Philip Morris USA Inc. v. FDA

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WHY IT MADE THE LIST

Philip Morris v. FDA[1] represents the latest in a string of (generally successful) industry challenges to aspects of the U.S. Food and Drug Administration's (FDA's) implementation of the Family Smoking Prevention and Tobacco Control Act of 2009 (TCA). The challenge yielded an order halting the agency's plans to require premarket authorization for changes to the label of a tobacco product. The U.S District Court for the District of Columbia's decision avoided the First Amendment questions implicated by the now-vacated label policy. However, the court's interpretation of the operative statutory language raised new questions about FDA's administration of its authorities for premarket review of "new tobacco products."

DISCUSSION

Background

Under the Federal Food, Drug, and Cosmetic Act (FDCA), as amended by the TCA, a "new tobacco product" must undergo premarket (or, in some cases, retroactive) review by FDA. The law defines a "new tobacco product" as "any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007," as well as "any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007." 21 U.S.C. § 387j(a)(1).

The law created three premarket review pathways, including the so-called "substantial equivalence" (SE) process. To obtain a marketing authorization via the SE pathway, a sponsor must demonstrate that a new tobacco product is "substantially equivalent" to an appropriate "predicate" product (i.e., a grandfathered product that does not qualify as a "new tobacco product" or a product that has previously been

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found to be substantially equivalent to a grandfathered product).[2] Section 910(a)(3)(A) of the FDCA provides that a new tobacco product is substantially equivalent to a predicate if it "has the same characteristics as the predicate tobacco product" or "has different characteristics and the information submitted contains information . . . that demonstrates that . . . the product does not raise different questions of public health." 21 U.S.C. § 387j(a)(3)(A).

FDA's Substantial Equivalence Guidance

In September 2011, FDA issued a "Draft Guidance for Industry and FDA Staff: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions" (Draft Guidance). In the Draft Guidance, FDA stated that "[a] change to any part of a tobacco product after February 15, 2007[,] makes that product a 'new tobacco product'" and "[t]he label and packaging of a tobacco product is considered a 'part' of that product." The Draft Guidance indicated that FDA would exercise discretion not to enforce the premarket review requirements for certain categories of label and packaging changes made to grandfathered products (e.g., label changes necessary to comply with new requirements under the TCA, changing a cigarette product's package from a hard pack to a soft pack or vice versa). Several industry members submitted comments to the Draft Guidance's docket taking issue with the position that a change to a product's label or packaging creates a new tobacco product as contrary to the language of the FDCA.

Three and a half years after issuing the Draft Guidance, FDA issued a new version entitled, "Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions" (First SE Guidance) (March 4, 2015). The First SE Guidance departed from the Draft Guidance in two significant ways.

First, while the Draft Guidance stated that the label was part of the tobacco product, the First SE Guidance concluded that it was not. However, the latter stated that, "if a product's label is modified in any way that renders the product distinct from the predicate, even if its characteristics remain the same, the modified product is a new product . . . because that product was not commercially marketed in the United States as of February 15, 2007." With respect to the "distinctness" analysis, the First SE Guidance stated that "[w]hether a product with a label change results in a distinct product depends on the circumstances." It provided examples of modifications that might result in a distinct new tobacco product, such as "changes to logo, identifiable patterns of color, product descriptors, or any combination thereof" that "would lead consumers to believe that the product is different from the predicate."

Thus, the First SE Guidance advised industry to evaluate whether consumers would perceive a product with a modified label as distinct from its predicate, and provided a chart with examples of changes that "may" or "may not" render a predicate product with a modified label "distinct" and therefore a "new tobacco product." For example, the chart indicated that changing the label's background color from green to red "might" make a product distinct, but changing it from white to cream "might not." Likewise, the chart indicated that changing the object depicted in a logo (e.g., a star to a lion) "may" make the product distinct, but reducing the size of the same object on the new label "may not."

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[2] A "grandfathered" product is one that was commercially marketed in the United States as of February 15, 2007. *See* 21 U.S.C. § 387j(a)(1).

Under the First SE Guidance, a "distinct" label change would transform a predicate product into a new tobacco product requiring premarket review. As ostensible consolation, the First SE Guidance announced a policy permitting submission of a streamlined "Same Characteristics SE Report" to facilitate label changes that would render a product "distinct." The Same Characteristics SE Report would include full identification information for both the new and predicate products, a statement regarding the manufacturer's intent to commercially market both the new and predicate products (or only the new product) after receiving an SE order, a health information summary, an environmental assessment, and a specified certification statement confirming that the only modification involved a change to the label and describing that change. The Same Characteristics SE Report would need to include neither detailed information about the (shared) physical characteristics of the new or predicate products nor copies of either product's label.

Second, the First SE Guidance expressly addressed product quantity changes. The guidance stated that a change in the per-package quantity of a predicate product qualified as a modification that would create a new tobacco product. As it did for label changes with the Same Characteristics SE Report, the First SE Guidance offered ostensible consolation in announcing a streamlined "Product Quantity Change SE Report" option. A sponsor could submit a Product Quantity Change SE Report when the "product quantity has changed, but the per weight composition, design features, heating source, and all other features are otherwise identical to the predicate product."[3] The prescribed contents of a Product Quantity Change SE Report mirrored those of the Same Characteristics SE Report, except that the former also would have to include "[s]cientific data demonstrating that the change in product quantity is not likely to alter consumer use behavior of the new product as compared to the predicate product."

Approximately one month after issuance of the First SE Guidance, Philip Morris USA Inc., R.J. Reynolds Tobacco Co., U.S. Smokeless Tobacco Co. LLC and others filed suit in the United States District Court for the District of Columbia challenging the First SE Guidance, specifically its positions that label changes and per-package product quantity changes trigger premarket review requirements, on statutory and constitutional grounds. Shortly thereafter, in response to FDA's announcement that it would not enforce the First SE Guidance until it either had issued a revised guidance or announced that it would not make revisions, the companies agreed to a voluntarily dismissal without prejudice.

On September 8, 2015, FDA issued a revised "Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 2)" (Second SE Guidance), in which the agency doubled-down on its assertions that product quantity changes and product label changes that render a product "distinct" require premarket authorization. FDA included additional discussions of its rationales for these positions and left in place the policies permitting submission of Same Characteristics and Product Quantity Change SE Reports.

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[3] For example, the First SE Guidance offered that a sponsor could submit a Product Quantity Change SE Report to obtain authorization to increase the number of cigarettes in a predicate product's package from 20 to 24 or to decrease the quantity of smokeless tobacco in a predicate product's package from 24 grams to 5 grams.

The Second SE Guidance provided further explanation of FDA's legal rationale for asserting that certain label changes may render a product "a new tobacco product" subject to the premarket review provisions of the FDCA. It first described Section 910(a)(3)(A) of the FDCA, which provides that a new tobacco product is substantially equivalent to a predicate if it "has the same characteristics as the predicate tobacco product" or "has different characteristics and the information submitted contains information . . . that demonstrates that . . . the product does not raise different questions of public health." It then observed that the FDCA defines "characteristics" in terms of the physical attributes of a product, i.e., "the materials, ingredients, design, composition, heating source, or other features of a tobacco product." Accordingly, the Second SE Guidance explained, the "same characteristics" prong of the substantially equivalent standard (in contrast to the second "different characteristics" prong) relates to a product that is physically identical to the cited predicate product. In FDA's view, that the statute permits a finding of substantial equivalence under the "same characteristics" prong meant Congress must have contemplated that there would be new tobacco products that are physically identical to predicate products. FDA reasoned that a product with a label distinct from the predicate product but with identical physical characteristics would fall into this category.

FDA's position on product quantity changes remained unchanged in the Second SE Guidance, which reiterated the agency's claimed need to fully evaluate such changes due to their potential to affect initiation and cessation of product use. The Second SE Guidance also claimed that "another important purpose of requiring these SE Reports is to help FDA keep abreast of products in the marketplace so that it can properly evaluate whether products are in compliance with the [FDCA]." Consistent with the terms of the "same characteristics" prong of the definition of "substantial equivalence" in Section 910, which requires no scientific showing on the part of the applicant, the Second SE Guidance contemplated no substantive review of the label changes triggering the submission of Same Characteristics SE Reports (or even submission of the labels in question). Therefore, FDA could cite "keep[ing] abreast of products in the marketplace" as the lone practical justification for requiring submission of such reports.

The Court's Ruling

On September 30, 2015, three weeks after FDA issued the Second SE Guidance, the plaintiffs filed a new complaint in the U.S. District Court for the District of Columbia. The complaint alleged that the Second SE Guidance was inconsistent with the FDCA, violated the Administrative Procedure Act (APA), and infringed the First Amendment. The plaintiffs filed a motion for summary judgment, and FDA filed a competing motion to dismiss or, in the alternative, for summary judgment in its favor.

Ripeness

The court was able to reach the merits of the case because it rejected FDA's (common) defense that the issues raised were not "ripe" for judicial resolution. FDA argued that, since the Second SE Guidance merely represented the agency's "current thinking," and since the agency had not yet attempted to enforce the challenged legal interpretations described in the guidance, the court should defer review. While acknowledging that "[n]on-legislative agency statements of the type at issue here generally do not qualify as [reviewable] final agency action," the court rejected FDA's

reasoning, finding the reviewability standard met because: (1) FDA had taken a "definitive legal position" regarding its statutory authority in the guidance (and admitted it had no plans to change it); (2) the challenge presented a purely legal question of statutory interpretation (i.e., the court would not have benefitted from additional factual development in the context of a specific enforcement action); and (3) the guidance imposed an immediate and significant practical burden on industry (e.g., by the terms of the guidance, failure to file a streamlined SE report for covered label and quantity changes by the compliance dates would expose products to enforcement action). That this burden involved commercial speech restrictions apparently also helped the plaintiffs' case for reviewability.

Label Changes

The court agreed with the plaintiffs that, based on the text, context, and structure of the TCA, Congress did not intend for FDA to require premarket review of label changes under Section 910 of the FDCA, which governs review of "new tobacco products." For example, the court found FDA's interpretation of Section 910, which references only physical characteristics of tobacco products, to be inconsistent with other provisions that permit or require premarket review of label statements in certain situations, discussed below.

In evaluating the arguments, the court rejected FDA's position that the fact that the definition of "substantially equivalent" applies to products with the "same characteristics" means that Congress envisioned premarket review of products with identical physical characteristics but different labels. The court instead interpreted the "same characteristics" prong of the definition of "substantially equivalent" as "seemingly . . . intended for physical changes that were more than 'minor,' [and thus not eligible for an SE exemption,] but yet not so significant so as to require a showing, through clinical data if demanded, that 'the product does not raise different questions of public health.'"

The court based this reading, in part, on Congress's intention that FDA implement the SE requirements consistent with FDA's preexisting SE pathway for medical devices.[4] In the medical device context, as in the tobacco product context, the FFDCA creates two tiers of substantial equivalence review, one for products with the "same technological characteristics" and the other for products with "different technological characteristics." The court observed that the term "different technological characteristics" was defined to mean "a *significant change* in the materials, design, energy source, or other features of the device from those of the predicate device." The court found it "reasonable to conclude" that Congress intended for "different characteristics" as used in the TCA "likewise to mean a 'significant' change in characteristics."

The court also noted that "Congress clearly delegated to the FDA the authority to regulate label changes in other Sections of the Act." *See, e.g.*, Section 903(b) of the FDCA, 21 U.S.C. 387c(b) (permitting FDA to "by regulation, require prior approval of statements made on the label of a tobacco product to ensure that such statements do not violate [the FDCA]"); Section 911 of the FDCA, 21 U.S.C. § 387k (requiring premarket FDA review of "modified risk" label claims). In contrast, Section 910 is silent regarding FDA's ability to require review of labeling changes generally. The

[4] *See* Section 510(k) of the FDCA, 21 U.S.C. § 360(k).

court explained, "It is simply too far-fetched to believe . . . that the same Congress that expressly made labeling changes trigger FDA review in some Sections of the TCA, at the same time intended to provide the same or similar authority through an unintuitive, creative reading of Section 910."

Last, the court dismissed the agency's argument that "same characteristics" in Section 910 means "identical characteristics" in light of the existence of the SE exemption provision in Section 905(j)(3), 21 U.S.C. § 387e(j)(3). Under this section, FDA may exempt a product from the need to make a full demonstration of substantial equivalence if the product is "modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive," and FDA determines that:

(i) such modification would be a minor modification of a tobacco product that can be sold under [the TCA];

(ii) [an SE] report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the public health; and

(iii) an exemption is otherwise appropriate.

Here, Congress explicitly excluded from the need to show substantial equivalence certain new products that, although physically different from the predicate, do not raise sufficient health risks to warrant FDA review. The court therefore concluded that "Congress surely did not intend . . . for products with *identical* physical characteristics, and thus with previously known effects, to be subject to a more intensive substantial equivalency showing under the 'same characteristics' prong" than certain products with *different* physical characteristics that qualify for an SE exemption.

Having found that the position unlawfully conflicted with the TCA under step one of the familiar *Chevron* analysis, the court declined to address the plaintiffs' APA and First Amendment arguments.

Quantity Changes

The court rejected the plaintiffs' challenge to FDA's interpretation that changes in product quantity trigger premarket review requirements. The court easily found that a change in the quantity of a product contained in a package qualifies as a modification to the content or design of the product by looking to the plain text of Section 910's definition of "new tobacco product." It stated, "Congress' use of the word 'any' suggests that even the slightest change to the physical components of an existing tobacco product would create a new tobacco product." In so doing, the court rejected the plaintiffs' arguments, including their assertion that the definition's reference to "any modification" applies only to the per-weight or per-portion characteristics of a product. The court also found FDA's position that quantity changes can affect the initiation and cessation behaviors of youth supported by the overall purpose of the TCA.

Procedural Issues

Last, the court rejected the plaintiffs' procedural APA objections to use of the guidance process over notice-and-comment rulemaking for announcing the Same Characteristics and Product Quantity Change SE Report pathways. The court reasoned that, in that FDA's position on product quantity changes was consistent with the text and structure of the statute, the guidance was an "interpretive" rule that did not require such rulemaking.

The court also concluded that it could sever the guidance document's treatment of label changes versus quantity changes. It therefore vacated the guidance's treatment of label changes and affirmed its treatment of quantity changes.

IMPACT

Following the court's decision, in October 2016, FDA reposted the Second SE Guidance with a cover sheet disclaimer acknowledging the court's decision that "a modification to an existing [tobacco] product's label does not result in a 'new tobacco product'" and the fact that the court vacated the Second SE Guidance "insofar as it interprets a labeling change as creating a 'new tobacco product' under the [TCA]." In December 2016, FDA issued a third edition of the SE Guidance, which states that, in light of the court's decision, "manufacturers need not receive premarket authorization for existing products that are the subject of a label change only (e.g., a product that has a new name but is otherwise identical to the predicate)." The third edition continues to include the prior version's discussions regarding quantity changes and the streamlined Product Quantity SE Report option.

While clearly addressing label and product quantity changes, the *Philip Morris* decision's rationale raised—but did not answer—new questions about the "same characteristics" prong of Section 910's definition of "substantially equivalent." How will FDA determine when an SE report involves a product, as described by the court, with the "same characteristics" as the cited predicate product (i.e., differences that do not qualify as minor modifications to tobacco additives but that are not "significant" enough to qualify the products' characteristics as "different" and therefore trigger a showing that the new product does not raise "different questions of public health")? What review standard applies? What data must the sponsor submit?

In implementing the TCA thus far, it appears that FDA has taken the position that any physical difference between the compared products means the products have "different characteristics" requiring a showing that the new product does not raise different questions of public health. This decision appears to gut that approach and create a new category of non-significant physical changes for SE purposes: those that do not render the products' characteristics "different" and instead permit a finding that they remain the "same." Seemingly, in such cases, the statute does not permit substantive review at all (as with the now-moot Same Characteristics SE report for label changes). The impacts of this decision, therefore, could reach well beyond the issue of label changes and significantly alter (and expose to challenge) FDA's implementation of the SE pathway to date.

The opinion also contains language that potentially undermines FDA's longstanding interpretation that "*as of* February 15, 2007," in the statute's definition of "new tobacco product" means "*on* February 15, 2007," thereby meaning that products commercially marketed before—but not on—the date do not have grandfathered status under Section 910. In reciting the legal framework at issue in the case, the court stated, "Thus, Congress placed beyond the FDA's premarket approval authority any tobacco product that was commercially marketed *before* February 15, 2007" (emphasis added). While FDA would likely argue that this language qualifies as "dicta," a challenger to FDA's questionable position could certainly cite it as supportive.

Last, the opinion's analysis and language arguably undermine FDA's recent preamble statements that certain forms of packaging (e.g., cellophane used to wrap cigars, e-liquid vials) qualify as components or parts of tobacco products, the modification of which could trigger premarket review requirements. *See* 81 Fed. Reg. 28,974, 29,015-29,016 (May 10, 2016). The court stated, "Finally, it is important that none of the actual terms that Congress used to define the term 'new tobacco product'—and thus to initiate substantial equivalence review—can be read to encompass anything other the physical attributes of the product itself, as distinct from its label or the *package* in which it is contained" (emphasis added). It further added, "The term 'modification' is described parenthetically to 'include[e] a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient.' . . . Again, all of those terms refer only to the physical attributes of a tobacco product—not its labeling or *packaging*" (emphasis added).

It appears that FDA has in fact treated this language as non-binding "dicta." In a January 2017 decision overturning an internally appealed "Not Substantially Equivalent" order, the Deputy Director of FDA's Center for Tobacco Products wrote, " . . . [P]ackaging is a component or part where it is intended or reasonably expected to alter or affect the tobacco product's performance, composition, constituents, or characteristics. . . . FDA refers to this subset of packaging as the 'container closure system.' As a result, where packaging is a component or part of a tobacco product, evaluation of changes to the packaging is within the scope of the SE review process."[5] This determination provides some clarity on the question of how the agency will approach packaging changes following the *Philip Morris* decision.

However, questions remain, including precisely which types of packaging FDA will consider "components" or "parts" under this standard. Note that FDA's pre-*Philip Morris* preamble language included some examples but promised an opportunity for public comment and guidance or regulations on the subject. One also could reasonably question whether FDA's approach will withstand a legal challenge under *Philip Morris*, especially FDA's preamble assertion that packaging materials that are generally intended to prevent unintended changes to the characteristics of the tobacco product, but that can impact the moisture level or shelf life of the product, meet the definition of "component" or "part," the modification of which triggers premarket review under Section 910.

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[5] Letter to Gerard J. Roerty, Jr., Swedish Match North America, Inc., re FDA Submission Tracking Number AP0000017 (Jan. 13, 2017), https://www.fda.gov/downloads/TobaccoProductsLabeling/MarketingandAdvertising/UCM540974.pdf.