ORAL ARGUMENT SCHEDULED FOR SEPTEMBER 23, 2010

No. 10-5032

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

SMOKING EVERYWHERE, INC., ,
Plaintiff-Appellee,
and

SOTTERA, INC., d/b/a NJOY,
Intervenor-Plaintiff-Appellee,

v.

FOOD AND DRUG ADMINISTRATION, et al.,
Defendants-Appellants.

On Appeal From The United States District Court
For The District Of Columbia

REPLY BRIEF FOR APPELLANTS

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GLOSSARY

CSA	Controlled Substances Act
DEA	Drug Enforcement Administration
FDA	Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
PACT Act	Prevent All Cigarette Trafficking Act, Pub. L. No. 111-154, 124 Stat. 1087 (2010)
Tobacco Control Act	Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 776 (2009)

INTRODUCTION AND SUMMARY

After our opening brief was filed, plaintiff Smoking Everywhere voluntarily dismissed its complaint and withdrew from this appeal. The government filed an unopposed motion to vacate the preliminary injunction to the extent that it applies to Smoking Everywhere and its products. Intervenor NJOY continues to defend the remainder of the injunction, which bars FDA from refusing entry to NJOY's "electronic cigarettes" under the drug and device provisions of the Federal Food, Drug, and Cosmetic Act unless FDA shows that NJOY's products are intended to have a "therapeutic effect." JA 544. Because NJOY chose to seek emergency relief without exhausting its administrative remedies, JA 522 n.7, there is no administrative record with respect to NJOY's products, and the district court did not resolve any factual issues concerning NJOY's products or the manner in which they are marketed. *Ibid*. Accordingly, the only merits issues before this Court are pure issues of law**.**

NJOY advances two distinct legal arguments. The first — and remarkably broad — contention is that *no* product is a drug or device unless it is intended to have a "therapeutic" effect. This argument, which formed no part of the district court's reasoning, is inconsistent with the plain language of the FDCA, settled agency practice, and this Court's precedent. Drugs are defined to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," 21 U.S.C. § 321(g)(1)(B), as well as "articles (other than food) intended to affect the

structure or any function of the body," *id*. § 321(g)(1)(C). Under the second prong of this definition, a substance may be a drug "even though it has only a physiologic, rather than a therapeutic, effect." *E.R. Squibb & Sons, Inc. v. Bowen*, 870 F.2d 678, 682 (D.C. Cir. 1989). FDA thus has long regulated a variety of substances that are not "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," including substances that mimic illegal street drugs.

In the alternative, NJOY asks this Court to affirm the reasoning of the district court, which held that "electronic cigarettes" are carved out from the usual scope of the FDCA under the reasoning of *FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120 (2000). As our opening brief explained, the *Brown & Williamson* decision rested on other federal statutes specifically governing cigarettes and smokeless tobacco products. NJOY recognizes as much, and identifies no basis for extending the Court's reasoning to battery-powered nicotine-delivery devices.

Our opening brief explained that the district court's balancing of the harms gave extraordinarily little weight to public health concerns protected by the FDCA. NJOY discounts the dangers that its products pose, insisting that "many of the same things can be said about excessive exposure to coffee, sugar, or spicy foods." NJOY Br. 54. But NJOY's website acknowledges that "[n]icotine is addictive" and "very

toxic by inhalation."[1] The potential for harm posed by the unrestricted distribution of untested products containing unknown quantities of toxic and addictive chemicals is evident. NJOY's products are not in compliance with the manufacturing and labeling controls applicable to FDA-approved nicotine products. Nor are NJOY's products subject to the federal requirements that govern cigarettes. "Electronic cigarettes" are not required to bear health warnings; they are not subject to the restrictions on sale to children; and they are not subject to the ban on flavored cigarettes.

In sum, NJOY offers no basis on which the district court's injunction may be sustained.

ARGUMENT

A. Drugs and devices are not confined to articles intended for therapeutic use.

1. The FDCA defines the term "drug" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," 21 U.S.C. § 321(g)(1)(B), as well as "articles (other than food) intended to affect the structure or any function of the body," *id*. § 321(g)(1)(C). The definition of "device" mirrors that language. *See id*. § 321(h). Products that combine features of a drug and device are subject to both the drug and device authorities. JA 521 n.11; 21 U.S.C. § 353(g)(1).

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[1] http://shop.njoy.com/index.php?p=page&page_id=FAQs (visited July 19, 2010) (copy attached)

NJOY's principal contention is that the structure/function prong of the drug and device definitions includes "only articles intended to offer therapeutic benefits." NJOY Br. 27; *see also id*. at 26, Subtitle A(1). This argument disregards the plain language of the FDCA and removes the structure/function prong of the statutory definition.[2]

Both prongs of the statutory definition are based on the "intended use" of a product, which "is determined from its label, accompanying labeling, promotional claims, advertising, and any other relevant source." *Action on Smoking and Health v. Harris*, 655 F.2d 236, 239 (D.C. Cir. 1980); 21 C.F.R. §§ 201.128, 801.4. The first prong — "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" — may encompass even products such as honey and mineral water, if marketed to prevent or treat disease. *See United States v. 250 Jars ... "Cal's Tupelo Blossom U.S. Fancy Pure Honey*," 344 F.2d 288 (6th Cir. 1965) (honey); *Bradley v. United States*, 264 F. 79 (5th Cir. 1920) (mineral water).

The second prong — "articles (other than food) intended to affect the structure or any function of the body" — contains no requirement that the article be intended

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[2] NJOY's incorrectly states (Br. 3) that FDA "acknowledged" that its products are not marketed for a therapeutic purpose. In the cited footnote, FDA described the scope of the NJOY injunction, which reserved the question whether NJOY's products are marketed with therapeutic claims. *See* JA 535 n.17.

for therapeutic use. As this Court has explained, "Congress added the 'structure or ... function' definition to the FDCA in 1938 in order to bring within the regulatory framework certain drugs having only physiologic effects." *E.R. Squibb & Sons, Inc. v. Bowen*, 870 F.2d 678, 682 (D.C. Cir. 1989). Under the structure/function provision, a substance may be a drug "even though it has only a physiologic, rather than a therapeutic, effect." *Ibid*.

Accordingly, the structure/function provision has been applied since 1938 to a wide assortment of products intended for uses that are not therapeutic. For example, FDA has approved weight reduction products and birth control pills "as to which only physiologic claims are made and which have not been proven medically beneficial." *Ibid*. FDA regulates sunlamps and other tanning devices even though these devices have no therapeutic purpose and in fact cause harms such as skin burns, eye injury, premature aging, and skin cancer.[3] FDA regulates breast implants used for cosmetic breast augmentation despite the risks posed by rupture.[4] FDA regulates "Botox Cosmetic" injected for temporary reduction of facial wrinkles despite the "possibility

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[3] http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/ucm116447.htm#Description (sunlamps and other tanning devices).

[4] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm063719.htm (breast implants)

of experiencing potentially life-threatening distant spread of toxin effect from the injection site after local injection."[5] It regulates products intended to grow hair,[6] and products intended to remove unwanted hair.[7]

FDA also regulates products intended to mimic the effects of illicit street drugs, and it has never been suggested that such regulation is based on claims of their "therapeutic" properties. *See United States v. Storage Spaces*, 777 F.2d 1363, 1366-67 (9th Cir. 1985) (sustaining FDA's determination that products "promoted and intended . . . to be used as cocaine substitutes" were "drugs" because they were "intended to affect the structure or any function of the body of man."). The Ninth Circuit rejected as "frivolous" the contention that the alternative prongs of the "drug" definition should be interpreted to establish a conjunctive test. *Id*. at 1366 n.4. The court thus sustained the regulation of recreational drugs, declining to accept the

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[5] http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm175011.htm (risks of using Botox Cosmetic); http://www.fda.gov/downloads/Drugs/DrugSafety/ucm176360.pdf (Botox medication guide); *see also United States v. Article Consisting of 46 Devices "Dynatone*," 315 F. Supp. 588 (D. Minn. 1970) (facial muscle exerciser to improve appearance); *United States v. Article Consisting of 36 Boxes ... Labeled "Lineaway*," 284 F. Supp. 107 (D. Del. 1968) (temporary wrinkle smoother), *aff'd*, 415 F.2d 369 (3d Cir. 1969)

[6] 21 C.F.R. § 310.527 (hair growth)

[7] http://www.fda.gov/Radiation-EmittingProducts/ResourcesForYouRadiationEmitting Products/Consumers/ucm142607.htm#1 (laser hair removal)

argument made here by NJOY, which insists that the structure/function prong must be read to "incorporate a therapeutic or medical limitation." NJOY Br. 27.

Similarly, in *United States v. Travia*, 180 F. Supp. 2d 115 (D.D.C. 2001), FDA brought criminal charges against individuals who had distributed nitrous oxide, commonly known as laughing gas, at a rock concert at RFK Stadium. *Id*. at 116. The court held that the laughing gas-filled balloons were drugs within the meaning of the FDCA, rejecting the defendants' argument that the products could not be drugs because "there was no labeling on the balloons[.]" *Id*. at 118-119. The court concluded from "the surrounding circumstances of the sales alleged in this case that the government has made a sufficient showing that the defendants' intent to sell the nitrous oxide was to affect 'the structure or any function of the body of man,' 21 U.S.C. § 321(g)(1)(C), and thus, the nitrous oxide involved in this case is a 'drug' for the purposes of the FDCA." *Id*. at 119.

The position advanced by NJOY is flatly at odds with these cases and with FDA's published guidance regarding substances intended to mimic illegal street drugs. In 2000, in response to "the proliferation of various products that are being manufactured, marketed, or distributed as alternatives to illicit street drugs," FDA issued *Guidance for Industry on Street Drug Alternatives*. *See* 65 Fed. Reg. 17512 (Apr. 3, 2000). FDA explained that it "considers any product that is promoted as a

street drug alternative to be an unapproved new drug and a misbranded drug in violation of" the FDCA. *Ibid*. It explained that these products are generally labeled as containing botanicals; that they are marketed under a variety of brand names with claims implying that the products mimic the effects of controlled substances; and that they are "intended to be used for recreational purposes to effect psychological states." *Ibid*. FDA noted that "these products are being abused by individuals, including minors, and pose a potential threat to the public health." *Ibid*.; *see also United States v. Undetermined Quantities of Articles of Drug*, 145 F. Supp. 2d 692, 697 (D. Md. 2001) (finding the *Guidance* to be "highly persuasive in light of the text and purposes of the FDCA," and sustaining FDA's seizure of herbal products intended to produce effects comparable to the illegal street drugs Ecstacy, marijuana, psychotropic mushrooms, and other street drugs).

Since the *Guidance* was issued, FDA has taken numerous enforcement actions arising out of the marketing of street drug alternatives, and it has advised Congress of such actions in testimony before congressional committees. For example, on March 31, 2003, FDA sent warning letters to eight firms selling products on the Internet with brand names such as "Legal Speed capsules,"[8] "TRIP2NIGHT

[8] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2003/ucm147399.htm (3/31/2003 warning letter to Stardust Industries)

capsules,"[9] "Herbal Ecstacy Organic (ephedra free!) pills,"[10] and "Druids Fantasy capsules."[11] In July 2003, FDA Commissioner Mark McClellan advised Congress that FDA took these enforcement actions after FDA investigations revealed that "the firms sold products for 'recreational' purposes with claims to produce such effects as euphoria, a 'high' or hallucinations." *Ephedrine Alkaloid-Containing Dietary Supplements: Hearing Before the Subcommittees on Commerce, Trade, and Consumer Protection and Oversight and Investigations, House Committee on Energy and Commerce*, 108th Cong. 236 (July 24, 2003) (Statement of FDA Commissioner Mark B. McClellan).[12]

In the same congressional testimony, Commissioner McClellan described FDA actions taken against firms that marketed "Yellow Jackets," promoted on the Internet

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[9] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2003/ucm147398.htm (3/31/2003 warning letter to Shaun Roberts)

[10] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2003/ucm147396.htm (3/31/2003 warning letter to Brian Petruzzi)

[11] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2003/ucm147397.htm (3/31/2003 warning letter to Jason Pacey); *see also* http://www.accessdata.fda.gov/scripts/warningletters/wlSearchResult.cfm?subject=Street%20Drug%20Alternative (links to similar warning letters issued on 3/31/2003); http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048406.htm (1/31/2008 warning letter to firm marketing product under the name "Blow," which is "well known street drug terminology for illicit cocaine")

[12] 2003 WL 21718656 (July 24, 2003) (McClellan testimony)

as a street drug alternative. *Ibid*. After a 16-year-old who had taken "Yellow Jackets" died, FDA determined that one source was a distributor in the Netherlands and placed that company's products on an import alert. *Ibid*. FDA also took enforcement action against a domestic manufacturer, witnessing the firm's voluntary destruction of street-drug-alternative products with a retail value of between $4 and $5 million. *Ibid*. In subsequent congressional testimony, FDA again described these and other FDA enforcement actions against the marketers of street drug alternatives. *The Status of Dietary Supplements in the United States: Hearing Before the Subcommittee on Human Rights and Wellness, House Committee on Government Reform*, 108th Cong. 57-59 (March 24, 2004) (Statement of Robert E. Brackett).[13]

In 2004, FDA issued a consumer alert warning that products that were claimed to provide "safe legal highs" or marketed as "street drug alternatives" by an identified company should not be purchased or used. *FDA Expands Warning About "Green Hornet" To Include All Other Products By Cytotec Solutions, Inc*. (April 9, 2004).[14] In that consumer alert, Acting Commissioner Lester Crawford explained that "FDA has taken numerous actions against various products that are being manufactured,

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[13] 2004 WL 730324 (March 24, 2004) (Brackett testimony)

[14] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108277.htm (4/9/2004 consumer alert)

marketed, or distributed as street drug alternatives." *Ibid*. Acting Commissioner Crawford stressed that "these products pose a potential public health concern, and FDA is concerned that these products may be misused or abused by individuals, especially minors and young adults." *Ibid*.

2. NJOY recognizes (Br. 36) that the position it advances here conflicts with the Ninth Circuit's decision in *Storage Spaces* and with FDA's exercise of jurisdiction over street drug alternatives "intended to be used for recreational" purposes. 65 Fed. Reg. 17512. NJOY nevertheless declares that FDA "ordinarily disavows jurisdiction over drugs used solely for recreational purposes." Br. 36.

For that proposition, NJOY cites testimony regarding the regulation of marijuana, a Schedule 1 substance under the Controlled Substances Act ("CSA"). FDA did not disavow jurisdiction; it advised Congress that FDA "generally defers to DEA on criminal enforcement efforts related to Schedule 1 controlled substances." *Marijuana and Medicine: The Need for a Science-Based Approach: Hearing Before the Subcomm. on Criminal Justice, Drug Policy, and Human Resources, House Comm. on Government Reform*, 108th Cong. 36 (April 1, 2004) (statement of Robert J. Meyer, M.D.).[15] FDA explained that "[t]he criminal penalties related to Schedule I controlled substances are far greater under the CSA than those available under the

[15] 2004 WL 790344 (April 1, 2004) (Meyer testimony)

FD&C Act for the distribution of an unapproved drug." *Ibid*. That testimony has no bearing on substances that are *not* regulated under the Controlled Substances Act, such as nitrous oxide, street drug alternatives, and — as particularly relevant here — nicotine. DEA has no jurisdiction over such products, and enforcement is thus the responsibility of FDA alone.

NJOY also relies (Br. 34-35) on an October 17, 2002 letter from then Chief Counsel Daniel E. Troy to the manufacturer of "VeriChip," a subcutaneous microminiature transponder used to store information. The specific determination at issue in that letter — that VeriChip is not a "device" if used to store financial and other non-medical information — is unremarkable and irrelevant here. A broader statement in the letter — that "FDA only regulates products if they are marketed with claims of medical or therapeutic utility" (quoted at NJOY Br. 35) — is inconsistent with settled precedent and agency practice, including the enforcement policy described in FDA's 2000 *Guidance for Industry on Street Drug Alternatives* and by Commissioner McClellan in his 2003 congressional testimony. The Troy letter did not constitute either an advisory opinion or formal guidance, which are the two methods, short of rulemaking, for FDA to announce policy of general applicability. *See* 21 C.F.R. § 10.85(a)-(c) (advisory opinions); 21 U.S.C. § 317(h) (guidance); 21 C.F.R. § 10.115(f)-(g) (guidance). The Troy letter therefore was not a formal

position binding on the agency and has no precedential value in evaluating agency jurisdiction over other products. *See* 21 C.F.R. § 10.85(k) (communication from an FDA employee that does not meet the requirements of an advisory opinion does not "represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed"); *see also* 21 C.F.R. § 10.115(e) ("The agency may not use documents or other means of communication that are excluded from the definition of guidance document to informally communicate new or different regulatory expectations to a broad public audience for the first time.").

3. As this Court observed, FDA does not assert jurisdiction over articles that merely have "some remote physical effect upon the body." *Squibb*, 870 F.2d at 682. The physical effects of nicotine cannot plausibly be characterized as remote. The mechanism by which nicotine binds to nerve cell receptors and the resulting physiological effects are discussed in detail in the administrative record. *See*, *e.g.*, JA 438-462; JA 479-481. In brief, nicotine causes the release of neurotransmitters in the brain, and it is the release of these neurotransmitters that is responsible for nicotine's rewarding effects and its effects on mood, cognition, and behavior. JA 438. Nicotine produces physical dependence, which is caused by the cellular adaptation that results from chronic use and requires continued use for normal functioning. JA 479. Besides avoiding withdrawal and craving, reasons for smoking

include experiencing the pharmacologically rewarding effects of nicotine such as stimulation and alleviation of stress. JA 480.

Smoking "satisfaction" or "pleasure" cannot be divorced from the pharmacological effects of nicotine. To the contrary, "[s]mokers' enjoyment of the sensory aspects of smoking is ... an example of associative learning, as stimuli that are initially unpleasant (e.g., irritation of the throat) become repeatedly paired with nicotine delivery." JA 480. Nicotine is thus "critical to the satisfaction that smokers derive from smoking." *Ibid*.

For good reason, NJOY does not contest these findings or rely on this Court's parenthetical statement that "although nicotine may stimulate the senses, it does not affect either the structure or any function of the body." *Squibb*, 870 F.2d at 683. The *Squibb* parenthetical was written in 1989 and cited this Court's 1980 decision in *Action on Smoking and Health*. It rested on an understanding of nicotine that has since been repudiated by every major public health authority. *See*, *e.g.*, National Cancer Institute, Monograph 13, at 40 (2001) ("Nicotinic receptor activation works, at least in part, by facilitating the release of neurotransmitters, including acetylcholine, norepinephrine, dopamine, beta endorphin, glutamate, gamma aminobutyric acid (GABA), and others."); Institute of Medicine, "Ending the Tobacco Problem: A Blueprint for the Nation," at 5 (2007) (nicotine is "one of the

most addictive substances used by humans"); Report of the President's Cancer Panel, at vii (2007) ("Nicotine in tobacco causes addiction as powerful and self-reinforcing as addiction to drugs such as cocaine and heroin."). The earlier misconceptions regarding nicotine resulted in part from the concealment of research data and false public statements by the major cigarette companies. *See United States v. Philip Morris USA, Inc., et al*., 566 F.3d 1095, 1127-28 (D.C. Cir. 2009), *cert*. *denied*, __ S. Ct. __ (June 28, 2010) (contrasting the industry's undisclosed research "documenting the impact of nicotine on the body" with its "numerous statements trivializing and outright denying the dependence cigarettes cause"); *see also* 155 Cong. Rec. S6408 (June 10, 2009) (Sen. Kennedy) ("No one can forget the parade of tobacco executives who testified under oath before Congress that smoking cigarettes is not addictive. Overwhelming evidence in industry documents obtained through the discovery process proves that the companies not only knew of this addictiveness for decades, but actually relied on it as the basis for their marketing strategy.").

These significant physiological effects easily distinguish nicotine products from articles that merely "come[] into contact with the senses." *Squibb*, 870 F.2d at 683. NJOY's observation (Br. 5) that the structure/ function definition does not encompass "everything under the sun" is irrelevant because the definition readily encompasses products intended to produce the pharmacological effects of nicotine.

B. The special rule announced in *Brown & Williamson* for cigarettes does not apply to "electronic cigarettes."

1. NJOY argues in the alternative that this Court should accept the reasoning of the district court, which held that "electronic cigarettes" must be carved out from the normal operation of the FDCA for the same reason that cigarettes and smokeless tobacco products were excluded in *Brown & Williamson*. *See* NJOY Br. 37-45.

As our opening brief explained, the contention that *Brown & Williamson* is controlling here rests on a fundamental misreading of that decision. The Supreme Court invalidated a rule that would have, for the first time, asserted FDA jurisdiction over cigarettes and smokeless tobacco as customarily marketed. As NJOY acknowledges (Br. 45), the decision rested on "specific tobacco-related statutes" governing the marketing of cigarettes and smokeless tobacco.

An "electronic cigarette" is not a "cigarette" within the meaning of federal law. *See* 15 U.S.C. § 1332(1); 21 U.S.C. § 387(3). It is a high-tech device that includes a battery and electronics, an atomizer, and a disposable plastic container filled with liquid nicotine, water, propylene glycol, and glycerol. JA 39 ¶¶ 15-16. Indeed, the chief selling point of an "electronic cigarette" is that the vaporized nicotine it delivers is *not* "actual tobacco smoke." JA 39 ¶ 14.

Thus, as NJOY does not dispute, "electronic cigarettes" are not subject to the panoply of federal regulations invoked by the Supreme Court. They are not subject to the provisions that "require that health warnings appear on all packaging and in all print and outdoor advertisements," *Brown & Williamson,* 529 U.S. at 143; they are not covered by the prohibitions on "advertisement of tobacco products through 'any medium of electronic communication' subject to regulation by the Federal Communications Commission," *id*. at 144; they were not addressed in the triennial reports of the Secretary of Health and Human Services on the "addictive property of tobacco," *ibid*.; and they are not subject to the federal law that makes state receipt of certain block grants contingent on a prohibition on sales to minors, *ibid*. Indeed, until recently, no state regulated the sale of "electronic cigarettes," which NJOY offers in child-friendly flavors such as vanilla, apple, and strawberry. JA 53.[16]

It was crucial to the holding of *Brown & Williamson* that specific federal laws governed the marketing of cigarettes and smokeless tobacco. The Supreme Court explained that "the collective premise of these statutes is that cigarettes and smokeless tobacco will continue to be sold in the United States," *Brown & Williamson*, 529 U.S. at 139, a premise incompatible with the regulation of these

[16] In January 2010, New Jersey prohibited the sale of "electronic cigarettes" to minors. *See* http://www.nj.com/ news/index.ssf/2010/01/nj_put_limits_on_sale_of_eletr.html.

products under the FDCA, *id*. at 137. The Court concluded that, given the inherent qualities of cigarettes and smokeless tobacco, FDA regulation of these tobacco products as drugs under the FDCA would require the agency to ban them, an option that Congress had foreclosed through other statutes. *Id*. at 136.

By contrast, regulation of *other* types of nicotine products under the FDCA does not require that they be banned. In fact, FDA already has approved several nicotine replacement therapies in the form of chewing gums, transdermal patches, nasal sprays, inhalers, and lozenges. NJOY is free to submit an application to market its product as a nicotine replacement product. Moreover, as in other contexts, FDA may exercise enforcement discretion with respect to nicotine replacement products that are marketed while a new drug application is under review. Previously, FDA has found certain products to be "new drugs" that require the submission of drug applications, but announced that it did not intend to bring enforcement action while the new drug applications were prepared, provided certain time frames and other specified conditions were met. *See, e.g.*, 66 Fed. Reg. 36794 (July 13, 2001) ("This guidance discusses how FDA plans to exercise its enforcement discretion ... with regard to levothyroxine sodium products that are marketed without approved applications."); 72 Fed. Reg. 60860 (Oct. 26, 2007) (FDA "intends to continue to exercise enforcement discretion to ensure the continued availability of exocrine

pancreatic insufficiency drug products" during "the additional time needed by manufacturers to obtain marketing approval").

NJOY currently disclaims (Br. 49 n.9) any interest in helping existing cigarette smokers to reduce their dependence on cigarettes; its goal is apparently that of "encouraging nicotine use." JA 532. But there is not — and has never been — a congressional policy of protecting the importation of battery-operated cartridges filled with liquid nicotine for the purpose of addicting new users.

2. Contrary to NJOY's contention (Br. 37), FDA has not disavowed jurisdiction over all nicotine products. The statements that NJOY quotes (Br. 37-40) concerned the regulation of cigarettes or smokeless tobacco.

By contrast, as NJOY admits (Br. 42), FDA asserted jurisdiction in 1987 over a product that was materially indistinguishable from the products at issue here. The "Favor Smokeless Cigarette" was a small tube containing "a plug impregnated with a nicotine solution" that allowed the user to inhale nicotine vapor, and it was marketed to provide "cigarette satisfaction without smoke." JA 416, 425-426. Although the manufacturer made no express therapeutic claims, FDA advised the company that the product was "a nicotine delivery system intended to satisfy a nicotine dependence and to affect the structure and one or more functions of the body" and therefore an unapproved new drug. JA 426. As NJOY also recognizes (Br. 41), FDA has

repeatedly asserted jurisdiction over products such as Nicotine Lollipops, Nicotine Lip Balm, Nicotine Water, and Nicogel Tobacco Hand Gel. JA 427-437, JA 473-495.

NJOY insists that FDA's assertion of jurisdiction over Favor Smokeless Cigarettes was unlawful, Br. 42, and that products such Nicotine Lollipops and Nicotine Lip Balm are immune from regulation under the FDCA unless their manufacturers make express therapeutic claims, Br. 41. But as FDA explained in rejecting an identical argument made by Nicogel's manufacturer (JA 474, 487-492), *Brown & Williamson* provides no support for this implausible contention. The Supreme Court "held that FDA exceeded its statutory authority when the agency attempted to regulate *cigarettes and smokeless tobacco products* under the FD&C Act, but expressly based its holding on Congress' enactment of an alternative regulatory scheme specifically *for those particular products*." JA 487 (emphases in original). The decision has no application to these novel nicotine-delivery products, which were not the subject of any alternative regulatory scheme. JA 490-491.

C. The Tobacco Control Act does not constrict FDA's preexisting authority under the FDCA.

The Tobacco Control Act was passed while this case was pending in district court. In supplemental district court briefing, FDA explained that the Act provided no ground for FDA to revisit the enforcement actions challenged in this lawsuit.

FDA explained that the new legislation excludes drugs and devices from the definition of "tobacco product" and expressly provides that they shall continue to be regulated under FDA's drug and device authority. *See* Docket Entry 41; *see also* FDA Opening Br. 19-20.

NJOY conceded these points below, *see* JA 519 n.4, and its appellate brief admits that "the definition of 'tobacco product' expressly excludes any 'article that is a drug ..., a device ..., or a combination product' within the meaning of the FDCA." NJOY Br. 7 (quoting 21 U.S.C. § 321(rr)(2)). NJOY does not dispute that a "modified risk tobacco product" is a subset of "tobacco product" and thus subject to the same limitation. *See* 21 U.S.C. § 387k(b)(1). Accordingly, it is undisputed that the Tobacco Control Act "did not move the definitional line between tobacco products and drugs." JA 519 n.4.

NJOY nevertheless engages in an extended discussion of the Tobacco Control Act that has no bearing on the issue before this Court. The new legislation does not compel FDA to treat a battery-powered electronic device filled with liquid nicotine as if it were a cigarette. "Electronic cigarettes" do not meet the definition of "cigarette" in the Tobacco Control Act, 21 U.S.C. § 387(3), and are thus not subject to the Act's cigarette-specific provisions. *See*, *e.g.*, 15 U.S.C. § 1333 (requiring that cigarette packages bear specified new warnings occupying 50% of the front and rear panels of

the pack); 21 U.S.C. § 387g(1)(A) (banning flavored cigarettes). Nor are "electronic cigarettes" subject to the Prevent All Cigarette Trafficking ("PACT") Act, Pub. L. No. 111-154, 124 Stat. 1087 (2010), which (among other things) prevents sales to minors by banning the delivery of cigarettes through the U.S. mail.

At a minimum, FDA's position is entitled to deference. This case concerns the intersection of two statutes that FDA is charged with administering. It is settled that FDA's interpretation of the FDCA is entitled to *Chevron* deference. *Novartis Pharmaceuticals Corp. v. Leavitt*, 435 F.3d 344, 349 (D.C. Cir. 2006) ("We have held on a number of occasions that FDA interpretations of the FDCA receive deference"). This deference extends to FDA determinations embodied in informal adjudications such as agency decision letters. *Mylan Laboratories, Inc. v. Thompson*, 389 F.3d 1272, 1279-80 (D.C. Cir. 2004); *see also Apotex, Inc. v. FDA*, 226 Fed. Appx. 4, 2007 WL 754768 (D.C. Cir. Feb. 23, 2007) (unpub.) ("the district judge's opinion, which grants *Chevron* deference to the FDA's statutory interpretation of 21 U.S.C. § 355(j)(5)(B)(iv) embodied in FDA approval letters (i.e., informal adjudications), is supported by the Supreme Court's post-*Mead* decision in *Barnhart v. Walton*, 535 U.S. 212, 222 (2002), as well as our own decision in *Mylan Laboratories*").

It is equally clear that FDA's implementation of the Tobacco Control Act is owed deference. The Act explicitly vests FDA with responsibility to determine which

products it "by regulation deems to be subject to" the new provisions. 21 U.S.C. § 387a(b).

It is certainly reasonable for FDA to conclude — on the basis of its public health and scientific expertise — that NJOY's products should be subject to the same regulatory framework that governs other nicotine replacement products, such as the nicotine patch and nicotine gum. If different categories of nicotine replacement products were subject to different regulatory regimes, there would be significant adverse consequences for the public health. As discussed in the *amicus* brief filed by major public health groups, products that were not required to obtain FDA approval would compete with FDA-approved products whose safety and efficacy was demonstrated through scientific studies. Moreover, exempting products like NJOY's "electronic cigarettes" from the drug and device scheme would undermine the incentive for companies to develop improved nicotine replacement products — products that would provide a major benefit to the public health. *See* Brief of *Amici* American Academy of Pediatrics, *et al*.

NJOY contends (Br. 22) that deference to FDA's judgment must be withheld because the Tobacco Control Act was passed while this case was pending and FDA thus has addressed the new law in legal briefing only. An agency view does not cease to command deference because it is offered in a brief. *Auer v. Robbins*, 519 U.S. 452,

462 (1997). Denying deference would be manifestly inappropriate here because NJOY failed to exhaust the administrative procedures in which the FDA might have set out its views, insisting in district court that exhaustion would be "futile." JA 522 n.7. Accepting that argument, the district court cited FDA's "unwavering position in this litigation (even after passage of the Tobacco Act)." *Ibid*. Having thus bypassed its administrative remedies, NJOY cannot now contend that FDA's position "does not reflect the agency's fair and considered judgment on the matter in question." *Auer*, 519 U.S. at 462.

D. The harm caused by the importation of NJOY's products would be immediate, irreparable, and contrary to the public interest.

As discussed in our opening brief, the immediate importation of NJOY's products would pose a serious public health risk. NJOY trivializes the dangers that its nicotine-delivery devices pose, declaring that "many of the same things can be said about excessive exposure to coffee, sugar, or spicy foods." Br. 54. On its website, however, NJOY admits to the serious dangers its liquid-nicotine-filled cartridges present.[17] The website acknowledges that "[n]icotine is addictive and habit forming" and "very toxic by inhalation, in contact with the skin and if swallowed." It states that "ingestion of the non-vaporized concentrated ingredients in the cartridges can be

[17] http://shop.njoy.com/index.php?p=page&page_id=FAQs (visited July 19, 2010); JA 53 (NJOY labeling refers users to its website for additional product information)

poisonous." It warns of the "danger of serious damage to health by prolonged exposure if swallowed," and states that "after contact with skin" users should "wash immediately with plenty of water and seek medical advice." It advises users to "consult a physician" if they "experience nicotine misuse symptoms such as nausea, vomiting, dizziness, diarrhea, weakness and rapid heart-beat or hypertension."

As NJOY also does not dispute, its devices are not in compliance with the manufacturing controls or other labeling requirements applicable to FDA-approved nicotine products. Its website states that its products are "manufactured to NJOY (USA) supplier standards, distributed globally, and made in China." As discussed in the Woodcock declaration, FDA's laboratory analysis found that three different NJOY cartridges with the same label (menthol high) each provided a markedly different amount of nicotine with each puff. JA 548 ¶ 10. The nicotine levels per puff ranged from 26.8 to 43.2 mcg nicotine/100 mL. *Ibid*. (describing findings of B.J. Westberger, "Evaluation of e-cigarettes," pp. 3, 5 (May 4, 2009)[18]).

Moreover, as noted, NJOY's products are not covered by the federal laws that govern cigarettes, including the provisions that require health warnings, 15 U.S.C. § 1333; ban flavored cigarettes, 21 U.S.C. § 387g(1)(A); ban free cigarette samples,

[18] http://www.fda.gov/downloads/drugs/scienceresearch/ucm173250.pdf

id. § 387a-1(a)(2)(G); ban sales to minors, *id*. § 387a-1(a)(2); 21 C.F.R. § 1140.14; and prohibit the delivery of cigarettes through the U.S. mail, 18 U.S.C. § 1716E.

Without discussing these provisions, NJOY asserts that the "suggestion" that its products "are likely to be attractive to minors has no support in the record." NJOY Br. 56. But by NJOY's own account, its electronic nicotine-delivery devices "mimic with remarkable accuracy the process and pleasures of smoking." JA 38 ¶ 13; *see also* JA 39 ¶ 15. It is well documented that the vast majority of new cigarette smokers are underage. *See*, *e.g.*, 21 U.S.C. § 387 Note, Legislative Findings 4 & 31; Institute of Medicine, "Ending the Tobacco Problem: A Blueprint for the Nation," at 31 (2007) ("[a]pproximately 90 percent of adult smokers began smoking as teenagers"); *United States v. Philip Morris USA, Inc., et al*., 449 F. Supp. 2d 1, 562 (D.D.C. 2006) ("over 80% of smokers start smoking before they turn eighteen").

NJOY's attempt to find support for the injunction in the Tobacco Control Act reflects a complete disregard for Congress's objective. Congress enacted the new legislation because it found that use of tobacco products is a pediatric disease that results in new generations of addicted children and adults. 21 U.S.C. § 387 Note, Finding 1. Nothing in the new law remotely supports an injunction intended to allow the importation of battery-powered nicotine-delivery devices aimed at "*encouraging* nicotine use." JA 532.

CONCLUSION

For the foregoing reasons and for the reasons stated in our opening brief, the preliminary injunction should be vacated.

Respectfully submitted.

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JULY 2010

CERTIFICATE OF COMPLIANCE WITH
FEDERAL RULE OF APPELLATE PROCEDURE 32(a)(7)(B)

I hereby certify that this brief complies with the type-face and volume limitations set forth in Federal Rule of Appellate Procedure 32(a)(7)(B) as follows: the type face is fourteen-point Times Roman font, and number of words is 5824.

/s/ Alisa B. Klein

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Alisa B. Klein

CERTIFICATE OF SERVICE

I hereby certify that on this 22nd day of July, 2010, I caused the foregoing reply brief to be filed with the Court in hard copy and through the ECF system, which will send notification of such filing to the following registered users:

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Alisa B. Klein

ADDENDUM

NJOY

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New! "Camo" Style NPRO

SHOP NOW!

Our most popular line

SHOP NOW!

Longer model

SHOP NOW!

Cases, chargers, & parts

SHOP NOW!

FAQs

Frequently Asked Questions

How does NJOY work?

When using NJOY, the act of inhaling (smoking) triggers a vaporizing process that releases simulated smoke which is actually a vapor mist that evaporates into the air within a few seconds.

What are the leading reasons people use NJOY?

Most people who smoke, smoke because they enjoy the tactile, emotional and physical sensations. The leading reasons people use NJOY include:

- No first or second hand smoke
- Virtually odorless
- No tar
- Contains no tobacco
- No more embarassment or guilt
- Non-flammable, produces no smoke
- Easy to use, convenient
- "Tobacco-like" taste and flavors
- Lower cost than traditional smoking
- Won't stain teeth or damage skin.

How do the ingredients compare to those in tobacco smoking products?

The primary cartridge ingredient is propylene glycol, and the secondary ingredients are water, nicotine and a flavor to replicate the taste of traditional smoking.

- **Propylene Glycol** - The Food and Drug Administration (FDA) has determined propylene glycol to be "generally recognized as safe" for use in food, cosmetics, and medicines. It is used in food coloring, and flavoring, as an additive to keep food, medicines and cosmetics moist, and in machines that simulate smoke, although usage in simulating smoking devices is not currently included in the list of uses generally recognized as safe by the FDA. In NJOY, propylene glycol functions to provide the vapor mist that looks like smoke and to suspend flavor
- **Water** - The water used in NJOY cartridges is filtered via a reverse-osmosis process
- **Nicotine** - is an alkaloid found in certain plants, predominately tobacco, and in lower quantities, tomatoes, potatoes, eggplants, cauliflower, bell-peppers and some teas.
- **Ethanol** - is 200% proof alcohol (same as used in making alcoholic beverages, and is used to extract nicotine from the tobacco leaf.
- **Glycerol (glycerin)** - Glycerol is a chemical compound also commonly called glycerin or glycerine. It is a colorless, odorless, viscous liquid that is widely used in pharmaceutical formulations. For human consumption, glycerol is classified by the FDA among the sugar alcohols as a caloric macronutrient.
- **Acetylpyrazine** - Used in the creation and/or manufacturing of cocoa, coffee, roasted peanuts, tea, beer, breakfast cereals, ice cream, candy, and other food products and nicotine cartridges and has been deemed safe for use by people.
- **Guaiacol** - is an ingredient use to give the smoky taste.
- **Myosmine**- is found in nut products, as well as tobacco
- **Cotinine**- is metabolite of nicotine. Some studies have suggested that cotinine (as well as nicotine) improves memory and prevents neuron death
- **Vanillin**- is used in the food industry as a flavoring agent in foods, beverages and pharmaceuticals.

What is propylene glycol?

The Food and Drug Administration (FDA) has determined propylene glycol to be "generally recognized as safe" for use in food, cosmetics, and medicines. It is used in food coloring, and

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flavoring, as an additive to keep food, medicines and cosmetics moist, and in machines that simulate smoke, although usage in simulating smoking devices is not currently included in the list of uses generally recognized as safe by the FDA. In NJOY, propylene glycol functions to provide the vapor mist that looks like smoke and to suspend flavor.

What does NJOY taste and smell like?

Most users of NJOY will tell you the flavor or taste of our products closely replicate cigarettes. NJOY cartridges are available in popular smoking flavors like regular "tobacco" and menthol flavors.

The odor from NJOY is barely noticeable and does not linger, unlike traditional smoking products that create lasting, difficult-to-neutralize smells in rooms, cars and clothing. NJOY provides a way to smoke in places, depending on your location where its use may not be prohibited by statutes or ordinances that otherwise prohibit smoking.

How long does a cartridge last?

If you experience little or no vapor when using, ensure that your battery is fully charged and properly attached to the NJOY product, and that the cartridge is firmly inserted in the end of the product. When the vapor volume is reduced below a satisfactory level, replace with a new NJOY cartridge.

Store cartridges in a cool and dry place. Shelf life is 24 months from purchase date. You should never place other liquids in an NJOY cartridge and doing so will void the product warranty.

How long does the battery charge last?

An NJOY battery will last 1-3 days before needing re-charging, depending on the intensity and quantity of puffs. The indicator light tip will blink multiple times when the battery is getting low on power. We encourage you to carry with you an extra, charged battery.

Charge a new battery initially for about 3 hours. Subsequent recharges should take about 2 hours. A battery can be recharged in excess of 300 times before reaching its useful life. NJOY also offers an automobile cigarette lighter charger for your convenience, which can be purchased at www.NJOY.com.

NJOY uses a 3.6V special lithium battery and charger, which cannot be replaced by other lithium batteries or chargers. The input supply voltage of the charger is AC100-240V, 50/60Hz, or DC 12-24V. When traveling, ensure that the local electrical supply is in accordance with these specifications.

Does NJOY cost more or less than traditional smoking products?

With ever-increasing taxes and price hikes on tobacco products, NJOY can save you money and is more affordable than traditional tobacco smoking.

If you average smoking one pack of tobacco cigarettes per day, at an average cost of $6 per pack, you would spend $2,190 per year.

Using the NCIG or NPRO at a similar rate would cost you approximately $1,050 per year, a savings of more than $1,000.

In fact, if you used NJOY as a **smoking alternative** product to tobacco smoking, by your 23rd day of using NCIG or NPRO, you would start ringing up the savings. Depending on what State and/or Country you live, the savings may vary!

Tell me more about NJOY's product styles?

The NPRO is similar in size to a traditional cigarette and comes in white, black, silver and burgundy colors. It weighs only 0.5 oz., measures 4 inches in length and is rechargeable.

The NCIG is a longer, stylish cigarette akin to those used in Hollywood in the mid-1900s and comes in black, white and burgundy colors. It weighs only 0.8 oz., measures 6 inches in length and is rechargeable.

Where does the "smoke" go?

NJOY emits what appears to be smoke but is actually a virtually odorless mist that evaporates into the air within seconds, similar to the functioning of a humidifier. NJOY leaves no visual residue in the air or lingering smell in clothes, a home or car, or other places, whereas tobacco smoking can leave an unsightly, acrid cloud known to irritate eyes and bother people's senses.

Can I smoke NJOY anywhere?

Since NJOY is non-flammable, contains no tobacco and emits no second hand smoke, depending on your location, its use may not be prohibited by statutes or ordinances that otherwise prohibit smoking.

Still, do not be surprised when people ask about you smoking NJOY. After all, to the casual observer, using NJOY creates the appearance of tobacco smoking. Customers report that simply explaining to others how NJOY works usually creates acceptance for using the product.

Is NJOY right for anyone?

NJOY products are intended for use by persons of legal smoking age, not by non-smokers or by children, women who are pregnant or breastfeeding, or persons with or at risk of heart disease, high blood pressure, hypertension, diabetes, or taking medicine for depression or asthma. Consult a physician if you experience nicotine misuse symptoms such as nausea, vomiting, dizziness, diarrhea, weakness and rapid heart-beat or hypertension. If you smoke tobacco products, you are encouraged to stop. NJOY products are not a smoking cessation product and have not been tested as such. Please keep NJOY products out of the reach of children and pets; ingestion of certain pieces can present a choking hazard, and ingestion of the non-vaporized concentrated ingredients in the cartridges can be poisonous. This product and the statements made within have not been evaluated by the US Food and Drug Administration or any other international health or regulatory authority, unless otherwise noted in NJOY's materials. These statements and NJOY products are not intended to diagnose, treat, cure, or prevent any condition, disorder, disease or physical or mental conditions and should not be used as a substitute for your own physician's advice. NJOY is manufactured to NJOY (USA) supplier standards, distributed globally, and made in China. Warnings: Nicotine is addictive and habit forming; very toxic by inhalation, in contact with the skin and if swallowed; danger of serious damage to health by prolonged exposure if swallowed; irritating to eyes and skin; may cause sensitization by skin contact; may cause harm to the unborn child; vapors may cause drowsiness or dizziness; very toxic; very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment; after contact with skin, wash immediately with plenty of water and seek medical advice; in case of accident or if you feel unwell, seek medical advice (show the label when possible); this material and its container must be disposed of in a safe way; use appropriate containment to avoid environmental contamination. Warning for California Residence: This product contains nicotine, a chemical known to the State of California to cause birth defects or other reproductive harm.

Is there a limited warranty?

Subject to the conditions and limitations set forth on www.NJOY.com and the Warranty Card, NJOY products are guaranteed against defects in workmanship and materials, if purchased from NJOY or an authorized NJOY dealer, for a period of 12 months from the date of purchase. If the product fails to operate satisfactorily, return to:

For USA, Mexico and Canada

NJOY

15455 N. Greenway-Hayden Loop Rd. Suite C-15

Scottsdale, Arizona 85260 USA

For Europe, Asia, Middle East, Australia, and other countries:

NJOY

c/o Micro Tech

Unit 2, Worth Enterprise Park

Valley Road

Keighley

West Yorkshire

BD21 4LZ

Remember to pack the unit securely and obtain appropriate shipping insurance. Include a full description of the defect or particulars of the claim, along with your return address, telephone number, and legible proof of purchase. The place of purchase, manufacturer or importer is not responsible for damage or loss incurred as a result of postal handling or damage caused during transit. Whenever possible send only the component in question, not the NPRO Starter Kit as a whole.

Is NJOY a smoking cessation product?

NJOY products are not a smoking cessation product and have not been tested as such. **NJOY electronic cigarettes** are alternative products that offer the freedom, depending on your location where its use may not be prohibited by statutes or ordinances that otherwise prohibit smoking, social inclusion versus isolation, no first or second hand smoke, virtually odor-free smoking, non-flammability, no tar, convenience, and lower cost than traditional smoking.

How do you use NJOY?

NJOY products are very easy-to-use and convenient. Each NJOY product is rigid, doesn't easily crush and can be stored in a purse, pocket, drawer and any other handy location. NJOY offers two exciting products for your pleasure, and here's how to use each:

NPRO is similar in size and color to a traditional cigarette. When you are ready to use the NPRO, screw a fully-charged battery onto the vaporizer. Then at the opposite end of the product, insert (by sliding) your choice of NPRO cartridge. Now, you are ready to draw on the NPRO.

NCIG is a longer, more stylish device akin to those used in Hollywood in the mid-1900s. When you are ready to use the NCIG, screw a fully-charged battery to the vaporizer. Then at the opposite end of the product, insert (firmly) your choice of NCIG cartridge. Now, you are ready to draw on the NCIG.

Are there any maintenance issues with NJOY?

NJOY is very easy to use. In general, the only maintenance required is charging and replacing batteries, as well as inserting fresh cartridges. Here are other NJOY maintenance tips:

When removing the NPRO cartridge, grasp the cartridge toward the tip, twist and pull off. Should you experience difficulty in removing the NPRO cartridge, apply a small amount of petroleum jelly or lip balm to the shaft of the vaporizer.

Keep NJOY away from extreme high and low temperature environments while in use or storage.

Keep NJOY out of reach of children.

Protect the NJOY products from contacting metal articles in your pocket, wallet or other bags. The conductors can bring about a short circuit, heating or damages to the battery and atomizer component.

Keep NJOY products away from magnetic sources and static electricity.

Keep NJOY away from cell phones as the magnetic signal to and from the phone can damage the operating system of the product.

How do I buy refill cartridges?

The easiest way to make sure you have the volume of cartridges you want is to use our automatic refill program. Rather than reordering or shopping every time you run out, the refill program mails cartridges to you each month, automatically. You can contact us at cs@njoy.com or 1-888-669-6569 and change the your reorder at any time.

I was registered in your automatic refill program, but I cannot log in to see my account.

Due to system problems, we needed to change our website to a new service platform. As a result, users cannot log in to their automatic refill accounts. Please contact us if you need to modify your automatic refill order at cs@njoy.com or 1-888-669-6569.

Are there aspects about NJOY I should be aware of

before using it?

NJOY products are intended for use by persons of legal smoking age, not by non-smokers or by children, women who are pregnant or breastfeeding, or persons with or at risk of heart disease, high blood pressure, hypertension, diabetes, or taking medicine for depression or asthma. Consult a physician if you experience nicotine misuse symptoms such as nausea, vomiting, dizziness, diarrhea, weakness and rapid heart-beat or hypertension. If you smoke tobacco products, you are encouraged to stop. NJOY products are not a smoking cessation product and have not been tested as such. Please keep NJOY products out of the reach of children and pets; ingestion of certain pieces can present a choking hazard, and ingestion of the non-vaporized concentrated ingredients in the cartridges can be poisonous. This product and the statements made within have not been evaluated by the US Food and Drug Administration or any other international health or regulatory authority, unless otherwise noted in NJOY's materials. These statements and NJOY products are not intended to diagnose, treat, cure, or prevent any condition, disorder, disease or physical or mental conditions and should not be used as a substitute for your own physician's advice. NJOY is manufactured to NJOY (USA) supplier standards, distributed globally, and made in China. Warnings: Nicotine is addictive and habit forming; very toxic by inhalation, in contact with the skin and if swallowed; danger of serious damage to health by prolonged exposure if swallowed; irritating to eyes and skin; may cause sensitization by skin contact; may cause harm to the unborn child; vapors may cause drowsiness or dizziness; very toxic; very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment; after contact with skin, wash immediately with plenty of water and seek medical advice; in case of accident or if you feel unwell, seek medical advice (show the label when possible); this material and its container must be disposed of in a safe way; use appropriate containment to avoid environmental contamination. Warning for California Residents: This product contains nicotine, a chemical known to the State of California to cause birth defects or other reproductive harm.