No. 98-1152

In The

Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, ET AL.,

Petitioners,

v.

BROWN AND WILLIAMSON TOBACCO CORP., ET AL.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Fourth Circuit

BRIEF AMICUS CURIAE OF ACTION ON SMOKING AND HEALTH (ASH) IN SUPPORT OF PETITIONERS

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INTEREST OF AMICUS CURIAE[1]

Amicus Curiae, Action on Smoking and Health (ASH), is the oldest and largest anti-smoking organization in the country dedicated solely to the issues of tobacco and smoking. It is also the organization responsible for the D.C. Circuit's decision in *ASH v. Harris*, 655 F.2d 236 (D.C. Cir. 1980) ("*ASH*"), which first enunciated that the FDA could determine that it had authority to regulate cigarettes if new evidence justified a departure from its prior position. In ASH's view, that decision has been misconstrued in the Fourth Circuit's majority opinion (hereinafter the "Fourth Circuit").

ASH is a national non-profit scientific and educational organization which for over 30 years has focused on the problems of tobacco. ASH and its Executive Director, John F. Banzhaf III, have brought many legal actions related to smoking, including *Banzhaf v. FCC*, 405 F.2d 1082 (D.C. Cir. 1968) (upholding FCC ruling that television and radio stations must provide substantial free time for anti-smoking messages); *Capital Broadcasting Co. v. Mitchell*, 333 F.Supp. 582 (D.C. Cir. 1971), *aff'd*, 405 U.S. 1000 (1972) (upholding the Congressional ban on cigarette commercials); *National Ass'n of Motor Bus Owners v. United States*, 370 F.Supp. 408 (D.D.C. 1974) (upholding ICC regulation restricting smoking on buses); and, *ASH v. CAB*, 699 F.2d 1209 (D.C. Cir. 1983) (requiring former Civil Aeronautics Board to adopt reasonable regulations for non-smoking sections on airplanes).

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[1] John F. Banzhaf III, Chief Counsel and Kathleen E. Scheg, Legislative Counsel authored the brief for ASH. No counsel for either party authored the brief in whole or in part and no one apart from ASH's donor members made a monetary contribution to the preparation or submission of this brief.

Consent to the filing of this brief has been granted by the parties. Their letters of consent are attached.

ASH has a special interest in the instant case because over 20 years ago, in 1977, Action on Smoking and Health petitioned the FDA to regulate tobacco products as "drugs". In 1978, ASH again petitioned the FDA to regulate cigarettes, this time as "devices," under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.* These petitions led to the decision of the D.C. Circuit in *ASH* which held that the FDA could consider so-called "extrinsic evidence" to determine manufacturers' "intent" that nicotine is an addictive drug.

Underlying the legal issues presented in this case is the source of the leading preventable cause of death, disease and disability in the Nation. Each year cigarette smoking kills more than 400,000 American smokers – more than alcohol, motor vehicles, AIDS, crime, and illegal drugs *combined*! – and costs the American economy over $100 billion.

During the past several years there has been an explosive increase in smoking among teens – approximately 3,000 try it for the first time every single day, and approximately half become addicted – exactly the problem towards which the FDA's regulations are addressed. There is no more important public health issue, and the authority of the FDA to regulate tobacco products will affect millions of people – most of them now children – well into the next millennium.

SUMMARY OF ARGUMENT

Under *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984) ("*Chevron*"), the Fourth Circuit should have deferred to the FDA's interpretation of its statute because Congress has not clearly addressed the precise issue of the agency's jurisdiction over cigarettes. Instead, the Fourth Circuit suggests, incorrectly, that *Chevron* does not apply to issues of an agency's jurisdiction; that Congressional inaction many

years ago is more decisive on this issue than two recently-passed statutes which deal directly with it; and that the Fourth Circuit's disagreement with the agency's decisions regarding matters of policy and how best to regulate cigarettes provides a justification for avoiding *Chevron*.

Alternatively, the FDA's decision should be upheld because it simply applied an accepted definition of a statutory term as upheld in the *ASH* case, and applied it to newly-discovered but long-concealed evidence of manufacturers' intent which is a sufficient prerequisite for jurisdiction. The need for agencies to reevaluate prior decisions, especially in light of new evidence, has long been established, and the *ASH* court, faced with virtually the same legislative history as the Fourth Circuit, expressly recognized the need regarding this issue.

To the extent that legislative history is relevant, Congress' refusal to head off the FDA's widely-announced plans to regulate cigarettes or to limit the regulations once adopted – as it has done in many other situations – negates any idea of a clear and precise intent regarding this issue. Moreover, in two recent statutory enactments, Congress has made it clear that it is not opposed to FDA regulation of cigarettes under the existing act – a precondition for avoiding the application of *Chevron* to the FDA's determination.

The Supreme Court should reverse the instant decision and, in remanding, permit the FDA's regulations to become effective pending any further proceedings. The public interest in protecting approximately 3000 children a day from becoming addicted to nicotine far outweighs the industry's interest in avoiding regulations more modest than those imposed on most other drug makers; most of which they had agreed to as part of a proposed (but failed) national tobacco settlement.

ARGUMENT

I. THE FDA'S INTERPRETATION OF ITS STATUTE MUST BE DEFERRED TO UNDER THE *CHEVRON* DOCTRINE BECAUSE CONGRESS HAS NOT SPOKEN DIRECTLY TO THE PRECISE QUESTION AT ISSUE, AND FOLLOWING REPEATED REQUESTS THAT IT DO SO, CONGRESS THEN EXPRESSLY DECLINED TO ADDRESS THE LEGAL ISSUE OF THE FDA'S JURISDICTION OVER TOBACCO

In the instant case, the Fourth Circuit erred in not deferring to the Federal Food and Drug Administration (FDA)'s interpretation of the Food Drug and Cosmetic Act (FDCA), 21 U.S.C. 321 *et seq.*, and to FDA's expert assessment as to the impact of previously secret tobacco-industry documents, the first of which were uncovered after 1990 and therefore not previously available for consideration by Congress or the agency prior to then.

Under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), courts should defer to permissible agency interpretations of statutory terms unless the intent of Congress on the issue has been clearly and precisely stated. In reviewing an agency's construction of a statute such as the Food, Drug and Cosmetic Act, §§ 201(g)(i)(c),(h)(3), 520(e), as amended, 21 U.S.C. §§ 321(g)(i)(c),(h)(3) 360(e), *Chevron* requires a two-step analysis.

The first step is to determine whether Congress has spoken *directly* to the precise question at issue. When Congress has not directly addressed the precise question at issue, then, under *Chevron*, the second step is for the court to determine if the agency's interpretation is a permissible construction of its statute. *Chevron* at 842-43.[2]

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[2] The Fourth Circuit's conclusion that the *Chevron* analysis does not apply where the underlying issue is the agency's jurisdiction seems inconsistent with this Court's precedents.

A. After Virtually Conceding That Congress Had Never Directly Addressed the Issue of the FDA's Jurisdiction Over Tobacco, the Fourth Circuit Cited Dubious Indicia of "Congressional Intent" – Most Largely Irrelevant Because They Occurred Before the Crucial Evidence Was Uncovered – to Justify Substituting Its Own Judgment for that of the FDA

The first issue, under *Chevron*, is whether Congress has *directly* spoken on the *precise* question at issue.

"The Commission now argues explicitly in favor of Chevron deference; Oklahoma Natural Gas resists, on the ground that deference is inappropriate for jurisdictional issues. Although not directly ruling upon the matter of deference on such issues, *the Supreme Court has in practice deferred even on jurisdictional issues*. See Reiter v. Cooper, 507 U.S. 258, ___, 113 S.Ct. 1213, 1221, 122 L.Ed.2d 604 (1993) (applying Chevron to ICC's determination that statute did not grant it 'initial jurisdiction . . . with respect to the award of reparations'); Commodity Futures Trading Comm'n v. Schor, 478 U.S. 833, 844-45, 106 S.Ct. 3245, 3253, 92 L.Ed.2d 675 (1986) (applying Chevron to scope of the Commission's jurisdiction over counterclaims); NLRB v. City Disposal Systems, Inc., 465 U.S. 822, 830 n. 7, 104 S.Ct. 1505, 1510 n. 7, 79 L.Ed.2d 839 (1984) (pre-Chevron decision expressly rejecting proposition that a different level of deference guides review of 'a jurisdictional or legal question concerning the coverage of the National Labor Relations Act). See generally, Comment, Chevron Deference to Agency Interpretations that Delimit the Scope of the Agency's Jurisdiction, 61 U.Chi.L.Rev. (1994). So have we.' *Oklahoma Natural Gas Co. v. Federal Energy Regulatory Commission*, 28 F.3d 1281, 1283 (D.C. Cir. 1994)."

Moreover just last year, in *Bragdon v. Abbott*, 524 U.S. 624 (1998), this Court held that HIV infection is a "disability" under the ADA, based in part upon regulations promulgated by the U.S. Department of Justice which is charged by law with enforcing Title III of the ADA in court – thereby expanding its jurisdiction to cover this condition.

Chevron at 842. The *precise* question at issue here is whether the FDA has authority to regulate cigarettes as "drugs" or as "devices" under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 321 *et seq.*, absent certain claims. Neither respondents nor the Fourth Circuit has shown any instance in which Congress has directly spoken on the issue of the FDA's authority to regulate tobacco products as drugs and devices under the FDCA. This is because Congress has never directly spoken on that issue.

Rather, the Fourth Circuit attempts to circumvent the first step in the *Chevron* doctrine by instead entering into a convoluted analysis of Congressional intent despite "as much as conceding that tobacco products fit the FDA's 'literal' definition of a drug," *Brown and Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 175 (4th Cir. 1998) ("*Brown*") and that "[a] mechanical reading of only the definitions provisions may appear to support the government's position that tobacco products fit within the Act's definitions of drugs and devices."[3] *Id.* at 163.

The Fourth Circuit entered into this convoluted analysis of Congressional intent because it could not find a direct Congressional statement denying the FDA authority to regulate tobacco products – similar to those Congress expressly included in so many other statutes, *see* discussion *infra*, part III. B. – because no such congressional denial of FDA authority exists.

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[3] The Fourth Circuit's decision to overturn the FDA's conclusion that it had jurisdiction, even after apparently concluding that cigarettes containing nicotine meet the statutory definition, also seems to fly in the face of *United States v. Bacto-Unidisk*, 394 U.S. 784 (1969). There this Court said "that Congress fully intended that the Act's coverage be *as broad as its literal language indicates* and equally clearly, broader than any strict medical definition might otherwise allow." *Id.* at 798 [emphasis added].

In fact, when the issue was very recently and directly before Congress in the "Food and Drug Administration Modernization Act of 1997", Public Law 105-115, sec.422 (Nov. 21, 1997), Congress deliberately chose not to address it, but rather to maintain the status quo and defer to whatever authority the FDA had under the FDCA. *See* discussion *infra*, part III. C. The *Chevron* doctrine is clear. To stop the *Chevron* analysis at step one, and to permit a court to override the judgment of an agency, there must be an unambiguous expression of Congressional intent on the precise issue. Here, as the Fourth Circuit concedes, there is none.

Instead, and in its place, the Fourth Circuit seeks to substitute a catalog of statements by the FDA to Congress, and Congress' non-action regarding regulation of tobacco by the FDA, as so-called evidence of a Congressional determination that the FDA does not have jurisdiction. However, virtually all of these events are irrelevant because they occurred prior to the time key evidence was uncovered.

As both the *Brown* court and the *ASH* court noted, a key and necessary element to finding jurisdiction over a "drug" or "device" in this context is the intent of the manufacturer. [*Brown*, 153 F.3d at 17, *ASH*, 655 F.2d at 10-11]

In other words, it is not enough that the substance "affect the structure or any function of the body." It must also be the intent of the manufacturers that it do so.[4] But

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[4] Without this second part of the definition, substances like house paint, paint thinner, airplane glue, and other common products could be considered "drugs" because they do in fact affect the functioning of the body when inhaled (*i.e.*, create a "high" manifested by marked changes in pulse rate, blood pressure, etc.). However, since there is no evidence that the manufacturers intend such a use, or that most purchasers use the product to create such effects (from which such an intent

the evidence that cigarette manufacturers knew of nicotine's addictive and other drug effect properties, and – through manipulation of nicotine levels and ph levels, cultivation of high-nicotine plants, and other means – intended these effects, were kept secret by the industry.

Since the recently disclosed documents are a key element of the definition and of the proof necessary to conclude that a substance meets the definition, the fact that prior to their discovery the FDA testified that it had no jurisdiction is irrelevant. Indeed, to allow cigarettes to continue their unique status as virtually unregulated products[5] simply because their makers concealed evidence of their intent from the FDA, Congress, and others, would be to permit them to profit from their wrongdoing.

As Joseph A. Califano, Jr., former U.S. Secretary of Health, Education, and Welfare, testified before the House Energy and Commerce Committee's Subcommittee on Health, May 17, 1994, this previously hidden information would have altered the FDA's regulatory posture.

> The *evasions, lies, and transfer of documents overseas* by the tobacco industry to prevent any Government agency or cigarette-injured patient from finding them *has distorted U.S. Government policy for 30 years.*
>
> Had we known what the tobacco companies knew and had we been privy to their research on the addictive nature of nicotine and their ability to manipulate the amount of nicotine in cigarettes, the 1979 Surgeon General's report would have found cigarettes addictive and *we would have moved to regulate them.* Unfortunately, the President of the United States, the Secretary of Health, Education, and Welfare, and the Surgeon General of the United States were *all victims of the concealment and disinformation campaign of the tobacco companies.* (emphasis added)

might be inferred using the second prong of the *ASH* test), they are not "drugs."

[5] Although cigarettes are regulated for tax purposes, and the FTC has jurisdiction over their advertising, cigarettes are virtually the only consumer product not substantively regulated by the Consumer Product Safety Commission or any other agency.

B. The Fourth Circuit Also Violated the *Chevron* Doctrine By Not Only Substituting its Policy Judgments for FDA's Reasonable Determinations, But By Using Its Own Judgments as Evidence of Congressional Intent

The *Chevron* doctrine requires deference to the agency for a permissible construction of its statute if the statute is silent or at all ambiguous with respect to the specific issue. *Chevron* at 842-43. This is true even if the court might prefer a different construction of the statute. *Chevron* at 845. In short, a court is not permitted to substitute its policy judgments for those of the agency.

Yet, ironically, here the Fourth Circuit not only substituted its judgments as to matters of public health and policy; it sought to add those judgments to its recitations of irrelevant Congressional history to circumvent the first prong of the *Chevron* test.

As further so-called evidence that Congress' intent that the FDA has no jurisdiction over tobacco is clear and unambiguous, the Fourth Circuit cites as what it calls "Intrinsic Evidence" various determinations which the agency has made regarding cigarettes under its statute. It criticizes the agency for:

★ concluding "that withdrawal of tobacco from the market poses significant health risks to addicted adults which outweighs the risks of leaving tobacco products on the market";

★ characterizing "tobacco products as combination products containing drug and device components";

★ "exempting tobacco products under § 352(f) without any assurances of safety";

★ failing to require cigarettes to bear "adequate warnings against use . . . by children where its use may be dangerous to health";

★ improperly choosing the category for regulating cigarette as medical devices;

★ deciding not to issue an immediate cease distribution order for all such tobacco products.

But these determinations – how best to protect the public health from a product to which tens of millions of people are already addicted – are exactly the kind of decisions Congress wished to place initially in the hands of an agency with specific expertise in this area, and the ability to conduct and evaluate studies, seek out experts, invite a wide range of public opinion, etc. These, of course, are exactly the capabilities the courts – including the Fourth Circuit – lack.[6]

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[6] The FDA meticulously addressed each of these issues in its decision – using not only its expertise and experience, but also the policy-making power Congress delegated to it – to determine the most appropriate remedies and regulation for a unique product to which approximately 50 million Americans are already addicted, and where congressionally-mandated health warnings already appear.

As this Court noted in *Chevron*, "[t]he *arguments over policy* that are advanced in the parties' briefs create the impression that respondents are now waging in a judicial forum a specific policy battle which they ultimately lost in the agency. . . . *Such policy arguments are more properly addressed to legislators or administrators, not to judges.*" 467 U.S. at 864. [emphasis added]

Here it appears that the Fourth Circuit is likely seeking not only to review these complex policy determinations in the judicial forum, but to use their disagreement with the agency's policy determination as a basis to avoid complying with *Chevron*.

Applying *Chevron* to permit agencies latitude to decide questions which Congress has not precisely and definitively addressed does not, of course, mean that the agency will have the last word, or that only the courts can correct inappropriate use of regulatory authority.

For example, when the FDA initially determined that vitamins and other dietary supplements met certain regulatory requirements and Congress disagreed, it passed the Dietary Supplement Health and Educational Act of 1994, Public Law 103-417. This substantially limited the FDA's authority, and adopted standards which Congress believed were more appropriate to the problem.[7]

Similarly, when it was held that the Consumer Product Safety Commission (CPSC) had jurisdiction over so-called "high tar" cigarettes, Congress reacted by passing, *within only 60 days*, a statute removing this jurisdiction. *See generally, ASH* at 18.

Thus, if Congress decides in the future that the FDA should not regulate cigarettes, or that it should regulate them in ways other than it has chosen to do, Congress is certainly free to act in this instance as it did with dietary supplements or the CPSC.

II. THE FDA'S INTERPRETATION OF ITS STATUTE HAS NOT CHANGED – IT HAS SIMPLY APPLIED THE EXISTING STATUTORY TEST, ONE ALREADY CONFIRMED BY THE *ASH* DECISION, TO NEWLY DISCOVERED EVIDENCE OF MANUFACTURERS' INTENT

In the alternative, it is respectfully suggested that the situation can also be analyzed as one in which the agency didn't so much reinterpret a statutory term as it applied

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[7] Comment, Melatonin Mania: Can the FDA Regulate Hormonal Dietary Supplements to Protect Consumer Interests in Light of the Dietary Supplement Health and Education Act of 1994?, 22 Dayton L. Rev. 77 (1996).

an existing statutory definition to newly-discovered evidence. Thus, the statutory term(s) – the definition of a "drug" or "device" upon which the FDA relied – remained the same as that set out in the D.C.'s Circuit's *ASH* decision. What changed was that the FDA applied it to evidence which was not known when the agency had previously testified before Congress, and when it had concluded in the *ASH* case that the evidence known at that time did not justify its regulation of cigarettes as either "drugs" or "devices."

A. An Overwhelming Amount of New Evidence Clearly Showing That Cigarette Manufacturers Intended to Use and Even Manipulate Nicotine to Create and Maintain Addiction More Than Justified the FDA's Reconsideration of Its Prior Position

In the instant case, there can be no doubt that there have been dramatically changed circumstances affecting the FDA's knowledge of the drug and device properties of cigarettes. In only the past few years, reams of previously secret tobacco-industry information about its products have come to light from various sources including leaks, litigation discovery, exposure by some Members of Congress, and other sources.[8] These include documents showing:

★ that tobacco industry executives considered nicotine to be an addictive drug, and themselves to be in the drug business

[8] Some highlights of these documents will be found in the testimony of FDA Commissioner Dr. David Kessler before Congress on this issue, *See* discussion *infra* part III. A. Many of the documents relied upon are set forth in the FDA's discussion of its regulations in 60 Fed. Reg. 41,314 (1995) and 61 Fed. Reg. 44,396 (1996).

★ that they were concerned that, if information about certain secret activities leaked out, it would provide a basis for FDA jurisdiction over cigarettes

★ that cigarette manufacturers conducted extensive-but-secret experiments confirming the addictive and other drug effect properties of nicotine, and even how to increase its addictiveness

★ that the industry developed and patented special high-nicotine tobacco plants, apparently in an effort to increase the drug effect properties of cigarettes

In the light of such evidence, it was only reasonable for the FDA to reconsider its earlier position that cigarettes do not fall within its jurisdiction because there is no evidence of manufacturers' intent.

Indeed, by expressly incorporating a very broad and flexible statutory definition – which is of necessity based upon factual findings of issues like drug effects on the body and of manufacturers' intent – it is clear that Congress wished the FDA to be able to revisit prior decisions in light of new evidence, rather than waiting for Congress to act on it.

B. The *ASH* Court Set the Stage For a Reevaluation by the FDA of its Cigarette-Jurisdiction Decision in Light of New Evidence Which Might Be Discovered in the Future, and Held That Such Reevaluation Would Be Appropriate and Judged by the "Arbitrary and Capricious" Standard of Review

In *ASH*, the U.S. Court of Appeals, even prior to this Court's *Chevron* decision, used the most permissive standard to review the FDA's determination of whether it had

jurisdiction over cigarettes as either "drugs" or "devices."[9]

Even while deferring to the FDA's decision not to regulate cigarettes as drugs or devices in 1980, the D.C. Circuit Court of Appeals foresaw that the agency might need to reconsider its position at a later date. The Court – having before it virtually the same legislative history as the Fourth Circuit, nevertheless held that:

> Nothing in the opinion should suggest that the Administration 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. *See Intl. Union, United Auto., Aero. & Agric. Implement Workers of American (UAW) v. NLRB,* 148 U.S. App. D.C. 305, 459 F.2d 1329, 1344 (D.C. Cir. 1972). The very structure of the Act which the FDA must administer, moreover, calls for case-by-case analysis. 655 F.2d at 242 FN. 10.

Over 20 years ago, when the FDA denied ASH's petitions to have cigarettes regulated as "drugs" or "devices" under the FDCA, the FDA had already been exercising its jurisdiction over certain cigarettes, and that jurisdiction had been upheld by the courts.[10]

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[9] "According the Administration's interpretation proper deference, we do not find this agency action *arbitrary, capricious, or contrary to law* and therefore affirm the judgment of the district court." *ASH,* 655 F.2d at 236 "The Commissioner's determination, that this is not the proper case in which some evidence of consumer use, even if demonstrating the appropriate intent, may suffice to establish the requisite statutory intent, was thus *neither arbitrary nor capricious." ASH,* 655 F.2d at 240 [emphasis added to both]

[10] *See, United States v. 46 Cartons More or Less, Containing Fairfax Cigarettes,* 113 F.Supp. 336 (D.N.J. 1953), and *United States v. 354 Bulk Cartons***Trim Reducing-Aid Cigarettes,* 178 F.Supp. 847 (D.N.J. 1959).

Additionally, in recent years, the FDA has also regulated nicotine in patches, chewing gum and inhalants. Thus, it has been recognized for over 40 years that the FDA has authority over cigarettes in some situations, and over other products because they contain nicotine.

The dispute in *ASH,* therefore, was not over whether the FDA had the authority to regulate cigarettes at all but whether, at that time, the FDA had sufficient evidence of the manufacturers' "intent" to exercise that jurisdiction in the absence of specific claims.

Then Commissioner Donald Kennedy denied the petitions because at that time the FDA was focused upon the manufacturers' representations, and was only exercising its jurisdiction over cigarettes when the vendors or manufacturers made explicit health claims. He did not deem ASH's then largely-unsupported argument that some smokers used cigarettes to affect the structure and function of their bodies as sufficient in itself to justify asserting jurisdiction over cigarettes. Nor, of course, did ASH have or present any other extrinsic evidence of intent.[11]

The door, however, was left open for further regulation of cigarettes based upon additional evidence. The court in reviewing the FDA's decision, made it clear it believed the FDA could, at a later date, consider evidence of consumer intent, along with other relevant evidence:

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[11] Now, however, the picture has completely changed. New evidence from previously-secret tobacco documents shows that most cigarette users smoke because of the changes which nicotine produces in their bodies.

Moreover, there is now abundant "extrinsic evidence" that manufacturers intend these drug-like effects to occur. Not only do they carefully study them and discuss cigarettes as nicotine-delivery devices; they also use various practices to enhance the nicotine actually delivered to the smoker and to make it more addictive (*e.g.*, by adjusting ph levels).

> [W]e do not read these statements to mean either that the Commissioner will never consider evidence of consumer intent on this question. Rather, by failing to introduce any evidence of vendors' intent – whether based on subjective vendor claims or *objective evidence* such as labeling, promotional materials, and advertising – ASH placed itself in the position of having to meet the high standard established in cases where the statutory 'intent' is derived *from consumer use alone*. Clearly, it is well established 'that the "intended use" of a product, within the meaning of the Act, is determined from its label, accompanying labeling, promotional claims, advertising, *and any other relevant source.' Hanson v. United States*, 417 F.Supp. 30, 35 (D.Minn.), aff'd, 540 F.2d 947 (8th Cir. 1976). *Whether evidence of consumer intent* is a 'relevant source' for these purposes *depends upon whether such evidence is strong enough to justify* an inference as to the vendors' intent. (emphasis added) *ASH*, 655 F.2d at 239

Most significantly, the Court, citing Judge Friendly in an analogous situation, went on to state that "we agree that a factfinder should be free to pierce all of a manufacturer's subjective claims for intent and even his misleading labels to find actual therapeutic intent on the basis of objective evidence in a proper case. . . . "*Id* at 239, citing *National Nutritional Foods Association v. Food & Drug Administration*, 504 F.2d 761, 789 (2d Cir. 1974) (high-dosage vitamin products not per se therapeutic), *cert. denied*, 420 U.S. 946, 95 S.Ct. 1326, 43 L.Ed.2d 424 (1975).

It is hard to imagine a more appropriate case than this one justifying the FDA's decision to pierce the manufacturers' subjective claims of intent. The information that has been uncovered in the last few years from previously secret tobacco industry documents shows over and over again that the tobacco industry knew and intended its

cigarettes to "affect the function and structure of the body"; they also intended to deceive the public and the FDA by denying publicly what they knew internally.

The information about the manufacturers' true intent having not been originally publicly disclosed or made available to the FDA, it was appropriate for the FDA to reevaluate its decision to regulate cigarettes when the new evidence became available. It is new evidence, not a change in the underlying authority of the FDA, that led to the regulations under review. For almost 50 years, the FDA has regulated cigarettes and other nicotine products when it has had sufficient evidence of the manufacturers' intent to "affect the structure and function of the body." It now has that information, and the regulations under review are the result.

As former Secretary Califano indicated, had this information been available earlier, the FDA could have moved to regulate cigarettes then. It is only the tobacco manufacturers' concealment of the relevant information that has prevented the FDA from protecting the public by regulating cigarettes. Such corporate deceit cannot be sanctioned, much less rewarded – as it would be if the FDA's jurisdiction is overturned simply because Congress and the agency were deceived about the drug effects of nicotine and the manufacturers' intent regarding it.

C. In any Event, Courts Have Always Held That Agencies Have the Flexibility to Review and Revise Their Interpretations and Other Determinations, and That Such Determinations Must be Given Deference

Under the *Chevron* doctrine, a revised agency interpretation deserves deference. "An initial agency interpretation is not instantly carved in stone." *Chevron* at 863. Rather particularly "in the context of implementing policy decisions in a technical and complex arena. . . . the agency, to engage in informed rulemaking, must consider

varying interpretations and the wisdom of its policy on a continuing basis." *Id* at 863-64; *Rust v. Sullivan*, 500 U.S. 173, 186 (1991).

As stated in *Rust*, changing circumstances necessitate an agency revising its statutory interpretation. *Rust* at 186-187 citing *Motor Vehicle Mfrs. Assoc. of United States, Inc. v. State Farm Mut. Auto. Ins. Cos.*, 463 U.S. 29, 42, quoting *Permian Basin Area Rate Cases*, 390 U.S. 747, 784 (1968).

D. Alternatively, FDA Authority To Regulate Cigarettes Is Justified Even Viewed As A Revised Interpretation Of Its Statute

Chevron, the leading case on deference to an agency's interpretation of its own statute, was itself a case involving a revised interpretation of a statute. The Court there stated:

> The fact that the agency has from time to time changed its interpretation . . . does not . . . lead us to conclude that no deference should be accorded the agency's interpretation of the statute. An initial agency *interpretation is not instantly carved in stone*. On the contrary, the agency, to engage informed rulemaking, *must consider varying interpretations* and the wisdom of its policy *on a continuing basis*. *Chevron*, 467 U.S. at 863-64 (emphasis added)

Rather, an agency such as the U.S. Department of Health and Human Services "must be given ample latitude to 'adapt (its) rules and policies to the demands of changing circumstances.' " *Rust*, 500 U.S. at 187, citing *Motor Vehicle Mfrs. Assoc.*, 463 U.S. at 42 (1983).

There can be no doubt that circumstances have changed dramatically in regard to tobacco products in the last few years. As discussed more fully, *infra*, the change was so dramatic that then FDA Commissioner Kessler spent two days testifying before Congress on the new

revelations. Even in the three months that elapsed between those two Congressional dates, substantial new information became available.

III. TO THE EXTENT THAT LEGISLATIVE HISTORY IS RELEVANT UNDER *CHEVRON*, IT DEMONSTRATES THAT CONGRESS HAS NOT CONCLUSIVELY DECIDED THAT THE FDA SHOULD NOT REGULATE CIGARETTES; INDEED, TWO RECENT STATUTORY ENACTMENTS EXPRESSLY SET FORTH THAT PRECISE DETERMINATION

ASH contends that the FDA's jurisdiction to regulate tobacco products can be upheld based on deference to the FDA's interpretation of its own statute under *Chevron* and other decisions, and that there is no need to look to so-called "extrinsic evidence" (*e.g.*, Congressional inaction) as the Fourth Circuit did. However, a review of Congressional intent actually supports FDA regulation of tobacco products.

The Fourth Circuit erroneously relies on historical inaction by the FDA – and in particular the agency's refusal in *ASH* to assert its jurisdiction over tobacco products – as a basis for finding that Congress didn't intend to give the FDA authority over tobacco products. Contrary to the suggestion that *ASH* supports the Fourth Circuit opinion, that case actually provides the foundation for the FDA's decision to regulate tobacco products by making it clear that the agency could, if it wished, consider extrinsic evidence (including user intent) to infer the legislatively required intent of cigarette manufacturers.

Now an abundance of new information has come to light in recent years through the release of tens of thousands of previously secret tobacco industry documents, a number of which clearly show that tobacco products meet the statutory definition of "drugs" or "devices", 21 U.S.C.

§ 321(g)(1)(C) and (h)(3), and that the tobacco industry has known this for years and withheld the information from the public.

These previously secret tobacco industry documents provided substantial new facts on which the FDA could reevaluate its decision to regulate tobacco products. As Judge Hall recognized in his dissent:

> It is a familiar canon of administrative law that an agency can change its view of what action is possible or necessary, particularly when new facts come to light. *See Rust v. Sullivan*, 500 U.S. 173, 186-87 (1991) ("An agency . . . must be given latitude to adapt its rules and policies to the demands of changing circumstances") (citations and internal quotation marks omitted). Even when upholding the FDA's earlier denial of its own power to regulate tobacco, the court (U.S. Court of Appeals, District of Columbia Circuit) added the following caveat:
>
> Nothing in this opinion should suggest that the [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. . . . The very structure of the [FDCA] which the FDA must administer, moreover, calls for case-by-case analysis. Should an agency depart from its prior interpretations, however, it must provide a reasoned explanation for its action. . . . *ASH*, 655 F.2d at 242 n.10 [citations omitted].

Despite acknowledging "the general reluctance of courts to rely on congressional inaction as a basis for statutory interpretation, *see Brecht v. Abrahamson*, 507 U.S. 619, 632 (1993) (noting that "[a]s a general matter, 'we are reluctant to draw inferences from Congress' failure to act' ") (quoting *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 306 (1988)), *Brown* at 170, the Fourth Circuit then

interprets Congress' failure to enact legislation specifically granting the FDA jurisdiction over tobacco products as legislative acquiescence in FDA's earlier decision not to regulate tobacco. Yet, certainly more significant than congressional inaction during the years when the tobacco companies concealed the relevant information about the addictive properties of nicotine and their manipulation of the drug from Congress and the public at large, thereby providing Congress with no basis for action, is the Congressional inaction in light of the FDA regulations on tobacco currently under review.

A. Even After Congress Was Repeatedly Warned That New Evidence Would Require FDA Regulation of Cigarettes, and the FDA Did in Fact Move Towards Such Regulations And Eventually Adopted Them, Congress Took No Action – A Strong Indication That There Was No Established Consensus Against That Regulation

In 1994, then FDA Commissioner Dr. David Kessler appeared formally before Congress twice to warn that this newly discovered evidence would probably lead to FDA regulation of cigarettes.

On March 25, 1994, more than a year before the proposed regulations were published and over two years before the regulations became final, Commissioner Kessler testified before the House Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives, specifically on the subject of "Regulating Cigarettes".[12]

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[12] Hearings on Regulating Cigarettes Before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, 103rd Cong., 2nd Sess. (1994) (statement of David A. Kessler, M.D., Commissioner, Food and Drug Administration).

He pointedly notified Congress that the FDA was seriously addressing the question of "whether nicotine-containing cigarettes should be regulated as drugs" due in large part to the mounting evidence, which had not previously been available to the FDA, that tobacco products were intended to affect the structure or function of the human body. Commissioner Kessler informed Congress that:

> Although FDA has long recognized that the nicotine in tobacco produces drug-like effects, we never stepped in to regulate most tobacco products as drugs. *One of the obstacles has been a legal one.* A product is subject to regulation as a drug based primarily on its intended use. Generally, there must be an intent that the product be used either in relation to a disease or to affect the structure or function of the body. *With certain exceptions, we have not had sufficient evidence of such intent* with regard to nicotine in tobacco products.
>
> Mr. Chairman, *we now have cause to reconsider this historical view. The question now before us all is whether nicotine-containing cigarettes should be regulated as drugs.* . . . This question arises today because of an accumulation of information in recent months and years. (emphasis added)

In that testimony, Commissioner Kessler was clearly alerting Congress to the dramatically changing circumstances which were prompting the FDA to consider regulating cigarettes. He informed Congress that:

> I do not have all the facts or all the answers today. The picture is still incomplete. But from a number of pieces of information, from a number of sources, a picture of tobacco company practices is beginning to emerge. . . . *Some of today's cigarettes may, in fact, qualify as high technology nicotine delivery systems* that deliver nicotine in

> precisely calculated quantities. . . . (emphasis added)

He concluded by telling Congress that *"[t]he next task facing the FDA is to determine whether nicotine-containing cigarettes are 'drugs' within the meaning of the Federal Food, Drug, and Cosmetic Act."* (emphasis added) He then went on to specifically ask Congress for guidance on some of the broader social issues that could arise from the FDA's regulation of cigarettes. He told the Committee:

> It is important to note that the *possibility of FDA exerting jurisdiction over cigarettes* raises many broader public health and *social issues for Congress to contemplate.* There is the possibility that *regulation of the nicotine in cigarettes as drugs* would result in the removal of nicotine-containing cigarettes from the market, limiting the amount of nicotine in cigarettes to levels that are not addictive, or otherwise restricting access to them, unless the industry could show that nicotine containing cigarettes are safe and effective. If nicotine were removed, the nation would face a host of issues involving the withdrawal from addiction that would be experienced by millions of Americans who smoke. (emphasis added)

Then on June 21, 1994, Commissioner Kessler returned to testify before the Subcommittee on Health and the Environment.[13] The newly discovered information that ultimately led to the FDA's regulation of cigarettes had increased significantly in only three months. In relevant part, Commissioner Kessler stated:

> In my last appearance before this subcommittee on March 25, 1994, *I raised the question of whether*

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[13] Hearings on Regulating Tobacco Products Before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, 103rd Cong., 2nd Sess. (1994) (statement of David A. Kessler, Commissioner, M.D., Food and Drug Administration).

> *the Food and Drug Administration should regulate nicotine-containing cigarettes as drugs under the Federal Food, Drug, and Cosmetic Act.* . . . The information that I presented about industry control and manipulation of nicotine the last time I testified before you *was suggestive. Today* I am going to provide you with *actual instances of control and manipulation of nicotine* by some in the tobacco industry that have been uncovered through painstaking investigational work over the last three months. (emphasis added)

Referring to some of these studies, Commissioner Kessler was explicit in notifying the Committee that the FDA considered them *"relevant to the determination of whether nicotine-containing cigarettes are drugs for purposes of the Federal Food, Drug, and Cosmetic Act."* (emphasis added)

In these most newsworthy remarks, Commissioner Kessler was clearly telling Congress that the newly-discovered evidence about the addictive nature of nicotine, and cigarette maker's knowledge of this property and their efforts to manipulate it, would force the FDA to regulate nicotine in cigarettes – as it has long regulated nicotine in other forms (*e.g.*, in patches, chewing gum, and inhalants). Most telling of all, however, was his final comment regarding the blatant admission found in a tobacco industry document showing that the industry had known for many years that cigarettes were drugs. A memorandum by Brown & Williamson's then General Counsel Addison Yeaman stated: *"We are, then, in the business of selling nicotine, an addictive drug.* . . . "[14]

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[14] Addison Yeaman, "Implications of Battelle Hippo I & II and the Griffith Filter," 1963, quoted in John Slade et al., "Nicotine and Addiction: The Brown and Williamson Documents," J.Am.Med. Ass'n, Vol. 274, No. 3, pp. 225-33, July 19, 1995 (emphasis added).

Those widely-reported hearings were held more than five years ago. Congress was thus clearly on notice that the FDA was diligently advancing toward regulation of cigarettes under the Federal Food, Drug and Cosmetic Act, and yet it took no action in view of the virtual certainty of such regulation.

Indeed, even after the President's televised announcement on August 10, 1995 that the FDA was going to regulate cigarettes, the publication of a notice of proposed rulemaking to that effect on August 11, 1995 [60 Fed. Reg. 41,314], the publication of the final regulations on August 28, 1996 [61 Fed. Reg. 44,396], and numerous media reports that the rules requiring photo ID cards to purchase cigarettes had gone into effect, there has been no serious Congressional attempt to remove FDA's authority to regulate tobacco products, an indication surely of legislative acquiescence not only in FDA's authority generally to regulate tobacco products, but specifically an acceptance of the particular and limited FDA regulations for tobacco products now before the Court.

B. The Fact That Congress Has Frequently Passed Statutes Prohibiting the Regulation of Cigarettes By Other Agencies, But Has Declined – As Recently as 1994 – To Do So Regarding the FDA, Strongly Suggests That Congress Does Not Disagree With the FDA's Decision

Additionally, it is instructive to note that Congress has often excluded tobacco products from other federal laws, and obviously could have done so with the Food, Drug and Cosmetic Act. Federal laws which specifically excluded tobacco products include, for example:

1. *Federal Hazardous Substances Act*: Under the heading "definitions", the Federal Hazardous Substance Act specifies that the term "hazardous substance" does not

include "tobacco and tobacco products" sec.2(f)(2). Pub.L. No. 86-613, signed July 12, 1960.

2. *Fair Packaging And Labeling Act*: Under the heading "definitions", the Fair Packaging and Labeling Act specifies that the term "consumer commodity" does not include "any . . . tobacco or tobacco product" sec.10(a)(1), Pub.L. No. 89-755, signed November 3, 1966.

3. *Consumer Product Safety Act*: Under the heading "definitions", the Consumer Product Safety Act specifies that the term "consumer product" does not include "tobacco and tobacco products." sec.3(a)(1)(B), Pub.L. No. 92-573, signed October 27, 1972.

4. *Toxic Substances Control Act*: Under the heading "definitions", the Toxic Substance Control Act specifies that the term "chemical substances" does not include "tobacco or any tobacco product." sec.3(2)(B)(iii), Pub.L. No. 94-469, signed October 11, 1976.

Most significantly, as recently as 1994, Congress explicitly excluded tobacco from the jurisdiction of the FDA, but only under the "dietary supplements" exemption from the definitions of a "drug" in the FDCA itself.[15] Clearly, Congress could have excluded tobacco entirely from the coverage of the FDCA at the time – particularly since it was focusing on exactly the same agency, and it passed the act just months *after* then Commissioner Kessler had twice warned Congress in widely-reported testimony that the FDA was likely to regulate cigarettes as a "drug" and/or "device." Congress, however, did not.

Thus it can be argued that by excluding tobacco from the "dietary supplements" definition of the FDCA, but not at the same time dealing in any way with its proposed inclusion under other sections of the agency's act, Congress was expressing its intent to retain FDA jurisdiction over tobacco as a "drug". At the very least, it clearly

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[15] Pub.L. No. 103-407, sec.2(a), 108 Stat. 4325, 4327 (codified at 21 U.S.C. § 321(ff)(1)).

and unambiguously indicated that this power did not contradict the will of Congress.

C. The Most Important – and, Indeed, the Only Controlling – Evidence of Congressional Intent Regarding FDA Jurisdiction Over Cigarettes Was The Passage of Legislation Expressly Leaving the Issue Open and Unresolved

Courts are understandably very reluctant to interpret statutes – and even more reluctant to overturn an agency's own interpretation of its own statute – based upon a legislative history consisting of inaction; exactly the type of evidence the Fourth Circuit relied upon in its ruling. Far more important – and indeed, the only controlling – evidence of legislative intent occurs when Congress passes legislation which becomes law.

On November 21, 1997, more than a year after the FDA regulations governing cigarettes had become final, and some of them were already in effect, Congress passed the omnibus "Food and Drug Administration Modernization Act of 1997," Pub.L. No. 105-115 (Nov, 21, 1997) (hereinafter Modernization Act). Although Congress' attention was obviously focused on the FDA, and every Member of Congress undoubtedly knew of its cigarette regulations, the bill did not seek to re-define, clarify, modify, or otherwise address the issue of FDA jurisdiction over cigarettes. Instead, in a very telling move, Congress explicitly declined to take action on the question of the FDA's authority to regulate tobacco products, and deferred to whatever authority the FDA had under the FDCA, providing in relevant part:

> Nothing in this Act or the amendments made by this Act shall be construed to affect the question of *whether the Secretary* of Health and Human Services *has any authority to regulate any tobacco product*, tobacco ingredient, or tobacco additive. Such authority, if any, shall be exercised under

> the Federal Food, Drug, and Cosmetic Act *as in effect on the day before the date of the enactment of this Act.* (emphasis added)

As of November 20, 1997 the day before the enactment of that Act, the FDA had determined that it had jurisdiction over cigarettes and its basic jurisdiction had been upheld in *Coyne Beahm, Inc. v. FDA*, 966 F.Supp. 1374 (M.D. N.C. 1997) ("*Coyne*") which had been decided on April 25, 1997. Although *Coyne* was subsequently reversed in the instant case on August 14, 1998, *Coyne* governed on November 20, 1997. The *Coyne* decision had been widely publicized so there can be no doubt that Congress would have been aware that the FDA had been held to have authority to regulate tobacco products when it passed the Modernization Act, and explicitly deferred to whatever authority the FDA had as of November 20, 1997.

Whether one interprets this statutory language to mean that Congress affirmatively agrees with the FDA's and the *Coyne* decision that the FDA does have the jurisdiction to regulate cigarettes, or that the passage of the Modernization Act should not be construed to change whatever the scope of the FDA's jurisdiction over tobacco products under the existing statute should be, one thing is clear. Congress did not remove the FDA's jurisdiction over tobacco as it previously had done in the Federal Hazardous Substances Act; Fair Packaging And Labeling Act; Consumer Product Safety Act; and the Toxic Substances Control Act. Moreover, it did not expand on its earlier decision to remove tobacco products under the "dietary supplements" exemption from the definitions of a "drug" in the FDCA itself. Rather, it took no action in that direction whatsoever.

It is respectfully submitted that such legislative language is entirely inconsistent with the Fourth Circuit's view that Congress had such a clear and precise intent on this issue that *Chevron* does not even apply, and that the

agency's interpretation is not entitled to deference. If such a clear and precise intent emerged from the snippets of testimony cited by the Fourth Circuit, surely Congress would have taken this opportunity to reaffirm it – now that the FDA was already regulating cigarettes. At very worst, Congress would have remained silent. But by legislating vaguely and generally that this new modernization statute is not to change the agency's jurisdiction over cigarettes, Congress could not have said more plainly that there exists no clear and precise intent in Congress that the FDA have no jurisdiction whatsoever over cigarettes.

CONCLUSION

Amicus Curiae, Action on Smoking and Health (ASH), respectfully submits that the Fourth Circuit erred in three major ways.

First, instead of applying the deference due agency determinations (including those involving jurisdiction) under *Chevron* whenever Congress has not spoken clearly on the precise issue, the Fourth Circuit utilized long-past Congressional inaction, ignored two recent statutes which addressed the issue, and substituted its own policy judgments regarding how best to deal with a deadly drug to which tens of millions of Americans are already addicted.

Second, instead of recognizing, as the *ASH* court did, that an agency's interpretation of its jurisdiction which involve issues of fact can be reconsidered from time to time, especially in light of the mountains of newly-discovered but previously-secret evidence of manufacturer intent, the Fourth Circuit relied upon the *ASH* decision and agency pronouncements pre-dating the discovery of this vital evidence to preclude the FDA from reconsidering this matter in light of new facts.

Third, to the extent that legislative history is even relevant, the Fourth Circuit overlooked two recently passed statutes in which Congress expressly declined to

take (or reaffirm) any position regarding the FDA's jurisdiction over cigarettes, as well as Congress' inaction in seeking to prevent the FDA from proceeding to regulate cigarettes or to even modify the regulations once issued.

ASH respectfully suggests that this Court should not only reverse the Fourth Circuit's decision, but also provide that the FDA's regulations should become effective pending any further proceedings. The public interest in protecting approximately 3000 children a day from first trying cigarettes, and almost half that number from becoming addicted to nicotine, far outweighs the industry's interest in avoiding these regulations. After all, they are far less restrictive than those imposed upon manufacturers of many other drugs which are far less dangerous and not even addictive. Moreover, virtually all of them were agreed to by the cigarette manufacturers themselves as part of a proposed (but failed) national tobacco settlement – a clear indication that they will not impose a major hardship upon the industry.

Respectfully submitted,

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