SPEAKER'S NOTES

Logical Contradiction Doctrine: Buckman for Textualists

Slide 1

Welcome to the inaugural presentation of the PLAC HLTh Group Webinar Series

The intent of this series is to provide targeted presentations on issues of particular relevance to the prescription medical product industry, and to do so in greater detail than possible at PLAC annual meetings

No better way to start off this series than to examine *Buckman Co. v. Plaintiffs Legal Committee*, 531 U.S. 341 (2001)

Everyone who defends prescription medical product liability litigation relies on *Buckman*

For two propositions, that are by now generally accepted

- That private parties, such as product liability plaintiffs cannot enforce the Food, Drug & Cosmetic Act – hereafter the "FDCA"
- That plaintiffs cannot collaterally attack the truthfulness or completeness of a defendant's submissions to the FDA – at least to a jury

While *Buckman* was unanimous in finding preemption, its continuing vitality at the United States Supreme Court level has been in question since the 2008 4-4 split in *Warner-Lambert Co. v. Kent*, 552 U.S. 440 (2008)

Buckman was not cited at all in the *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (U.S. 2019), or *Mutual Pharmaceutical*

Co. v. Bartlett, 570 U.S. 472 (2013), implied preemption decisions, cited only by the dissent in *Wyeth v. Levine*, 555 U.S. 555 (2009), and rated only a "*cf.*" citation in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011)

Justice Thomas, who concurred in *Buckman*, is the only justice left from the Court that decided *Buckman*

Justice Thomas, whose preemption views are idiosyncratic, is probably the key vote in any revisiting of *Buckman*

But all is hardly lost, I believe that both essential holdings for which defendants commonly cite *Buckman* are compatible with the Supreme Court's current preemption jurisprudence, and still command a majority of the Court

We just have to argue them differently

However, preserving *Buckman* requires crafting and preserving new arguments that defendants are not accustomed to making, given that in the lower courts, *Buckman* as it currently exists is binding precedent

If not articulated and preserved – particularly in a situation like Kent, where the defendant lost below on a restrictive reading of *Buckman* − these arguments could be waived at the Supreme Court level

Slide 2 − <u>Buckman</u> Basics

Buckman arose in the MDL context in the 1990s, when a mass tort of several thousand plaintiffs was considered extraordinarily large

The petitioner-defendent, Pamela Buckman, was an FDA consultant to a medical device manufacturer

Buckman allegedly created a §510(k) clearance strategy for the manufacturer, which had been unsuccessful in convincing the FDA that the use of orthopedic bone screws in the spine was substantially equivalent to a prior use in long bones

Plaintiffs claimed that, using Buckman's strategy, the manufacturer broke its system into components, obtained a "long bone" intended use for the components that it never intended to market, with the intent of marketing the product off-label for spinal use

This purported "fraud" on the agency resulted in the medical device being allowed on the market, so any injury was "caused" by the fraud, regardless of surgeon knowledge of the risks – to avoid the learned intermediary rule

The "fraud" claim lacked any FDA basis – by the time *Buckman* was briefed in the Supreme Court, the FDA knew about all the allegations in great detail

The FDA never found fraud, and supported Buckman's preemption arguments with amicus briefs, both at the petition and merits stages

During the *Bone Screw* litigation, *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), was decided – removing express preemption as a defense for manufacturers of §510(k) products

So defendants moved on fraud on the FDA under an implied preemption theory and won. Since it was the sole theory against Buckman, she obtained an appealable order

Buckman and supporting defense amici argued that fraud on the FDA claims inherently conflicted, because their success depends on juries ignoring an in-force FDA decision due to "fraud"

Buckman decided on somewhat different grounds

First, relying on 21 U.S.C. §337(a) that "all proceedings" to enforce or prevent violations of the FDCA "shall be by and in the name of the United States," *Buckman* held that private attempts to claim that submissions misled the FDA were preempted

Second, relying on a variety of practical considerations – that I will address in a moment – the court held that fraud-on-the-FDA claims impermissibly interfered with the FDA's regulatory scheme

As I will discuss more, later, all nine justices agreed that the fraud-on-the-FDA claims in *Buckman* were preempted, but Justices Stevens and Thomas concurred in the result, finding causation precluded because the FDA had not found fraud

Slide 3 – Obstacle Implied Preemption

Because of *Buckman*'s emphasis on practical considerations, and it's occasional use of the term "objectives," it has generally been categorized as an example of the "purposes and objectives" form of implied preemption

Buckman itself, however did not use that terminology or rely upon precedent that expressly invoked that theory – nor did the concurrence joined by Justice Thomas take that view

"Obstacle" preemption has roots in Supreme Court jurisprudence that reach back over a century

The first decision to describe implied preemption in these terms was the *Savage v. Jones*, 225 U.S. 501 (1912), Pure Food Act case from 1912, quoted in the slide

A state statute requiring disclosure of the ingredients composing certain federally-regulated food

Court looked to the "entire" statutory scheme

That statute was not in "actual conflict" with the Pure Food Act, the "object" of which was "to prevent adulteration and misbranding"

Savage was the only case cited in *Hines v. Davidowitz*, 312 U.S. 52 (1941), in 1941, where the Court articulated the modern formulation of the "obstacle," or "purposes and objectives" prong of implied preemption

Slide 4 – Buckman − Fraud on the FDA Claims Interfere with the FDCA's Regulatory Scheme

Buckman did indeed take a holistic approach to the relationship between the FDCA and fraud-on-the-FDA claims

The Court first held that the FDA had "ample" power and remedies to protect itself from fraud and to prosecute fraudsters

In particular, the FDA has administrative flexibility to choose from enforcement options, a "measured response," whereas plaintiffs assume the product would have been removed from the market

Flexibility is key given competing statutory objectives, particularly as they concern off-label use of FDA-regulated products

Off-label use is a corollary of the FDA's mission to regulate but not interfere with medical practice – the "balance"

Fraud-on-the-FDA claims thus "inevitably conflict" with FDA policing fraud consistent with its other objectives

Varying state-law claims would dramatically increase the burden on persons required to interact with the FDA

Discourage some applicants altogether

Deter submission of products with foreseeable off-label uses

Fear of state-law insufficiency creates "incentive to submit a deluge of information that the Administration neither wants nor needs"

Imposes burdens on both the FDA and applicants

Slide 5 – Buckman − Private Plaintiffs Cannot Bring Fraud on the FDA Claims

The other half of *Buckman* has to do with the identity of the plaintiff

States have never been in the business of regulating interactions between government agencies and those they regulate

Therefore no presumption against preemption

All defendant's interactions with the FDA were governed by FDCA and FDA regulations

Thus all of defendant's alleged wrongs were really claims that the FDCA was violated

In §337(a), the FDCA expressly limits enforcement to the "United States"

While §337(a) is not an express preemption clause, it necessarily precludes FDCA based claims raised by private plaintiffs

It is "clear evidence" that Congress intended FDCA enforcement "exclusively " by the FDA and Department of Justice

Section 337(a) prohibits state-law claims based "solely" on FDCA violations

State law claims must "rely[] on traditional state tort law" that "predate[s] the federal enactments"

Plaintiffs cannot pursue claims having "federal enactments" as a "critical element"

Slide 6 – Justice Thomas and Buckman

Justice Thomas concurred in the result in *Buckman*, joining a four-paragraph opinion by Justice Stevens

Buckman "did not fit neatly" into the various categories of preemption recognized in the Supreme Court's prior precedent

Thus Justice Thomas did not view *Buckman* at the time as being an "obstacle," or "purposes and objectives" preemption case

That is likely a key point to convince him to preserve the substance of *Buckman* preemption

Rather, preemption in *Buckman* was due to lack of causation

But for causation would require the FDA to have removed the devices from the market which it in fact has not done despite being aware of plaintiffs' alleged facts

Would be different if FDA had removed product from market – but then there wouldn't be very many cases

Claim would no longer depend on "speculation" about possible "contrafactual" FDA actions

Claim would not require "second-guessing the FDA's decisionmaking or overburdening its personnel"

Such claims would have "no adverse consequences upon the operation or integrity of the regulatory process"

Would allow private fraud-on-the-FDA claims where the FDA had concluded it was defrauded and had removed a product from the market

I will now review Justice Thomas' implied preemption decisions in some detail, because to preserve the essence of *Buckman* preemption a defendant in a product liability case will have to win his vote

Slide 7 – Justice Thomas and Obstacle Preemption − Early Decisions

When he joined the Court in 1991, Justice Thomas had no particular view about obstacle preemption, as reflected in the *Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995), decision that he joined in 1995

He joined a decision that found no preemption by virtue of a governmental decision not to regulate in *Myrick* and did not object to boilerplate description of obstacle preemption as an accepted preemption category

Then in the 5-4 *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), airbag case in 2000, Justice Thomas joined an dissent by Justice Stevens that included a complaint about obstacle preemption being a "freewheeling judicial inquiry into whether state law is in tension with federal objectives" and finding no "direct and irreconcilable" contradiction with the statute itself

Buckman followed the next year, as Thomas continued to follow Justice Stevens' lead in obstacle preemption in common-law cases

However, in 2002 in the *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355 (2002), ERISA case, Justice Thomas wrote a pro-preemption dissent that included a finding of obstacle preemption

ERISA had a "broad goal of uniformity"

ERISA's civil enforcement provision "provides the exclusive vehicle for actions asserting a claim for benefits under health plans governed by ERISA"

As of *Rush Prudential* in 2002, Justice Thomas was still a conventional, if occasionally reluctant, follower of established implied preemption precedent

Slide 8 – Justice Thomas and Obstacle Preemption − Continuing Evolution

In *Pharmaceutical Research & Manufacturers v. Walsh*, 538 U.S. 644 (2003), in 2003, we begin to sense a breaking point

- Not joining with anyone, he concurs in the judgment against preemption
- It was futile to discern any particular "purpose" in the sprawling Medicare Act, which reflected legislative "compromises"
- It was "impossible" to define "purposes in complex statutes at the "high level of abstraction" that the plaintiffs contended
- The obstacle preemption analysis created a danger of preemption based on "arbitrary selection of one purpose to the exclusion of others"
- The Medicare agency had discretion and had not acted, therefore deference under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), created "perhaps-insurmountable barrier" to finding obstacle preemption

In the *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), FIFRA preemption case, involving product liability claims, Justice Thomas dissented in part, expressing "increasing reluctance" to utilize the "freewheeling" analysis allowed in obstacle preemption

- Thomas' *Bates* opinion was not entirely anti-preemption; whenever state law "imposes liability for statements on the label" where the federal statute "would not," state law was preempted

Finds obstacle preemption precluded by the "ordinary meaning" of an express preemption clause – which is contrary to *Buckman*'s holding the express and implied preemption operate independently

For that reason *Bates* comported with an "increasing reluctance" to use obstacle preemption to "expand federal statutes beyond their terms"

Then came the *Kemp* 4-4 split (with Justice Roberts recused) that affirmed by operation of law a narrow Second Circuit reading of *Buckman* that allowed state courts to adjudicate fraud-on-the-FDA claims where they were written into state statutes as exceptions to compliance non-defectiveness presumptions

Justice Thomas is widely believed to have been the fourth anti-preemption vote, based on *Buckman* having been presented to the Court as an obstacle preemption case in the petitioners' briefing

That is suspected because Justice Thomas' next implied preemption opinion, a year and a day later, was *Wyeth v. Levine*, 555 U.S. 555 (2009), concurring in the 6-3 no-preemption result. The main points of his *Levine* concurrence were:

Agreement with the majority's analysis of the CBE regulation making unilateral label strengthening possible

Belief that "federal law does not give drug manufacturers an unconditional right to market their federally approved drug at all times with the precise label initially approved by the FDA"

Outright rejection of "obstacle"/"purposes and objectives" preemption

Only "law" as defined in the Supremacy Clause and passed by Congress, is preemptive, not judicial views of the purposes and objectives of legislation

This view of "law" becomes a Justice Thomas constant

Objectives preemption analysis is "vague" and "boundless"

"Congressional and agency musings" do not satisfy the Supremacy Clause

Preemptive purpose must exist "in the text and structure" of a statute, including "authorized" federal regulations, which are interpreted according to "ordinary meaning"

"Impossibility" preemption need not be limited to "narrow physical impossibility" – a "directly conflicting command" given by state law should be enough

Where "federal law gives . . . the right to engage in certain behavior that state law prohibits" is an example of implied preemption despite lack of physical impossibility

This is the framework into which defendants need to fit the *Buckman* holdings

Slide 9 – Justice Thomas on Implied Preemption Since Rejecting Obstacle Preemption I

Justice Thomas has continued to refine his views on implied preemption since rejecting obstacle preemption

In *Haywood v. Drown*, 556 U.S. 729 (2009), a civil rights case decided a year after *Levine* Justice Thomas dissented, partially joined by three other conservative justices, from use of obstacle preemption to strike down state procedural rules

- Mere "burdening" the exercise of a federal right does not require preemption
- No preemption by "extratextual considerations of the purposes underlying," in that case, "congressional inaction"
- Obstacle preemption leads to "illegitimate − and thus, unconstitutional − invalidation of state laws"

Justice Thomas concurred in the 2011 *Williamson v. Mazda Motor, Inc.*, 562 U.S. 323 (2011), no-preemption product liability involving three-point versus two-point seatbelts

- Would not consider implied preemption at all because the statute contained a savings clause – rejecting *Geier*/*Buckman* holding that implied preemption operates independently of express preemption
- Objectives preemption is based on judicial "conceptions of a policy which Congress has not expressed and which is not plainly to be inferred" citing dissent in *Hines*

Rejects "unenacted hopes and dreams" of regulators as a basis for implied preemption

Slide 10 – Justice Thomas on Implied Preemption Since Rejecting Obstacle Preemption II

The 2011 *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), generic preemption decision marked another major turn in Justice Thomas' preemption views, particularly since he wrote the majority opinion, except for one section

- Where Congress has spoken, Justice Thomas can be a friend of implied preemption
- Congress did not provide a unilateral means of changing FDA labels to generic drug manufacturers; instead their labels had to remain the "same" as the referenced branded label
- So impossibility preemption even though the policy objections to the preemptive outcome being no different from *Levine*
- Thomas refuses to "read the Supremacy Clause to permit an approach to pre-emption that renders conflict pre-emption all but meaningless"
  - State law cannot create a duty to propose updated labels to federal regulators such as the FDA
  - Leads to a contrafactual parade of "what ifs" – which Thomas called a "mouse trap game" that depart from what the statute and regulations actually say
- *Mensing* repeatedly deferred to FDA readings of FDCA regulations

In his dissent in the *Arizona v. United States*, 567 U.S. 387 (2012), immigration case, again rejected obstacle preemption as giving force to "judicially divined legislative purposes"

Nothing in the text of federal immigration statutes "indicates that Congress intended enforcement . . . to be exclusively the province of the Federal Government"

States allowed to "enforce the very registration requirements that Congress created"

Slide 11 – Justice Thomas' Alternative Implied Preemption Model I

In addition to tearing down obstacle preemption, Justice Thomas was creating an alternative model of implied preemption

We see that most in *Mensing*, in that part of the decision that did not command a majority

Justice Thomas (with three other justices agreeing) views the Supremacy Clause as a constitutional "non-obstante" provision – "anything to the contrary notwithstanding"

It "describe[s] federal law as effectively repealing contrary state law"

Given the Supremacy Clause acting as a repealer, "courts should not strain to find ways to reconcile federal law with seemingly conflicting state law"

Thus, there should be no presumption against preemption in implied, as well as express, preemption cases

No need to "distort" new law in order to "accommodate" old law

Thus preemption "should not involve speculation about ways in which federal agency and third-party actions could potentially reconcile federal duties with conflicting state duties"

Rejects requiring defendants "continually to prove the counterfactual conduct of the FDA" "to establish the supremacy of federal law"

Justice Thomas did "not think the Supremacy Clause contemplates that sort of contingent supremacy"

Preemption applies "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance" and thus cannot "independently satisfy" state-law duties

Other recent cases:

Hillman v. Maretta, 569 U.S. 483 (2013), concurrence regarding preemption concerning insurance policies of federal employees – supports preemption when the "ordinary meaning" of a federal statute "effectively repeals contrary state law" by virtue of a "direct conflict"

Oneok, Inc. v. Learjet, Inc., 575 U.S. 373 (2015), concurrence in no-preemption Natural Gas Act decision – preemptive effect only to "federal standards and policies" "set forth in or necessarily following from" statutory text; defining preemptive scope in terms of statutory "objectives" is invalid

Slide 12 – Justice Thomas' Alternative Implied Preemption Model II

Here are a couple more recent Justice Thomas implied preemption opinions:

Justice Thomas has now come full circle from his earlier endorsement of extensive ERISA preemption in the 2002 *Rush Prudential* case in concurrence in *Gobeille v. Liberty Mutual Insurance Co.*, 577 U.S. 312 (2016)

Doubts whether the extremely broad ERISA preemption provision is constitutional

Rejects "atextual" reading that narrows ERISA preemption clause in favor of questioning the constitutionality of a provision preempting "entire areas of traditional state concern," including "areas having nothing to do with the regulation of commercial activities"

The standard Thomas criticizes review of the "objectives" of ERISA and "the nature of the effect" of state law on ERISA plans

So Thomas is prepared to re-examine even his own previous preemption decisions

In 2019 Justice Thomas concurred in denial of *certiorari* in *Lipschultz v. Charter Advanced Services (MN), LLC*, 140 S.Ct. 6 (2019)

Provides a roadmap to litigants who wish to avoid, or to assert, preemption under his view of the law

The Supremacy Clause is a *non obstante* provision

It preempts only state law that "logically contradicted the Constitution"

Mere federal "policy" is not "law" for Supremacy Clause purposes

Must be final agency action

Preemption arises only from "federal standards and policies that are set forth in, or necessarily follow from, the statutory text"

Slide 13 – Justice Gorsuch Also Rejects Obstacle Preemption

Justice Thomas is no longer a lone voice crying in the preemption wilderness

In three recent opinions, Justice Gorsuch has signed onto Justice Thomas' views, including his rejection of obstacle preemption

In a 2019 plurality opinion in *Virginia Uranium, Inc. v. Warren*, 139 S.Ct. 1894 (2019), Justice Gorsuch, along with Thomas and Kavanaugh rejected preemption of state uranium mining moratorium

Supremacy Clause cannot be "deployed" "to elevate abstract and unenacted legislative desires above state law," only "law" has preemptive effect

"Evidence of preemptive purpose" must come from "the text and structure of the statute at issue"

"[I]n piling inference upon inference about hidden legislative wishes we risk displacing the legislative compromises actually reflected in the statutory text"

"The only thing a court can be sure of is what can be found in the law itself."

Justice Gorsuch also joined Justice Thomas' concurrence in *Lipschultz*, 140 S.Ct. 6

That is effectively a buy in to Justice Thomas's alternative view of implied preemption

In 2020 Justice Gorsuch joined Justice Thomas' no-preemption concurrence in the *Kansas v. Garcia*, 140 S.Ct. 791 (2020), immigration identity theft case

Specifically to call for "explicit abandonment" of "purposes and objectives preemption"

Both the *non obstante* and no need to "strain" to avoid preemption rationales

Use "accepted methods of interpretation to ascertain whether the ordinary meaning of federal and state law directly conflict" – a "logical contradiction" standard

Slide 14 – Albrecht − Justice Thomas Applies His "Logical Contradiction" Model

The most thorough application of Justice Thomas' model of "logical contradiction" as a basis for implied preemption is his concurrence in the 2019 *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S.Ct. 1668 (2019), preemption decision

Justice Thomas was the only Justice actually to decide whether the state-law claims were preempted – he found they were not

His logical contradiction approach is broader than the "physical impossibility" that limits the impossibility prong of implied preemption, but far narrower than objectives preemption

- Preemptive "logical contradiction" may exist "even if it is possible" to comply with both federal and state requirements
- Defendant "does not advance" a logical contradiction standard, and it would probably fail
- The federal brand name scheme does not necessarily "insulate" the defendant from state-law liability "simply because the FDA has approved a particular label," since CBE supplement can change unilaterally
- "FDA approval does not represent a finding that the drug, as labeled, can never be deemed unsafe" – contrast with other FDA actions that cannot be changed unilaterally
- Labeling changes are not necessarily impossible under the branded drug labeling scheme – "[t]he very point of the CBE process is that a manufacturer can "unilaterally" make a labeling change"

Non-final FDA communications are mere "agency musings" without preemptive effect of "law" under the Supremacy Clause

An FDA complete response letter is not final agency action making it "law," but "merely informs" drug sponsors of what further steps are available

Indications "that the FDA would have denied a future labeling change" asserts "hypothetical agency action" that is not "law"

Slide 15 – The Problem *Buckman* Poses for Defendants

So, how does all this affect the two main preemption holdings in *Buckman*, concerning lack of private FDCA enforcement?

Manufacturers of prescription medical products, as defendants in product liability litigation, cannot expect to win implied preemption arguments without the votes of, first Justice Thomas, and now Justice Gorsuch

Perhaps Justices Kavanaugh and Barrett as well – Kavanaugh signed onto the Thomas approach in *Virginia Uranium*, but not other cases, and Barrett has no preemption track record

While the three "liberal" justices have no problem with employing traditional obstacle preemption, no "liberal" has ever voted for implied preemption in a product liability case since *Buckman* itself

The two generic drug implied preemption cases, *Mensing* and *Bartlett*, were both 5-4

Levine was 6-3, but even had Justice Kennedy joined the three dissenters, without Thomas that is still a loss

Kent, as previously discussed ended up 4-4, presumably because Justice Thomas defected on the defendants' framing of *Buckman* as an objectives preemption decision

So the last line of this slide is the bottom line – the defense side cannot expect to win at the Supreme Court level with only "conservative" justices willing to apply *Buckman* as an objectives preemption cases

There are no more than four such justices, and possibly as few as two (Chief Justice Roberts & Justice Alito)

But the entire thesis of my presentation is that all is not lost – the essence of *Buckman* can be preserved by viewing it alternatively as a “logical contradiction” case

Slide 16 – *Buckman*'s "No Private FDCA Enforcement" Prong as a Logical Contradiction

This part is actually fairly easy, as long as defendants remember to preserve the "logical contradiction" argument

As *Buckman* held, §337(a) of the FDCA, is "clear evidence" that Congress not only did not intend private enforcement, but wrote that prohibition directly into the statute itself

The "clear evidence" holding in *Buckman* translates well to current law, such as *Albrecht*, which uses the same standard in other implied preemption areas

That is undeniably "law" as Justice Thomas defines it – "statutory text that was produced through the constitutionally required bicameral and presentment procedures" – so it has preemptive force

The "logical contradiction" between the prohibition on private enforcement and tort plaintiffs asserting purported FDCA violations is obvious – it just needs to be framed this way

Justice Thomas' *non obstante* view of the Supremacy Clause is actually more favorable to defendants than current law – since it explicitly rejects any presumption against preemption, and is not limited to *Buckman*'s not-a-traditional-activity rationale

Thus, no reason to "strain" to find ways to view state-law violation claims as somehow consistent with §337(a)

To the extent there is currently an "atextual" gloss on statutory FDCA language, it is the concept of "parallel claims" when compared to §337(a)

That is why I mention in the slide that the ultimate preemptive impact of §337(a) under Justice Thomas' logical contradiction rationale could be an improvement on *Lohr*

As mentioned Justice Thomas has looked favorably on the preemptive nature of exclusive enforcement in ERISA cases and has rejected preemption in *Arizona* where there was no statutory equivalent to §337(a)

Slide 17 – *Buckman*'s Preemption of FDA Fraud Claims Prong as a Logical Contradiction I

This prong is somewhat more involved than the no-private-right-of-action argument because it is not directly based on statutory language

The *Buckman* rationale about off-label use and the effect of possible information overload on both the agency and those it regulates would not be relevant to a logical contradiction analysis

Fortunately, in *Buckman* Justice Thomas did not consider *Buckman* actually to be a case that fit into existing implied preemption categories

Both in *Buckman* itself, in *Mensing* ("mouse trap game"; "contrafactual conduct"), and even in *Albrecht* ("hypothetical agency action"), Justice Thomas was open to preemption of claims based on the plaintiff's speculation over the possibility of different agency action than what actually occurred

The "logical contradiction" arises from the nature of an allegation that the FDA (or any other agency) would have taken some different action had it received different informational inputs

Such claims amount to collateral state-law attacks on in-force agency actions

For such a claim to succeed – or to be "causal" as the *Buckman* concurrence phrased it – a factfinder must ignore what the FDA actually did

As *Buckman* held, such claims "inevitably conflict" with what the FDA actually did

A final FDA action, such as the approval of a drug or device – including its warnings – is "law" under Justice Thomas' reading of the Supremacy Clause

Thus a claim that the FDA would have taken some different final agency action, had it received different information than it in fact did, logically contradicts what the FDA actually did

Slide 18 – *Buckman*'s Preemption of FDA Fraud Claims Prong as a Logical Contradiction II

Justice Thomas in *Mensing* coined a phrase that aptly describes state-law collateral attacks on FDA (or other federal) actions based on alleged inadequacies in the administrative process – "contingent supremacy"

If state-law claims can put at issue the basis on which the FDA took final agency action, then the FDA's decisions would improperly enjoy only "contingent supremacy"

Unlike the warnings at issue in *Albrecht* and *Levine*, which are subject to unilateral CBE revision based on newly acquired information, the FDA's decisions to approve, clear, or otherwise allow a product to be marketed are final decisions that cannot be rescinded without following legally mandated procedures

State claims that wipe away this protection by claiming "fraud," failure to report" or some similar problem with the data on which the FDA's action was based are thus in "logical contradiction" to the FDA's power to act on information is finds sufficient

This approach also harmonizes *Albrecht*'s decision to allow judicial review of whether the FDA was "fully informed" about a potential label change

That is a legal determination of a defense to preemption to be decided by the judge as a matter of law

It is not a cause of action or an attempt to have a jury disregard in force, final FDA agency action

Slide 19 – Defendants Need To Articulate *Buckman*-Preserving Preemption Arguments Early On

I read a lot of cases and look at a lot of briefs

I have never seen a defendant, in a case where it is asserting *Buckman* preemption, yet make an argument based on the Thomas/Gorsuch "logical contradiction" theory of implied preemption

The defendant made no logical contradiction argument in *Albrecht* – because Justice Thomas mentioned that omission

But to have a chance at the Supreme Court level to obtain affirmance of *Buckman* preemption, these arguments need to be made at the trial court level, and at the intermediate appellate level

The most likely context for review at the United States Supreme Court level will be in a case where a lower court makes a ruling – as in *Kemp* – that refuses to follow *Buckman* on a core issue in that opinion

That means that Supreme Court review is most likely to occur in a case that our side, the defense side, has lost below

But while an appellate court can affirm on any basis, even one not argued by the prevailing party, it cannot reverse on any basis

If a defendant loses a *Buckman* issue at trial, or in a Court of Appeals, that defendant can only argue the two main *Buckman* issues as preemptive on a logical contradiction basis if it has made that argument unsuccessfully in the lower courts

To argue *Buckman* solely as it was argued in 2001, and as defendants have successfully argued it ever since, as a form of obstacle preemption case, is to invite failure at the Supreme Court level

So my bottom line is that good arguments exist to view as preemptive "logical contradictions" both the core preemption issues for which defendants have successfully cited *Buckman* for the last twenty years

We just need to do so