U.S. FOOD & DRUG ADMINISTRATION
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF ADMINISTRATIVE LAW JUDGES

Center for Tobacco Products, Complainant,

v.

Orton Motor Co., d/b/a Orton's Bagley, Respondent

INITIAL DECISION AND ORDER
DOCKET NUMBER FDA-2015-H-3414

PROCEDURAL SUMMARY AND SUMMARY OF DECISION

The Complainant Center for Tobacco Products (CTP), U.S. Food and Drug Administration, U.S. Department of Health and Human Services, filed a complaint on October 1, 2015, seeking a civil monetary penalty in the amount of $500 from Respondent Orton Motor Company, doing business as Orton's Bagley, for violating the federal Food, Drug, and Cosmetic Act (FDCA). Court Exhibit (CE) I.* The CTP alleged three violations within a twenty-four month period. The Respondent answered the complaint (CE III) and raised an issue that required briefing. The Order is CE V. The Parties responded to the briefing order with CE XI and CE XII.

As the case progressed toward a hearing, the Parties requested a prehearing conference to discuss the briefing order and to determine the future course of the case. CE XIV. Based on developments at that prehearing conference, the Parties were requested to submit cross-motions for summary decision based on facts to which they were willing to stipulate. The cross-motions, CE XIX, and this decision have mooted the Respondent's request for discovery and the Complainant's request for a protective order (all in CE XV).

Orton requested oral argument (CE XVII, opposed in CE XVIII) before I ruled on the motions for summary decision. While oral argument is frequently a useful tool to refine or clarify the legal issues before the court, in this case I have sufficient argument from the Parties' Memoranda of Law. Accordingly, Orton's request for oral argument is denied.

Having considered the CTP's allegation, the Respondent's answer, the stipulated facts (contained within an Appendix to CE XV at pages 31 and 32 of the document scanned into the electronic case file), and the Parties' motions for summary decision (supported, in part, by their earlier briefing on the central issue), I conclude that Orton's Bagley misbranded a tobacco product on May 16, 2015, and will be sanctioned by a civil monetary penalty of $0 and a judicial Warning Letter.

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* All the exhibits are listed and described in an Appendix to this decision. All exhibits are housed in the Federal Docket Management System, an electronic database, under Docket Number FDA-2015-H-3414.

SCOPE OF THE DECISION

The purpose of this decision is simply to find facts, apply the law to the facts, and resolve the issue of Orton's liability, mindful that when interpreting a statute (or a regulation) and giving it effect, it is not enough to read it in isolation. Rather, the statute or regulation must be read in the context of the overall statutory scheme. *See, e.g., Davis v. Mich. Dep't of Treasury*, 489 U.S. 803, 809 (1989).

An agency to which Congress has delegated policy-making responsibilities may, within the limits of that delegation, properly rely upon the incumbent administration's views of wise policy to inform its judgments, and it is not the place for an administrative law judge to substitute his policy judgments for that of the agency. *See Chevron U.S.A., Inc., v. Natural Resources Defense Council*, 467 U.S. 837, 864-65 (1984). There was a clear delegation of the responsibility to write regulations, and the Secretary's regulations represent a reasonable and considered exercise of that delegated authority. *See id.* at 844-45.

While an ALJ will not substitute his policy judgment for that of the agency, it is also not the purpose of this decision to endorse or invalidate guidance that the CTP has provided to merchants and other members of the tobacco industry; such guidance can be useful, but it is not binding on an ALJ. *E.g., Estate of Landers v. Leavitt*, 545 F.3d 98, 107 (2d Cir. 2008). It is less useful, however, when it treats similar acts of "misbranding" differently depending on when they occur. *See id.* (citing *United States v. Mead Corp.*, 533 U.S. 218, 228 [2001], for the proposition that an agency's consistency in the application of guidance is an important factor in gauging the weight to be accorded the guidance). *See Guidance for Industry and FDA Staff, Civil Money Penalties for Tobacco Retailers, Responses to Frequently Asked Questions (Revised)*, at http://www.fda.gov/downloads/tobaccoproducts/labeling/rulesregulationsguidance/ucm339438.pdf, where CTP acknowledges, in Question 43, that it will treat multiple "violations" as a single "violation" on the first inspection, whereas the same "violations" are counted "individually" on subsequent inspections.

In deciding this case, I have considered the overall purpose of the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009)(TCA), which is in its own terms to maintain the right of adults to purchase tobacco products while at the same time ensuring that they are not sold or accessible to underage purchasers. TCA § 3(7), 123 Stat. 1782. *See generally United States v. Wiltberger*, 18 U.S. (5 Wheat.) 76, 95 (1820)(interpretation must give effect to the intent of the legislature). I recognize the Secretary's authority to draft regulations to effect the TCA's purposes, and I have striven to apply the regulations as drafted to the facts stipulated by the Parties.

LIABILITY UNDER THE "LAW"

In an "initial decision," the presiding officer must determine "whether respondent's actions identified in the complaint violated the law." In CE I, CTP alleges a "violation," actually a number of them within a particular amount of time, but the term "violation" is not adequately defined in statute or regulation. It is thus necessary to define what constitutes a "violation". To

define the "violation," moreover, is to define the "unit of prosecution," and accordingly the existence of liability and the amount of a penalty under the "law." *See Nat'l Ass'n of Home Builders v. Occupational Safety & Health Admin.*, 602 F.3d 464, 467 (D.C. Cir. 2010).

Determining the unit of prosecution is an issue of statutory interpretation. "[T]he real question is simply what the statute means." *Mo., Kan. & Tex. Ry. Co. v. United States,* 231 U.S. 112, 119 (1913). If a statute is ambiguous as to the proper unit of prosecution, the rule of lenity applies and requires interpreting the statute in favor of the respondent. *See generally Ladner v. United States,* 358 U.S. 169 (1958); *see also Bell v. United States,* 349 U.S. 81, 84 (1955). "Unit of prosecution" problems are further not limited to criminal law; they may arise as well in interpreting civil enforcement provisions. *See Nat'l Ass'n of Home Builders*, 602 F.3d at 467.

The "law" in this case is actually a combination of statutes and regulations. The 2009 amendments to the FDCA contained within the TCA charged the Secretary with, among other things, creating regulations to govern tobacco sales. The TCA created a new subchapter of the FDCA dealing exclusively with tobacco products, 21 U.S.C. §§ 387-387u, and it also modified other parts of the FDCA explicitly to include tobacco products among the regulated products whose misbranding can give rise to civil, and in some cases criminal, liability. The Secretary's regulations on tobacco products appear in Part 1140 of title 21, Code of Federal Regulations. The statutory scheme and the Secretary's regulations have created a "unit of prosecution" consisting of a misbranded tobacco product.

"When seeking a statute's unit of prosecution — when asking what the minimum amount of activity a defendant must undertake, what he must do, to commit each new and independent violation of a criminal statute — the feature that naturally draws our immediate attention is the statute's verb." *United States v. Rentz*, 777 F.3d 1105, 1109 (10th Cir. 2015)(*en banc*). While *Rentz* involved a criminal prosecution for firearms violations, its analytic approach applies as well to civil monetary penalty cases brought under the TCA.

When pursuing a civil monetary penalty for violation of regulations, the CTP invokes a specific part of the TCA, 21 U.S.C. § 387f(d), to place a tobacco product in a "misbranded" status. A "misbranded tobacco product" is different from something that "violates a requirement of this chapter which relates to tobacco products" (21 U.S.C. § 333[f][9]). The TCA included specific requirements for registering manufacturers (21 U.S.C. § 387e), for submitting health information (21 U.S.C. § 387d), for limiting flavorings and additives (21 U.S.C. § 387g), and the like; these are the "requirements" of the chapter. As is clear from its complaint, the CTP is seeking to impose a civil monetary penalty for misbranding, not for violation of a specific statutory requirement (improperly adding flavorings, 21 U.S.C. § 387g, for example). There is no "requirement" that a product *not* be misbranded; there are simply consequences for the entity guilty of the misbranding if the product is misbranded.

As is discussed in the "Penalty" portion of this decision, the Secretary's schedule of punishments, produced in 21 C.F.R. § 17.2, buttresses the argument that the "unit of punishment" here is a misbranded tobacco product, not a "violation of a requirement" of the FDCA. The schedule of punishments notes the specific statutory authority for each stated penalty. The schedule cites section 333(f)(9) for penalties that go as high as $10,000,000. The

schedule then cites "section 333 note" for much smaller penalties, using language that tracks the TCA. *Compare* 21 C.F.R. § 17.2 *with* TCA § 103(q)(2), 123 Stat. 1839-40.

The provision that CTP uses as its vehicle for enforcement is subsection 331(k) of title 21, United States Code, which prohibits "alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to" a product that "results in such article being adulterated or misbranded." It is this statutory provision, not violation of the individual requirements of 21 C.F.R. Part 1140, that actually triggers the civil monetary penalty. The question is whether subsection 331(k) permits multiple penalties when a sale of a tobacco product violates more than one regulatory requirement.

Under CTP's interpretation, selling cigarettes or smokeless tobacco to a person under 18 years of age, in violation of 21 C.F.R. 1140.14(a), is an "act" that results in the product's being misbranded, violating 21 U.S.C. 331(k) and triggering a civil monetary penalty, and selling such products without checking the purchaser's photographic identification, in violation of 21 C.F.R. 1140.14(b), is a different "act" that exposes the retailer to further liability, even if based on the sale of the same product. Although multiple parts of the Part 1140 regulations might be violated, only one *statutory* provision has been violated, 21 U.S.C. § 331(k), and the question is whether this statutory provision counts, or supports counting, each violation of the regulations associated with a single sale as a separate act.

The *Rentz* opinion's discussion about sentencing is also pertinent here. *See* 777 F.3d at 1111-12. Both the number and the frequency of violations bear on the amount of the civil monetary penalty that may be assessed; were separate cases of misbranding found for each manner in which the product is misbranded, the penalties would accelerate rapidly. As in *Rentz*, the escalating penalties indicate a legislative policy judgment that each successive penalty reflects a greater degree of blameworthiness, a "failure to learn one's lessons," so to speak, and the legislative logic is undercut if a single sale of a single product on a single occasion can lead immediately to a "more blameworthy" penalty.

A complaint that seeks to assess liability for each type of misbranding overstates the merchant's civil misconduct and unreasonably increases the merchant's punitive exposure. *Cf. United States v. Quiroz*, 55 M.J. 334, 338-39 (C.A.A.F. 2001)(endorsing a five-factor test for unreasonable multiplication of charges in a criminal setting). Because the sanctions for misbranding can be both civil and criminal, 21 U.S.C. § 333, reference to criminal law is particularly apt. *Crandon v. United States*, 494 U.S. 152, 158 (1990). *See also Blockburger v. United States*, 284 U.S. 299, 304 (1932), for the proposition that separate convictions and punishments are proper only for violation of "two distinct statutory provisions."

The TCA legislation "deems" misbranded any tobacco product that is sold or distributed in violation of regulations prescribed by the Secretary. 21 U.S.C. § 387c(a)(7)(B). The Secretary, meanwhile, has defined "misbranding" broadly, declaring in regulations that "the failure to comply with *any* applicable provision in this part in the sale, distribution, and use of cigarettes and smokeless tobacco renders the product misbranded under the act." 21 C.F.R. § 1140.1(b) (emphasis supplied). "This part," Part 1140 of title 21, sets out various provisions that govern manufacturers, distributors, and retailers, and whether a respondent fails in one criterion,

all criteria, or something in between does not really matter, as the result is the same: a misbranded tobacco product. It might be misbranded because it was delivered to a purchaser of any age through a vending machine in an area to which persons under the age of 18 had access; it might be misbranded because it was delivered to a person under the age of 18; it might be misbranded because it was sold to a person who did not display proper photographic identification. *See also* 21 C.F.R. § 1140.14, which sets out a conjunctive, not disjunctive, list of requirements that retailers must observe regarding cigarette and smokeless tobacco sales.

The CTP must prove at least one "failure" from Part 1140 to establish liability under the TCA for a misbranded tobacco product, but the elements of proof are different from the unit of prosecution, because Congress has legislated that it is the fact of misbranding, not the type of misbranding, that is the basis for imposing a civil monetary penalty. "A statute often makes punishable the doing of one thing or another . . . sometimes thus specifying a considerable number of things. Then, by proper and ordinary construction, a person who in one transaction does all, violates the statute but once, and incurs only one penalty." *Griffin v. United States,* 502 U.S. 46, 51 (1991)(citations omitted); s*ee also Schad v. Arizona.,* 501 U.S. 624, 636 (1991) (plurality opinion)(noting that "legislatures frequently enumerate alternative means of committing a crime without intending to define separate elements or separate crimes"). *See also Schad*, 501 U.S. at 649-50 (Scalia, J., concurring in part and concurring in the judgment)(citing long-standing rule that when a crime can be committed in a number of ways, jurors need not unanimously agree on the means). *Cf. Rentz*, 777 F.3d at 1117 (Matheson, J., concurring)(elements of proof different from unit of prosecution).

Even if one were to take a more expansive view of the language in the TCA authorizing the civil monetary penalties, *see* TCA § 103(q)(2), 123 Stat. 1839-40 (allowing for penalties for "violations of restrictions promulgated [under the delegated rulemaking authority]"), the Secretary's phrasing of the regulations mandates the outcome here. As noted above, the Secretary has declared that failure to abide by "any" restriction renders a product misbranded under the FDCA, 21 C.F.R. § 1140.1(b), and the Secretary has composed the "additional responsibilities for retailers," 21 C.F.R. § 1140.14, with the word "and," not the word "or," before the final element of the responsibilities, implying therefore an expectation that failing to observe any single one of the responsibilities causes the tobacco product to be misbranded. The Secretary's use of the term "misbranded," furthermore, is significant, as it recognizes that a misbranded tobacco product is one that gives rise to a civil monetary penalty liability. *See* 61 Fed. Reg. 44423, Aug. 28, 1996 (history of the predecessor to current section 1140.1[b], noting that the sentence "is intended to remind parties that violations of a regulation for a restricted device and other actions relating to the sale of a device may cause a device to be 'misbranded' under the act.")

Once again, viewing the TCA amendments to the FDCA and the Secretary's regulations as part of the whole legislative scheme, it is the "misbranded tobacco product," not the type of misbranding, that leads to the liability for a civil monetary penalty. The legislation and regulations combine to prohibit, and penalize, misbranding a tobacco product. "That" a tobacco product is misbranded is the test; "why" it is misbranded is not, at least as far as the "unit of prosecution" is concerned.

It also bears repeating that the Secretary's choice of language – that violation of *any* applicable provision in Part 1140 results in the product's being misbranded under the Act – helps determine what is the unit of prosecution: a misbranded tobacco product. To say that the "violation" of a regulation describing a misbranded product is the unit of punishment is to mischaracterize the retailer's culpability under the TCA and unreasonably increase the retailer's punitive exposure.

This discussion applies with equal force to the allegation in the complaint about an incident in July, 2013, where Orton was alleged to have misbranded a different tobacco product. Because Orton has admitted specific facts regarding that incident, it is unnecessary to discuss whether the allegation in the complaint would have placed Orton on sufficient notice to defend itself; likewise, it is unimportant for this decision whether Orton was afforded any sort of due process under the Administrative Procedure Act before the Agency issued a Warning Letter.

PENALTY FOR THE VIOLATION

Penalties for violations are found in section 17.2 of title 21, Code of Federal Regulations. The statutory basis for the penalties is section 333(f)(5) of title 21; *see also* 21 U.S.C. § 333(f)(9). The former provision specifically requires that the Secretary afford the respondent a hearing under the Administrative Procedure Act before a penalty may be imposed.

In terms of specific punishments available, the legislation that provides the basis for assessing civil monetary penalties divides retailers into two categories: those that have "an approved training program" and those that do not. Retailers with an approved program face no more than a warning letter for their first violation; retailers without such a program begin paying monetary penalties with their first. TCA § 103(q)(2), 123 Stat. 1839, *codified at* 21 U.S.C. § 333 note. *See* 21 C.F.R. § 17.2. The FDA has informed the regulated public that "at this time, and until FDA issues regulations setting the standards for an approved training program, all applicable CMPs will proceed under the reduced penalty schedule." FDA REGULATORY ENFORCEMENT MANUAL, Aug 2015, ¶ 5-8-1. Because of this reasonable exercise of discretion, the starting point for punishments and the rate at which they mount are clear – the lower and slower schedules.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

Based on the stipulated facts, I find that Orton misbranded a package of Camel Crush Regular Fresh cigarettes on May 16, 2015, by (a) selling the cigarettes to a person under the age of 18 and (b) failing to demand photographic identification from the purchaser. Based as well on the stipulated facts, I find that Orton misbranded a package of Marlboro cigarettes on July 10, 2013, by (a) selling the cigarettes to a person under the age of 18 and (b) failing to demand photographic identification from the purchaser. A period of 22 months elapsed between the two cases of misbranding. It is therefore unnecessary to the legal efficacy of the "Warning Letter" referred to in paragraph 10 of the Complaint, as the quantity and frequency of the established incidents of misbranding authorize but one penalty. *See* 21 C.F.R. § 17.2.

Because this is the first instance in which the Respondent has received the process required by statute, and because the FDA has a policy of treating all respondents as if they had an "approved training program" in place (thus warranting lighter punishments), the only permissible sanction is a monetary penalty of $0.00 and a Warning Letter for the allegations which are the subject of this summary decision. The Warning Letter is appended to this decision.

PROCEDURAL INSTRUCTIONS

This initial decision becomes final and binding on the Parties 30 days after it is issued. 21 C.F.R. § 17.11(b). Either party may appeal this decision to the Departmental Appeals Board (DAB) within 30 days after this initial decision is issued. 21 C.F.R. § 17.47. The Parties are directed to the cited regulations, available at www.gpo.gov, for specific requirements. Further information on filing an appeal is available at the DAB's website, www.hhs.gov/dab, or by telephone at (202) 565-0208.

Lewis T. Booker Jr -A

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LEWIS T. BOOKER, JR.
U.S. Administrative Law Judge

Attachments

(1) Exhibit List
(2) Service List
(3) Warning Letter

FDA-2015-H-3414 EXHIBIT LIST

COURT EXHIBIT (CE) I	Complaint of 01 October 2015
CE II	Proof of Service
CE III	Orton's Answer
CE IV	Order to Schedule
CE V	Briefing Order
CE VI	FDA's Entry of Appearance
CE VII	FDA's Response to Extension Request
CE VIII	Order Granting Extension for Briefing
CE IX	Case Management Order
CE X	Certificate of Service for CE IX
CE XI	FDA's Memorandum of Law
CE XII	Orton's Memorandum of Law
CE XIII	Supplementary Material for CE XII
CE XIV	Joint Request for Status Conference
CE XV	FDA's Motion for Protective Order
CE XVI	Post-Status Conference Order
CE XVII	Orton's Motion for Oral Argument
CE XVIII	FDA's Response Opposing Oral Argument
CE XIX	Cross Motion for Summary Decision

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SERVICE LIST

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

WARNING LETTER

To: Orton Motor Company, d/b/a Orton's Bagley, FDA-2015-H-3414

You have violated a provision of the Tobacco Control Act and this Warning Letter is the penalty authorized in law for the violation.

This Warning Letter is issued under the authority of sections 331 and 333 of title 21, United States Code, and section 17.2 of title 21, Code of Federal Regulations. It is issued as an Appendix to the Initial Decision in this case; the Findings of Fact and Conclusions of Law in the Initial Decision are incorporated into this letter by reference.

I reviewed the complaint submitted by the Center for Tobacco Products, your response, the stipulated facts in this case, and the arguments of the Parties. You misbranded a package of Camel Crush Regular Fresh cigarettes on May 16, 2015, by (a) selling the cigarettes to a person under the age of 18 and (b) failing to demand photographic identification from the purchaser.

The Act provides for graduated penalties for violations. Because this is your first adjudicated violation, you are receiving this Warning Letter. The law allows this letter and the facts relative to the violation noted above to be used in future cases involving your establishment to determine an appropriate penalty to impose in case of further violations.

Lewis T. Booker Jr -A

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LEWIS T. BOOKER, JR.
U.S. Administrative Law Judge