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2nd Circ. Baby Food Ruling Disregards FDA's Expertise

By **Eric Kraus, Joshua Glasgow and Kenneth Manning** (March 25, 2024, 3:52 PM EDT)


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The U.S. Court of Appeals for the Second Circuit is one of the most respected appellate courts in the country, and has a long and illustrious history in the annals of U.S. jurisprudence.

From luminaries such as Judges Learned Hand and Henry Friendly, to future U.S. Supreme Court Justices John Marshall Harlan II, Thurgood Marshall and Sonia Sotomayor, Second Circuit judges have often shaped the legal landscape of the country.

But the Second Circuit is not infallible. And its January decision in White v. Beech-Nut Nutrition Co. may be a case in point.

In White, the court considered whether the primary jurisdiction doctrine should defer litigation until the U.S. Food and Drug Administration weighs in on issues that are central to the case. Those issues include evaluating the health risks, if any, presented by the presence of certain heavy metals in baby foods.

The U.S. District Court for the Northern District of New York determined that the doctrine applied. It ordered that the case should be stayed, without prejudice, to permit the FDA to complete its analysis of these complex science- and policy-based issues.[1]

The Second Circuit reversed, on the grounds that the FDA was taking too long in its analysis of the toxicity of lead, cadmium, arsenic and mercury. It relied primarily on its 2022 decision in Palmer v. Amazon.com Inc., and its 2006 decision in Ellis v. Tribune Television Co.

The Second Circuit reasoned "that any advantages of deferring to the FDA under the primary jurisdiction doctrine are outweighed by the potential costs resulting from the delay in administrative proceedings."[2] This decision, however, ignored other considerations addressed by Palmer and Ellis.

What is the primary jurisdiction doctrine?

The doctrine of primary jurisdiction grew out of two different sets of considerations: the need for uniformity, and the need to defer to the subject-matter expertise wielded by various administrative agencies.

Regarding the need to avoid inconsistent decisions by various courts, the Supreme Court explained in

1907, in Texas & Pacific Railway Co. v. Abilene Cotton Oil Co., that if decisions were left to juries and courts, "it would follow that, unless all courts reached an identical conclusion, a uniform standard of rates in the future would be impossible."[3]

The doctrine was expanded 15 years later by Justice Louis Brandeis, who noted in Great Northern Railway Co. v. Merchants Elevator Co. that the "inquiry is essentially one of fact and of discretion in technical matters ... [that] is commonly to be found only in a body of experts."[4]

As described in its Ellis v. Tribune Television Co. decision, the Second Circuit developed a four-prong test for evaluating whether the doctrine should be applied:

- Whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise;
- Whether the question at issue is particularly within the agency's discretion;
- Whether there exists a substantial danger of inconsistent rulings; and
- Whether a prior application to the agency has been made.[5]

The Second Circuit also noted, in its 1995 decision in National Communications Association Inc. v. American Telephone & Telegraph Co., that the "court must also balance the advantages of applying the doctrine against the potential costs resulting from complications and delay in the administrative proceedings."[6]

What did the Second Circuit say in the White case?

In White, the Second Circuit ignored the so-called Ellis factors — a point it acknowledged — and instead concluded "that any advantages of deferring to the FDA under the primary jurisdiction doctrine are outweighed by the potential costs resulting from the delay in administrative proceedings."[7]

The court recited various changes in the timeline initially set by the FDA and anticipated by the district court:

> In deferring under the primary jurisdiction doctrine, the district court reasoned that the FDA is presently working on its initiative, Closer to Zero: Action Plan for Baby Foods (Action Plan). The district court explained that under the Action Plan, "by April 2024, the FDA plans to finalize action levels for lead and propose action levels for arsenic, with cadmium and mercury consideration and decisions to follow."
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> But since the district court's decision, the FDA has abandoned these previously announced timelines. The FDA no longer expects to finalize lead action levels in April 2024 and has also revised its expected timeline for issuing draft guidance on proposed action levels for arsenic and cadmium. For arsenic and cadmium, the FDA now indicates only that it expects to reach the interagency review process sometime in 2024 — a step that precedes issuing draft guidance. [8]

Should the Second Circuit have considered the other Ellis factors?

The question of whether specific heavy metals carry health risks in this context, and if so, at what levels,

is unquestionably a highly technical one that requires expertise across a range of scientific and medical disciplines.

The FDA has already embarked on its evaluation through a review process announced on April 8, 2021.[9] There is also no question that evaluating the safety of ingredients of food products is well within the portfolio of the FDA.[10]

The real issues are: (1) whether the Second Circuit was correct in ignoring the Ellis factors in favor of evaluating only the risks and benefits of delaying judicial intervention into the dispute of the case; and (2) whether considering only the risk/benefit factor was consistent with the rationale of earlier Second Circuit decisions upon which the determination in White was based. The answer to both questions is no.

Will a district court resolve the issues surrounding baby food litigation faster than the FDA?

The Second Circuit is correct that the FDA is taking a long time to consider the issues that are also part of the underlying allegations in the litigation. But that duration is a reflection of the complexities of the issues, and does not suggest that a district court will be able to resolve these issues with greater alacrity or more efficiency.

Expert reports, expert depositions, Daubert hearings and related determinations by the court would likely push the duration of court proceedings well beyond the time when the FDA will issue relevant guidance. At that point, expert reports will need to be revised and supplemented, additional expert depositions will need to be scheduled, and Daubert hearings, if commenced already, might need to be reopened.

Alternatively, the court might issue rulings that contradict the findings of the FDA, raising the risk of inconsistent decisions and verdicts as other jurisdictions consider similar class action claims.

For example, class actions against different baby food manufacturers are pending in different jurisdictions, including the U.S. District Court for the Northern District of California,[11] the U.S. District Court for the Eastern District of New York[12] and the U.S. District Court for the Southern District of New York.[13]

Indeed, many cases involving scientific and medical issues take an exceedingly long time when left to the devices of a judge or jury. For example, In re: Zofran (Ondansetron) Products Liability Litigation,[14] a case involving an anti-nausea drug, was commenced in 2015, and did not conclude until June 2021, when the U.S. District Court for the District of Massachusetts issued a decision dismissing all claims.[15]

It is no wonder that the FDA is taking its time in answering the questions it is considering under its action plan. These are important, complex issues that implicate, in some instances, novel scientific and medical questions, such as:

- What testing methods are most reliable in measuring lower levels of contaminants in food?
- What is the variability in concentrations of heavy metals in foods eaten by infants and young children?
- At what dose does the presence of a heavy metal present a health risk to infants and young children?

- What is the scientific basis for establishing action levels?

- Are there other nutrients that help protect against the health effects associated with contaminants?[16]

Further, while the timeline originally proposed by the FDA to answer these and other questions has proven to be overly ambitious, the agency has already achieved certain goals, such as setting draft guidance for lead in juices, developing action levels, and submitting draft guidance for interagency review for lead in baby foods and for young children.[17]

Although the Second Circuit declined to address the Ellis factors, there is no reason to believe that the district court's considerations of these factors were inaccurate or wrongly decided. Indeed, in its analysis, the district court found that three of the four Ellis factors supported invoking the doctrine:

- "[R]esolution of plaintiffs' claims depends on 'technical and policy considerations within the FDA's field of expertise.'"

- "[F]ood safety standards are within the FDA's authority and discretion."

- "[T]here is a substantial danger of inconsistent rulings if individual courts make determinations regarding heavy metals."[18]

As for the fourth factor, the district court noted that the defendant conceded the parties had "not made any previous application to the FDA on the issues before this Court."[19] This factor was the only one that militated against a finding that the FDA had primary jurisdiction over the dispute.

However, even that factor is muted by virtue of the fact that, while no party had specifically made an application to the FDA, the agency was already evaluating the issues regarding baby food toxicity even before the findings of the congressional subcommittee were released, which were then followed by the first of many related class actions.[20]

The White court also addressed the risk/benefit question:

> Finally, the Court acknowledges that applying the primary jurisdiction doctrine would necessarily delay plaintiffs' case. However, not applying the doctrine to this case will also result in increased costs and complications because it will force the parties to litigate a case that forthcoming FDA pronouncements will likely render moot.[21]

Whether waiting for the FDA to speak on these issues will render the claims moot or result in duplicate efforts regarding experts and their reports, depositions and Daubert proceedings, the district court was correct in recognizing that the benefits of letting the agency experts weigh in on the issues outweigh the cost of deferral and delay.

The Second Circuit provides no indication that the district court will be any better — or faster, but with equal scientific rigor — at addressing these questions, each of which may play a role in bringing the class action to a close.

Is the risk/benefit analysis of White consistent with Palmer and other Second Circuit precedents?

The White court's reliance on Palmer v. Amazon.com Inc. to justify its determination as to the primary

jurisdiction doctrine is misplaced. The Palmer case involved a workplace dispute at an Amazon warehouse during the COVID-19 pandemic.

The plaintiffs — employees at the warehouse and members of their households — alleged that Amazon was violating federal and state guidance by discouraging social distancing, handwashing and disinfecting work stations, and that the company did not adequately track employees who tested positive for COVID-19.

The Palmer court did not dismiss the Ellis factors, but instead addressed each on the merits. It found that none of the Ellis factors warranted exercise of the primary jurisdiction doctrine:

- "[T]he question[s] at issue [there were well] within the conventional experience of judges";
- The questions at issue were not "particularly within the agency's discretion";
- There did not appear to be a "danger of inconsistent rulings"; and
- The plaintiffs had not made any "prior application to the [relevant] agency" — the Occupational Safety and Health Administration — that might otherwise support a finding that primary jurisdiction was appropriate.[22]

Thus, the four Ellis factors all militated against invoking the primary jurisdiction doctrine in Palmer.

The Palmer court also addressed the cost/benefit analysis. It noted that OSHA was overwhelmed with other responsibilities during the pandemic and concluded that "it is not apparent that OSHA is likely, as a policy matter, to shift gears and prioritize developing more general workplace COVID-19 safety standards — much less standards that would provide meaningful guidance with respect to Amazon's JFK8 facility."[23]

In other words, unlike in White, the agency had not even indicated an interest in dealing with the issues presented, much less started its investigation. In White, the FDA is fully invested in analyzing the relevant issues and promulgating rules regarding the alleged toxicity of heavy metals in baby food.

The Second Circuit also cited its 2021 decision in Seneca Nation of Indians v. New York for the proposition that "deferring to the FDA would 'unnecessarily prolong [this] case,' likely for upwards of several years."[24] But that case, too, presents a very different and distinguishing set of circumstances.

Seneca Nation centered on a contract dispute between the Seneca Nation and the state of New York regarding casino gambling proceeds. The matter had already been fully arbitrated, but the Seneca Nation, under the Federal Arbitration Act, sought to overturn the award, while New York sought to enforce it.

The court declined to overturn the award, and also declined the Seneca Nation's request to refer the matter to the U.S. Department of Interior pursuant to the primary jurisdiction doctrine.

At the heart of the matter was a contract dispute resolved by arbitration that the parties had agreed to put before the district court. Moreover, in considering the Ellis factors, the court noted that "[c]ontract interpretation is a basic competency of courts."[25] Thus, the factors that motivated the Seneca Nation court to decline to defer jurisdiction are simply not present in White.

The Second Circuit's refusal to consider the four Ellis factors suggests that the risk/benefit analysis trumps every other consideration, but no prior decision suggests that this is true. In Palmer, Ellis and Seneca Nation, the court addressed all five of the factors of the doctrine, and gave no indication that one deserved more consideration than another.

By declining to allow the FDA — the agency charged with evaluating all the scientific and medical evidence — to do so, the Second Circuit has asked a great deal of the district court and, potentially, jurors in the U.S. District Court for the Northern District of New York. If the district court proceeds expeditiously, it may be deprived of the sophisticated analyses that the FDA is uniquely competent to conduct.

In fact, if it proceeds without regard for the FDA's expertise, it may turn out that much time and effort will have been expended that could have been saved if the Second Circuit had granted the FDA primary jurisdiction and waited for the agency's input.

In any event, it appears that the Second Circuit, at least in certain cases — particularly where agency action is likely to take significant time to come to a conclusion — will allow a risk/benefit analysis to take precedence over any of the other Ellis factors.

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[1] See In re: Beech-Nut Nutrition Co. Baby Food Litig., 651 F. Supp. 3d 629 (N.D.N.Y. 2023), vacated and remanded sub nom. White v. Beech-Nut Nutrition Co., No. 23-220-CV, 2024 WL 194699 (2d Cir. Jan. 18, 2024).

[2] White, 2024 WL 194699, at *2.

[3] Texas & Pac. Ry. Co. v. Abilene Cotton Oil Co., 204 U.S. 426, 440 (1907).

[4] Great N. Ry. Co. v. Merchants Elevator Co., 259 U.S. 285, 291 (1922).

[5] See Ellis, 443 F.3d at 82-83.

[6] Nat'l Commc'ns Ass'n Inc. v. Am. Tel. & Tel. Co., 46 F.3d 220, 223 (2d Cir. 1995) (citing Ricci v. Chicago Mercantile Exch., 409 U.S. 289, 321 (1973)).

[7] White, 2024 WL 194699, at *2.

[8] White, 2024 WL 194699, at *2 (citations omitted).

[9] In re: Beech-Nut Nutrition Co. Baby Food Litig., 651 F. Supp. 3d at 633.

[10] See 21 C.F.R. pt. 117 (2024). See also, U.S. Food & Drug Admin., Producing a Food Product that is Regulated by FDA (May 7, 2019), https://www.fda.gov/food/food-industry/producing-food-product-

regulated-fda#:~:text=The%20agency%20regulates%20all%20foods,specific%20nature%20of%20your%20product.

[11] In re: Plum Baby Food Litig., No. 21-CV-00913 (N.D. Cal. filed Feb. 5, 2021).

[12] In re: Hain Celestial Heavy Metals Baby Food Litig., No. 21-CV-00678 (E.D.N.Y. filed Feb. 8, 2021).

[13] In re: Nurture Baby Food Litig., No. 21-CV-1217 (S.D.N.Y. filed Feb. 10, 2021).

[14] In re: Zofran (Ondansetron) Prods. Liab. Litig., No. 1:15-md-2657 (D. Mass. filed Oct. 13, 2015).

[15] See In re: Zofran (Ondansetron) Prods. Liab. Litig., 541 F. Supp. 3d 164 (D. Mass. 2021), aff'd, 57 F.4th 327 (1st Cir. 2023).

[16] U.S. Food & Drug Admin., Closer to Zero: Reducing Childhood Exposure to Contaminants from Foods (Feb. 21, 2024), https://www.fda.gov/food/environmental-contaminants-food/closer-zero-reducing-childhood-exposure-contaminants-foods.

[17] Id.

[18] In re: Beech-Nut Nutrition Co. Baby Food Litig., 651 F. Supp. 3d at 635-36 (quoting In re: Gerber Prods. Co. Heavy Metals Baby Food Litig., No. 1:21-cv-269, 2022 WL 10197651, at *13 (E.D. Va. Oct. 17, 2022)).

[19] Id. at 636.

[20] See, Staff Report of the Subcommittee on Economic & Consumer Policy, Committee on Oversight & Reform, U.S. House of Representatives, Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury (Feb. 4, 2021), https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf and U.S. Food & Drug Admin., FDA Response to Questions About Levels of Toxic Elements in Baby Food, Following Congressional Report (Feb. 16, 2021), https://www.fda.gov/food/cfsan-constituent-updates/fda-response-questions-about-levels-toxic-elements-baby-food-following-congressional-report.

[21] In re: Beech-Nut Nutrition Co. Baby Food Litig., 651 F. Supp. 3d at 636.

[22] Palmer at 506.

[23] Palmer, 51 F.4th at 511.

[24] White, 2024 WL 194699, at *2 (alteration in original) (quoting Seneca Nation of Indians, 988 F.3d at 629).

[25] Seneca Nation of Indians, 988 F.3d at 629.