Merck Sharp & Dohme Corp. v. Albrecht[1]

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WHY IT MADE THE LIST

Since 2008, parties to pharmaceutical product liability cases have struggled with the "clear evidence" implied preemption standard articulated by the United States Supreme Court in *Wyeth v. Levine*.[3] In cases of allegedly inadequate warnings about FDA-approved prescription drugs, *Levine* rejected the contention that FDA approval, by itself, preempted state-law warning-based claims. Preemption could occur, *Levine* held, if "the FDA would not have approved" the label that the plaintiff claim state law required, so that simultaneous compliance with state and federal law would be "impossible."[4]

Following *Levine*, courts varied in the rigor with which they applied the "would not have approved" standard described by the Supreme Court. However, in those situations where FDA had actually rejected the warning being advocated by the plaintiff, most courts held that such warning claims was preempted.[5] Another area of general agreement was that preemption generally, and the question of what FDA "would have" done in particular, was a question of law for courts, as opposed to juries, to determine.[6]

However, in *In re Fosamax (Alendronate Sodium) Products Liability Litigation*, 852 F.3d 268 (3d Cir. 2017), the Third Circuit departed from both of these points of post-*Levine* consensus and imposed a standard for impossibility preemption that was effectively impossible to meet. Preemption in *Fosamax* had been recognized by the lower court because "approximately one month" after the plaintiff's injury, "FDA sent

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[1] ___ U.S. ___, 139 S. Ct. 1668 (U.S. 2019).

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[3] 555 U.S. 555 (2009) ("Levine").

[4] *Id.* at 571.

[5] Cerveny v. Aventis, Inc., 855 F.3d 1091, 1101–03 (10th Cir. 2017); Rheinfrank v. Abbott Laboratories, 680 F. Appx. 369, 386 (6th Cir. 2017); Chambers v. Boehringer Ingelheim Pharm., Inc., 2018 WL 849081, at *4–5 (M.D. Ga. Jan. 2, 2018); Amos v. Biogen Idec, Inc., 249 F. Supp.3d 690, 699–700 (W.D.N.Y. 2017); Willis v. Abbott Laboratories, 2017 WL 5988215, at *4 (W.D. Ky. Dec. 1, 2017); Swanson v. Abbott Laboratories, 2017 WL 5903362, at *7–8 (S.D. Ohio Nov. 28, 2017); Christison v. Biogen Idec, Inc., 199 F. Supp.3d 1315, 1347–48 (D. Utah 2016); *In re* Depakote, 87 F. Supp.3d 916, 921–23 (S.D. Ill. 2015); Cleary v. Biogen, Inc., 2017 WL 4126240, at *5–6 (Mass. Super. Sept. 13, 2017); Gentile v. Biogen Idec, Inc., 2016 WL 4128159, at *8 (Mass. Super. July 25, 2016).

[6] Guilbeau v. Pfizer, Inc., 880 F.3d 304, 318 (7th Cir. 2018); *Cerveny*, 855 F.3d at 1096; Caplinger v. Medtronic, Inc., 784 F.3d 1335, 1343 (10th Cir. 2015); *In re* Pharm. Industry Average Wholesale Price Litigation, 582 F.3d 156, 173 (1st Cir. 2009); Lofton v. McNeil Consumer & Specialty Pharm., 672 F.3d 372, 375 (5th Cir. 2012); Risperdal & Invega Product Liability Cases, 2017 WL 4100102, at *7 (Cal. Super. March 16, 2017).

Defendant a letter approving the change to the Adverse Reactions section of the label but denying the change to the Precautions section."[7]

The Third Circuit vacated and remanded, while addressing the "cryptic and open-ended" nature of the "clear evidence" preemption inquiry under *Levine*.[8] The Third Circuit viewed "clear evidence" as an "undefined" "anomaly."[9] To address this anomaly, the Third Circuit first equated *Levine's* reference to "clear evidence" with the heightened "clear and convincing" standard of proof.[10] However, imposition of a more stringent burden of proof was at odds with United States Supreme Court precedent, which rejected heightened implied preemption standards of proof.[11] Second, in a singular result, ignoring prior in-circuit precedent,[12] *Fosamax* held that the "counterfactual" preemption question of whether FDA would have rejected the plaintiff's proposed label change was a question of fact for the jury, not an issue of law for the judge.[13] Under *Fosamax*, had that decision stood, "[a] state-law failure-to-warn claim will only be preempted if a jury concludes it is highly probable that the FDA would not have approved a label change."[14] The likelihood of summary judgment on preemption was even more remote, available only when no "reasonable juror, looking at all the evidence and trying to reconstruct a hypothetical event, could conclude that it is less than highly probable that the FDA would have rejected the change."[15]

The defendant appealed to the United States Supreme Court, and on June 28, 2018, the Supreme Court granted *certiorari*.[16]

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[7] *In re* Fosamax (Alendronate Sodium) Prods. Liab. Litig., 951 F. Supp.2d 695, 702 (D.N.J. 2013) (citation omitted).

[8] 852 F.3d at 282.

[9] *Id.* at 284.

[10] *Id.* at 285 (noting that to establish impossibility preemption by clear evidence, "[t]he manufacturer must prove that the FDA would have rejected a warning not simply by a preponderance of the evidence, as in most civil cases," but by "clear and convincing evidence").

[11] Geier v. Am. Honda Motor Co., 529 U.S. 861, 870 (2000) ("Neither do we believe that the pre-emption provision, the saving provision, or both together, create some kind of 'special burden' beyond that inherent in ordinary pre-emption principles—which 'special burden' would specially disfavor pre-emption here.").

[12] Two of those prior decisions, *Fosamax* dismissed as "offhand" rulings. 852 F.3d at 288 & n.106 (disregarding rulings in *In re* Federal-Mogul Global Inc., 684 F.3d 355, 364 n.16 (3d Cir. 2012), and Horn v. Thoratec Corp., 376 F.3d 163, 166 (3d Cir. 2004)). However, many more such rulings existed. *See* South Jersey Sanitation Co. v. Applied Underwriters Captive Risk Assurance Co., 840 F.3d 138, 143 (3d Cir. 2016); Roth v. Norfalco LLC, 651 F.3d 367, 374 (3d Cir. 2011); Elassaad v. Independence Air, Inc., 613 F.3d 119, 124 (3d Cir. 2010); Deweese v. Nat'l R.R. Passenger Corp., 590 F.3d 239, 244 n.8 (3d Cir. 2009); Orson, Inc. v. Miramax Film Corp., 189 F.3d 377, 380 (3d Cir. 1999) (en banc); Taj Mahal Travel, Inc. v. Delta Airlines, Inc., 164 F.3d 186, 190 (3d Cir. 1998); Travitz v. Northeast Dep't ILGWU Health & Welfare Fund, 13 F.3d 704, 708 (3d Cir. 1994); Pennsylvania Med. Soc'y v. Marconis, 942 F.2d 842, 846 (3d Cir. 1991); Ayers v. Philadelphia Hous. Auth., 908 F.2d 1184, 1188 (3d Cir. 1990); Pokorny v. Ford Motor Co., 902 F.2d 1116, 1119 (3d Cir. 1990).

[13] 852 F.3d at 297. The rationale for this ruling was that, since the preemption question involved the likelihood of a future event, the decision maker had to weigh conflicting evidence, draw inferences, and assess the motives and thought processes of FDA officials. *Id.* at 289–91.

[14] *Id.* at 293.

[15] *Id.* at 297.

[16] Merck Sharp & Dohme Corp v. Albrecht, 138 S. Ct. 2705 (2018).

DISCUSSION OF THE FACTS, HOLDING, AND RATIONALE

Fosamax is an FDA approved prescription drug made by defendant Merck Sharp & Dohme Corp. ("Merck"). This drug was FDA approved for prevention and treatment of osteoporosis in postmenopausal women.[17] Fosamax is one of a class of drugs, called bisphosphonates, whose chemical properties allow them to retard the resorption of calcium in post-menopausal women's bones, thereby maintaining bone strength and mass. Retarding calcium loss unfortunately has some drawbacks, alleged by plaintiffs, that over the long term can lead to "microcracks" that increase the otherwise very low risk of "atypical" femoral fractures ("AFF").[18] That risk is what the *Fosamax* litigation is about.

This risk of AFF from long-term Fosamax use had also been the subject of FDA review, which gave rise to Merck's preemption defense. The initial labeling for Fosamax, following its 1995 FDA approval, did not mention AFF."[19] In 2008, Merck submitted a safety update addressing AFF and, based on some recent medical articles, suggested there might be association between long-term bisphosphonate use and AFF, which it called "stress fractures."[20]

FDA did not act before Merck filed a new drug application (NDA) supplement, seeking FDA approval to add AFF-related language to the label that did not confirm causation. Substantial dialogue with FDA ensued, with FDA looking toward classwide labeling for all bisphosphonates. Ultimately, in May 2009, FDA formally approved changes to the Adverse Reactions section but rejected the rest of Merck's NDA supplement.[21]

The FDA explained that the defendant's "justification" for the proposed change to the Precautions section was "inadequate" because "[i]dentification of 'stress fractures' may not be clearly related to the atypical subtrochanteric fractures that have been reported in the literature." FDA invited Merck to "resubmit" its application and to "fully address all the deficiencies listed."[22]

Defendant instead withdrew its application, which according to the majority meant that the label was unchanged until 2011, when FDA completed its own investigation and mandated language that referenced AFF rather than stress fractures.[23]

As in *Levine*,[24] the majority in *Albrecht* was accused of playing fast and loose with the facts to minimize the basis for preemption.[25] Justices concurring in the result in *Albrecht* mentioned a number of additional facts: (1) at the time the label change was pending, AFF was still considered a form of "stress fracture"; (2) also while the label

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[17] Merck Sharp & Dohme Corp. v. Albrecht, ___ U.S. ___, 139 S. Ct. 1668, 1673, 203 L. Ed. 2d 822 (2019) ("*Albrecht*").

[18] *Id.* at 1673–74. *See* Eve Donnelly, Anas Saleh, Aasis Unnanuntana & Joseph M. Lane, *Atypical Femoral Fractures: Epidemiology, Etiology, and Patient Management*, 6(3) CURRENT OPINION SUPPORT PALLIATIVE CARE 348 (Sept. 2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4556525/.

[19] *Albrecht*, 139 S. Ct. at 1674.

[20] *Id.*

[21] *Id.*

[22] *Id.*

[23] *Id.* at 1674-75.

[24] 555 U.S. at 613-19.

[25] *Albrecht*, 139 S. Ct. at 1685 (Alito, J, for the Chief Justice and Kavanaugh, J.).

change was pending, FDA took the position that "the data that FDA has reviewed have not shown a clear connection between bisphosphonate use and a risk of" AFF; (3) in 2010, an FDA task force again found "no established causal association" between bisphosphonates and AFF; and (4) FDA's amicus brief in *Albrecht* confirmed that "FDA's decision not to require a label change prior to October 2010 reflected the [Agency's] determination that a new warning should not be included in the labeling."[26]

The Supreme Court unanimously reversed the Third Circuit's legal rulings but did not reach the ultimate preemption question. All nine justices agreed that preemption is "a question of law, normally for a judge to decide without a jury."[27] "We here decide that a judge, not a jury, must decide the pre-emption question."[28] Further, "where we have determined that the question is 'for the judge and not the jury,' we have also held that 'courts may have to resolve subsidiary factual disputes' that are part and parcel of the broader legal question."[29] *Albrecht* analogized to patent cases, where courts have long decided any subsidiary factual issues involved in patent construction.[30]

The majority gave several reasons: preemption "involves the use of legal skills"; "judges . . . are better equipped" both "to evaluate the nature and scope of an agency's determination" and "to understand and to interpret agency decisions"; "judges are normally familiar with principles of administrative law"; and "uniformity is . . . a virtue" when "determin[ing]" the "scope and effect" of the nationally applicable decisions of a federal agency.[31]

As a consequence of preemption being a legal question, the second aspect of the Third Circuit's decision—the heightened burden of proof—became a non-issue. When deciding preemption as a legal question, "the judge must simply ask himself or herself whether the relevant federal and state laws irreconcilably conflict."[32] Also of general consequence, *Albrecht* marks the Supreme Court's first recognition of overwarning as a legitimate FDA concern. "Label information is designed to 'prevent overwarning' so that less important information does not 'overshadow' more important information."[33]

Specifically with respect to prescription drugs, *Albrecht* reiterated that the boundaries of implied impossibility preemption remain tied to a manufacturer's ability to use an FDA regulatory process permitting certain label changes without prior FDA approval. "[A]n FDA regulation called the 'changes being effected' or 'CBE'

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[26] *Id.* at 1685–86 (citations and quotation marks omitted).

[27] *Id.* at 1679. Similarly, Justice Alito's concurrence stated, "I agree with the Court's decision on the only question that it actually decides, namely, that whether federal law allowed [defendant] to include in the [drug] label the warning alleged to be required by state law is a question of law to be decided by the courts." *Id.* at 1684.

[28] *Id.* at 1676.

[29] *Id.* at 1680 (quoting Teva Pharm. USA, Inc. v. Sandoz, Inc., 574 U.S. 318, 135 S. Ct. 831, 838 (2015)).

[30] *Id.* at 1679–80 (relying on Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996)).

[31] *Id.* at 1679–80 (citations omitted).

[32] *Id.* at 1679 (citations and quotation marks omitted).

[33] *Id.* at 1673 (quoting 73 Fed. Reg. 49603, 49605–06 (FDA Aug. 22, 2008) & 73 Fed. Reg. 2848, 2851 (FDA Jan. 16, 2008)). *See* Ridings v. Maurice, 444 F. Supp. 3d 973, 992 (W.D. Mo. 2020); Sabol v. Bayer HealthCare Pharm., Inc., 439 F. Supp. 3d 131, 147 (S.D.N.Y. Feb. 12, 2020); McGrath v. Bayer HealthCare Pharm., Inc., 393 F. Supp. 3d 161, 169 (E.D.N.Y. 2019); Klein v. Bayer HealthCare Pharm., Inc., 2019 WL 3945652, at *5 (D. Nev. Aug. 21, 2019) (all discussing overwarning post-*Albrecht*).

regulation permits drug manufacturers to change a label without prior FDA approval if the change . . . 'add[s] or strengthen[s] a . . . warning where there is 'newly acquired information' about the 'evidence of a causal association' between the drug and a risk of harm."[34] The Court also emphasized that only agency actions constituting "law" for Supremacy Clause purposes have preemptive effect.[35] These actions include "notice-and-comment rulemaking," "formally rejecting a warning label," and any "other agency action carrying the force of law."[36] Where "the CBE regulation permits changes . . . a drug manufacturer will not ordinarily be able to show that there is an actual conflict between state and federal law such that it was impossible to comply with both."[37]

Although the only issue actually decided by *Albrecht* was that preemption was a question of law,[38] the majority did "elaborate"[39] on the criteria for "clear evidence" of impossibility preemption in cases "like" *Levine*.[40] Concerning the *Levine* formulation that "clear evidence that the FDA would not have approved a change to [the drug's] label," being required for impossibility preemption,[41] the majority opined:

> In a case like [*Levine*], showing that federal law prohibited the drug manufacturer from adding a warning that would satisfy state law requires the drug manufacturer to show that it fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve changing the drug's label to include that warning.[42]

The "question of [FDA's] disapproval 'method' [was] not now before" the Court in *Albrecht*, so that aspect of preemption was not addressed.[43]

IMPACT

The greatest impact of *Albrecht* will be on preemption itself. The Court's rationale is not limited to any particular form of preemption. Disputes involving compliance with the FDCA in preemption cases will be resolved by judges whether they arise in the context of implied preemption, as in *Albrecht*, or in a determination of express

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[34] *Albrecht*, 139 S. Ct. at 1673 (quoting 21 C.F.R. §314.70(c)(6)(iii)(A)).

[35] *Id.* at 1679.

[36] *Id.* (citing, *inter alia*, 21 U.S.C. §355(o)(4)(A)). This regulatory provision requires that FDA "shall promptly notify" a manufacturer whenever the Agency "becomes aware of new information . . . that the Secretary determines should be included in the labeling of the drug." Thus, "the only agency actions that can determine the answer to the preemption question . . . are agency actions taken pursuant to the FDA's congressionally delegated authority." *Albrecht*, 139 S. Ct. at 1672, 1679.

[37] *Id.* at 1679.

[38] *See* Dolin v. GlaxoSmithKline LLC, 951 F.3d 882, 891 (7th Cir. 2020) ("[I]n *Albrecht*, the principal holding was that the 'clear evidence' standard for the impossibility preemption defense is a question of law for a court to decide.").

[39] *Albrecht*, 139 S. Ct. at 1676.

[40] *Id.* at 1678.

[41] *Levine*, 555 U.S. at 571.

[42] *Albrecht*, 139 S. Ct. at 1678.

[43] *Id.* at 1679.

preemption. This ruling should have significant effect in medical device express preemption cases, where "parallel claims" alleging FDCA violations are the primary means to avoid preemption.[44] Preemption being a legal issue should also reduce both sides' reliance on regulatory experts in preemption cases, since experts are not permitted to opine on questions of law,[45] and one court has already so held.[46]

The determination that preemption is solely a legal issue, including resolution of "contested brute facts,"[47] should also impact how courts address preemption questions. In patent cases, for instance, dispositive motions involving patent construction are decided without a weighted viewing of the facts most favorably to the non-moving party.[48] Also, on appeal, judicial factfinding in patent cases cannot be overturned unless the trial court's result is "clearly erroneous."[49] The same level factual playing field may become the norm in preemption determinations as well. Finally, interlocutory appeal of preemption decisions may become more available, since the purely legal question of preemption is no longer tied to any jury's ultimate resolution of litigation.

The majority's emphasis on formal regulatory actions alone having preemptive effect will circumscribe the universe of possible FDA actions that defendants can assert as a basis for preemption. Informal give and take between manufacturers and the agency are insufficient, so potential defendants will have to utilize more formal avenues if they anticipate future reliance on FDA actions as preemptive.[50] The preemptive effect of FDA guidance documents is questionable under this standard, as are warning letters and other preliminary FDA enforcement activity—none of which

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[44] *See* Delfino v. Medtronic, Inc., 2019 WL 2415049, at *10 (Minn. App. June 10, 2019) (express preemption case; "the issue of whether [something] constituted a federal requirement is a question of law to be decided by a judge"); Conley v. St. Jude Med., LLC, ___ F. Supp. 3d ___, 2020 WL 5087889, at *8 (M.D. Pa. Aug. 28, 2020) (express preemption case; "Preemption is a matter of law.").

[45] *See*, *e.g.*, Burkhart v. Washington Metro. Area Transit Auth., 112 F.3d 1207, 1213 (D.C. Cir. 1997) ("Each courtroom comes equipped with a 'legal expert,' called a judge, and it is his or her province alone to instruct the jury on the relevant legal standards.").

[46] *Delfino*, 2019 WL 2415049, at *12 ("determining compliance with a regulation . . . is a question of law"; "expert opinion as to a legal matter is generally inadmissible," so trial court "did not abuse its discretion by prohibiting [plaintiff's expert] from opining on a legal question").

[47] *Id.* at 1680.

[48] Business Objects, S.A. v. Microstrategy, Inc., 393 F.3d 1366, 1371–72 (Fed. Cir. 2005); Searfoss v. Pioneer Consol. Corp., 374 F.3d 1142, 1148 (Fed. Cir. 2004); Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc., 261 F.3d 1329, 1336 (Fed. Cir. 2001).

[49] The Court so held in the *Teva v. Sandoz* decision cited in *Albrecht*. *See* 135 S. Ct. at 836–37. *See* Obasi Inv. Ltd. v. Tibet Pharm., Inc., 931 F.3d 179, 188 n.9 (3d Cir. 2019) (applying "clearly erroneous" standard under *Albrecht*).

[50] *Albrecht*'s "language could be understood as indicating that less formal exchanges of correspondence . . . are not enough to provide such 'clear evidence.'" *Dolin*, 951 F.3d at 890. *See In re* Avandia Mktg., Sales & Prods. Liab. Litig., 945 F.3d 749, 760 (3d Cir. 2019) ("informal phone conversations with an FDA official" could not support preemption after *Albrecht*); Crockett v. Luitpold Pharm., Inc., 2020 WL 433367, at *7–8 (E.D. Pa. Jan. 28, 2020) (inconsistent FDA "non-approvable letters" not preemptive).

are, in and of themselves, legally binding.[51] Any form of "formal" FDA activity, however, retains preemptive force.[52]

Finally, every clause of *Albrecht*'s "like" *Levine* "elaboration" on the "clear evidence" standard for implied impossibility preemption will generate legal arguments, as product liability plaintiffs utilize every available avenue to escape preemption. "*Albrecht* is better understood as a clarification of the impossibility standard in [*Levine*] rather than as a repudiation of it."[53] Perhaps most significantly in this regard, unlike *Levine*:

> In *Albrecht*, the Court wrote that the "clear evidence" needed is "evidence . . . that the FDA, in turn, . . . would not approve a change to the drug's label. . . ." That language implies that the manufacturer must have actually requested a change and that the FDA rejected it.[54]

Albrecht's "elaboration" also refers to warning changes advanced by "manufacturers," so whether impossibility preemption can be based on the results of formal FDA proceedings instituted by others—most notably citizen's petitions[55]—will be litigated. Post-*Albrecht* decisions so far continue to treat FDA resolution of citizen petitions as preemptive.[56] *Albrecht*'s statement about FDA being "fully informed" invites plaintiffs to attack the adequacy of submissions to the Agency, something prohibited in *Buckman*,[57] a decision nowhere cited by the majority. After *Albrecht*, some defendants have been required to come forward with evidence that a "fully informed" FDA would reject the language advocated by the plaintiff.[58] Exposing FDA's decision-making process to outside scrutiny is unlikely,[59] so

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[51] FDA guidance documents typically recite that they are not legally binding. *Cf.* Kelsey v Alcon Laboratories, Inc., 2019 WL 1884225, at *6–7, 10–11 (Utah Dist. April 22, 2019) (involving a guidance document expressly incorporated as medical device "special controls"). FDA "regulatory letters do not constitute final agency action." Exela Pharma Sciences, LLC v. Sandoz, Inc., ___ F. Supp. 3d ___, 2020 WL 5535026, at *13 (W.D.N.C. Sept. 15, 2020) (citation and quotation marks omitted). *See, e.g.*, *Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 943 (D.C. Cir. 2012) ("FDA's warning letters . . . neither mark the consummation of the agency's decisionmaking process nor determine [anyone's] legal rights or obligations.") (footnote omitted).

[52] *Dolin*, 951 F.3d at 891 ("formal[] FDA mandate[] that all [similar drugs] carry a uniform, class-wide warning label" was preemptive); Thomas v. Bracco Diagnostics, Inc., 2020 WL 1016273, at *10 (W.D. La. Feb. 27, 2020) (same).

[53] *Dolin*, 951 F.3d at 888.

[54] *Id.* at 890 (quoting *Albrecht*, 139 S. Ct. at 1972). *See Crockett*, 2020 WL 433367, at *7 ("[I]t is not sufficient for the proponent to contend that if it had submitted a new label—with additional warnings—to the FDA, the FDA *would have* rejected the warning.").

[55] FDA Citizen petitions initiate the sort of "official" administrative proceeding that *Albrecht* required. *See* 21 C.F.R. §10.30.

[56] Cerveny v. Aventis, Inc., 783 F. Appx. 804, 808 n.9 (10th Cir. 2019); State v. Purdue Pharma L.P., 2019 WL 3776653, at *2–3 (N.D. Dist. July 22, 2019).

[57] *See* Buckman Co. v. Plaintiffs Legal Comm., 531 U.S. 341, 351 (2001) (finding preempted "claims [that] would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court").

[58] A.Y. v. Janssen Pharm., Inc., 224 A.3d 1, 16 (Pa. Super. 2019); *In re* Testosterone Replacement Therapy Products Liability Litigation Coordinated Pretrial Proceedings, 430 F. Supp. 3d 516, 531 (N.D. Ill. 2019).

[59] United States *ex rel.* Touhy v. Ragen, 340 U.S. 462 (1951).

determinations of whether FDA received full information could be referred to the Agency itself for adjudication.[60] Under *Albrecht*, "the FDA, and only the FDA, can determine what information is "material" to its *own* decision to approve or reject a labelling change."[61]

Finally, to the extent that *Albrecht* makes litigation of *Levine*'s "clear evidence" standard more complicated and expensive, another effect will be to shift the focus of preemption in prescription drug cases to the other requirements of FDA's CBE regulation. Chief among these is the regulation's requirement that a manufacturer possess "newly acquired information" concerning a "clinically significant adverse reaction[]."[62] *Albrecht* did not address any aspects of prescription drug preemption beyond the *Levine* "clear evidence standard," so these other prerequisites to the application of the CBE regulation are unaffected[63] as defining the boundaries of implied impossibility preemption.[64]

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[60] Such an approach has been taken in the *Zofran* MDL, where the defendant filed a citizen petition with FDA to determine if the Agency was "fully informed." Other alternatives are to assert FDA "primary jurisdiction" or to ask FDA—as the Supreme Court did in *Albrecht*—for its views as *amicus curiae*. *See* Williams v. Mentor Worldwide LLC, 2019 WL 4750843, at *6 (N.D. Ohio Sept. 30, 2019) (post-*Albrecht* preemption decision relying on FDA amicus brief). *See* Kisor v. Wilkie, ___ U.S. ___, 139 S. Ct. 2400, 2418 n.6 (2019) (an agency appearing as amicus is "not a party to the litigation," so "there [is] simply no reason to suspect that the interpretation [does] not reflect the agency's fair and considered judgment").

[61] *Avandia*, 945 F.3d at 759 (emphasis in original). *Avandia* rejected preemption where FDA "stated that it had reviewed the data . . . and found that the information presented is inadequate." *Id.* at 758 (citation and quotation marks omitted).

[62] 21 C.F.R. §201.57(c)(6)(i) ("newly acquired information" for purposes of CBE regulation must involve a risk that is "potentially fatal," "serious even if infrequent," or can "be prevented or mitigated through appropriate use of the drug").

[63] Courts have declined to hold that these CBE prerequisites are subsumed within the clear evidence test. Boone v. Boehringer Ingelheim Pharm., Inc., ___ A.3d ___, 2020 WL 2121063, at *13 n.33 (Conn. May 4, 2020) ("The clear evidence standard in [*Albrecht*] applies only when a defendant seeks to prove that compliance with a state law obligation remains impossible notwithstanding its ability to act unilaterally under federal law."). Accord Estep v. Boehringer Ingelheim Pharm., Inc., 2020 WL 5290777, at *4–5 (Conn. Super. Aug. 25, 2020); Adkins v. Boehringer Ingelheim Pharm., Inc., 2020 WL 1890681, at *4 (Conn. Super. Mar. 13, 2020); Pradaxa Cases, 2019 WL 6043513, at *2 n.3 (Cal. Super. Nov. 8, 2019); Roberto v. Boehringer Ingelheim Pharm., Inc., 2019 WL 5068452, *12 n.20 (Conn. Super. Sept. 11, 2019).

[64] Indeed, quite a few courts have gone this route, deciding preemption cases post-*Albrecht* by determining that either lack of "new" evidence or absence of a "clinically significant risk" precluded resort to CBE warning changes, and thus supported dismissal of warning claims as preempted. Gayle v. Pfizer Inc., ___ F. Supp. 3d ___, 2020 WL 1685313, at *5–6 (S.D.N.Y. Apr. 7, 2020); Mahnke v. Bayer Corp., 2020 WL 2048622, at *3–5 (C.D. Cal. Mar. 10, 2020); Ridings v. Maurice, 444 F. Supp. 3d 973, 992–93 (W.D. Mo. 2020); Thomas v. Bracco Diagnostics, Inc., 2020 WL 1016273, at *9–10 (W.D. La. Feb. 27, 2020); Sabol v. Bayer HealthCare Pharm., Inc., 439 F. Supp. 3d 131, 147–48 (S.D.N.Y. Feb. 12, 2020); Drescher v. Bracco Diagnostics Inc., 2020 WL 699878, at *5 (D. Ariz. Jan. 31, 2020); McGrath v. Bayer HealthCare Pharm., Inc., 393 F. Supp. 3d 161, 171 (E.D.N.Y. 2019); Goodell v. Bayer HealthCare Pharm., Inc., 2019 WL 4771136, at *4 (D. Mass. Sept. 30, 2019); Klein v. Bayer Healthcare Pharm., Inc., 2019 WL 3945652, at *5 (D. Nev. Aug. 21, 2019); *Estep*, 2020 WL 5290777, at *7–12; *Adkins*, 2020 WL 1890681, at *5–7; *Pradaxa Cases*, 2019 WL 6043513, at *3–4 (Cal. Super. Nov. 8, 2019); *Roberto*, 2019 WL 5068452, at *13.