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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
WEST PALM BEACH DIVISION
CASE NO. 20-md-02924-ROSENBERG

IN RE: ZANTAC (RANITIDINE) .
PRODUCTS LIABILITY . West Palm Beach, FL
LITIGATION. . June 4, 2021
. .
. .

MOTION to DISMISS PROCEEDINGS (through Zoom)
BEFORE THE HONORABLE ROBIN L. ROSENBERG
UNITED STATES DISTRICT JUDGE

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1 *THE COURT:* Good morning, everyone. We are here for
2 the second day of hearings in the case of In Re: Zantac
3 Products Liability Litigation, MDL 2924. We are here through
4 the Zoom platform due to the COVID pandemic. The hearings
5 yesterday were also conducted in that fashion and no counsel
6 are is here in the courtroom, it is just me and our court
7 reporter, everyone else is appearing remotely.

8 The first motion that will be heard this morning is
9 the branded Defendants' Rule 12 partial Motion to Dismiss
10 Plaintiffs' three master complaints as preempted by Federal law
11 and incorporated memorandum of law.

12 As with our format yesterday, everything remains the
13 same, so we will call up -- and this is Docket Entry 3114, and
14 so we can call up Defense counsel, who will be allotted 15
15 minutes to argue her motion, and she can tell me if she wants
16 any warnings and whether you want to reserve any time for your
17 rebuttal.

18 *MS. EISENSTEIN:* Good morning, your Honor, Ilana
19 Eisenstein, I represent Sanofi and the branded Defendants on
20 this motion. I would like five minutes for rebuttal and if I
21 could have a warning at two minutes, that would be good. Thank
22 you, your Honor.

23 *THE COURT:* A warning after eight minutes, and you
24 will finish up at ten minutes and reserve five minutes?

25 *MS. EISENSTEIN:* That is right, your Honor.

1 *THE COURT:* Good morning. You may proceed.

2 *MS. EISENSTEIN:* Thank you, your Honor.

3 The branded Defendants seek to dismiss the Plaintiffs'
4 consumer class action refund claim, their unjust enrichment
5 claims and the failure to warn the FDA claims as preempted by
6 Federal law. Let me start with express preemption.

7 Express preemption bars Plaintiffs' refund claims in
8 the amended consumer class action and their unjust enrichment
9 claims. Plaintiffs have abandoned any argument that these
10 claims are saved under 379r(e), which was one of their primary
11 arguments in the first round of Motions to Dismiss, and that is
12 for good reason.

13 These claims, which seek simply a refund of the
14 purchase price of the product, are by no means a product
15 liability claim under the definition that is given by Federal
16 law for that term, or for that matter, any state law
17 definition.

18 Plaintiffs, moreover, fail to plead a parallel claim.
19 In Wolicki-Gables the Eleventh Circuit made clear that
20 Plaintiffs have the burden to allege the Defendant violated a
21 particular Federal regulation, and they need factual detail to
22 substantiate these crucial allegations.

23 They make no effort to defend the claims that they had
24 made previously and that are sprinkled throughout their
25 complaint that Zantac was purportedly misbranded because it

1 was unsafe, and this is in line with this Court's
2 prior preemption ruling that challenges to the FDA approved
3 characteristics of Zantac are preempted to the extent that they
4 are premised on the design of the product, or for that matter,
5 the FDA approved labeling.

6 Instead, Plaintiffs have shifted onto the thin thread
7 that the FDA approved label itself was misleading by failing to
8 disclose the risk of NDMA, and therefore misbranded. It is
9 a variant of the misbranding claim that they had asserted
10 before.

11 This theory would be the exception to express
12 preemption that swallowed the rule. It would eliminate decades
13 of well-established precedent that failure to warn claims and
14 similar claims challenging the label are preempted, including
15 the Supreme Court's decision in Riegel which addressed exactly
16 this type of argument.

17 In Riegel, the Plaintiffs claimed that the product was
18 misbranded by lack of an adequate warning and the Supreme Court
19 in Riegel squarely rejected that argument as a basis for
20 avoiding express preemption, in that case, based on the very
21 analogous and similarly worded medical device amendment
22 360(k)(a).

23 Plaintiffs cannot recharacterize their failure to warn
24 theory as a misbranding argument for two reasons. First,
25 Zantac carried the FDA approved label, and as a result, it was

1 not misbranded. Even if FDA itself could deem its own label
2 was misbranded, that does not permit a private set of
3 Plaintiffs to impose OTC labeling requirements that conflict
4 with the approved label.

5 Let me start with the first proposition. The FDA
6 approved label does not render a product misbranded. The
7 Plaintiffs are simply incorrect that Section 352 makes it a
8 crime to label and produce a product that complies with the FDA
9 approved label. No court, no enforcement action and no other
10 authority has ever interpreted the misbranding provisions to
11 cover a label specifically approved by the FDA through a new
12 drug application process.

13 Plaintiffs rely solely on the Government's amicus
14 brief in *PLIVA v. Mensing*, but the Court in that case found
15 there was no preemption, even assuming such a duty existed to
16 provide an adequate warning, and even assuming that the FDA
17 could in theory find that lack of such a warning rendered the
18 product misbranded.

19 Misbranding, moreover, is not a catch-all exception to
20 Federal preemption. This Court doesn't even need to reach this
21 theoretical question of whether the FDA could find the
22 Defendants violated 352, because even if they could, Section
23 379 still preempts private Plaintiffs from seeking a product
24 refund based -- on the basis of a challenge to the FDA approved
25 label.

1 The case law on regulations are clear here, the
2 generalized proposition of misbranding cannot avoid preemption
3 of claims that seek to add to or differ from specific
4 requirements mandated by Federal law, and this certainly
5 includes the labeling approved by the FDA through an NDA
6 process.

7 Riegel, as I said before, addressed exactly this
8 issue. It cited to the 360k(a) regulations which provide a
9 helpful guidepost to this Court. Those regulations state that
10 state law misbranding claims are preempted when they have the
11 effect of establishing a substantive requirement for a specific
12 device, i.e. a specific labeling requirement that is different
13 from or in addition to Federal requirements, and the Supreme
14 Court said that means that this express preemption provision
15 preempts a jury determination that the FDA approved labeling
16 for a piece maker violated state common law requirements for
17 additional warnings.

18 That is exactly what Plaintiffs seek in their consumer
19 class action complaint and their claims for refund.

20 The cases relied on by Plaintiffs at page 9 of their
21 opposition make exactly this point. Where Federal law
22 specifically regulates the subject matter of a Plaintiff's
23 state law claims, and those claims seek to impose requirements
24 that differ from and are not identical to Federal requirements,
25 those claims are preempted. That is the Canale versus Colgate

1 case that is cited by Plaintiffs. The same analysis was
2 applied in Zolwinski and Prescott, cases cited by the
3 Plaintiffs.

4 Moving on to the implied preemption of the failure to
5 warn the FDA.

6 The failure to warn the FDA claims are rife with
7 problems. You heard yesterday how no state recognizes the
8 attenuated theory of liability that revolves around
9 submission of unidentified adverse event reports to the FDA and
10 depends on a recall which is yet to happen of the product based
11 on those non-pleaded reports.

12 This is not a warnings claim, it is a flat-out effort
13 to enforce the FDCA requirements, something that is not only
14 inadequately pleaded, but is also impliedly preempted. Implied
15 preemption bars this failure to report to the FDA theory
16 because it relies on the FDCA and the FDA as critical elements
17 of their claim, and it goes even a step further by relying on
18 FDA's discretionary action to have taken a recall or to remove
19 the product in light of information that the Plaintiffs claim
20 should have been reported to FDA.

21 These principles were applied by the Eleventh Circuit
22 in Mink, in Markland, in Sybaris, and by your colleague in the
23 Southern District of Florida in the TraceAll products
24 liability. In each case, the claims that Plaintiffs should
25 have reported to the FDA adverse event reports, data, or other

1 information were held to be squarely in the preempted category
2 under Buckman.

3 Plaintiffs make things worse, not better, for
4 themselves by asserting that they are not trying to enforce
5 duties imposed by the FDCA, but rather state law requirements
6 that would require gratuitous warnings to the FDA that are not
7 mandated by Federal law.

8 Here, the sole recipient of the information that
9 Plaintiffs claim should have received this unreported
10 information is the FDA itself. This is totally unlike claims
11 that have been recognized in the handful of jurisdictions where
12 the theory is that the FDA would have publicized the
13 information that would have reached consumers or physicians.

14 *THE COURT:* That is eight minutes.

15 *MS. EISENSTEIN:* Thank you, your Honor.

16 Rather, the unprecedented theory advanced by
17 Plaintiffs is that the adverse event reports or other
18 information that supposedly should have been given to FDA would
19 have caused researchers to conduct studies of Zantac and the
20 potential to form NDMA, and that that research would have
21 resulted in discretionary action by the FDA to recall the
22 product.

23 This is squarely in line with *Mensing*, which held that
24 preemption applies when the manufacturer's ability to comply
25 with state law depends on uncertain Federal agency action or

1 third-party decisions. It is a variant of the stop selling
2 rationale rejected by the Supreme Court in Bartlett and
3 Mensing, here, based on the idea that FDA would have more
4 quickly or would have ever recalled the product. And the only
5 path to making out this claim runs right through the FDCA and
6 the FDA, its reporting structure and its discretionary
7 decision-making. That is an impliedly preempted theory.

8 I will reserve the rest of my time for rebuttal, your
9 Honor.

10 *THE COURT:* Okay. That was nine minutes and 13
11 seconds, so you have a little over five minutes left.

12 From the Plaintiff, if you would state your appearance
13 for the record, and let me know if you need any warnings.

14 *MR. KELLER:* Good morning, your Honor, Ashley Keller
15 for the Plaintiffs. I am happy to keep my own time. Can you
16 see me and hear me okay?

17 *THE COURT:* I can see you and hear you okay.

18 *MR. KELLER:* Very good. Good morning, your Honor.
19 May it please the Court, Ashley Keller again on behalf of
20 Plaintiffs.

21 I would like to begin with express preemption under
22 Section 379r, and then turn to Plaintiffs' failure to warn
23 through the FDA claims. I know these arguments will have a
24 familiar ring to the Court because the brands have largely
25 repeated assertions they made in the first round of briefing.

1 Section 379r is the over-the-counter express
2 preemption clause. It only preempts state requirements that
3 are "different from, or in addition to, or otherwise not
4 identical with Federal law." Interpreting similar language in
5 express preemption clauses, the Supreme Court has made two
6 important points to frame our discussion.

7 First, in cases such as *Bates*, *Lohr*, and *Riegel*, the
8 Court noted once again that preemption is about comparing state
9 and Federal duties. If the duties are the same, or parallel,
10 there is no preemption. If they are different, express
11 preemption applies.

12 Second, when determining whether state and Federal
13 duties are the same, those same cases emphasize that state law
14 doesn't have to use the same words or have the same naming
15 conventions as federal requirements. Indeed, "it would be
16 surprising if a common law requirement used the same
17 phraseology as its corresponding Federal requirement." That's
18 from *Bates*, 544 U.S., at 454. What matters is the substance of
19 the duties and whether they match or depart from Federal law.

20 With those principles in view, let's turn to the
21 state duty pleaded in the amended complaints. Simply put, the
22 state duties we allege throughout the amended consumer class
23 action complaint is to have an accurate label. A drug with a
24 false or misleading label is a breach of that duty under the
25 relevant claims.

1 Now, it is true the causes of action under state law
2 imposing this duty have different names under various state
3 laws. Some states have a Deceptive Trade Practices Act that
4 forbids false or misleading labels. Some states categorize a
5 false or misleading --

6 *THE COURT:* Wait, wait. Mr. Keller, I stopped the
7 clock, so don't worry. We stopped off at some states have -- I
8 think you need to slow down a little bit for purposes of --

9 *MR. KELLER:* Of course. I know she has the hardest
10 job in the courtroom. I will start the whole thought over.

11 It is true enough that the causes of action imposing
12 this duty under state law have different naming conventions.
13 Some states refer to it as a Deceptive Trade Practices Act
14 violation. Some states categorize a false or misleading label
15 as unfair competition. Other states forbid false or misleading
16 labels under a False Advertising Statute, and still other
17 jurisdictions treat a false or misleading label as a breach of
18 warranty.

19 But the title of the causes of action doesn't matter.
20 What matters is that in substance these state causes of action
21 impose a duty on manufacturers not to have a false or
22 misleading label. That state duty is parallel to the duty
23 imposed by the Federal Misbranding Statute.

24 The Food, Drug and Cosmetic Act is not ambiguous on
25 this score. The statute makes it unlawful to sell a drug in

1 interstate commerce if its label is "false or misleading in any
2 particular," or if it "is dangerous to health when used in the
3 dose or manner, or with the frequency or duration prescribed,
4 recommended, or suggested on the labeling thereof." That's
5 from 21 U.S.C. 352(a)(1) and (j).

6 When you line up state and Federal duties
7 side-by-side, it is obvious they are the same. State law
8 imposes a duty not to have a false or misleading labels.
9 Federal law imposes a duty not to have false or misleading
10 labels. Those requirements are identical. It is therefore
11 straightforward that there is no express preemption under
12 Section 379r.

13 In response, the brands dust off two points from the
14 last round of briefing, but neither is persuasive. First, as
15 you just heard, the Defendants say that a drug by definition
16 cannot be misbranded under Federal law so long as it matches
17 the label approved by the FDA. In this case, that means the
18 label approved by the agency four decades ago when Ranitidine
19 first hit the market. Ignore new science, ignore new
20 information, ignore new studies. If the four-decade old label
21 is affixed to the drug the manufacturer gets a shield from
22 liability.

23 The brands, in their briefing, offer two citations in
24 an effort to bolster this definition of a misbranded drug.
25 They turn initially to Beecher, a 1993 District of Minnesota

1 case, but it is hard for Plaintiffs to see how this case is
2 even relevant, let alone how it supports the brand's definition
3 of misbranding.

4 The case involved a box of tampons and whether the
5 warning of toxic shock syndrome was placed in a sufficiently
6 conspicuous location on the package. After initially reserving
7 summary judgment on that question, the Court found that the
8 warning was in a conspicuous enough spot that there was no
9 issue of material fact.

10 The Court never interpreted or even cited the
11 misbranding provision of the Food, Drug and Cosmetic Act, and
12 it never stated or even intimated that a drug is only
13 misbranded if a manufacturer departs from the FDA approved
14 label.

15 Even more remarkably, the other source of authority
16 that the brands rely on in their opening brief is this Court's
17 prior order. They say that this Court recognized their
18 definition of misbranding. This is their motion at page 10.

19 Your Honor is, of course, the best arbiter of what you
20 did or did not recognize, so let me simply read to you what
21 your Honor wrote verbatim in that prior order.

22 "Finally, brand name manufacturer Defendants argued
23 during the hearing that a drug is only misbranded if it fails
24 to contain the FDA approved labeling. Defendants have not
25 pointed to any authority providing that definition of

1 misbranding. The statute delineating when a drug is misbranded
2 does not contain the definition that Defendants and brand name
3 manufacturer Defendants propose, nor is it apparent that the
4 FDA defines misbranding in such a way."

5 From Plaintiffs' vantage point, your Honor, it is
6 still true that the Defendants have not pointed to any
7 authority providing their definition of misbranding. You just
8 heard my friend bring up Riegel now at argument based on FDA
9 regulations for medical devices, but where the FDA has
10 regulated medical devices, they point to no regulations
11 similarly for drugs or over-the-counter drugs. That shows
12 exactly our point. The FDA knows how to agree with the brands
13 when it wants to, and it didn't for over-the-counter drugs.
14 All of the actually on-point authority runs in the other
15 direction.

16 The first source of authority is the plain text of the
17 statute itself, which my friend continues to run away from.
18 The Supreme Court keeps saying so, so it bears repeating again.
19 Where the statutory text is plain, the sole function of the
20 Courts is to enforce the statute according to its terms. A
21 drug is misbranded if its label is false or misleading in any
22 particular.

23 Those words are clear. Congress never said that FDA
24 approval in the past means that a label cannot be false or
25 misleading in the present. There isn't even a hint of the

1 brand's argument in the plain statutory text.

2 And the FDA's interpretation of that text agrees with
3 us, not the brands. As you heard my friend concede just a
4 moment ago, the agency made that view clear in its amicus brief
5 before the Supreme Court in *Mensing*, and the Supreme Court
6 never rejected the agency's view. The FDA's view is therefore
7 entitled to Auer or Skidmore deference.

8 Moreover, the FDA promulgated a regulation pursuant to
9 notice and comment rulemaking that gets an even higher level of
10 Chevron deference. In 21 CFR 314.170, the agency reiterated
11 that all drugs, including those that the FDA approves, are
12 subject to the adulteration and misbranding provisions of the
13 Food, Drug and Cosmetic Act. That regulation only makes sense
14 if FDA approval in the past doesn't mean a drug automatically
15 escapes misbranding in the present.

16 Relying on the agency's view, the Supreme Court agreed
17 with us again in footnote 4 to *Bartlett*, while the Court
18 reserved the question of preemption, as your Honor noted in
19 your previous order, it also emphatically stated the
20 "misbranding statute requires a manufacturer to pull even an
21 FDA approved drug from the market when it is dangerous to
22 health" as labeled. The label the Court was referring to was
23 the FDA approved label.

24 The Supreme Court's statement would make no sense on
25 the brands' view. There is simply no authority that supports

1 the brands' definition of misbranding. Loudly repeating their
2 made-up definition does not make it any more sound.

3 Unable to establish a conflict between the substance
4 of state and Federal duties, the brands fallback argument is to
5 focus on state naming conventions. They observe correctly that
6 most of our complaints' causes of action don't use the word
7 "misbranding" and that the word misbranding doesn't appear all
8 that often in the complaints.

9 We have a simple response: So what? The Supreme
10 Court could not have been clearer that when gauging of state
11 law is different from or in addition to Federal law, the
12 phraseology of state law doesn't matter. Bates said this in no
13 uncertain terms. So, it is entirely irrelevant that state
14 law imposes a duty under statutes called, for example,
15 Deceptive Trade Practices Act, while federal law refers to
16 misbranding. The complaints could have never used the word
17 misbranding a single solitary time and the preemption outcome
18 would be the same.

19 What matters is whether state and Federal law are
20 substantively the same, and they are. State law forbids false
21 and misleading labels. Federal law forbids false and
22 misleading labels. There is no daylight between state and
23 Federal duties, and that is the end of the express preemption
24 inquiry.

25 Let me turn to our failure to warn consumers through

1 the FDA claims to show that they, too, are not preempted. Once
2 again we begin the analysis by focusing on duty. As for state
3 law duties, the amended master personal injury complaint pleads
4 for 15 jurisdictions that recognize a traditional common law
5 duty to warn third parties as the most effective way to warn
6 consumers.

7 Under the law of states such as California,
8 "manufacturers bear a duty to convey warnings to a third party
9 that can reasonably be expected to warn the consumer." That's
10 paragraph 1407. Warning the third party fully satisfies the
11 manufacturer's duty.

12 By simply telling the warning to the third party, the
13 manufacturer has met its state law obligation goes, regardless
14 of what the third party does with the information.

15 As noted in the pleadings, the brands could have
16 fulfilled this duty by submitting adverse event reports to the
17 FDA, yes, but they also could have fulfilled the duty "through
18 other communication channels that were available, including
19 ordinary correspondence with the agency or regulatory
20 reporting." That is at paragraph 1412. So, emails, phone
21 calls and letters all could have all sufficed as ways to convey
22 Ranitidine's danger to the FDA based on emerging science.

23 Let's compare the state law duty to the Federal duty
24 to see that there is no conflict. Federal law requires adverse
25 event reports, and according to the FDA, ordinary

1 correspondence is required as well, but at a minimum, ordinary
2 correspondence is at least permitted. Remarkably, there is no
3 dispute about any of this. As a result, there can be no
4 preemption.

5 State law says warn the FDA to fulfill your duty to
6 consumers, federal law says you must, or at least may, warn the
7 FDA of risks. Those duties are not in any form of conflict, so
8 the conflict preemption doctrine is not a bar to these claims.

9 In an effort to undermine that straightforward
10 conclusion, the brands principally rely on the Supreme Court's
11 decision in Buckman and claim erroneously that the Plaintiffs
12 are just bringing a "fraud on the FDA claim" that is based
13 exclusively on Federal law.

14 That is simply not what Count 5 says. Count 5 rests
15 on traditional state tort law principles. The 15 jurisdictions
16 that recognize this duty don't base it on Federal law at all.
17 Indeed, returning to California as the example, the duty to
18 warn third parties was first applied to a ski
19 manufacturer which had a duty to warn a ski rental shop as the
20 most effective party to get warnings to the ski renters.
21 Federal law was not even a part of the analysis, and there is
22 no Federal law, to my knowledge, regulating ski manufacturers.

23 It goes without saying that such a claim counts as
24 "traditional state tort law" and that the existence of the
25 Food, Drug and Cosmetic Act is not "a critical element in

1 Plaintiffs' case." That is from Buckman, 531 U.S. at 353.
2 Indeed, the Food, Drug and Cosmetic Act isn't an element at
3 all, let alone a critical element, in the Plaintiffs' claims.
4 None of the causes of action have an element that depends on
5 the breach of any Federal rule.

6 To see that, if the Food, Drug and Cosmetic Act
7 were repealed by Congress tomorrow, the state law duties under
8 the common law would be exactly the same. There is no Buckman
9 problem under those circumstances, which is exactly why the
10 unanimous en banc Ninth Circuit in Stengel, the Fifth Circuit
11 in Hughes, the Sixth Circuit in White, and the Seventh Circuit
12 in Bausch have all allowed these claims to survive a preemption
13 defense.

14 Notwithstanding this wall of appellate precedent, the
15 brands suggest that the Eleventh Circuit went the other way in
16 Mink, but that is an inaccurate reading of the Court's opinion.
17 The first clue that that is an inaccurate reading and that we
18 are correct on this score is that Mink doesn't cite the Ninth
19 Circuit case in Stengel at all, even though it is the leading
20 case in this area, and cites the Seventh Circuit's decision in
21 Stryker approvingly, even though that case is on our side of
22 the ledger.

23 Typically, a Court of Appeals does not open a sharp
24 conflict with every other Court of Appeals without saying so.
25 It candidly grapples with the competing authority and explains

1 why it is going in a different direction, but the Eleventh
2 Circuit said nary a word about charting a different path from
3 other Courts.

4 The reason for that is because the decision turned on
5 the particulars of Florida negligence law. The Court did say
6 that "Florida law recognizes the common law duty of failure to
7 warn as a basis for a negligence claim." That is in the
8 opinion at 1329. But Mr. Mink's theory as pleaded alleged that
9 the manufacturer's "duty is owed to the FDA," and was not "one
10 that state tort law has traditionally occupied." That is in
11 the opinion at 1330.

12 If the duty is owed to FDA, of course Federal law is a
13 critical element of the claim because only Federal law governs
14 duties that run to the agency. The Court distinguished
15 that theory from manufacturing defect where the manufacturer's
16 duty was owed to Mr. Mink, and was therefore not preempted.

17 We agree that states which impose duties that run to
18 the FDA or that seek to make a violation of the Food, Drug and
19 Cosmetic Act an element of the state claim are unavailable
20 under Buckman. That is why we carefully pleaded this only for
21 15 jurisdictions and we did not include Florida on this list.

22 *THE COURT:* That is 15 minutes.

23 *MR. KELLER:* Very good, your Honor. I finished my
24 sentence, so I will stop there.

25 *THE COURT:* Okay. Thank you so much.

1 You have a little over five minutes left for rebuttal.

2 *MS. EISENSTEIN:* Thank you, your Honor. Let me start
3 with the express preemption argument that Mr. Keller just
4 advanced. It makes clear that the issue here is what level of
5 specificity we are talking about.

6 He wants to have the general rule the specific. He
7 points to the general misbranding regulations, false and
8 misleading, but he ignores the arguments that this would
9 conflict with the specific requirements, mainly the label that
10 was approved by the FDA in the NDA, and he does not address at
11 all the argument that I just made that his own cases make
12 exactly this distinction.

13 In each of those cases, and I think it is worth a
14 little bit of attention on this, the Canale case for example,
15 turned on exactly this distinction in that case with tooth
16 whitening toothpaste. The question there was whether the false
17 and misleading would govern or whether there was specific
18 Federal requirements that governed the particular statements
19 that the Defendant was making, and it was only because the FDA
20 had not regulated those tooth whitening statements that Canale
21 let those claims go forward.

22 By contrast, in Riegel, which is the medical device
23 context, but identically worded express preemption provision,
24 the Court found that a challenge to the FDA approved label is
25 squarely preemptive.

1 The medical device amendments -- regulations make this
2 clear, too, but you don't have to even just go there because
3 the OTC regulations themselves talk about what renders a
4 product "not misbranded," and we cite those regulations at 21
5 CFR 310.1, .10 and .14. Each of those regulations, and those
6 govern OTC drugs specifically, talk about what renders a drug
7 not misbranded, in essence, following the FDA approved labeling
8 and requirements and applying the monograph in instances of a
9 monographic drug renders an OTC product not misbranded.

10 Even if there was some argument, and this is -- this
11 Mr. Keller does not address at all -- that a drug could be
12 determined to be misbranded by the FDA, and that is the
13 province of the FDA to do it, there is no way in which the
14 private Plaintiff can claim simply by asserting a drug is
15 misleadingly labeled, or that there should have been additional
16 information in the warning or the instructions for use, that
17 that could avoid express preemption.

18 It would throw out decades of failure to warn
19 jurisprudence in express preemption context that have held that
20 those claims are preempted all the way up to the Supreme Court.

21 Let me talk a minute about the failure to warn the FDA
22 claim. Mr. Keller focuses on Coleman and the California
23 Supreme Court, Stengel, Hughes, Bausch, but those claims
24 differed from these claims in an important respect.

25 First of all, respectfully, I think they were wrongly

1 decided, but even if they were correct and they, at least in
2 Coleman, established a theory of liability recognized by
3 California law, at least in the intermediary court, the theory
4 of liability there was that the medical device reports would be
5 reported to the FDA, the FDA had a practice of publicizing
6 those adverse event reports on a public website, and that the
7 physician who was prescribing that device would view those
8 adverse event reports and change the prescribing decision as a
9 result.

10 The theory of liability that Plaintiffs assert is
11 nothing like that. The warning ends with the FDA. It goes to
12 the FDA and it is part and parcel of the FDA reporting process.

13 In Mink, the Court did not hinge on whether the duty
14 was one that was a state law duty, it was -- was a state law
15 duty, an independent state law duty, it was based on the theory
16 of liability that went through the FDCA and the FDA process,
17 and it was based on a theory of liability, not a duty, that
18 depended on Federal law that Mink held that those claims were
19 preempted.

20 And to be clear, Mink did not say that this was an
21 issue of an absence of a parallel state law duty, it recognized
22 that Florida had a duty to warn third parties.

23 This is not a warning claim at all; it is a claim that
24 FDA itself should have been put on notice of purportedly
25 adverse events, of information with respect to risks of NDMA

1 formation. This is a preempted theory of liability.

2 In short, your Honor, the branded Defendants ask this
3 Court to dismiss the refund claims and the consumer class
4 action claim, the unjust enrichment claim as
5 expressly preempted, and the failure to warn the FDA claims as
6 impliedly preempted.

7 *THE COURT:* Thank you so much. If both counsel can
8 come on, I have a few questions.

9 Okay. So, this question is for the Defendants, and it
10 most certainly touches on topics that you have addressed, both
11 of you, in your presentation, so if you want to refer me back
12 to what you said, that is fine. If you want to repeat what you
13 said, that is fine, or if by the way I am asking it you have a
14 different way of answering it, that is fine, too.

15 I think we are all probably talking about the same
16 issue.

17 So, this first of the questions goes to the issue of
18 the brands' argument theory that an OTC drug can never be a
19 misbranded drug.

20 So, putting aside for a moment, so in this first
21 question for Defense, putting aside your argument that an OTC
22 drug can never be alleged to be misbranded, put that aside,
23 what do you think a Plaintiff must allege for a product to be
24 Federally misbranded?

25 In other words, by way of example, are the

1 requirements for Federal misbranding more than, or different
2 from, what the misbranding statute sets forth in 21 U.S.C.
3 Section 252? And we know from what Plaintiffs have told us
4 before that they are relying in particular on (a)(1) and (j).

5 So, if so, if the requirements are something different
6 than what the statute sets forth, what is the legal basis for
7 your position? That is the first question for Defense.

8 *MS. EISENSTEIN:* Your Honor, the provisions in 352(a)
9 and (j) that the Plaintiffs rely upon are general misbranding
10 provisions, so they are not really a stand-alone set of
11 specifications for how a product must be labeled, what its
12 content or composition would be, or how it is designed.

13 Typically, these are derivative claims of other
14 violation, so there is some deviation from the FDA rules and
15 regulations in another respect, but then leave the product to
16 be in violation of Federal law and therefore render misbranded,
17 or in a parallel provision, adulterated.

18 Let me give you an example. If the product were not
19 to carry the FDA approved label, if there were deviations from
20 what the FDA approved, that would render it misbranded.
21 Frequently that 352(a) is also applied to non-labeling claims.
22 So, the Courts have recognized parallel claims in certain
23 instances where Defendants have gone outside the substance of
24 the FDA approved label and made claims that were false and
25 misleading, and that has run afoul at times of the misbranding

1 provision and constituted a parallel claim. There are
2 situations where other specific regulatory requirements of FDA
3 are violated.

4 But consider this: How would a Defendant be on notice
5 that the label that was approved by FDA through an NDA process
6 was in and of itself misbranded, perhaps has some other
7 violation of Federal law just on some free-floating theory of
8 it being misleading? That kind of vague admonition would be a
9 crime under Plaintiffs' theory, not just a tort and an economic
10 class action, and that just doesn't hold up.

11 There has to be some specific violation, and that is
12 certainly true in the context of preemption, and that is the
13 Wolicki-Gables lesson, is Wolicki-Gables. You have to point to
14 some specific violation of Federal law, not some generalized
15 notion of the product --

16 *THE COURT:* So, is your position that the Statute 352
17 doesn't impose in and of itself duties upon a manufacturer to
18 comply with the dictates of the statute, it imposes no duties,
19 but rather, there would need to be a violation of a state or
20 Federal law separate from 352 that, if proven, may or would
21 give rise to, therefore, a violation of 352?

22 *MS. EISENSTEIN:* So, I think it applies in two
23 instances, your Honor. One is in that instance where there is
24 a violation of some specific Federal requirement, and the other
25 is where it's an area where the FDA doesn't regulate it at all,

1 and that is the cases that Plaintiff cite at page nine of its
2 opposition that we were just talking about, this Walinski case,
3 the toothpaste case that we were discussing. Those are cases
4 in which the FDA simply didn't regulate along the lines of the
5 area that was being challenged by Plaintiffs.

6 I think those are two areas where misleading -- that
7 general statement of requirement can have force, but it can't
8 trump the specific requirements that FDA has imposed on a
9 product, and that would create an impossible conflict for the
10 manufacturer to both change its label in a way that rendered
11 it, according to Plaintiffs, not misleading.

12 So, if that type of conflict between the general
13 admonition and non-misleading label and a specific requirement
14 that have a product with the NDA and FDA approved label, that
15 simply cannot stand in this context.

16 *MR. KELLER:* Your Honor, can I briefly respond to
17 that?

18 *THE COURT:* I am going to have some questions for you
19 that actually may be very similar.

20 *MR. KELLER:* Perfect.

21 *THE COURT:* If you will wait, and if I haven't asked
22 the question that allows you to respond, make a note of it and
23 you can, but I think you will find my questions do.

24 Following up, the first question for Defense, I had
25 asked you to put aside your argument that an OTC drug can be

1 alleged to be Federally misbranded, and I know on page 8 of
2 your reply you say because OTC Zantac carried the FDA approved
3 label it cannot be criminally misbranded under 352, so I had
4 asked you to put that aside for the previous question.

5 Do you rely upon anything other than the FDA
6 regulations for your position?

7 Again, we have been talking about it, so I don't want
8 you to have to repeat yourself. I know you rely upon the FDA's
9 OTC medication regulations which have numerous
10 provisions delineating what renders various OTC products
11 "misbranded and not misbranded," and specified that OTC
12 medications that conform to the conditions contained in
13 monograph are "considered generally recognized as safe and
14 effective and not misbranded," and therefore need not be
15 approved through a new drug application.

16 One or the other of you cited, I think Mr. Keller may
17 have, to the 21 CFR Section 330.10, as well as the other 330
18 provision.

19 So, other than what we have been discussing in the FDA
20 regulations that you cite, is there anything else that you are
21 relying upon for the proposition and the argument that an OTC
22 drug cannot be Federally misbranded?

23 *MS. EISENSTEIN:* So, I want to be clear, your Honor,
24 that our position is not that an OTC drug --

25 *THE COURT:* FDA approved.

1 *MS. EISENSTEIN:* It is not that it can never be
2 misbranded, it is that it cannot be deemed misbranded based on
3 a theory that it has a misleading label where the reason that
4 it is misleading, according to the Plaintiff, is that it
5 followed the FDA approved label through an NDA.

6 It is really that specific a proposition because the
7 cases that Plaintiffs cite to the contrary are all ones in
8 which the FDA -- it involved areas of activity like homeopathic
9 products that the FDA doesn't regulate at all, or advertising
10 claims that are not part of what the FDA approved or
11 disapproved.

12 So, to your question, though, your Honor, your
13 question specifically was what authority did we rely on. I
14 think that one of the striking things here is the absence of
15 any enforcement authority, any case that has recognized such a
16 claim. In *U.S. versus Smalls* the Supreme Court recognized that
17 this type of prosecution history is an empirical fact that the
18 Court can consider when construing a criminal provision.

19 I think the fact that this is a crime is significant
20 as well in interpreting what it must require of the parties
21 that it seeks to regulate and would indeed subject to criminal
22 liability, the idea that a party could be liable for following
23 the mandates of the FDA and what constitutes a label, without
24 any other violation of Federal law, and that is the point.

25 Here Plaintiffs, this is the sole basis for their

1 claim that there is a parallel claim under state law, is that
2 this parallels a misleading component, not that there is any
3 specific violation of Federal law that they can point to.

4 *THE COURT:* Following up, why would a consumer be able
5 to question the judgment of the FDA in approving a drug before
6 it becomes OTC, pursuant to Wyeth, 55 U.S. at 575. Quoting,
7 "Congress did not intend FDA oversight to be the exclusive
8 means of ensuring drug safety and effectiveness, but then once
9 a drug becomes OTC a jury loses its power to question the FDA."

10 *MS. EISENSTEIN:* Your Honor, the argument that we are
11 making is in a very specific context, which is express
12 preemption under 21 U.S.C. 379r. Wyeth versus Levine was an
13 possibility preemption case involving conflict preemption, and
14 it was a products liability case, which is exempted from 379r,
15 as your Honor knows.

16 The questions are just different from one another,
17 which is, under Wyeth, the question is whether or not a
18 manufacturer was capable of changing its label to include newly
19 acquired information, but here, the fact that a manufacturer
20 may change its label is not the question. That would add to,
21 be different from, or not identical with Federal requirements,
22 and that is a critical distinction with express preemption.

23 Under express preemption, you have to show that the
24 manufacturer violated Federal law by failing to update its
25 label, not that it was permitted to change its label under

1 Federal law, and that is the key difference between Wyeth and
2 this case.

3 *THE COURT:* Following up further, how is your -- and
4 maybe it is a similar answer because it is sort of a similar
5 question. How is your position a jury cannot decide whether an
6 OTC drug is misbranded compatible with Bates, which expressly
7 held that juries may decide whether a product is misbranded,
8 albeit for a product -- OTC that wasn't an OTC -- for a product
9 pesticide that wasn't an OTC drug? Is it kind of a similar
10 response?

11 *MS. EISENSTEIN:* Right. So, in the context of express
12 preemption, it is not that a jury can't make this
13 determination; it is the question of whether this determination
14 adds to, or is different from, or not identical with Federal
15 requirements, not Federal duties, Federal requirements.

16 Federal law puts a specific requirement on
17 manufacturers to follow the NDA approved label. What
18 Plaintiffs want to do is take a generalized proposition under
19 the misbranding and say that that should have been what was
20 followed, and that's different from the FDA approved label, and
21 that is exactly what Riegel addressed.

22 The allegation was that the device there was
23 misbranded and dangerous, and the Court found that did not
24 avoid express preemption because, first of all, it would impose
25 civil liability in that context based on the jury's finding,

1 but also because it would impose requirements that were
2 different from the specific FDA imposed requirements on that
3 device. The same is true here.

4 So, I think in other contexts juries have been
5 recognized to be able to make that determination, but here
6 there is simply a conflict with the specific requirements to
7 which manufacturers were subject under the labeling
8 requirements here.

9 The fact that they were potentially evil to modify
10 their label would be something they could allege, and have
11 alleged in their product liability claims in the AMPIC, doesn't
12 save their refund claims from express preemption.

13 *THE COURT:* You have pointed out that the FDA imposes
14 a duty to follow the label, use the label. Doesn't the FDA
15 also impose a duty to correct a deficient or misleading label?

16 *MS. EISENSTEIN:* It does, your Honor. I think that
17 falls into the same category as what we were discussing.

18 I think it also bears noting that that is a
19 determination that the FDA would typically make if there was
20 going to be either a requirement that the label should have
21 been updated or that it was rendered misleading or misbranded
22 because it was not updated, and that has not happened here.

23 I think it goes back to the same argument we were
24 talking about before, which is this generalized requirement
25 around avoiding misleading labels versus the specific

1 requirements of what should be on an OTC label and what was
2 approved in the NDA.

3 It is also noteworthy, and Courts have focused on
4 this, that where the FDA has failed to make a determination
5 that a product was misbranded or violated that provision, that
6 it is incompatible with or would be in addition to Federal
7 requirements for Plaintiffs to assert such a requirement.

8 *THE COURT:* Are you aware of any Court that has
9 expressly found that an OTC drug can never be alleged to be
10 misbranded?

11 *MS. EISENSTEIN:* No, your Honor. As I said, I don't
12 think that is what we are alleging here either. There are
13 Court after Court that have said that claims that challenge
14 the --

15 *THE COURT:* Can we turn the audio off of the person
16 who is speaking right now. Thank you.

17 *MS. EISENSTEIN:* It is not our position that an OTC
18 drug can never be misbranded. In case after case, Plaintiffs
19 have raised claims that the warnings were inadequate, and in
20 fact, in Carter, for example, the claim was that the label was
21 misleading because it misrepresented the safety risk of for
22 children under 12. The Court found that that was a preempted
23 claim.

24 So, while the Plaintiffs didn't use the term
25 misbranded under Federal law, the result of that case would be

1 the exact opposite if Plaintiffs' theory was true.

2 That has been the result certainly in the OTC context
3 and in the medical device context. These claims have been more
4 regularly raised by Plaintiffs and more regularly rejected,
5 including by the Supreme Court in Riegel.

6 *THE COURT:* When can an OTC drug be found to be
7 misbranded by a civil jury, not the FDA?

8 *MS. EISENSTEIN:* As I said, your Honor, I think it is
9 this question of comparing the generalized obligation of the
10 misbranding statute compared with the specific requirements
11 under Federal law, and that is the exercise that Courts have
12 gone through in evaluating these types of claims with respect
13 to not only what rarely happens in the OTC drug context, but in
14 the analogous context of cosmetics and other over-the-counter
15 products like sunscreens and toothpaste.

16 Courts have looked at that issue and said that where
17 there is no FDA -- where the FDA hasn't engaged in any form of
18 regulation over the particular activity or conduct in question,
19 then the general misbranding provision can be something that
20 goes to the jury, or where the Plaintiff alleges that the
21 Defendant violated provisions, specific provisions of Federal
22 law that also rendered it misbranded, that can go to a jury.

23 For example, the advertising, the non-labeling
24 advertising type claims that are different in substance than
25 the FDA approved label have been a good example of where juries

1 can make the determination that that is violative of the
2 misbranding provisions.

3 *THE COURT:* Can you think of a fact pattern involving
4 a drug, not a toothpaste or a lotion or cosmetic, where an OTC
5 drug could be found to be misbranded by a civil jury?

6 *MS. EISENSTEIN:* I think I raised this before. If the
7 product carried information on it that was different than what
8 was approved by the FDA, if, for example, the product contained
9 different ingredients than the FDA had approved, and there have
10 been some cases around that where the product was supposed to
11 contain a certain set of ingredients, and the label said as
12 much, but in fact it did not contain those ingredients, that is
13 an example where products have been determined to be
14 misbranded.

15 Where the allegation is that the product was what the
16 FDA approved, and the label was as the FDA approved it, that is
17 not a situation where misbranding can apply.

18 *THE COURT:* Okay. Let me shift gears just slightly.
19 Do you believe that the Mensing decision addressed preemption
20 against brand manufacturers in any way? And if so, what text
21 do you rely upon in Mensing for that proposition? And if not,
22 why do you rely upon Mensing to advance your preemption
23 argument?

24 I am speaking specifically about your reply on page 5,
25 as well as other pages, where you say Mensing dealt with

1 impossibility preemption based on generics' duty of sameness,
2 rather than express preemption, nonetheless, it stands for the
3 proposition that misbranding is not some catchall exception to
4 Federal preemption principles.

5 *MS. EISENSTEIN:* Your Honor, the reason we rely on the
6 Mensing decision is because one of the only authorities that
7 the Plaintiffs rely upon for their misbranding theory is the
8 amicus brief that the Government filed in that case.

9 The Court addressed that amicus brief, and while it
10 didn't grapple with the issue that we have just been discussing
11 about whether or not a drug could, in theory, ever be
12 misbranded based on the FDA approved label -- in that case it
13 was the generic's label that was following the label of the
14 branded manufacturer -- it found, nevertheless, that preemption
15 existed even assuming such a duty to update the label existed.

16 It was exactly a parallel argument, which was that the
17 Government and the Plaintiffs in that case had argued that the
18 duty of sameness was trumped by this duty to have a
19 non-misleading label under the misbranding regulations, and the
20 Supreme Court rejected that as a way in which to avoid, in that
21 case, impossibility preemption based on the generic's duty of
22 sameness.

23 Now, that doesn't have -- that has an analogy here,
24 because the question here under express preemption is whether
25 Plaintiffs are trying to impose a set of requirements as to the

1 label that is different from, in addition to, and not identical
2 with Federal requirements, and that is the express preemption
3 provision we have here.

4 The only way they can get around that is by pointing
5 to some violation of Federal law, and they are trying to use,
6 just like they did in Mensing, the purported violation of the
7 misbranding requirements to say that trumps the duty of
8 identicalness that is imposed by the express preemption
9 provision.

10 And just as in Mensing, and this is what Riegel said
11 as well in the context of express preemption of the medical
12 device, that theory does not avoid express preemption absent a
13 violation of specific Federal requirements. That is also what
14 Wolicki-Gables requires under the Eleventh Circuit standard for
15 pleading a parallel violation that can survive express
16 preemption.

17 *THE COURT:* Okay. I have two more questions. One, I
18 am going to circle back to the exchange we had before I pivoted
19 to Mensing.

20 Do I understand your position to be that a jury could
21 find a drug misbranded, or it could not find a drug misbranded,
22 OTC, when the manufacturer fully complied with the label that
23 the FDA previously approved? We are in a world where the FDA
24 has approved the label.

25 What are the ramifications for that in terms of what a

1 jury could or could not find with respect to misbranding?

2 *MS. EISENSTEIN:* I agree with your Honor that the jury
3 could not find that the FDA approved label -- that the FDA
4 approved label was misbranded and therefore avoided preemption.
5 That was word-for-word what the Supreme Court said in Riegel.

6 Let me read from it. It says "that means the MDA" --
7 which is the medical device amendment, identically worded to
8 379r, except that 379 adds identical with, not just in addition
9 to or different from. "The MDA expressly preempts a jury
10 determination that the FDA approved labeling for a pacemaker
11 violated the state common law requirement for additional
12 warnings."

13 That was directly in response to the Plaintiffs'
14 argument that the label of that device was misbranded and
15 misleading. The Supreme Court looked at the regulations that
16 required a particular label and the PMA approval of that device
17 and said that the MDA preempts that jury determination. The
18 same is true here.

19 *THE COURT:* Okay. Assume for argument's sake that I
20 were to conclude, or there was a conclusion that the
21 Plaintiffs' have alleged Ranitidine was Federally misbranded.
22 Would you agree that, upon reaching that conclusion, the Court
23 would then have to turn to carefully comparing the elements of
24 each state cause of action to the Federal misbranding statute,
25 and then decide the extent to which each state claim is

1 parallel?

2 *MS. EISENSTEIN:* I think that is right, your Honor,
3 and in doing that exercise, I agree with Mr. Keller that it is
4 not a question just of a label, it is a question of what
5 substantive requirements the state would impose, and to
6 the extent to which the state would impose a label that is
7 different from that which the FDA had approved, that that would
8 be the preempted.

9 *THE COURT:* Again, in a world in which the Court is --
10 if the Court were to find misbranding, and then turns to a
11 comparison, you are agreeing that the Court would need to
12 compare the elements of the state cause of action to the
13 Federal misbranding statute, that is, undertake a state
14 specific element challenge from the brands if we were to get to
15 that point?

16 *MS. EISENSTEIN:* I don't think that the elements of a
17 state law cause of action have to be identical to some elements
18 of a Federal -- there is no Federal claim. I think that the
19 question is what requirements the state law imposes, and
20 whether those would also constitute a violation of specific
21 Federal law requirements.

22 I want to add one more thing, and this comes from the
23 parallel claim case law. It is not just any violation, it is
24 one that causes the Defendant's injury.

25 The Courts in the parallel claim arena have been

1 clear, it is not enough to just point to a specific violation
2 of Federal law that is untethered to the injury of the
3 Plaintiff, it has to be a specific violation of -- a specific
4 violation of both state law duties that also constitute a
5 violation of Federal duties that cause the Plaintiff's injury.
6 So, in doing that comparison, that is what gets beyond, if the
7 Plaintiffs can succeed in that, Federal preemption.

8 One thing I heard yesterday that sort of concerned me
9 about that in the Plaintiffs' response to the omnibus Motion to
10 Dismiss was, in trying to avoid dismissal on standing grounds,
11 the Plaintiffs seem to be suggesting that the reason they
12 survived express preemption -- sorry, the reason that they
13 survived as a matter of state law was that the product was
14 inherently unsafe.

15 If that is their theory of liability here, that would
16 still be a preempted theory because it wouldn't be based on a
17 purportedly misleading label that didn't have notice of NDMA
18 formation or a cancer risk warning, but rather, based on the
19 inherent lack of safety of the product.

20 So, that is an example of where it -- when you get
21 past there is a violation of potential Federal law that also
22 constitutes a requirement under the state law, it's not enough
23 if that is not what caused the purported injury that Plaintiffs
24 are asserting.

25 *THE COURT:* Right, but assuming there are allegations

1 that it caused the injury, would you agree that what the Court
2 has now in its briefing from both parties would not allow the
3 Court to undertake that kind of an analysis?

4 *MS. EISENSTEIN:* I agree, your Honor, there hasn't
5 been a state specific analysis of these claims.

6 *THE COURT:* So, would that be an issue -- I understand
7 you are saying we don't even get to that, but if in some
8 scenario we got to that, would that be an issue that, for
9 example, under PTO 61, is a state specific issue relevant at a
10 later stage in the litigation and it would be addressed by the
11 parties at that point?

12 *MS. EISENSTEIN:* I think potentially, to the extent to
13 which it isn't encompassed in the omnibus briefing on some of
14 these issues with respect to specific unfair competition laws,
15 yes.

16 *THE COURT:* All right. Thank you so much.

17 From the Plaintiffs, what do you think a Plaintiff
18 must allege for an OTC product to be Federally misbranded? Are
19 the requirements more than what the misbranding statute sets
20 forth in 21 U.S.C. Section 252; and if so, what is the legal
21 basis for your position?

22 That is virtually an identical question that I had
23 asked to Defense and I think that is what you wanted to weigh
24 in on.

25 *MR. KELLER:* I appreciate that, your Honor. No, the

1 Plaintiffs don't have to plead anything more than contained,
2 and just to correct your Honor, I think it is Section 352 of
3 U.S.C.

4 My friend has referred I think three or four different
5 times to Section 352(a)(1) and (j) as general provisions of
6 law. It is not general provisions, it is the definition of
7 misbranding under the Food, Drug and Cosmetic Act. There are
8 different sections of the statute that set forth the criminal
9 penalties associated with selling a misbranded drug, but that
10 is Congress' definition under the statute.

11 So, to just say, oh, that is some general stuff, you
12 can't focus on the general when there are more specific things
13 to look at, you do get to focus on the words that Congress
14 chose for the definition of an important provision of a
15 Federal statute.

16 Now, it is true, under agency law principles, cases
17 like Chevron, the FDA is the agency Congress entrusted to
18 enforce the Food, Drug and Cosmetic Act, has the authority to
19 promulgate regulations that when it is consistent with the
20 statutory text has the force of law.

21 Here is the crucial point on that, and my friend
22 conceded this, although tries to brush it under the rug, the
23 FDA agrees with us, it interprets its own regulations to say we
24 are right and the brands are wrong, and it went in the
25 different direction with medical devices, and that is fine.

1 Agencies are allowed to disagree with themselves as to what
2 should apply for a medical device versus a pharmaceutical
3 product, but with respect to the pharmaceutical space, we have
4 the FDA's position, and it is our position.

5 *THE COURT:* All right. Are you aware of any case post
6 Bartlett or post Mensing where a claim for a drug, where any
7 claim was not preempted because the Plaintiff alleged that the
8 drug was misbranded?

9 *MR. KELLER:* I am not aware of a case in either
10 direction, for us or for the other side.

11 *THE COURT:* Regardless of -- so, what I would like for
12 you to do, Mr. Keller, in your own words, is to summarize what
13 your allegations are about the brands' obligation not to sell
14 Ranitidine under Federal misbranding law.

15 At what point in time did the Federal misbranding law
16 impose a duty on the brands not to sell Ranitidine? Upon what
17 allegations do you rely upon for your position, and relatedly,
18 what inferences, if any, are you requesting that the Court make
19 for your position?

20 *MR. KELLER:* Sure, your Honor. The brands had an
21 obligation not to sell a drug, Ranitidine, with a false or
22 misleading label. When they knew or should have known that
23 Ranitidine was false or misleading is a question of fact. We
24 think that we can establish it pretty early in time after the
25 FDA approved the drug, but that is a question that is going to

1 be subject to a lot of disagreement between the parties based
2 on the different interpretations of the facts.

3 Once the label became false or misleading, that is
4 where the Federal misbranding statute comes into play.
5 To plead state causes of action that are parallel to the
6 Federal misbranding statute we have to claim there was a breach
7 of duty under various state laws to sell a drug with a false or
8 misleading label.

9 I hope during my prepared remarks I covered the
10 different types of causes of action that we plead in the
11 amended consumer class action complaint that set forth that you
12 do have a duty when you are selling a product not to sell it
13 with a false or misleading label.

14 I do want to return to something that your Honor
15 brought up in the last set of questions that you asked my
16 friend, which is, okay, assuming that you believe that the
17 Federal misbranding statute can be violated sometimes and a
18 case can go to a jury sometimes, do we have to carefully look
19 at all of the elements of state law to see if it matches up
20 with the elements of Federal law, and the answer to that is a
21 resounding no.

22 The only element that you are supposed to focus on for
23 preemption purposes is duty. I think you can consult the
24 Supreme Court's decision in Moore, which was reaffirmed in
25 Bates, for that proposition.

1 The element of causation, for example, which my friend
2 referenced, yes, under state law we have to plead and prove
3 causation for many of these causes of action. In some states
4 we have to prove reliance, in other states we don't, but that
5 doesn't matter for purposes of 379r and preemption and whether
6 the supremacy clause kills our claims.

7 The only thing that matters for purposes of section
8 379r, the Supreme Court has interpreted the word "requirements"
9 to be focused on duty, so we are only comparing the element of
10 duty under state law to see if it matches up with the Federal
11 misbranding statute.

12 *THE COURT:* Would you agree that the Court doesn't
13 have briefing on the duty of -- in each of these states where
14 you are bringing the claims, to the extent the Court got to
15 that point, such an analysis would need to be done perhaps
16 pursuant to the agreement that the parties reached that certain
17 issues fall, under PTO 61, for another day?

18 *MR. KELLER:* Yes, I would agree with that, your Honor.
19 I don't think the Defendants have briefed whether our state
20 causes of action adequately plead a parallel duty or not.
21 Their position is just that by definition the Federal
22 misbranding statute is not triggered. So, I don't think that
23 they have briefed that, and we, therefore, didn't either.

24 *THE COURT:* All right. Okay. Thank you so much, I
25 appreciate it. That was very helpful to the Court and very

1 much appreciate both of your presentations and carefully
2 thought-out responses to my questions that maybe weren't as
3 carefully thought out as your answers.

4 So, it was an attempt to try to make sure I understood
5 everything that you were putting forth. It is a difficult
6 issue, so I appreciate your thoughts on it.

7 *MR. KELLER:* Thank you, your Honor.

8 *THE COURT:* Thank you so much.

9 *MS. EISENSTEIN:* Thank you, your Honor.

10 *THE COURT:* Okay. The next motion that we are going
11 to go to -- as I had indicated, we might get to the
12 distributors in the morning as well. Let me hear argument from
13 counsel for the retailer and pharmacy Defendants, Motion to
14 Dismiss amended master personal injury complaint and
15 incorporated memorandum of law. That motion appears at Docket
16 Entry 3112.

17 I am going to hear from Defense and then hear from the
18 Plaintiffs. Then I will ask that counsel for the distributors
19 come up from the Defense, then from the Plaintiff on 3107,
20 which is the distributor Defendants' Motion to Dismiss amended
21 master personal injury complaint and incorporated memorandum of
22 law.

23 Then I am going to have all counsel come on for those
24 motions and I have questions that I think I can overlap and I
25 would just as soon have everyone there, and then we will be

1 able to conclude for the morning session and go to the store
2 brand and the generic motions.

3 Ms. Johnston has her screen on. Good morning. Would
4 you like to use your full ten minutes? Do you want any warning
5 and/or any rebuttal time?

6 *MS. JOHNSTON:* Thank you, your Honor, and good
7 morning. Sarah Johnston on behalf of the retailer and pharmacy
8 Defendants. In terms of timing, I think I plan to use only
9 about five or six minutes. In the event that I creep past
10 that, a two-minute warning would be welcome.

11 *THE COURT:* All right. You may proceed.

12 *MS. JOHNSTON:* Thank you.

13 Your Honor, my goal here today for the retailers and
14 the pharmacy Defendants -- I am just going to say retailers for
15 brevity -- is to keep this pretty succinct.

16 We are well into the fourth day of Motions to Dismiss
17 in this MDL and I think at this point, the Court is very
18 familiar with the arguments and the legal principles underlying
19 the retailers' arguments.

20 For purposes of orienting the Court, and also in the
21 interest of efficiency, I have spoken to Mr. Kaplan, and
22 because there are some overlapping issues in both the retailer
23 and distributor motions, he is going to take on the issues of
24 punitive damages and unjust enrichment because of the overlap
25 in the two briefs and the arguments there, and for my part, I

1 am going to handle the substance of the retailers' briefing,
2 which is the general negligence claims. With that, I will jump
3 in.

4 Yesterday, during the first argument of the day, I was
5 struck by something that Mr. Heinz said on behalf of
6 Plaintiffs, and that was a cite to Rule 1 of the Federal Rules
7 of Civil Procedure and the idea that Rule 1 stands for the
8 proposition that the Federal rules are meant to be construed
9 and administered to ensure fairness in the disposition of all
10 cases.

11 I think the specific language he was referring to is
12 that the just, speedy, and inexpensive determination of every
13 action, but I like Mr. Heinz's paraphrasing the idea of
14 fairness because I think that is a perfect frame for the
15 retailers' overall arguments here.

16 So, stepping back, let's talk about where we are
17 today.

18 Back in December, Mr. Keller, who is here again today,
19 he and I argued the original retailer Motions to Dismiss, and
20 those were a very different set of motions. Back then, Mr.
21 Keller and the Plaintiffs conceded that the retailers didn't
22 actually do anything wrong with respect to Ranitidine.

23 Instead, they argued that the retailers were
24 "absolutely liable." Essentially, this was an argument that
25 the retailers were some sort of insurer or pass through insurer

1 for the safety of Ranitidine, and Plaintiffs' pleading, their
2 briefing, their argument all conceded that the retailers owed
3 no duty with respect to Ranitidine and were not alleged to have
4 affected the overall safety of the drug in any respect.

5 When faced with the preemption arguments that were
6 raised during the first motion hearings, Plaintiffs changed
7 their course leaning on a theory of negligence that didn't
8 exist in the first complaint, and essentially, as it was raised
9 during argument back in December, it was sort of a coin
10 flip theory, that either the retailers failed to store
11 Ranitidine at the lowest end of the labeled range or that we
12 collectively and as an entire industry disregarded the label
13 and instead, elected to ship and store Ranitidine however we
14 wanted to.

15 Following those hearings and in the December 31st
16 order, the Court took a firm line on its preemption findings,
17 and your Honor is well familiar with those decisions, so I
18 won't repeat them. But at bottom, the Court gave Plaintiffs
19 some limited leeway to try to plead this new negligence claim.
20 As I read it, it was basically, fine, if that is your theory,
21 and if you can get around preemption, give it a shot, but as it
22 stands, it is not pled in the complaint.

23 It is important to remember that the Court's order
24 wasn't open season for Plaintiffs to bring whatever claims they
25 wanted to. Instead, it was a narrow and very specific

1 directive, and the Plaintiffs were to plead per the order in
2 a manner that reconciled their global theory of the inherent
3 molecular instability of Ranitidine with this new theory that
4 some after-the-fact shipping or storage issue affected the drug
5 in a way that that wasn't preempted.

6 More importantly, Plaintiffs were told that they
7 needed to plead with specificity with reference made to the
8 specific state law duties that form the basis of their new
9 claim.

10 And so, in response, Plaintiffs filed the AMPIC, and
11 in response, we got 18 paragraphs. And by "we" I mean 22
12 retailers and half a dozen distributors together. And whittled
13 down to the actual allegations themselves, we got three
14 paragraphs collectively, industry-wide, and based on
15 information and belief.

16 So, essentially, Plaintiffs put forth their theory in
17 those three paragraphs that on information and belief the
18 retailers and distributors systematically exposed Ranitidine to
19 "excessive levels of heat and humidity", again, on information
20 and belief that the retailers and distributors failed to
21 implement policies that would ensure that Ranitidine wouldn't
22 be exposed to this "excessive heat and humidity."

23 Then, finally, a for example that some retailers and
24 some distributors shipped Ranitidine sometimes through the
25 mail, and that was it.

1 I lost count of the number of Defendants in this case,
2 I think it nears a hundred, but I think it is a fair ballpark
3 to assume that the retailers and distributors collectively make
4 up about a third of the Defendants in this litigation, and we
5 got three paragraphs.

6 Notably, nowhere in the 600 or so pages of the AMPIC
7 do Plaintiffs define what excessive means, nowhere do they
8 attempt to differentiate among the 25 plus Defendants in
9 various levels of the supply chain to allege any independent
10 actions, any independent existence to support a negligence
11 claim, and nowhere in that 600 or so pages do Plaintiffs
12 identify a single legally recognized duty to support the
13 theories that are based on their information and belief.

14 This is not what the Court asked for, and it doesn't
15 meet basic pleading standards.

16 So, going back to the discussion of fairness and
17 efficiency under Rule 1, I think it is important to point out
18 that despite all this, despite two rounds of briefing and two
19 very voluminous complaints, Plaintiffs, in their opposition to
20 our motion, say outright at page ten, "It is true that there is
21 nothing that the retailers could have done that would change
22 whether Ranitidine was unreasonably dangerous at the time the
23 retailers sold it or at any point thereafter through its shelf
24 life."

25 That is the claim, and back in December the Court very

1 generously gave Plaintiffs some latitude, and this was to get
2 their claims right. While that leave was narrow, it
3 importantly wasn't narrow in the sense that the Plaintiffs were
4 confined by space limits or page limit restrictions such that
5 they basically didn't have the room or the real estate to get
6 into the factual and legal bases of their claims. They simply
7 elected to focus their energies elsewhere.

8 The retailers' position is that the Court has given
9 Plaintiffs more than ample opportunity to figure out what they
10 want to allege against the retailers. They haven't done it,
11 they have elected not to, and more importantly, for the reasons
12 we state in our brief, they can't.

13 We think our briefing adequately lays out the
14 grounds for our position, including why Plaintiffs have failed
15 to satisfy Rule 8, why Plaintiffs have failed to meet the
16 Court's directives, why Plaintiffs claims don't
17 constitute negligence under any construction, why the claims
18 continue to be preempted, and ultimately why those claims
19 should be dismissed.

20 With that, your Honor, I will stop and reserve the
21 rest of my time. Thank you.

22 *THE COURT:* Thank you. That was just shy of eight
23 minutes. All right.

24 And for the Plaintiffs, you have 13 minutes. Would
25 you like any warning?

1 *MR. SNIDOW:* Yes, your Honor, if you would maybe give
2 me a two-minute warning, and I appreciate the extra time.

3 *THE COURT:* All right. You may state your appearance
4 for the record and proceed.

5 *MR. SNIDOW:* This is JJ Snidow on behalf of the
6 Plaintiffs. Your Honor, I do have a presentation that I will
7 try to show. Your Honor, I hope you can just see a black
8 screen at this point.

9 *THE COURT:* I do.

10 *MR. SNIDOW:* May it please the Court. Before turning
11 to Defendants' arguments, I want to detail the key allegations
12 in the complaint because we have figured out the nature of
13 these claims and we have pled them specifically succinctly and
14 we have pled them plausibly.

15 First, the science allegations. Yes, as counsel
16 pointed out, the complaint alleges that Ranitidine always
17 degrades into NDMA, and thus is always dangerous, but the
18 complaint also alleges that the drug degrades into NDMA more
19 quickly and thus becomes more dangerous once exposed to high
20 heat and humidity, and that scientific allegation, your Honor,
21 is at the center of all the claims against the retailer
22 Defendants.

23 The complaint then specifically links that level of
24 NDMA exposure to the Plaintiffs' cancer. The more NDMA that
25 someone ingests, the higher the risk of cancer.

1 The label for Ranitidine, meanwhile, contains specific
2 instructions for storage and transport. The label required
3 Ranitidine to be stored at between 68 and 77 degrees and not in
4 the presence of excessive heat and humidity. Here is the crux
5 of the claim which is pled, the complaint alleges that the
6 retailers did not actually follow the label. It alleges that
7 they did not store Ranitidine in the required temperature and
8 humidity range.

9 Now, Defendants criticize us for not explaining how
10 this happened, but the complaint is actually quite clear on
11 this point. Even though the label said to keep the drug cool
12 and dry, the Defendants shipped it through the ordinary mail
13 and other common carriers, whether in a summer warehouse, in a
14 closed mailbox, left in the sun, or a number of other
15 situations that obviously and foreseeably led Ranitidine to be
16 subject to high heat and humidity.

17 Finally, the complaint alleges that it is this
18 differential increase in NDMA that led to their injuries. In
19 other words, we allege that Plaintiffs' cancers were caused by
20 the additional NDMA that built up as a result of the high heat
21 and humidity.

22 Now, Defendants might wish to dispute those
23 allegations during discovery, and that is, of course, their
24 right, but this is a Motion to Dismiss, and that, of course,
25 means that each of the allegations that I just ticked through

1 must be taken as true.

2 Defendants call -- in the brief, they say these
3 allegations are conclusory, but the law is clear on the
4 distinction between factual allegations and legal conclusions.
5 Only legal conclusions may be disregarded on a Motion to
6 Dismiss, as Iqbal and Twombly say. The allegations that I just
7 ticked through, each of them, they are not formulaic
8 recitations of the causes of action, they are not legal
9 conclusions, they are facts.

10 As we say in our briefs, either the Defendants shipped
11 and stored the drug properly or they didn't, but either way,
12 that is a classic factual issue.

13 What did Defendants say in response? In their brief,
14 though we have heard less of it today, their primary argument
15 is that the factual allegations are unlikely, as they say, or
16 specious. Of course, that is just fighting the complaint.
17 Even if Defendants disbelieved the allegations and, frankly,
18 even if the Court thinks they are unlikely to be proven at
19 trial, they must be accepted as true on a Motion to Dismiss.

20 Second, Defendants argue that there is not enough
21 detail about their conduct, and that seemed to be the premise
22 of Ms. Johnston's argument today, that even though we had named
23 several Defendants, we have spent not very much time on each of
24 them in the complaint, but that also is not a basis for
25 dismissal.

1 A complaint does not need to include detailed factual
2 allegations. That is exactly what Twombly says. The complaint
3 makes clear the overall basis for the claim is that Defendants
4 failed to ship and store the drug in accordance with the label
5 and that gives Defendants ample ability to prepare their
6 defense. They know what they are being accused of doing.

7 Next, Defendants argue the complaint fails to specify
8 the who. They say we didn't allege who failed to ship and
9 store the drug in accordance with the label, but of course,
10 that is just not accurate.

11 The complaint clearly defines the term "retailer
12 Defendants" as the entities listed in paragraphs 169, 218. In
13 the paragraph cited we list each of the retailer Defendants
14 here from Albertson's all the way down to Winn-Dixie, and then
15 the complaint alleges what each of the retailer Defendants did.
16 Namely, that they shipped and stored the drug in high
17 temperatures humidity levels.

18 That kind of pleading is perfectly proper and a valid
19 way of stating a claim because when each Defendant is alleged
20 to have done the exact same thing, there is simply no reason to
21 repeat the name of each Defendant before leveling the exact
22 same allegation. Instead, it is perfectly proper to plead
23 against them collectively.

24 That is also why the complaint does not raise any
25 shotgun pleading concerns. The problem with grouping

1 Defendants is that it sometimes can create confusion about
2 which Defendant is alleged to have done which act. For
3 example, if the complaint identifies Defendants A, B, C, and D,
4 and then alleges that Defendants did acts X, Y, and Z, it can
5 be unclear whether the complaint is saying Defendant A did act
6 X, or Defendant A did act Y, Defendant A did act Z, or perhaps
7 Defendant A did all three things, and that is a problem because
8 in that situation, the Defendant doesn't actually know what he
9 is being accused of doing and that thwarts his ability to
10 prepare his defense.

11 That is not what is going on here. The complaint does
12 identify the retailer Defendants, but then it makes clear that
13 each of them did the exact same thing, they failed to ship and
14 store the drug properly.

15 Turning to preemption, the operative question is
16 probably all too familiar to the Court by now, but it is
17 whether it would have been impossible for the Defendant to
18 comply with the state law duty without violating any Federal
19 law. So, it's a two-step process, identify the state law
20 duty and then ask whether Federal law forbade the Defendant to
21 satisfy it.

22 The state law duty here is a duty to exercise
23 reasonable care in storage and shipment, and more specifically,
24 to store and ship the drug in accordance with its label. So,
25 having stated the state law duty, the question is this: What

1 Federal law forbade shipping and storing according to the
2 label? The screen is black because, of course, there is no
3 Federal provision that forbids a Defendant to do exactly that.

4 To know whether the claim is preempted, Defendants'
5 state law duty is to ship and store the drug in accordance with
6 the label, there is no Federal law duty forbidding someone from
7 doing that, so Defendant can do this without violating this.
8 That means it is not impossible to do both and the claim is not
9 preempted by the Supreme Court's impossibility preemption
10 doctrine.

11 In response, Defendants say that we are really arguing
12 that they needed to stop selling the drug, but I will say this
13 as clearly as I can, we are not arguing that now, and we didn't
14 allege that in the complaint, full stop. Even though
15 Ranitidine is unreasonably dangerous, our allegation, of
16 course, is that these Defendants could have made it less
17 dangerous by shipping and storing it properly, not that they
18 should have ceased selling the drug.

19 To support this stop selling argument Defendants
20 basically take a hyper technical reading of this one clause in
21 the complaint, they note the fact that we said the words
22 "unreasonably dangerous." But that paragraph makes clear that
23 we are not suggesting they should have stopped selling.

24 Now, to be candid with the Court, I suppose we could
25 have said to ensure that the drug was not even more

1 unreasonably dangerous than it already was, but in context, it
2 is clear what we are saying. In any event, we simply would not
3 have a claim against these Defendants in this complaint if they
4 had shipped and stored the drug properly.

5 It is even more clear if you look at the state law sub
6 counts which we detail for each of the states in accordance
7 with this Court's rulings. There is no mention of unreasonably
8 dangerous or inherent defects or any of the other phrases that
9 the Defendants cherry pick. The duty is just to ship and store
10 the drug properly and Defendants could have done that without
11 violating any Federal law.

12 Now, it is true that, under this Court's orders, other
13 state law duties are preempted, like the duty to change the
14 label or redesign the drug, but when analyzing a statute, the
15 fact that one provision is preempted doesn't mean that every
16 provision is preempted, and the exact same thing is true under
17 the common law.

18 In the Mink case, which is exactly on point, the
19 Plaintiff brought three negligence theories. The Court held
20 that one of the theories was preempted, but the others were
21 not. The same thing is true here.

22 To illustrate the point, there is actually a spectrum
23 of things that any Defendant could have done to make Ranitidine
24 safer; they could have stored it at lower temperature and
25 humidity, they could have added a cancer warning, they could

1 have redesigned the drug and, yes, they could have stopped
2 selling it.

3 Under this Court's rulings, three of those things are
4 preempted, but the fourth one is not. No Federal law forbade
5 Defendants from shipping and storing the drug in accordance
6 with the label, so that claim isn't preempted even though the
7 other ones are under this Court's orders.

8 Turning to punitive damages, Defendants argue that we
9 haven't pled facts to make that request plausible under Iqbal
10 and Twombly. There are two problems with that argument.

11 The first is that Twombly and Iqbal don't apply to
12 requests for punitives because those cases are interpreting
13 Rule 882, which applies to claims, and a request for punitive
14 damages is simply a request for a type of relief which is
15 governed by Rule 883, and Twombly and Iqbal don't apply to that
16 provision of Rule 8.

17 That is exactly what Courts in this district have
18 held. The Doe versus Royal Caribbean case says exactly this,
19 that 882 is about claims, 883 is about relief, and critically,
20 that as a result, a complaint does not need to plead facts
21 underlying a request for punitive damages.

22 The second reason that argument is wrong is because we
23 have alleged facts plausibly showing entitlement to punitives.
24 We allege Defendants were reckless, we allege that they knew
25 the risk of failing to ship and store Ranitidine properly, and

1 we allege that they ignored that risk.

2 Under the law in this Court, that is plainly enough to
3 survive a Motion to Dismiss, as the L.A. versus Royal Caribbean
4 case makes clear. At a bare minimum, we have alleged -- made
5 general allegations of wonton, willful, or outrageous conduct
6 and on a Motion to Dismiss that is sufficient to support a
7 demand for punitives.

8 Finally, Defendants argue this Court did not permit us
9 to replead unjust enrichment, and on this point, your Honor, I,
10 of course, defer to the Court on the proper interpretation of
11 its prior orders, but we read, I think fairly, the order to
12 only forbid claims based on design for label.

13 The unjust enrichment claims here are not based on
14 design or labeling, they are based on failure to ship and store
15 Ranitidine in accordance with the label, so we repled it.

16 For these reasons, the retailer Defendants motion
17 should be denied, and I am happy to answer any questions the
18 Court might have.

19 *THE COURT:* Thank you so much. All right. Was there
20 any rebuttal? You had some time left, Ms. Johnston.

21 *MS. JOHNSTON:* Yes, your Honor, just briefly because I
22 know that Mr. Kaplan will likely cover some of this.

23 In terms of pleading, counsel cites to the Guarino
24 case, which I believe is also cited in their brief, for the
25 proposition that they do not need to set forth factual

1 allegations or other detailed factual allegations in order to
2 properly plead a claim. The portion of that case that they
3 cite is directly followed by a portion that they omit that
4 requires that Plaintiffs must plead enough details -- must
5 contain enough facts to indicate the presence of the required
6 elements of the claim, which they have not done here, and that
7 conclusory allegations then warranted deductions of fact, or
8 legal conclusions masquerading as facts, will not prevent
9 dismissal.

10 So, the case that they cited in terms of the adequacy
11 of their pleading against this very large group of Defendants
12 proves the point, rather than disputes it.

13 In terms of preemption, I think the Court is well
14 familiar the principles of Bartlett and Mensing preemption and
15 likely may have some questions on that that we will be prepared
16 to answer.

17 But the preliminary point that I want to highlight,
18 that counsel and I both agree on, is that the preliminary
19 question to determine is the existence of a duty, which we have
20 outlined at length, and I believe the generic Defendants have
21 as well, that there has not been a legally recognized duty that
22 has been alleged, must less with the specificity the Court has
23 requested.

24 *THE COURT:* Okay, thank you.

25 I am going to call you back up after the distributors

1 argue and we will have everybody up for questions.

2 So that I don't lose my train of thought in light of
3 what Mr. Snidow just argued with respect to paragraph 2220 in
4 the AMPIC, I want to give you an opportunity to respond, the
5 allegation that the retailer and distributor Defendants ignored
6 this risk, they did not ensure Ranitidine-containing products
7 were stored at low humidity or within the temperature range on
8 the label.

9 Instead, some Ranitidine was subjected to excessive
10 humidity and heat during storage, transportation, and shipping,
11 which caused the drug to degrade, leading to the formation of
12 excessive levels of NDMA.

13 *MS. JOHNSTON:* Would you like me to address that now,
14 your Honor?

15 *THE COURT:* Yes.

16 *MS. JOHNSTON:* Certainly. So, starting first from the
17 concept that the retailers ignored the risk, I think it is
18 clear throughout the complaint that there is no allegation that
19 the retailers were aware of the risk of formation of NDMA in
20 Ranitidine.

21 Throughout both master complaints we have never been
22 alleged to be -- I think we were left out of what was called
23 the knowledge Defendants in the first master complaint and
24 the allegations respecting knowledge in the amended master PI
25 complaint followed that same logic. The retailers were not

1 alleged to have known of the risk of NDMA in exposure to heat
2 and humidity.

3 In terms of the allegations regarding exposure to
4 excessive heat or humidity in the shipping and storage process,
5 the first point that I would make on that in response is that
6 Plaintiffs have not defined what excessive heat or humidity is,
7 or what proper storage is. All they have said is on
8 information and belief, here are the label conditions we think
9 sometimes --

10 *THE COURT:* You froze there. We will wait for one
11 moment because I am not hearing what you are saying.

12 I don't know if you can hear me, Ms. Johnston. It
13 looks like we lost Ms. Johnston. Okay.

14 For the record we will -- oh, you are back.

15 *MS. JOHNSTON:* I thought maybe shutting my video off
16 might help.

17 *THE COURT:* Now I can see you and hear you. You were
18 right in the middle of a sentence.

19 *MS. JOHNSTON:* I am not sure what sentence that was,
20 but setting aside the issue of knowledge, which I think I
21 addressed, the allegations regarding the propriety of storage
22 conditions are all based on this -- the concept that there was
23 an industry-wide disregard to these storage requirements, which
24 is not borne out in any factual way in the complaints as
25 pleaded, specifically as to such a large group of Defendants.

1 Moreover, Plaintiffs haven't defined why, even were
2 Ranitidine stored outside of the specific labeled range -- they
3 haven't, for instance, given a range of temperatures that would
4 subject Ranitidine to increased likelihood of development of
5 NDMA, nor have they defined what excessive heat would
6 constitute, among the other things that would put the retailers
7 on notice of what exactly they are alleged to have done wrong.

8 *THE COURT:* All right. Thank you so much.

9 So, at this point, if we could have the Defense
10 counsel for -- Mr. Kaplan for 3107, the distributor Defendants
11 Motion to Dismiss, and we are still in the morning hour, good
12 morning. You have ten minutes, do you want any warning or are
13 you keeping your time?

14 *MR. KAPLAN:* Good morning, Judge Rosenberg, Andrew
15 Kaplan, I represent Cardinal Health, Inc. I am here to argue
16 the distributor Defendants' Motion to Dismiss, docket 3107.

17 I would like to reserve maybe a minute of time at the
18 end, and I am happy to keep track of my own time.

19 *THE COURT:* Okay. You may proceed.

20 *MR. KAPLAN:* Thank you, your Honor, and may it please
21 the Court.

22 Your Honor, the distributors were not brought into
23 this litigation at the outset. They were first named in the
24 original master complaints as an afterthought. The voluminous
25 complaints barely mentioned the distributors. There were no

1 direct claims of negligence, as Ms. Johnston pointed out.

2 After the Court dismissed all of the claims against
3 distributors, most with prejudice, the Court allowed Plaintiffs
4 to attempt to plead essentially one narrow claim, a theory of
5 direct negligence.

6 More than a month later, the Plaintiffs came back with
7 the AMPIC, a lengthy pleading of more than 3200 paragraphs, of
8 which only three paragraphs attempt to address any purported
9 negligence by distributors, but the three conclusory,
10 unsupported allegations group pled against all six distributors
11 and more than 20 retailers, and conspicuously pled upon
12 information and belief, come nowhere near the level of pleading
13 required under Twombly and Iqbal.

14 16 months after the commencement of this MDL, and
15 almost a year after the distributors were brought into this
16 litigation, it is clear that Plaintiffs cannot plead a viable
17 claim against distributors.

18 We respectfully request that the Court grant the
19 distributors' Motion to Dismiss all claims against them with
20 prejudice and release distributors from this litigation.

21 I will briefly touch on the issues we raise in our
22 motion papers. Most fundamentally, Plaintiffs fail to make any
23 plausible allegation that gives rise to a claim for negligent
24 storage and transportation. As I mentioned, the sum total of
25 the allegations of misconduct are three paragraphs of the AMPIC

1 in which Plaintiffs allege, upon information and belief, that
2 distributors and retailers purportedly systematically exposed
3 Ranitidine to "excessive levels of heat and humidity,"
4 purportedly failed to implement rigorous policies to ensure
5 compliance with heat and humidity requirements on product
6 labels, and purportedly shipped product through the mail, which
7 allowed the product to be exposed to "excessive heat and
8 humidity."

9 These paragraphs suffer from numerous deficiencies.
10 First, the Court gave Plaintiffs the opportunity to replead
11 their complaint at the outset of this MDL before any Motion to
12 Dismiss practice, but Plaintiffs declined. After voluminous
13 briefing and argument, the Court dismissed all the claims
14 against distributors and specifically cautioned against the
15 improper shotgun pleading.

16 In its order on the shotgun pleading motion the Court
17 said in no uncertain terms, "The Court is particularly
18 concerned by the way in which the MPIC lumps MPIC shotgun
19 Defendants across entire groups, e.g. retailers grouped with
20 distributors." The order went on to say that the Court
21 understand certain groups to conduct fundamentally different
22 activities than others.

23 Plaintiffs simply ignored this caution and filed the
24 AMPIC with almost 30 separate Defendants lumped into one count
25 with the same three conclusory allegations made against all.

1 While it is a technical pleading failure, it also has a
2 practical problem. It allows the Plaintiffs to avoid having to
3 put forth factual allegations about even one instance where any
4 specific Defendant purportedly undertook the alleged negligent
5 conduct.

6 Second, if Plaintiffs were correct that every
7 distributor systematically exposed Ranitidine to undefined
8 excessive heat and humidity, then it would mean that no
9 distributor handled any of their products correctly, and there
10 is no suggestion that there is a separate Ranitidine-only
11 handling policy. This is implausible on its face as the Court
12 already expressed serious reservations about such a theory in
13 its order on distributors' original Motion to Dismiss.

14 Third, while Plaintiffs lob the vague and
15 conclusory allegations of exposing Ranitidine to undefined
16 excessive heat and humidity, they notably do not allege
17 anywhere how high the temperatures allegedly were or for how
18 long. This failure is especially important given that the U.S.
19 Pharmacopoeia, or USP, states that controlled room temperature
20 product, which is the category Ranitidine falls into, is
21 allowed to have temperature excursions up to 104 degrees for up
22 to 24 hours.

23 Plaintiffs have not alleged anywhere that any
24 distributor allowed any product to exceed those allowances.

25 Fourth, and importantly, the allegations Plaintiffs

1 make against distributors are directly contradicted by the
2 discovery they have from distributors. By the time Plaintiffs
3 filed their AMPIC, the distributors had completed their
4 document productions under their core discovery agreements and
5 have reduced thousands of pages of policies and procedures
6 regarding storage and transportation. Plaintiffs have since
7 taken multiple distributor storage and transportation 30(b)(6)
8 depositions.

9 It is troubling that Plaintiffs could continue to
10 argue to this Court that distributors purportedly failed to
11 implement rigorous policies to ensure compliance with heat and
12 humidity requirements on product labels while being in
13 possession of voluminous documents that say just the opposite.

14 Fifth and finally on this issue, as noted earlier, the
15 allegations of negligence against distributors are made upon
16 information and belief. Multiple Courts in the Eleventh
17 Circuit, including this Court, have stated that the allegations
18 made upon information and belief are not necessarily entitled
19 to a presumption of truth.

20 The lack of support behind these allegations was
21 highlighted by Plaintiffs' own arguments yesterday. Yesterday,
22 when attempting to support the sufficiency of the economic loss
23 complaint, Plaintiffs' counsel argued that they don't just
24 allege that they "believe" that there is a safety issue with
25 Ranitidine, they plead actual facts in support of their

1 allegations, such as -- the example was scientific studies.

2 I leave the issues about the insufficiency of that
3 complaint to my colleagues, but implicit in Plaintiffs'
4 argument is that the Plaintiffs' belief alone is not sufficient
5 to state a claim, and that is all we have here.

6 I will briefly touch on the other claims against the
7 distributors.

8 First, the Plaintiffs' state law sub counts fail for
9 the same reason as the general negligence claim. Plaintiffs
10 add no specific allegations for any state negligence claims.
11 Moreover, they don't attempt to tether any state law to any
12 Defendant.

13 There are, for example, state law sub counts for
14 states where there is not a single Plaintiff asserting a claim
15 against any distributor.

16 Second, Plaintiffs' derivative claims, loss of
17 consortium, survival, and wrongful death, Counts 15 through 17,
18 must rest upon a viable substantive claim to survive. Because
19 the negligence claim should not survive, these claims must fail
20 as well.

21 Third, Plaintiffs allege punitive damages against all
22 Defendants. Of course, if the negligence count fails, so does
23 the damages request. But in isolation, the request for
24 punitive damages is still deficient. Plaintiffs' argue that
25 their request for punitive damages is not a claim and therefore

1 cannot be dismissed under 12(b)(6).

2 Courts often treat Motions to Dismiss and Motions to
3 Strike punitive damages requests interchangeably. We cite
4 multiple Federal Florida cases in our reply brief on that
5 point.

6 Whether this Court dismisses or strikes the request
7 for punitives, it should not survive. More important than the
8 mechanism for excising this request is Plaintiffs' inability to
9 sufficiently plead entitlement to such damages.

10 Plaintiffs' bid for punitives is in paragraphs 473 and
11 474 of the AMPIC. The alleged misconduct described in those
12 paragraphs has nothing to do with distributors. It relates
13 only to conduct allegedly undertaken by manufacturers, that is
14 labeling, marketing, and purportedly misleading research.

15 Thus, the argument Plaintiffs make in their briefing
16 is flatly contradicted by their own complaint. They plead no
17 conduct against distributors that could warrant such damages.

18 Finally, for unjust enrichment, Count 14, this claim
19 suffers from an even bigger problem. The Court dismissed it
20 already with prejudice in its order on the first round of
21 Motions to Dismiss. But even if the Court had allowed
22 Plaintiffs to replead, the amendment fails because once again
23 what Plaintiffs argue in their briefing is flatly contradicted
24 by their own complaint.

25 Plaintiffs' unjust enrichment count incorporates and

1 relies on paragraphs 1 through 475 of the AMPIC, which do not
2 allege that distributors had any knowledge of the purported
3 risks of Ranitidine, and the underlying allegedly wrongful
4 conduct that they point to in paragraph 2725 is marketing,
5 promotions, and advertisement, all conduct that does not apply
6 to distributors.

7 With that, I will yield to Mr. Longer and reserve any
8 remaining time. Thank you.

9 *THE COURT:* Thank you. You have about a minute and 20
10 seconds left. If we could have Mr. Longer come up.

11 Would you like any kind of a warning, Mr. Longer? You
12 have ten minutes.

13 *MR. LONGER:* Can you hear me, your Honor?

14 *THE COURT:* I can.

15 *MR. LONGER:* A warning would be nice. Give me a
16 minute warning.

17 *THE COURT:* Okay. You may proceed.

18 *MR. LONGER:* Thank you, and may it please the Court.
19 Fred Longer on behalf of the Plaintiffs.

20 Your Honor just heard Mr. Snidow present a lot of
21 argument for Plaintiffs, and a lot of it overlapped, as you
22 could hear, between the retailer Defendants and the distributor
23 Defendants.

24 So, I would just like to address a couple of the
25 points that we just heard, and after that, I will just go into

1 some remarks, but one of the things that I did just hear is
2 that Mr. Kaplan suggested that a lot of information has been
3 provided in discovery, and we have had depositions, but of
4 course, that occurred after the amended complaint was already
5 filed.

6 So, to suggest that discovery that was later produced
7 gave us any information about how to plead this amended
8 complaint is not well founded. In fact, a couple of the
9 distributor Defendants have yet to produce any documents,
10 Geri-Care and Golden State. McKesson didn't produce
11 documents in an ununitized manner until after the amended
12 complaint was filled, so the argument about production of
13 documents is unfounded and unhelpful.

14 So, based on what we did have, the Plaintiffs pled the
15 complaint which provided more than adequate notice of our
16 claims of negligence against the Defendants.

17 Despite the Plaintiffs taking the Court's guidance to
18 heart and carefully crafting and recrafting our pleading, once
19 again the Defendants' label, the amended personal injury
20 complaint, shotgun pleading, although yesterday I did hear that
21 it was an improvement, so I guess we have done better, but
22 nonetheless, the Defendants' biggest beef is that they are
23 calling our allegations regarding the distributor Defendants a
24 group pleading.

25 They contend we improperly lumped all the distributors

1 and retailers together indiscriminately, but the AMPIC is
2 anything but a shotgun pleading. We took great pains to avoid
3 any of the so-called Wyland sins. Our claims in Count 10 are
4 limited to negligence involving storage and transportation
5 outside the labeling range. The distributor Defendants are
6 down the chain of distribution, but they are in the business of
7 storing and moving the products they sell across the country
8 and are properly categorized together.

9 The distributor Defendants are not confused by the
10 amended complaint. They contend that we are not permitted to
11 plead that all of the Defendants engaged in the same act, such
12 as using the United States Postal Service to ship their
13 products, because they call that circular reasoning that just
14 wouldn't be plausible, but facts are stubborn things, your
15 Honor, and here we alleged a fact that these distributors, each
16 one of them, used common carriers, like the United States
17 Postal Service, to mail their products, and that there was not
18 temperature or humidity control when they did so.

19 That fact was alleged as to each Defendant. What is
20 not plausible about that fact? Using a carrier that doesn't
21 control conditions makes it more than plausible that
22 temperature and humidity conditions exceeded the product label
23 as to each and every Defendant. They can take issue with that,
24 but that is on a summary judgment motion. Right now they have
25 admitted that fact for purposes of the Motion to Dismiss. It

1 is to be assumed to be true, and it is supported by examples.

2 So, there is more than plausibility here, we have
3 given examples of how the fact is actually proven.

4 The principle case that the Defendants provide in
5 their reply brief is Parker Auto Body. That is an antitrust
6 case, your Honor, it doesn't support them on this point.
7 Magistrate Judge Smith ruled that there are cases in which
8 group pleading is acceptable, and he cites to the Eleventh
9 Circuit case that we cited, Crow versus Coleman, and he said it
10 endorsed the use of group pleading.

11 Judge Smith even quotes the same quote we quoted:
12 "When multiple Defendants are named in a complaint the
13 allegations can be, and usually are to be read in such a way
14 that each Defendant is having the allegation made about him
15 individually." And the Parker Court noted that provided the
16 Plaintiffs used the Defendants are in fact intended to
17 encompass every single Defendant, then it is acceptable
18 practice to do so.

19 We also cite in our opposition, your Honor, Sprint
20 Soles at 44 F.3d, a Judge Cohn opinion. He said that Plaintiff
21 may plead claims against multiple Defendants by referring to
22 them collectively, for example, by referring to groups of
23 Defendants as Defendants.

24 That is exactly what we have done here. The
25 Defendants aren't confused by the pleading, they are taking

1 advantage of it. They want us to plead evidence, but we are
2 still under a notice pleading standard, and provided the
3 Defendants have adequate notice of the claim against them, that
4 they each failed to ship and store Ranitidine under the
5 temperature and humidity conditions required by the label, then
6 the pleading is adequate.

7 In the end, your Honor, this is a personal injury
8 complaint. Under notice of pleading, we are only supposed to
9 say, you hurt us. We did more than that. There are so many
10 allegations that give the road map of liability to this
11 litigation.

12 Instead of owning up to these allegations that we
13 asserted, the Defendants say that they don't understand them,
14 but being purposely obtuse should not be permitted as a
15 defense. This is not a shotgun pleading, your Honor.

16 We also heard Mr. Kaplan argue that our claims of
17 negligence are not well stated, but we provided all of the
18 elements of negligence, duty, breach, causation, damages, and
19 they dispute the factual assertions.

20 They suggest that we say each of them separately did
21 these things, and that is implausible, but these allegations,
22 as I mentioned before, are to be accepted as true and entitled
23 to every reasonable inference. If they want to deny the facts,
24 now is not the time.

25 These allegations put them on notice of our claims,

1 and in response, they just come up with more challenges. They
2 say that the duty must be pleaded, but in their reply they
3 acknowledge that duty is a matter of law, and that it is a pure
4 question of law.

5 Yes, this Court in National Fire said that a complaint
6 may be dismissed for failure to establish a duty, but unlike
7 that case, where the Plaintiff failed to plead any facts
8 according to his undertaker liability theory, here we have
9 artfully explained how Defendants failed to maintain proper
10 temperature and humidity, and as I said, we even provided
11 examples.

12 Paragraph 224 says the distributor Defendants
13 systematically followed a standard practice or policy to allow
14 Ranitidine to be outside the labeled range. They denied that
15 allegation, but the facts that we have pled are not conclusory,
16 they are not postulation, they are not hypothetical, they are
17 plausible. We know that -- we know this, and we pleaded it on
18 information and belief, but we also provided facts to support
19 the allegations.

20 As I mentioned, the Defendants didn't provide us the
21 documents that Mr. Kaplan said that he provided to us prior to
22 the complaint being -- the amended complaint being filed, so it
23 is not a fair assertion on his part to say, oh, and we are
24 having more discovery. As we go through more discovery, they
25 are confirming our facts.

1 So, at this point, the pleadings are sufficient, your
2 Honor, and the motion should be denied.

3 *THE COURT:* That is nine minutes.

4 *MR. LONGER:* Fair enough. As to punitive damages, I
5 am going to rely on what Mr. Snidow argued. I thought he did a
6 fine job.

7 The last point I will address, your Honor, is the
8 contest of the sub counts, and I just think that the Defendants
9 basically ignore the formulaic -- I am sorry, they contend that
10 we simply pled formulaic elements of the complaint
11 without specific allegations of conduct, but those sub counts
12 incorporated the main count where the facts are alleged. So,
13 on that point the argument fails.

14 Again, this is a master complaint. The Defendants
15 have also argued that there are some Plaintiffs that are not
16 for this -- they have not yet filed claims in certain
17 jurisdictions. This was a master complaint that we were
18 obliged to file under PTO 24, your Honor, so, naturally,
19 because it was a master complaint, there are no individual
20 Plaintiffs in it, so we were pleading broadly --

21 *THE COURT:* That is ten minutes.

22 *MR. LONGER:* Thank you, your Honor. We were pleading
23 broadly to capture any possibility, is my point. Thank you
24 very much.

25 *THE COURT:* Thank you so much.

1 Could we have everybody turn your video on for the
2 retailers and the distributors, Plaintiffs and Defendants, so
3 we can address questions, which should not take too long and we
4 will be able to have a reasonable lunch break.

5 *MR. KAPLAN:* Your Honor, may I --

6 *THE COURT:* I am sorry, you're right, you have a
7 minute, 20. Go ahead before we get into the questions.

8 *MR. KAPLAN:* Thank you very much, your Honor. Just
9 briefly, the one purported example of the vague excessive
10 temperature argument is this mailing product through common
11 carriers. The mail allegations simply don't apply to
12 distributors. Plaintiffs know that now and they know that from
13 the discovery and the depositions, yet they are still here
14 arguing otherwise.

15 To correct Mr. Longer, I know Cardinal Health, my
16 client, produced more than 1500 pages policies and procedures
17 before the amended complaint was filed. This is exactly why
18 group pleading is was so problematic, as the Parker Auto Body
19 case says, and Mr. Longer omitted the relevant language.

20 I would like to just read that and I will finish with
21 this.

22 As the Supreme Court emphasized in *Iqbal*, a District
23 Court's task in determining whether a complaint states a claim
24 upon which relief can be granted is a context specific test
25 that requires the Court to draw on its judicial experience and

1 common sense, but at a minimum, Plaintiffs should allege
2 specific facts specific to each Defendant, or at least each
3 corporate family of Defendants to tie that Defendant to the
4 wrongdoing alleged.

5 Without those averments it is not plausible to believe
6 that every Defendant made the same statements to every
7 prospective customer, or that every customer who elected to use
8 one of the Defendants preferred shops was unlawfully steered by
9 a Defendant.

10 Accordingly, I respectfully recommend that all of the
11 claims be dismissed as improper shotgun and group pleadings.
12 Thank you.

13 *THE COURT:* All right. Thank you very much, and again
14 I apologize.

15 This is a question for the Plaintiffs. Do you concede
16 that you have not alleged that the retailers or the
17 distributors had any knowledge of the propensity of Ranitidine
18 to form NDMA when exposed to heat? Do you concede that,
19 acknowledge that?

20 *MR. SNIDOW:* That allegation is not necessary for
21 these claims, your Honor --

22 *THE COURT:* State your name for the record.

23 *MR. SNIDOW:* I'm sorry, JJ Snidow on behalf of
24 Plaintiffs.

25 *THE COURT:* I apologize, I think I mispronounced your

1 name earlier.

2 I am not asking whether it is relevant or not. You
3 concede that you have not alleged that the retailers or
4 distributors had any knowledge of the propensity of Ranitidine
5 to form into NDMA when exposed to heat; yes or no?

6 *MR. SNIDOW:* No, we don't concede that.

7 *THE COURT:* What paragraphs in the complaint establish
8 the knowledge?

9 *MR. SNIDOW:* Paragraph 1968.

10 *THE COURT:* 1968?

11 *MR. SNIDOW:* Yes, your Honor.

12 *THE COURT:* Any other paragraph?

13 *MR. SNIDOW:* That is where that is alleged.

14 *THE COURT:* Of the AMPIC?

15 *MR. SNIDOW:* Yes, your Honor.

16 *THE COURT:* Defendants knew or should have known that
17 it was foreseeable that consumers such as Plaintiffs would
18 suffer injuries as a result of Defendants' failure to exercise
19 ordinary care in the design, manufacture, testing, marketing,
20 labeling, packaging, handling, distribution, storage, and/or
21 sale of Ranitidine containing products?

22 *MR. SNIDOW:* Yes, your Honor.

23 *THE COURT:* Did you want to follow up?

24 *MR. SNIDOW:* There is one more. If your Honor is
25 asking specifically with respect to punitive damages, paragraph

1 473.

2 *THE COURT:* Putting aside, for Plaintiffs, your
3 arguments about retailers and distributors knowing of the need
4 to comply with the temperature ranges on a drug's label, would
5 you agree that without the knowledge of Ranitidine's alleged
6 defect the retailers or distributors could not be found
7 negligent for failing to take steps to safeguard consumers from
8 that defect?

9 *MR. SNIDOW:* No, I don't agree with that, your Honor,
10 because the retailers and distributors certainly knew that they
11 needed to comply with the FDA's instructions on the label and
12 we have plausibly alleged that they failed to follow those
13 instructions.

14 *THE COURT:* Going back to your paragraph 1968, what
15 part of that allegation puts the retailers and distributors on
16 notice, or that you are alleging they are on notice that they
17 have knowledge of the propensity of Ranitidine to form NDMA
18 when exposed to heat?

19 *MR. SNIDOW:* I meant that it was the injuries were
20 foreseeable there. For NDMA specifically I would lean on 473.

21 *THE COURT:* You lean on 473. Okay. Any other
22 paragraph?

23 *MR. SNIDOW:* That is what I'd lean on, your Honor. I
24 am citing you two paragraphs because your Honor asked if we
25 conceded it, and I did want to point out that these allegations

1 were made. I do want to emphasize it is not -- those
2 allegations are not necessary for the actual claims that we
3 allege against the retailer and distributor Defendants.

4 *THE COURT:* Okay. Let me let Defendants then respond,
5 if you would like, to anything that Plaintiffs have said as to
6 those two questions, because I don't have those questions
7 directed to you. I did want to give you an opportunity to
8 respond if you wanted to.

9 *MR. KAPLAN:* Your Honor, Andrew Kaplan. If I may
10 briefly respond to the question of whether knowledge was
11 alleged.

12 I don't see that in the paragraphs that were pointed
13 to, but importantly, as we note in our reply brief, if you look
14 at paragraphs 439, 504, 505, and 940 through 43, the Plaintiffs
15 allege that the manufacturers hid the issue with -- the alleged
16 issue with Ranitidine from everybody.

17 So, not only do those paragraphs pointed to not say
18 that the distributors and retailers had knowledge, they in fact
19 allege the exact opposite throughout the complaint.

20 *MS. JOHNSTON:* Your Honor, Sarah Johnston for the
21 retailer Defendants. I would just add that the knowledge
22 requirement in the pleadings -- I will give an example. At
23 Paragraph 429, and I think this is repeated at various points
24 throughout the AMPIC, but the allegations related to things
25 like publicly available scientific information and the knew or

1 should have known of the defect allegations are directed to the
2 manufacturer Defendants and not any other Defendants.

3 I would also highlight page 9 of the retailer
4 Defendants reply brief at Docket 3504 where we cite to the
5 hearing transcript from the original Motion to Dismiss.

6 When asked a question on this particular issue,
7 Plaintiffs' counsel stated that "a retailer is not in any
8 position to know if the product is defective, that is
9 particularly so for drugs. Unlike a manufacturer who could
10 have certainly caught that their product was defective, there
11 is nothing a retailer or distributor could do to make that same
12 sort of catch."

13 That is citing the December 15, 2020 hearing
14 transcript at 107-23 to 108-5.

15 *THE COURT:* What is the Plaintiffs' response to that?

16 *MR. SNIDOW:* I will address the manufacturing stuff as
17 well. With respect to the manufacturer Defendants, it is a
18 basis of the claim that they had that knowledge. It is not
19 part of the basis of the claim against the retailers and
20 distributors, which is why we don't allege knowledge in the
21 same way we do against the manufacturers.

22 As for the snippet from the hearing transcript, there,
23 of course, we were addressing an entirely different theory of
24 liability, that was premised on absolute liability for
25 retailers and distributors, and the Court should interpret that

1 in that context. We were saying in an absolute liability,
2 notwithstanding whether anyone has knowledge or not.

3 Here, of course, our theory is a very different one.

4 *THE COURT:* So, going back, I think what you said was
5 maybe 473, the reckless disregard for human life allegation,
6 Defendants were fully aware of safety risks of Ranitidine. Are
7 you saying that that kind of an allegation is sufficient to put
8 anyone, the public, on knowledge about the carcinogenic risks
9 of Ranitidine?

10 *MR. SNIDOW:* No, your Honor. What that paragraph
11 alleges, that the Defendants in particular, not just members of
12 the public, had knowledge. Depending on the state law, the
13 question could be ultimately actual knowledge, it could be
14 constructive knowledge, it could be some sort of imputed
15 knowledge based on testing requirements.

16 For purposes of these particular claims, what the
17 actual basis is, is not that the retailer Defendants knew
18 that Ranitidine was going to degrade into NDMA, it is that they
19 knew that the FDA required the drug to be stored at the
20 temperature and humidity conditions stated on the label and
21 that that was the specific risk that they disregarded.

22 That doesn't actually depend on the retailer and
23 distributors knowing exactly what was going to happen if they
24 failed to follow the label. It is enough. With a prescription
25 pharmaceutical product, there are good reasons they should be

1 stored and shipped in the way that the label says, and
2 disregarding that is negligent for purposes of the claim, and
3 reckless for purposes of punitive damages.

4 *THE COURT:* Is there an allegation anywhere in the
5 complaint that there is a state law that somehow imposes a duty
6 on a retailer to test the drugs that they sell? Are you
7 alleging that?

8 *MR. SNIDOW:* I think we allege it at a higher level of
9 generality.

10 Let me take a step back. With respect to the
11 retailers, we are not saying they needed to have tested it in
12 order to know to ship and store the drug in accordance with the
13 label. That was apparent to them from the face of the label,
14 which requires them to ship and store in certain ways.

15 Again, we don't have that specific allegation as a
16 part of the claims because it is not a necessary part of these
17 claims.

18 *THE COURT:* Okay.

19 *MS. JOHNSTON:* Your Honor, if I may briefly, just to
20 go into the specific paragraphs that counsel identified, 473
21 and 1968, 1968 is a part of Count 8 for failure to test, which
22 is not asserted against the retailers or the distributors.
23 473, likewise, is not incorporated into Count 10, which is the
24 only count asserted against the retailers and distributors.

25 *MR. SNIDOW:* Your Honor, I agree with that and that is

1 why --

2 *THE COURT:* But I asked the question as to whether
3 there was an allegation as to these Defendants.

4 I know you take the position it is not necessary, but
5 that was a bit misleading if you are now saying that 1968 and
6 473, while there, are not incorporated into the allegations
7 against the retailers and distributors.

8 Do you agree that 473 and 1968 are not incorporated
9 into the allegations against the retailers and distributors?

10 *MR. SNIDOW:* Yes, your Honor, I do.

11 *THE COURT:* Going back to my original question, would
12 the answer then be yes? Do you concede that you have not
13 alleged that the retailers or the distributors had any
14 knowledge of the propensity of Ranitidine to form NDMA when
15 exposed to heat? Would the answer be yes?

16 *MR. SNIDOW:* With respect to these claims, the answer
17 is yes.

18 *THE COURT:* Any claims against the retailers and the
19 distributors.

20 *MR. SNIDOW:* With respect to any claims against the
21 retailers and distributors.

22 With apologies, your Honor, I just want to be clear.
23 I interpreted your question as do we concede as a general
24 matter that, in reality, they didn't have knowledge. I do
25 concede, with respect to the claims against the retailers and

1 Defendants, we do not level those allegations.

2 *THE COURT:* I think you misspoke. You said retailers
3 and Defendants, you mean retailers and distributors.

4 *MR. SNIDOW:* That's right.

5 *THE COURT:* I do appreciate your position it is not
6 relevant, but on certain specific questions, I just wanted to
7 make sure I got clear answers. Okay.

8 So, this is a question, and it is a long one, and it
9 is going to be for the Plaintiffs and the Defendants. I don't
10 want to have to repeat it, so I am going to speak slowly and
11 ask you to listen carefully.

12 Maybe I will tell you what the underpinning to my
13 question is and that might put it all in context.

14 It is from page 18 of the Plaintiffs' response to the
15 retailers' motion which says that, undersigned counsel was
16 charged with prosecuting viable claims for all Plaintiffs in
17 this MDL, and this claim is more than viable. Counsel cannot
18 abandon viable theories of recovery simply because not every
19 Plaintiff can invoke every one of them successfully.

20 Plaintiffs, nonetheless, believe common issues of law
21 and fact associated with these claims make an MDL an efficient
22 proceeding to address them.

23 So, with that backdrop in mind, I would like to hear
24 from the Plaintiffs and the Defendants on this.

25 The Defendants have asked the Court to dismiss the

1 negligence claim, Count 10, because it is implausibly pled.

2 The Court construes the Plaintiff's argument to be
3 that so long as a single Plaintiff could bring a negligence
4 claim, the claim should remain in the master complaint, so one
5 Plaintiff out of well over a thousand, perhaps even over a
6 hundred thousand if the claimants ever file in this case.

7 I want to understand the Plaintiffs' position as to
8 why a claim, or how a claim should remain in the master
9 complaint even if almost no Plaintiff could plausibly state or
10 bring such a claim. Stated another way, if the negligence
11 claim is implausibly pled for 99.9 percent of the Plaintiffs
12 against the retailers and the distributors, why must the claim
13 stay in the master complaint?

14 It is my understanding that if I were to find that it
15 shouldn't remain in, that I would not be dismissing any claim
16 from an individual case because this is the master complaint.
17 I wouldn't be precluding such a claim from being prosecuted
18 after remand, nor could I because I lack the authority to do
19 so.

20 I wouldn't even be concluding that the retailers and
21 the distributors no longer need to defend from Federal claims,
22 only that they no longer face any claims in the master
23 complaint.

24 What I am looking for is argument about the impact of
25 a dismissal from the master complaint. What is the prejudice

1 on the Plaintiffs, if any, when a claim is dismissed from the
2 master complaint when nothing would preclude them from seeking
3 to press that claim at a later point outside of the master
4 complaint should a transferee judge permit the claim to proceed
5 for, let's say, the .1 percent of the Plaintiffs that could
6 plausibly state it or plead it?

7 So, I would like to hear Plaintiffs' position on that
8 first, and then the Defendants' position.

9 *MR. SNIDOW:* Your Honor, I think I will start with a
10 couple of cases from the MDL panel, In re Zimmer Duron and In
11 re Denture Cream, which say that issues are -- it is
12 appropriate for an MDL to consider a case even if there is not
13 a majority of overlap of identical factual issues. It is
14 common in most, if not all, MDLs for some issues not to be
15 raised by not just every Plaintiff, but even as these cases
16 say, a majority of the Plaintiffs.

17 And I would also say that the reason why it is okay to
18 keep these claims in the MDL is because each Plaintiff is
19 essentially choosing allegations and claims from the master
20 complaint to incorporate into their short-form complaint. Some
21 of them will likely include claims against the retailer
22 Defendants, some perhaps not, but I do not think that is a
23 reason not to include it in the MDL because the allegations
24 against the retailer Defendants, they do share common issues of
25 fact.

1 MR. LONGER: Your Honor, Fred Longer, if I could. The
2 way this is arranged is complicated --

3 THE COURT: No, Plaintiffs can answer, both counsel,
4 and then I will turn to Defense.

5 MR. LONGER: I completely agree with Mr. Snidow, but
6 let me also amplify it, which is, the whole purpose of the
7 master complaint in this MDL for the personal injury master
8 complaint, it is not the operative complaint, it really is just
9 the smorgasbord by which persons who register into the MDL or
10 file their own short-form of complaint can choose which claims
11 they wish to assert.

12 So, this was, I guess, known well from the beginning
13 of the litigation how as to we were going to proceed. There
14 was a lot of discussion before we even got to how Plaintiffs
15 were going to submit a master complaint. There was discussion
16 about the amendment -- I am sorry, not the amendment, but the
17 appending of a short-form complaint as a model, so that it was
18 known how people were going to plead in this complaint going
19 forward.

20 Your Honor has had several case management orders
21 addressing how to have the Plaintiffs go forward going forward
22 pleading using the master complaint as sort of the template and
23 the short-form complaint as checking boxes and identifying what
24 their claims would be.

25 The master complaint should remain as is so that in

1 the future, because there is no prohibition to someone coming
2 in later and filing a new complaint, that they should be
3 permitted to check that box.

4 So, you know, one point that we had -- and I am making
5 this up, but let's say no one is here from Kansas, but a future
6 Plaintiff may come forward from Kansas and they have to have a
7 box to check, and that is the purpose of the master complaint.
8 It is not the operative complaint, so it is really just the
9 form from which others can come in and say that is what I am
10 asserting in a very abbreviated fashion in the short-form
11 complaint.

12 So it would be inappropriate, in my opinion, your
13 Honor, for you to dismiss those claims going forward because
14 the future is unknown as to who is going to come in and may be
15 taking from the master complaint, and otherwise, you would be
16 requiring them to separately plead and that defeats the
17 efficiency of the master complaint and this is what all the
18 parties wanted.

19 So, I find it to be unnecessary and pretty much -- let
20 me just say, it is not needed to be done at this time from a
21 procedural standpoint.

22 *THE COURT:* So I understand your response, and then I
23 will turn to Defense, and then we'll wrap it up for lunch.

24 It is kind of like a case management argument, it is
25 not a dismissal or a prejudice argument because of a

1 hypothetical dismissal under the hypothetical scenario I
2 posited would be a without prejudice. You are speaking from a
3 case management efficiency, this is the purpose of a master
4 complaint in an MDL standpoint?

5 *MR. LONGER:* Yes. What I was saying is, I wanted to
6 amplify what Mr. Snidow was saying, which is there is the
7 practical impact as well, and that ought to be taken into
8 account.

9 What Mr. Snidow was saying, although I think I just
10 lost him, I don't see him on the screen. There he is.

11 His point is equally valid. I am just saying there
12 are other valid reasons, and I wish the Court would take that
13 into consideration as well.

14 *THE COURT:* Okay. From the Defense.

15 *MS. JOHNSTON:* Your Honor, Sarah Johnston for the
16 retailer Defendants, just a few things briefly.

17 First, we disagree with the concept that the master
18 complaint is meant to serve as a template for short-form
19 complaint serving as the more operative complaint in a
20 litigation of this size. We are months and months of Motion to
21 Dismiss briefing in on these master complaints, and it is
22 disheartening to hear that now they may not actually matter.

23 I would say that, to address your point on prejudice
24 and using the Court's example of 99.9 percent of the claims not
25 being able to proceed against the retailers and distributors

1 because they are not plausibly pled, to otherwise hold these
2 Defendants hostage in a litigation where there are no viable
3 claims against them, or virtually no viable claims against
4 them, is extremely prejudiced.

5 Finally, substantively, the fact that Plaintiffs have
6 had the opportunities that they have had to bring claims that
7 they have attempted to assert here, and after this much time
8 and this much paper, haven't been able to do it, suggests that
9 there is not just a shotgun pleading lack of notice
10 plausibility issue, there is a fundamental problem with the
11 claims as they are pleaded such that it doesn't matter if we
12 are talking about this as an MDL or an individual action,
13 Plaintiffs have had the opportunity to state the basis for
14 their claims, and have not done so.

15 *THE COURT:* Thank you. Mr. Kaplan.

16 *MR. KAPLAN:* Yes, briefly, your Honor. I want to echo
17 what Ms. Johnston said and amplify it a little bit.

18 First, we think that nobody, that zero percent could
19 plausibly allege a claim against the distributors, so we don't
20 believe there should be any claim left. We are aware of no
21 authority that allows -- legal authority that the Plaintiffs
22 have cited to in their briefing that allows a master complaint
23 to obviate the rules of civil procedure.

24 Each Defendant needs an opportunity to be able to
25 challenge the pleadings and to extricate itself from the

1 litigation if there is no viable claim.

2 If I heard Plaintiffs correctly, it is astounding that
3 they are suggesting that nothing can be dismissed from the
4 master complaint and that every Defendant must remain in the
5 litigation, incurring costs, under the theory that someone some
6 day could come along and possibly assert a claim that no
7 Plaintiff has yet been able to so far in the 16 months of this
8 litigation. Thank you.

9 *THE COURT:* Thank you. Anything further?

10 *MR. SNIDOW:* Your Honor, if I may just briefly?

11 *THE COURT:* Yes.

12 *MR. SNIDOW:* I don't think there is any question that
13 the master complaint is not the operative complaint for the
14 simple reason there aren't any Plaintiffs named in the master
15 complaint. That means it has to be true that when Plaintiffs
16 file short-form complaints they are borrowing from provisions
17 in the master complaint and, in fact, they are barred from
18 doing anything else under the Court's orders.

19 As to the exact number of Plaintiffs that are going to
20 be able to assert one type of claim against one Defendant,
21 another type of claim against another Defendant, it is far too
22 soon to say that. I don't think the Court, or I, or anyone
23 else knows the exact breakdown. That is simply not a basis for
24 dismissing the claims.

25 If the claims are plausibly alleged, as they are here,

1 they need to stay in the complaint. It is not a basis for
2 dismissing a claim just because we don't know exactly how many
3 Plaintiffs are actually going to incorporate those claims in
4 their short-form complaints.

5 *THE COURT:* Okay. All right. Well done, thank you,
6 everyone. We will break now for lunch. It is exactly when we
7 broke yesterday.

8 It is about 12:24 -- it is exactly 12:24. We will
9 come back at 1:25, it is about an hour break for lunch today.

10 At that point, counsel for the store brand retailer
11 Defendants' Motion to Dismiss should be prepared and followed
12 by the generic.

13 Have a good lunch. As with yesterday, it worked well,
14 keep your computers logged in if you are going to stay around
15 for the afternoon, turn your mute on and your video off, and we
16 will be back at 1:25. Thanks so much.

17 *MS. JOHNSTON:* Thank you, your Honor.

18 *(Thereupon, a short recess was taken.)*

19 *THE COURT:* Okay, welcome back, everybody, from lunch.
20 We are going to hear 3113 now, the store brand motion.

21 So, it looks like Ms. Johnston is back with us. Is
22 she coming back on?

23 *MS. JOHNSTON:* Is my video working?

24 *THE COURT:* No.

25 *MS. JOHNSTON:* Okay.

1 *THE COURT:* Well, do you want to argue as is? I am
2 okay with that.

3 *MS. JOHNSTON:* I am fine with that if you are fine
4 with that, your Honor.

5 *THE COURT:* I am. Do you want any warning and do you
6 want to reserve any time?

7 *MS. JOHNSTON:* I don't think so. I think this is
8 going to be fairly quick, at least on my end, but I will try
9 and keep track of my own time. If I get into the danger zone,
10 certainly feel free to let me know. All right.

11 *THE COURT:* Go ahead.

12 *MS. JOHNSTON:* Good afternoon again, your Honor, Sarah
13 Johnston on behalf of the retailer and pharmacy Defendants,
14 specifically CVS, Walgreens, Rite-Aid, and Wal-Mart, who
15 collectively have been deemed the store brand retailers in the
16 master class action complaints.

17 I will start off by reiterating what I just said,
18 which is that if the goal of our argument on the amended PI
19 complaint was brevity, I think the goal here is to beat that.

20 The retailers' motion here is styled primarily as a
21 Motion to Strike, and the reason we did that was to highlight
22 an argument that is unique to the retailers that was not
23 captured in the omnibus motions on the class complaints, to
24 which the retailers are also a part and the arguments of which
25 the retailers have, in fact, incorporated by reference.

1 From our perspective, this is a pretty straightforward
2 inquiry, which is, did Plaintiffs have leave to do what they
3 did here?

4 That is, were Plaintiffs granted leave to file amended
5 class claims that created a new ancillary tier in the supply
6 chain that restyled certain of the retailers as a hybrid of
7 both seller and of manufacture, and then to bring sweeping
8 claims against these retailers that far exceeded the Court's
9 original orders?

10 From our perspective, the plain reading of the Court's
11 order makes this an affirmative and very simple no, they did
12 not have that leave.

13 The Court's order was clear, and it was that claims
14 against retailer Defendants could not be reasserted to more
15 than the general negligence claim across all of the complaints,
16 and more specifically, the Court did not permit any new claims
17 to be asserted against these retailers other than a general
18 negligence count that was premised on Plaintiffs' temperature
19 theory, full stop.

20 The Court's order that applies here did not make any
21 distinctions regarding leave to amend in the class complaints
22 and leave to amend in the PI complaints. No leave was granted
23 to amend those any differently one from the other, nor did the
24 Plaintiffs seek any leave to amend.

25 Rather, Plaintiffs' claim that because certain

1 retailers were previously named as repackagers, the Court's
2 leave to amend granted under the order on the generic and
3 repackagers Motions to Dismiss can be construed as giving
4 Plaintiffs blanket authority to recast these retailers as
5 anything that Plaintiffs want to, and to far exceed what the
6 Court has granted as limited authority to amend.

7 As the pleadings here and the briefing make clear, the
8 retailers here are not manufacturers, they are not repackagers.
9 So, the order that is applicable as Defendants doesn't have any
10 weight here. The only operative order that can be construed to
11 apply is the retailer order at Docket 2513, and that order did
12 not permit what has occurred here.

13 So, with that, I will stop and reserve the rest of my
14 time. Thank you.

15 *THE COURT:* Okay. Thank you so much. And for the
16 Plaintiffs.

17 *MS. FEGAN:* Good afternoon, your Honor, Elizabeth
18 Fegan for Plaintiffs. It is good to see you again. Your
19 Honor, I have a short PowerPoint, I will share my screen if
20 that is okay. I think I can do it.

21 *THE COURT:* All right. Yes, you can, you did.

22 *MS. FEGAN:* Hopefully you see the white screen.

23 *THE COURT:* I do.

24 *MS. FEGAN:* I would like to focus for just a moment on
25 what we are talking about here when we talk about the

1 retailers. We are talking about retailers that are private
2 label distributors. This is a separate category defined by the
3 FDA with respect to a particular drug, a person who did not
4 manufacture, repack, relabel, or salvage the drug, but under
5 whose label or trade name the drug is distributed.

6 We are not alleging here that the retailers are
7 manufacturers. We are alleging that the four retailers that we
8 have sued in the class complaint are retailers that want to
9 sell a type of product under their own names, that they sought
10 out manufacturers to manufacture these products according to
11 their own specifications, they contracted for the manufacture
12 at those specifications, and they sold these
13 Ranitidine-containing products under their own name and only on
14 their own store shelves.

15 This is different from a manufacturer brand. A
16 manufacturer brand is a brand that is owned and initiated by
17 manufacturers. For example, Heinz ketchup, neither Winn-Dixie,
18 CVS, Wal-Mart sets any kind of specifications for ketchup, it
19 just orders the ketchup and arranges it on its shelf space.

20 This is distinct from private label brands which are
21 owned and initiated by retailers. The retailer decides what
22 product it wants to sell under its brand, it decides whether it
23 wants AAA or AA batteries, and it goes to a manufacturer and
24 sets the specifications according to a contract.

25 For context here in this case, the manufacturer brand

1 is the Zantac brand, and the private label brands, those that
2 are owned and initiated by the retailers, are the one that we
3 are focused on for these counts. For Wal-Mart it's the Equate
4 brand, for CVS, it's the CVS Health brand, for Walgreens its
5 the Wal-Zan brand, and for Rite-Aid, it's the Rite-Aid brand.
6 These brands are controlled by the private label distributors.

7 Again, just to differentiate so that we know what we
8 are talking about here, with the manufacturer brand, the
9 manufacturer decides to manufacture the Zantac, the
10 manufacturer sells it to the distributors and retailers
11 nationwide, and it sits on shelves of many different retailers,
12 and those retailers don't pick the specifications. The only
13 thing that they do is set the price and arrange the shelf
14 space.

15 On the other hand -- and I have put the paragraph
16 numbers here with respect to Wal-Mart, but we do the same for
17 each retailer -- the private label distributor decides to sell
18 the store brand Ranitidine. It goes out to a contract
19 manufacturing organization, it determines the specifications
20 for that product. The contract manufacturing organization
21 manufactures that Ranitidine product for the specific private
22 label distributor.

23 That private label distributor is responsible for
24 and audits for compliance with CGMPs, current good
25 manufacturing practices, and for quality, and that particular

1 product is then sold only at that particular store.

2 Your Honor, here the constellation of the Court's
3 prior orders allowed us to plead these particular counts
4 against these four specific retailers. I would like to walk
5 through the Court's orders.

6 First, your Honor, what we call the retailer order at
7 ECF 2513, that particular order recognized that Defendants can
8 fall within more than one category of Defendant, and the Court
9 mentioned manufacturers, repackagers, and retailers.

10 The retailer order specifically focused on the control
11 that a retailer could play over manufacturer branded Zantac.
12 For example, the Court focused on the authority of a pharmacy
13 or retailer to change a label of a manufacturer branded drug,
14 in other words, the liability of a retailer for drugs stocked
15 on its shelves under other brands the Court ordered dismissed.

16 Similarly, the Court focused on the liability of a
17 retailer with respect to being a dispenser of prescription
18 drugs. Again, those prescription drugs are manufacturer
19 branded drugs.

20 The retailer order did not consider, and I will
21 concede it is because Plaintiffs did not clearly plead, the
22 private label distributor's responsibility for a product it
23 chooses to have manufactured, for which it sets specifications,
24 for which it audits for compliance for CGMPs, and for which it
25 holds out is safe and effective under its own brand's name.

1 Then we go to the Court's generic order at ECF 2512,
2 that focused in part on the repackager Defendants. In
3 preparation for today, I went back to the original consolidated
4 class complaint at ECF 889 and confirmed that there we did
5 define the retailers also as repackagers. In the Court's
6 generic order, the Court granted Plaintiffs leave to replead as
7 to the repackager Defendants with respect to non-preempted
8 claims, for example, with respect to expiration dates.

9 Finally, your Honor, the Court's shotgun order,
10 colloquially, at ECF 2515. There your Honor pointed out the
11 way in which we had lumped Defendants together, we had created
12 confusion, we made it difficult to understand the distinction
13 among groups which conducted fundamentally different
14 activities.

15 In the original consolidated complaint in just one
16 place we obliquely allege that "many retailers also use their
17 own brand names on relabeled Ranitidine-containing products."
18 That is at paragraph 368. But we did not elucidate what that
19 meant or how that differentiated those retailers from those who
20 just stocked their shelves with manufacturer branded products.

21 Thus, the shotgun order was right on, specifically
22 encouraging us to plead with precision and granted us leave to
23 replead with clarity.

24 Your Honor, that is what we have done here, we have
25 excised all but four retailers from the class complaints and we

1 have excised all claims against those retailers, except those
2 tied to their roles as private label distributors, and rather
3 than lump those allegations into the general fact section, we
4 separated the allegations out as to each private label
5 distributor, Walgreens, Wal-Mart, CVS, and Rite-Aid, starting
6 at paragraph 912, and we narrowed the claims to ensure that we
7 stayed within the confines of permitted claims in the generic
8 order, expiration dates and package sizes, two areas in which
9 we allege the private label distributors could exercise
10 independent control or control independent of the FDA, and
11 consistent with their Federal and state law obligations.

12 Dismissing the retailers at this point, based on
13 arguments that contradict allegations of the complaint is not
14 permissible. Plaintiffs allege that the private label
15 distributors control the quality, the expiration dates, the
16 package size of the products that they have chosen to have
17 manufactured for their store brands.

18 Finally, Defendants attempt to seek dismissal on the
19 Court's prior orders when these allegations were not previously
20 tested or clarified should be disfavored. As Justice Brandeis
21 remarked in the Eleventh Circuit, quoted in Graham versus R.G.
22 Reynolds Tobacco, "Sunlight is said to be the best of
23 disinfectants and electric light the most efficient policeman."

24 We ask that these allegations be tested by the light
25 and not dismissed on a technicality. Therefore, we ask that

1 the store brand retailers' Motion to Dismiss be denied.

2 Thank you, your Honor.

3 *THE COURT:* Thank you. Okay, Ms. Johnston, did you
4 have any rebuttal?

5 *MS. JOHNSTON:* Briefly, your Honor. I will start by
6 saying that, you know, the Court's orders are pretty
7 straightforward, they are clear. The first slide that counsel
8 showed was the definition of private label distributor, which
9 is 21 CFR 207.1. We highlight this in both our brief and I
10 believe also in our reply, and where Ms. Fegan concedes that
11 private label distributors are not manufacturers, she left out
12 the part that private label distributors are also not
13 repackagers.

14 So, again, whatever we are styling these Defendants
15 as, they are not manufacturers, they are not repackagers. The
16 order applicable to those Defendants doesn't apply here, and
17 respectfully, counsel's arguments are not a whole lot more than
18 an attempt to rewrite the Court's order as it exists.

19 Secondly, I would say that I think that as a matter of
20 common sense, the idea that these four retailers are somehow
21 unique and distinct from the larger group of retailers is just
22 not correct. Private label products are not unique to these
23 four retailers. Gas stations and retail stores sell private
24 label products.

25 So, the attempt to turn these retailers into a unique

1 classification of Defendants is an end around the Court's
2 existing orders with respect to both scope and authority that
3 was granted.

4 And I think, finally, I would say that in the slides
5 that we saw that cite back to the paragraphs of the master
6 complaint, I think it is tellings that the support for the
7 positions -- and I'm specifically thinking of the upside down
8 pyramid slide. It is telling that the positions here are
9 citing back to the allegations in the complaint themselves, not
10 to actual legal authority.

11 So, in other words, based on counsel's own
12 allegations, if we were to substantively consider these claims
13 as accurate -- the Court is being asked to accept as true the
14 idea that there is an entirely new group of Defendants with
15 authority to do more respecting labeling and testing.

16 But where Plaintiffs only cite back to their own
17 allegations without any legal authority cited and, you know,
18 whether these -- whether these retailers sold private label
19 products or engaged in a contractual relationship with an
20 actual manufacturer of those products doesn't usurp FDA
21 regulations and does not change the analysis that the Court has
22 already gone through on multiple occasions.

23 In other words, the fact that a contract may exist
24 that says, you know, that a retailer wants a label to say
25 something or wants a manufacture or do something with respect

1 to design or testing or something else, it doesn't alter the
2 existing regulatory landscape. And so, while there are a lot
3 of allegations here, there is not legal authority to support
4 it.

5 In closing, I will go back to the original point,
6 which is, your Honor, you know best what the scope of the
7 orders as written was. We, in reading those orders, believe
8 that they did not give the leave here to add new claims against
9 a new group of Defendants.

10 *THE COURT:* Okay, thank you.

11 All right. So, I have a few questions, if Ms. Fegan
12 wants to come back on. We know Ms. Johnston is here by audio
13 only, and that is fine. Most of my questions are directed to
14 Plaintiffs in this regard.

15 So, I want to be clear, is it correct that when it
16 comes to the AMPIC, your storage -- the Plaintiffs' storage and
17 transportation claims against CVS, Rite-Aid, Walgreens, and
18 Wal-Mart are brought under Count 10, the negligent storage and
19 transportation count against retailers?

20 *MS. FEGAN:* That is a very good question, your Honor,
21 and I would have to defer to my mass tort compatriots. I have
22 been referring to the consolidated class action complaint where
23 we have focused on these claims with respect to expiration
24 dates.

25 I have gotten a text that says claims against the

1 store brand retailers may not be in the AMPIC, but I am doing
2 this by text. I can get you an answer on this, your Honor.

3 *THE COURT:* All right. Why don't you monitor your
4 channel of communication there and see if you can get me a
5 definitive answer one way or the other.

6 *MS. FEGAN:* Okay.

7 *THE COURT:* Turning to the MMC, which does not name a
8 category of store brand retailer Defendants, Plaintiffs raise
9 negligent storage and transportation claims against the four
10 Defendants, CVS, Rite-Aid, Walgreens, and Wal-Mart, that, to
11 the Court's reading, are similar to the negligent storage and
12 transportation claims against the manufacturer Defendants in
13 the MMC. Is that correct?

14 *MS. FEGAN:* Yes, your Honor.

15 *THE COURT:* So, for the purpose of the negligent
16 storage and transportation claims, are the Plaintiffs intending
17 that these four Defendants be treated as retailers under the
18 AMPIC, and to be treated similarly to manufacturers under the
19 MMC, understanding that in your opening statements you are not
20 alleging that they are manufacturers? So, I need clarity on
21 that.

22 *MS. FEGAN:* Your Honor, with respect to the store
23 brand products, we are not alleging that they are
24 manufacturers. They did have obligations with respect to
25 storage and transport and with respect to setting

1 specifications, and in the class economic loss complaint we
2 focused only on expiration date and package size allegations.
3 We do not include storage and transport in the economic loss
4 class complaint, which is the citations that I provided you
5 today.

6 And I am told in the AMPIC, we do not categorize the
7 retailers that way, just as retailers and distributors in Count
8 10.

9 *THE COURT:* So, CVS, Rite-Aid, Walgreens, and Wal-Mart
10 are retailers in the AMPIC under Count 10.

11 *MS. FEGAN:* I believe that is correct.

12 *THE COURT:* Okay. Are you suing the store brand
13 Defendants in the MMC for negligent storage and transportation
14 of the API, not only the finished Ranitidine products?

15 You are alleging that these stores were negligent
16 because they did not ensure that the manufacturers cooled API
17 in the manufacturing process. That is at like paragraphs 967,
18 969, 971. Can you explain that to me?

19 *MS. FEGAN:* Your Honor, I believe it is because, with
20 respect again, the control starts at the top. The store brand
21 retailers choose to have a particular product manufactured,
22 they contract out for those services. As a result, they are
23 responsible for the specifications of the particular product.

24 That includes storage and transport, that includes the
25 quality of the API used, and ultimately, each of the retailers,

1 as we allege, has an audit process in place, some of them hire
2 third parties to conduct those audits, but an audit process in
3 place to ensure that the CGMP is complied with at each stage in
4 the manufacturing process.

5 *THE COURT:* Is the answer, yes, that you are alleging
6 that these stores were negligent because they did not ensure
7 that the manufacturers cooled API in the manufacturing process?

8 *MS. FEGAN:* I believe so, your Honor.

9 *THE COURT:* Plaintiffs bring claims in the MMC and the
10 ELC against CVS, Rite-Aid, Walgreens, and Wal-Mart that are
11 based on failure to shorten expiration dates and improper
12 product containers, like in paragraphs -- in the MMC,
13 paragraphs 430 and 431. You do not bring claims based on
14 failure to shorten expiration dates and improper product
15 packaging against those Defendants in the AMPIC.

16 So, am I correct about that, or do you want to wait
17 for a message on that one?

18 *MS. FEGAN:* I believe --

19 *THE COURT:* What is that show where you get a call --
20 phone a friend.

21 *MS. FEGAN:* Yes, exactly. I believe that is correct,
22 your Honor. I believe that the focus here with respect to
23 package size -- misrepresentation based on package size with
24 respect to these four store brand Defendants, as well as --
25 specifically expiration date are in the economic loss

1 complaint.

2 *THE COURT:* So, is it correct that for the purpose of
3 analyzing the expiration date and product container claims, the
4 Plaintiffs intend these four Defendants be treated differently
5 under the AMPIC than under the MMC and the ELC?

6 *MS. FEGAN:* Your Honor, I don't know that it is
7 treated differently. Maybe I need to back up and -- I do wish
8 I could phone a friend.

9 The product liability claims are broader and allow a
10 broader range of conduct and damages than were allowed on the
11 non-physical injury claims because of the preemption orders.
12 What we tried to do here in the economic loss context was
13 thread that needle and focus on that conduct which we can bring
14 for pure economic loss.

15 So, it is a subset of the overall negligent conduct
16 that is alleged in the AMPIC, so it may not be alleged with as
17 much precision as we have alleged in the economic loss
18 complaint, but I don't want to foreclose the idea that the
19 negligence alleged in the AMPIC is broad as to the conduct at
20 large that is not otherwise preempted because that is allowed
21 in the product liability context.

22 We, in the economic loss complaint, I think really,
23 because of the confusion we created on the front end and trying
24 to plead with precision, really focused in and tried to walk
25 the Court through the misrepresentation in terms of labeling

1 and packaging so that it was very clear that we were complying
2 with or excising the preempted claims.

3 *THE COURT:* It is just a practical question, not
4 necessarily a pleading question, but how does that play out,
5 say, at a trial? Same Defendants, but different theories for
6 different --

7 *MS. FEGAN:* Ultimately, if we think about what happens
8 here, I think there was a recent stipulation among the parties
9 that for purposes of the class claims, post class certification
10 they will get remanded back for trial in the Defendant's home
11 state. For example, the case against Wal-Mart in Arkansas, I
12 think, isn't going to happen contemporaneously with or
13 alongside a particular bellwether trial that may happen before
14 your Honor, or that may happen in a place where someone was
15 injured.

16 So, I don't think it is inconsistent with the idea
17 here, I think it probably provides a more narrow path in
18 discovery for the class side as we move forward with the
19 retailers, but I think that that is consistent with MDL Court's
20 charge in marshaling us through discovery to a place where
21 either the cases are tried before you or remanded back to the
22 particular locations.

23 So, I think it doesn't create a conflict here in this
24 MDL.

25 *THE COURT:* Okay. You name this category of store

1 brand Defendants that you maintain are not exactly like
2 manufacturers, repackagers or retailers, and you allege that
3 the store brand Defendants had, for example, a duty to use
4 reasonable care to adequately warn of the risk a product posed,
5 a duty to use reasonable care in choosing and making product
6 containers, and a duty to use reasonable care in transporting
7 and storing products, and that would be, for example, in the
8 MMC, paragraphs 7519, 7534, and 7548 by way of example.

9 What legal authority supports the existence of these
10 duties under state law? That is, are Plaintiffs relying on
11 authority providing duties for manufacturers, for retailers, or
12 is there authority providing state law duties for store brand
13 Defendants?

14 *MS. FEGAN:* Your Honor, with respect to package size
15 and with respect to expiration date, and focusing on the
16 economic loss complaint, we are specifically focused on
17 Consumer Protection Act and warranty claims. In that context,
18 the Consumer Protection Act claims, for example, the majority
19 of them are considered what are called little FTC acts, and
20 that is in part why we have referred here to -- and cited in
21 our complaint, for example, at paragraph 947 provisions that
22 are parallel both between the FDA and the FTC as to how package
23 size can be misleading or deceptive.

24 That particular type of claim is then incorporated
25 into state law Consumer Protection Act claims that recognize

1 that something is deemed to be misleading in the Federal
2 context here, FTC, FDA, that is also deceptive or unfair under
3 particular state laws.

4 It is not that, for example, the Consumer Fraud Act
5 specifically named store brand retailers. They talk more
6 generally about the type of conduct that can be considered
7 deceptive or misleading, borrowing from Federal law, and that
8 is what we have focused on here, your Honor.

9 *THE COURT:* Okay. Do you have authority for the
10 proposition that non-ANDA holders have the duties of ANDA
11 holders? I will ask the question again.

12 Do you have authority for the proposition that
13 non-ANDA holders have the duties of ANDA holders?

14 *MS. FEGAN:* Your Honor, I knew this question would
15 come, and it is one of the most difficult question, I will
16 concede that.

17 There is not a direct statement to that effect, but
18 what I do have for your Honor -- certainly what we could plead
19 if necessary are FDA warning letters where the FDA has sent
20 warning letters to private label distributors and specifically
21 said things like, as a distributor that contracts with other
22 manufacturers to manufacture a package or label, that your firm
23 releases for distribution under your firm's name, your firm has
24 an obligation to know what and how manufacturing activities are
25 performed so that you can make decisions related to whether to

1 sell the product or release the products for distribution.

2 So, certainly I could provide your Honor with the FDA
3 warning letters that incorporate this duty into its statements.

4 There isn't a specific CFR cite that I can give you,
5 but we believe that -- that is why we have kind of
6 painstakingly gone through not just alleging the duty, but
7 alleging how that duty is elucidated through the regulations on
8 misbranding.

9 *THE COURT:* I don't know if the answer to this
10 question that I am about to ask is the same as the answer you
11 just gave, but I will ask the question and see.

12 Do you have authority for the proposition that store
13 brand Defendants have duties to instruct manufactures to
14 manufacture products in a particular way, to instruct them.

15 *MS. FEGAN:* That would be the same, your Honor, in
16 terms of the warning letters that the FDA has said, you are
17 going out and choosing the contracting organization, you are
18 instructing them on what you want, and you have a duty to
19 ensure that they comply with CGMPs.

20 What we have also done is to back end that in our
21 complaint, we have also then alleged what the Defendants
22 publish, what they do to comply with those duties. So, we
23 haven't just alleged the duty itself, we have tried to bolster
24 that with the actual published information, for example,
25 Wal-Mart and Walgreens have as to how they could fulfill those

1 duties.

2 We have actually alleged and quoted from their
3 websites, we have quoted how they use third parties in their
4 own words, so that makes it more plausible with factual
5 allegations and actual facts of how they are fulfilling these
6 duties to kind of show that the duties exist in the first
7 place.

8 So, it is not just us saying it, it is coming out
9 through FDA warning letters, but then also demonstrating that,
10 in fact, these store brand retailers are taking on those duties
11 and demonstrating how they comply with them.

12 *THE COURT:* To be clear, the legal duty that you are
13 speaking of to warn, for example, comes from an FDA warning
14 letter?

15 *MS. FEGAN:* No, it doesn't come from the FDA warning
16 letter. The FDA warning letters demonstrate the existence of
17 it.

18 *THE COURT:* But it doesn't come from a regulation?

19 *MS. FEGAN:* The regulation generally requires -- let
20 me see. What we are generally talking about are the CGMPs, and
21 the CGMPs require each person in the distribution scheme to
22 comply with those CGMPs based on what they have control over.

23 What is important here is that the private label
24 distributors have control at the outset of the decision not
25 just to sell the drug, but to have the drug manufactured in the

1 first place.

2 Ultimately, although we don't have them yet -- during
3 discovery, one of the things that we will get are the contracts
4 that elucidate the duties and elucidate who had primary
5 responsibility. One of the key things here is that this isn't
6 a matter of these Defendants having just one manufacturer, they
7 went out and chose the manufacturers and we have alleged at
8 different times they hired or contracted with Perrigo, Apotex,
9 Dr. Reddy and others.

10 They chose the manufacturer, they went out and said
11 this is what we are looking to do. They chose the package
12 size. That is not a manufacturer set item. And they could
13 have chosen, for example, to only have 14 days -- they could
14 have had package sizes of 28 pills, but they chose to, for
15 example, sell packages of 220 pills or 90 pills.

16 So, the idea here is control, and that is what the
17 CGMPs recognize and that is what we have pled.

18 *THE COURT:* So, are they contractual duties?

19 *MS. FEGAN:* No, I am sorry, they are delegating their
20 duties through their contract with their contract manufacturing
21 organization. Delegation of those duties doesn't remove the
22 requirement that they comply in the first place.

23 *THE COURT:* I want to make sure I understand the
24 answer. Where do the duties come from?

25 *MS. FEGAN:* From, in part, the Current Good

1 Manufacturing Practices.

2 *THE COURT:* Is there a particular provision of the
3 Good Manufacturing Practices and a paragraph where you allege
4 that?

5 *MS. FEGAN:* For example, we allege at paragraph 938 in
6 the economic loss complaint, 21 CFR 210.1, which talks about
7 CGMPs that apply to manufacturing, processing, packaging and
8 holding. 21 CFR 211.142, which talks about warehousing, and I
9 think the idea here is that these CGMPs don't apply to -- they
10 don't say this only applies to manufacturers or it only applies
11 to distributors. It is the idea that a drug through the
12 system has to -- any person in the system needs to comply with
13 the CGMPs.

14 I can't give your Honor a cite to a particular CFR
15 that says private label distributors must X.

16 *THE COURT:* Okay. Could the particular Plaintiffs
17 that you allege were injured by the store brand Defendants'
18 Ranitidine products and are suing the store brands for failure
19 to shorten expiration dates also sue the manufacturers of those
20 same products for failure to shorten the expiration dates?

21 That is, is the duty to shorten expiration dates in
22 this instance on the store, the manufacturer, or both?

23 *MS. FEGAN:* We have sued the manufacturers also for
24 the same claims. So, immediately after our store brand
25 retailer claims, we then allege claims against the store brand

1 manufacturers, the ones I just named. So, we are suing both,
2 and it may be that the two point fingers at each other, and
3 that will come out during discovery, and there may be a time
4 where that choice gets made in some way or that liability
5 shared, but certainly we understand that they both can and may
6 play a role.

7 *THE COURT:* So, that was my last question on that
8 topic. Does the existence of the store's duty to shorten
9 expiration dates relieve the manufacturer of the same duty?

10 *MS. FEGAN:* I don't believe so, your Honor.

11 *THE COURT:* Okay. You allege -- the Plaintiffs allege
12 that the store brand Defendants knew or should have known of
13 the risk of Ranitidine degrading into NDMA such as, for
14 example, in paragraph 939 where it is alleged that the
15 Defendants knew or should have known that Ranitidine had an
16 inherent risk of degrading, and it goes on in paragraph 939.

17 How do you plausibly allege that the store brand
18 Defendants knew that Ranitidine products could degrade with
19 time and exposure to humidity such that they would have known
20 to instruct manufacturers to shorten the expiration dates and
21 to use different product containers?

22 *MS. FEGAN:* So, I think that this is what, in part,
23 differentiates these allegations from the discussion this
24 morning.

25 Again, if there is a manufacturer branded product, I

1 don't think that necessarily -- well, Wal-Mart would not have
2 opened Sanofi Zantac and tested it. Here, because of Current
3 Good Manufacturing Practices, we have alleged, for example,
4 that Wal-Mart requires its suppliers to submit to audits -- I
5 am looking at paragraph 929 -- through a third party chosen by
6 Wal-Mart to actually do these tests under the Current Good
7 Manufacturing Practices, to ensure that they comply and to
8 provide particular certifications.

9 And, for example, in 930 we talk about items showing
10 nonconformance to standards requires submission of corrective
11 measures. I am quoting from Wal-Mart's requirements. The idea
12 here is that during the manufacture audits and testing are done
13 on the product, so that, had the proper testing been done,
14 should have revealed the presence of NDMA because we see later
15 when Valisure does its testing and the FDA does its testing,
16 this information comes out.

17 There is the opportunity -- this isn't a matter of a
18 boxed product showing up at a retailer, and I am not saying
19 they need to open it and do some kind of testing. I am saying
20 that this testing was supposed to be done along the way,
21 because there is a requirement that the CPMGs be followed, and
22 the retailers actually say that they were doing these audits,
23 so they should have put them on notice of the presence of NDMA.

24 *THE COURT:* You are not saying that Wal-Mart had the
25 legal duty to test, for example, but through the Good

1 Manufacturing Practices, it had --

2 *MS. FEGAN:* I am sorry. It did have a duty to test
3 its own products.

4 *THE COURT:* Wal-Mart had a duty?

5 *MS. FEGAN:* Yes, and it fulfilled that duty by hiring,
6 according to its website, a third party to do that testing, but
7 that was its duty and that is how it was fulfilling its duty.

8 *THE COURT:* That is the premise on which the store
9 brand Defendants knew or should have known of the risk?

10 *MS. FEGAN:* That is correct.

11 *THE COURT:* I don't have any particular questions for
12 the Defense. Is there anything that was said, if you wanted to
13 just respond.

14 *MS. JOHNSTON:* Yes, your Honor, just a couple of
15 things. The Court's questions on the interplay, or rather, the
16 inconsistencies across the complaints is an important one.

17 We heard this morning in the last argument that the
18 allegation that the retailers had any knowledge regarding the
19 inherent risks of NDMA formation in Ranitidine, that they are
20 not alleged to have that knowledge.

21 That is important because the personal injury
22 complaints involve these same four retailers, and the personal
23 injury complaint isn't exclusive to any Ranitidine product, it
24 includes store brand Ranitidine. The retailers are not alleged
25 to have any duty to test, they are not alleged to have been the

1 NDA or ANDA holders for any NDMA product, and they are not
2 alleged to have the ability to exert any control on the
3 labeling, design, testing of those products. That is
4 consistent with everything in the master PI complaint, which is
5 not exclusive of any particular Ranitidine product, including a
6 private label one.

7 So, to now claim that these four retailers selected as
8 selected arbitrarily among countless store brand products, not
9 only have this knowledge that was disclaimed a couple of hours
10 ago, but are now under a significant obligation to direct
11 generic manufacturers to do the very things that generic
12 manufacturers themselves can't do is really hard to reconcile.

13 I think that -- going to the issue of whether there is
14 legal authority for any of these things, I don't agree with the
15 position that there is no authority that addresses this that is
16 on point. This is exactly the discussion that we had back in
17 December respecting the abilities to alter the design and
18 labeling of a product under Bartlett and Mensing.

19 At the end of the day, when we are talking about a
20 generic product that is manufactured by a generic manufacturer
21 and then sold by a retailer as a seller, then we are clearly in
22 Bartlett Mensing territory and Bartlett and Mensing don't apply
23 to PI cases.

24 I think that the recent supplemental briefing that
25 Plaintiffs submitted on a number of issues on a number of

1 different states is telling here because there are states that
2 Plaintiffs submitted authority for that expressly do not
3 recognize the ability to sue a seller of a product simply by
4 virtue of the fact that they put their own name on the product,
5 a private label product.

6 Alabama is one of the three states that the Court had
7 Plaintiffs brief, and Alabama is one of those states. It is a
8 common statutory provision, it doesn't show up anywhere in
9 Plaintiffs' briefing or in their pleadings, and it essentially
10 ignored for purposes of making this argument, that is not
11 supported by the regulatory landscape.

12 Again, we are going back to, well, if we get into
13 discovery and contracts are produced and the contracts say that
14 Wal-Mart said that it could make all of its packaging out of
15 bubble wrap, that doesn't change the fact that the regulatory
16 landscape still exists. That trumps the contract.

17 So, this is not an issue for discovery or for further
18 analysis down the road; this is an issue that not only has the
19 Court has decided, but is pretty well settled law.

20 *THE COURT:* Okay.

21 *MS. FEGAN:* Your Honor, may I respond briefly?

22 *THE COURT:* Yes.

23 *MS. FEGAN:* Your Honor, this is beyond what Defendants
24 have briefed, and if we were going to get into state law
25 issues, just as an example, California jury instruction civil

1 9.23 says that a seller who puts out as its own product a
2 product manufactured by another has the same duty of care as
3 that of the manufacturer.

4 So, it is not well settled that private label
5 distributors have no liability. If for example, Amazon Basics,
6 battery excluded, Amazon Basic, Amazon would be liable for
7 that.

8 This goes beyond what the retailers -- the private
9 label distributors chose to focus on here, and going back
10 fundamentally to the briefing of these issues, we focused in
11 large part on the Court's orders, and I appreciate that our
12 original pleadings didn't have the clarity that they do now,
13 but that is why we tried to go back and replead and focus.

14 And finally, your Honor, with respect to one thing,
15 these four retailers were not chosen arbitrarily, they were
16 chosen based on market share. So, this didn't make sense for
17 us in the class complaint to go against every gas station that
18 might sell a particular product, but we focused on the largest
19 given that we are focused on class chains.

20 *THE COURT:* If the Court wanted to see GMP cites, are
21 you able to give those to the Court?

22 *MS. FEGAN:* Yes, your Honor. For example, we allege
23 them in our economic loss complaint, so I can direct the Court
24 in the Wal-Mart section, and we do this for each retailer, but
25 just using this as an example, at paragraphs 938, 939, and then

1 separately with respect to containers, that is a slightly
2 different provision, it is not the CGMPs. It is 21 -- at
3 paragraph 947, it is a reference to the U.S. Code, 21 U.S.C.
4 Section 352i(1).

5 But they are in our complaints because we did try to
6 walk through it because we knew this was going to be a focus of
7 the Court.

8 *THE COURT:* All right. Thank you both very much, I
9 appreciate it. I think we have covered store brands.

10 *MS. JOHNSTON:* Thank you, your Honor.

11 *MS. FEGAN:* Thank you, your Honor.

12 *THE COURT:* Okay. Last, but certainly not least, the
13 generic Defendants' Rule 12 Motion to Dismiss on the ground of
14 preemption and incorporated memorandum of law, Docket Entry
15 3105.

16 If we could have the Defense put your videos on. We
17 have 23 minutes allotted for you, if you want to tell me how
18 you want to divide your time.

19 There is 23 minutes because I understood you have an
20 LDC and/or next gen attorney, but I don't see that attorney on
21 the screen. Are the two of you going to be arguing?

22 *MR. BARNES:* Yes, we are actually in the same room
23 now.

24 *THE COURT:* Okay. How do you want your 23 minutes
25 split up?

1 *MR. BARNES:* I think we can handle the split. Halfway
2 through my argument, Mr. Gugerty will take some of the
3 argument, then I will end the argument. We will just reserve
4 any time at the end to the extent we have some extra time for
5 rebuttal.

6 *THE COURT:* Okay. So, I don't need to do anything?

7 *MR. BARNES:* Just relax and enjoy the ride.

8 *THE COURT:* Okay.

9 *MR. BARNES:* Thank you. This is the last argument of
10 the day, and I appreciate that your Honor has had a very
11 grueling few days, so I thought I'd start off with a little
12 levity.

13 Good afternoon. This is Richard Barnes on behalf of
14 Perrigo and co-liaison counsel for generic manufacturing
15 Defendants.

16 In its preemption ruling this past December this Court
17 applied the holding of *Mensing* and *Bartlett* for generic drug
18 preemption and this Court summarized those holdings as follows:
19 "If a Defendant cannot independently, and while remaining in
20 compliance with Federal law, do what needs to be done to avoid
21 liability under a state cause of action, the cause of action is
22 preempted." That is at page 37 of your order.

23 Applying that standard, the Court held that all
24 Plaintiffs' claims in the original master complaints were
25 preempted because they required either warning about

1 the presence of NDMA in Ranitidine or else changing
2 Ranitidine's basic design. Those actions are barred by Federal
3 law for generic manufacturers.

4 Importantly, this Court did not prune away preempted
5 warnings and design allegations out of Plaintiffs' original
6 claims. Instead, this Court held that including preempted
7 allegations within a count required that the count be dismissed
8 in its entirety.

9 This is what is required by Bartlett. The Bartlett
10 Court found that a New Hampshire tort cause of action required
11 taking remedial actions, such as changing labeling or design,
12 that were prohibited by a Federal law for generic
13 manufacturers. The Supreme Court held that this direct
14 conflict between state and Federal law required that the whole
15 cause of action be preempted and dismissed.

16 Courts routinely hold that when a generic manufacturer
17 cannot avoid liability under a state law cause of action
18 without violating Federal law, the entire claim is preempted
19 and must be dismissed.

20 Examples of this include the Eleventh Circuit's
21 decision in Guarino, the Fourth Circuit's decision in Drager,
22 and the Fifth Circuit's decision in Morris. All these cases
23 were extensively briefed last year in connection with the first
24 round of motions practice before your Honor.

25 So, even though the original complaints claims were

1 dismissed, this Court let the Plaintiffs replead, but it
2 instructed them to separate each count, while clearly
3 identifying "the elements under each state's law and what state
4 law would require of Defendants to avoid liability." That is
5 at page 37 of your order at Docket Entry 2512.

6 Each substantive count in the AMPIC asserts that state
7 law required generic Defendants to do one of two things; one,
8 warn consumers about all of the alleged risks of Ranitidine
9 use, or ensure that Ranitidine products were safe from those
10 risks.

11 The generic Defendants could avoid state law liability
12 only by taking preempted actions. Plaintiffs allege
13 that Ranitidine always risks forming NDMANDMA no matter how it
14 is stored or transported, or when it is ingested. They allege
15 that all Ranitidine when ingested breaks down to form NDMA in
16 the stomach. That was the subject of our PowerPoint slide
17 yesterday from Plaintiffs' counsel.

18 Plaintiffs allege that Ranitidine always risks forming
19 NDMA no matter how it is stored or transported or when it is
20 ingested. They allege that all Ranitidine when ingested breaks
21 down to form NDMA in the stomach, so that the Ranitidine
22 molecule by its intrinsic nature is never reasonably safe to
23 use due to the inevitable degradation into NDMA.

24 In this regard the amended complaints do not differ
25 from the original complaints. Because the Plaintiffs allege an

1 inherent design flaw, generic Defendants could only meet their
2 state law duties by issuing a cancer warning, changing
3 Ranitidine's design, or stopping all sales of the product.

4 But generic Defendants could not do any of these
5 things without violating Federal law. That is why Plaintiffs'
6 claims are preempted.

7 We saw and heard of a spoiled milk analogy yesterday
8 from Plaintiffs' counsel, but like their complaint, this
9 example really does not defeat a preemption. Your Honor, milk
10 is safe to drink at the outset, it only transitions from safe
11 to unsafe if it sits too long or it is mishandled.

12 In contrast here, the Plaintiffs allege that
13 Ranitidine is fundamentally different from spoiled milk. They
14 claim that Ranitidine is defective and unsafe from its
15 inception. In their view, it is never safe. It is ingested,
16 the action in the stomach breaks it down into NDMAGeneric
17 Defendants could not avoid state law liability for a product
18 that is allegedly never safe without taking preempted acts,
19 issuing warnings, changing the formulation, or stop selling.
20 That should end the case as it relates to the generic
21 Defendants.

22 I will turn this over now to my associate, Mr.
23 Gugerty, to walk through the allegations in the complaint that
24 further demonstrate these points. Thank you, your Honor.

25 *THE COURT:* Thank you.

1 MR. GUGERTY: Thank you, your Honor, Sean Gugerty
2 appearing on behalf of Perrigo. I have have a few slides that
3 will put on the screen in a moment.

4 As Mr. Barnes mentioned, I am going to go through the
5 AMPIC and show how each count against generic Defendants would
6 require generics to take preempted acts to avoid state law
7 liability. I will start with Count 4, negligent failure to
8 warn through proper expiration dates.

9 In Count 4, Plaintiffs assert that generic Defendants
10 should have included a shorter expiration date on Ranitidine
11 labels. The Plaintiffs do not allege that a -- excuse me -- a
12 shorter expiration date alone would satisfy the state law duty
13 to warn.

14 Instead, in paragraph 1162, Plaintiffs assert a duty
15 to warn of "the risks associated with the use of Ranitidine."
16 The supplemental authorities Plaintiffs recently filed are just
17 as clear on this point.

18 For example, for their Alabama sub count for Count 4,
19 Plaintiffs cite to Richards v Michelin Tire, which held that
20 under an Alabama negligence cause of action a manufacturer has
21 a duty to give adequate warnings of "any dangers known to it."
22 That is at 21 F.3d., at 1058.

23 And Plaintiffs are equally clear as to what risks and
24 dangers they allege were present in Ranitidine.

25 In paragraph 1167, within Count 4, Plaintiffs again

1 allege that generic Defendants needed to warn about
2 the dangerous risks associated with Ranitidine, and in the very
3 next sentence they say that those risks included "the
4 carcinogenic characteristics of NDMA."

5 Plaintiffs also allege in paragraph 1150 within that
6 count that Ranitidine degrades to form NDMA as it breaks down
7 in the human digestive system.

8 So, to sum up, Plaintiffs allege in Count 4 that the
9 generics had a duty to warn of the risks associated with
10 ingesting Ranitidine, specifically including NDMA forming and
11 allegedly causing cancer when Ranitidine is ingested, but a
12 shorter expiration date does not warn about that cancer risk.
13 It is just a string of six digits.

14 For all the consumer knows, the expiration date
15 could simply mean the date by which the product will lose its
16 potency. Instead, avoiding liability under Count 4 would
17 require a written warning that this product may form an alleged
18 carcinogen, which Plaintiffs allege is NDMA, and because adding
19 that type of cancer warning would violate Federal law, Count 4
20 is preempted.

21 Plaintiffs' other expiration date claims, Counts 3 and
22 7, have the same allegations and are preempted for the same
23 reasons as Count 4.

24 Plaintiffs' negligent storage and transportation
25 claim, Count 11, and their negligent product containers claim,

1 Count 9, are also preempted.

2 In those counts, Plaintiffs allege that generics
3 should have taken certain actions to reduce exposure to heat
4 and humidity, and both counts are based on a duty of care to
5 ensure that consumers received a reasonably safe product.

6 For example, in AMPIC paragraph 2453, within Count 11,
7 Plaintiffs allege that the state law duty is a duty to exercise
8 reasonable care in the storage and transportation of
9 Ranitidine, both API and finished products, to "ensure the
10 products are not unreasonably dangerous to consumers and
11 users."

12 And in their notice of supplemental authority, for
13 their Alabama storage and transportation count, as well as for
14 their Alabama product container sub count, Plaintiffs cite to
15 this pattern jury instruction stating that, "Negligence is the
16 failure to use reasonable care to prevent harm to others."

17 I want to highlight this instruction, your Honor,
18 because you heard earlier today during the discussion on the
19 retailers' motion, Plaintiffs' counsel showed your Honor an
20 Alabama sub count for the storage and transportation sub count
21 against the retailers, which is substantively similar to that
22 brought against the generics for storage and transportation.
23 Plaintiffs' counsel argued that the duty under Alabama law was
24 limited to "a duty to exercise reasonable care in transporting
25 and storing products."

1 Based on Plaintiffs' own submission to the Court in
2 response to your Honor's order for supplemental authority, that
3 is not accurate and the actual Alabama duty is much broader, a
4 duty to use reasonable care to prevent harm to others.

5 The problem for Plaintiffs in both the negligent
6 products containers count and the storage and transportation
7 count is that the changes they call for wouldn't meet that state
8 law duty.

9 Plaintiffs incorporate into these counts an allegation
10 that Ranitidine degrades to form NDMA over time even in "normal
11 transport and storage," and that is at paragraph 389.

12 So, Plaintiffs are alleging that Ranitidine is never
13 safe to consume, even if stored and transported appropriately.

14 Given that allegation, generic Defendants could not
15 meet the state law duty to ensure a reasonably safe product
16 unless they took other actions that would violate Federal law,
17 like changing the drug's design, so both of those counts
18 are preempted.

19 Plaintiffs also bring a negligent failure to test
20 claim for just two states, Kansas and Texas. As was
21 pointed out in the Omnibus Motion to Dismiss, neither
22 state actually recognizes a negligent testing claim, but even
23 if they did, it would still be preempted.

24 Plaintiffs assert that additional testing would have
25 prompted actions by third parties, such as the FDA issuing a

1 recall, but as the Supreme Court held in *Mensing*, the question
2 for impossibility preemption is whether the private party could
3 "independently do under Federal law what state law requires of
4 it." That is at 564 U.S. at 620.

5 Here, generic Defendants could not independently avoid
6 liability under the testing claim without taking preemptive
7 acts, so the testing claim should also be found preempted.

8 Plaintiffs' final remaining substantive claim in the
9 AMPIC as to the generic Defendants is for failure to warn the
10 FDA, Count 5. Of course, that count depends entirely on
11 actions that FDA might have taken, which are in turn dependent
12 on the exercise of the FDA's judgment.

13 So, that count, too, is preempted under a
14 straightforward application of *Mensing*.

15 To sum up, your Honor, I have now gone through why all
16 of the substantive claims in the AMPIC brought against generic
17 Defendants are preempted.

18 Plaintiffs have also filed, as your Honor knows, an
19 amended ELC and a new MMC. The claims in those class
20 complaints rely on the same underlying facts and theories of
21 liability as the AMPIC claims, at least as to generic
22 Defendants.

23 So, the class complaint claims are also preempted
24 under *Mensing* and *Bartlett*.

25 In addition, Plaintiffs' storage and transport claims

1 and their product containers claims are also separately
2 preempted under the "major change" regulation, which is 21 CFR
3 314.70(b)(2), and we have outlined our major change argument in
4 detail in our briefing.

5 We also fully agree with the arguments that
6 Ms. Eisenstein went through this morning regarding Buckman
7 preemption for Plaintiffs' failure to warn FDA claim and on
8 Section 379r, express preemption for OTC drugs, and we
9 incorporated those arguments into our briefing.

10 And now I will transition back to Mr. Barnes to
11 address how Plaintiffs have failed to effectively rebut Mensing
12 and Bartlett preemption of all of their claims.

13 *MR. BARNES:* Richard Barnes on behalf of generic
14 Defendants.

15 Your Honor, Plaintiffs' arguments opposing preemption
16 do not survive scrutiny under Supreme Court precedent and as
17 applied by dozens of Federal Courts.

18 Plaintiffs first argue that this Court should ignore
19 the duties and requirements of their causes of action that
20 conflict with Federal law. So, for example, Plaintiffs argue
21 that the Court should ignore the duty to warn of the risks of
22 NDMA and cancer, even though that duty is an essential part of
23 the expiration date causes of action that Plaintiffs have pled.

24 First, that approach is contrary to the preemption
25 rulings this Court has already made. The Court held that if a

1 Defendant could not independently do what needs to be done to
2 avoid liability under a state cause of action without taking
3 acts that are barred by Federal law, the entire cause of action
4 is preempted and it should be dismissed.

5 If you read the Supreme Court cases, which I know you
6 have, the Plaintiffs' position lacks legal support. Plaintiffs
7 seize upon a single statement appearing in *English v General*
8 *Electric*, 496 U.S. at 79, that "state law is preempted to the
9 extent that it actually conflicts with Federal law." But the
10 Supreme Court in *Bartlett* quoted that very language from
11 *English* and reached a completely opposite conclusion than
12 Plaintiffs.

13 Specifically, the *Bartlett* Court held that when a
14 state cause of action imposes a duty to take remedial measures
15 that are barred by Federal law, the entire cause of action is
16 preempted and must be dismissed. That is found at 570 U.S.,
17 pages 490 to 492.

18 In *Bartlett* the Supreme Court carefully analyzed "the
19 content of the duty" under New Hampshire design defect cause of
20 actions, and specifically with reference to a generic
21 manufacturer. That is found at page 482. And in looking at
22 that, the New Hampshire duty was the duty not to sell an
23 unreasonably dangerous drug, the same duty as many of
24 Plaintiffs' claims assert here.

25 Because the only way to satisfy the state law duty was

1 to change warning labeling or change the design, the entire
2 state law cause of action for design defect was held preempted.

3 The same approach was taken by the Supreme Court in
4 *Mensing*, which held that Minnesota and Louisiana state law
5 causes of action for failure to warn were preempted because the
6 state law duties conflicted with Federal law. Similarly, the
7 more than 150 Federal Courts that have applied *Mensing* and
8 *Bartlett* in generic drug cases apply preemption to dismiss
9 entire claims, not to partially preempt certain
10 requirements within the claims.

11 Plaintiffs have not provided a single example of a
12 Court at any level that has applied conflict preemption to
13 ignore or strike certain parts of a state law cause of action
14 and allow a Plaintiff to proceed on what remains.

15 None of the Supreme Court cases cited in the footnote
16 at page one of the Plaintiffs' opposition reached that holding.

17 I will spend a minute on the *Cliff versus Payco* case,
18 which the Plaintiffs rely on, and that is at 363 F.3d 1113, a
19 2004 decision.

20 This case does not assist Plaintiffs' cause. *Cliff*
21 involved a Florida consumer protection statute that had a long
22 list of prohibited debt collection practices, each with its own
23 subsection, and the Florida statute provided a private right of
24 action to enforce any one of those subsections.

25 In analyzing conflict preemption, the Eleventh Circuit

1 limited its analysis to a single subsection at issue in the
2 Plaintiffs' cause of action, and it found that specific
3 subsection, that specific subsection did not conflict with
4 Federal law so the action was allowed to proceed.

5 It was not material that another subsection not at
6 issue in the Plaintiffs' cause of action may have conflicted
7 with Federal law.

8 When the Cliff Court talked about applying conflict
9 preemption on a provision-by-provision basis, it was in
10 reference to that specific section in which the provision has
11 its own separate and distinct cause of action. The Cliff case
12 is entirely consistent with the generic manufacturers' position
13 before your Honor, each substantive count requires its own
14 preemption analysis.

15 But the problem for Plaintiffs is that all of their
16 counts contain requirements that conflict with Federal law, so
17 all of those counts are preempted.

18 One last thing I will comment on, your Honor, about
19 Plaintiffs' approach to preemption is that it would also
20 contravene the Erie Doctrine. There has been a lot of
21 discussion about Erie yesterday and today, but the Plaintiffs,
22 when they ask the Court to prune away preemptive elements, they
23 are really violating Erie.

24 What the Court should realize is that it would become
25 the first Court to actually recognize a new claim that

1 materially differs from the claims that are recognized by state
2 courts. Plaintiffs have not shown any authority that any state
3 would recognize, for example, an expiration date claim divorced
4 from the actual state law duty to give an adequate warning to
5 consumers of the risks of injury, or a negligent storage and
6 transportation claim divorced from the duty of ordinary care to
7 ensure a product is not unreasonably dangerous.

8 I'll spend a moment on the failure to warn FDA claim.
9 I will add a few points to Ms. Eisenstein's argument this
10 morning. I will focus on two arguments that we made in our
11 reply brief, and there are several others, I'll refer the Court
12 to our briefing.

13 But the first one is, I point the Court to the
14 Eleventh Circuit case of Guarino versus Wyeth, 719 F.3d at
15 1245, and there are other Courts that have held any state
16 failure to warn claim brought against a generic drug
17 manufacturer is preempted. A failure to warn FDA claim is
18 still a warning claim based on traditional state failure to
19 warn principles and should be preempted.

20 No Court has held that a failure to warn FDA claim in
21 a generic drug case evades preemption under Mensing and
22 Bartlett. As the Supreme Court held, Courts cannot accept
23 arguments that effectively render the whole body of
24 preemption case law all but meaningless. This Court previously
25 relied on that language and rejected Plaintiff's earlier

1 parallel misbranding theory against the generics. It should do
2 the same for Plaintiffs' failure to warn FDA claim here.

3 Second, as set forth in *Mensing* and in this Court's
4 own preemption order, only actions that a manufacturer can
5 independently take to avoid liability under state law are
6 relevant to the preemption analysis.

7 Of course, a failure to warn FDA claim requires a jury
8 to speculate as to what the FDA might have done at a prior time
9 given certain information by the generic manufacturers, so the
10 failure to warn FDA claim is also preempted for that reason.

11 So, your Honor, in conclusion, *Mensing* and *Bartlett*
12 drew a very bright line, if generics must violate Federal law
13 to avoid state law liability, the claim is preempted.

14 The Court told Plaintiffs explicitly what they needed
15 to do on repleading: Present state law causes of action with
16 elements that generic Defendants could fully satisfy without
17 violating federal law. Plaintiffs have failed to do that.

18 Instead, they presented an assortment of discrete
19 actions that a generic manufacturer allegedly could take
20 without violating Federal law. That is not enough. Plaintiffs
21 expiring, storage, transportation, and packaging claims are all
22 preempted because generic manufacturers cannot avoid state law
23 liability unless and until they redesign Ranitidine, add a
24 cancer warning, or stop selling. Each of those remedies are
25 preempted as a matter of law.

1 For these reasons, the claims against generic
2 manufacturers should be dismissed with prejudice as to all
3 three master complaints.

4 I will reserve any remaining time for rebuttal. Thank
5 you, your Honor.

6 *THE COURT:* Thank you. You have about a minute and a
7 half left. Okay. From the Plaintiff.

8 *MR. KELLER:* Good afternoon, your Honor. It is Ashley
9 Keller on behalf of the Plaintiffs, and though I can't see her,
10 for Ms. Stipes' benefit, I want you to know that I switched to
11 decaffeinated coffee, so hopefully that will slow me down some,
12 but by all means, interject if I am still going too fast.

13 *THE COURT:* She will.

14 *MR. KELLER:* I hope she will, but hopefully it also
15 won't be necessary. I will keep my own time, your Honor.

16 *THE COURT:* Okay.

17 *MR. KELLER:* Once again, Ashley Keller on behalf of
18 the Plaintiffs.

19 I want to begin with the main event, which is the
20 scope of preemption, because that is obviously a source of
21 significant disagreement between the parties on what the state
22 of the law is.

23 But let me begin instead by noting some areas of
24 common ground. Accepting the amended master personal injury
25 complaint as true, it is a fact that Ranitidine breaks down

1 into NDMA in multiple different ways, and it is a fact that
2 NDMA exposure causes multiple forms of deadly cancer.

3 Remarkably, the generic manufacturers no longer
4 dispute that there were at least some actions they could have
5 taken consistent with Federal law that would have reduced
6 Plaintiffs' exposure in NDMA.

7 In a complete reversal from the first round of Motion
8 to Dismiss briefing, generics now concede that they could have
9 lawfully used the CBE process to shorten expiration dates; that
10 they were at perfect liberty to test Ranitidine to determine if
11 it had NDMA; or that FDA regulations required them to provide
12 adverse event data, and required -- or at least allowed them to
13 informally correspond with the agency to apprise it of new and
14 emerging risks.

15 Generics, similarly, do not dispute that each of those
16 actions were required under the law of some or all states. The
17 generics agree that the common law of failure to warn requires
18 accurate expiration dates; that the common law of negligence
19 requires reasonable testing of potentially dangerous products;
20 and that the law of some states requires warnings to third
21 parties as the most effective way to disseminate warnings to
22 the end consumer.

23 Those points of agreement between the parties should
24 be the beginning, middle, and end of any impossibility
25 preemption argument. It can't be impossible to do under state

1 law that which the Defendant concedes is possible or even
2 required under Federal law as well.

3 Yet we are still talking about preemption because the
4 generics have, without a single solitary case in support,
5 invoked a rule as illogical as it is imaginary. The generics
6 claim that if they cannot meet every requirement imposed by a
7 state common law cause of action, then it must be impossible
8 for them to perform any requirement imposed by that cause of
9 action.

10 Let me state the generics rule as a syllogism.
11 Premise one, we can comply with some things required by state
12 law. Premise two, we cannot comply with all things required by
13 state law. Conclusion, we therefore can comply with no things
14 required by state law. An amateur logician could spot that
15 fallacy a mile away.

16 Since Congress passed the Pure Food and Drug Act in
17 1906, state tort law has complimented Federal regulations and
18 played a crucial role in ensuring patient health and safety.
19 The FDA has repeatedly noted and approved of this dynamic. So
20 did the Supreme Court in Wyeth versus Levine.

21 But if the generics rule were accepted, it would
22 preempt virtually every pharmaceutical case. It would
23 disrespect federalism principles and undermine state
24 sovereignty, and it would convert the supremacy clause from a
25 narrow provision that displaces state law only to the extent it

1 differs with Federal law into a sweeping provision that shields
2 Defendants from liability even where holding them accountable
3 serves, rather than undermines, Congress' policy aims.

4 The generics are so obviously wrong that there are
5 multiple different ways to see it. The first way is through
6 common practice.

7 Federal Courts routinely hear challenges to state law
8 either under the Federal Constitution or Federal statutes.
9 Your Honor no doubt has experience with such challenges.
10 Regardless of which source of Federal law is invoked, the
11 supremacy clause is doing the analytical work in these cases,
12 because it is the supremacy clause that makes Federal law, be
13 it constitutional or statutory, supreme over state law.

14 Think about any such challenges your Honor has heard
15 in the past. If your Honor believed that some aspect of state
16 law was unconstitutional, would you strike down the entirety of
17 the state law? No. Just the opposite is true.

18 Federal Courts routinely apply the severability
19 doctrine, which has existed since the dawn of our republic.
20 What is the severability doctrine? It is a presumption that,
21 absent manifest intent by the state law giver to the contrary,
22 the portions of state law that are preempted can be severed,
23 leaving in place the portions that do not conflict with Federal
24 law.

25 The generics say in the first page of their reply

1 brief, and you heard it just a few moments ago, that you can't
2 take a blue pencil or prune away offending provisions of state
3 law. But that is precisely what Federal Courts do, and that is
4 the whole point of the severability doctrine. Courts only
5 preempt any thing in state law that offends Federal law under
6 Article VI.

7 The severability doctrine has been applied to state
8 law in every area the Court can think of, from
9 telecommunications rules to state antitrust law to abortion
10 statutes to firearm ordinances to healthcare regulations. The
11 bottom line is always the same, absent clear state law to the
12 contrary, the Court severs the preempted aspects of state law.
13 The aspects of state law consistent with Federal law remain
14 fully in effect.

15 That is why binding precedent emphatically rejects the
16 generics' newfangled distortion of preemption doctrine.

17 Every time the Supreme Court lays down the rule for
18 preemption, it says the doctrine applies only "to the extent of
19 the difference" between state and Federal law. What do the
20 words "to the extent of the difference" even mean if not that
21 the generics' approach is incorrect?

22 The Eleventh Circuit's decision in *Cliff v. Payco*
23 illustrates the principle. In that case, Cliff sued a debt
24 collector under the Florida Consumer Collection Practices Act.
25 There were 17 different subsections of the law that regulated

1 how debt collectors interacted with debtors.

2 The Eleventh Circuit acknowledged that many of them
3 seemed incompatible with the Federal statute. That is because
4 Federal law gave certain protections to debt collectors who
5 were seeking to collect student loan debt of the type that Mr.
6 Cliff owed, but the particular provision Cliff sued under was
7 not inconsistent with Federal law.

8 The Eleventh Circuit said that preemption must be
9 analyzed "provision by provision" under the statute. Because
10 the particular provision Cliff invoked was not preempted, his
11 case was allowed to proceed.

12 That holding is incompatible with the generics'
13 position. Recall that the generics say the entire cause of
14 action is preempted if you can't entirely avoid liability under
15 the relevant provisions of state law. But as the
16 generics point out themselves on page 4 of their reply, the
17 Florida law prohibited a person for failing to comply with any
18 provision of the statute. Because many of those provisions did
19 conflict with Federal law, there was no way for a debt
20 collector to meet all of its state law responsibilities.
21 Nonetheless, the provision-by-provision approach embraced by
22 the Eleventh Circuit meant that Cliff's non-preempted theory
23 based on a single breach of duty could proceed.

24 Now, it is true Cliff dealt with a statute, not the
25 common law, but the preemption analysis is precisely the same

1 for both. To see that, let's apply the logic of Cliff to the
2 law of negligence. As every first year law student knows,
3 negligence is a state common law cause of action, the elements
4 of which are duty, breach, causation, and damages.

5 What is the duty created by the common law? At a high
6 level of generality, it is to behave as a reasonably prudent
7 person would under the circumstances, the so-called reasonable
8 man or woman standard.

9 Applying that high level standard to the particular
10 facts and circumstances of any individual case, there may well
11 be 17 different duties imposed by the common law, just as there
12 were 17 different duties under the Florida Consumer Collection
13 Practices Act. To name but a few common law duties that would
14 apply to a reasonably prudent manufacturer of Ranitidine, it
15 had a duty to warn that the drug causes cancer, and a duty to
16 warn of the proper expiration date, and a duty to redesign the
17 molecule to make it safer.

18 It is true enough that the generics could not perform
19 two of those duties consistent with Federal law, but the
20 crucial point is that a failure to perform any one of them is
21 sufficient to support the element of breach for the cause of
22 action in negligence.

23 It is just like the statute in Cliff where violating
24 any one of the 17 provisions of Florida law allowed Plaintiff
25 to obtain a recovery.

1 So, I want to be really clear on this point, your
2 Honor, because it is extremely important. We are not asking
3 the Court to redefine the elements of negligence or any other
4 cause of action. Negligence still requires duty, breach,
5 causation, and damages.

6 We are simply saying that the generics cannot ask the
7 Court to ignore the element of breach under one theory, failure
8 to have an accurate expiration date, just because another
9 theory of breach, for example, failure to add a cancer warning,
10 is concededly unavailable.

11 The entire cause of action for negligence does not
12 fall to preemption just because one theory is foreclosed, just
13 as the entire cause of action under the Florida Consumer
14 Collection Practices Act was not preempted just because some
15 theories were.

16 The Court doesn't have to speculate about this. The
17 Eleventh Circuit has already agreed with us in Mink, which is a
18 case the generics have invoked time and time again when they
19 think it suits them. In Mink, the Eleventh Circuit noted that
20 Mr. Mink brought three theories under a cause of action for
21 negligence. Two were preempted, one was not.

22 Did the entire cause of action for negligence fail
23 even though, as pleaded by Mr. Mink, the Defendant Smith &
24 Nephew could not comply with all of the duties imposed by state
25 negligence law? No. Just the opposite holding obtained. The

1 preempted theories were disallowed, the viable theory could
2 proceed. That is Mink, 860 F.3d at 1329.

3 There is no doubt that we plead a non-preempted theory
4 of negligence. For instance, in Count 3 of the amended master
5 personal injury complaint we plead state by state that "the
6 warnings included on each Ranitidine containing product were
7 inadequate because the expiration date improperly instructed
8 the Plaintiffs that Ranitidine containing products were safe
9 when consumed long after manufacture, when in fact the products
10 degraded into NDMA over time." That is paragraph 965.

11 We then plead in the very next paragraph that that
12 breach of duty is what caused the exposure to NDMA for the
13 Plaintiff that in turn caused the Plaintiffs' injuries.

14 Yes, the generics could not also have warned on the
15 label about cancer while still meeting Federal obligations.
16 Yes, their failure to do so would be considered negligent under
17 state law. But just as in Mink, the inability to pursue that
18 theory has no bearing on whether we have pleaded a viable,
19 non-preempted claim that can proceed.

20 The final way to see the error of the generics rule is
21 that it leads to absurd results. We illustrated this through
22 straightforward examples in our opposition. The generics say
23 that our examples are inapt, but they did not grapple with them
24 at all in their reply or in the presentation that you just
25 heard.

1 First, they ignore the point that your Honor allowed
2 us to replead design defect claims against the brands. That
3 begs a simple question: Why did you do that? Recall that in
4 many states design defect imposes at least two different
5 duties, to redesign an unsafe drug, which the brands could not
6 do, and to add appropriate warnings to the label, which the
7 brands could do using the changes being effected regulation.

8 But if the entire cause of action fails when you
9 cannot meet all of the duties imposed by state law, repleading
10 was a waste of time. Preemption was already conclusively
11 established.

12 Of course, repleading was not meaningless, and not
13 even the brands were brazen enough to move to dismiss our
14 repleaded design defect claims. Your Honor allowed repleading
15 because our labeling based theory is not preempted and your
16 Honor was simply following the path set forth by the Supreme
17 Court in *Bartlett*, where the Court considered both
18 design defect theories and found both preempted before
19 concluding that the Plaintiff lost.

20 So the generics have *Bartlett* exactly backwards.
21 *Bartlett*'s decision to consider the labeling theory was a waste
22 of time if the entire design defect cause of action failed once
23 the Court concluded that the generic could not redesign the
24 molecule. Your order, too, would have been a waste of time on
25 the generics' logic, but, of course, your Honor was correct to

1 let us replead and the generics are mistaken.

2 Adding to the absurdity of the generics' position,
3 their rule would require the Court to dismiss even the core
4 failure to warn claim against the brands affirmed by Wyeth v.
5 Levine. If the state failure to warn cause of action requires
6 any warning that the brands couldn't act, for instance a colder
7 temperature range on the label, or a black box warning with a
8 skull and cross bones, or the big bolded font example from our
9 brief, then the entire cause of action would fail.

10 This despite it being undisputed for purposes of this
11 Motion to Dismiss that the brands could have used the CBE
12 process to add a cancer warning, as required by state failure
13 to warn law. The generics rule would render Wyeth effectively
14 meaningless in virtually every case, including this one. As
15 your Honor has previously noted, that cannot be the law.

16 Let me transition, if I could, to the generics'
17 argument about our storage and transportation claims. I think
18 we are ships passing in the night here, your Honor. The
19 generics believe that we are asking them to change the
20 temperature range on the label. This is in their reply at 12.
21 That is not the duty we allege. We are saying they didn't even
22 comply with their own lab's temperature range.

23 Count 11 makes this clear in paragraphs 2446 and 2449
24 of the amended master personal injury complaint. It should go
25 without saying that it is not impossible to comply with the

1 generics' own FDA approved label.

2 Our disagreement is starker with respect to packaging.
3 The complaint alleges that the generics had a duty to reduce
4 the number of pills in each container and to switch to blister
5 packs, both of which would have reduced Ranitidine's exposure
6 to excessive humidity.

7 The generics pretend that these would have been major
8 changes that would have required FDA pre-approval. To support
9 that argument, they selectively quote 21 CFR, Section
10 314.70(b)(2)(iv) to say that any change that "may affect the
11 impurity profile" of the drug is a major change.

12 That is simply false, your Honor. All of the specific
13 examples contained in the (b)(2) category are a subset of the
14 sorts of changes that count as "major changes." The standard
15 for what counts as a major change is stated in 21 CFR
16 314.70(b)(1), not (b)(2). A manufacturer needs pre-approval
17 from FDA for changes that have "a substantial potential to have
18 an adverse effect on the identity, strength, quality, purity,
19 or potency" of the drug.

20 Respectfully, omitting the word "adverse" conceals the
21 most important part of the standard. Changing from multiple
22 dose packaging to single dose packaging or switching to a
23 blister pack has virtually no chance of having an adverse
24 effect on Ranitidine.

25 Yes, it can affect the purity profile of the drug, but

1 only in a salubrious, not an adverse way. That is exactly the
2 sort of change that belongs under Sections 314.70(c) or (d) for
3 moderate or minor changes that do not require FDA pre-approval.
4 Don't take our word for it, your Honor, just ask the FDA.

5 That is exactly the position the agency took in its
6 2004 guidance document to NDA and ANDA holders. It says that
7 the sort of changes we propose can be done in an annual report
8 because they are minor changes that do not require FDA
9 pre-approval.

10 The generics ignore this and claim that the FDA really
11 says that if there is any doubt as to a reporting category, a
12 manufacturer should use the higher standard, but that is not
13 what the FDA said. It instead said that if a manufacturer is
14 submitting more than one change at once, and one falls into a
15 higher category and another in a lower category, the agency
16 recommends that the manufacturer submit them both in the higher
17 category.

18 That has nothing to do with ambiguity. The FDA does
19 not consider the changes we are talking about ambiguous in the
20 first place. The law is instead is clear. Plaintiffs allege
21 that the generics have a duty to use safer packaging. Federal
22 regulations allowed them to switch to safer packaging without
23 pre-approval. It was thus entirely possible for generics to
24 meet their state law duty without violating Federal law. There
25 is no impossibility preemption under these circumstances.

1 Finally, your Honor, let me address the Plaintiffs'
2 failure to warn through the FDA claims. We have already
3 discussed these claims in the morning session, particularly
4 with regard to Buckman and objectives and purposes preemption.
5 I want to emphasize here that nothing about these claims runs
6 afoul of Mensing and the impossibility preemption doctrine.

7 Once again, preemption is about comparing state and
8 Federal duties. In Mensing, the state law duty Plaintiffs
9 allege was to change the label of a generic drug to add a
10 warning, but that was impossible under Federal law as it would
11 violate the duty of sameness. The Supreme Court agreed that if
12 the FDA were told about the drugs' risks, it might order
13 generics to change the label.

14 The Court further agreed that telling the FDA about
15 the risks was something the generics could do, but that
16 permissible action, telling the FDA about risks associated with
17 a drug, would not have satisfied the manufacturers' state law
18 duty.

19 As the Court said, "Although requesting FDA assistance
20 would have satisfied the manufacturers' Federal duty, it would
21 not have satisfied their state tort law duty to provide
22 adequate labeling. State law demanded a safer label, it did
23 not instruct the manufacturers to communicate with the FDA
24 about the possibility of a safer label. Indeed, Mensing and
25 Demahy deny that their state tort law claims are based on the

1 manufacturers' alleged failure to ask the FDA for assistance in
2 changing the labels." That is at page 619 of the opinion.

3 As the Court noted in the next page of its opinion,
4 "The question for impossibility is whether the private party
5 could independently do under Federal law what state law
6 requires of it." Then at page 524 of the opinion the Court
7 noted that where state law imposes a duty to add a safer label
8 and Federal law imposes a duty only to warn the FDA, the
9 Federal duty is "not a matter of state law concern."

10 For the 15 jurisdictions pleaded in Count 5 to the
11 amended master personal injury complaint, state law imposes a
12 duty to warn consumers through the FDA. As paragraph 1408 --

13 *THE COURT:* That is 20 minutes.

14 *MR. KELLER:* Very good. I will pause there and wait
15 for your questions.

16 *THE COURT:* The Defendants have about a minute and a
17 half left.

18 *MR. GUGERTY:* Thank you, your Honor. I just have a
19 few brief points. So --

20 *THE COURT:* Hold on. Restate your name for the
21 record.

22 *MR. GUGERTY:* I apologize. For the record, Sean
23 Gugerty appearing on behalf of Perrigo.

24 So, Mr. Keller stated that the Supreme Court in many
25 cases have stated preemption applies only to the extent of the

1 difference. The lead case that says that, and a frequently
2 quoted one, is the English opinion, but as pointed out in our
3 briefing, in the very first line of the English opinion it
4 states that the decision before the Supreme Court is whether
5 Federal law preempts a state law cause of action.

6 So, in line with the crystallization of the bright
7 line rule in your Honor's preemption order, and in line with
8 the holdings in Mensing and Bartlett, English in fact supports
9 that preemption -- although preemption applies to the extent of
10 the difference, the Court looks to preempt entire causes of
11 action if there is a conflict between the duty element and
12 Federal law, and, of course, that was the holding in Mensing
13 and Bartlett.

14 The duty in Bartlett was actually to avoid -- the same
15 as in many of Plaintiffs' counts, to avoid actions that would
16 be unreasonably safe. In that particular instance there were
17 two ways to satisfy that, two theories. So, contrary to what
18 Mr. Keller is stating, our argument is totally consistent with
19 Bartlett, it would not prevent claims against brand
20 manufacturers.

21 Lastly, I would just say, your Honor, that we welcome
22 the comparison to the Cliff case. The Cliff cause of action,
23 as is made very clear in the opinion at page 1127, that was a
24 cause of action brought just to enforce subsection 9 of the
25 Florida statute, only that, and it was only that duty that the

1 Court in section -- subsection 9 that the Court looked at, for
2 that reason, and because the duty was preempted --

3 *THE COURT:* Time.

4 *MR. GUGERTY:* Thank you, your Honor.

5 *THE COURT:* Thanks. Okay. What we are going to do
6 is, I have one or two questions that I want to ask now and then
7 we are going to take a break, our mid-afternoon break. If we
8 could have all counsel come on the screen with your videos on.
9 Just a few questions, and then we will take our break and I
10 will have additional questions.

11 Plaintiffs, the Court wants to be sure that it
12 understands the way you have pled your claims in the AMPIC.
13 Take the claims for failure to warn through proper expiration
14 dates, for example, such as -- well, Counts 3, 4, and 7. You
15 allege that "Plaintiffs or their doctors would have read and
16 heeded these warnings referring to shorter expiration dates.
17 As a result, Plaintiffs would not have consumed the volume of
18 NDMANDMA they ultimately did and would not have been harmed by
19 NDMA." That is coming from paragraph 966.

20 Are the Plaintiffs alleging that the expiration date
21 being too long was the only reason that Plaintiffs came to
22 consume NDMA, and therefore the only reason they were harmed?
23 And if that is not your allegation, can you explain to the
24 Court what you are alleging?

25 So, if you can answer the first question first.

1 *MR. KELLER:* No is the answer to the first question,
2 your Honor.

3 *THE COURT:* So, you are not alleging that the
4 expiration date being too long was the only reason that the
5 Plaintiffs consumed the NDMA and were harmed. That is not what
6 you are alleging in that paragraph?

7 *MR. KELLER:* This is Ashley Keller for the Plaintiffs.
8 That is correct, your Honor.

9 *THE COURT:* So, then, can you explain just that?

10 *MR. KELLER:* Yes, I can. The key word that your Honor
11 focused on that I took to heart is "only". You were asking if
12 the too long expiration date was the only reason that the
13 Plaintiff consumed too much NDMA that ultimately caused their
14 injury, and I said no to that.

15 We are alleging that the NDMA that the Plaintiffs
16 consumed because the expiration date was too long was a legally
17 sufficient cause of the Plaintiffs' injuries, and the causation
18 inquiry is going to vary state by state. Some states have a
19 but for cause, some have a substantial contributing factor
20 standard for causation.

21 We are alleging that there was enough NDMA that the
22 Plaintiff consumed because the expiration date was too long to
23 be a legally sufficient cause of their injury, but it was not
24 the only reason.

25 *THE COURT:* Okay. A legally sufficient cause for the

1 Plaintiff to have consumed NDMA and to be harmed.

2 *MR. KELLER:* Correct, your Honor.

3 *THE COURT:* Okay. Just so I am clear, the Court has
4 the same question for the failure to warn claims brought only
5 against the brand manufacturers for lack of adequate labeling,
6 the negligent product container claims, and the negligent
7 storage and transportation claims, such as Counts 1, 2, 6, 9,
8 10, and 11.

9 *MR. KELLER:* Same answer, your Honor, exactly the same
10 answer.

11 *THE COURT:* Okay. So, if my question is, are the
12 Plaintiffs alleging that the inadequate labeling was the only
13 reason that Plaintiffs came to consume NDMA, and therefore the
14 only reason they were harmed, the answer would be no, but it is
15 a legally sufficient reason to have caused them harm.

16 *MR. KELLER:* That is precisely correct, your Honor.

17 *THE COURT:* And the same goes for improper product
18 containers?

19 *MR. KELLER:* Yes, your Honor.

20 *THE COURT:* And improper storage and transportation
21 conditions?

22 *MR. KELLER:* Yes, your Honor.

23 *THE COURT:* Okay. Are Plaintiffs pleading the causes
24 of harm in the alternative? For example, you may know what I
25 mean, but just to be sure you know what I mean, are you

1 pleading that Plaintiffs got cancer because Ranitidine
2 products' labeling was inadequate, Counts 1, 2, and 6, or
3 alternatively, because products' expiration dates were too
4 long, Counts 3, 4, and 7, or alternatively, because product
5 containers were improper, Count 9, or alternatively, because
6 the products or their ingredients got too hot, Counts 10 and
7 11, or are you pleading that some or all of the alleged defects
8 pled in these counts in combination caused cancers?

9 *MR. KELLER:* Your Honor --

10 *THE COURT:* Put it in your own words, because if I --

11 *MR. KELLER:* I think your words were perfectly fine,
12 and I understood the question. I hope you don't consider this
13 too cute of an answer. The latter is what we intended, meaning
14 that we think each source is a sufficient legal cause of a
15 Plaintiff's injuries.

16 However, you still shouldn't dismiss, even if you
17 disagree that we haven't pleaded that adequately, because we
18 are allowed to plead in the alternative. It is not our
19 intention to plead in the alternative here.

20 We think that each count provides a sufficient basis
21 to establish causation as a matter of law, and when multiple
22 different sources of a harm are present factually, the law in
23 most jurisdictions would allow a recovery, and that hasn't been
24 briefed here, as your Honor is aware, and we haven't gone
25 through a 50-state causation analysis.

1 Even if you disagree with that, we are, of course,
2 allowed to plead in the alternative. The counts could stand as
3 an alternative basis for the exposure to NDMA even if you
4 didn't agree with my first proposition.

5 *THE COURT:* But as pled, it is not pled in the
6 alternative.

7 *MR. KELLER:* That is correct.

8 *THE COURT:* Why don't we take a break until 3:30. We
9 will have the same group come back on with your videos and I
10 will continue with the questions. Thanks so much, have a good
11 break.

12 *(Thereupon, a short recess was taken.)*

13 *THE COURT:* All right. If we could have our attorneys
14 arguing the generic preemption motion come on. Okay.

15 All right. Most of these questions are for the
16 Plaintiffs, actually, so you don't have to state your name each
17 time, Mr. Keller.

18 Plaintiffs, Mr. Keller, most of the state law duties
19 that you plead for the failure to warn claims require in some
20 iteration an adequate warning of the product's risks or danger.

21 Would the law of any state consider an expiration date
22 a warning of a cancer risk for the purpose of satisfying that
23 duty?

24 *MR. KELLER:* I think the answer is yes, your Honor, to
25 the extent that the reasoning behind the expiration date being

1 shortened was to aver to Plaintiffs' exposure to a carcinogen.
2 The common law which imposes a requirement to behave reasonably
3 on manufacturers would encompass that.

4 I don't think that the expiration date would have to
5 explain with extra words why it was being shortened, even if
6 the manufacturer would privately know those reasons. Simply
7 shortening the expiration date could satisfy the duty.

8 *THE COURT:* And would the law of any state consider a
9 shorter expiration date an adequate warning of a cancer risk
10 for the purpose of satisfying that duty?

11 *MR. KELLER:* Depending on the amounts involved, your
12 Honor, that were formed as a result of the longer expiration
13 date and that were formed as a result of the shorter expiration
14 date, yes, I think the law could consider that adequate.

15 *THE COURT:* Are these legal questions for a Court to
16 decide or factual ones for a jury to decide?

17 *MR. KELLER:* The existence of duty is a question of
18 law for the Court.

19 *THE COURT:* So, now would be the stage, at the
20 pleading stage, for the Court to determine whether, as a matter
21 of law, any state would consider a shorter expiration date to
22 be an adequate warning, or even that an expiration date is a
23 warning of a cancer risk?

24 *MR. KELLER:* To the extent that your Honor thinks that
25 the Defendants have adequately briefed the issue and moved to

1 dismiss on the basis of each jurisdiction's duty juris
2 prudence, then you could address it as a matter of law at the
3 pleadings.

4 That is not how I read their papers, but it is a
5 question that theoretically could be addressed on a 12(b)(6)
6 because the existence of duty is a question of law, and the
7 contours of duty is a question of law.

8 *THE COURT:* Is there any legal support that you have
9 found in any of the allegations that have been made in the
10 complaint upon which state duties you are relying that -- and
11 state laws, common law, that encompass duties that an
12 expiration date is a warning of a cancer risk?

13 *MR. KELLER:* No, your Honor. As I said before, I
14 don't think that an expiration date is itself warning about
15 cancer, it is warning when a consumer should not continue to
16 take the product and it doesn't provide the explanation behind
17 it. In this particular case, it is obviously because of
18 exposure to a carcinogen, but the expiration date itself is
19 just a warning to a consumer not to consume a product, but I
20 think it is worth pausing on this point.

21 The common law, which is what all of these causes of
22 action are, is usually stated by the state common law courts at
23 a pretty high level of generality. You then have to get to the
24 specific facts and circumstances of a particular case to apply
25 that general standard.

1 For example, paragraph 964 of the amended master
2 personal injury complaint -- I am just jumping up a few
3 paragraphs from the one that your Honor cited before. Under
4 Alabama law, a manufacturer has the duty to provide an adequate
5 warning to consumers of a product's danger when used in its
6 intended manner.

7 That is going to be the sorts of statements that you
8 see throughout the common law courts. There might be slight
9 variations jurisdiction to jurisdiction, but they are not going
10 to get to the specific issue of expiration dates count as a
11 warning unless the facts of a particular case presents it that
12 way, but there is no reason to think that Alabama's Supreme
13 Court wouldn't recognize an improper expiration date that told
14 the consumer, you can consume this for two years, when it is
15 only reasonable to consume it for six weeks, and say that is
16 not tripping that general statement of the duty.

17 I think it is important to understand how the common
18 law actually operates in practice.

19 *THE COURT:* So, hypothetically, if this case is
20 remanded and you are in Alabama, and you are arguing to the
21 jury that the Defendants breached their duty under Alabama law
22 to provide an adequate warning, you would envision arguing to
23 the jury that the way they violated that duty was by not having
24 a shorter expiration date.

25 *MR. KELLER:* For this particular count, your Honor,

1 and the ones that incorporate expiration dates, absolutely,
2 that is how I would envision it.

3 *MR. YOO:* Your Honor --

4 *THE COURT:* Yes. Defendants, do you want to respond
5 on this point?

6 *MR. YOO:* Yes, your Honor, thank you. This is Thomas
7 Yoo on behalf of the generics.

8 Your Honor, I think it is important to look at the
9 allegations that the Plaintiffs have actually made with the --

10 *THE COURT:* Well, I am going to get into other
11 allegations, and be assured that if you haven't had a chance to
12 say what you want to say, since most of my questions are for
13 the Plaintiffs, although I will try to give you an opportunity
14 to respond, but for purposes of the question, if you want to
15 respond to the particular question, I appreciate that if you
16 want to, but I will give you an opportunity if there is
17 something you haven't been able to say generally. I don't want
18 to go off on tangents and lose my focus on these particular
19 questions.

20 *MR. YOO:* Thank you, your Honor. I don't want to
21 interrupt the Court's train of thought. I will take the
22 opportunity later to look at the specific allegations the
23 Plaintiffs have made, but for purposes of this issue, I will
24 say at this time that the Plaintiffs have very much alleged
25 that the Defendants needed to provide more than a series of

1 four or six digits, a new expiration date.

2 Their complaint is replete with allegations that the
3 Defendants actually needed to provide a clinical warning about
4 cancer in order to meet their state law duties.

5 I think there is a disconnect between what Mr. Keller
6 is telling the Court for purposes of opposing this motion and
7 what the Plaintiffs have actually done. I would be happy to
8 review the specifics at another opportunity.

9 Furthermore, to the extent -- I think Mr. Keller is
10 saying that the Plaintiffs would view a new expiration date as
11 a type of warning that would somehow communicate the risk of
12 NDMA or cancer to consumers. If that is the purposes of a new
13 expiration date, I would dispute the notion that that is
14 something that could be accomplished by a CBE 30.

15 An expiration date, as was discussed earlier with the
16 Court, serves various purposes and is based on stability
17 testing that goes to things like color, hardness, dissolution,
18 et cetera, of the drug product.

19 The purpose of an expiration date is not to cover the
20 risk of a serious adverse event like or cancer, and the
21 Plaintiffs like to say, let's look at what the FDA actually
22 did. I would remind the Court that if you do look at what the
23 FDA actually did, the FDA did not tell manufacturers, go ahead
24 and pick an expiration date and put your Ranitidine products
25 back on the market.

1 To the contrary, as Mr. Petrosinelli covered with the
2 Court yesterday, the FDA said we are going to do testing, we,
3 the FDA, we are going to analyze the data. So, for now, we
4 request that everyone who hasn't already withdrawn the product,
5 do so.

6 So, this notion that we all each independently could
7 determine what is a safe expiration date in order to prevent
8 the risk of cancer, slap that on the side of a box and continue
9 to sell Ranitidine, I think is a fallacy.

10 *MR. KELLER:* Your Honor, I don't think that Mr. Yoo
11 was responding to what I was responding to. I think you heard
12 a lot of different arguments there, which I would be pleased to
13 respond to if you want to give me the opportunity, or we can go
14 on to other stuff.

15 But I don't think that he stayed within the confines
16 of what he promised you when he started his answer.

17 *THE COURT:* You can briefly respond to the point. I
18 do have other questions, but if you would like an opportunity
19 to briefly respond.

20 *MR. KELLER:* I would, your Honor, and I really
21 appreciate that.

22 First, on the CBE process, the generics are now
23 backtracking from their briefing. They made the argument about
24 the CBE regulation and how they couldn't change expiration
25 dates without the FDA's special permission and assistance in

1 the first round of Motion to Dismiss briefing. They completely
2 dropped that in this round and now you have just heard Mr. Yoo
3 resurrect it.

4 Relying on your order and *Excelsior*, I think that is
5 completely inappropriate to get sandbagged by that for the
6 first time at oral argument.

7 Second, we are not saying that the expiration date was
8 designed to warn consumers about the NDMA that they were going
9 to consume. An expiration date, just as a matter of common
10 sense, tells a consumer, don't take the product after this
11 particular date. It doesn't matter what the reasons are at
12 that point. If you didn't properly warn them that it wasn't
13 safe for whatever reason to take the product after a particular
14 date, justified by the facts, then it was an inadequate
15 warning.

16 There is a stark disagreement that we were candid
17 about in my presentation. Mr. Yoo is correct, state law would
18 also require the generics to do more, it would require them to
19 add a cancer warning, but we cannot plead that against them
20 because of preemption, and that is not what our theory is based
21 on with respect to expiration dates.

22 Again, if you look, for example, at paragraphs 963,
23 64, 65, and 66, which is the sub count for Alabama in Count 3,
24 the only one that I think you could fairly say suggests that
25 they also had a duty to warn about cancer is the one that we

1 were talking about, paragraph 964. Under Alabama law, a
2 manufacturer has the duty to provide an adequate warning to
3 consumers of a product's danger when used in its intended
4 manner.

5 Yes, that would also, under state law, include a
6 cancer warning, but we weren't going to conceal that general
7 statement of the duty from your Honor just to avoid preemption.

8 *THE COURT:* Is that an example of you couldn't make
9 that claim under Alabama law because of the way the duty is
10 phrased, an adequate warning to consumers of a product's
11 danger?

12 You would concede, wouldn't you, that changing an
13 expiration date doesn't warn the consumer about the risk of
14 cancer or even -- I mean, or even not to consume, maybe,
15 arguably, not to consume after a certain period of time, right?

16 *MR. KELLER:* I absolutely concede that an expiration
17 date by itself would not warn the consumer of the risk of
18 cancer, of course that is true. It would, as your Honor just
19 suggested quite correctly, suggest to the consumer don't
20 consume it after this date, and if that is causally connected
21 to the Plaintiff's ultimate consumption of too much NDMA that
22 leads to cancer, we have pled enough for causation.

23 Effectively what I would say, your Honor, is because
24 the common law is stated at a high level of generality,
25 paragraph 964, which we think states the duty under Alabama

1 law, actually imposes at least two duties on manufacturers.

2 The reasonably prudent manufacturer would, number one,
3 provide an accurate expiration date, and they failed to do
4 that. The breach of that by itself is enough to support the
5 element of breach for the cause of action.

6 It would, admittedly, also impose a duty under purely
7 state law to warn about cancer. We can't support that theory
8 because it is preempted and we agree that if we tried to go to
9 a jury with that we should get JAMOLed. That would be an
10 improper theory and an improper set of facts to present to the
11 jury because the inadequacy of the cancer warning is not
12 something that the generics could fulfill.

13 *THE COURT:* You are still claiming you could pursue a
14 non-preempted claim under Alabama law, given that Alabama duty?

15 *MR. KELLER:* Yes, your Honor.

16 *THE COURT:* So, can we assume that an Alabama jury
17 instruction would sort of match that duty, so it would be along
18 the lines of, you know, a duty to give an adequate warning of a
19 product's danger, and so -- you know, most Courts don't like to
20 modify their jury instructions, so if a standard jury
21 instruction was given, how would that work?

22 *MR. KELLER:* That is a fantastic question, your Honor,
23 I am glad you asked that. Typically, you are correct, you
24 shouldn't tinker with the pattern jury instructions, but look
25 at the Supreme Court's decision in Bates. It specifically

1 addresses this and says that if the Defendants are concerned
2 that the Plaintiffs are going to try and veer into preempted
3 territory, they are entitled to limiting instructions in the
4 jury instructions to make sure the Plaintiffs stay in the
5 non-preempted lane.

6 That is exactly what could happen here. I would also
7 say it would be improper for us to submit evidence to the
8 jury of any sort of failure to provide a cancer warning, and if
9 we did, that evidence should be excluded and the jury could
10 once again be instructed, you can't consider that.

11 *THE COURT:* That was another lingering question I had.
12 So, would you envision that trials against generics and brands
13 would be severed, they would have to be tried separately?
14 Because clearly you would acknowledge that the level of
15 evidence that you have at least -- the allegations that you
16 have made against the brands -- but I am going to get to
17 another point, which is that many of the allegations have also
18 been made against the generics, but just assume for a moment
19 everything that you have alleged against the brands and you
20 believe is not necessarily preempted and hasn't been challenged
21 as being preempted, that could not -- it is not relevant in a
22 generic lawsuit, and in fact could be very prejudicial, how
23 would that work?

24 *MR. KELLER:* That is another great question, your
25 Honor, not least because I have to confess I hadn't even

1 thought of that yet.

2 Speaking off the cuff, I think your Honor would
3 certainly, if it was a trial that you were conducting, would
4 have discretion to sever under the rules for precisely the
5 reason you just indicated. The arguments that we're permitted
6 and the proof that we're permitted to put in varies by
7 categories of Defendant, and if you thought it was too
8 prejudicial vis-a-vis a particular category, you could sever
9 them out of the case so that we could only present the evidence
10 against them that would be appropriate under preemption.

11 A different possibility is that juries are typically
12 trusted to follow the instructions that the Court gives and to
13 adhere to what the Court says is the law, and through jury
14 instructions you could cure any prejudice.

15 I would have to concede, again just off the cuff here,
16 that your Honor would have ample discretion, if you were
17 concerned about this issue, to say that brands and generics
18 can't be tried together. That is only going to be relevant, of
19 course, for a Plaintiff, at least on the personal injury side,
20 who has consumed both branded and generic Ranitidine, but there
21 are admittedly many Plaintiffs in this MDLMDL who fall into
22 that dual Defendant category.

23 *THE COURT:* So, another followup question, putting
24 aside whether brands and generics come together or they're
25 separate, whether there are limiting instructions, modification

1 to jury instructions, et cetera, et cetera, there are many
2 allegations that you have made in the complaints that are
3 incorporated into the allegations of the causes of action
4 against the generics, albeit you have parceled out some of
5 them, or many of them that were in the previous complaints for
6 reasons, I'm sure, to try to conform to the Court's orders.

7 But nevertheless, I mean, it is further down in my
8 questioning, but -- I will get more particular when I come
9 across it, but flowing from this conversation, you have charged
10 the generics with such knowledge of -- through your allegations
11 of the danger of Zantac, of how it was manufactured, of the
12 heat, of the breakdown, of the degradation, the carcinogenic
13 elements of NDMA.

14 I would imagine you would anticipate bringing such
15 evidence into a trial against the generics, but yet, how does
16 that relate to very -- so, it is okay for the generics to know
17 what Ranitidine does in the stomach, but they can sell it
18 anyway, just have a shorter expiration date and --

19 *MR. KELLER:* Yes, is the answer to your Honor's
20 question. All of that evidence is relevant to what the
21 expiration date should have been, and you will instruct, we
22 would suggest --

23 *THE COURT:* Sorry to interrupt, but I am not just
24 talking about evidence about expiration date. I would think
25 that evidence about expiration date would be relevant to the

1 claim based on expiration date, but there is a lot of other
2 allegations that go beyond expiration date as to the molecular
3 composition of NDMA, what it is, what it looks like, how it
4 acts, not just within an expiration date period after one to
5 two months and before 24 months, everything else you have put
6 into the complaint.

7 So, how do you take all of that information, impute
8 that knowledge to the generics through the incorporation of
9 those allegations, but proceed on fairly narrow grounds given
10 the gravity, the enormity of the dangers and the safety risks
11 that have been alleged in the complaint?

12 *MR. KELLER:* I completely understand, or at least I
13 think I do, your Honor, the thrust of your question.

14 Obviously, we are here on a 12(b)(6), and we are
15 pleading facts against the generics that we think help
16 establish our claims. All of the ultimate evidentiary
17 decisions that your Honor, or a trial court would make if these
18 cases are remanded, as to what gets in, what is prejudicial,
19 and what ticks off the boxes of being fairly in play for the
20 elements of the claim is for a later day.

21 I actually, very respectfully, want to disagree that
22 all of those knowledge allegations that we allege, again, just
23 focusing on expiration dates, for example, are not relevant to
24 just that claim. The generics' knowledge of the Ranitidine
25 molecule, their knowledge about how it reacts to heat and

1 moisture under ordinary circumstances, all of that is relevant
2 to what they should have been testing for to set the proper
3 expiration date based on the actual life cycle of these drugs
4 on a grocer's shelves and then ultimately in the consumer's
5 possession.

6 You could import that over to the claims about their
7 packaging, should they have used blister packs. Their
8 knowledge of how Ranitidine degrades more quickly under
9 conditions of excessive moisture are absolutely relevant to the
10 fact that they should have make a change and consider to do so,
11 using the CBE process or the minor change update in the annual
12 report.

13 So, I would respectfully submit that even though those
14 are broad allegations that accuse the generics of pretty
15 serious misconduct, they are relevant to the narrower set of
16 claims that we are allowed to bring against them.

17 I can see how logically you would say it is even more
18 obviously relevant to the brands because they could have
19 actually added the cancer warning, but I still think the
20 expiration date claim, again sticking with that, ties in well
21 with all of those knowledge-based allegations.

22 *THE COURT:* Response from the Defense. If you don't
23 have one, that's fine. I just want to give you that
24 opportunity.

25 *MR. YOO:* Your Honor, I do have a response. I will

1 try to keep it short.

2 This is the primary point of our motion, your Honor,
3 that the Plaintiffs, as Mr. Keller just admitted, have made
4 extremely broad allegations about all of it, the inherent risk,
5 the inherent defect, our supposed knowledge, et cetera, and you
6 just heard Mr. Keller clarify, if the Plaintiffs' pleadings
7 weren't clear enough, that they view it as absolutely relevant
8 to the generics, and they intend to present evidence to the
9 jury on all of it.

10 So, how is this not an attempt at an end run around
11 Mensing and Bartlett?

12 Thank you, your Honor, I will stop there for now.

13 *THE COURT:* All right. Let me -- for the Plaintiffs,
14 Mr. Keller, in the AMPIC Count 9, you alleged under the law 52
15 jurisdictions, "A pharmaceutical manufacturer has a duty to
16 exercise reasonable care in choosing and making the containers
17 for its products." That's, for example, if we are sticking
18 with Alabama, paragraph 2000 under Alabama law, a
19 pharmaceutical manufacturer has a duty to exercise reasonable
20 care in choosing and making the containers for its products.

21 The Court wants to be sure that it is clear as to the
22 Plaintiffs' position. Is it your position that Count 9 as a
23 negligence claim, that the duty at issue is the typical
24 negligence duty to use reasonable care, and that one factual
25 way that the Defendants could have satisfied that duty is by

1 using appropriate containers for their products, or is it the
2 Plaintiffs' position that any jurisdiction has a separate cause
3 of action for negligent product containers with its own special
4 legal duty?

5 *MR. KELLER:* The former, your Honor. The reason we
6 pleaded it as the title of the cause of action negligent
7 product containers, we were just trying to be really specific
8 in view of your Honor's previous order and wanted to get to
9 that level of granularity, but this is just a negligence claim.

10 *THE COURT:* Okay. Maybe I asked for this then.

11 *MR. KELLER:* I didn't say that, your Honor

12 *THE COURT:* Just following along just to be clear,
13 same question for AMPIC Counts 10 and 11, where Plaintiffs
14 allege "a duty to exercise reasonable care in transporting and
15 storing products." So that would be, we will pick on Alabama,
16 paragraph 2461 under Alabama law, a pharmaceutical manufacturer
17 has a duty to exercise reasonable care in transporting and
18 storing products.

19 Is it the Plaintiffs' position that those counts are
20 negligence claims with the legal duty being to use reasonable
21 care, and that a factual way to satisfy the duty to use care is
22 to use care in storing and transporting?

23 *MR. KELLER:* Exactly right, your Honor.

24 *THE COURT:* Okay. I never really saw that in the
25 briefing, this notion of a factual way to satisfy a duty. It

1 was a bit unclear as to whether it was its own duty or, as you
2 are saying now, it is a general duty, it is a negligence
3 ordinary care duty, reasonable care, an ordinary
4 manufacturer -- reasonable manufacturer using ordinary care,
5 and that this is a factual way.

6 So, is the factual way to satisfy the duty becoming
7 the duty or -- again, you have this very broad duty to use
8 reasonable care. You have allegations about the dangerous
9 nature and the propensity of what Zantac does, can do.

10 There would be many things, arguably, that, again,
11 generics being charged with this knowledge of these dangerous
12 propensities, would have to do to fulfill a general ordinary
13 care, reasonable care duty, and I am not -- you know, to think
14 of it as a one-way, a factual way as being elevated to the
15 duty, I am just trying to see how you are connecting the dots.

16 I guess on that point -- I know you pointed to Mink,
17 and I am aware that Mink was pled as a -- in the second amended
18 complaint, Count 1, as a negligence count, and the Court did,
19 among other things, say of Mr. Mink's three theories of
20 liability for his negligence claim, only the manufacturing
21 defect theory may proceed. The improper training theory is
22 barred by Florida law and the failure to report theory is
23 impliedly preempted.

24 I am not sure -- by the way, that was not an
25 impossibility preemption case, as you know, so I did want to

1 hear on how you analogize Mink when it really wasn't grappling
2 with impossibility preemption, but that is kind of a second
3 question I had about Mink.

4 But I see you saying that there is a factual way that
5 the generics could comply with a broad duty, and I see Mink as
6 negligence and different theories of how the Defendants were
7 negligent, and a couple theories went away, but one theory
8 remained.

9 There weren't factual ways in which a duty couldn't be
10 complied with, at least I didn't see it that way, but
11 admittedly, you just made the argument about Mink before the
12 break, so this was a short review, although I am familiar with
13 the case. I don't think you had made that argument before,
14 that I recall, so I would want to look at it with a little more
15 time. But what is your response to that?

16 *MR. KELLER:* Sure, your Honor, a couple of different
17 points to unpack there. First of all, the buck stops with me
18 on the briefing, so if there was anything unclear, it wasn't
19 the amazing team that you helped assemble, that was on me. I
20 apologize if it was unclear.

21 What we are trying to aim at is not elevating a
22 particular factual way of stating the duty, we are talking
23 about a theory of breach, which is, of course, an element of
24 the cause of action, and I think it is useful to think about
25 this in the branded context, for example.

1 If you look at a high level, the common law of most of
2 the states, there may be some slight variation in the word
3 choice, but it is going to say you have a duty to reasonably
4 act to warn consumers of known or knowable risks.

5 No Court is ever going to consider the particular
6 factual warning that the Defendants are proposing in a case
7 like Albrecht, for example. There is not going to be that
8 level of specificity. So, it is the same point with respect to
9 all of these counts.

10 The high level standard that is going to be the
11 announcement of the common law from the State Supreme Courts
12 and intermediate Appellate Courts is never going to be
13 considering the particular facts and circumstances. So, that
14 is why -- and I would commend to your Honor giving Mink a more
15 careful look -- each of our the different possible ways of
16 recovering against the generics is a different theory of the
17 element of breach.

18 We are not trying to redefine any of the causes of
19 action, we are not trying to say that the common law says there
20 is such a granular cause of action that it is titled failure to
21 have an adequate expiration date. It is still going to be just
22 the general common law failure to warn, but there is a specific
23 way on the facts and circumstances of this case that the
24 generics behaved unreasonably.

25 The way that we are allowed to plead, for example, is

1 that they didn't have an adequate expiration date. That ticks
2 off the element of breach. We still have to prove causation
3 and damages, and all of the other things that you would expect
4 for the elements of these torts. We are not trying to redefine
5 any of them, but in Mink, I think that is what happened.

6 Mr. Mink tried to plead three different theories of
7 negligence, the Court said one is okay, and two are not. The
8 entire negligence cause of action didn't fall away, just the
9 two impermissible theories were disallowed.

10 You are correct, by the way, your Honor, Mink was not
11 an impossibility preemption case, but it was both an express
12 and implied preemption case, and I would actually say that
13 impossibility is a much more difficult standard for the
14 generics to satisfy than the objectives and purposes implied
15 preemption doctrine under Buckman.

16 Objectives and purposes lets the Court say here is
17 what Congress was really getting at, the policy aims of
18 Congress. Even though it is not technically possible for the
19 Defendants to comply with state and Federal law, we are still
20 going to find preemption because it would frustrate Congress'
21 purpose to let the claims proceed.

22 Impossibility is much stricter than that, it has to
23 actually not be possible for the Defendant to do its state law
24 duties consistent with Federal law.

25 *THE COURT:* Brief response.

1 *MR. YOO:* Your Honor, I hope we are not confusing
2 Mink's express preemption portion of the holding with the
3 Mensing analysis because, as I think we went over on the last
4 round of the Motion to Dismiss, those are distinct areas of
5 law.

6 We cited Mink for the proposition that as it relates
7 to Buckman implied preemption, the allegation that the
8 Defendants are liable because they failed to report adverse
9 events to the FDA is preempted under Buckman.

10 *THE COURT:* No, I know it was raised in the context of
11 failure to warn the FDA, but it was mentioned by Mr. Keller
12 before the break as it relates to this negligence claim and
13 three different theories. So, I wanted to pull the case up
14 again and pull the complaint up and try to follow his thinking.

15 *MR. YOO:* As to the broader point, your Honor, if I
16 may, I think Bartlett included a statement about doing a
17 straightforward analysis under Mensing to arrive at the result
18 that the Court did.

19 I would say the same thing applies here. We don't
20 need to get afield of Mensing and Bartlett and those opinions
21 themselves in order to find the right result here because the
22 touchstone, as your Honor knows and as your Honor pointed out
23 in the December order, is what must a Defendant do, according
24 to the Plaintiffs' allegations, in order to avoid liability.

25 It is not, as Mr. Keller suggested earlier, what could

1 a Defendant have done, what was possible or impossible for a
2 Defendant to do to minimize exposure to NDMA or to mitigate
3 risk. That is not the test. It is what is it, all of it, that
4 a Defendant needs to do in order to avoid liability altogether,
5 based on what the Plaintiffs have alleged.

6 What is clear not only from the amended complaints
7 themselves, but the discussion we are having today, is that the
8 Plaintiffs have doubled down on this idea that the generics are
9 responsible for everything that they are saying about
10 Ranitidine, a fact that as a part of the normal digestive
11 system Ranitidine becomes NDMA. That is knowledge they want to
12 charge us with.

13 Then they want to tack on expiration dating and
14 containers and everything else.

15 Back to Mensing, what is it, according to the
16 Plaintiffs, that we needed to do to avoid liability? It is to
17 have taken care of all of that, which, as my colleagues pointed
18 out earlier, is, in summary, either change Ranitidine, provide
19 a cancer warning that the Plaintiffs would deem adequate, or
20 don't sell it, and the Court ruled in December that those are
21 all preempted claims and allegations and theories.

22 Here we are right back to square one, and I think it
23 has been made clear in argument today that the Plaintiffs
24 absolutely intend to continue to embrace those primary
25 allegations against the generics, and that is why all of the

1 claims are preempted and should be dismissed.

2 *THE COURT:* Let me ask, did Mr. -- did you intend to
3 put your video on? You should probably turn it off, then.

4 Mr. Yoo, if -- Plaintiffs have said they have not done
5 this, but if Plaintiffs, hypothetically, had alleged in the
6 alternative a narrow theory with only one thing wrong with
7 Ranitidine, the expiration date, what then?

8 *MR. YOO:* Well, putting aside for the moment, your
9 Honor, our argument about under Buckman, and some of the things
10 that they are alleging being major changes that we could not
11 independently do --

12 *THE COURT:* Let's just take expiration date.

13 *MR. YOO:* I would say this, your Honor. If the
14 Plaintiffs -- the Plaintiffs would have to concede and make it
15 very clear that, as to the generics, no Ranitidine made
16 pursuant to an ANDA is defective, could not have caused the
17 Plaintiffs' cancers and could not be a basis for liability
18 against the generics.

19 *THE COURT:* Is that really a pleading issue, though,
20 or is that a factual question, you know, for another day?

21 I am just talking about pleading right now.

22 *MR. YOO:* I believe it is both because Mr. Keller, for
23 example, made clear today that they have pled it because they
24 view it as absolutely relevant and they intend to present
25 evidence on all of this at the time of trial.

1 I think the pleadings would have to make clear that
2 the Plaintiffs are limiting their claims against the generics
3 solely to cancers that they could prove were caused by some
4 additive level of NDMA associated with an expiration date
5 beyond the two months, or whatever it is that they were
6 positing the other day, and that these Plaintiffs would not
7 otherwise have gotten cancer.

8 Unless they are going to limit themselves to that, all
9 they are doing is taking claims that are clearly preempted
10 under Mensing and Bartlett, tacking on, in the words of the
11 Guarino Court, an additional garb, and saying that those
12 preempted claims are no longer preempted and they can present
13 evidence on all of it at the time of trial.

14 *MR. KELLER:* Your Honor, can I respond? Because it
15 actually may be useful to limit some of the issues between us.

16 *THE COURT:* Okay. Wait. It's Mr. Keller.

17 *MR. KELLER:* I'm sorry, Ms. Stipes.

18 I actually agree with Mr. Yoo, for our expiration date
19 claims only -- let's not think about packaging and failure to
20 warn the FDA. For our expiration date claims, we have to prove
21 that because of the negligent or strict liability improper
22 expiration date, the amount of NDMA that that particular
23 Plaintiff was exposed to caused his or her cancer. So, we
24 completely agree with that.

25 But there is a difference under the law for what the

1 duty is, which is the subject of preemption inquiry, and what
2 evidence is admissible in a trial proceeding, which is not the
3 subject of a 12(b)(6), this is not a Motion in Limine, but what
4 evidence are we allowed to submit to show that the generics
5 breached their duty and had too long of an expiration date.

6 So, conflating the evidence that we are allowed
7 to present ultimately to the trier of fact, and you may decide
8 that we are not allowed to present as much as we think we
9 should be able to present, that is absolutely a question for a
10 different day.

11 We agree with Mr. Yoo on what we are going to
12 ultimately have to prove for these claims. We don't agree that
13 we have to excise from our complaint all of the knowledge that
14 the generics had because we think those are factually relevant
15 pieces of information that would go into how they are supposed
16 to set the expiration date.

17 *THE COURT:* Why did you limit your agreement with Mr.
18 Yoo just to expiration? What about the other two?

19 *MR. KELLER:* Only to make sure linguistically I said
20 it the right way. For, for example, the blister packs claim,
21 we would agree that for that count that Plaintiff, in order for
22 her to recover, would have to show that the amount of NDMA that
23 she was exposed to was the legal cause of her cancer because
24 the generics failed to comply with their duty to use blister
25 packs.

1 So, for each of the claims that we are alleging
2 against the generics, we would limit it in that same principled
3 way.

4 *THE COURT:* Mr. Yoo, putting aside evidentiary
5 rulings, Motions in Limine, what evidence comes in at trial, if
6 Mr. Keller is agreeing that the intent of the pleading -- now,
7 we are talking about in the alternative right now, because that
8 was my hypothetical. I will pivot in a moment.

9 But let's assume a world in which these claims against
10 the generics are pled in the alternative, and all that Mr.
11 Keller is actually agreeing would be put to the jury,
12 regardless of what evidence comes in, is did the failure to
13 short -- the failure to shorten the expiration date caused the
14 Plaintiff to have cancer, and that is the claim against the
15 generic.

16 Is there a preemption argument there?

17 *MR. YOO:* There is, your Honor, because I don't think
18 the Plaintiffs could survive the pleading motions because they
19 still have the problem with their allegation that all
20 Ranitidine to some extent turns into NDMA in the body, and that
21 is the nature of Ranitidine, which was approved by the FDA, and
22 we were given ANDAs to make that very molecule.

23 So, how could we be charged with liability for making
24 a drug that we were authorized to make which is, because of its
25 nature, the basis of the Plaintiffs' allegation that it exposed

1 users to cancer?

2 *THE COURT:* Right. I guess I am focused on, for
3 preemption purposes, what it is that the Plaintiffs in this
4 world of an alternative theory of pleading -- let's even assume
5 for a moment that there aren't allegations that -- or facts
6 that come in, evidence that comes in as to what happens in the
7 stomach when it is mixed with nitrates, you know, whatever it
8 is that ultimately is presented to the Court as to the
9 evidence, the science behind why it is an expiration date
10 causes cancer. It is not before the Court today, so I am not
11 going there.

12 But, you know, this is like a one count complaint,
13 let's pretend it is a one count complaint against the generics,
14 and the allegation is that the generics were negligent because
15 they didn't change the expiration date, and it would be -- you
16 know, the Plaintiffs would have to prove that. They would have
17 to eventually get past Daubert and whatever it is to be able to
18 get to a jury to make the case that it was the expiration date
19 and the expiration date only that caused the cancer.

20 *MR. YOO:* Your Honor, I would say if that is the
21 narrow path that the Plaintiffs are going to be permitted to
22 walk, then that should be made clear in the pleadings, because
23 the pleadings currently are the exact opposite of that.

24 *THE COURT:* We can put that aside and I didn't say
25 permitted. I am not saying anything. I want to know what your

1 legal position is on that. This is all about preemption, so I
2 just want to understand, because it really wasn't briefed. So,
3 what is the legal position of the generics in that world?

4 *MR. YOO:* We are, obviously, talking about
5 hypotheticals here. I think we would have to look at that, but
6 if what you are saying is the Plaintiffs would not be able to
7 plead anything related to the nature of Ranitidine, which was
8 approved by the FDA, and we were allowed to make with our
9 ANDAs, and that it was a stand-alone cause of action based
10 solely on an allegation that an expiration date should have
11 been X months as opposed to Y months, then we would have to
12 look at that, and perhaps there is an Iqbal/Twombly challenge
13 to be made on plausibility, but we would have to assess that
14 separately.

15 *THE COURT:* Right.

16 *MR. YOO:* That is, obviously, not what we are
17 presented with currently.

18 *MR. GUGERTY:* Your Honor, this is Sean Gugerty for the
19 generics. May I be heard very briefly on this point to
20 elucidate something that was in our briefing?

21 *THE COURT:* Yes.

22 *MR. GUGERTY:* Thank you, your Honor. As I understand
23 your Honor's hypothetical, it's a one-count complaint on
24 expiration dates, and in the alternative to everything else.
25 If the Plaintiffs included the allegations about notice as part

1 of that complaint, notice from --

2 *THE COURT:* Somebody has their audio on who should
3 not. If you could please turn it off. Thank you.

4 *MR. GUGERTY:* If the generics were on notice
5 that Ranitidine has a propensity to degrade based on its very
6 molecular structure, as Plaintiffs have consistently alleged,
7 and the state law duty is a negligence for failure to warn,
8 there is no such thing, your Honor, as just a negligence for
9 failing to have expiration dates, and to create such a
10 claim would contravene Erie.

11 *THE COURT:* Mr. Keller has acknowledged there is no
12 such thing.

13 *MR. GUGERTY:* Right. If the Plaintiffs' one-count
14 complaint included any allegations about notice of Ranitidine's
15 molecular structure, anything about its propensity to degrade,
16 anything about --

17 *THE COURT:* Well, what if their argument was that was
18 relevant to the expiration date? All they were going to argue
19 is the expiration date, but we are not making Motions in Limine
20 rulings today, or at the pleading stage, nor should you be
21 expected to make such arguments, but point well taken. I think
22 maybe there is an argument that the Plaintiffs can make that
23 some of this stuff is relevant to how you get to being able to
24 present to a jury why the expiration date should be shortened.

25 Suffice it to say that if the claim is just about the

1 expiration date, the Court should be allowing only that
2 evidence which the Plaintiffs have successfully argued to the
3 Court is relevant and, you know, not unduly prejudicial to make
4 the claim to the jury.

5 *MR. GUGERTY:* Of course, your Honor. The basic point
6 I was trying to make is that, based on the jury instructions
7 and other information that the Plaintiffs recently submitted in
8 response to your Honor's supplemental order, the duty is to
9 warn of all the risks that we knew about.

10 Of course this is a factual matter and would depend,
11 as Mr. Yoo was just saying, would depend on the nature of what
12 was pleaded. It is a little hard to discuss in the abstract,
13 but the point that I was trying to make is that I think it
14 would take a very strangely constructed complaint to create a
15 universe where the only fact, the only risk that we knew of and
16 the only warning that we had to give would be consume this a
17 little bit more quickly. It would sort of go completely
18 contrary to the entire theory of this case from its very
19 inception.

20 That was why I wanted to stand up and make that point.
21 Perhaps I should sit down.

22 *THE COURT:* No, no, that is fine. I don't think that
23 is, you know, a point that is escaping any of us, and I think
24 maybe, Mr. Keller, that is one of the problems.

25 The complaint began one way, the Court made certain

1 rulings and, you know, to the Plaintiffs' credit, they took
2 advantage of the ability to replead and have tried to find a
3 way to replead that is consistent with the Court's rulings and
4 the law as the Court has interpreted the law, but certain
5 aspects of the complaint really haven't changed, certain
6 fundamental allegations about the nature of Zantac, the
7 molecule, the causation theories of cancer.

8 In fact, they didn't necessarily need to change for
9 certain Defendants, like the brands, so it is not surprising
10 that they didn't change, but we do have the brands and the
11 generics together in the complaints, and that may be what is
12 causing such -- so many challenges, I suppose, is that there is
13 a lot in there. There were labeling charges initially and
14 allegations of design defect, and much went away, but it is
15 kind of like the essence of the dangers and the safety risks
16 are still there.

17 And then again, when you go back to sort of
18 negligence, you think of the duty to use -- a reasonable
19 manufacturer using ordinary -- reasonable care -- it is late in
20 the day, so I am getting my reasonable and my ordinary -- duty
21 to use ordinary care, so it is kind of a hard concept to --
22 maybe this is where the Court is struggling and the generics
23 are struggling.

24 How are they expected to, you know, meet the duty, the
25 common law duty with the common law jury instruction, the

1 pattern jury instruction on an expiration theory only, let's
2 say? We are in the world now of just the expiration date.

3 *MR. KELLER:* I totally understand your Honor's
4 question. Trust me, I know that the amended master personal
5 injury complaint has a lot of information, and it is not a tiny
6 document. So, I acknowledge that.

7 A couple of points. As a technical point, I think it
8 is important to forget what transpired before, there is only
9 one operative complaint before your Honor, it is the amended
10 master personal injury complaint. That is what the Defendants
11 have moved to dismiss.

12 We did take very seriously your Honor's previous
13 orders, so they can't point to theories that existed in an old
14 document that is no longer operative. We have to take the
15 amended master personal injury complaint on its own terms.

16 To the pattern jury instruction point, again, we
17 recognize that the common law is broader than all of the things
18 that the generics could actually do, and I think limiting
19 instructions or modifications to those pattern instructions
20 would be appropriate to make sure that the Plaintiffs can only
21 obtain a recovery from a jury based on a permissible
22 non-preempted theory.

23 But I keep hearing that we shouldn't be allowed to
24 plead against them that they knew that Ranitidine was
25 dangerous, and they knew how it breaks down, and again, I

1 appreciate that this is not a Motion in Limine, and I
2 definitely don't want to convert it into one, but just thinking
3 about how a manufacturer would set the expiration date for any
4 product, a drug or something else, how would they do that if
5 they don't know about the nature of the product?

6 If they are not charged with knowledge about how the
7 product works and degrades over time -- some of those factual
8 allegations have got to be relevant for the expiration dating
9 duty, and there, in this Motion to Dismiss, is no dispute that
10 the generics could have changed the expiration date consistent
11 with the duty of sameness.

12 So, my friends on the other side keep bringing up
13 Mensing, but they don't actually have the courage of their
14 convictions. They are not arguing anymore that they couldn't
15 have changed expiration date, so Federal law is off the table.

16 The only question is state law, and under state law,
17 we think that the common law incorporates through reasonable
18 behavior the obligation to behave as a reasonably prudent
19 person would, putting an accurate expiration date on your
20 label. They have to know something about Ranitidine to set the
21 expiration date.

22 I don't know how in any product you could say that you
23 have to put an expiration date on it, but you don't have to
24 know anything about how the product works or degrades. That
25 doesn't make any sense.

1 *THE COURT:* So, for example, in Florida, the jury
2 instruction 401.4 on negligence reads "Negligence is the
3 failure to use reasonable care, which is the care that a
4 reasonably careful person would use under like circumstances.
5 Negligence is doing something that a reasonably careful person
6 would not do under like circumstances, or failing to do
7 something that a reasonably careful person would do under like
8 circumstances."

9 So, let's say the jury has read that jury instruction
10 in Florida on the negligence claim and the argument that the
11 Plaintiffs are making, based on their pleadings, so they would
12 be limited to what they pled, and let's just say this world of
13 the one-count expiration date, that is what you are arguing to
14 the jury as why the generics failed to use reasonable care, but
15 at the same time, maybe if you are successful in your Motion in
16 Limine practice, all of this other evidence comes in about how
17 Ranitidine works, and the jury comes back and finds that the
18 Plaintiffs -- the Defendants were negligent.

19 How would we know that the jury was basing their
20 finding of negligence on a non-preempted reason as opposed to a
21 preempted reason when they are hearing a lot of other things,
22 and then particularly if the generics are being tried with the
23 brands? Look, most Courts don't look for ways to sever cases.

24 *MR. KELLER:* Plaintiffs don't typically like that
25 either, your Honor.

1 *THE COURT:* They do it in certain situations, but it
2 is not the norm. So, how could the generics be assured that
3 they weren't being found negligent for preempted activity,
4 because they are hearing about these things and they are maybe
5 thinking to themselves, gee, why didn't they put a warning on
6 there at a minimum, or why did they let it go off into the
7 shipment process knowing what heat and humidity can do? Why
8 did they design it this way?

9 *MR. KELLER:* That is a completely fair question and
10 the generics would be entitled to raise it. And again, we are
11 not at the jury instruction phase, and as you know, the law
12 would say they have a duty to propose limiting instructions and
13 there would be a whole process.

14 What I would suggest to your Honor is look at Bates,
15 which specifically talks about this in the preemption context
16 and says that limiting instructions are appropriate. I didn't
17 have the Florida instructions at my fingertips, but they are
18 very similar to the instructions that you see for negligence in
19 other cases.

20 So, what I would say off the cuff to your Honor, not
21 turning this into a jury instruction exercise, is after reading
22 those instructions verbatim, you would then say if you were the
23 trial court judge, and I am instructing you as a matter of law
24 for reasons that you don't need to know about that the only
25 way, in your hypothetical, your Honor, where we have only

1 brought the expiration date claim, for example, the only way
2 that the Plaintiffs can recover is if you find that the
3 generics breached their duty because the expiration date on the
4 product was too long, and that was their failure to engage in
5 reasonably prudent behavior.

6 If you find that they were not reasonably prudent for
7 any other reason, you must return a Defense verdict.

8 You wouldn't say it exactly the way I did, there would
9 be more careful back and forth to make sure that that language
10 was accurate, but that is what I would envision. All the
11 evidence that you referred to that could be prejudicial, you
12 know, we would try, as Plaintiffs do, to get everything in, and
13 you would say you have to put in only these things, but we
14 would be allowed to put in evidence that showed that the
15 generics should have had a shorter expiration date and that
16 they had enough information to shorten their expiration dates.

17 We don't have to argue anymore about exactly what the
18 contours of that are, but I still would submit to you that it
19 has to be something, they have to be charged with knowledge of
20 how Ranitidine works and degrades and how it operates in order
21 to set an expiration date.

22 And by the way, the FDA presumes that ANDA holders,
23 just as much as NDA holders, have that information. That is
24 why they are allowed to have separate and shorter expiration
25 dates from the reference list of drugs. So, we are not

1 conjuring this out of thin air; the Federal regulatory
2 landscape requires them to have this sort of information.

3 *THE COURT:* Just back to in the alternative, you
4 haven't plead in the alternative. You said you could or you
5 would, if need be. What do you think, given this discussion --
6 and then I will turn this question to the Defense -- the result
7 of pleading in the alternative versus not pleading in the
8 alternative has on the topic of preemption and -- I am hearing
9 you say each independent theory stands on its own and supports
10 a breach of a duty that causes cancer.

11 It is not as if you would be seeking multiple
12 recoveries for a claim. So I am trying to understand, is there
13 prejudice to the Plaintiffs to plead in the alternative? And
14 then I am wondering whether it is the Plaintiffs or the Defense
15 who answers this question. What does pleading in the
16 alternative do or not do to address the preemption issues we
17 have been discussing?

18 Maybe Plaintiffs first and then Defense.

19 *MR. KELLER:* Sure, your Honor. Let me start with the
20 preemption question. Whether we plead in the alternative or
21 not I think has no bearing on preemption. The claims that we
22 allege against the generics, your Honor will either find that
23 they are impossible or expressly preempted, or you won't.
24 Hopefully you will say that all of the ones we pleaded against
25 the generics are not preempted because that is what we think is

1 supported by the law.

2 But whether they can comply with their state duties
3 and their Federal duties simultaneously, that is a pure
4 question of law for the Court and it doesn't depend on whether
5 we are offering these as alternative theories.

6 The pleading in the alternative I think goes to the
7 element of causation. To the extent that your Honor believed
8 that the only plausible way for us to recover would be to say
9 it was either the expiration dates or the blister packs, but
10 not both, that is a causation issue, and respectfully, I don't
11 think that issue has been briefed by the other side because
12 this is a preemption argument. So, I think that they would
13 agree with us that the alternative issue is not a preemption
14 concern.

15 If you did want briefing on that, we would show your
16 Honor that the law of many states says that where there are
17 more than one cause of an injury, each one of which is
18 sufficient to provide enough exposure to, for example, a cancer
19 causing compound to cause a Plaintiff's cancer, each one of
20 those is independently actionable.

21 That is a pure question of state law. We could get
22 into the restatement, it is Restatement Third of Torts,
23 physical harm, Section 27, comment D and comment G, and many
24 states have adopted that. I don't think that that is an
25 inquiry that we need to go into further here because it is not

1 properly teed up before your Honor.

2 *THE COURT:* Okay. From the Defense.

3 *MR. YOO:* Your Honor, I think it is clear from
4 everything that has been said and the allegations that
5 Plaintiffs have made that it is not possible for any Defendant
6 to meet the alleged duty of reasonable care to ensure that
7 consumers are not exposed to the alleged inherent risk of
8 Ranitidine regarding a carcinogenRanitidine and cancer through
9 expiration dating. Even Mr. Keller stated during this argument
10 that an expiration date is not a cancer warning.

11 So, I think the Court can make the conclusion under
12 Mensing, and Mensing looked at what it would take to satisfy
13 the alleged state law requirement, and what would a Defendant
14 have to do to avoid liability.

15 I think the Court could look at everything that has
16 been presented to the Court and make the determination that it
17 is impossible through expiration dating to meet this alleged
18 duty of reasonable care to ensure that people are not exposed
19 to the risk of cancer with regard to a drug that is alleged to
20 inherently turn into a carcinogen in the human body.

21 *THE COURT:* Okay. Let me just -- I have a couple of
22 questions here. Plaintiffs, you mention on page 20 of your
23 opposition to the motion the generics' ability to satisfy a
24 portion of the duty. You say Plaintiffs only allege the duty
25 or a portion of the duty that could be satisfied.

1 What did you mean when you said "a portion of the
2 duty?"

3 *MR. KELLER:* This is the part of my previous answer,
4 your Honor, when I said that state common law typically
5 announces the duty at a high level of generality and then
6 basically creates different sub duties for the specific facts
7 and circumstances. That is what we meant by a portion of the
8 duty.

9 Behave as a reasonably prudent person would in
10 particular circumstances is going to impose a lot of different
11 duties on a manufacturer of a pharmaceutical product, of which
12 expiration dating and proper packaging are two examples, but
13 they are not the only examples.

14 *THE COURT:* Thank you. You mentioned reducing risks
15 and reducing the danger, for example, on pages 14 and 15 of
16 your opposition where you say they could have done something,
17 reduced risks and saved lives, and you say these simple
18 measures would have reduced the danger.

19 Are you arguing that any state imposes a duty on drug
20 manufacturers to, for example, reduce the risk or mitigate
21 harm, or is it your position that a state imposes such a duty,
22 you know --

23 *MR. KELLER:* Yes, your Honor.

24 *THE COURT:* Have you pled that?

25 *MR. KELLER:* I think that states requiring parties

1 like the Defendants to behave reasonably requires them to take
2 action that reduces risk, even if they can't eliminate it
3 entirely. So I think that is completely compatible with state
4 law, what a reasonable person would do.

5 *THE COURT:* So, that is also under the ordinary
6 negligence standard?

7 *MR. KELLER:* Yes, your Honor. I think ordinary
8 negligence law would impose that obligation.

9 *THE COURT:* So, just to reduce the risk, but not to
10 get rid of it altogether?

11 *MR. KELLER:* Yes, your Honor. I think there are lots
12 of circumstances where you can't completely eliminate risk, and
13 state law would then say reduce it.

14 *THE COURT:* Does Defense have a response?

15 *MR. YOO:* Your Honor, that is not any law the
16 Plaintiffs have cited. Even the things we have looked at
17 during the hearing, everything from the jury instructions to
18 what Plaintiffs have alleged is a duty on the generics,
19 according to the Plaintiffs, is avoid, prevent, make sure
20 consumers are not subjected to the risk of an unreasonably
21 unsafe product. No one gets a pass because they tried and
22 mitigated some of the risk.

23 The test is whether a Defendant acted reasonably and
24 prevented a Plaintiff from being subjected to an unreasonable
25 risk.

1 This takes us right back to Mensing, your Honor. The
2 test is what must we have done to avoid liability, to eliminate
3 that risk to the Plaintiffs altogether, not simply to reduce
4 (inaudible) -- mitigate some of the alleged harm.

5 *MR. KELLER:* Your Honor, can I offer a very simple
6 example that used to be the sort of thing that was in the
7 pattern complaint in the Federal rules before Iqbal and
8 Twombly?

9 *THE COURT:* Yes.

10 *MR. KELLER:* Imagine someone is driving and they are
11 speeding, and then they swerve into my lane without using their
12 blinker and they cause me injury. I can sue them for breach of
13 their duty under common law negligence for not using their
14 blinker. I don't also have to sue them for speeding as my
15 theory of recovery, even though they were also speeding, and
16 that would also be a breach of the common law duty.

17 This is ordinary practice in State Court, Plaintiff
18 gets to choose the theories of recovery that they are going to
19 pursue, and preemption doesn't change that.

20 The entire cause of action from negligence in that
21 hypothetical wouldn't fall away because I didn't also sue for
22 speeding.

23 *MR. GUGERTY:* Your Honor, may I briefly be heard in
24 response to this? Sean Gugerty on behalf of generics.

25 *THE COURT:* Yes.

1 MR. GUGERTY: I do agree that Plaintiffs get to choose
2 the causes of action that they bring under state law, but I
3 don't think -- and I believe that Erie stands for the
4 proposition that neither this Court nor the Plaintiffs, through
5 the type of judicial admission that they offer in their brief
6 that your Honor was asking about just a moment ago, can rewrite
7 what those duties would be within a particular cause of action.

8 I think that is effectively what Mr. Keller is
9 proposing with some of his reconstruction of just expiration
10 date count that is completely divorced from the underlying duty
11 to warn, or just change storage and transport practice, that is
12 divorced from the duty to deliver a reasonably safe product.

13 I don't believe that the Plaintiffs have shown in
14 their AMPIC, in their pleading -- excuse me, in their briefing
15 to this Court, or in their supplemental responses to this
16 Court's order that there is any state that recognizes a duty
17 just to reduce harm.

18 I think, in fact, that several of the jury
19 instructions and cases submitted in response to your Honor's
20 supplemental order are directly to the contrary of that. The
21 duty is -- for the failure to warn is to warn of all of the
22 risks, as one of the Plaintiffs' cases say, or to deliver a
23 product that is safe from any latent dangers, as another case
24 stated.

25 Thank you, your Honor.

1 *THE COURT:* Thank you. Okay. Plaintiffs, generic
2 Defendants argue on page 31 and 32 of their Motion to Dismiss
3 that all of the claims against them in the ELC are necessarily
4 preempted if the claims against them in AMPIC are preempted.

5 Do you agree with that?

6 *MR. KELLER:* I believe I do, your Honor.

7 *THE COURT:* Your claims against the generic Defendants
8 in the ELC for OOTC products are based on improper expiration
9 dates and product containers.

10 When it comes to express preemption under 379r, do you
11 maintain that the expiration dates and product containers
12 rendered Ranitidine products misbranded?

13 *MR. KELLER:* I would maintain, your Honor, certainly
14 that the expiration date rendered the product misbranded
15 because the label would be false or misleading in any
16 particular.

17 *THE COURT:* What about product containers?

18 *MR. KELLER:* Based on your Honor's previous order
19 which limited the scope of misbranding to just the label, I
20 think I would have to concede that the product container is not
21 the label itself, and so the product container would not count
22 to satisfy the misbranding definition.

23 *THE COURT:* Anything that Defense wanted to say in
24 response to any of the last answers?

25 *MR. YOO:* No, your Honor.

1 *THE COURT:* Okay. All right. Here is what I am going
2 to do. I think that it is a good time to conclude for today
3 because I think we've gone over a lot, and in fairness, I want
4 to give you a break because it has been a long time that you
5 have been on call to answer my questions.

6 You have been patient and I appreciate that, and I
7 think that some things have come up that maybe hadn't really
8 been delved into, you know, in the four corners of your
9 briefing, and maybe much prompted by the Court's question.

10 I had asked the parties, all parties, to keep the
11 Monday open in case the Court had any followup questions, and I
12 think what I would like to say at this point is, really,
13 actually only as to this last motion might the Court -- might
14 the Court have followup questions for Monday.

15 There are no other counsel for any other parties, for
16 any other motions, in other words, that need to be on standby
17 for Monday, but I would like to ask all counsel who have been
18 responsible for arguing this last motion of the day, the
19 generic motion, if you could be available beginning at one
20 o'clock on Monday.

21 I will endeavor to try to get word as soon before then
22 if I know that we are not going to need to have you come back
23 to answer any questions.

24 We would be using the same Zoom link because that was
25 already part of the plan, and that was already set out, so

1 nothing new, same instructions.

2 I just think it would be a good idea to take a break
3 now and I would just hate not to have you on standby, and then
4 there is a question or two that I wanted to get clarification
5 on and I didn't have the opportunity to do so. By the same
6 token, it may be that you have exhausted the topics that I
7 wanted to cover and there will be no need.

8 Does that sound like an acceptable plan to counsel?

9 *MR. KELLER:* Yes for Plaintiffs, your Honor

10 *MR. YOO:* And for the generics as well. Thank you,
11 your Honor.

12 *THE COURT:* Okay. Assume you will log on at 1:00,
13 until or unless I communicate, in all likelihood through the
14 special master, that it won't be necessary. Okay?

15 *MR. YOO:* Yes, your Honor.

16 *MR. KELLER:* Yes, your Honor.

17 *MR. YOO:* Thank you very much.

18 *THE COURT:* Okay, thank you all. That will conclude
19 our hearing for the day. Everybody have a very nice weekend.

20 Again, for those who argued today, thank you, and
21 everybody did a very, very good job, I appreciate it. I
22 appreciate the patience and time that has been devoted to
23 arguing the motions that I know has taken a lot of time over
24 these last two days.

25 Thank you, and have a great weekend.

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(Thereupon, the hearing concluded.)

* * *

I certify that the foregoing is a correct transcript
from the record of proceedings in the above matter.

Date: June 10, 2021

/s/ Pauline A. Stipes, Official Federal Reporter

Signature of Court Reporter

<p>MR. BARNES: [5] 126/21 126/25 127/6 127/8 136/12</p> <p>MR. GUGERTY: [11] 130/25 156/17 156/21 158/3 190/17 190/21 191/3 191/12 192/4 204/22 204/25</p> <p>MR. KAPLAN: [6] 66/13 66/19 80/4 80/7 84/8 95/15</p> <p>MR. KELLER: [63] 10/13 10/17 12/8 21/22 28/15 28/19 42/24 44/8 44/19 46/17 47/6 142/7 142/13 142/16 156/13 158/25 159/6 159/9 160/1 160/8 160/15 160/18 160/21 161/8 161/10 162/6 162/23 163/10 163/16 163/23 164/12 165/24 168/9 168/19 170/15 171/14 171/21 172/23 174/18 175/11 178/4 178/10 178/22 180/15 186/13 186/16 187/18 194/2 196/23 197/8 199/18 202/2 202/22 202/24 203/6 203/10 204/4 204/9 206/5 206/12 206/17 208/8 208/15</p> <p>MR. LONGER: [8] 73/12 73/14 73/17 79/3 79/21 91/25 92/4 94/4</p> <p>MR. SNIDOW: [26] 53/25 54/4 54/9 81/19 81/22 82/5 82/8 82/10 82/12 82/14 82/21 82/23 83/8 83/18 83/22 85/15 86/9 87/7 87/24 88/9 88/15 88/19 89/3 91/8 96/9 96/11</p> <p>MR. YOO: [19] 166/2 166/5 166/19 176/24 182/25 183/14 185/7 185/12 185/21 188/16 189/19 190/3 190/15 201/2 203/14 206/24 208/9 208/14 208/16</p> <p>MS. EISENSTEIN: [23] 3/17 3/24 4/1 9/14 22/1 26/7 27/21 29/22 29/25 31/9 32/10 33/15 34/10 34/16 35/7 36/5 37/4 39/1 40/1 40/15 42/3 42/11 47/8</p> <p>MS. FEGAN: [32] 100/16 100/21 100/23 108/19 109/5 109/13 109/21 110/10 110/18 111/7 111/17 111/20 112/5 113/6 114/13 115/13 116/14 117/14 117/18 118/18 118/24 119/4 119/22 120/9 120/21 122/1 122/4 122/9 124/20 124/22 125/21 126/10</p> <p>MS. JOHNSTON: [19] 48/5 48/11 62/20 64/12 64/15 65/14 65/18 84/19 87/18 94/14 97/16 97/22 97/24 98/2 98/6 98/11 106/4 122/13 126/9</p> <p>THE COURT: [199] 2/21 3/22 3/25 9/13 10/9 10/16 12/5 21/21 21/24 25/6 27/15 28/17 28/20 29/24 31/3 32/2 33/12 34/7 34/14 35/5 36/2 36/17 38/16 39/18 40/8 41/24 42/5</p>	<p>42/15 44/4 44/10 46/11 46/23 47/7 47/9 48/10 53/21 54/2 54/8 62/18 63/23 64/14 65/9 65/16 66/7 66/18 73/8 73/13 73/16 79/2 79/20 79/24 80/5 81/12 81/21 81/24 82/6 82/9 82/11 82/13 82/15 82/22 83/1 83/13 83/20 84/3 85/14 86/3 87/3 87/17 88/1 88/10 88/17 89/1 89/4 92/2 93/21 94/13 95/14 96/8 96/10 97/4 97/18 97/23 97/25 98/4 98/10 100/14 100/20 100/22 106/2 108/9 109/2 109/6 109/14 110/8 110/11 111/4 111/8 111/18 112/1 113/2 113/24 115/8 116/8 117/11 117/17 118/17 118/22 119/1 119/15 120/6 120/10 121/23 122/3 122/7 122/10 124/19 124/21 125/19 126/7 126/11 126/23 127/5 127/7 130/24 142/5 142/12 142/15 156/12 156/15 156/19 158/2 158/4 159/2 159/8 159/24 160/2 160/10 160/16 160/19 160/22 161/9 162/4 162/7 162/12 163/7 163/14 163/18 164/7 165/18 166/3 166/9 168/16 170/7 171/12 171/15 172/10 173/22 174/22 176/21 177/12 178/9 178/11 178/23 182/24 183/9 185/1 185/11 185/18 186/15 187/16 188/3 189/1 189/23 190/14 190/20 191/1 191/10 191/16 192/21 195/25 196/25 199/2 201/1 201/20 202/13 202/23 203/4 203/8 203/13 204/8 204/24 205/25 206/6 206/16 206/22 206/25 208/11 208/17</p> <hr/> <p>.</p> <p>.1 [1] 91/5 .10 [1] 23/5 .14 [1] 23/5</p> <hr/> <p>/</p> <p>/s [1] 209/7</p> <hr/> <p>1</p> <p>10 [11] 14/18 75/3 87/23 90/1 108/18 110/8 110/10 160/8 161/6 178/13 209/6</p> <p>1001 [1] 2/3 1019 [1] 1/17 104 degrees [1] 69/21 1050 [1] 1/19 1058 [1] 131/22 107-23 [1] 85/14 108-5 [1] 85/14 11 [6] 132/25 133/6 152/23 160/8 161/7 178/13</p> <p>1113 [1] 138/18 1127 [1] 157/23 1150 [1] 132/5 1162 [1] 131/14 1167 [1] 131/25</p>	<p>12 [8] 3/9 34/22 72/1 126/13 152/20 164/5 175/14 187/3 1245 [1] 140/15 12:24 [2] 97/8 97/8 13 [2] 10/10 53/24 1329 [2] 21/8 150/2 1330 [1] 21/11 14 [3] 72/18 118/13 202/15 1407 [1] 18/10 1408 [1] 156/12 1412 [1] 18/20 15 [9] 3/14 18/4 19/15 21/21 21/22 71/17 85/13 156/10 202/15 150 [3] 1/13 1/16 138/7 1500 [1] 80/16 16 [2] 67/14 96/7 169 [1] 57/12 17 [5] 71/17 146/25 148/11 148/12 148/24 18 [2] 51/11 89/14 1906 [1] 144/17 19103 [1] 2/7 19106 [1] 1/23 1968 [7] 82/9 82/10 83/14 87/21 87/21 88/5 88/8 1993 [1] 13/25 1:00 [1] 208/12 1:25 [2] 97/9 97/16</p> <hr/> <p>2</p> <p>20 [5] 67/11 73/9 80/7 156/13 201/22 20-md-02924-ROSENBERG [1] 1/3 2000 [1] 177/18 20004 [1] 2/3 20006 [1] 1/20 2004 [2] 138/19 154/6 202-624-2500 [1] 2/4 2020 [1] 85/13 2021 [2] 1/5 209/6 2029 [1] 2/16 207.1 [1] 106/9 21 [16] 13/5 16/10 23/4 26/2 29/17 31/12 42/20 106/9 119/6 119/8 126/2 126/3 131/22 136/2 153/9 153/15 210.1 [1] 119/6 211.142 [1] 119/8 21202 [1] 2/10 213-896-2400 [1] 2/14 215-656-3307 [1] 2/7 218 [1] 57/12 22 [1] 51/11 220 [1] 118/15 2220 [1] 64/3 224 [1] 78/12 23 [4] 85/14 126/17 126/19 126/24 24 [3] 69/22 79/18 175/5 2400 [1] 2/14 2446 [1] 152/23 2449 [1] 152/23 2453 [1] 133/6 2461 [1] 178/16 25 [1] 52/8 2500 [1] 2/4</p>
---	---	---

2	474 of [1] 72/11 475 [1] 73/1 482 [1] 137/21 490 [1] 137/17 492 [1] 137/17 496 [1] 137/8	969 [1] 110/18 971 [1] 110/18 99.9 percent [2] 90/11 94/24
2512 [2] 104/1 129/5 2513 [2] 100/11 103/7 2515 [1] 104/10 252 [2] 26/3 42/20 27 [1] 200/23 2725 [1] 73/4 28 [1] 118/14 2924 [1] 3/3	5	A
3	50-state [1] 161/25 500 [2] 1/20 1/22 5000 [1] 2/6 504 [1] 84/14 505 [1] 84/14 510 [1] 1/22 52 [1] 177/14 5222 [1] 1/14 524 of [1] 156/6 531 [1] 20/1 544 [1] 11/18 55 [1] 31/6 564 [1] 135/4 570 [1] 137/16 575 [1] 31/6	a colder [1] 152/6 a complaint [1] 80/23 a Deceptive [1] 12/3 A did [1] 58/5 a flat-out [1] 8/12 a variant [1] 5/9 a viable [1] 71/18 AA [1] 101/23 AAA [1] 101/23 abandon [1] 89/18 abandoned [1] 4/9 abbreviated [1] 93/10 abilities [1] 123/17 ability [7] 9/24 57/5 58/9 123/2 124/3 193/2 201/23 able [15] 31/4 33/5 48/1 80/4 94/25 95/8 95/24 96/7 96/20 125/21 166/17 187/9 189/17 190/6 191/23 abortion [1] 146/9 about [120] 11/8 19/3 21/2 22/5 23/3 23/6 23/21 25/15 28/2 29/7 33/24 36/24 37/11 41/9 44/13 48/9 49/16 52/4 56/21 58/1 61/19 61/19 69/3 69/12 71/2 73/9 74/7 74/12 75/20 76/14 83/3 86/8 90/24 92/16 95/12 97/8 97/9 100/25 100/25 101/1 102/8 111/16 113/7 115/6 116/10 117/20 119/6 119/8 121/9 123/19 127/25 129/8 132/1 132/12 139/8 139/18 139/21 142/6 144/3 145/14 149/16 150/15 152/17 154/19 155/5 155/7 155/12 155/14 155/16 155/24 156/16 164/14 167/3 168/23 169/8 169/17 169/25 170/1 170/13 171/7 173/17 174/24 174/24 174/25 175/25 176/6 177/4 179/8 180/3 180/11 180/23 180/24 183/16 184/9 185/9 185/21 186/19 187/18 188/7 190/1 190/4 190/25 191/14 191/15 191/16 191/25 192/9 193/6 195/3 195/5 195/6 195/20 195/24 196/16 197/4 197/15 197/24 198/17 205/6 206/17 above [1] 209/4 absence [2] 24/21 30/14 absent [3] 38/12 145/21 146/11 absolute [2] 85/24 86/1 absolutely [8] 49/24 166/1 170/16 176/9 177/7 184/24 185/24 187/9 abstract [1] 192/12 absurd [1] 150/21 absurdity [1] 152/2 accept [2] 107/13 140/22 acceptable [3] 76/8 76/17 208/8
30 [3] 68/24 70/7 167/14 300 [1] 2/16 31 [1] 206/2 310-284-3798 [1] 2/17 310.1 [1] 23/5 3105 [1] 126/15 3107 [3] 47/19 66/10 66/16 3112 [1] 47/16 3113 [1] 97/20 3114 [1] 3/13 312-741-1019 [1] 1/17 312-741-5222 [1] 1/14 314.170 [1] 16/10 314.70 [4] 136/3 153/10 153/16 154/2 31st [1] 50/15 32 [1] 206/2 3200 [1] 67/7 330 [1] 29/17 330.10 [1] 29/17 3307 [1] 2/7 3504 [1] 85/4 352 [11] 6/7 6/22 13/5 26/8 26/21 27/16 27/20 27/21 29/3 43/2 43/5 352i [1] 126/4 353 [1] 20/1 360 [1] 5/22 360k [1] 7/8 363 [1] 138/18 368 [1] 104/18 37 [2] 127/22 129/5 379 [2] 6/23 39/8 3798 [1] 2/17 379r [11] 4/10 10/22 11/1 13/12 31/12 31/14 39/8 46/5 46/8 136/8 206/10 389 [1] 134/11 3:30 [1] 162/8	6	
4	7	
400 [1] 2/13 4000 [1] 2/11 401.4 [1] 196/2 410-783-4000 [1] 2/11 4270 [1] 1/13 429 [1] 84/23 43 [1] 84/14 430 [1] 111/13 431 [1] 111/13 439 [1] 84/14 44 [1] 76/20 454 [1] 11/18 473 [9] 72/10 83/1 83/20 83/21 86/5 87/20 87/23 88/6 88/8	600 [2] 52/6 52/11 60606 [2] 1/14 1/17 61 [2] 42/9 46/17 619 [1] 156/2 620 [1] 135/4 64 [1] 169/23 65 [1] 169/23 66 [1] 169/23 68 [1] 55/3	
	8	
	719 [1] 140/14 7519 [1] 114/8 7534 [1] 114/8 7548 [1] 114/8 77 degrees [1] 55/3 772.467.2337 [1] 2/21 79 [1] 137/8	
	9	
	860 [1] 150/2 882 [2] 61/13 61/19 883 [2] 61/15 61/19 889 [1] 104/4 8th [1] 2/13	
	9.23 [1] 125/1 90 [1] 118/15 90067 [1] 2/17 90071 [1] 2/13 912 [1] 105/6 929 [1] 121/5 930 [1] 121/9 938 [2] 119/5 125/25 939 [3] 120/14 120/16 125/25 940 [1] 84/14 947 [2] 114/21 126/3 963 [1] 169/22 964 [3] 165/1 170/1 170/25 965 [1] 150/10 966 [1] 158/19 967 [1] 110/17	

A	131/6 135/7 137/3 175/4	affected [2] 50/4 51/4
accepted [3] 56/19 77/22 144/21	actual [12] 51/13 70/25 84/2 86/13 86/17 107/10 107/20 116/24 117/5 134/3 140/4 176/3	affirmative [1] 99/11
Accepting [1] 142/24	actually [37] 15/14 28/19 49/22 55/6 55/10 58/8 60/22 76/3 86/22 94/22 97/3 117/2 121/6 121/22 126/22 134/22 137/9 139/25 157/14 162/16 165/18 166/9 167/3 167/7 167/21 167/23 171/1 175/21 176/19 182/12 182/23 186/15 186/18 188/11 194/18 195/13 207/13	affirmed [1] 152/4
accomplished [1] 167/14	add [14] 7/3 31/20 40/22 71/10 84/21 108/8 140/9 141/23 149/9 151/6 152/12 155/9 156/7 169/19	affixed [1] 13/21
accordance [8] 57/4 57/9 58/24 59/5 60/6 61/5 62/15 87/12	added [2] 60/25 176/19	afield [1] 183/20
according [12] 15/20 18/25 28/11 30/4 59/1 78/8 101/10 101/24 122/6 183/23 184/15 203/19	adding [2] 132/18 152/2	afoul [2] 26/25 155/6
Accordingly [1] 81/10	addition [7] 7/13 11/3 17/11 34/6 38/1 39/8 135/25	after [24] 3/23 14/6 34/13 34/18 44/24 51/4 63/25 67/2 67/14 67/15 68/12 73/25 74/4 74/11 90/18 95/7 119/24 150/9 169/10 169/13 170/15 170/20 175/4 197/21
account [1] 94/8	additional [7] 7/17 23/15 39/11 55/20 134/24 158/10 186/11	after remand [1] 90/18
accountable [1] 145/2	additive [1] 186/4	after-the-fact [1] 51/4
accurate [9] 11/23 57/10 107/13 134/3 143/18 149/8 171/3 195/19 198/10	address [14] 22/10 23/11 64/13 67/8 73/24 79/7 80/3 85/16 89/22 94/23 136/11 155/1 164/2 199/16	afternoon [6] 97/15 98/12 100/17 127/13 142/8 158/7
accuse [1] 176/14	addressed [9] 5/15 7/7 25/10 32/21 36/19 37/9 42/10 65/21 164/5	afterthought [1] 66/24
accused [2] 57/6 58/9	addresses [2] 123/15 172/1	again [40] 10/19 11/8 15/18 16/17 18/2 29/7 40/9 49/18 51/19 72/22 74/19 79/14 81/13 87/15 98/12 100/18 102/7 103/18 106/14 110/20 115/11 120/25 124/12 131/25 142/17 149/18 155/7 169/22 172/10 173/15 175/22 176/20 179/7 179/10 183/14 193/17 194/16 194/25 197/10 208/20
acknowledge [4] 78/3 81/19 172/14 194/6	addressing [2] 85/23 92/21	against [92] 36/20 53/10 54/21 57/23 60/3 63/11 67/2 67/10 67/17 67/19 68/14 68/14 68/25 70/1 70/15 71/6 71/15 71/21 72/17 74/16 76/21 77/3 84/3 85/19 85/21 87/22 87/24 88/7 88/9 88/18 88/20 88/25 90/12 91/21 91/24 94/25 95/3 95/3 95/19 96/20 96/21 99/8 99/14 99/17 103/4 105/1 108/8 108/17 108/19 108/25 109/9 109/12 111/10 111/15 113/11 119/25 125/17 131/5 133/21 133/22 135/16 140/16 141/1 142/1 151/2 152/4 157/19 160/5 169/19 172/12 172/16 172/18 172/19 173/10 174/4 174/15 175/15 176/16 181/16 184/25 185/18 186/2 188/2 188/9 188/14 189/13 194/24 199/22 199/24 206/3 206/4 206/7
acknowledged [2] 147/2 191/11	adequately [5] 46/20 53/13 114/4 161/17 163/25	Agencies [1] 44/1
acquired [1] 31/19	adhere [1] 173/13	agency [11] 9/25 13/18 16/4 16/10 18/19 21/14 43/16 43/17 143/13 154/5 154/15
across [5] 68/19 75/7 99/15 122/16 174/9	administered [1] 49/9	agency's [2] 16/6 16/16
act [27] 12/3 12/13 12/24 14/11 16/13 17/15 19/25 20/2 20/6 21/19 43/7 43/18 58/2 58/5 58/6 58/6 75/11 114/17 114/18 114/25 115/4 144/16 146/24 148/13 149/14 152/6 181/4	admissible [1] 187/2	ago [5] 13/18 16/4 123/10 146/1 205/6
acted [1] 203/23	admission [1] 205/5	agree [28] 15/12 21/17 39/2 39/22 40/3 42/1 42/4 46/12 46/18 63/18 83/5 83/9 87/25 88/8 92/5 123/14 136/5 143/17 162/4 171/8 186/18 186/24 187/11 187/12 187/21 200/13 205/1 206/5
action [84] 4/4 4/8 6/9 7/19 8/18 9/21 9/25 11/23 12/1 12/11 12/19 12/20 17/6 20/4 25/4 27/10 39/24 40/12 40/17 45/5 45/10 45/11 46/3 46/20 49/13 56/8 95/12 98/16 108/22 127/21 127/21 128/10 128/15 128/17 130/16 131/20 136/19 136/23 137/2 137/3 137/14 137/15 138/2 138/5 138/13 138/24 139/2 139/4 139/6 139/11 141/15 144/7 144/9 147/14 148/3 148/22 149/4 149/11 149/13 149/20 149/22 151/8 151/22 152/5 152/9 155/16 157/5 157/11 157/22 157/24 164/22 171/5 174/3 178/3 178/6 180/24 181/19 181/20 182/8 190/9 203/2 204/20 205/2 205/7	admitted [2] 75/25 177/3	agreed [4] 16/16 149/17 155/11 155/14
action adequately [1] 46/20	admittedly [3] 171/6 173/21 180/11	agreeing [3] 40/11 188/6 188/11
action to [1] 8/18	admonition [2] 27/8 28/13	agreement [3] 46/16 143/23
actionable [1] 200/20	adopted [1] 200/24	
actions [14] 52/10 128/2 128/11 129/12 133/3 134/16 134/25 135/11 137/20 141/4 141/19 143/4 143/16 157/15	adulterated [1] 26/17	
activities [3] 68/22 104/14 115/24	adulteration [1] 16/12	
activity [3] 30/8 35/18 197/3	advance [1] 36/22	
acts [7] 58/4 114/19 130/18	advanced [2] 9/16 22/4	
	advantage [2] 77/1 193/2	
	adverse [15] 8/9 8/25 9/17 18/16 18/24 24/6 24/8 24/25 143/12 153/18 153/20 153/23 154/1 167/20 183/8	
	advertisement [1] 73/5	
	advertising [4] 12/16 30/9 35/23 35/24	
	affect [2] 153/10 153/25	

<p>A</p> <p>agreement... [1] 187/17</p> <p>agreements [1] 70/4</p> <p>agrees [2] 16/2 43/23</p> <p>ahead [3] 80/7 98/11 167/23</p> <p>Aid [8] 98/14 102/5 102/5 105/5 108/17 109/10 110/9 111/10</p> <p>aim [1] 180/21</p> <p>aims [2] 145/3 182/17</p> <p>air [1] 199/1</p> <p>Alabama [23] 124/6 124/7 131/18 131/20 133/13 133/14 133/20 133/23 134/3 165/4 165/20 165/21 169/23 170/1 170/9 170/25 171/14 171/14 171/16 177/18 177/18 178/15 178/16</p> <p>Alabama's [1] 165/12</p> <p>albeit [2] 32/8 174/4</p> <p>Albertson's [1] 57/14</p> <p>Albrecht [1] 181/7</p> <p>all [130] 6/19 15/14 16/11 17/7 18/21 18/21 19/16 20/3 20/12 20/19 22/11 23/11 23/20 23/25 24/23 25/15 27/25 30/7 30/9 32/24 42/16 44/5 45/19 46/24 47/23 48/11 49/9 50/2 52/18 53/23 54/3 54/21 57/14 58/7 58/16 62/19 65/7 65/22 66/8 67/2 67/10 67/19 68/13 68/25 71/5 71/21 73/5 74/25 75/11 77/17 81/10 81/13 89/13 89/16 91/14 93/17 97/5 98/10 99/15 100/21 104/25 105/1 108/11 109/3 124/14 126/8 127/23 128/22 129/8 129/15 129/20 130/3 132/14 135/15 136/12 139/15 139/17 140/24 141/21 142/2 142/12 143/16 144/12 147/20 149/24 150/24 151/9 153/12 158/8 161/7 162/13 162/15 164/21 168/6 174/20 175/7 175/16 175/22 176/1 176/21 177/4 177/9 177/13 180/17 181/9 182/3 184/3 184/17 184/21 184/25 185/25 186/8 186/13 187/13 188/10 188/19 190/1 191/18 192/9 194/17 196/16 198/10 199/24 205/21 206/3 207/1 207/10 207/17 208/13 208/18</p> <p>all the [1] 74/25</p> <p>allegation [26] 32/22 36/15 54/20 57/22 59/15 64/5 64/18 67/23 76/14 78/15 81/20 83/15 86/5 86/7 87/4 87/15 88/3 122/18 134/9 134/14 158/23 183/7 188/19 188/25 189/14 190/10</p> <p>allegation was [1] 32/22</p> <p>allegations [94] 4/22 41/25 44/13 44/17 51/13 54/11 54/15 55/23 55/25 56/3 56/4 56/6 56/15 56/17 57/2 62/5 63/1 63/1 63/7 64/24 65/3</p>	<p>65/21 67/10 67/25 68/25 69/3 69/15 69/25 70/15 70/17 70/20 71/1 71/10 74/23 76/13 77/10 77/12 77/21 77/25 78/19 79/11 80/11 83/25 84/2 84/24 85/1 88/6 88/9 89/1 91/19 91/23 105/3 105/4 105/13 105/19 105/24 107/9 107/12 107/17 108/3 110/2 117/5 120/23 128/5 128/7 130/23 132/22 164/9 166/9 166/11 166/22 167/2 172/15 172/17 174/2 174/3 174/10 175/2 175/9 175/22 176/14 176/21 177/4 179/8 183/24 184/21 184/25 189/5 190/25 191/14 193/6 193/14 195/8 201/4</p> <p>allegations that [1] 189/5</p> <p>allege [60] 4/20 11/22 25/23 33/10 42/18 52/9 53/10 55/19 57/8 59/14 61/24 61/24 62/1 68/1 69/16 70/24 71/21 73/2 81/1 84/3 84/15 84/19 85/20 87/8 95/19 104/16 105/9 105/14 111/1 114/2 119/3 119/5 119/17 119/25 120/11 120/11 120/17 125/22 129/12 129/14 129/18 129/20 129/25 130/12 131/11 131/24 132/1 132/5 132/8 132/18 133/2 133/7 152/21 154/20 155/9 158/15 175/22 178/14 199/22 201/24</p> <p>allege that [2] 55/19 131/11</p> <p>alleged [64] 21/8 25/22 29/1 33/11 34/9 39/21 44/7 50/3 57/19 58/2 61/23 62/4 63/22 64/22 65/1 66/7 69/4 69/23 72/11 75/15 75/19 79/12 81/4 81/16 82/3 82/13 83/5 83/12 84/11 84/15 88/13 96/25 112/16 112/16 112/17 112/19 116/21 116/23 117/2 118/7 120/14 121/3 122/20 122/24 122/25 123/2 129/8 132/17 156/1 161/7 166/24 172/19 175/11 177/14 184/5 185/5 191/6 201/6 201/7 201/13 201/17 201/19 203/18 204/4</p> <p>allegedly [6] 69/17 72/13 73/3 130/18 132/11 141/19</p> <p>alleges [10] 35/20 54/16 54/18 55/5 55/6 55/17 57/15 58/4 86/11 153/3</p> <p>alleging [21] 34/12 83/16 87/7 101/6 101/7 109/20 109/23 110/15 111/5 116/6 116/7 134/12 158/20 158/24 159/3 159/6 159/15 159/21 160/12 185/10 188/1</p> <p>allotted [2] 3/14 126/17</p> <p>allow [5] 42/2 78/13 112/9 138/14 161/23</p> <p>allowances [1] 69/24</p> <p>allowed [28] 20/12 44/1 67/3 68/7 69/21 69/24 72/21 103/3 112/10 112/20 139/4 143/12</p>	<p>147/11 148/24 151/1 151/14 154/22 161/18 162/2 176/16 181/25 187/4 187/6 187/8 190/8 194/23 198/14 198/24</p> <p>allowing [1] 192/1</p> <p>allows [4] 28/22 69/2 95/21 95/22</p> <p>almost [3] 67/15 68/24 90/9</p> <p>alone [6] 14/2 20/3 26/10 71/4 131/12 190/9</p> <p>along [5] 28/4 96/6 121/20 171/17 178/12</p> <p>alongside [1] 113/13</p> <p>already [12] 60/1 69/12 72/20 74/4 107/22 136/25 149/17 151/10 155/2 168/4 207/25 207/25</p> <p>also [61] 3/5 8/14 16/19 18/17 26/21 33/1 33/15 33/18 34/3 35/22 38/13 40/20 41/4 41/21 48/20 54/18 56/24 57/24 62/24 69/1 76/19 77/16 78/18 79/15 85/3 91/17 92/6 98/24 104/5 104/16 106/10 106/12 115/2 116/20 116/21 117/9 119/19 119/23 132/5 133/1 134/19 135/7 135/18 135/23 136/1 136/5 139/19 141/10 142/14 150/14 169/18 169/25 170/5 171/6 172/6 172/17 203/5 204/14 204/15 204/16 204/21</p> <p>also be [1] 135/7</p> <p>alter [2] 108/1 123/17</p> <p>alternative [21] 160/24 161/18 161/19 162/2 162/3 162/6 185/6 188/7 188/10 189/4 190/24 199/3 199/4 199/7 199/8 199/13 199/16 199/20 200/5 200/6 200/13</p> <p>alternatively [3] 161/3 161/4 161/5</p> <p>although [8] 43/22 74/20 94/9 118/2 155/19 157/9 166/13 180/12</p> <p>altogether [3] 184/4 203/10 204/3</p> <p>always [5] 54/16 54/17 129/13 129/18 146/11</p> <p>am [63] 10/15 25/13 28/18 36/24 38/18 44/9 47/17 47/23 48/14 49/1 62/17 63/25 65/11 65/19 66/15 66/18 79/5 79/9 80/6 82/2 83/24 89/10 90/24 92/16 93/4 93/9 94/11 98/1 98/3 98/5 109/1 110/6 111/16 116/10 118/19 121/5 121/11 121/18 121/19 122/2 131/4 142/12 160/3 165/2 166/10 171/23 172/16 174/23 179/13 179/15 179/17 179/24 180/12 185/21 189/2 189/10 189/25 193/20 197/23 199/8 199/12 199/14 207/1</p> <p>amateur [1] 144/14</p> <p>amateur logician [1] 144/14</p> <p>amazing [1] 180/19</p> <p>Amazon [3] 125/5 125/6 125/6</p>
--	--	---

A	another [17] 26/15 31/16 46/17 90/10 96/21 96/21 125/2 139/5 149/8 154/15 167/8 172/11 172/17 172/24 173/23 185/20 205/23	Appeals [2] 20/23 20/24 Appeals does [1] 20/23 appear [1] 17/7 appearance [2] 10/12 54/3 appearing [4] 3/7 131/2 137/7 156/23 appears [1] 47/15 appellate [2] 20/14 181/12 appending [1] 92/17 applicable [2] 100/9 106/16 application [3] 6/12 29/15 135/14 applied [9] 8/2 8/21 19/18 26/21 127/17 136/17 138/7 138/12 146/7 applies [11] 9/24 11/11 27/22 61/13 99/20 119/10 119/10 146/18 156/25 157/9 183/19 apply [16] 36/17 44/2 61/11 61/15 73/5 80/11 100/11 106/16 119/7 119/9 123/22 138/8 145/18 148/1 148/14 164/24 apply to [1] 61/11 applying [4] 23/8 127/23 139/8 148/9 appreciate [15] 42/25 46/25 47/1 47/6 54/2 89/5 125/11 126/9 127/10 166/15 168/21 195/1 207/6 208/21 208/22 apprise [1] 143/13 approach [5] 136/24 138/3 139/19 146/21 147/21 appropriate [6] 91/12 151/6 173/10 178/1 194/20 197/16 appropriately [1] 134/13 approval [8] 15/24 16/14 39/16 153/8 153/16 154/3 154/9 154/23 approved [50] 5/2 5/5 5/7 5/25 6/4 6/6 6/9 6/11 6/24 7/5 7/15 13/17 13/18 14/13 14/24 16/21 16/23 22/10 22/24 23/7 26/19 26/20 26/24 27/5 28/14 29/2 29/15 29/25 30/5 30/10 32/17 32/20 34/2 35/25 36/8 36/9 36/16 36/16 37/12 38/23 38/24 39/3 39/4 39/10 40/7 44/25 144/19 153/1 188/21 190/8 approves [1] 16/11 approving [1] 31/5 approvingly [1] 20/21 arbiter [1] 14/19 arbitrarily [2] 123/8 125/15 are [425] are liable [1] 183/8 are preempted [1] 134/18 area [4] 20/20 27/25 28/5 146/8 areas [5] 28/6 30/8 105/8 142/23 183/4 aren't [3] 76/25 96/14 189/5 arena [1] 40/25 arguably [2] 170/15 179/10 argue [17] 3/15 56/20 57/7 61/8 62/8 64/1 66/15 70/10
ambiguity [1] 154/18 ambiguous [2] 12/24 154/19 amend [6] 99/21 99/22 99/23 99/24 100/2 100/6 amended [29] 4/8 11/21 11/22 18/3 45/11 47/14 47/20 64/24 74/4 74/7 74/11 74/19 75/10 78/22 80/17 98/18 99/4 129/24 135/19 142/24 150/4 152/24 156/11 165/1 179/17 184/6 194/4 194/9 194/15 amendment [5] 5/21 39/7 72/22 92/16 92/16 amendments [1] 23/1 amicus [4] 6/13 16/4 37/8 37/9 among [6] 52/8 66/6 104/13 113/8 123/8 179/19 amount [2] 186/22 187/22 amounts [1] 163/11 AMPIC [33] 33/11 51/10 52/6 64/4 67/7 67/25 68/24 70/3 72/11 73/1 75/1 82/14 84/24 108/16 109/1 109/18 110/6 110/10 111/15 112/5 112/16 112/19 129/6 131/5 133/6 135/9 135/16 135/21 158/12 177/14 178/13 205/14 206/4 AMPIC and [1] 131/5 ample [3] 53/9 57/5 173/16 amplify [3] 92/6 94/6 95/17 analogize [1] 180/1 analogous [2] 5/21 35/14 analogy [2] 37/23 130/7 analysis [15] 8/1 18/2 19/21 42/3 42/5 46/15 107/21 124/18 139/1 139/14 141/6 147/25 161/25 183/3 183/17 analytical [1] 145/11 analyze [1] 168/3 analyzed [2] 137/18 147/9 analyzing [3] 60/14 112/3 138/25 ancillary [1] 99/5 and are [1] 7/24 and audits [1] 102/24 and constituted [1] 27/1 and Cosmetic [1] 43/18 and cross [1] 152/8 and finished [1] 133/9 and produce [1] 6/8 and specified [1] 29/11 and they [1] 24/1 and transport [1] 135/25 and transportation [2] 70/6 133/20 and/or [3] 48/5 82/20 126/20 ANDA [8] 115/10 115/10 115/13 115/13 123/1 154/6 185/16 198/22 ANDAs [2] 188/22 190/9 ANDREW [3] 2/2 66/14 84/9 Angeles [2] 2/13 2/17 announcement [1] 181/11 announces [1] 202/5 annual [2] 154/7 176/11	answer [26] 32/4 45/20 62/17 63/16 88/12 88/15 88/16 92/3 109/2 109/5 111/5 116/9 116/10 118/24 158/25 159/1 160/9 160/10 160/14 161/13 162/24 168/16 174/19 202/3 207/5 207/23 answering [1] 25/14 answers [4] 47/3 89/7 199/15 206/24 anticipate [1] 174/14 antitrust [2] 76/5 146/9 any [143] 3/16 3/16 4/9 4/16 10/13 13/1 14/25 15/6 15/21 17/2 19/3 19/7 20/5 30/15 30/15 30/24 31/2 34/8 35/17 36/20 40/23 44/5 44/6 44/18 48/4 48/5 50/4 52/9 52/10 52/23 53/17 53/25 57/24 58/18 60/2 60/8 60/11 60/23 62/17 62/20 65/24 66/12 67/8 67/22 68/11 69/3 69/9 69/23 69/24 71/10 71/11 71/11 71/15 73/2 73/7 73/11 74/7 74/9 75/3 78/7 79/23 81/17 82/4 82/12 83/21 85/2 85/7 88/13 88/18 88/20 90/15 90/22 91/1 95/20 96/12 96/14 98/5 98/6 99/16 99/20 99/23 99/24 100/9 101/18 106/4 107/17 119/12 122/11 122/18 122/23 122/25 123/1 123/2 123/5 123/14 127/4 130/4 131/21 138/12 138/24 140/2 140/2 140/15 142/4 143/24 144/8 145/14 146/5 147/17 148/10 148/20 148/24 149/3 152/6 153/10 154/11 162/21 163/8 163/21 164/8 164/9 172/8 173/14 178/2 181/18 182/5 191/14 192/23 195/3 195/22 195/25 198/7 201/5 202/19 203/15 205/16 205/23 206/15 206/24 207/11 207/15 207/16 207/23 any impossibility [1] 143/24 anymore [2] 195/14 198/17 anyone [3] 86/2 86/8 96/22 anything [18] 29/5 29/20 43/1 49/22 75/2 84/5 96/9 96/18 100/5 122/12 127/6 180/18 189/25 190/7 191/15 191/16 195/24 206/23 anyway [1] 174/18 anywhere [4] 69/17 69/23 87/4 124/8 API [5] 110/14 110/16 110/25 111/7 133/9 apologies [1] 88/22 apologize [4] 81/14 81/25 156/22 180/20 Apotex [1] 118/8 apparent [2] 15/3 87/13	

<p>A</p> <p>argue... [9] 71/24 72/23 77/16 98/1 136/18 136/20 191/18 198/17 206/2</p> <p>argued [11] 14/22 37/17 49/19 49/23 64/3 70/23 79/5 79/15 133/23 192/2 208/20</p> <p>arguing [12] 59/11 59/13 80/14 126/21 162/14 165/20 165/22 195/14 196/13 202/19 207/18 208/23</p> <p>argument [66] 4/9 5/16 5/19 5/24 15/8 16/1 17/4 22/3 22/11 23/10 25/18 25/21 28/25 29/21 31/10 33/23 36/23 37/16 39/14 47/12 49/4 49/24 50/2 50/9 56/14 56/22 59/19 61/10 61/22 68/13 71/4 72/15 73/21 74/12 79/13 80/10 90/2 90/24 93/24 93/25 98/18 98/22 122/17 124/10 127/2 127/3 127/3 127/9 136/3 140/9 143/25 152/17 153/9 157/18 168/23 169/6 180/11 180/13 184/23 185/9 188/16 191/17 191/22 196/10 200/12 201/9</p> <p>argument's [1] 39/19</p> <p>arguments [22] 4/11 10/23 22/8 48/18 48/19 48/25 49/15 50/5 54/11 70/21 83/3 98/24 105/13 106/17 136/5 136/9 136/15 140/10 140/23 168/12 173/5 191/21</p> <p>Arkansas [1] 113/11</p> <p>around [8] 8/8 33/25 36/10 38/4 50/21 97/14 107/1 177/10</p> <p>arrange [1] 102/13</p> <p>arranged [1] 92/2</p> <p>arranges [1] 101/19</p> <p>arrive [1] 183/17</p> <p>artfully [1] 78/9</p> <p>Article [1] 146/6</p> <p>as [294]</p> <p>ASHLEY [6] 1/12 10/14 10/19 142/8 142/17 159/7</p> <p>aside [11] 25/20 25/21 25/22 28/25 29/4 65/20 83/2 173/24 185/8 188/4 189/24</p> <p>ask [16] 25/2 47/18 58/20 89/11 105/24 105/25 115/11 116/10 116/11 139/22 149/6 154/4 156/1 158/6 185/2 207/17</p> <p>asked [14] 28/21 28/25 29/4 42/23 45/15 52/14 83/24 85/6 88/2 89/25 107/13 171/23 178/10 207/10</p> <p>asking [7] 25/13 82/2 82/25 149/2 152/19 159/11 205/6</p> <p>aspect [1] 145/15</p> <p>aspects [3] 146/12 146/13 193/5</p> <p>assemble [1] 180/19</p> <p>assert [10] 24/10 34/7 92/11 95/7 96/6 96/20 131/9 131/14</p>	<p>134/24 137/24</p> <p>asserted [5] 5/9 77/13 87/22 87/24 99/17</p> <p>asserting [5] 9/4 23/14 41/24 71/14 93/10</p> <p>assertion [1] 78/23</p> <p>assertions [2] 10/25 77/19</p> <p>asserts [1] 129/6</p> <p>assess [1] 190/13</p> <p>assist [1] 138/20</p> <p>assist Plaintiffs' [1] 138/20</p> <p>assistance [3] 155/19 156/1 168/25</p> <p>associate [1] 130/22</p> <p>associated [7] 43/9 89/21 131/15 132/2 132/9 155/16 186/4</p> <p>assortment [1] 141/18</p> <p>assume [7] 39/19 52/3 171/16 172/18 188/9 189/4 208/12</p> <p>assumed [1] 76/1</p> <p>assuming [5] 6/15 6/16 37/15 41/25 45/16</p> <p>assured [2] 166/11 197/2</p> <p>astounding [1] 96/2</p> <p>attempt [9] 47/4 52/8 67/4 67/8 71/11 105/18 106/18 106/25 177/10</p> <p>attempted [1] 95/7</p> <p>attempting [1] 70/22</p> <p>attention [1] 22/14</p> <p>attenuated [1] 8/8</p> <p>attorney [2] 126/20 126/20</p> <p>attorneys [1] 162/13</p> <p>audio [3] 34/15 108/12 191/2</p> <p>audit [2] 111/1 111/2</p> <p>audits [6] 102/24 103/24 111/2 121/4 121/12 121/22</p> <p>Auer [1] 16/7</p> <p>authorities [2] 37/6 131/16</p> <p>authority [34] 6/10 14/15 14/25 15/7 15/14 15/16 16/25 20/25 30/13 30/15 43/18 90/18 95/21 95/21 100/4 100/6 103/12 107/2 107/10 107/15 107/17 108/3 114/9 114/11 114/12 115/9 115/12 116/12 123/14 123/15 124/2 133/12 134/2 140/2</p> <p>authorized [1] 188/24</p> <p>Auto [2] 76/5 80/18</p> <p>automatically [1] 16/14</p> <p>available [3] 18/18 84/25 207/19</p> <p>Avenue [2] 1/19 2/3</p> <p>aver [1] 163/1</p> <p>averments [1] 81/5</p> <p>avoid [29] 7/2 23/17 32/24 37/20 38/12 41/10 69/2 75/2 127/20 128/17 129/4 129/11 130/17 131/6 135/5 137/2 141/5 141/13 141/22 147/14 157/14 157/15 170/7 183/24 184/4 184/16 201/14 203/19 204/2</p> <p>avoid dismissal [1] 41/10</p> <p>avoid state [1] 131/6</p>	<p>avoided [1] 39/4</p> <p>avoiding [3] 5/20 33/25 132/16</p> <p>aware [8] 34/8 44/5 44/9 64/19 86/6 95/20 161/24 179/17</p> <p>away [9] 15/17 128/4 139/22 144/15 146/2 180/7 182/8 193/14 204/21</p> <p>away offending [1] 146/2</p> <p>B</p> <p>back [46] 25/11 33/23 38/18 49/16 49/18 49/20 50/9 52/16 52/25 63/25 65/14 67/6 83/14 86/4 87/10 88/11 97/9 97/16 97/19 97/21 97/22 104/3 107/5 107/9 107/16 108/5 108/12 112/7 113/10 113/21 116/20 123/16 124/12 125/9 125/13 136/10 162/9 167/25 184/15 184/22 193/17 196/17 198/9 199/3 204/1 207/22</p> <p>backdrop [1] 89/23</p> <p>backtracking [1] 168/23</p> <p>backwards [1] 151/20</p> <p>ballpark [1] 52/2</p> <p>Baltimore [1] 2/10</p> <p>banc [1] 20/10</p> <p>banc Ninth [1] 20/10</p> <p>bar [1] 19/8</p> <p>bare [1] 62/4</p> <p>barely [1] 66/25</p> <p>BARNES [6] 2/8 2/15 127/13 131/4 136/10 136/13</p> <p>barred [5] 96/17 128/2 137/3 137/15 179/22</p> <p>bars [2] 4/7 8/15</p> <p>bars Plaintiffs' [1] 4/7</p> <p>Bartlett [28] 10/2 16/17 44/6 63/14 123/18 123/22 123/22 127/17 128/9 128/9 135/24 136/12 137/10 137/13 137/18 138/8 140/22 141/11 151/17 151/20 157/8 157/13 157/14 157/19 177/11 183/16 183/20 186/10</p> <p>Bartlett's [1] 151/21</p> <p>base [1] 19/16</p> <p>based [51] 5/20 6/24 8/10 10/3 15/8 18/22 19/12 24/15 24/17 30/2 32/25 37/1 37/12 37/21 41/16 41/18 45/1 51/14 52/13 62/12 62/13 62/14 65/22 74/14 86/15 105/12 107/11 111/11 111/13 111/23 117/22 125/16 133/4 134/1 140/18 147/23 151/15 155/25 167/16 169/20 175/1 176/3 176/21 184/5 190/9 191/5 192/6 194/21 196/11 206/8 206/18</p> <p>bases [1] 53/6</p> <p>basic [4] 52/15 125/6 128/2 192/5</p> <p>basically [5] 50/20 53/5 59/20 79/9 202/6</p> <p>Basics [1] 125/5</p>
--	--	---

B	108/22 121/13 122/25 139/20 146/7 151/24 153/7 158/18 161/23 164/9 166/17 172/18 172/20 174/21 175/11 176/2 184/23 190/11 199/17 200/11 201/4 201/16 207/4 207/5 207/6 207/8 207/17 208/22	biggest [1] 74/22 binding [1] 146/15 bit [6] 12/8 22/14 88/5 95/17 179/1 192/17 black [3] 54/7 59/2 152/7 blanket [1] 100/4 blinker [2] 204/12 204/14 blister [6] 153/4 153/23 176/7 187/20 187/24 200/9 blue [1] 146/2 body [5] 76/5 80/18 140/23 188/20 201/20 bolded [1] 152/8 bolster [2] 13/24 116/23 bones [1] 152/8 borne [1] 65/24 borrowing [2] 96/16 115/7 both [32] 25/7 25/10 28/10 41/4 42/2 47/1 48/22 59/8 63/18 64/21 92/3 99/7 106/9 107/2 114/22 119/22 120/1 120/5 126/8 133/4 133/9 134/5 134/17 148/1 151/17 151/18 153/5 154/16 173/20 182/11 185/22 200/10 bottom [2] 50/18 146/11 box [5] 14/4 93/3 93/7 152/7 168/8 boxed [1] 121/18 boxes [2] 92/23 175/19 brand [43] 14/22 15/2 36/20 48/2 97/10 97/20 98/15 101/15 101/16 101/16 101/22 101/25 102/1 102/4 102/4 102/5 102/5 102/8 102/18 104/17 106/1 109/1 109/8 109/23 110/12 110/20 111/24 114/1 114/3 114/12 115/5 116/13 117/10 119/17 119/24 119/25 120/12 120/17 122/9 122/24 123/8 157/19 160/5 brand Defendants [1] 116/13 brand's [3] 14/2 16/1 103/25 branded [12] 3/9 3/19 4/3 25/2 37/14 103/11 103/13 103/19 104/20 120/25 173/20 180/25 Brandeis [1] 105/20 brands [37] 10/24 13/13 13/23 14/16 15/12 16/3 17/4 18/15 19/10 20/15 40/14 43/24 44/16 44/20 101/20 102/1 102/6 103/15 105/17 119/18 126/9 151/2 151/5 151/7 151/13 152/4 152/6 152/11 172/12 172/16 172/19 173/17 173/24 176/18 193/9 193/10 196/23 brands affirmed [1] 152/4 brands' [4] 16/25 17/1 25/18 44/13 brazen [1] 151/13 breach [20] 11/24 12/17 20/5 45/6 77/18 147/23 148/4 148/21 149/4 149/7 149/9 150/12 171/4 171/5 180/23 181/17 182/2 199/10 204/12 204/16
basing [1] 196/19 basis [21] 5/19 6/24 21/7 26/6 30/25 42/21 51/8 56/24 57/3 85/18 85/19 86/17 95/13 96/23 97/1 139/9 161/20 162/3 164/1 185/17 188/25 Bates [7] 11/7 11/18 17/12 32/6 45/25 171/25 197/14 batteries [1] 101/23 battery [1] 125/6 Bausch [2] 20/12 23/23 be [273] be nice [1] 73/15 be preempted [1] 134/23 BEACH [3] 1/2 1/5 2/21 bear [1] 18/8 bearing [2] 150/18 199/21 bears [2] 15/18 33/18 bears repeating [1] 15/18 beat [1] 98/19 became [1] 45/3 because [132] 4/25 6/22 8/16 10/24 21/4 21/13 22/19 23/2 29/2 30/6 32/4 32/24 33/1 33/22 34/21 37/6 37/24 41/16 44/7 48/22 48/24 49/14 54/12 57/19 58/7 59/2 61/12 61/22 62/21 65/11 71/18 72/22 75/13 79/19 83/10 83/24 84/6 87/16 89/18 90/1 90/16 90/18 91/18 91/23 93/1 93/13 93/25 95/1 97/2 99/25 103/21 110/16 110/19 111/6 112/11 112/20 112/23 121/2 121/14 121/21 122/21 124/1 126/5 126/6 126/19 127/25 129/25 132/18 133/18 137/25 138/5 141/22 142/20 144/3 145/12 147/3 147/9 147/18 149/2 149/8 149/12 149/14 150/7 151/15 154/8 158/2 159/16 159/22 161/1 161/3 161/4 161/5 161/10 161/17 164/6 164/17 169/20 170/9 170/23 171/8 171/11 172/14 172/25 176/18 182/20 183/3 183/8 183/21 185/22 185/23 186/14 186/21 187/14 187/23 188/7 188/17 188/18 188/24 189/14 189/22 190/2 197/4 198/3 199/25 200/11 200/25 203/21 204/21 206/15 207/3 207/4 207/24 Because the [1] 129/25 become [1] 139/24 becomes [4] 31/6 31/9 54/19 184/11 becoming [1] 179/6 Beecher [1] 13/25 beef [1] 74/22 been [55] 8/20 9/11 9/18 17/10 23/15 24/24 29/7 29/19 32/19 33/4 33/21 35/2 35/3 35/25 36/10 36/13 37/10 40/25 42/5 58/17 63/21 63/22 64/21 74/2 95/8 96/7 98/15	before [34] 1/9 5/10 7/7 16/5 26/4 31/5 33/24 36/6 38/18 54/10 57/21 68/11 77/22 80/7 80/17 92/14 113/13 113/21 128/24 139/13 151/18 157/4 164/13 165/3 175/5 180/11 180/13 183/12 189/10 194/8 194/9 201/1 204/7 207/21 began [1] 192/25 begin [4] 10/21 18/2 142/19 142/23 beginning [3] 92/12 143/24 207/19 begs [1] 151/3 behalf [15] 10/19 48/7 49/5 54/5 73/19 81/23 98/13 127/13 131/2 136/13 142/9 142/17 156/23 166/7 204/24 behave [5] 148/6 163/2 195/18 202/9 203/1 behaved [1] 181/24 behavior [2] 195/18 198/5 behind [4] 70/20 162/25 164/16 189/9 being [28] 27/8 28/5 57/6 58/9 70/12 77/14 78/22 78/22 90/17 94/25 103/17 107/13 151/7 152/10 158/21 159/4 162/25 163/5 172/21 175/19 178/20 179/11 179/14 185/10 191/23 196/22 197/3 203/24 being effected [1] 151/7 belief [11] 51/15 51/17 51/20 52/13 65/8 67/12 68/1 70/16 70/18 71/4 78/18 believe [24] 36/19 45/16 62/24 63/20 70/24 81/5 89/20 95/20 106/10 108/7 110/11 110/19 111/8 111/18 111/21 111/22 116/5 120/10 152/19 172/20 185/22 205/3 205/13 206/6 believed [2] 145/15 200/7 bellwether [1] 113/13 belongs [1] 154/2 benefit [1] 142/10 Berman [1] 1/22 best [3] 14/19 105/22 108/6 best arbiter [1] 14/19 better [2] 9/3 74/21 between [16] 17/3 17/22 28/12 32/1 45/1 55/3 56/4 73/22 114/22 128/14 142/21 143/23 146/19 157/11 167/5 186/15 beyond [5] 41/6 124/23 125/8 175/2 186/5 bid [1] 72/10 big [1] 152/8 bigger [1] 72/19	

<p>B</p> <p>breached [3] 165/21 187/5 198/3</p> <p>break [12] 80/4 97/6 97/9 158/7 158/7 158/9 162/8 162/11 180/12 183/12 207/4 208/2</p> <p>breakdown [2] 96/23 174/12</p> <p>breaks [6] 129/15 129/20 130/16 132/6 142/25 194/25</p> <p>brevity [2] 48/15 98/19</p> <p>brief [21] 6/14 14/16 16/4 37/8 37/9 53/12 56/2 56/13 62/24 72/4 76/5 84/13 85/4 106/9 124/7 140/11 146/1 152/9 156/19 182/25 205/5</p> <p>briefed [8] 46/19 46/23 124/24 128/23 161/24 163/25 190/2 200/11</p> <p>briefing [32] 10/25 13/14 13/23 42/2 42/13 46/13 49/1 50/2 52/18 53/13 68/13 72/15 72/23 94/21 95/22 100/7 123/24 124/9 125/10 136/4 136/9 140/12 143/8 157/3 168/23 169/1 178/25 180/18 190/20 200/15 205/14 207/9</p> <p>briefly [16] 28/16 62/21 67/21 71/6 80/9 84/10 87/19 94/16 95/16 96/10 106/5 124/21 168/17 168/19 190/19 204/23</p> <p>briefs [2] 48/25 56/10</p> <p>bright [2] 141/12 157/6</p> <p>bring [12] 15/8 50/24 90/3 90/10 95/6 99/7 111/9 111/13 112/13 134/19 176/16 205/2</p> <p>bringing [4] 19/12 46/14 174/14 195/12</p> <p>broad [5] 112/19 176/14 177/4 179/7 180/5</p> <p>broader [5] 112/9 112/10 134/3 183/15 194/17</p> <p>broadly [2] 79/20 79/23</p> <p>broke [1] 97/7</p> <p>brought [12] 45/15 60/19 66/22 67/15 108/18 133/22 135/16 140/16 149/20 157/24 160/4 198/1</p> <p>brush [1] 43/22</p> <p>bubble [1] 124/15</p> <p>buck [1] 180/17</p> <p>Buckman [11] 9/2 19/11 20/1 20/8 21/20 136/6 155/4 182/15 183/7 183/9 185/9</p> <p>built [1] 55/20</p> <p>burden [1] 4/20</p> <p>business [1] 75/6</p> <p>but an [1] 111/2</p> <p>but is [1] 8/14</p> <p>but of [1] 57/9</p> <p>by Federal [1] 137/15</p>	<p>call [9] 3/13 3/14 56/2 63/25 75/13 103/6 111/19 134/7 207/5</p> <p>called [5] 17/14 64/22 75/3 114/19 148/7</p> <p>calling [1] 74/23</p> <p>calls [1] 18/21</p> <p>came [3] 67/6 158/21 160/13</p> <p>can [100] 3/14 3/15 10/15 10/17 18/9 19/3 23/14 25/7 25/18 25/22 28/7 28/16 28/23 28/25 30/1 30/18 31/3 34/9 34/15 34/18 35/6 35/19 35/22 36/1 36/3 36/17 38/4 38/15 41/7 44/24 45/17 45/18 45/23 47/24 50/21 54/7 58/1 58/4 59/7 59/13 65/12 65/17 73/13 73/14 75/23 76/13 80/3 80/24 89/19 92/3 92/10 93/9 96/3 100/3 100/10 100/20 100/21 103/7 109/2 109/4 110/18 112/13 114/23 115/6 115/25 116/4 120/5 125/23 127/1 141/4 144/11 144/13 145/22 146/8 150/19 153/25 154/7 158/23 158/25 159/9 159/10 165/14 168/13 168/17 171/16 174/17 176/17 179/9 186/12 186/14 189/24 191/22 194/20 197/7 198/2 200/2 201/11 204/5 204/12 205/6</p> <p>can comply [1] 144/11</p> <p>can make [1] 115/25</p> <p>can succeed [1] 41/7</p> <p>can't [16] 28/7 32/12 43/12 53/12 119/14 123/12 142/9 143/25 146/1 147/14 171/7 172/10 173/18 194/13 203/2 203/12</p> <p>Canale [3] 7/25 22/14 22/20</p> <p>cancer [50] 41/18 54/24 54/25 60/25 130/2 132/11 132/12 132/19 136/22 141/24 143/2 148/15 149/9 150/15 152/12 161/1 162/22 163/9 163/23 164/12 164/15 167/4 167/12 167/20 168/8 169/19 169/25 170/6 170/14 170/18 170/22 171/7 171/11 172/8 176/19 184/19 186/7 186/23 187/23 188/14 189/1 189/10 189/19 193/7 199/10 200/18 200/19 201/8 201/10 201/19</p> <p>cancers [4] 55/19 161/8 185/17 186/3</p> <p>candid [2] 59/24 169/16</p> <p>candidly [1] 20/25</p> <p>cannot [22] 5/23 7/2 13/16 15/24 28/15 29/3 29/22 30/2 32/5 67/16 72/1 89/17 127/19 128/17 140/22 141/22 144/6 144/12 149/6 151/9 152/15 169/19</p> <p>capable [1] 31/18</p> <p>capture [1] 79/23</p> <p>captured [1] 98/23</p> <p>carcinogen [4] 132/18 163/1 164/18 201/20</p>	<p>carcinogenic [3] 86/8 132/4 174/12</p> <p>carcinogenRanitidine [1] 201/8</p> <p>Cardinal [2] 66/15 80/15</p> <p>care [35] 58/23 74/10 82/19 114/4 114/5 114/6 125/2 133/4 133/8 133/16 133/24 134/4 140/6 177/16 177/20 177/24 178/14 178/17 178/21 178/21 178/22 179/3 179/3 179/4 179/8 179/13 179/13 184/17 193/19 193/21 196/3 196/3 196/14 201/6 201/18</p> <p>careful [5] 181/15 196/4 196/5 196/7 198/9</p> <p>carefully [8] 21/20 39/23 45/18 47/1 47/3 74/18 89/11 137/18</p> <p>Caribbean [2] 61/18 62/3</p> <p>carried [3] 5/25 29/2 36/7</p> <p>carrier [1] 75/20</p> <p>carriers [3] 55/13 75/16 80/11</p> <p>carry [1] 26/19</p> <p>Carter [1] 34/20</p> <p>case [86] 1/3 3/2 5/20 6/14 7/1 8/1 8/24 13/17 14/1 14/1 14/4 20/1 20/19 20/20 20/21 22/14 22/15 28/2 28/3 30/15 31/13 31/14 32/2 34/18 34/18 34/25 37/8 37/12 37/17 37/21 40/23 44/5 44/9 45/18 52/1 60/18 61/18 62/4 62/24 63/2 63/10 76/4 76/6 76/9 78/7 80/19 90/6 90/16 91/12 92/20 93/24 94/3 101/25 113/11 130/20 138/17 138/20 139/11 140/14 140/21 140/24 144/4 144/22 146/23 147/11 148/10 149/18 152/14 157/1 157/22 164/17 164/24 165/11 165/19 173/9 179/25 180/13 181/6 181/23 182/11 182/12 183/13 189/18 192/18 205/23 207/11</p> <p>cases [30] 7/20 8/2 11/7 11/13 22/11 22/13 28/1 28/3 30/7 36/10 43/16 49/10 61/12 72/4 76/7 91/10 91/15 113/21 123/23 128/22 137/5 138/8 138/15 145/11 156/25 175/18 196/23 197/19 205/19 205/22</p> <p>catch [2] 6/19 85/12</p> <p>catch-all [1] 6/19</p> <p>catchall [1] 37/3</p> <p>categories [1] 173/7</p> <p>categorize [3] 12/4 12/14 110/6</p> <p>categorized [1] 75/8</p> <p>category [14] 9/1 33/17 69/20 101/2 103/8 109/8 113/25 153/13 154/11 154/15 154/15 154/17 173/8 173/22</p> <p>caught [1] 85/10</p> <p>causally [1] 170/20</p> <p>causation [14] 46/1 46/3 77/18 148/4 149/5 159/17 159/20 161/21 161/25 170/22</p>
<p>C</p> <p>CA [2] 2/13 2/17</p> <p>California [5] 18/7 19/17 23/22 24/3 124/25</p>		

C		
causation... [4] 182/2 193/7 200/7 200/10	challenges [6] 5/2 78/1 145/7 145/9 145/14 193/12	cited [16] 7/8 8/1 8/2 14/10 29/16 57/13 62/24 63/10 76/9 95/22 107/17 114/20 138/15 165/3 183/6 203/16
cause [56] 39/24 40/12 40/17 41/5 127/21 127/21 128/10 128/15 128/17 131/20 137/2 137/3 137/14 137/15 137/19 138/2 138/13 138/20 139/2 139/6 139/11 144/7 144/8 147/13 148/3 148/21 149/4 149/11 149/13 149/20 149/22 151/8 151/22 152/5 152/9 157/5 157/22 157/24 159/17 159/19 159/23 159/25 161/14 171/5 178/2 178/6 180/24 181/20 182/8 187/23 190/9 200/17 200/19 204/12 204/20 205/7	challenging [1] 5/14	cites [4] 20/20 62/23 76/8 125/20
caused [15] 9/19 41/23 42/1 55/19 64/11 150/12 150/13 159/13 160/15 161/8 185/16 186/3 186/23 188/13 189/19	chance [2] 153/23 166/11	citing [3] 83/24 85/13 107/9
causes [26] 12/1 12/11 12/19 12/20 17/6 20/4 40/24 45/5 45/10 46/3 46/20 56/8 136/19 136/23 138/5 141/15 143/2 148/15 157/10 160/23 164/21 174/3 181/18 189/10 199/10 205/2	change [30] 24/8 28/10 31/20 31/25 52/21 60/13 103/13 107/21 124/15 136/2 136/3 138/1 138/1 152/19 153/10 153/11 153/15 154/2 154/14 155/9 155/13 168/24 176/10 176/11 184/18 189/15 193/8 193/10 204/19 205/11	civil [6] 32/25 35/7 36/5 49/7 95/23 124/25
causing [3] 132/11 193/12 200/19	changed [4] 50/6 193/5 195/10 195/15	claim [131] 4/4 4/15 4/18 5/9 8/12 8/17 8/19 9/9 10/5 19/11 19/12 19/23 21/7 21/13 21/19 23/14 23/22 24/23 24/23 25/4 25/4 27/1 30/16 31/1 31/1 34/20 34/23 39/25 40/18 40/23 40/25 44/6 44/7 45/6 50/19 51/9 52/11 52/25 55/5 57/3 57/19 59/4 59/8 60/3 61/6 63/2 63/6 67/4 67/17 67/23 71/5 71/9 71/14 71/18 71/19 71/25 72/18 77/3 80/23 85/18 85/19 87/2 89/17 90/1 90/4 90/4 90/8 90/8 90/10 90/11 90/12 90/15 90/17 91/1 91/3 91/4 95/19 95/20 96/1 96/6 96/20 96/21 97/2 99/15 99/25 114/24 123/7 128/18 130/14 132/25 132/25 134/20 134/22 135/6 135/7 135/8 136/7 139/25 140/3 140/6 140/8 140/16 140/17 140/18 140/20 141/2 141/7 141/10 141/13 144/6 150/19 152/4 154/10 170/9 171/14 175/1 175/20 175/24 176/20 177/23 178/9 179/20 183/12 187/20 188/14 191/10 191/25 192/4 196/10 198/1 199/12
caution [1] 68/23	changes [11] 134/7 151/7 153/8 153/14 153/14 153/17 154/3 154/7 154/8 154/19 185/10	claim under [1] 171/14
cautioned [1] 68/14	changes that [1] 153/14	claim would [1] 191/10
CBE [6] 143/9 152/11 167/14 168/22 168/24 176/11	changing [9] 31/18 128/1 128/11 130/2 130/19 134/17 153/21 156/2 170/12	claimants [1] 90/6
ceased [1] 59/18	channel [1] 109/4	claimed [1] 5/17
center [1] 54/21	channels [1] 18/18	claiming [1] 171/13
center of [1] 54/21	characteristics [2] 5/3 132/4	claims [182] 4/5 4/5 4/7 4/9 4/10 4/13 4/23 5/13 5/14 7/3 7/10 7/19 7/23 7/23 7/25 8/6 8/24 9/10 10/23 11/25 18/1 19/8 20/3 20/12 22/21 23/20 23/23 23/24 24/18 25/3 25/5 26/13 26/21 26/22 26/24 30/10 33/11 33/12 34/13 34/19 35/3 35/12 35/24 42/5 46/6 46/14 49/2 50/24 53/2 53/6 53/16 53/17 53/18 54/13 54/21 61/13 61/19 62/12 62/13 67/1 67/2 67/19 68/13 71/6 71/10 71/16 71/19 74/16 75/3 76/21 77/16 77/25 79/16 81/11 81/21 84/2 86/16 87/16 87/17 88/16 88/18 88/20 88/25 89/16 89/21 90/21 90/22 91/18 91/19 91/21 92/10 92/24 93/13 94/24 95/3 95/3 95/6 95/11 95/14 96/24 96/25 97/3 99/5 99/8 99/13 99/16 104/8 105/1 105/6 105/7 107/12 108/8 108/17
Century [1] 2/16	characteristics of [1] 132/4	
certain [20] 26/22 36/11 46/16 68/21 79/16 87/14 89/6 99/6 99/25 133/3 138/9 138/13 141/9 147/4 170/15 192/25 193/4 193/5 193/9 197/1	charge [2] 113/20 184/12	
certainly [14] 7/4 25/10 27/12 35/2 64/16 83/10 85/10 98/10 115/18 116/2 120/5 126/12 173/3 206/13	charged [6] 89/16 174/9 179/11 188/23 195/6 198/19	
certification [1] 113/9	charges [1] 193/13	
certifications [1] 121/8	charting [1] 21/2	
certify [1] 209/3	check [2] 93/3 93/7	
cetera [4] 167/18 174/1 174/1 177/5	checking [1] 92/23	
CFR [11] 16/10 23/5 29/17 106/9 116/4 119/6 119/8 119/14 136/2 153/9 153/15	cherry [1] 60/9	
CGMP [1] 111/3	Chevron [2] 16/10 43/17	
CGMPs [11] 102/24 103/24 116/19 117/20 117/21 117/22 118/17 119/7 119/9 119/13 126/2	Chicago [2] 1/14 1/17	
chain [3] 52/9 75/6 99/6	children [1] 34/22	
chains [1] 125/19	choice [2] 120/4 181/3	
challenge [6] 6/24 22/24 34/13 40/14 95/25 190/12	choose [4] 92/10 110/21 204/18 205/1	
challenged [2] 28/5 172/20	chooses [1] 103/23	
	choosing [5] 91/19 114/5 116/17 177/16 177/20	
	chose [6] 43/14 118/7 118/10 118/11 118/14 125/9	
	chosen [5] 105/16 118/13 121/5 125/15 125/16	
	circle [1] 38/18	
	Circuit [20] 4/19 8/21 20/10 20/10 20/11 20/11 20/15 20/19 21/2 38/14 70/17 76/9 105/21 138/25 140/14 147/2 147/8 147/22 149/17 149/19	
	Circuit noted [1] 149/19	
	Circuit's [5] 20/20 128/20 128/21 128/22 146/22	
	circular [1] 75/13	
	circumstances [14] 20/9 148/7 148/10 154/25 164/24 176/1 181/13 181/23 196/4 196/6 196/8 202/7 202/10 203/12	
	citations [2] 13/23 110/4	
	cite [16] 20/18 23/4 28/1 29/20 30/7 49/6 63/3 72/3 76/19 85/4 107/5 107/16 116/4 119/14 131/19 133/14	

C		
claims... [69] 108/23 108/25 109/9 109/12 109/16 111/9 111/13 112/3 112/9 112/11 113/2 113/9 114/17 114/18 114/25 119/24 119/25 119/25 127/24 128/6 128/25 130/6 132/21 135/16 135/19 135/21 135/23 135/25 136/1 136/12 137/24 138/9 138/10 140/1 141/21 142/1 151/2 151/14 152/17 155/2 155/3 155/5 155/25 157/19 158/12 158/13 160/4 160/6 160/7 162/19 175/16 176/6 176/16 178/20 182/21 184/21 185/1 186/2 186/9 186/12 186/19 186/20 187/12 188/1 188/9 199/21 206/3 206/4 206/7	Code [1] 126/3 coffee [1] 142/11 Cohn [1] 76/20 coin [1] 50/9 colder [1] 152/6 Coleman [3] 23/22 24/2 76/9 Colgate [1] 7/25 colleague [1] 8/22 colleagues [2] 71/3 184/17 collect [1] 147/5 collection [4] 138/22 146/24 148/12 149/14 collectively [6] 50/12 51/14 52/3 57/23 76/22 98/15 collector [2] 146/24 147/20 collectors [2] 147/1 147/4 colloquially [1] 104/10 color [1] 167/17 combination [1] 161/8 come [25] 25/8 47/19 47/23 67/12 73/10 78/1 93/6 93/9 93/14 96/6 97/9 108/12 115/15 117/15 117/18 118/24 120/3 158/8 162/9 162/14 173/24 174/8 189/6 207/7 207/22 comes [11] 40/22 45/4 108/16 117/13 121/16 188/5 188/12 189/6 196/16 196/17 206/10 coming [4] 93/1 97/22 117/8 158/19 commencement [1] 67/14 commend [1] 181/14 comment [4] 16/9 139/18 200/23 200/23 commerce [1] 13/1 common [45] 7/16 11/16 18/4 20/8 21/6 39/11 55/13 60/17 75/16 80/10 81/1 89/20 91/14 91/24 106/20 124/8 142/24 143/17 143/18 144/7 145/6 147/25 148/3 148/5 148/11 148/13 163/2 164/11 164/21 164/22 165/8 165/17 169/9 170/24 181/1 181/11 181/19 181/22 193/25 193/25 194/17 195/17 202/4 204/13 204/16 communicate [3] 155/23 167/11 208/13 communication [2] 18/18 109/4 compare [2] 18/23 40/12 compared [1] 35/10 comparing [5] 11/8 35/9 39/23 46/9 155/7 comparison [3] 40/11 41/6 157/22 compatible [2] 32/6 203/3 compatriots [1] 108/21 competing [1] 20/25 competition [2] 12/15 42/14 complaint [146] 4/25 7/19 11/23 18/3 45/11 47/14 47/21 50/8 50/22 54/12 54/16 54/18 54/23 55/5 55/10 55/17 56/16 56/24 57/1 57/2 57/7 57/11 57/15 57/24 58/3 58/5 58/11 59/14 59/21 60/3 61/20 64/18	64/23 64/25 68/11 70/23 71/3 72/16 72/24 74/4 74/8 74/12 74/15 74/20 75/10 76/12 77/8 78/5 78/22 78/22 79/10 79/14 79/17 79/19 80/17 80/23 82/7 84/19 87/5 90/4 90/9 90/13 90/16 90/23 90/25 91/2 91/4 91/20 91/20 92/7 92/8 92/8 92/10 92/15 92/17 92/18 92/22 92/23 92/25 93/2 93/7 93/8 93/11 93/15 93/17 94/4 94/18 94/19 94/19 95/22 96/4 96/13 96/13 96/15 96/17 97/1 98/19 101/8 104/4 104/15 105/13 107/6 107/9 108/22 110/1 110/4 112/1 112/18 112/22 114/16 114/21 116/21 119/6 122/23 123/4 125/17 125/23 130/8 130/23 135/23 142/25 150/5 152/24 153/3 156/11 164/10 165/2 167/2 175/6 175/11 179/18 183/14 187/13 189/12 189/13 190/23 191/1 191/14 192/14 192/25 193/5 194/5 194/9 194/10 194/15 204/7 complaint alleges [1] 57/15 complaint pleads [1] 18/3 complaint should [1] 91/4 complaints [31] 3/10 11/21 17/8 17/16 52/19 64/21 65/24 66/24 66/25 94/21 96/16 97/4 98/16 98/23 99/15 99/21 99/22 104/25 122/16 122/22 126/5 127/24 128/25 129/24 129/25 135/20 142/3 174/2 174/5 184/6 193/11 complaints' [1] 17/6 complete [1] 143/7 completed [1] 70/3 completed their [1] 70/3 completely [11] 92/5 137/11 169/1 169/5 175/12 186/24 192/17 197/9 203/3 203/12 205/10 compliance [5] 68/5 70/11 102/24 103/24 127/20 complicated [1] 92/2 complied [3] 38/22 111/3 180/10 complies [1] 6/8 complimented [1] 144/17 comply [23] 9/24 27/18 58/18 83/4 83/11 116/19 116/22 117/11 117/22 118/22 119/12 121/7 144/11 144/12 144/13 147/17 149/24 152/22 152/25 180/5 182/19 187/24 200/2 complying [1] 113/1 component [1] 31/2 composition [2] 26/12 175/3 compound [1] 200/19 computers [1] 97/14 conceal [1] 170/6 conceals [1] 153/20 concede [16] 16/3 81/15 81/18 82/3 82/6 88/12 88/23 88/25 103/21 115/16 143/8
claims as [1] 25/5 clarification [1] 208/4 clarified [1] 105/20 clarify [1] 177/6 clarity [3] 104/23 109/20 125/12 class [24] 4/4 4/8 7/19 11/22 25/3 27/10 45/11 98/16 98/23 99/5 99/21 101/8 104/4 104/25 108/22 110/1 110/4 113/9 113/9 113/18 125/17 125/19 135/19 135/23 classic [1] 56/12 classification [1] 107/1 clause [6] 11/2 46/6 59/20 144/24 145/11 145/12 clause from [1] 144/24 clauses [1] 11/5 clear [45] 4/19 7/1 15/23 16/4 22/4 23/2 24/20 29/23 41/1 55/10 56/3 57/3 58/12 59/22 60/2 60/5 62/4 64/18 67/16 88/22 89/7 99/13 100/7 106/7 108/15 113/1 117/12 131/17 131/23 146/11 149/1 152/23 154/20 157/23 160/3 177/7 177/21 178/12 184/6 184/23 185/15 185/23 186/1 189/22 201/3 clear as [1] 131/23 clearer [1] 17/10 clearly [7] 57/11 59/13 103/21 123/21 129/2 172/14 186/9 client [1] 80/16 Cliff [14] 138/17 138/20 139/8 139/11 146/22 146/23 147/6 147/6 147/10 147/24 148/1 148/23 157/22 157/22 Cliff to [1] 148/1 Cliff's [1] 147/22 clinical [1] 167/3 clock [1] 12/7 closed [1] 55/14 closing [1] 108/5 clue [1] 20/17 co [1] 127/14 co-liaison [1] 127/14		

<p>C</p> <p>concede... [5] 170/12 170/16 173/15 185/14 206/20</p> <p>conceded [4] 43/22 49/21 50/2 83/25</p> <p>concededly [1] 149/10</p> <p>concedes [2] 106/10 144/1</p> <p>concept [4] 64/17 65/22 94/17 193/21</p> <p>concern [2] 156/9 200/14</p> <p>concerned [4] 41/8 68/18 172/1 173/17</p> <p>concerns [1] 57/25</p> <p>conclude [4] 39/20 48/1 207/2 208/18</p> <p>concluded [2] 151/23 209/1</p> <p>concluding [2] 90/20 151/19</p> <p>conclusion [7] 19/10 39/20 39/22 137/11 141/11 144/13 201/11</p> <p>conclusions [4] 56/4 56/5 56/9 63/8</p> <p>conclusively [1] 151/10</p> <p>conclusory [6] 56/3 63/7 67/9 68/25 69/15 78/15</p> <p>conclusory allegations [1] 69/15</p> <p>conditions [9] 29/12 65/8 65/22 75/21 75/22 77/5 86/20 160/21 176/9</p> <p>conduct [17] 9/19 35/18 56/21 62/5 68/21 69/5 72/13 72/17 73/4 73/5 79/11 111/2 112/10 112/13 112/15 112/19 115/6</p> <p>conducted [2] 3/5 104/13</p> <p>conducting [1] 173/3</p> <p>confess [1] 172/25</p> <p>confined [1] 53/4</p> <p>confines [2] 105/7 168/15</p> <p>confirmed [1] 104/4</p> <p>confirming [1] 78/25</p> <p>conflating [1] 187/6</p> <p>conflict [22] 6/3 17/3 18/24 19/7 19/8 20/24 22/9 28/9 28/12 31/13 33/6 113/23 128/14 136/20 138/12 138/25 139/3 139/8 139/16 145/23 147/19 157/11</p> <p>conflicted [2] 138/6 139/6</p> <p>conflicts [1] 137/9</p> <p>conform [2] 29/12 174/6</p> <p>confused [2] 75/9 76/25</p> <p>confusing [1] 183/1</p> <p>confusion [3] 58/1 104/12 112/23</p> <p>Congress [8] 15/23 20/7 31/7 43/13 43/17 144/16 182/17 182/18</p> <p>Congress' [3] 43/10 145/3 182/20</p> <p>conjuring [1] 199/1</p> <p>connected [1] 170/20</p> <p>Connecticut [1] 1/19</p> <p>connecting [1] 179/15</p> <p>connection [1] 128/23</p> <p>consider [15] 27/4 30/18</p>	<p>91/12 103/20 107/12 151/21 154/19 161/12 162/21 163/8 163/14 163/21 172/10 176/10 181/5</p> <p>consideration [1] 94/13</p> <p>considered [5] 29/13 114/19 115/6 150/16 151/17</p> <p>considering [1] 181/13</p> <p>consistent [12] 43/19 105/11 113/19 123/4 139/12 143/5 146/13 148/19 157/18 182/24 193/3 195/10</p> <p>consistently [1] 191/6</p> <p>consolidated [3] 104/3 104/15 108/22</p> <p>consortium [1] 71/17</p> <p>conspicuous [2] 14/6 14/8</p> <p>conspicuously [1] 67/11</p> <p>constellation [1] 103/2</p> <p>constitute [4] 40/20 41/4 53/17 66/6</p> <p>constitute negligence [1] 53/17</p> <p>constituted [1] 27/1</p> <p>constitutes [2] 30/23 41/22</p> <p>Constitution [1] 145/8</p> <p>constitutional [1] 145/13</p> <p>constitutional or [1] 145/13</p> <p>constructed [1] 192/14</p> <p>construction [1] 53/17</p> <p>constructive [1] 86/14</p> <p>construed [3] 49/8 100/3 100/10</p> <p>construes [1] 90/2</p> <p>construing [1] 30/18</p> <p>consult [1] 45/23</p> <p>consume [11] 134/13 158/22 160/13 164/19 165/14 165/15 169/9 170/14 170/15 170/20 192/16</p> <p>consumed [8] 150/9 158/17 159/5 159/13 159/16 159/22 160/1 173/20</p> <p>consumer [25] 4/4 4/8 7/18 11/22 18/9 25/3 31/4 45/11 114/17 114/18 114/25 115/4 132/14 138/21 143/22 146/24 148/12 149/13 164/15 164/19 165/14 169/10 170/13 170/17 170/19</p> <p>consumer's [1] 176/4</p> <p>consumers [19] 9/13 17/25 18/6 19/6 82/17 83/7 129/8 133/5 133/10 140/5 156/12 165/5 167/12 169/8 170/3 170/10 181/4 201/7 203/20</p> <p>consumers or [1] 9/13</p> <p>consumers received [1] 133/5</p> <p>consumption [1] 170/21</p> <p>contain [6] 14/24 15/2 36/11 36/12 63/5 139/16</p> <p>contained [4] 29/12 36/8 43/1 153/13</p> <p>container [6] 112/3 133/14 153/4 160/6 206/20 206/21</p> <p>containers [18] 111/12 114/6 120/21 126/1 132/25 134/6 136/1 160/18 161/5 177/16</p>	<p>177/20 178/1 178/3 178/7 184/14 206/9 206/11 206/17</p> <p>containers claim [1] 132/25</p> <p>containing [6] 64/6 82/21 101/13 104/17 150/6 150/8</p> <p>contains [1] 55/1</p> <p>contemporaneously [1] 113/12</p> <p>contend [3] 74/25 75/10 79/9</p> <p>content [2] 26/12 137/19</p> <p>contest [1] 79/8</p> <p>context [24] 22/23 23/19 27/12 28/15 31/11 32/11 32/25 35/2 35/3 35/13 35/14 38/11 60/1 80/24 86/1 89/13 101/25 112/12 112/21 114/17 115/2 180/25 183/10 197/15</p> <p>contexts [1] 33/4</p> <p>continue [6] 53/18 70/9 162/10 164/15 168/8 184/24</p> <p>continues [1] 15/17</p> <p>contours [2] 164/7 198/18</p> <p>contract [8] 101/24 102/18 102/20 107/23 110/22 118/20 118/20 124/16</p> <p>contract with [1] 118/20</p> <p>contracted [2] 101/11 118/8</p> <p>contracting [1] 116/17</p> <p>contracts [4] 115/21 118/3 124/13 124/13</p> <p>contractual [2] 107/19 118/18</p> <p>contradict [1] 105/13</p> <p>contradicted [3] 70/1 72/16 72/23</p> <p>contrary [8] 30/7 136/24 145/21 146/12 157/17 168/1 192/18 205/20</p> <p>contrary to [1] 136/24</p> <p>contrast [2] 22/22 130/12</p> <p>contravene [2] 139/20 191/10</p> <p>contributing [1] 159/19</p> <p>control [11] 75/18 75/21 103/10 105/10 105/10 105/15 110/20 117/22 117/24 118/16 123/2</p> <p>controlled [2] 69/19 102/6</p> <p>conventions [3] 11/15 12/12 17/5</p> <p>conversation [1] 174/9</p> <p>convert [2] 144/24 195/2</p> <p>convey [2] 18/8 18/21</p> <p>convictions [1] 195/14</p> <p>cool [1] 55/11</p> <p>cooled [2] 110/16 111/7</p> <p>core [2] 70/4 152/3</p> <p>corners [1] 207/8</p> <p>corporate [1] 81/3</p> <p>correct [23] 20/18 24/1 33/15 43/2 69/6 80/15 106/22 108/15 109/13 110/11 111/16 111/21 112/2 122/10 151/25 159/8 160/2 160/16 162/7 169/17 171/23 182/10 209/3</p> <p>correct that [1] 69/6</p> <p>corrective [1] 121/10</p> <p>correctly [4] 17/5 69/9 96/2 170/19</p> <p>correspond [1] 143/13</p>
--	---	---

<p>C</p> <p>correspondence [3] 18/19 19/1 19/2</p> <p>corresponding [1] 11/17</p> <p>cosmetic [10] 12/24 14/11 16/13 19/25 20/2 20/6 21/19 36/4 43/7 43/18</p> <p>cosmetics [1] 35/14</p> <p>costs [1] 96/5</p> <p>could [130] 3/21 6/1 6/17 6/21 6/22 17/10 17/16 18/15 18/17 18/21 23/11 23/17 30/22 33/10 36/5 37/11 38/20 38/21 39/1 39/1 39/3 52/21 59/16 59/24 60/10 60/23 60/24 60/25 60/25 61/1 66/9 70/9 72/17 73/10 73/22 80/1 83/6 85/9 85/11 86/13 86/13 86/14 90/3 90/9 90/18 91/5 92/1 95/18 96/6 99/14 103/11 105/9 112/8 115/18 116/2 116/25 118/12 118/13 119/16 120/18 124/14 126/16 129/11 130/1 130/4 130/17 132/15 134/14 135/2 135/5 137/1 141/16 141/19 143/4 143/8 144/14 147/23 148/18 149/24 150/1 150/14 151/5 151/7 151/23 152/11 152/16 155/15 156/5 158/8 162/2 162/13 163/7 163/14 164/2 164/5 167/14 168/6 169/24 171/12 171/13 172/6 172/9 172/21 172/22 173/8 173/9 173/14 176/6 176/18 177/25 180/5 183/25 185/10 185/16 185/17 186/3 188/18 188/23 191/3 194/18 195/10 195/22 197/2 198/11 199/4 200/21 201/15 201/25 202/16 207/19</p> <p>could simply [1] 132/15</p> <p>couldn't [5] 152/6 168/24 170/8 180/9 195/14</p> <p>counsel [27] 3/5 3/14 25/7 47/13 47/18 47/23 54/15 62/23 63/18 66/10 70/23 85/7 87/20 89/15 89/17 92/3 97/10 106/7 127/14 129/17 130/8 133/19 133/23 158/8 207/15 207/17 208/8</p> <p>counsel's [2] 106/17 107/11</p> <p>count [68] 19/14 19/14 52/1 68/24 71/22 72/18 72/25 75/3 79/12 87/21 87/23 87/24 90/1 99/18 108/18 108/19 110/7 110/10 128/7 128/7 129/2 129/6 131/5 131/7 131/9 131/18 131/18 131/25 132/6 132/8 132/16 132/19 132/23 132/25 133/1 133/6 133/13 133/14 133/20 133/20 134/6 134/7 135/10 135/10 135/13 139/13 150/4 152/23 153/14 156/10 161/5 161/20 165/10 165/25 169/23 169/23 177/14 177/22 179/18 179/18 187/21 189/12 189/13 190/23 191/13</p>	<p>196/13 205/10 206/21</p> <p>count provides [1] 161/20</p> <p>counter [4] 11/1 15/11 15/13 35/14</p> <p>countless [1] 123/8</p> <p>country [1] 75/7</p> <p>counts [28] 19/23 60/6 71/8 71/13 71/17 79/8 79/11 102/3 103/3 132/21 133/2 133/4 134/9 134/17 139/16 139/17 153/15 157/15 158/14 160/7 161/2 161/4 161/6 161/8 162/2 178/13 178/19 181/9</p> <p>counts which [1] 60/6</p> <p>couple [9] 73/24 74/8 91/10 122/14 123/9 180/7 180/16 194/7 201/21</p> <p>courage [1] 195/13</p> <p>course [26] 12/9 14/19 21/12 50/7 55/23 55/24 56/16 57/9 59/2 59/16 62/10 71/22 74/4 85/23 86/3 135/10 141/7 151/12 151/25 157/12 162/1 170/18 173/19 180/23 192/5 192/10</p> <p>course Federal [1] 21/12</p> <p>court [210]</p> <p>Court dismissed [1] 68/13</p> <p>Court found [1] 22/24</p> <p>Court's [43] 5/1 5/15 14/16 16/24 19/10 20/16 45/24 50/23 53/16 59/9 60/7 60/12 61/3 61/7 74/17 80/23 94/24 96/18 99/8 99/10 99/13 99/20 100/1 103/2 103/5 104/1 104/5 104/9 105/19 106/6 106/18 107/1 109/11 113/19 122/15 125/11 141/3 166/21 171/25 174/6 193/3 205/16 207/9</p> <p>courtroom [2] 3/6 12/10</p> <p>courts [26] 15/20 21/3 26/22 34/3 35/11 35/16 40/25 61/17 70/16 72/2 128/16 136/17 138/7 140/2 140/15 140/22 145/7 145/18 146/3 146/4 164/22 165/8 171/19 181/11 181/12 196/23</p> <p>Courts that [1] 138/7</p> <p>cover [4] 6/11 62/22 167/19 208/7</p> <p>covered [3] 45/9 126/9 168/1</p> <p>COVID [1] 3/4</p> <p>CPMGs [1] 121/21</p> <p>crafting [1] 74/18</p> <p>Cream [1] 91/11</p> <p>create [5] 28/9 58/1 113/23 191/9 192/14</p> <p>created [4] 99/5 104/11 112/23 148/5</p> <p>creates [1] 202/6</p> <p>credit [1] 193/1</p> <p>creep [1] 48/9</p> <p>crime [3] 6/8 27/9 30/19</p> <p>criminal [3] 30/18 30/21 43/8</p> <p>criminally [1] 29/3</p> <p>critical [5] 8/16 19/25 20/3</p>	<p>21/13 31/22</p> <p>critically [1] 61/19</p> <p>criticize [1] 55/9</p> <p>cross [1] 152/8</p> <p>Crow [1] 76/9</p> <p>Crowell [1] 2/2</p> <p>crucial [4] 4/22 43/21 144/18 148/20</p> <p>crux [1] 55/4</p> <p>crystallization [1] 157/6</p> <p>cuff [3] 173/2 173/15 197/20</p> <p>cure [1] 173/14</p> <p>current [4] 102/24 118/25 121/2 121/6</p> <p>currently [2] 189/23 190/17</p> <p>customer [2] 81/7 81/7</p> <p>cute [1] 161/13</p> <p>CVS [9] 98/14 101/18 102/4 102/4 105/5 108/17 109/10 110/9 111/10</p> <p>cycle [1] 176/3</p> <hr/> <p>D</p> <p>D.C [2] 1/20 2/3</p> <p>damages [19] 48/24 61/8 61/14 61/21 71/21 71/23 71/24 71/25 72/3 72/9 72/17 77/18 79/4 82/25 87/3 112/10 148/4 149/5 182/3</p> <p>danger [10] 18/22 98/9 162/20 165/5 170/3 170/11 171/19 174/11 202/15 202/18</p> <p>dangerous [19] 13/2 16/21 32/23 52/22 54/17 54/19 59/15 59/17 59/22 60/1 60/8 132/2 133/10 137/23 140/7 143/19 179/8 179/11 194/25</p> <p>dangers [5] 131/21 131/24 175/10 193/15 205/23</p> <p>Dann [1] 2/9</p> <p>data [3] 8/25 143/12 168/3</p> <p>date [94] 110/2 111/25 112/3 114/15 131/10 131/12 132/12 132/14 132/15 132/21 136/23 140/3 148/16 149/8 150/7 158/20 159/4 159/12 159/16 159/22 162/21 162/25 163/4 163/7 163/9 163/13 163/14 163/21 163/22 164/12 164/14 164/18 165/13 165/24 167/1 167/10 167/13 167/15 167/19 167/24 168/7 169/7 169/9 169/11 169/14 170/13 170/17 170/20 171/3 174/18 174/21 174/24 174/25 175/1 175/2 175/4 176/3 176/20 181/21 182/1 185/7 185/12 186/4 186/18 186/20 186/22 187/5 187/16 188/13 189/9 189/15 189/18 189/19 190/10 191/18 191/19 191/24 192/1 194/2 195/3 195/10 195/15 195/19 195/21 195/23 196/13 198/1 198/3 198/15 198/21 201/10 205/10 206/14 209/6</p> <p>date claim [1] 140/3</p> <p>date improperly [1] 150/7</p> <p>dates [29] 104/8 105/8</p>
---	--	---

D	95/24 96/4 96/20 96/21 103/8 127/19 137/1 144/1 149/23 173/7 173/22 182/23 183/23 184/1 184/2 184/4 201/5 201/13 203/23	101/2
dates... [27] 105/15 108/24 111/11 111/14 119/19 119/20 119/21 120/9 120/20 131/8 143/9 143/18 158/14 158/16 161/3 165/10 166/1 168/25 169/21 175/23 190/24 191/9 198/16 198/25 200/9 206/9 206/11	Defendant's [2] 40/24 113/10 DEFENDANTS [176] 2/1 3/19 4/3 6/22 13/15 14/22 14/24 15/2 15/3 15/6 25/2 25/9 26/23 46/19 47/13 48/8 48/14 52/1 52/4 52/8 54/22 55/9 55/12 55/22 56/2 56/10 56/13 56/17 56/20 56/23 57/3 57/5 57/7 57/12 57/13 57/15 58/1 58/3 58/4 58/12 59/11 59/16 59/19 60/3 60/9 60/10 61/5 61/8 61/24 62/8 62/16 63/11 63/20 64/5 64/23 65/25 66/10 68/19 68/24 71/22 73/22 73/23 74/9 74/16 74/23 75/5 75/9 75/11 76/4 76/12 76/16 76/21 76/23 76/23 76/25 77/3 77/13 78/9 78/12 78/20 79/8 79/14 80/2 81/3 81/8 82/16 84/3 84/4 84/21 85/2 85/2 85/4 85/17 86/6 86/11 86/17 88/3 89/1 89/3 89/9 89/24 89/25 91/22 91/24 94/16 95/2 98/13 99/14 100/9 103/7 104/2 104/7 104/11 105/18 106/14 106/16 107/1 107/14 108/9 109/8 109/10 109/12 109/17 110/13 111/15 111/24 112/4 113/5 114/1 114/3 114/13 116/13 116/21 118/6 120/12 120/15 120/18 122/9 124/23 127/15 129/4 129/7 129/11 130/1 130/4 130/17 130/21 131/5 131/9 132/1 134/14 135/5 135/9 135/17 135/22 136/14 141/16 145/2 156/16 163/25 165/21 166/4 166/25 167/3 172/1 177/25 180/6 181/6 182/19 183/8 193/9 194/10 196/18 203/1 206/2 206/7	defines [2] 15/4 57/11 definitely [1] 195/2 definition [17] 4/15 4/17 13/15 13/24 14/2 14/18 14/25 15/2 15/7 17/1 17/2 43/6 43/10 43/14 46/21 106/8 206/22 definition does [1] 17/2 definitive [1] 109/5 degradation [2] 129/23 174/12 degrade [5] 64/11 86/18 120/18 191/5 191/15 degraded [1] 150/10 degrades [8] 54/17 54/18 132/6 134/10 176/8 195/7 195/24 198/20 degrading [2] 120/13 120/16 degrees [2] 55/3 69/21 delegating [1] 118/19 Delegation [1] 118/21 delineating [2] 15/1 29/10 deliver [2] 205/12 205/22 delved [1] 207/8 Demahy [1] 155/25 demand [1] 62/7 demanded [1] 155/22 demonstrate [2] 117/16 130/24 demonstrating [2] 117/9 117/11 denied [4] 62/17 78/14 79/2 106/1 Denture [1] 91/11 deny [2] 77/23 155/25 depart [1] 11/19 departs [1] 14/13 departs from [1] 14/13 depend [4] 86/22 192/10 192/11 200/4 depended [1] 24/18 dependent [1] 135/11 Depending [2] 86/12 163/11 depends [4] 8/10 9/25 20/4 135/10 depositions [3] 70/8 74/3 80/13 derivative [2] 26/13 71/16 described [1] 72/11 design [23] 5/4 62/12 62/14 82/19 108/1 123/3 123/17 128/2 128/5 128/11 130/1 130/3 134/17 137/19 138/1 138/2 151/2 151/4 151/14 151/18 151/22 193/14 197/8 design defect [1] 151/18 designed [2] 26/12 169/8 despite [4] 52/18 52/18 74/17 152/10 detail [5] 4/21 54/11 56/21 60/6 136/4 detailed [2] 57/1 63/1 details [1] 63/4 determination [11] 7/15 32/13 32/13 33/5 33/19 34/4 36/1 39/10 39/17 49/12 201/16
dating [5] 184/13 195/8 201/9 201/17 202/12		
Daubert [1] 189/17		
dawn [1] 145/19		
day [14] 3/2 46/17 48/16 49/4 96/6 123/19 127/10 175/20 185/20 186/6 187/10 193/20 207/18 208/19		
daylight [1] 17/22		
days [3] 118/13 127/11 208/24		
deadly [1] 143/2		
dealt [2] 36/25 147/24		
death [1] 71/17		
debt [6] 138/22 146/23 147/1 147/4 147/5 147/19		
debtors [1] 147/1		
decade [1] 13/20		
decades [3] 5/12 13/18 23/18		
decaffeinated [1] 142/11		
December [9] 49/18 50/9 50/15 52/25 85/13 123/17 127/16 183/23 184/20		
deceptive [6] 12/3 12/13 17/15 114/23 115/2 115/7		
decide [6] 32/5 32/7 39/25 163/16 163/16 187/7		
decided [2] 24/1 124/19		
decides [4] 101/21 101/22 102/9 102/17		
decision [18] 5/15 10/7 19/11 20/20 21/4 24/8 36/19 37/6 45/24 117/24 128/21 128/21 128/22 138/19 146/22 151/21 157/4 171/25		
decision-making [1] 10/7		
decisions [4] 10/1 50/17 115/25 175/17		
declined [1] 68/12		
deductions [1] 63/7		
deem [2] 6/1 184/19		
deemed [3] 30/2 98/15 115/1		
defeat [1] 130/9		
defeats [1] 93/16		
defect [14] 21/15 83/6 83/8 85/1 137/19 138/2 151/2 151/4 151/14 151/18 151/22 177/5 179/21 193/14		
defective [4] 85/8 85/10 130/14 185/16		
defects [2] 60/8 161/7		
defend [2] 4/23 90/21		
Defendant [46] 4/20 22/19 27/4 35/21 57/19 57/21 58/2 58/5 58/6 58/6 58/7 58/8 58/17 58/20 59/3 59/7 60/23 69/4 71/12 75/19 75/23 76/14 76/17 81/2 81/3 81/6 81/9		
	Defendants cherry [1] 60/9 Defendants could [1] 130/4 Defendants preferred [1] 81/8 Defendants shipped [1] 56/10 Defendants' [12] 3/9 47/20 54/11 59/4 66/16 74/19 74/22 82/18 91/8 97/11 119/17 126/13 defense [25] 3/14 20/13 25/21 26/7 28/24 42/23 47/17 47/19 57/6 58/10 66/9 77/15 92/4 93/23 94/14 122/12 126/16 176/22 198/7 199/6 199/14 199/18 201/2 203/14 206/23 defer [2] 62/10 108/21 deference [2] 16/7 16/10 deficiencies [1] 68/9 deficient [2] 33/15 71/24 define [2] 52/7 104/5 defined [4] 65/6 66/1 66/5	

D		
determine [4] 63/19 143/10 163/20 168/7	differently [3] 99/23 112/4 112/7	disposition [1] 49/9
determined [2] 23/12 36/13	differs [2] 140/1 145/1	dispute [7] 19/3 55/22 77/19 143/4 143/15 167/13 195/9
determines [1] 102/19	difficult [4] 47/5 104/12 115/15 182/13	disputes [1] 63/12
determining [2] 11/12 80/23	digestive [2] 132/7 184/10	disregard [2] 65/23 86/5
development [1] 66/4	digits [2] 132/13 167/1	disregarded [3] 50/12 56/5 86/21
deviation [1] 26/14	direct [6] 67/1 67/5 115/17 123/10 125/23 128/13	disregarding [1] 87/2
deviations [1] 26/19	directed [3] 84/7 85/1 108/13	disrespect [1] 144/23
device [14] 5/21 7/12 22/22 23/1 24/4 24/7 32/22 33/3 35/3 38/12 39/7 39/14 39/16 44/2	direction [4] 15/15 21/1 43/25 44/10	disseminate [1] 143/21
devices [3] 15/9 15/10 43/25	directive [1] 51/1	dissolution [1] 167/17
devoted [1] 208/22	directives [1] 53/16	distinct [4] 101/20 106/21 139/11 183/4
DeVries [1] 2/9	directly [4] 39/13 63/3 70/1 205/20	distinction [5] 22/12 22/15 31/22 56/4 104/12
dictates [1] 27/18	disagree [5] 44/1 94/17 161/17 162/1 175/21	distinctions [1] 99/21
did [83] 14/20 14/20 21/5 21/21 24/13 24/20 30/13 31/7 32/23 36/12 38/6 44/15 55/6 55/7 56/13 57/15 58/4 58/5 58/6 58/6 58/7 58/13 62/8 64/6 74/1 74/14 74/20 75/18 77/9 77/20 79/5 82/23 83/25 84/7 98/21 99/2 99/3 99/11 99/16 99/20 99/23 100/11 100/21 101/3 103/20 103/21 104/4 104/18 106/3 108/8 109/24 110/16 111/6 122/2 126/5 128/4 134/23 139/3 144/20 147/18 149/22 150/23 151/3 155/22 158/18 167/22 167/23 167/23 172/9 179/18 179/25 183/18 185/2 185/2 187/17 188/12 194/12 197/6 197/8 198/8 200/15 202/1 208/21	disagreement [4] 45/1 142/21 153/2 169/16	distinctly [1] 21/14
didn't [32] 15/13 28/4 34/24 37/10 41/17 46/23 49/21 50/7 53/5 56/11 57/8 59/13 74/10 78/20 88/24 125/12 125/16 152/21 162/4 169/12 178/11 180/10 182/1 182/8 189/15 189/24 193/8 193/10 197/5 197/16 204/21 208/5	disagreement is [1] 153/2	distortion [1] 146/16
differ [3] 7/3 7/24 129/24	disallowed [2] 150/1 182/9	distributed [1] 101/5
differed [1] 23/24	disapproved [1] 30/11	distribution [5] 75/6 82/20 115/23 116/1 117/21
difference [6] 32/1 146/19 146/20 157/1 157/10 186/25	disbelieved [1] 56/17	distributor [24] 47/20 48/23 64/5 66/10 66/16 69/7 69/9 69/24 70/7 71/15 73/22 74/9 74/23 75/5 75/9 78/12 84/3 85/11 102/17 102/22 102/23 105/5 106/8 115/21
different [59] 7/12 11/3 11/10 12/2 12/12 17/11 21/1 21/2 25/14 26/1 26/5 31/16 31/21 32/14 32/20 33/2 35/24 36/7 36/9 38/1 39/9 40/7 43/4 43/8 43/25 45/2 45/10 49/20 68/21 85/23 86/3 101/15 102/11 104/13 113/5 113/6 118/8 120/21 124/1 126/2 130/13 143/1 145/5 146/25 148/11 148/12 151/4 161/22 168/12 173/11 180/6 180/16 181/15 181/16 182/6 183/13 187/10 202/6 202/10	disclaimed [1] 123/9	distributor's [1] 103/22
differential [1] 55/18	disclose [1] 5/8	distributors [70] 47/12 47/18 51/12 51/18 51/20 51/24 52/3 63/25 66/22 66/25 67/3 67/9 67/10 67/15 67/17 67/20 68/2 68/14 68/20 70/1 70/2 70/3 70/10 70/15 71/7 72/12 72/17 73/2 73/6 74/25 75/15 80/2 80/12 81/17 82/4 83/3 83/6 83/10 83/15 84/18 85/20 85/25 86/23 87/22 87/24 88/7 88/9 88/13 88/19 88/21 89/3 90/12 90/21 94/25 95/19 101/2 102/6 102/10 105/2 105/9 105/15 106/11 106/12 110/7 115/20 117/24 119/11 119/15 125/5 125/9
differentiate [2] 52/8 102/7	disconnect [1] 167/5	distributors control [1] 105/15
differentiated [1] 104/19	discover [14] 55/23 70/2 70/4 74/3 74/6 78/24 78/24 80/13 113/18 113/20 118/3 120/3 124/13 124/17	distributors' [2] 67/19 69/13
differentiates [1] 120/23	discrete [1] 141/18	district [7] 1/1 1/2 1/10 8/23 13/25 61/17 80/22
	discretion [2] 173/4 173/16	divide [1] 126/18
	discretionary [3] 8/18 9/21 10/6	DIVISION [1] 1/2
	discuss [1] 192/12	divorced [4] 140/3 140/6 205/10 205/12
	discussed [2] 155/3 167/15	Dixie [2] 57/14 101/17
	discussing [5] 28/3 29/19 33/17 37/10 199/17	DLA [1] 2/5
	discussion [10] 11/6 52/16 92/14 92/15 120/23 123/16 133/18 139/21 184/7 199/5	do [148] 23/13 25/23 28/23 29/5 32/18 36/19 36/21 36/22 38/20 42/17 43/13 44/12 44/17 45/12 45/14 45/18 48/4 49/22 52/7 52/7 52/11 54/6 54/9 59/3 59/7 59/8 62/25 66/12 69/16 72/12 73/1 76/18 81/15 81/18 84/1 84/17 85/11 85/21 88/8 88/10 88/12 88/23 88/24 89/1 89/5 90/18 91/22 91/24 95/8 98/1 98/5 98/5 99/2 100/20 100/23 102/13
	disfavored [1] 105/20	
	disheartening [1] 94/22	
	disinfectants [1] 105/23	
	dismiss [44] 1/9 3/9 4/3 4/11 25/3 41/10 47/14 47/20 48/16 49/19 55/24 56/6 56/19 62/3 62/6 66/11 66/16 67/19 68/12 69/13 72/2 72/21 75/25 85/5 89/25 93/13 94/21 97/11 100/3 106/1 126/13 134/21 138/8 143/8 151/13 152/3 152/11 161/16 164/1 169/1 183/4 194/11 195/9 206/2	
	dismissal [7] 41/10 56/25 63/9 90/25 93/25 94/1 105/18	
	dismissed [19] 53/19 67/2 68/13 72/1 72/19 78/6 81/11 91/1 96/3 103/15 105/25 128/7 128/15 128/19 129/1 137/4 137/16 142/2 185/1	
	dismisses [1] 72/6	
	dismissing [4] 90/15 96/24 97/2 105/12	
	dispenser [1] 103/17	
	displaces [1] 144/25	

<p>D</p> <p>do... [92] 102/16 107/15 107/25 110/3 110/6 111/13 111/16 112/7 112/12 115/9 115/12 115/18 116/12 116/22 118/11 118/24 120/17 121/6 121/19 122/6 123/11 123/12 124/2 125/12 125/24 126/24 127/6 127/20 129/7 129/24 130/4 131/11 135/3 136/16 137/1 141/1 141/15 141/17 143/15 143/25 145/23 146/3 146/19 150/16 151/3 151/6 151/7 154/3 154/8 154/18 155/15 156/5 158/5 166/4 167/22 168/2 168/5 168/18 169/18 171/3 175/7 175/13 176/10 176/25 179/9 179/12 182/23 183/23 184/2 184/4 184/16 185/11 193/10 194/18 195/4 196/6 196/6 196/7 197/1 197/7 198/12 199/5 199/16 199/16 201/14 203/4 205/1 206/5 206/6 206/10 207/2 208/5</p> <p>docket [7] 3/13 47/15 66/16 85/4 100/11 126/14 129/5</p> <p>doctors [1] 158/15</p> <p>doctrine [11] 19/8 59/10 139/20 145/19 145/20 146/4 146/7 146/16 146/18 155/6 182/15</p> <p>document [4] 70/4 154/6 194/6 194/14</p> <p>documents [5] 70/13 74/9 74/11 74/13 78/21</p> <p>documents in [1] 74/11</p> <p>Doe [1] 61/18</p> <p>does [33] 6/2 6/6 15/2 17/2 18/14 20/23 22/10 23/11 33/16 38/12 57/1 57/24 58/11 61/20 71/22 73/5 107/21 109/7 113/4 120/8 121/15 121/15 130/9 132/12 138/20 149/11 154/18 174/15 174/17 179/9 199/15 203/14 208/8</p> <p>doesn't [40] 6/20 11/14 12/19 16/14 17/7 17/12 20/18 27/10 27/17 27/25 30/9 33/11 33/14 37/23 46/5 46/12 52/14 58/8 60/15 75/20 76/6 86/22 95/11 100/9 106/16 107/20 108/1 113/23 117/15 117/18 118/21 124/8 124/15 149/16 164/16 169/11 170/13 195/25 200/4 204/19</p> <p>doesn't provide [1] 164/16</p> <p>doing [12] 40/3 41/6 57/6 58/9 59/7 96/18 109/1 121/22 145/11 183/16 186/9 196/5</p> <p>don't [84] 12/7 17/6 19/16 23/2 29/7 34/11 40/16 42/7 43/1 46/4 46/19 46/22 53/16 61/11 61/15 64/2 65/12 70/23 71/11 77/13 80/11 82/6 83/9 84/6 84/12 85/20 87/15 89/9 94/10 95/19 96/12 96/22 97/2</p>	<p>98/7 102/12 109/3 112/6 112/18 113/16 116/9 118/2 119/9 119/10 120/10 121/1 122/11 123/14 123/22 126/20 127/6 154/4 161/12 162/8 162/16 163/4 164/14 166/17 166/20 168/10 168/15 169/10 170/19 171/19 176/22 180/13 183/19 184/20 187/12 188/17 192/22 195/2 195/5 195/13 195/22 195/23 196/23 196/24 197/24 198/17 200/10 200/24 204/14 205/3 205/13</p> <p>done [28] 46/15 52/21 53/10 57/20 58/2 60/10 60/23 63/6 66/7 74/21 76/24 93/20 95/14 97/5 104/24 116/20 121/12 121/13 121/20 127/20 137/1 141/8 154/7 167/7 184/1 185/4 202/16 204/2</p> <p>done to [1] 60/23</p> <p>dose [3] 13/3 153/22 153/22</p> <p>dots [1] 179/15</p> <p>doubled [1] 184/8</p> <p>doubt [3] 145/9 150/3 154/11</p> <p>down [18] 12/8 51/13 57/14 75/6 107/7 124/18 129/15 129/21 130/16 132/6 142/11 142/25 145/16 146/17 174/7 184/8 192/21 194/25</p> <p>down to [1] 129/15</p> <p>dozen [1] 51/12</p> <p>dozens [1] 136/17</p> <p>Dr [1] 118/9</p> <p>Drager [1] 128/21</p> <p>draw [1] 80/25</p> <p>drew [1] 141/12</p> <p>drink [1] 130/10</p> <p>Drive [1] 1/16</p> <p>driving [1] 204/10</p> <p>dropped [1] 169/2</p> <p>drug [99] 6/12 11/23 12/24 12/25 13/15 13/21 13/24 14/11 14/12 14/23 15/1 15/21 16/13 16/14 16/21 19/25 20/2 20/6 21/18 23/6 23/9 23/11 23/14 25/18 25/19 25/22 28/25 29/15 29/22 29/24 31/5 31/8 31/9 32/6 32/9 34/9 34/18 35/6 35/13 36/4 36/5 37/11 38/21 38/21 43/7 43/9 43/18 44/6 44/8 44/21 44/25 45/7 50/4 51/4 54/18 55/11 56/11 57/4 57/9 57/16 58/14 58/24 59/5 59/12 59/18 59/25 60/4 60/10 60/14 61/1 61/5 64/11 86/19 87/12 101/3 101/4 101/5 103/13 117/25 117/25 119/11 127/17 137/23 138/8 140/16 140/21 144/16 148/15 151/5 153/11 153/19 153/25 155/9 155/17 167/18 188/24 195/4 201/19 202/19</p> <p>drug becomes [1] 31/9</p> <p>drug renders [1] 23/9</p> <p>drug with [1] 45/7</p> <p>drug's [2] 83/4 134/17</p> <p>drugs [14] 15/11 15/11 15/13</p>	<p>16/11 23/6 85/9 87/6 103/14 103/18 103/18 103/19 136/8 176/3 198/25</p> <p>drugs' [1] 155/12</p> <p>dry [1] 55/12</p> <p>dual [1] 173/22</p> <p>due [2] 3/4 129/23</p> <p>duration [1] 13/3</p> <p>during [13] 14/23 45/9 49/4 50/6 50/9 55/23 64/10 118/2 120/3 121/12 133/18 201/9 203/17</p> <p>Duron [1] 91/10</p> <p>dust [1] 13/13</p> <p>duties [59] 9/5 11/9 11/9 11/13 11/19 11/22 13/6 17/4 17/23 18/3 19/7 20/7 21/14 21/17 27/17 27/18 32/15 41/4 41/5 51/8 60/13 114/10 114/11 114/12 115/10 115/13 116/13 116/22 117/1 117/6 117/6 117/10 118/4 118/18 118/20 118/21 118/24 130/2 136/19 138/6 148/11 148/12 148/13 148/19 149/24 151/5 151/9 155/8 162/18 164/10 164/11 167/4 171/1 182/24 200/2 200/3 202/6 202/11 205/7</p> <p>duties and [1] 136/19</p> <p>duty [210]</p> <p>duty and [1] 58/20</p> <p>duty to [2] 155/21 193/18</p> <p>dynamic [1] 144/19</p> <hr/> <p>E</p> <p>e.g [1] 68/19</p> <p>each [52] 8/24 22/13 23/5 39/24 39/25 46/13 55/25 56/7 56/23 57/13 57/15 57/19 57/21 58/13 60/6 75/15 75/19 75/23 76/14 77/4 77/20 81/2 81/2 91/18 95/24 102/17 105/4 110/25 111/3 117/21 120/2 125/24 129/2 129/3 129/6 131/5 138/22 139/13 141/24 143/15 150/6 153/4 161/14 161/20 162/16 164/1 168/6 181/15 188/1 199/9 200/17 200/19</p> <p>earlier [7] 70/14 82/1 133/18 140/25 167/15 183/25 184/18</p> <p>early [1] 44/24</p> <p>East [1] 2/16</p> <p>ECF [4] 103/7 104/1 104/4 104/10</p> <p>echo [1] 95/16</p> <p>economic [12] 27/9 70/22 110/1 110/3 111/25 112/12 112/14 112/17 112/22 114/16 119/6 125/23</p> <p>effect [5] 7/11 115/17 146/14 153/18 153/24</p> <p>effected [1] 151/7</p> <p>effective [5] 18/5 19/20 29/14 103/25 143/21</p> <p>effectively [5] 136/11</p>
---	---	---

E	77/7 98/8 107/1 112/23 116/20 123/19 127/3 127/4 130/20 143/22 143/24 177/10	establishing [1] 7/11 estate [1] 53/5 et [4] 167/18 174/1 174/1 177/5 evades [1] 140/21 evaluating [1] 35/12 even [69] 6/1 6/15 6/16 6/20 6/22 8/17 14/2 14/10 14/12 14/15 15/25 16/9 16/20 19/21 20/19 20/21 23/2 23/10 24/1 37/15 42/7 55/11 56/17 56/18 56/22 59/14 59/25 60/5 61/6 66/1 69/3 72/19 72/21 76/11 78/10 90/5 90/9 90/20 91/12 91/15 92/14 128/25 134/10 134/13 134/22 136/22 144/1 145/2 146/20 149/23 151/13 152/3 152/21 161/16 162/1 162/3 163/5 163/22 170/14 170/14 172/25 176/13 176/17 182/18 189/4 201/9 203/2 203/16 204/15 event [12] 8/9 8/25 9/17 18/16 18/25 24/6 24/8 48/9 60/2 142/19 143/12 167/20 events [2] 24/25 183/9 eventually [1] 189/17 ever [5] 6/10 10/4 37/11 90/6 181/5 ever interpreted [1] 6/10 every [21] 20/24 49/12 60/15 69/6 75/23 76/17 77/23 81/6 81/6 81/7 89/18 89/19 91/15 96/4 125/17 144/6 144/22 146/8 146/17 148/2 152/14 everybody [6] 64/1 80/1 84/16 97/19 208/19 208/21 everyone [5] 3/1 3/7 47/25 97/6 168/4 everything [12] 3/12 47/5 123/4 172/19 175/5 184/9 184/14 190/24 198/12 201/4 201/15 203/17 evidence [23] 77/1 172/7 172/9 172/15 173/9 174/15 174/20 174/24 174/25 177/8 185/25 186/13 187/2 187/4 187/6 188/5 188/12 189/6 189/9 192/2 196/16 198/11 198/14 evidentiary [2] 175/16 188/4 evil [1] 33/9 exact [9] 35/1 57/20 57/21 58/13 60/16 84/19 96/19 96/23 189/23 exactly [34] 5/15 7/7 7/18 7/21 15/12 20/8 20/9 22/12 22/15 32/21 37/16 57/2 59/3 60/18 61/17 61/18 66/7 76/24 80/17 86/23 97/2 97/6 97/8 111/21 114/1 123/16 151/20 154/1 154/5 160/9 172/6 178/23 198/8 198/17 example [70] 17/14 19/17 22/14 25/25 26/18 34/20 35/23 35/25 36/8 36/13 41/20 42/9 46/1 51/23 58/3 71/1 71/13 76/22 80/9 84/22 94/24
effectively... [4] 140/23 152/13 170/23 205/8 effectiveness [1] 31/8 efficiency [4] 48/21 52/17 93/17 94/3 efficient [2] 89/21 105/23 effort [4] 4/23 8/12 13/24 19/9 eight [3] 3/23 9/14 53/22 EISENSTEIN [3] 2/5 3/19 136/6 Eisenstein's [1] 140/9 either [14] 33/20 34/12 44/9 46/23 50/10 56/10 56/11 113/21 127/25 145/8 184/18 196/25 199/22 200/9 ELC [5] 111/10 112/5 135/19 206/3 206/8 elected [4] 50/13 53/7 53/11 81/7 electric [2] 105/23 137/8 element [18] 19/25 20/2 20/3 20/4 21/13 21/19 40/14 45/22 46/1 46/9 148/21 149/7 157/11 171/5 180/23 181/17 182/2 200/7 elements [18] 8/16 39/23 40/12 40/16 40/17 45/19 45/20 63/6 77/18 79/10 129/3 139/22 141/16 148/3 149/3 174/13 175/20 182/4 elevated [1] 179/14 elevating [1] 180/21 Eleventh [17] 4/19 8/21 20/15 21/1 38/14 70/16 76/8 105/21 128/20 138/25 140/14 146/22 147/2 147/8 147/22 149/17 149/19 eliminate [4] 5/12 203/2 203/12 204/2 ELIZABETH [2] 1/15 100/17 else [10] 3/7 29/20 96/18 96/23 108/1 128/1 175/5 184/14 190/24 195/4 elsewhere [1] 53/7 elucidate [4] 104/18 118/4 118/4 190/20 elucidated [1] 116/7 emails [1] 18/20 embrace [1] 184/24 embraced [1] 147/21 emerging [2] 18/22 143/14 emphasis [1] 11/13 emphasize [2] 84/1 155/5 emphasized [1] 80/22 emphatically [2] 16/19 146/15 emphatically rejects [1] 146/15 empirical [1] 30/17 en [1] 20/10 encompass [3] 76/17 163/3 164/11 encompassed [1] 42/13 encouraging [1] 104/22 end [15] 17/23 50/11 66/18	endeavor [1] 207/21 endorsed [1] 76/10 ends [1] 24/11 energies [1] 53/7 enforce [6] 8/13 9/4 15/20 43/18 138/24 157/24 enforcement [2] 6/9 30/15 engage [1] 198/4 engaged [3] 35/17 75/11 107/19 English [5] 137/7 137/11 157/2 157/3 157/8 enjoy [1] 127/7 enormity [1] 175/10 enough [19] 12/11 14/8 41/1 41/22 56/20 62/2 63/4 63/5 79/4 86/24 141/20 148/18 151/13 159/21 170/22 171/4 177/7 198/16 200/18 enrichment [8] 4/4 4/8 25/4 48/24 62/9 62/13 72/18 72/25 ensure [19] 49/9 51/21 59/25 64/6 68/4 70/11 105/6 110/16 111/3 111/6 116/19 121/7 129/9 133/5 133/9 134/15 140/7 201/6 201/18 ensuring [2] 31/8 144/18 entire [18] 50/12 68/19 128/18 137/3 137/15 138/1 138/9 147/13 149/11 149/13 149/22 151/8 151/22 152/9 157/10 182/8 192/18 204/20 entirely [8] 17/13 85/23 107/14 135/10 139/12 147/14 154/23 203/3 entirety [2] 128/8 145/16 entities [1] 57/12 entitled [5] 16/7 70/18 77/22 172/3 197/10 entitlement [2] 61/23 72/9 entrusted [1] 43/17 Entry [4] 3/13 47/16 126/14 129/5 Entry 3112 [1] 47/16 envision [4] 165/22 166/2 172/12 198/10 equally [2] 94/11 131/23 Equate [1] 102/3 Erie [5] 139/20 139/21 139/23 191/10 205/3 erroneously [1] 19/11 error [1] 150/20 escapes [1] 16/15 escaping [1] 192/23 especially [1] 69/18 ESQ [10] 1/12 1/15 1/18 1/21 2/2 2/5 2/8 2/9 2/12 2/15 essence [2] 23/7 193/15 essential [1] 136/22 essentially [6] 49/24 50/8 51/16 67/4 91/19 124/9 establish [6] 17/3 44/24 78/6 82/7 161/21 175/16 established [3] 5/13 24/2 151/11	

<p>E</p> <p>example... [49] 101/17 103/12 104/8 113/11 114/3 114/7 114/8 114/18 114/21 115/4 116/24 117/13 118/13 118/15 119/5 120/14 121/3 121/9 121/25 124/25 125/5 125/22 125/25 130/9 131/18 133/6 136/20 138/11 140/3 149/9 152/8 158/14 160/24 165/1 169/22 170/8 175/23 177/17 180/25 181/7 181/25 185/23 187/20 196/1 198/1 200/18 202/15 202/20 204/6</p> <p>examples [9] 76/1 76/3 78/11 128/20 150/22 150/23 153/13 202/12 202/13</p> <p>exceed [2] 69/24 100/5</p> <p>exceeded [2] 75/22 99/8</p> <p>Excelsior [1] 169/4</p> <p>except [2] 39/8 105/1</p> <p>exception [3] 5/11 6/19 37/3</p> <p>excessive [16] 51/19 51/22 52/7 55/4 64/9 64/12 65/4 65/6 66/5 68/3 68/7 69/8 69/16 80/9 153/6 176/9</p> <p>exchange [1] 38/18</p> <p>excise [1] 187/13</p> <p>excised [2] 104/25 105/1</p> <p>excising [2] 72/8 113/2</p> <p>excluded [2] 125/6 172/9</p> <p>exclusive [3] 31/7 122/23 123/5</p> <p>exclusively [1] 19/13</p> <p>excursions [1] 69/21</p> <p>excuse [2] 131/11 205/14</p> <p>exempted [1] 31/14</p> <p>exercise [13] 35/11 40/3 58/22 82/18 105/9 133/7 133/24 135/12 177/16 177/19 178/14 178/17 197/21</p> <p>exert [1] 123/2</p> <p>exhausted [1] 208/6</p> <p>exist [3] 50/8 107/23 117/6</p> <p>existed [5] 6/15 37/15 37/15 145/19 194/13</p> <p>existence [8] 19/24 52/10 63/19 114/9 117/16 120/8 163/17 164/6</p> <p>existence of [1] 19/24</p> <p>existing [2] 107/2 108/2</p> <p>exists [2] 106/18 124/16</p> <p>expect [1] 182/3</p> <p>expected [3] 18/9 191/21 193/24</p> <p>experience [2] 80/25 145/9</p> <p>experience with [1] 145/9</p> <p>expiration [125] 104/8 105/8 105/15 108/23 110/2 111/11 111/14 111/25 112/3 114/15 119/19 119/20 119/21 120/9 120/20 131/8 131/10 131/12 132/12 132/14 132/21 136/23 140/3 143/9 143/18 148/16 149/8 150/7 158/13 158/16 158/20 159/4 159/12 159/16 159/22 161/3 162/21 162/25</p>	<p>163/4 163/7 163/9 163/12 163/13 163/21 163/22 164/12 164/14 164/18 165/10 165/13 165/24 166/1 167/1 167/10 167/13 167/15 167/19 167/24 168/7 168/24 169/7 169/9 169/21 170/13 170/16 171/3 174/18 174/21 174/24 174/25 175/1 175/2 175/4 175/23 176/3 176/20 181/21 182/1 184/13 185/7 185/12 186/4 186/18 186/20 186/22 187/5 187/16 187/18 188/13 189/9 189/15 189/18 189/19 190/10 190/24 191/9 191/18 191/19 191/24 192/1 194/1 194/2 195/3 195/8 195/10 195/15 195/19 195/21 195/23 196/13 198/1 198/3 198/15 198/16 198/21 198/24 200/9 201/9 201/10 201/17 202/12 205/9 206/8 206/11 206/14</p> <p>expiring [1] 141/21</p> <p>explain [4] 110/18 158/23 159/9 163/5</p> <p>explained [1] 78/9</p> <p>explaining [1] 55/9</p> <p>explains [1] 20/25</p> <p>explanation [1] 164/16</p> <p>explicitly [1] 141/14</p> <p>exposed [15] 51/18 51/22 54/19 68/2 68/7 69/7 81/18 82/5 83/18 88/15 186/23 187/23 188/25 201/7 201/18</p> <p>exposing [1] 69/15</p> <p>exposure [14] 54/24 65/1 65/3 120/19 133/3 143/2 143/6 150/12 153/5 162/3 163/1 164/18 184/2 200/18</p> <p>express [33] 4/6 4/7 5/11 5/20 7/14 10/21 11/1 11/5 11/10 13/11 17/23 22/3 22/23 23/17 23/19 31/11 31/22 31/23 32/11 32/24 33/12 37/2 37/24 38/2 38/8 38/11 38/12 38/15 41/12 136/8 182/11 183/2 206/10</p> <p>express preemption [2] 23/19 136/8</p> <p>expressed [1] 69/12</p> <p>expressly [6] 25/5 32/6 34/9 39/9 124/2 199/23</p> <p>expressly preempted [2] 25/5 199/23</p> <p>extensively [1] 128/23</p> <p>extent [17] 5/3 39/25 40/6 42/12 46/14 127/4 137/9 144/25 146/18 146/20 156/25 157/9 162/25 163/24 167/9 188/20 200/7</p> <p>extra [3] 54/2 127/4 163/5</p> <p>extremely [3] 95/4 149/2 177/4</p> <p>extricate [1] 95/25</p> <hr/> <p>F</p> <p>F.3d [5] 76/20 131/22 138/18 140/14 150/2</p>	<p>face [3] 69/11 87/13 90/22</p> <p>face as [1] 69/11</p> <p>faced [1] 50/5</p> <p>fact [42] 14/9 30/17 30/19 31/19 33/9 34/20 36/3 36/12 44/23 51/4 59/21 60/15 63/7 74/8 75/15 75/19 75/20 75/25 76/3 76/16 84/18 89/21 91/25 95/5 96/17 98/25 105/3 107/23 117/10 124/4 124/15 142/25 143/1 150/9 157/8 172/22 176/10 184/10 187/7 192/15 193/8 205/18</p> <p>factor [1] 159/19</p> <p>facts [28] 45/2 56/9 61/9 61/20 61/23 63/5 63/8 70/25 75/14 77/23 78/7 78/15 78/18 78/25 79/12 81/2 117/5 135/20 148/10 164/24 165/11 169/14 171/10 175/15 181/13 181/23 189/5 202/6</p> <p>factual [27] 4/21 53/6 56/4 56/12 56/15 57/1 62/25 63/1 65/24 69/3 77/19 91/13 117/4 163/16 177/24 178/21 178/25 179/5 179/6 179/14 180/4 180/9 180/22 181/6 185/20 192/10 195/7</p> <p>factually [2] 161/22 187/14</p> <p>fail [6] 4/18 67/22 71/8 71/19 149/22 152/9</p> <p>fail for [1] 71/8</p> <p>failed [22] 34/4 50/10 51/20 53/14 53/15 57/4 57/8 58/13 68/4 70/10 77/4 78/7 78/9 83/12 86/24 136/11 141/17 151/22 171/3 183/8 187/24 196/14</p> <p>failed to [1] 51/20</p> <p>failing [7] 5/7 31/24 61/25 83/7 147/17 191/9 196/6</p> <p>fails [6] 14/23 57/7 71/22 72/22 79/13 151/8</p> <p>failure [61] 4/5 5/13 5/23 8/4 8/6 8/15 10/22 17/25 21/6 23/18 23/21 25/5 62/14 69/1 69/18 78/6 82/18 87/21 111/11 111/14 119/18 119/20 131/7 133/16 134/19 135/9 136/7 138/5 140/8 140/16 140/17 140/18 140/20 141/2 141/7 141/10 143/17 148/20 149/7 149/9 150/16 152/4 152/5 152/12 155/2 156/1 158/13 160/4 162/19 172/8 179/22 181/20 181/22 183/11 186/19 188/12 188/13 191/7 196/3 198/4 205/21</p> <p>fair [4] 52/2 78/23 79/4 197/9</p> <p>fairly [5] 62/11 98/8 169/24 175/9 175/19</p> <p>fairness [4] 49/9 49/14 52/16 207/3</p> <p>fall [6] 46/17 103/8 149/12 173/21 182/8 204/21</p> <p>fallacy [2] 144/15 168/9</p> <p>fallback [1] 17/4</p>
---	---	--

F	18/24 19/6 19/13 19/16 19/21 19/22 20/5 21/12 21/13 22/18 24/18 26/1 26/16 27/7 27/14 27/20 27/24 30/24 31/3 31/21 31/24 32/1 32/14 32/15 32/15 32/16 34/6 34/25 35/11 35/21 37/4 38/2 38/5 38/13 39/24 40/13 40/18 40/18 40/21 41/2 41/5 41/7 41/21 43/15 44/14 44/15 45/4 45/6 45/17 45/20 46/10 46/21 49/6 49/8 58/18 58/20 59/1 59/3 59/6 60/11 61/4 72/4 90/21 105/11 115/1 115/7 127/20 128/2 128/12 128/14 128/18 130/5 132/19 134/16 135/3 136/17 136/20 137/3 137/9 137/15 138/6 138/7 139/4 139/7 139/16 141/12 141/17 141/20 143/5 144/2 144/17 145/1 145/7 145/8 145/8 145/10 145/12 145/18 145/23 146/3 146/5 146/13 146/19 147/3 147/4 147/7 147/19 148/19 150/15 154/21 154/24 155/8 155/10 155/20 156/5 156/8 156/9 157/5 157/12 182/19 182/24 195/15 199/1 200/3 204/7 209/7	133/9 Fire [1] 78/5 Fire said [1] 78/5 firearm [1] 146/10 firm [3] 50/16 115/22 115/23 firm's [1] 115/23 first [58] 3/8 4/11 5/24 6/5 10/25 11/7 13/14 13/19 15/16 19/18 20/17 23/25 25/17 25/20 26/7 28/24 32/24 49/4 50/6 50/8 54/15 61/11 64/16 64/23 65/5 66/23 68/10 71/8 72/20 91/8 94/17 95/18 103/6 106/7 117/6 118/1 118/22 128/23 136/18 136/24 139/25 140/13 143/7 145/5 145/25 148/2 151/1 154/20 157/3 158/25 158/25 159/1 162/4 168/22 169/1 169/6 180/17 199/18 five [6] 2/6 3/20 3/24 10/11 22/1 48/9 FL [2] 1/5 2/21 flat [1] 8/12 flatly [2] 72/16 72/23 flaw [1] 130/1 flip [1] 50/10 flip theory [1] 50/10 floating [1] 27/7 Floor [1] 2/13 FLORIDA [19] 1/2 8/23 21/5 21/6 21/21 24/22 72/4 138/21 138/23 146/24 147/17 148/12 148/24 149/13 157/25 179/22 196/1 196/10 197/17 flowing [1] 174/9 focus [13] 17/5 43/12 43/13 45/22 53/7 100/24 111/22 112/13 125/9 125/13 126/6 140/10 166/18 focus on [1] 112/13 focused [17] 34/3 46/9 102/3 103/10 103/12 103/16 104/2 108/23 110/2 112/24 114/16 115/8 125/10 125/18 125/19 159/11 189/2 focus [1] 23/22 focusing [3] 18/2 114/15 175/23 follow [8] 32/17 33/14 55/6 82/23 83/12 86/24 173/12 183/14 followed [7] 30/5 32/20 63/3 64/25 78/13 97/11 121/21 following [9] 23/7 28/24 30/22 31/4 32/3 37/13 50/15 151/16 178/12 follows [1] 127/18 followup [3] 173/23 207/11 207/14 font [1] 152/8 Food [10] 12/24 14/11 16/13 19/25 20/2 20/6 21/18 43/7 43/18 144/16 footnote [2] 16/17 138/15 footnote 4 [1] 16/17 for storage [1] 55/2 for wouldn't [1] 134/7
falls [3] 33/17 69/20 154/14 false [25] 11/24 12/4 12/5 12/14 12/15 12/16 12/17 12/21 13/1 13/8 13/9 15/21 15/24 17/20 17/21 22/7 22/16 26/24 44/21 44/23 45/3 45/7 45/13 153/12 206/15 familiar [6] 10/24 48/18 50/17 58/16 63/14 180/12 family [1] 81/3 fantastic [1] 171/22 far [4] 96/7 96/21 99/8 100/5 fashion [2] 3/5 93/10 fast [1] 142/12 FDA [170] 4/5 5/2 5/5 5/7 5/25 6/1 6/5 6/8 6/11 6/16 6/21 6/24 7/5 7/15 8/5 8/6 8/9 8/15 8/16 8/20 8/25 9/6 9/10 9/12 9/18 9/21 10/3 10/6 10/23 13/17 14/13 14/24 15/4 15/8 15/9 15/12 15/23 16/8 16/11 16/14 16/21 16/23 18/1 18/17 18/22 18/25 19/5 19/7 19/12 21/9 21/12 21/18 22/10 22/19 22/24 23/7 23/12 23/13 23/21 24/5 24/5 24/11 24/12 24/12 24/16 24/24 25/5 26/14 26/19 26/20 26/24 27/2 27/5 27/25 28/4 28/8 28/14 29/2 29/5 29/19 29/25 30/5 30/8 30/9 30/10 30/23 31/5 31/7 31/9 32/20 33/2 33/13 33/14 33/19 34/4 35/7 35/17 35/17 35/25 36/8 36/9 36/16 36/16 37/12 38/23 38/23 39/3 39/3 39/10 40/7 43/17 43/23 44/25 86/19 101/3 105/10 107/20 114/22 115/2 115/19 115/19 116/2 116/16 117/9 117/13 117/15 117/16 121/15 134/25 135/10 135/11 136/7 140/8 140/17 140/20 141/2 141/7 141/8 141/10 143/11 144/19 153/1 153/8 153/17 154/3 154/4 154/8 154/10 154/13 154/18 155/2 155/12 155/14 155/16 155/19 155/23 156/1 156/8 156/12 167/21 167/23 167/23 168/2 168/3 183/9 183/11 186/20 188/21 190/8 198/22 FDA in [1] 31/5 FDA is [1] 43/17 FDA issuing [1] 134/25 FDA's [8] 8/18 16/2 16/6 29/8 44/4 83/11 135/12 168/25 FDCA [5] 8/13 8/16 9/5 10/5 24/16 federal [154] 3/10 4/6 4/15 4/21 6/20 7/4 7/13 7/21 7/24 9/7 9/25 11/4 11/9 11/12 11/15 11/17 11/19 12/23 13/6 13/9 13/16 17/4 17/11 17/15 17/19 17/21 17/23 18/23	federalism [1] 144/23 Federally [5] 25/24 29/1 29/22 39/21 42/18 feel [1] 98/10 FEGAN [5] 1/15 1/16 100/18 106/10 108/11 few [11] 25/8 94/16 108/11 127/11 131/2 140/9 146/1 148/13 156/19 158/9 165/2 Fifth [3] 20/10 70/14 128/22 fighting [1] 56/16 figure [1] 53/9 figured [1] 54/12 file [5] 79/18 90/6 92/10 96/16 99/4 filed [10] 37/8 51/10 68/23 70/3 74/5 78/22 79/16 80/17 131/16 135/18 filing [1] 93/2 filled [1] 74/12 final [2] 135/8 150/20 finally [12] 14/22 51/23 55/17 62/8 70/14 72/18 95/5 104/9 105/18 107/4 125/14 155/1 find [16] 6/17 6/21 28/23 38/21 38/21 39/1 39/3 40/10 90/14 93/19 182/20 183/21 193/2 198/2 198/6 199/22 finding [2] 32/25 196/20 findings [1] 50/16 finds [1] 196/17 fine [12] 25/12 25/13 25/14 43/25 50/20 79/6 98/3 98/3 108/13 161/11 176/23 192/22 fingers [1] 120/2 fingertips [1] 197/17 finish [2] 3/24 80/20 finished [3] 21/23 110/14	

F	FTC [3] 114/19 114/22 115/2	166/7 168/22 169/18 171/12
forbade [3] 58/20 59/1 61/4	fulfill [4] 19/5 116/25	172/12 172/18 173/17 173/24
forbid [2] 12/15 62/12	171/12 179/12	174/4 174/10 174/15 174/16
forbidding [1] 59/6	fulfilled [3] 18/16 18/17	175/8 175/15 176/14 177/8
forbids [4] 12/4 17/20 17/21	122/5	179/11 180/5 181/16 181/24
59/3	fulfilling [2] 117/5 122/7	182/14 184/8 184/25 185/15
force [2] 28/7 43/20	full [3] 48/4 59/14 99/19	185/18 186/2 187/4 187/14
foreclose [1] 112/18	fully [6] 18/10 38/22 86/6	187/24 188/2 188/10 189/13
foreclosed [1] 149/12	136/5 141/16 146/14	189/14 190/3 190/19 191/4
foregoing [1] 209/3	function [1] 15/19	193/11 193/22 194/18 195/10
foreseeable [2] 82/17 83/20	fundamental [2] 95/10 193/6	196/14 196/22 197/2 197/10
foreseeably [1] 55/15	fundamentally [5] 67/22	198/3 198/15 199/22 199/25
foreseeably led [1] 55/15	68/21 104/13 125/10 130/13	203/18 204/24 208/10
forget [1] 194/8	further [8] 8/17 32/3 96/9	generics behaved [1] 181/24
form [21] 9/20 19/7 35/17	124/17 130/24 155/14 174/7	generics point [1] 147/16
51/8 81/18 82/5 83/17 88/14	200/25	generics pretend [1] 153/7
91/20 92/17 92/23 93/9 93/10	Furthermore [1] 167/9	generics' [10] 37/1 146/16
94/18 96/16 97/4 129/15	future [3] 93/1 93/5 93/14	146/21 147/12 151/25 152/2
129/21 132/6 132/17 134/10		152/16 153/1 175/24 201/23
format [1] 3/12	G	generously [1] 53/1
formation [5] 25/1 41/18	Gables [4] 4/19 27/13 27/13	Geri [1] 74/10
64/11 64/19 122/19	38/14	Geri-Care [1] 74/10
formed [2] 163/12 163/13	garb [1] 186/11	get [37] 19/20 38/4 40/14
former [1] 178/5	gas [2] 106/23 125/17	41/20 42/7 43/13 47/11 50/21
forming [3] 129/13 129/18	gauging [1] 17/10	53/1 53/5 80/7 98/9 109/2
132/10	gave [6] 50/18 53/1 68/10	109/4 111/19 113/10 118/3
forms [1] 143/2	74/7 116/11 147/4	124/12 124/24 164/23 165/10
formulaic [3] 56/7 79/9	gears [1] 36/18	166/10 169/5 171/9 172/16
79/10	gee [1] 197/5	174/8 178/8 183/20 189/17
formulation [1] 130/19	gen [1] 126/20	189/18 191/23 198/12 200/21
forth [12] 26/2 26/6 42/20	general [24] 22/6 22/7 26/9	203/10 205/1 207/21 208/4
43/8 45/11 47/5 51/16 62/25	28/7 28/12 35/19 43/5 43/6	gets [7] 13/21 16/9 41/6
69/3 141/3 151/16 198/9	43/11 43/12 49/2 62/5 71/9	120/4 175/18 203/21 204/18
forth in [1] 42/20	88/23 99/15 99/17 105/3	getting [2] 182/17 193/20
forward [7] 22/21 92/19	137/7 164/25 165/16 170/6	give [22] 26/18 27/21 50/21
92/21 92/21 93/6 93/13	179/2 179/12 181/22	54/1 64/4 73/15 77/10 84/7
113/18	generality [5] 87/9 148/6	84/22 108/8 116/4 119/14
found [18] 6/14 14/7 22/24	164/23 170/24 202/5	125/21 131/21 140/4 166/13
32/23 34/9 34/22 35/6 36/5	generalized [5] 7/2 27/14	166/16 168/13 171/18 176/23
37/14 83/6 128/10 135/7	32/18 33/24 35/9	192/16 207/4
137/16 137/21 139/2 151/18	generally [5] 29/13 115/6	given [14] 4/15 9/18 53/8
164/9 197/3	117/19 117/20 166/17	66/3 69/18 76/3 125/19
founded [1] 74/8	generic [51] 48/2 63/20	134/14 141/9 171/14 171/21
four [17] 13/18 13/20 43/4	97/12 100/2 104/1 104/6	175/9 188/22 199/5
101/7 103/4 104/25 106/20	105/7 123/11 123/11 123/20	giver [1] 145/21
106/23 109/9 109/17 111/24	123/20 126/13 127/14 127/17	gives [3] 57/5 67/23 173/12
112/4 122/22 123/7 125/15	128/3 128/12 128/16 129/7	giving [2] 100/3 181/14
167/1 207/8	129/11 130/1 130/4 130/20	glad [1] 171/23
fourth [4] 48/16 61/4 69/25	131/5 131/9 132/1 134/14	global [1] 51/2
128/21	135/5 135/9 135/16 135/21	GMP [1] 125/20
frame [2] 11/6 49/14	136/13 137/20 138/8 139/12	go [28] 22/21 23/2 35/22
frankly [1] 56/17	140/16 140/21 141/9 141/16	45/18 47/11 48/1 73/25 78/24
fraud [2] 19/12 115/4	141/19 141/22 142/1 143/3	80/7 87/20 92/21 98/11 104/1
Fred [2] 73/19 92/1	151/23 155/9 162/14 172/22	108/5 125/13 125/17 131/4
FREDERICK [1] 1/21	173/20 188/15 206/1 206/7	152/24 166/18 167/23 168/13
free [2] 27/7 98/10	207/19	171/8 175/2 187/15 192/17
free-floating [1] 27/7	generic manufacturers' [1]	193/17 197/6 200/25
frequency [1] 13/3	139/12	goal [3] 48/13 98/18 98/19
frequently [2] 26/21 157/1	generic's [2] 37/13 37/21	goes [14] 8/17 18/13 19/23
friend [9] 15/8 15/17 16/3	generics [85] 131/6 132/9	24/11 25/17 33/23 35/20
43/4 43/21 45/16 46/1 111/20	133/2 133/22 141/1 141/12	101/23 102/18 120/16 125/8
112/8	143/8 143/15 143/17 144/4	160/17 167/17 200/6
friends [1] 195/12	144/5 144/10 144/21 145/4	goes out [1] 102/18
front [1] 112/23	145/25 147/13 147/16 148/18	going [73] 21/1 28/18 33/20
froze [1] 65/10	149/6 149/18 150/14 150/20	38/18 44/25 47/10 47/17
frustrate [1] 182/20	150/22 151/20 152/1 152/13	47/23 48/14 48/23 49/1 52/16
Ft [1] 2/21	152/19 153/3 153/7 154/10	58/11 63/25 79/5 83/14 86/4
	154/21 154/23 155/13 155/15	86/18 86/23 88/11 89/9 89/10

G	guidance [2] 74/17 154/6	has yet [1] 96/7
going... [51] 92/13 92/15	guidepost [1] 7/9	hasn't [5] 35/17 42/4 161/23
92/18 92/18 92/21 93/13	H	168/4 172/20
93/14 96/19 97/3 97/14 97/20	had [65] 4/23 5/9 19/19	hate [1] 208/3
98/8 113/12 116/17 123/13	22/20 24/5 24/22 28/24 29/3	have [446]
124/12 124/24 125/9 126/6	36/9 37/17 38/18 40/7 42/22	have the [1] 7/10
126/21 131/4 142/12 158/5	44/20 47/11 56/22 60/4 62/20	haven't [13] 28/21 53/10
158/7 159/18 165/7 165/9	70/3 72/21 73/2 74/3 81/17	61/9 66/1 66/3 95/8 116/23
166/10 168/2 168/3 169/8	82/4 84/18 85/18 86/12 88/13	161/17 161/24 166/11 166/17
170/6 172/2 172/16 173/18	92/20 93/4 95/6 95/6 95/13	193/5 199/4
181/3 181/5 181/7 181/10	104/11 104/11 114/3 118/4	haven't pled [1] 61/9
181/12 181/21 182/20 186/8	118/14 120/15 121/13 121/24	having [8] 58/25 69/2 76/14
187/11 189/11 189/21 191/18	122/1 122/4 122/18 123/16	78/24 118/6 153/23 165/23
202/10 204/18 207/1 207/22	124/6 127/10 132/9 138/21	184/7
Golden [1] 74/10	143/11 148/15 153/3 166/11	he [17] 22/6 22/6 22/8 22/10
gone [7] 26/23 35/12 107/22	169/25 172/11 180/3 180/13	48/23 49/11 49/19 58/8 76/8
116/6 135/15 161/24 207/3	185/5 187/5 187/14 192/16	76/9 76/20 78/21 79/5 94/10
good [33] 3/1 3/18 3/21 4/1	198/15 198/16 207/10 207/11	168/15 168/16 168/16
4/12 10/14 10/18 10/18 21/23	hadn't [2] 172/25 207/7	health [6] 13/2 16/22 66/15
35/25 48/3 48/6 66/11 66/14	half [3] 51/12 142/7 156/17	80/15 102/4 144/18
86/25 97/13 98/12 100/17	Halfway [1] 127/1	healthcare [1] 146/10
100/18 102/24 108/20 118/25	Hampshire [3] 128/10 137/19	healthcare regulations [1]
119/3 121/3 121/6 121/25	137/22	146/10
127/13 142/8 156/14 162/10	hand [1] 102/15	hear [17] 10/16 10/17 47/12
207/2 208/2 208/21	handful [1] 9/11	47/17 47/17 65/12 65/17
Goodell [1] 2/9	handle [2] 49/1 127/1	73/13 73/22 74/1 74/20 89/23
got [10] 42/8 46/14 51/11	handled [1] 69/9	91/7 94/22 97/20 145/7 180/1
51/13 52/5 89/7 92/14 161/1	handling [2] 69/11 82/20	heard [22] 3/8 8/7 13/15
161/6 195/8	happen [6] 8/10 86/23 113/12	15/8 16/3 41/8 56/14 73/20
gotten [2] 108/25 186/7	113/13 113/14 172/6	73/25 77/16 96/2 122/17
govern [2] 22/17 23/6	happened [3] 33/22 55/10	130/7 133/18 145/14 146/1
governed [2] 22/18 61/15	182/5	150/25 168/11 169/2 177/6
Government [2] 37/8 37/17	happens [3] 35/13 113/7	190/19 204/23
Government's [1] 6/13	189/6	hearing [12] 14/23 65/11
governs [1] 21/13	happy [4] 10/15 62/17 66/18	85/5 85/13 85/22 194/23
Graham [1] 105/21	167/7	196/21 197/4 199/8 203/17
grant [1] 67/18	hard [4] 14/1 123/12 192/12	208/19 209/1
granted [8] 80/24 99/4 99/22	193/21	hearings [4] 3/2 3/4 50/6
100/2 100/6 104/6 104/22	hardest [1] 12/9	50/15
107/3	hardness [1] 167/17	heart [2] 74/18 159/11
granular [1] 181/20	harm [9] 133/16 134/4 160/15	heat [25] 51/19 51/22 54/20
granularity [1] 178/9	160/24 161/22 200/23 202/21	55/4 55/16 55/20 64/10 65/1
grapple [2] 37/10 150/23	204/4 205/17	65/4 65/6 66/5 68/3 68/5
grapples [1] 20/25	harmed [5] 158/18 158/22	68/7 69/8 69/16 70/11 81/18
grappling [1] 180/1	159/5 160/1 160/14	82/5 83/18 88/15 133/3
gratuitous [1] 9/6	has [90] 6/10 11/5 12/9 15/9	174/12 175/25 197/7
gravity [1] 175/10	18/13 21/10 26/25 27/6 27/11	headed [1] 158/16
great [3] 75/2 172/24 208/25	28/8 30/3 30/15 33/22 34/4	Heinz [2] 49/5 101/17
grocer's [1] 176/4	34/8 35/2 37/23 38/24 41/3	Heinz's [1] 49/13
ground [2] 126/13 142/24	42/2 43/4 43/18 43/20 46/8	held [19] 9/1 9/23 23/19
grounds [3] 41/10 53/14	48/3 53/8 63/21 63/22 63/22	24/18 32/7 60/19 61/18
175/9	69/1 72/12 74/2 86/2 92/20	127/23 128/6 128/13 131/19
grounds for [1] 53/14	96/7 96/15 100/6 100/12	135/1 136/25 137/13 138/2
group [12] 63/11 65/25 67/10	107/21 111/1 115/19 115/23	138/4 140/15 140/20 140/22
74/24 76/8 76/10 80/18 81/11	116/16 119/12 124/18 124/19	help [2] 65/16 175/15
106/21 107/14 108/9 162/9	125/2 127/10 131/20 136/25	helped [1] 180/19
grouped [1] 68/19	138/12 139/10 139/20 140/20	helpful [2] 7/9 46/25
grouping [1] 57/25	144/17 144/19 145/9 145/14	her [6] 3/15 48/3 142/9
groups [4] 68/19 68/21 76/22	145/19 146/7 149/17 150/18	186/23 187/22 187/23
104/13	152/15 153/23 154/18 160/3	here [98] 3/1 3/3 3/6 7/1
grueling [1] 127/11	165/4 170/2 173/20 177/15	9/8 10/3 22/4 30/14 30/25
Guarino [4] 62/23 128/21	177/19 178/2 178/17 182/22	31/19 33/3 33/5 33/8 33/22
140/14 186/11	184/23 191/2 191/5 191/11	34/12 37/23 37/24 38/3 39/18
guess [4] 74/21 92/12 179/16	193/4 194/5 196/9 198/19	41/15 43/21 48/13 49/15
189/2	199/8 199/21 200/11 201/4	49/18 55/4 57/14 58/11 58/22
GUGERTY [7] 2/9 127/2 130/23	201/15 207/4 208/22 208/23	60/21 62/13 63/6 65/8 66/15
131/1 156/23 190/18 204/24	has the [1] 12/9	71/5 75/15 76/2 76/24 78/8
		80/13 86/3 93/5 95/7 96/25

H	26/11 26/12 27/4 32/3 32/5 55/9 69/17 69/17 74/7 76/3 78/9 90/8 92/13 92/14 92/18 92/21 97/2 104/19 113/4 114/22 115/24 116/7 116/25 117/3 117/5 117/11 120/17 122/7 126/17 126/24 129/13 129/19 131/5 136/11 147/1 164/4 165/17 166/2 168/24 171/21 172/22 174/11 174/15 175/3 175/7 175/25 176/8 176/17 177/10 179/15 180/1 180/6 187/15 188/23 191/23 193/24 194/25 195/3 195/4 195/6 195/22 195/24 196/16 196/19 197/2 198/20 198/20	illustrate [1] 60/22 illustrated [1] 150/21 illustrates [1] 146/23 imaginary [1] 144/5 imagine [2] 174/14 204/10 immediately [1] 119/24 impact [2] 90/24 94/7 impermissible [1] 182/9 implausible [2] 69/11 77/21 implausibly [2] 90/1 90/11 implement [3] 51/21 68/4 70/11 implement rigorous [1] 68/4 implicit [1] 71/3 implied [5] 8/4 8/14 182/12 182/14 183/7 impliedly [4] 8/14 10/7 25/6 179/23 import [1] 176/6 important [15] 11/6 23/24 43/14 50/23 52/17 69/18 72/7 117/23 122/16 122/21 149/2 153/21 165/17 166/8 194/8 importantly [6] 51/6 53/3 53/11 69/25 84/13 128/4 impose [15] 6/3 7/23 12/21 21/17 27/17 32/24 33/1 33/15 37/25 40/5 40/6 44/16 171/6 202/10 203/8 imposed [10] 9/5 12/23 28/8 33/2 38/8 144/6 144/8 148/11 149/24 151/9 imposes [16] 13/8 13/9 17/14 27/18 33/13 40/19 87/5 137/14 151/4 156/7 156/8 156/11 163/2 171/1 202/19 202/21 imposing [2] 12/2 12/11 impossibility [13] 37/1 37/21 59/9 135/2 143/24 154/25 155/6 156/4 179/25 180/2 182/11 182/13 182/22 impossible [10] 28/9 58/17 59/8 143/25 144/7 152/25 155/10 184/1 199/23 201/17 improper [14] 68/15 81/11 111/11 111/14 160/17 160/20 161/5 165/13 171/10 171/10 172/7 179/21 186/21 206/8 improperly [2] 74/25 150/7 improvement [1] 74/21 impurity [1] 153/11 impute [1] 175/7 imputed [1] 86/14 in discretionary [1] 9/21 in every [1] 146/8 in Stengel [1] 20/10 inability [2] 72/8 150/17 inaccurate [2] 20/16 20/17 inadequacy [1] 171/11 inadequate [5] 34/19 150/7 160/12 161/2 169/14 inadequately [1] 8/14 inappropriate [2] 93/12 169/5 inapt [1] 150/23 inaudible [1] 204/4 Inc [1] 66/15
here... [55] 98/19 98/20 99/3 99/20 100/7 100/8 100/10 100/12 100/25 101/6 101/25 102/8 102/16 103/2 104/24 106/16 107/8 108/3 108/8 108/12 111/22 112/12 113/8 113/17 113/23 114/20 115/2 115/8 117/23 118/5 118/16 119/9 121/2 121/12 124/1 125/9 130/12 135/5 137/24 141/2 152/18 155/5 161/19 161/24 172/6 173/15 175/14 182/16 183/19 183/21 184/22 190/5 200/25 201/22 207/1 hid [1] 84/15 high [12] 54/19 55/16 55/20 57/16 69/17 148/5 148/9 164/23 170/24 181/1 181/10 202/5 higher [6] 16/9 54/25 87/8 154/12 154/15 154/16 highlight [5] 63/17 85/3 98/21 106/9 133/17 highlighted [1] 70/21 him [3] 76/14 94/10 94/10 hinge [1] 24/13 hint [1] 15/25 hire [1] 111/1 hired [1] 118/8 hiring [1] 122/5 his [12] 22/11 58/9 58/10 78/8 78/23 94/11 147/10 168/16 179/20 183/14 186/23 205/9 history [1] 30/17 hit [1] 13/19 hold [4] 27/10 95/1 128/16 156/20 holders [8] 115/10 115/11 115/13 115/13 123/1 154/6 198/22 198/23 holding [8] 119/8 127/17 138/16 145/2 147/12 149/25 157/12 183/2 holdings [2] 127/18 157/8 holds [1] 103/25 Holland [1] 2/12 home [1] 113/10 homeopathic [1] 30/8 HON [1] 2/20 Honor [235] Honor allowed [1] 151/14 Honor's [10] 134/2 157/7 174/19 178/8 190/23 192/8 194/3 194/12 205/19 206/18 HONORABLE [1] 1/9 hope [6] 2/13 45/9 54/7 142/14 161/12 183/1 hopefully [4] 100/22 142/11 142/14 199/24 hostage [1] 95/2 hot [1] 161/6 hour [2] 66/11 97/9 hours [2] 69/22 123/9 how [71] 8/7 14/1 14/2 15/12	however [2] 50/13 161/16 Hughes [2] 20/11 23/23 human [3] 86/5 132/7 201/20 humidity [29] 51/19 51/22 54/20 55/4 55/8 55/16 55/21 57/17 60/25 64/7 64/10 65/2 65/4 65/6 68/3 68/5 68/8 69/8 69/16 70/12 75/18 75/22 77/5 78/10 86/20 120/19 133/4 153/6 197/7 hundred [2] 52/2 90/6 hurt [1] 77/9 hybrid [1] 99/6 hyper [1] 59/20 hypothetical [7] 78/16 94/1 94/1 188/8 190/23 197/25 204/21 hypothetically [2] 165/19 185/5 hypotheticals [1] 190/5	
I	I'd [2] 83/23 127/11 I'll [2] 140/8 140/11 I'm [4] 81/23 107/7 174/6 186/17 i.e [1] 7/12 idea [14] 10/3 30/22 49/7 49/13 106/20 107/14 112/18 113/16 118/16 119/9 119/11 121/11 184/8 208/2 identical [10] 7/24 11/4 13/10 31/21 32/14 38/1 39/8 40/17 42/22 91/13 identically [2] 22/23 39/7 identicalness [1] 38/8 identified [1] 87/20 identifies [1] 58/3 identify [3] 52/12 58/12 58/19 identifying [2] 92/23 129/3 identity [1] 153/18 ignore [10] 13/19 13/19 13/20 79/9 136/18 136/21 138/13 149/7 151/1 154/10 ignored [5] 62/1 64/5 64/17 68/23 124/10 ignores [1] 22/8 IL [2] 1/14 1/17 ILANA [2] 2/5 3/18 illogical [1] 144/5 illogical as [1] 144/5	

I		
inception [2]	130/15 192/19	
include [8]	21/21 31/18 57/1 91/21 91/23 110/3 128/20 170/5	
included [6]	131/10 132/3 150/6 183/16 190/25 191/14	
includes [4]	7/5 110/24 110/24 122/24	
including [10]	5/14 16/11 18/18 35/5 53/14 70/17 123/5 128/6 132/10 152/14	
incompatible [3]	34/6 147/3 147/12	
inconsistencies [1]	122/16	
inconsistent [2]	113/16 147/7	
incorporate [5]	91/20 97/3 116/3 134/9 166/1	
incorporated [12]	3/11 47/15 47/21 79/12 87/23 88/6 88/8 98/25 114/24 126/14 136/9 174/3	
incorporates [2]	72/25 195/17	
incorporation [1]	175/8	
incorrect [2]	6/7 146/21	
increase [1]	55/18	
increased [1]	66/4	
incurring [1]	96/5	
indeed [5]	11/15 19/17 20/2 30/21 155/24	
independent [6]	24/15 52/9 52/10 105/10 105/10 199/9	
independently [9]	127/19 135/3 135/5 137/1 141/5 156/5 168/6 185/11 200/20	
indicate [1]	63/5	
indicated [2]	47/11 173/5	
indiscriminately [1]	75/1	
individual [4]	79/19 90/16 95/12 148/10	
individually [1]	76/15	
industry [3]	50/12 51/14 65/23	
industry-wide [2]	51/14 65/23	
inevitable [1]	129/23	
inexpensive [1]	49/12	
inference [1]	77/23	
inferences [1]	44/18	
informally [1]	143/13	
information [35]	8/19 9/1 9/8 9/10 9/13 9/18 13/20 18/14 23/16 24/25 31/19 36/7 51/15 51/17 51/19 52/13 65/8 67/12 68/1 70/16 70/18 74/2 74/7 78/18 84/25 116/24 121/16 141/9 175/7 187/15 192/7 194/5 198/16 198/23 199/2	
ingested [6]	129/14 129/15 129/20 129/20 130/15 132/11	
ingesting [1]	132/10	
ingests [1]	54/25	
ingredients [4]	36/9 36/11 36/12 161/6	
inherent [9]	41/19 51/2 60/8 120/16 122/19 130/1 177/4 177/5 201/7	
inherently [2]	41/14 201/20	
initially [3]	13/25 14/6 193/13	
initiated [3]	101/16 101/21 102/2	
injured [2]	113/15 119/17	
injuries [6]	55/18 82/18 83/19 150/13 159/17 161/15	
injury [28]	18/3 40/24 41/2 41/5 41/23 42/1 47/14 47/21 74/19 77/7 92/7 112/11 122/21 122/23 140/5 142/24 150/5 152/24 156/11 159/14 159/23 165/2 173/19 194/5 194/10 194/15 200/17 204/12	
inquiry [5]	17/24 99/2 159/18 187/1 200/25	
instability [1]	51/3	
instance [7]	27/23 66/3 69/3 119/22 150/4 152/6 157/16	
instances [3]	23/8 26/23 27/23	
instead [14]	5/6 49/23 50/13 50/25 57/22 64/9 77/12 128/6 131/14 132/16 141/18 142/23 154/13 154/20	
instruct [5]	116/13 116/14 120/20 155/23 174/21	
instructed [3]	129/2 150/7 172/10	
instructing [2]	116/18 197/23	
instruction [12]	124/25 133/15 133/17 171/17 171/21 193/25 194/1 194/16 196/2 196/9 197/11 197/21	
instructions [23]	23/16 55/2 83/11 83/13 171/20 171/24 172/3 172/4 173/12 173/14 173/25 174/1 192/6 194/19 194/19 197/12 197/16 197/17 197/18 197/22 203/17 205/19 208/1	
insufficiency [1]	71/2	
insurer [2]	49/25 49/25	
intend [6]	31/7 112/4 177/8 184/24 185/2 185/24	
intended [4]	76/16 161/13 165/6 170/3	
intending [1]	109/16	
intent [2]	145/21 188/6	
intention [1]	161/19	
interacted [1]	147/1	
interchangeably [1]	72/3	
interest [1]	48/21	
interject [1]	142/12	
intermediary [1]	24/3	
intermediate [1]	181/12	
interplay [1]	122/15	
interpret [1]	85/25	
interpretation [2]	16/2 62/10	
interpretations [1]	45/2	
interpreted [5]	6/10 14/10 46/8 88/23 193/4	
interpreting [3]	11/4 30/20 61/12	
interprets [1]	43/23	
interrupt [2]	166/21 174/23	
interstate [1]	13/1	
intimated [1]	14/12	
intrinsic [1]	129/22	
invoke [1]	89/19	
invoked [4]	144/5 145/10 147/10 149/18	
involve [1]	122/22	
involved [4]	14/4 30/8 138/21 163/11	
involving [3]	31/13 36/3 75/4	
Iqbal [8]	56/6 61/9 61/11 61/15 67/13 80/22 190/12 204/7	
Iqbal/Twombly [1]	190/12	
irrelevant [1]	17/13	
is [1019]		
is an [1]	41/20	
is hard [1]	14/1	
is in [1]	31/11	
is meant [1]	94/18	
is the [1]	37/7	
isn't [9]	15/25 20/2 42/13 61/6 113/12 116/4 118/5 121/17 122/23	
isolation [1]	71/23	
issue [36]	7/8 14/9 22/4 24/21 25/16 25/17 35/16 37/10 42/6 42/8 42/9 47/6 51/4 56/12 65/20 70/14 70/24 75/23 84/15 84/16 85/6 95/10 123/13 124/17 124/18 139/1 139/6 163/25 165/10 166/23 173/17 177/23 185/19 200/10 200/11 200/13	
issues [16]	42/14 46/17 48/22 48/23 67/21 71/2 89/20 91/11 91/13 91/14 91/24 123/25 124/25 125/10 186/15 199/16	
issues with [1]	42/14	
issuing [3]	130/2 130/19 134/25	
it [549]		
it's [8]	27/25 41/22 58/19 102/3 102/4 102/5 186/16 190/23	
item [1]	118/12	
items [1]	121/9	
iteration [1]	162/20	
its [68]	6/1 10/6 10/6 11/17 13/1 15/20 15/21 16/4 18/13 26/11 28/1 28/10 31/9 31/18 31/20 31/24 31/25 42/2 43/23 50/16 52/23 58/24 62/11 68/16 69/11 69/13 72/20 80/25 101/19 101/22 102/4 103/15 103/25 116/3 121/4 121/15 121/15 122/3 122/6 122/7 122/7 124/14 125/1 127/16 128/8 129/22 130/14 132/15 138/22 139/1 139/11 139/13 147/20 154/5 156/3 165/5 170/3 177/17 177/20	

<p>I</p> <p>its... [9] 178/3 179/1 182/23 188/24 191/5 191/15 192/18 194/15 199/9</p> <p>itself [14] 5/7 6/1 9/10 15/17 24/24 27/6 27/17 95/25 116/23 164/14 164/18 170/17 171/4 206/21</p> <p>iv [1] 153/10</p>	<p>101/19 102/7 104/15 104/20 106/21 110/7 113/3 116/6 116/11 116/23 117/8 117/25 118/6 120/1 122/13 122/14 124/25 125/25 127/3 127/7 131/16 132/13 134/20 145/17 146/1 148/11 148/23 149/8 149/12 149/12 149/14 149/25 150/17 150/24 154/4 156/18 157/21 157/24 158/9 159/9 160/3 160/25 164/19 165/2 169/2 169/9 170/7 170/18 172/18 173/5 173/15 174/18 174/23 175/4 175/22 175/24 176/23 177/3 177/6 178/7 178/9 178/12 178/12 179/15 180/11 181/21 182/8 185/12 185/21 187/18 190/2 191/8 191/25 192/11 194/2 195/2 196/12 198/23 199/3 201/21 203/9 205/6 205/9 205/11 205/17 206/19 208/2 208/3</p> <p>just fighting [1] 56/16</p> <p>Justice [1] 105/20</p> <p>justified [1] 169/14</p>	<p>108/12 112/6 115/24 116/9 137/5 142/10 160/24 160/25 163/6 171/18 171/19 174/16 179/13 179/16 179/25 183/10 185/20 189/7 189/12 189/16 189/25 192/3 192/23 193/1 193/24 194/4 195/5 195/20 195/22 195/24 196/19 197/11 197/24 198/12 202/22 207/8 207/22 208/23</p> <p>know these [1] 10/23</p> <p>knowable [1] 181/4</p> <p>knowing [3] 83/3 86/23 197/7</p> <p>knowledge [39] 19/22 64/23 64/24 65/20 73/2 81/17 82/4 82/8 83/5 83/17 84/10 84/18 84/21 85/18 85/20 86/2 86/8 86/12 86/13 86/14 86/15 88/14 88/24 122/18 122/20 123/9 174/10 175/8 175/22 175/24 175/25 176/8 176/21 177/5 179/11 184/11 187/13 195/6 198/19</p> <p>knowledge-based [1] 176/21</p> <p>known [12] 44/22 65/1 82/16 85/1 92/12 92/18 120/12 120/15 120/19 122/9 131/21 181/4</p> <p>knows [7] 15/12 31/15 96/23 132/14 135/18 148/2 183/22</p>
<p>J</p> <p>JAMOLed [1] 171/9</p> <p>JJ [2] 54/5 81/23</p> <p>job [3] 12/10 79/6 208/21</p> <p>JOHN [1] 1/18</p> <p>JOHNSTON [14] 2/15 48/3 48/7 62/20 65/12 65/13 67/1 84/20 94/15 95/17 97/21 98/13 106/3 108/12</p> <p>Johnston's [1] 56/22</p> <p>judge [7] 1/10 66/14 76/7 76/11 76/20 91/4 197/23</p> <p>judgment [4] 14/7 31/5 75/24 135/12</p> <p>judicial [2] 80/25 205/5</p> <p>jump [1] 49/2</p> <p>jumping [1] 165/2</p> <p>June [2] 1/5 209/6</p> <p>juries [4] 32/7 33/4 35/25 173/11</p> <p>juris [1] 164/1</p> <p>jurisdiction [3] 165/9 165/9 178/2</p> <p>jurisdiction's [1] 164/1</p> <p>jurisdictions [9] 9/11 12/17 18/4 19/15 21/21 79/17 156/10 161/23 177/15</p> <p>jurisprudence [1] 23/19</p> <p>jury [51] 7/15 31/9 32/5 32/12 35/7 35/20 35/22 36/5 38/20 39/1 39/2 39/9 39/17 45/18 124/25 133/15 141/7 163/16 165/21 165/23 171/9 171/11 171/16 171/20 171/20 171/24 172/4 172/8 172/9 173/13 174/1 177/9 188/11 189/18 191/24 192/4 192/6 193/25 194/1 194/16 194/21 196/1 196/9 196/9 196/14 196/17 196/19 197/11 197/21 203/17 205/18</p> <p>jury of [1] 172/8</p> <p>jury's [1] 32/25</p> <p>just [153] 3/6 13/15 15/7 16/3 19/12 22/3 22/11 23/2 27/7 27/9 27/10 28/2 31/16 36/18 37/10 38/6 38/10 39/8 40/4 40/23 41/1 43/2 43/11 46/21 47/25 48/14 49/12 53/22 54/7 55/25 56/6 56/16 57/10 60/9 62/21 64/3 70/13 70/23 73/20 73/24 73/25 73/25 74/1 75/13 78/1 79/8 80/8 80/20 84/21 86/11 87/19 88/22 89/6 91/15 92/8 93/8 93/20 94/9 94/11 94/16 95/9 96/10 97/2 98/17 100/24</p>	<p>K</p> <p>Kansas [2] 93/5 93/6</p> <p>KansasKansas [1] 134/20</p> <p>KAPLAN [10] 2/2 48/21 62/22 66/10 66/15 74/2 77/16 78/21 84/9 95/15</p> <p>keep [12] 10/15 48/15 55/11 66/18 91/18 97/14 98/9 142/15 177/1 194/23 195/12 207/10</p> <p>keeping [1] 66/13</p> <p>keeps [1] 15/18</p> <p>KELLER [35] 1/12 1/12 10/14 10/19 12/6 22/3 23/11 23/22 29/16 40/3 44/12 49/18 49/21 142/9 142/17 156/24 157/18 159/7 162/17 162/18 167/5 167/9 177/3 177/6 177/14 183/11 183/25 185/22 186/16 188/6 188/11 191/11 192/24 201/9 205/8</p> <p>ketchup [3] 101/17 101/18 101/19</p> <p>key [4] 32/1 54/11 118/5 159/10</p> <p>kills [1] 46/6</p> <p>kind [14] 27/8 32/9 42/3 57/18 73/11 86/7 93/24 101/18 116/5 117/6 121/19 180/2 193/15 193/21</p> <p>knew [17] 44/22 61/24 82/16 83/10 84/25 86/17 86/19 115/14 120/12 120/15 120/18 122/9 126/6 192/9 192/15 194/24 194/25</p> <p>Knight [1] 2/12</p> <p>know [65] 10/13 10/23 12/9 26/3 29/1 29/8 57/6 58/8 59/4 62/22 65/12 78/17 78/17 80/12 80/12 80/15 85/8 87/12 88/4 93/4 97/2 98/10 102/7 106/6 107/17 107/24 108/6</p>	<p>L</p> <p>L.A [1] 62/3</p> <p>lab's [1] 152/22</p> <p>label [140] 5/7 5/14 5/25 6/1 6/4 6/6 6/8 6/9 6/11 6/25 11/23 11/24 12/14 12/17 12/22 13/1 13/17 13/18 13/20 14/14 15/21 15/24 16/22 16/23 22/9 22/24 26/19 26/24 27/5 28/10 28/13 28/14 29/3 30/3 30/5 30/23 31/18 31/20 31/25 31/25 32/17 32/20 33/10 33/14 33/14 33/15 33/20 34/1 34/20 35/25 36/11 36/16 37/12 37/13 37/13 37/15 37/19 38/1 38/22 38/24 39/3 39/4 39/14 39/16 40/4 40/6 41/17 44/22 45/3 45/8 45/13 50/12 55/1 55/2 55/6 55/11 57/4 57/9 58/24 59/2 59/6 60/14 61/6 62/12 62/15 64/8 65/8 74/19 75/22 77/5 83/4 83/11 86/20 86/24 87/1 87/13 87/13 101/2 101/5 101/20 102/1 102/6 102/17 102/22 102/23 103/13 103/22 105/2 105/4 105/9 105/14 106/8 106/11 106/12 106/22 106/24 107/18 107/24 115/20 115/22 117/23 119/15 123/6 124/5 125/4 125/9 125/13 151/6 152/7 152/20 153/1 155/9 155/13 155/22 155/24 156/7 195/20 206/15 206/19 206/21</p> <p>label and [1] 86/20</p> <p>labeled [6] 16/22 23/15</p>

L	99/22 99/24 100/2 104/6 104/22 108/8	liable [4] 30/22 49/24 125/6 183/8
labeled... [4] 26/11 50/11 66/2 78/14	leaving [1] 145/23	liaison [1] 127/14
labeling [29] 5/5 6/3 7/5 7/12 7/15 13/4 14/24 23/7 26/21 33/7 35/23 39/10 62/14 72/14 75/5 82/20 107/15 112/25 123/3 123/18 128/11 138/1 151/15 151/21 155/22 160/5 160/12 161/2 193/13	led [2] 55/15 55/18	liberty [1] 143/10
labels [11] 12/4 12/16 13/8 13/10 17/21 17/22 33/25 68/6 70/12 131/11 156/2	ledger [1] 20/22	life [3] 52/24 86/5 176/3
lack [7] 5/18 6/17 41/19 70/20 90/18 95/9 160/5	leech [1] 2/9	light [4] 8/19 64/2 105/23 105/24
lacks [1] 137/6	leeway [1] 50/19	like [52] 3/20 10/21 24/11 30/8 35/15 38/6 43/17 44/11 48/4 49/13 53/25 60/13 64/13 65/13 66/17 73/11 73/24 75/16 80/20 84/5 84/25 89/23 91/7 93/24 97/21 100/24 103/4 110/17 111/12 114/1 115/21 130/8 134/17 148/23 167/17 167/20 167/21 168/18 171/19 175/3 181/7 189/12 193/9 193/15 196/4 196/6 196/7 196/24 203/1 207/12 207/17 208/8
landscape [4] 108/2 124/11 124/16 199/2	legal [25] 26/6 42/20 48/18 53/6 56/4 56/5 56/8 63/8 95/21 107/10 107/17 108/3 114/9 117/12 121/25 123/14 137/6 161/14 163/15 164/8 178/4 178/20 187/23 190/1 190/3	likelihood [2] 66/4 208/13
lane [2] 172/5 204/11	legally [6] 52/12 63/21 159/16 159/23 159/25 160/15	likely [3] 62/22 63/15 91/21
language [6] 11/4 49/11 80/19 137/10 140/25 198/9	length [1] 63/20	likewise [1] 87/23
large [4] 63/11 65/25 112/20 125/11	lengthy [1] 67/7	Limine [5] 187/3 188/5 191/19 195/1 196/16
largely [1] 10/24	Lenkner [1] 1/12	limit [5] 53/4 186/8 186/15 187/17 188/2
larger [1] 106/21	less [3] 56/14 59/16 63/22	limited [7] 50/19 75/4 100/6 133/24 139/1 196/12 206/19
largest [1] 125/18	lesson [1] 27/13	limiting [6] 172/3 173/25 186/2 194/18 197/12 197/16
last [14] 13/14 45/15 79/7 120/7 122/17 126/12 127/9 128/23 139/18 183/3 206/24 207/13 207/18 208/24	let [33] 4/6 6/5 10/13 14/2 14/20 17/25 20/3 22/2 22/21 23/21 26/18 36/18 39/6 47/12 84/4 84/4 87/10 92/6 93/19 98/10 117/19 129/1 142/23 144/10 152/1 152/16 155/1 177/13 182/21 185/2 197/6 199/19 201/21	limits [1] 53/4
lastly [1] 157/21	let's [15] 11/20 18/23 49/16 91/5 93/5 148/1 167/21 185/12 186/19 188/9 189/4 189/13 194/1 196/9 196/12	line [10] 5/1 9/23 13/6 50/16 141/12 146/11 157/3 157/6 157/7 157/7
late [1] 193/19	lets [1] 182/16	lines [2] 28/4 171/18
latent [1] 205/23	letter [2] 117/14 117/16	lingering [1] 172/11
later [8] 42/10 67/6 74/6 91/3 93/2 121/14 166/22 175/20	letters [7] 18/21 115/19 115/20 116/3 116/16 117/9 117/16	linguistically [1] 187/19
latitude [1] 53/1	level [18] 16/9 22/4 54/23 67/12 87/8 89/1 138/12 148/6 148/9 164/23 170/24 172/14 178/9 181/1 181/8 181/10 186/4 202/5	link [1] 207/24
latter [1] 161/13	leveling [1] 57/21	links [1] 54/23
law [315]	levels [5] 51/19 52/9 57/17 64/12 68/3	list [4] 21/21 57/13 138/22 198/25
law as [1] 155/10	Levin [1] 1/22	listed [1] 57/12
law by [1] 31/24	Levine [3] 31/12 144/20 152/5	listen [1] 89/11
law depends [1] 9/25	levity [1] 127/12	litigation [14] 1/5 3/3 42/10 52/4 66/23 67/16 67/20 77/11 92/13 94/20 95/2 96/1 96/5 96/8
law duty [1] 134/15	liability [52] 1/5 3/3 4/15 8/8 8/24 13/22 24/2 24/4 24/10 24/16 24/17 25/1 30/22 31/14 32/25 33/11 41/15 77/10 78/8 85/24 85/24 86/1 103/14 103/16 112/9 112/21 120/4 125/5 127/21 128/17 129/4 129/11 130/17 131/7 132/16 135/6 135/21 137/2 141/5 141/13 141/23 145/2 147/14 179/20 183/24 184/4 184/16 185/17 186/21 188/23 201/14 204/2	little [10] 10/11 12/8 22/1 22/14 95/17 114/19 127/11 180/14 192/12 192/17
law imposes [1] 17/14	liability as [1] 135/21	lives [1] 202/17
law obligations [1] 105/11	liability even [1] 145/2	LLC [2] 1/12 1/16
law refers [1] 17/15		LLP [6] 1/22 2/2 2/5 2/9 2/12 2/15
law requirements [1] 7/16		loan [1] 147/5
law requires [1] 18/24		lob [1] 69/14
law what [1] 135/3		location [1] 14/6
lawfully [1] 143/9		locations [1] 113/22
laws [5] 12/3 42/14 45/7 115/3 164/11		log [1] 208/12
lawsuit [1] 172/22		logged [1] 97/14
lays [2] 53/13 146/17		logic [3] 64/25 148/1 151/25
LDC [1] 126/20		logically [1] 176/17
lead [1] 157/1		logician [1] 144/14
leading [2] 20/19 64/11		Lohr [1] 11/7
leads [2] 150/21 170/22		long [17] 13/16 69/18 80/3 89/8 90/3 130/11 138/21 150/9 158/21 159/4 159/12
lean [3] 83/20 83/21 83/23		
leaning [1] 50/7		
least [17] 19/2 19/6 24/1 24/3 81/2 98/8 126/12 135/21 143/4 143/12 151/4 171/1 172/15 172/25 173/19 175/12 180/10		
leave [14] 26/15 53/2 71/2 99/2 99/4 99/12 99/21 99/22		

L	major [7] 136/2 136/3 153/7 153/11 153/14 153/15 185/10	123/11 123/12 128/3 128/13 141/9 141/22 142/2 143/3 155/23 157/20 160/5 163/3 167/23 171/1 202/20
long... [6] 159/16 159/22 161/4 187/5 198/4 207/4	majority [3] 91/13 91/16 114/18	manufacturers no [1] 143/3
longer [14] 1/21 73/7 73/10 73/11 73/19 80/15 80/19 90/21 90/22 92/1 143/3 163/12 186/12 194/14	make [56] 4/23 7/21 9/3 16/24 17/2 21/18 22/11 23/1 28/22 32/12 33/5 33/19 34/4 36/1 44/18 47/4 52/3 60/23 61/9 65/5 67/22 70/1 72/15 85/11 89/7 89/21 99/20 100/7 115/25 118/23 124/14 125/16 148/17 170/8 172/4 175/17 176/10 185/14 186/1 187/19 188/22 188/24 189/18 190/8 191/21 191/22 192/3 192/6 192/13 192/20 194/20 195/25 198/9 201/11 201/16 203/19	manufacturers' [4] 139/12 155/17 155/20 156/1
look [19] 43/13 45/18 60/5 84/13 166/8 166/22 167/21 167/22 169/22 171/24 180/14 181/1 181/15 190/5 190/12 196/23 196/23 197/14 201/15	maker [1] 7/16	manufactures [2] 102/21 116/13
looked [5] 35/16 39/15 158/1 201/12 203/16	makes [13] 6/7 12/25 16/13 22/4 57/3 58/12 59/22 62/4 75/21 99/11 117/4 145/12 152/23	manufacturing [18] 21/15 85/16 102/19 102/20 102/25 110/17 111/4 111/7 115/24 118/20 119/1 119/3 119/7 121/3 121/7 122/1 127/14 179/20
looking [4] 90/24 118/11 121/5 137/21	making [12] 10/5 10/7 22/19 31/11 93/4 114/5 124/10 177/16 177/20 188/23 191/19 196/11	many [19] 46/3 77/9 97/2 102/11 104/16 137/23 147/2 147/18 151/4 156/24 157/15 172/17 173/21 174/1 174/5 179/10 193/12 200/16 200/23
looks [4] 65/13 97/21 157/10 175/3	man [1] 148/8	map [1] 77/10
Los [2] 2/13 2/17	management [3] 92/20 93/24 94/3	market [5] 2/6 13/19 16/21 125/16 167/25
lose [3] 64/2 132/15 166/18	mandated [2] 7/4 9/7	marketing [3] 72/14 73/4 82/19
loses [1] 31/9	mandates [1] 30/23	Markland [1] 8/22
loss [12] 70/22 71/16 110/1 110/3 111/25 112/12 112/14 112/17 112/22 114/16 119/6 125/23	manifest [1] 145/21	marshaling [1] 113/20
lost [4] 52/1 65/13 94/10 151/19	manner [5] 13/3 51/2 74/11 165/6 170/4	Mart [18] 98/14 101/18 102/3 102/16 105/5 108/18 109/10 110/9 111/10 113/11 116/25 121/1 121/4 121/6 121/24 122/4 124/14 125/24
lot [16] 45/1 73/20 73/21 74/2 92/14 106/17 108/2 139/20 168/12 175/1 193/13 194/5 196/21 202/10 207/3 208/23	manufacture [11] 82/19 99/7 101/4 101/10 101/11 102/9 107/25 115/22 116/14 121/12 150/9	Mart's [1] 121/11
lotion [1] 36/4	manufactured [7] 103/23 105/17 110/21 117/25 123/20 125/2 174/11	masquerading [1] 63/8
lots [1] 203/11	manufacturer [61] 13/21 14/13 14/22 15/3 16/20 18/13 19/19 27/17 28/10 31/18 31/19 31/24 37/14 38/22 85/2 85/9 85/17 101/15 101/16 101/23 101/25 102/8 102/9 102/10 103/11 103/13 103/18 104/20 107/20 109/12 118/6 118/10 118/12 119/22 120/9 120/25 123/20 125/3 128/16 131/20 137/21 140/17 141/4 141/19 148/14 153/16 154/12 154/13 154/16 163/6 165/4 170/2 171/2 177/15 177/19 178/16 179/4 179/4 193/19 195/3 202/11	mass [1] 108/21
Loudly [1] 17/1	manufacturer which [1] 19/19	master [50] 3/10 18/3 47/14 47/21 64/21 64/23 64/24 66/24 79/14 79/17 79/19 90/4 90/8 90/13 90/16 90/22 90/25 91/2 91/3 91/19 92/7 92/7 92/15 92/22 92/25 93/7 93/15 93/17 94/3 94/17 94/21 95/22 96/4 96/13 96/14 96/17 98/16 107/5 123/4 127/24 142/3 142/24 150/4 152/24 156/11 165/1 194/4 194/10 194/15 208/14
Louisiana [1] 138/4	manufacturer's [4] 9/24 18/11 21/9 21/15	master personal [1] 152/24
low [1] 64/7	manufacturers [45] 12/21 18/8 19/22 32/17 33/7 36/20 72/13 84/15 85/21 100/8 101/7 101/10 101/17 103/9 106/11 106/15 109/18 109/20 109/24 110/16 111/7 114/2 114/11 115/22 118/7 119/10 119/19 119/23 120/1 120/20	match [2] 11/19 171/17
lower [2] 60/24 154/15		matches [3] 13/16 45/19 46/10
lowest [1] 50/11		material [2] 14/9 139/5
lump [1] 105/3		materially [1] 140/1
lumped [3] 68/24 74/25 104/11		matter [26] 4/16 5/4 7/22 12/19 17/12 41/13 46/5 78/3 88/24 94/22 95/11 106/19 118/6 121/17 129/13 129/19 141/25 156/9 161/21 163/20 164/2 169/9 169/11 192/10 197/23 209/4
lumps [1] 68/18		matters [4] 11/18 12/20 17/19 46/7
lunch [6] 80/4 93/23 97/6 97/9 97/13 97/19		may [49] 4/1 10/19 19/6 27/20 28/19 29/16 31/20 32/7 48/11 54/3 54/10 56/5 63/15 66/19 66/20 73/17 73/18 76/21 78/6 80/5 84/9 87/19 93/6 93/14 94/22 96/10
M		
made [39] 4/19 4/24 10/25 11/5 16/4 17/2 22/11 26/24 51/7 59/16 62/4 68/25 70/15 70/18 76/14 81/6 84/1 104/12 120/4 136/25 140/10 157/23 164/9 166/9 166/23 168/23 172/16 172/18 174/2 177/3 180/11 180/13 184/23 185/15 185/23 189/22 190/13 192/25 201/5		
made-up [1] 17/2		
Magistrate [1] 76/7		
mail [5] 51/25 55/12 68/6 75/17 80/11		
mailbox [1] 55/14		
mailing [1] 80/10		
main [2] 79/12 142/19		
mainly [1] 22/9		
maintain [4] 78/9 114/1 206/11 206/13		

M		
may... [23] 107/23 109/1	127/17 135/1 135/14 135/24	40/10 40/13 42/19 43/7 44/14
112/16 113/13 113/14 120/2	136/11 138/4 138/7 140/21	44/15 45/4 45/6 45/17 46/11
120/3 120/5 124/21 132/17	141/3 141/11 155/6 155/8	46/22 116/8 141/1 206/19
139/6 148/10 153/10 160/24	155/24 157/8 157/12 177/11	206/22
179/21 181/2 183/16 186/15	183/3 183/17 183/20 184/15	misconduct [3] 67/25 72/11
187/7 190/19 193/11 204/23	186/10 195/13 201/12 201/12	176/15
208/6	204/1	mishandled [1] 130/11
may decide [1] 32/7	Mensing and [2] 127/17 155/6	misleading [43] 5/7 11/24
maybe [18] 32/4 47/2 54/1	mention [2] 60/7 201/22	12/4 12/5 12/14 12/15 12/17
65/15 66/17 86/5 89/12 112/7	mentioned [8] 66/25 67/24	12/22 13/1 13/8 13/9 15/21
170/14 178/10 191/22 192/24	77/22 78/20 103/9 131/4	15/25 17/21 17/22 22/8 22/17
193/22 196/15 197/4 199/18	183/11 202/14	26/25 27/8 28/6 28/11 28/13
207/7 207/9	message [1] 111/17	30/3 30/4 31/2 33/15 33/21
McKesson [1] 74/10	met [1] 18/13	33/25 34/21 37/19 39/15
md [2] 1/3 2/10	Michelin [1] 131/19	41/17 44/22 44/23 45/3 45/8
MDA [3] 39/6 39/9 39/17	mid [1] 158/7	45/13 72/14 88/5 114/23
MDL [16] 3/3 48/17 67/14	mid-afternoon [1] 158/7	115/1 115/7 206/15
68/11 89/17 89/21 91/10	middle [2] 65/18 143/24	misleading labels [1] 12/4
91/12 91/18 91/23 92/7 92/9	might [12] 47/11 55/22 62/18	misleadingly [1] 23/15
94/4 95/12 113/19 113/24	65/16 89/13 125/18 135/11	mispronounced [1] 81/25
MDLMDL [1] 173/21	141/8 155/12 165/8 207/13	misrepresentation [2] 111/23
MDLs [1] 91/14	207/13	112/25
me [47] 3/6 3/15 4/6 6/5	might order [1] 155/12	misrepresented [1] 34/21
10/13 10/16 10/16 14/20	mile [1] 144/15	misspoke [1] 89/2
17/25 22/2 23/21 25/11 26/18	milk [3] 130/7 130/9 130/13	mistaken [1] 152/1
36/18 39/6 41/8 47/12 54/2	mind [1] 89/23	mitigate [3] 184/2 202/20
64/13 65/12 73/13 73/15 84/4	minimize [1] 184/2	204/4
87/10 92/6 93/20 98/10 109/4	minimum [4] 19/1 62/4 81/1	mitigated [1] 203/22
110/18 117/20 126/17 131/11	197/6	mixed [1] 189/7
142/11 142/23 144/10 152/16	Mink [25] 8/22 20/16 20/18	MMC [9] 109/7 109/13 109/19
155/1 168/13 177/13 180/17	21/16 24/13 24/18 24/20	110/13 111/9 111/12 112/5
180/19 185/2 194/4 199/19	60/18 149/17 149/19 149/20	114/8 135/19
201/21 204/12 205/14	149/23 150/2 150/17 179/16	model [1] 92/17
mean [12] 16/14 51/11 60/15	179/17 180/1 180/3 180/5	moderate [1] 154/3
69/8 89/3 132/15 146/20	180/11 181/14 182/5 182/6	modification [1] 173/25
160/25 160/25 170/14 174/7	182/10 183/6	modifications [1] 194/19
202/1	Mink's [3] 21/8 179/19 183/2	modify [2] 33/9 171/20
meaning [1] 161/13	Minnesota [2] 13/25 138/4	moisture [2] 176/1 176/9
meaningless [3] 140/24	minor [3] 154/3 154/8 176/11	molecular [4] 51/3 175/2
151/12 152/14	minute [10] 23/21 48/10 54/2	191/6 191/15
means [11] 4/14 7/14 13/17	66/17 73/9 73/16 80/7 138/17	molecule [6] 129/22 148/17
15/24 31/8 39/6 52/7 55/25	142/6 156/16	151/24 175/25 188/22 193/7
59/8 96/15 142/12	minutes [23] 3/15 3/20 3/21	moment [11] 16/4 25/20 65/11
meant [6] 49/8 83/19 94/18	3/23 3/24 3/24 9/14 10/10	100/24 131/3 140/8 172/18
104/19 147/22 202/7	10/11 21/22 22/1 48/4 48/9	185/8 188/8 189/5 205/6
meanwhile [1] 55/1	53/23 53/24 66/12 73/12 79/3	moments [1] 146/1
measures [3] 121/11 137/14	79/21 126/17 126/19 126/24	Monday [4] 207/11 207/14
202/18	156/13	207/17 207/20
mechanism [1] 72/8	misbranded [54] 4/25 5/8	monitor [1] 109/3
medical [11] 5/21 15/9 15/10	5/18 6/1 6/2 6/6 6/18 13/16	monograph [2] 23/8 29/13
22/22 23/1 24/4 35/3 38/11	13/24 14/13 14/23 15/1 15/21	monographic [1] 23/9
39/7 43/25 44/2	23/4 23/7 23/9 23/12 25/19	month [1] 67/6
medication [1] 29/9	25/22 25/24 26/16 26/20 27/6	months [9] 67/14 94/20 94/20
medications [1] 29/12	29/1 29/3 29/11 29/11 29/14	96/7 175/5 175/5 186/5
meet [13] 52/15 53/15 130/1	29/22 30/2 30/2 32/6 32/7	190/11 190/11
134/7 134/15 144/6 147/20	32/23 33/21 34/5 34/10 34/18	months after [1] 67/14
151/9 154/24 167/4 193/24	34/25 35/7 35/22 36/5 36/14	Moore [1] 45/24
201/6 201/17	37/12 38/21 38/21 39/4 39/14	more [56] 10/3 14/15 17/2
meeting [1] 150/15	39/21 42/18 43/9 44/8 206/12	26/1 35/3 35/4 38/17 40/22
members [1] 86/11	206/14	42/19 43/1 43/12 51/6 53/9
memorandum [4] 3/11 47/15	misbranding [52] 5/9 5/24	53/11 54/18 54/19 54/24
47/21 126/14	6/10 6/19 7/2 7/10 12/23	58/23 59/25 60/5 67/6 67/7
Mensing [42] 6/14 9/23 10/3	14/3 14/11 14/18 15/1 15/4	67/11 72/7 74/15 75/21 76/2
16/5 36/19 36/21 36/22 36/25	15/7 16/12 16/15 16/20 17/1	77/9 78/1 78/24 78/24 80/16
37/6 38/6 38/10 38/19 44/6	17/7 17/7 17/16 17/17 22/7	82/24 89/17 94/19 99/14
63/14 123/18 123/22 123/22	26/1 26/2 26/9 26/25 32/19	99/16 103/8 106/17 107/15
	35/10 35/19 36/2 36/17 37/3	113/17 115/5 117/4 138/7
	37/7 37/19 38/7 39/1 39/24	154/14 166/25 169/18 174/8

M	106/3 108/12	120/13 121/14 121/23 122/19
more... [8] 176/8 176/17	Ms. Stipes' [1] 142/10	123/1 128/1 129/15 129/19
180/14 181/14 182/13 192/17	much [33] 21/25 25/7 36/12	129/21 129/23 132/4 132/6
198/9 200/17	42/16 46/24 47/1 47/8 56/23	132/10 132/18 134/10 136/22
moreover [5] 4/18 6/19 16/8	62/19 66/8 79/24 79/25 80/8	143/1 143/2 143/6 143/11
66/1 71/11	81/13 93/19 95/7 95/8 97/16	150/10 150/12 158/19 158/22
morning [19] 2/2 3/1 3/8	100/15 112/17 126/8 134/3	159/5 159/13 159/15 159/21
3/18 4/1 10/14 10/18 47/12	159/13 162/10 166/24 170/21	160/1 160/13 162/3 167/12
48/1 48/3 48/7 66/11 66/12	182/13 182/22 187/8 193/14	169/8 170/21 174/13 175/3
66/14 120/24 122/17 136/6	198/23 207/9 208/17	184/2 184/11 186/4 186/22
140/10 155/3	multiple [12] 70/7 70/16	187/22 188/20
morning regarding [1] 136/6	72/4 76/12 76/21 107/22	NDMAGeneric [1] 130/16
Morris [1] 128/22	143/1 143/2 145/5 153/21	NDMANDMA [2] 129/13 158/18
most [19] 17/6 18/5 19/20	161/21 199/11	near [1] 67/12
25/10 67/3 67/22 91/14	must [24] 19/6 25/23 26/11	nears [1] 52/2
105/23 108/13 115/15 143/21	30/20 42/18 56/1 56/19 63/4	necessarily [6] 70/18 113/4
153/21 161/23 162/15 162/18	63/4 63/22 71/18 71/19 78/2	121/1 172/20 193/8 206/3
166/12 171/19 181/1 196/23	90/12 96/4 119/15 128/19	necessary [7] 81/20 84/2
motion [56] 1/9 3/8 3/9 3/15	137/16 141/12 144/7 147/8	87/16 88/4 115/19 142/15
3/20 14/18 41/9 47/10 47/13	183/23 198/7 204/2	208/14
47/15 47/20 50/6 52/20 55/24	mute [1] 97/15	need [26] 4/21 6/20 10/13
56/5 56/19 62/3 62/6 62/16	my [54] 10/8 10/15 15/8	12/8 27/19 29/14 40/11 46/15
66/11 66/16 67/19 67/22	15/17 16/3 19/22 21/23 28/23	57/1 61/20 62/25 83/3 90/21
68/11 68/16 69/13 75/24	43/4 43/21 45/9 45/15 46/1	97/1 109/20 112/7 121/19
75/25 79/2 85/5 89/15 94/20	47/2 48/13 48/25 53/21 64/2	127/6 183/20 193/8 197/24
97/11 97/20 98/20 98/21	65/15 66/18 71/3 79/23 80/15	199/5 200/25 207/16 207/22
106/1 126/13 133/19 134/21	88/11 89/12 90/14 93/12	208/7
143/7 152/11 162/14 167/6	97/23 98/8 98/9 100/13	needed [10] 51/7 59/12 83/11
169/1 177/2 183/4 187/3	100/19 108/13 108/21 120/7	87/11 93/20 132/1 141/14
195/1 195/9 196/15 201/23	127/2 130/22 142/15 160/11	166/25 167/3 184/16
206/2 207/13 207/18 207/19	162/4 166/12 166/18 169/17	needle [1] 112/13
motion that [1] 47/10	174/7 184/17 188/8 193/20	needs [6] 95/24 119/12
motions [18] 4/11 47/24 48/2	193/20 195/12 197/17 202/3	127/20 137/1 153/16 184/4
48/16 48/23 49/19 49/20 72/2	204/11 204/14 207/5	negligence [63] 21/5 21/7
72/2 72/21 98/23 100/3		49/2 50/7 50/19 52/10 53/17
128/24 188/5 188/18 191/19	N	60/19 67/1 67/5 67/9 70/15
207/16 208/23	name [15] 14/22 15/2 57/21	71/9 71/10 71/19 71/22 74/16
move [2] 113/18 151/13	81/22 82/1 101/5 101/13	75/4 77/17 77/18 90/1 90/3
moved [2] 163/25 194/11	103/25 109/7 113/25 115/23	90/10 99/15 99/18 112/19
moving [2] 8/4 75/7	124/4 148/13 156/20 162/16	131/20 133/15 143/18 148/2
MPIC [2] 68/18 68/18	name but [1] 148/13	148/3 148/22 149/3 149/4
Mr [70] 12/6 21/8 21/16 22/3	named [7] 56/22 66/23 76/12	149/11 149/21 149/22 149/25
23/11 23/22 29/16 40/3 44/12	96/14 100/1 115/5 120/1	150/4 177/23 177/24 178/9
48/21 49/5 49/13 49/18 49/20	Namely [1] 57/16	178/20 179/2 179/18 179/20
62/22 64/3 66/10 73/7 73/10	names [3] 12/2 101/9 104/17	180/6 182/7 182/8 183/12
73/11 73/20 74/2 77/16 78/21	naming [3] 11/14 12/12 17/5	191/7 191/8 193/18 196/2
79/5 80/15 80/19 92/5 94/6	narrow [9] 50/25 53/2 53/3	196/2 196/5 196/10 196/20
94/9 95/15 127/2 130/22	67/4 113/17 144/25 175/9	197/18 203/6 203/8 204/13
131/4 136/10 147/5 149/20	185/6 189/21	204/20
149/23 156/24 157/18 162/17	narrow and [1] 50/25	negligence against [1] 70/15
162/18 167/5 167/9 168/1	narrowed [1] 105/6	negligent [29] 67/23 69/4
168/10 169/2 169/17 177/3	narrowed the [1] 105/6	83/7 87/2 108/18 109/9
177/6 177/14 179/19 182/6	narrower [1] 176/15	109/11 109/15 110/13 110/15
183/11 183/25 185/2 185/4	nary [1] 21/2	111/6 112/15 131/7 132/24
185/22 186/16 186/18 187/11	National [1] 78/5	132/25 134/5 134/19 134/22
187/17 188/4 188/6 188/10	nationwide [1] 102/11	140/5 150/16 160/6 160/6
191/11 192/11 192/24 201/9	naturally [1] 79/18	178/3 178/6 180/7 186/21
205/8	nature [9] 54/12 129/22	189/14 196/18 197/3
Ms [3] 56/22 140/9 186/17	179/9 188/21 188/25 190/7	neither [4] 13/14 101/17
Ms. [13] 48/3 62/20 65/12	192/11 193/6 195/5	134/21 205/4
65/13 67/1 95/17 97/21 106/3	NDA [10] 7/5 22/10 27/5	Nephew [1] 149/24
106/10 108/11 108/12 136/6	28/14 30/5 32/17 34/2 123/1	never [17] 14/10 14/12 15/23
142/10	154/6 198/23	16/6 17/16 25/18 25/22 30/1
Ms. Eisenstein [1] 136/6	NDMA [62] 5/8 9/20 24/25	34/9 34/18 64/21 129/22
Ms. Fegan [2] 106/10 108/11	41/17 54/17 54/18 54/24	130/15 130/18 134/12 178/24
Ms. Johnston [9] 48/3 62/20	54/24 55/18 55/20 64/12	181/12
65/12 65/13 67/1 95/17 97/21	64/19 65/1 66/5 81/18 82/5	nevertheless [2] 37/14 174/7
	83/17 83/20 86/18 88/14	new [24] 6/11 13/19 13/19

N		
new... [21] 13/20 29/15 50/19 51/3 51/8 93/2 99/5 99/16 107/14 108/8 108/9 128/10 135/19 137/19 137/22 139/25 143/13 167/1 167/10 167/12 208/1	not permit [1] 62/8 not prune [1] 128/4 not survive [1] 136/16 not warn [1] 132/12 notably [2] 52/6 69/16 note [3] 28/22 59/21 84/13 noted [10] 11/8 16/18 18/15 70/14 76/15 144/19 149/19 152/15 156/3 156/7 noteworthy [1] 34/3 nothing [9] 24/11 52/21 72/12 85/11 91/2 96/3 154/18 155/5 208/1 notice [19] 16/9 24/24 27/4 41/17 66/7 74/15 77/2 77/3 77/8 77/25 83/16 83/16 95/9 121/23 133/12 190/25 191/1 191/4 191/14 notice and [1] 16/9 noting [2] 33/18 142/23 notion [4] 27/15 167/13 168/6 178/25 notwithstanding [2] 20/14 86/2 now [42] 12/1 15/8 34/16 37/23 42/2 43/16 55/9 55/22 58/16 59/13 59/24 60/12 64/13 65/17 75/24 77/24 80/12 88/5 94/22 97/6 97/20 123/7 123/10 125/12 126/23 130/22 135/15 136/10 143/8 147/24 158/6 163/19 168/3 168/22 169/2 177/12 179/2 185/21 188/6 188/7 194/2 208/3 nowhere [4] 52/6 52/7 52/11 67/12 number [7] 52/1 55/14 96/19 123/25 123/25 153/4 171/2 numbers [1] 102/16 numerous [2] 29/9 68/9 NW [2] 1/19 2/3	of the [1] 27/15 off [17] 12/7 13/13 34/15 65/15 97/15 98/17 127/11 166/18 173/2 173/15 175/19 182/2 185/3 191/3 195/15 197/6 197/20 offending [1] 146/2 offends [1] 146/5 offer [3] 13/23 204/5 205/5 offering [1] 200/5 Official [2] 2/20 209/7 often [2] 17/8 72/2 oh [3] 43/11 65/14 78/23 okay [60] 10/10 10/16 10/17 21/25 25/9 36/18 38/17 39/19 45/16 46/24 47/10 63/24 65/13 66/19 73/17 83/21 84/4 87/18 89/7 91/17 94/14 97/5 97/19 97/25 98/2 100/15 100/20 106/3 108/10 109/6 110/12 113/25 115/9 119/16 120/11 124/20 126/12 126/24 127/6 127/8 142/7 142/16 158/5 159/25 160/3 160/11 160/23 162/14 174/16 178/10 178/24 182/7 186/16 201/2 201/21 206/1 207/1 208/12 208/14 208/18 old [2] 13/20 194/13 omit [1] 63/3 omitted [1] 80/19 omitting [1] 153/20 omnibus [4] 41/9 42/13 98/23 134/21 on FDA [1] 15/8 on Federal [1] 24/18 on the [1] 67/21 on-point [1] 15/14 once [12] 11/8 18/1 31/8 45/3 54/19 72/22 74/18 142/17 151/22 154/14 155/7 172/10 one [94] 2/6 2/10 4/10 21/9 24/14 27/23 29/16 30/14 31/16 37/6 38/17 40/22 40/24 41/8 59/20 60/15 60/20 61/4 65/10 67/4 68/24 69/3 74/1 75/16 80/9 81/8 82/24 86/3 89/8 89/19 90/4 93/4 93/5 96/20 96/20 99/23 102/2 103/8 104/15 109/5 111/17 115/15 118/3 118/5 118/6 122/16 123/6 124/6 124/7 125/14 129/7 129/7 138/16 138/24 139/18 140/13 144/11 148/20 148/24 149/7 149/12 149/21 152/14 154/14 154/14 157/2 158/6 165/3 169/24 169/25 171/2 175/4 176/23 177/24 179/14 180/7 182/7 184/22 185/6 189/12 189/13 190/23 191/13 192/24 192/25 194/9 195/2 196/13 200/17 200/17 200/19 203/21 205/22 207/19 one of [1] 138/16 one-count [3] 190/23 191/13 196/13
newfangled [1] 146/16 newly [1] 31/18 next [6] 47/10 57/7 126/20 132/3 150/11 156/3 nice [2] 73/15 208/19 night [1] 152/18 night here [1] 152/18 nine [3] 10/10 28/1 79/3 Ninth [2] 20/10 20/18 nitrates [1] 189/7 no [98] 1/3 3/5 4/14 4/23 6/9 6/9 6/9 6/15 8/7 11/10 13/11 14/8 15/10 16/24 16/25 17/12 17/22 18/24 19/2 19/3 19/22 20/8 23/13 27/18 34/11 35/17 40/18 42/25 45/21 50/3 57/20 59/2 59/6 60/7 61/4 64/18 66/25 68/17 69/8 69/10 71/10 72/16 79/19 82/5 82/6 83/9 86/10 90/9 90/21 90/22 92/3 93/1 93/5 95/2 95/3 95/20 96/1 96/6 97/24 99/11 99/22 117/15 118/19 123/15 125/5 129/13 129/19 140/20 143/3 144/13 145/9 145/17 147/19 149/25 150/3 150/18 153/23 154/25 159/1 159/14 160/14 164/13 165/12 181/5 183/10 185/15 186/12 191/8 191/11 192/22 192/22 194/14 195/9 199/21 203/21 206/25 207/15 208/7 no Federal [1] 19/22 nobody [1] 95/18 non [16] 8/11 26/21 28/13 35/23 37/19 104/7 112/11 115/10 115/13 147/22 150/3 150/19 171/14 172/5 194/22 196/20 non-ANDA [2] 115/10 115/13 non-labeling [2] 26/21 35/23 non-misleading [2] 28/13 37/19 non-physical [1] 112/11 non-pleaded [1] 8/11 non-preempted [8] 104/7 147/22 150/3 150/19 171/14 172/5 194/22 196/20 nonconformance [1] 121/10 None [2] 20/4 138/15 nonetheless [4] 37/2 74/22 89/20 147/21 norm [1] 197/2 normal [2] 134/10 184/10 normal digestive [1] 184/10 not [425] not comply [1] 149/24 not going [1] 165/9 not include [1] 110/3 not level [1] 89/1	O o'clock [1] 207/20 objectives [3] 155/4 182/14 182/16 obligation [8] 18/13 35/9 44/13 44/21 115/24 123/10 195/18 203/8 obligations [3] 105/11 109/24 150/15 obliged [1] 79/18 obliquely [1] 104/16 observe [1] 17/5 obtain [2] 148/25 194/21 obtained [1] 149/25 obtuse [1] 77/14 obviate [1] 95/23 obvious [1] 13/7 obvious they [1] 13/7 obviously [8] 55/15 142/20 145/4 164/17 175/14 176/18 190/4 190/16 occasions [1] 107/22 occupied [1] 21/10 occurred [2] 74/4 100/12 of appellate [1] 20/14	

<p>O</p> <p>one-way [1] 179/14</p> <p>ones [6] 30/7 61/7 120/1 163/16 166/1 199/24</p> <p>only [86] 8/13 10/4 11/2 14/12 14/23 16/13 21/13 21/20 22/19 35/13 37/6 38/4 45/22 46/7 46/9 48/8 56/5 62/12 67/8 69/10 72/13 77/8 84/17 87/24 90/22 100/10 101/13 102/12 103/1 107/16 108/13 110/2 110/14 118/13 119/10 119/10 123/9 124/18 129/12 130/1 130/10 137/25 141/4 144/25 146/4 146/18 154/1 156/8 156/25 157/25 157/25 158/21 158/22 159/4 159/11 159/12 159/24 160/4 160/12 160/14 165/15 169/24 173/9 173/18 179/20 184/6 185/6 186/19 187/19 189/19 192/1 192/15 192/15 192/16 194/1 194/8 194/20 195/16 197/24 197/25 198/1 198/13 200/8 201/24 202/13 207/13</p> <p>only element [1] 45/22</p> <p>only preempts [1] 11/2</p> <p>only thing [1] 46/7</p> <p>OOTC [1] 206/8</p> <p>open [4] 20/23 50/24 121/19 207/11</p> <p>opened [1] 121/2</p> <p>opening [2] 14/16 109/19</p> <p>operates [2] 165/18 198/20</p> <p>operative [8] 58/15 92/8 93/8 94/19 96/13 100/10 194/9 194/14</p> <p>opinion [11] 20/16 21/8 21/11 76/20 93/12 156/2 156/3 156/6 157/2 157/3 157/23</p> <p>opinion it [1] 157/3</p> <p>opinions [1] 183/20</p> <p>opportunities [1] 95/6</p> <p>opportunity [15] 53/9 64/4 68/10 84/7 95/13 95/24 121/17 166/13 166/16 166/22 167/8 168/13 168/18 176/24 208/5</p> <p>opposed [2] 190/11 196/20</p> <p>opposing [2] 136/15 167/6</p> <p>opposite [7] 35/1 70/13 84/19 137/11 145/17 149/25 189/23</p> <p>opposition [8] 7/21 28/2 52/19 76/19 138/16 150/22 201/23 202/16</p> <p>or it [1] 130/11</p> <p>or minor [1] 154/3</p> <p>or Skidmore [1] 16/7</p> <p>oral [1] 169/6</p> <p>order [53] 14/17 14/21 16/19 50/16 50/23 51/1 62/11 63/1 68/16 68/20 69/13 72/20 87/12 99/11 99/13 99/20 100/2 100/9 100/10 100/11 100/11 103/6 103/7 103/10</p>	<p>103/20 104/1 104/6 104/9 104/21 105/8 106/16 106/18 127/22 129/5 134/2 141/4 151/24 155/12 157/7 167/4 168/7 169/4 178/8 183/21 183/23 183/24 184/4 187/21 192/8 198/20 205/16 205/20 206/18</p> <p>ordered [1] 103/15</p> <p>orders [18] 60/12 61/7 62/11 92/20 96/18 99/9 101/19 103/3 103/5 105/19 106/6 107/2 108/7 108/7 112/11 125/11 174/6 194/13</p> <p>ordinances [1] 146/10</p> <p>ordinary [17] 18/19 18/25 19/1 55/12 82/19 140/6 176/1 179/3 179/3 179/4 179/12 193/19 193/20 193/21 203/5 203/7 204/17</p> <p>organization [4] 102/19 102/20 116/17 118/21</p> <p>orienting [1] 48/20</p> <p>original [14] 49/19 66/24 69/13 85/5 88/11 99/9 104/3 104/15 108/5 125/12 127/24 128/5 128/25 129/25</p> <p>OTC [29] 6/3 23/3 23/6 23/9 25/18 25/21 28/25 29/2 29/9 29/10 29/11 29/21 29/24 31/6 31/9 32/6 32/8 32/8 32/9 34/1 34/9 34/17 35/2 35/6 35/13 36/4 38/22 42/18 136/8</p> <p>OTC Zantac [1] 29/2</p> <p>other [72] 6/9 8/25 9/17 12/15 12/16 14/15 15/14 18/18 20/15 20/24 21/3 25/25 26/13 27/2 27/6 27/24 29/5 29/16 29/17 29/19 30/24 33/4 35/14 36/25 44/10 46/4 55/13 55/14 55/19 60/8 60/12 61/7 63/1 66/6 71/6 82/12 83/21 85/2 94/12 99/17 99/23 102/15 103/14 103/15 107/11 107/23 109/5 115/21 120/2 132/21 134/16 140/15 149/3 166/10 168/14 168/18 175/1 179/19 182/3 186/6 187/18 192/7 195/12 196/16 196/21 197/19 198/7 200/11 207/15 207/15 207/16 207/16</p> <p>others [7] 60/20 68/22 93/9 118/9 133/16 134/4 140/11</p> <p>otherwise [6] 11/3 80/14 93/15 95/1 112/20 186/7</p> <p>ought [1] 94/7</p> <p>our [74] 3/6 3/12 11/6 15/12 17/6 17/25 20/21 29/24 34/17 44/4 46/6 46/19 52/20 53/12 53/13 53/14 56/10 59/15 67/21 72/4 74/15 74/18 74/23 75/3 76/19 77/16 77/25 78/25 84/13 86/3 98/18 99/1 99/10 106/9 106/10 114/21 116/20 119/24 125/11 125/23 126/5 129/16 136/3 136/4 136/9 140/10 140/12 145/19 150/22 150/23 151/13 151/15 152/8</p>	<p>152/17 153/2 154/4 157/2 157/18 158/7 158/9 161/18 162/13 169/20 175/16 177/2 177/5 181/15 185/9 186/18 186/20 187/13 190/8 190/20 208/19</p> <p>our failure [1] 17/25</p> <p>our theory [1] 169/20</p> <p>out [42] 8/12 10/5 23/18 33/13 47/2 47/3 52/17 53/9 53/13 54/12 54/16 64/22 65/24 67/1 83/25 90/5 101/10 102/18 103/25 104/10 105/4 106/11 110/22 113/4 116/17 117/8 118/7 118/10 120/3 121/16 124/14 125/1 128/5 134/21 147/16 157/2 173/9 174/4 183/22 184/18 199/1 207/25</p> <p>outcome [1] 17/17</p> <p>outlined [2] 63/20 136/3</p> <p>outrageous [1] 62/5</p> <p>outright [1] 52/20</p> <p>outset [4] 66/23 68/11 117/24 130/10</p> <p>outside [5] 26/23 66/2 75/5 78/14 91/3</p> <p>over [21] 10/11 11/1 12/10 15/11 15/13 22/1 35/14 35/18 90/5 90/5 103/11 117/22 130/22 134/10 145/13 150/10 176/6 183/3 195/7 207/3 208/23</p> <p>over-the-counter [4] 11/1 15/11 15/13 35/14</p> <p>overall [4] 49/15 50/4 57/3 112/15</p> <p>overlap [3] 47/24 48/24 91/13</p> <p>overlapped [1] 73/21</p> <p>overlapping [1] 48/22</p> <p>oversight [1] 31/7</p> <p>owed [5] 21/9 21/12 21/16 50/2 147/6</p> <p>own [36] 6/1 10/15 22/11 43/23 44/12 66/18 70/21 72/16 72/24 92/10 98/9 101/9 101/11 101/13 101/14 103/25 104/17 107/11 107/16 117/4 122/3 124/4 125/1 134/1 138/22 139/11 139/13 141/4 142/15 152/22 153/1 161/10 178/3 179/1 194/15 199/9</p> <p>owned [3] 101/16 101/21 102/2</p> <p>owning [1] 77/12</p> <hr/> <p>P</p> <p>PA [2] 1/23 2/7</p> <p>pacemaker [1] 39/10</p> <p>pack [1] 153/23</p> <p>package [11] 14/6 105/8 105/16 110/2 111/23 111/23 114/14 114/22 115/22 118/11 118/14</p> <p>packages [1] 118/15</p> <p>packaging [14] 82/20 111/15 113/1 119/7 124/14 141/21</p>
--	--	---

P	165/11 165/25 166/15 166/18 169/11 169/13 173/8 174/8 180/22 181/5 181/13 186/22 202/10 205/7 206/16	156/11 165/2 173/19 194/4 194/10 194/15
packaging... [8] 153/2 153/22 153/22 154/21 154/22 176/7 186/19 202/12	particularly [4] 68/17 85/9 155/3 196/22	persons [1] 92/9
packs [5] 153/5 176/7 187/20 187/25 200/9	particulars [1] 21/5	perspective [2] 99/1 99/10
page [21] 7/20 14/18 28/1 29/1 36/24 52/20 53/4 85/3 89/14 127/22 129/5 137/21 138/16 145/25 147/16 156/2 156/3 156/6 157/23 201/22 206/2	parties [20] 18/5 19/18 24/22 30/20 42/2 42/11 45/1 46/16 93/18 111/2 113/8 117/3 134/25 142/21 143/21 143/23 202/25 207/10 207/10 207/15	persuasive [1] 13/14
pages [7] 36/25 52/6 52/11 70/5 80/16 137/17 202/15	parties in [1] 117/3	pesticide [1] 32/9
pains [1] 75/2	parts [1] 138/13	Petrosinelli [1] 168/1
pains to [1] 75/2	party [11] 10/1 18/8 18/10 18/12 18/14 19/20 30/22 121/5 122/6 135/2 156/4	pharmaceutical [8] 44/2 44/3 86/25 144/22 177/15 177/19 178/16 202/11
painstakingly [1] 116/6	pass [2] 49/25 203/21	Pharmacopoeia [1] 69/19
PALM [3] 1/2 1/5 2/21	passed [1] 144/16	pharmacy [5] 47/13 48/7 48/14 98/13 103/12
pandemic [1] 3/4	passing [1] 152/18	phase [1] 197/11
panel [1] 91/10	past [7] 15/24 16/14 41/21 48/9 127/16 145/15 189/17	Philadelphia [2] 1/23 2/7
paper [1] 95/8	path [5] 10/5 21/2 113/17 151/16 189/21	phone [3] 18/20 111/20 112/8
papers [2] 67/22 164/4	patience [1] 208/22	phrased [1] 170/10
paragraph [39] 18/10 18/20 57/13 59/22 64/3 73/4 78/12 82/9 82/12 82/25 83/14 83/22 84/23 86/10 102/15 104/18 105/6 114/21 119/3 119/5 120/14 120/16 121/5 126/3 131/14 131/25 132/5 133/6 134/11 150/10 150/11 156/12 158/19 159/6 165/1 170/1 170/25 177/18 178/16	patient [2] 144/18 207/6	phraseology [2] 11/17 17/12
paragraphs [27] 51/11 51/14 51/17 52/5 57/12 67/7 67/8 67/25 68/9 72/10 72/12 73/1 82/7 83/24 84/12 84/14 84/17 87/20 107/5 110/17 111/12 111/13 114/8 125/25 152/23 165/3 169/22	pattern [7] 36/3 133/15 171/24 194/1 194/16 194/19 204/7	phraseology as [1] 11/17
parallel [17] 4/18 11/9 12/22 24/21 26/17 26/22 27/1 31/1 37/16 38/15 40/1 40/23 40/25 45/5 46/20 114/22 141/1	Pauline [2] 2/20 209/7	phrases [1] 60/8
parallels [1] 31/2	pause [1] 156/14	physical [2] 112/11 200/23
paraphrasing [1] 49/13	pausing [1] 164/20	physician [1] 24/7
parcel [1] 24/12	Payco [2] 138/17 146/22	physicians [1] 9/13
parceled [1] 174/4	penalties [1] 43/9	PI [5] 64/24 98/18 99/22 123/4 123/23
Park [1] 2/16	pencil [1] 146/2	pick [4] 60/9 102/12 167/24 178/15
Parker [3] 76/5 76/15 80/18	Pennsylvania [1] 2/3	piece [1] 7/16
part [23] 19/21 24/12 30/10 48/25 78/23 83/15 85/19 87/16 87/16 87/21 98/24 104/2 106/12 114/20 118/25 120/22 125/11 136/22 153/21 184/10 190/25 202/3 207/25	people [2] 92/18 201/18	pieces [1] 187/15
partial [1] 3/9	per [1] 51/1	Pierce [1] 2/21
partially [1] 138/9	percent [4] 90/11 91/5 94/24 95/18	Pierce/West [1] 2/21
particular [50] 4/21 13/2 15/22 22/18 26/4 35/18 39/16 85/6 86/11 86/16 101/3 102/25 103/1 103/3 103/7 110/21 110/23 113/13 113/22 114/24 115/3 116/14 119/2 119/14 119/16 121/8 122/11 123/5 125/18 147/6 147/10 148/9 157/16 164/17 164/24	perfect [3] 28/20 49/14 143/10	pills [4] 118/14 118/15 118/15 153/4
	perfectly [3] 57/18 57/22 161/11	pills in [1] 153/4
	perform [3] 144/8 148/18 148/20	Piper [1] 2/5
	performed [1] 115/25	pivot [1] 188/8
	perhaps [7] 27/6 46/15 58/6 90/5 91/22 190/12 192/21	pivoted [1] 38/18
	period [2] 170/15 175/4	place [10] 104/16 111/1 111/3 113/14 113/20 117/7 118/1 118/22 145/23 154/20
	permissible [3] 105/14 155/16 194/21	placed [1] 14/5
	permission [1] 168/25	plain [4] 15/16 15/19 16/1 99/10
	permit [5] 6/2 62/8 91/4 99/16 100/12	plainly [1] 62/2
	permitted [10] 19/2 31/25 75/10 77/14 93/3 105/7 173/5 173/6 189/21 189/25	Plaintiff [36] 10/12 23/14 25/23 28/1 30/4 35/20 41/3 42/17 44/7 47/19 60/19 71/14 76/20 78/7 89/19 90/3 90/5 90/9 91/15 91/18 93/6 96/7 138/14 142/7 148/24 150/13 151/19 159/13 159/22 160/1 173/19 186/23 187/21 188/14 203/24 204/17
	Perrigo [4] 118/8 127/14 131/2 156/23	Plaintiff brought [1] 60/19
	person [12] 34/15 101/3 117/21 119/12 147/17 148/7 195/19 196/4 196/5 196/7 202/9 203/4	Plaintiff's [7] 7/22 41/5 90/2 140/25 161/15 170/21 200/19
	personal [17] 18/3 47/14 47/21 74/19 77/7 92/7 122/21 122/22 142/24 150/5 152/24	PLAINTIFFS [258]
		Plaintiffs simply [1] 68/23
		Plaintiffs' [72] 3/10 4/3 4/7 10/22 15/5 20/1 20/3 27/9 35/1 39/13 39/21 41/9 50/1 54/24 55/19 70/21 70/23 71/3 71/4 71/8 71/16 71/24 72/8 72/10 72/25 85/7 85/15 89/14 90/7 91/7 99/18 99/25 108/16 124/9 127/24 128/5 129/17 130/5 130/8 132/21

P	PMA [1] 39/16	76/18 78/13 128/24 145/6
Plaintiffs'... [32] 132/24	point [69] 7/21 15/5 15/10	165/18 196/16 204/17 205/11
133/19 133/23 134/1 135/8	15/12 15/14 27/13 30/24 31/3	practices [13] 12/3 12/13
135/25 136/7 136/15 137/6	40/15 41/1 42/11 43/21 44/15	17/15 102/25 119/1 119/3
137/24 138/16 138/20 139/2	46/15 48/17 52/17 52/23 54/8	121/3 121/7 122/1 138/22
139/6 139/19 141/2 143/6	55/11 60/18 60/22 62/9 63/12	146/24 148/13 149/14
150/13 155/1 157/15 159/17	63/17 65/5 66/9 72/5 73/4	pre [5] 153/8 153/16 154/3
163/1 177/6 177/22 178/2	76/6 79/1 79/7 79/13 79/23	154/9 154/23
178/19 183/24 185/17 188/25	83/25 91/3 93/4 94/11 94/23	pre-approval [5] 153/8
191/13 193/1 205/22	97/10 105/12 108/5 120/2	153/16 154/3 154/9 154/23
plan [3] 48/8 207/25 208/8	123/16 131/17 140/13 146/4	precedent [4] 5/13 20/14
platform [1] 3/4	147/16 148/20 149/1 151/1	136/16 146/15
plausibility [3] 76/2 95/10	164/20 166/5 168/17 169/12	precedent that [1] 5/13
190/13	172/17 177/2 179/16 181/8	precisely [4] 146/3 147/25
plausible [9] 61/9 67/23	183/15 190/19 191/21 192/5	160/16 173/4
75/14 75/20 75/21 78/17 81/5	192/13 192/20 192/23 194/7	precision [3] 104/22 112/17
117/4 200/8	194/13 194/16 207/12	112/24
plausibly [9] 54/14 61/23	pointed [13] 14/25 15/6	preclude [1] 91/2
83/12 90/9 91/6 95/1 95/19	33/13 54/16 67/1 84/12 84/17	precluding [1] 90/17
96/25 120/17	104/10 134/21 157/2 179/16	preempt [4] 138/9 144/22
play [5] 45/4 103/11 113/4	183/22 184/17	146/5 157/10
120/6 175/19	pointing [1] 38/4	preempted [99] 3/10 4/5 5/3
played [1] 144/18	points [11] 11/6 13/13 22/7	5/14 7/10 7/25 8/14 9/1 10/7
Plaza [1] 1/13	73/25 84/23 130/24 140/9	18/1 21/16 23/20 24/19 25/1
plead [45] 4/18 43/1 45/5	143/23 156/19 180/17 194/7	25/5 25/6 34/22 40/8 41/16
45/10 46/2 46/20 50/19 51/7	policeman [1] 105/23	44/7 51/5 53/18 59/4 59/9
57/22 61/20 63/2 63/4 67/4	policies [5] 51/21 68/4 70/5	60/13 60/15 60/16 60/20 61/4
67/16 70/25 72/9 72/16 74/7	70/11 80/16	61/6 104/7 112/20 113/2
75/11 76/21 77/1 78/7 91/6	policy [4] 69/11 78/13 145/3	127/22 127/25 128/4 128/6
92/18 93/16 103/3 103/21	182/17	128/15 128/18 129/12 130/6
104/22 112/24 115/18 150/3	policy aims [1] 145/3	130/18 131/6 132/20 132/22
150/5 150/11 161/18 161/19	portion [7] 63/2 63/3 183/2	133/1 134/18 134/23 135/7
162/2 162/19 169/19 181/25	201/24 201/25 202/1 202/7	135/13 135/17 135/23 136/2
182/6 190/7 194/24 199/4	portions [2] 145/22 145/23	137/4 137/8 137/16 138/2
199/13 199/20	posed [1] 114/4	138/5 139/17 140/17 140/19
pleaded [16] 8/11 8/14 11/21	posited [1] 94/2	141/10 141/13 141/22 141/25
21/8 21/20 65/25 78/2 78/17	positing [1] 186/6	145/22 146/12 147/10 147/14
95/11 149/23 150/18 156/10	position [34] 26/7 27/16	147/22 149/14 149/21 150/1
161/17 178/6 192/12 199/24	29/6 29/24 32/5 34/17 38/20	150/3 150/19 151/15 151/18
pleading [45] 38/15 50/1	42/21 44/4 44/4 44/17 44/19	158/2 171/8 171/14 172/2
52/15 57/18 57/25 62/23	46/21 53/8 53/14 85/8 88/4	172/5 172/20 172/21 179/23
63/11 67/7 67/12 68/15 68/16	89/5 90/7 91/7 91/8 123/15	183/9 184/21 185/1 186/9
69/1 74/18 74/20 74/24 75/2	137/6 139/12 147/13 152/2	186/12 186/12 194/22 196/20
76/8 76/10 76/25 77/2 77/6	154/5 177/22 177/22 178/2	196/21 197/3 199/23 199/25
77/8 77/15 79/20 79/22 80/18	178/19 190/1 190/3 202/21	206/4 206/4
92/22 95/9 113/4 160/23	positions [2] 107/7 107/8	preemption [126] 4/6 4/7 5/2
161/1 161/7 163/20 175/15	possession [2] 70/13 176/5	5/12 5/20 6/15 6/20 7/2 7/14
185/19 185/21 188/6 188/18	possibility [4] 31/13 79/23	8/4 8/15 9/24 10/21 11/2
189/4 191/20 199/7 199/7	155/24 173/11	11/5 11/8 11/10 11/11 13/11
199/15 200/6 205/14	possible [7] 144/1 154/23	16/18 17/17 17/23 19/4 19/8
pleadings [14] 18/15 79/1	181/15 182/18 182/23 184/1	20/12 22/3 22/23 23/17 23/19
81/11 84/22 95/25 100/7	201/5	27/12 31/12 31/13 31/13
124/9 125/12 164/3 177/6	possibly [1] 96/6	31/22 31/23 32/12 32/24
186/1 189/22 189/23 196/11	post [3] 44/5 44/6 113/9	33/12 36/19 36/22 37/1 37/2
pleads [1] 18/3	Postal [2] 75/12 75/17	37/4 37/14 37/21 37/24 38/2
please [5] 10/19 54/10 66/20	postulation [1] 78/16	38/8 38/11 38/12 38/16 39/4
73/18 191/3	potency [2] 132/16 153/19	41/7 41/12 45/23 46/5 50/5
pleased [1] 168/12	potential [3] 9/20 41/21	50/16 50/21 58/15 59/9 63/13
pled [25] 50/22 54/13 54/14	153/17	63/14 112/11 126/14 127/16
55/5 61/9 67/10 67/11 74/14	potentially [3] 33/9 42/12	127/18 130/9 135/2 136/7
78/15 79/10 90/1 90/11 95/1	143/19	136/8 136/12 136/15 136/24
118/17 136/23 158/12 161/8	potentially dangerous [1]	138/8 138/12 138/25 139/9
162/5 162/5 170/22 179/17	143/19	139/14 139/19 140/21 140/24
185/23 188/10 196/12 202/24	power [1] 31/9	141/4 141/6 142/20 143/25
PLIVA [1] 6/14	PowerPoint [2] 100/19 129/16	144/3 146/16 146/18 147/8
PLLC [1] 1/19	practical [3] 69/2 94/7	147/25 149/12 151/10 154/25
plus [1] 52/8	113/3	155/4 155/6 155/7 156/25
	practice [10] 24/5 68/12	157/7 157/9 157/9 162/14

<p>P</p> <p>preemption... [24] 169/20 170/7 173/10 179/25 180/2 182/11 182/12 182/15 182/20 183/2 183/7 187/1 188/16 189/3 190/1 197/15 199/8 199/16 199/20 199/21 200/12 200/13 204/19 206/10</p> <p>preemption and [1] 199/8</p> <p>preemption based [1] 37/21</p> <p>preemption case [1] 140/24</p> <p>preemption is [1] 37/24</p> <p>preemptive [3] 22/25 135/6 139/22</p> <p>preempts [6] 6/23 7/15 11/2 39/9 39/17 157/5</p> <p>preferred [1] 81/8</p> <p>prejudice [10] 67/3 67/20 72/20 90/25 93/25 94/2 94/23 142/2 173/14 199/13</p> <p>prejudiced [1] 95/4</p> <p>prejudicial [5] 172/22 173/8 175/18 192/3 198/11</p> <p>preliminary [2] 63/17 63/18</p> <p>premise [4] 56/21 122/8 144/11 144/12</p> <p>premised [3] 5/4 85/24 99/18</p> <p>preparation [1] 104/3</p> <p>prepare [2] 57/5 58/10</p> <p>prepared [3] 45/9 63/15 97/11</p> <p>Prescott [1] 8/2</p> <p>prescribed [1] 13/3</p> <p>prescribing [2] 24/7 24/8</p> <p>prescription [3] 86/24 103/17 103/18</p> <p>presence [5] 55/4 63/5 121/14 121/23 128/1</p> <p>present [15] 15/25 16/15 73/20 131/24 141/15 161/22 171/10 173/9 177/8 185/24 186/12 187/7 187/8 187/9 191/24</p> <p>presentation [4] 25/11 54/6 150/24 169/17</p> <p>presentations [1] 47/1</p> <p>presented [4] 141/18 189/8 190/17 201/16</p> <p>presents [1] 165/11</p> <p>press [1] 91/3</p> <p>presumes [1] 198/22</p> <p>presumption [2] 70/19 145/20</p> <p>presumption that [1] 145/20</p> <p>pretend [2] 153/7 189/13</p> <p>pretty [8] 44/24 48/15 93/19 99/1 106/6 124/19 164/23 176/14</p> <p>prevent [6] 63/8 133/16 134/4 157/19 168/7 203/19</p> <p>prevented [1] 203/24</p> <p>previous [7] 16/19 29/4 174/5 178/8 194/12 202/3 206/18</p> <p>previously [6] 4/24 38/23 100/1 105/19 140/24 152/15</p> <p>price [2] 4/14 102/13</p> <p>primarily [1] 98/20</p>	<p>primary [5] 4/10 56/14 118/4 177/2 184/24</p> <p>principally [1] 19/10</p> <p>principle [2] 76/4 146/23</p> <p>principled [1] 188/2</p> <p>principles [9] 8/21 11/20 19/15 37/4 43/16 48/18 63/14 140/19 144/23</p> <p>prior [8] 5/2 14/17 14/21 62/11 78/21 103/3 105/19 141/8</p> <p>prior preemption [1] 5/2</p> <p>private [31] 6/2 6/23 23/14 101/1 101/20 102/1 102/6 102/17 102/21 102/23 103/22 105/2 105/4 105/9 105/14 106/8 106/11 106/12 106/22 106/23 107/18 115/20 117/23 119/15 123/6 124/5 125/4 125/8 135/2 138/23 156/4</p> <p>privately [1] 163/6</p> <p>probably [4] 25/15 58/16 113/17 185/3</p> <p>problem [9] 20/9 57/25 58/7 69/2 72/19 95/10 134/5 139/15 188/19</p> <p>problematic [1] 80/18</p> <p>problems [3] 8/7 61/10 192/24</p> <p>procedural [1] 93/21</p> <p>procedure [2] 49/7 95/23</p> <p>procedures [2] 70/5 80/16</p> <p>proceed [17] 4/1 48/11 54/4 66/19 73/17 91/4 92/13 94/25 138/14 139/4 147/11 147/23 150/2 150/19 175/9 179/21 182/21</p> <p>proceeding [2] 89/22 187/2</p> <p>proceedings [2] 1/9 209/4</p> <p>process [18] 6/12 7/6 24/12 24/16 27/5 58/19 65/4 110/17 111/1 111/2 111/4 111/7 143/9 152/12 168/22 176/11 197/7 197/13</p> <p>processing [1] 119/7</p> <p>produce [3] 6/8 74/9 74/10</p> <p>produced [3] 74/6 80/16 124/13</p> <p>product [115] 4/14 4/14 5/4 5/17 6/6 6/8 6/18 6/23 8/10 8/19 9/22 10/4 23/4 23/9 25/23 26/11 26/15 26/18 27/15 28/9 28/14 32/7 32/8 32/8 33/11 34/5 36/7 36/8 36/10 36/15 41/13 41/19 42/18 44/3 45/12 68/5 68/6 68/7 69/20 69/24 70/12 75/22 80/10 85/8 85/10 86/25 101/9 101/22 102/20 102/21 103/1 103/22 110/21 110/23 111/12 111/14 112/3 112/9 112/21 114/4 114/5 116/1 120/21 120/25 121/13 121/18 122/23 123/1 123/5 123/18 123/20 124/3 124/4 124/5 125/1 125/2 125/18 130/3 130/17 132/15 132/17 132/25 133/5 133/14 134/15 136/1 140/7</p>	<p>150/6 160/6 160/17 161/4 164/16 164/19 167/18 168/4 169/10 169/13 178/3 178/7 195/4 195/5 195/7 195/22 195/24 198/4 202/11 203/21 205/12 205/23 206/9 206/11 206/14 206/17 206/20 206/21</p> <p>product posed [1] 114/4</p> <p>product will [1] 132/15</p> <p>product's [5] 162/20 165/5 170/3 170/10 171/19</p> <p>production [1] 74/12</p> <p>productions [1] 70/4</p> <p>products [51] 1/5 3/3 8/23 29/10 30/9 31/14 35/15 36/13 64/6 69/9 75/7 75/13 75/17 82/21 101/10 101/13 104/17 104/20 105/16 106/22 106/24 107/19 107/20 109/23 110/14 114/7 116/1 116/14 119/18 119/20 120/18 122/3 123/3 123/8 129/9 133/9 133/10 133/25 134/6 143/19 150/8 150/9 161/6 167/24 177/17 177/20 178/1 178/15 178/18 206/8 206/12</p> <p>products like [1] 35/15</p> <p>products' [2] 161/2 161/3</p> <p>profile [2] 153/11 153/25</p> <p>prohibited [3] 128/12 138/22 147/17</p> <p>prohibition [1] 93/1</p> <p>promised [1] 168/16</p> <p>promotions [1] 73/5</p> <p>prompted [2] 134/25 207/9</p> <p>promulgate [1] 43/19</p> <p>promulgated [1] 16/8</p> <p>proof [1] 173/6</p> <p>propensities [1] 179/12</p> <p>propensity [7] 81/17 82/4 83/17 88/14 179/9 191/5 191/15</p> <p>proper [11] 57/18 57/22 62/10 65/7 78/9 121/13 131/8 148/16 158/13 176/2 202/12</p> <p>properly [10] 56/11 58/14 59/17 60/4 60/10 61/25 63/2 75/8 169/12 201/1</p> <p>propose [3] 15/3 154/7 197/12</p> <p>proposing [2] 181/6 205/9</p> <p>proposition [16] 6/5 7/2 29/21 30/6 32/18 36/21 37/3 45/25 49/8 62/25 115/10 115/12 116/12 162/4 183/6 205/4</p> <p>propriety [1] 65/21</p> <p>prosecuted [1] 90/17</p> <p>prosecuting [1] 89/16</p> <p>prosecution [1] 30/17</p> <p>prospective [1] 81/7</p> <p>protection [4] 114/17 114/18 114/25 138/21</p> <p>protections [1] 147/4</p> <p>protections to [1] 147/4</p> <p>prove [7] 46/2 46/4 182/2 186/3 186/20 187/12 189/16</p> <p>proven [3] 27/20 56/18 76/3</p>
--	---	---

<p>P</p> <p>proves [1] 63/12</p> <p>provide [18] 6/16 7/8 76/4 78/20 116/2 121/8 143/11 155/21 164/16 165/4 165/22 166/25 167/3 170/2 171/3 172/8 184/18 200/18</p> <p>provided [11] 74/3 74/15 76/15 77/2 77/17 78/10 78/18 78/21 110/4 138/11 138/23</p> <p>provides [2] 113/17 161/20</p> <p>providing [4] 14/25 15/7 114/11 114/12</p> <p>province [1] 23/13</p> <p>provision [30] 7/14 14/11 22/23 27/1 29/18 30/18 34/5 35/19 38/3 38/9 43/14 59/3 60/15 60/16 61/16 119/2 124/8 126/2 139/9 139/9 139/10 144/25 145/1 147/6 147/9 147/9 147/10 147/18 147/21 147/21</p> <p>provision, [1] 26/17</p> <p>provision, adulterated [1] 26/17</p> <p>provision-by-provision [1] 139/9</p> <p>provision-by-provision approach [1] 147/21</p> <p>provisions [16] 6/10 16/12 26/8 26/10 29/10 35/21 35/21 36/2 43/5 43/6 96/16 114/21 146/2 147/15 147/18 148/24</p> <p>provisions delineating [1] 29/10</p> <p>provisions of [1] 16/12</p> <p>prudence [1] 164/2</p> <p>prudent [7] 148/6 148/14 171/2 195/18 198/5 198/6 202/9</p> <p>prudent for [1] 198/6</p> <p>prudent manufacturer [1] 148/14</p> <p>prune [3] 128/4 139/22 146/2</p> <p>PTO [3] 42/9 46/17 79/18</p> <p>public [3] 24/6 86/8 86/12</p> <p>publicized [1] 9/12</p> <p>publicizing [1] 24/5</p> <p>publicly [1] 84/25</p> <p>publish [1] 116/22</p> <p>published [1] 116/24</p> <p>pull [3] 16/20 183/13 183/14</p> <p>punitive [11] 48/24 61/8 61/13 61/21 71/21 71/24 71/25 72/3 79/4 82/25 87/3</p> <p>punitives [5] 61/12 61/23 62/7 72/7 72/10</p> <p>purchase [1] 4/14</p> <p>pure [5] 78/3 112/14 144/16 200/3 200/21</p> <p>purely [1] 171/6</p> <p>purity [2] 153/18 153/25</p> <p>purported [5] 38/6 41/23 67/8 73/2 80/9</p> <p>purportedly [9] 4/25 24/24 41/17 68/2 68/4 68/6 69/4 70/10 72/14</p>	<p>purportedly misleading [1] 72/14</p> <p>purpose [9] 92/6 93/7 94/3 109/15 112/2 162/22 163/10 167/19 182/21</p> <p>purposely [1] 77/14</p> <p>purposes [21] 12/8 45/23 46/5 46/7 48/20 75/25 86/16 87/2 87/3 113/9 124/10 152/10 155/4 166/14 166/23 167/6 167/12 167/16 182/14 182/16 189/3</p> <p>pursuant [4] 16/8 31/6 46/16 185/16</p> <p>pursue [3] 150/17 171/13 204/19</p> <p>put [27] 11/21 24/24 25/22 28/25 29/4 51/16 66/6 69/3 77/25 86/7 89/13 102/15 121/23 124/4 126/16 131/3 161/10 167/24 173/6 175/5 185/3 188/11 189/24 195/23 197/5 198/13 198/14</p> <p>puts [3] 32/16 83/15 125/1</p> <p>putting [8] 25/20 25/21 47/5 83/2 173/23 185/8 188/4 195/19</p> <p>pyramid [1] 107/8</p> <p>Q</p> <p>quality [4] 102/25 105/15 110/25 153/18</p> <p>question [84] 6/21 14/7 16/18 22/16 25/9 25/21 26/7 28/22 28/24 29/4 30/12 30/13 31/5 31/9 31/17 31/20 32/5 32/13 35/9 35/18 37/24 40/4 40/4 40/19 42/22 44/23 44/25 58/15 58/25 63/19 78/4 81/15 84/10 85/6 86/13 88/2 88/11 88/23 89/8 89/13 96/12 108/20 113/3 113/4 115/11 115/14 115/15 116/10 116/11 120/7 135/1 151/3 156/4 158/25 159/1 160/4 160/11 161/12 163/17 164/5 164/6 164/7 166/14 166/15 171/22 172/11 172/24 173/23 174/20 175/13 178/13 180/3 185/20 187/9 194/4 195/16 197/9 199/6 199/15 199/20 200/4 200/21 207/9 208/4</p> <p>questioning [1] 174/8</p> <p>questions [36] 25/8 25/17 28/18 28/23 31/16 38/17 45/15 47/2 47/24 62/17 63/15 64/1 80/3 80/7 84/6 84/6 89/6 108/11 108/13 122/11 122/15 156/15 158/6 158/9 158/10 162/10 162/15 163/15 166/12 166/19 168/18 201/22 207/5 207/11 207/14 207/23</p> <p>quick [1] 98/8</p> <p>quickly [4] 10/4 54/19 176/8 192/17</p> <p>quite [2] 55/10 170/19</p> <p>quote [2] 76/11 153/9</p> <p>quoted [6] 76/11 105/21</p>	<p>117/2 117/3 137/10 157/2</p> <p>quotes [1] 76/11</p> <p>quoting [2] 31/6 121/11</p> <p>R</p> <p>R.G [1] 105/21</p> <p>raise [4] 57/24 67/21 109/8 197/10</p> <p>raised [7] 34/19 35/4 36/6 50/6 50/8 91/15 183/10</p> <p>ramifications [1] 38/25</p> <p>range [11] 50/11 55/8 64/7 66/2 66/3 75/5 78/14 112/10 152/7 152/20 152/22</p> <p>ranges [1] 83/4</p> <p>RANITIDINE [111] 1/4 13/18 39/21 44/14 44/16 44/21 44/23 49/22 50/1 50/3 50/11 50/13 51/3 51/18 51/21 51/24 52/22 54/16 55/1 55/3 55/7 55/15 59/15 60/23 61/25 62/15 64/6 64/9 64/20 66/2 66/4 68/3 69/7 69/10 69/15 69/20 70/25 73/3 77/4 78/14 81/17 82/4 82/21 83/17 84/16 86/6 86/9 86/18 88/14 101/13 102/18 102/21 104/17 110/14 119/18 120/13 120/15 120/18 122/19 122/23 122/24 123/5 128/1 129/8 129/9 129/13 129/15 129/18 129/20 129/21 130/13 130/14 131/10 131/15 131/24 132/2 132/6 132/10 132/11 133/9 134/10 134/12 141/23 142/25 143/10 148/14 150/6 150/8 153/24 161/1 167/24 168/9 173/20 174/17 175/24 176/8 184/10 184/11 184/18 185/7 185/15 188/20 188/21 190/7 191/5 194/24 195/20 196/17 198/20 201/8 206/12</p> <p>Ranitidine to [1] 143/10</p> <p>Ranitidine's [6] 18/22 83/5 128/2 130/3 153/5 191/14</p> <p>Ranitidine-containing [3] 64/6 101/13 104/17</p> <p>Ranitidine-only [1] 69/10</p> <p>rarely [1] 35/13</p> <p>rather [10] 9/5 9/16 27/19 37/2 41/18 63/12 99/25 105/2 122/15 145/3</p> <p>rationale [1] 10/2</p> <p>re [4] 1/4 3/2 91/10 91/11</p> <p>reach [1] 6/20</p> <p>reached [4] 9/13 46/16 137/11 138/16</p> <p>reaching [1] 39/22</p> <p>reacts [1] 175/25</p> <p>read [10] 14/20 39/6 50/20 62/11 76/13 80/20 137/5 158/15 164/4 196/9</p> <p>reading [7] 20/16 20/17 59/20 99/10 108/7 109/11 197/21</p> <p>reads [1] 196/2</p> <p>reaffirmed [1] 45/24</p> <p>real [1] 53/5</p>
---	---	--

R		
reality [1]	88/24	
realize [1]	139/24	
really [22]	26/10 30/6 59/11 92/8 93/8 112/22 112/24 123/12 130/9 139/23 149/1 154/10 168/20 178/7 178/24 180/1 182/17 185/19 190/2 193/5 207/7 207/12	
reason [30]	4/12 21/4 30/3 37/5 41/11 41/12 57/20 61/22 71/9 91/17 91/23 96/14 98/21 141/10 158/2 158/21 158/22 159/4 159/12 159/24 160/13 160/14 160/15 165/12 169/13 173/5 178/5 196/20 196/21 198/7	
reasonable [32]	58/23 77/23 80/4 114/4 114/5 114/6 133/8 133/16 133/24 134/4 143/19 148/7 165/15 177/16 177/19 177/24 178/14 178/17 178/20 179/3 179/4 179/8 179/13 193/18 193/19 193/20 195/17 196/3 196/14 201/6 201/18 203/4	
reasonably [19]	18/9 129/22 133/5 134/15 148/6 148/14 163/2 171/2 181/3 195/18 196/4 196/5 196/7 198/5 198/6 202/9 203/1 203/23 205/12	
reasoning [2]	75/13 162/25	
reasons [11]	5/24 53/11 62/16 86/25 94/12 132/23 142/1 163/6 169/11 174/6 197/24	
reasserted [1]	99/14	
rebut [1]	136/11	
rebuttal [9]	3/17 3/20 10/8 22/1 48/5 62/20 106/4 127/5 142/4	
recall [7]	8/10 8/18 9/21 135/1 147/13 151/3 180/14	
recalled [1]	10/4	
recast [1]	100/4	
received [2]	9/9 133/5	
recent [2]	113/8 123/24	
recently [2]	131/16 192/7	
recess [2]	97/18 162/12	
recharacterize [1]	5/23	
recipient [1]	9/8	
recipient of [1]	9/8	
recitations [1]	56/8	
reckless [3]	61/24 86/5 87/3	
reckless for [1]	87/3	
recognize [10]	14/20 18/4 19/16 114/25 118/17 124/3 139/25 140/3 165/13 194/17	
recognized [13]	9/11 14/17 24/2 24/21 26/22 29/13 30/15 30/16 33/5 52/12 63/21 103/7 140/1	
recognizes [4]	8/7 21/6 134/22 205/16	
recommend [1]	81/10	
recommended [1]	13/4	
recommends [1]	154/16	
reconcile [1]	123/12	
reconciled [1]	51/2	
reconstruction [1]	205/9	
record [7]	10/13 54/4 65/14 81/22 156/21 156/22 209/4	
record we [1]	65/14	
recover [3]	187/22 198/2 200/8	
recoveries [1]	199/12	
recovering [1]	181/16	
recovery [6]	89/18 148/25 161/23 194/21 204/15 204/18	
recrafting [1]	74/18	
Reddy [1]	118/9	
redefine [3]	149/3 181/18 182/4	
redesign [5]	60/14 141/23 148/16 151/5 151/23	
redesign Ranitidine [1]	141/23	
redesigned [1]	61/1	
reduce [7]	133/3 153/3 202/20 203/9 203/13 204/3 205/17	
reduced [5]	70/5 143/5 153/5 202/17 202/18	
reduces [1]	203/2	
reducing [2]	202/14 202/15	
refer [3]	12/13 25/11 140/11	
reference [6]	51/7 98/25 126/3 137/20 139/10 198/25	
referenced [1]	46/2	
referred [3]	43/4 114/20 198/11	
referring [6]	16/22 49/11 76/21 76/22 108/22 158/16	
refers [1]	17/15	
refund [7]	4/4 4/7 4/13 6/24 7/19 25/3 33/12	
regard [4]	108/14 129/24 155/4 201/19	
regarding [8]	65/3 65/21 70/6 74/23 99/21 122/18 136/6 201/8	
regardless [4]	18/13 44/11 145/10 188/12	
Regardless of [1]	44/11	
register [1]	92/9	
regularly [2]	35/4 35/4	
regulate [4]	27/25 28/4 30/9 30/21	
regulated [3]	15/10 22/20 146/25	
regulates [1]	7/22	
regulating [1]	19/22	
regulation [9]	4/21 16/8 16/13 35/18 117/18 117/19 136/2 151/7 168/24	
regulations [24]	7/1 7/8 7/9 15/9 15/10 22/7 23/1 23/3 23/4 23/5 26/15 29/6 29/9 29/20 37/19 39/15 43/19 43/23 107/21 116/7 143/11 144/17 146/10 154/22	
regulatory [6]	18/19 27/2 108/2 124/11 124/15 199/1	
reiterated [1]	16/10	
reiterating [1]	98/17	
rejected [6]	5/19 10/2 16/6 35/4 37/20 140/25	
rejects [1]	146/15	
relabel [1]	101/4	
reabeled [1]	104/17	
relate [1]	174/16	
related [3]	84/24 115/25 190/7	
relatedly [1]	44/17	
relates [4]	72/12 130/20 183/6 183/12	
relationship [1]	107/19	
relax [1]	127/7	
release [2]	67/20 116/1	
releases [1]	115/23	
relevant [24]	11/25 14/2 42/9 80/19 82/2 89/6 141/6 147/15 172/21 173/18 174/20 174/25 175/23 176/1 176/9 176/15 176/18 177/7 185/24 187/14 191/18 191/23 192/3 195/8	
reliance [1]	46/4	
relied [2]	7/20 140/25	
relief [3]	61/14 61/19 80/24	
relies [2]	8/16 73/1	
relieve [1]	120/9	
rely [15]	6/13 14/16 19/10 26/9 29/5 29/8 30/13 36/21 36/22 37/5 37/7 44/17 79/5 135/20 138/18	
relying [7]	8/17 16/16 26/4 29/21 114/10 164/10 169/4	
Relying on [1]	16/16	
relying that [1]	164/10	
remain [6]	90/4 90/8 90/15 92/25 96/4 146/13	
remained [1]	180/8	
remaining [4]	73/8 127/19 135/8 142/4	
remains [2]	3/12 138/14	
remand [1]	90/18	
remanded [4]	113/10 113/21 165/20 175/18	
remarkably [3]	14/15 19/2 143/3	
remarked [1]	105/21	
remarks [2]	45/9 74/1	
remedial [2]	128/11 137/14	
remedies [1]	141/24	
remember [1]	50/23	
remind [1]	167/22	
remotely [1]	3/7	
remove [2]	8/18 118/21	
render [5]	6/6 26/16 26/20 140/23 152/13	
rendered [6]	6/17 28/10 33/21 35/22 206/12 206/14	
renders [4]	23/3 23/6 23/9 29/10	
rental [1]	19/19	
renters [1]	19/20	
repack [1]	101/4	
repackager [2]	104/2 104/7	
repackagers [8]	100/1 100/3 100/8 103/9 104/5 106/13 106/15 114/2	

R		
repealed [1] 20/7	requires [20] 16/20 18/24 38/14 63/4 80/25 87/14 117/19 121/4 121/10 135/3 139/13 141/7 143/17 143/19 143/20 149/4 152/5 156/6 199/2 203/1	73/22 84/3 84/21 85/3 85/7 85/11 86/17 86/22 87/6 91/21 91/24 94/16 97/10 98/13 99/14 100/11 101/21 102/17 103/6 103/10 103/11 103/13 103/14 103/17 103/20 107/24 109/8 119/25 121/18 123/21 125/24
repeat [5] 25/12 29/8 50/18 57/21 89/10	requires a [1] 16/20	retailers [102] 48/13 48/14 49/21 49/23 49/25 50/2 50/10 51/12 51/18 51/20 51/23 52/3 52/21 52/23 53/10 55/6 64/17 64/19 64/25 66/6 67/11 68/2 68/19 75/1 80/2 81/16 82/3 83/3 83/6 83/10 83/15 84/18 85/19 85/25 87/11 87/22 87/24 88/7 88/9 88/13 88/18 88/21 88/25 89/2 89/3 90/12 90/20 94/25 98/15 98/22 98/24 98/25 99/6 99/8 99/17 100/1 100/4 100/8 101/1 101/1 101/6 101/7 101/8 101/21 102/2 102/10 102/11 102/12 103/4 103/9 104/5 104/16 104/19 104/25 105/1 105/12 106/20 106/21 106/23 106/25 107/18 108/19 109/1 109/17 110/7 110/7 110/10 110/21 110/25 113/19 114/2 114/11 115/5 117/10 121/22 122/18 122/22 122/24 123/7 125/8 125/15 133/21
repeated [2] 10/25 84/23	requiring [2] 93/16 202/25	return [2] 45/14 198/7
repeatedly [1] 144/19	research [2] 9/20 72/14	returning [1] 19/17
repeating [2] 15/18 17/1	researchers [1] 9/19	revealed [1] 121/14
replead [12] 51/1 62/9 68/10 72/22 104/6 104/23 125/13 129/1 151/2 152/1 193/2 193/3	reservations [1] 69/12	reversal [1] 143/7
repleaded [1] 151/14	reserve [10] 3/16 3/24 10/8 53/20 66/17 73/7 98/6 100/13 127/3 142/4	review [2] 167/8 180/12
repleading [4] 141/15 151/9 151/12 151/14	reserved [1] 16/18	revolves [1] 8/8
repled [1] 62/15	reserving [1] 14/6	rewrite [2] 106/18 205/6
replete [1] 167/2	resounding [1] 45/21	Reynolds [1] 105/22
reply [13] 29/2 36/24 72/4 76/5 78/2 84/13 85/4 106/10 140/11 145/25 147/16 150/24 152/20	respect [38] 23/24 24/25 26/15 35/12 39/1 42/14 44/3 49/22 50/3 50/4 64/3 82/25 85/17 87/10 88/16 88/20 88/25 101/3 102/16 103/17 104/7 104/8 107/2 107/25 108/23 109/22 109/24 109/25 110/20 111/22 111/24 114/14 114/15 125/14 126/1 153/2 169/21 181/8	RICHARD [3] 2/8 127/13 136/13
report [5] 8/15 154/7 176/12 179/22 183/8	respectfully [8] 23/25 67/18 81/10 106/17 153/20 175/21 176/13 200/10	Richards [1] 131/19
reported [3] 8/20 8/25 24/5	respecting [3] 64/24 107/15 123/17	rid [1] 203/10
reporter [4] 2/20 3/7 209/7 209/8	respond [15] 28/16 28/22 64/4 84/4 84/8 84/10 122/13 124/21 166/4 166/14 166/15 168/13 168/17 168/19 186/14	ride [1] 127/7
reporting [4] 10/6 18/20 24/12 154/11	responding [2] 168/11 168/11	Riegel [11] 5/15 5/17 5/19 7/7 11/7 15/8 22/22 32/21 35/5 38/10 39/5
reports [9] 8/9 8/11 8/25 9/17 18/16 18/25 24/4 24/6 24/8	response [24] 13/13 17/9 32/10 39/13 41/9 51/10 51/11 56/13 59/11 65/5 78/1 85/15 89/14 93/22 134/2 176/22 176/25 180/15 182/25 192/8 203/14 204/24 205/19 206/24	rife [1] 8/6
represent [2] 3/19 66/15	responses [2] 47/2 205/15	right [45] 3/25 10/5 32/11 34/16 40/2 41/25 42/16 43/24 44/5 46/24 48/11 53/2 53/23 54/3 55/24 62/19 65/18 66/8 75/24 80/6 81/13 89/4 97/5 98/10 100/21 104/21 108/11 109/3 126/8 138/23 162/13 162/15 170/15 177/13 178/23 183/21 184/22 185/21 187/20 188/7 189/2 190/15 191/13 204/1 207/1
republic [1] 145/19	responsibilities [1] 147/20	rigorous [2] 68/4 70/11
request [11] 61/9 61/13 61/14 61/21 67/18 71/23 71/23 71/25 72/6 72/8 168/4	responsibility [2] 103/22 118/5	ring [1] 10/24
request is [1] 72/8	responsible [4] 102/23 110/23 184/9 207/18	rise [2] 27/21 67/23
requested [1] 63/23	rest [4] 10/8 53/21 71/18 100/13	risk [38] 5/8 34/21 41/18 54/25 61/25 62/1 64/6 64/17
requesting [2] 44/18 155/19	Restate [1] 156/20	
requests [2] 61/12 72/3	restatement [2] 200/22 200/22	
require [12] 9/6 30/20 117/21 129/4 131/6 132/17 152/3 154/3 154/8 162/19 169/18 169/18	restrictions [1] 53/4	
required [23] 19/1 39/16 55/2 55/7 63/5 67/13 77/5 86/19 127/25 128/7 128/9 128/10 128/14 129/7 143/11 143/12 143/16 144/2 144/11 144/12 144/14 152/12 153/8	rests [1] 19/14	
requirement [20] 7/11 7/12 11/16 11/17 27/24 28/7 28/13 32/16 33/20 33/24 34/7 39/11 41/22 84/22 118/22 121/21 144/6 144/8 163/2 201/13	restyled [1] 99/6	
requirement on [1] 32/16	result [15] 5/25 19/3 24/9 34/25 35/2 55/20 61/20 82/18 110/22 158/17 163/12 163/13 183/17 183/21 199/6	
requirements [45] 6/3 7/4 7/13 7/16 7/23 7/24 8/13 9/5 11/2 11/15 13/10 22/9 22/18 23/8 26/1 26/5 27/2 28/8 31/21 32/15 32/15 33/1 33/2 33/6 33/8 34/1 34/7 35/10 37/25 38/2 38/7 38/13 40/5 40/19 40/21 42/19 46/8 65/23 68/5 70/12 86/15 121/11 136/19 138/10 139/16	resulted [1] 9/21	
requirements within [1] 138/10	results [1] 150/21	
	resurrect [1] 169/3	
	retail [1] 106/23	
	retailer [42] 47/13 48/7 48/22 49/19 54/21 57/11 57/13 57/15 58/12 62/16 64/5	

R	50/1 50/4 70/24 86/6 144/18 175/10 193/15	166/17 166/24 167/21 169/24 170/23 172/7 173/17 176/17 178/11 179/19 181/3 181/19 182/12 182/16 183/19 185/13 189/20 189/24 191/25 194/2 195/22 196/9 196/12 197/12 197/20 197/22 198/8 198/13 199/9 199/24 200/8 201/24 202/16 202/17 203/13 205/22 206/23 207/12
risk... [30] 64/19 65/1 86/21 114/4 120/13 120/16 122/9 132/12 162/22 163/9 163/23 164/12 167/11 167/20 168/8 170/13 170/17 177/4 184/3 192/15 201/7 201/19 202/20 203/2 203/9 203/12 203/20 203/22 203/25 204/3	said [51] 7/7 7/14 15/23 17/12 21/2 25/12 25/13 34/11 34/13 35/8 35/16 36/11 38/10 39/5 39/17 49/5 55/11 59/21 59/25 65/7 68/17 76/9 76/20 78/5 78/10 78/21 84/5 86/4 89/2 95/17 98/17 105/22 115/21 116/16 118/10 122/12 124/14 147/8 154/13 154/13 155/19 159/14 164/13 168/2 182/7 185/4 187/19 199/4 201/4 202/1 202/4	say that [2] 68/20 199/24 saying [32] 15/18 19/23 20/24 42/7 58/5 60/2 65/11 86/1 86/7 87/11 88/5 94/5 94/6 94/9 94/11 106/6 117/8 121/18 121/19 121/24 149/6 152/21 152/25 167/10 169/7 179/2 180/4 184/9 186/11 189/25 190/6 192/11
risks [29] 19/7 24/25 73/3 86/6 86/8 122/19 129/8 129/10 129/13 129/18 131/15 131/23 132/2 132/3 132/9 136/21 140/5 143/14 155/12 155/15 155/16 162/20 175/10 181/4 192/9 193/15 202/14 202/17 205/22	said is [1] 65/7 said nary [1] 21/2 said that [1] 147/8 sake [1] 39/19 sale [1] 82/21 sales [1] 130/3 salubrious [1] 154/1 salvage [1] 101/4 same [62] 3/13 8/1 11/9 11/13 11/13 11/14 11/14 11/16 13/7 17/18 17/20 20/8 25/15 33/3 33/17 33/23 39/18 57/20 57/22 58/13 60/16 60/21 64/25 68/25 71/9 75/11 76/11 81/6 85/11 85/21 102/16 113/5 116/10 116/15 119/20 119/24 120/9 122/22 125/2 126/22 132/22 132/22 135/20 137/23 138/3 141/2 146/11 147/25 157/14 160/4 160/9 160/9 160/17 162/9 178/13 181/8 183/19 188/2 196/15 207/24 208/1 208/5	says [23] 19/5 19/6 19/14 39/6 57/2 61/18 78/12 80/19 87/1 89/15 107/24 108/25 119/15 125/1 146/18 154/6 154/11 157/1 172/1 173/13 181/19 197/16 200/16 scenario [2] 42/8 94/1 scheme [1] 117/21 science [4] 13/19 18/22 54/15 189/9 scientific [3] 54/20 71/1 84/25 scope [4] 107/2 108/6 142/20 206/19 score [2] 12/25 20/18 Scott [1] 1/16 screen [9] 48/3 54/8 59/2 94/10 100/19 100/22 126/21 131/3 158/8 scrutiny [1] 136/16 SEAN [5] 2/9 131/1 156/22 190/18 204/24 season [1] 50/24 second [10] 3/2 11/12 56/20 61/22 69/6 71/16 141/3 169/7 179/17 180/2
Rite [8] 98/14 102/5 102/5 105/5 108/17 109/10 110/9 111/10	sales [1] 130/3 salubrious [1] 154/1 salvage [1] 101/4 same [62] 3/13 8/1 11/9 11/13 11/13 11/14 11/14 11/16 13/7 17/18 17/20 20/8 25/15 33/3 33/17 33/23 39/18 57/20 57/22 58/13 60/16 60/21 64/25 68/25 71/9 75/11 76/11 81/6 85/11 85/21 102/16 113/5 116/10 116/15 119/20 119/24 120/9 122/22 125/2 126/22 132/22 132/22 135/20 137/23 138/3 141/2 146/11 147/25 157/14 160/4 160/9 160/9 160/17 162/9 178/13 181/8 183/19 188/2 196/15 207/24 208/1 208/5	screen [9] 48/3 54/8 59/2 94/10 100/19 100/22 126/21 131/3 158/8 scrutiny [1] 136/16 SEAN [5] 2/9 131/1 156/22 190/18 204/24 season [1] 50/24 second [10] 3/2 11/12 56/20 61/22 69/6 71/16 141/3 169/7 179/17 180/2 Secondly [1] 106/19 seconds [2] 10/11 73/10 section [19] 6/7 6/22 10/22 11/1 13/12 26/3 29/17 42/20 43/2 43/5 46/7 105/3 125/24 126/4 136/8 139/10 153/9 158/1 200/23 sections [2] 43/8 154/2 Sedran [1] 1/22 see [30] 10/16 10/17 14/1 18/24 20/6 45/19 46/10 54/7 65/17 84/12 94/10 100/18 100/22 109/4 116/11 117/20 121/14 125/20 126/20 142/9 145/5 148/1 150/20 165/8 176/17 179/15 180/4 180/5 180/10 197/18
Rite-Aid [8] 98/14 102/5 102/5 105/5 108/17 109/10 110/9 111/10	same analysis [1] 8/1 sameness [5] 37/1 37/18 37/22 155/11 195/11 sandbagged [1] 169/5 Sanofi [2] 3/19 121/2 SARAH [5] 2/15 48/7 84/20 94/15 98/12 sate [1] 134/7 satisfied [5] 155/17 155/20 155/21 177/25 201/25 satisfies [1] 18/10 satisfy [14] 53/15 58/21 131/12 137/25 141/16 157/17 163/7 178/21 178/25 179/6 182/14 201/12 201/23 206/22 satisfying [2] 162/22 163/10 save [1] 33/12 saved [2] 4/10 202/17 saw [3] 107/5 130/7 178/24 say [91] 13/15 14/17 21/5 24/20 29/2 32/19 36/25 38/7 43/11 43/23 48/14 52/20 56/2 56/6 56/10 56/13 56/15 57/8 59/11 59/12 68/20 70/13 77/9 77/13 77/20 78/2 78/23 84/17 91/5 91/11 91/16 91/17 93/5 93/9 93/20 94/23 96/22 106/19 107/4 107/24 113/5 119/10 121/22 124/13 132/3 145/25 147/13 150/22 153/10 157/21 165/15 166/12 166/12	SEAN [5] 2/9 131/1 156/22 190/18 204/24 season [1] 50/24 second [10] 3/2 11/12 56/20 61/22 69/6 71/16 141/3 169/7 179/17 180/2 Secondly [1] 106/19 seconds [2] 10/11 73/10 section [19] 6/7 6/22 10/22 11/1 13/12 26/3 29/17 42/20 43/2 43/5 46/7 105/3 125/24 126/4 136/8 139/10 153/9 158/1 200/23 sections [2] 43/8 154/2 Sedran [1] 1/22 see [30] 10/16 10/17 14/1 18/24 20/6 45/19 46/10 54/7 65/17 84/12 94/10 100/18 100/22 109/4 116/11 117/20 121/14 125/20 126/20 142/9 145/5 148/1 150/20 165/8 176/17 179/15 180/4 180/5 180/10 197/18 seek [8] 4/3 4/13 7/3 7/18 7/23 21/18 99/24 105/18 seeking [4] 6/23 91/2 147/5 199/11 seeks [1] 30/21 seem [1] 41/11
Riverside [1] 1/13 road [2] 77/10 124/18 ROBIN [2] 1/9 2/20 role [2] 120/6 144/18 roles [1] 105/2 room [3] 53/5 69/19 126/22 ROSENBERG [4] 1/3 1/9 2/20 66/14 round [9] 4/11 10/25 13/14 72/20 128/24 143/7 169/1 169/2 183/4 rounds [1] 52/18 routinely [3] 128/16 145/7 145/18 Royal [2] 61/18 62/3 rug [1] 43/22 rule [20] 3/9 5/12 20/5 22/6 49/6 49/7 52/17 53/15 61/13 61/15 61/16 126/13 144/5 144/10 144/21 146/17 150/20 152/3 152/13 157/7 ruled [2] 76/7 184/20 rulemaking [1] 16/9 rules [7] 26/14 49/6 49/8 95/23 146/9 173/4 204/7 ruling [2] 5/2 127/16 rulings [7] 60/7 61/3 136/25 188/5 191/20 193/1 193/3 run [5] 15/17 21/14 21/17 26/25 177/10 runs [3] 10/5 15/14 155/5	same analysis [1] 8/1 sameness [5] 37/1 37/18 37/22 155/11 195/11 sandbagged [1] 169/5 Sanofi [2] 3/19 121/2 SARAH [5] 2/15 48/7 84/20 94/15 98/12 sate [1] 134/7 satisfied [5] 155/17 155/20 155/21 177/25 201/25 satisfies [1] 18/10 satisfy [14] 53/15 58/21 131/12 137/25 141/16 157/17 163/7 178/21 178/25 179/6 182/14 201/12 201/23 206/22 satisfying [2] 162/22 163/10 save [1] 33/12 saved [2] 4/10 202/17 saw [3] 107/5 130/7 178/24 say [91] 13/15 14/17 21/5 24/20 29/2 32/19 36/25 38/7 43/11 43/23 48/14 52/20 56/2 56/6 56/10 56/13 56/15 57/8 59/11 59/12 68/20 70/13 77/9 77/13 77/20 78/2 78/23 84/17 91/5 91/11 91/16 91/17 93/5 93/9 93/20 94/23 96/22 106/19 107/4 107/24 113/5 119/10 121/22 124/13 132/3 145/25 147/13 150/22 153/10 157/21 165/15 166/12 166/12	SEAN [5] 2/9 131/1 156/22 190/18 204/24 season [1] 50/24 second [10] 3/2 11/12 56/20 61/22 69/6 71/16 141/3 169/7 179/17 180/2 Secondly [1] 106/19 seconds [2] 10/11 73/10 section [19] 6/7 6/22 10/22 11/1 13/12 26/3 29/17 42/20 43/2 43/5 46/7 105/3 125/24 126/4 136/8 139/10 153/9 158/1 200/23 sections [2] 43/8 154/2 Sedran [1] 1/22 see [30] 10/16 10/17 14/1 18/24 20/6 45/19 46/10 54/7 65/17 84/12 94/10 100/18 100/22 109/4 116/11 117/20 121/14 125/20 126/20 142/9 145/5 148/1 150/20 165/8 176/17 179/15 180/4 180/5 180/10 197/18 seek [8] 4/3 4/13 7/3 7/18 7/23 21/18 99/24 105/18 seeking [4] 6/23 91/2 147/5 199/11 seeks [1] 30/21 seem [1] 41/11
S		
safe [17] 29/13 103/25 129/9 129/22 130/10 130/10 130/15 130/18 133/5 134/13 134/15 150/8 157/16 168/7 169/13 205/12 205/23 safe without [1] 130/18 safeguard [1] 83/7 safer [7] 60/24 148/17 154/21 154/22 155/22 155/24 156/7 safety [10] 31/8 34/21 41/19		

S		
seemed [2] 56/21 147/3	shield [1] 13/21	side [9] 13/7 13/7 20/21 44/10 113/18 168/8 173/19 195/12 200/11
seize [1] 137/7	shields [1] 145/1	side-by-side [1] 13/7
selected [2] 123/7 123/8	shift [1] 36/18	Signature [1] 209/8
selectively [1] 153/9	shifted [1] 5/6	significant [3] 30/19 123/10 142/21
sell [20] 12/25 44/13 44/16 44/21 45/7 45/12 75/7 87/6 101/9 101/22 102/17 106/23 116/1 117/25 118/15 125/18 137/22 168/9 174/17 184/20	ship [13] 50/13 57/4 57/8 58/13 58/24 59/5 60/9 61/25 62/14 75/12 77/4 87/12 87/14	similar [9] 5/14 11/4 28/19 32/4 32/4 32/9 109/11 133/21 197/18
seller [4] 99/7 123/21 124/3 125/1	shipment [2] 58/23 197/7	similarly [6] 5/21 15/11 103/16 109/18 138/6 143/15
selling [10] 10/1 43/9 45/12 59/12 59/18 59/19 59/23 61/2 130/19 141/24	shipped [7] 51/24 55/12 56/10 57/16 60/4 68/6 87/1	simple [6] 17/9 96/14 99/11 151/3 202/17 204/5
sells [1] 102/10	shipping [6] 51/4 59/1 59/17 61/5 64/10 65/4	simply [27] 4/13 6/7 11/21 14/20 16/25 18/12 19/14 23/14 28/4 28/15 33/6 53/6 57/20 60/2 61/14 68/23 79/10 80/11 89/18 96/23 124/3 132/15 149/6 151/16 153/12 163/6 204/3
sense [8] 16/13 16/24 53/3 81/1 106/20 125/16 169/10 195/25	ships [1] 152/18	simultaneously [1] 200/3
sent [1] 115/19	shock [1] 14/5	since [4] 70/6 144/16 145/19 166/12
sentence [4] 21/24 65/18 65/19 132/3	shop [1] 19/19	single [11] 17/17 52/12 71/14 76/17 90/3 137/7 138/11 139/1 144/4 147/23 153/22
separate [9] 27/20 68/24 69/10 101/2 129/2 139/11 173/25 178/2 198/24	shops [1] 81/8	sins [1] 75/3
separated [1] 105/4	short [14] 25/2 91/20 92/17 92/23 93/10 94/18 96/16 97/4 97/18 100/19 162/12 177/1 180/12 188/13	sit [1] 192/21
separately [6] 77/20 93/16 126/1 136/1 172/13 190/14	short-form [7] 91/20 92/17 92/23 93/10 94/18 96/16 97/4	sits [2] 102/11 130/11
series [1] 166/25	short0form [1] 92/10	situation [2] 36/17 58/8
serious [3] 69/12 167/20 176/15	shorten [10] 111/11 111/14 119/19 119/20 119/21 120/8 120/20 143/9 188/13 198/16	situations [3] 27/2 55/15 197/1
seriously [1] 194/12	shortened [3] 163/1 163/5 191/24	six [6] 2/6 48/9 67/10 132/13 165/15 167/1
serve [1] 94/18	shortening [1] 163/7	Sixth [1] 20/11
serves [2] 145/3 167/16	shorter [11] 131/10 131/12 132/12 158/16 163/9 163/13 163/21 165/24 174/18 198/15 198/24	size [8] 94/20 105/16 110/2 111/23 111/23 114/14 114/23 118/12
Service [2] 75/12 75/17	shot [1] 50/21	sizes [2] 105/8 118/14
services [1] 110/22	shotgun [11] 57/25 68/15 68/16 68/18 74/20 75/2 77/15 81/11 95/9 104/9 104/21	ski [4] 19/18 19/19 19/20 19/22
serving [1] 94/19	should [70] 8/20 8/24 9/9 9/18 23/15 24/24 32/19 33/20 34/1 44/2 44/22 53/19 59/18 59/23 62/17 71/19 72/7 77/14 79/2 80/3 81/1 82/16 85/1 85/25 86/25 90/4 90/8 91/4 92/25 93/2 95/20 97/11 105/20 120/12 120/15 121/14 121/23 122/9 130/20 131/10 133/3 135/7 136/18 136/21 137/4 139/24 140/19 141/1 142/2 143/23 152/24 154/12 164/15 171/9 172/9 174/21 176/2 176/7 176/10 185/1 185/3 187/9 189/22 190/10 191/2 191/20 191/24 192/1 192/21 198/15	Skidmore [1] 16/7
session [2] 48/1 155/3	should interpret [1] 85/25	skull [1] 152/8
set [21] 6/2 26/10 36/11 37/25 43/8 45/11 45/15 49/20 62/25 102/13 118/12 141/3 151/16 171/10 176/2 176/15 187/16 195/3 195/20 198/21 207/25	shouldn't [4] 90/15 161/16 171/24 194/23	slap [1] 168/8
sets [6] 26/2 26/6 42/19 101/18 101/24 103/23	show [10] 18/1 31/23 54/7 111/19 117/6 124/8 131/5 187/4 187/22 200/15	slide [3] 106/7 107/8 129/16
setting [2] 65/20 109/25	showed [3] 106/8 133/19 198/14	slides [2] 107/4 131/2
settled [2] 124/19 125/4	showing [3] 61/23 121/9 121/18	slight [2] 165/8 181/2
Seventh [2] 20/11 20/20	shown [2] 140/2 205/13	slightly [2] 36/18 126/1
sever [3] 173/4 173/8 196/23	shows [1] 15/11	slow [2] 12/8 142/11
severability [4] 145/18 145/20 146/4 146/7	shutting [1] 65/15	slowly [1] 89/10
several [4] 56/23 92/20 140/11 205/18	shy [1] 53/22	Smalls [1] 30/16
severed [2] 145/22 172/13		Smith [3] 76/7 76/11 149/23
severs [1] 146/12		smorgasbord [1] 92/9
share [3] 91/24 100/19 125/16		SNIDOW [9] 1/18 54/5 64/3 73/20 79/5 81/23 92/5 94/6 94/9
shared [1] 120/5		snippet [1] 85/22
sharp [1] 20/23		so [241]
she [8] 3/15 3/15 12/9 97/22 106/11 142/13 142/14 187/23		so-called [2] 75/3 148/7
shelf [3] 52/23 101/19 102/13		sold [5] 52/23 101/12 103/1 107/18 123/21
shelves [5] 101/14 102/11 103/15 104/20 176/4		sole [3] 9/8 15/19 30/25
shelves under [1] 103/15		solely [3] 6/13 186/3 190/10
		Soles [1] 76/20
		solitary [2] 17/17 144/4
		some [69] 12/3 12/4 12/7

S	165/10 166/22 178/7 181/22 202/6	17/20 17/22 18/2 18/13 18/23 19/5 19/15 19/24 20/7 21/10 21/19 24/14 24/14 24/15 24/21 27/19 31/1 39/11 39/24 39/25 40/5 40/6 40/12 40/13 40/17 40/19 41/4 41/13 41/22 42/5 42/9 45/5 45/7 45/19 46/2 46/10 46/19 51/8 53/12 54/3 58/18 58/19 58/22 58/25 59/5 60/5 60/13 71/5 71/8 71/10 71/11 71/13 74/10 81/22 86/12 87/5 90/9 91/6 95/13 105/11 113/11 114/10 114/12 114/25 115/3 124/24 127/21 128/14 128/17 129/3 129/6 129/11 130/2 130/17 131/6 131/12 133/7 134/15 134/22 135/3 137/2 137/8 137/14 137/25 138/2 138/4 138/6 138/13 140/1 140/2 140/4 140/15 140/18 141/5 141/13 141/15 141/22 142/21 143/25 144/7 144/10 144/11 144/13 144/14 144/17 144/23 144/25 145/7 145/13 145/15 145/17 145/21 145/22 146/2 146/5 146/7 146/9 146/11 146/12 146/13 146/19 147/15 147/20 148/3 149/24 150/5 150/5 150/17 151/9 152/5 152/12 154/24 155/7 155/8 155/17 155/21 155/22 155/25 156/5 156/7 156/9 156/11 157/5 159/18 159/18 161/25 162/16 162/18 162/21 163/8 163/21 164/10 164/11 164/22 167/4 169/17 170/5 171/7 181/11 182/19 182/23 191/7 195/16 195/16 200/2 200/21 201/13 202/4 202/19 202/21 203/3 203/13 204/17 205/2 205/16
some... [66] 12/13 12/14 23/10 26/14 27/6 27/7 27/11 27/14 27/14 27/24 28/18 36/10 37/3 38/5 40/17 42/7 42/13 43/11 46/3 48/22 49/25 50/19 51/4 51/23 51/24 53/1 62/20 62/22 63/15 64/9 74/1 79/15 86/14 91/14 91/20 91/22 96/5 111/1 120/4 121/19 127/2 127/4 142/11 142/23 143/4 143/16 143/20 144/11 145/15 149/14 159/18 159/19 161/7 162/19 174/4 181/2 185/9 186/3 186/15 188/20 191/23 195/7 203/22 204/4 205/9 207/7	specific requirements [1] 22/9 specifically [26] 6/11 7/22 23/6 30/13 36/24 54/13 54/23 58/23 65/25 68/14 82/25 83/20 98/14 99/16 103/10 104/21 107/7 111/25 114/16 115/5 115/20 132/10 137/13 137/20 171/25 197/15 specifications [10] 26/11 101/11 101/12 101/18 101/24 102/12 102/19 103/23 110/1 110/23 specificity [4] 22/5 51/7 63/22 181/8 specifics [1] 167/8 specified [1] 29/11 specify [1] 57/7 specious [1] 56/16 spectrum [1] 60/22 speculate [2] 141/8 149/16 speeding [4] 204/11 204/14 204/15 204/22 speedy [1] 49/12 spend [2] 138/17 140/8 spent [1] 56/23 split [2] 126/25 127/1 spoiled [2] 130/7 130/13 spoken [1] 48/21 spot [2] 14/8 144/14 sprinkled [1] 4/24 Sprint [1] 76/19 square [1] 184/22 squarely [4] 5/19 9/1 9/23 22/25 stability [1] 167/16 stage [5] 42/10 111/3 163/19 163/20 191/20 stand [5] 26/10 28/15 162/2 190/9 192/20 stand-alone [2] 26/10 190/9 standard [15] 38/14 77/2 78/13 127/23 148/8 148/9 153/14 153/21 154/12 159/20 164/25 171/20 181/10 182/13 203/6 standards [2] 52/15 121/10 standby [2] 207/16 208/3 standing [1] 41/10 standpoint [2] 93/21 94/4 stands [5] 37/2 49/7 50/22 199/9 205/3 stark [1] 169/16 starker [1] 153/2 start [10] 4/6 6/5 12/10 22/2 91/9 98/17 106/5 127/11 131/7 199/19 started [1] 168/16 starting [2] 64/16 105/5 starts [1] 110/20 state [203] 4/16 7/9 7/10 7/16 7/23 8/7 9/5 9/25 10/12 11/2 11/8 11/12 11/13 11/21 11/22 12/1 12/2 12/12 12/20 12/22 13/6 13/7 17/4 17/5 17/10 17/12 17/13 17/19	state actually [1] 134/22 state duty [1] 11/21 state law [1] 156/11 state's [1] 129/3 stated [15] 14/12 16/19 58/25 70/17 77/17 85/7 86/20 90/10 153/15 156/24 156/25 164/22 170/24 201/9 205/24 statement [7] 16/24 28/7 115/17 137/7 165/16 170/7 183/16 statement appearing [1] 137/7 statements [6] 22/18 22/20 81/6 109/19 116/3 165/7 states [34] 1/1 1/10 12/3 12/4 12/7 12/13 12/14 12/15 18/7 21/17 46/3 46/4 46/13 60/6 69/19 71/14 75/12 75/16 80/23 124/1 124/1 124/6 124/7 134/20 143/16 143/20 151/4 157/4 159/18 170/25 181/2 200/16 200/24 202/25 states forbid [1] 12/15 stating [4] 57/19 133/15 157/18 180/22
Somebody [1] 191/2 somehow [3] 87/5 106/20 167/11 someone [6] 54/25 59/6 93/1 96/5 113/14 204/10 something [21] 8/13 26/5 33/10 35/19 45/14 49/5 107/25 107/25 108/1 115/1 155/15 166/17 167/14 171/12 190/20 195/4 195/20 196/5 196/7 198/19 202/16 sometimes [5] 45/17 45/18 51/24 58/1 65/9 soon [3] 47/25 96/22 207/21 sorry [9] 41/12 79/9 80/6 81/23 92/16 118/19 122/2 174/23 186/17 sort [15] 32/4 41/8 49/25 50/9 85/12 86/14 92/22 154/2 154/7 171/17 172/8 192/17 193/17 199/2 204/6 sorts [2] 153/14 165/7 sought [1] 101/9 sound [2] 17/2 208/8 source [5] 14/15 15/16 142/20 145/10 161/14 source of [1] 145/10 sources [1] 161/22 South [1] 2/10 SOUTHERN [2] 1/2 8/23 sovereignty [1] 144/24 space [4] 44/3 53/4 101/19 102/14 speak [1] 89/10 speaking [5] 34/16 36/24 94/2 117/13 173/2 special [3] 168/25 178/3 208/14 specific [59] 7/3 7/11 7/12 22/6 22/9 22/17 27/2 27/11 27/14 27/24 28/8 28/13 30/6 31/3 31/11 32/16 33/2 33/6 33/25 35/10 35/21 38/13 40/14 40/20 41/1 41/3 41/3 42/5 42/9 42/14 43/12 49/11 50/25 51/8 55/1 66/2 69/4 71/10 79/11 80/24 81/2 81/2 86/21 87/15 87/20 89/6 102/21 103/4 116/4 139/2 139/3 139/10 153/12 164/24		

S	60/4 60/24 64/7 66/2 86/19 87/1 129/14 129/19 134/13	107/12 133/21
station [1] 125/17	stores [3] 106/23 110/15 111/6	succeed [1] 41/7
stations [1] 106/23	stores sell [1] 106/23	successful [1] 196/15
statute [32] 12/16 12/23 12/25 15/1 15/17 15/20 16/20 26/2 26/6 27/16 27/18 35/10 39/24 40/13 42/19 43/8 43/10 43/15 45/4 45/6 45/17 46/11 46/22 60/14 138/21 138/23 147/3 147/9 147/18 147/24 148/23 157/25	storing [9] 59/1 59/17 61/5 75/7 114/7 133/25 178/15 178/18 178/22	successfully [2] 89/19 192/2
statutes [3] 17/14 145/8 146/10	straightforward [7] 13/11 19/9 99/1 106/7 135/14 150/22 183/17	succinct [1] 48/15
statutory [5] 15/19 16/1 43/20 124/8 145/13	strangely [1] 192/14	succinctly [1] 54/13
stay [4] 90/13 97/1 97/14 172/4	Street [4] 1/22 2/6 2/10 2/13	such [39] 6/15 6/17 11/7 15/4 18/7 19/23 30/15 34/7 37/15 46/15 53/4 65/25 69/12 71/1 72/9 72/17 75/11 76/13 82/17 90/10 90/17 95/11 120/13 120/19 128/11 134/25 145/9 145/14 158/14 160/7 174/10 174/14 181/20 191/8 191/9 191/12 191/21 193/12 202/21
stayed [2] 105/7 168/15	strength [1] 153/18	sue [5] 119/19 124/3 204/12 204/14 204/21
steered [1] 81/8	strict [1] 186/21	sued [4] 101/8 119/23 146/23 147/6
Stengel [3] 20/10 20/19 23/23	stricter [1] 182/22	suffer [2] 68/9 82/18
step [3] 8/17 58/19 87/10	strike [4] 72/3 98/21 138/13 145/16	suffers [1] 72/19
stepping [1] 49/16	strikes [1] 72/6	Suffice [1] 191/25
steps [1] 83/7	striking [1] 30/14	sufficed [1] 18/21
sticking [2] 176/20 177/17	string [1] 132/13	sufficiency [1] 70/22
still [24] 6/23 12/16 15/6 41/16 66/11 71/24 77/2 80/13 124/16 134/23 140/18 142/12 144/3 149/4 150/15 161/16 171/13 176/19 181/21 182/2 182/19 188/19 193/16 198/18	struck [1] 49/5	sufficient [12] 62/6 71/4 79/1 86/7 148/21 159/17 159/23 159/25 160/15 161/14 161/20 200/18
Stipes [3] 2/20 186/17 209/7	structure [3] 10/6 191/6 191/15	sufficiently [2] 14/5 72/9
Stipes' [1] 142/10	struggling [2] 193/22 193/23	suggest [6] 20/15 74/6 77/20 170/19 174/22 197/14
stipulation [1] 113/8	Stryker [1] 20/21	suggested [4] 13/4 74/2 170/19 183/25
stocked [2] 103/14 104/20	stubborn [1] 75/14	suggesting [3] 41/11 59/23 96/3
stomach [5] 129/16 129/21 130/16 174/17 189/7	student [2] 147/5 148/2	suggestion [1] 69/10
stop [11] 10/1 21/24 53/20 59/12 59/14 59/19 99/19 100/13 130/19 141/24 177/12	studies [3] 9/19 13/20 71/1	suggests [2] 95/8 169/24
stopped [4] 12/6 12/7 59/23 61/1	stuff [4] 43/11 85/16 168/14 191/23	suing [3] 110/12 119/18 120/1
stopping [1] 130/3	styled [1] 98/20	Suite [5] 1/13 1/20 1/22 2/6 2/16
stops [1] 180/17	styling [1] 106/14	suits [1] 149/19
storage [37] 51/4 55/2 58/23 64/10 65/4 65/7 65/21 65/23 67/24 70/6 70/7 75/4 82/20 108/16 108/16 108/18 109/9 109/11 109/16 109/25 110/3 110/13 110/24 132/24 133/8 133/13 133/20 133/22 134/6 134/11 135/25 140/5 141/21 152/17 160/7 160/20 205/11	sub [11] 60/5 71/8 71/13 79/8 79/11 131/18 133/14 133/20 133/20 169/23 202/6	sum [3] 67/24 132/8 135/15
store [46] 48/1 50/10 50/13 55/7 57/4 57/9 58/14 58/24 59/5 60/9 61/25 62/14 77/4 87/12 87/14 97/10 97/20 98/15 101/14 102/18 103/1 105/17 106/1 109/1 109/8 109/22 110/12 110/20 111/24 113/25 114/3 114/12 115/5 116/12 117/10 119/17 119/18 119/22 119/24 119/25 120/12 120/17 122/8 122/24 123/8 126/9	subject [10] 7/22 16/12 30/21 33/7 45/1 55/16 66/4 129/16 187/1 187/3	summarize [1] 44/12
store's [1] 120/8	subjected [3] 64/9 203/20 203/24	summarized [1] 127/18
stored [12] 55/3 56/11 57/16	submission [3] 8/9 121/10 134/1	summary [3] 14/7 75/24 184/18
	submission of [1] 8/9	summer [1] 55/13
	submit [7] 92/15 121/4 154/16 172/7 176/13 187/4 198/18	sun [1] 55/14
	submitted [4] 123/25 124/2 192/7 205/19	Sunlight [1] 105/22
	submitting [2] 18/16 154/14	sunscreens [1] 35/15
	subsection [7] 138/23 139/1 139/3 139/3 139/5 157/24 158/1	supplemental [7] 123/24 131/16 133/12 134/2 192/8 205/15 205/20
	subsections [2] 138/24 146/25	suppliers [1] 121/4
	subset [2] 112/15 153/13	supply [2] 52/9 99/5
	substance [6] 11/18 12/20 17/3 26/23 35/24 49/1	support [18] 52/10 52/12 59/19 62/6 70/20 70/22 70/25 76/6 78/18 107/6 108/3 137/6 144/4 148/21 153/8 164/8 171/4 171/7
	substantial [2] 153/17 159/19	support a [1] 62/6
	substantial contributing [1] 159/19	supported [3] 76/1 124/11 200/1
	substantiate [1] 4/22	supports [5] 14/2 16/25 114/9 157/8 199/9
	substantive [7] 7/11 40/5 71/18 129/6 135/8 135/16 139/13	suppose [2] 59/24 193/12
	substantively [4] 17/20 95/5	

<p>S</p> <p>supposed [6] 36/10 45/22 77/8 121/20 177/5 187/15</p> <p>supposedly [1] 9/18</p> <p>supremacy [4] 46/6 144/24 145/11 145/12</p> <p>supreme [42] 5/15 5/18 7/13 10/2 11/5 15/18 16/5 16/5 16/16 16/24 17/9 19/10 23/20 23/23 30/16 35/5 37/20 39/5 39/15 45/24 46/8 59/9 80/22 128/13 135/1 136/16 137/5 137/10 137/18 138/3 138/15 140/22 144/20 145/13 146/17 151/16 155/11 156/24 157/4 165/12 171/25 181/11</p> <p>sure [17] 44/20 47/4 65/19 89/7 118/23 158/11 160/25 172/4 174/6 177/21 179/24 180/16 187/19 194/20 198/9 199/19 203/19</p> <p>surprising [2] 11/16 193/9</p> <p>survival [1] 71/17</p> <p>survive [8] 20/12 38/15 62/3 71/18 71/19 72/7 136/16 188/18</p> <p>survived [2] 41/12 41/13</p> <p>swallowed [1] 5/12</p> <p>sweeping [2] 99/7 145/1</p> <p>swerve [1] 204/11</p> <p>switch [2] 153/4 154/22</p> <p>switched [1] 142/10</p> <p>switching [1] 153/22</p> <p>Sybaris [1] 8/22</p> <p>syllogism [1] 144/10</p> <p>syndrome [1] 14/5</p> <p>syndrome was [1] 14/5</p> <p>system [4] 119/12 119/12 132/7 184/11</p> <p>system has [1] 119/12</p> <p>systematically [4] 51/18 68/2 69/7 78/13</p>	<p>29/7 33/24 95/12 100/25 101/1 102/8 117/20 123/19 144/3 154/19 170/1 174/24 180/22 185/21 188/7 190/4</p> <p>talks [3] 119/6 119/8 197/15</p> <p>tampons [1] 14/4</p> <p>tangents [1] 166/18</p> <p>task [1] 80/23</p> <p>team [1] 180/19</p> <p>technical [3] 59/20 69/1 194/7</p> <p>technicality [1] 105/25</p> <p>technically [1] 182/18</p> <p>teed [1] 201/1</p> <p>telecommunications [1] 146/9</p> <p>tell [4] 3/15 89/12 126/17 167/23</p> <p>telling [6] 18/12 107/8 124/1 155/14 155/16 167/6</p> <p>tellings [1] 107/6</p> <p>tells [1] 169/10</p> <p>temperature [16] 55/7 60/24 64/7 69/19 69/21 75/18 75/22 77/5 78/10 80/10 83/4 86/20 99/18 152/7 152/20 152/22</p> <p>temperatures [3] 57/17 66/3 69/17</p> <p>template [2] 92/22 94/18</p> <p>ten [6] 3/24 48/4 52/20 66/12 73/12 79/21</p> <p>term [3] 4/16 34/24 57/11</p> <p>terms [12] 15/20 17/13 38/25 48/8 62/23 63/10 63/13 65/3 68/17 112/25 116/16 194/15</p> <p>territory [2] 123/22 172/3</p> <p>test [11] 80/24 87/6 87/21 121/25 122/2 122/25 134/19 143/10 184/3 203/23 204/2</p> <p>tested [4] 87/11 105/20 105/24 121/2</p> <p>testing [20] 82/19 86/15 107/15 108/1 121/12 121/13 121/15 121/15 121/19 121/20 122/6 123/3 134/22 134/24 135/6 135/7 143/19 167/17 168/2 176/2</p> <p>tests [1] 121/6</p> <p>tether [1] 71/11</p> <p>Texas [1] 134/20</p> <p>text [8] 15/16 15/19 16/1 16/2 36/20 43/20 108/25 109/2</p> <p>than [40] 26/1 26/6 29/5 29/19 35/24 36/7 36/9 37/2 42/19 43/1 53/9 60/1 63/12 67/6 67/7 67/11 68/22 72/7 74/15 75/21 76/2 77/9 80/16 89/17 99/15 99/17 103/8 105/3 106/17 112/5 112/10 137/11 138/7 145/3 154/14 166/25 182/14 182/22 194/17 200/17</p> <p>thank [63] 3/21 4/2 9/15 21/25 22/2 25/7 34/16 42/16 46/24 47/7 47/8 47/9 48/6 48/12 53/21 53/22 62/19 63/24 66/8 66/20 73/8 73/9 73/18 79/22 79/23 79/25 80/8</p>	<p>81/12 81/13 95/15 96/8 96/9 97/5 97/17 100/14 100/15 106/2 106/3 108/10 126/8 126/10 126/11 127/9 130/24 130/25 131/1 142/4 142/6 156/18 158/4 166/6 166/20 177/12 190/22 191/3 202/14 205/25 206/1 208/10 208/17 208/18 208/20 208/25</p> <p>Thanks [3] 97/16 158/5 162/10</p> <p>that [1715]</p> <p>that duty [1] 11/24</p> <p>that including [1] 128/6</p> <p>that maybe [1] 47/2</p> <p>that particular [1] 103/7</p> <p>that Ranitidine [3] 86/18 129/13 191/5</p> <p>that requires [1] 80/25</p> <p>that the [2] 49/12 200/16</p> <p>that theory [1] 21/15</p> <p>that's [7] 11/17 13/4 18/9 32/20 89/4 176/23 177/17</p> <p>the agency [1] 16/4</p> <p>the allegations [1] 64/24</p> <p>the approved [1] 6/4</p> <p>the CBE [1] 143/9</p> <p>the claims [1] 8/24</p> <p>The Courts [1] 40/25</p> <p>the dangerous [1] 132/2</p> <p>the Decender [1] 85/13</p> <p>the Defendant [1] 58/17</p> <p>the Defense [1] 66/9</p> <p>the distributors [1] 67/15</p> <p>The Doe [1] 61/18</p> <p>The element [1] 46/1</p> <p>the Eleventh [1] 138/25</p> <p>the extent [2] 40/6 42/12</p> <p>the FDA [1] 19/5</p> <p>the FDA's [1] 16/2</p> <p>the FDCA [1] 10/5</p> <p>The Food [1] 12/24</p> <p>the four-decade [1] 13/20</p> <p>the frequency [1] 13/3</p> <p>The improper [1] 179/21</p> <p>the L.A. [1] 62/3</p> <p>the labeling [1] 75/5</p> <p>the medical [1] 35/3</p> <p>the minor [1] 176/11</p> <p>the Plaintiffs [1] 194/20</p> <p>the point [1] 151/1</p> <p>the presence [1] 128/1</p> <p>the product [1] 26/15</p> <p>the question [1] 16/18</p> <p>the same [1] 157/14</p> <p>the slides [1] 107/4</p> <p>the subject [1] 7/22</p> <p>The voluminous [1] 66/24</p> <p>their [139] 4/4 4/8 4/10 4/24 5/23 7/18 7/19 7/20 8/17 13/23 14/16 14/17 14/18 15/7 17/1 30/25 33/10 33/11 33/12 37/7 41/15 46/21 50/1 50/2 50/7 51/2 51/8 51/16 52/13 52/19 53/2 53/6 53/7 55/18 55/23 56/13 56/14 56/21 57/5 62/24 63/11 68/11 69/9 70/3 70/3 70/4 70/25</p>
<p>T</p> <p>table [1] 195/15</p> <p>tack [1] 184/13</p> <p>tacking [1] 186/10</p> <p>take [32] 32/18 48/23 59/20 75/23 80/3 83/7 87/10 88/4 94/12 127/2 131/6 137/14 141/5 141/19 146/2 154/4 158/7 158/9 158/13 162/8 164/16 166/21 169/10 169/13 175/7 185/12 192/14 194/12 194/14 201/12 203/1 208/2</p> <p>taken [13] 8/18 56/1 70/7 94/7 97/18 133/3 135/11 138/3 143/5 162/12 184/17 191/21 208/23</p> <p>takes [1] 204/1</p> <p>taking [10] 74/17 76/25 93/15 117/10 128/11 129/12 130/18 135/6 137/2 186/9</p> <p>talk [7] 23/3 23/6 23/21 49/16 100/25 115/5 121/9</p> <p>talked [1] 139/8</p> <p>talking [19] 22/5 25/15 28/2</p>		

T	193/7 194/13 200/5 204/18	42/14 46/3 46/13 54/13 56/2
their... [92] 71/25 72/15	theory [65] 5/11 5/24 6/17	59/16 60/3 62/16 65/23 68/9
72/16 72/23 72/24 75/12	8/8 8/15 9/12 9/16 10/7 21/8	70/20 71/19 75/15 77/12
75/17 76/5 78/2 85/10 91/20	21/15 24/2 24/3 24/10 24/15	77/21 77/21 77/25 81/21
92/10 92/24 95/14 95/22 97/4	24/17 25/1 25/18 27/7 27/9	83/25 86/16 87/16 88/3 88/16
101/9 101/11 101/13 101/14	30/3 35/1 37/7 37/11 38/12	89/21 91/15 91/18 94/21 95/1
104/16 104/20 105/2 105/11	41/15 41/16 50/7 50/10 50/20	99/8 99/17 100/4 101/10
105/17 107/16 117/2 117/3	51/2 51/3 51/16 67/4 69/12	101/12 102/3 102/6 103/3
118/19 118/20 118/20 124/4	78/8 85/23 86/3 96/5 99/19	103/4 105/19 105/24 106/14
124/9 130/1 130/8 130/15	141/1 147/22 149/7 149/9	106/20 106/22 106/25 107/12
131/18 132/25 133/12 133/13	149/12 150/1 150/3 150/18	107/18 107/18 108/23 109/17
133/14 136/1 136/12 136/19	151/15 151/21 169/20 171/7	110/15 111/6 111/24 112/4
139/15 145/25 147/16 150/16	171/10 179/21 179/21 179/22	114/9 117/5 117/10 118/6
150/24 152/3 152/20 152/22	180/7 180/23 181/16 185/6	119/9 120/23 121/6 121/22
154/24 155/21 155/25 158/15	189/4 192/18 194/1 194/22	122/22 123/7 123/14 125/10
159/13 159/23 161/6 164/4	199/9 204/15	125/15 128/22 130/4 130/24
165/21 167/2 167/4 168/23	there [177] 6/15 11/10 13/11	134/9 142/1 145/11 153/7
171/20 175/25 176/6 176/7	14/8 15/25 16/25 17/22 18/24	154/25 155/3 155/5 158/16
178/1 186/2 187/5 187/24	19/2 19/3 19/21 20/8 21/24	161/8 162/15 163/15 164/21
188/19 191/2 191/17 195/13	22/16 22/17 23/2 23/10 23/13	166/18 175/17 176/3 179/11
196/11 196/19 198/3 198/4	23/15 24/4 26/14 26/19 27/1	181/9 182/4 186/6 187/12
198/16 200/2 200/3 204/11	27/11 27/19 27/23 29/20 31/1	188/9 197/4 198/13 200/5
204/13 204/13 205/5 205/14	31/2 32/22 33/6 33/19 34/12	202/17 208/24
205/14 205/14 205/15 206/2	35/17 36/9 39/20 40/18 41/21	they [307]
them [61] 50/18 54/13 54/14	41/25 42/4 43/7 43/12 45/6	they have [1] 105/16
56/7 56/24 57/23 58/13 67/19	47/25 48/22 48/25 52/20	they presented [1] 141/18
75/16 76/6 76/22 77/3 77/13	56/20 57/20 59/2 59/6 60/7	they're [1] 173/24
77/20 77/25 87/13 87/14	60/22 61/10 62/19 63/21	thin [2] 5/6 199/1
89/19 89/22 91/2 91/21 93/16	64/18 65/10 65/22 66/25 69/9	thing [16] 40/22 41/8 46/7
95/3 95/4 111/1 114/19	69/10 70/24 71/13 71/14	57/20 58/13 60/16 60/21
116/14 116/18 117/11 118/2	75/17 76/2 76/7 77/9 79/15	102/13 125/14 139/18 146/5
121/23 125/23 129/2 143/11	79/19 82/24 83/20 85/10	183/19 185/6 191/8 191/12
143/12 144/8 145/2 147/2	85/22 86/25 87/4 87/5 88/3	204/6
148/20 149/19 150/23 152/19	88/6 91/12 92/13 92/15 93/1	things [34] 9/3 30/14 43/12
154/16 154/22 160/15 169/12	94/6 94/10 94/11 95/2 95/9	58/7 60/23 61/3 66/6 74/1
169/18 169/19 173/9 173/10	95/10 95/20 96/1 96/12 96/14	75/14 77/21 84/24 94/16
174/5 174/5 176/16 182/5	104/4 104/10 107/14 108/2	115/21 118/3 118/5 122/15
194/24 199/2 203/1 204/12	108/3 109/4 113/8 114/12	123/11 123/14 129/7 130/5
204/14 206/3 206/4	115/17 116/4 119/2 120/3	144/11 144/12 144/13 167/17
themselves [11] 9/4 23/3	120/25 121/17 121/21 122/12	179/10 179/19 182/3 185/9
44/1 51/13 107/9 123/12	123/13 123/15 124/1 126/19	194/17 196/21 197/4 198/13
147/16 183/21 184/7 186/8	139/20 140/11 140/15 143/4	203/16 207/7
197/5	145/4 146/25 147/19 148/10	think [154] 12/8 22/13 23/25
then [68] 10/22 26/15 31/8	148/11 150/3 154/11 154/24	25/15 25/23 27/22 28/6 28/23
35/19 39/23 39/25 40/10	156/14 157/11 157/16 159/21	29/16 30/14 30/19 33/4 33/16
47/17 47/18 47/19 47/23	164/8 165/8 165/12 166/16	33/18 33/23 34/12 35/8 36/3
47/25 49/20 51/23 54/23	167/5 168/12 169/16 173/20	36/6 40/2 40/16 40/18 42/12
57/14 58/4 58/12 58/20 63/7	173/25 174/1 175/1 177/12	42/17 42/23 43/2 43/4 44/24
69/8 76/17 77/5 84/4 88/12	179/10 180/4 180/9 180/17	45/23 46/19 46/22 47/24 48/8
91/8 92/4 93/22 93/23 99/7	180/18 181/2 181/7 181/19	48/17 49/11 49/14 52/2 52/2
103/1 104/1 114/24 116/21	181/22 186/25 188/16 188/16	52/17 53/13 62/11 63/13
117/9 119/25 123/21 123/21	188/17 189/5 189/11 190/12	64/17 64/22 65/8 65/20 79/8
125/25 127/3 144/7 150/11	191/8 191/11 191/22 193/12	81/25 84/23 86/4 87/8 89/2
152/9 156/6 158/6 158/9	193/13 193/13 193/16 194/8	91/9 91/22 94/9 95/18 96/12
159/9 164/2 164/23 169/14	195/9 197/6 197/13 198/8	96/22 98/7 98/7 98/19 100/20
176/4 178/10 184/13 185/3	199/12 200/16 203/11 205/16	106/19 107/4 107/6 112/22
185/7 189/22 190/11 193/17	207/15 208/4 208/7	113/7 113/8 113/12 113/16
196/22 197/22 199/6 199/14	thereafter [1] 52/23	113/17 113/19 113/23 119/9
199/18 202/5 203/13 204/11	therefore [14] 5/8 13/10	120/22 121/1 123/13 123/24
207/21 208/3	16/6 21/16 26/16 27/21 29/14	126/9 127/1 145/14 146/8
theoretical [1] 6/21	39/4 46/23 71/25 105/25	149/19 152/17 161/11 161/14
theoretically [1] 164/5	144/13 158/22 160/13	161/20 162/24 163/4 163/14
theories [22] 52/13 60/19	thereof [1] 13/4	164/14 164/20 165/12 165/17
60/20 89/18 113/5 135/20	Thereupon [3] 97/18 162/12	166/8 167/5 167/9 168/9
149/15 149/20 150/1 151/18	209/1	168/10 168/11 168/15 169/4
157/17 179/19 180/6 180/7	these [107] 4/9 4/13 4/22	169/24 170/25 173/2 174/24
182/6 182/9 183/13 184/21	8/21 10/23 12/20 19/8 20/12	175/13 175/15 176/19 179/13
	23/24 26/13 35/3 35/12 42/5	180/13 180/24 180/24 182/5

T	142/3 149/20 179/19 182/6 183/13	today [17] 48/13 49/17 49/18 56/14 56/22 97/9 104/3 110/5 133/18 139/21 184/7 184/23 185/23 189/10 191/20 207/2 208/20
think... [40] 183/3 183/16 184/22 186/1 186/19 187/8 187/14 188/17 190/5 191/21 192/13 192/22 192/23 193/18 194/7 194/18 195/17 199/5 199/21 199/25 200/6 200/11 200/12 200/24 201/3 201/11 201/15 202/25 203/3 203/7 203/11 205/3 205/8 205/18 206/20 207/2 207/3 207/7 207/12 208/2	through [57] 1/9 3/3 6/11 7/5 10/5 10/23 17/25 18/17 24/16 27/5 29/15 30/5 35/12 49/25 51/24 52/23 55/12 55/25 56/7 68/6 71/17 73/1 78/24 80/10 84/14 103/5 107/22 112/25 113/20 116/6 116/7 117/9 118/20 119/11 121/5 121/25 126/6 127/2 130/23 131/4 131/8 135/15 136/6 145/5 150/21 155/2 156/12 158/13 161/25 173/13 174/10 175/8 195/17 201/8 201/17 205/4 208/13	together [7] 51/12 75/1 75/8 104/11 173/18 173/24 193/11
think that [1] 123/13	through an [1] 7/5	token [1] 208/6
thinking [4] 107/7 183/14 195/2 197/5	throughout [7] 4/24 11/22 64/18 64/21 84/19 84/24 165/8	told [6] 26/3 51/6 110/6 141/14 155/12 165/13
thinks [2] 56/18 163/24	throw [1] 23/18	tomorrow [1] 20/7
third [18] 10/1 18/5 18/8 18/10 18/12 18/14 19/18 24/22 52/4 69/14 71/21 111/2 117/3 121/5 122/6 134/25 143/20 200/22	thrust [1] 175/13	too [23] 18/1 23/2 25/14 58/16 80/3 96/21 130/11 135/13 142/12 151/24 158/21 159/4 159/12 159/13 159/16 159/22 161/3 161/6 161/13 170/21 173/7 187/5 198/4
third-party [1] 10/1	thus [5] 54/17 54/19 72/15 104/21 154/23	took [6] 50/16 75/2 134/16 154/5 159/11 193/1
this [305]	thwarts [1] 58/9	tooth [2] 22/15 22/20
this in [1] 17/12	ticked [2] 55/25 56/7	toothpaste [4] 22/16 28/3 35/15 36/4
THOMAS [2] 2/12 166/6	ticks [2] 175/19 182/1	top [1] 110/20
Thornburg [1] 2/15	tie [1] 81/3	topic [2] 120/8 199/8
those [105] 7/9 7/23 7/25 8/11 11/13 11/20 13/10 15/23 16/11 19/7 20/9 22/13 22/20 22/21 23/4 23/5 23/5 23/20 23/23 24/6 24/7 24/18 28/3 28/6 36/12 40/20 47/23 49/20 50/15 50/17 51/17 53/18 55/22 61/3 61/12 69/24 72/11 79/11 81/5 83/12 84/1 84/6 84/6 84/17 89/1 93/13 97/3 99/23 101/12 102/1 102/12 103/18 104/19 104/19 105/1 105/1 105/3 106/16 107/20 108/7 110/22 111/2 111/15 116/22 116/25 117/10 117/22 118/21 119/19 123/3 124/7 125/21 127/18 128/2 129/9 132/3 133/2 134/17 135/19 136/9 138/24 139/17 141/24 143/15 143/23 147/18 148/19 163/6 175/9 175/22 176/13 176/21 178/19 183/4 183/20 184/20 184/24 186/11 187/14 194/19 195/7 197/22 200/20 205/7 208/20	tied [1] 105/2	topics [2] 25/10 208/6
though [16] 20/19 20/21 30/12 55/11 56/14 56/22 59/14 61/6 128/25 136/22 142/9 149/23 176/13 182/18 185/19 204/15	tier [1] 99/5	tort [9] 19/15 19/24 21/10 27/9 108/21 128/10 144/17 155/21 155/25
thought [10] 12/10 47/2 47/3 64/2 65/15 79/5 127/11 166/21 173/1 173/7	ties [1] 176/20	tort cause [1] 128/10
thought-out [1] 47/2	time [53] 3/16 10/8 10/15 17/17 44/15 44/24 48/5 52/22 53/21 54/2 56/23 62/20 66/13 66/17 66/18 70/2 73/8 77/24 93/20 95/7 98/6 98/9 100/14 120/3 120/19 126/18 127/4 127/4 134/10 141/8 142/4 142/15 146/17 149/18 149/18 150/10 151/10 151/22 151/24 158/3 162/17 166/24 169/6 170/15 180/15 185/25 186/13 195/7 196/15 207/2 207/4 208/22 208/23	torts [2] 182/4 200/22
thoughts [1] 47/6	times [3] 26/25 43/5 118/8	total [1] 67/24
thousand [2] 90/5 90/6	timing [1] 48/8	totally [3] 9/10 157/18 194/3
thousands [1] 70/5	tinker [1] 171/24	touch [2] 67/21 71/6
thread [2] 5/6 112/13	tiny [1] 194/5	touches [1] 25/10
three [18] 3/10 43/4 51/13 51/17 52/5 58/7 60/19 61/3 67/8 67/9 67/25 68/25 124/6	Tire [1] 131/19	touchstone [1] 183/22
	title [2] 12/19 178/6	toxic [1] 14/5
	titled [1] 181/20	TraceAll [1] 8/23
	to absurd [1] 150/21	track [2] 66/18 98/9
	to advance [1] 36/22	trade [4] 12/3 12/13 17/15 101/5
	to communicate [1] 155/23	traditional [4] 18/4 19/15 19/24 140/18
	to comply [1] 182/19	traditionally [1] 21/10
	to enforce [1] 15/20	train [2] 64/2 166/21
	to ignore [1] 149/7	training [1] 179/21
	to obviate [1] 95/23	transcript [4] 85/5 85/14 85/22 209/3
	To plead [1] 45/5	transferee [1] 91/4
	to present [1] 187/7	transition [2] 136/10 152/16
	to prevent [2] 134/4 168/7	transitions [1] 130/10
	to provide [1] 165/4	transpired [1] 194/8
	to ship [1] 57/4	transport [7] 55/2 109/25 110/3 110/24 134/11 135/25 205/11
	to show [1] 54/7	transportation [22] 64/10 67/24 70/6 70/7 75/4 108/17 108/19 109/9 109/12 109/16 110/13 132/24 133/8 133/13 133/20 133/22 134/6 140/6 141/21 152/17 160/7 160/20
	to store [1] 50/10	transported [3] 129/14 129/19 134/13
	to sue [1] 204/14	transporting [5] 114/6 133/24 178/14 178/17 178/22
	to warn [1] 140/20	treat [2] 12/17 72/2
	Tobacco [1] 105/22	treated [4] 109/17 109/18 112/4 112/7

T	33/19 171/23 173/11 196/24 202/4	199/12
trial [12] 56/19 113/5 113/10 113/13 173/3 174/15 175/17 185/25 186/13 187/2 188/5 197/23	U	understanding [2] 90/14 109/19
trials [1] 172/12	U.S [9] 11/18 20/1 30/16 31/6 69/18 126/3 135/4 137/8 137/16	understands [1] 158/12
tried [12] 112/12 112/24 113/21 116/23 125/13 171/8 172/13 173/18 182/6 193/2 196/22 203/21	U.S.C [6] 13/5 26/2 31/12 42/20 43/3 126/3	understood [3] 47/4 126/19 161/12
trier [1] 187/7	ultimate [2] 170/21 175/16	undertake [2] 40/13 42/3
tries [1] 43/22	ultimately [11] 53/18 86/13 110/25 113/7 118/2 158/18 159/13 176/4 187/7 187/12 189/8	undertaken [1] 72/13
triggered [1] 46/22	Unable [1] 17/3	undertaker [1] 78/8
tripping [1] 165/16	unanimous [1] 20/10	undertook [1] 69/4
troubling [1] 70/9	unavailable [2] 21/19 149/10	undisputed [1] 152/10
true [23] 12/1 12/11 15/6 27/12 33/3 35/1 39/18 43/16 52/20 56/1 56/19 60/12 60/16 60/21 76/1 77/22 96/15 107/13 142/25 145/17 147/24 148/18 170/18	uncertain [3] 9/25 17/13 68/17	unduly [1] 192/3
true in [1] 27/12	unclear [4] 58/5 179/1 180/18 180/20	unfair [3] 12/15 42/14 115/2
trump [1] 28/8	unconstitutional [1] 145/16	unfounded [1] 74/13
trumped [1] 37/18	undefined [2] 69/7 69/15	unhelpful [1] 74/13
trumps [2] 38/7 124/16	under [144] 4/10 4/15 9/2 10/21 11/24 12/1 12/2 12/12 12/16 13/11 13/16 17/14 18/7 20/7 20/9 21/20 27/9 29/3 31/1 31/12 31/17 31/23 31/25 32/18 33/7 34/22 34/25 35/11 37/19 37/24 38/14 41/22 42/9 43/7 43/10 43/16 43/22 44/14 45/7 46/2 46/10 46/17 52/17 53/17 60/12 60/16 61/3 61/7 61/9 62/2 67/13 70/4 72/1 77/2 77/4 77/8 79/18 94/1 96/5 96/18 100/2 101/4 101/9 101/13 101/22 103/15 103/25 108/18 109/17 109/18 110/10 112/5 112/5 114/10 115/2 115/23 121/6 123/10 123/18 127/21 128/17 129/3 131/20 132/16 133/23 135/3 135/6 135/13 135/24 136/2 136/16 137/2 137/19 140/21 141/5 143/16 143/25 144/2 145/8 146/5 146/24 147/6 147/9 147/14 148/7 148/12 149/7 149/13 149/20 150/16 154/2 154/25 155/10 156/5 165/3 165/21 170/1 170/5 170/9 170/25 171/6 171/14 173/4 173/10 176/1 176/8 177/14 177/18 178/16 182/15 183/9 183/17 185/9 186/10 186/25 195/16 196/4 196/6 196/7 201/11 203/5 204/13 205/2 206/10	unidentified [1] 8/9
Trust [1] 194/4	Under the [1] 18/7	unique [4] 98/22 106/21 106/22 106/25
trusted [1] 173/12	underlying [5] 48/18 61/21 73/3 135/20 205/10	UNITED [4] 1/1 1/10 75/12 75/16
truth [1] 70/19	undermine [2] 19/9 144/23	universe [1] 192/15
try [12] 47/4 50/19 54/7 98/8 126/5 166/13 172/2 174/6 177/1 183/14 198/12 207/21	undermines [1] 145/3	unjust [8] 4/4 4/8 25/4 48/24 62/9 62/13 72/18 72/25
trying [14] 9/4 37/25 38/5 41/10 112/23 178/7 179/15 180/21 181/18 181/19 182/4 192/6 192/13 199/12	undersigned [1] 89/15	unknown [1] 93/14
turn [18] 10/22 11/20 13/25 17/25 34/15 39/23 80/1 92/4 93/23 97/15 106/25 130/22 135/11 150/13 185/3 191/3 199/6 201/20	understand [15] 38/20 42/6 68/21 77/13 90/7 93/22 104/12 118/23 120/5 165/17 175/12 190/2 190/22 194/3	unlawful [1] 12/25
turned [2] 21/4 22/15		unlawfully [1] 81/8
turning [5] 54/10 58/15 61/8 109/7 197/21		unless [5] 134/16 141/23 165/11 186/8 208/13
turns [2] 40/10 188/20		unlike [3] 9/10 78/6 85/9
two [40] 3/21 5/24 11/5 13/13 13/23 27/22 28/6 38/17 48/10 48/25 52/18 52/18 54/2 58/19 61/10 83/24 84/6 105/8 120/2 126/21 129/7 134/20 140/10 144/12 148/19 149/21 151/4 157/17 157/17 158/6 165/14 171/1 175/5 182/7 182/9 186/5 187/18 202/12 208/4 208/24		unlikely [2] 56/15 56/18
two-minute [2] 48/10 54/2		unnecessary [1] 93/19
two-step [1] 58/19		unpack [1] 180/17
Two-bly [8] 56/6 57/2 61/10 61/11 61/15 67/13 190/12 204/8		unprecedented [1] 9/16
type [14] 5/16 28/12 30/17 35/24 61/14 96/20 96/21 101/9 114/24 115/6 132/19 147/5 167/11 205/5		unreasonable [1] 203/24
types [2] 35/12 45/10		unreasonably [11] 52/22 59/15 59/22 60/1 60/7 133/10 137/23 140/7 157/16 181/24 203/20
typical [1] 177/23		unreasonably safe [1] 157/16
typically [7] 20/23 26/13		unreported [1] 9/9

<p>U</p> <p>us... [21] 77/1 77/9 78/20 78/21 97/21 103/3 104/22 104/22 113/20 117/8 125/17 149/17 151/2 152/1 172/7 184/12 186/15 192/23 200/8 200/13 204/1</p> <p>use [34] 11/14 17/6 23/16 33/14 34/24 38/5 48/4 48/8 76/10 81/7 104/16 114/3 114/5 114/6 117/3 120/21 129/9 129/23 131/15 133/16 134/4 154/12 154/21 177/24 178/20 178/21 178/22 179/7 187/24 193/18 193/21 196/3 196/4 196/14</p> <p>used [12] 11/16 13/2 17/16 75/16 76/16 110/25 143/9 152/11 165/5 170/3 176/7 204/6</p> <p>useful [2] 180/24 186/15</p> <p>users [2] 133/11 189/1</p> <p>using [13] 75/12 75/20 92/22 94/24 125/25 151/7 176/11 178/1 179/4 193/19 204/11 204/13 207/24</p> <p>USP [1] 69/19</p> <p>usually [2] 76/13 164/22</p> <p>usurp [1] 107/20</p>	<p>97/23 185/3</p> <p>videos [3] 126/16 158/8 162/9</p> <p>view [12] 11/20 16/4 16/6 16/6 16/16 16/25 24/7 130/15 167/10 177/7 178/8 185/24</p> <p>violate [4] 132/19 134/16 141/12 155/11</p> <p>violated [10] 4/20 6/22 7/16 27/3 31/24 34/5 35/21 39/11 45/17 165/23</p> <p>violating [10] 58/18 59/7 60/11 128/18 130/5 139/23 141/17 141/20 148/23 154/24</p> <p>violation [23] 12/14 21/18 26/14 26/16 27/7 27/11 27/14 27/19 27/21 27/24 30/24 31/3 38/5 38/6 38/13 38/15 40/20 40/23 41/1 41/3 41/4 41/5 41/21</p> <p>violation of [1] 41/3</p> <p>violative [1] 36/1</p> <p>virtually [5] 42/22 95/3 144/22 152/14 153/23</p> <p>virtue [1] 124/4</p> <p>vis [2] 173/8 173/8</p> <p>vis-a-vis [1] 173/8</p> <p>volume [1] 158/17</p> <p>voluminous [4] 52/19 66/24 68/12 70/13</p>	<p>166/12 166/14 166/16 166/17 166/20 168/13 175/21 176/23 179/25 180/14 184/11 184/13 189/25 190/2 195/2 200/15 207/3</p> <p>wanted [15] 42/23 50/14 50/25 84/8 89/6 93/18 94/5 122/12 125/20 178/8 183/13 192/20 206/23 208/4 208/7</p> <p>wants [10] 3/15 15/13 22/6 101/22 101/23 107/24 107/25 108/12 158/11 177/21</p> <p>warehouse [1] 55/13</p> <p>warehousing [1] 119/8</p> <p>warn [67] 4/5 5/13 5/23 8/5 8/6 10/22 17/25 18/5 18/5 18/9 19/5 19/6 19/18 19/19 21/7 23/18 23/21 24/22 25/5 114/4 117/13 129/8 131/8 131/13 131/15 132/1 132/9 132/12 135/9 136/7 136/21 138/5 140/8 140/16 140/17 140/19 140/20 141/2 141/7 141/10 143/17 148/15 148/16 152/4 152/5 152/13 155/2 156/8 156/12 158/13 160/4 162/19 169/8 169/12 169/25 170/13 170/17 171/7 181/4 181/22 183/11 186/20 191/7 192/9 205/11 205/21 205/21</p>
<p>V</p> <p>vague [3] 27/8 69/14 80/9</p> <p>valid [3] 57/18 94/11 94/12</p> <p>Valisure [1] 121/15</p> <p>vantage [1] 15/5</p> <p>variant [2] 5/9 10/1</p> <p>variation [1] 181/2</p> <p>variations [1] 165/9</p> <p>varies [1] 173/6</p> <p>various [6] 12/2 29/10 45/7 52/9 84/23 167/16</p> <p>vary [1] 159/18</p> <p>veer [1] 172/2</p> <p>verbatim [2] 14/21 197/22</p> <p>verdict [1] 198/7</p> <p>versus [13] 7/25 30/16 31/12 33/25 44/2 61/18 62/3 76/9 105/21 138/17 140/14 144/20 199/7</p> <p>very [50] 5/20 10/18 21/23 28/19 31/11 46/25 46/25 48/17 49/20 50/25 52/19 52/25 56/23 63/11 79/24 80/8 81/13 86/3 93/10 99/11 108/20 113/1 123/11 126/8 127/10 132/2 137/10 141/12 150/11 156/14 157/3 157/23 166/24 172/22 174/16 175/21 179/7 185/15 188/22 190/19 191/5 192/14 192/18 194/12 197/18 204/5 208/17 208/19 208/21 208/21</p> <p>VI [1] 146/6</p> <p>viable [10] 67/16 71/18 89/16 89/17 89/18 95/2 95/3 96/1 150/1 150/18</p> <p>video [5] 65/15 80/1 97/15</p>	<p>W</p> <p>Wacker [1] 1/16</p> <p>wait [7] 12/6 12/6 28/21 65/10 111/16 156/14 186/16</p> <p>Wal [20] 98/14 101/18 102/3 102/5 102/16 105/5 108/18 109/10 110/9 111/10 113/11 116/25 121/1 121/4 121/6 121/11 121/24 122/4 124/14 125/24</p> <p>Wal-Mart [17] 98/14 101/18 102/3 102/16 105/5 108/18 109/10 110/9 113/11 116/25 121/1 121/4 121/6 121/24 122/4 124/14 125/24</p> <p>Wal-Mart that [1] 111/10</p> <p>Wal-Mart's [1] 121/11</p> <p>Wal-Zan [1] 102/5</p> <p>Walgreens [8] 98/14 102/4 105/5 108/17 109/10 110/9 111/10 116/25</p> <p>Walinski [1] 28/2</p> <p>walk [5] 103/4 112/24 126/6 130/23 189/22</p> <p>wall [1] 20/14</p> <p>Walnut [1] 1/22</p> <p>Walsh [1] 1/19</p> <p>want [61] 3/16 25/11 25/12 29/7 29/23 32/18 40/22 45/14 48/4 53/10 54/11 63/17 64/4 66/12 77/1 77/23 82/23 83/25 84/1 84/7 88/22 89/10 90/7 95/16 98/1 98/5 98/6 100/5 101/8 108/15 111/16 112/18 116/18 118/23 126/17 126/18 126/24 133/17 142/10 142/19 149/1 155/5 158/6 166/4</p>	<p>warn as [1] 21/7</p> <p>warn the [1] 183/11</p> <p>warned [1] 150/14</p> <p>warning [72] 3/21 3/23 5/18 6/16 6/17 14/5 14/8 18/10 18/12 23/16 24/11 24/23 41/18 48/4 48/10 53/25 54/2 60/25 66/12 73/11 73/15 73/16 98/5 115/19 115/20 116/3 116/16 117/9 117/13 117/15 117/16 127/25 130/2 132/17 132/19 138/1 140/4 140/18 141/24 149/9 152/6 152/7 152/12 155/10 162/20 162/22 163/9 163/22 163/23 164/12 164/14 164/15 164/19 165/5 165/11 165/22 167/3 167/11 169/15 169/19 170/2 170/6 170/10 171/11 171/18 172/8 176/19 181/6 184/19 192/16 197/5 201/10</p> <p>warnings [17] 3/16 7/17 8/12 9/6 10/13 18/8 19/20 34/19 39/12 128/5 130/19 131/21 143/20 143/21 150/6 151/6 158/16</p> <p>warrant [1] 72/17</p> <p>warranted [1] 63/7</p> <p>warranty [2] 12/18 114/17</p> <p>was [254]</p> <p>was unsafe [1] 5/1</p> <p>Washington [2] 1/20 2/3</p> <p>wasn't [9] 32/8 32/9 50/24 51/5 53/3 169/12 180/1 180/18 190/2</p> <p>waste [3] 151/10 151/21 151/24</p> <p>way [64] 15/4 18/5 20/15</p>

W		
way... [61] 23/13 23/20 25/13 25/14 25/25 28/10 36/20 37/20 38/4 51/5 56/11 57/14 57/19 65/24 68/18 76/13 85/21 87/1 90/10 92/2 104/11 109/5 110/7 114/8 116/14 120/4 121/20 137/25 143/21 145/5 147/19 150/20 154/1 158/12 165/12 165/23 170/9 177/25 178/21 178/25 179/5 179/6 179/14 179/14 179/24 180/4 180/10 180/22 181/23 181/25 182/10 187/20 188/3 192/25 193/3 197/8 197/25 198/1 198/8 198/22 200/8	158/22 159/5 159/11 160/14 161/3 161/5 161/11 163/12 163/13 169/8 169/16 170/1 173/3 173/16 174/5 178/7 180/6 182/9 186/3 186/5 188/22 188/24 189/14 190/8 191/4 191/18 193/13 196/18 197/22 198/6 204/15	63/19 64/11 65/20 65/23 67/8 68/1 68/6 68/18 69/20 73/1 74/15 76/7 80/3 80/24 85/20 87/14 87/21 87/23 89/15 91/11 92/6 92/9 92/10 93/9 94/6 98/18 98/24 98/24 99/2 101/20 103/23 103/24 103/24 104/11 104/13 105/8 106/8 108/6 109/7 110/4 112/13 119/6 119/8 122/8 123/4 131/19 132/15 132/18 133/21 135/11 136/2 137/5 138/4 138/18 139/10 142/19 144/1 145/10 145/19 148/4 149/17 151/5 151/6 153/5 163/2 164/10 164/21 168/12 169/23 170/25 172/17 180/9 180/23 184/17 187/1 187/2 188/9 188/21 188/24 190/7 192/2 196/3 197/15 200/17 202/11 206/19
ways [8] 18/21 87/14 143/1 145/5 157/17 180/9 181/15 196/23	were repealed [1] 20/7 were subject [1] 33/7 weren't [5] 47/2 170/6 177/7 180/9 197/3	which Plaintiffs [1] 68/1 while [13] 16/17 17/15 34/24 37/9 53/2 69/1 69/14 70/12 88/6 108/2 127/19 129/2 150/15
we [409]	WEST [3] 1/2 1/5 2/21	white [2] 20/11 100/22
we welcome [1] 157/21	what [235]	whitening [2] 22/16 22/20
we'll [1] 93/23	whatever [6] 50/24 106/14 169/13 186/5 189/7 189/17	whittled [1] 51/12
we're [2] 173/5 173/6	when [65] 7/10 9/24 11/12 13/2 13/6 13/18 15/1 15/13 16/21 17/10 30/18 35/6 38/22 41/20 43/12 43/19 44/22 45/12 50/5 57/19 60/14 70/22 75/18 76/12 81/18 82/5 83/18 85/6 88/14 91/1 91/2 96/15 97/6 100/25 105/19 108/15 121/15 123/19 128/16 129/14 129/15 129/19 129/20 132/11 137/13 139/8 139/22 149/18 150/9 150/9 151/8 161/21 164/15 165/5 165/14 168/16 170/3 174/8 180/1 189/7 193/17 196/21 202/1 202/4 206/10	who [23] 3/14 24/7 34/16 49/18 57/8 57/8 81/7 85/9 92/9 93/14 98/14 101/3 104/19 118/4 125/1 147/4 168/4 173/20 173/21 191/2 199/15 207/17 208/20
we've [1] 207/3	when Plaintiffs [1] 96/15	who could [1] 85/9
website [2] 24/6 122/6	where [59] 7/21 9/11 15/9 15/19 21/15 26/23 27/2 27/23 27/25 27/25 28/6 30/3 34/4 35/16 35/17 35/20 35/25 36/4 36/10 36/13 36/15 36/17 36/25 38/23 41/20 44/6 44/6 45/4 46/13 49/16 69/3 71/14 78/7 79/12 82/13 85/4 95/2 106/10 107/16 108/22 111/19 113/14 113/20 115/19 118/24 119/3 120/4 120/14 145/2 148/23 151/17 156/7 178/13 192/15 193/22 197/25 200/16 202/16 203/12	who has [1] 173/20
websites [1] 117/3	where it [1] 41/20	whole [7] 12/10 92/6 106/17 128/14 140/23 146/4 197/13
weekend [2] 208/19 208/25	whether [48] 3/16 6/21 11/12 11/19 14/4 17/19 22/16 22/17 24/13 31/17 32/5 32/7 32/13 37/11 37/24 40/20 46/5 46/19 52/22 55/13 58/5 58/17 58/20 59/4 72/6 80/23 82/2 84/10 86/2 88/2 101/22 107/18 107/18 115/25 123/13 135/2 150/18 156/4 157/4 163/20 173/24 173/25 179/1 199/14 199/20 200/2 200/4 203/23	whose [1] 101/5
weeks [1] 165/15	which [129] 4/10 4/13 5/15 7/8 8/10 9/23 15/17 19/19 20/9 21/17 22/22 23/13 28/4 29/9 30/8 31/11 31/14 31/17 32/6 33/7 33/24 37/16 37/20 39/7 39/25 40/6 40/7 40/9 42/13 45/16 45/24 46/1 47/20 49/2 55/5 58/2 58/2 60/6 60/18 61/13 61/14 62/24 63/6	why [39] 20/9 21/1 21/20 31/4 36/22 53/14 53/15 53/16 53/17 53/18 57/24 66/1 80/17 85/20 88/1 90/8 90/12 91/17 109/3 114/20 116/5 125/13 130/5 135/15 146/15 151/3 162/8 163/5 181/14 184/25 187/17 189/9 191/24 192/20 196/14 197/5 197/6 197/7 198/24
weigh [1] 42/23		wide [2] 51/14 65/23
weight [1] 100/10		will [91] 3/8 3/13 3/14 3/24 10/8 10/23 12/10 21/24 28/21 28/23 47/18 47/25 49/2 53/20 54/6 59/12 62/22 63/8 63/15 64/1 65/10 65/14 67/21 71/6 73/7 73/25 79/7 80/4 80/20 84/22 85/16 89/12 91/9 91/21 92/4 93/23 97/6 97/8 97/16 98/8 98/17 100/13 100/19 103/20 106/5 108/5 113/10 115/11 115/15 116/11 118/3 120/3 127/2 127/3 127/3 130/22 131/3 131/7 132/15 136/10 138/17 139/18 140/9 140/10 142/4 142/11 142/13 142/14 142/15 156/14 158/9 158/10 162/9 162/10 166/13
welcome [3] 48/10 97/19 157/21		
well [37] 5/13 19/1 29/17 30/20 36/25 38/11 47/12 48/16 50/17 63/13 63/21 71/20 74/8 77/17 85/17 90/5 92/12 94/7 94/13 97/5 97/13 98/1 111/24 121/1 124/12 124/19 125/4 133/13 144/2 148/10 158/14 166/10 176/20 185/8 191/17 191/21 208/10		
well-established [1] 5/13		
went [11] 20/15 24/16 43/24 68/20 104/3 118/7 118/10 136/6 180/7 183/3 193/14		
were [125] 3/5 8/21 9/1 18/18 20/7 23/25 24/1 24/18 26/18 26/19 26/24 28/2 28/3 33/1 33/7 33/9 33/17 33/23 34/19 39/20 40/10 40/14 47/5 49/20 49/23 49/25 50/3 50/5 51/1 51/6 53/3 55/19 60/20 61/24 64/7 64/19 64/22 64/25 65/17 66/1 66/22 66/23 66/25 67/15 69/6 69/17 79/17 79/20 79/22 83/19 84/1 84/12 85/23 86/1 86/6 90/14 92/13 92/15 92/18 99/4 100/1 105/19 107/12 110/15 111/6 112/10 113/1 119/17 121/22 124/24 125/15 125/15 127/24 128/12 128/23 128/25 129/9 131/24 138/5 143/4 143/10 143/16 144/21 146/25 147/5 148/12 149/15 149/21 150/1 150/6 150/8 151/13 155/12 157/16		

<p>W</p> <p>will... [16] 166/16 166/21 166/23 174/8 174/21 176/25 177/12 178/15 188/8 199/6 199/22 199/24 207/21 208/7 208/12 208/18</p> <p>willful [1] 62/5</p> <p>Winn [2] 57/14 101/17</p> <p>Winn-Dixie [2] 57/14 101/17</p> <p>wish [4] 55/22 92/11 94/12 112/7</p> <p>with Perrigo [1] 118/8</p> <p>with respect [1] 44/3</p> <p>withdrawn [1] 168/4</p> <p>within [11] 64/7 103/8 105/7 128/7 131/25 132/5 133/6 138/10 168/15 175/4 205/7</p> <p>without [24] 19/23 20/24 30/23 58/18 59/7 60/10 79/11 81/5 83/5 94/2 107/17 128/18 130/5 130/18 135/6 137/2 141/16 141/20 144/4 152/25 154/22 154/24 168/25 204/11</p> <p>without specific [1] 79/11</p> <p>without violating [1] 59/7</p> <p>Wolicki [4] 4/19 27/13 27/13 38/14</p> <p>Wolicki-Gables [4] 4/19 27/13 27/13 38/14</p> <p>woman [1] 148/8</p> <p>won't [4] 50/18 142/15 199/23 208/14</p> <p>wondering [1] 199/14</p> <p>wonton [1] 62/5</p> <p>word [12] 17/6 17/7 17/16 21/2 39/5 39/5 46/8 153/20 154/4 159/10 181/2 207/21</p> <p>word-for-word [1] 39/5</p> <p>worded [3] 5/21 22/23 39/7</p> <p>words [17] 11/14 15/23 25/25 43/13 44/12 55/19 59/21 103/14 107/11 107/23 117/4 146/20 161/10 161/11 163/5 186/10 207/16</p> <p>work [3] 145/11 171/21 172/23</p> <p>worked [1] 97/13</p> <p>working [1] 97/23</p> <p>works [4] 195/7 195/24 196/17 198/20</p> <p>world [7] 38/23 40/9 188/9 189/4 190/3 194/2 196/12</p> <p>worry [1] 12/7</p> <p>worse [1] 9/3</p> <p>worth [2] 22/13 164/20</p> <p>would [270]</p> <p>wouldn't [10] 41/16 51/21 75/14 90/17 90/20 134/7 165/13 170/12 198/8 204/21</p> <p>wrap [2] 93/23 124/15</p> <p>written [2] 108/7 132/17</p> <p>wrong [6] 43/24 49/22 61/22 66/7 145/4 185/6</p> <p>wrong that [1] 145/4</p> <p>wrongdoing [1] 81/4</p> <p>wrongful [2] 71/17 73/3</p> <p>wrongly [1] 23/25</p>	<p>wrote [1] 14/21</p> <p>Wyeth [8] 31/6 31/12 31/17 32/1 140/14 144/20 152/4 152/13</p> <p>Wyland [1] 75/3</p> <hr/> <p>Y</p> <p>year [3] 67/15 128/23 148/2</p> <p>years [1] 165/14</p> <p>yes [52] 18/17 42/15 46/2 46/18 54/1 54/15 61/1 62/21 64/15 78/5 82/5 82/11 82/15 82/22 88/10 88/12 88/15 88/17 94/5 95/16 96/11 100/21 109/14 111/5 111/21 122/5 122/14 124/22 125/22 126/22 150/14 150/16 153/25 159/10 160/19 160/22 162/24 163/14 166/4 166/6 170/5 171/15 174/19 190/21 202/23 203/7 203/11 204/9 204/25 208/9 208/15 208/16</p> <p>yesterday [14] 3/5 3/12 8/7 41/8 49/4 70/21 70/21 74/20 97/7 97/13 129/17 130/7 139/21 168/2</p> <p>yet [9] 8/10 74/9 79/16 80/13 96/7 118/2 144/3 173/1 174/15</p> <p>yield [1] 73/7</p> <p>YOO [11] 2/12 166/7 168/10 169/2 169/17 185/4 186/18 187/11 187/18 188/4 192/11</p> <p>you [437]</p> <p>you're [1] 80/6</p> <p>your [326]</p> <p>yourself [1] 29/8</p> <hr/> <p>Z</p> <p>Zan [1] 102/5</p> <p>ZANTAC [14] 1/4 3/2 4/25 5/3 5/25 9/19 29/2 102/1 102/9 103/11 121/2 174/11 179/9 193/6</p> <p>zero [2] 2/6 95/18</p> <p>Zimmer [1] 91/10</p> <p>Zolwinski [1] 8/2</p> <p>zone [1] 98/9</p> <p>Zoom [3] 1/9 3/4 207/24</p>	
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