the issue of design defect under Florida law:

> A product is defectively designed if the product is in an unreasonably dangerous condition and the product is expected to and does reach the user without substantial change affecting that condition. A prescription drug is unreasonably dangerous if the risks of the drug outweigh its benefits. In determining whether the risk of danger outweigh[s] the benefits, you should consider the feasibility of an alternative safer design given the scientific and technical knowledge that existed at the time of manufacture; that is, in this case prior to [the date of plaintiff's injury]. *You should consider not only the benefits and risks to plaintiff, but also the overall risks and benefits to the public as a whole.*

See 6 Joint App'x, ECF No. 73, at 1547, *Graves v. Merck & Co., Inc.*, No. 10-4875 (2d Cir. Aug. 2, 2011) (emphasis added); *see also* 7 Joint App'x, ECF No. 150-2,

at 1946, *Secrest*, No. 11-4358 (2d Cir. June 6, 2012) (same). Indeed, as this Court just held in affirming *Secrest*, the district court's later approach properly reflected the "objective" standard of the Restatement (Second). *Secrest*, 2013 WL 335987, at *2 & n.1 (explaining that the Court could not find any decision applying Florida law that "limited the jury's consideration" to "a particular user or a subcategory of users" despite the district court's prior "reject[ion] [of] the language of the 'objective' standard"). The district court should have done the same here, and because it did not, Merck is entitled to a new trial in which the jury is properly instructed. *See Sanders*, 361 F.3d at 758 ("[a]n instruction that improperly instructs the jury on whether the plaintiff has satisfied her burden of proof is generally not harmless").

B. The District Court Abused Its Discretion In Admitting The Mucci Report Because The Report Was Not A Final Finding Of The FDA.

Merck is also entitled to a new trial because the district court abused its discretion in admitting the Mucci report, an unsigned internal FDA document authored by an FDA statistician, that was central to Plaintiff's theory that Fosamax only shows fracture reduction efficacy in patients with a T-score below -2.5. Because the Mucci report's findings did not reflect the final views of the FDA (indeed, it contradicted them), the unsigned report was inadmissible hearsay. And

because it formed an essential part of Plaintiff's presentation, admission of the report caused clear prejudice to Merck, necessitating reversal.

1. The Mucci Report Was Inadmissible Hearsay.

Under former Fed. R. Evid. 803(8)(C),[23] "a report is not excluded by the hearsay rule if it sets forth 'factual findings resulting from an investigation made pursuant to authority granted by law, unless the sources of information or other circumstances indicate a lack of trustworthiness.'" *Ariza v. City of New York*, 139 F.3d 132, 134 (2d Cir. 1998) (quoting Fed. R. Evid. 803(8)(C)). It is well established that this exception to the hearsay rule does not apply to *all* reports or findings by a government employee, but only to a "*final* report or findings of a government agency." *City of New York v. Pullman Inc.*, 662 F.2d 910, 914 (2d Cir. 1981) (emphasis added). As one court explained the reasoning for these distinctions:

> [The Rule 803(8)(C)] exception is grounded on assumptions about the reliability of the public agencies usually conducting the investigation, and their lack of any motive for conducting the studies other than to inform the public fairly and adequately . . . . Consequently, this presumption typically does not apply to render hearsay admissible where the findings are merely proposed, tentative or second-hand.

Appleby v. Glaxo Wellcome, Inc., 2005 WL 3440440, at *3 (D.N.J. Dec. 13, 2005) (internal quotation marks and citations omitted).

[23] This Rule has since been renumbered Fed. R. Evid. 803(8)(A)(iii).

Merck moved in limine to exclude the Mucci analysis as inadmissible notwithstanding this exception to the hearsay rule. As Merck explained, the unsigned report was not "final" and thus did not qualify as a public record. [*See* A-133-35.] Indeed, the FDA implicitly rejected the report when it later approved the 1999 labeling for Fosamax that asserted efficacy in patients with T-scores below -2.0. Nonetheless, the district court found "no indication that the review . . . is tentative or subject to revision." [SPA-9, Tr. 490.] The court cited three facts that it found indicative of the report's finality: (1) the report "was obtained directly from the FDA, specifically references the Fosamax NDA file, and every page is stamped FDACDER"; (2) two doctors "concurred" with the report's results and "copies were sent to other FDA officials who worked on the Fosamax application"; and (3) Dr. Santora, Merck's director of clinical research, "corroborate[d] the trustworthiness of the [Mucci report's] analysis and findings." [*Id.*]

None of these considerations converted Dr. Mucci's analysis from inadmissible hearsay into a final statement of the FDA. *First*, the mere fact that the report was "obtained directly from the FDA" is hardly suggestive of finality. The law is clear that the "positions and opinions of individual staff members" – as opposed to the government agency that employs them – do not satisfy the Rule 803(8)(C) hearsay exception. *Smith v. Isuzu Motors Ltd.*, 137 F.3d 859, 862 (5th Cir. 1998), *cert. denied*, 525 U.S. 1142 (1999); *In re September 11 Litig.*, 621 F.

Supp. 2d 131, 155 (S.D.N.Y. 2009) ("Staff Monographs and Staff Statements" that "inform[ed] the development of [the Commission's] recommendations" were not admissible pursuant to 803(8)(C) because they "were findings of the Commission's staff, and not a public office or agency"). Thus, courts routinely hold that an agency's "tentative or interim" findings do not fall under Rule 803(8)(C), particularly where – as here – those findings reflect the views of individual staff members that are not adopted by the agency. *See Pullman*, 662 F.2d at 914 (staff report did not fall under Rule 803(8)(C) where agency's administrator "did not accept the recommendation of the staff report"); *Smith*, 137 F.3d at 862 ("positions and opinions of individual staff members, which the agency ultimately declined to accept" did "not satisfy Rule 803(8)(C)").

In *Toole v. McClintock*, 999 F.2d 1430 (11th Cir. 1993), for example, the Eleventh Circuit reversed the district court's denial of a defendant's motion for a new trial in a product-liability action involving allegedly defective breast implants. The district court had permitted the plaintiff to use an FDA document under Rule 803(8)(C) that proposed that the agency "require pre-market approval for silicone-gel filled breast prostheses . . . [and] also stated the agency's 'proposed findings' on risks posed by the devices." *Id.* at 1433-34. Specifically, "[t]he report said that FDA thought human carcinogenicity and autoimmune disease to be among the 'significant risks' of implants." *Id.* at 1434. The plaintiffs had relied on this

finding at trial to corroborate the testimony of a key expert witness, who provided "[t]he only evidence" to support plaintiffs' contention that Ms. Toole "is at increased risk for cancer and immune system diseases" as a result of her implantation. *Id.* at 1434 n.9. The Eleventh Circuit reversed, explaining that the document "contained only 'proposed findings'" as demonstrated by "differences between the final rule report and the proposed rule report." *Id.* at 1434, 1435 n. 11. In particular, unlike the FDA's proposed findings, which described the risk of cancer and autoimmune disease as "'significant,'" the final report was "substantially more equivocal about these risks" and indicated that the "uncertainty surrounding th[e] risk [of autoimmune disease] *requires that it be investigated*." *Id.* at 1435 n.11 (quoting Final Report) (emphasis in original). Because "Rule 803 makes no exception for tentative or interim reports subject to revision or review," the court found that the report should have been excluded from trial and that the defendant was entitled to a new trial. *Id.* at 1434-35.

The same reasoning applies here. As in *Toole*, the Mucci report is "tentative or interim." Indeed, the report does not have a reviewer signature, a signature date, or a document stamped date. *See* 21 C.F.R. § 10.70(c)(2) (1998) (governing "[d]ocumentation of significant [FDA] decisions in administrative file") ("A written document placed in an administrative file must . . . [b]e dated and signed by the author."). Nor is it on the FDA's website with all other completed reviews.

[*See* A-133.][24] Moreover, as in *Toole*, where the proposed findings were contradicted by the FDA's final rule report, "which was substantially more equivocal about [the proposed] risks," *Toole*, 999 F.2d at 1435 n.11, the Mucci report's conclusions that the FIT data only demonstrated efficacy for patients with a T-score below -2.5 and is limited to three years of use were *not* formally adopted by the FDA. To the contrary, the FDA's review of the FIT data resulted in its approval of new labeling language stating that the FIT data showed Fosamax *was* effective in preventing fractures in patients at -2.0 or below, without any limitation on length of use. [A-711.] In short, the Mucci analysis was nothing more than the "position[] and opinion[] of [one] individual staff member[]" and was thus not admissible under Rule 803(8)(C). *Smith*, 137 F.3d at 862.

Second, the fact that copies of the report were seen or "concurred" in by other FDA officers is likewise immaterial. The mere review of one official's tentative report by other officials in the same agency does not convert the report into the official and final view of the agency. *Appleby*, 2005 WL 3440440 at *3 (information and recommendations considered by the FDA Gastrointestinal Drugs Advisory Committee did not constitute "final opinions by the agency" and

[24] The tentative nature of the Mucci report is also underscored by its methodological flaws. As noted above, Dr. Mucci misunderstood the FIT study's patient population, again echoing *Toole*, which noted mistakes in the FDA report at issue there. *See* 999 F.2d at 1435 n.11 (noting that various references were "miscited" in the initial report).

therefore were not admissible pursuant to the 803(8)(C) exception); *In re September 11 Litig.*, 621 F. Supp. 2d at 155 (documents prepared by Commission's staff that "inform[ed] the development of the Commission's recommendations" were "tentative judgments" that did not fall within the 803(8)(C) hearsay exception). As a logical matter, far more pertinent than the fact that two of Mucci's colleagues allegedly agreed with him is the fact that the FDA's final resolution of the issue – as reflected in the labeling it approved for Fosamax – rejected the view Mucci expressed in his report.

Third, the district court's assertion that Dr. Santora "corroborate[d] the trustworthiness of the [Mucci report's] analysis and findings" is not only factually wrong,[25] but also misapprehends the rule. For purposes of Rule 803(8)(C), finality is a prerequisite to trustworthiness, regardless whether some individual unaffiliated with the agency agrees with one of its tentative reports. *See Smith*, 137 F.3d at 862. In *Smith*, for example, the plaintiff sought to make use of tentative reports of individual officers of the National Highway Traffic Safety Administration, pointing out that the officers had used the same methodology embraced by their expert witness. *Id.* The Fifth Circuit rejected this argument on the ground that the

[25] When he was first shown the Mucci document, Dr. Santora testified that he did not recognize it or know if he had previously reviewed it. [A-146.] After thoroughly examining the Mucci document, Dr. Santora testified that it was wrong because Mucci incorrectly believed that the "osteoporotic cohort" in FIT included only patients with a T-score of -2.5 or below. [A-208-14, *Boles I* Tr. 2126-2152.]

documents lacked trustworthiness. The focus of its trustworthiness analysis was not whether the reports' analyses had been corroborated, but whether they reflected the final views of the agency: "If memoranda reflecting the preliminary opinions of agency staff members were admissible under Rule 803(8)(A), then Rule 803(8)(C)'s [trustworthiness] limitations would be meaningless." *Id.* Because the Mucci document only reported "opinions of individual staff members, which the agency ultimately declined to accept," *id.*, it should not have been admitted under Rule 803(8)(C).

2. The Error Substantially Prejudiced Merck.

The district court's erroneous admission of the Mucci report was not harmless error. Error is harmless where "the evidence was unimportant in relation to everything else the jury considered on the issue in question." *Cameron*, 598 F.3d at 61 (internal quotation marks and citation omitted). By contrast, evidentiary error likely warrants a new trial where "the testimony bore on an issue that is plainly critical to the jury's decision . . . [or] was material to the establishment of a critical fact." *Id.* (citation omitted).

Such is the case here. The Mucci report was the only document presented to the jury that explicitly questioned Fosamax's efficacy for patients like Plaintiff. Thus, the report was "plainly critical" to the jury's risk-benefit calculus. Indeed, the report played a role similar to the inadmissible report in *Toole*, where the

plaintiffs used the FDA's "tentative or interim reports," containing only "proposed findings," to bolster expert opinions that were otherwise not "generally accepted" in the medical community. 999 F.2d at 1434 & n.9, 1435. Here, for example, Dr. Furberg relied on the Mucci report to corroborate his opinions that Fosamax is only effective for patients with a T-score worse than -2.5 and should only be taken for three years, opinions that are contradicted by the relevant medical literature and the FDA's findings. [A-335-36, A-339, A-340, Tr. 803-10, 819-21, 824-26; A-784, A-786; A-798, A-805, A-711.] And counsel repeatedly referred to the Mucci analysis in summation. [A-431, A-437-39,Tr. 1667, 1669, 1692, 1697, 1699.] Thus, as in *Toole*, Plaintiff was able to argue that the FDA agreed with her position based solely on the inadmissible statements of one FDA official, resulting in substantial and unfair prejudice to Merck. 999 F.2d at 1435. For this reason, too, the Court should reverse and remand for a new trial.

C. The District Court Abused Its Discretion In Denying Merck's Motion For A New Trial Because The Jury's Verdict Was Tainted By Plaintiff's Counsel's Misconduct.

Finally, the district court abused its discretion by failing to grant Merck a new trial despite acknowledging the "outrageous" conduct of Plaintiff's counsel. Counsel's misconduct – unprecedented in the trial judge's half century of experience – plainly prejudiced Merck, as confirmed by the jury's swift and inflated verdict.

1. Counsel's Misconduct Prejudiced Merck.

Attorney misconduct at trial can take many forms: referring to matters that are not in the record; making "improper personal references" to counsel or parties; offering arguments based on "personal belief"; mischaracterizing evidence; and "engag[ing] in repeated name-calling." *Koufakis v. Carvel*, 425 F.2d 892, 903-05 (2d Cir. 1970). Plaintiff's counsel here did all of these things, and Judge Keenan stated that he had "never heard a more outrageous summation in [his] life." [A-454-55, Tr. 1756-57.] The district court also detailed counsel's various transgressions over the course of the entire trial in a nine-point order to show cause why counsel should not be sanctioned.[26] [A-1010.] The impact of counsel's misconduct on the jury was obvious: whereas the preceding trial of the same case, based on the same evidence, produced deliberations spanning five days and resulted in a mistrial after all but one of the jurors were prepared to return a verdict for Merck, the jury in this trial deliberated approximately three hours, returning with a verdict that exceeded the amount requested by Plaintiff's counsel *by $3 million*.

A new trial should have followed as a matter of course. "[W]hen the conduct of counsel in argument causes prejudice to the opposing party and unfairly

[26] The court ultimately sanctioned Plaintiff's counsel, explaining that his summation improperly injected the issue of punitive damages into the case. [SPA-89-94, SPA-98.]

influences a jury's verdict, a new trial should be granted." *Pappas*, 963 F.2d at 540. In assessing the prejudicial effect of counsel's misconduct, the court must examine the "totality of the circumstances," including "the nature of the comments . . . their frequency . . . the strength of the case[,] and [] the verdict itself." *Granfield v. CSX Transp., Inc.*, 597 F.3d 474, 490 (1st Cir. 2010). An excessive verdict is a "significant" indicium of prejudice, *e.g.*, *Whittenburg v. Werner Enterprises Inc.*, 561 F.3d 1122, 1132-33 (10th Cir. 2009); *see also City of Cleveland v. Peter Kiewit Sons' Co*., 624 F.2d 749, 759 (6th Cir. 1980) (excessive verdict suggests prejudice as to both liability and damages), as is a swift verdict in a lengthy and closely contested trial, *see, e.g.*, *Cadorna v. City and Cnty. of Denver*, *Colo*., 245 F.R.D. 490, 496 (D. Colo. 1997). Where a jury verdict "is the product of passion and prejudice[,] [it] cannot be cured by remittitur and a new trial is required." *Blair v. Eagle-Picher Indus., Inc*., 962 F.2d 1492, 1499 (10th Cir. 1992), *cert. denied*, 506 U.S. 974 (1992).

Consistent with these principles, this Court has reversed trial courts for failing to grant a new trial based on less egregious conduct than that engaged in here. In *Koufakis*, 425 F.2d 892, for example, the district court remitted a $187,500 jury verdict to $126,000 in a breach-of-contract action because of "improper and prejudicial arguments of plaintiff's trial counsel," *id.* at 894. This Court found, however, that remittitur was not enough; according to the Court, the

failure to grant a new trial was an abuse of discretion because of "the numerous grossly prejudicial arguments made by plaintiff's counsel in summation and during trial, against which the trial judge's comments and charge gave little or no protection." *Id.* In its ruling, the Court focused on the district court's inability to understand how "'[the jury] computed'" the damages and the fact that the award was "grossly in excess of the maximum recoverable under the theory of the case." *Id.* at 901. Accordingly, the court concluded, "[t]he prejudice" was "clear on the face of the record." *Id.*

The Court then itemized the lawyer's misconduct. Among other improprieties, counsel in that case "liken[ed] [defendant] to a head man in [the Mafia]" while casting the plaintiff as "a 'little' and virtuous man of modest resources against a powerful and unscrupulous man with untold wealth.'" *Id.* at 902; *see also id.* at 903 (referring to counsel's "repeated name-calling"). The Court found this reference to wealth particularly disturbing since it improperly "suggest[ed] that the defendant should respond in damages because he is rich and the plaintiff is poor," itself a "ground[] for a new trial." *Id.* at 902. Counsel also "made improper remarks which called the attention of the jury to other litigation which was not part of the record." *Id.* at 903. And counsel's summation was "replete with improper personal references to himself and [trial counsel]," and was "based on an appeal to passion not warranted by proof." *Id.* 904 (citation omitted).

Notably, the Court was "particularly" troubled by counsel's summation, which "went far beyond the permissible limits of fair comment on what was before the jury and dealt altogether too much with matters and considerations outside the record which were obviously intended to prejudice the appellants." *Id.*

The record here is much the same. As in *Koufakis*, the damages award was "grossly in excess" of any reasonable "maximum," *id.* at 901 – $3 million higher than the $5 million requested by counsel in closing argument, and much higher still than the amount to which the district court would have reduced it. In addition, like the district court in *Koufakis*, the district court here could not discern how "[the jury] computed" the verdict, *id.*, confessing that it could not "point definitively to anything in the record that caused the surplus." [SPA-148.]

If anything, the jury's reaction here is even starker than the one in *Koufakis*, as the jury's speed in calculating the award was at least as remarkable as the final amount. After a three-week trial involving complex medical testimony in "an unusually confrontational and hard-fought case" [SPA-84], the jury needed only approximately three hours to return the verdict, *see, e.g.*, *Cadorna*, 245 F.R.D. at 496 (noting that the jury's return with a plaintiff verdict in an age-discrimination case after only three hours of deliberation after a 7.5-day trial "suggest[ed] the strong probability . . . that its verdict was the result of impermissible passion and prejudice inflamed by [counsel's] unacceptable trial tactics"). This swift verdict is

particularly compelling evidence of prejudice since the first trial, involving "largely comparable" evidence [SPA-104], ended in a hung jury (with all but one juror siding for Merck) after five days of deliberation.

The nature of counsel's conduct is also similar to that condemned as unduly prejudicial in *Koufakis*. Here too, the district court repeatedly admonished counsel for his improper conduct throughout the course of trial. For example, the court noted the "rude treatment" of Merck and its witnesses. In particular, counsel treated Dr. Glickman "with sarcasm, mockery, and condescending questions," during a cross-examination that was marked by "scorn and derision" [SPA-137], and similarly "mocked the testimony of Dr. Anne de Papp" [SPA-139]. The district court further reprimanded counsel's improper reference to other litigation – specifically, other Fosamax MDL cases – notwithstanding prior rulings making it clear that such allusions were not permitted. [A-356, Tr. 984-86.]

Despite these repeated warnings by the trial court, counsel pushed the limits even further during his closing argument. For example, he mocked Merck's conduct as synonymous with membership in the "Flat Earth Society," and he used a demonstrative exhibit on-screen during closing argument that contained a single word "**HYPOCRISY**" in bold, capitalized letters. [A-433-35, Tr. 1678-79, 1682, 1684; SPA-140.] He also leveled improper attacks against Merck's relationship with the FDA, describing it as "incestuous" and suggesting that Merck and other

drug companies essentially bribe the FDA to approve their products. [SPA-140-41 (noting statements that FDA "gives cursory reviews and expedited approvals of new drug applications 'in exchange' for funding"); A-434-35, Tr. 1680-82, 1686.]

Much like the counsel in *Koufakis*, counsel emphasized Merck's economic condition, repeatedly claiming that Merck's "goal" was to "sell more pills" without regard to consumer welfare. [SPA-89-90; *see also id.* ("They sell it for profit.").] Counsel also referred to other matters not supported by the evidence, including a slide in closing suggesting that Dr. Kimmel knew of a report of ONJ as early as 1999 despite the fact that "there was no [such] testimony." [SPA-141.] And counsel "insidiously sought to inject" punitive-damages issues into his closing argument despite their exclusion from trial. [SPA-89.] Not surprisingly, the district court declared it the most "outrageous" closing argument it had ever witnessed. [A-454-55, Tr. 1756-57.]

In short, as in *Koufakis*, "the large verdict was due in great part to [counsel's] improper conduct," and Merck is "entitled to a new trial at which [it] will be free from such mistreatment by counsel." 425 F.2d at 905.

2. The District Court's Failure To Recognize This Prejudice Was An Abuse Of Discretion.

Despite the "outrageous[ness]" of counsel's conduct, the district court found that there was no prejudice to Merck because: (1) counsel's misconduct did not directly bear upon "key evidence," which was sufficient to support the verdict; (2)

counsel's conduct was so palpably outrageous that it would have been "difficult [for the jury] to take him seriously"; and (3) the court's curative instructions diminished any prejudice. [SPA-145, SPA-147.] The court granted remittitur but did not tie that ruling to counsel's misconduct. [SPA-148.] The court was wrong on each of these points, and its conclusion constituted an abuse of discretion.

The conduct bore on key evidence in a close case. The district court's conclusion that a new trial was not warranted because the "majority of questionable conduct . . . did not touch on the key evidence of the case" [SPA-145] was wrong. For starters, the district court had too narrow a view of the "key evidence" in the case. The court described the "fundamental questions" in the case as whether "Fosamax's risks outweigh its benefits" and whether Fosamax caused plaintiff's injury. [*Id.*] But foreseeability was also a crucial question – one that the district court itself addressed at length [SPA-120-24] – and counsel's improper slide falsely suggesting that Dr. Kimmel knew of a report of ONJ as early as 1999 bore directly on that question by suggesting that two Merck witnesses were aware of a report of ONJ as far back as 1999. So too was the question of Merck's relationship with the FDA. Although this issue did not go to a specific element of plaintiff's claims, the centrality of the FDA in a prescription-drug case is self-evident. *See, e.g.*, *In re Fosamax*, 645 F. Supp. 2d at 191 (noting that the FDA's "complex regulatory framework . . . informs the standard of care in the

pharmaceutical industry"). And counsel's unsubstantiated suggestion that Merck paid off the FDA to approve Fosamax likely had a highly prejudicial impact on Merck. *Cf., e.g.*, *Winter v. Novartis Pharm. Corp.*, 2012 WL 827245, at *3 (W.D. Mo. Mar. 8, 2012) (granting motion in limine to "exclude reference to drug companies as having an incestuous relationship with the FDA").

In any event, the district court was also wrong to focus only on the question whether the misconduct bore directly on "key evidence" in the case. As other courts have recognized, the danger in close and difficult cases like this one is that the jury will *ignore* the evidence and instead decide the matter based on "passion and prejudice." *Edwards v. Sears, Roebuck & Co*., 512 F.2d 276, 283-85 (5th Cir. 1975) (court erred in remitting damages instead of granting new trial where prejudicial remarks were made in summation because and where "the liability issue" was "hard fought and closely contested"). [*See* SPA-84 (acknowledging that this was a "hard-fought case").] Such a danger is particularly potent where, as here, counsel's summation contains "numerous and serious violations" of the "rules of proper argument." *Draper v. Airco, Inc*., 580 F.2d 91, 97 (3d Cir. 1978). After all, closing argument is "the final occasion for the jury to hear from either the parties or their attorneys before they beg[i]n their deliberations," rendering "the prejudicial impact of these final remarks . . . especially acute." *Commercial Credit Bus. Loans, Inc. v. Martin*, 590 F. Supp. 328, 335 (E.D. Pa. 1984). For all of these

reasons, the district court's belief that the "key evidence" was untouched by counsel's misconduct was both mistaken and inapposite.

There was no basis to conclude the jury would hold the misconduct against the plaintiff. The district court's view that it would have been "difficult [for the jury] to take [plaintiff's counsel] seriously" [SPA-145], was also misplaced. Indeed, this Court rejected an identical self-assurance by the district court in *Koufakis*. Despite the repeated misconduct and the "particularly" objectionable summation, the district court there rationalized its rejection of a new trial in part by claiming that the jury "simply didn't take" counsel "seriously" because his statements were obviously the "exaggeration[s]" of "a flamboyant individual." 425 F.2d at 905. This Court disagreed: "We cannot accept the trial judge's conclusion that the jury did not take [counsel] seriously as to much, if not all, that he said in his summation," particularly in light of "the large verdict." *Id.* That reasoning was far more sound than that of the district court, which effectively rewarded Plaintiff's counsel for his behavior because it was *too* outrageous.

The brief and belated curative instruction did not undo hours of misbehavior. Nor was the district court correct in being "confident that any prejudice resulting from [counsel's] summation was dispelled by the curative instruction" it gave the day after closing arguments. [*See* SPA-147.] The court relied on two cases for the general proposition that juries are presumed to follow instructions [*see id.*], but

other cases recognize that jury instructions are less effective in the face of repeated and egregious misconduct.

As this Court explained in *Koufakis*, "where the number and gravity of counsel's improprieties reach the level presented by this record, the admonitions by the trial judge in the charge and in response to specific objections cannot possibly serve to cure all prejudice." 425 F.2d at 904; *accord, e.g.*, *Fineman v. Armstrong World Indus.*, 980 F.2d 171 (3d Cir. 1992) (affirming grant of new trial where district court determined curative instructions were "insufficient to expunge the prejudicial impact of plaintiffs' trial counsel's closing remarks"); *O'Rear v. Fruehauf Corp.*, 554 F.2d 1304, 1308-09 (5th Cir. 1977) (remarks made in closing argument could not be cured by cautionary instructions where counsel consistently made prejudicial comments in front of the jury after having been prohibited from doing so). This is particularly so where the instruction does not issue until the following day, as occurred here. *See, e.g.*, *Draper*, 580 F.2d at 97 (curative instruction following improper statements made in closing argument was "not sufficient to remove the probability of prejudice" where "the instruction was given the day after the closing argument"). In short, the misconduct in this case, coupled with the district court's delayed response, made for a textbook example of an ineffective curative instruction, and the district court's "confidence" in that instruction was misplaced.

Remittitur was not an acceptable substitute. Finally, the district court was also wrong to the extent it believed that remittitur was an "appropriate remedy" for the misconduct. [SPA-148 (capitalization altered).] "A remittitur should be granted only where the trial has been free of prejudicial error." *Ramirez v. New York City Off-Track Betting Corp.*, 112 F.3d 38, 40 (2d Cir. 1997) (citing *Werbungs und Commerz Union Austalt v. Collectors' Guild, Ltd.*, 930 F.2d 1021, 1027-28 (2d Cir. 1991)). Where the misconduct of counsel taints the verdict, the proper remedy is a new trial, not remittitur. *See Koufakis*, 425 F.2d at 894 (noting that district court had remitted the damages but reversing and remanding for new trial in light of misconduct); *see also, e.g.*, *Blair*, 962 F.2d at 1499 (trial court erred in granting remittitur of $1.2 million jury verdict to $600,000 instead of new trial where plaintiff appeared in court "in an acutely ill condition," resulting in jury verdict that was "tainted by passion and prejudice"); *Edwards*, 512 F.2d at 283-85 (similar).

To be sure, the district court never expressly stated that it had adopted a remittitur to cure the prejudice of counsel's misconduct. Rather, it claimed that the remittitur was necessary strictly to cure an excessive award, untraceable to "anything in the record." [SPA-148.] In reality, however, the record is replete with many reasons for the excessive award, all of which stem from counsel's

misconduct. The two were clearly intertwined. For all of these reasons, the district court abused its discretion in not ordering a new trial.

CONCLUSION

For the reasons set forth above, the Court should reverse the judgment of the district court and enter judgment as a matter of law for Merck or, in the alternative, remand for a new trial.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because this brief contains 13,725 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

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