Altria
Altria Client Services

James E. Dillard III
Senior Vice President
Regulatory Affairs

August 14, 2013

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. FDA-2012-N-0920 – Comments on Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products

Altria Client Services Inc. ("ALCS"), on behalf of Philip Morris USA Inc. ("PM USA") and U.S. Smokeless Tobacco Company LLC ("USSTC"),[1] submits these comments in response to the above-referenced docket and the Federal Register notice of May 31, 2013 (the "Notice" or the "Proposed Rule").[2] The Proposed Rule would implement the tobacco product user fee provisions of Section 919 of the Federal Food, Drug and Cosmetic Act ("FDCA" or the "Act"), 21 U.S.C. § 387s.[3]

We appreciate the opportunity to provide the Food and Drug Administration ("FDA" or the "Agency") with our perspective on this important topic. Our comments discuss three significant points. *First*, under the Act, the manufacturers and importers of *all* tobacco product classes subject to user-funded federal regulation must pay user fees to fund that regulation. *Second*, FDA must allocate the statutorily prescribed annual user fees among the six classes of tobacco products listed in Section 919(b) based on current – not repealed – federal excise tax ("FET") rates. *Finally,* FDA should clarify the Proposed Rule's data verification provisions and consider possible legislative options for enhancing the proper enforcement and collection of the user fees.

---

[1] PM USA and USSTC are wholly-owned subsidiaries of Altria Group, Inc. ("Altria"). ALCS provides certain services, including regulatory affairs, to the Altria family of companies. "We" and "our" are used throughout to refer to PM USA and USSTC.

[2] 78 Fed. Reg. 32,581 (May 13, 2013).

[3] Section 919 was added to the FDCA by the Family Smoking Prevention and Tobacco Control Act of 2009 ("FSPTCA"), Pub. L. No. 111-31,123 Stat. 1776 (2009).

Altria Client Services Inc.
2325 Bells Road
Richmond, Virginia 23234
(804) 335-2679
James.E.Dillard@altria.com

I. Manufacturers and Importers of All Tobacco Products Subject to User-Funded Regulation Must Pay to Support that Regulation.

Unlike other FDA Centers, the Center for Tobacco Products ("CTP") is funded entirely through industry-paid user fees. FDA highlights the importance of these fees when it states that:

> *Funding for the Center and tobacco regulation support activities will come from user fees paid by manufacturers and importers of tobacco.*[4]

As a matter of administrative consistency – and fundamental fairness – FDA must ensure that all regulated tobacco product manufacturers and importers contribute to the funding of the CTP. The Notice, however, erroneously exempts from Section 919(a)'s user fee requirement any regulated tobacco products that fall outside the six tobacco product classes listed in Section 919(b).[5] This exemption is contrary to the Act, violates the Administrative Procedure Act ("APA"),[6] and must be eliminated from the Proposed Rule.

A. Section 919(a) Mandates that All Manufacturers and Importers of Regulated Tobacco Products Pay User Fees.

The Family Smoking Prevention and Tobacco Control Act ("FSPTCA") requires the FDA to impose user fees on all manufacturers and importers of regulated products. Section 919(a), enacted as part of the FSPTCA, is clear on this point: "[T]he Secretary shall in accordance with this section assess user fees on, and collect such fees from, *each manufacturer and importer of tobacco products subject to [Chapter IX of the FDCA].*"[7] Section 901(b) states that FDA's regulatory authority under Chapter IX "shall apply" not only to traditional product categories, such as cigarettes and smokeless tobacco, but also to "*any other tobacco products that the Secretary by regulation deems to be subject to this chapter.*"[8] The Act expressly and broadly defines the "tobacco products" subject to such deeming regulation to include "any product made or derived from tobacco that is intended for human consumption."[9] The Act thus imposes Section 919(a)'s user fee requirement on all regulated tobacco products, not just on those regulated

---

[4] *See* U.S. Food and Food Administration, Tobacco User Fees, *available at* http://www.fda.gov/ForIndustry/UserFees/TobaccoProductFees/default.htm (last visited Aug. 9, 2013).

[5] *See* 78 Fed. Reg. at 32,586 ("[U]nder the Proposed Rule, if a tobacco product that is not included in one of the six classes specified in section 919(b)(2)(B)(i) of the FD&C Act is deemed by regulation to be subject to chapter IX of the FD&C Act, [user] fees would not be allocated to such product"). The six tobacco product classes listed in Section 919(b)(2)(B)(i) – cigarettes, cigars, snuff, chewing tobacco, pipe tobacco and roll-your-own tobacco – are the same six classes listed in the Fair and Equitable Tobacco Reform Act of 2004 (Title VI of the American Jobs Creation Act of 2004, Pub. L. No. 108-357, 118 Stat. 1418 (2004)), also known as FETRA, and in the Internal Revenue Code of 1986, 26 U.S.C. § 5702 (imposing FET on the specified classes of tobacco products).

[6] *See* 5 U.S.C. § 701 *et seq.*

[7] FSPTCA § 919(a), 21 U.S.C. § 387s(a) (emphasis added). As the Notice recognizes, "this chapter" refers to Chapter IX of the FDCA. 78 Fed. Reg. at 32,582.

[8] FSPTCA § 901(b), 21 U.S.C. § 387a(b) (emphasis added).

[9] *See* FSPTCA § 201(rr), 21 U.S.C. § 321(rr); *see also Sottera, Inc. v. FDA*, 627 F.3d 891, 898-99 (D.C. Cir. 2010) (holding that e-cigarettes meet the statutory definition of a "tobacco product," and that if FDA wishes to regulate them it must do so under Chapter IX of the FDCA).

products that fall within the six product categories listed in Section 919(b). In other words, the statute does not permit "free riders" – all manufacturers and importers must share in the cost of regulations to which they are subject and for which the FDA incurs regulatory costs on their behalf (such as for premarket review pathways for new and modified tobacco products, and for modified risk tobacco products).

The reason for this prohibition on "free riders" is clear. Because user fees are allocated on a zero-sum basis, if one regulated tobacco product class does not pay the fee, the rest of the regulated community necessarily must pay more (and those user fees are significant – $505 million in the current fiscal year, increasing to $712 million for fiscal 2019 and for all years beyond). In that case, some regulated manufacturers and importers would have to pay the cost of their own regulation *plus* the cost of regulating the non-paying manufacturers and importers. Such an unfair burden would violate the statute and raise substantial policy concerns. Non-paying manufacturers would enjoy a potentially significant competitive advantage in terms of reduced relative costs and prices for their products. If, for example, FDA requires product pathway provisions akin to Section 905 or Section 910 for newly deemed products, the Proposed Rule would force manufacturers and importers of the six listed tobacco products to pay for the review and potential introduction of new products of other manufacturers.

Unless this inappropriate exemption is eliminated, the Proposed Rule will violate the requirements of the Act and the APA, as well as undercut the fundamental policy goal of funding tobacco regulation through the market-based allocation of user fees among *all* FDA-regulated tobacco products.

B. Section 919(b) Does Not Override the "No Free Riders" Requirement of Section 919(a).

The Proposed Rule apparently assumes that Section 919(b) overrides the clear statutory requirement in Section 919(a) that all manufacturers and importers of regulated products must pay, by freezing the user fee categories to the six product classes in Section 919(b)(2). This assumption, however, misinterprets Section 919(b)(2), which establishes how user fees must be allocated *among* the enumerated six classes, *but does not exempt* products outside them.

Section 919(a)'s requirement that FDA collect user fees on regulated products "in accordance with this section" does not alter the Act's express determination that all regulated products are subject to such fees. The "in accordance" language simply provides that the *methods* FDA uses to allocate and collect user fees on all Chapter IX-regulated products must be in accordance with Section 919, including the requirement that allocations are to be made among the six classes listed in Section 919(b) utilizing the FET-based methodology required by the Fair and Equitable Tobacco Reform Act ("FETRA").[10] However, Section 919(b) does not exempt future classes of tobacco products deemed subject to FDA regulation.

FDA can, and must, implement the "no free riders" requirement of Section 919(a) in accordance with the provisions of Section 919(b). It can do so by, for example:

[10] Pub. L. No. 108-357, 118 Stat. 1418 (2004).

- Treating annual user fees as allocable among all tobacco products (whether listed specifically in Section 919(b) or not) that FDA regulates that year, *see* §§ 901(b), 919(a)-(b);[11]

- Giving effect to Section 919(b)(2)(B)(ii), which requires FET-based allocations for the six enumerated product categories pursuant to FETRA, while reading the remainder of section 919(b)(2) as allowing FDA to develop alternate methods for allocating fees to newly-regulated products, whether or not they are subject to FET; and

- Allocating total annual user fees among all regulated product classes in a way that preserves the "same relative percentage" allocations, *cf.* § 919(b)(2)(B)(iv), among the six listed six classes that FETRA would impose.[12]

Such harmonization of the Section 919(a) mandate with the remainder of the statute (using this or other methods) is required by the APA and settled rules of statutory construction, and is necessary to achieve the FSPTCA's overarching goal of creating a user-funded regulatory regime that keeps pace with FDA regulation of new product classes. The Notice does not adequately address these requirements and principles.[13] FDA should delete the proposed user fee exemption for new product classes and, instead, recognize the requirement (clearly stated in FSPTCA Sections 919(a), 901(b) and FDCA Section 101) that manufacturers and importers of *all* deemed tobacco products must join in paying the user fees.

FDA need not decide in this rulemaking exactly "how user fee calculations would be made" for regulated products that fall outside the product classes enumerated in Section 919(b).[14] It would be premature for FDA to address that question at this time, because none of the relevant new products, such as e-cigarettes, have yet been deemed subject to Chapter IX, and it is impossible to predict with accuracy now what their tax and other circumstances may be if and when FDA deems them subject to regulation. Accordingly, FDA should eliminate the proposed fee exemption for regulated products that are not within the Section 919(b) classes and reserve (as it

---

[11] Consistent with the directive under Section 919(a) that the FDA assess user fees on each regulated manufacturer and importer, Section 919(b)(iii)-(iv) contemplates that user fees be assessed on any class of tobacco products not listed in 901(b) which are "deemed by the Secretary in a regulation under [Section 901(b)] to be subject to this subchapter."

[12] FDA could, for example, subtract the user fees its assesses on regulated products not included in the six Section 919(b) classes from the annual total, and then use the FETRA methodology to allocate the remainder of the annual fee among the Section 919(b) categories.

[13] A proposed rule will violate the APA if the promulgating agency fails to address factors "it must consider under its organic statute," *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1216 (D.C. Cir. 2004), or if it does not address those factors in light of their statutory context and purposes of the "overall regulatory scheme." *Sottera*, 627 F.3d at 894 (citing *FDA v. Brown & Williamson*, 529 U.S. 120, 126 (2000)). A rule will also fail APA scrutiny if it fails to reflect the agency's consideration of non-frivolous concerns with, or alternatives to, its proposed approach. *See, e.g., Bus. Roundtable v. SEC*, 647 F.3d 1144, 1149, 1154-55 (D.C. Cir. 2011) (agency violated APA by failing to "respond to substantial problems raised by commenters" and by failing adequately to explain how rule satisfied statutory requirements); *Chamber of Commerce v. SEC*, 412 F.3d 133, 145 (D.C. Cir. 2005) (agency violated APA by failing to consider an alternative that "was neither frivolous nor out of bounds"); *Laclede Gas Co. v. FERC*, 873 F.2d 1494, 1498 (D.C. Cir. 1989) ("[W]here a party raises facially reasonable alternatives . . . the agency must either consider those alternatives or give some reason . . . for declining to do so.").

[14] 78 Fed. Reg. 32,581, 32,586 (May 13, 2013).

does for cigar assessments)[15] its right to address how to allocate user fees to such products at the time it decides to regulate them.

II. FDA Can – and Should – Allocate User Fees Based on *Current* FET Rates to Best Serve the Purposes of the FSPTCA.

Consistent with Section 919, the Proposed Rule provides for the statutorily-prescribed annual user fee to be first allocated among the tobacco product classes (commonly referred to as "Step A") and then allocated among the manufacturers and importers within each class ("Step B"). Step A requires an allocation across multiple classes of products for which there is no common unit of production: cigarettes and cigars are measured in "sticks" (each cigarette and cigar being counted as a single stick), while all other classes – pipe tobacco, roll-your-own, and smokeless tobacco – are measured by weight in pounds. Thus, Step A requires a common metric to measure each class's share of the tobacco market. Section 919 provides that the Step A allocations for the six listed classes of tobacco products are to be "determined" under FETRA, which uses the relative FET burdens of the tobacco product classes, expressed in dollars, to allocate the user fee among those classes, as described below.[16]

The Proposed Rule, however, would calculate these relative FET burdens for Step A using tax rates that were repealed by Congress before the FSPTCA was even enacted – rather than current FET rates. The Proposed Rule would adopt this approach simply because USDA used the repealed rates for FETRA purposes. But USDA was wrong in doing so. In following USDA's erroneous approach, the Proposed Rule fails to address the history and purposes of the FSPTCA and ignores the significant policy problems created by the use of repealed rates. It makes no sense for FDA to base user fee assessments for all future years on already repealed tax rates. By failing to address this issue, the Proposed Rule violates both the statute and the APA.

A. USDA Has Erroneously Used Repealed FET Rates for Purposes of FETRA.

FETRA requires USDA to make ten annual payments to tobacco growers and quota holders to ease their transition to a free-market system upon elimination of the federal price support and quota programs for leaf tobacco that had been in place since the 1930s. These payments are funded by quarterly assessments on the manufacturers and importers of tobacco products. The specific class allocation percentages for fiscal year 2005 were set forth in FETRA, and Congress required USDA to "adjust" that initial percentage to determine the allocations "[f]or subsequent fiscal years."[17] Through reverse engineering, USDA determined that Congress had used the then-current maximum FET rates to calculate the estimated tax burdens in the initial allocation of the user fee among the tobacco product classes, and USDA further determined that the FETRA class allocations for years after fiscal year 2005 should be calculated using the same methodology.

In 2009, Congress passed, and the President signed, the Children's Health Insurance Program Reauthorization Act ("CHIPRA"),[18] which raised and adjusted the FET rates on all tobacco

---

[15] *Id.*
[16] FDCA §§ 919(b)(2)(B)(ii), 919(b)(4).
[17] 7 U.S.C. § 518d(c)(2).
[18] Pub. L. No. 111-3, 123 Stat. 8 (2009).

product classes, but increased the maximum rates on large cigars and on roll-your-own tobacco proportionately more than it raised the rates on cigarettes. This disproportionate increase, which reflected a Congressional determination that cigars and roll-your-own had previously been under-taxed relative to cigarettes, was enacted even though Congress had been repeatedly warned that doing so would produce a corresponding rise of the FETRA user fee assessments on these tobacco product classes.[19] However, despite the intent of Congress, USDA has continued to use the superseded FET rates that were in effect in 2004 when FETRA was enacted – and, to do so, USDA amended its own regulations, which previously mandated the use of current FET rates for the class allocations at Step A.

USDA's refusal to use the current rates is the subject of ongoing litigation brought by PM USA. An appeal is pending before the United States Court of Appeals for the Fourth Circuit of a decision by the United States District Court for the Eastern District of Virginia, which upheld USDA's action. The district court concluded that FETRA was ambiguous on this point, that the use of superseded rates was one (but not the only) permissible reading of the statute, and that USDA was entitled to substantial deference when it determined that the use of superseded rates best effectuated the policy objectives of FETRA.[20]

B. FDA Need Not and Should Not Adopt USDA's Erroneous Use of Repealed Rates.

The Proposed Rule simply adopts the USDA's interpretation that repealed FET rates should be used to allocate the user fee among the six classes listed in Section 919(b), without discussing either the policy implications of that decision or how such an interpretation may be inconsistent with the structure and purposes of the FSPTCA. FDA must now consider these issues and should revise the Proposed Rule to use current, and not repealed, FET rates for these six classes.

First, FDA is not required to adopt USDA's use of repealed tax rates, regardless of the outcome of the pending appeal challenging USDA's determination. Section 919(b)(2) of the FDCA requires that FDA use allocation percentages that are "determined" under FETRA, which means that FDA must use the *methods* specified in FETRA but need *not* follow USDA's *current* interpretation of FETRA.[21] Instead, FDA must make its own determination as to whether the

---

[19] *See infra* notes 21-22 and accompanying text.

[20] *Philip Morris, USA Inc. v. Vilsack*, 896 F. Supp. 2d 512 (E.D. Va. 2012), *appeal docketed,* No. 12-2498 (4th Cir. Mar. 4, 2013). Briefing on the appeal was completed on May 13, 2013. Oral argument is scheduled for September 19, 2013.

[21] One agency is not bound by the interpretations of another agency when both administer the same statute. *See* 1 Admin. L. & Prac. §§ 4:41, 4:42 (3d ed. 2013) (observing that agencies must exercise independent judgment in the rulemaking process). Moreover, an agency can change its own interpretation of a statute as long as it does not violate the statutory language. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983) ("[A]n agency must be given ample latitude to adapt their rules and policies to . . . changing circumstances," but departures require "a reasoned analysis for the change."); *Chevron, U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 843 (1984) (Agency interpretations must be "based on a permissible construction of the statute."); *ConocoPhillips Co. v. EPA*, 612 F.3d 822 (5th Cir. 2010) (stating that an agency has the flexibility to change its statutory interpretations); *see also Nat'l Cable & Telecomm. Ass'n v. Brand X Internet Serv.*, 545 U.S. 967, 982 (2005) (holding that judicial precedent cannot "foreclose an agency from interpreting an ambiguous statute," because to do so would violate the premise of *Chevron*). As described below, USDA's own regulation at the time FSPTCA was enacted mandated the use of current FET rates for purposes of the class allocation. *See* 7 C.F.R. § 1463.5 (2005).

current or repealed tax rates best serve the policies of the FSPTCA, and must explain this determination in the Proposed Rule. FDA has not yet done so.

Second, current FET rates reflect important policy decisions made by Congress regarding the relative cost burdens to be borne by each tobacco product class. Rate changes occurred four times in the decade and a half before FETRA and again in 2009. Further rate change proposals are now before Congress.[22] Each time Congress amends the rates, it makes a new determination of how costs should be distributed among the classes.[23] USDA erred when it concluded that these changing policy choices should be ignored for purposes of the FETRA class allocations. Under the APA, FDA cannot simply adopt USDA's error. Instead, FDA should revise the Proposed Rule to reflect policy choices that have been made since 2004 and that will continue to be made over time.

Third, it would be contrary to the text and structure of the FSPTCA to use repealed FET rates in perpetuity. Unlike the FETRA assessments, which terminate after fiscal year 2014, the Section 919 user fees continue forever, and so, under the Proposed Rule, the repealed rates would also continue to be used forever. This would mean, for example, that user fee allocations in 2059 would be determined by multiplying the quantities of tobacco products produced in that year (2059) by tax rates that were repealed half a century earlier. The allocations would thus be driven by purely hypothetical numbers – current production multiplied by long-repealed rates – that do not correspond to anything in the real world.

Finally, the use of the repealed rates ignores the legislative histories of both CHIPRA and the FSPTCA, which strongly support the use of current FET rates in making user fee class allocations. When Congress enacted the FET rate increases under CHIPRA in 2009, it had been repeatedly told by the cigar industry that the rate increases would automatically impact USDA's calculations under FETRA, but refused to shield the cigar class from this impact.[24] Similarly, when FSPTCA was enacted shortly after the new FET rates under CHIPRA came into effect (but before USDA announced it would use the repealed FET rates), Congress again refused to shield the cigar industry from the impact of the new FET rates on future FSPTCA user fees. Instead, Congress explained that "[t]he method of assessing [FSPTCA] fees shall be the same as that

---

[22] *See* Tobacco Tax and Enforcement Reform Act, S. 826, 113th Cong. (2013) (proposing to increase excise tax rate on tobacco products); Healthy Lifestyles and Prevention America Act, S. 39, 113th Cong. (2013) (proposing to increase excise tax on all tobacco products); H.R. 1578, 113th Cong. (2013) (proposing to increase excise tax rate on cigarettes for the period between 2014 and 2024 to fund participation in temporary high-risk insurance program under the Patient Protection and Affordable Care Act).

[23] *See* 113 CONG. REC. S466 (daily ed. Feb. 4, 2013) (statement of Sen. Durbin) (noting that CHIPRA deliberately "set the tax rate for small cigars and roll-your-own cigarettes at the same level as cigarettes"); U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-12-475, TOBACCO TAXES: LARGE DISPARITIES IN RATES FOR SMOKING PRODUCTS TRIGGER SIGNIFICANT MARKET SHIFTS TO AVOID HIGHER TAXES 8, 41 (2012) (noting that in CHIPRA, "Congress equalized the tax rates on roll-your-own tobacco and small cigars with the cigarette tax rate in part in response to concerns that smokers had been using these two products as substitutes for higher-taxed factory-made cigarettes" and noting that similar concerns prompted the increase in the large cigar cap rate).

[24] *See* Reply Brief for Appellant Philip Morris USA Inc. at 21, *Philip Morris USA Inc. v. Vilsack*, No. 12-2498 (4th Cir. May 13, 2013) (observing that "[i]t is uncontested that the cigar industry broadcast the message that, under USDA's interpretation of FETRA, '[a]ny increase in the [relative] federal excise tax rates' on cigars would correspondingly increase the cigar industry's FETRA assessments," citing the Appendix at p. 118, and noting that USDA conceded that "'a great many . . . members [of Congress]'" received this message).

currently used by [USDA] . . . to fund [FETRA]."[25] The method then used by USDA was based on current FET rates, not repealed rates.[26] Therefore, Congress intended, when it enacted the FSPTCA, that current FET rates would be used in the class allocations.[27]

FDA acknowledges that its Proposed Rule can and should vary from USDA's approach as necessary "to reflect differences between FETRA and the FD&C Act."[28] These differences include, among other things, the fact that FDA fee assessments serve statutory and regulatory goals that are substantively and temporally distinct from the 10-year transition payments in the soon to expire FETRA regime.

The Proposed Rule must adequately address these differences and tailor the allocation scheme to serve the purposes of the FSPTCA. FDA cannot satisfy this obligation simply by adopting the decisions that a different agency (USDA) made based on its erroneous application of a different statute (FETRA). It is a clear violation of the APA for FDA to adopt USDA's use of repealed FET rates without providing adequate legal and policy justifications for the use of such rates in the FDCA context, particularly in the face of known objections and alternatives (notably the use of current rates). Based upon a consideration of the factors outlined above, the Proposed Rule should be revised to allocate user fees among the six classes listed in Section 919(b) using current FET rates and not the rates that were repealed before the FSPTCA was enacted.

III. FDA Should Clarify the Proposed Rule's Data Verification Provisions and Consider Possible Legislative Options for Enhancing the Proper Enforcement and Collection of User Fees.

The Proposed Rule cites claims that some manufacturers and importers of regulated tobacco products are evading the user fee by failing accurately to report their domestic production.[29] FDA seeks to address this problem by providing that "[a]nnually, FDA will make any necessary adjustments to individual domestic manufacturer or importer assessments if needed to account for any corrections (*for example, to include domestic manufacturers or importers that were not included in a relevant assessment calculation*)" (emphasis added). The preamble to the Proposed Rule explains that "FDA intends to use information we have from registrations, along with any

---

[25] H.R. REP. 111-58, pt. 1, at 47 (2009).

[26] *See* 7 C.F.R. § 1463.5(a) (2005) (In Step A, USDA would "divide[] [the assessments] among each class of tobacco based upon [its] determination of each class's share of the excise taxes paid."). For these purposes, "[t]he value of the excise taxes paid for each class of tobacco will be based upon the reports filed by domestic manufacturers and importers of tobacco products." *Id.* In FETRA, Congress required that manufacturers of tobacco products regularly submit a form containing only "the payment of the [FET] taxes imposed under cha[p]ter 52" of the Internal Revenue Code of 1986. *See* 7 U.S.C. § 518d(h)(2)(B) (discussing, *inter alia*, TTB Form 5000.24); *see also id.* at § 518d(g)(1). Information about taxes paid in a given period will, of course, reflect *actual* taxes paid under current rates, not *repealed* former rates.

[27] A well-recognized principle of statutory construction states that "[i]t is always appropriate to assume that our elected representatives . . . know the law," including agency interpretations of statutes. *Traynor v. Turnage*, 485 U.S. 535, 546 (1988) (internal quotation marks omitted); *accord Lorillard v. Pons*, 434 U.S. 575, 580 (1978) ("Congress is presumed to be aware of an administrative . . . interpretation of a statute . . . .").

[28] 78 Fed. Reg. 32,581, 32,584 (May 13, 2013).

[29] RAI Services Company, Citizen Petition to the Food and Drug Administration, FDA-2013-P-2080 (Mar. 6, 2013).

other available information, to help ensure that domestic manufacturers and importers are providing the information that would be required under the proposed rule."[30]

We support the use of such additional data sources for the purpose of identifying manufacturers and importers who are not providing FDA with required market share information (non-reporters) or are understating such information in their reports (under-reporters). But the use of such third-party information for any other purposes, such as the calculation of actual market shares, should be carefully limited.

Such caution is necessary because third-party data sources are often collected in ways that make them unreliable proxies for precise market shares. For example, tobacco sales data and "market shares" are compiled by A.C. Nielsen, but these are based on limited samples of the entire market and do not include information on sales from a number of outlets including specialty tobacco stores, Native America retail outlets, wholesale clubs, smaller grocery (or "mom and pop" stores), or direct sales (e.g., mail order or Internet sales).

FDA should clarify the Proposed Rule to reflect that, for currently regulated products and any other products within the six classes enumerated in Section 919(b), third-party market share data may only be used to identify non-reporters or under-reporters, and cannot be used to calculate actual market shares, which must be calculated using FET data. Similarly, in the case of new tobacco products (outside the six classes) that are regulated by FDA, third-party data should be used to calculate market shares only if FDA determines that there is no better alternative available. This means that if the new products are subject to FET, the user fees allocated to such products presumably should be based on FET data, and third-party data should be used only to identify non-reporters or under-reporters. If the new products are not subject to FET, then FDA must carefully review how the various available third-party data sources are collected and compiled to determine which source or combination of sources best measures market shares.

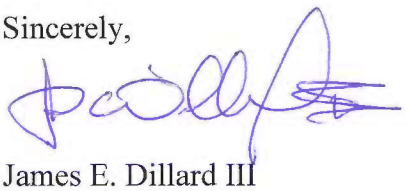
Moreover, once FDA identifies all manufacturers and importers of regulated tobacco products, and imposes the correct user fees on them, it will still need to ensure that the amounts imposed are, in fact, paid. This means that FDA will need to bring enforcement actions against non-compliers and, to do so, will have to establish certain facts, often using FET data. Section 6103 of the Internal Revenue Code ("IRC"), 26 U.S.C. § 6103, prohibits any government official from disclosing tax-return information. CHIPRA amended IRC Section 6103(o) to confirm that excise tax information may be used in enforcement proceedings to collect assessments owed under FETRA, but this provision did not extend to the FDA user fees which had not yet been enacted. FDA may wish to seek a legislative amendment to extend IRC Section 6103(o) to expressly cover actions to enforce the user fee provisions of FDCA Section 919.

[30] 78 Fed. Reg. at 32,586.

* * * * *

We urge FDA to consider the important points raised in this document. As the sole source of funding, user fees are crucial to supporting CTP's efforts. FDA must collect user fees in a way that respects the law, statutory history and fundamental fairness. All companies subject to regulation must pay their fair share. We appreciate the opportunity to submit these comments and look forward to engaging further with the Agency as it considers these issues.

Sincerely,



James E. Dillard III