NLWJC - Kagan
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Tobacco-Litigation [3]

Tobacco - litigation

U.S. Department of Justice

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May 1, 1997

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VIA FACSIMILE
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Ms. Margaret Porter
General Counsel, FDA
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RE: Coyne Beahm, Inc.; Am. Advertising Federation; United States Tobacco Company and Nat'l Ass'n of Convenience Stores v. FDA M.D. N.C. (Osteen), Case Nos. 2:95CV00591, 2:95CV00706, 2:95CV00593 and 6:95CV00665

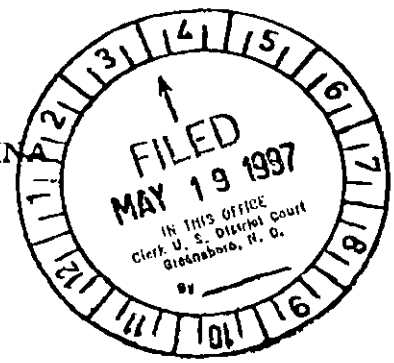
Dear Ms. Kagan, Ms. Drye, Ms. Rabb and Ms. Porter:

Enclosed is a copy of our Response In Opposition To Plaintiffs POPAI's Rule 59(e) Motion To Amend Judgment which we filed in the Greensboro District Court yesterday. The Fourth Circuit still has not issued a scheduling order.

Sincerely,

George J. Phillips

Enclosure
cc: Frank W. Hunger



UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
GREENSBORO DIVISION

AMERICAN ADVERTISING FEDERATION, et al.,	)	
Plaintiffs,	)	
v.	)	2:95CV00593
DAVID A. KESSLER, M.D., et al.,	)	
Defendants.	)	

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFF POPAI'S RULE 59(e) MOTION TO AMEND JUDGMENT

Pursuant to Local Rule 202(f), MDNC, defendants hereby oppose the motion of plaintiff Point of Purchase Advertising Institute ("POPAI") to amend this Court's Order of April 25, 1997, with respect to self-service displays. As fully set forth in Defendants' Brief in Opposition to Plaintiff POPAI's Rule 59(e) Motion to Amend Judgment, submitted herewith, POPAI's motion fails to meet the requirements for consideration under Rule 59(e); and, because this Court's decision with respect to self-service displays is correct, there is no basis to amend that decision.

WHEREFORE, defendants request that the Court summarily deny plaintiff POPAI's Rule 59(e) Motion to Amend Judgment.

Respectfully submitted,

FRANK W. HUNGER
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United States Attorney

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Assistant Attorney General
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CERTIFICATE OF SERVICE

I certify that on May 16, 1997, I served copies of Defendants' Response in Opposition to Plaintiff POPAI's Rule 59(e) Motion to Amend Judgment and Defendants' Brief in Opposition to Plaintiff POPAI's Rule 59(e) Motion to Amend Judgment upon counsel for plaintiffs as follows:

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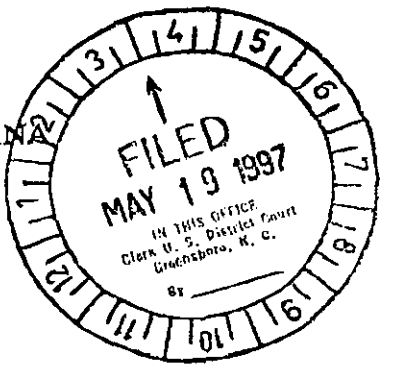

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
GREENSBORO DIVISION

AMERICAN ADVERTISING FEDERATION, et al., Plaintiffs, v. DAVID A. KESSLER, M.D., et al., Defendants.	2:95CV00593

DEFENDANTS' BRIEF IN OPPOSITION TO PLAINTIFF POPAI'S RULE 59(e) MOTION TO AMEND JUDGMENT

I. INTRODUCTION

On April 25, 1997, the Court issued its Order and Memorandum Opinion on plaintiffs' motions for summary judgment challenging the validity of regulation of cigarettes and smokeless tobacco products by the Food and Drug Administration ("FDA"). The heart of the Court's ruling is its determination that, under the Federal Food, Drug, and Cosmetic Act, FDA is empowered to regulate access to and labeling of cigarettes and smokeless tobacco products but lacks authority under 21 U.S.C. § 360j(e) to regulate advertising and promotion of those products. Recognizing that its decision involves controlling questions of law and that an immediate appeal may materially advance this litigation, the Court certified the decision for interlocutory appeal pursuant to 28 U.S.C. § 1292(b).

Within the 10-day period specified in § 1292(b), various plaintiffs and the defendants each petitioned the United States Court of Appeals for the Fourth Circuit to accept an

interlocutory appeal of this Court's Order. Additionally, defendants filed a Notice of Appeal from those portions of the Order adverse to them, inasmuch as the effect of those portions of the Order was to enjoin the implementation of certain parts of FDA's regulations. See 28 U.S.C. § 1292(a)(1).

Plaintiff Point of Purchase Advertising Institute ("POPAI") is apparently dissatisfied with this Court's determination that FDA can regulate self-service displays of tobacco products pursuant to its authority to regulate access to those products. Rather than joining in any of the other plaintiffs' § 1292(b) petitions to the Court of Appeals, or filing such a petition of its own, however, POPAI has elected to move this Court under Fed. R. Civ. P. 59(e) to amend its decision. As we show below, POPAI's motion fails to meet the requirements for consideration under Rule 59(e).[1/] Moreover, because this Court's decision with respect to self-service displays is correct, there is no basis to amend that decision. Defendants therefore request that the Court summarily reject the motion.[2/]

[1/] It is questionable whether POPAI's motion is properly characterized as a Rule 59(e) motion to amend a judgment at all. POPAI seeks amendment of a "minor" aspect of this Court's Order granting in part and denying in part plaintiff's motions for summary judgment. POPAI Motion at 4, ¶ 9. An order partially granting and partially denying summary judgment is not a "judgment" within the meaning of Rule 59(e). See Fed. R. Civ. P. 54(a).

[2/] Summary disposition of POPAI's motion may also speed the ultimate resolution of this litigation by ensuring that the motion will not delay consideration of this Court's April 25 decision by the Court of Appeals. The plaintiffs in this case, including POPAI, have argued to the Fourth Circuit that, under Fed. R. App. P. 4(a)(4), POPAI's Rule 59(e) motion renders the notice of appeal filed by the government ineffective and that any appeal (including the interlocutory appeals under 28 U.S.C. § 1292(b) which the Fourth Circuit has now accepted) in these cases must await this Court's resolution of the Rule 59(e) motion. While the government disagrees with the plaintiffs' reading of Fed. R. App. P. 4(a)(4), and has so argued to the Fourth Circuit, summary rejection of POPAI's motion will assure that the appeals proceed promptly.

II. ARGUMENT

A. POPAI's Motion Is Improper Under Rule 59(e)

POPAI acknowledges that in the Fourth Circuit the grounds for amending a judgment under Rule 59(e) are "(1) to accommodate an intervening change in controlling law; (2) to account for new evidence not available at trial; or (3) to correct a clear error of law or prevent manifest injustice." Hutchinson v. Staton, 994 F.2d 1076, 1081 (1993). What POPAI fails to recognize, however, is that:

> [A] Rule 59(e) motion is not a vehicle for obtaining post judgment reargument on issues already decided. Mere disagreement with the court's interpretation of the law is not an appropriate ground for a Rule 59(e) motion. Where the motion asserts only an erroneous view of the law, the proper recourse is appeal.

International Longshoremen's Ass'n v. Virginia Int'l Terminals, Inc., 932 F. Supp. 761, 762 (E.D. Va. 1996) (citing Hutchinson, 994 F.2d at 1082; Durkin v. Taylor, 444 F. Supp. 879, 889-90 (E.D. Va. 1977)). See also Charles Alan Wright, Arthur R. Miller, & Mary Kay Kane, Federal Practice and Procedure § 2810.1 at 127-28 (2d ed. 1995) ("The Rule 59(e) motion may not be used to relitigate old matters, or to raise arguments or present evidence that could have been raised prior to the entry of judgment.").

Here, POPAI purports to assert, as grounds for its Rule 59(e) motion, a "clear error of law" in the Court's treatment of self-service displays. POPAI Motion at 2, ¶ 5; POPAI Memorandum at 4. But there is nothing in POPAI's motion that either was not or could not have been argued in its original motion for summary judgment. POPAI simply disagrees with the view of self-service displays embodied in the Court's decision and wants a chance to reargue the issue.

With regard to self-service displays the Court ruled as follows:

> The court finds that the requirement that tobacco products be stored behind a counter and sold in a face-to-face exchange between a retailer and a consumer does not implicate the First Amendment. Retailers may still exhibit store displays promoting the sale of tobacco products. They simply will be prohibited from storing tobacco products on such displays.

Memorandum Opinion at 60 n.32. Thus, the Court determined that FDA's regulation of self-service displays is a restriction on access to rather than advertising or promotion of tobacco products.

POPAI claims that "[w]ithout the benefit of the Court's framework, the particular impact of the Court's ruling on SSDs [self-service displays] was never meaningfully addressed by any party." POPAI Memorandum at 4. To the contrary, as the Court noted, "Plaintiff National Association of Convenience Stores assert[ed] that the Regulation's ban on self-service displays implicates the First Amendment." Memorandum Opinion at 60 n.32. Indeed, POPAI concedes that "[t]he National Association of Convenience Stores plaintiffs argued that SSDs constitute 'advertising.'" POPAI Memorandum at 4 n.1. Therefore, even if it had never occurred independently to POPAI that FDA was regulating self-service displays as a means of access to tobacco products, by the time POPAI (and the other plaintiffs in this case) filed their summary judgment reply brief, POPAI could have followed the lead of the Convenience Store plaintiffs and made the arguments that it seeks to raise now.

More fundamentally, though, POPAI should not be heard to argue that it needed the benefit of the Court's "framework" in order to argue that self-service displays are advertising and not means of access to tobacco products. In the preamble to the very regulations that

POPAI is challenging in this lawsuit, FDA made clear its intention to regulate self-service displays as a means of access to tobacco products:

> FDA does agree, however, that the rule should be clarified so that the reference to displays in § 897.16(c) is understood to cover self-service sales or merchandisers rather than advertising displays that contain no products and has amended the rule accordingly.

61 Fed. Reg. 44396 at 44456 (col. 2) (1996). For reasons best known to itself, POPAI chose not to challenge this distinction prior to the Court's ruling. That the Court agreed with FDA's distinction between displays that provide access to tobacco products and those that simply advertise the products should not provide POPAI with grounds to argue under Rule 59(e) a point it could readily have addressed in its summary judgment papers.

Here, as in the Durkin case:

> The plaintiff in [its] brief brings forward no matter that could not have been argued before judgment was entered herein. [Its] brief in support of [its] motion is no more than an expression of a view of the law contrary to that set forth in the Court's opinion. Whatever may be the purpose of Rule 59(e) it should not be supposed that it is intended to give an unhappy litigant one additional chance to sway the judge.

444 F. Supp. at 889. And here, as in Durkin, the Court should not countenance such a misuse of Rule 59(e).

B. The Court's Ruling Regarding Self-Service Displays Is Correct

Even if the Court were to revisit the self-service display issue, there is no basis on which to amend its decision that regulation of such displays constitutes a permissible access restriction. While POPAI claims the Court made a "clear error of law," it does not cite a single legal authority for the proposition that self-service displays constitute advertising for, rather than a means of access to, tobacco products. Instead, POPAI seizes on the Court's

conclusion that, while FDA can regulate the "sale, distribution, or use" of tobacco products under 21 U.S.C. § 360j(e), the agency cannot regulate advertising under that provision and then argues that because, as a factual matter, self-service displays serve an important advertising function, they cannot be regulated by FDA. To quote POPAI:

> POPAI respectfully submits that the Court erred in treating the ban on SSDs as an "access" regulation, rather than an "advertising" regulation. The error is understandable because, in the context of the Court's particular statutory and definitional framework, the term "self-service display" is a misnomer. SSDs do not, in fact, involve "self-service."

POPAI Memorandum at 2 (emphasis added). Such circular reasoning cannot withstand scrutiny.

POPAI has already conceded that the facts as found by FDA are controlling for purposes of POPAI's motion for summary judgment. See Third Brief in Support of Plaintiffs' Motion for Summary Judgment at 4 n.3. See also Memorandum Opinion at 1 n.1. The facts as found by FDA leave no doubt that its restrictions on self-service displays restrict access to, not advertising of, tobacco products.

For instance, FDA supported its ban on self-service displays with a "report [that] found that over 40 percent of [grade school] students who smoked daily shoplifted cigarettes from self-service displays." 61 Fed. Reg. at 44453 (col. 3). Obviously, removal of tobacco products from those displays will obviate that opportunity for shoplifting and thereby reduce the access of children to the products.

The fact that shoplifting is not "sale" of the products does not, as POPAI argues (POPAI Memorandum at 8-9), diminish FDA's authority to reduce such access. As this Court found, and as POPAI effectively concedes for purposes of its Rule 59(e) motion (e.g.

POPAI Memorandum at 4-5), FDA has authority to restrict not only the "sale" but also the "distribution or use" of tobacco products. Memorandum Opinion at 54-60. By adopting a regulation that will reduce shoplifting of tobacco products, FDA has effectively limited the distribution of those products to, and their use by, children.

POPAI not only fails in its attack on the anti-shoplifting basis for FDA's restriction of self-service displays, it does not even address the other substantial factual underpinnings of the restriction. The agency cited a study "showing that tobacco sales to young people dropped 40 to 80 percent after enactment of ordinances prohibiting self-service displays and requiring vendor assisted sales." 61 Fed. Reg. at 44453 (col. 3) (emphasis added). The agency reasoned that "removing self-service displays should increase interaction between retailers and potential consumers because the retailer, under this rule, must physically hand the product to the consumer." Id. at 44456 (col. 1). Additionally, the FDA found that "the rule eliminates a young person's ability to take a package of cigarettes or smokeless tobacco, leave money on the counter, and leave the retailer's premises without having to provide proof of age." Id. All of these factors further refute POPAI's claim that FDA's restriction on self-service displays is an impermissible ban on advertising rather than a restriction on access.

Finally, whatever advertising or promotional function may or may not be served by including tobacco products on self-service displays, it is clear from POPAI's own authorities that it is the distribution function of such displays that is paramount. Even assuming POPAI's newly submitted assertion that "'*Highlighting a product*--showing it while telling about it--is basic to successful in-store selling,'" POPAI Memorandum at 7 (quoting B.

Menin & A. Benning, The Power of Point-of-Purchase Advertising 11 (1992)), the Court's ruling does nothing to interfere with that function. As the Court said, "retailers may still exhibit store displays promoting sale of tobacco products," Memorandum Opinion at 60 n.32, presumably including displays that "show" the product pictorially or by mock-up. It is only "storing tobacco products on such displays" that is prohibited by the Court's decision. Id. And as even POPAI admits, what those kinds of displays are "ultimately designed to do [is] to enable marketers (manufacturers and retailers) to fight the competition in getting their products into the customer's shopping bag." POPAI Memorandum at 7 n.4 (quoting T. Shimp, Promotion Management and Marketing Communications 465 (1990)) (emphasis added).

III. CONCLUSION

For all of the foregoing reasons, the Court should summarily deny POPAI's motion to amend this Court's decision with respect to self-service displays.

Respectfully submitted,

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Assistant Attorney General
Civil Division

Walter C. Holton Jr.

WALTER C. HOLTON, JR.
United States Attorney

GEORGE J. PHILLIPS
Counselor to the
Assistant Attorney General
Civil Division

tobacco - litigation

Elizabeth Drye
05/13/97 05:57:25 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc: Joshua Silverman/WHO/EOP, Jennifer D. Dudley/WHO/EOP
Subject: 4th Circuit Schedule for Tobacco Rule Appeal

The 4th Circuit has granted ours and plaintiff's petitions for interlocutory appeal but denied our motion for expedited appeal. However, the court's briefing schedule is close to the schedule we proposed. Plaintiffs file opening brief 6/3; gov't files opening brief 6/23; plaintiffs file answering brief 7/11; we file reply brief 7/21 (we requested 7/3 deadline for reply briefs). This schedule leaves open the possibility that, as we proposed, the court will rule before August 28, the effective date of most of the rule's provisions.

Message Sent To:

Bruce R. Lindsey/WHO/EOP
Bruce N. Reed/OPD/EOP
Elena Kagan/OPD/EOP
Anne E. McGuire/WHO/EOP
Barbara D. Woolley/WHO/EOP
Michelle Crisci/WHO/EOP

Tobacco-Litigation

Elizabeth Drye
04/28/97 02:04:06 PM

Record Type: Record

To: Bruce R. Lindsey/WHO/EOP, Elena Kagan/OPD/EOP, Bruce N. Reed/OPD/EOP

cc: Michelle Crisci/WHO/EOP, Jennifer D. Dudley/WHO/EOP
Subject: Good News!

Another step forward on tobacco.
---------- Forwarded by Elizabeth Drye/OPD/EOP on 04/28/97 02:06 PM ----------

Toby Donenfeld @ OVP
04/28/97 01:46:55 PM

Record Type: Record

To: Donald H. Gips/OVP @ OVP, Elizabeth Drye/OPD/EOP, Virginia M. Terzano/OVP @ OVP, Heidi Kukis/OVP @ OVP

cc:
Subject: Good News!

Scotus-Billboards,550
Ban on cigarette, liquor billboards upheld

WASHINGTON (AP) The Supreme Court, in an apparent victory for President Clinton's proposed crackdown on tobacco advertising, today left intact Baltimore's bans on billboard ads for cigarettes and alcoholic beverages.

The justices, without comment, turned away arguments that the city's twin bans on such ads violate free-speech rights.

A federal judge in North Carolina left that constitutional question unanswered last week when he ruled that existing federal law doesn't allow the Food and Drug Administration to restrict cigarette advertising and promotion.

But the judge also handed tobacco companies a big setback in ruling that the FDA can regulate tobacco as a drug.

President Clinton said that part of the judge's ruling on advertising and promoting would be appealed.

The president has proposed forbidding cigarette brand advertising at sports events, on T-shirts and billboards within 1,000 feet of schools and playgrounds, and in magazines likely to be read by teen-agers.

Opponents of the proposal contend it runs afoul of a constitutionality test created by a 1980 Supreme Court ruling.

In it, the court said commercial speech that is truthful and not misleading may be limited only if government has a substantial interest, the limitation directly advances that interest and is no

more extensive than necessary.

The Baltimore dispute dates back to a pair of 1994 ordinances that forced the removal of cigarette and alcoholic beverage ads from most city billboards.

The ordinances were aimed at reducing illegal underage drinking and smoking.

The 4th U.S. Circuit Court of Appeals upheld the bans last year, but was ordered by the Supreme Court to restudy its rulings in light of the justices' decision last May giving advertisers significantly greater protection from government regulation.

The trend of rulings by the nation's highest court in recent years is to give commercial speech enhanced protections from government regulation.

But after reconsidering each of Baltimore's bans, the 4th Circuit court again upheld both in August.

The appeals court said the bans withstood the scrutiny required under the Supreme Court's 1980 ruling, and that the May ruling did not apply to the billboard dispute.

The lower court added that measures to protect children deserve ``special solicitude'' by courts.

``Baltimore's interest is to protect children who are not yet independently able to assess the value of the message presented,'' the appeals court said. ``This decision thus conforms to the Supreme Court's repeated recognition that children deserve special solicitude in the First Amendment balance.''

The amendment guarantees freedom of speech.

The alcoholic-beverage ad ban was challenged by Anheuser-Busch, brewer of such popular beers as Budweiser and Michelob, and Penn Advertising of Baltimore, a billboard-leasing company.

Penn Advertising challenged the city's cigarette ad ban.

Alcoholic beverages still can be advertised in Baltimore on city buses, taxicabs, delivery trucks and stores licensed to sell such drinks. The city's ban also did not affect television, radio, newspaper and magazine advertisements.

The city's cigarette-advertising ban also permits ads on buses and taxis, stores licensed to sell cigarettes and at professional sports stadiums.

The cases are Anheuser-Busch vs. Schmoke, 96-1428, and Penn-Advertising vs. Schmoke, 96-1429.

APNP-04-28-97 1013EDT

Received by NewsEDGE/LAN: 4/28/97 10:02 AM

U.S. Department of Justice
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May 1, 1997

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Ms. Harriet Rabb
General Counsel
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RE: Coyne Beahm, Inc.; Am. Advertising Federation; United States Tobacco Company and Nat'l Ass'n of Convenience Stores v. FDA M.D. N.C. (Osteen), Case Nos. 2:95CV00591, 2:95CV00706, 2:95CV00593 and 6:95CV00665

Dear Mr. Lindsey, Ms. Kagan, Ms. Drye, Mr. Burson, Mr. Klain, and Ms. Rabb:

Enclosed is the petition for permission to appeal from an interlocutory order filed by the tobacco plaintiffs on Tuesday, April 29, 1997, in the United States Court of Appeals for the Fourth Circuit. I am sorry we did not learn of this earlier, but we just received it. Instead of sending us a copy of the petition by hand-delivery or facsimile on the same day as filing, as had been their and our earlier practice, they simply dropped it in the mail from Richmond.

Sincerely,

George J. Phillips

Enclosure
cc: Frank W. Hunger

IN THE UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

APPEAL NO. _____

BROWN & WILLIAMSON TOBACCO CORPORATION, ET AL., v. UNITED STATES FOOD & DRUG ADMINISTRATION, ET AL.

LORILLARD TOBACCO COMPANY, ET AL., v. UNITED STATES FOOD & DRUG ADMINISTRATION, ET AL.

PHILIP MORRIS, INCORPORATED ET AL., v. UNITED STATES FOOD & DRUG ADMINISTRATION, ET AL.

R.J. REYNOLDS TOBACCO COMPANY, ET AL., v. UNITED STATES FOOD & DRUG ADMINISTRATION, ET AL.

PETITION FOR PERMISSION TO APPEAL FROM AN INTERLOCUTORY ORDER OF THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF NORTH CAROLINA, Civil Action, File Nos. 2:95CV00591

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Attorneys for Petitioners
Brown & Williamson Tobacco Corp., et al.

April 29, 1997

DISCLOSURE OF CORPORATE AFFILIATIONS AND
OTHER ENTITIES WITH A DIRECT FINANCIAL INTEREST IN LITIGATION

Pursuant to FRAP 26.1 and Local Rule 26.1

BROWN & WILLIAMSON TOBACCO CORPORATION, who is an appellant makes the following disclosure:

1. Is the party a publicly held corporation or other publicly held entity?

   Answer: No.

2. Is the party a parent, subsidiary, or affiliate of, or a trade association representing a publicly held corporation, or other publicly held entity (see Local Rule 26.1(b))?

   Answer: Yes. Brown & Williamson Tobacco Corporation is the indirect subsidiary of B.A.T. Industries, P.L.C.

3. Is there any other publicly held corporation, or other publicly held entity, that has a direct financial interest in the outcome of the litigation (see Local Rule 26.1(b))?

   Answer: No.

DISCLOSURE OF CORPORATE AFFILIATIONS AND OTHER ENTITIES WITH A DIRECT FINANCIAL INTEREST IN LITIGATION

Pursuant to FRAP 26.1 and Local Rule 26.1

LORILLARD TOBACCO COMPANY, who is an appellant makes the following disclosure:

1. Is the party a publicly held corporation or other publicly held entity?

   Answer: No.

2. Is the party a parent, subsidiary, or affiliate of, or a trade association representing a publicly held corporation, or other publicly held entity (see Local Rule 26.1(b))?

   Answer: Yes. Lorillard Tobacco Company is the indirect subsidiary of Loews Corporation.

3. Is there any other publicly held corporation, or other publicly held entity, that has a direct financial interest in the outcome of the litigation (see Local Rule 26.1(b))?

   Answer: No.

DISCLOSURE OF CORPORATE AFFILIATIONS AND
OTHER ENTITIES WITH A DIRECT FINANCIAL INTEREST IN LITIGATION

Pursuant to FRAP 26.1 and Local Rule 26.1

PHILIP MORRIS INCORPORATED who is an appellant makes the following disclosure:

1. Is the party a publicly held corporation or other publicly held entity?

   Answer: No.

2. Is the party a parent, subsidiary, or affiliate of, or a trade association representing a publicly held corporation, or other publicly held entity (see Local Rule 26.1(b))?

   Answer: Yes. Philip Morris Incorporated is the indirect subsidiary of Philip Morris Companies Inc.

3. Is there any other publicly held corporation, or other publicly held entity, that has a direct financial interest in the outcome of the litigation (see Local Rule 26.1(b))?

   Answer: No.

DISCLOSURE OF CORPORATE AFFILIATIONS AND OTHER ENTITIES WITH A DIRECT FINANCIAL INTEREST IN LITIGATION

Pursuant to FRAP 26.1 and Local Rule 26.1

R.J. REYNOLDS TOBACCO COMPANY, who is an appellant makes the following disclosure:

1. Is the party a publicly held corporation or other publicly held entity?

   Answer: No.

2. Is the party a parent, subsidiary, or affiliate of, or a trade association representing a publicly held corporation, or other publicly held entity (see Local Rule 26.1(b))?

   Answer: Yes. R.J. Reynolds Tobacco Company is the indirect subsidiary of RJR Nabisco Holdings Corp. (R.J. Reynolds Tobacco Company is wholly owned by RJR Nabisco, Inc., which is wholly owned by RJR Nabisco Holdings Corp. which is publicly held). Nabisco Holdings Corp. is the publicly held affiliate of R.J. Reynolds Tobacco Co.

3. Is there any other publicly held corporation, or other publicly held entity, that has a direct financial interest in the outcome of the litigation (see Local Rule 26.1(b))?

   Answer: No.

CERTIFICATE OF TYPE SIZE AND STYLE

This Petition for Permission to Appeal has been prepared in accordance with Local Rule 32(a) regarding the typeface for briefs.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

MISCELLANEOUS

ISSUES PRESENTED FOR REVIEW

Whether this Court should grant petitioners' request for interlocutory review of the issues that (i) were ruled upon by the district court in denying in part plaintiffs' motions for summary judgment, and (ii) were certified in the district court's order as appropriate for review by this Court under 28 U.S.C. § 1292(b). Those issues are:

(1) Whether Congress has withheld jurisdiction from the Food and Drug Administration ("FDA") over tobacco products as customarily marketed.

(2) Whether the Federal Food, Drug, and Cosmetic Act ("FDCA") applies to tobacco products as customarily marketed.

(3) Whether such products can be regulated as medical "devices" within the scope of the FDCA.

(4) Whether 21 U.S.C. § 360j(e) authorizes any of FDA's restrictions on tobacco products.

I. INTRODUCTION.

The district court has ruled in a matter of vast public importance on four issues of law that will need to be determined in this case, and that can be decided now. The district court has sua sponte certified the case under 28 U.S.C. § 1292(b) stating:

> "This order involves controlling questions of law as to which there is substantial ground for difference of opinion. Furthermore, an immediate appeal from this order may materially advance the ultimate termination of the litigation. Therefore, the court certifies this order for an interlocutory appeal pursuant to 28 U.S.C. § 1292(b)."

Petitioners hereby petition this Court to decide (1) whether Congress has withheld from the Food and Drug Administration ("FDA") jurisdiction over tobacco products as customarily marketed; (2) whether the Federal Food, Drug, and Cosmetic Act ("FDCA") applies to tobacco products; (3) whether such products can be regulated as medical "devices" within the meaning of the FDCA; and (4) whether 21 U.S.C. § 360j(e) authorizes any of FDA's restrictions on tobacco products.

These questions arise from a ruling by the U.S. District Court for the Middle District of North Carolina on April 25, 1997 that denied in part petitioners' motions for summary judgment that FDA has no jurisdiction over tobacco products as customarily marketed, and that all of FDA's tobacco regulations are invalid. The district court's decision accompanies this petition as Exhibit 1. See Appendix (hereinafter "*Exh.* ___").

The April 25, 1997 Order granting and denying relief and certifying that ruling for interlocutory review (the "Order") also accompanies this petition (*Exh. 2*).

Prompt appellate review of these issues will effectively and efficiently resolve several of the important legal aspects of petitioners' challenge to FDA's tobacco regulations, and could very well resolve the entire case. Thus, the appeal will present "controlling question[s] of law as to which there [are] substantial ground[s] for difference of opinion," and because resolution of the issues now "may materially advance the ultimate termination of the litigation," interlocutory review is warranted. 28 U.S.C. § 1292(b).

II. STATEMENT OF FACTS.

No disputed issues of fact were decided by the district court, and none is presented for review in this Court. The issues presented are purely legal.

STATEMENT OF THE MATTER BEFORE THE COURT

The legal issues presented for review arise in a challenge to FDA's assertion of jurisdiction over the entire cigarette and smokeless tobacco industry, and to FDA's tobacco regulations promulgated under the asserted authority of the FDCA.

On August 28, 1996, FDA issued a final rule, in which it asserted plenary jurisdiction over tobacco products (cigarettes and smokeless tobacco). 61 Fed. Reg. 44,396, 44,615-18 (Aug. 28, 1996) (*Exh. 3*). FDA's unprecedented regulations cover, inter alia, tobacco manufacturing, product names, the

labels and other aspects of tobacco packages, and the sale, distribution, advertising, and promotion of tobacco products. FDA's assertion of jurisdiction over these products may also presage attempts by FDA to regulate the design and content of tobacco products.

Two FDA regulations relating to the retail sale of tobacco products to persons under 18 years of age (proof of age and related matters) went into effect on February 28, 1997, during the pendency of petitioners' motions for summary judgment. Under the district court's Order, those two regulations remain in effect. FDA's other tobacco regulations were scheduled to go into effect on August 28, 1997 and August 28, 1998. The effectiveness of all of those regulations has been enjoined or stayed by the district court.[1/]

Petitioners' Complaints challenged these regulations on many grounds. In support of their motions for summary judgment, petitioners contended that (1) Congress has withheld from FDA jurisdiction to regulate tobacco products as customarily marketed; (2) the FDCA does not authorize FDA to exercise jurisdiction over tobacco products at all; (3) it does not authorize FDA to regulate them as medical "devices"; (4) 21 U.S.C. § 360j(e), a provision of the FDCA, does not authorize any of FDA's restrictions on tobacco products, (5) § 360j(e) does not

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1/ The Order stayed FDA from implementing "any of the additional Regulations set for implementation on August 28, 1997, pending further orders by the court." *Exh. 2.*

authorize FDA to regulate their advertising or promotion; and (6) FDA's restrictions on tobacco advertising and promotion violate the First Amendment to the United States Constitution, by impermissibly restricting substantially more speech than is necessary in pursuit of FDA's asserted regulatory goals.

In its decision, the district court ruled against petitioners on issues (1)-(4); it ruled in their favor on issue (5); and it did not reach issue (6). Thus, the issues tendered for review in this petition are issues (1)-(4).[2/] These issues relate to FDA's jurisdiction over tobacco products at all, to FDA's treatment of these products as medical "devices," which is the basis for all of FDA's tobacco regulations, and to the applicability of § 360j(e) in circumstances where, in FDA's view, restrictions under that provision would not prevent the regulated products from being unsafe.

ARGUMENT

I. THE DISTRICT COURT'S RULING PARTIALLY DENYING PETITIONERS' MOTIONS FOR SUMMARY JUDGMENT IS PROPERLY REVIEWABLE UNDER 28 U.S.C. § 1292(b).

Title 28 U.S.C. § 1292(b) provides that, if a district judge

> in making in a civil action an order not otherwise appealable under this section, shall be of the opinion that such order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal may materially

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2/ If on an appeal by the Government this Court were to reverse the district court's decision that FDA has no statutory authority to regulate tobacco advertising and promotion, the district court would then need to reach the First Amendment issues.

> advance the ultimate termination of the litigation, he shall so state in writing such order.

28 U.S.C. § 1292(b). The section further states:

> The Court of Appeals which would have jurisdiction of an appeal of such action may thereupon, in its discretion, permit an appeal to be taken from such order, if application is made to it within ten days after the entry of the order[.]

Id. An order denying a motion for summary judgment in whole or in part is just such an otherwise non-final order, non-appealable as of right, but in appropriate circumstances suitable for certification under section 1292(b). Shaw v. Stroud, 13 F.3d 791, 797-98 (4th Cir. 1994); Lum v. City & Cty. of Honolulu, 963 F.2d 1167, 1169-70 (9th Cir.) ("the appropriate forum to review the denial of a summary judgment motion is through interlocutory appeal under [§ 1292(b)]"), cert. denied, 506 U.S. 1022, 113 S. Ct. 659, 121 L.Ed.2d 585 (1992); Consolidated Exp., Inc. v. New York Shipping Assoc., 602 F.2d 494, 501 (3d Cir. 1979) (same; certification granted where review of issue could make summary judgment appropriate).

Here, the district court's Order states the findings required by § 1292(b).

Under § 1292(b), this Court thus has the discretion to review the issues certified in the district court's Order.

II. STATEMENT OF 28 U.S.C. § 1292(b) FACTORS WARRANTING INTERLOCUTORY REVIEW.

Section 1292(b) identifies three determinations for the Court regarding the propriety of interlocutory review: (1) the presence of controlling questions of law; (2) the existence of

substantial grounds for difference of opinion on those questions; and (3) the possibility of material advancement of the litigation through interlocutory review of the district court's ruling. In the instant case, as the district court has determined, all three of these requirements -- as applied in this Circuit and elsewhere -- are satisfied.

First, the district court has decided questions of law that are controlling. They are pure questions of statutory construction; no issues of fact were raised or decided. The issues of congressional intent and statutory authorization with respect to FDA jurisdiction over tobacco products as customarily marketed at all and, in particular, as medical "devices" are controlling as to petitioners' challenge to FDA's assertion of jurisdiction over petitioners' tobacco products and as to the statutory validity of all of FDA's tobacco regulations. Resolution of either of these sets of issues in petitioners' favor would fully resolve the litigation.

Second, as demonstrated by the authorities cited by the petitioners and the government in the district court -- and the diametrically opposed, competing interpretations of those authorities offered by the parties -- there exist substantial grounds for difference of opinion on these issues. Indeed, the district court so stated. See Exh. 2.

Third, interlocutory review of these legal issues may well materially advance the termination of this litigation. Such review would be much more efficient than proceeding in the

district court to the next phase of petitioners' challenge to the regulations.[3/] The legal issues raised have the potential to end the litigation swiftly and finally. The district court's decision on the remaining issues would almost certainly be appealed to this Court, however the district court decides them. Interlocutory review may both expedite the resolution of the case and preserve the federal courts' resources, by obviating the need for extensive further proceedings.

A. The District Court's Ruling Involves Controlling Questions of Law as to Which Substantial Grounds Exist for Difference of Opinion.

1. The Ruling Involves Controlling Questions of Law.

A "controlling question of law" is one that is important or crucial to the case, and determination of which would substantially resolve the litigation. "Although the resolution of an issue need not . . . terminate an action in order to be 'controlling,'" "it is clear that a question of law is controlling if reversal of the district court's order would terminate the action." 'Klinghoffer v. SNC Achille Lauro, 921 F.2d 21, 24 (2d Cir. 1990). "Controlling" may also be defined with reference to an issue's importance to a wide spectrum of cases and parties. See id.

3/ The next phase would be a series of challenges to individual regulations on a broad range of grounds: e.g., FDA's lack of statutory authority for particular regulatory provisions, a lack of factual support in the record, procedural irregularities in the rulemaking, and additional constitutional infirmities in individual regulations.

As petitioners' memoranda in support of their motions for summary judgment on statutory grounds made clear (see *Exh.* 4-5), the questions of congressional intent and statutory construction with regard to FDA jurisdiction over tobacco products in general and as medical devices in particular and the structure of the FDCA and its ability to accommodate regulatory authority over tobacco products are all questions of law (no issues of fact are raised), and all potentially control the outcome of this litigation.

In their motions for summary judgment in the district court, and now in this Court, petitioners do not challenge any of the factual findings FDA made in support of its assertion of jurisdiction and its tobacco regulations (though petitioners do challenge legal conclusions drawn from those findings).[1/] Thus, the issues that would be presented on this appeal do not involve any disputed issues of fact.

A ruling for petitioners on any one of the issues of FDA jurisdiction, applicability of the FDCA to tobacco products, or whether tobacco products can be regulated as medical "devices" would invalidate all of FDA's tobacco regulations, and terminate the litigation.

Where such controlling questions of congressional intent and statutory construction are present, this Court regularly grants interlocutory review. See, e.g., Duane v.

1/ If necessary, petitioners will challenge FDA's findings at a later stage of the litigation. See n. 3, supra.

GEICO, 37 F.3d 1036, 1037-38 (4th Cir. 1994) (interlocutory review to determine whether 42 U.S.C. § 1981 applies to private alienage discrimination); Madonia v. Blue Cross & Blue Shield of Va., 11 F.3d 444, 446 (4th Cir. 1993) (ERISA preemption); Sejman v. Warner-Lambert Co., 845 F.2d 66, 67 (4th Cir. 1988) (same); Terry v. Chauffeurs, Teamsters & Helpers, Local 391, 676 F. Supp. 659, 660-665 (M.D.N.C. 1994) (right to jury trial on claim under § 301 of LMRA).

Here, FDA's interpretation of the FDCA (a statute in effect since 1938[5/]) to support its assertion of jurisdiction over tobacco products is unprecedented. This interpretation is at odds with many decades of past interpretations of the FDCA and its predecessor statute,[6/] and a different determination of its validity could end the litigation. A question of agency jurisdiction under an organic statute is particularly fit for interlocutory review. See Consumer Product Safety Comm'n v. Anaconda Co., 593 F.2d 1314, 1316 (D.C. Cir. 1979) (interlocutory review of agency jurisdiction under Consumer Product Safety Act).

The district court's ruling attempted to reconcile FDA's interpretation of the FDCA with Congress's comprehensive program of tobacco-specific legislation. Such an attempt to reconcile potentially conflicting statutes is well-suited for certification and interlocutory review. See, e.g., Read v.

5/ Pub. L. No. 75-447, 52 Stat 111 (1938).

6/ Pub. L. No. 59-384, 34 Stat. 768 (1906).

United Transp. Union, 828 F.2d 1066, 1066-67 (4th Cir. 1987) (interlocutory review of question of whether limitations period from NLRA applies to proceedings under LMRDA), rev'd on the merits, 488 U.S. 319, 109 S. Ct. 621, 102 L.Ed.2d 665 (1989); White v. Nat'l Steel Corp., 938 F.2d 474, 480 (4th Cir. 1991) (interlocutory review of LMRA preemption, relationship with other statutes).

In Farmer v. Employment Sec. Comm'n of North Carolina, 4 F.3d 1274 (4th Cir. 1993), an interlocutory appeal, this Court was confronted with the task of reconciling two federal statutes as part of a comprehensive statutory scheme, (1) the 1988 Amendments to the 1968 Fair Housing Act, and (2) the Immigration Reform and Control Act of 1986. See id. at 1279. There were competing statutory interpretations; no court had definitively resolved the issue; and, although the district court had ruled for the defendants, the plaintiffs' reading had "in the abstract, . . . some merit," sufficient to support certification and interlocutory review. See id. at 1281-83; see also Metrix Warehouse, Inc. v. Daimler-Benz AG, 716 F.2d 245, 246 (4th Cir. 1983) (interpretation of Robinson-Patman Act).

Here, the district court's ruling also addressed FDA's construction of its statute taken by itself, and whether that construction does violence to the statute and whether it is in keeping with past agency interpretations, as FDA claims. This set of issues also is controlling, in that a decision for the petitioners would end the case. The validity of an

interpretation of crucial provisions of a statute is an issue well-suited for interlocutory review. See Palumbo v. Waste Technologies Industries., 989 F.2d 156, 158-59 (4th Cir. 1993) (interpretation of "citizen suit" language of RCRA in context of other statutory sections); Scott v. Jones, 964 F.2d 314, 316 (4th Cir. 1992) (meaning of "debt collector" under Federal Debt Collection Practices Act).

2. There Are Substantial Grounds for Difference of Opinion about the district court's Ruling.

Section 1292(b) requires that there be "substantial grounds for difference of opinion." In giving meaning to this phrase, courts have found such grounds in a wide range of circumstances. See, e.g., Camacho v. Mancuso, 53 F.3d 48, 49-50 (4th Cir. 1995) (question of first impression in the Circuit); Ferguson v. United States, 712 F. Supp. 775, 786 (N.D.Cal. 1989) (no existing law on the subject, and "[a] determination on this critical, novel issue would aid the parties and the court"); Rector v. Local Union No. 10, Int'l Union of Elevator Constructors, 625 F. Supp. 174, 181 (D.Md. 1985) (disagreement between district court and other courts demonstrates substantial ground for difference of opinion); U.S. v. Sasser, 738 F. Supp. 177, 180 (D.S.C. 1990) (substantial grounds for difference of opinion even where district court followed Fourth Circuit precedent and implications of Supreme Court opinion); Virginia Hosp. Ass'n v. Baliles, 868 F.2d 653, 657 (4th Cir. 1989) (district court in disagreement with two other courts of appeals); Foyle v. Lederle Labs., 674 F. Supp. 530, 533 (E.D.N.C.

1987) (district court joined majority of circuits that had considered issue but certified nonetheless).

Here, the substantial grounds for disagreement with the district court's decision are set forth in the petitioners' memoranda on the statutory issues, filed below and submitted herewith (Exh. 4-5). These differences are actually spelled out to some extent in the district court's opinion.

FDA's assertion of jurisdiction over tobacco products as customarily marketed is unprecedented and sweeping. Substantial authority and authoritative indicia of congressional intent conflict with this assertion of jurisdiction, as set forth in Exhibits 4 and 5. The district court's construction of Congress's tobacco-specific statutes and of the FDCA constitutes a dramatic break with long-established understandings of these laws, including prior interpretations by both FDA and the courts.

The district court's interpretation of the FDCA to include tobacco products even though they are not represented to affect a structure or function of the body is contrary to long-established principles of food and drug law. Moreover, the district court's upholding of FDA's determination that these tobacco products are medical "devices" as defined in the FDCA is contrary to the plain meaning of § 326(h) of the FDCA.

In sum, there are substantial grounds for difference of opinion on the issues of law decided by the district court.

B. Review of the district court's Order May Materially Advance the Ultimate Termination of this Challenge to the Agency's Action.

A litigant seeking interlocutory review must show that such review may expedite resolution of the case, serve the goals of efficiency and simplicity, and not prolong the case through piecemeal appeals. 9 J. MOORE, B. WARD & J.D. LUCAS, MOORE'S FEDERAL PRACTICE AND PROCEDURE 110.22[2], at 275 (2d ed. 1991). Here, a grant of interlocutory review should make possible (though obviously not certain) the conservation of resources through avoidance of further district court proceedings. Id.; cf. J.P. Stevens Empys. Educ. Comm. v. NLRB, 582 F.2d 326, 327 (4th Cir. 1978). "Material advance[ment]" may also be explored in light of the amount of resources, number of litigants, and persons affected by the ruling. In re Showa Denko K.K. L-Tryptophan Liability Litigation II, 953 F.2d 162, 165 (4th Cir. 1992).

In this case, the efficiencies of interlocutory review are not mere conjecture. Immediate review of the district court's ruling may materially advance the ultimate termination of this litigation by (1) preventing further lower court proceedings that may not be necessary if the legal issues are resolved differently during interlocutory review; and (2) expediting final resolution of the controlling legal issues, thus allowing the courts to resolve whether the regulations will be put in place or the government must seek congressional action with respect to FDA jurisdiction over tobacco products.

A fact-intensive proceeding as to the sufficiency of FDA's findings to support its regulations may be avoided altogether if this Court resolves the controlling legal questions in petitioners' favor. A conclusion that FDA does not have jurisdiction over tobacco products as customarily marketed, for example, would terminate the case. Cf. J.P. Stevens Empys. Educ. Comm. v. NLRB, 582 F.2d at 327. Likewise, a conclusion that FDA has impermissibly distorted the FDCA to try to make it fit tobacco products would end this litigation. These eventualities should be definitively explored and resolved by this Court sooner rather than later, to preserve the federal courts' resources. Ferguson v. United States, 712 F. Supp. 775, 786 (N.D.Cal. 1989).

An immediate appeal also does not represent an additional expenditure of federal judicial resources, because the issues for which certification is urged will be appealed by one side or the other regardless of the outcome of the district court proceedings. Hirsch v. Blue Cross & Blue Shield of Maryland, Inc., 1991 U.S. Dist. LEXIS 20963, *17-*19 (D.Md. 1991) (certification appropriate where different legal disposition would obviate later need for trial; especially appropriate if legal issues are going to be appealed regardless)(*Exh. 6*); Ferguson, 712 F. Supp. at 786 (same; government had expressed intent to appeal legal issues, whatever the trial outcome).

CONCLUSION

For the foregoing reasons, this Court should grant petitioners' petition and allow an interlocutory appeal with respect to the issues certified by the district court.

Respectfully submitted,

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Brown & Williamson Tobacco Corp.,
et al.

Dated: April 29, 1997

Tobacco - Litigation

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
GREENSBORO DIVISION

FILED
APR 2 5 1997
IN THIS OFFICE
Clerk, U. S. District Court
Greensboro, N. C.
By ....

COYNE BEAHM, INC., BROWN & WILLIAMSON TOBACCO CORPORATION, LIGGETT GROUP, INC., LORILLARD TOBACCO COMPANY, PHILIP MORRIS, INCORPORATED, and R.J. REYNOLDS TOBACCO COMPANY,	)	
Plaintiffs,	)	
v.	)	2:95CV00591
UNITED STATES FOOD & DRUG ADMINISTRATION and DAVID A. KESSLER, M.D., Commissioner of Food and Drugs,	)	
Defendants.	)	

* * * * * * * * * * * * *

AMERICAN ADVERTISING FEDERATION, AMERICAN ASSOCIATION OF ADVERTISING AGENCIES, INC., ASSOCIATION OF NATIONAL ADVERTISERS, INC., MAGAZINE PUBLISHERS OF AMERICA, OUTDOOR ADVERTISING ASSOCIATION OF AMERICA, POINT OF PURCHASE ADVERTISING INSTITUTE,	)	1. Go to FTC 2. Massive c/advert 3. Legislation - give FDA juris over advert (only of cigs??) 4. Medicare suits
Plaintiffs,	)	
v.	)	2:95CV00593
DAVID A. KESSLER, M.D., Commissioner of Food and Drugs, and UNITED STATES FOOD & DRUG ADMINISTRATION,	)	
Defendants.	)	

* * * * * * * * * * * * *

O R D E R

OSTEEN, District Judge

For the reasons set forth in the memorandum opinion entered contemporaneously herewith,

IT IS THEREFORE ORDERED AND ADJUDGED that Plaintiffs' Motion for Summary Judgment is granted as to the Regulations' restrictions on the promotion and advertising of tobacco products.

IT IS FURTHER ORDERED AND ADJUDGED that Plaintiffs' Motion for Summary Judgment is denied as to the Regulations' access restrictions and labeling requirements.

This order involves controlling questions of law as to which there is substantial ground for difference of opinion. Furthermore, an immediate appeal from this order may materially advance the ultimate termination of the litigation. Therefore, the court certifies this order for an interlocutory appeal pursuant to 28 U.S.C. § 1292(b).

IT IS FURTHER ORDERED that the Regulations heretofore implemented prohibiting the sale of tobacco products to minors shall remain in full force and effect pending appeal by Plaintiffs.

IT IS FURTHER ORDERED that the Food and Drug Administration shall not implement any of the additional Regulations set for implementation on August 28, 1997, pending further orders by the court.

IT IS FURTHER ORDERED that nothing set forth in this order concerning the time of implementation of the Regulations shall prohibit either side from presenting motions to the court for a reconsideration as to the implementation of the Regulations pending appeal.

IT IS FURTHER ORDERED that absent a timely appeal or absent permission of the Court of Appeals for the Fourth Circuit to proceed with an interlocutory appeal, this matter shall proceed for ultimate disposition by the court.

This the 25th day of April, 1997.

William L Osteen

United States District Judge

MEMORANDUM OPINION

OSTEEN, District Judge

This case comes before the court on Plaintiffs' Motion for Summary Judgment.[1] In August 1996, the Food and Drug Administration ("FDA") published in the Federal Register "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents" ("Regulations"). 61 Fed. Reg. 44,396 (1996). Plaintiffs now seek summary judgment claiming that Congress has withheld the authority to regulate tobacco products as customarily marketed from FDA and that the Federal Food, Drug, and Cosmetic Act ("FDCA" or "Act")[2] does not authorize FDA to regulate tobacco products as "drugs" or "devices."

For the reasons discussed herein, Plaintiffs' Motion for Summary Judgment will be granted in part and denied in part.

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[1]For purposes of their motion for summary judgment, Plaintiffs do not dispute the finding of facts made in FDA's jurisdictional determination and preamble to the Regulations. Although FDA did not formally move for summary judgment, it suggests in its Response Brief that the court can and should enter summary judgment in its favor. Since Plaintiffs would contest FDA's factual findings for purposes of a motion by FDA for summary judgment, summary judgment in favor of FDA would not be appropriate.

[2]21 U.S.C. § 321 et. seq.

I. DISCUSSION

A. Summary Judgment Principles.

Summary judgment is appropriate in those cases where it is established through pleadings, affidavits, depositions, and other discovery documents that there exists no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48, 106 S. Ct. 2505, 2510, 91 L. Ed. 2d 202 (1986). Thus, it is the burden of the moving party to show the court that no material factual issues exist for trial. Of course, the court must draw any permissible inference from the underlying facts as established in the record in the light most favorable to the nonmoving party. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587-88, 106 S. Ct. 1348, 1356-57, 89 L. Ed. 2d 538 (1986); Pulliam Inv. Co. v. Cameo Properties, 810 F.2d 1282, 1286 (4th Cir. 1987).

When the moving party has carried its burden, the nonmoving party must come forward with evidence which shows more than some "metaphysical doubt" that genuine and material factual issues exist. Matsushita, 475 U.S. at 586, 106 S. Ct. at 1356. A mere scintilla of evidence presented by the nonmoving party is insufficient to circumvent summary judgment. Anderson, 477 U.S. at 252, 106 S. Ct. at 2512. Rather, the nonmoving party must convince the court that, upon the record taken as a whole, a

rational trier of fact could find for the nonmoving party. Id. at 248-49, 106 S. Ct. at 2510-11.

B. Congress Has Not Withheld Jurisdiction to Regulate Tobacco Products from the Food and Drug Administration.

Plaintiffs assert that Congress clearly intended to withhold jurisdiction to regulate tobacco products from FDA. Plaintiffs urge that the general structure and history of the FDCA and three federal statutes which address tobacco products reveal Congress' intent to reserve to itself the authority to shape federal policy regarding tobacco products and, moreover, that the Regulations directly conflict with and are precluded by the three congressional tobacco-specific statutes.

The court reviews FDA's construction of the FDCA under the analysis set forth in Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 104 S. Ct. 2778, 81 L. Ed. 2d 694 (1984). The first responsibility is to determine whether Congress has directly spoken to the precise question at issue for "[i]f the intent of Congress is clear, that is the end of the matter." Id. 467 U.S. at 842, 104 S. Ct. at 2781. If, however, the statute "is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." Id. 467 U.S. at 843, 104 S. Ct. at 2782.

1. Congress Expressed No Clear Intent in the Federal Food, Drug, and Cosmetic Act to Withhold Jurisdiction to Regulate Tobacco Products from the Food and Drug Administration.

a. The Text of the Federal Food, Drug, and Cosmetic Act.

The precise question presented to the court is whether Congress has evidenced its clear intent to withhold from FDA jurisdiction to regulate tobacco products as customarily marketed.[3] The inquiry as to whether Congress has directly spoken to the issue should begin with an examination of the text of the FDCA.[4] Mead Corp. v. Tilley, 490 U.S. 714, 722, 109 S. Ct. 2156, 2162, 104 L. Ed. 2d 796 (1989); Kofa v. INS, 60 F. 3d 1084, 1088 (4th Cir. 1995). A product is subject to the FDCA if it meets the statute's definition of a "food," "drug," "device," or "cosmetic." See 21 U.S.C. § 321. Rather than itemize each

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[3]Plaintiffs do not dispute that FDA has authority to regulate tobacco products marketed as providing medical or other health benefits. See United States v. 354 Bulk Cartons Trim Reducing-Aid Cigarettes, 178 F. Supp. 847 (D.N.J. 1959) (manufacturer claimed in display cards, circulars, and point-of-sale materials that its brand was effective for weight reduction); United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes, 113 F. Supp. 336 (D.N.J. 1953) (manufacturer promoted the cigarettes through leaflets as effective in preventing certain diseases).

[4]In support of their assertion that Congress has clearly withheld from FDA jurisdiction over tobacco products, Plaintiffs devote only a small portion of their brief to an examination of the text of the FDCA. Plaintiffs contend that neither the text of the FDCA nor its direct legislative history addresses tobacco products and that the court should, therefore, focus its inquiry on federal legislation that specifically addresses tobacco products. The court will instead first examine the text and legislative history of the FDCA.

product subject to regulation under the FDCA, Congress defined these categories broadly so that each encompasses a wide range of products.

As will be discussed more fully regarding the second issue raised by Plaintiffs, the court finds that tobacco products fit within the FDCA's definitions of "drug" and "device." Therefore, Plaintiffs must prove to the court that Congress has expressed its clear intent to withhold from FDA jurisdiction to regulate tobacco products in some place other than the text of the FDCA.

b. The Legislative History of the Federal Food, Drug, and Cosmetic Act.

Both parties find support for their arguments in the FDCA's legislative history. Plaintiffs first note that tobacco products not only were highly visible in the years preceding passage of the FDCA, but also were recognized by the federal government as a separate sector of the economy. (Pls.' First Br. Supp. Mot. Summ. J. at 8-9.) Plaintiffs contend that had Congress meant to place such highly visible and controversial products within FDA's jurisdiction, the legislative history of the FDCA would reveal some discussion of the matter. FDA, on the other hand, argues that in its enactment of the FDCA in 1938, Congress broadened the scope of the previous food and drug law, and, despite the high visibility of tobacco products, never excluded them from the FDCA's reach.

Congress passed the first food and drug law, the Pure Food and Drugs Act, in 1906. Pub. L. No. 59-384, 34 Stat. 768 (1906).

The 1906 Act defined "drug" to include "all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substances or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals." Id. In 1938, Congress passed the FDCA and expanded the definition of "drug" to include articles "intended to affect the structure or function of the body." 21 U.S.C. § 321(g)(1)(C). The House Report accompanying the FDCA explained that the expansion of the definition of "drug" was intended to "amplif[y] and strengthen[]" the FDCA. H.R. Rep. No. 75-2139, at 2 (1938).

In addition to expanding the definition of "drug," Congress added the "device" category to the FDCA in 1938 and included within its definition "instrument[s], apparatus, implement[s], machine[s], contrivance[s], . . . including any component, part, or accessory . . . intended to affect the structure or any function of the body." 21 U.S.C. § 321(h)(3). Congress determined that the "expansion of the definition of the term 'drug' and the inclusion of devices are essential if the consumer is to be protected against a multiplicity of abuses not subject to the present law." S. Rep. No. 74-646, at 1 (1935). Thus Congress, intending to expand the scope of the federal food and drug laws, broadly defined the categories of products to which the FDCA would apply.

In their examination of the legislative history of the FDCA, Plaintiffs focus on the absence of any discussion of tobacco products and assert that although Congress was aware of the possibility of extending FDA's jurisdiction to reach tobacco products, it chose not to. Plaintiffs note that in 1914, FDA's predecessor agency, the Bureau of Chemistry in the Department of Agriculture, expressed its view that it could not regulate tobacco products as customarily marketed under the 1906.Act. Bureau of Chemistry, U.S. Department of Agriculture, Service & Regulatory Announcements, No. 13 (Apr. 2, 1914). Plaintiffs also note that in 1929, legislation which would have amended the 1906 Act to cover tobacco products was introduced and referred to the Committee on Agriculture and Forestry, but never passed. S. 1468, 71st Cong. (1929). Thus, Plaintiffs contend that Congress was aware of both the highly visible tobacco products and of the possibility of extending jurisdiction under the food and drug laws to cover tobacco products. Plaintiffs conclude that had Congress contemplated placing tobacco products within the reach of the FDCA, there would have been opposition to, or, at the very least, discussion of the matter. (Pls.' First Br. Supp. Mot. Summ. J. at 9, n.9.)

The legislative history's silence regarding tobacco products does not indicate that Congress clearly intended to exempt such products from the Act. The FDCA applies to any product which meets one of the broad definitions of the Act, and the absence of discussion of the Act's application to even a highly visible

product does not foreclose regulation of that product under the Act. This court is convinced that neither the text nor the legislative history of the FDCA evidences clear congressional intent to withhold from FDA authority to regulate tobacco products.

c. The Food and Drug Administration's Representations to Congress, Statements of Members of Congress, and Unenacted Legislation.

Plaintiffs contend that FDA's past representations to Congress, the remarks of certain members of Congress, and a series of unenacted bills reveal not only that Congress believed that FDA lacked authority to regulate tobacco products, but also that Congress acquiesced to and ratified that position.

FDA officials testified before congressional committees on numerous occasions that the agency lacked jurisdiction to regulate tobacco products. For example, FDA informed Congress in 1963 that tobacco products as customarily marketed did not meet the definitions in the FDCA for food, drug, device, or cosmetic. See Letter from FDA Bureau of Enforcement (May 23, 1963), reprinted in Hearings Before the Consumer Subcomm. of the Senate Comm. on Commerce on S. 1454, 92d Cong., 2d Sess. 240 (1972) ("1972 Hearings"). In 1965, an FDA official testified at a congressional hearing that FDA "has no jurisdiction under the [FDCA] over tobacco, unless it bears drug claims." Cigarette Labeling and Advertising, Hearing Before the House Comm. on Interstate and Foreign Commerce on H.R. 2248, 89th Cong. 193

(1965). In 1972, FDA Commissioner Charles Edwards testified that although cigarettes and other tobacco products would be drugs within the meaning of the FDCA if medical claims were made for them, "cigarettes recommended for smoking pleasure are beyond the [FDCA]." 1972 Hearings at 239. In 1989, FDA Commissioner Frank Young once again conveyed to Congress that "it doesn't look like it is possible to regulate [tobacco] under the [FDCA] even though smoking, I think, has been widely recognized as being harmful to human health." Hearing Before the Subcomm. on Rural Development, Agriculture, and Related Agencies of the House Comm. on Appropriations, 100th Cong. 409 (1989).

In addition to expressing its view to Congress that it lacked jurisdiction to regulate tobacco products, FDA defended that position in court. In May 1977, an anti-tobacco group, Action on Smoking and Health ("ASH"), petitioned FDA to regulate cigarettes as "drugs." Citizen Petition, Dkt. No. 77P-0185 at 4-11 (May 26, 1977). FDA rejected ASH's petition and the circuit court upheld FDA's decision. See ASH v. Harris, 655 F. 2d 236 (D.C. Cir. 1980). One year later, ASH petitioned FDA to regulate cigarettes as "devices," Citizen Petition, Dkt. No. 78P-0338 (Oct. 2, 1978), and FDA rejected ASH's petition. Letter from Acting Commissioner Mark Novitch for Commissioner of Food and Drugs to John F. Banzhaf, III, at 3 (November 25, 1980), Dkt. Nos. 77P-0185, 78P-0338/CP.

There is little question that members of Congress agreed with FDA's assertions that it lacked jurisdiction and, in an

effort to remedy the situation, introduced numerous bills which would have expressly granted FDA authority to regulate tobacco products. None of the bills passed. See, e.g., H.R. 11280, 84th Cong. (1956); S. 2554, 85th Cong. (1957); H.R. 592, 85th Cong. (1957); S. 1682, 88th Cong. (1963); H.R. 5973, 88th Cong. (1963); H.R. 9512, 88th Cong. (1963); H.R. 2248, 89th Cong. (1965); H.R. 2419, 95th Cong. (1977); H.R. 3879, 95th Cong. (1977); H.R. 7168, 95th Cong. (1977); S. 3317, 95th Cong. (1978); H.R. 279, 96th Cong. (1979); H.R. 3294, 99th Cong. (1987); H.R. 1494, 100th Cong. (1989); S. 769, 100th Cong. (1989). In introducing many of these bills, members of Congress stated that the legislation was needed to give FDA jurisdiction to regulate tobacco products.

Thus, there is evidence not only that FDA previously asserted that it lacked jurisdiction to regulate tobacco products as customarily marketed, but also that some members of Congress agreed with FDA and introduced legislation to expressly grant FDA jurisdiction. Plaintiffs conclude that Congress believed FDA lacked jurisdiction and that its rejection of bills designed to expressly grant FDA such jurisdiction, its amendment of the FDCA without granting such jurisdiction, and its enactment of other tobacco-specific legislation reveal that Congress acquiesced to and ratified FDA's assertion of lack of jurisdiction. The court must first determine whether Congress acquiesced to or ratified FDA's previous assertions of lack of authority, and, if the court

finds that Congress did, determine whether FDA permissibly adapted its position to new evidence.

i. Congress Neither Acquiesced to Nor Ratified the Food and Drug Administration's Position.

The Supreme Court has recognized that unenacted bills generally provide rather unpersuasive evidence of congressional intent. See Central Bank of Denver v. First Interstate Bank of Denver, 511 U.S. 164, ___, 114 S. Ct. 1439, 1453, 128 L. Ed. 2d 119 (1994) ("[F]ailed legislative proposals are a particularly dangerous ground on which to rest an interpretation of a prior statute.") (internal citations omitted). Further, "the interpretation given by one Congress (or a committee or member thereof) to an earlier statute is of little assistance in discerning the meaning of that statute." Id. at ___, 114 S. Ct. at 1452 (quoting Public Employees Retirement Sys. of Ohio v. Betts, 492 U.S. 158, 168, 109 S. Ct. 2854, 2861, 106 L. Ed. 2d 134 (1989)).

Despite its general reluctance to rely on unenacted bills and statements by members of Congress as evidence of congressional intent, the Supreme Court has held that the rejection of bills by Congress may be relevant to a determination of congressional intent where there are extraordinary circumstances. See Bob Jones University v. United States, 461 U.S. 574, 600-02, 103 S. Ct. 2017, 2032-34, 76 L. Ed. 2d 157 (1983) (Where "exhaustive hearings" were held on specific issue and "no fewer than 13 bills introduced," Congress' "failure to

act" was relevant.); United States v. Riverside Bayview Homes, Inc., 474 U.S. 121, 137, 106 S. Ct. 455, 464, 88 L. Ed. 2d 419 (1985) (Congress' failure to act is relevant "particularly where the administrative construction has been brought to Congress' attention through legislation specifically designed to supplant it."). Plaintiffs contend that FDA's previous assertions that it lacked jurisdiction, Congress' rejection of legislation designed to grant FDA jurisdiction, and the belief of some members of Congress that FDA lacked jurisdiction are extraordinary circumstances which are relevant to a determination of congressional intent. The court is persuaded that the circumstances presented fall short of the extraordinary circumstances found in Riverside Bayview Homes and Bob Jones University.

In Riverside Bayview Homes, the Army Corps of Engineers exercised jurisdiction over wetlands pursuant to the Clean Water Act. Soon thereafter, while considering amendments to the Clean Water Act, Congress specifically considered the regulations. After lengthy debates in both chambers regarding the Corps' assertion of jurisdiction, the Senate version, which did not deny the Corps jurisdiction over wetlands, passed. The House version, however, which denied the Corps jurisdiction, failed to pass. The Court noted that although it would not usually attribute significance to Congress' failure to act, a refusal by Congress to overrule agency construction of a statute, particularly where that construction was brought to the attention of Congress by

means of legislation specifically designed to supplant it, was persuasive.

In Bob Jones University, the Supreme Court upheld a challenged Internal Revenue Service ("IRS") ruling. Noting congressional failure to modify the ruling despite full awareness of it and refusal to pass 13 bills which had been introduced to reverse the ruling, the Court stated that Congress had done more than merely fail to act on legislative proposals and had actually acquiesced to the IRS's interpretation. The Court also noted that Congress had affirmatively manifested acquiescence to the policy when it reenacted a version of the section at issue without altering the position taken by the IRS.

Both Riverside Bayview Homes and Bob Jones University are distinguishable from this case. First, the regulations at issue in Riverside Bayview Homes generated a greater response in Congress than did any of FDA's assertions of lack of jurisdiction. Specifically, in Riverside Bayview Homes, Congress rejected legislation that would have altered the Corps' regulations and passed legislation that did not alter those regulations only after extensive debate in both chambers. In this case, of the numerous bills introduced to grant FDA jurisdiction over tobacco products, none were reported out of committee. (Defs.' Br. Opp'n Mot. Summ. J. at 36.) Moreover, both Riverside Bayview Homes and Bob Jones University involved congressional consideration not of an agency's assertion of inability to act, but of agency action. Thus, in both Riverside

Bayview Homes and Bob Jones University, the agency took action,[5] Congress subsequently considered the matter, and ultimately decided not to invalidate the agency action. In this case, Plaintiffs urge the court to find that Congress acquiesced not to agency action, but rather to assertions by an agency that it lacked power to act. No case finding congressional acquiescence after an agency's assertion of lack of jurisdiction to act has been cited to the court. The acquiescence argument is less persuasive in this context.

Even if Congress acquiesced to or ratified FDA's prior position that it lacked jurisdiction to regulate tobacco products, the Supreme Court has held that congressional acquiescence to or ratification of agency policy would not necessarily connote approval or disapproval of the agency's later alteration of that policy. See Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 45, 103 S. Ct. 2856, 2867-68, 77 L. Ed. 2d 443 (1983) ("While an agency's interpretation of a statute may be confirmed or ratified by subsequent congressional failure to change that interpretation, . . . even an unequivocal ratification — short of statutory incorporation — of the [agency's interpretation] would not connote approval or disapproval of an agency's later decision to

[5]The Army Corps of Engineers promulgated regulations in United States v. Riverside Bayview Homes, Inc., 474 U.S. 121, 106 S. Ct. 455, 88 L. Ed. 2d 419 (1985), and the Internal Revenue Service issued rulings in Bob Jones University v. United States, 461 U.S. 574, 103 S. Ct. 2017, 76 L. Ed. 2d 157 (1983).

[alter that interpretation]."). Even if Congress acquiesced to FDA's assertion of lack of jurisdiction, such acquiescence would not necessarily connote Congress' opposition to FDA's assertion of jurisdiction.

ii. The Food and Drug Administration May Adapt its Position to New Evidence.

The Supreme Court has held that an agency is entitled to adapt its policies. See Chevron, 467 U.S. at 863-64, 104 S. Ct. at 2792 ("An initial agency interpretation is not instantly carved in stone. On the contrary, the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis."). For example, in Motor Vehicles Mfrs. Ass'n, 463 U.S. 29, 103 S. Ct. 2856, the Court reviewed the Secretary of Transportation's rescission of a requirement that automobiles be equipped with passive restraint systems and held that previous congressional support for the passive restraint requirement did not preclude a change in policy. The Court noted that it "fully recognize[d] that regulatory agencies do not establish rules of conduct to last forever" and that "an agency must be given ample latitude to adapt [its] rules and policies to the demands of changing circumstances." Id. at 42, 103 S. Ct. at 2866 (internal citations omitted); see also Rust v. Sullivan, 500 U.S. 173, 111 S. Ct. 1759, 114 L. Ed. 2d 233 (1991) (Noting that an agency may revise a previous interpretation, the Court rejected the plaintiffs' argument that the challenged regulations were not

entitled to deference under the second prong of Chevron analysis because they reversed the agency's longstanding interpretation of the statute.); ASH, 655 F. 2d 236, 242 n.10 (D.C. Cir. 1980) (The court noted, in upholding FDA's denial of jurisdiction to regulate cigarettes, that "[n]othing in this opinion should suggest that [FDA] is irrevocably bound by any long-standing interpretation and representations thereof to the legislative branch. An administrative agency is clearly free to revise its interpretations.").

FDA contends that it has not altered its interpretation of the FDCA but rather has applied its longstanding interpretation to new evidence. As more fully addressed in the court's discussion of the second issue raised by Plaintiffs, the court finds FDA's contention to be reasonable. Chevron, Motor Vehicles Mfrs. Ass'n, and Rust support the finding that FDA is entitled to adapt its position in light of new evidence.

Thus, the text of the FDCA, its legislative history, and the body of evidence consisting of FDA's representations to Congress, unenacted bills, and statements by members of Congress do not clearly indicate that Congress intended to withhold from FDA the authority to regulate tobacco products.

2. Congress' Tobacco-Specific Legislation Does Not Reveal that Congress Intended to Withhold Jurisdiction to Regulate Tobacco Products from the Food and Drug Administration.

Plaintiffs assert that Congress has reserved to itself the authority to set federal policy regarding tobacco products.

Plaintiffs explain that the structure and history of the Federal Cigarette Labeling and Advertising Act ("FCLAA"),[6] the Comprehensive Smokeless Tobacco Health Education Act ("CSTHEA"),[7] and the Alcohol, Drug Abuse, and Mental Health Reorganization Act of 1992 ("ADAMHA Amendments")[8] reveal Congress' clear intent on the matter. Plaintiffs further urge that conflict between the Regulations and Congress' tobacco-specific legislation supports their argument that Congress clearly reserved to itself the authority to regulate tobacco products. Each statute must be separately addressed.

a. The Federal Cigarette Labeling and Advertising Act.

Plaintiffs' position is that Congress, believing that FDA lacked jurisdiction to regulate tobacco products, decided to address the concerns raised by tobacco use. Plaintiffs further assert that Congress, in enacting and later amending the FCLAA, expressed its clear intent to shape federal policy regarding tobacco products and to deny FDA a role in implementing that policy. The FCLAA's declaration of policy and purpose states:

> It is the policy of Congress, and the purpose of this chapter, to establish a comprehensive Federal program to deal with cigarette labeling and advertising

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[6] 15 U.S.C. §§ 1331-40.

[7] 15 U.S.C. §§ 4401-08.

[8] 42 U.S.C. § 300x-26.

with respect to any relationship between smoking and health, whereby —

> (1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and
>
> (2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.

15 U.S.C. § 1331. Plaintiffs conclude that this statement of policy evidences Congress' intent to set all federal policy regarding cigarette labeling and advertising.

From a review of only the FCLAA's statement of policy and purpose, Congress arguably intended to preempt any regulation of tobacco products not specifically ordered by Congress. Yet Congress drafted the FCLAA's separate preemption provision very narrowly so as to provide, in relevant part, only that "[n]o statement relating to smoking and health, other than the statement required by section 1333 of this title, shall be required on any cigarette package." 15 U.S.C. § 1334.[9]

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[9]The court acknowledges that federal-state preemption law does not directly govern the issue of FDA's jurisdiction to regulate tobacco products. Nevertheless, principles from federal-state preemption law apply to the issue of whether Congress has forbidden FDA from regulating tobacco products. Indeed, both the FCLAA and the CSTHEA contain "preemption" sections which specifically address the authority of federal agencies to regulate both cigarettes and smokeless tobacco products, respectively. See 15 U.S.C. §§ 1334, 4406.

The relatively narrow preemptive scope of § 1334 precludes a finding that Congress intended to reserve to itself alone the power to regulate tobacco products. Although § 1331 states that the FCLAA is designed to establish a comprehensive federal program, Congress did not expressly preclude other regulation of tobacco products in § 1334. "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted." Cipollone v. Liggett Group, Inc., 505 U.S. 504, 517, 112 S. Ct. 2608, 2618, 120 L. Ed. 2d 407 (1992) (discussing preemptive scope of § 1334(b), which addresses federal preemption of state law).

Plaintiffs also assert that portions of the FCLAA directly conflict with FDA's assertion of authority. Specifically, Plaintiffs assert that the FCLAA conflicts with the Regulations in the following areas. First, they say that Congress currently permits the manufacture and sale of cigarettes that comply with the FCLAA, and conclude from that fact that Congress in the FCLAA decided that print advertising of tobacco products "should remain lawful, so long as it carries the congressionally-mandated warnings." (Pls.' First Br. Supp. Mot. Summ. J. at 32.) Such conclusion is unwarranted. The fact that Congress has up to this date allowed the manufacture and sale of cigarettes that carry the required warnings does not clearly demonstrate that Congress has determined that no other requirements may be imposed. Congress crafted narrow preemption language in the FCLAA which does not evidence an intention to preclude other regulation of

tobacco products. FDA's restrictions on advertising and promotion do not conflict with either the language or the purpose of the FCLAA.

Second, Plaintiffs assert that the Regulations' requirement that cigarette packages state the "established name" of the product (e.g., "cigarette," "cigarette tobacco") and bear the statement "Nicotine-Delivery Device for Persons 18 or Older" is expressly preempted by the FCLAA. FDA agrees that the FCLAA prohibits FDA from requiring packages or advertisements to carry any statement related to smoking and health. FDA argues, however, that the inclusion of the established name merely provides basic information to those coming into contact with the product and that the statement of intended use merely advises consumers about the product's intended use. According to FDA, neither statement relates to smoking and health within the meaning of § 1334 because neither qualifies as a cautionary statement and that, therefore, neither statement is preempted by the FCLAA.

The Supreme Court addressed the preemptive scope of the FCLAA in Cipollone, 505 U.S. 504, 112 S. Ct. 2608 (1992). The Court was faced in part with the issue of whether the FCLAA preempted state common law claims of failure to warn. The Court stated that the phrase "No statement relating to smoking and health"

> referred to the sort of warning provided for in [§ 1333], which set forth verbatim the warning Congress determined to be appropriate. Thus, on their face, these provisions merely prohibited state and federal

> rule-making bodies from mandating particular cautionary statements on cigarette labels . . . or in cigarette advertisements . . . .

Id. at 518, 112 S. Ct. at 2618.[10] Neither the statement of intended use nor the established name required by the Regulations is a particular cautionary statement of the type required in § 1333. Thus, neither is expressly preempted by the FCLAA.

The Regulations do not conflict with the text of the FCLAA, and the general structure and purpose of the FCLAA do not evidence Congress' clear intent to withhold jurisdiction from FDA to regulate tobacco products.

b. The Comprehensive Smokeless Tobacco Health Education Act.

Plaintiffs assert that Congress, when it passed the CSTHEA in 1986, reserved to itself the authority to set federal policy regarding smokeless tobacco products. The CSTHEA, like the FCLAA, contains a relatively narrow preemption provision, which provides in relevant part that:

> (a) Federal action
>
> No statement relating to the use of smokeless tobacco products and health, other than the statements required by section 4402 of this title, shall be required by any Federal agency to appear on any package or in any advertisement (unless the advertisement is an outdoor billboard advertisement) of a smokeless tobacco product.

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[10]Section 1334(b), rather than § 1334(a), was at issue in Cipollone v. Liggett Group, Inc., 505 U.S. 504, 112 S. Ct. 2608, 120 L. Ed. 2d 407 (1992). Nonetheless, the Court's analysis is applicable because the relevant language in the two sections is the same.

15 U.S.C. § 4406. Thus, although the CSTHEA is entitled the Comprehensive Smokeless Tobacco Health Education Act, and although Congress addressed in the CSTHEA several of the concerns addressed by FDA in the Regulations, the court finds that Congress did not intend to reserve to itself the exclusive authority to regulate smokeless tobacco products. Rather, the preemptive scope of the CSTHEA is defined by § 4406 because "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted." Cipollone, 505 U.S. at 517, 112 S. Ct. at 2618. The narrow effect of § 4406 precludes a finding that Congress intended that the CSTHEA preclude all FDA regulation of smokeless tobacco products.

Plaintiffs urge that the CSTHEA expressly preempts the Regulations. Specifically, they contend that FDA's requirement that tobacco products bear a statement of intended use is preempted because the statement relates to the use of smokeless tobacco products and health. The preemption clause of the CSTHEA, like that of the FCLAA, does not preempt FDA's requirement that tobacco products bear both a statement of intended use and the established name of the product.

Thus, the Regulations do not conflict with the text of the CSTHEA, and the general structure and purpose of the CSTHEA do not evidence Congress' clear intent to withhold from FDA jurisdiction to regulate tobacco products.

c. The Alcohol, Drug Abuse, and Mental Health Reorganization Act of 1992.

Plaintiffs assert that Congress' enactment of the ADAMHA Amendments in 1992 evidences Congress' intent to deny FDA jurisdiction over tobacco products. The ADAMHA Amendments withhold federal substance abuse block grants from states that fail to enact and enforce laws prohibiting tobacco sales to minors. Plaintiffs contend that in enacting the ADAMHA Amendments, Congress determined that the initiative for addressing youth access to tobacco products should remain at the state level, and that the appropriate federal role in tackling youth access to tobacco products is to encourage and help the states in the implementation and enforcement of state policy regarding tobacco products. Plaintiffs further assert that FDA's national program conflicts directly with what Plaintiffs contend is the thrust of the ADAMHA Amendments, which is to place the initiative for development of regulations addressing youth access to tobacco products at state level.

Plaintiffs find that the conflict between the ADAMHA Amendments and the Regulations is clearly demonstrated by the FDCA's preemption provision, which preempts the states from imposing on devices "requirements" that are different from or in addition to those imposed by FDA. 21 U.S.C. § 360k. The argument proceeds that if the FDCA applies to tobacco products, § 360k would prohibit states from addressing the issue of youth access. FDA responds that the Regulations will not affect many

aspects of state regulation of underage smoking and that states may qualify for exemptions from the Regulations pursuant to 21 U.S.C. § 360k(b). The Regulations will not prevent states from separately enforcing their own laws regarding underage access or from imposing other restrictions on the access to tobacco products.

Finally, Plaintiffs find in the ADAMHA Amendments a congressional statement of policy regarding tobacco products that is not apparent to the court. The ADAMHA Amendments restructured several federal substance abuse and mental health programs to create two block grants, one directed to drug and alcohol abuse programs, and the other to community mental health services. To receive funds under the substance abuse block grant program, states must conform to a number of conditions, only a few of which relate to the availability of tobacco products to children under the age of 18.[11] The ADAMHA Amendments merely establish conditions for the receipt of federal funds and do not represent an all-encompassing last-word pronouncement of federal policy on underage smoking. The discretionary block grant scheme established by the ADAMHA Amendments does not impliedly preclude

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[11]The conditions relating to underage access restrictions provide that states must: (i) prohibit sales to children under 18; (ii) enforce that prohibition "in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18"; (iii) conduct annual random, unannounced inspections of tobacco retailers; and (iv) make annual reports to the Department of Health and Human Services concerning the method and effects of the state enforcement efforts. 42 U.S.C. § 300x-26.

further federal requirements regarding tobacco products. Therefore, the court finds that the Regulations conflict with neither the text nor the structure of the ADAMHA Amendments.

Plaintiffs would have the court find from the structure, history, and specific provisions of the FCLAA, the CSTHEA, and the ADAMHA Amendments that Congress clearly intended to reserve to itself, and to withhold from FDA, jurisdiction to regulate tobacco products. Further, Plaintiffs say that the three statutes, working together, comprise Congress' comprehensive policy regarding tobacco products. These conclusions are not justified. Congress, in enacting and later amending the three statutes, adopted narrow preemption language, evidencing its intent not to prohibit other agency action in the area. Moreover, the court cannot find, as Plaintiffs urge, that the three statutes, construed together, evidence Congress' clear intent to withhold from FDA jurisdiction to regulate tobacco products.[12]

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[12]The court is not presented with a situation similar to that in International Bhd. of Teamsters v. Daniel, 439 U.S. 551, 99 S. Ct. 790, 58 L. Ed. 2d 808 (1979). The issue in International Bhd. of Teamsters was whether the Securities Exchange Act ("SEA"), as asserted by the Securities and Exchange Commission ("SEC"), appearing as amicus, applied to noncontributory compulsory pension plans. The Court noted that the Employee Retirement Income Security Act ("ERISA"), which was enacted after the SEA, constituted comprehensive legislation governing the use and terms of employee pension plans and found that Congress had enacted ERISA in order to fill the regulatory gap that had been created regarding pension plans. The Court noted that SEC had never before interpreted the SEA to apply to noncontributory compulsory pension plans and found that SEC's new interpretation was precluded by the later comprehensive ERISA. As explained

(continued...)

In conclusion, the FDCA, the FCLAA, the CSTHEA, and the ADAMHA Amendments do not reveal that Congress clearly intended to withhold from FDA authority to regulate tobacco products.

C. The Food and Drug Administration May Regulate Tobacco Products Pursuant to the Federal Food, Drug, and Cosmetic Act.

Plaintiffs assert that tobacco products do not fall within the FDCA's definitions of "drug" and "device." Plaintiffs further assert that FDA misapplied the provisions of the FDCA to tobacco products, and that FDA's misapplication of the Act further demonstrates that FDA lacks jurisdiction to regulate tobacco products under the FDCA. The court's responsibility is to determine whether tobacco products fit within the FDCA's definitions of "drug" and "device" and then to examine FDA's application of the Act to tobacco products.

1. Tobacco Products Fall Within the "Drug" and "Device" Definitions of the Federal Food, Drug, and Cosmetic Act.

The FDCA defines "drug" and "device," in relevant part, as follows:

> The term "drug" means . . . (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect

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[12](...continued)
above, the FCLAA, the CSTHEA, and the ADAMHA Amendments, unlike ERISA, do not create a comprehensive federal approach to the regulation of tobacco products, making this case distinguishable from International Bhd. of Teamsters.

> the structure or any function of the body of man or other animals.
>
> 21 U.S.C. § 321(g)(1).
>
> The term "device" . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is —
>
> . . . .
>
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (3) intended to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.
>
> 21 U.S.C. § 321(h).[13]

FDA offers that tobacco products fall within the FDCA's definitions of "drugs" and "devices" because they are "intended to affect the structure or any function of the body." FDA explains that the nicotine in tobacco products affects the structure or function of the body by causing and sustaining

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[13]The court will refer to §§ 321(g)(1)(C) and (h)(3) as the "structure-or-function" definitions of "drug" and "device," respectively, and to §§ 321(g)(1)(B) and (h)(2) as the "treatment-of-disease" definitions of "drug" and "device," respectively. The court includes the treatment-of-disease definition because of its relevance to the court's discussion of the meaning of intended use. Specifically, since both definitions refer to the intended use of a product, both are relevant to the court's interpretation of the phrase.

addiction and by acting as a stimulant, sedative, and weight regulator. FDA further argues that manufacturers intend nicotine to produce such effects. Plaintiffs disagree, claiming that tobacco products neither "affect the structure or any function of the body" nor are intended to affect the structure or function of the body within the meaning of the FDCA.

a. Tobacco Products' Effects are "Intended" Within the Meaning of the Federal Food, Drug, and Cosmetic Act.

Plaintiffs claim that a product's "intended use" can be established only by manufacturer representations about the product.[14] FDA counters that it appropriately relied on evidence of foreseeability, consumer use, and internal manufacturer memoranda to establish intended use. The text, legislative history, and past judicial and agency interpretation of the structure-or-function definitions of "drug" and "device" reveal that intended use may be established by evidence other than manufacturer representations.

Since the FDCA does not define "intend," the court must give the term its ordinary meaning. See Asgrow Seed Co. v. Winterboer, 513 U.S. 179, 115 S. Ct. 788, 793, 130 L. Ed. 2d 682 (1995) ("When terms used in a statute are undefined, we give them

[14]FDA does not contend that tobacco manufacturers make any representations in connection with the sale of tobacco products. Therefore, if intended use can be established only by manufacturer representations, tobacco products would not be subject to regulation pursuant to the FDCA.

their ordinary meaning."). FDA directs the court to two definitional sources. First, a dictionary defines "intend" as "[t]o have in mind; plan . . . . [t]o design for a specific purpose. . . . [t]o have in mind for a particular use." The American Heritage Dictionary 668 (2d ed. 1991). Second, according to FDA, the court should consider the legal usage of "intend," which includes the principle that one intends the readily foreseeable consequences of his actions. See Agnew v. United States, 165 U.S. 36, 53, 17 S. Ct. 235, 242, 41 L. Ed. 2d 624 (1897) ("The law presumes that every man intends the legitimate consequences of his own acts."). From this definition and usage, the plain meaning of "intend" does not indicate that intent must be proven by any particular kind of evidence. In addition, the text of the structure-or-function and the treatment-of-disease definitions does not limit the type of evidence upon which FDA may rely to establish intended use. Indeed, Plaintiffs have made no attempt to argue that the text of the FDCA supports their position that only manufacturer representations can establish intended use. It is clear that the plain language of the structure-or-function definition does not prohibit consideration of evidence other than manufacturer representations in determining a product's intended use. Since, however, the text does not disclose the types of evidence upon which FDA may rely to establish intended use, it is necessary to examine the relevant legislative history.

Plaintiffs assert that the legislative history of the phrases "intended to affect" and "intended for use" is unambiguous and, furthermore, supports their argument that intended use must be established by manufacturer representations. (Pls.' Second Br. Supp. Mot. Summ. J. at 8.) First, Plaintiffs note the following section of a Senate Report which addresses the method of determining whether a product would, for example, meet the Act's "food" or "drug" definitions:

> The use to which the product is to be put will determine the category into which it will fall . . . . The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put.

S. Rep. No. 74-361, at 4 (1935); see also S. Rep. No. 73-493, at 111-12 (1934) (same). This statement is not unambiguous, and, moreover, does not clearly support Plaintiffs' position. The first sentence is consistent with FDA's position that the use of the product can establish intended use. In addition, the second sentence does not reveal that Congress intended to limit the types of evidence that could be relied on to establish intended use. Indeed, Congress' use of "can" rather than "will" arguably shows that Congress did not intend for manufacturer representations to provide the only evidence of intended use.

Second, Plaintiffs cite to testimony of FDA Chief Campbell in which he explained that an ordinary product, such as a lamp, would be subject to FDA's jurisdiction if, for example, it were marketed as a cure for blindness. Testimony on S. 2800, 73d Cong., at 518 (1934). Plaintiffs conclude that this legislative

history clearly reveals that both Congress and FDA understood that FDA's jurisdiction "was limited to products represented to provide medical or other health benefits." (Pls.' Second Br. Supp. Mot. Summ. J. at 9.) As mentioned above regarding the first issue, the court should be and is unable to conclude from the testimony of one FDA representative to a congressional committee that Congress expressly incorporated that person's understanding of the bill into the final legislation. In any event, these two pieces of legislative history are not "unambiguous" and, moreover, do not clearly show that Congress intended FDA to rely exclusively upon evidence of manufacturer representations to establish intended use.

Plaintiffs find support for their interpretation of "intended use" in prior judicial construction of the phrase and reason that courts have construed the FDCA to require evidence of manufacturer representations to establish intended use. Although it is true that no court has ever found that a product is "intended for use" or "intended to affect" within the meaning of the FDCA absent manufacturer claims as to that product's use, no court has held that intended use can be established solely by promotional representations. Furthermore, courts have acknowledged, albeit in dicta, that FDA may rely on other types of evidence to establish intended use. See United States v. An Article of Drug "Sudden Change," 409 F. 2d 734, 739 (2d Cir. 1969) ("It is well settled that the intended use of a product may be determined from its label, accompanying labeling, promotional

material, advertising and any other relevant source."); ASH v. Harris, 655 F. 2d 236, 239 (D.C. Cir. 1980) (In the absence of promotional claims, FDA would need to make a substantial showing of evidence of consumer use to justify an inference as to vendor intent.); National Nutritional Foods Ass'n v. FDA, 504 F. 2d 761, 789 (2d Cir. 1974) (In considering whether high potency vitamins sold without therapeutic representations are drugs, FDA is "free to pierce . . . a manufacturer's . . . misleadingly 'nutritional' labels to find actual therapeutic intent on the basis of objective evidence."); United States v. 250 Jars U.S. Fancy Pure Honey, 218 F. Supp. 208, 211 (E.D. Mich. 1963) (To find intended use, a "court is not limited to the labels on such article or to the labeling which accompanies it, but may look at all relevant sources."), aff'd, 344 F. 2d 288 (6th Cir. 1965); United States v. Ten Cartons Ener-B Vitamin B-12, 72 F. 3d 285, 287 (2d Cir. 1995) (An article can be a drug under 21 U.S.C. § 321(g)(1)(C) for reasons other than claims made in the label or labeling, such as "method of intake."). Certainly, courts have recognized that evidence other than manufacturer claims could be used to establish intended use within the meaning of § 321(h)(3).

Finally, Plaintiffs argue that FDA's own regulations require evidence of manufacturer representations to establish intended use. See 21 C.F.R. §§ 201.128, 801.4 (defining "intended use" regarding drugs and devices, respectively).[15] Although the

[15]21 C.F.R. §§ 201.128 and 801.4 provide, in relevant part, that:

(continued...)

regulations defining "intended use" clearly anticipate the establishment of intended use through evidence of promotional claims, the plain language does not prohibit the establishment of intended use by other evidence. To illustrate, the regulations specifically provide that intent may be shown by circumstances surrounding the sale of the article and that one such circumstance could be the offering and use of a product for a purpose for which it is neither advertised nor labeled with the manufacturer's knowledge. The regulations defining "intended use" do not prohibit reliance on evidence other than manufacturer representations to establish intended use.

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[15](...continued)

> The words "intended uses" or words of similar import . . . refer to the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.

The plain language and the legislative history of the drug and device definitions do not reveal that Congress clearly intended for FDA to rely only upon evidence of manufacturer representations to establish intended use. In addition, past judicial and agency construction of the definitions does not foreclose consideration by FDA of other evidence to establish intended use. Even so, the court must still determine whether FDA properly relied upon evidence of foreseeability, actual consumer use, and internal manufacturer memoranda to establish intended use.

i. Foreseeable Use.

Although the text of the "drug" and "device" definitions does not expressly state that FDA may consider evidence of foreseeability to establish intended use, nothing in the text or the legislative history of the FDCA prohibits consideration of such evidence. Thus, Congress has not expressed a clear intent regarding whether FDA may consider evidence of foreseeability to establish intended use within the meaning of the FDCA and, finding FDA's interpretation to be reasonable, this court will defer to it. See Chevron, 467 U.S. at 845, 104 S. Ct. at 2783 ("Once [the court] determine[s], after its own examination of the legislation, that Congress did not actually have an intent regarding [the issue], the question before it [is] . . . whether the [agency's] view . . . is a reasonable one.").

ii. Actual Consumer Use.

Plaintiffs assert that FDA may not rely on evidence of actual use to establish intended use within the meaning of the FDCA. Nothing in the text or legislative history of the FDCA prohibits consideration of actual use to establish intended use. Indeed, one House Report expressly contemplates reliance upon such evidence. See H.R. Rep. No. 94-853, at 14 (1976) (FDA may consider "actual use of a product in determining whether or not it is a device."); see also United States v. 22 Devices "The Ster-o-lizer MD-200", 714 F. Supp. 1159, 1165 (D. Utah 1989) (Objective intent may be shown "not only by a product's labeling claims, advertising or written statements relating to the circumstances of a product's distribution, but also by a product's actual use.") (internal citations omitted). Moreover, although no court has expressly held that intended use may be established by evidence of actual use, no court has ever prohibited reliance on such evidence. Some courts have even noted in dicta that evidence of consumer use may establish intended use within the meaning of the FDCA. See ASH v. Harris, 655 F. 2d 236, 240 (D.C. Cir. 1980) (If consumers "use the product predominantly - and in fact nearly exclusively - with the appropriate intent . . .[,] the requisite statutory intent can be inferred."); National Nutritional Foods A'ssn v. Weinberger, 512 F. 2d 688, 703 (2d Cir. 1975) (intended use under the treatment-of-disease definition could possibly be inferred from evidence of near exclusive consumer use). Other courts have also noted in

dicta that evidence of manufacturer intent can be corroborated by evidence of consumer use. See United States v. Kasz Enterprises, Inc., 855 F. Supp. 534, 539 (D.R.I. 1994) (Intended use "can be demonstrated by . . . evidence that the vendor is aware that his product is being offered or used by others for a purpose for which it is neither labeled nor advertised."), modified on other grounds, 862 F. Supp. 717 (D.R.I. 1994); United States v. 789 Cases Latex Surgeons' Gloves, 799 F. Supp. 1275, 1285, 1294-95 (D.P.R. 1992) (intended use determined by all the facts, including "actual use"); United States v. Two Plastic Drums, 761 F. Supp. 70, 72 (C.D. Ill. 1991) ("[A] court should examine a wide range of evidence, including . . . actual use of the product."), aff'd, 984 F. 2d 814 (7th Cir. 1993). Still other courts have expressly relied on actual use as a factor contributing to the establishment of intended use. See United States v. An Article of Device Toftness Radiation Detector, 731 F. 2d 1253, 1257 (7th Cir. 1984) (intended use established in part by witness testimony that device had been used to treat patients); United States v. 22 Devices "The Ster-o-lizer MD-200", 714 F. Supp. at 1165 (court noted that the product was used in the surgical treatment of patients); United States v. An Article of Device "Cameron Spitler Amblyo-Syntonizer", 261 F. Supp. 243, 245 (D. Neb. 1966) (although claimant contended that no representations had been made about the product, he admitted the use of the product).

Again, the FDCA does not reveal that Congress clearly intended to permit or prohibit reliance on evidence of actual use to establish intended use. Finding FDA's determination that it may consider evidence of actual use to establish intended use to be reasonable, especially in light of judicial recognition of the possibility, the court will defer to FDA's interpretation. See Chevron, 467 U.S. at 845, 104 S. Ct. at 2783 ("Once [the court] determine[s], after its own examination of the legislation, that Congress did not actually have an intent regarding [the issue], the question before it [is] . . . whether the [agency's] view . . . is a reasonable one.").

iii. Statements, Knowledge, and Action of Manufacturers.

Plaintiffs assert that FDA may not establish intended use based on evidence of the subjective intent of manufacturers. As previously discussed in the sections regarding evidence of foreseeability and actual use, neither the text nor the legislative history of the FDCA reveals Congress' clear intent to prohibit consideration of such evidence. The court agrees, however, that FDA's own regulations defining "intended use" provide that intended use may be established only by evidence of objective intent. See 21 C.F.R. §§ 201.128, 801.4 ("The words 'intended uses' or words of similar import . . . refer to the objective intent of the persons legally responsible for the labeling of drugs."). Nonetheless, since FDA found that each of the three types of evidence upon which it relied provided

independent bases for finding intended use within the meaning of the Act, 61 Fed. Reg. at 44,632-33, the court concludes that FDA adequately and properly supported its finding of intended use with evidence of foreseeability and consumer use.

b. Tobacco Products Affect the Structure or Function of the Body Within the Meaning of the Federal Food, Drug, and Cosmetic Act.

Plaintiffs infer that Congress intended for the structure-or-function definition of device to "apply only to products that are marketed to provide some medical or other health benefit to users." (Pls.' Second Br. Supp. Mot. Summ. J. at 5.) They support their argument in part by noting that Congress entitled its 1976 amendments to the FDCA's device provisions the "Medical Device Amendments" ("MDA"). The definition of device, however, expressly includes those products "intended to affect the structure or any function of the body of man or other animals" and gives no indication that it is to apply only to those devices with a medical purpose. 21 U.S.C. § 321(h). The plain language of the structure-or-function definition of "device" does not limit the statute's reach to only those devices with a medical purpose.

Neither does the legislative history indicate that Congress intended to limit the scope of the structure-or-function definition to apply only to devices with a medical purpose. Congress included the structure-or-function definition in the FDCA in 1938. Nothing in the legislative history of the 1938 Act

specifically addresses the meaning of the phrase "intended to affect the structure or any function of the body." Congress did explain that the FDCA was intended to broaden the scope of the older food and drug laws to reach, among other things, "therapeutic devices." See H.R. Rep. 75-2139, at 2 (1938). The legislative history of the MDA also reveals some discussion of the general purpose of the device provisions. For example, the Senate Report accompanying the MDA states that "[i]ncreasing numbers of patients have been exposed to increasingly complex devices which pose serious risk if inadequately tested or improperly designed or used" and that FDA lacked the tools under the FDCA to adequately regulate such devices. S. Rep. No. 94-33 (1976). It also notes that Congress recognized the need for "regulation to assure that the public is protected and that health professionals can have more confidence in the performance of devices." Id. The Report further states that the medical device legislation was "intended to assure that medical devices . . . meet the requirements of safety and effectiveness before they are put in widespread use throughout the United States." Id.

Consequently, the legislative history of the structure-or-function definition of "device" suggests that Congress was concerned about the lack of regulation of devices that posed a danger to the public. Although Congress clearly intended that the FDCA apply to devices used within the medical community, nothing in the legislative history indicates that Congress

intended to limit the FDCA's reach to devices offered for beneficial or therapeutic purposes. The fact that Congress contemplated the Act's application to certain medical devices does not foreclose application of the Act to other devices, especially where the text does not preclude such application.

Finally, Plaintiffs urge the court to narrowly construe the structure-or-function definition of device, claiming that acceptance of FDA's regulation of non-therapeutic devices could result in FDA regulating almost anything that can be said to affect the structure or function of the body. This argument lacks merit. See United States v. Sullivan, 332 U.S. 689, 694, 68 S. Ct. 331, 335, 92 L. Ed. 297 (1948) ("The scope of the [statute] . . . is not to be judicially narrowed . . . by envisioning extreme possible applications . . . . There will be opportunity enough to consider such contingencies should they ever arise.").

The four corners of the text and the legislative history of the structure-or-function definition of device do not reveal the clear intent of Congress to include only medical or therapeutic devices within the jurisdiction of the FDCA. FDA's application of the FDCA to non-therapeutic devices is reasonable and entitled to deference from the court. See Chevron, 467 U.S. at 845, 104 S. Ct. at 2783 ("Once [the court] determine[s], after its own examination of the legislation, that Congress did not actually have an intent regarding [the issue], the question before it [is] . . . whether the [agency's] view . . . is a reasonable one.").

2. The Food and Drug Administration May Regulate Tobacco Products as Medical Devices Pursuant to its Device Authorities.

FDA determined that tobacco products are combination products consisting of the drug nicotine and device components which are intended to deliver nicotine to the body. FDA elected to regulate tobacco products pursuant to its device authorities. Plaintiffs argue that FDA has both contorted and evaded the FDCA and that FDA's application of the Act confirms Plaintiffs' assertion that the FDCA's device provisions "simply do not fit tobacco products." (Pls.' Second Br. Supp. Mot. Summ. J. at 47.) The court must first determine whether tobacco products are combination products within the meaning of the FDCA and then ascertain whether FDA has applied the Act to tobacco products in a permissible manner.

a. Tobacco Products are Combination Products Within the Meaning of the Federal Food, Drug, and Cosmetic Act.

Plaintiffs assert that tobacco products are not combination products within the meaning of the Act for three reasons. First, Plaintiffs urge that "a combination product must consist of two products, each of which could be separately regulated" and that tobacco products do not meet that definition. (Pls.' Second Br. Supp. Mot. Summ. J. at 29.) FDA responds that a combination product consists of a combination of a drug, device, and/or biological product, and that the total product need only contain components that meet two of those definitions.

The FDCA does not separately define "combination product," stating only that a combination product is a product "that constitute[s] a combination of a drug, device, or biological product." 21 U.S.C. § 353(g)(1). The plain language of the definition, therefore, does not reveal whether it was Congress' intention that each component be subjected separately to regulation.[16] Since Congress has not expressed its intent

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[16]FDA's regulations define "combination product" to include:

> (1) A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
>
> (2) Two or more separate products packaged together in a single package or as a unit and comprised of drugs and device products, device and biological products, or biological and drug products;
>
> (3) A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
>
> (4) Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.
>
> (f) Device has the meaning given the term in [21 U.S.C. § 321(h)].

(continued...)

regarding whether combination products must be comprised of two separately regulable products, and since FDA's interpretation is reasonable, the court should and will uphold that interpretation. See Chevron, 467 U.S. at 845, 104 S. Ct. at 2783 ("Once [the court] determine[s], after its own examination of the legislation, that Congress did not actually have an intent regarding [the issue], the question before it [is] . . . whether the [agency's] view . . . is a reasonable one.").

Second, Plaintiffs contend that the device component of tobacco products does not meet the definition of "device" because it does not itself affect the structure or function of the body. FDA responds that the device component need only have an indirect effect on the structure or function of the body to meet the definition of "device." The plain language of the structure-or-function definition does not preclude FDA's interpretation. Additionally, FDA has regulated as devices products that do not themselves directly affect the structure or function of the body, but instead deliver to the body an agent or substance that has such a direct effect. See, e.g., 21 C.F.R. § 878.4635 (ultraviolet lamps that deliver ultraviolet light which causes

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[16](...continued)

(g) Drug has the meaning given the term in [21 U.S.C. § 321(g)].

21 C.F.R. § 3.2.

FDA avows that it routinely regards the following products as combination products: pre-filled delivery systems, such as pre-filled syringes, intravenous infusion pumps, nebulizers, metered dose inhalers, and nicotine patches. 61 Fed. Reg. at 45,211.

tanning); 21 C.F.R. § 878.4800 (surgical stapler that delivers staples that affect body tissues by holding them together); 21 C.F.R. § 880.5475 (jet lavage that delivers sterile fluid that cleans wounds); 21 C.F.R. § 880.5570 (hypodermic needle that delivers drug substance to site on body); 21 C.F.R. § 868.5580 (oxygen mask that delivers oxygen for absorption by the lungs).

Nothing in the text nor the history of the FDCA suggests that a product must directly, rather than indirectly, affect the structure or function of the body to be subject to regulation under the Act. Furthermore, FDA's interpretation is reasonable. See Chevron, 467 U.S. at 845, 104 S. Ct. at 2783 ("Once [the court] determine[s], after its own examination of the legislation, that Congress did not actually have an intent regarding [the issue], the question before it [is] . . . whether the [agency's] view . . . is a reasonable one.").

Third, Plaintiffs protest that tobacco products have no device components within the meaning of the Act because they fall within an explicit exception of the device definition. The FDCA excludes from the definition of "device" a product "which . . . achieve[s] its primary intended purposes through chemical action within or on the body of man or other animals and which is . . . dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h)(3). FDA has found that the primary mode of action of tobacco products is that of a drug. 61 Fed. Reg. at 44,400-03, 45,209-18. Plaintiffs conclude that, under FDA's own analysis, tobacco products achieve

their primary intended purposes through chemical action within or on the body of man and depend upon being metabolized for the achievement of their primary intended purposes.

FDA responds that it found tobacco products to be combination products and that, although a device or device component cannot achieve its primary purpose by chemical action within or on the body under the Act, a combination product consisting of a drug and a device may. FDA further contends that the device component of tobacco products does not rely on chemical actions within or on the body to achieve its primary function and thereby is not excluded from the device definition. FDA has found that the device component of cigarettes consists of the tobacco blend, filter, and cigarette ventilation system, and that the device component of smokeless tobacco consists of the processed tobacco, and, in some products, the pouch. FDA states that the primary function of the device component of cigarettes is to "release a nicotine-containing aerosol, i.e., the tobacco smoke, that, upon combustion outside the body, is inhaled by the smoker and serves as a vehicle for nicotine delivery." 61 Fed. Reg. at 45,209. FDA claims that the primary function of the device component of smokeless tobacco is to "deliver the nicotine to the cheek and gum tissue for absorption," 61 Fed. Reg. at 45,213, and, where the porous pouch is used, to "hold[] the processed tobacco in position in the mouth, controlling the absorption of nicotine into the buccal mucosa." 61 Fed. Reg. at 45,214.

The court finds that the device components of tobacco products fully satisfy the device definition even though the drug component achieves its primary intended purpose through a series of chemical actions inside the body.

b. The Food and Drug Administration May Regulate Tobacco Products Pursuant to its Device Authorities.

Upon determination that tobacco products' primary mode of action is that of a drug, FDA, in accordance with 21 U.S.C. § 353(g),[17] assigned to the agency's Center for Drug Evaluation and Research ("CDER") the responsibility of premarket review. FDA also directed CDER to apply the Act's device

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[17]21 U.S.C. § 353(g) provides, in relevant part, that:

(g) Combinations of drugs, devices, or biological products

(1) The Secretary shall designate a component of the [FDA] to regulate products that constitute a combination of a drug, device, or biological product. The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of —

(A) a drug (other than a biological product), the persons charged with premarket review of drugs shall have primary jurisdiction,

(B) a device, the persons charged with premarket review of devices shall have primary jurisdiction,

. . . .

(2) Nothing in this subsection shall prevent the Secretary from using any agency resources of the [FDA] necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article.

provisions because FDA thought that regulation of tobacco products as devices "is the available option that is the most consistent with both the [A]ct and the agency's mission to protect the public health." 61 Fed. Reg. at 44,398.

Plaintiffs contend that once FDA determined that the primary mode of action of tobacco products is that of a drug, FDA lacked discretion to regulate them pursuant to its device, rather than its drug, authorities. As Plaintiffs note, the distinction between "drug" and "device" has legal and practical significance because different regulatory schemes apply to each. Plaintiffs assert that, just as FDA lacks discretion to regulate what it deems to be a "drug" pursuant to its device authorities or to regulate what it deems to be a "device" pursuant to its drug authorities,[18] it lacks discretion to choose which authorities to

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[18]In the Medical Device Amendments of 1976 ("MDA"), Congress amended the "device" definition to provide that a device "does not achieve its primary intended purposes through chemical action within or on the body of man . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes." The reports accompanying the MDA suggest that Congress amended the definition to draw a clearer line between the "drug" and "device" definitions at least in part in response to the Supreme Court's decision in United States v. An Article of Drug Bacto-Unidisk, 394 U.S. 784, 89 S. Ct. 1410, 22 L. Ed. 726 (1969). See H.R. Rep. No. 94-853 (1976); S. Rep. No. 94-33 (1975). Bacto-Unidisk involved a challenge to FDA's decision to regulate a product as a drug, rather than as a device. FDA wanted to subject the product to premarket review, but, at that time, lacked authority to subject a device to premarket review. Thus, FDA tried to regulate the product as a drug. The Supreme Court upheld FDA's actions, noting that the statute was of little assistance in determining precisely what differentiated a "drug" from a "device." The House and Senate Reports indicate that Congress amended the "device" definition to clarify the distinction between "drugs" and "devices" and to assist FDA in avoiding entanglement in legal battles. Id.
(continued...)

apply to combination products. Although it is clear to the court that FDA may not regulate as a "device" a product that meets only the definition of "drug," the question remains how FDA is to regulate a product that contains both drug and device components and thereby meets the definition of a combination product under the Act.

Section 353(g), the only provision of the FDCA relevant to the regulation of combination products, provides that FDA must determine the primary mode of action of a combination product, and that FDA's determination directs the regulatory path by which FDA conducts premarket review of the product. FDA contends that a product need not be regulated pursuant to FDA's drug authorities merely because the CDER has primary jurisdiction for premarket review of the product.

FDA's interpretation of § 353(g) is not prohibited by the plain language of the section. The section merely provides that, for example, the persons charged with premarket review of drugs shall have primary jurisdiction over combination products whose primary mode of action is that of a drug. Thus, the text of § 353(g) does not reveal whether Congress intended for FDA to have discretion to regulate a combination product pursuant to the authority of its choice.

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[11](...continued)
Although Plaintiffs interpret the legislative history of the MDA as indicating that Congress intended to limit FDA's discretion to choose regulatory authorities, the court interprets the legislative history as primarily revealing Congress' concern that FDA's device authority was deficient and its intent to enhance those authorities. Id.

The legislative history of § 353(g) provides little guidance regarding Congress' intent. Congress included the combination product provision in the Safe Medical Devices Act ("SMDA") of 1990. The Senate Report states that:

> The Committee is aware of the difficulty under the present law in determining the jurisdictional base for regulating products that are comprised of combinations of drugs, devices, or biologics. This provision will provide the Secretary with firm ground rules to direct products promptly to that part of the FDA responsible for reviewing the article that provides the primary mode of action of the combination product. Various persons from industry have expressed the view that a weakness in FDA's premarket review process is the determination of how to regulate combination products. This provision should assist the Secretary in avoiding delays in making that determination, and is important since more combination products are coming before the agency for premarket review . . . .

S. Rep. No. 101-513, 101st Cong., 2nd Sess. (1990). The House Conference Report refers to § 353(g) as describing the "general procedures for determining the appropriate component of the FDA to review premarket submissions for products that are comprised of any combination of drugs, devices, or biologicals." H.R. Conf. Rep. No. 101-959, at 29 (1990). The court does not find in this legislative history the clear intent of Congress that FDA apply its drug authorities to combination products whose primary mode of action is that of a drug and its device authorities to combination products whose primary mode of action is that of a device.

The court finds that Congress has not expressed any intent as to whether FDA has discretion to apply the regulatory authority of its choice to combination products. The court

acknowledges that FDA may not apply the regulatory authority of its choice to non-combination products. On the other hand, the court notes that Congress may have intended for FDA, with its expertise, to apply what it deemed to be the most appropriate regulatory authority to different combination products.[19] In any event, absent any guidance from Congress, the court is constrained by the principles of statutory construction set forth in Chevron. Thus, although the court hesitates to agree with FDA that the agency has unfettered discretion to apply the regulatory authority of its choice to combination products, the court finds that the intent of Congress is not clear and, finding FDA's interpretation to be at least reasonable, defers to FDA's interpretation. See Chevron, 467 U.S. at 845, 104 S. Ct. at 2783 ("Once [the court] determine[s], after its own examination of the legislation, that Congress did not actually have an intent regarding [the issue], the question before it [is] . . . whether the [agency's] view . . . is a reasonable one.").

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[19]FDA notes that, shortly following passage of the Safe Medical Devices Act ("SMDA") in 1990, it adopted implementing regulations and delegations of authority which reflect its contemporaneous interpretation of the SMDA as authorizing it to apply the most appropriate regulatory authorities to any given combination product. See 61 Fed. Reg. at 44,402-03. In addition, FDA notes that it has previously exercised discretion to apply what it considered to be the most appropriate regulatory authority to a combination product when it regulated the intravenous infusion pump as a device. An intravenous infusion pump is a drug delivery device which consists of a device (the pump) and a drug (the diluent) and which is designed to be sold prefilled. FDA states that it exercised its discretion to regulate intravenous pumps as devices because whereas the agency was familiar with the drug component of the product, it was not familiar with the device component which was new and raised significant regulatory questions. See 61 Fed. Reg. at 44,403.

3. Portions of the Food and Drug Administration's Restrictions are Not Authorized Under the Federal Food, Drug, and Cosmetic Act's Device Authorities.

The court has found that FDA properly regulated tobacco products pursuant to its device authorities. The question remains whether FDA has properly applied its device authorities to tobacco products. The Regulations' requirements fall into essentially three categories: restrictions on advertising and promotion,[20] restrictions on access,[21] and labeling requirements.[22] FDA promulgated the first two categories of restrictions pursuant to 21 U.S.C. § 360j(e), and the last pursuant to 21 U.S.C. § 352. The court will address each category of restrictions in turn.

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[20]The promotional and advertising restrictions limit certain advertising to a black-and-white text-only format, restrict the trade or brand name of certain tobacco products, prohibit the sale or distribution of brand-identified promotional nontobacco items such as hats and tee shirts, and prohibit use of a brand name of a tobacco product to sponsor entries, teams, sporting and other events.

[21]The access restrictions prohibit the sale of tobacco products to individuals under the age of 18, require retailers to verify a purchaser's age by photographic identification, prohibit the sale of tobacco products through vending machines and self-service displays except in facilities where individuals under the age of 18 are not permitted, prohibit distribution of free samples, and prohibit the sale of cigarette packages containing fewer than 20 cigarettes.

[22]FDA requires tobacco product packages, cartons, and boxes to bear the established name of the product and a statement of intended use.

a. Section 360j(e) Does Not Authorize Restrictions on the Promotion and Advertisement of Tobacco Products.

Section 360j(e), entitled "Restricted devices," provides:

> (1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use —
>
> (A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or
>
> (B) upon such other conditions as the Secretary may prescribe in such regulation,
>
> if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. No condition prescribed under subparagraph (B) may restrict the use of a device to persons with specific training or experience in its use or to persons for use in certain facilities unless the Secretary determines that such a restriction is required for the safe and effective use of the device. No such condition may exclude a person from using a device solely because the person does not have the training or experience to make him eligible for certification by a certifying board recognized by the American Board of Medical Specialties or has not been certified by such a Board. A device subject to a regulation under this subsection is a restricted device.
>
> (2) The label of a restricted device shall bear such appropriate statements of the restrictions required by a regulation under paragraph (1) as the Secretary may in such regulation prescribe.

21 U.S.C. § 360j(e).

FDA determined that tobacco products are restricted devices within the meaning of § 360j(e) because, due to the "unique circumstances surrounding the use of tobacco products, the only way to provide a reasonable assurance of the safety of these

products is to prevent children and adolescents from using and becoming addicted to them" and that, "without the restrictions contained in the Regulations, there cannot be a reasonable assurance of the safety and effectiveness of these products." (Defs.' Br. Opp'n Pls.' Mot. Summ. J. at 93.) FDA asserts that since tobacco products are restricted devices, it may restrict their "sale, distribution, or use," pursuant to § 360j(e). FDA further asserts that it may restrict the advertising and promotion of tobacco products, explaining that advertising and promotion constitutes an "offer of sale" and, moreover, that an "offer of sale" is part of the "sale" of a product.

Plaintiffs contend, and the court agrees, that FDA may not restrict advertising and promotion pursuant to § 360j(e). First, both as ordinarily defined[23] and as used in the phrase "may . . . be restricted to sale, distribution, or use," the word "sale" does not encompass the advertising or promotion of a product. Second, as Plaintiffs note, although Congress expressly used the

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[23]A dictionary defines sale as:

> 1. The exchange of goods or services for an amount of money or its equivalent; the act of selling. 2. An instance of selling property. 3. An opportunity for selling or being sold; demand. 4. Availability for purchase; *a store where pets are for sale*. 5. A selling of property to the highest bidder; auction. 6. A special disposal of goods at lowered prices; *coats on sale this week*. 7. sales. a. Activities involved in the selling of goods or services. b. Gross receipts.

The American Heritage Dictionary 1085 (2d ed. 1991). The only part of the definition that could encompass promotion and advertising is part 7, which defines "sales." Section 360j(e) does not authorize FDA to restrict general "sales" activities.

words "offer for sale"[24] and "advertising" or "advertisements"[25] elsewhere in the FDCA, it chose not to use such language in § 360j(e).

Even if "sale," as used within § 360j(e), could be construed to encompass the advertising and promotion of a product, the court finds that the section's grant of authority to FDA to impose "other conditions" on the sale, distribution, or use of restricted devices does not authorize FDA to restrict advertising and promotion. The phrase "other conditions" must be construed within the context of § 360j(e) and other relevant sections of the FDCA. Section 360j(e) authorizes FDA to restrict the sale, distribution, or use of certain devices to prescription sale or other conditions necessary to provide a reasonable assurance of safety and effectiveness. The restriction on the advertising and promotion of a product does not fit within this framework. Furthermore, § 360j(e) must be construed in relation to 21 U.S.C. § 353(b),[26] which Plaintiffs assert is the counterpart to

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[24]See 21 U.S.C. §§ 331(m), 331(o), and 353(c).

[25]See 21 U.S.C. §§ 321(n), 331(l), 331(n), 352(n), 352(q), and 352(r).

[26]Section 353(b) provides:

(1) A drug intended for use by man which —

(A) is a habit-forming drug to which section 352(d) of this title applies; or

(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner

(continued...)

§ 360j(e) and which authorizes FDA to constrain certain drugs to prescription status. Section 353(b), like § 360j(e), authorizes FDA to restrict drugs to prescription sale. It is true, as FDA notes, that FDA's authority is broader under § 360j(e) than under § 353(b) because FDA may impose pursuant to the former "other conditions" (than prescription req.) on the sale, distribution, or use of a restricted device. Nonetheless, the meaning of "other conditions" cannot be considered without context, and the court finds that "other conditions" cannot be so broadly construed as to encompass conditions on advertising and promotion.[27]

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[26](...continued)
licensed by law to administer such drug; or

(C) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such a drug,

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

[27]The court also notes that the legislative history of the restricted device provision, which was enacted as part of the MDA in 1976, suggests that Congress did not intend to give to FDA the authority to impose unlimited conditions on the sale of restricted devices. The House Report provides, in relevant part, as follows:

Restricted Devices. — Because of the sophistication and potentially hazardous nature of some medical devices, the proposed legislation authorizes the Secretary to
(continued...)

In addition, the court finds that Congress' delegation to FDA of limited authority to restrict the advertising of devices elsewhere in the FDCA suggests that § 360j(e) should not be construed so as to allow FDA to restrict advertising and promotion. The court notes that just as Congress gave FDA authority to limit drugs to prescription status in § 353(b), but gave FDA authority to regulate prescription drug advertisements in § 352(n), Congress gave FDA authority to limit certain devices to prescription status in § 360j(e), but gave FDA authority to

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[27](...continued)
require that the sale or distribution of a device be restricted if he determines that, because of its potentiality for harmful effect or the collateral measures necessary to its use, there cannot otherwise be reasonable assurance of its safety and effectiveness. Under this provision . . ., such a device may be restricted to the extent that it may be sold or distributed only upon the oral or written authorization of a practitioner licensed by law to administer or use the device, or upon such other conditions as the Secretary may prescribe, except that no condition limiting the use of a device to categories of physicians defined by their training or experience may be imposed.

This provision supersedes and adds to existing authority utilized by [FDA] to require that certain devices be dispensed only upon prescription . . . .

In addition to authorizing the Secretary to limit a device to prescription status, conditions on sale or distribution could include use only within hospitals or clinics. Also, there are categories of health professionals other than physicians that have unique skills appropriate to the use of medical devices such that certain devices which would not be appropriate for use by the ordinary layman could be authorized for use by trained nurses and technicians.

H.R. 94-853 at 24-25 (1976).

regulate the advertising of such devices in §§ 353(q)[28] and 352(r).[29] Indeed, the fact that Congress has specifically granted to FDA the authority to regulate advertising of restricted devices in a separate section supports the court's finding that Congress did not intend to grant FDA such authority under § 360j(e).[30]

Thus, the court finds that § 360j(e) does not grant to FDA the authority to impose restrictions on the advertisement and promotion of tobacco products. The court will, therefore, strike

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[28]21 U.S.C. § 352(q) provides, in relevant part:

A drug or device shall be deemed to be misbranded —

. . . .

(q) Restricted devices using false or misleading advertising or used in violation of regulations

In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360j(e) of this title.

[29]Section 352(r) requires that advertisements for any restricted device include certain information: the established name of the device; a brief statement of the intended uses of the device and relevant warnings; and, if determined necessary after a hearing, a description of the device's components. Section 352(r) further provides that "no advertisement of a restricted device . . . shall, with respect to the matters specified in this paragraph or covered by regulations issued hereunder, be subject to" the Federal Trade Commission Act. Plaintiffs contend, and the court agrees, that § 352(r) reveals Congress' intention that the Federal Trade Commission have primary jurisdiction over advertising.

[30]The court finds that § 352(q) does not provide independent authority for advertising restrictions, but rather was intended to enable FDA to take action against an advertised product that violated the restrictions validly imposed pursuant to § 360j(e).

those regulations restricting the advertisement and promotion of tobacco products.[31]

b. Section 360j(e) Authorizes the Food and Drug Administration to Impose Restrictions on Access to Tobacco Products.

The court finds that § 360j(e) can be construed to authorize the access restrictions imposed by FDA. First, the access restrictions imposed by FDA, unlike its advertising and promotion restrictions, directly restrict the sale or distribution of tobacco products within the meaning of § 360j(e). Second, the court finds that such conditions on the sale or distribution of tobacco products fit within what Congress intended for FDA to impose pursuant to its authority to impose "other conditions." Thus, FDA's access restrictions will stand.[32]

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[31]The court does not find, as Plaintiffs urge, that FDA's unlawful imposition of advertising and promotion restrictions pursuant to § 360j(e) evidences that FDA lacks jurisdiction to regulate tobacco products under the FDCA. The court has found that tobacco products fall within the definitions of the FDCA and that FDA may regulate tobacco products pursuant to its device authorities.

[32]Plaintiff National Association of Convenience Stores asserts that the Regulations' ban on self-service displays implicates the First Amendment. The court finds that the requirement that tobacco products be stored behind a counter and sold in a face-to-face exchange between a retailer and a consumer does not implicate the First Amendment. Retailers may still exhibit store displays promoting the sale of tobacco products. They simply will be prohibited from storing tobacco products on such displays.

c. Section 352 Authorizes the Food and Drug Administration to Impose Labeling Restrictions on Tobacco Products.

FDA, pursuant to § 352(r), requires tobacco products to have a statement of intended use and the established name printed on the packages. The court finds that § 352(r) clearly authorizes FDA to require restricted devices to bear the product's established name and a statement of intended use.

In conclusion, although FDA has the authority under the FDCA to impose access restrictions and labeling requirements on tobacco products, FDA lacks the authority to restrict their advertising and promotion.

II. CONCLUSION

For the reasons discussed herein, Plaintiffs' Motion for Summary Judgment will be granted in part and denied in part.[33]

An order in accordance with this memorandum opinion shall be filed contemporaneously herewith.

This the 25th day of April, 1997.

William L. Osteen
United States District Judge

[33]In light of the court's finding that FDA lacks authority under the FDCA to restrict the promotion and advertising of tobacco products, the court declines to determine whether the promotion and advertising restrictions violate the First Amendment.