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Section 3: Business and Commerce

Institute of Bill of Rights Law, William & Mary Law School

BUSINESS AND COMMERCE

In This Section:

Last Term:

KUMHO Tire Company, LTD., *et al.*, petitioners,
v.
Patrick CARMICHAEL, etc., *et al.*

No. 97-1709

Supreme Court of the United States

Decided March 23, 1999

RULING EXTENDS JUDGES' RIGHT TO BAR NONSCIENTIFIC TESTIMONY

***The Des Moines* Register**

Wednesday, March 24, 1999

Richard Carelli, Associated Press

Washington, D.C. The Supreme Court gave American businesses more ammunition to fend off product-liability lawsuits Tuesday by extending the reach of guidelines that let trial judges exclude "junk science" as evidence.

Those guidelines, fashioned in a 1993 decision, also apply to the planned testimony of all expert witnesses, the court said. Insurers predicted the decision could play a huge role in anticipated lawsuits over Year 2000 computer problems.

The unanimous decision, written by Justice Stephen Breyer, ended a family's lawsuit against a tire manufacturer over a 1993 Alabama traffic accident that killed one person and injured seven others.

Separately, the justices voted 8-1 in ruling that a federal trial judge correctly barred an engineer from giving testimony that linked the accident to a tire defect. Breyer said the judge rightly doubted whether the engineer's methodology could reliably explain why the tire failed.

Tuesday's ruling "enhances judicial power" at the expense of letting juries assess evidence, said Gerson Smoger, a Dallas attorney with Trial Lawyers for Public Justice.

But Craig Berrington, general counsel of the American Insurance Association, called the decision a victory "for honest trials and honest decisions." He noted that in many disputes over Y2K computer problems -in which machines may misconstrue the year 2000 as 1900 and malfunction –"the expert testimony of software engineers or computer science experts will be essential" to claims of alleged design defects.

The nation's highest court in 1993 told judges deciding on the admissibility of expert evidence to consider whether the theory or technique had been tested, whether it had been reviewed by others,

what its possible rate of error might be and whether it was generally accepted by scientists.

The guidelines apply directly to federal courts only, but most state courts model their rules after their federal counterparts.

In the Alabama case, the 11th U.S. Circuit Court of Appeals had ruled that the 1993 guidelines do not apply to nonscientific testimony. Its ruling gave the Patrick Carmichael family another chance to show that engineer David Carlson's testimony should have been allowed in their lawsuit against the Kumho Tire Co.

But in Tuesday's ruling, Breyer said the trial court judge had acted within his discretion in barring the testimony.

TRIAL JUDGES TOLD TO SCREEN EXPERTS

Supreme Court Grants New Leeway to Exclude Dubious, Irrelevant Testimony

The Washington Post

Wednesday, March 24, 1999

Joan Biskupic, Washington Post *Staff Writer*

The Supreme Court yesterday enhanced the power of judges to screen out what they consider dubious expert testimony in medical malpractice, defective product and other personal injury disputes.

By a unanimous vote in a case that addresses the so-called battle of the experts, the court ruled that trial judges must ensure that testimony from all experts is relevant and reliable before it reaches a jury. The ruling expands the breadth of a 1993 decision that set rules for "scientific" evidence. The court now requires that any expert witness, scientific or otherwise, be scrutinized before testifying.

Writing for the court, Justice Stephen G. Breyer said judges should "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor" required in the expert's "relevant field." He added, however, that judges have great leeway in determining whether an expert's methods and conclusion are sound.

In a pithy concurrence, Justice Antonin Scalia observed that the point of the judge's discretion is to exclude "expertise that is fausse and science that is junky."

The widespread use of expert witnesses in civil cases has prompted numerous complaints about "junk science," dueling experts and the manipulation of jurors. Frequently a judge's decision on whether to allow a case to proceed or a jury's verdict can turn on whether or not an expert witness was convincing. Underscoring the high stakes for businesses and the people who sue them, dozens of manufacturers, insurance groups, engineers, scientists, trial lawyers and academics submitted "friend-of-the-court" briefs.

The Supreme Court's ruling endorsed a trial judge's decision to block testimony from a tire expert employing questionable methodology who claimed that a manufacturing defect caused a fatal 1993 blowout on an Alabama highway. After the right rear tire of the minivan driven by Patrick Carmichael blew out, the vehicle flipped over, killing one person and injuring seven others in the Carmichael family.

Breyer agreed that the trial judge was right to doubt that an engineer hired by the Carmichaels could reliably claim that a manufacturing defect in the tire, which was more than five years old and inadequately repaired, caused the blowout. That testimony was crucial to the Carmichael family's case and after the judge excluded it, the judge summarily ruled for the manufacturer, Kumho Tire Co.

The 11th U.S. Circuit Court of Appeals reinstated the Carmichaels' case,

saying that the tire testimony was not covered by the guidelines dealing with scientific testimony and thus should have been presented to a jury.

Yesterday's high court reversal, while favoring Kumho Tire over the Carmichaels, nonetheless offered something for advocates on both sides of the broader debate.

Lawyers for manufacturers praised the expanded "gatekeeper" role for judges as a significant step toward ensuring that jurors do not hear, and subsequently rely on, untrustworthy expert testimony.

Robert P. Charrow, representing a group of manufacturers and others favoring limits on lawsuits, said the court's guidelines would exclude methods that are not tried and true, as well as questionable conclusions. "Basically what the Supreme Court has been trying to do is prevent experts from testifying that the Earth is flat or that we can predict the future using astrology," he said.

On the other hand, trial lawyers focused generally on language in Breyer's opinion allowing judges considerable leeway in looking at experts' credentials and rejecting a more rigid approach used by many lower court judges after the 1993 ruling that plaintiffs' lawyers said hurt their cases.

"If the courts read this as an instruction from up above to use some common sense and flexibility, that's going to help us," commented Jeffrey Robert White of the Association of Trial Lawyers of America.

Justice John Paul Stevens agreed with the rest of the Supreme Court in Kumho Tire Co. v. Carmichael on the standards for all expert testimony, but he dissented in the part of the Alabama case that endorsed the trial judge's exclusion of the tire expert, saying the dispute should be returned to lower courts for their reconsideration.

Justice Stephen G. Breyer says trial judges should weigh the "intellectual rigor" and methodological soundness of expert testimony.

Last Term:

Esteban ORTIZ, *et al.*, petitioners
v.
FIBREBOARD Corporation, *et al.*

No. 97-1704

Supreme Court of the United States

Decided June 23, 1999

HIGH COURT OVERTURNS ASBESTOS SETTLEMENT
Ruling Limits Firms' Options in Class Actions

***The Washington* Post**

Thursday, June 24, 1999

Sharon Walsh, Washington* Post *Staff Writer

The Supreme Court overturned a $ 1.5 billion asbestos settlement yesterday in a decision that on two fronts makes it more difficult for companies to resolve thousands of lawsuits through a single settlement. The justices ruled, 7 to 2, that a company cannot limit the amount it is willing to pay and that people in the group with conflicting interests must have separate lawyers.

The decision reined in a legal tool increasingly used by manufacturers and other defendants to settle claims seeking damages for a class of people, potentially affecting product-liability cases involving tobacco, pacemakers and silicone breast implants as well as civil rights and employment discrimination cases.

Trial lawyers generally praised the decision, saying companies had abused the class action procedure to limit the size of awards and protect themselves from financial harm. But others said it will drag out suits and leave victims waiting years for resolution of a claim.

While various courts have been extensively involved in crafting global settlements in these massive cases, the justices noted that only Congress can change the law that defines the limits of class actions. Justice David H. Souter, writing for the majority, pleaded with Congress to address the "elephantine mass" of asbestos claims legislatively.

"This litigation defies customary judicial administration and calls for national legislation," Souter wrote at the outset of his decision. In a footnote, he added: "To date, Congress has not responded." Yesterday was the third time in a decade the court has asked for the help of Congress in dealing with the issue.

In the case, Esteban Ortiz v. Fibreboard Corp., the justices overturned a 1993 global class settlement involving about 186,000 asbestos personal injury

claims against the Fibreboard Corp., a maker of vinyl siding that is now a subsidiary of Owens Corning. In that settlement, the company established a limited fund to settle all claims. As part of the agreement, no one in the class could reject the settlement and sue the company as an individual.

But the justices said if a company is going to set aside limited money and not allow what are known as opt-outs, the fund must truly be limited. In this case, insurance companies were providing most of the funds for the settlement and Fibreboard retained virtually all its net worth. Thus, the justices said, the fund could not be considered limited.

In addition, Souter noted that there were a number of different types of claimants, including those who are currently sick and those who may get sick in the future. In such cases, claimants with different interests must be represented by different lawyers, Souter said.

Asbestos causes a lung disease called mesothelioma, which can have a latency period of as much as 40 years, so people currently in their sixties may have been exposed to asbestos in oil fields or shipyards decades ago and still not know whether they will develop the disease.

"This is very, very important," said Linda S. Mullenix, a professor at the University of Texas School of Law and a consultant on previous asbestos settlements. "Every class action lawyer in the country has been waiting for this decision."

It will prevent companies from "picking a number" to settle such cases, said Laurence Tribe, the Harvard lawyer who argued the case for the claimants who opposed the settlement. And it will mean that in all class action suits, people with different interests will have to have separate representation.

"This was a scary device," Tribe said, "creating by agreement with an insurance company a limited fund and selling down the river the rights of all sorts of people."

"This is absolutely a huge victory for asbestos victims, consumers and anybody concerned about class action abuse," said Arthur H. Bryant of the Trial Lawyers for Public Justice, a group that is supported by some of the country's biggest class action lawyers.

Others disagreed.

"I don't think this is a big victory for victims," said Mullenix, who said she generally favors class action settlements. "Asbestos victims have received nothing after all these years. This is a case where justice delayed is justice denied." Many asbestos victims die before their claims are settled.

Owens Corning, which bought Fibreboard after the case had been initiated, said it was pleased with the outcome. The company, which also formerly made asbestos, has already begun a national settlement program to resolve the claims.

Chief Justice William H. Rehnquist -- along with Justices Antonin Scalia, Anthony M. Kennedy, Clarence Thomas, Ruth Bader Ginsburg and Sandra Day O'Connor -- joined Souter in the decision.

Stephen G. Breyer and John Paul Stevens dissented. Breyer wrote for the two that in such complex cases, the district court should be given the discretion to reach an equitable resolution.

Although there have been various legislative proposals over the years regarding asbestos claims, none has ever made it to the floor of Congress.

"The majority of the Supreme Court is saying that if asbestos is going to be solved, Congress has to solve it," said one lawyer who is not involved in this case. But, he added: "Congress will never touch this with a 10-foot pole. The trial lawyers are too entrenched."

THE SUPREME COURT: LIABILITY LAW

Justices Throw Out $1.5 Billion Asbestos Settlement, Citing Possible Conflict of Interest

The New York Times

Thursday, June 24, 1999

Stephen Labaton

The Supreme Court today set aside a $1.5 billion landmark settlement that was to have resolved the claims of as many as 186,000 victims of asbestos poisoning against the Fibreboard Corporation, one of the leading makers of products using the fire-retardant substance.

The Justices concluded that the lawyers for the claimants had a possible conflict of interest: getting the most for their clients and striking a quick deal that would garner huge legal fees. They also found that in approving an agreement that would have sharply limited any other lawsuits brought against Fibreboard, the lower court had failed to consider that there was almost certainly more money available for the claims, because Fibreboard was only contributing $500,000, with its insurers putting up the rest. Fibreboard was sold to Owens Corning two years ago for $515 million.

"It hardly appears that such a regime is the best that can be provided for class members," Justice David H. Souter wrote in the majority opinion.

The 7-to-2 decision clarified the standards for class-action lawsuits and raised the barriers for corporations seeking to resolve large and complex product-liability cases involving tobacco, breast implants and handguns.

In recent years, companies that have been sued in class-action cases over cigarettes, orthopedic bone screws, diet pills and pesticides have tried to limit their liability by striking settlements that prohibit any current or future claimants from dropping out of the cases to file their own suits. But today's decision will make it far more difficult for companies to reach such settlements without either paying top dollar or resorting to bankruptcy protection, as some defendants in asbestos and other large cases in have done in the past to limit their liability.

The decision was also a repudiation of a small group of plaintiffs' lawyers who had tried to settle the cases facing Fibreboard, which had managed through skillful negotiation and legal tactics to structure a deal in which its insurers would have paid virtually all of the costs. The $1.535 billion deal at the center of today's decision was struck in August 1993, on the eve of an important appeals court hearing, in Tyler, Tex.

Both the majority opinion and concurring and dissenting opinions called on Congress to find a solution to "the elephantine mass of asbestos cases" and expressed deep frustration with the procedural rules that have limited the ability of judges to resolve the asbestos litigation crisis facing state and Federal courts.

The final toll of asbestos-related health problems remains unknown, in large part because illnesses often occur many years after exposure, although one

judicial study concluded that there may be as many as 265,000 deaths by the year 2015 and many millions more health problems from exposure to asbestos.

The court cases, while largely failing to resolve hundreds of thousands of claims, have cost millions of dollars in lawyers' bills that might otherwise have been used to help victims. Indeed, the judicial study described in today's opinions noted that 61 cents of every dollar that might otherwise be available for victims of asbestos exposure was now going to lawyers and other litigation costs.

While the House Judiciary Committee is set to hold hearings next week on legislation that would set up an administrative agency to resolve asbestos claims, opposition from trial lawyers, the A.F.L.-C.I.O and some asbestos manufacturers has blocked such legislation in the past.

Fibreboard was a defendant in one of the first asbestos cases filed, in 1967, against a group of asbestos makers and users. The company has been a defendant in many cases because from the 1920s through 1971 it made a variety of products containing asbestos, mostly for high-temperature industrial applications.

Today's decision, Ortiz v. Fibreboard Corporation, No. 97-1704, was the second time in two years that the Supreme Court had analyzed the class-action rules embodied in Rule 23 of the Federal Rules of Civil Procedure to strike down a major asbestos settlement. In 1997, the Justices threw out a $1.3 billion class action settlement that had been reached by 20 large asbestos makers.

In that case, Amchem Products v. Windsor, the Court concluded that the asbestos victims had interests that were too diverse to be represented in a single class-action lawsuit. The Justices also found a conflict in the way the settlement treated current asbestos victims and those whose exposure to asbestos had not yet resulted in serious illness.

Five days after handing down the Amchem decision, the Justices asked the United States Court of Appeals for the Fifth Circuit, sitting in Texas, to apply its principles in reconsidering the $1.5 billion settlement in the Fibreboard case. In contrast to the Amchem settlement, the Fibreboard deal was binding on all current and future claimants against the company on the theory that there was a highly limited amount of money that was available to Fibreboard.

In part because of these differences, the Fifth Circuit appeared to give short shrift to the Supreme Court's decision in the Amchem case, affirming the Fibreboard settlement in a five-paragraph opinion.

But in asking the Supreme Court to reverse the appeals court, Professor Laurence H. Tribe of Harvard Law School began his brief in rather unorthodox style. "Some people just can't take a hint," he wrote of the appeals court.

Today, the majority of the Supreme Court agreed that the Fifth Circuit court had largely ignored its 1997 Amchem ruling. Justice Souter's opinion was laced with criticisms of the reasoning of the appeals court and district court that had approved the settlement.

The Justices faulted the lower courts for failing to undertake an independent evaluation of the potential insurance funds available, simply accepting the settlement terms at face value. While a proposed settlement might ordinarily be good evidence of the amount of money available for claims, the court said, the potentially huge fees for the plaintiffs'

lawyers might have unfairly tainted the agreement.

"In a strictly rational world, plaintiffs' counsel would always press for the limit of what the defense would pay," the Court wrote. "But with an already enormous fee within counsel's grasp, zeal for the client may relax sooner than it would in a case brought on behalf of one claimant."

The Court concluded that the proposed settlement's distribution scheme was unfair and that it had unfairly excluded too many actual and potential asbestos victims. The Justices also said that by only giving up $500,000, Fibreboard had failed to supply enough money to justify the requirement that no claimants covered by the settlement be permitted to sue on their own terms.

Justice Stephen G. Breyer, joined by Justice John Paul Stevens, argued in a dissenting opinion that the alternative to the settlement would not be an opportunity for each potential plaintiff to have his or her own day in court.

"Unusually high litigation costs, unusually long delays, and limitations upon the total amount of resources available for payment, together mean that most potential plaintiffs may not have a realistic alternative," Justice Breyer wrote.

Justices Breyer and Stevens maintained that the Court should have given more latitude to district courts to find remedies to resolve the explosion of asbestos litigation. Justice Breyer also concluded that the settlement would have made far more money available to the claimants than they might otherwise have gotten as long as Congress failed to address the issue.

Last Term:

AT & T Corporation, petitioners
v.
IOWA Utilities Board, *et al.*

No. 97-826

Supreme Court of the United States

Decided January 25, 1999

HIGH COURT SAYS FCC TO SET TELEPHONE RULES

Iowa Utilities Regulators Had Said They Should Decide How Rates Are Set When Local Phone Firms Lease Networks

***The Des Moines* Register**

Tuesday, January 26, 1999

Kevin O'Donoghue, Register Business Writer

The U.S. Supreme Court on Monday ruled that the Federal Communications Commission, not state regulators, will set the ground rules for opening local telephone service to competition.

The Iowa Utilities Board and other state utilities regulators had maintained that they should decide how rates are set when local phone companies lease their networks to competitors.

"What we were trying to do is say these are issues of local concern," said Diane Munns, general counsel for the state agency.

The ruling was not expected to result in any significant changes to rates paid by local telephone service customers in Iowa, said Chuck Seel, customer service manager the Utilities Board.

U.S. West Communications said in a statement that it had supported the states because "we believe state regulators are better judges of what's best for their specific states."

For example, operating local phone service networks in a rural state with some thinly populated areas is more expensive than doing so in a densely populated state, U.S. West spokeswoman Lynn Gipple said.

Therefore, the company thinks state regulators should decide how to set the rates that local phone service providers charge for their networks.

At issue was whether the FCC had jurisdiction to implement the local competition provisions of the Telecommunications Act of 1996.

In deciding that it did, the high court overturned a decision by the 8th Circuit Court of Appeals.

AT&T vs. Iowa Utilities Board became the test case for the conflict after

long distance carriers sued regulators in multiple states that were trying to regulate the wholesale leasing of local phone companies' networks.

The Utilities Board has approved 19 companies to offer local telephone service in addition to existing providers. But those providing service have typically gone after only commercial customers, Gipple said.

DIVIDED COURT SAYS FCC CAN SET RULES FOR LOCAL PHONE COMPETITON

The Legal Intelligencer

Tuesday, January 26, 1999

Richard Carelli, Associated Press

WASHINGTON – The Supreme Court yesterday reinstated federal rules aimed at quickly opening the $110 billion local telephone market to competition.

The court, in splintered voting, said a 1996 law lets the Federal Communications Commission set pricing rules for long-distance companies and others that want to start offering local phone service. The ruling is a big, although not complete, victory for the government's goal of speedily letting customers nationwide choose their local phone companies much as they now can choose long-distance companies. The Clinton administration had argued that such competition will happen sooner if price rules are set by the federal government rather than by each of the 50 states. State regulators and companies that now monopolize local phone service had said the pricing rules must be set by the states. Writing for the court, Justice Antonin Scalia said the Federal Communications Commission has general jurisdiction to implement the local-competition provisions of the Telecommunications Act of 1996. "It would be gross understatement to say that the Telecommunications Act of 1996 is not a model of clarity," Scalia wrote. "It is in many important respects a model of ambiguity or indeed even self-contradiction. . . . But Congress is well aware that the ambiguities it chooses to produce in a statute will be resolved by the implementing agency. ... We can only enforce the clear limits that the 1996 act contains," Scalia added. Although they lost yesterday, state regulators and local phone companies still can return to a lower court and challenge the substance of the federal rules. In all, four of the eight court members wrote opinions in the case. Justice Sandra Day O'Connor, who long has owned AT&T stock, did not participate in the decision. The court also upheld most of the FCC's rules aimed at prohibiting local phone companies from separating parts of their network and then requiring a customer who leases those parts to pay the cost of reassembling them. The commission contends that such "unbundling" imposes unneeded costs on a competitor. But the justices said the FCC "did not adequately consider" all factors when it passed a rule requiring a local phone company to provide competitors with access to various local network elements. The court concluded that the commission's Rule 319 is inconsistent with the 1996 law. The court also ruled that the commission can impose a "pick and choose" rule on local phone companies, which allows competitors to buy or lease any service or network element under the same terms as they were provided under any previous agreement without having to accept the entire agreement. Supporters of local phone competition hope it will lead to lower prices like the 70 percent drop in long-distance costs after competition was introduced during the 1980s.yesterday's ruling reversed key portions of a federal appeals court decision that said the FCC

could not regulate the prices competitors must pay to connect to local phone companies' networks. Joining the federal government in supporting the FCC price rules were long-distance companies, including AT&T and MCI, that hope to begin offering local phone service. Opposing the federal rules were state utility regulators and existing local phone monopolies such as Bell Atlantic and BellSouth. The vote to let the FCC set the pricing rules was 5-3. Joining Scalia were Justices John Paul Stevens, David H. Souter, Anthony M. Kennedy and Ruth Bader Ginsburg. Chief Justice William H. Rehnquist and Justices Clarence Thomas and Stephen G. Breyer dissented. The voting on other aspects of the dispute also was split.

FOOD & DRUG ADMINISTRATION
v.
BROWN & WILLIAMSON TOBACCO CORPORATION *ET AL.*

Does the FDA Have the Authority to Regulate Tobacco?

Matthew Frey *

Perhaps having thought it had performed satisfactory penance when it last year agreed to settle for $206 billion a lawsuit launched by 40 states to recover their costs in treating ill smokers, the American tobacco industry today finds itself heading into the 21st century with its prospects more in doubt than at any time in recent memory.

Amid the news that a Miami jury recently sided with scores of Florida smokers in the first class action lawsuit filed by smokers to come to trial, and widespread concern over how that jury's damages award might influence the course of future tobacco litigation, the tobacco industry finds itself having this upcoming term to defend a Fourth Circuit Court of Appeals decision that reversed District Judge William L. Osteen Sr.'s 1997 opinion granting authority to the Food and Drug Administration to regulate tobacco products.

"It will be the most important public health case the Supreme Court hears in decades," said Dr. David Kessler, a pediatrician and lawyer who oversaw the formulation of the FDA's tobacco regulations when he headed the agency in the mid-1990's.

The FDA had claimed jurisdiction over tobacco products under the Food, Drug and Cosmetic Act (FDCA) after the agency ruled that cigarettes and smokeless tobacco constituted "combination products," products which exhibit characteristics, in this case, of both drugs and devices, two categories the FDCA granted the FDA power to regulate.

Writing for the 2-1 majority, however, Fourth Circuit Judge H. Emory Widener Jr. criticized the FDA for basing its decision to pursue jurisdiction over tobacco products merely on the "definitions section" of the FDCA, and ignoring the true reasons Congress passed the FDCA in 1938. "We are of [the] opinion that the FDA's limited, mechanistic inquiry is insufficient to determine Congress' intent," the court wrote, later citing the landmark Supreme Court case *Chevron v. Natural Resources Defense Council*, whose two-part test requires courts to scrutinize legislative intent before passing judgment on whether an agency's interpretation is "permissible."

The majority noted that the lower court had been correct to seek answers in the FDCA's legislative history but had picked the wrong question to ask. The issue at hand, Judge Widener wrote, invoking a distinction familiar to students of administrative law, was not "whether Congress has evidenced its clear intent to withhold from FDA jurisdiction [the authority] to regulate tobacco products," but "whether Congress intended to delegate such jurisdiction to the FDA." In other words, contrary to the district court, the appeals court ruled that its inquiry into the legislative history of the FDCA should proceed under the presumption that Congress *had not* intended to grant the FDA jurisdiction over tobacco.

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Finding nothing in the FDCA's legislative history to contradict their presumption, the majority ruled that Congress' intent was clear. "Congress did not intend to delegate jurisdiction over tobacco products to the FDA," Judge Widener wrote. Yet even if Congress had intended to grant jurisdiction to the FDA, the court suggested, it had done a poor job of it, since the FDA's claimed authority over tobacco subverted the agency's basic regulatory mission.

Pursuing this fundamental discrepancy, the majority wondered how the FDA would square its mission to protect the public from unsafe and ineffective drugs and devices with its new authority to regulate tobacco products—products the FDA sought to regulate precisely because it had judged them "dangerous, unsafe, and the cause of 'great pain and suffering' . . . ." "[T]he FDA cannot comply with the terms of the very statutory provision it has chosen as it basis for regulation," the majority concluded, chiding the FDA for the "obvious sophistry" it employed in an effort to circumvent this catch-22. If nothing else, the FDA's argument on this point reinforced the main thrust of the majority's opinion. "Again, the contortions that the FDA has gone through demonstrate that Congress did not intend its jurisdictional grant to the FDA to extend to tobacco products," the court wrote.

Senior U.S. Circuit Judge Kenneth K. Hall, writing in dissent, disagreed with the relative weight the majority assigned to the text and legislative history of the FDCA. He criticized his colleagues for overlooking a common-sense reading of the language of the statute in favor of a legislative history clouded by recent disclosures of material contained in secret tobacco industry documents.

"While as much as conceding that tobacco products fit the FDCA's 'literal' definition of drug," Judge Hall wrote, "the majority concentrates instead on what it believes is abundant evidence elsewhere demonstrating that Congress has never intended that tobacco come under FDA authority." Despite the majority's reliance on evidence that Congress and the FDA had been traditionally reluctant to assert jurisdiction over tobacco, the dissent continued, times had changed. "No other court . . . has been confronted with the type and quantity of evidence collected during the rulemaking process in this case," Judge Hall began. "[T]he strength of nicotine's addictive qualities, the extent of the health problems created by tobacco products, and the complicity of the manufacturers bring us to a different place than we have been before."

In Judge Hall's view, the majority failed to discern that Congress had chosen inherently flexible language in which to fix its legislative intent. "The operative congressional intent [behind the FDCA] was simply to confer broad discretionary powers on the FDA to regulate 'drugs' and 'devices.' The FDCA was written broadly enough to accommodate both new products and evolving knowledge about existing ones, and it was written that way on purpose."

98-1152 Food and Drug Administration v. Brown & Williamson Tobacco Corp.

Ruling below (4th Cir., 153 F.3d 155, 67 U.S.L.W. 1005):

Food and Drug Administration's authority under Food, Drug, and Cosmetic Act to regulate "drugs" and "devices" does not extend to access restrictions and labeling requirements for tobacco products.

Question presented: Given FDA's findings, are tobacco products subject to regulation under Food, Drug, and Cosmetic Act as "drugs" and "devices"?

FOOD & DRUG ADMINISTRATION, Appellant
v.
BROWN & WILLIAMSON TOBACCO CORPORATION *et al.*, Appellees

United States Court of Appeals
for the Fourth Circuit

Decided August 14, 1998

WIDENER, Circuit Judge.

On August 28, 1996, the Food and Drug Administration (FDA) published a final rule entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents." * * * In general, this rule set out regulations restricting the sale and distribution of cigarettes and smokeless tobacco (collectively referred to as "tobacco products") to minors and limiting the advertising and promotion of tobacco products. Plaintiffs (cigarette and smokeless tobacco manufacturers, convenience store retailers, and advertisers) filed these consolidated actions in federal district court, challenging the FDA's jurisdiction over tobacco products and seeking declaratory and injunctive relief. * * * Plaintiffs then filed a motion for summary judgment in the district court, alleging that, as a matter of law: (1) Congress has withheld from the FDA the jurisdiction to regulate tobacco products as marketed by plaintiffs; and (2) the Federal Food, Drug, and Cosmetic Act (Act) does not permit the FDA to regulate tobacco products either as drugs or as devices. In denying plaintiffs' motion for summary judgment in part and granting the motion in part, the district court held that Congress did not "[intend] to withhold from FDA" the jurisdiction to regulate tobacco products. * * * The district court also concluded that the FDA had authority to regulate tobacco products under the device provision of the Act, but disapproved the FDA's restrictions on advertising as inconsistent with its statutory authority. * * * Finally, the district court stayed implementation of the majority of the FDA's regulations pending appeal. * * *

Because this case arises from a motion for summary judgment, we review the judgment of the district court de novo. * * * For purposes of these appeals, plaintiffs do not dispute the factual findings of the FDA. Based on our review of the record and the relevant legal authorities, we are of opinion that the FDA lacks jurisdiction to regulate tobacco products. For the reasons set forth below, all of the FDA's August 28, 1996 regulations of tobacco products are thus invalid. Accordingly, we reverse the judgment of the district court.

I. FDA's Asserted Basis for Jurisdiction

The FDA * * * has authority to regulate products only if they fall within one of the categories defined by Congress in the Act. * * * [The categories of products subject to regulation by the FDA are food, drugs, devices, and cosmetics.] In the jurisdictional determination attached to its August 28, 1996 regulations, the FDA asserted jurisdiction over tobacco products under the drug

* * * and device * * * definitions in the Act. * * *

According to the FDA, tobacco products fit within these definitions because they are "intended to affect the structure or any function of the body." More specifically, the FDA concluded that tobacco products are "combination products consisting of nicotine, a drug that causes addiction and other significant pharmacological effects on the human body, and device components that deliver nicotine to the body." * * * Based on its classification of tobacco products as combination products, the FDA claimed that it could exercise its discretion in deciding whether the drug provisions or device provisions of the Act should apply. * * * Although finding that tobacco products function primarily as drugs, * * * the FDA concluded that tobacco products are most properly regulated under the device provisions of the Act, in particular the restricted devices section. * * * The FDA's jurisdictional determination encompasses over 600 pages in the Federal Register; however, its basic premise can be fairly summarized in one sentence. That is, the FDA asserted jurisdiction over tobacco products based on its conclusion that tobacco products fit within the literal definitions of drug and device as set forth in the Act. In short, the FDA's inquiry began and ended with the definitions section of the Act.

We are of opinion that the FDA's limited, mechanistic inquiry is insufficient to determine Congress' intent. Therefore, as directed by Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., * * * we employ the traditional tools of statutory construction to ascertain congressional intent regarding whether the FDA has authority to regulate tobacco products.

II. Jurisdictional Analysis

We begin with the basic proposition that agency power is "not the power to make law. Rather, it is 'the power to adopt regulations to carry into effect the will of Congress as expressed by the statute.' " * * * Thus, our initial inquiry is whether Congress intended to delegate to the FDA authority to regulate tobacco products as "customarily marketed." * * * The district court framed the issue as "whether Congress has evidenced its clear intent to withhold from FDA jurisdiction to regulate tobacco products as customarily marketed." * * * However, we are of opinion that the issue is correctly framed as whether Congress intended to delegate such jurisdiction to the FDA. * * * This fundamental misconception by the district court of the principal issue in the case unavoidably skewed the remainder of its analysis.

Applying the principles set forth by the Supreme Court in *Chevron*, we examine whether Congress intended to give the FDA jurisdiction over tobacco products. Under *Chevron*, we first consider the intent of Congress because "[I]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." * * * It is only if the intent of Congress is ambiguous that we defer to a permissible interpretation by the agency. * * * And we note, with emphasis, that the Supreme Court has stated that "[a] precondition to deference under Chevron is a congressional delegation of administrative authority." * * * Accordingly, no deference is due the

FDA's construction of the Act unless it is acting within the bounds of its congressionally-established authority. If the court can ascertain Congress' intent on a particular question by applying the traditional rules of statutory construction, then it must give effect to that intent. * * * We also note that ascertaining congressional intent is of particular importance where, as here, an agency is attempting to expand the scope of its jurisdiction. * * *

Although the task of statutory construction generally begins with the actual language of the provision in question, * * * the inquiry does not end there. * * * The Supreme Court has often emphasized the crucial role of context as a tool of statutory construction. For example, the Court has stated that when construing a statute, courts "must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy." * * * Thus, the traditional rules of statutory construction to be used in ascertaining congressional intent include: the overall statutory scheme; * * * legislative history; "the history of evolving congressional regulation in the area"[;] * * * and a consideration of other relevant statutes. * * * With these general principles in mind, we begin our inquiry into the issue of whether Congress intended to delegate jurisdiction over tobacco products to the FDA.

A. Intrinsic Evidence

The FDA correctly contends that the language of the statute must be the starting point of our analysis. We agree that the first step of statutory construction is determining the plain meaning of the statutory text. In fact, the Court instructs that the inquiry ends with the statutory language when the language is unambiguous and "the statutory scheme is coherent and consistent." ***

However, the flaw in the limited approach suggested by the FDA and taken by the district court is that they examine only the literal meaning of the statutory definitions of drug and device. * * *

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 or devices. However, an initial problem with the government's theory is that the definitions of drug and device require not only that the article "affect the structure or any function of the body," but also that these effects be intended. * * * As noted by the district court, "no court has ever found that a product is 'intended for use' or 'intended to affect' within the meaning of the [Act] absent manufacturer claims as to that product's use." * * * Even the FDA does not contend that tobacco manufacturers make any such claims. * * *

Even if we were to accept the FDA's position that no other inquiry is permissible if tobacco products fall within the literal definition of drug or device, the jurisdictional inquiry would not end there. Both the FDA and the district court failed to examine the literal definitions in view of the language and structure of the Act as a whole. Such holistic approach to statutory construction is well-supported by the case law. * * * Accordingly, our task is to examine whether tobacco

products fit into the overall regulatory scheme created by Congress.

According to FDA Deputy Commissioner Schultz, "[a] fundamental precept of drug and device regulation in this country is that these products must be proven safe and effective before they can be sold." * * * In fact, the FDA's congressionally-established mission statement provides that the FDA is charged with protecting the public health by ensuring that human drugs are "safe and effective" and that "there is a reasonable assurance of the safety and effectiveness of devices intended for human use." * * * During its rulemaking, the FDA found that tobacco products are "dangerous," "unsafe," and the cause of "great pain and suffering from illness such as cancer, respiratory illnesses, and heart disease." * * * In addition, the FDA determined that over 400,000 people die each year from tobacco use. * * * Yet, the FDA has proposed to regulate tobacco products under a statutory provision that requires conditions on sale and distribution which provide a reasonable assurance of safety. * * * According to the FDA, a determination of safety under the Act requires consideration of the risks of a product compared to the "countervailing effects of use of that product, including the consequences of not permitting the product to be marketed." * * * Thus, the FDA concluded that withdrawal of tobacco from the market poses significant health risks to addicted adults which outweigh the risks of leaving tobacco products on the market. * * *

But that test is contrary to the statute. The statutory provision * * * provides that safety and effectiveness are to be determined by "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." * * * According to the language of [the statute] the FDA's obligation is to strike a balance between the risks and benefits of the use of a certain product, not to weigh the risks of leaving a product on the market against the risks of taking a product off the market. The FDA is unable to state any real health benefit derived from leaving tobacco products on the market. This is not to say that there are not other public policy reasons, such as impact on the national economy and the potential for a black market, weighing against a ban on tobacco products. However, this type of decision involving countervailing national policy concerns is just the type of decision left for Congress. By statute, the FDA's authority is limited to the balancing of health benefits and risks. * * * Thus, its attempted analogy between tobacco products and chemotherapy drugs is not well taken. * * * These cancer-fighting drugs may be considered high-risk, but they have not been deemed "unsafe" by the FDA. Under the Act, the key to allowing these drugs to remain on the market is that their use produces affirmative health benefits which outweigh their risks. * * * According to the FDA's own findings, tobacco products do not meet this test, for there is no health benefit from the use of tobacco. The FDA's inquiry into whether the risks of removing tobacco products from the market are greater than the risks of leaving them on the market is irrelevant under [the statute].

In the proposed regulations, the FDA characterized tobacco products as combination products containing drug and device components, but purported to regulate tobacco products as restricted devices under § 360j(e) of the Act.

Section 360j(e) permits the FDA to place restrictions on the sale, distribution or use of a product which are necessary for a "reasonable assurance of safety" of the product. * * * However, based on the FDA's characterization of tobacco products as unsafe, it is impossible to create regulations which will provide a reasonable assurance of safety. Thus, the FDA cannot comply with the terms of the very statutory provision it has chosen as its basis for regulation. In addition to the fundamental conflicts described above, at least six internal inconsistencies arise when tobacco products are forced into the drug or device regulatory schemes of the Act.

First, § 355(a) of the Act requires that all new drugs be approved by the FDA before marketing. * * * The Act requires the FDA to disapprove applications for new drugs if the drug is deemed unsafe or if there is not substantial evidence of its effectiveness. * * * This mandatory approval process presents an insurmountable problem for the FDA with respect to tobacco products because of the FDA's finding that they are unsafe. * * * In fact, the FDA has conceded that under the mandatory approval provisions, tobacco products would constitute unapproved new drugs. * * * As such, the Act would require the prohibition of the distribution and marketing of tobacco products. * * *

The FDA attempts to avoid the problem inherent in the new drug approval requirement by classifying tobacco products as combination products and then choosing to regulate them as devices rather than as drugs. The Act directs the FDA to determine the primary mode of action of a combination product. * * * If the FDA determines that the primary mode of action is that of a drug, then it must assign "primary jurisdiction" over the product to the persons charged with premarket review of drugs. * * * The FDA concedes that the "primary mode of action" of tobacco products is that of a drug. * * * Yet, it chose to regulate tobacco products devices under § 360j(e) of the Act. This transparent action by the FDA, obvious sophistry, taken in order to avoid the new drug provisions of the Act, reinforces the conclusion that regulation of tobacco products under the Act was not intended by Congress. However, the FDA's classification of tobacco products as devices could not avoid similar problems caused by other provisions of the Act.

Section 331(a) of the Act prohibits the introduction into or delivery in interstate commerce of any drug or device that is misbranded. * * * Under § 352(j), a drug or device is deemed to be misbranded if it is dangerous to health when used in the manner suggested in the labeling. * * * The FDA has concluded that the use of tobacco products is dangerous to health. * * * Thus, it is impossible for the labeling of tobacco products to suggest a nondangerous use. Accordingly, §§ 331(a) and 352(j) operate to make the continued marketing of tobacco products illegal.

A drug or device is also considered misbranded, and thus prohibited under § 331(a), if it does not include "adequate directions for use." * * * According to the FDA, the requirement of adequate directions for use means "directions under which the layman can use a device safely and for the purposes for which it is intended." * * * The FDA can exempt drugs and devices from § 352(f)(1)'s directions requirement, but only if the information is "not necessary for the

protection of public health." * * * The FDA has previously interpreted § 352(f) to mean that an exemption from the direction requirements may be granted when other circumstances (such as a physician's prescription) can reasonably assure safe use of the drug or device. * * *

The FDA now contends that an exemption for tobacco products is appropriate, * * * because everyone knows how to use tobacco products and thus directions are not needed. * * * However, the FDA violated its own interpretation of the Act by exempting tobacco products under § 352(f) without any assurances of safety. Because of the FDA's finding that tobacco products are unsafe, * * * it is impossible to provide directions for safe use as required by the statute. In addition, the exemption is inapplicable because no assurance of safety can be given for inherently unsafe products such as tobacco. Again, the FDA's need to apply the statutory exemption demonstrates that the Act does not and cannot apply to tobacco products.

Similarly, a drug or device is also considered misbranded, and thus prohibited by § 331(a), if it fails to bear "adequate warnings against use . . . by children where its use may be dangerous to health." * * * Unlike § 352(f)(1), this section does not permit any exemptions from the warning requirement. In support of its proposed regulations, the FDA cited widespread use of tobacco products by minors and focused on controlling youth use as a means of decreasing tobacco-related illnesses and deaths. * * * The FDA concluded that the warnings mandated by other federal statutes satisfy the Act's requirement for adequate warnings to children even though none of the statutorily-prescribed warnings address the particular dangers of youth use repeatedly emphasized by the FDA. * * * The FDA was constrained to find that the warnings mandated by other federal statutes are sufficient because the applicable federal statutes do not permit federal agencies to add to or modify the congressionally-mandated warnings. * * * Again, the contortions that the FDA has gone through demonstrate that Congress did not intend its jurisdictional grant to the FDA to extend to tobacco products.

Furthermore, under 21 U.S.C. § 360c(b)(1), all devices intended for human use must be classified into one of three categories, Class I, II, or III, based on ascending degrees of dangerousness. Placement is appropriate in the class that will provide a "reasonable assurance of the safety and effectiveness of the device." * * * As discussed above, safety and effectiveness are determined by "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." * * * Three years after it first introduced the proposed regulations, the FDA has yet to place tobacco products into one of the three categories. However, the agency's own findings with respect to dangers to health require classification of tobacco products as a Class III device subject to premarket approval because they "[present] a potential unreasonable risk of illness or injury." * * * Under the premarket approval process, tobacco products could not be approved without a showing that there is a reasonable assurance of safety and effectiveness of the products when used in the manner suggested by the labeling. * * * The FDA contends that it will classify tobacco products at some point in the future and that the long delay is consistent with both the statutory framework and the agency's prior actions for other devices. * * *

However, the real problem with attempting a classification is that all three categories of devices require reasonable assurances of safety and effectiveness for the product. * * * As discussed earlier, the FDA cannot provide reasonable assurances of safety for a product that it has found to be inherently unsafe and dangerous. Thus, it has not, and more importantly, cannot comply with Congress' statutory classification directive because complying with the statute would trigger a ban on tobacco products, a result not intended by Congress.

Finally, the Act requires the FDA to issue an immediate cease-distribution order for all products found to cause "serious, adverse health consequences or death." * * * This order begins an agency process that may ultimately result in a recall order for the device. * * * The FDA has found that "tobacco use is the single leading cause of preventable death in the United States. More than 400,000 people die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease, often suffering long and painful deaths." * * * According to the terms of the Act, these findings, standing alone, mandate that the FDA issue a cease-distribution order for tobacco products. Nevertheless, the FDA has no intention of complying with the requirements of the Act. * * * The necessity of the FDA's avoidance of the statutory directives again demonstrates that Congress did not intend that the Act regulate tobacco products. A faithful application of the statutory language would lead to a ban on tobacco products—a result not intended by Congress.

The FDA makes a linguistic argument in an attempt to avoid the problem presented by this section. The statute provides that if the FDA finds there is a reasonable probability that a device will cause health problems or death, then the FDA "shall issue an order requiring . . . [the immediate] cease distribution of such device." * * * However, the FDA contends that "shall" should be interpreted to mean "may." * * * Even if we were to adopt this interpretation, the substance of our analysis would not change. As discussed above, the FDA has made the requisite finding of dangerousness under the statute. Thus, even if "shall" were interpreted as "may," the FDA still could exercise its discretion under the statute and ban tobacco products. And a failure to ban a product as dangerous as is tobacco, by the FDA's own findings, would necessarily be an abuse of discretion. But because an absolute ban falls outside the scope of congressional intent, construing the Act to cover tobacco products would be inconsistent with the will of Congress.

As demonstrated by the examples provided above, the FDA's need to maneuver around the obstacles created by the operative provisions of the Act reflects congressional intent not to include tobacco products within the scope of the FDA's authority. The FDA argues that even if it has misapplied the Act, this error does not bear on the jurisdictional issue. However, the point is not merely that the FDA misapplied the Act, but these examples demonstrate the FDA's need to ignore and misapply the operative provisions of the Act before it can attain its end, not the end contemplated by Congress. * * * The fact is that Congress did not equip the FDA with tools appropriate for the regulation of tobacco because it had no intention that the Act apply to tobacco products.

We do not dispute in this case that Congress has charged the FDA with protecting the public health and that tobacco products present serious health risks for the public. However, the Supreme Court has warned that "[I]n our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." * * * Based on our examination of the regulatory scheme created by Congress, we are of opinion that the FDA is attempting to stretch the Act beyond the scope intended by Congress.

B. Extrinsic Evidence

[The court here traces Congressional and FDA attitudes toward regulating tobacco over the past century, and concludes that legislative inaction, combined with the FDA's historical reluctance to assume authority over tobacco products, "provide strong evidence of congressional intent that it, and not the FDA, controls the regulation of tobacco products."]

* * *

III. Conclusion

This is not a case about whether additional or different regulations are needed to address legitimate concerns about the serious health problems related to tobacco use, and particularly youth tobacco use, in this country. At its core, this case is about who has the power to make this type of major policy decision. As the Supreme Court has previously stated about a different agency and its enabling statute, neither federal agencies nor the courts can substitute their policy judgments for those of Congress. * * * In rejecting the agency's interpretation of its enabling statute, the *MCI* Court characterized the agency's action as "effectively the introduction of a whole new regime of regulation ... which may well be a better regime but is not the one that Congress established." * * * Accordingly, we do not, indeed cannot, pass judgment on the merits of the regulatory scheme proposed by the FDA. By its ultra vires action, the FDA has exceeded the authority granted to it by Congress, and its rulemaking action cannot stand.

We are thus of opinion that Congress did not intend to delegate jurisdiction over tobacco products to the FDA. Accordingly, the judgment of the district court is

REVERSED.

K.K. HALL, Circuit Judge, dissenting.

The FDCA delegates to the FDA the duty of promulgating and enforcing regulations aimed at protecting the nation's citizens from misbranded and unsafe drugs and food. After years of considering an array of evidence, much of it only recently brought to light, the FDA decided to regulate a product that is estimated to cause some 400,000 deaths a year. While not actually disputing that tobacco products deliver a drug, nicotine, into the body, the majority would deny to the FDA the authority to act to address this acknowledged health threat. I dissent.

Tobacco products fit comfortably into the FDCA's definitions of "drug" and

"device." Inasmuch as cigarettes and smokeless tobacco are responsible for illness and death on a vast scale, FDA regulations aimed at curbing tobacco use by children cannot possibly be contrary to the general intent of the FDCA to protect the public health. But even when we expand our search for legislative intent beyond the words of the statute, the evidence falls far short of demonstrating that Congress intended to deny or withdraw jurisdiction over tobacco from the FDA. Therefore, on the major question before us, I would affirm the district court's denial of summary judgment to the companies to the extent such judgment turns on the issue of the FDA's authority to regulate tobacco products.

* * *

I

* * *

The majority devotes approximately three paragraphs to the words that form the heart of the FDA's jurisdictional claim: "[T]he term 'drug' means ... articles (other than food) intended to affect the structure or function of the body." * * * While as much as conceding that tobacco products fit the FDCA's "literal" definition of drug, the majority concentrates instead on what it believes is abundant evidence elsewhere demonstrating that Congress has never intended that tobacco come under FDA authority. Despite the apparent agreement about the "literal" meaning of "drug" and "device," a few words are necessary to set the stage before moving on to a discussion of the "context" of the FDCA.

A

The rulemaking record contains voluminous evidence of the pharmacological effects of nicotine; in addition to being highly addictive, nicotine acts as a stimulant, tranquilizer and appetite suppressant. * * * Under these assumed facts, nicotine clearly "affect[s] the structure or function of the body of man . . .", and I do not understand the majority to be saying otherwise. The only arguable impediment to a complete fit between the terms of the statute and tobacco products is the word "intended."

B

Building on the conclusion that the nicotine in tobacco products is highly addictive, the FDA proffered four independent rationales to satisfy the additional requirement that tobacco products be "intended" to affect the body: (1) a reasonable manufacturer would foresee that consumers would use the product to satisfy addiction; * * * (2) most consumers do in fact use tobacco products to satisfy addiction; * * * (3) the manufacturers have long known that consumers use the products for the pharmacological effects; * * * and (4) the manufacturers design the products to deliver active doses of nicotine. * * * On reasoning with which I agree, the district court held that the FDA could proffer evidence in support of the first and second of these rationales. * * * In addition, I would also permit the use of recently disclosed evidence, including heretofore-secret company documents, that establish that the companies have known about the addictive qualities of their products for years and that cigarettes

are deliberately manipulated to create and sustain addiction to nicotine.

My dictionary contains the following definitions of "intend": "1. To have in mind: PLAN. 2a. To design for a particular purpose. B. To have in mind for a particular purpose." WEBSTER'S II NEW RIVERSIDE UNIVERSITY DICTIONARY (1984). As a matter of simple English, the resultant effect on the body—nicotine addiction—is intended when the manufacturer (as we are assuming for the purposes of this appeal) deliberately designs the product to have that effect. This meaning is the primary, literal, and most common one attached to the word "intend," and it is ordinarily the one we should use. * * * The majority's argument does not convince me that we should abandon this common sense rule in this situation.

Prior to these rules, the FDA had "asserted jurisdiction over cigarettes only when health claims were made by the vendors or manufacturers." * * * No other court, however, has been confronted with the type and quantity of evidence collected during the rulemaking process in this case; the strength of nicotine's addictive qualities, the extent of the health problems created by tobacco products, and the complicity of the manufacturers bring us to a different place than we have been before.

Products deliberately designed to create and sustain addiction are not likely to be marketed as such; indeed, such products are more likely listed elsewhere in Title 21 among the illegal controlled substances. It strikes me as patently absurd to contend that cigarettes and smokeless tobacco, products that are (under the assumed facts) actually designed to exert powerful and quintessentially drug-like effects on the users, should escape FDA regulation because the products are marketed as essential accoutrements of a more exciting or more sophisticated lifestyle.

II

Tobacco products, then, come squarely within the plain terms of the FDCA. If the words of a statute are plain, "absent any 'indication that doing so would frustrate Congress's clear intention or yield patent absurdity, our obligation is to apply the statute as Congress wrote it.' " * * * The questions, then, should be: Does upholding FDA jurisdiction over tobacco frustrate clear congressional intent to withhold such jurisdiction? Is it patently absurd? Does it "conflict with any other section of the Code, or with any important state or federal interest, [or] is a contrary view suggested by the legislative history[?]" * * * In other words, given the plain language used * * *, the question should be whether the intent manifested by the words used—that tobacco products are "drugs delivery devices" subject to FDA regulation—is trumped by evidence to the contrary.

* * *

A

The majority opens with this argument: The FDA's mandate is to prevent the marketing of any drug or device that is found to be unsafe; tobacco products are unsafe; to allow the continued sale of cigarettes is completely at odds with such mandate; ergo, the regulations must be struck down. But whether the regulations contravene the

statute is a question wholly apart from whether any regulations could be issued. How the FDA has chosen to regulate tobacco has no bearing on the question of whether that agency has the authority to regulate it at all, particularly when it is agreed that the power to regulate under the FDCA includes the power (under the assumed facts) to ban tobacco products completely. The FDA made an eminently reasonable decision to focus on preventing addiction among children while permitting sales to adults. * * * It is no argument to say that the FDA can do nothing because it could have done more.

B

The majority's analysis of the "extrinsic evidence" of congressional intent stands on three legs: The lack of any mention of tobacco in the statute itself or the legislative history of the 1938 Act; the FDA's consistent disavowal of any intention of taking jurisdiction over tobacco, and, concomitantly, the general assumption that the agency was right; and the series of tobacco-related statutes enacted over the last thirty years. * * *

The FDCA

In construing remedial legislation, we must be ever mindful of the salutary purpose of the statute[:]

> The historical expansion of the definition of drug, and the creation of a parallel concept of devices, clearly show, we think, 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. [W]e are all the more convinced that we must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health. . . .

The majority starts off on the wrong foot when it asks "whether Congress intended to delegate jurisdiction over tobacco products to the FDA."

Congress did not "intend" that any particular product be included; as the district court noted, "[r]ather than itemize each product subject to regulation under the FDCA, Congress defined these categories broadly so that each encompasses a wide range of products." * * * An exhaustive list of covered products was neither feasible nor necessary; effective regulation required flexibility within broad parameters.

Pointing out the obvious—that the FDCA was not originally directed at tobacco—gets us nowhere. No one contends that Congress foresaw in 1938 that tobacco was or might someday be included as a "drug" under the FDCA. The operative congressional intent at the outset was simply to confer broad discretionary powers on the FDA to regulate "drugs" and "devices." The FDCA was written broadly enough to accommodate both new products and evolving knowledge about existing ones, and it was written that way on purpose.

FDA's Prior Position

Until the rulemaking began in 1995, the FDA had interpreted the FDCA to include tobacco products only when

health claims were made. * * * The agency's refusal even extended to opposing citizens' petitions to regulate cigarettes on essentially the same basis that is used in the regulations today. * * * The agency's current position is a response to the increasing level of knowledge about the addictive nature of nicotine and the manufacturer's deliberate design to enhance and sustain the additive effect of tobacco products. When the early tobacco-specific statutes were being debated in Congress, the essential link between tobacco and illness had not yet been proven to the satisfaction of all. For instance, during the floor debate on amendments to the FCLAA, Rep. Perkins stated that

> [I]t is my feeling that not one of the tobacco farmers in my district would knowingly produce any commodity which, when consumed, would cause the dread diseases which have been claimed to be associated with tobacco. But the claims . . . are not proved. Tobacco has been impeached in passion but it had not been convicted in fact. Facts, cold hard facts are the basis upon which congress should legislate. * * *

Well, the "cold hard facts" are now in.

* * *

C

Tobacco is different from the articles commonly associated with the word "drugs," the FDA regulations are indeed the result of turnaround in agency thinking, and tobacco was most probably not on anyone's mind when the FDCA was enacted. But the FDCA was broadly worded by design. In an area in which complex new products (and old products, seen in the light of new evidence) pose the potential for grievous harm, Congress deemed it necessary to delegate to an expert—the FDA—the job of monitoring drugs. Cigarettes and smokeless tobacco clearly fit within the literal terms of the FDCA. Absent a showing that following these statutory terms would be absurd or somehow frustrate congressional intent, we are bound to uphold FDA jurisdiction.

* * *

V

I would affirm the district court's judgment to the extent that it denies summary judgment to the tobacco companies on the issues of the FDA's authority to regulate tobacco products under the FDCA and to regulate such products as "combination products." I would vacate the judgment below to the extent it grants summary judgment to the companies on the issue of the FDA's authority to regulate the advertising of tobacco products.

COURT TO DECIDE F.D.A. POWER ON TOBACCO

The New York Times

Tuesday, April 27, 1999

Linda Greenhouse

The Supreme Court offered itself today as the next battleground in the tobacco wars, announcing that it would decide whether the Food and Drug Administration has authority to regulate tobacco products as drugs and cigarettes as "drug delivery devices."

In accepting an appeal by the Clinton Administration, the Court kept alive the prospect that the extensive regulations the Federal agency issued in 1996, aimed at deterring smoking by minors through restrictions on cigarette sales and advertising, may yet take effect.

The regulations were struck down last year by the Federal appeals court in Richmond on the ground that Congress had not given the Food and Drug Administration the authority to regulate tobacco products.

In its appeal to the Supreme Court, the Administration said the 2-to-1 ruling last August by the United States Court of Appeals for the Fourth Circuit would "deprive the public of an unparalleled opportunity to prevent millions of children from acquiring a highly addictive habit that often leads to premature death."

The appeal, filed by Solicitor General Seth P. Waxman, said the regulations were a result of "the most important public health and safety rule-making that F.D.A. has conducted in the past 50 years."

The tobacco industry, which had brought the suit to block the regulations as soon as they were issued, tried to dissuade the Justices from taking the case by arguing that the settlement reached last fall between the industry and 46 states already included an array of restrictions.

In addition, the industry argued, the question of the Food and Drug Administration's jurisdiction remained before Congress. In his State of the Union speech in January, President Clinton renewed his request to Congress for legislation "to reaffirm" the agency's authority—authority that the appeals court's majority found had never existed.

The case, Food and Drug Administration v. Brown and Williamson Tobacco Corp., No. 98-1152, is likely to be argued in November, with a decision some time next spring. Even if the agency prevails, however, the case will be far from over. The tobacco industry has raised a variety of statutory and constitutional objections to the regulations, including a First Amendment challenge to the advertising restrictions. Having concluded that the agency lacked authority to issue the regulations, the appeals court did not address these specific issues but would have to do so if the Supreme Court disagreed with its jurisdictional conclusion.

In the Food, Drug and Cosmetic Act of 1938, Congress gave the Food and Drug Administration jurisdiction over drugs and "devices," both of which the law defined as items "intended to affect the structure or any function of the body." For years the agency viewed this language as not conveying authority to regulate tobacco products.

But it changed its mind in the mid-1990's after studying the issue in light of new disclosures from tobacco industry witnesses and documents showing that manufacturers carefully controlled the amount of nicotine in cigarettes and viewed their product as a means for delivering doses of a habit-forming chemical. Thus, the agency concluded, nicotine not only had obvious effects on bodily functions but was also "intended" by the cigarette industry to have those effects. Judge William L. Osteen Sr. of Federal District Court in Greensboro, N.C., agreed, upholding the F.D.A.'s authority in a 1997 ruling that the appeals court then overturned.

The appellate panel's majority said that while a "mechanical reading" of the statute appeared to support the agency's assertion of jurisdiction, the overall structure of the Food, Drug, and Cosmetic Act did not. The court said that since the F.D.A. had concluded that cigarettes were fundamentally unsafe, its only option under the law was not to regulate them but to ban them, as it would ban any other unsafe drug—something Congress had clearly not intended, in the majority's view.

While acknowledging that the outlook at the Supreme Court is uncertain, antismoking advocates greeted the Court's announcement today with relief. Matthew L. Myers, executive vice president of the Campaign for Tobacco-Free Kids, said the Court's decision to take the case "has to be interpreted as an appreciation of the public health importance of the issues raised."

Mr. Myers, a lawyer, said the outcome might well be determined by whether the case strikes the Justices as "about an agency that reached out for authority it was never given or about an industry seeking to be rewarded for decades of hiding the truth."

Thirty-nine states filed a brief urging the Justices to hear the Administration's appeal. They said that despite last year's multistate settlement, the Federal agency's regulations "address matters that cannot be effectively addressed by the states alone."

Like the regulations, the terms of the settlement include specific provisions aimed at smoking by minors, but the F.D.A. regulation had broader restrictions on outdoor signs, other advertising and certain retail practices, including limits on vending machines, self-service sales, and coupon redemptions.

The Court granted a second case today, agreeing to decide whether a Reconstruction-era civil rights law bars discrimination against noncitizens in the making of private contracts.

The lower Federal courts have been in dispute on the question for years, and the Justices' effort to decide it four years ago was thwarted when the parties settled a case the Court had agreed to decide.

The case today, United Brotherhood of Carpenters v. Anderson, No. 98-958, is an appeal by a labor union that dismissed its business manager, a legal immigrant from Jamaica, because he was not a United States citizen.

The United States Court of Appeals for the Second Circuit, in Manhattan, ruled last year that the man was entitled to bring a discrimination suit under the Federal law known as Section 1981, which guarantees to "all persons" the same right to make and enforce contracts "as is enjoyed by white citizens." While that law, derived from the Civil Rights Act of 1866, clearly applies to race, the question is whether it also bars discrimination against aliens.

Nine years ago, Congress revisited the law and strengthened its protects to overturn a Supreme Court decision that had narrowed it. Among other things, Congress made clear that the law barred private as well as state-sponsored discrimination.

But Congress did not address the question of the law's application to citizenship in the first place. This case was evidently the subject of unusual behind-the-scenes activity among the Justices, who considered what to do with it at eight successive closed-door conferences before issuing today's order.

HIGH COURT WILL HEAR NICOTINE ARGUMENTS

The Federal Government Wants Court to Decide Whether the FDA has Jurisdiction Over Tobacco

***The Raleigh* News-Observer**

Tuesday, April 27, 1999

James Rosen, Washington Correspondent

WASHINGTON – The Supreme Court volunteered Monday to referee a major dispute between the federal government and the tobacco industry over whether the Food and Drug Administration has the power to regulate nicotine as a drug. In deciding to hear the government's appeal of a lower court's rejection of FDA jurisdiction over tobacco, the high court keeps alive the centerpiece initiative of President Clinton's drive to reduce teen smoking.

Clinton cheered the justices' decision to take on the issue of FDA regulation of tobacco, which anti-smoking lawmakers tried unsuccessfully last year to mandate through legislation.

"Every day, 3,000 young people become regular smokers and 1,000 will have their lives cut short as a result," Clinton said. "I remain firmly committed to the FDA rule, which will help stop young people from smoking before they start by eliminating advertising aimed at children and curbing minors' access to tobacco products."

Lawyers for the government and the cigarette makers probably will make oral arguments before the Supreme Court by the end of the year, with a ruling expected in the first half of next year.

"It will be the most important public health case the Supreme Court hears in decades," said Dr. David Kessler, a pediatrician and dean of the Yale University Medical School.

Kessler formulated the FDA regulations and persuaded Clinton to push them when Kessler headed the agency in the mid-1990s.

The FDA rules impose sweeping new advertising limits on the industry and ban most cigarette vending machines, cigarette self-service displays and free samples. They require tobacco vendors to verify their customers' age with photo identification.

Cigarette makers are also prohibited under the regulations from putting brand names or images on the promotional products that are so popular with youths, such as baseball caps, T-shirts and gym bags. And the rules outlaw use of tobacco brands to sponsor sporting or entertainment events.

But the regulations have been under attack from the tobacco industry almost from the day Clinton announced them in August 1996. The industry filed suit soon after they were proposed, and lower courts have overturned most of them.

The government says authority to regulate tobacco is vested in the FDA under the Food, Drug and Cosmetics Act. That law, it says, enables the agency to control nicotine as a drug and to oversee

the production and distribution of cigarettes as drug-delivery devices.

The tobacco industry counters that Congress didn't intend tobacco to be one of the products regulated by the FDA in setting up the agency, and that it would have to pass a separate law to give the FDA that power. Unfettered FDA control, the industry says, would lead to an eventual ban on smoking.

Democratic Sen. John Edwards of North Carolina said he was surprised by the high court's willingness to hear the case because he believes that the 4th U.S. Circuit Court of Appeals ruled correctly last year in striking down FDA jurisdiction.

"I think congressional intent in this area is clear," Edwards said. "Congress has never shown the slightest intent to put tobacco under the FDA, and it's had numerous opportunities to do so. There have been a number of bills introduced, and they've never gone anywhere."

Age verification with photo ID is the only provision of the FDA rules in effect because lower courts struck down the rest in earlier rulings. A three-judge panel of the 4th Circuit ruled last August that the FDA lacks legal power to regulate tobacco.

"We believe the 4th Circuit correctly interpreted and applied the laws regarding FDA authority, and we believe that court's opinion will be upheld by the Supreme Court," said Charles A. Blixt, executive vice president of R.J. Reynolds Tobacco Co. in Winston-Salem, N.C.

Mary Carnovale, a spokeswoman for Philip Morris Inc., said the world's largest cigarette manufacturer already has implemented some of the FDA regulations as part of the industry's settlement of states' lawsuits over the cost of treating sick smokers.

"We have removed all billboard and transit advertising nationwide, discontinued tobacco brand merchandise and apparel, and provided substantial funding for public research and youth-smoking prevention efforts," she said. "Preventing kids from smoking is an important business priority."

Matthew Myers, executive vice president of the Campaign for Tobacco-Free Kids, said tobacco is the only legal product that is not subject to health and safety regulations.

"Today's decision reflects the Supreme Court's appreciation of the extraordinary public health implications of this case, separate from the legal issues," he said. "It will determine whether an industry can escape federal legislation by hiding the truth from Congress and federal regulators for decades."

Myers and other public health advocates say lawmakers failed to place controls on tobacco because the cigarette makers deceived Congress and the public by withholding information about the health effects of their products.

The tobacco industry agreed to accept FDA regulation, with certain restrictions, as part of a proposed settlement with state attorneys general in June 1997.

That settlement package required congressional approval because it gave the industry liability protections against a range of class-action and other civil lawsuits. The bill that eventually emerged from the package died in the Senate last June after a month of debate, and the tobacco firms reached a more modest settlement with the states.

JUSTICES TO DECIDE FDA'S TOBACCO AUTHORITY

The Washington Post

Tuesday, April 27, 1999

Joan Biskupic, Washington Post *Staff Writer*

The Supreme Court agreed yesterday to determine whether the Food and Drug Administration has authority to regulate tobacco products, in a case testing the government's effort to control cigarette makers and prevent young people from smoking.

The FDA asserted broad authority over tobacco in 1996 in light of evidence that manufacturers deliberately fed smokers' nicotine habits and targeted young people with their advertising. But a federal appeals court panel ruled 2 to 1 last August that the agency went too far by imposing policy that is the domain of Congress.

By granting the government's appeal for a review of the case later this year, the court is intervening in a high-stakes dispute over the government's crusade against tobacco at a time of escalating legal and political attacks on the industry.

Government lawyers say the FDA rules restricting teenagers' access to cigarettes and preventing tobacco companies from promoting their products to young people offer "an unparalleled opportunity to curb tobacco use by children." Among the new mandates was a national minimum age of 18 for buying cigarettes and smokeless tobacco and a requirement that retailers check the photo identification of any purchaser who looks younger than 27.

"Every day, 3,000 young people become regular smokers and 1,000 will have their lives cut short as a result," President Clinton said in a statement applauding the court's decision to hear the appeal. "I remain firmly committed to the FDA rule, which will help stop young people from smoking before they start."

But the cigarette companies, which had urged the justices to let stand the ruling by the U.S. Court of Appeals for the 4th Circuit, contend that Congress has repeatedly denied the agency authority over tobacco products. The FDA regulation, said the tobacco manufacturers and distributors in their brief, "short-circuit[ed] an ongoing political process."

"We believe the [lower court] correctly interpreted and applied the laws regarding FDA authority, and we believe that court's opinion will be upheld by the Supreme Court," said Charles A. Blixt, general counsel for R.J. Reynolds Tobacco Co..

For years the federal government, state officials and individuals have waged war in an effort to discourage smoking, especially among the young, and to hold the industry financially responsible for smoking-related illnesses. A proposed national tobacco bill in the Senate that would have guaranteed federal authority over tobacco collapsed last year.

But the states and industry soon after signed a more limited pact in which tobacco companies agreed to pay states $ 246 billion. Meanwhile, individual lawsuits brought by smokers have led to a recent spate of big jury awards against the companies.

When the FDA asserted authority over tobacco, it brought the cigarette industry under its purview for the first time.

"Without the Food and Drug Administration there is no governmental agency with the authority to rein in the tobacco industry's marketing to children or to require them to reduce the harm caused by the product," said Matthew Myers of the National Center for Tobacco-Free Kids.

In 1996, the agency reversed a decades-old stance that it lacked control over tobacco. The FDA decided tobacco products are "drugs" and "devices" under the Federal Food, Drug and Cosmetic Act, partly based on the fact that nicotine in tobacco products "affects the structure or any function of the body." The agency relied heavily on newly disclosed industry documents that showed companies long knew of nicotine's addictive quality and manipulated the drug in cigarettes.

The FDA said it was focusing on children rather than adults in part because "the sudden withdrawal from the market of products to which so many millions of people are addicted would be dangerous."

The new rules would ban most cigarette vending machines and self-service displays in stores, as well as require retailers to verify that a purchaser is at least 18 years old. Tobacco advertising would be prohibited within 1,000 feet of schools and playgrounds and limited to black and white text. In addition, tobacco brand names would be kept off some sports gear. During the litigation, the only rule in effect has been the national minimum age and a photo ID requirement for purchasers who look younger than 27.

A federal district judge upheld the FDA authority to regulate tobacco products as drugs and devices but said the agency lacked jurisdiction to restrict advertising. Last year, a panel of the U.S. Court of Appeals for the 4th Circuit reversed the district court, saying the agency lacked all authority over tobacco products.

"In the 60 years following the passage of the act [in 1938], the FDA has repeatedly informed Congress that cigarettes marketed without therapeutic claims do not fit within the scope of the act," the appeals court said in an opinion, stressing that "neither federal agencies nor the courts can substitute their policy judgments for those of Congress."

The high court's decision to take Food and Drug Administration v. Brown and Williamson Tobacco means that at least four justices voted to review the 4th Circuit ruling in the term that begins next fall. But nothing in the justices' past writings make clear how a majority (at least five) would decide the merits of the case that could have broad consequences for Big Tobacco, the FDA and all agencies' asserting authority not explicitly sanctioned by Congress.

Staff writers John Schwartz and Saundra Torry contributed to this report.

Background

The FDA and Tobacco

1996: The FDA for the first time determines that tobacco products can be considered "drugs" and "devices" under the Food, Drug and Cosmetic Act and imposes regulations aimed at reducing teenage smoking and restricting marketing of products. Among other rules, the FDA establishes 18 as the national minimum age for buying tobacco products and orders retailers to check the photo ID of

any purchaser who looks younger than 27. Tobacco companies immediately file suit, arguing that Congress never gave the FDA such authority.

1997: U.S. district judge upholds FDA authority to regulate cigarettes and smokeless tobacco products as drugs and devices but says the agency lacks jurisdiction to restrict advertising.

1998: By a 2 to 1 vote, a panel of the U.S. Court of Appeals for the 4th Circuit reverses the district court and rules that the FDA lacks all authority to regulate tobacco products. The court notes that for six decades after passage of the act, the FDA had repeatedly said tobacco was not within its scope. The opinion stresses that "neither federal agencies nor the courts can substitute their policy judgments for those of Congress."

Yesterday: The U.S. Supreme Court announces it will take up the FDA's appeal of 4th Circuit ruling. Oral arguments are to be heard in the fall.

FDA ASKS SUPREME COURT TO REVIEW OPINION INVALIDATING TOBACCO REGS

Tobacco Industry Litigation Reporter

Friday, January 29, 1999

The opinion by the Fourth Circuit U.S. Court of Appeals invalidating the FDA's tobacco regulations was based on a "fundamentally flawed approach to the interpretation of the Federal Fo od, Drug, and Cosmetic Act," according to a petition for review filed earlier this month with the Supreme Court by the Food and Drug Administration. Food and Drug Administration v. Brown & Williamson Tobacco Corp., No. 98-1152 (Jan. 19, 1999, certiorari petition); see Tobacco Industry LR, Nov. 13, 1998, P. 18.

The Fourth Circuit ruled last August that the Food and Drug Administration has no authority to regulate cigarettes as a drug or as a drug-delivery device, and that all tobacco regulations issued by the FDA in August 1996 are invalid.

The FDA issued its regulations on Aug. 28, 1996; they were intended to restrict the sale and distribution of cigarettes and smokeless tobacco to minors and to limit the advertising and promotion of tobacco products.

A group of tobacco companies, convenience store retailers and advertisers challenged the regulations with actions filed in the Middle District of North Carolina, in which they challenged the FDA's jurisdiction over tobacco products. In a motion for summary judgment, the challengers argued that Congress has withheld from the FDA the jurisdiction to regulate tobacco products and that the Federal Food, Drug and Cosmetic Act does not permit the FDA to regulate tobacco products either as drugs or as devices. In a 1997 opinion, U.S. District Judge William L. Osteen Sr. ruled that Congress did not intend to withhold jurisdiction over tobacco from the FDA, and that the FDA had authority to regulate tobacco products under the provisions of the Food, Drug and Cosmetic Act giving the agency authority to regulate medical devices. However, he also determined that the FDA lacked authority to impose restrictions on tobacco advertising. The judge stayed implementation of the FDA regulations pending appeal, and he certified his ruling for interlocutory appeal.

Tobacco companies then appealed the ruling that the FDA has authority to regulate nicotine and tobacco products, and the FDA appealed the ruling that it lacks authority to regulate tobacco advertising.

In its Aug. 14 opinion reversing the District Court, a two-judge majority held that Congress did not intend for the FDA to regulate tobacco products when it enacted the Federal Food, Drug and Cosmetic Act. "The fact is that Congress did not equip the FDA with tools appropriate for the regulation of tobacco because it had no intention that the Act apply to tobacco products," the majority said.

The Fourth Circuit panel based its ruling on its analysis of the operative provisions of the Act, which it said "simply cannot accommodate tobacco products," and on events surrounding the 1938 passage of the act and subsequent statements and actions by Congress and the FDA.

The opinion recites a litany of guidelines, hearings and court rulings showing that the FDA has avoided tobacco regulation for much of this century. It includes statements by two former FDA commissioners, one in 1972 and one in 1989, that the agency could not regulate tobacco under the act. It also notes that Congress has rejected 15 bills that would have given it authority to regulate tobacco.

"We believe that the actions rejected and taken by Congress with respect to the regulation of tobacco provide strong evidence of congressional intent that it, and not the FDA, controls the regulation of tobacco products," Judge H. Emory Widener Jr. wrote for the majority.

Senior U.S. Circuit Judge Kenneth K. Hall dissented. He noted that recently disclosed evidence has shown that tobacco companies have known about the addictive nature of their products for years and that they have deliberately manipulated the nicotine content of their products to create and sustain the addictions of smokers. With this background, FDA regulations intended to prevent minors from smoking "cannot possibly be contrary" to Congress' intent expressed in the Food, Drug & Cosmetic Act of protecting the public health.

The Fourth Circuit denied the FDA's rehearing petition in November.

In its 30-page petition for a writ of certiorari, FDA says that the Fourth Circuit ruled that it had no jurisdiction to regulate tobacco products unless tobacco manufacturers market their products with specific therapeutic claims for their products, a holding which it says is based on a serious misreading of the act.

The Agency contends that the act gives it authority to regulate drugs and devices unless a product is expressly excluded from the act's definition of "drug" or "device"; that the act does not exclude tobacco from either definition; and that it applied this standard to conclude that tobacco products fall within the act's statutory definitions of a "drug" and "device."

The FDA also says it based its conclusion on "an overwhelming factual record" showing that (1) the nicotine in tobacco causes and sustains addiction, and acts as a sedative, stimulant and appetite suppressant; (2) most persons who use tobacco products do so in order to achieve those effects; (3) tobacco manufacturers know that consumer use their products for those purposes; and (4) tobacco manufacturers design their products to deliver pharmacologically actives doses of nicotine.

Given this evidence, the agency argues, it reasonably concluded that tobacco products fall within the act's definitions of "drug" and "device," and its reasonable interpretation of the act was "entitled to deference" by the Fourth Circuit.

The agency next argues that the Fourth Circuit's ruling that it lacked authority to regulate tobacco was based on three legal errors. First, it says that the court started with the "wrong question" when it asked whether Congress intended to give the FDA jurisdiction over tobacco products. Congress did not intend that any particular product be included, it says. Instead, it enacted general definitions of "drug" and "device" so that the FDA could decide whether a particular product is subject to regulation as drug or device.

Second, FDA says that the Fourth Circuit's decision rests on "fundamental misconceptions" concerning when an appeals court is required to defer an agency's findings. Under the Supreme Court's 1984 opinion in Chevron U.S.A.

Inc. v. Natural Resources Defense Council, Inc., the FDA argues, an agency's findings are entitled to deference "as long as an agency is reasonably interpreting a provision it enforces."

Third, the FDA argues that in concluding that Congress intended to preclude FDA from regulating tobacco products, the Fourth Circuit's decision conflicts with the plain language of the controlling definitions of "drug" and "device."

"In sum, when the standard that Congress has selected for determining whether a product is a drug or a device is applied to the extensive evidence before FDA, it is clear that FDA acted reasonably in concluding that tobacco products are subject to regulation under the Act as 'drugs' and 'devices.' This Court should grant certiorari to review the panels' contrary conclusion," FDA insists.

The FDA is represented in the action by Solicitor General Seth P. Waxman; Assistant Attorney General Frank W. Hunger; Deputy Solicitor General Edwin S. Kneedler; Assistant to the Solicitor General Irving L. Gornstein; and DOJ attorneys Eugene Thirolf Douglas Letter, Gerald C. Kell and Christine N. Kohl. FDA chief Counsel Margaret Jan Porter and Associate Chief Counsel Karen E. Schiefter and Patricia J. Kaeding were also involved in the briefing.

STATES SETTLE WITH BIG TOBACCO

The Washington Post

Updated December 23, 1998

The tobacco industry in November 1998 clinched a $206 billion deal to settle all state lawsuits pending against it, rebounding from an unprecedented assault to ensure its financial health and secure significant legal protection for years to come.

The deal, while under attack from health groups and congressional tobacco foes, marks a turning point in the decades-long struggle over smoking. It ends the most formidable legal challenge ever launched against the powerful industry, returning the battle largely to Congress and state legislatures.

The settlement will pour billions into state treasuries over the next 25 years and provide about $1.5 billion for research and advertising against underage tobacco use—all of it coming from an industry that had never paid a cent in damages despite decades of litigation.

Another likely result is that cigarette makers will pass the cost along to smokers, increasing the price per pack by about 40 cents by 2003, which could translate into an even larger price boost for consumers.

The settlement, agreed to by 46 states, the District and four territories, is far narrower than either the unsuccessful tobacco deal proposed in 1997 or the tobacco bill championed in 1998 by Sen. John McCain (R-Ariz.) but killed by the Senate's Republican leadership.

Those measures would have forced huge price increases on cigarettes, granted the Food and Drug Administration broad authority over tobacco and imposed financial penalties if smoking rates failed to decline.

None of those provisions are included in the deal with the states.

The earlier proposals would also have included strong marketing and advertising restrictions. While they would have banished cartoon characters and human figures forever from cigarette ads, Philip Morris Co.'s Marlboro Man remains alive under the deal with the states.

On the other side of the ledger, the industry failed to get its most coveted wish—broad protection from all individual and class-action lawsuits. Those legal challenges remain, including a major class-action case in Florida. But they do not represent as immediate and broad a threat as the suits filed by the chief law enforcement officers in 40 states. The Justice Department is also continuing its wide-ranging investigation of the industry.

Many health advocates have pronounced the deal a disaster, at best a pact that will bring money and some public health advances to states, and at worst one that will give the tobacco industry a weapon against more substantive anti-smoking measures.

Given the strong hand tobacco foes held as recently as five months earlier and the industry's defensive position at that time, the deal seemed an anticlimax. Then, the industry faced 40 state lawsuits and about a dozen class-action cases financed by some of the deepest pockets in the trial bar. A judge had ruled in favor of strong FDA jurisdiction over tobacco, and a Republican-controlled Senate committee

had blessed a bill that would have raised cigarette prices $1.10 per pack in five years.

But Big Tobacco fought back. The industry spent millions of dollars lobbying, making substantial contributions to the Republican Party, and launching an unprecedented $40 million advertising campaign. In June 1998 Senate GOP leaders killed the McCain bill—which had a majority of votes in its favor—by setting a parliamentary hurdle of 60 votes.

Smoking foes say the fight is far from over, but industry sources have said they hope the deal with the states will buy them several years of "peace" on the national front.

This Tobacco Special Report includes key Post stories on five major tobacco-related topics: Politics and Policy, Lawsuits, Health Issues, Teen Smoking and Industry News. Each page also includes relevant Web links. You can also read the latest Post opinions and editorials.

Also This Term:

98–896 Friends of the Earth v. Laidlaw Environmental Services (TOC) Inc.

Ruling below (4th Cir., 149 F.3d 303, 46 Envt. Rep. Cas. 2025):

Clean Water Act citizen suit against incinerator operator that violated terms of discharge permit is now moot, because, although past violations arguably gave citizens standing to initiate suit, only remedy currently available to them – civil penalties to U.S. Treasury – will not redress any injury they have suffered; plaintiffs' failure to obtain relief on merits of their claims precludes any recovery of attorneys' fees or other litigation costs, which are available only to "prevailing party or substantially prevailing party," 33 U.S.C. § 1365(d).

Question presented: (1) Is citizen suit seeking civil penalties under Section 505 of Clean Water Act constitutionally moot under *Steel Co. v. Citizens for Better Environment*, 66 U.S.L.W. 4174 (U.S. 1998), due to lack of redressability, when plaintiffs had standing at time of complaint and have shown continuing injury-in-fact but have not obtained injunctive relief? (2) Is citizen suit seeking civil penalties under Section 505 of Clean Water Act constitutionally moot under *Steel Co.*, due to lack of redressability, when district court has rendered judgment as to liability and issue of liability was contested? (3) Could plaintiffs not be awarded attorneys' fees or litigation costs because case was dismissed for mootness, even if litigation was responsible for bringing defendant into compliance with Clean Water Act?

98–896 Shalala v. Illinois Council on Long Term Care Inc.

Ruling below (7th Cir., 143 F.3d 1072):

Medicare providers' legal challenge to implementing Medicare regulations prior to their enforcement is not barred by 42 U.S.C. § 405(h), which is incorporated into Medicare Act by 42 U.S.C. § 1395ii.

Question presented: Does 42 U.S.C. § 405(h), incorporated into Medicare Act by 42 U.S.C. § 1395ii, permit skilled nursing facilities participating in Medicare program to obtain judicial review under 28 U.S.C. §§ 1331 and 1346 to challenge validity of Medicare regulations?

98-1101 Drye v. United States

Ruling below (8th Cir., 152 F.3d 892, 67 U.S.L.W. 1126):

Taxpayer's right under state law to inherit decedent's estate is "right to property" subject to pre-existing federal tax liens under Section 6321 of Internal Revenue Code, regardless of taxpayer's subsequent disclaimer of estate upon decedent's death.

Question presented: Does interest of heir in estate constitute "property" or "right to property" to which federal tax lien attaches under 26 U.S.C. § 6321 even though heir thereafter purports retroactively to disclaim interest under state law?

98-1480 Beck v. Prupis

Ruling below (11th Cir., 162 F.3d 1090, 67 U.S.L.W. 1380):

Plaintiff asserting civil conspiracy claim under Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962(d), must prove that overt act in furtherance of conspiracy by which plaintiff was injured was "act of racketeering" as defined in 18 U.S.C. § 1961(1).

Question presented: May employee who is terminated for both blowing whistle on and refusing to participate in pattern of predicate acts of racketeering forbidden by RICO assert civil RICO conspiracy claim when he has been injured by overt act in furtherance of RICO conspiracy, which overt act is not, itself, predicate act of racketeering?

98-896 Rotella v. Wood

Ruling below (5th Cir., 147 F.3d 438):

Civil actions under Racketeer Influenced and Corrupt Organizations Act accrue upon discovery of injury alone, and not upon discovery of both injury and pattern of racketeering activity.

Question presented: In calculating statute of limitations for civil RICO claim, does cause of action accrue when injury alone happens, or when plaintiff has both suffered injury and discovered that it results from pattern of RICO activity?