United States Court of Appeals
For the Third Circuit.

Albert ORAN; Terry Adolphs; Philip Morris; James Doyle Lupo; Paul H. Maurer, individually and on behalf of a class of others similarly situated, Appellants,

v.

John R. STAFFORD; Robert G. Blount; Joseph J. Carr; Louis L. Hoynes, Jr.; William J. Murray; David M. Olivier; John R. Considine; Paul J. Jones; Fred Hassan; American Home Products Corporation.

No. 99-5184.

Argued Feb. 29, 2000.
Filed Sept. 7, 2000.

Before: ALITO and STAPLETON, Circuit Judges, and POLLAK, District Judge.[FN*]

FN* The Honorable Louis H. Pollak, Senior Judge of the United States District Court for the Eastern District of Pennsylvania, sitting by designation.

OPINION OF THE COURT

ALITO, Circuit Judge:

Plaintiffs brought this securities class action against American Home Products Corporation ("AHP") and certain of its directors and officers [FN1] after AHP, in response to reports of serious medical side effects, withdrew its prescription weight-loss drugs Pondimin and Redux from the market. Stockholder plaintiffs allege that AHP made material misrepresentations and omissions regarding the safety of the drugs while failing to disclose several studies linking the drugs to heart-valve damage. As a result, plaintiffs claim, they suffered substantial financial loss when AHP's stock prices dropped following public disclosure of the withheld information. The District Court dismissed all claims on the pleadings for failure to state a claim, and we affirm.

FN1. The individual defendants are: (1) John R. Stafford, AHP's Chief Executive Officer and President, and Chairman of its Board of Directors; (2) Robert J. Blount, a Senior Executive Vice President and Director; (3) Joseph J. Carr, a Senior Vice President; (4) Louis L. Hoynes, Jr., General Counsel and Senior Vice President; (5) William J. Murray, a Senior Vice President; (6) John R. Considine, Vice President of Finance; (7) Paul J. Jones, Comptroller and Vice President; and (8) Fred

Hassan, a senior executive and Director.

I.

[1] Because this is an appeal from the District Court's grant of a motion for judgment on the pleadings, we accept as true all allegations in the complaint and draw all reasonable inferences in favor of the plaintiffs. *See Consolidated Rail Corp. v. Portlight, Inc.*, 188 F.3d 93, 94 (3d Cir.1999). Plaintiffs' complaint sets forth the following facts.

A. *The Heart Valve Reports.*

Defendant American Home Products Corporation ("AHP"), a Delaware corporation headquartered in New Jersey, is engaged in the research, development, manufacture and marketing of prescription and over-the-counter medications. During the period relevant to this litigation, AHP marketed the weight-loss drugs Pondimin (fenfluramine) and Redux (dexfenfluramine). Pondimin was marketed together with another drug, phentermine, in a combination popularly known as "fen-phen." Pondimin was approved by the Food and Drug Administration in 1973. Redux was recommended for approval by an FDA Advisory Committee in November 1995 and approved by the FDA in 1996.

In February 1994, AHP learned that a Belgian cardiologist had documented leaky heart valves in seven patients who had been taking diet pills containing Pondimin and Redux. By the time the FDA Advisory Committee voted to approve Redux in November 1995, AHP knew of at least 31 cases of heart valve abnormalities in European diet-pill users, but had informed the FDA about only eight of those cases. During the same time period, AHP also received hundreds of adverse reaction reports of patients displaying symptoms often associated with heart and lung problems. AHP represented to the FDA that these symptoms were reactions to the drugs and were not caused by any underlying heart condition.

In March 1997, AHP representatives met separately with cardiologists from the Mayo Clinic and MeritCare Health Systems,***280** who informed AHP that they had documented heart-valve abnormalities in a total of 17 fen-phen users. Dr. Heidi Connolly, the Mayo cardiologist, informed AHP that she had never seen this type of valve damage except in patients with rare cancers or in those who had taken ergotamine, a migraine drug that, like Redux and Pondimin, affects the body's serotonin level. Although AHP continued to investigate the Mayo data throughout 1997, it did not immediately release the reports to the public.

The Mayo data, which by that time included 24 reports of heart-valve abnormalities in fen-phen users, was finally disclosed to the public on July 8, 1997. On that date, AHP, Mayo, MeritCare and the FDA each made a public announcement concerning the reports. The Mayo announcement noted that the information "raise[d] significant concern that this

combination of appetite suppressants has important implications regarding valvular disease." (App.52-53.) AHP's announcement similarly stated that the company was investigating "the potential association of valvular heart disorders with the combination use of [fen-phen]." (App.56.) The Mayo, FDA, and AHP announcements, however, all emphasized that there was no conclusive evidence establishing a causal relationship between fen-phen and heart valve disorders and that further study was needed before such a link could be confirmed. Following these announcements, there was no decline in the New York Stock Exchange price of AHP common stock.

B. *The Withdrawal of Redux and Pondimin*

On September 12, 1997, the FDA informed AHP of a survey showing that 92 of 291 fen-phen users had developed heart-valve abnormalities. The next business day, September 15, 1997, AHP announced that it was withdrawing Pondimin and Redux from the market. The same day, AHP issued a press release estimating total lost profits of 14 cents per share for 1997 and 1998 as a result of lost sales of the two drugs, as well as a one-time product withdrawal loss of $200 million to $300 million. On September 15, the day of the withdrawal announcement, the closing price of AHP common stock fell 3 11/16 points, to 73 1/4.

On September 16, 1997, a *Wall Street Journal* article reported that AHP "face [s] lawsuits, including one seeking class-action status, from people who claim to have been harmed by the drugs. American Home says it is likely it will face legal action." (App.103.) Nevertheless, AHP's stock rose slightly for the day. On September 17, 1997, articles in the *Wall Street Journal* and the *New York Times* reported that AHP had known about possible heart-valve abnormalities since at least March 1997, and that the company faced substantial personal injury liability exposure. That day, AHP stock suffered a 4 1/4 point decline, to close at 69 15/16.

C. *AHP's Public Statements During the Class Period.*

Plaintiffs allege that from March 1, 1997, through September 16, 1997 (the "Class Period"), AHP made material misrepresentations and omissions regarding the safety of Pondimin and Redux, as well as AHP's knowledge of the heart-valve reports. For example, on March 27, 1997, AHP issued its Annual Report, which contained a statement that "Redux, the first prescription weight-loss drug to be cleared by the FDA in more than 20 years, was one of the most successful drug launches ever." (App.47.) The report contained no reference to either the European or the Mayo data. On April 21, 1997, AHP issued a press release addressing newspaper reports of a death that had been mistakenly attributed to Redux by an FDA official. The press release noted that "[s]cientific evidence has shown Redux to be safe and effective when used as indicated." (App.50.) In addition, in various releases listing Redux and Pondimin's side effects, AHP omitted any mention of

heart-valve damage.

***281** Plaintiffs also contend that, following the public disclosure of the Mayo data on July 8, 1997, AHP issued further misleading statements that were designed to minimize the impact of that data. Although AHP's statements to the public discussed "a possible serious heart valve disorder" and "an unusual type of serious regurgitant valvular heart disease," AHP failed to disclose that it had been aware of the Mayo data since March 1997, and of the European data since early 1995. (App.57.) According to plaintiffs, this omission served to materially mislead investors as to AHP's potential exposure to damages from products liability litigation arising out of the two drugs.

D. *Stock Sales By Individual Defendants.*

In the period between the March meeting with Mayo and the end of the Class Period, seven of the individual defendants sold a total of $40 million of AHP stock, resulting in profits of $25 million. Plaintiffs allege that these sales were consciously designed to take advantage of AHP's artificially-inflated stock price prior to public disclosure of the heart-valve data.

E. *The District Court Decision.*

Plaintiffs filed this securities class action in federal court on September 18, 1997, alleging that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. § § 78j(b) and 78t(a), as well as Rule 10b-5, 17 C.F.R. § 240.10b-5. On January 30, 1998, the plaintiffs filed an Amended Class Action Complaint (the "Amended Complaint"). Defendants moved to dismiss the complaint, and the District Court granted their motion in its entirety without leave for plaintiffs to amend further. *See Oran v. Stafford,* 34 F.Supp.2d 906 (D.N.J.1999).

Finding that plaintiffs had failed to plead any material misstatement or omission under federal securities law, the court noted that on July 8, 1997-halfway through the Class Period-there had been full disclosure of the Mayo data without any appreciable effect on AHP's stock price. As a result, the court concluded, "the medical data disclosed by AHP on July 8, 1997 was immaterial as a matter of law." *Id*. at 911. The court also held that disclosure of the European data and earlier adverse reaction reports would not have materially altered the substance of the July 8 release. In addition, the court held that AHP's failure to disclose when it had first learned of the adverse health data was not a material omission. As to the individual defendants, the District Court held that the Amended Complaint was not pled with sufficient particularity to give rise to the necessary strong inference of scienter required under the PSLRA. Plaintiffs appealed.

II.

[2][3][4] Plaintiffs raise four arguments on appeal. First, they claim that the District Court erred in holding that AHP's misstatements and omissions were not material as a matter of law. Second, they argue that AHP violated SEC Regulation S-K, Item 303(a), which requires disclosure of "known trends and uncertainties," and that such a violation can support a claim under Section 10(b) of the Securities Exchange Act and Rule 10b-5. Third, plaintiffs maintain that the District Court erred by holding that the claims against AHP's insiders were not stated with sufficient particularity to satisfy the heightened pleading requirements of Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act of 1995 (PSLRA), 15 U.S.C. § 78u-4 *et seq*. Finally, plaintiffs claim that the District Court should have granted leave to amend in order to remedy any deficiencies in the Amended Complaint. We address these contentions in turn.[FN2]

FN2. We exercise plenary review over the District Court's dismissal of the Amended Complaint for failure to state a claim, accepting plaintiffs' factual allegations as true. *See In re Westinghouse Sec. Litig.*, 90 F.3d 696, 707 (3d Cir.1996). We also have plenary review over the District Court's interpretation of the federal securities laws. *See Shapiro v. UJB Financial Corp.*, 964 F.2d 272, 279 (3d Cir.1992). We review the District Court's denial of leave to amend for abuse of discretion. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1417 (3d Cir.1997).

***282** A.

[5] To state a valid securities fraud claim under Rule 10b-5, a plaintiff must first establish that defendant, in connection with the purchase or sale of a security, "made a materially false or misleading statement or omitted to state a material fact necessary to make a statement not misleading." *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1417 (3d Cir.1997). The plaintiff must additionally establish that the defendant acted with scienter and that plaintiff's reasonable reliance on defendant's misstatement proximately caused him injury. *See In re Phillips Petroleum Sec. Litig.*, 881 F.2d 1236, 1244 (3d Cir.1989).

The District Court held that the misrepresentations pled by the plaintiffs were immaterial as a matter of law, and we begin by addressing this issue. Plaintiffs maintain that they pled several material misrepresentations and omissions, namely: (1) that AHP failed to disclose the Mayo data prior to June 8, 1997, and issued misleading statements minimizing the import of that data following disclosure; (2) that AHP failed to disclose the European data and adverse reaction reports, even after the Mayo data became public; (3) that AHP misled investors by publicizing the fact of Redux's FDA approval without disclosing that it had withheld much of the European data from the FDA; and (4) that AHP failed to disclose when it had first learned about the European data, the adverse reaction reports, or the Mayo data. Before we address these alleged omissions and

misrepresentations in detail, we briefly review this Circuit's explication of the materiality standard.

[6][7] Material information is "information that would be important to a reasonable investor in making his or her investment decision." *Burlington,* 114 F.3d at 1425. Generally, undisclosed information is considered material if "there is a substantial likelihood that the disclosure would have been viewed by the reasonable investor as having 'significantly altered the "total mix" of information' available to that investor." *See In re Westinghouse Sec. Litig.*, 90 F.3d 696, 714 (3d Cir.1996) (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449, 96 S.Ct. 2126, 48 L.Ed.2d 757 (1976)).

[8] In *Burlington*, however, this Court fashioned a special rule for measuring materiality in the context of an efficient securities market. This rule was shaped by the basic economic insight that in an open and developed securities market like the New York Stock Exchange, the price of a company's stock is determined by all available material information regarding the company and its business. In such an efficient market, "information important to reasonable investors ... is immediately incorporated into the stock price." *Burlington*, 114 F.3d at 1425. As a result, when a stock is traded in an efficient market, the materiality of disclosed information may be measured post hoc by looking to the movement, in the period immediately following disclosure, of the price of the firm's stock. Because in an efficient market "the concept of materiality translates into information that alters the price of the firm's stock," if a company's disclosure of information has no effect on stock prices, "it follows that the information disclosed ... was immaterial as a matter of law." *Burlington*, 114 F.3d at 1425.

With these standards in mind, we turn to plaintiffs' specific allegations of material misrepresentation.

1.

[9] AHP first learned of the Mayo data suggesting a link between fen-phen and ***283** heart-valve disorders in March 1997. It did not, however, release this data to the public until July 8, 1997. The District Court concluded that AHP's failure to disclose this data prior to July 8 was not a material omission, and we agree.

Because the Mayo data was actually disclosed on July 8, we apply *Burlington* and look to the movement in the price of AHP's stock following disclosure to determine if the information was material.[FN3] As the District Court noted, the July 8 disclosure had no appreciable negative effect on the company's stock price; in fact, AHP's share price rose by $3.00 during the four days after the Mayo disclosure. Under *Burlington's* market test, this price stability is dispositive of the question of materiality.

FN3. Plaintiffs allege that "the market for AHP common stock was an efficient market." Amended Complaint, para. 38. (App.12.)

Plaintiffs counter, however, that this lack of adverse price movement may be traceable to defendant's own "spinning" of the Mayo data-which, plaintiffs maintain, itself constituted a material misrepresentation. Plaintiffs argue, in effect, that had AHP not deceptively downplayed the significance of the Mayo data through its sanguine and allegedly misleading statements, investors would have realized the import of the information, and share prices would have tumbled following the June 8 announcement.

We reject this argument, and agree with the District Court that AHP's so-called "spinning" of the Mayo data was not materially misleading. AHP, in its public statements, did characterize the Mayo data as "limited and therefore inconclusive," and emphasized that "additional scientific investigation must be conducted before any possible link can be confirmed." (App.56.) There is, however, nothing in these statements that could reasonably be characterized as inaccurate. The FDA's own June 8 press release confirmed that "[p]resently there is no conclusive evidence establishing a causal relationship between [Pondimin and Redux] and valvular heart disease ." (App.54.) Mayo's public statement that same day was similarly ambivalent: "We believe these cases raise significant concern that this combination of appetite suppressants has important implications regarding valvular heart disease. *But more comprehensive study is needed to confirm the associations*." (App.52-53) (emphasis added).

These third-party statements support the District Court's conclusion that AHP's characterization of the Mayo data as "inconclusive" was neither false nor misleading. Plaintiffs do not allege that, when AHP made its statements on June 8 and afterward, there was any conclusive medical evidence linking its products to heart valve disorders. From the face of the Amended Complaint, then, it is clear that AHP's characterization of the Mayo data cannot serve as the basis for liability under the federal securities laws.

2.

[10] Plaintiffs next argue that AHP's statements regarding the Mayo data must be viewed in light of the company's failure to disclose the European data and the adverse reaction reports. In their view, had this data not been withheld, it would have corroborated the Mayo report and alerted investors to the possibility of a significant link between the two drugs and valvular heart disease. In particular, plaintiffs assert that AHP's statements characterizing the Mayo data as "inconclusive" became materially misleading in light of this additional withheld data.

Plaintiffs do not allege that the European data and adverse reaction reports, taken by themselves, established any statistically significant relationship between AHP's products and valvular heart disease. Nor does the Amended Complaint assert that the withheld

data, even when ***284** viewed in conjunction with the Mayo report, could have demonstrated any medically conclusive link in light of the millions of prescriptions written for Pondimin and Redux. In fact, plaintiffs never clearly explain how the accumulation of additional anecdotal data, short of the point of statistical significance, would have added anything to the disclosures already made on July 8, 1997. Because the link between the two drugs and heart-valve disorders was never definitively established during the relevant period even after the withheld data is taken into account, AHP's failure to disclose this data cannot render its statements about the inconclusiveness of the relationship materially misleading.

[11] AHP characterized the Mayo data as inconclusive. Had it simultaneously disclosed the European data and the adverse reaction reports, the aggregate of available information would nevertheless have led a reasonable investor to the same conclusion-that the relationship between the two drugs and heart valve disorders was still inconclusive. As the Second Circuit has noted, "[d]rug companies need not disclose isolated reports of illnesses suffered by users of their drugs until those reports provide statistically significant evidence that the ill effects may be caused by-rather than randomly associated with-use of the drugs and are sufficiently serious and frequent to affect future earnings." *In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153, 157 (2d Cir.1998). The withheld reports did not provide such statistically significant evidence. Therefore, we agree with the District Court that the disclosure of the European data and the adverse reaction reports would not have "significantly altered the 'total mix' of information" available to AHP's investors. *Westinghouse*, 90 F.3d at 714.

3.

[12] Plaintiffs next contend that they were materially misled about the FDA approval process for Redux. Although AHP had become aware of at least 31 cases of heart valve abnormalities in European diet-pill users by the time that the FDA Advisory Committee voted to approve Redux in 1995, the company informed the FDA of only eight of those reports. This non-disclosure, plaintiffs contend, rendered materially misleading AHP's later statements about the approval process, which plaintiffs claim suggested that AHP had disclosed to the agency all available safety data.[FN4]

> FN4. For example, on August 19, 1997, AHP issued a press release stating that "[t]he FDA cleared Redux for marketing in April, 1996 following a thorough review of more than 17 clinical trials which indicated that, at the dose recommended for treatment of obesity, dexfenfluramine is an effective appetite suppressant with an acceptable safety profile." (App.60.)

As an initial matter, we note that plaintiffs do not allege that AHP withheld any information that it was legally required to disclose to the FDA. Certainly, the simple

failure to disclose the additional European cases-which, as we have explained above, fail to establish a statistically significant causal relationship-cannot by itself serve as a basis for securities fraud liability.

Plaintiffs, however, argue that AHP put the subject of FDA approval "in play" by publicizing the agency's determination that Redux was safe, and that once that subject was in play, AHP was required to disclose any material facts that would have tended to contradict its positive representations. Plaintiffs rely principally on *Shapiro v. UJB Financial Corp.*, 964 F.2d 272, 281 (3d Cir.1992), which dealt with a defendant's characterization of its financial management practices as "adequate." Finding that such a statement could, in some circumstances, be actionable, this Court reasoned that

if a defendant has not commented on the nature and quality of the management practices that it has used to reach a particular statement of loan loss reserves, earnings, assets, or net worth, it ***285** is not a violation of the securities laws to fail to characterize these practices as inadequate, meaningless, out of control, or ineffective. However, where a defendant affirmatively characterizes management practices as "adequate," "conservative," "cautious," and the like, the subject is "in play." For example, if a defendant represents that its lending practices are "conservative" and that its collateralization is "adequate," the securities laws are clearly implicated if it nevertheless intentionally or recklessly omits certain facts contradicting these representations. Likewise, if a defendant characterizes loan loss reserves as "adequate" or "solid" even though it knows they are inadequate or unstable, it exposes itself to possible liability for securities fraud. By addressing the quality of a particular management practice, a defendant declares the subject of its representation to be material to the reasonable shareholder, and thus is bound to speak truthfully.

Id. at 281-82 (citation omitted).

We do not believe that AHP's statements regarding the FDA approval process were materially misleading under *Shapiro.* Unlike the defendant in *Shapiro,* AHP did not make any "affirmative characterization" that the FDA's approval was based on a complete review of every piece of relevant medical information. Rather, AHP made a simple (and accurate) factual assertion that the FDA had found that Redux had an "acceptable safety profile" following a "thorough review of more than 17 clinical trials." (App.60.) Accordingly, we find that these statements did not constitute any material misrepresentation or omission.

4.

[13] Finally, plaintiffs charge that AHP's failure to disclose the dates on which it first learned of the European data, adverse reaction reports, and Mayo data constituted a material omission. This information was material to investors, they assert, because of the light it would have cast on AHP's potential products liability exposure. According to the

plaintiffs, the materiality of this undisclosed information was confirmed by the four-percent drop in share prices on September 17, the day that the *New York Times* and *Wall Street Journal* reported that AHP had known about possible heart-valve abnormalities since at least March 1997.

[14][15][16] Under the rationale of *Burlington,* this share price activity does suggest that investors viewed this final category of undisclosed information as material.[FN5] This does not end our inquiry, however. Even non-disclosure of material information will not give rise to liability under Rule 10b-5 unless the defendant had an affirmative duty to disclose that information. "Silence, absent a duty to disclose, is not misleading under Rule 10b-5." *Basic Inc. v. Levinson,* 485 U.S. 224, 239 n. 17, 108 S.Ct. 978, 99 L.Ed.2d 194 (1988); *see also Burlington*, 114 F.3d at 1432 ("Except for specific periodic reporting requirements ... there is no general duty on the part of a company to provide the public with all material information."). Such a duty to disclose may arise when there is insider trading, a statute requiring disclosure, or an inaccurate,***286** incomplete or misleading prior disclosure. *See Glazer v. Formica Corp.*, 964 F.2d 149, 157 (2d Cir.1992); *Backman v. Polaroid Corp.*, 910 F.2d 10, 12 (1st Cir.1990) (en banc); *In re General Motors Class E Stock Buyout Sec. Litig.*, 694 F.Supp. 1119, 1129 (D.Del.1988).

> FN5. The District Court pointed to an alternative explanation for this share price drop that it found more plausible: a delayed investor reaction to AHP's withdrawal of Pondimin and Redux two days earlier. While we agree that this is a reasonable explanation-more reasonable, perhaps, than that proffered by plaintiffs-we note that in deciding a motion to dismiss, a court must draw all reasonable inferences in favor of the non-moving party. Here, there is nothing inherently implausible in the theory advanced by plaintiffs. Consequently, we believe that the District Court erred in adopting its own interpretation of the September 17 share price drop rather than accepting the theory put forward by plaintiffs. We believe, however, that this error was harmless because, as we explain below, plaintiffs have not pled any affirmative duty on AHP's part to disclose the disputed information.

None of these circumstances were present here. Plaintiffs do not allege that there was any statute requiring disclosure of this information.[FN6] Nor do they allege that AHP was trading in its own stock during the relevant period.[FN7] *Accord Staffin v. Greenberg,* 672 F.2d 1196, 1203 (3d Cir.1982).

> FN6. For the reasons discussed in section IIB, *infra,* we reject plaintiffs' claim that SEC Regulation S-K, Item 303(a) imposed an affirmative duty of disclosure on AHP that could give rise to a claim under Rule 10b-5. Moreover, we note that the last of the SEC filings that are governed by the regulation was filed in August 1997, well before there was anything more than a speculative possibility of tort liability for AHP.

FN7. We address the insider trading claims asserted against the individual officer-defendants in section IIC, *infra*.

Plaintiffs argue, however, that AHP's prior disclosures regarding its potential liability-particularly its July 8 disclosure of the Mayo study-were incomplete and therefore misleading because they failed to mention when the company first became aware of the adverse heart-valve data. We cannot agree. As an initial matter, it is clear that until the FDA notified AHP on September 12 of its own data showing a link between the two drugs and heart-valve disorders, there was no statistically significant evidence establishing a serious health risk. Prior to that date, then, the threat of product liability exposure was purely speculative, and any evidence of when AHP first learned of the adverse Mayo and European data was immaterial as a matter of law.

[17] Moreover, AHP had no legal duty to correct or update even following its September 12 receipt of the FDA report. The duty to correct exists "when a company makes a historical statement that, at the time made, the company believed to be true, but as revealed by subsequently discovered information actually was not." *Burlington*, 114 F.3d at 1431 (quoting *Stransky v. Cummins Engine Co., Inc.*, 51 F.3d 1329, 1331-32 (7th Cir.1995)). Here, because AHP never made any prior statement regarding when it learned of the heart-valve data, there can be no legal duty to correct.

[18] The duty to update, in contrast, "concerns statements that, although reasonable at the time made, become misleading when viewed in the context of subsequent events." *Burlington,* 114 F.3d at 1431. After the release of the FDA study, which established a probable link between AHP's drugs and heart-valve disorders, AHP's notice of the earlier data could be viewed as material by a reasonable investor because it beared on the company's potential liability. Nevertheless, the omission of material information from a prior statement is actionable under a duty to update theory only if the previous statement contained an "implicit factual representation that remained 'alive' in the minds of investors as a continuing representation." *Burlington,* 114 F.3d at 1432. In this case, AHP never made any factual representation-implicit or explicit-regarding when it was first placed on notice about potential heart-valve problems. AHP's earlier statements about the Mayo and European data did not relate any incorrect or misleading information about when the company had learned of that data; rather, they were simply silent on the subject. In the absence of a misleading prior representation, AHP was under no legal duty to update.

In short, even assuming arguendo that the date on which AHP was put on notice of the adverse health data was material at the time the public learned of it, we hold that AHP was under no affirmative duty to disclose this information under federal securities***287** law. Therefore, this omission cannot form the basis for liability.

B.

Plaintiffs next argue that AHP had an affirmative obligation to disclose the heart-valve data's effect on AHP's future prospects under SEC Regulation S K, Item 303(a) ("S-K 303"), 17 C.F.R. § 229 .303. S-K 303 requires a company to include in its SEC filings a discussion of "any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." 17 C.F.R. § 229.303(a)(3)(ii). Plaintiffs allege that by omitting material information concerning the link between its drugs and valvular heart disorder from its 1996 Form 10-K and Annual Report, and its 1997 First and Second Quarter Form 10-Qs,[FN8] AHP breached its duty of disclosure under the regulation.

FN8. AHP filed its 1996 Annual Report and Form 10-K on March 27, 1997, its First Quarter 1997 Form 10-Q on May 13, 1997, and its Second Quarter 1997 Form 10-Q on August 13, 1997.

To succeed on this claim, however, plaintiffs must first establish either that S-K 303 creates an independent private right of action, or that the regulation imposes an affirmative duty of disclosure on AHP that, if violated, would constitute a material omission under Rule 10b-5. We address these possibilities in turn.

[19] In *Burlington,* this Court noted that "[i]t is an open issue whether violations of Item 303 create an independent cause of action for private plaintiffs." *Burlington,* 114 F.3d at 1419 n. 7. Today, we hold that they do not. Neither the language of the regulation nor the SEC's interpretative releases construing it suggest that it was intended to establish a private cause of action, and courts construing the provision have unanimously held that it does not do so. *See, e.g., In re Sofamor Danek Group, Inc.*, 123 F.3d 394, 402 (6th Cir.1997); *In re Boston Tech., Inc. Sec. Litig.*, 8 F.Supp.2d 43, 67 (D.Mass.1998); *In re Canandaigua Sec. Litig.*, 944 F.Supp. 1202, 1209 n. 4 (S.D.N.Y.1996); *In re F & M Distrib., Inc. Sec. Litig.*, 937 F.Supp. 647, 654 (E.D.Mich.1996); *Kriendler v. Chemical Waste Mgmt., Inc.*, 877 F.Supp. 1140, 1157 (N.D.Ill.1995).

[20] Plaintiffs respond, however, that even if there is no independent private cause of action under SK-303, the regulation nevertheless creates a duty of disclosure that, if violated, constitutes a material omission under Section 10(b) of the Securities Exchange Act and Rule 10b-5. In evaluating this argument, we must examine whether the disclosure mandated by SK-303 is governed by standards consistent with those that the Supreme Court has imposed for private fraud actions under the federal securities laws.

The SEC, whose interpretation is entitled to considerable deference, has characterized a company's disclosure obligations under SK-303 as follows:
Where a trend, demand, commitment, event or uncertainty is known, management must

make two assessments:

(1) Is the known trend, demand, commitment, event or uncertainty likely to come to fruition? If management determines that it is not reasonably likely to occur, no disclosure is required.

(2) If management cannot make that determination, it must evaluate objectively the consequences of the known trend, demand, commitment, event or uncertainty, on the assumption that it will come to fruition. Disclosure is then required unless management determines that a material effect on the registrant's financial condition or results of operations is not reasonably likely to occur.

Management's Discussion and Analysis of Financial Condition and Results of Operations, Exchange Act Release No. 34-26831, ***288** 54 Fed.Reg. 22427, 22430 (May 24, 1989). This test varies considerably from the general test for securities fraud materiality set out by the Supreme Court in *Basic Inc. v. Levinson,* which premised forward-looking disclosure "upon a balancing of both the indicated probability that the event will occur and the anticipated magnitude of the event in light of the totality of the company activity." 485 U.S. 224, 237, 108 S.Ct. 978, 99 L.Ed.2d 194 (1988) (quoting *SEC v. Texas Gulf Sulphur Co.*, 401 F.2d 833, 849 (2d Cir.1968) (en banc)). As the SEC specifically noted, "[t]he probability/magnitude test for materiality approved by the Supreme Court in *Basic* ... is inapposite to Item 303 disclosure"; rather, SK-303's disclosure obligations extend considerably beyond those required by Rule 10b-5. Exchange Act Release No. 34-26831, 54 Fed.Reg. at 22430 n.27.

Because the materiality standards for Rule 10b-5 and SK-303 differ significantly, the "demonstration of a violation of the disclosure requirements of Item 303 does not lead inevitably to the conclusion that such disclosure would be required under Rule 10b-5. Such a duty to disclose must be separately shown." *Alfus v. Pyramid Tech. Corp.*, 764 F.Supp. 598, 608 (N.D.Cal.1991); *see also Sofamor,* 123 F.3d at 402; *In re Quintel Entertainment, Inc. Sec. Litig.*, 72 F.Supp.2d 283, 293 (S.D.N.Y.1999); *Wilensky v. Digital Equip. Corp.*, 903 F.Supp. 173, 181 & n. 10 (D.Mass.1995), *rev'd in part on other grounds sub nom. Shaw v. Digital Equip. Corp.*, 82 F.3d 1194 (1st Cir.1996); *Kriendler,* 877 F.Supp. at 1157. [FN9] We find this reasoning persuasive, and thus hold that a violation of SK-303's reporting requirements does not automatically give rise to a material omission under Rule 10b-5. Because plaintiffs have failed to plead any actionable misrepresentation or omission under that Rule, SK-303 cannot provide a basis for liability.

> FN9. In *Steckman v. Hart Brewing, Inc.*, 143 F.3d 1293, 1296 (9th Cir .1998), the Ninth Circuit held that allegations which state a claim under SK-303 also sufficiently state a claim under Sections 11 and 12(a)(2) of the Securities Exchange Act. The court carefully limited its holding, however, making clear that it did not extend to claims under Section 10(b) or Rule 10b-5. *See id.* (citing *In re VeriFone*

Sec. Litig., 11 F.3d 865, 870 (9th Cir.1993)). Accordingly, *Steckman* does not support plaintiffs' position here.

C.

Having affirmed the District Court's dismissal of the claims against AHP, we turn now to plaintiffs' claims against the individual officer-defendants. The District Court dismissed these claims because plaintiffs' allegations concerning the individual defendants' motive and opportunity to commit fraud failed to meet the PSLRA's rigorous requirements for pleading scienter. The court noted that two of the officer-defendants, Stafford and Jones, were not alleged to have traded stock during the Class Period. As to the other officers, the court held that there was no allegation that their disputed trades were not routine or that the profits made were "substantial enough in relation to the compensation levels ... to produce a suspicion that they might have had an incentive to commit fraud." *Oran*, 34 F.Supp.2d at 910 (quoting *Burlington*, 114 F.3d at 1423).

Both the PSLRA and Federal Rule of Civil Procedure 9(b) impose heightened pleading requirements on plaintiffs who allege securities fraud. Rule 9(b) requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." The PSLRA more specifically requires that a securities fraud complaint "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). In *Burlington,* this Court held that a plaintiff may establish this strong inference "either (a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious ***289** misbehavior or recklessness." 114 F.3d at 1418; *see also In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 534-35 (3d Cir.1999).

The gravamen of plaintiffs' case against the individual officer-defendants is that they intentionally concealed material information in order to artificially inflate the price of AHP's stock, and then profited by selling their own stock at this inflated price shortly before the public disclosure of the Mayo data.

[21] Plaintiffs do not dispute that Stafford and Jones traded no stock during the relevant period. This reason alone requires that we affirm the District Court's dismissal of the claims against these two defendants.

[22] As to the remaining defendants, plaintiffs attempt to show motive and opportunity for fraud by alleging that, in the period from May through July 1997, these seven AHP executives sold over $40 million of AHP stock at a profit of $24.98 million. The Amended Complaint sets forth the number of shares sold by each officer-defendant, the dates of the trades, and the profit realized on each transaction. (App.73.) However, the Amended Complaint does not allege the total number of shares held by each of the officers or the amounts of their base compensation. The District Court found that the absence of this

information was fatal to plaintiffs' case against the officer-defendants because "plaintiffs provide[d] no information as to whether the trades were normal and routine for each executive." *Oran*, 34 F.Supp.2d at 910.

[23] On appeal, appellants urge this Court to take judicial notice of the defendants' compensation levels and their total direct stockholdings at the time of the trades. Appellants argue that the information is a matter of public record, derived from Form 4s and 5s and Form 14A Proxy statements filed with the SEC.[FN10]

> FN10. The Form 14As, which provide information on the executives' base compensation, were not presented to the District Court in any form.

Federal Rule of Evidence 201 permits a court to take judicial notice of facts that are "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Fed.R.Evid. 201(b)(2). A number of our sister circuits have held that this rule permits a court, in deciding a motion for judgment on the pleadings, to take judicial notice of properly-authenticated public disclosure documents filed with the SEC. *See Bryant v. Avado Brands, Inc.*, 187 F.3d 1271, 1276 (11th Cir.1999); *Lovelace v. Software Spectrum, Inc.*, 78 F.3d 1015, 1018 (5th Cir.1996); *Kramer v. Time Warner, Inc.*, 937 F.2d 767, 774 (2d Cir.1991); *see also In re Rockefeller Ctr. Properties, Inc. Sec. Litig.*, 184 F.3d 280, 293 (3d Cir.1999) (Nygaard, Circuit Judge, concurring in part and dissenting in part). As the Second Circuit reasoned,

the documents are required by law to be filed with the SEC, and no serious questions as to their authenticity can exist. Second, the documents are the very documents alleged to contain the various misrepresentations or omissions and are relevant not to prove the truth of their contents but only to determine what the documents stated.

Kramer, 937 F.2d at 774. We find this reasoning persuasive. Moreover, we note that there is no risk of unfair prejudice or surprise here because defendants do not object to our considering the proffered forms. *See* Appellee's Br. 54 n.32. Accordingly, we will take judicial notice of the SEC filings.

[24] Our perusal of the Amended Complaint and the SEC documents taken together yields the following information on trading activity during the Class Period:

Defendant	Date of Trade	Shares Traded	Total Shares	Percent Traded	Proceeds	Base Pay
Blount	6/12/1997	93,333	105,164	88.75%	$ 7,366,744	$650,000
Carr	6/12/1997	20,600	44,017	46.8%	$ 1,606,800	$350,000
Considine	5/6/1997	25,000	38,390	65.12%	$ 1,778,000	unknown
	7/25/1997	41,800	49,803	83.93%	$ 3,536,280	
Hassan	5/6/1997	233,200	257,082	90.71%	$18,189,600	$589,000
Hoynes	7/31/1997	41,800	58,527	71.42%	$ 3,437,632	$407,000
Murray	5/6/1997	6,000	11,407	52.6%	$ 426,000	unknown
Olivier	6/12/1997	71,200	105,899	67.24%	$ 5,553,600	$457,083

***290** While we will not infer fraudulent intent from the mere fact that some officers sold stock, "if the stock sales were unusual in scope or timing, they may support an inference of scienter." *Advanta*, 180 F.3d at 540. Defendants correctly note that these trades were not suspicious in scope; all seven of the defendants sold similar numbers of shares in the previous year. Indeed, a chart relied on by plaintiffs during oral argument on the motion to dismiss demonstrates that Blount, Carr, Hoynes, Murray, and Olivier all disposed of more shares in 1996 than in 1997. (App.360.) FN11

FN11. SEC filings disclose that in the six-and-a-half month period immediately preceding the Class Period, the officer-defendants disposed of the following numbers of shares: Blount: 93,333; Carr: 63,200; Hoynes: 80,200; Murray: 18,000; Olivier: 130,000; Considine: 40,000. (Supp.App.40-68.)

Plaintiffs counter, however, that the 1997 sales were unusual in timing because the seven officer-defendants sold stock during the months of May, June and July 1997 (the three months immediately prior to the Mayo disclosure), while in 1996, those same defendants sold stock only in January, February, March, November, and December. However, the relevant filings show that, while the officer-defendants did make substantial trades during the Class Period, there was also significant trading activity throughout the rest of 1997. In February 1997-a month before AHP first learned of the Mayo data-these individual defendants collectively disposed of over 233,000 shares. Moreover, in August 1996-approximately six months before the beginning of the Class Period-one defendant (Blount) had sold an additional 177,600 shares. Taken together, the SEC disclosures merely reveal that the individual officer-defendants engaged in trading activity during various months in both 1996 and 1997; they do not demonstrate any concerted insider effort to dispose of shares during the Class Period. Consequently, we do not believe that the individual defendants' trading patterns establish the requisite strong inference of scienter.

Nor have plaintiffs alleged facts that constitute strong circumstantial evidence of

misbehavior or recklessness. In essence, plaintiffs argue that because the District Court found a sufficiently strong inference of conscious misbehavior or recklessness as to AHP, the same state of mind should be imputed against the individual defendants. This approach, however, is foreclosed by the PSLRA. This Court has held that "[g]eneralized imputations of knowledge do not suffice regardless of the defendant's position within the company." *Advanta*, 180 F.3d at 539. Plaintiffs did not aver which officer-defendants, if any, were aware of the Mayo data prior to its public release. Nor have they made any allegations regarding individual knowledge or recklessness with respect to the European data. Therefore, plaintiffs cannot meet the heightened pleading requirements under this theory.

Because plaintiffs have failed to meet their burden of alleging particularized facts that give rise to a strong inference of fraudulent intent, we will affirm the District Court's dismissal of the counts against the individual officer-defendants.

D.

[25] After dismissing all of the plaintiffs' claims, the District Court denied plaintiffs leave to amend their complaint. ***291** We review this ruling for abuse of discretion.

[26] The Federal Rules of Civil Procedure express a preference for liberally granting leave to amend. *See* Fed.R.Civ.Proc. 15(a) ("[L]eave shall be freely given when justice so requires."). Nonetheless, a District Court may deny leave to amend on the grounds that amendment would cause undue delay or prejudice, or that amendment would be futile. *See Foman v. Davis,* 371 U.S. 178, 182, 83 S.Ct. 227, 9 L.Ed.2d 222 (1962); *Burlington*, 114 F.3d at 1434. In this case, the District Court denied leave to amend because of undue delay and futility of amendment. *See Oran,* 34 F.Supp.2d at 913-14.

In denying leave to amend, the District Court correctly noted that "[f]utility is governed by the same standard of legal sufficiency that applies under rule 12(b)(6)." *Id*. (citing *Burlington,* 114 F.3d at 1435). The court had earlier determined that the information allegedly omitted from the July 8 press release was not material because it would not have "altered the basic mix of information" available to investors. In arguing that amendment would not be futile, plaintiffs rely on a number of "new" facts that they claim have emerged since the Amended Complaint was filed. *See* Reply Br. at 30. Plaintiffs attach particular importance to the facts that (1) the FBI has reportedly begun an investigation into Redux's FDA approval process, and (2) that AHP has reached a $4.4 billion settlement in a products liability class action arising from its sale of the two drugs. We fail to see, however, how the inclusion of these additional allegations would change the analysis underpinning the District Court's dismissal.

Moreover, plaintiffs have not rebutted the District Court's findings regarding undue delay. The court noted that plaintiffs had already amended their complaint once, that "the case

[was] already one and a half years old; no discovery had been taken; and plaintiffs had four months to file the instant Amended Class Action Complaint." *Oran*, 34 F.Supp.2d at 914. In light of these facts, we hold that the District Court did not abuse its discretion in denying plaintiffs leave to amend.

III.

For the foregoing reasons, the judgment of the District Court is affirmed.