TOBACCO
DRAFT

4/3/00 TO: Eric Gill
FROM: Eng Gould
Background on FDA bill for meeting w/ Frist staff.

Summary of FDA Provisions in S.1415

- **Overview of FDA Provisions:** S. 1415 creates a separate chapter in the FDCA that explicitly gives FDA authority over access to and advertising of tobacco products. In nearly all respects this authority is comparable to the authority that FDA asserted in its 1996 rule, which asserted FDA jurisdiction over tobacco products on the ground that nicotine is an addictive drug and that cigarettes and smokeless tobacco products are combination drug/device products under the Federal Food, Drug and Cosmetic Act (FDCA). S.1415, however, created a separate chapter in order to respond to concerns raised by medical device companies that tobacco statutory interpretations and other policies issued under the device provisions of the FDCA could adversely affect those companies.

  The most significant difference between S. 1415 and current law is the standard that products must meet in order to be marketed. Under current law the standard is "reasonable assurance of safety and effectiveness." This standard obviously does not fit tobacco products because tobacco products are inherently unsafe. Therefore, S. 1414 adopts the standard of "appropriate for the protection of the public health," which allows FDA to take into account the fact that over 40 million Americans are addicted to tobacco in making decisions about how to regulate the product.

- **1996 FDA Tobacco Rule in Effect:** S. 1415 provides that the tobacco regulation that FDA finalized in 1996 will remain in effect as though it were issued under the new law. Because the effective date of certain portions of the regulation has been delayed due to the industry's judicial challenge to the rule, the bill would authorize FDA to establish effective dates for those provisions not yet in effect.

- **Access Restrictions:** S. 1415 authorizes FDA to establish restrictions on the sale or distribution of tobacco products. By affirming the 1996 rule's access restrictions, the bill sets the minimum age of purchase at 18 years; requires age verification by photo ID for anyone 26 or younger; requires face-to-face sales (except for mail order sales); bans vending machines and self-service displays except in facilities where only adults are permitted; prohibits the sales of single cigarettes or "loosies"; bans free samples; and sets the minimum package size at 20 cigarettes. However, S. 1415 constrains FDA from prohibiting the sale of tobacco products in face-to-face transactions by specific categories of retail stores (such as a ban on sale of cigarettes by gas stations).

- **Advertising Restrictions and Warning Labels:** S. 1415 expressly authorizes FDA to establish restrictions related to the advertising and promotion of a tobacco product. By affirming the 1996 rule's advertising restrictions, the bill bans outdoor advertising within 1000 feet of schools and public playgrounds; restricts advertising to black-and-white text only (publications, outdoor, point of purchase, direct mail, etc.), except in publications with a predominant adult readership or at adult only facilities; prohibits the sale or giveaways of products like caps or gym bags that carry cigarette or smokeless tobacco product brand names or logos; and prohibits brand-name sponsorship of sporting or entertainment events, but permits it in the corporate name.

S. 1415 also requires stronger and larger warning labels than existing law on tobacco products (to replace the "Surgeon General's warning"), and provides authority for FDA to modify the text, format, and type size requirements of these statements.

- **Submission of Health Information to the Secretary**: S. 1415 requires tobacco product manufacturers and importers, within 6 months of enactment (and annually thereafter), to submit to FDA specific categories of information relevant to FDA regulation of tobacco products.

- **Good Manufacturing Practice Requirements:** Authorizes FDA to issue regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, of a tobacco product conform to good manufacturing practice (GMPs). The bill also makes explicit that the Secretary has the authority to grant either temporary or permanent exemptions or variances from a GMP requirement.

- **Performance Standards:** S. 1415 confirms FDA's authority to issue standards for tobacco for tobacco products (for example limiting the amount of certain ingredients) if FDA determines that a standard is appropriate for protection of the public health. This authority is the same as that for devices.

  -- In issuing a performance standard, FDA must consider the health effects on tobacco users as well as potential users (such as children).

  -- In order to give Congress a chance to vote on any standard that eliminates all cigarettes, all smokeless tobacco products, or any similar class of tobacco products, or requires the reduction of nicotine yields of a tobacco product to zero, such a standard will not go into effect until two years after the President has notified Congress of such a standard.

- **Testing and Reporting of Tobacco Smoke Constituents:** S. 1415 directs the Secretary to issue regulations to require the testing, reporting, and disclosure of tobacco smoke constituents (e.g., tar, nicotine and carbon monoxide) and ingredients that "the Secretary determines should be disclosed to the public in order to protect the public health."

- **Reduced Risk Tobacco Products:** S. 1415 contains a provision that allows FDA to designate a product as a "reduced risk tobacco product" if it finds that "the product will significantly reduce harm to individuals caused by a tobacco product and is otherwise appropriate to protect the public health."

- **Preservation of State and Local Authority**: S. 1415 makes clear that except as expressly provided, states and localities may adopt and enforce tobacco product requirements that are in addition to, or more stringent than, requirements established under FDCA for tobacco products.

  -- State and local requirements related to access and advertising are not preempted by the FDCA.

  -- State and local requirements related to performance standards, good manufacturing practices, and other similar FDCA requirements, are preempted, but States and localities may apply for exemptions pursuant to procedures that parallel provisions in device law.

  -- S.1415 modifies the Federal Cigarette Labeling and Advertising Act in order to ensure that restrictions on advertising imposed under State laws are not preempted.

- **Full Enforcement Authority:** S. 1415 provides for the same civil and criminal penalties that the agency may use in enforcing the device law. The bill also provides that FDA may issue, after an administrative hearing before an Administrative Law Judge, a no tobacco sale order prohibiting the sale of tobacco products at a particular retail outlet based on repeated violations by that outlet. The bill also imposes the same requirements for the export of tobacco products that do not meet the requirements of the FDCA that apply to devices.

REGULATORY AUTHORITY OVER TOBACCO PRODUCTS IS APPROPRIATELY PLACED AT FDA

- The Food and Drug Administration (FDA) is the leading public health agency with authority to protect public health and to provide regulatory oversight of products that affect the human body, such as foods, drugs, and medical devices.

  - There are other federal public health agencies and there are other federal regulatory agencies. But FDA is the only agency that has extensive experience in both areas. This experience, combined with its recent development of the tobacco access and advertising regulations, makes it the only federal agency that can hit the ground running to implement the regulatory program to combat youth tobacco use in S. 1415.

- Under S. 1415, tobacco products fit appropriately into the regulatory framework that FDA has had in place for over sixty years.

- The scientific and regulatory expertise that resides within FDA is uniquely suited to provide the oversight that will be needed to protect the public health from the hazards of nicotine products. FDA's medical experts already evaluate and approve nicotine replacement drug and device products. In addition, regulatory offices within the agency are experienced in industry-wide product regulation.

- FDA's enforcement authorities, which S. 1415 expressly extends to tobacco products, are essential in order to protect public health. Enforcement actions are necessary to ensure that manufacturers and retailers comply with requirements such as those in the final rule issued in 1996 to protect young people from the hazards of tobacco products, and to protect the public from future violations.

- A distinctive feature of FDA's regulatory authority is the flexibility inherent in the Federal Food, Drug, and Cosmetic Act, and in the new provisions added to that Act by S. 1415, that enable FDA to swiftly and effectively address problems linked to the products for which it is responsible. As tobacco companies design new marketing campaigns or develop new products, FDA has a great amount of flexibility to respond to industry actions that could harm public health.

ID'S OF PURCHASERS UNDER THE AGE OF 27 MUST BE CHECKED

- Under the FDA rule, a retailer must not sell cigarettes or smokeless tobacco to anyone under 18. Therefore, purchasers must be 18 or older.

- Under the FDA rule, retailers must require customers under the age of 27 to present a photo ID (any photo ID with a birth date is acceptable).

  - FDA's rule contains this requirement because the evidence compiled by the agency during its rulemaking showed that it is very difficult to judge the age of many teenagers and young adults simply from their appearance, partly because young people mature at different rates. To ensure that older-looking teenagers are asked for ID, it makes sense to set the requirement to check identification somewhere above 18.

  - FDA's requirement is consistent with a report prepared by twenty-six State Attorneys General recommending that the age for photo ID should be significantly higher than the minimum age of sale.

  - In addition, materials developed and distributed to retailers by the tobacco industry and leading retailer organizations specifically recommended that retailers card anyone who appears to be under 26.

- Under the FDA rule, a retailer is not required to check the ID's of regular customers who are known to be at least 18 years old every time they buy tobacco products. Retailers must check a customer's photo ID at least once to ensure that the customer is at least 18 years old.

S. 1415 PROVIDES AMPLE OPPORTUNITY FOR CONGRESS TO REVIEW ANY FDA DECISION TO ELIMINATE NICOTINE OR A CLASS OF TOBACCO PRODUCTS

- Because of the importance of any decision by FDA to eliminate all cigarettes, all smokeless tobacco products, or any similar class of tobacco products, or to require the reduction of nicotine yields to of a tobacco product to zero, S. 1415 recognizes that it is appropriate for Congress to have the opportunity to review such a decision and enact legislation to override it.

- S. 1415 recognizes this by requiring that FDA may not begin implementing any such standard until at least ***two years*** after the President notifies Congress that a final regulation imposing the restriction has been issued.

- S. 1415's provision ensures that Congress will have sufficient time and opportunity to review the standard and, if desired, vote on whether the standard should be rejected.

- FDA has no plans to use this authority, but scientific developments in the future may make its use appropriate.

- FDA has demonstrated that it would administer its authority to eliminate nicotine reasonably.

  - Although FDA had the authority to reduce or eliminate nicotine at the time it issued its tobacco regulations, the agency did not do so, because, among other reasons, there was not a sufficient scientific basis to conclude that reducing or eliminating nicotine from tobacco products would reduce tobacco use.

  - FDA's refusal to ban cigarettes or smokeless tobacco products was based in part on the significant weight the agency accorded to the risks that a black market would be created and that addicted tobacco users would suffer as a result of sudden withdrawal from nicotine-containing products.

  - FDA is required under S.1415 to take these same factors into account in promulgating any standard eliminating nicotine from tobacco products.

- S. 1415 imposes many procedural requirements on FDA before the agency can issue a performance standard eliminating nicotine from tobacco products.

  - FDA must issue a notice of proposed rulemaking, containing a finding with supporting justification that the performance standard is appropriate for protection of the public health.

  - The notice must contain proposed findings with respect to the risk of illness or injury that the standard is intended to address.

- FDA must invite interested persons to submit an existing or draft performance standard.

- FDA must invite participation from informed persons, including industry representatives.

- FDA must consider the risks to the health of tobacco users and non-users from elimination of nicotine, including the risk that a black market will be created.

- FDA must, at the request of an interested party, refer the proposed standard to an advisory committee.

- A performance standard eliminating nicotine could not be issued in the absence of scientific evidence that such elimination would significantly reduce the risks of illness or injury from tobacco products.

  - Development of such evidence would require reliable information showing that elimination of nicotine would reduce the risks of tobacco use, and that the benefits of this reduction in use were not outweighed by the risks of a black market or of precipitous withdrawal by addicted tobacco users.

S. 1415 APPROPRIATELY MAKES EXPLICIT FDA'S AUTHORITY TO RESTRICT TOBACCO PRODUCT ADVERTISING

- S. 1415 expressly provides that FDA may by regulation require that a tobacco product be restricted to sale, distribution, or use upon such conditions, ***including restrictions on the access to and the advertising and promotion of the tobacco product***, if FDA determines that such regulation would be appropriate for the protection of the public health.
  - This provision has no effect on FDA's regulation of drugs and devices.
- Advertising restrictions are a critical component of FDA regulation of tobacco products.
  - Two recent, comprehensive analyses by the National Academy of Science's Institute of Medicine and the Surgeon General found that tobacco advertising plays a significant role in the decisions of young people to use cigarettes and smokeless tobacco.
    - The two studies are the Institute of Medicine's Report, *Growing Up Tobacco Free, Preventing Nicotine Addiction in Children and Youth* (1994), see especially chapter 4; and the Department of Health and Human Services' Centers for Disease Control and Prevention's Report, *Preventing Tobacco Use Among Young People, A Report of the Surgeon General* (1994), see especially chapter 5.
    - The Institute of Medicine's 1998 Report, *Taking Action to Reduce Tobacco Use* (1998) reaffirms the 1994 IOM Report.
  - In addition, the nation's largest psychological association, the American Psychological Association, concluded that tobacco advertising "plays directly to the factors" that are most appealing to youth.
  - During its rulemaking, FDA found, based on the evidence and comments received, that comprehensive advertising restrictions are necessary to ensure that the access restrictions on access are not undermined by the product appeal that advertising for these products creates for young people.
    - Otherwise, tobacco companies will continue to use advertising to appeal to kids, associating tobacco with fun, sex, glamour, and sports. As long as the tobacco companies are allowed to advertise to kids and create a demand for tobacco products, it will be impossible to effectively address the problem of youth tobacco use.

- FDA also concluded that ***both*** access ***and*** advertising restrictions are necessary to meet public health goals because they are complementary —
  - The effectiveness of access restrictions on youth access would be substantially diminished if the manufacturers were free to entice children and adolescents to circumvent the access restrictions.

- Because advertising restrictions are so critical, the agency's authority in this area should not be left ambiguous and open to lengthy court challenges.

S. 1415 ENSURES THAT FDA WILL ADEQUATELY CONSIDER WHETHER A PROPOSED REGULATORY ACTION WILL RESULT IN HEIGHTENED DEMAND FOR CONTRABAND

- S. 1415 requires that FDA find that regulations to be imposed on a tobacco product "are appropriate for the protection of the public health."
  - In making this finding, FDA is directed to consider the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and
  - Taking into account the increased or decreased likelihood that: (1) existing users of tobacco products will stop using such products, and (2) those who do not use tobacco products will initiate use.
  - FDA is to weigh a variety of consequences resulting from possible new regulations on tobacco products, ***including the use of contraband products and the development of black markets***, and consider the effects of the regulation on both users and nonusers of the products.
  - This standard is not be applied to any other product regulated under the Federal Food, Drug, and Cosmetic Act.
- Requiring FDA to affirmatively ***find*** that a particular regulatory action will not result in the heightened demand for contraband would severely restrict the Agency's authority as it would be forced to prove an unknown.
  - It could be very difficult to prove a negative—that a black market will not occur.
  - If FDA makes the finding, its decision would be delayed by extended litigation.
- FDA's 1996 tobacco rule reflects the agency's consideration of the contraband issue:
  - Considering the large number of Americans who are currently addicted to nicotine, FDA determined that a ban on cigarettes and smokeless tobacco would unlikely be effective in protecting consumers from the serious risks of these products. FDA found that black markets and smuggling could develop, offering products that likely "would be even more dangerous than those currently marketed."

- FDA concluded that, to address effectively the death and disease caused by cigarettes and smokeless tobacco, addiction to these products must be eliminated or substantially reduced.

- FDA found that this goal could be achieved best by preventing minors from beginning use of tobacco products, and not by banning the products.

American Medical Association
Physicians dedicated to the health of America

Statement

FOR IMMEDIATE RELEASE March 25, 2000

AMA: AFTER SUPREME COURT SETBACK – NOW CONGRESS MUST ACT ON DEADLY TOBACCO SCOURGE

Statement attributable to: Randolph D. Smoak, Jr., MD
AMA President-elect

"President Clinton has been a true leader in working to regulate deadly tobacco products and protect our nation's children from the dangers of tobacco. Now that the Supreme Court has delivered its setback decision, the AMA stands ready to assist President Clinton and Congress in passing responsible bipartisan tobacco legislation that would rectify the Supreme Court's unfortunate decision."

"Since 1989, the AMA has strongly urged Congress to give the FDA the same authority over tobacco products that it has over other 'drugs' and 'devices.' The FDA's ability to regulate tobacco products should be commensurate with tobacco's inherent dangers."

"Preventing children and teens from starting to smoke and helping smokers quit remains a public health challenge of enormous proportions. We now turn to Congress to provide protections for America's youth by making a solid commitment to regulate this dangerous and addictive drug. America's children are too important to ignore."

#

For more information or an interview with Dr. Smoak, please contact: **Brenda L. Craine 202/789-7447**

FOR MORE INFORMATION, CONTACT:
Roger Salazar
The American Cancer Society
(202) 661-5710
E-MAIL: rsalazar@cancer.org

American Cancer Society Joins the White House in Urging Congressional Action on Meaningful FDA Oversight Over Tobacco

WASHINGTON, D.C. (*EMBARGOED UNTIL 10:15 a.m., March 25, 2000)* — The American Cancer Society, America's leading voluntary health organization, today joined President Bill Clinton in calling upon Congress to urgently pass meaningful and comprehensive FDA authority over tobacco products.

"The Supreme Court's decision earlier this week underscores the fact and the urgent need for Congress to act quickly," said John R. Seffrin, Ph.D., Chief Executive Officer of the American Cancer Society. "Justice Sandra Day O'Connor noted, in the majority decision, that tobacco use among children 'poses perhaps the single most significant threat to the public health in the United States'. Between now and the end of this year's congressional session, almost 600,000 children will try tobacco products for the first time. Of those, nearly 200,000 will become addicted to nicotine, and a third of those children eventually die of cancer."

Now that the Supreme Court has made its decision, the Society believes that Congress is presented with an excellent opportunity to protect the public health.

"Our federal policymakers must seize this opportunity and pass meaningful FDA authority over tobacco as outlined in the bipartisan provisions of the 1998 Senate tobacco bill," said Seffrin. "We join in the President's call for Congress to work in a bipartisan manner to support regulation of tobacco products and protect the lives of our children."

-More-

The American Cancer Society is the nationwide community-based voluntary health organization dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives and diminishing suffering from cancer, through research, education, advocacy and service. For information about cancer, call toll-free anytime 1-800-ACS-2345 or visit the American Cancer Society website at www.cancer.org.

# # #

American Heart Association®
Fighting Heart Disease and Stroke

Embargoed for Release
10:00 a.m. ET, Saturday
March 25, 2000

Contact: Kelly Kennai
202/452-7925

American Heart Association CEO M. Cass Wheeler applauds President Clinton's call for congressional action on FDA authority of tobacco products

American Heart Association says Supreme Court decision is not the end of the line in debate over tobacco regulation.

Washington, DC – The American Heart Association commends President Clinton for calling upon Congress to grant the Food and Drug Administration comprehensive authority over tobacco products in his radio address today. His statement reinforces the Association's position that it is time for Congress to end the cycle of addiction to tobacco – one of the nation's leading killers.

This week's Supreme Court decision denying FDA authority over tobacco is not the end of the road in this long fought debate. It is merely an invitation for Congress to pick up the ball and do what is right – enact legislation that gives the FDA clear and comprehensive oversight of the tobacco industry.

The Court's decision was a matter of law, not a matter of public health. The ruling did not dispute the need for federal regulation of the tobacco industry. It only stipulated that the FDA did not have authority over tobacco products under its existing statutory authority. Even Justice O'Connor recognized in writing the majority opinion that tobacco is the single most dangerous threat to our nation's health and must be dealt with by Congress.

The President's appeal to Congress to take up the bipartisan legislation negotiated by Senators Bill Frist and John McCain in 1998 is quite simply, the right thing to do. The legislation – supported by 57 Senators, almost the entire public health community and agreed upon by the tobacco industry itself – should be the minimum standards for any law passed.

Congress should act quickly, yet not in haste to pass a strong law granting the FDA full authority over tobacco. Anything less than the provisions set forth in the Frist-McCain legislation is just window dressing. The tobacco industry has played the sheep in wolf's clothing for a long time and we can expect it to play the same game this time around by lobbying for weak provisions that do nothing to protect the nation's children from these deadly goods.

Every year more than 400,000 Americans die of tobacco related illnesses. More than half those deaths are from heart disease or stroke. The American Heart Association joins the President in his call to Congress to provide the FDA meaningful and comprehensive authority to regulate tobacco products. It is time to set the bar high and enforce the provisions set forth in the 1998 Senate legislation.

###

CAMPAIGN for TOBACCO-FREE Kids®

EMBARGOED FOR RELEASE
10 a.m. March 25, 2000

CONTACTS: Vince Willmore/Joel Spivak
202-296-5469

Statement of Matthew L. Myers
President of the
CAMPAIGN FOR TOBACCO-FREE KIDS
Regarding the President's Radio Address
Calling on Congress to Enact Tobacco Regulation

Earlier this week, the United States Supreme Court called tobacco use "perhaps the single most significant threat to public health in the United States." Today, the President has added to the sense of urgency by devoting his radio address to the tobacco epidemic even in a week when he has worked to bring peace to Southeast Asia and the Middle East. Now it is Congress' responsibility to act. Will Congress put our kids and families first and enact meaningful regulation of tobacco this year or will it put Big Tobacco's profits first and enact either weak legislation or nothing at all?

The Supreme Court's ruling made it clear that only Congress can decide how many more children will become addicted to tobacco and how many more people will die prematurely as a result. The urgency of the problem requires that Congress put aside partisan bickering and get the job done even in this election year. We already have a bipartisan framework for action in the form of the legislation granting FDA authority over tobacco that was drafted by Senator Bill Frist, endorsed by every major public health group, and included in the 1998 McCain bill. A bipartisan majority of at least 57 senators supported this legislation. There is no reason for delay in reintroducing this legislation and enacting it into law. If Philip Morris and the other tobacco companies are serious about supporting regulation of tobacco, they should line up behind this legislation as well.

Three thousand more kids become regular smokers every day, and 1,000 of them will die prematurely as a result. The American people should hold Congress responsible if it fails to act to address this public health crisis.

ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS
1275 K Street, N.W., Suite 800, Washington, D.C. 20005-4006
(202) 371-9090 FAX (202) 371-9797

March 22, 2000

Contact Dr. George E. Hardy Jr.
at 202-371-9090

— NEWS RELEASE —

STATE HEALTH OFFICIALS URGE PROMPT CONGRESSIONAL RESPONSE TO THE SUPREME COURT TOBACCO DECISION

The Association of State and Territorial Health Officials (ASTHO), representing the nations' chief state public health officials, urges Congress to respond expeditiously to the Supreme Court decision denying the Food and Drug Administration (FDA) jurisdiction over the regulation of tobacco products.

"The Court affirmed that Congress now has the opportunity to grant this authority, we trust they will do so as quickly as possible," says ASTHO President, Patricia A. Nolan, MD, MPH, Director of the Rhode Island Department of Health. "ASTHO policy has long supported increased regulation of all tobacco products, giving FDA the necessary authority to regulate nicotine as a drug and tobacco products as drug delivery devices," added Dr. Nolan. Justice Sandra Day O'Connor writing for the majority and in remarks from the bench made clear that tobacco-use is a major public health threat, but that specific Congressional action would be necessary to provide FDA with authority to regulate the production, promotion, and sale of this product.

Over 400,000 Americans die each year from smoking related diseases, and thousands more are disabled by smoking related cancer, heart, and lung disease. Ninety percent of these individuals become addicted to tobacco before age 15. For that reason, ASTHO particularly supports the proposition that children should be protected from access to tobacco by the kind of marketing and sales regulation proposed by the FDA in 1996.

The Food and Drug Administration has been given the authority by Congress to prevent the distribution and sale of dangerous drugs, cosmetics, and food. It is now time for Congress to provide FDA the necessary authority to protect the nation's children and youth from the deadly epidemic of tobacco addiction.

###

Fran Du Melle
Deputy Managing Director

Washington Office
1726 M Street, NW
Suite 902
Washington, DC 20036-4502
Phone: (202) 785-3355
FAX: (202) 452-1805
E-mail: info@lungusa.org
America Online: keyword ALA
Internet: http://www.lungusa.org

National Headquarters:
1740 Broadway
New York, NY 10019-4374

John R. Garrison
CEO

When You Can't Breathe, Nothing Else Matters[7]

Founded in 1904, the American Lung Association includes affiliated associations throughout the U.S., and a medical section, the American Thoracic Society.

AMERICAN LUNG ASSOCIATION®

Embargoed for Release
10 a.m. ET, Saturday
March 25, 2000

Contact: Diane Maple
202/494-8513

American Lung Association Welcomes White House Call For Congress To Act on FDA Tobacco Authority
Statement of John R. Garrison, CEO, American Lung Association

The American Lung Association welcomes President Clinton's leadership in urging Congress to give the Food and Drug Administration the full authority to regulate the manufacture, labeling, distribution, advertising, sales and marketing of tobacco products. The president's statement today during his weekly radio address is heartening.

Congress should stand up to the tobacco lobby and its millions of dollars in campaign contributions. Bipartisan legislation has been introduced in the House by Rep. Henry Waxman (D-CA) to grant full FDA authority. We expect a bipartisan Senate bill soon. We call on House Speaker Hastert (R-IL) and Senate Majority Leader Lott (R-MS) to make tobacco legislation a top priority this year.

The American Lung Association has been fighting lung disease for nearly 100 years. With the generous support of the public and the help of volunteers, the Lung Association has seen many advances against lung disease. However, the work is not finished. As the Lung Association looks forward to its second century, it will continue to strive to make breathing easier for everyone through programs of education, community service, advocacy, and research. American Lung Association® activities are supported by donations to Christmas Seals® and other voluntary contributions. You may obtain additional information at the American Lung Association web at http://www.lungus.org.

# # #

Tobacco FDA Rule

PRESIDENT CLINTON HIGHLIGHTS STRATEGY TO FIGHT TOBACCO USE AMONG YOUNG PEOPLE
March 24, 2000

In his radio address today, President Clinton will call on Congress to enact legislation protecting our children from the harms of tobacco and he will also highlight his broad strategy to reduce youth smoking. Earlier this week the Supreme Court ruled that the FDA must get explicit authorization from Congress to regulate tobacco products. Fortunately, there is bipartisan support for legislation to provide that authority, and to restrict tobacco advertising aimed at children and curb tobacco sales to minors. The President today will urge Congress to pass this legislation. He will also emphasize that his Administration will fight on all fronts to bring down youth smoking. In particular, he will tout his proposals to increase the cigarette prices, impose penalties on tobacco companies if youth smoking is not cut, and make smoking cessation drug treatments more widely available. He will also call on Congress not to undermine federal litigation against the tobacco industry, and will challenge states to use the funds they have collected from tobacco settlements for anti-smoking efforts. More than 3,000 children under 18 become regular smokers each day, and 1,000 will have their lives cut short as a result. The President will remind Americans that by working across party lines, we can save lives.

CALLING ON CONGRESS TO ENACT PROTECTIONS FOR OUR CHILDREN. Both the President and Vice President have worked hard since taking office to protect our nation's children from the dangers of tobacco. Five years ago, the Food and Drug Administration put forward an important proposal to eliminate advertising aimed at children and curb minors' access to tobacco products. Although the Supreme Court ruled this week that FDA lacks the legislative authority to regulate tobacco, the Court did affirm the Administration's view that tobacco use by children "poses perhaps the single most significant threat to public health in the United States." Even some in the tobacco industry, after fighting the FDA rule in court, now say they support regulation of tobacco. So today the President will point out that it is now up to Congress to enact the protections in the original FDA rule. These protections have strong bipartisan support -- in 1998, 57 Senators from both parties supported a bill with provisions comparable to the FDA regulation -- and the President will urge Congress to pass such legislation.

FIGHTING ON ALL FRONTS TO CUT YOUTH SMOKING. President Clinton today will also emphasize that his Administration will continue to work on many fronts to reduce youth smoking. In particular, he will highlight his budget proposals to increase the excise on cigarettes by an additional 25 cents a pack, and to charge the tobacco industry a $3,000 assessment for every underage smoker in 2004 if youth smoking is not cut in half. The President's budget also includes an important initiative to ensure Medicaid beneficiaries have access to drug treatments to help quit smoking. Finally, the Justice Department has begun litigation to recover federal tobacco-related health costs from tobacco manufacturers. The President will urge the Congress to support this effort -- and not undermine it, as some have threatened -- so that tobacco companies finally answer to the taxpayers in court for their actions.

CHALLENGING STATES TO DELIVER ON THEIR PROMISE TO REDUCE TOBACCO USE. When the states settled their lawsuits against the tobacco companies in 199X for a total of $246 billion, state officials promised that the settlement would be just the first step

in their efforts to reduce tobacco use, particularly among children. But far too many states have failed to live up to that promise. The President today will challenge states to spend their tobacco settlement proceeds on efforts to combat youth smoking. He will also point out that in some states, such efforts have already shown powerful results. For instance, as a result of an aggressive tobacco control program, smoking rates among Florida middle school students dropped from 18.5 percent in 1998 to 8.6 percent in 2000, a 54 percent decline. In Oregon, smoking declined by 32 percent among 8th graders and by 17 percent among 11th graders between 1998 and 1999. And in Massachusetts, smoking among high school students fell 15 percent between 1995 and 1999.

Draft 03/23/00 4:45pm
Heather Hurlburt

PRESIDENT WILLIAM J. CLINTON
RADIO ADDRESS
MUMBAI, INDIA
March 24, 2000

Good morning. As I reach the end of my week in South Asia, I want to talk to you about what has happened this week in Washington, and the challenge we now face to keep our kids safe from the dangers of tobacco.

Every single day, another 3,000 American children smoke their first cigarette. Most of them will be hooked for life – and fully one-third will die early as a result.

That is why my Administration has worked so hard to highlight the health threat teen smoking poses – and to keep tobacco products out of the hands of children. We've supported state and local efforts to stop underage smoking before it starts. And we know those efforts work: Massachusetts has used education programs to reduce high school student smoking by 15 percent; and Oregon cut eight-graders' smoking rates by almost a third in just one year.

Five years ago, we asked the Food and Drug Administration to start a campaign to slash teen smoking in every state – and to treat nicotine like the dangerous drug that it is. The FDA wrote strong, effective rules to prevent any child under 18 from buying any tobacco product, anywhere in the United States. The FDA was also prepared to end tobacco advertising that is shamelessly aimed at addicting another generation of our young people.

Our effort had strong support from public health leaders and both parties in Congress – but it collapsed under the pressure of tobacco companies and the Republican leadership, while the tobacco industry challenged the rules in court. This week, the Supreme Court ruled that the FDA must have explicit authorization from Congress before it can regulate tobacco.

All 9 Justices made it perfectly clear that they believe tobacco is dangerous, especially to our young people; their majority opinion called it "perhaps the most significant threat to health in the United States." The American people know this. They've known it for a long time. Now the ball is in Congress's court. They should do the right thing, show that they also understand the danger to our young people -- and give the FDA's tobacco regulations the force of law.

This is not a partisan issue. It is a health issue for our nation and a life-and-death issue for our children. In 1998, Senators McCain and Frist introduced a bill that would have let the FDA's campaign move forward. It had the support of 57 Senators from both sides of the aisle. And this week, Representative Waxman, joined by Representatives Hansen and Meehan, introduced similar legislation in the House. I urge both houses of Congress to stand up and pass it promptly.

The FDA rule has been just one part of our efforts to make tobacco harder for kids to get and less appealing to use. My Administration will continue to push on every front. My budget includes a 25-cents-per-pack tax increase on cigarettes, because we know that raising the price is one of the best ways to stop kids from smoking. It proposes tough penalties on tobacco companies that do not follow through on their promises to reduce teen smoking. And it helps working Americans pay for drugs and treatment programs to quit smoking.

The Justice Department has also sued the tobacco manufacturers, to recover the costs of tobacco-related illnesses and to make sure they are held accountable for their actions. I call on Congress to support, not undermine, these efforts.

I also ask Congress to work with me to take action to protect the financial security of tobacco farmers and their communities.

Finally, I challenge the states to do their part as well – by dedicating the money they have collected from the tobacco settlements to fund anti-smoking programs for children and young people.

Preventing our kids from smoking is our common responsibility. It is a fight we can win. And it is a fight we must win – starting right now.

Thanks for listening.

Nanda Chitre
03/21/2000 12:32:34 PM

Record Type: Record

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

cc:
Subject: Statement By the President: Supreme Court Ruling on Tobacco

THE WHITE HOUSE

Office of the Press Secretary
(New Delhi, India)

For Immediate Release March 21, 2000

STATEMENT BY THE PRESIDENT

Since we took office, Vice President Gore and I have worked hard to protect our children from the dangers of tobacco. Five years ago, the FDA put forward an important proposal to protect children from tobacco by eliminating advertising aimed at children and curbing minors' access to tobacco products. Today's Supreme Court opinion, while holding that Congress has not given FDA the authority to regulate tobacco products, does affirm our view that tobacco use by young people "poses perhaps the single most significant threat to public health in the United States."

If we are to protect our children from the harms of tobacco, Congress must now enact the provisions of the FDA rule. Fortunately, those protections have strong bipartisan support: in 1998, 57 Senators supported a bill negotiated by Senators Bill Frist and John McCain containing provisions comparable to those included in the FDA regulation.

So today I call upon the leadership of Congress to take up the bipartisan Frist-McCain legislation. Nearly 4 million children under the age of 18 smoke cigarettes - 3,000 more start each day and 1,000 will have their lives cut short as a result. Every year, more than 400,000 Americans die of tobacco-related diseases; nearly 80 percent of them started smoking as children. Even some in the tobacco industry - after fighting the FDA rule in court - now say they support regulation of tobacco. I believe that by working together across party lines, we can protect our children and save lives.

###

Message Sent To:

DPC -- Tobacco. This morning, in a 5-4 decision, the Supreme Court invalidated our 1996 FDA anti-smoking rule, holding that FDA does not have authority to regulate tobacco products. As you know, that rule would have restricted tobacco advertising to children and would have required age verification and other steps to discourage tobacco sales to minors. While Justice O'Connor's opinion makes clear that Congress did not give FDA regulatory authority, it does affirm the Administration's view that tobacco use by young people "poses perhaps the single most significant threat to public health in the United States." We noted this in a statement we released from you, and also emphasized that it is now up to Congress to enact the protections of the FDA rule. Those protections have had strong bipartisan support: in 1998, 57 Senators supported a bill negotiated by Senators Frist and McCain containing provisions comparable to those in the FDA regulation. Frist is reportedly open to a narrower legislative solution, but made no commitments today, while McCain said only that he had always had doubts about FDA's authority and was thus not surprised by the Court's decision.

NATIONAL JOURNAL'S
CongressDaily

SEARCH CONGRESSIONAL CALENDAR RECENT ISSUES

Tuesday, March 21, 2000

▶ HEALTH

Court Rules FDA Lacks Authority To Regulate Tobacco ...

The Supreme Court today put an end to one of President Clinton's signature healthcare initiatives, ruling 5-4 that the FDA lacks authority to regulate tobacco. The ruling, which was largely expected, invalidates the FDA's historic 1996 anti-smoking initiative — which would regulate the sale and marketing of tobacco products to minors. But even as the battle comes to a close in the courts, it is likely to erupt again almost immediately on Capitol Hill *(see story below)*. Clinton issued a statement from India, where he is traveling, calling for Congress to act. And in interviews today, top anti-smoking activists said they would quickly ratchet up their push for legislation.

"There is no excuse for Congress not acting," said Campaign for Tobacco-Free Kids President Matthew Myers. "We intend to push for adoption of legislation this year." Another leading activist, Diane Canova, agreed, saying, "We hope it will energize the anti-tobacco community in the fight" for legislation to grant FDA authority. Canova co-chairs ENACT, a coalition of anti-smoking groups led by the American Heart Association, the American Cancer Society and the Campaign for Tobacco-Free Kids. She asserted that although the groups have been focused this year on state legislatures, they have the resources and commitment to launch an effort in Washington.

A senior aide to a leading Senate foe of tobacco indicated while there is no specific legislative strategy in place, anti-tobacco forces will move very quickly now that the high court has spoken. However, given it is an election year and the current session will be short, officials who will be involved indicated that legislation to address the ruling might be relatively narrow. Instead of trying to pass a bill that would accomplish various anti-smoking objectives — such as encoding parts of the 1996 FDA regulation into law or raising tobacco taxes — legislation might only put the FDA in charge of tobacco, a goal for which anti-smoking forces believe there is bipartisan support. "Right now, it is paramount to get Congress to give FDA the authority to regulate tobacco," Canova said, noting that a new FDA rule could address other issues. She added, "A lot of the things that would be done piecemeal [by Congress] could be dealt with if FDA had authority over tobacco."

The vehicle for such action is being crafted by **Sen. Jack Reed**, D-R.I., who for the past month has been writing a narrowly tailored bill allowing the FDA to promulgate rules governing the manufacture and distribution of tobacco. Reed may introduce the legislation as early as next week. The bill also would create an advisory panel of experts to work with the FDA in creating the regulation. Myers suggested, however, that the template for action already exists — legislation written by **Sen Bill Frist**, R-Tenn., that would make tobacco a separate category regulated by FDA. Clinton today argued that Congress should adopt the Frist bill. But a senior Senate aide argued that such legislation, which was part of the failed 1998 bill by **Commerce Chairman McCain**, was less likely than a simpler measure. "We went through a lot of contortions" to craft the Frist FDA provisions, he noted. — *by Keith Koffler*

... As Senate Democrats Vow Attempt To Overturn Ruling

While describing today's Supreme Court ruling as a disappointment, Senate Democrats said this afternoon that they plan to try to parlay the loss into fairly narrow legislation giving the FDA the authority it needs to regulate tobacco. **Senate Health, Education, Labor and Pensions ranking member Edward Kennedy**, D-Mass., said he already has contacted **Health, Education, Laborand Pensions Public Health Subcommittee Chairman Bill Frist**, R-Tenn., in an effort to build bipartisan support for

the effort. Kennedy described Frist as being "open" to the introduction of such legislation, but wanting a chance to review the court's ruling before making any commitments. Citing the "solid groundwork" of a similar bipartisan agreement reached by the Senate two years ago that would have given the FDA authority over the sale and marketing of tobacco products, "the Senate should be able to act expeditiously to grant the FDA the full authority it needs," Kennedy stated.

Sen. Frank Lautenberg, D-N.J., also suggested **Commerce Chairman McCain's** return to the Senate from the presidential campaign trail bodes well for such an effort — noting that the Arizona Republican "could very well be an ally on this." But McCain said he was not surprised by the court's decision, saying, "I always had concerns about FDA regulation of tobacco." McCain, the sponsor of a major tobacco bill in 1998, also said he did not see any movement on new tobacco legislation — and added he is "bitterly disappointed" at how some states have used tobacco settlement money for purposes other than education and smoking reduction programs. "Instead, they've used it as a pot of gold to fund all their needs," McCain said.

Senate HELP member Tom Harkin, D-Iowa, called for quick action on the bill to establish FDA authority over tobacco, saying, "We've got to do something, and we've got to do it fast." Harkin also challenged both Vice President Gore and Texas Gov. George W. Bush — the all-but-certain presidential nominees — to contact their respective party leaders in the Senate "and urge them to act in a bipartisan fashion to overcome with legislation the Supreme Court's ruling today." Depending on the Senate's receptivity to their effort, the Democrats said they might seek to attach their tobacco legislation to an FY2001 appropriations bill. "We'll use the opportunities that come before us," said Lautenberg. "We've got to move quickly." — *by Pamela Barnett and Mark Wegner*

▶HEALTH

States, FDA Split On Web Drug Sale Regulation Approach

State and federal officials today called for congressional action to regulate the sale of prescription drugs over the Internet, but disagreed over exactly what that action should entail. Testifying before the Senate Health, Education, Labor and Pensions Committee, FDA Commissioner Jane Henney said the administration's proposal, announced by President Clinton in January, would be in legislative form "in a few weeks." Generally, she testified, "under this proposal, the traditional role of the states in regulating the practice of medicine and pharmacy would be maintained." The plan, however, would impose some new federal requirements on Internet sites that sell drugs, including providing information on ownership, state licensing, name of the pharmacist in charge, and a telephone number to contact a pharmacist. Henney also told the committee the FDA is seeking an additional $10 million in appropriations this year for its stepped up enforcement effort against Web sites that are selling illegal products such as the "date rape" drug GHB; those selling products without proper medical oversight; and those selling products that are counterfeit, expired, or illegally diverted.

If Congress does not act soon to curb such practices, Henney warned, "I honestly believe it will become an increasingly serious problem." Representatives of state pharmacy boards and state attorneys general also called for stepped up actions, but not necessarily those being pushed by the FDA. Kansas Attorney General Carla Stovall said the ratio of Internet pharmacies complying with the law and those not complying is 3-200. She said Congress should give states authority to pursue national injunctions against rogue Internet drug sellers similar to authority granted for illegal telemarketing schemes, and backed the FDA's proposed disclosure requirements. But she warned that Congress should not "federalize the issue just because Internet pharmacies cross state lines."

Meanwhile, John McManus, an aide to **House Ways and Means Health Subcommittee Chairman Bill Thomas**, R-Calif., today said Republicans want to pass a prescription drug benefit for seniors this year, using private insurance, and they still have time to do it. Speaking at an American Society of Consultant Pharmacists briefing, McManus said that since health insurers have expressed concern about how to cover seniors with high drug costs and those with low incomes, the government should perhaps cover the top 5 percent of seniors in this high risk category. He also said Republicans

Tobacco/ FDA Supreme Court Case
Q&A
March 21, 2000

Q: What is the Administration's reaction to the Supreme Court ruling against the FDA regulation and will you support a legislative change instead?

A: We are disappointed that the Supreme Court ruled that the Food and Drug Administration cannot proceed to protect our children from tobacco. This administration has done everything possible to protect our children from the dangers of tobacco. Five years ago, the FDA put forward a landmark regulation to protect children from tobacco by eliminating advertising aimed at children and curbing minors' access to tobacco products. Today's Supreme Court ruling, while holding that Congress has not given FDA the authority to regulate tobacco products, does affirm our view that tobacco use by young people "poses perhaps the single most significant threat to public health in the United States." If we are to protect our children from the harms of tobacco, Congress must now enact the provisions of the FDA rule. Fortunately, there is strong bipartisan support in the Congress for enacting those protections: in 1998, 57 Senators supported a bill negotiated by Senators Bill Frist and John McCain containing provisions comparable to those included in the FDA regulation.

So the President will call upon the leadership of Congress to take up the bipartisan Frist legislation and act now to protect our children from tobacco. Nearly 4 million children under the age of 18 smoke cigarettes – every day more than 6,000 try their first cigarette, 3,000 become regular smokers, and 1,000 will have their lives cut short as a result. Every year, more than 400,000 Americans die of tobacco-related diseases; nearly 80 percent of them started smoking as children. Some in the tobacco industry – after fighting the FDA rule in court – now say they support regulation of tobacco. We challenge them to demonstrate that support by endorsing the Frist-McCain legislation. We believe that by working together across party lines, we can protect our children and save lives.

Q: What does this mean and what's the immediate effect?

A: We are still reviewing the opinion so that we clearly understand the Court's ruling. However, one immediate effect of this decision is that the FDA youth access enforcement program cannot continue. This program, operated through FDA contracts with states, was designed to keep young people from purchasing cigarettes. A termination order is being issued to the states and territories under contract with FDA so that no additional enforcement activity will occur.

Q: Where does FDA currently have contracts and what are these contracts for?

A: When the tobacco companies filed suit after the final rule was published in August 1996, the federal district court ordered the FDA not to put in place the rule's restrictions on

tobacco advertising and other marketing aimed at children, but did allow the FDA to go forward with certain important rules restricting youth access to tobacco products. These access restrictions set 18 as the minimum age for purchasing tobacco products and require retailers to check photo ID of anyone younger than age 27. FDA, through an appropriation with Congress, enforced these restrictions through inspections, conducted primarily through contracts with the states and territories. FDA had arranged for enforcement of the rule in all 50 states plus D.C., the Virgin Islands and American Samoa.

Q: Does this decision have any effect on the Synar amendment requirements on states?

A: No. Under the Synar amendment, states must have laws forbidding tobacco sales to children under age 18, must enforce these laws, and must meet increasing performance standards regarding the percentage of retailers that sell to underage youth, or lose a portion of their federal Substance Abuse Block Grant. These rules, in statute before the 1996 FDA rule was promulgated, will continue. However, these rules do not hold retailers who sell to underage youth accountable through fines and other action, as the FDA rule does, nor does it ensure retailers seek photo ID from young people up to age 27 to ensure underage youth who appear older do not purchase tobacco products. Instead, the Synar amendment holds states accountable for monitoring enforcement of their laws.

While this decision does not effect Synar requirements on states, it will disrupt the major vehicle by which states test and enforce compliance with those requirements. Currently, states and SAMHSA rely on the FDA's youth access enforcement contracts to implement Synar. The Court's ruling will force FDA to discontinue those contracts. SAMHSA will be working with states to ensure that there is no disruption in the enforcement of Synar requirements.

Q: How exactly would the FDA rule have regulated tobacco?

A: These provisions would have helped stop young people from smoking before they start by eliminating advertising aimed at children and curbing minors' access to tobacco products. Provisions include:

- Restricting Advertising Aimed at Children – including banning outdoor advertising within a 1000 feet of schools and public playgrounds and limiting advertising ion publications with significant youth readership to black-and-white text.

- Discouraging Tobacco Sales to Minors – including requiring age verification by photo ID for anyone appearing age 26 or younger and banning vending machines except in adult-only facilities.

Another critical component of the effective tobacco regulation was ensuring that the FDA has sufficient authority to impose additional restrictions as future circumstances warrant.

Affirming FDA Authority to Prevent Advertising and Marketing to Children

By reaffirming the full authority of the FDA to regulate tobacco products, S.1415 will prevent the tobacco industry from advertising and marketing to children, and establish tough access restrictions on tobacco products to stop sales to children.

Reaffirms 1996 Rule: Many of the measures to reduce teen smoking and protect the public health contained in S.1415 are in the 1996 FDA rule, but have not yet gone into effect because of pending litigation. The bill would put these provisions into effect immediately, protecting American children from the dangers of smoking. These provisions include: 1) banning outdoor advertising within 1000 feet of schools and playgrounds; 2) restricting advertising to black-and-white text only except in adult only facilities or publications with predominantly adult readership; 3) prohibiting the sale or giveaway of promotional products with brand names or logos; 4) prohibiting brand-name sponsorship of sporting or entertainment events; 5) setting the minimum age for purchase of tobacco products at 18 years and requiring age verification for anyone age under 27.

Creates a Separate Chapter for Regulating Tobacco: S.1415 creates a separate chapter in the Food, Drug and Cosmetic Act that gives the FDA explicit authority over access to and advertising of tobacco products, in order to ensure that FDA regulation of tobacco does not impinge on the regulation of other products.

Establishes New Standard for Regulating Tobacco: Instead of requiring tobacco products to meet the traditional safety and efficacy standard required of drugs and devices, S.1415 imposes a new standard which would require FDA regulation of tobacco products to be "appropriate for the protection of public health". This standard better meets the characteristics of tobacco products and allows the FDA to take the addiction of over 40 million Americans into account in making decisions about how to regulate these products.

Provides Necessary Flexibility: Full FDA authority to regulate tobacco products provides the agency with the flexibility it needs to protect the public health. However, any FDA effort to eliminate any particular class of tobacco products or eliminate nicotine cannot go into effect for two years in order to provide Congress with an opportunity to weigh in and vote on the measure.

Preserves State and Local Authority: S.1415 makes clear that except as expressly provided, states and localities may adopt and enforce tobacco product requirements that are in addition to, or more stringent than, requirements established under the Food, Drug and Cosmetic Act for tobacco products.

Provides Full Enforcement Authority: S.1415 provides for the same civil and criminal penalties that the agency may use in enforcing device law.

Tobacco
Q&A
March 3, 2000 – DRAFT

Q: What's the Administration's response to statements by Philip Morris Senior Vice President Steven Parrish today?

A: As the President said in his statement on Tuesday, he is heartened that the nation's leading cigarette maker is now willing to accept government regulation of tobacco. However, if we are to reduce youth smoking and protect the public health, we need comprehensive and meaningful regulations like the FDA regulations proposed by the President in 1996, which were agreed to on a bipartisan basis, in a bill negotiated by Senator Bill Frist, in the U.S. Senate in 1998. If the industry is serious about reducing youth smoking, they will agree to these rules.

Q: Mr. Parrish said yesterday that Philip Morris will not accept regulations as comprehensive as the FDA rule the President put in place in 1996. Is the Administration willing to negotiate with Philip Morris on a tobacco regulation that is less comprehensive than the FDA rule?

A: No, we are not. We need comprehensive and meaningful regulations to reduce youth smoking and protect the public health. The FDA rule will help stop young people from smoking before they start by eliminating advertising aimed at children and curbing minors' access to tobacco products. These same regulations were agreed to on a bipartisan basis, in a bill negotiated by Senator Bill Frist, in the U.S. Senate in 1998. If the industry is serious about reducing youth smoking, they will agree to these rules.

Q: Mr. Parrish expressed a willingness to consider changing the legal age of purchase from 18 to 21. Does the Administration have a position on this?

A: Our priority has been to ensure underage children, under age 18, cannot purchase tobacco products, and eliminating advertising and marketing aimed at children. We are of course open to such a change, but are not actively considering it at this time.

Q: Has Philip Morris contacted the Administration to begin discussions on these issues?

A: No, they have not.

Q: How exactly would the FDA rule and the Frist provisions regulate tobacco?

A: Throughout the life of this Administration, President Clinton and Vice President Gore have done everything they could to protect our children from the dangers of tobacco. Five years ago, we put forward a landmark rule affirming the FDA's authority to regulate tobacco products. These provisions will help stop young people from smoking before

they start by eliminating advertising aimed at children and curbing minors' access to tobacco products. The provisions include:

- Restricting Advertising Aimed at Children, including banning outdoor advertising within 1000 feet of schools and public playgrounds and limiting advertising in publications with significant youth readership to black-and-white text.
- Discouraging Tobacco Sales to Minors, including requiring age verification by photo ID for anyone appearing age 26 or younger and banning vending machine except in adult-only facilities.

Another critical component of effective tobacco regulation is ensuring that the FDA has sufficient authority to impose additional restrictions as future circumstances warrant.

Q: Didn't the 1998 state settlement put in place many of these advertising restrictions?

A: No. The FDA's restrictions are necessary to halt advertising and marketing aimed at children. The FDA's rules are much more comprehensive than those the tobacco companies agreed to in the 1998 settlement and will do much more to prevent youth smoking. For example, the FDA rule limits tobacco ads in newspapers and magazines with significant youth readership to black and white text, while the 1998 settlement did not limit print advertising at all. Moreover, the FDA rule banned all tobacco advertising within 1000 feet of a school, and limited all outdoor advertising to black and white text, while the state settlement allows retailers and other non-billboard ads near schools and with color ads that appeal to children.

Q: Would government regulation of tobacco include banning tobacco?

A: No. This Administration does not support a ban on tobacco products. The FDA regulation does not restrict adults' access to tobacco products – instead it is aimed at preventing underage youth from smoking by eliminating advertising aimed at children and curbing minors' access to tobacco products.

A ban on tobacco products would create a black market or cause addicted smokers to suffer sudden withdrawal of nicotine.

Q: Where does the Supreme Court case regarding the FDA rule stand?

A: The case is now pending, and we expect the Supreme Court to rule this session. The court agreed to take the case on April 26, 1999 and heard oral arguments on December 1, 1999. The case stems from challenges from the tobacco industry filed in 1996 immediately after the FDA published its tobacco regulation. The Administration strongly believes FDA has the authority to regulate tobacco products and has urged the court to uphold the rule.

Q: Are the FDA advertising restrictions really needed, now that the tobacco companies agreed to certain restrictions – such as eliminating billboards -- as part of last year's settlement with the states?

A: Yes, the FDA's restrictions were needed to halt tobacco advertising and marketing aimed at children. The FDA's rules were far more comprehensive than those the tobacco companies agreed to in the settlement and will do much more to prevent youth smoking. For example the FDA rule would have limited tobacco ads in newspapers and magazines with significant youth readership to black and white text, while last year's settlement did not limit print advertising at all. Moreover, the FDA rule would have banned all tobacco advertising within 1,000 feet of a school, and limited all outdoor advertising to black and white text, while the state settlement allows retailer and other non-billboard ads near schools and with color images that appeal to children.

Q: What is the Administration planning to do next on tobacco?

A: The President will continue to fight to protect this nation's children from the death and diseases caused by tobacco. We should not let the tobacco industry recruit 3,000 young people a day as "replacement" smokers and sentence 1,000 of those to early deaths from lung cancer and other diseases.

The President and Vice President call upon the leadership of Congress to take up the bipartisan Frist-McCain legislation and act now to protect our children from tobacco. In 1998, 57 Senators supported a bill containing provisions, negotiated by Senators Bill Frist and John McCain, like those included in the FDA regulation, and these measures were in the bill agreed to by the Senate Commerce Committee by a 19-1 vote. It's our hope that we can work together across party lines to protect our children and save lives.

The Administration will continue to fight to reduce youth smoking with proposals that hold the tobacco industry accountable by charging the tobacco industry an assessment for every underage smoker, increasing the price of cigarettes by 25 cents a pack, protecting tobacco farmers and their communities and putting in place an important initiative to ensure Medicaid beneficiaries have access to drug treatments to help them quit smoking. The Justice Department is also working to recover from the tobacco companies the billions of dollars in direct health costs incurred by the federal government as a result of smoking.

Q: How does the Supreme Court case relate to the case brought by the Justice Department against the tobacco industry?

A: These cases are completely separate and different. The Justice Department should comment on the specifics of either case but the suit filed against the tobacco industry by the Justice Department last September is about recovering the federal costs of smoking-related illnesses. Smoking has cost taxpayers billions of dollars through Medicare, veterans' health and other federal health care programs. Today's Supreme Court ruling

was on a challenge by the tobacco industry to the Food and Drug Administration's regulation protecting children from tobacco.

Q: What else is the Administration doing in the meantime to reduce youth tobacco use?

A: We will not stand still and let new generations of our citizens become victims of nicotine addiction. Eighty percent of those who use tobacco begin before age 18. We will continue to:

- Fight to reduce youth smoking with budget proposals that hold the tobacco industry accountable by charging the tobacco industry an assessment for every underage smoker and increasing the price of cigarettes by 25 cents a pack.

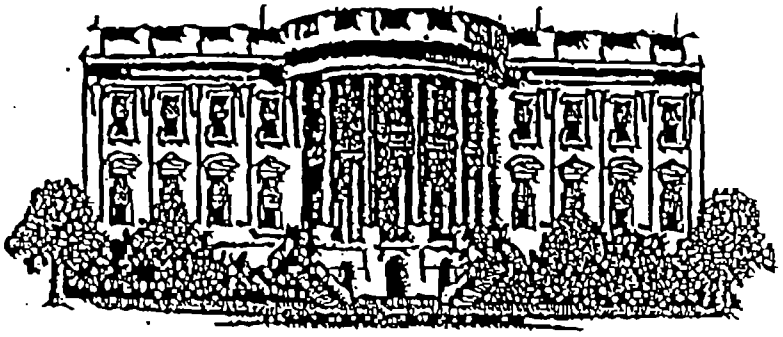
- Advocate that states use the money from the master tobacco settlement for tobacco prevention and control. Sustained and comprehensive programs, including community and school interventions, are needed to reduce tobacco use and address this serious public health problem. Efforts in states such as Oregon, Massachusetts, and Florida show that these programs work.

- Enforce the Synar regulation, which requires states, as a condition of receiving certain SAMHSA block grant funds, to enforce state laws that reduce the availability of tobacco products to minors.

- Work with public health officials, health policymakers, community leaders, and others nationwide to reach the Healthy People 2010 objective of reducing the percentage of minors buying tobacco products to five percent or less by 2010. Fund basic state tobacco control and prevention programs through CDC and provide technical assistance to all the states and territories with state-funded programs.

- Pursue a vigorous research agenda at the NIH to improve our ability to detect and treat lung cancer and other smoking-related diseases, and to develop effective community-based tobacco control and prevention strategies.

- Pursue the suit filed against the tobacco industry by the Justice Department to recover the federal costs of smoking-related illnesses.



THE WHITE HOUSE

Domestic Policy Council

DATE: 2/28/00

FACSIMILE FOR: Anna Richter

FAX:
PHONE: 62878

FACSIMILE FROM: Cynthia Rice, Special Assistant to the President for Domestic Policy

FAX: 202-456-7431
PHONE: 202-456-2846

NUMBER OF PAGES (INCLUDING COVER): 17

COMMENTS: FDA Tobacco Case

Oral arguments at Supreme Ct

Cynthia A. Rice 12/01/99 03:33:28 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP@EOP, Eric P. Liu/OPD/EOP@EOP

cc: J. Eric Gould/OPD/EOP@EOP, Eugenia Chough/OPD/EOP@EOP

Subject: Supreme Court arguments on FDA case

I hear the oral arguments went badly for our side -- many of the justices expressed skepticism about whether FDA has the authority to regulate – looks like it could be 5-4 or 6-3. There's some more detail in the wire stories below.

q&a1201 fda.doJustice and HHS OK'd these q&as if we need them.

Justices Doubt Tobacco Regulations

WASHINGTON (AP)

Several Supreme Court justices expressed doubts today about whether the Food and Drug Administration can regulate tobacco as a drug and crack down on cigarette sales to minors. Solicitor General Seth Waxman asked the court to let the FDA regulate tobacco because the nicotine it contains is a "highly addictive" substance that acts as a stimulant, a sedative, an appetite suppressant and is used to feed smokers' addictions. But tobacco industry lawyer Richard M. Cooper insisted the government's 1996 decision to regulate tobacco was "lawless" because cigarettes are not promoted as having effects on health.

United Press International

December 1, 1999, Wednesday 02:26 PM Eastern Time

SECTION: WASHINGTON DATELINE GENERAL NEWS

LENGTH: 789 words

HEADLINE: UPI Focus;
Court looks at future of tobacco

BYLINE: By MICHAEL KIRKLAND

DATELINE: WASHINGTON, Dec. 1

BODY:

A divided U.S. Supreme Court heard argument Wednesday on the future of tobacco.

At issue is whether the Food and Drug Administration has the authority to regulate tobacco as a drug, something the domestic industry fears could ultimately lead to the banning of its product in the United States.

A lower court has said the FDA cannot regulate tobacco either as a "drug" or as a "device" that delivers a drug, nicotine.

But the Clinton administration, acting for the FDA, has taken the case to the Supreme Court.

With the nine-member court dividing largely along ideological lines, Justice Anthony Kennedy, a moderate, appeared during Wednesday's argument to have the swing vote in any eventual decision.

The court's three genuine conservatives, Chief Justice William Rehnquist and Justices Antonin Scalia and Clarence Thomas, are expected to vote against regulation.

Rehnquist and Scalia expressed skepticism about the authority of the FDA to regulate tobacco. Though Thomas, as usual, did not speak from the bench, he consistently votes with his fellow conservatives.

All three are off-and-on smokers, though that is not expected to influence their votes.

Justice Sandra Day O'Connor, who at times holds a key swing vote though less often than Kennedy announced up front that she did not believe tobacco fit under the law governing which products are regulated by the FDA.

Kennedy, though he did not commit himself and his vote could still be up for grabs, appeared to be leaning against regulation and could make up a five-member majority in a final decision.

Even one of the four liberals expected to eventually side with the FDA, Justice David Souter, said he was convinced the agency was right on the details was still waiting to be convinced that the FDA was right on the "totality" of the case.

The court's remaining liberals, Justices John Paul Stevens, Ruth Bader Ginsburg and Stephen Breyer, appeared ready to side with the FDA.

Under prodding from President Clinton, the FDA first tried to regulate tobacco in 1996, placing severe

restrictions on advertising and access to tobacco by minors.

The agency considered, but ultimately rejected, an outright ban on tobacco because "the sudden withdrawal from the market of products to which so many millions of people are addicted would be dangerous," the government said in a brief to the Supreme Court. The agency also feared the effects of a black market.

The major tobacco companies and their allies immediately challenged the regulations as outside the scope of the law in federal court in North Carolina, and eventually won their case before a federal appeals court.

The companies also complained to the media and to Congress that even if the FDA did not outlaw tobacco, FDA regulation would open up the opportunity for private lawsuits that would inevitably force the agency to ban the product as a "dangerous drug."

Speaking before the Supreme Court for the FDA Wednesday, U.S. Solicitor General Seth Waxman said nicotine acts on the body in four "quintessentially drug-like ways": It is "highly addictive," and it simultaneously acts as a sedative, a stimulant and an appetite suppressant.

Waxman also rejected the argument that because a product faces the possibility of an outright ban, it should not be regulated.

Arguing for the major tobacco companies, Washington attorney Richard Cooper contended that a raft of laws passed by Congress and aimed specifically at tobacco "preclude FDA regulation."

Congress enacted the federal Food, Drug and Cosmetic Act in 1938, and President Franklin Roosevelt signed it into law. Besides eventually providing the FDA with its mandate, the act expanded the legal definition of a "drug" to include non-food "articles intended to affect the structure or any function of the body of man or other animals."

Cooper argued Wednesday that "the purpose of this statute is to regulate a product that claims to have benefits" for health or cosmetic reasons. Tobacco products have never made those claims in the marketplace, Cooper repeatedly argued, and therefore do not come under the provisions of the act.

The 1960s federal law requiring cigarettes to carry warning labels but not requiring a ban on tobacco

"shows there's more at stake than health," Cooper said, adding that there are "economic issues and issues of (personal) choice....These are beyond the FDA."

In rebuttal, Waxman argued that an industry should not be allowed to escape regulation just by not claiming that a product had "benefits." He said, "It would create the largest regulatory hole in existence."

The Supreme Court is expected to rule in the case within the next several months.

LANGUAGE: ENGLISH

LOAD-DATE: December 1, 1999

THE WHITE HOUSE

Office of the Press Secretary

Administration decides to appeal to Supreme Ct

For
Immediate Release

August 14, 1998

STATEMENT BY THE PRESIDENT

The Solicitor General has today authorized the filing of a petition in the Court of Appeals for the Fourth Circuit seeking rehearing en banc of the three-judge panel's decision regarding FDA regulation of tobacco products. I am firmly committed to the FDA's rule and its role in protecting our children from tobacco. Confirming the FDA's authority over tobacco products is necessary to help stop young people from smoking before they start by stopping advertising targeted at children and curbing minors' access to tobacco products. Almost 3,000 young people become regular smokers each day, and 1,000 of them will die prematurely as a result. If the leadership in Congress would act responsibly, it would enact bipartisan comprehensive tobacco legislation to confirm the FDA's authority and take this matter out of the courtroom.

-30-30-30-

Supreme Ct agrees to hear case

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release April 26, 1999

STATEMENT BY THE PRESIDENT

I am very pleased that the Supreme Court has agreed to take up the case regarding the Food and Drug Administration's regulation of tobacco products. Almost three years ago, the FDA put in place a regulation to protect our children from tobacco, which the tobacco companies challenged in court. Every day, 3,000 young people become regular smokers and 1,000 will have their lives cut short as a result. 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.

###

One pager on case from FDA

FDA BACKGROUNDER

CURRENT & USEFUL INFORMATION FROM THE FOOD & DRUG ADMINISTRATION

Summary of U.S. Court of Appeals for the Fourth Circuit Ruling on FDA's Jurisdiction Over, and Regulation of, Cigarettes and Smokeless Tobacco

Aug. 21, 1998

On Aug. 14, 1998, a majority of a three-judge panel of the U.S. Court of Appeals for the Fourth Circuit in Richmond, Va., ruled that FDA lacks the jurisdiction to regulate tobacco products, reversing the decision of the U.S. District Court for the Middle District of North Carolina. Because the majority found that the agency lacked jurisdiction, it invalidated FDA's Aug. 28, 1996, regulations that restricted the sale and distribution of cigarettes and smokeless tobacco to children and adolescents. Circuit Judge H. Emory Widener Jr. wrote the majority opinion. Senior Circuit Judge Kenneth K. Hall wrote a dissenting opinion.

The government will seek review of this decision by the full Fourth Circuit. Under the court of appeals' rules, unless otherwise directed by the Fourth Circuit, the effect of the decision is automatically stayed, meaning the status quo is maintained until the court has the opportunity to rule on the government's rehearing request. This means, pending the court's review, the parts of the FDA tobacco program that have been in effect since February 1997 will remain in effect.

This case involves an appeal of an April 25, 1997, decision from Judge William Osteen of the U.S. District Court in Greensboro, N.C. The district court ruled that FDA does have jurisdiction under the Federal Food, Drug, and Cosmetic (FD&C) Act to regulate nicotine-containing cigarettes and smokeless tobacco as drug-delivery devices, upholding the restrictions that involved youth access and labeling, including the two provisions that went into effect Feb. 28, 1997: a prohibition on sales of these products to persons under age 18 and a requirement that retailers check photo IDs of purchasers under age 27. Judge Osteen, however, invalidated FDA's restrictions on the advertising and promotion of cigarettes and smokeless tobacco, finding that the agency exceeded its statutory authority. Both sides then appealed.

In the Fourth Circuit, the majority opinion held that FDA's jurisdiction to regulate drugs and devices does not include cigarettes and smokeless tobacco. The court, however, did not reject FDA's conclusion that these products fall within the FD&C Act's definitions of "drugs" and "devices." Instead, the majority opinion concluded, based on several sources of evidence, that Congress did not intend the FD&C Act to apply to these products. This evidence included what the court viewed as a lack of regulatory tools in the act appropriate for the regulation of tobacco products; prior statements by FDA that it lacked authority to regulate tobacco products in the absence of express claims; congressional inaction on bills to grant FDA explicit jurisdiction over tobacco products; and tobacco-specific legislation approved by Congress such as the Federal Cigarette Labeling and Advertising Act, the Comprehensive Smokeless Tobacco Health Education Act, and the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992.

Judge Hall agreed with FDA on all issues and dissented from the majority opinion. He concluded that tobacco products fit comfortably within the FD&C Act's "drug" and "device" definitions, and that the evidence falls far short of demonstrating that Congress intended to deny FDA jurisdiction over tobacco products. He wrote that he would have found that not only does FDA have jurisdiction to regulate tobacco products, but that all of FDA's regulations, including the advertising restrictions, are within the agency's authority. He explained that how FDA has chosen to regulate tobacco products has no bearing on the question of whether the agency has the authority to regulate them at all.

As noted earlier, the access restrictions in effect since February 1997 remain in effect pending the court's review of the government's rehearing request. Therefore, FDA is continuing to enforce the age and picture ID provisions of the tobacco regulations, which prohibit retailers from selling cigarettes and smokeless tobacco to persons younger than 18 years of age, and require retailers to examine the photo ID of persons younger than age 27 before selling these products to them. FDA will continue to disseminate an advertising campaign in states where contracts for enforcement are active, and will continue to bring civil money penalty actions against retailers who violate the provisions now in effect.

BG 98-4

More detailed history of case from DOJ

HISTORY OF THE FDA TOBACCO CASE

THE SOLICITOR GENERAL FILES A PETITION FOR A WRIT OF CERTIORARI WITH THE SUPREME COURT SEEKING REVIEW OF THE FOURTH CIRCUIT'S REVERSAL OF THE DISTRICT COURT'S DECISION UPHOLDING THE FOOD AND DRUG ADMINISTRATION'S TOBACCO REGULATIONS

On January 19, 1999, the Solicitor General filed a Petition for a Writ of Certiorari that requests the Supreme Court to review the August 14, 1998 decision of the United States Court of Appeals for the Fourth Circuit which reversed the decision of the United States District Court for the Middle District of North Carolina. The Tobacco Companies filed their Respondents' Brief in Opposition to Petition for a Writ of Certiorari on March 22, 1999, and on April 7, 1999, the Solicitor General filed a Reply Brief for the Petitioners.

The District Court had upheld the Food and Drug Administration's (FDA) legal authority to regulate cigarettes and smokeless tobacco products as "drugs" and "devices" under the Federal Food, Drug, and Cosmetic Act.

The Fourth Circuit's August decision struck down all of the FDA's 1996 regulations that were designed to limit the access of children under age 18 to cigarettes and smokeless tobacco and to restrict the advertising that makes those products attractive to youth.

The Solicitor General's petition argues that tobacco products fall squarely within the Act's "drug" and "device" definitions because the overwhelming evidence in the administrative record shows that they are intended to affect the structure or function of the body. The petition argues further that the Court of Appeals erroneously failed to defer to the Food and Drug Administration's reasonable interpretation of the Act, as Supreme Court precedent requires.

Filing the Petition stays the issuance of the Fourth Circuit's mandate while the Supreme Court considers the government's request. The FDA's age and identification regulations therefore remain in effect pending Supreme Court review.

CASE HISTORY

On August 23, 1996, the FDA made a final determination that it has jurisdiction over cigarettes and smokeless tobacco, and issued regulations restricting the sale and advertising of tobacco products in order to protect children and adolescents.

Tobacco manufacturers, retailers, and advertisers filed several actions in the United States District Court for the Middle District of North Carolina, challenging FDA's tobacco assess and advertising restrictions on both statutory and constitutional grounds. The cases were argued before the Honorable William L. Osteen, Sr.

DECISION BY THE DISTRICT COURT

On April 25, 1997, the District Court upheld the Food and Drug Administration's legal authority to regulate cigarettes and smokeless tobacco products as "drugs" and "devices" under the Food, Drug, and Cosmetic Act.

In doing so, Judge Osteen squarely rejected the tobacco manufacturers' argument that Congress, through enactment of the Federal Cigarette Labeling and Advertising Act and other statutes, intended to prevent FDA from exercising the jurisdiction it has now exercised. Judge Osteen, moreover, also rejected the plaintiffs' claim that prior statements by FDA officials relating to the agency's tobacco jurisdiction were binding in the face of new evidence.

Judge Osteen also upheld the FDA's application of its combination product and restricted devices provisions to these products. The Court concluded that tobacco products are "combination products," within the meaning of the FDCA, consisting of both drug and device components, and that FDA has the discretion to regulate tobacco pursuant to its device authorities. Finally, the Court concluded that the access restrictions and labeling requirements imposed by the agency were permissible exercises of its device authorities, but that the advertising and promotion restrictions were not. The regulations concerning advertising and promotion were enjoined.

Judge Osteen held, purely as a matter of statutory interpretation, that the FDA's restricted device authority (21 U.S.C. § 360j(e)) did not permit the agency to regulate tobacco advertising and promotion. Judge Osteen held that the grant of statutory authority under this provision, which allows FDA to establish "such other conditions" on the sale, distribution, and use of devices, did not allow FDA to restrict tobacco promotion or advertising. As a result of this construction of the statute, which invalidated the FDA's tobacco advertising restrictions, Judge Osteen did not reach the First Amendment issues the plaintiffs had raised.

On May 9, 1997, after Judge Osteen had issued his decision, one industry plaintiff, the Point of Purchase Advertising Institute, asked the Judge to amend his Order to say that self-service tobacco displays are advertising and promotion beyond FDA's reach, and not a means of access to tobacco products subject to FDA regulation. On June 4, 1997, Judge Osteen rejected that argument, and therefore declined to amend his Order.

TOBACCO COMPANY BRIEFS IN DISTRICT COURT

In their First Brief, filed October 15, 1996, the plaintiffs argued that FDA has no authority over tobacco products under the Food, Drug, and Cosmetic Act so long as they are sold without express medical claims, and that Congress has withheld such authority from FDA by enacting the Federal Cigarette Labeling and Advertising Act, Comprehensive Smokeless Tobacco Health Education Act, and other statutes.

In their Second Brief, filed October 15, 1996, the plaintiffs argued that tobacco products are not

"drugs" or "devices" as those terms are defined in the Food, Drug, and Cosmetic Act, and that FDA is misapplying the device laws to those products, further demonstrating that the agency does not have jurisdiction over those products.

In their Third Brief, filed October 15, 1996, the plaintiffs contended that FDA's regulations addressing tobacco advertising (which, among other things, limit most advertisements to black and white text, prohibit outdoor advertising within 1,000 feet of schools or playgrounds, and ban brand name sponsorships of sporting and cultural programs) violate First Amendment protection of commercial speech.

GOVERNMENT RESPONSE BRIEF IN DISTRICT COURT

The government filed one unified Response Brief to respond to all of the plaintiffs' briefs. The government argued:

(1) By enacting the Federal Food, Drug, and Cosmetic Act, Congress provided the FDA with the authority to regulate cigarettes and smokeless tobacco, and nothing that Congress has done in the past, either by affirmatively enacting other legislation or by inaction, has deprived FDA of that authority;

(2) FDA's finding that cigarettes and smokeless tobacco meet the Act's drug and device definitions because they are intended to affect the structure or function of the body, and its regulation of cigarettes and smokeless tobacco under the Act's device provisions, are appropriate exercises of its authority under the Act; and

(3) The restrictions adopted by FDA on advertising and other promotional activities for cigarettes and smokeless tobacco are consistent with the First Amendment.

AMICUS BRIEFS IN DISTRICT COURT

A number of states and private parties filed amicus ("friend of the court") briefs supporting or opposing FDA's regulation of tobacco. Amicus Brief 1 submitted in support of FDA by Public Citizen, National Center for Tobacco Free Kids, American Academy of Pediatrics, American Cancer Society, American College of Preventive Medicine, American Heart Association, American Lung Association, American Medical Association, American Medical Women's Association, American Public Health Association, American Society of Addiction Medicine, The HMO Group, National Association of African Americans for Positive Imagery, National Association of Elementary School Principals, National Association of Secondary School Principals, and National PTA. The groups argued that: Congress has not precluded FDA from regulating tobacco products; the Food, Drug, and Cosmetic Act authorizes FDA to regulate tobacco products; and FDA's regulations pass muster under the First Amendment.

Amicus Brief 2 of the State of Minnesota on behalf of itself and 32 other states, the territory of

Guam, and the City of San Francisco, California. The State of Minnesota argued in support of FDA's regulations that FDA's authority to regulate tobacco products is: authorized by law; not preempted; and an important part of the traditional federal and state concurrent regulation of matters affecting the public health and safety.

REPLY BRIEFS IN DISTRICT COURT

The plaintiffs, tobacco manufacturers and others, filed on December 23, 1996, three briefs in reply to the Government's Response Brief (above). Reply Brief 1, and Reply Brief 2, Reply Brief 3 reiterated the arguments made in the Tobacco Company Briefs (above).

PROCEEDINGS IN THE FOURTH CIRCUIT

The government and many of the industry plaintiffs appealed various aspects of the District Court's ruling to the Fourth Circuit Court of Appeals. The government appealed the District Court's decision that FDA lacks authority to regulate the promotion and advertising of tobacco products, and the Court's decision to enjoin certain access and labeling regulations that the Court had found to be within FDA's authority. The industry plaintiffs appealed the remainder of Judge Osteen's decision.

The government filed its opening brief on June 11, 1997. In that brief, the government argues that FDA has reasonably interpreted 21 U.S.C. § 360j(e) to authorize restrictions on advertising and promotion of tobacco products. The government also argues that there is no basis for the District Court's preliminary injunction against the access and labeling regulations.

In addition, two sets of groups filed amicus ("friend of the court") briefs in support of FDA. The State of Minnesota on behalf of itself, 37 other states, and the City of San Francisco, California filed a brief arguing that FDA's regulation of tobacco is well within its jurisdictional authority and that FDA's regulation of the advertising and promotion of tobacco products is fully consistent with the Federal Food, Drug, and Cosmetic Act.

Public Citizen, American Academy of Pediatrics, American Cancer Society, American College of Preventive Medicine, American Heart Association, American Lung Association, American Medical Association, American Medical Women's Association, American Public Health Association, American Society of Addiction Medicine, The HMO Group, National Association of Elementary School Principals, National Association of Secondary School Principals, and National Center for Tobacco-Free Kids, also filed an amicus brief in which they argue that FDA has authority to regulate tobacco products and to regulate the adverting and promotion of those products.

The industry filed its opening brief and response to the government's brief on June 27, 1997, along with supplemental briefs by the smokeless tobacco, advertising, and convenience store plaintiffs. The government filed its combined response to the industry brief and reply on July 14, 1997. The

industry's reply brief was filed on July 28, 1997.

On August 11, 1997, in Warm Springs, Virginia, a panel of the Court of Appeals for the Fourth Circuit, Circuit Judges Russell and Hall and Senior District Court Judge Michael, heard oral arguments on the issues raised by these appeals. Acting Solicitor General Walter Delinger argued for the government. Richard Cooper, of Williams & Connolly, argued for the plaintiff tobacco manufacturers. Larry Sitton, of Smith, Helms, Mullins & Moore, argued for the smokeless tobacco plaintiffs. John Oberdorfer, of Patton & Boggs, argued for the advertiser plaintiffs. William MacLeod, of Collier, Shannon, Rill & Scott, argued for the convenience store plaintiffs.

Due to the death of Judge Russell, on April 16, 1998, the Court of Appeals ordered that the case be reargued and on June 9, 1998, in Charleston, West Virginia, a panel of the Court, Circuit Judge Widener, Senior Circuit Judge Hall and Senior United States District Judge Michael, reheard oral arguments on these appeals. Gerald Kell argued for the government. Richard Cooper, of Williams & Connolly, argued for the plaintiff tobacco manufacturers. Larry Sitton, of Smith, Helms, Mullins & Moore, argued for the smokeless tobacco plaintiffs. John Oberdorfer, of Patton & Boggs, argued for the advertiser plaintiffs. William MacLeod, of Collier, Shannon, Rill & Scott, argued for the convenience store plaintiffs.

On August 14, 1998, the Court of Appeals issued its decision reversing the decision of the United States District Court. On September 25, 1998, the United States petitioned the Fourth Circuit for rehearing by the panel or by the Court en banc. In its petition for rehearing, the government noted that important public health issues were at stake and argued that the panel majority failed to follow the analytical course prescribed by the Supreme Court in Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984).

On November 10, 1998, the United States Court of Appeals for the Fourth Circuit denied the government's petition. Six judges voted against rehearing en banc (Widener, Ervin, Niemeyer, Luttig, Williams, and Traxler), three voted for (Murnaghan, M. Blane Michael, and Motz), and four did not participate (Wilkinson, Wilkins, Hamilton, and King). On November 18, 1998, in response to the government's request, the Fourth Circuit granted a 30 stay of the issuance of the mandate, and on December 17, 1998, extended the stay for another 30 days. With the filing of the government's Petition for a Writ of Certiorari, the issuance of the Fourth Circuit's mandate continues to be stayed pending Supreme Court review.

April 21, 1999
This summary, with links to referenced court briefs, is posted on the Department of Justice's web site at http://www.usdoj.gov/civil/cases/tobacco/index.htm.

About the FDA Rule

FDA Rule: Asserting its authority over tobacco products, the FDA in June 1996 issued regulations which prohibited the sale of tobacco products to minors. Specifically, the Rule establishes:

1) Youth Access Restrictions
- Sets minimum age of purchase at 18 years
- Requires age verification by photo ID for anyone 26 or younger
- Requires face-to-face sales (except for mail order sales)
- Bans vending machines and self-service displays except in facilities where only adults are permitted

2) Advertising Restrictions
- Bans outdoor advertising within 1000 feet of schools and public playgrounds
- Restricts advertising to black-and-white text only (publications, outdoor, point of purchase, direct mail, etc.), except in publications with a predominant adult readership or at adult only facilities
- Prohibits sale or giveaways of products like caps or gym bags that carry cigarette or smokeless tobacco product brand names or logos
- Prohibits brand-name sponsorship of sporting or entertainment events, but permits it in the corporate name

3) Point of Purchase Restrictions
- Prohibits sales of single cigarettes or "loosies"
- Bans free samples
- Sets minimum package size at 20 cigarettes
- Restricts all point of purchase advertising and labeling to black-and-white text only, except in adult only facilities

Comparison of FDA Tobacco Rule and 1998 Attorney General Tobacco Industry Agreement

	1996 FDA Rule	1998 Attorney General Tobacco Industry Agreement
Youth Access Restrictions	Sets 18 as minimum age for purchasing tobacco products and requires retailers to check photo ID of anyone who appears younger than 27 (implemented in Feb. 1997)	Not Required
Vending Machines	Limits vending machine sales and self service displays to places where minors are not allowed.	Not Required
Minimum Pack	Prohibits the sale of loose cigarettes and requires min. "20" packs.	Requires minimum "20" packs..
Giveaways	Prohibits free giveaways of tobacco products	Free Sampling limited to adult facilities.
Outdoor Advertising	Bans outdoor tobacco advertising within 1,000 ft. Of schools and playgrounds.	Bans billboards and transit ads but permits small signs on buildings were tobacco is sold, including near schools.
Advertising Images	Limits all outdoor advertising to b&w text only. Display advertising using color or images is allowed only inside places minors are not allowed to enter.	Not Addressed
Print Media	Limits advertising in publications with signicant youth readerhip to b&w only.	Newspaper and magazine ads not limited
Brand Name Merchandise	Prohibits industry sales or giveaways of non-tobacco merchandise or products that carry brand names or logos.	Bands tobacco brand name merchandise, except at tobacco sposored events.
Offers of Non-Tobacco Items or Gifts Based on Proof of Purchase	Prohibits industry from giving away non-tobacco items in exchange for the purchase of tobacco.	Banned to children.
Brand Name Sponsorship	Prohibits industry from establishing brand name sponsorship of sporting or entertainment events, but permits it in the companies' corporate names.	Prohibited for concerts, events in which any contestants are under 18, or in football, baseball, soccer, or hockey; except for Kool jazz Festival or GPC Country Music Festival. Otherwise limitd to one event or series annually (i.e., Winston Cup Race Tour)
Tobacco Product Placement in Movies and on TV	Not Addressed	Banned

About FDA authority as incorporated into McCain bill (separate chapter etc) (1)

Affirming FDA Authority to Prevent Advertising and Marketing to Children

By reaffirming the full authority of the FDA to regulate tobacco products, S.1415 will prevent the tobacco industry from advertising and marketing to children, and establish tough access restrictions on tobacco products to stop sales to children.

Reaffirms 1996 Rule: Many of the measures to reduce teen smoking and protect the public health contained in S.1415 are in the 1996 FDA rule, but have not yet gone into effect because of pending litigation. The bill would put these provisions into effect immediately, protecting American children from the dangers of smoking. These provisions include: 1) banning outdoor advertising within 1000 feet of schools and playgrounds; 2) restricting advertising to black-and-white text only except in adult only facilities or publications with predominantly adult readership; 3) prohibiting the sale or giveaway of promotional products with brand names or logos; 4) prohibiting brand-name sponsorship of sporting or entertainment events; 5) setting the minimum age for purchase of tobacco products at 18 years and requiring age verification for anyone age under 27.

Creates a Separate Chapter for Regulating Tobacco: S.1415 creates a separate chapter in the Food, Drug and Cosmetic Act that gives the FDA explicit authority over access to and advertising of tobacco products, in order to ensure that FDA regulation of tobacco does not impinge on the regulation of other products.

Establishes New Standard for Regulating Tobacco: Instead of requiring tobacco products to meet the traditional safety and efficacy standard required of drugs and devices, S.1415 imposes a new standard which would require FDA regulation of tobacco products to be "appropriate for the protection of public health". This standard better meets the characteristics of tobacco products and allows the FDA to take the addiction of over 40 million Americans into account in making decisions about how to regulate these products.

Provides Necessary Flexibility: Full FDA authority to regulate tobacco products provides the agency with the flexibility it needs to protect the public health. However, any FDA effort to eliminate any particular class of tobacco products or eliminate nicotine cannot go into effect for two years in order to provide Congress with an opportunity to weigh in and vote on the measure.

Preserves State and Local Authority: S.1415 makes clear that except as expressly provided, states and localities may adopt and enforce tobacco product requirements that are in addition to, or more stringent than, requirements established under the Food, Drug and Cosmetic Act for tobacco products.

Provides Full Enforcement Authority: S.1415 provides for the same civil and criminal penalties that the agency may use in enforcing device law.

(2)

Summary of FDA Provisions in S.1415

- **Overview of FDA Provisions:** S. 1415 creates a separate chapter in the FDCA that explicitly gives FDA authority over access to and advertising of tobacco products. In nearly all respects this authority is comparable to the authority that FDA asserted in its 1996 rule, which asserted FDA jurisdiction over tobacco products on the ground that nicotine is an addictive drug and that cigarettes and smokeless tobacco products are combination drug/device products under the Federal Food, Drug and Cosmetic Act (FDCA). S.1415, however, created a separate chapter in order to respond to concerns raised by medical device companies that tobacco statutory interpretations and other policies issued under the device provisions of the FDCA could adversely affect those companies.

  The most significant difference between S. 1415 and current law is the standard that products must meet in order to be marketed. Under current law the standard is "reasonable assurance of safety and effectiveness." This standard obviously does not fit tobacco products because tobacco products are inherently unsafe. Therefore, S. 1414 adopts the standard of "appropriate for the protection of the public health," which allows FDA to take into account the fact that over 40 million Americans are addicted to tobacco in making decisions about how to regulate the product.

- **1996 FDA Tobacco Rule in Effect:** S. 1415 provides that the tobacco regulation that FDA finalized in 1996 will remain in effect as though it were issued under the new law. Because the effective date of certain portions of the regulation has been delayed due to the industry's judicial challenge to the rule, the bill would authorize FDA to establish effective dates for those provisions not yet in effect.

- **Access Restrictions:** S. 1415 authorizes FDA to establish restrictions on the sale or distribution of tobacco products. By affirming the 1996 rule's access restrictions, the bill sets the minimum age of purchase at 18 years; requires age verification by photo ID for anyone 26 or younger; requires face-to-face sales (except for mail order sales); bans vending machines and self-service displays except in facilities where only adults are permitted; prohibits the sales of single cigarettes or "loosies"; bans free samples; and sets the minimum package size at 20 cigarettes. However, S. 1415 constrains FDA from prohibiting the sale of tobacco products in face-to-face transactions by specific categories of retail stores (such as a ban on sale of cigarettes by gas stations).

- **Advertising Restrictions and Warning Labels:** S. 1415 expressly authorizes FDA to establish restrictions related to the advertising and promotion of a tobacco product. By affirming the 1996 rule's advertising restrictions, the bill bans outdoor advertising within 1000 feet of schools and public playgrounds; restricts advertising to black-and-white text only (publications, outdoor, point of purchase, direct mail, etc.), except in publications with a predominant adult readership or at adult only facilities; prohibits the sale or giveaways of products like caps or gym bags that carry cigarette or smokeless tobacco product brand names or logos; and prohibits brand-name sponsorship of sporting or entertainment events, but permits it in the corporate name.

(3)

S. 1415 also requires stronger and larger warning labels than existing law on tobacco products (to replace the "Surgeon General's warning"), and provides authority for FDA to modify the text, format, and type size requirements of these statements.

- **Submission of Health Information to the Secretary:** S. 1415 requires tobacco product manufacturers and importers, within 6 months of enactment (and annually thereafter), to submit to FDA specific categories of information relevant to FDA regulation of tobacco products.

- **Good Manufacturing Practice Requirements:** Authorizes FDA to issue regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, of a tobacco product conform to good manufacturing practice (GMPs). The bill also makes explicit that the Secretary has the authority to grant either temporary or permanent exemptions or variances from a GMP requirement.

- **Performance Standards:** S. 1415 confirms FDA's authority to issue standards for tobacco for tobacco products (for example limiting the amount of certain ingredients) if FDA determines that a standard is appropriate for protection of the public health. This authority is the same as that for devices.

  - In issuing a performance standard, FDA must consider the health effects on tobacco users as well as potential users (such as children).

  - In order to give Congress a chance to vote on any standard that eliminates all cigarettes, all smokeless tobacco products, or any similar class of tobacco products, or requires the reduction of nicotine yields of a tobacco product to zero, such a standard will not go into effect until two years after the President has notified Congress of such a standard.

- **Testing and Reporting of Tobacco Smoke Constituents:** S. 1415 directs the Secretary to issue regulations to require the testing, reporting, and disclosure of tobacco smoke constituents (e.g., tar, nicotine and carbon monoxide) and ingredients that "the Secretary determines should be disclosed to the public in order to protect the public health."

- **Reduced Risk Tobacco Products:** S. 1415 contains a provision that allows FDA to designate a product as a "reduced risk tobacco product" if it finds that "the product will significantly reduce harm to individuals caused by a tobacco product and is otherwise appropriate to protect the public health."

(4)

- **Preservation of State and Local Authority**: S. 1415 makes clear that except as expressly provided, states and localities may adopt and enforce tobacco product requirements that are in addition to, or more stringent than, requirements established under FDCA for tobacco products.

  -- State and local requirements related to access and advertising are not preempted by the FDCA.

  -- State and local requirements related to performance standards, good manufacturing practices, and other similar FDCA requirements, are preempted, but States and localities may apply for exemptions pursuant to procedures that parallel provisions in device law.

  -- S.1415 modifies the Federal Cigarette Labeling and Advertising Act in order to ensure that restrictions on advertising imposed under State laws are not preempted.

- **Full Enforcement Authority:** S. 1415 provides for the same civil and criminal penalties that the agency may use in enforcing the device law. The bill also provides that FDA may issue, after an administrative hearing before an Administrative Law Judge, a no tobacco sale order prohibiting the sale of tobacco products at a particular retail outlet based on repeated violations by that outlet. The bill also imposes the same requirements for the export of tobacco products that do not meet the requirements of the FDCA that apply to devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Melissa T. Skolfield

Assistant Secretary for Public Affairs

Phone: (202)690-7850 **Fax: (202)690-5673**

To: Bruce Reed

Fax: 456-5542 Phone: _____

Date: 3/21/00 Total number of pages sent: 5

Comments:

Attached are the tobacco strategy & Q+A's that Kevin Thurm has discussed w/you.

200 Independence Avenue, S.W., Bldg. HHH, Room 647-D, Washington, D.C. 20201

March 21, 2000

HHS-Proposed Tobacco Message Strategy

Goal:

Disseminate a clear, strong message that the Administration will continue to work vigorously to secure FDA's authority over tobacco products and to reduce youth tobacco use and access through federal and state level efforts.

Messages:

A Loss for America and its Children
Today's Supreme Court decision is a loss for the American people, and especially, it is a loss for our children. Every day, 3,000 kids become regular smokers and a third of them will die from smoking-related causes. Without the authority to prevent children from smoking, the Food and Drug Administration cannot stop the endless progression of kids getting hooked on cigarettes and other tobacco products and dying early from tobacco use.

Pursuing FDA Authority
Today, I am renewing our pledge to work with a bipartisan coalition in Congress to seek full authority for the FDA to protect our children from nicotine addiction. I call on Congress to pass legislation that will affirm FDA's authority over tobacco products like that in the McCain bill that passed the Senate Commerce Committee two years ago. I challenge the Congress to move quickly and enact legislation that provides FDA with the authority it needs and fills the gap in protection for our children created by the Supreme Court decision.

A Challenge to the Tobacco Industry
Since 1996, the tobacco industry has fought our efforts to regulate tobacco at every turn. Recently, the nation's leading cigarette maker, Philip Morris, has expressed its willingness to accept government regulation of tobacco. I welcome that pledge, but now it's time to judge the tobacco industry by its actions, not by its words. Philip Morris and the other companies must demonstrate their support for legislation affirming FDA's authority that is at least as protective of children as the McCain bill, which passed the Senate Commerce Committee two years ago.

Continuing Our Fight to Reduce Teen Smoking
We will not stand still and let new generations of our citizens become victims of nicotine addiction. Eighty percent of those who use tobacco begin before age 18. We will continue to:

- Advocate that states use the money from the master tobacco settlement for tobacco prevention and control. Sustained and comprehensive programs, including community and school interventions, are needed to reduce tobacco use and address this serious public health problem. Efforts in states such as Oregon, Massachusetts, and Florida show that these programs work.

- Enforce the Synar regulation, which requires states, as a condition of receiving certain SAMHSA block grant funds, to enforce state laws that reduce the availability of tobacco products to minors.

- Work with public health officials, health policymakers, community leaders, and others nationwide to reach the Healthy People 2010 objective of reducing the percentage of minors buying tobacco products to five percent or less by 2010.

- Fund basic state tobacco control and prevention programs through CDC and provide technical assistance to all the states and territories with state-funded programs.

- Pursue a vigorous research agenda at the NIH to improve our ability to detect and treat lung cancer and other smoking-related diseases, and to develop effective community-based tobacco control and prevention strategies.

- Pursue the suit filed against the tobacco industry by the Justice Department to recover the federal costs of smoking-related illnesses.

Key upcoming events for message delivery:

April 5—Kick Butts Day, Secretary gives remarks
April/May—Release of CDC Youth Risk Behavior Survey data
May 17-26—World Health Assembly, Geneva
Early June—Release of AHRQ Smoking Cessation Guideline Update
July—Rollout of Surgeon General Report on Successful Tobacco Interventions
August 6-10—World Conference on Tobacco
August—Release of SAMHSA National Household Survey Data
September—Rollout of Surgeon General Report on Health Consequences of Tobacco Use in Women

Other message opportunities:

- Op-ed articles by the Secretary, Surgeon General, Dr. Koplan, validators
- Upcoming speeches and commencement addresses by the Secretary and Surgeon General

Validators:
- Campaign for Tobacco Free Kids
- Public Health Groups (ACS, APHA, etc)
- Congress
- State legislators/governors
- others

March 21, 2000
For Internal Use Only

Q&As on Supreme Court Decision on FDA's Authority to Regulate Tobacco

Q: What is the Administration's response to today's Supreme Court decision?

A: Today's Supreme Court decision is a loss for the American people, and especially, it is a loss for our children. Every day, 3,000 kids become regular smokers and a third of them will die from smoking-related causes. Without the authority to prevent children from smoking, the Food and Drug Administration cannot stop the endless progression of kids getting hooked on cigarettes and dying early from tobacco use.

Q: Doesn't this decision effectively end your ability to pursue regulatory authority over tobacco? What will the Administration do now?

A: No. Today's decision does not end our efforts to pursue FDA regulatory authority over tobacco and to protect our children from dying early from tobacco use. We are renewing our pledge to work with a bipartisan coalition in Congress to seek full authority for the FDA to protect our children from nicotine addiction. The President has called on Congress to pass legislation that will affirm FDA's authority over tobacco products like that in the McCain bill that passed the Senate Commerce Committee two years ago. The President has challenged the Congress to move quickly and enact legislation that fully restores the FDA's authority and fills the gap in protection for our children created by the Supreme Court decision.

We also will continue to advocate that states use the money from the master tobacco settlement for tobacco prevention and control programs, and we will continue to enforce the Synar regulation, which requires states to enforce state laws that reduce the availability of tobacco products to minors. In addition, we will continue to: work to reach the Healthy People 2010 objective of reducing the percentage of minors buying tobacco products to five percent or less by 2010; fund basic state tobacco control and prevention programs through CDC; pursue a vigorous research agenda at the NIH to improve our ability to detect and treat lung cancer and other smoking-related diseases, and to develop effective community-based tobacco control and prevention strategies. Finally, we will continue to pursue the suit filed against the tobacco industry by the Justice Department to recover the federal costs of smoking-related illnesses.

Q: Philip Morris says they are willing to agree to government regulation of tobacco products. What do you think of that?

A: We need comprehensive regulation to reduce youth smoking and protect the public health. We welcome Philip Morris' pledge to accept government regulation of tobacco,

but now it's time to judge the tobacco industry by its actions, not by its words. Philip Morris and the other tobacco companies must demonstrate their support for legislation affirming FDA's authority that is at least as protective of children as the McCain bill that passed the Senate Commerce Committee two years ago. If the industry is serious about reducing youth smoking, they will agree to these rules.

Q: Has Philip Morris contacted the Administration?

A: No, they have not.

Q: What does the FDA do now?

A: FDA will act consistent with the court orders. First, FDA will immediately issue a stop work order to those states and territories that were under contact with FDA to conduct retailer compliance checks. Second FDA will begin an orderly shutdown of its enforcement program. Third, consideration will be given to reprogramming funds not needed to pay contract claims or to shutdown program operations to other FDA priority programs.

Q: What happens to the contracts that FDA has with some states?

A: For a period of time following an adverse ruling, states would have an opportunity to submit vouchers for work done under the contracts prior to the ruling.

Q: Does this decision have any effect on the Synar Amendment requirements on states?

A: For the **15-20? (SAMHSA please correct)** states that are using FDA access control contracts to fund the require compliance checks under Synar, the court decision will stop further FDA funding of these activities. These states will still be subject to the requirements of the Synar amendment and will be expected to use alternative sources of funding to comply with the Synar amendment and meet their compliance rate targets.

In the United States, 12-17 year olds smoke more than 900 million packs of cigarettes per year.

Do Something...

Initiatives
Take Action
Tobacco News
Research Center
Press Office
Interactive
Special Reports
About Us

The Tobacco Toll
Find out what tobacco has done to your state!

Select a State...

Evidence Supporting the FDA Rule

Tobacco use is the leading preventable cause of death among Americans, and more than 80 percent of smokers pick up the habit before they turn 18. The U.S. Food & Drug Administration (FDA) Tobacco Rule offers a multifaceted approach to reduce youth tobacco use, and consequently reduce tobacco-related disease and death. Available data and research establish that the FDA Rule's provisions would significantly reduce youth smoking both by making it more difficult for kids to obtain cigarettes and by eliminating certain tobacco company marketing practices that lure kids into smoking. Tobacco industry documents illustrate how the FDA Rule and comprehensive tobacco-control legislation are needed to counteract the tobacco companies' ability to subvert effective anti-smoking measures and continue turning thousands of teens into addicted customers each day.

The Problem of Underage Smoking Is Getting Worse

- The number of kids who become regular smokers each year increased by 73 percent between 1988 and 1996.[1]
- 4.5 million kids age 12-17 are current smokers; in 1997, smoking among high-school seniors reached a 19-year high at 36.9 percent.[2] Smoking among this group dropped slightly in 1998, to 35.1 percent.
- Since 1991, past-month smoking has increased by one-third among eighth and tenth graders.[3]
- 48.2 percent of high school boys report past-month use of tobacco (cigarettes, smokeless tobacco, and/or cigars); and 16 percent of boys in grades 9-12 report past-month smokeless tobacco use.[4]
- The typical youth smoker first experiments with smoking when he or she is 13 years old.[5] More than 3,000 teens become regular smokers every day, and about a third of them will die prematurely from smoking-related causes.[6] Overall, more than 5 million children under age 18 who are alive today will die from smoking-related disease, unless current smoking rates are reversed.[7]

The FDA Provisions to Reduce Kids' Access to Cigarettes Offer a Powerful and Much-Needed Anti-Smoking Tool

The FDA Rule establishes 18 years as the national minimum age for purchasing cigarettes and smokeless tobacco and requires retailers to check the identification of all buyers who appear younger than 27. These provisions have been operative since February 28, 1997, but enforcement levels vary from place to place. The FDA has contracted with 41 states and

two territories to perform compliance checks of tobacco product retailers, and 30 of these states currently have programs up and running. Since the summer of 1997, approximately 75,000 compliance checks have been completed.

Available data and research show that illegal sales of tobacco products to underage buyers are a major problem, and that the FDA provisions, if aggressively enforced, could dramatically reduce such sales and consequently reduce youth smoking levels. In contrast, the tobacco

companies' own voluntary efforts to reduce youth access have been shown to be ineffective, but their efforts to subvert enforcement of the FDA Rule and other youth access provisions have not.

- Prior to the implementation of the FDA Rule's provisions, minors had easy access to tobacco products. Research studies have found that the vast majority of underage smokers simply bought their own cigarettes, and that almost half had *never* been asked to show proof of age when they purchased cigarettes.[8] An analysis of 13 different studies of over-the-counter sales of tobacco found that, on average, children and adolescents were successful in buying tobacco products 67 percent of the time.[9]
- Numerous studies have shown that laws that require retailers to check the identification of younger-looking buyers of tobacco products and not sell to any under 18 years of age, such as the FDA Rule, can significantly reduce youth access to cigarettes and also reduce kids' smoking levels if they are rigorously enforced.[10]
- Tobacco companies have been actively fighting the enactment of any new laws to reduce youth access, and have been working to impede the enforcement of both the state youth access laws and the FDA provisions that are already in effect. To block more effective state legislation, the tobacco industry and its allies have supported and helped pass legislative alternatives that are riddled with loopholes and exceptions. Furthermore, many of the bills supported by the tobacco companies would also restrict the authority of local governments from either enacting stronger laws or rigorously enforcing retailer compliance with state laws or the FDA Rule. Another frequent tobacco company strategy is to push bills that would turn enforcement efforts toward penalizing kids who smoke or buy tobacco products, thereby reducing enforcement efforts directed at stopping retailers from illegally selling to underage buyers.[11]
- Tobacco companies support voluntary programs as alternatives to the FDA Rule or new state laws, but past experience has shown their own voluntary programs to be ineffective publicity smokescreens. Phillip Morris, for example, promised to deny merchandising benefits to retailers caught selling cigarettes to kids, but when Minnesota Attorney General Hubert Humphrey III gave Philip Morris a list of stores caught selling tobacco to minors, the company took no action against the retailers.[12] Similarly, a study of retailers participating in the Tobacco Institute's voluntary youth access prevention program "It's the Law" were found to be just as likely to make illegal sales as those merchants who were not participants.[13] The tobacco companies' true intentions are reflected in a quote from an internal Tobacco Institute memo that discussed a tobacco industry initiative purportedly designed to reduce youth access: "It seems to me our objective is. . . a 'media event' which in itself promises a lot but produces little." [14]

Without the FDA Rule, the Tobacco Companies Will Continue to Successfully Market to Kids and Turn Many Into Addicted Smokers

The second part of the FDA Rule focuses on restricting the tobacco company marketing practices that help to lure many kids into smoking. The provisions would require that all cigarette billboard and display advertising (such as signs and posters in stores), as well as all advertising magazines with significant underage readership, consist of black-and-white text only. The provisions would also prohibit the tobacco companies from selling or distributing non-tobacco merchandise (such as caps, t-shirts, and key chains) decorated with their brand name or logos, from giving away free cigarettes or other tobacco products, and from sponsoring sporting or entertainment events.

- The tobacco industry's own documents show that the tobacco companies have consistently targeted kids through their product development, marketing, and advertising.

–An internal R.J. Reynolds (RJR) memo reveals that in the 1970s the company discussed plans to develop a cigarette brand that would appeal specifically to the "14-to-18 year old." [15]

–Other RJR documents from that time reveal that the tobacco company also developed specific strategies to sell cigarettes to the youth market. As one company executive wrote, "Realistically, if our company is to survive and prosper, over the long term, we must get our share of the youth market."[16] And another reports on a RJR marketing vice president discussion of recent RJR losses of customers in the 14 to 24 age group to Phillip Morris, in which he concludes: "Our strategy becomes clear for our established brands: 1. Direct advertising appeal to the younger smokers." [17]

–U.S. Tobacco (UST), which sells mostly smokeless tobacco, has developed products with candy flavors and lower concentrations of nicotine. A former UST sales representative was quoted, " Cherry Skoal is for somebody who likes the taste of candy, if you know what I'm saying."[18]

–An internal document from Phillip Morris states that "Today's teenager is tomorrow's potential regular customer, and the overwhelming majority of smokers first begin to smoke while still in their teens . . . The smoking patterns of teenagers are particularly important to Philip Morris." [19]

- Tobacco companies currently spend over $5 billion each year (nearly $14 million every day) promoting their products in order to replace the thousands of customers who either die or quit each day. Studies show that the tobacco companies' advertising and other marketing practices not only attract underage smokers to specific brands but also increase the numbers of kids who try smoking and who become addicted smokers.

–A 1998 longitudinal study of teenagers in the *Journal of the American Medical Association* showed that tobacco industry promotional activities influenced non-smokers to become susceptible to or experiment with smoking. [20]

–A study published in the *Journal of the National Cancer Institute* found that teens are more likely to be influenced to smoke by cigarette advertising than they are by peer pressure. [21]

–A 1996 study in the *Journal of Marketing* found that teenagers are three times as sensitive as adults to cigarette advertising.[22]

–Between 1989 and 1993, when advertising for the new Joe Camel campaign jumped from $27 million to $43 million, Camel's share among youth increased by more than 50 percent, while its adult market share did not change at all. Research published in the *Journal of the American Medical Association* documented a rapid and unprecedented increase in the smoking initiation rate of adolescent girls subsequent to the launch in the late 1960s of women's cigarette brands like Virginia Slims.[23]

–An April, 1999 poll conducted for the Campaign for Tobacco-Free Kids found that young people were more likely to notice tobacco advertising than adults. Three quarters of youth surveyed reported seeing advertising in the two weeks prior to the survey, compared with less than one-third of adults surveyed.[24]

4/22/1999

###

1 U.S. Centers for Disease Control and Prevention (CDC), "Incidence of Initiation of

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

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

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

No. 98–1152. Argued December 1, 1999– Decided March 21, 2000

The Food, Drug, and Cosmetic Act (FDCA), 21 U. S. C. §301 *et seq.*, grants the Food and Drug Administration (FDA), as the designee of the Secretary of Health and Human Services (HHS), the authority to regulate, among other items, "drugs" and "devices," §§321(g)–(h), 393. In 1996, the FDA asserted jurisdiction to regulate tobacco products, concluding that, under the FDCA, nicotine is a "drug" and cigarettes and smokeless tobacco are "devices" that deliver nicotine to the body. Pursuant to this authority, the FDA promulgated regulations governing tobacco products' promotion, labeling, and accessibility to children and adolescents. The FDA found that tobacco use is the Nation's leading cause of premature death, resulting in more than 400,000 deaths annually, and that most adult smokers begin when they are minors. The regulations therefore aim to reduce tobacco use by minors so as to substantially reduce the prevalence of addiction in future generations, and thus the incidence of tobacco-related death and disease. Respondents, a group of tobacco manufacturers, retailers, and advertisers, filed this suit challenging the FDA's regulations. They moved for summary judgment on the ground, *inter alia*, that the FDA lacked jurisdiction to regulate tobacco products as customarily marketed, that is, without manufacturer claims of therapeutic benefit. The District Court upheld the FDA's authority, but the Fourth Circuit reversed, holding that Congress has not granted the FDA jurisdiction to regulate tobacco products. The court concluded that construing the FDCA to include tobacco products would lead to several internal inconsistencies in the Act. It also found that evidence external to the FDCA– that the FDA consistently stated before 1995 that it lacked jurisdiction over tobacco, that Congress has en-

Syllabus

acted several tobacco-specific statutes fully cognizant of the FDA's position, and that Congress has considered and rejected many bills that would have given the agency such authority– confirms this conclusion.

Held: Reading the FDCA as a whole, as well as in conjunction with Congress' subsequent tobacco-specific legislation, it is plain that Congress has not given the FDA the authority to regulate tobacco products as customarily marketed. Pp. 8–40.

(a) Because this case involves an agency's construction of a statute it administers, the Court's analysis is governed by *Chevron U. S. A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U. S. 837, under which a reviewing court must first ask whether Congress has directly spoken to the precise question at issue, *id.*, at 842. If so, the court must give effect to Congress' unambiguously expressed intent. *E.g., Id.*, at 843. If not, the court must defer to the agency's construction of the statute so long as it is permissible. See, *e.g., INS* v. *Aguirre-Aguirre*, 526 U. S. 415, 424. In determining whether Congress has specifically addressed the question at issue, the court should not confine itself to examining a particular statutory provision in isolation. Rather, it must place the provision in context, interpreting the statute to create a symmetrical and coherent regulatory scheme. *Gustafson* v. *Alloyd Co.*, 513 U. S. 561, 569. In addition, the meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand. See, *e.g., United States* v. *Estate of Romani*, 523 U. S. 517, 530–531. Finally, the court must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of such economic and political magnitude to an administrative agency. Cf. *MCI Telecommunications Corp.* v. *American Telephone & Telegraph Co.*, 512 U. S. 218, 231. Pp. 8–10.

(b) Considering the FDCA as a whole, it is clear that Congress intended to exclude tobacco products from the FDA's jurisdiction. A fundamental precept of the FDCA is that any product regulated by the FDA that remains on the market must be safe and effective for its intended use. See, *e.g.*, §393(b)(2). That is, the potential for inflicting death or physical injury must be offset by the possibility of therapeutic benefit. *United States* v. *Rutherford*, 442 U. S. 544, 556. In its rulemaking proceeding, the FDA quite exhaustively documented that tobacco products are unsafe, dangerous, and cause great pain and suffering from illness. These findings logically imply that, if tobacco products were "devices" under the FDCA, the FDA would be required to remove them from the market under the FDCA's misbranding, see, *e.g.*, §331(a), and device classification, see, *e.g.*, §360e(d)(2)(A), provisions. In fact, based on such provisions, the FDA itself has previously

asserted that if tobacco products were within its jurisdiction, they would have to be removed from the market because it would be impossible to prove they were safe for their intended use. Congress, however, has foreclosed a ban of such products, choosing instead to create a distinct regulatory scheme focusing on the labeling and advertising of cigarettes and smokeless tobacco. Its express policy is to protect commerce and the national economy while informing consumers about any adverse health effects. See 15 U. S. C. §1331. Thus, an FDA ban would plainly contradict congressional intent. Apparently recognizing this dilemma, the FDA has concluded that tobacco products are actually "safe" under the FDCA because banning them would cause a greater harm to public health than leaving them on the market. But this safety determination– focusing on the relative harms caused by alternative remedial measures– is not a substitute for those required by the FDCA. Various provisions in the Act require the agency to determine that, at least for some consumers, the product's therapeutic benefits outweigh the risks of illness or serious injury. This the FDA cannot do, because tobacco products are unsafe for obtaining any therapeutic benefit. The inescapable conclusion is that there is no room for tobacco products within the FDCA's regulatory scheme. If they cannot be used safely for any therapeutic purpose, and yet they cannot be banned, they simply do not fit. Pp. 10–20.

(c) The history of tobacco-specific legislation also demonstrates that Congress has spoken directly to the FDA's authority to regulate tobacco products. Since 1965, Congress has enacted six separate statutes addressing the problem of tobacco use and human health. Those statutes, among other things, require that health warnings appear on all packaging and in all print and outdoor advertisements, see 15 U. S. C. §§1331, 1333, 4402; prohibit the advertisement of tobacco products through any electronic communication medium regulated by the Federal Communications Commission, see §§1335, 4402(f); require the Secretary of HHS to report every three years to Congress on research findings concerning tobacco's addictive property, 42 U. S. C. §290aa–2(b)(2); and make States' receipt of certain federal block grants contingent on their prohibiting any tobacco product manufacturer, retailer, or distributor from selling or distributing any such product to individuals under age 18, §300x–26(a)(1). This tobacco-specific legislation has created a specific regulatory scheme for addressing the problem of tobacco and health. And it was adopted against the backdrop of the FDA consistently and resolutely stating that it was without authority under the FDCA to regulate tobacco products as customarily marketed. In fact, Congress several times considered and rejected bills that would have given the FDA

Syllabus

such authority. Indeed, Congress' actions in this area have evidenced a clear intent to preclude a meaningful policymaking role for any administrative agency. Further, Congress' tobacco legislation prohibits any additional regulation of tobacco product labeling with respect to tobacco's health consequences, a central aspect of regulation under the FDCA. Under these circumstances, it is evident that Congress has ratified the FDA's previous, long-held position that it lacks jurisdiction to regulate tobacco products as customarily marketed. Congress has created a distinct scheme for addressing the subject, and that scheme excludes any role for FDA regulation. Pp. 20–37.

(d) Finally, the Court's inquiry is shaped, at least in some measure, by the nature of the question presented. *Chevron* deference is premised on the theory that a statute's ambiguity constitutes an implicit delegation from Congress to the agency to fill in the statutory gaps. See 467 U. S., at 844. In extraordinary cases, however, there may be reason to hesitate before concluding that Congress has intended such an implicit delegation. This is hardly an ordinary case. Contrary to the agency's position from its inception until 1995, the FDA has now asserted jurisdiction to regulate an industry constituting a significant portion of the American economy. In fact, the FDA contends that, were it to determine that tobacco products provide no "reasonable assurance of safety," it would have the authority to ban cigarettes and smokeless tobacco entirely. It is highly unlikely that Congress would leave the determination as to whether the sale of tobacco products would be regulated, or even banned, to the FDA's discretion in so cryptic a fashion. See *MCI Telecommunications*, 512 U. S., at 231. Given tobacco's unique political history, as well as the breadth of the authority that the FDA has asserted, the Court is obliged to defer not to the agency's expansive construction of the statute, but to Congress' consistent judgment to deny the FDA this power. Pp. 37–39.

(e) No matter how important, conspicuous, and controversial the issue, and regardless of how likely the public is to hold the Executive Branch politically accountable, an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress. Courts must take care not to extend a statute's scope beyond the point where Congress indicated it would stop. *E.g., United States* v. *Article of Drug . . . Bacto-Unidisk*, 394 U. S. 784, 800. P. 40.

153 F. 3d 155, affirmed.

O'CONNOR, J., delivered the opinion of the Court, in which REHNQUIST, C. J., and SCALIA, KENNEDY, and THOMAS, JJ., joined. BREYER, J., filed a dissenting opinion, in which STEVENS, SOUTER, and GINSBURG, JJ., joined.

SUPREME COURT OF THE UNITED STATES

No. 98–1152

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

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

[March 21, 2000]

JUSTICE O'CONNOR delivered the opinion of the Court.

This case involves one of the most troubling public health problems facing our Nation today: the thousands of premature deaths that occur each year because of tobacco use. In 1996, the Food and Drug Administration (FDA), after having expressly disavowed any such authority since its inception, asserted jurisdiction to regulate tobacco products. See 61 Fed. Reg. 44619–45318. The FDA concluded that nicotine is a "drug" within the meaning of the Food, Drug, and Cosmetic Act (FDCA or Act), 52 Stat. 1040, as amended, 21 U. S. C. §301 *et seq.*, and that cigarettes and smokeless tobacco are "combination products" that deliver nicotine to the body. 61 Fed. Reg. 44397 (1996). Pursuant to this authority, it promulgated regulations intended to reduce tobacco consumption among children and adolescents. *Id.*, at 44615–44618. The agency believed that, because most tobacco consumers begin their use before reaching the age of 18, curbing tobacco use by minors could substantially reduce the prevalence of addiction in future generations and thus the incidence of tobacco-related death and disease. *Id.*, at

44398–44399.

Regardless of how serious the problem an administrative agency seeks to address, however, it may not exercise its authority "in a manner that is inconsistent with the administrative structure that Congress enacted into law." *ETSI Pipeline Project* v. *Missouri*, 484 U. S. 495, 517 (1988). And although agencies are generally entitled to deference in the interpretation of statutes that they administer, a reviewing "court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron U. S. A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U. S. 837, 842–843 (1984). In this case, we believe that Congress has clearly precluded the FDA from asserting jurisdiction to regulate tobacco products. Such authority is inconsistent with the intent that Congress has expressed in the FDCA's overall regulatory scheme and in the tobacco-specific legislation that it has enacted subsequent to the FDCA. In light of this clear intent, the FDA's assertion of jurisdiction is impermissible.

I

The FDCA grants the FDA, as the designee of the Secretary of Health and Human Services, the authority to regulate, among other items, "drugs" and "devices." See 21 U. S. C. §§321(g)–(h), 393 (1994 ed. and Supp. III). The Act defines "drug" to include "articles (other than food) intended to affect the structure or any function of the body." 21 U. S. C. §321(g)(1)(C). It defines "device," in part, as "an instrument, apparatus, implement, machine, contrivance, . . . or other similar or related article, including any component, part, or accessory, which is . . . intended to affect the structure or any function of the body." §321(h). The Act also grants the FDA the authority to regulate so-called "combination products," which "constitute a combination of a drug, device, or biologic product."

§353(g)(1). The FDA has construed this provision as giving it the discretion to regulate combination products as drugs, as devices, or as both. See 61 Fed. Reg. 44400 (1996).

On August 11, 1995, the FDA published a proposed rule concerning the sale of cigarettes and smokeless tobacco to children and adolescents. 60 Fed. Reg. 41314–41787. The rule, which included several restrictions on the sale, distribution, and advertisement of tobacco products, was designed to reduce the availability and attractiveness of tobacco products to young people. *Id.*, at 41314. A public comment period followed, during which the FDA received over 700,000 submissions, more than "at any other time in its history on any other subject." 61 Fed. Reg. 44418 (1996).

On August 28, 1996, the FDA issued a final rule entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents." *Id.*, at 44396. The FDA determined that nicotine is a "drug" and that cigarettes and smokeless tobacco are "drug delivery devices," and therefore it had jurisdiction under the FDCA to regulate tobacco products as customarily marketed– that is, without manufacturer claims of therapeutic benefit. *Id.*, at 44397, 44402. First, the FDA found that tobacco products " 'affect the structure or any function of the body' " because nicotine "has significant pharmacological effects." *Id.*, at 44631. Specifically, nicotine "exerts psychoactive, or mood-altering, effects on the brain" that cause and sustain addiction, have both tranquilizing and stimulating effects, and control weight. *Id.*, at 44631–44632. Second, the FDA determined that these effects were "intended" under the FDCA because they "are so widely known and foreseeable that [they] may be deemed to have been intended by the manufacturers," *id.*, at 44687; consumers use tobacco products "predominantly or nearly exclusively" to obtain these effects, *id.*, at

44807; and the statements, research, and actions of manufacturers revealed that they "have 'designed' cigarettes to provide pharmacologically active doses of nicotine to consumers," *id.*, at 44849. Finally, the agency concluded that cigarettes and smokeless tobacco are "combination products" because, in addition to containing nicotine, they include device components that deliver a controlled amount of nicotine to the body, *id.*, at 45208–45216.

Having resolved the jurisdictional question, the FDA next explained the policy justifications for its regulations, detailing the deleterious health effects associated with tobacco use. It found that tobacco consumption was "the single leading cause of preventable death in the United States." *Id.*, at 44398. According to the FDA, "[m]ore than 400,000 people die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease." *Ibid.* The agency also determined that the only way to reduce the amount of tobacco-related illness and mortality was to reduce the level of addiction, a goal that could be accomplished only by preventing children and adolescents from starting to use tobacco. *Id.*, at 44398–44399. The FDA found that 82% of adult smokers had their first cigarette before the age of 18, and more than half had already become regular smokers by that age. *Id.*, at 44398. It also found that children were beginning to smoke at a younger age, that the prevalence of youth smoking had recently increased, and that similar problems existed with respect to smokeless tobacco. *Id.*, at 44398–44399. The FDA accordingly concluded that if "the number of children and adolescents who begin tobacco use can be substantially diminished, tobacco-related illness can be correspondingly reduced because data suggest that anyone who does not begin smoking in childhood or adolescence is unlikely ever to begin." *Id.*, at 44399.

Based on these findings, the FDA promulgated regulations concerning tobacco products' promotion, labeling,

and accessibility to children and adolescents. See *id.*, at 44615–44618. The access regulations prohibit the sale of cigarettes or smokeless tobacco to persons younger than 18; require retailers to verify through photo identification the age of all purchasers younger than 27; prohibit the sale of cigarettes in quantities smaller than 20; prohibit the distribution of free samples; and prohibit sales through self-service displays and vending machines except in adult-only locations. *Id.*, at 44616–44617. The promotion regulations require that any print advertising appear in a black-and-white, text-only format unless the publication in which it appears is read almost exclusively by adults; prohibit outdoor advertising within 1,000 feet of any public playground or school; prohibit the distribution of any promotional items, such as T-shirts or hats, bearing the manufacturer's brand name; and prohibit a manufacturer from sponsoring any athletic, musical, artistic, or other social or cultural event using its brand name. *Id.*, at 44617–44618. The labeling regulation requires that the statement, "A Nicotine-Delivery Device for Persons 18 or Older," appear on all tobacco product packages. *Id.*, at 44617.

The FDA promulgated these regulations pursuant to its authority to regulate "restricted devices." See 21 U. S. C. §360j(e). The FDA construed §353(g)(1) as giving it the discretion to regulate "combination products" using the Act's drug authorities, device authorities, or both, depending on "how the public health goals of the act can be best accomplished." 61 Fed. Reg. 44403 (1996). Given the greater flexibility in the FDCA for the regulation of devices, the FDA determined that "the device authorities provide the most appropriate basis for regulating cigarettes and smokeless tobacco." *Id.*, at 44404. Under 21 U. S. C. §360j(e), the agency may "require that a device be restricted to sale, distribution, or use . . . upon such other conditions as [the FDA] may prescribe in such regulation,

if, because of its potentiality for harmful effect or the collateral measures necessary to its use, [the FDA] determines that there cannot otherwise be reasonable assurance of its safety and effectiveness." The FDA reasoned that its regulations fell within the authority granted by §360j(e) because they related to the sale or distribution of tobacco products and were necessary for providing a reasonable assurance of safety. 61 Fed. Reg. 44405–44407 (1996).

Respondents, a group of tobacco manufacturers, retailers, and advertisers, filed suit in United States District Court for the Middle District of North Carolina challenging the regulations. See *Coyne Beahm, Inc.* v. *FDA*, 966 F. Supp. 1374 (1997). They moved for summary judgment on the grounds that the FDA lacked jurisdiction to regulate tobacco products as customarily marketed, the regulations exceeded the FDA's authority under 21 U. S. C. §360j(e), and the advertising restrictions violated the First Amendment. Second Brief in Support of Plaintiffs' Motion for Summary Judgment in No. 2:95CV00591 (MDNC), in 3 Rec. in No. 97–1604 (CA4), Tab No. 40; Third Brief in Support of Plaintiffs' Motion for Summary Judgment in No. 2:95CV00591 (MDNC), in 3 Rec. in No. 97–1604 (CA4), Tab No. 42. The District Court granted respondents' motion in part and denied it in part. 966 F. Supp., at 1400. The court held that the FDCA authorizes the FDA to regulate tobacco products as customarily marketed and that the FDA's access and labeling regulations are permissible, but it also found that the agency's advertising and promotion restrictions exceed its authority under §360j(e). *Id.*, at 1380–1400. The court stayed implementation of the regulations it found valid (except the prohibition on the sale of tobacco products to minors) and certified its order for immediate interlocutory appeal. *Id.*, at 1400–1401.

The Court of Appeals for the Fourth Circuit reversed,

holding that Congress has not granted the FDA jurisdiction to regulate tobacco products. See 153 F. 3d 155 (1998). Examining the FDCA as a whole, the court concluded that the FDA's regulation of tobacco products would create a number of internal inconsistencies. *Id.*, at 162–167. Various provisions of the Act require the agency to determine that any regulated product is "safe" before it can be sold or allowed to remain on the market, yet the FDA found in its rulemaking proceeding that tobacco products are "dangerous" and "unsafe." *Id.*, at 164–167. Thus, the FDA would apparently have to ban tobacco products, a result the court found clearly contrary to congressional intent. *Ibid.* This apparent anomaly, the Court of Appeals concluded, demonstrates that Congress did not intend to give the FDA authority to regulate tobacco. *Id.*, at 167. The court also found that evidence external to the FDCA confirms this conclusion. Importantly, the FDA consistently stated before 1995 that it lacked jurisdiction over tobacco, and Congress has enacted several tobacco-specific statutes fully cognizant of the FDA's position. See *id.*, at 168–176. In fact, the court reasoned, Congress has considered and rejected many bills that would have given the agency such authority. See *id.*, at 170–171. This, along with the absence of any intent by the enacting Congress in 1938 to subject tobacco products to regulation under the FDCA, demonstrates that Congress intended to withhold such authority from the FDA. *Id.*, at 167–176. Having resolved the jurisdictional question against the agency, the Court of Appeals did not address whether the regulations exceed the FDA's authority under 21 U. S. C. §360j(e) or violate the First Amendment. See 153 F. 3d, at 176, n. 29.

We granted the Government's petition for certiorari, 526 U. S. 1086 (1999), to determine whether the FDA has authority under the FDCA to regulate tobacco products as customarily marketed.

II

The FDA's assertion of jurisdiction to regulate tobacco products is founded on its conclusions that nicotine is a "drug" and that cigarettes and smokeless tobacco are "drug delivery devices." Again, the FDA found that tobacco products are "intended" to deliver the pharmacological effects of satisfying addiction, stimulation and tranquilization, and weight control because those effects are foreseeable to any reasonable manufacturer, consumers use tobacco products to obtain those effects, and tobacco manufacturers have designed their products to produce those effects. 61 Fed. Reg. 44632–44633 (1996). As an initial matter, respondents take issue with the FDA's reading of "intended," arguing that it is a term of art that refers exclusively to claims made by the manufacturer or vendor about the product. See Brief for Respondent Brown & Williamson Tobacco Corp. 6. That is, a product is not a drug or device under the FDCA unless the manufacturer or vendor makes some express claim concerning the product's therapeutic benefits. See *id.*, at 6–7. We need not resolve this question, however, because assuming, *arguendo*, that a product can be "intended to affect the structure or any function of the body" absent claims of therapeutic or medical benefit, the FDA's claim to jurisdiction contravenes the clear intent of Congress.

A threshold issue is the appropriate framework for analyzing the FDA's assertion of authority to regulate tobacco products. Because this case involves an administrative agency's construction of a statute that it administers, our analysis is governed by *Chevron U. S. A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U. S. 837 (1984). Under *Chevron*, a reviewing court must first ask "whether Congress has directly spoken to the precise question at issue." *Id.*, at 842. If Congress has done so, the

inquiry is at an end; the court "must give effect to the unambiguously expressed intent of Congress." *Id.*, at 843; see also *United States* v. *Haggar Apparel Co.*, 526 U. S. 380, 392 (1999); *Holly Farms Corp.* v. *NLRB*, 517 U. S. 392, 398 (1996). But if Congress has not specifically addressed the question, a reviewing court must respect the agency's construction of the statute so long as it is permissible. See *INS* v. *Aguirre-Aguirre*, 526 U. S. 415, 424 (1999); *Auer* v. *Robbins*, 519 U. S. 452, 457 (1997). Such deference is justified because "[t]he responsibilities for assessing the wisdom of such policy choices and resolving the struggle between competing views of the public interest are not judicial ones," *Chevron*, *supra*, at 866, and because of the agency's greater familiarity with the ever-changing facts and circumstances surrounding the subjects regulated, see *Rust* v. *Sullivan*, 500 U. S. 173, 187 (1991).

In determining whether Congress has specifically addressed the question at issue, a reviewing court should not confine itself to examining a particular statutory provision in isolation. The meaning– or ambiguity– of certain words or phrases may only become evident when placed in context. See *Brown* v. *Gardner*, 513 U. S. 115, 118 (1994) ("Ambiguity is a creature not of definitional possibilities but of statutory context"). It is a "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Davis* v. *Michigan Dept. of Treasury*, 489 U. S. 803, 809 (1989). A court must therefore interpret the statute "as a symmetrical and coherent regulatory scheme," *Gustafson* v. *Alloyd Co.*, 513 U. S. 561, 569 (1995), and "fit, if possible, all parts into an harmonious whole," *FTC* v. *Mandel Brothers, Inc.*, 359 U. S. 385, 389 (1959). Similarly, the meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand. See *United States* v. *Estate of Romani*, 523 U. S. 517, 530–531

(1998); *United States* v. *Fausto*, 484 U. S. 439, 453 (1988). In addition, we must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of such economic and political magnitude to an administrative agency. Cf. *MCI Telecommunications Corp.* v. *American Telephone & Telegraph Co.*, 512 U. S. 218, 231 (1994).

With these principles in mind, we find that Congress has directly spoken to the issue here and precluded the FDA's jurisdiction to regulate tobacco products.

A

Viewing the FDCA as a whole, it is evident that one of the Act's core objectives is to ensure that any product regulated by the FDA is "safe" and "effective" for its intended use. See 21 U. S. C. §393(b)(2) (1994 ed., Supp. III) (defining the FDA's mission); More Information for Better Patient Care: Hearing before the Senate Committee on Labor and Human Resources, 104th Cong., 2d Sess., 83 (1996) (statement of 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"). This essential purpose pervades the FDCA. For instance, 21 U. S. C. §393(b)(2) (1994 ed., Supp. III) defines the FDA's "mission" to include "protect[ing] the public health by ensuring that . . . drugs are safe and effective" and that "there is reasonable assurance of the safety and effectiveness of devices intended for human use." The FDCA requires premarket approval of any new drug, with some limited exceptions, and states that the FDA "shall issue an order refusing to approve the application" of a new drug if it is not safe and effective for its intended purpose. §§355(d)(1)–(2), (4)–(5). If the FDA discovers after approval that a drug is unsafe or ineffective, it "shall, after due notice and opportunity

for hearing to the applicant, withdraw approval" of the drug. 21 U. S. C. §§355(e)(1)–(3). The Act also requires the FDA to classify all devices into one of three categories. §360c(b)(1). Regardless of which category the FDA chooses, there must be a "reasonable assurance of the safety and effectiveness of the device." 21 U. S. C. §§360c(a)(1)(A)(i), (B), (C) (1994 ed. and Supp. III); 61 Fed. Reg. 44412 (1996). Even the "restricted device" provision pursuant to which the FDA promulgated the regulations at issue here authorizes the agency to place conditions on the sale or distribution of a device specifically when "there cannot otherwise be reasonable assurance of its safety and effectiveness." 21 U. S. C. §360j(e). Thus, the Act generally requires the FDA to prevent the marketing of any drug or device where the "potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit." *United States* v. *Rutherford,* 442 U. S. 544, 556 (1979).

In its rulemaking proceeding, the FDA quite exhaustively documented that "tobacco products are unsafe," "dangerous," and "cause great pain and suffering from illness." 61 Fed. Reg. 44412 (1996). It found that the consumption of tobacco products "presents extraordinary health risks," and that "tobacco use is the single leading cause of preventable death in the United States." *Id.*, at 44398. It stated that "[m]ore 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," and that "[t]obacco alone kills more people each year in the United States than acquired immunodeficiency syndrome (AIDS), car accidents, alcohol, homicides, illegal drugs, suicides, and fires, combined." *Ibid.* Indeed, the FDA characterized smoking as "a pediatric disease," *id.*, at 44421, because "one out of every three young people who become regular smokers . . . will die prematurely as a result," *id.*, at 44399.

These findings logically imply that, if tobacco products were "devices" under the FDCA, the FDA would be required to remove them from the market. Consider, first, the FDCA's provisions concerning the misbranding of drugs or devices. The Act prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adultered or misbranded." 21 U. S. C. §331(a). In light of the FDA's findings, two distinct FDCA provisions would render cigarettes and smokeless tobacco misbranded devices. First, §352(j) deems a drug or device misbranded "[i]f it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." The FDA's findings make clear that tobacco products are "dangerous to health" when used in the manner prescribed. Second, a drug or device is misbranded under the Act "[u]nless its labeling bears . . . adequate directions for use . . . in such manner and form, as are necessary for the protection of users," except where such directions are "not necessary for the protection of the public health." §352(f)(1). Given the FDA's conclusions concerning the health consequences of tobacco use, there are no directions that could adequately protect consumers. That is, there are no directions that could make tobacco products safe for obtaining their intended effects. Thus, were tobacco products within the FDA's jurisdiction, the Act would deem them misbranded devices that could not be introduced into interstate commerce. Contrary to the dissent's contention, the Act admits no remedial discretion once it is evident that the device is misbranded.

Second, the FDCA requires the FDA to place all devices that it regulates into one of three classifications. See §360c(b)(1). The agency relies on a device's classification in determining the degree of control and regulation necessary to ensure that there is "a reasonable assurance of

safety and effectiveness." 61 Fed. Reg. 44412 (1996). The FDA has yet to classify tobacco products. Instead, the regulations at issue here represent so-called "general controls," which the Act entitles the agency to impose in advance of classification. See *id.*, at 44404–44405. Although the FDCA prescribes no deadline for device classification, the FDA has stated that it will classify tobacco products "in a future rulemaking" as required by the Act. *Id.*, at 44412. Given the FDA's findings regarding the health consequences of tobacco use, the agency would have to place cigarettes and smokeless tobacco in Class III because, even after the application of the Act's available controls, they would "presen[t] a potential unreasonable risk of illness or injury." 21 U. S. C. §360c(a)(1)(C). As Class III devices, tobacco products would be subject to the FDCA's premarket approval process. See 21 U. S. C. §360c(a)(1)(C) (1994 ed., Supp. III); 21 U. S. C. §360e; 61 Fed. Reg. 44412 (1996). Under these provisions, the FDA would be prohibited from approving an application for premarket approval without "a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested on the labeling thereof." 21 U. S. C. §360e(d)(2)(A). In view of the FDA's conclusions regarding the health effects of tobacco use, the agency would have no basis for finding any such reasonable assurance of safety. Thus, once the FDA fulfilled its statutory obligation to classify tobacco products, it could not allow them to be marketed.

The FDCA's misbranding and device classification provisions therefore make evident that were the FDA to regulate cigarettes and smokeless tobacco, the Act would require the agency to ban them. In fact, based on these provisions, the FDA itself has previously taken the position that if tobacco products were within its jurisdiction, "they would have to be removed from the market because it would be impossible to prove they were safe for their

intended us[e]." Public Health Cigarette Amendments of 1971: Hearings before the Commerce Subcommittee on S. 1454, 92d Cong., 2d Sess., 239 (1972) (hereinafter 1972 Hearings) (statement of FDA Commissioner Charles Edwards). See also Cigarette Labeling and Advertising: Hearings before the House Committee on Interstate and Foreign Commerce, 88th Cong., 2d Sess., 18 (1964) (hereinafter 1964 Hearings) (statement of Department of Health, Education, and Welfare (HEW) Secretary Anthony Celebrezze that proposed amendments to the FDCA that would have given the FDA jurisdiction over "smoking product[s]" "might well completely outlaw at least cigarettes").

Congress, however, has foreclosed the removal of tobacco products from the market. A provision of the United States Code currently in force states that "[t]he marketing of tobacco constitutes one of the greatest basic industries of the United States with ramifying activities which directly affect interstate and foreign commerce at every point, and stable conditions therein are necessary to the general welfare." 7 U. S. C. §1311(a). More importantly, Congress has directly addressed the problem of tobacco and health through legislation on six occasions since 1965. See Federal Cigarette Labeling and Advertising Act (FCLAA), Pub. L. 89–92, 79 Stat. 282; Public Health Cigarette Smoking Act of 1969, Pub. L. 91–222, 84 Stat. 87; Alcohol and Drug Abuse Amendments of 1983, Pub. L. 98–24, 97 Stat. 175; Comprehensive Smoking Education Act, Pub. L. 98–474, 98 Stat. 2200; Comprehensive Smokeless Tobacco Health Education Act of 1986, Pub. L. 99–252, 100 Stat. 30; Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act, Pub. L. 102–321, §202, 106 Stat. 394. When Congress enacted these statutes, the adverse health consequences of tobacco use were well known, as were nicotine's pharmacological effects. See, *e.g.*, U. S. Dept. of Health, Education, and Welfare, U. S. Surgeon

General's Advisory Committee, Smoking and Health 25–40, 69–75 (1964) (hereinafter 1964 Surgeon General's Report) (concluding that cigarette smoking causes lung cancer, coronary artery disease, and chronic bronchitis and emphysema, and that nicotine has various pharmacological effects, including stimulation, tranquilization, and appetite suppression); U. S. Dept. of Health and Human Services, Public Health Service, Health Consequences of Smoking for Women 7–12 (1980) (finding that mortality rates for lung cancer, chronic lung disease, and coronary heart disease are increased for both women and men smokers, and that smoking during pregnancy is associated with significant adverse health effects on the unborn fetus and newborn child); U. S. Dept. of Health and Human Services, Public Health Service, Why People Smoke Cigarettes (1983), in Smoking Prevention Education Act, Hearings on H. R. 1824 before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, 98th Cong., 1st Sess., 32–37 (1983) (hereinafter 1983 House Hearings) (stating that smoking is "the most widespread example of drug dependence in our country," and that cigarettes "affect the chemistry of the brain and nervous system"); U. S. Dept. of Health and Human Services, Public Health Service, The Health Consequences of Smoking: Nicotine Addiction 6–9, 145–239 (1988) (hereinafter 1988 Surgeon General's Report) (concluding that tobacco products are addicting in much the same way as heroin and cocaine, and that nicotine is the drug that causes addiction). Nonetheless, Congress stopped well short of ordering a ban. Instead, it has generally regulated the labeling and advertisement of tobacco products, expressly providing that it is the policy of Congress that "commerce and the national economy may be . . . protected to the maximum extent consistent with" consumers "be[ing] adequately informed about any adverse health effects." 15 U. S. C. §1331. Congress'

decisions to regulate labeling and advertising and to adopt the express policy of protecting "commerce and the national economy . . . to the maximum extent" reveal its intent that tobacco products remain on the market. Indeed, the collective premise of these statutes is that cigarettes and smokeless tobacco will continue to be sold in the United States. A ban of tobacco products by the FDA would therefore plainly contradict congressional policy.

The FDA apparently recognized this dilemma and concluded, somewhat ironically, that tobacco products are actually "safe" within the meaning of the FDCA. In promulgating its regulations, the agency conceded that "tobacco products are unsafe, as that term is conventionally understood." 61 Fed. Reg. 44412 (1996). Nonetheless, the FDA reasoned that, in determining whether a device is safe under the Act, it must consider "not only the risks presented by a product but also any of the countervailing effects of use of that product, including the consequences of not permitting the product to be marketed." *Id.*, at 44412–44413. Applying this standard, the FDA found that, because of the high level of addiction among tobacco users, a ban would likely be "dangerous." *Id.*, at 44413. In particular, current tobacco users could suffer from extreme withdrawal, the health care system and available pharmaceuticals might not be able to meet the treatment demands of those suffering from withdrawal, and a black market offering cigarettes even more dangerous than those currently sold legally would likely develop. *Ibid.* The FDA therefore concluded that, "while taking cigarettes and smokeless tobacco off the market could prevent some people from becoming addicted and reduce death and disease for others, the record does not establish that such a ban is the appropriate public health response under the act." *Id.*, at 44398.

It may well be, as the FDA asserts, that "these factors must be considered when developing a regulatory scheme

that achieves the best public health result for these products." *Id.*, at 44413. But the FDA's judgment that leaving tobacco products on the market "is more effective in achieving public health goals than a ban," *ibid.*, is no substitute for the specific safety determinations required by the FDCA's various operative provisions. Several provisions in the Act require the FDA to determine that the *product itself* is safe as used by consumers. That is, the product's probable therapeutic benefits must outweigh its risk of harm. See *United States* v. *Rutherford*, 442 U. S., at 555 ("[T]he Commissioner generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use"). In contrast, the FDA's conception of safety would allow the agency, with respect to each provision of the FDCA that requires the agency to determine a product's "safety" or "dangerousness," to compare the aggregate health effects of alternative administrative actions. This is a qualitatively different inquiry. Thus, although the FDA has concluded that a ban would be "dangerous," it has *not* concluded that tobacco products are "safe" as that term is used throughout the Act.

Consider 21 U. S. C. §360c(a)(2), which specifies those factors that the FDA may consider in determining the safety and effectiveness of a device for purposes of classification, performance standards, and premarket approval. For all devices regulated by the FDA, there must at least be a "reasonable assurance of the safety and effectiveness of the device." See 21 U. S. C. §§360c(a)(1)(A)(i), (B), (C) (1994 ed. and Supp. III); 61 Fed. Reg. 44412 (1996). Title 21 U. S. C. §360c(a)(2) provides that

> "the safety and effectiveness of a device are to be determined–
>
> "(A) with respect to the persons for whose use the device is represented or intended,
>
> "(B) with respect to the conditions of use prescribed,

> recommended, or suggested in the labeling of the device, and
>
> "(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use."

A straightforward reading of this provision dictates that the FDA must weigh the probable therapeutic benefits of the device to the consumer against the probable risk of injury. Applied to tobacco products, the inquiry is whether their purported benefits– satisfying addiction, stimulation and sedation, and weight control– outweigh the risks to health from their use. To accommodate the FDA's conception of safety, however, one must read "any probable benefit to health" to include the benefit to public health stemming from adult consumers' continued use of tobacco products, even though the *reduction* of tobacco use is the *raison d'être* of the regulations. In other words, the FDA is forced to contend that the very evil it seeks to combat is a "benefit to health." This is implausible.

The FDA's conception of safety is also incompatible with the FDCA's misbranding provision. Again, §352(j) provides that a product is "misbranded" if "it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." According to the FDA's understanding, a product would be "dangerous to health," and therefore misbranded under §352(j), when, in comparison to leaving the product on the market, a ban would not produce "adverse health consequences" in aggregate. Quite simply, these are different inquiries. Although banning a particular product might be detrimental to public health in aggregate, the product could still be "dangerous to health" when used as directed. Section 352(j) focuses on dangers to the consumer from use of the product, not those stemming from the agency's remedial meas-

ures.

Consequently, the analogy made by the FDA and the dissent to highly toxic drugs used in the treatment of various cancers is unpersuasive. See 61 Fed. Reg. 44413 (1996); *post*, at 17 (opinion of BREYER, J.). Although "dangerous" in some sense, these drugs are safe within the meaning of the Act because, for certain patients, the therapeutic benefits outweigh the risk of harm. Accordingly, such drugs cannot properly be described as "dangerous to health" under 21 U. S. C. §352(j). The same is not true for tobacco products. As the FDA has documented in great detail, cigarettes and smokeless tobacco are an unsafe means to obtaining *any* pharmacological effect.

The dissent contends that our conclusion means that "the FDCA requires the FDA to ban outright 'dangerous' drugs or devices," *post*, at 14, and that this is a "perverse" reading of the statute, *id.*, at 14, 21. This misunderstands our holding. The FDA, consistent with the FDCA, may clearly regulate many "dangerous" products without banning them. Indeed, virtually every drug or device poses dangers under certain conditions. What the FDA may not do is conclude that a drug or device cannot be used safely for any therapeutic purpose and yet, at the same time, allow that product to remain on the market. Such regulation is incompatible with the FDCA's core objective of ensuring that every drug or device is safe and effective.

Considering the FDCA as a whole, it is clear that Congress intended to exclude tobacco products from the FDA's jurisdiction. A fundamental precept of the FDCA is that any product regulated by the FDA– but not banned– must be safe for its intended use. Various provisions of the Act make clear that this refers to the safety of using the product to obtain its intended effects, not the public health ramifications of alternative administrative actions by the FDA. That is, the FDA must determine that there is a reasonable assurance that the product's therapeutic bene-

fits outweigh the risk of harm to the consumer. According to this standard, the FDA has concluded that, although tobacco products might be effective in delivering certain pharmacological effects, they are "unsafe" and "dangerous" when used for these purposes. Consequently, if tobacco products were within the FDA's jurisdiction, the Act would require the FDA to remove them from the market entirely. But a ban would contradict Congress' clear intent as expressed in its more recent, tobacco-specific legislation. The inescapable conclusion is that there is no room for tobacco products within the FDCA's regulatory scheme. If they cannot be used safely for any therapeutic purpose, and yet they cannot be banned, they simply do not fit.

B

In determining whether Congress has spoken directly to the FDA's authority to regulate tobacco, we must also consider in greater detail the tobacco-specific legislation that Congress has enacted over the past 35 years. At the time a statute is enacted, it may have a range of plausible meanings. Over time, however, subsequent acts can shape or focus those meanings. The "classic judicial task of reconciling many laws enacted over time, and getting them to 'make sense' in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute." *United States* v. *Fausto*, 484 U. S., at 453. This is particularly so where the scope of the earlier statute is broad but the subsequent statutes more specifically address the topic at hand. As we recognized recently in *United States* v. *Estate of Romani*, "a specific policy embodied in a later federal statute should control our construction of the [earlier] statute, even though it ha[s] not been expressly amended." 523 U. S., at 530–531.

Congress has enacted six separate pieces of legislation

since 1965 addressing the problem of tobacco use and human health. See *supra*, at 14. Those statutes, among other things, require that health warnings appear on all packaging and in all print and outdoor advertisements, see 15 U. S. C. §§1331, 1333, 4402; prohibit the advertisement of tobacco products through "any medium of electronic communication" subject to regulation by the Federal Communications Commission (FCC), see §§1335, 4402(f); require the Secretary of Health and Human Services (HHS) to report every three years to Congress on research findings concerning "the addictive property of tobacco," 42 U. S. C. §290aa–2(b)(2); and make States' receipt of certain federal block grants contingent on their making it unlawful "for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under the age of 18," §300x–26(a)(1).

In adopting each statute, Congress has acted against the backdrop of the FDA's consistent and repeated statements that it lacked authority under the FDCA to regulate tobacco absent claims of therapeutic benefit by the manufacturer. In fact, on several occasions over this period, and after the health consequences of tobacco use and nicotine's pharmacological effects had become well known, Congress considered and rejected bills that would have granted the FDA such jurisdiction. Under these circumstances, it is evident that Congress' tobacco-specific statutes have effectively ratified the FDA's long-held position that it lacks jurisdiction under the FDCA to regulate tobacco products. Congress has created a distinct regulatory scheme to address the problem of tobacco and health, and that scheme, as presently constructed, precludes any role for the FDA.

On January 11, 1964, the Surgeon General released the report of the Advisory Committee on Smoking and Health. That report documented the deleterious health effects of

smoking in great detail, concluding, in relevant part, "that cigarette smoking contributes substantially to mortality from certain specific diseases and to the overall death rate." 1964 Surgeon General's Report 31. It also identified the pharmacological effects of nicotine, including "stimulation," "tranquilization," and "suppression of appetite." *Id.*, at 74–75. Seven days after the report's release, the Federal Trade Commission (FTC) issued a notice of proposed rulemaking, see 29 Fed. Reg. 530–532 (1964), and in June 1964, the FTC promulgated a final rule requiring cigarette manufacturers "to disclose, clearly and prominently, in all advertising and on every pack, box, carton or other container . . . that cigarette smoking is dangerous to health and may cause death from cancer and other diseases," *id.*, at 8325. The rule was to become effective January 1, 1965, but, on a request from Congress, the FTC postponed enforcement for six months. See *Cipollone* v. *Liggett Group, Inc.*, 505 U. S. 504, 513–514 (1992).

In response to the Surgeon General's report and the FTC's proposed rule, Congress convened hearings to consider legislation addressing "the tobacco problem." 1964 Hearings 1. During those deliberations, FDA representatives testified before Congress that the agency lacked jurisdiction under the FDCA to regulate tobacco products. Surgeon General Terry was asked during hearings in 1964 whether HEW had the "authority to brand or label the packages of cigarettes or to control the advertising there." *Id.*, at 56. The Surgeon General stated that "we do not have such authority in existing laws governing the . . . Food and Drug Administration." *Ibid.* Similarly, FDA Deputy Commissioner Rankin testified in 1965 that "[t]he Food and Drug Administration has no jurisdiction under the Food, Drug, and Cosmetic Act over tobacco, unless it bears drug claims." Cigarette Labeling and Advertising–1965: Hearings on H. R. 2248 before the House Committee on Interstate and Foreign Commerce, 89th Cong., 1st

Sess., 193 (hereinafter 1965 Hearings). See also Letter to Directors of Bureaus, Divisions and Directors of Districts from FDA Bureau of Enforcement (May 24, 1963), in 1972 Hearings 240 ("[T]obacco marketed for chewing or smoking without accompanying therapeutic claims, does not meet the definitions in the Food, Drug, and Cosmetic Act for food, drug, device or cosmetic"). In fact, HEW Secretary Celebrezze urged Congress *not* to amend the FDCA to cover "smoking products" because, in light of the findings in the Surgeon General's report, such a "provision might well completely outlaw at least cigarettes. This would be contrary to what, we understand, is intended or what, in the light of our experience with the 18th amendment, would be acceptable to the American people." 1964 Hearings 18.

The FDA's disavowal of jurisdiction was consistent with the position that it had taken since the agency's inception. As the FDA concedes, it never asserted authority to regulate tobacco products as customarily marketed until it promulgated the regulations at issue here. See Brief for Petitioners 37; see also Brief for Appellee (FDA) in *Action on Smoking and Health* v. *Harris*, 655 F. 2d 236 (CADC 1980), in 9 Rec. in No. 97–1604 (CA4), Tab No. 4, pp. 14–15 ("In the 73 years since the enactment of the original Food and Drug Act, and in the 41 years since the promulgation of the modern Food, Drug, and Cosmetic Act, the FDA has repeatedly informed Congress that cigarettes are beyond the scope of the statute absent health claims establishing a therapeutic intent on behalf of the manufacturer or vendor").

The FDA's position was also consistent with Congress' specific intent when it enacted the FDCA. Before the Act's adoption in 1938, the FDA's predecessor agency, the Bureau of Chemistry, announced that it lacked authority to regulate tobacco products under the Pure Food and Drug Act of 1906, ch. 3915, 34 Stat. 768, unless they were mar-

keted with therapeutic claims. See U. S. Dept. of Agriculture, Bureau of Chemistry, 13 Service and Regulatory Announcements 24 (Apr. 1914) (Feb. 1914 Announcements ¶13, Opinion of Chief of Bureau C. L. Alsberg). In 1929, Congress considered and rejected a bill "[t]o amend the Food and Drugs Act of June 30, 1906, by extending its provisions to tobacco and tobacco products." S. 1468, 71st Cong., 1st Sess., 1. See also 71 Cong. Rec. 2589 (1929) (remarks of Sen. Smoot). And, as the FDA admits, there is no evidence in the text of the FDCA or its legislative history that Congress in 1938 even considered the applicability of the Act to tobacco products. See Brief for Petitioners 22, n. 4. Given the economic and political significance of the tobacco industry at the time, it is extremely unlikely that Congress could have intended to place tobacco within the ambit of the FDCA absent any discussion of the matter. Of course, whether the Congress that enacted the FDCA specifically intended the Act to cover tobacco products is not determinative; "it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed." *Oncale* v. *Sundowner Offshore Services, Inc.*, 523 U. S. 75, 79 (1998); see also *TVA* v. *Hill*, 437 U. S. 153, 185 (1978) ("It is not for us to speculate, much less act, on whether Congress would have altered its stance had the specific events of this case been anticipated"). Nonetheless, this intent is certainly relevant to understanding the basis for the FDA's representations to Congress and the background against which Congress enacted subsequent tobacco-specific legislation.

Moreover, before enacting the FCLAA in 1965, Congress considered and rejected several proposals to give the FDA the authority to regulate tobacco. In April 1963, Representative Udall introduced a bill "[t]o amend the Federal Food, Drug, and Cosmetic Act so as to make that Act applicable to smoking products." H. R. 5973, 88th Cong., 1st Sess., 1. Two months later, Senator Moss introduced

an identical bill in the Senate. S. 1682, 88th Cong., 1st Sess. (1963). In discussing his proposal on the Senate floor, Senator Moss explained that "this amendment simply places smoking products under FDA jurisdiction, along with foods, drugs, and cosmetics." 109 Cong. Rec. 10322 (1963). In December 1963, Representative Rhodes introduced another bill that would have amended the FDCA "by striking out food, drug, device, or cosmetic, each place where it appears therein and inserting in lieu thereof food, drug, device, cosmetic, or smoking product.'" H. R. 9512, 88th Cong., 1st Sess., §3 (1963). And in January 1965, five months before passage of the FCLAA, Representative Udall again introduced a bill to amend the FDCA "to make that Act applicable to smoking products." H. R. 2248, 89th Cong., 1st Sess., 1. None of these proposals became law.

Congress ultimately decided in 1965 to subject tobacco products to the less extensive regulatory scheme of the FCLAA, which created a "comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health." Pub. L. 89–92, §2, 79 Stat. 282. The FCLAA rejected any regulation of advertising, but it required the warning, "Caution: Cigarette Smoking May Be Hazardous to Your Health," to appear on all cigarette packages. *Id.*, §4, 79 Stat. 283. In the Act's "Declaration of Policy," Congress stated that its objective was to balance the goals of ensuring that "the public may be adequately informed that cigarette smoking may be hazardous to health" and protecting "commerce and the national economy . . . to the maximum extent." *Id.*, §2, 79 Stat. 282 (codified at 15 U. S. C. §1331).

Not only did Congress reject the proposals to grant the FDA jurisdiction, but it explicitly preempted any other regulation of cigarette labeling: "No statement relating to smoking and health, other than the statement required by

. . . this Act, shall be required on any cigarette package." *Id.*, §5(a), 79 Stat. 283. The regulation of product labeling, however, is an integral aspect of the FDCA, both as it existed in 1965 and today. The labeling requirements currently imposed by the FDCA, which are essentially identical to those in force in 1965, require the FDA to regulate the labeling of drugs and devices to protect the safety of consumers. See 21 U. S. C. §352; 21 U. S. C. §352 (1964 ed. and Supp. IV). As discussed earlier, the Act requires that all products bear "adequate directions for use . . . as are necessary for the protection of users," 21 U. S. C. §352(f)(1); 21 U. S. C. §352(f)(1) (1964 ed.); requires that all products provide "adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health," 21 U. S. C. §352(f)(2); 21 U. S. C. §352(f)(2) (1964 ed.); and deems a product misbranded "[i]f it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof," 21 U. S. C. §352(j); 21 U. S. C. §352(j) (1964 ed.). In this sense, the FCLAA was– and remains– incompatible with FDA regulation of tobacco products. This is not to say that the FCLAA's preemption provision by itself necessarily foreclosed FDA jurisdiction. See *Cipollone* v. *Liggett Group, Inc.*, 505 U. S., at 518–519. But it is an important factor in assessing whether Congress ratified the agency's position– that is, whether Congress adopted a regulatory approach to the problem of tobacco and health that contemplated no role for the FDA.

Further, the FCLAA evidences Congress' intent to preclude *any* administrative agency from exercising significant policymaking authority on the subject of smoking and health. In addition to prohibiting any additional requirements for cigarette labeling, the FCLAA provided that "[n]o statement relating to smoking and health shall be required in the advertising of any cigarettes the packages

of which are labeled in conformity with the provisions of this Act." Pub. L. 89–92, §5(b), 79 Stat. 283. Thus, in reaction to the FTC's attempt to regulate cigarette labeling and advertising, Congress enacted a statute reserving exclusive control over both subjects to itself.

Subsequent tobacco-specific legislation followed a similar pattern. By the FCLAA's own terms, the prohibition on any additional cigarette labeling or advertising regulations relating to smoking and health was to expire July 1, 1969. See §10, 79 Stat. 284. In anticipation of the provision's expiration, both the FCC and the FTC proposed rules governing the advertisement of cigarettes. See 34 Fed. Reg. 1959 (1969) (FCC proposed rule to "ban the broadcast of cigarette commercials by radio and television stations"); *id.*, at 7917 (FTC proposed rule requiring manufacturers to disclose on all packaging and in all print advertising "that cigarette smoking is dangerous to health and may cause death from cancer, coronary heart disease, chronic bronchitis, pulmonary emphysema, and other diseases"). After debating the proper role for administrative agencies in the regulation of tobacco, see generally Cigarette Labeling and Advertising– 1969: Hearings before the House Committee on Interstate and Foreign Commerce, 91st Cong., 1st Sess., pt. 2 (1969), Congress amended the FCLAA by banning cigarette advertisements "on any medium of electronic communication subject to the jurisdiction of the Federal Communications Commission" and strengthening the warning required to appear on cigarette packages. Public Health Cigarette Smoking Act of 1969, Pub. L. 91–222, §§4, 6, 84 Stat. 88–89. Importantly, Congress extended indefinitely the prohibition on any other regulation of cigarette labeling with respect to smoking and health (again despite the importance of labeling regulation under the FDCA). §5(a), 84 Stat. 88 (codified at 15 U. S. C. §1334(a)). Moreover, it expressly forbade the FTC from taking any action on its

pending rule until July 1, 1971, and it required the FTC, if it decided to proceed with its rule thereafter, to notify Congress at least six months in advance of the rule's becoming effective. §7(a), 84 Stat. 89. As the chairman of the House committee in which the bill originated stated, "the Congress– the body elected by the people– must make the policy determinations involved in this legislation– and not some agency made up of appointed officials." 116 Cong. Rec. 7920 (1970) (remarks of Rep. Staggers).

Four years later, after Congress had transferred the authority to regulate substances covered by the Hazardous Substances Act (HSA) from the FDA to the Consumer Products Safety Commission (CPSC), the American Public Health Association, joined by Senator Moss, petitioned the CPSC to regulate cigarettes yielding more than 21 milligrams of tar. See *Action on Smoking and Health* v. *Harris*, 655 F. 3d 236, 241 (CADC 1980); R. Kluger, Ashes to Ashes 375–376 (1996). After the CPSC determined that it lacked authority under the HSA to regulate cigarettes, a District Court held that the Act did, in fact, grant the CPSC such jurisdiction and ordered it to reexamine the petition. See *American Public Health Association* v. *Consumer Product Safety Commission*, [1972–1975 Transfer Binder] CCH Consumer Prod. Safety Guide ¶75,081 (DC 1975), vacated as moot, No. 75–1863 (CADC 1976). Before the CPSC could take any action, however, Congress mooted the issue by adopting legislation that eliminated the agency's authority to regulate "tobacco and tobacco products." Consumer Product Safety Commission Improvements Act of 1976, Pub. L. 94–284, §3(c), 90 Stat. 503 (codified at 15 U. S. C. §1261(f)(2)). Senator Moss acknowledged that the "legislation, in effect, reverse[d]" the District Court's decision, 121 Cong. Rec. 23563 (1975), and the FDA later observed that the episode was "particularly" "indicative of the policy of Congress to limit the regulatory authority over cigarettes by Federal Agencies," Letter to

Action on Smoking and Health (ASH) Executive Director Banzhaf from FDA Commissioner Goyan (Nov. 25, 1980), App. 59. A separate statement in the Senate Report underscored that the legislation's purpose was to "unmistakably reaffirm the clear mandate of the Congress that the basic regulation of tobacco and tobacco products is governed by the legislation dealing with the subject, . . . and that any further regulation in this sensitive and complex area must be reserved for specific Congressional action." S. Rep. No. 94–251, p. 43 (1975) (additional views of Sens. Hartke, Hollings, Ford, Stevens, and Beall).

Meanwhile, the FDA continued to maintain that it lacked jurisdiction under the FDCA to regulate tobacco products as customarily marketed. In 1972, FDA Commissioner Edwards testified before Congress that "cigarettes recommended for smoking pleasure are beyond the Federal Food, Drug, and Cosmetic Act." 1972 Hearings 239, 242. He further stated that the FDA believed that the Public Health Cigarette Smoking Act "demonstrates that the regulation of cigarettes is to be the domain of Congress," and that "labeling or banning cigarettes is a step that can be take[n] only by the Congress. Any such move by FDA would be inconsistent with the clear congressional intent." *Ibid.*

In 1977, ASH filed a citizen petition requesting that the FDA regulate cigarettes, citing many of the same grounds that motivated the FDA's rulemaking here. See Citizen Petition, No. 77P–0185 (May 26, 1977), 10 Rec. in No. 97–1604 (CA4), Tab No. 22, pp. 1–10. ASH asserted that nicotine was highly addictive and had strong physiological effects on the body; that those effects were "intended" because consumers use tobacco products precisely to obtain those effects; and that tobacco causes thousands of premature deaths annually. *Ibid.* In denying ASH's petition, FDA Commissioner Kennedy stated that "[t]he interpretation of the Act by FDA consistently has been

that cigarettes are not a drug unless health claims are made by the vendors." Letter to ASH Executive Director Banzhaf (Dec. 5, 1977), App. 47. After the matter proceeded to litigation, the FDA argued in its brief to the Court of Appeals that "cigarettes are not comprehended within the statutory definition of the term 'drug' absent objective evidence that vendors represent or intend that their products be used as a drug." Brief for Appellee in *Action on Smoking and Health* v. *Harris*, 655 F. 2d 236 (CADC 1980), 9 Rec. in No. 97–1604 (CA4), Tab No. 4, pp. 27–28. The FDA also contended that Congress had "long been aware that the FDA does not consider cigarettes to be within its regulatory authority in the absence of health claims made on behalf of the manufacturer or vendor," and that, because "Congress has never acted to disturb the agency's interpretation," it had "acquiesced in the FDA's interpretation of the statutory limits on its authority to regulate cigarettes." *Id.*, at 23, 27, n. 23. The Court of Appeals upheld the FDA's position, concluding that "[i]f the statute requires expansion, that is the job of Congress." *Action on Smoking and Health* v. *Harris*, 655 F. 2d, at 243. In 1980, the FDA also denied a request by ASH to commence rulemaking proceedings to establish the agency's jurisdiction to regulate cigarettes as devices. See Letter to ASH Executive Director Banzhaf from FDA Commissioner Goyan (Nov. 25, 1980), App. 50–51. The agency stated that "[i]nsofar as rulemaking would relate to cigarettes or attached filters as customarily marketed, we have concluded that FDA has no jurisdiction under section 201(h) of the Act [21 U. S. C. §321(h)]." *Id.*, at 67.

In 1983, Congress again considered legislation on the subject of smoking and health. HHS Assistant Secretary Brandt testified that, in addition to being "a major cause of cancer," smoking is a "major cause of heart disease" and other serious illnesses, and can result in "unfavorable pregnancy outcomes." 1983 House Hearings 19–20. He

also stated that it was "well-established that cigarette smoking is a drug dependence, and that smoking is addictive for many people." *Id.*, at 20. Nonetheless, Assistant Secretary Brandt maintained that "the issue of regulation of tobacco . . . is something that Congress has reserved to itself, and we do not within the Department have the authority to regulate nor are we seeking such authority." *Id.*, at 74. He also testified before the Senate, stating that, despite the evidence of tobacco's health effects and addictiveness, the Department's view was that "Congress has assumed the responsibility of regulating . . . cigarettes." Smoking Prevention and Education Act: Hearings on S. 772 before the Senate Committee on Labor and Human Resources, 98th Cong., 1st Sess., 56 (1983) (hereinafter 1983 Senate Hearings).

Against this backdrop, Congress enacted three additional tobacco-specific statutes over the next four years that incrementally expanded its regulatory scheme for tobacco products. In 1983, Congress adopted the Alcohol and Drug Abuse Amendments, Pub. L. 98–24, 97 Stat. 175 (codified at 42 U. S. C. §290aa *et seq.*), which require the Secretary of HHS to report to Congress every three years on the "addictive property of tobacco" and to include recommendations for action that the Secretary may deem appropriate. A year later, Congress enacted the Comprehensive Smoking Education Act, Pub. L. 98–474, 98 Stat. 2200, which amended the FCLAA by again modifying the prescribed warning. Notably, during debate on the Senate floor, Senator Hawkins argued that the Act was necessary in part because "[u]nder the Food, Drug and Cosmetic Act, the Congress exempted tobacco products." 130 Cong. Rec. 26953 (1984). And in 1986, Congress enacted the Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA), Pub. L. 99–252, 100 Stat. 30 (codified at 15 U. S. C. §4401 *et seq.*), which essentially extended the regulatory provisions of the FCLAA to smokeless tobacco

products. Like the FCLAA, the CSTHEA provided that "[n]o statement relating to the use of smokeless tobacco products and health, other than the statements required by [the Act], shall be required by any Federal agency to appear on any package . . . of a smokeless tobacco product." §7(a), 100 Stat. 34 (codified at 15 U. S. C. §4406(a)). Thus, as with cigarettes, Congress reserved for itself an aspect of smokeless tobacco regulation that is particularly important to the FDCA's regulatory scheme.

In 1988, the Surgeon General released a report summarizing the abundant scientific literature demonstrating that "[c]igarettes and other forms of tobacco are addicting," and that "nicotine is psychoactive" and "causes physical dependence characterized by a withdrawal syndrome that usually accompanies nicotine abstinence." 1988 Surgeon General's Report 14. The report further concluded that the "pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine." *Id.*, at 15. In the same year, FDA Commissioner Young stated before Congress that "it doesn't look like it is possible to regulate [tobacco] under the Food, Drug and Cosmetic Act even though smoking, I think, has been widely recognized as being harmful to human health." Rural Development, Agriculture, and Related Agencies Appropriations for 1989: Hearings before a Subcommittee of the House Committee on Appropriations, 100th Cong., 2d Sess., 409 (1988). At the same hearing, the FDA's General Counsel testified that "what is fairly important in FDA law is whether a product has a therapeutic purpose," and "[c]igarettes themselves are not used for a therapeutic purpose as that concept is ordinarily understood." *Id.*, at 410. Between 1987 and 1989, Congress considered three more bills that would have amended the FDCA to grant the FDA jurisdiction to regulate tobacco products. See H. R. 3294, 100th Cong., 1st Sess. (1987); H. R. 1494,

101st Cong., 1st Sess. (1989); S. 769, 101st Cong., 1st Sess. (1989). As before, Congress rejected the proposals. In 1992, Congress instead adopted the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act, Pub. L. 102–321, §202, 106 Stat. 394 (codified at 42 U. S. C. §300x *et seq.*), which creates incentives for States to regulate the retail sale of tobacco products by making States' receipt of certain block grants contingent on their prohibiting the sale of tobacco products to minors.

Taken together, these actions by Congress over the past 35 years preclude an interpretation of the FDCA that grants the FDA jurisdiction to regulate tobacco products. We do not rely on Congress' failure to act– its consideration and rejection of bills that would have given the FDA this authority– in reaching this conclusion. Indeed, this is not a case of simple inaction by Congress that purportedly represents its acquiescence in an agency's position. To the contrary, Congress has enacted several statutes addressing the particular subject of tobacco and health, creating a distinct regulatory scheme for cigarettes and smokeless tobacco. In doing so, Congress has been aware of tobacco's health hazards and its pharmacological effects. It has also enacted this legislation against the background of the FDA repeatedly and consistently asserting that it lacks jurisdiction under the FDCA to regulate tobacco products as customarily marketed. Further, Congress has persistently acted to preclude a meaningful role for *any* administrative agency in making policy on the subject of tobacco and health. Moreover, the substance of Congress' regulatory scheme is, in an important respect, incompatible with FDA jurisdiction. Although the supervision of product labeling to protect consumer health is a substantial component of the FDA's regulation of drugs and devices, see 21 U. S. C. §352 (1994 ed. and Supp. III), the FCLAA and the CSTHEA explicitly prohibit any federal agency from imposing any health-related labeling requirements on

cigarettes or smokeless tobacco products, see 15 U. S C. §§1334(a), 4406(a).

Under these circumstances, it is clear that Congress' tobacco-specific legislation has effectively ratified the FDA's previous position that it lacks jurisdiction to regulate tobacco. As in *Bob Jones Univ.* v. *United States*, 461 U. S. 574 (1983), "[i]t is hardly conceivable that Congress– and in this setting, any Member of Congress– was not abundantly aware of what was going on." *Id.*, at 600–601. Congress has affirmatively acted to address the issue of tobacco and health, relying on the representations of the FDA that it had no authority to regulate tobacco. It has created a distinct scheme to regulate the sale of tobacco products, focused on labeling and advertising, and premised on the belief that the FDA lacks such jurisdiction under the FDCA. As a result, Congress' tobacco-specific statutes preclude the FDA from regulating tobacco products as customarily marketed.

Although the dissent takes issue with our discussion of the FDA's change in position, *post*, at 26–29, our conclusion does not rely on the fact that the FDA's assertion of jurisdiction represents a sharp break with its prior interpretation of the FDCA. Certainly, an agency's initial interpretation of a statute that it is charged with administering is not "carved in stone." *Chevron*, 467 U. S., at 863; see also *Smiley* v. *Citibank (South Dakota), N. A.*, 517 U. S. 735, 742 (1996). As we recognized in *Motor Vehicle Mfrs. Assn. of United States, Inc.* v. *State Farm Mut. Automobile Ins. Co.*, 463 U. S. 29 (1983), agencies "must be given ample latitude to 'adapt their rules and policies to the demands of changing circumstances.'" *Id.*, at 42 (quoting *Permian Basin Area Rate Cases*, 390 U. S. 747, 784 (1968)). The consistency of the FDA's prior position is significant in this case for a different reason: it provides important context to Congress' enactment of its tobacco-specific legislation. When the FDA repeatedly informed Congress

that the FDCA does not grant it the authority to regulate tobacco products, its statements were consistent with the agency's unwavering position since its inception, and with the position that its predecessor agency had first taken in 1914. Although not crucial, the consistency of the FDA's prior position bolsters the conclusion that when Congress created a distinct regulatory scheme addressing the subject of tobacco and health, it understood that the FDA is without jurisdiction to regulate tobacco products and ratified that position.

The dissent also argues that the proper inference to be drawn from Congress' tobacco-specific legislation is "critically ambivalent." *Post*, at 22. We disagree. In that series of statutes, Congress crafted a specific legislative response to the problem of tobacco and health, and it did so with the understanding, based on repeated assertions by the FDA, that the agency has no authority under the FDCA to regulate tobacco products. Moreover, Congress expressly preempted any other regulation of the labeling of tobacco products concerning their health consequences, even though the oversight of labeling is central to the FDCA's regulatory scheme. And in addressing the subject, Congress consistently evidenced its intent to preclude any federal agency from exercising significant policymaking authority in the area. Under these circumstances, we believe the appropriate inference– that Congress intended to ratify the FDA's prior position that it lacks jurisdiction– is unmistakable.

The dissent alternatively argues that, even if Congress' subsequent tobacco-specific legislation did, in fact, ratify the FDA's position, that position was merely a contingent disavowal of jurisdiction. Specifically, the dissent contends that "the FDA's traditional view was largely premised on a perceived inability to prove the necessary statutory 'intent' requirement." *Post*, at 30. A fair reading of the FDA's representations prior to 1995, however, demon-

strates that the agency's position was essentially unconditional. See, *e.g.*, 1972 Hearings 239, 242 (statement of Commissioner Edwards) ("[R]egulation of cigarettes is to be the domain of Congress," and "[a]ny such move by FDA would be inconsistent with the clear congressional intent"); 1983 House Hearings 74 (statement of Assistant Secretary Brandt) ("[T]he issue of regulation of tobacco . . . is something that Congress has reserved to itself"); 1983 Senate Hearings 56 (statement of Assistant Secretary Brandt) ("Congress has assumed the responsibility of regulating . . . cigarettes"); Brief for Appellee in *Action on Smoking and Health* v. *Harris*, 655 F. 2d 236 (CADC 1980), 9 Rec. in No. 97–1604 (CA4), Tab No. 4, pp. 27, n. 23 (because "Congress has never acted to disturb the agency's interpretation," it "acquiesced in the FDA's interpretation"). To the extent the agency's position could be characterized as equivocal, it was only with respect to the well-established exception of when the manufacturer makes express claims of therapeutic benefit. See, *e.g.*, 1965 Hearings 193 (statement of Deputy Commissioner Rankin) ("The Food and Drug Administration has no jurisdiction under the Food, Drug, and Cosmetic Act over tobacco, unless it bears drug claims"); Letter to ASH Executive Director Banzhaf from FDA Commissioner Kennedy (Dec. 5, 1977), App. 47 ("The interpretation of the Act by FDA consistently has been that cigarettes are not a drug unless health claims are made by the vendors"); Letter to ASH Executive Director Banzhaf from FDA Commissioner Goyan (Nov. 25, 1980), App. 67 ("Insofar as rulemaking would relate to cigarettes or attached filters as customarily marketed, we have concluded that FDA has no jurisdiction"). Thus, what Congress ratified was the FDA's plain and resolute position that the FDCA gives the agency no authority to regulate tobacco products as customarily marketed.

C

Finally, our inquiry into whether Congress has directly spoken to the precise question at issue is shaped, at least in some measure, by the nature of the question presented. Deference under *Chevron* to an agency's construction of a statute that it administers is premised on the theory that a statute's ambiguity constitutes an implicit delegation from Congress to the agency to fill in the statutory gaps. See *Chevron*, 467 U. S., at 844. In extraordinary cases, however, there may be reason to hesitate before concluding that Congress has intended such an implicit delegation. Cf. Breyer, Judicial Review of Questions of Law and Policy, 38 Admin. L. Rev. 363, 370 (1986) ("A court may also ask whether the legal question is an important one. Congress is more likely to have focused upon, and answered, major questions, while leaving interstitial matters to answer themselves in the course of the statute's daily administration").

This is hardly an ordinary case. Contrary to its representations to Congress since 1914, the FDA has now asserted jurisdiction to regulate an industry constituting a significant portion of the American economy. In fact, the FDA contends that, were it to determine that tobacco products provide no "reasonable assurance of safety," it would have the authority to ban cigarettes and smokeless tobacco entirely. See Brief for Petitioners 35–36; Reply Brief for Petitioners 14. Owing to its unique place in American history and society, tobacco has its own unique political history. Congress, for better or for worse, has created a distinct regulatory scheme for tobacco products, squarely rejected proposals to give the FDA jurisdiction over tobacco, and repeatedly acted to preclude any agency from exercising significant policymaking authority in the area. Given this history and the breadth of the authority that the FDA has asserted, we are obliged to defer not to

the agency's expansive construction of the statute, but to Congress' consistent judgment to deny the FDA this power.

Our decision in *MCI Telecommunications Corp.* v. *American Telephone & Telegraph Co.*, 512 U. S. 218 (1994), is instructive. That case involved the proper construction of the term "modify" in §203(b) of the Communications Act of 1934. The FCC contended that, because the Act gave it the discretion to "modify any requirement" imposed under the statute, it therefore possessed the authority to render voluntary the otherwise mandatory requirement that long distance carriers file their rates. *Id.*, at 225. We rejected the FCC's construction, finding "not the slightest doubt" that Congress had directly spoken to the question. *Id.*, at 228. In reasoning even more apt here, we concluded that "[i]t is highly unlikely that Congress would leave the determination of whether an industry will be entirely, or even substantially, rate-regulated to agency discretion– and even more unlikely that it would achieve that through such a subtle device as permission to 'modify' rate-filing requirements." *Id.*, at 231.

As in *MCI*, we are confident that Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion. To find that the FDA has the authority to regulate tobacco products, one must not only adopt an extremely strained understanding of "safety" as it is used throughout the Act– a concept central to the FDCA's regulatory scheme– but also ignore the plain implication of Congress' subsequent tobacco-specific legislation. It is therefore clear, based on the FDCA's overall regulatory scheme and the subsequent tobacco legislation, that Congress has directly spoken to the question at issue and precluded the FDA from regulating tobacco products.

* * *

By no means do we question the seriousness of the problem that the FDA has sought to address. The agency has amply demonstrated that tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States. Nonetheless, no matter how "important, conspicuous, and controversial" the issue, and regardless of how likely the public is to hold the Executive Branch politically accountable, *post*, at 31, an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress. And " '[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.' " *United States* v. *Article of Drug ... Bacto-Unidisk*, 394 U. S. 784, 800 (1969) (quoting *62 Cases of Jam* v. *United States*, 340 U. S. 593, 600 (1951)). Reading the FDCA as a whole, as well as in conjunction with Congress' subsequent tobacco-specific legislation, it is plain that Congress has not given the FDA the authority that it seeks to exercise here. For these reasons, the judgment of the Court of Appeals for the Fourth Circuit is affirmed.

It is so ordered.

SUPREME COURT OF THE UNITED STATES

No. 98–1152

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

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

[March 21, 2000]

JUSTICE BREYER, with whom JUSTICE STEVENS, JUSTICE SOUTER, and JUSTICE GINSBURG join, dissenting.

The Food and Drug Administration (FDA) has the authority to regulate "articles (other than food) intended to affect the structure or any function of the body . . . ." Federal Food, Drug and Cosmetic Act (FDCA), 21 U. S. C. §321(g)(1)(C). Unlike the majority, I believe that tobacco products fit within this statutory language.

In its own interpretation, the majority nowhere denies the following two salient points. First, tobacco products (including cigarettes) fall within the scope of this statutory definition, read literally. Cigarettes achieve their mood-stabilizing effects through the interaction of the chemical nicotine and the cells of the central nervous system. Both cigarette manufacturers and smokers alike know of, and desire, that chemically induced result. Hence, cigarettes are "intended to affect" the body's "structure" and "function," in the literal sense of these words.

Second, the statute's basic purpose– the protection of public health– supports the inclusion of cigarettes within its scope. See *United States* v. *Article of Drug ... Bacto-Unidisk*, 394 U. S. 784, 798 (1969) (FDCA "is to be given *a liberal construction consistent with [its] overriding purpose to protect the public health*" (emphasis added)).

Unregulated tobacco use causes "[m]ore than 400,000 people [to] die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease." 61 Fed. Reg. 44398 (1996). Indeed, tobacco products kill more people in this country every year "than . . . AIDS, car accidents, alcohol, homicides, illegal drugs, suicides, and fires, *combined.*" *Ibid.* (emphasis added).

Despite the FDCA's literal language and general purpose (both of which support the FDA's finding that cigarettes come within its statutory authority), the majority nonetheless reads the statute as *excluding* tobacco products for two basic reasons:

> (1) the FDCA does not "fit" the case of tobacco because the statute requires the FDA to prohibit dangerous drugs or devices (like cigarettes) outright, and the agency concedes that simply banning the sale of cigarettes is not a proper remedy, *ante*, at 19–20; and
>
> (2) Congress has enacted other statutes, which, when viewed in light of the FDA's long history of denying tobacco-related jurisdiction and considered together with Congress' failure explicitly to grant the agency tobacco-specific authority, demonstrate that Congress did not intend for the FDA to exercise jurisdiction over tobacco, *ante*, at 33–34.

In my view, neither of these propositions is valid. Rather, the FDCA does not significantly limit the FDA's remedial alternatives. See *infra*, at 14–21. And the later statutes do not tell the FDA it cannot exercise jurisdiction, but simply leave FDA jurisdictional law where Congress found it. See *infra*, at 21–26; cf. Food and Drug Administration Modernization Act of 1997, 111 Stat. 2380 (codified at note following 21 U. S. C. §321 (1994 ed., Supp. III)) (statute "shall" *not* "be construed to affect the question of whether" the FDA "has any authority to regulate any tobacco product").

The bulk of the opinion that follows will explain the basis for these latter conclusions. In short, I believe that the most important indicia of statutory meaning– language and purpose– along with the FDCA's legislative history (described briefly in Part I) are sufficient to establish that the FDA has authority to regulate tobacco. The statute-specific arguments against jurisdiction that the tobacco companies and the majority rely upon (discussed in Part II) are based on erroneous assumptions and, thus, do not defeat the jurisdiction-supporting thrust of the FDCA's language and purpose. The inferences that the majority draws from later legislative history are not persuasive, since (as I point out in Part III) one can just as easily infer from the later laws that Congress did not intend to affect the FDA's tobacco-related authority at all. And the fact that the FDA changed its mind about the scope of its own jurisdiction is legally insignificant because (as Part IV establishes) the agency's reasons for changing course are fully justified. Finally, as I explain in Part V, the degree of accountability that likely will attach to the FDA's action in this case should alleviate any concern that Congress, rather than an administrative agency, ought to make this important regulatory decision.

I

Before 1938, the federal Pure Food and Drug Act contained only two jurisdictional definitions of "drug":

> "[1] medicines and preparations recognized in the United States Pharmacopoeia or National Formulary . . . and [2] any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease." Act of June 30, 1906, ch. 3915, §6, 34 Stat. 769.

In 1938, Congress added a third definition, relevant here:

> "(3) articles (other than food) intended to affect the

> structure or any function of the body . . . ." Act of June 25, 1938, ch. 675, §201(g), 52 Stat. 1041 (codified at 21 U. S. C. §321(g)(1)(C)).

It also added a similar definition in respect to a "device." See §201(h), 52 Stat. 1041 (codified at 21 U. S. C. §321(h)). As I have mentioned, the literal language of the third definition and the FDCA's general purpose both strongly support a projurisdiction reading of the statute. See *supra*, at 1–2.

The statute's history offers further support. The FDA drafted the new language, and it testified before Congress that the third definition would expand the FDCA's jurisdictional scope significantly. See Hearings on S. 1944 before a Subcommittee of the Senate Committee on Commerce, 73d Cong., 2d Sess., 15–16 (1933), reprinted in 1 FDA, Legislative History of the Federal Food, Drug, and Cosmetic Act and Its Amendments 107–108 (1979) (hereinafter Leg. Hist.). Indeed, "[t]he purpose" of the new definition was to "make possible the regulation of a great many products that have been found on the market that cannot be alleged to be treatments for diseased conditions." *Id.*, at 108. While the drafters focused specifically upon the need to give the FDA jurisdiction over "slenderizing" products such as "antifat remedies," *ibid.*, they were aware that, in doing so, they had created what was "admittedly an inclusive, a wide definition." *Id.*, at 107. And that broad language was included *deliberately*, so that jurisdiction could be had over "*all* substances and preparations, other than food, and *all* devices intended to affect the structure or any function of the body . . . ." *Ibid.* (emphasis added); see also Hearings on S. 2800 before the Senate Committee on Commerce, 73d Cong., 2d Sess. 516 (1934), reprinted in 2 Leg. Hist. 519 (statement of then-FDA Chief Walter Campbell acknowledging that "[t]his definition of 'drugs' is all-inclusive").

After studying the FDCA's history, experts have written that the statute "is a purposefully broad delegation of discretionary powers by Congress," J. O'Reilly, 1 Food and Drug Administration §6.01, p. 6–1 (2d ed. 1995) (hereinafter O'Reilly), and that, in a sense, the FDCA "must be regarded as a *constitution*" that "establish[es] general principles" and "permit[s] implementation within broad parameters" so that the FDA can "implement these objectives through the most effective and efficient controls that can be devised." Hutt, Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act, 28 Food Drug Cosm. L. J. 177, 178–179 (1973) (emphasis added). This Court, too, has said that the

> "historical expansion of the definition of drug, and the creation of a parallel concept of devices, clearly show . . . 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." *Bacto-Unidisk*, 394 U. S., at 798.

That Congress would grant the FDA such broad jurisdictional authority should surprise no one. In 1938, the President and much of Congress believed that federal administrative agencies needed broad authority and would exercise that authority wisely– a view embodied in much Second New Deal legislation. Cf. *Gray* v. *Powell*, 314 U. S. 402, 411–412 (1941) (Congress "could have legislated specifically" but decided "to delegate that function to those whose experience in a particular field gave promise of a better informed, more equitable" determination). Thus, at around the same time that it added the relevant language to the FDCA, Congress enacted laws granting other administrative agencies even broader powers to regulate much of the Nation's transportation and communication. See, *e.g.*, Civil Aeronautics Act of 1938, ch. 601, §401(d)(1), 52 Stat.

987 (Civil Aeronautics Board to regulate airlines within confines of highly general "public convenience and necessity" standard); Motor Carrier Act of 1935, ch. 498, §204(a)(1), 49 Stat. 546 (Interstate Commerce Commission to establish "reasonable requirements" for trucking); Communications Act of 1934, ch. 652, §201(a), 48 Stat. 1070 (Federal Communications Commission (FCC) to regulate radio, later television, within confines of even broader "public interest" standard). Why would the 1938 New Deal Congress suddenly have hesitated to delegate to so well established an agency as the FDA all of the discretionary authority that a straightforward reading of the relevant statutory language implies?

Nor is it surprising that such a statutory delegation of power could lead after many years to an assertion of jurisdiction that the 1938 legislators might not have expected. Such a possibility is inherent in the very nature of a broad delegation. In 1938, it may well have seemed unlikely that the FDA would ever bring cigarette manufacturers within the FDCA's statutory language by proving that cigarettes produce chemical changes in the body and that the makers "intended" their product chemically to affect the body's "structure" or "function." Or, back then, it may have seemed unlikely that, even assuming such proof, the FDA actually would exercise its discretion to regulate so popular a product. See R. Kluger, Ashes to Ashes 105 (1997) (in the 1930's "Americans were in love with smoking . . .").

But it should not have seemed unlikely that, assuming the FDA decided to regulate and proved the particular jurisdictional prerequisites, the courts would rule such a jurisdictional assertion fully authorized. Cf. *United States* v. *Southwestern Cable Co.*, 392 U. S. 157, 172 (1968) (reading Federal Communications Act as authorizing FCC jurisdiction to regulate cable systems while noting that "Congress could not in 1934 have foreseen the development of"

advanced communications systems). After all, this Court has read more narrowly phrased statutes to grant what might have seemed even more unlikely assertions of agency jurisdiction. See, *e.g., Permian Basin Area Rate Cases,* 390 U. S. 747, 774–777 (1968) (statutory authority to regulate interstate "transportation" of natural gas includes authority to regulate "prices" charged by field producers); *Phillips Petroleum Co.* v. *Wisconsin,* 347 U. S. 672, 677–684 (1954) (independent gas producer subject to regulation despite Natural Gas Act's express exemption of gathering and production facilities).

I shall not pursue these general matters further, for neither the companies nor the majority denies that the FDCA's literal language, its general purpose, and its particular legislative history favor the FDA's present jurisdictional view. Rather, they have made several specific arguments in support of one basic contention: even if the statutory delegation is broad, it is not broad *enough* to include tobacco. I now turn to each of those arguments.

II

A

The tobacco companies contend that the FDCA's words cannot possibly be read to mean what they literally say. The statute defines "device," for example, as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article . . . intended to affect the structure or any function of the body . . . ." 21 U. S. C. §321(h). Taken literally, this definition might include everything from room air conditioners to thermal pajamas. The companies argue that, to avoid such a result, the meaning of "drug" or "device" should be confined to *medical* or *therapeutic* products, narrowly defined. See Brief for Respondent United States Tobacco Co. 8–9.

The companies may well be right that the statute should

not be read to cover room air conditioners and winter underwear. But I do not agree that we must accept their proposed limitation. For one thing, such a cramped reading contravenes the established purpose of the statutory language. See *Bacto-Unidisk*, 394 U. S., at 798 (third definition is "clearly, broader than any strict medical definition"); 1 Leg. Hist. 108 (definition covers products "that cannot be alleged to be treatments for diseased conditions"). For another, the companies' restriction would render the other two "drug" definitions superfluous. See 21 U. S. C. §§321(g)(1)(A), (g)(1)(B) (covering articles in the leading pharmacology compendia and those "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease").

Most importantly, the statute's language itself supplies a different, more suitable, limitation: that a "drug" must be a *chemical* agent. The FDCA's "device" definition states that an article which affects the structure or function of the body is a "device" only if it "does *not* achieve its primary intended purposes through chemical action within . . . the body," and "is *not* dependent upon being metabolized for the achievement of its primary intended purposes." §321(h) (emphasis added). One can readily infer from this language that at least an article that *does* achieve its primary purpose through chemical action within the body and that *is* dependent upon being metabolized is a "drug," provided that it otherwise falls within the scope of the "drug" definition. And one need not hypothesize about air conditioners or thermal pajamas to recognize that the chemical nicotine, an important tobacco ingredient, meets this test.

Although I now oversimplify, the FDA has determined that once nicotine enters the body, the blood carries it almost immediately to the brain. See 61 Fed. Reg. 44698–44699 (1966). Nicotine then binds to receptors on the surface of brain cells, setting off a series of chemical reac-

tions that alter one's mood and produce feelings of sedation and stimulation. See *id.*, at 44699, 44739. Nicotine also increases the number of nicotinic receptors on the brain's surface, and alters its normal electrical activity. See *id.*, at 44739. And nicotine stimulates the transmission of a natural chemical that "rewards" the body with pleasurable sensations (dopamine), causing nicotine addiction. See *id.*, at 44700, 44721–44722. The upshot is that nicotine stabilizes mood, suppresses appetite, tranquilizes, and satisfies a physical craving that nicotine itself has helped to create– all through chemical action within the body after being metabolized.

This physiology– and not simply smoker psychology– helps to explain why as many as 75% of adult smokers believe that smoking "reduce[s] nervous irritation," 60 Fed. Reg. 41579 (1995); why 73% of young people (10- to 22-year-olds) who begin smoking say they do so for "relaxation," 61 Fed. Reg. 44814 (1996); and why less than 3% of the 70% of smokers who want to quit each year succeed, *id.*, at 44704. That chemistry also helps to explain the Surgeon General's findings that smokers believe "smoking [makes them] feel better" and smoke more "in situations involving negative mood." *Id.*, at 44814. And, for present purposes, that chemistry demonstrates that nicotine affects the "structure" and "function" of the body in a manner that is quite similar to the effects of other regulated substances. See *id.*, at 44667 (FDA regulates Valium, NoDoz, weight-loss products). Indeed, addiction, sedation, stimulation, and weight loss are *precisely* the kinds of product effects that the FDA typically reviews and controls. And, since the nicotine in cigarettes plainly is not a "food," its chemical effects suffice to establish that it is as a "drug" (and the cigarette that delivers it a drug-delivery "device") for the purpose of the FDCA.

B

The tobacco companies' principal definitional argument focuses upon the statutory word "intended." See 21 U. S. C. §321(g)(1)(C). The companies say that "intended" in this context is a term of art. See Brief for Respondent Brown & Williamson Tobacco Corp. 2. They assert that the statutory word "intended" means that the product's maker has made an *express claim* about the effect that its product will have on the body. *Ibid.* Indeed, according to the companies, the FDA's inability to prove that cigarette manufacturers make such claims is precisely why that agency historically has said it lacked the statutory power to regulate tobacco. See *id.*, at 19–20.

The FDCA, however, does not use the word "claimed"; it uses the word "intended." And the FDA long ago issued regulations that say the relevant "intent" can be shown not only by a manufacturer's "expressions," *but also* "by the circumstances surrounding the distribution of the article." 41 Fed. Reg. 6896 (1976) (codified at 21 CFR §801.4 (1999)); see also 41 Fed. Reg. 6896 (1976) ("objective intent" shown if "article is, with the knowledge [of its makers], offered and used" for a particular purpose). Thus, even in the absence of express claims, the FDA has regulated products that affect the body if the manufacturer wants, and knows, that consumers so use the product. See, *e.g.*, 60 Fed. Reg. 41527–41531 (1995) (describing agency's regulation of topical hormones, sunscreens, fluoride, tanning lamps, thyroid in food supplements, novelty condoms– all marketed without express claims); see also O'Reilly, Food and Drug Administration §13.04, at 13–15 ("Sometimes the very nature of the material makes it a drug . . .").

Courts ordinarily reverse an agency interpretation of this kind only if Congress has clearly answered the interpretive question or if the agency's interpretation is unreasonable. *Chevron U. S. A. Inc.* v. *Natural Resources Defense*

Council, Inc., 467 U. S. 837, 842–843 (1984). The companies, in an effort to argue the former, point to language in the legislative history tying the word "intended" to a technical concept called "intended use." But nothing in Congress' discussion either of "intended" or "intended use" suggests that an express claim (which *often* shows intent) is *always* necessary. Indeed, the primary statement to which the companies direct our attention says only that a manufacturer can determine what kind of regulation applies– "food" or "drug"– because, "through his representations in connection with its sale, [the manufacturer] can determine" whether an article is to be used as a "food," as a "drug," or as "both." S. Rep. No. 361, 74th Cong., 1st Sess., 4 (1935), reprinted in 3 Leg. Hist. 696.

Nor is the FDA's "objective intent" interpretation unreasonable. It falls well within the established scope of the ordinary meaning of the word "intended." See *Agnew* v. *United States*, 165 U. S. 36, 53 (1897) (intent encompasses the known consequences of an act). And the companies acknowledge that the FDA can regulate a drug-like substance in the ordinary circumstance, *i.e.*, where the manufacturer makes an express claim, so it is not unreasonable to conclude that the agency retains such power where a product's effects on the body are so well known (say, like those of aspirin or calamine lotion), that there is no *need* for express representations because the product speaks for itself.

The companies also cannot deny that the evidence of their intent is sufficient to satisfy the statutory word "intended" as the FDA long has interpreted it. In the first place, there was once a time when they actually *did* make express advertising claims regarding tobacco's mood-stabilizing and weight-reducing properties– and historical representations can portend present expectations. In the late 1920's, for example, the American Tobacco Company urged weight-conscious smokers to " Reach for a Lucky in-

stead of a sweet.'" Kluger, Ashes to Ashes, at 77–78. The advertisements of RJ Reynolds (RJR) emphasized mood stability by depicting a pilot remarking that "It Takes Steady Nerves To Fly the Mail At Night . . . . That's why I smoke Camels. And I smoke plenty!'" *Id.*, at 86. RJR also advertised the stimulating quality of cigarettes, stating in one instance that "You get a Lift with a Camel,'" and, in another, that Camels are "'A Harmless Restoration of the Flow of Natural Body Energy.'" *Id.*, at 87. And claims of medical proof of mildness (and of other beneficial effects) once were commonplace. See, *e.g.*, *id.*, at 93 (Brown & Williamson advertised Kool-brand mentholated cigarettes as "a tonic to hot, tired throats"); *id.*, at 101, 131 (Phillip Morris contended that "[r]ecognized laboratory tests have conclusively proven the advantage of Phillip Morris"); *id.*, at 88 (RJR proclaimed "For Digestion's sake, smoke Camels! . . . Camels make mealtime more pleasant– digestion is stimulated– alkalinity increased"). Although in recent decades cigarette manufacturers have stopped making express health claims in their advertising, consumers have come to understand what the companies no longer need to express– that through chemical action cigarettes stabilize mood, sedate, stimulate, and help suppress appetite.

Second, even though the companies refused to acknowledge publicly (until only very recently) that the nicotine in cigarettes has chemically induced, and habit-forming, effects, see, *e.g.*, Regulation of Tobacco Products (Part 1): Hearings before the House Subcommittee on Health and the Environment, 103d Cong., 2d Sess., 628 (1994) (hereinafter 1994 Hearings) (heads of seven major tobacco companies testified under oath that they believed "nicotine is *not* addictive" (emphasis added)), the FDA recently has gained access to solid, documentary evidence proving that cigarette manufacturers have long *known* tobacco produces these effects within the body through the metabo-

lizing of chemicals, and that they have long *wanted* their products to produce those effects in this way.

For example, in 1972, a tobacco-industry scientist explained that "[s]moke is beyond question the most optimized vehicle of nicotine,'" and "the cigarette is the most optimized dispenser of smoke.'" 61 Fed. Reg. 44856 (1996). That same scientist urged company executives to

> "[t]hink of the cigarette pack as a storage container for a day's supply of nicotine. . . . Think of the cigarette as a dispenser for a dose unit of nicotine [and] [t]hink of a puff of smoke as a vehicle of nicotine.'" *Ibid.* (Philip Morris).

That same year, other tobacco industry researchers told their superiors that

> "in different situations and at different dose levels, nicotine appears to act as a stimulant, depressant, tranquilizer, psychic energizer, appetite reducer, antifatigue agent, or energizer. . . . Therefore, [tobacco] products may, in a sense, compete with a variety of other products with certain types of drug action.'" *Id.*, at 44669 (RJR).

A draft report prepared by authorities at Philip Morris said that nicotine

> "is a physiologically active, nitrogen containing substance [similar to] quinine, cocaine, atropine and morphine. [And] [w]hile each of these [other] substances can be used to affect human physiology, nicotine has a particularly broad range of influence.'" *Id.*, at 44668–44669.

And a 1980 manufacturer's study stated that

> "the pharmacological response of smokers to nicotine is believed to be responsible for an individual's smoking behaviour, providing the motivation for and the

degree of satisfaction required by the smoker.'" *Id.*, at 44936 (Brown & Williamson).

With such evidence, the FDA has more than sufficiently established that the companies "intend" their products to "affect" the body within the meaning of the FDCA.

C

The majority nonetheless reaches the "inescapable conclusion" that the language and structure of the FDCA as a whole "simply do not fit" the kind of public health problem that tobacco creates. *Ante*, at 20. That is because, in the majority's view, the FDCA requires the FDA to ban outright "dangerous" drugs or devices (such as cigarettes); yet, the FDA concedes that an immediate and total cigarette-sale ban is inappropriate. *Ibid.*

This argument is curious because it leads with similarly "inescapable" force to precisely the opposite conclusion, namely, that the FDA *does* have jurisdiction but that it must ban cigarettes. More importantly, the argument fails to take into account the fact that a statute interpreted as requiring the FDA to pick a more dangerous over a less dangerous remedy would be a perverse statute, *causing*, rather than preventing, unnecessary harm whenever a total ban is likely the more dangerous response. And one can at least imagine such circumstances.

Suppose, for example, that a commonly used, mildly addictive sleeping pill (or, say, a kind of popular contact lens), plainly within the FDA's jurisdiction, turned out to pose serious health risks for certain consumers. Suppose further that many of those addicted consumers would ignore an immediate total ban, turning to a potentially more dangerous black-market substitute, while a less draconian remedy (say, adequate notice) would wean them gradually away to a safer product. Would the FDCA still *force* the FDA to impose the more dangerous remedy? For the following reasons, I think not.

First, the statute's language does not restrict the FDA's remedial powers in this way. The FDCA permits the FDA to regulate a "combination product"– *i.e.*, a "device" (such as a cigarette) that contains a "drug" (such as nicotine)– under its "device" provisions. 21 U. S. C. §353(g)(1). And the FDCA's "device" provisions explicitly grant the FDA wide remedial discretion. For example, where the FDA cannot "otherwise" obtain "reasonable assurance" of a device's "safety and effectiveness," the agency may restrict by regulation a product's "sale, distribution, or use" upon *"such . . . conditions as the Secretary may prescribe.* §360j(e)(1) (emphasis added). And the statutory section that most clearly addresses the FDA's power to ban (entitled "Banned devices") says that, where a device presents "an unreasonable and substantial risk of illness or injury," the Secretary *"may"*– not *must*– "initiate a proceeding . . . to make such device a banned device." §360f(a) (emphasis added).

The Court points to other statutory subsections which it believes require the FDA to ban a drug or device entirely, even where an outright ban risks more harm than other regulatory responses. See *ante*, at 12–13. But the cited provisions do no such thing. It is true, as the majority contends, that "the FDCA requires the FDA to place all devices" in "one of three classifications" and that Class III devices require "premarket approval." *Ante*, at 12, 13. But it is not the case that the FDA *must* place cigarettes in Class III because tobacco itself "present[s] a potential unreasonable risk of illness or injury." 21 U. S. C. §360c(a)(1)(C). In fact, Class III applies *only* where *regulation* cannot otherwise "provide reasonable assurance of . . . safety." §§360c(a)(1)(A), 360c(a)(1)(B) (placing a device in Class I or Class II when regulation can provide that assurance). Thus, the statute plainly allows the FDA to consider the relative, overall "safety" of a device in light of its regulatory alternatives, and where the FDA has chosen

the least dangerous path, *i.e.*, the safest path, then it can– and does– provide a "reasonable assurance" of "safety" within the meaning of the statute. A good football helmet provides a reasonable assurance of safety for the player even if the sport itself is still dangerous. And the safest regulatory choice by definition offers a "reasonable" assurance of safety in a world where the other alternatives are yet more dangerous.

In any event, it is not entirely clear from the statute's text that a Class III categorization would require the FDA affirmatively to *withdraw* from the market dangerous devices, such as cigarettes, which are already widely distributed. See, *e.g.*, §360f(a) (when a device presents an "unreasonable and substantial risk of illness or injury," the Secretary "may" make it "a banned device"); §360h(a) (when a device "presents an unreasonable risk of substantial harm to the public health," the Secretary "may" require "notification"); §360h(b) (when a defective device creates an "unreasonable risk" of harm, the Secretary "may" order "repair, replacement, or refund"); cf. O'Reilly, Food and Drug Administration §18.08, at 18-38 (point of Class III "premarket approval" is to allow "careful scientific review" of each "truly new" device "*before* it is exposed" to users (emphasis added)).

Noting that the FDCA requires banning a "misbranded" drug, the majority also points to 21 U. S. C. §352(j), which deems a drug or device "misbranded" if "it is dangerous to health when used" as "prescribed, recommended, or suggested in the labeling." See *ante*, at 12. In addition, the majority mentions §352(f)(1), which calls a drug or device "misbranded" unless "its labeling bears . . . adequate directions for use" as "are necessary for the protection of users." *Ibid.* But this "misbranding" language is not determinative, for it permits the FDA to conclude that a drug or device is *not* "dangerous to health" and that it *does* have "adequate" directions *when regulated so as to render*

it as harmless as possible. And surely the agency can determine that a substance is comparatively "safe" (*not* "dangerous") whenever it would be *less* dangerous to make the product available (subject to regulatory requirements) than suddenly to withdraw it from the market. Any other interpretation risks substantial harm of the sort that my sleeping pill example illustrates. See *supra*, at 14. And nothing in the statute prevents the agency from adopting a view of "safety" that would avoid such harm. Indeed, the FDA already seems to have taken this position when permitting distribution of toxic drugs, such as poisons used for chemotherapy, that are dangerous for the user but are not deemed "dangerous to health" in the relevant sense. See 61 Fed. Reg. 44413 (1996).

The tobacco companies point to another statutory provision which says that if a device "would cause serious, adverse health consequences or death, the Secretary *shall* issue" a cease distribution order. 21 U. S. C. §360h(e)(1) (emphasis added). But that word "shall" in this context cannot mean that the Secretary must resort to the recall remedy *whenever* a device would have serious, adverse health effects. Rather, that language must mean that the Secretary "shall issue" a cease distribution order in compliance with the section's procedural requirements *if* the Secretary chooses *in her discretion* to use that particular subsection's recall remedy. Otherwise, the subsection would trump and make meaningless the same section's provision of other lesser remedies such as simple "notice" (which the Secretary similarly can impose if, but only if, she finds that the device "presents an unreasonable risk of substantial harm to the public"). §360h(a)(1). And reading the statute to compel the FDA to "recall" every dangerous device likewise would conflict with that same subsection's statement that the recall remedy "shall be *in addition to* [the other] remedies provided" in the statute. §360h(e)(3) (emphasis added).

The statute's language, then, permits the agency to choose remedies consistent with its basic purpose– the overall protection of public health.

The second reason the FDCA does not require the FDA to select the more dangerous remedy, see *supra*, at 14, is that, despite the majority's assertions to the contrary, the statute does not distinguish among the kinds of health effects that the agency may take into account when assessing safety. The Court insists that the statute only permits the agency to take into account the health risks and benefits of the "*product itself*" as used by individual consumers, *ante*, at 17, and, thus, that the FDA is prohibited from considering that a ban on smoking would lead many smokers to suffer severe withdrawal symptoms or to buy possibly stronger, more dangerous, black market cigarettes– considerations that the majority calls "the aggregate health effects of alternative administrative actions." *Ibid.* But the FDCA expressly *permits* the FDA to take account of comparative safety in precisely this manner. See, *e.g.*, 21 U. S. C. §360h(e)(2)(B)(i)(II) (no device recall if "risk of recal[l]" presents "a greater health risk than" no recall); §360h(a) (notification "unless" notification "would present a greater danger" than "no such notification").

Moreover, one cannot distinguish in this context between a "specific" health risk incurred by an individual and an "aggregate" risk to a group. *All* relevant risk is, at bottom, risk to an individual; *all* relevant risk attaches to "the product itself"; and *all* relevant risk is "aggregate" in the sense that the agency aggregates health effects in order to determine risk to the individual consumer. If unregulated smoking will kill 4 individuals out of a typical group of 1,000 people, if regulated smoking will kill 1 out of 1,000, and if a smoking ban (because of the black market) will kill 2 out of 1,000; then these three possibilities means that in each group four, one, and two individuals, on average, will die respectively. And the risk to each

individual consumer is 4/1000, 1/1000, and 2/1000 respectively. A "specific" risk to an individual consumer and "aggregate" risks are two sides of the same coin; each calls attention to the same set of facts. While there may be a theoretical distinction between the risk of the product itself and the risk related to the presence or absence of an intervening voluntary act (*e.g.*, the search for a replacement on the black market), the majority does not rely upon any such distinction, and the FDA's history of regulating "replacement" drugs such as methadone shows that it has long taken likely actual alternative consumer behavior into account.

I concede that, as a matter of logic, one could consider the FDA's "safety" evaluation to be different from its choice of remedies. But to read the statute to forbid the agency from taking account of the realities of consumer behavior either in assessing safety or in choosing a remedy could increase the risks of harm– doubling the risk of death to each "individual user" in my example above. Why would Congress insist that the FDA ignore such realities, even if the consequent harm would occur only unusually, say, where the FDA evaluates a product (a sleeping pill; a cigarette; a contact lens) that is already on the market, potentially habit forming, or popular? I can find no satisfactory answer to this question. And that, I imagine, is why the statute itself says nothing about any of the distinctions that the Court has tried to draw. See 21 U. S. C. §360c(a)(2) (instructing FDA to determine the safety and effectiveness of a "device" in part by weighing "*any* probable benefit to health . . . against *any* probable risk of injury or illness . . .") (emphasis added).

Third, experience counsels against an overly rigid interpretation of the FDCA that is divorced from the statute's overall health-protecting purposes. A different set of words, added to the FDCA in 1958 by the Delaney Amendment, provides that "no [food] additive shall be deemed to

be safe if it is found [after appropriate tests] to induce cancer in man or animal." §348(c)(3). The FDA once interpreted this language as requiring it to ban any food additive, no matter how small the amount, that appeared in any food product if that additive was ever found to induce cancer in any animal, no matter how large a dose needed to induce the appearance of a single carcinogenic cell. See H. R. Rep. No. 95–658, p. 7 (1977) (discussing agency's view). The FDA believed that the statute's ban mandate was absolute and prevented it from establishing a level of "safe use" or even to judge whether "the benefits of continued use outweigh the risks involved." *Id.*, at 5. This interpretation– which in principle could have required the ban of everything from herbal teas to mushrooms– actually led the FDA to ban saccharine, see 42 Fed. Reg. 19996 (1977), though this extremely controversial regulatory response never took effect because Congress enacted, and has continually renewed, a law postponing the ban. See Saccharin Study and Labeling Act, Pub. L. 95–203, §3, 91 Stat. 1452; *e.g.*, Pub. L. 102–142, Tit. VI, 105 Stat. 910.

The Court's interpretation of the statutory language before us risks Delaney-type consequences with even less linguistic reason. Even worse, the view the Court advances undermines the FDCA's overall health-protecting purpose by placing the FDA in the strange dilemma of either banning completely a potentially dangerous drug or device or doing nothing at all. Saying that I have misunderstood its conclusion, the majority maintains that the FDA "may clearly regulate many 'dangerous' products without banning them." *Ante*, at 19. But it then adds that the FDA *must* ban– rather than otherwise regulate– a drug or device that "cannot be used safely for any therapeutic purpose." *Ibid.* If I misunderstand, it is only because this linchpin of the majority's conclusion remains unexplained. *Why* must a widely-used but unsafe device

be withdrawn from the market when that particular remedy threatens the health of many and is thus more dangerous than another regulatory response? It is, indeed, a perverse interpretation that reads the FDCA to require the ban of a device that has no "safe" therapeutic purpose where a ban is the most dangerous remedial alternative.

In my view, where linguistically permissible, we should interpret the FDCA in light of Congress' overall desire to protect health. That purpose requires a flexible interpretation that both permits the FDA to take into account the realities of human behavior and allows it, in appropriate cases, to choose from its arsenal of statutory remedies. A statute so interpreted easily "fit[s]" this, and other, drug- and device-related health problems.

III

In the majority's view, laws enacted since 1965 require us to deny jurisdiction, whatever the FDCA might mean in their absence. But why? Do those laws contain language barring FDA jurisdiction? The majority must concede that they do not. Do they contain provisions that are inconsistent with the FDA's exercise of jurisdiction? With one exception, see *infra*, at 24, the majority points to no such provision. Do they somehow repeal the principles of law (discussed in Part II, *supra*) that otherwise would lead to the conclusion that the FDA has jurisdiction in this area? The companies themselves deny making any such claim. See Tr. of Oral Arg. 27 (denying reliance on doctrine of "partial repeal"). Perhaps the later laws "shape" and "focus" what the 1938 Congress meant a generation earlier. *Ante*, at 20. But this Court has warned against using the views of a later Congress to construe a statute enacted many years before. See *Pension Benefit Guaranty Corporation* v. *LTV Corp.*, 496 U. S. 633, 650 (1990) (later history is "'a hazardous basis for inferring the intent of an earlier' Congress" (quoting *United States* v. *Price*, 361 U. S.

304, 313 (1960))). And, while the majority suggests that the subsequent history "control[s] our construction" of the FDCA, see *ante*, at 20 (citation and internal quotation marks omitted), this Court expressly has held that such subsequent views are not "controlling." *Haynes* v. *United States*, 390 U. S. 85, 87–88, n. 4 (1968); accord, *Southwestern Cable Co.*, 392 U. S., at 170 (such views have "'very little, if any, significance'"); see also *Sullivan* v. *Finkelstein*, 496 U. S. 617, 632 (1990) (SCALIA, J., concurring) ("Arguments based on subsequent legislative history . . . should not be taken seriously, not even in a footnote.").

Regardless, the later statutes do not support the majority's conclusion. That is because, whatever individual Members of Congress after 1964 may have assumed about the FDA's jurisdiction, the laws they enacted did not embody any such "no jurisdiction" assumption. And one cannot automatically *infer* an antijurisdiction intent, as the majority does, for the later statutes are both (and similarly) consistent with quite a different congressional desire, namely, the intent to proceed without interfering with whatever authority the FDA otherwise may have possessed. See, *e.g.*, Cigarette Labeling and Advertising–1965: Hearings on H. R. 2248 et al. before the House Committee on Interstate and Foreign Commerce, 89th Cong., 1st Sess., 19 (1965) (hereinafter 1965 Hearings) (statement of Rep. Fino that the proposed legislation would *not* "erode" agency authority). As I demonstrate below, the subsequent legislative history is critically ambivalent, for it can be read *either* as (a) "ratif[ying]" a no-jurisdiction assumption, see *ante*, at 34, *or* as (b) leaving the jurisdictional question just where Congress found it. And the fact that both inferences are "equally tenable," *Pension Benefit Guaranty Corp.*, *supra*, at 650 (citation and internal quotation marks omitted); *Johnson* v. *Transportation Agency, Santa Clara Cty.*, 480 U. S. 616, 672 (1987) (SCALIA, J., dissenting), prevents the majority from drawing from the

later statutes the firm, antijurisdiction implication that it needs.

Consider, for example, Congress' failure to provide the FDA with express authority to regulate tobacco– a circumstance that the majority finds significant. See *ante*, at 21, 24–25, 32–33. But cf. *Southwestern Cable Co., supra*, at 170 (failed requests do not prove agency "did not already possess" authority). In fact, Congress *both* failed to grant express authority to the FDA when the FDA denied it had jurisdiction over tobacco *and* failed to take that authority expressly away when the agency later asserted jurisdiction. See, *e.g.*, S. 1262, 104th Cong., 1st Sess., §906 (1995) (failed bill seeking to amend FDCA to say that "[n]othing in this Act or any other Act shall provide the [FDA] with any authority to regulate in any manner tobacco or tobacco products"); see also H. R. 516, 105th Cong., 1st Sess., §2 (1997) (similar); H. R. Res. 980, reprinted in 142 Cong. Rec. 5018 (1996) (Georgia legislators unsuccessfully requested that Congress "rescind any action giving the FDA authority" over tobacco); H. R. 2283, 104th Cong., 1st Sess. (1995) (failed bill "[t]o prohibit the [FDA] regulation of the sale or use of tobacco"); H. R. 2414, 104th Cong., 1st Sess., §2(a) (1995) (similar). Consequently, the defeat of various different proposed jurisdictional changes proves nothing. This history shows only that Congress could not muster the votes necessary either to grant or to deny the FDA the relevant authority. It neither favors nor disfavors the majority's position.

The majority also mentions the speed with which Congress acted to take jurisdiction away from other agencies once they tried to assert it. See *ante*, at 22, 26–29. But such a congressional response again proves nothing. On the one hand, the speedy reply might suggest that Congress somehow resented agency assertions of jurisdiction in an area it desired to reserve for itself– a consideration that supports the majority. On the other hand, Congress'

quick reaction with respect to *other* agencies' regulatory efforts contrasts dramatically with its failure to enact any responsive law (at any speed) after the FDA asserted jurisdiction over tobacco more than three years ago. And that contrast supports the opposite conclusion.

In addition, at least one post-1938 statute reveals quite a different congressional intent than the majority infers. See Note following 21 U. S. C. §321 (1994 ed., Supp. III) (FDA Modernization Act of 1997) (law "shall [*not*] be construed to affect the question of whether the [FDA] has any authority to regulate any tobacco product," and "[s]uch authority, if any, shall be exercised under the [FDCA] as in effect on the day before the date of [this] enactment"). Consequently, it appears that the only interpretation that can reconcile *all* of the subsequent statutes is the inference that Congress did not intend, either explicitly or implicitly, for its later laws to answer the question of the scope of the FDA's jurisdictional authority. See 143 Cong. Rec. S8860 (Sept. 5, 1997) (the Modernization Act will "not interfere or substantially negatively affect any of the FDA tobacco authority").

The majority's historical perspective also appears to be shaped by language in the Federal Cigarette Labeling and Advertising Act (FCLAA), 79 Stat. 282, 15 U. S. C. §1331 *et seq.* See *ante*, at 25–26. The FCLAA requires manufacturers to place on cigarette packages, etc., health warnings such as the following:

> "SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy." 15 U. S. C. §1333(a).

The FCLAA has an express pre-emption provision which says that "[n]o statement relating to smoking and health, other than the statement required by [this Act], shall be required on any cigarette package." §1334(a). This pre-emption clause plainly prohibits the FDA from requiring

on "any cigarette package" any other "statement relating to smoking and health," but no one contends that the FDA has failed to abide by this prohibition. See, *e.g.*, 61 Fed. Reg. 44399 (1996) (describing the other regulatory prescriptions). Rather, the question is whether the FCLAA's pre-emption provision does *more*. Does it forbid the FDA to regulate at all?

This Court has already answered that question expressly and in the negative. See *Cipollone* v. *Liggett Group, Inc.*, 505 U. S. 504 (1992). *Cipollone* held that the FCLAA's pre-emption provision does not bar state or federal regulation outside the provision's literal scope. *Id.*, at 518. And it described the pre-emption provision as "merely prohibit[ing] state and federal rulemaking bodies from mandating particular cautionary statements on cigarette labels . . . ." *Ibid.*

This negative answer is fully consistent with Congress' intentions in regard to the pre-emption language. When Congress enacted the FCLAA, it focused upon the regulatory efforts of the Federal Trade Commission (FTC), not the FDA. See 1965 Hearings 1–2. And the Public Health Cigarette Smoking Act of 1969, Pub. L. 91–222, §7(c), 84 Stat. 89, expressly amended the FCLAA to provide that "[n]othing in this Act shall be construed to affirm or deny the [FTC's] holding that it has the authority to issue trade regulation rules" for tobacco. See also H. R. Conf. Rep. No. 91–897, p. 7 (1970) (statement of House Managers) (we have "no intention to resolve the question as to whether" the FTC could regulate tobacco in a different way); see also 116 Cong. Rec. 7921 (1970) (statement of Rep. Satterfield) (same). Why would one read the FCLAA's pre-emption clause– a provision that Congress intended to limit even in respect to the agency directly at issue– so broadly that it would bar a different agency from engaging in any other cigarette regulation at all? The answer is that the Court need not, and should not, do so.

And, inasmuch as the Court already has declined to view the FCLAA as pre-empting the entire field of tobacco regulation, I cannot accept that that same law bars the FDA's regulatory efforts here.

When the FCLAA's narrow pre-emption provision is set aside, the majority's conclusion that Congress clearly intended for its tobacco-related statutes to be the exclusive "response" to "the problem of tobacco and health," *ante*, at 35, is based on legislative silence. Notwithstanding the views voiced by various legislators, Congress itself has addressed expressly the issue of the FDA's tobacco-related authority only once– and, as I have said, its statement was that the statute was *not* to "be construed to affect the question of whether the [FDA] has any authority to regulate any tobacco product." Note following 21 U. S. C. §321 (1994 ed., Supp. III). The proper inference to be drawn from *all* of the post-1965 statutes, then, is one that interprets Congress' general legislative silence consistently with this statement.

IV

I now turn to the final historical fact that the majority views as a factor in its interpretation of the subsequent legislative history: the FDA's former denials of its tobacco-related authority.

Until the early 1990's, the FDA expressly maintained that the 1938 statute did not give it the power that it now seeks to assert. It then changed its mind. The majority agrees with me that the FDA's change of positions does not make a significant legal difference. See *ante*, at 34; see also *Chevron*, 467 U. S., at 863 ("An initial agency interpretation is not instantly carved in stone"); accord, *Smiley* v. *Citibank (South Dakota), N. A.*, 517 U. S. 735, 742 (1996) ("[C]hange is not invalidating"). Nevertheless, it labels those denials "important context" for drawing an inference about Congress' intent. *Ante*, at 34. In my view,

the FDA's change of policy, like the subsequent statutes themselves, does nothing to advance the majority's position.

When it denied jurisdiction to regulate cigarettes, the FDA consistently stated *why* that was so. In 1963, for example, FDA administrators wrote that cigarettes did not satisfy the relevant FDCA definitions– in particular, the "intent" requirement– because cigarette makers did not sell their product with accompanying "therapeutic claims." Letter to Directors of Bureaus, Divisions and Directors of Districts from FDA Bureau of Enforcement (May 24, 1963), in Public Health Cigarette Amendments of 1971: Hearings on S. 1454 before the Consumer Subcommittee of the Senate Committee on Commerce, 92d Cong., 2d Sess., 240 (1972) (hereinafter FDA Enforcement Letter). And subsequent FDA Commissioners made roughly the same assertion. One pointed to the fact that the manufacturers only "recommended" cigarettes "for smoking pleasure." Two others reiterated the evidentiary need for "health claims." Yet another stressed the importance of proving "intent," adding that "[w]e have not had sufficient evidence" of "intent with regard to nicotine." See, respectively, *id.*, at 239 (Comm'r Edwards); Letter of Dec. 5, 1977, App. 47 (Comm'r Kennedy); 1965 Hearings 193 (Comm'r Rankin); 1994 Hearings 28 (Comm'r Kessler). Tobacco company counsel also testified that the FDA lacked jurisdiction because jurisdiction "depends on . . . intended use," which in turn "depends, *in general*, on the claims and representations made by the manufacturer." Health Consequences of Smoking: Nicotine Addiction, Hearing before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, 100th Cong., 2d Sess., 288 (1988) (testimony of Richard Cooper) (emphasis added).

Other agency statements occasionally referred to additional problems. Commissioner Kessler, for example, said

that the "enormous social consequences" flowing from a decision to regulate tobacco counseled in favor of obtaining specific Congressional "guidance." 1994 Hearings 69; see also *ante*, at 31 (quoting statement of Health and Human Services Secretary Brandt to the effect that Congress wanted to make the relevant jurisdictional decision). But a fair reading of the FDA's denials suggests that the overwhelming problem was one of proving the requisite manufacturer intent. See *Action on Smoking and Health* v. *Harris*, 655 F. 2d 236, 238–239 (CADC 1980) (FDA "comments" reveal its "understanding" that "the crux of FDA jurisdiction over drugs lay in manufacturers' representations as revelatory of their intent").

What changed? For one thing, the FDA obtained evidence sufficient to prove the necessary "intent" despite the absence of specific "claims." See *supra*, at 12–14. This evidence, which first became available in the early 1990's, permitted the agency to demonstrate that the tobacco companies *knew* nicotine achieved appetite-suppressing, mood-stabilizing, and habituating effects through chemical (not psychological) means, even at a time when the companies were publicly denying such knowledge.

Moreover, scientific evidence of adverse health effects mounted, until, in the late 1980's, a consensus on the seriousness of the matter became firm. That is not to say that concern about smoking's adverse health effects is a new phenomenon. See, *e.g.*, Higginson, A New Counterblast, in Out-door Papers 179, 194 (1863) (characterizing tobacco as "'a narcotic poison of the most active class'"). It is to say, however, that convincing epidemiological evidence began to appear mid-20th century; that the First Surgeon General's Report documenting the adverse health effects appeared in 1964; and that the Surgeon General's Report establishing nicotine's addictive effects appeared in 1988. At each stage, the health conclusions were the subject of controversy, diminishing somewhat over time,

until recently– and only recently– has it become clear that there is a wide consensus about the health problem. See 61 Fed. Reg. 44701–44706 (1996).

Finally, administration policy changed. Earlier administrations may have hesitated to assert jurisdiction for the reasons prior Commissioners expressed. See *supra*, at 27–28. Commissioners of the current administration simply took a different regulatory attitude.

Nothing in the law prevents the FDA from changing its policy for such reasons. By the mid-1990's, the evidence needed to prove objective intent– even without an express claim– had been found. The emerging scientific consensus about tobacco's adverse, chemically induced, health effects may have convinced the agency that it should spend its resources on this important regulatory effort. As for the change of administrations, I agree with then-JUSTICE REHNQUIST's statement in a different case, where he wrote:

> 'The agency's changed view . . . seems to be related to the election of a new President of a different political party. It is readily apparent that the responsible members of one administration may consider public resistance and uncertainties to be more important than do their counterparts in a previous administration. A change in administration brought about by the people casting their votes is a perfectly reasonable basis for an executive agency's reappraisal of the costs and benefits of its programs and regulations. As long as the agency remains within the bounds established by Congress, it is entitled to assess administrative records and evaluate priorities in light of the philosophy of the administration." *Motor Vehicle Mfrs. Assn. of United States, Inc.* v. *State Farm Mut. Automobile Ins. Co.*, 463 U. S. 29, 59 (1983) (concurring in part and dissenting in part).

V

One might nonetheless claim that, even if my interpretation of the FDCA and later statutes gets the words right, it lacks a sense of their "music." See *Helvering* v. *Gregory*, 69 F. 2d 809, 810–811 (CA2 1934) (L. Hand, J.) ("[T]he meaning of a [statute] may be more than that of the separate words, as a melody is more than the notes . . ."). Such a claim might rest on either of two grounds.

First, one might claim that, despite the FDA's legal right to change its mind, its original statements played a critical part in the enactment of the later statutes and now should play a critical part in their interpretation. But the FDA's traditional view was largely premised on a perceived inability to prove the necessary statutory "intent" requirement. See, *e.g.*, FDA Enforcement Letter 240 ("The statutory basis for the exclusion of tobacco products from FDA's jurisdiction is the fact that tobacco marketed for chewing or smoking without accompanying therapeutic claims, does not meet the definitions . . . for food, drug, device or cosmetic"). The statement, "we cannot assert jurisdiction over substance X unless it is treated as a food" would not bar jurisdiction if the agency later establishes that substance X is, and is intended to be, eaten. The FDA's denials of tobacco-related authority sufficiently resemble this kind of statement that they should not make the critical interpretive difference.

Second, one might claim that courts, when interpreting statutes, should assume in close cases that a decision with "enormous social consequences," 1994 Hearings 69, should be made by democratically elected Members of Congress rather than by unelected agency administrators. Cf. *Kent* v. *Dulles*, 357 U. S. 116, 129 (1958) (assuming Congress did not want to delegate the power to make rules interfering with exercise of basic human liberties). If there is such a background canon of interpretation, how-

ever, I do not believe it controls the outcome here.

Insofar as the decision to regulate tobacco reflects the policy of an administration, it is a decision for which that administration, and those politically elected officials who support it, must (and will) take responsibility. And the very importance of the decision taken here, as well as its attendant publicity, means that the public is likely to be aware of it and to hold those officials politically accountable. Presidents, just like Members of Congress, are elected by the public. Indeed, the President and Vice President are the *only* public officials whom the entire Nation elects. I do not believe that an administrative agency decision of this magnitude– one that is important, conspicuous, and controversial– can escape the kind of public scrutiny that is essential in any democracy. And such a review will take place whether it is the Congress or the Executive Branch that makes the relevant decision.

* * *

According to the FDA, only 2.5% of smokers successfully stop smoking each year, even though 70% say they want to quit and 34% actually make an attempt to do so. See 61 Fed. Reg. 44704 (1996) (citing Centers for Disease Control and Prevention, Cigarette Smoking Among Adults– United States, 1993; 43 Morbidity and Mortality Weekly Report 929 (Dec. 23, 1994)). The fact that only a handful of those who try to quit smoking actually succeed illustrates a certain reality– the reality that the nicotine in cigarettes creates a powerful physiological addiction flowing from chemically induced changes in the brain. The FDA has found that the makers of cigarettes "intend" these physical effects. Hence, nicotine is a "drug"; the cigarette that delivers nicotine to the body is a "device"; and the FDCA's language, read in light of its basic

purpose, permits the FDA to assert the disease-preventing jurisdiction that the agency now claims.

The majority finds that cigarettes are so dangerous that the FDCA would require them to be banned (a result the majority believes Congress would not have desired); thus, it concludes that the FDA has no tobacco-related authority. I disagree that the statute would require a cigarette ban. But even if I am wrong about the ban, the statute would restrict only the agency's choice of remedies, not its jurisdiction.

The majority also believes that subsequently enacted statutes deprive the FDA of jurisdiction. But the later laws say next to nothing about the FDA's tobacco-related authority. Previous FDA disclaimers of jurisdiction may have helped to form the legislative atmosphere out of which Congress' own tobacco-specific statutes emerged. But a legislative atmosphere is not a law, unless it is embodied in a statutory word or phrase. And the relevant words and phrases here reveal nothing more than an intent not to change the jurisdictional status quo.

The upshot is that the Court today holds that a regulatory statute aimed at unsafe drugs and devices does not authorize regulation of a drug (nicotine) and a device (a cigarette) that the Court itself finds unsafe. Far more than most, this particular drug and device risks the life-threatening harms that administrative regulation seeks to rectify. The majority's conclusion is counter-intuitive. And, for the reasons set forth, I believe that the law does not require it.

Consequently, I dissent.

American Cancer Society **American Heart Association**
American Medical Association **American Public Health Association**
Campaign for Tobacco-Free Kids

For Immediate Release
March 2, 2000

Contacts: Joel Spivak/CTFK
202-296-5469
Roger Salazar, ACS
202-661-5710
Kelly Kennai/AHA
202-785-7900
Linda Stepanich/AMA
312-464-2410
Karin Wallestad/APHA
202-777-2435

Public Health Groups Call on Philip Morris to Support Meaningful FDA Regulation of Tobacco

– Groups Challenge Tobacco Giant to Match Rhetoric with Action –

Washington, DC (March 2, 2000) – Five leading public health organizations today called on tobacco giant Philip Morris to back up its rhetoric with action by supporting meaningful U.S. Food and Drug Administration (FDA) regulation of tobacco.

Earlier this week Philip Morris publicly announced it would support some measure of federal regulation of tobacco products, but did not provide specifics. During a press conference at the National Press Club, the five public health groups – the American Cancer Society, the American Heart Association, the American Medical Association, the American Public Health Association, and the Campaign for Tobacco-Free Kids – challenged Philip Morris to support FDA oversight as embodied in the FDA provisions of the 1998 tobacco control legislation considered by the Senate.

"We would welcome it if Philip Morris and the other tobacco companies would accept meaningful regulation of tobacco that protects the public health and reduces the death and disease caused by the use of tobacco products," said Francis L. Coolidge, Immediate Past Chairman of the American Cancer Society. "However, until we see the details, a healthy skepticism is in order given Philip Morris' long history of empty public relations gestures. In fact, we are deeply disappointed at Philip Morris' failure today to provide enough details for the American people to judge if this is just another smokescreen."

The five public health groups challenged Philip Morris to immediately take three specific actions to show it is now serious:

- End its opposition to the FDA's assertion of jurisdiction over tobacco, regardless of the outcome of the pending Supreme Court case.

- Support the FDA provisions of the Senate's 1998 tobacco control legislation. These provisions were drafted by Senator Bill Frist (R-TN) and were supported by a bipartisan majority of at least 57 senators who voted to continue debate on the bill.
- End its marketing and sales practices that impact kids, including advertising in magazines with high youth readership and with images such as the Marlboro Man that appeal to youth.

"Philip Morris should be judged by its actions, not its rhetoric," said Dr. Mohammad Akhter, Executive Director, American Public Health Association. "They owe the public straightforward and honest statements that will – in real terms – move use closer to the protection of public heath."

The five public health groups also outlined the components of meaningful FDA regulation over tobacco products as embodied in the 1998 Senate bill. These include:

- Authority to reduce and/or eliminate harmful components of tobacco products.
- Authority over youth access to tobacco products and tobacco advertising and marketing.
- Disclosure to the FDA of all tobacco industry information regarding the health effects of tobacco products.
- Authority to regulate the use of harmful ingredients and require the tobacco industry to provide the FDA with a complete list of all tobacco ingredients and additives by brand.
- Authority over health warnings on tobacco product packages and advertising, including size, location and color.
- Authority to prohibit or restrict unsubstantiated health claims about tobacco products and health claims that discourage people from quitting or encourage them to start.
- Authority to encourage and oversee the development of products that reduce the health risk to consumers and that serve as less harmful alternatives.

"The critical question is, what does Philip Morris mean by regulation," said Matthew L. Myers, President of the Campaign for Tobacco-Free Kids. "Will it consent to the same kind of regulatory authority that the Food and Drug Administration has over other drugs and foods, including the power to require that harmful ingredients like nicotine be reduced or eliminated in order to save lives? The real test of regulation or legislation will be whether it protects the health of the public, not the profits of Philip Morris."

Finally, the public health groups detailed Philip Morris' long history of making grand gestures when faced with political or legal challenges, as they do now, then failing to follow through with action. This strategy continues today:

- Philip Morris generated publicity by acknowledging on its web site that cigarette smoking is addictive and causes lung cancer, heart disease, and other serious illnesses. Yet a psychiatrist hired by Philip Morris and other tobacco companies recently testified in the pending Florida class action lawsuit that two smokers in that case were not addicted to tobacco.

- Philip Morris claims to support youth tobacco prevention programs. Yet it recently brought its corporate muscle to bear in censoring the tough anti-smoking advertising developed by the American Legacy Foundation.
- Philip Morris claims in its recently launched newspaper advertising campaign that its goal is to "responsibly market our products to adults who choose to smoke." Yet it continues to advertise in publications such as *People, TV Guide, Sports Illustrated,* and *Rolling Stone* that have youth readership totaling more than two million or more than 15 percent of overall readership. These are the very same publications in which Philip Morris agreed to restrict its advertising as part of the 1997 tobacco settlement.

"Philip Morris has a long history of talking the talk, but not walking the walk," said M. Cass Wheeler, CEO of the American Heart Association. "Therefore, it must bear the burden of proof to show it has truly changed and is now willing to accept meaningful government regulation of its tobacco products. We can only conclude that this is yet another public relations ploy aimed at avoiding the real change needed to reduce the deadly toll of tobacco in our country."

Dr. Randolph Smoak, Jr., President-elect of the American Medical Association, closed the press conference by calling on Congress and the President to judge Philip Morris by actions rather than words and to support the FDA provisions of the 1998 Senate legislation.

"We believe that the FDA provisions of the 1998 Senate bill represent the minimum standard for meaningful regulation of tobacco products," Smoak said. "While we are confident that the FDA already has the authority to regulate tobacco, we urge the Congress to support this legislation should the Supreme Court rule otherwise. We are heartened by the President's statement of support this week for the 1998 legislation, and we urge him to veto any bill that falls short."

###

FDA Authority Over Tobacco
(as drafted by Senator Frist for the Senate tobacco control legislation)

Authority to Reduce and/or Eliminate Harmful Components. Provides FDA with the authority to decide whether to reduce and, where appropriate, eliminate the harmful components of tobacco products, including nicotine, the component that causes addiction.

Authority Over Youth Access and Tobacco Advertising and Marketing. Provides FDA with rulemaking and enforcement authority over restrictions on 1) youth access to tobacco products, 2) tobacco advertising and marketing.

Health Information Disclosure. Entitles FDA to receive all documents and information in the tobacco industry's possession relating to health effects of tobacco products, nicotine and its effect on the body, addiction, marketing to children and the effect of marketing on children, and such other information that the HHS Secretary deems necessary to permit the FDA to protect the public health.

Ingredients. Provides FDA with the authority to require the tobacco industry to provide FDA with a complete list of all tobacco ingredients and additives, by brand and by quantity, and the authority to require that this information be given to the public in a manner that does not disclose legitimate trade secrets. Provides FDA with the authority to regulate the use of any ingredient or additive that is harmful or which contributes to the harm of the product. Places the burden on the tobacco manufacturer to demonstrate to the FDA that each ingredient and additive is safe in the quantity used under the conditions of intended use.

Health Warnings. Provides FDA the authority over health warnings on tobacco product packages and advertisements, including the power to revise and add health warnings and to alter the format including, but not limited to, size, location, and color.

Health Claims and Lower Risk Products. Provides FDA the authority to prohibit or restrict 1) unsubstantiated health claims, whether directly or indirectly made; and 2) health claims that have the effect of discouraging people from quitting or encouraging them to start. Provides FDA the authority to encourage the development of products that reduce the health risk to consumers and that serve as less harmful alternatives.

Safety Standard. The standard that FDA applies when approving drugs and devices is whether there is a "reasonable assurance that a product is *safe and effective*." There is no such thing as a safe cigarette. Therefore, the Senate tobacco control legislation creates a new standard for tobacco products. That standard is the "protection of the public health" with respect to the overall health risk to the American public and not just the risk to the current user. Consideration must be given to whether a product change or new rule will reduce or increase the overall number of tobacco users, including increasing the number of new users or decreasing the number who quit.

Preemption. As a general principle, establishes that FDA's rules should not be preemptive of stronger state or local tobacco control laws.

Scope of Authority. Provides FDA with the authority over all tobacco products, including but not limited to cigarettes, smokeless tobacco products, roll-your-own cigarettes and cigars.

Procedural Fairness. In general assures that FDA's ability to regulate tobacco products is not subject to different or more onerous standards or procedures than are applied to "drugs" or "devices".

CAMPAIGN for TOBACCO-FREE Kids®

A Long History of Empty Promises: The Tobacco Industry's Efforts to Avoid Meaningful Regulation

Philip Morris publicly announced this week that it supports some form of federal regulation of tobacco products, but failed to provide any specifics. Given its history of empty promises on tobacco regulation and tobacco prevention, there is plenty of reason to be skeptical of this latest announcement. In fact, this announcement follows a long line of company efforts to use public relations to fend off legal, regulatory, and legislative action that would require real change in its practices. Trial documents, public statements and private statements reveal that these efforts are really designed to generate the much-needed positive publicity among a critical Washington audience to avoid the fundamental changes in its business practices that would truly reduce tobacco use and save lives.

Previous Tobacco Industry Youth Smoking Programs

Most of the tobacco industry's programs have been launched at particularly sensitive political moments for the industry, and all have been designed more to relieve political pressure on the industry than to bring about regulation of the industry or discourage tobacco use by kids.

- In the 1980s, the Tobacco Institute, in response to Congressional interest in restrictions on tobacco ads and the problem of youth smoking, launched several programs, including "Helping Youth Decide" and "Helping Youth Say No." These programs emphasized decision-making for kids rather than warning them of the health dangers of tobacco. A study in the *Journal of Family Practice* found that the "Helping Youth Say No" program could actually encourage youth smoking by its suggestion that tobacco use is an adult activity.

- In 1990, the tobacco industry launched a new program called "It's the Law," again in response to Congressional interest in reducing tobacco use among youth. "It's the Law" shifted focus from youth decision-making to providing retailers with educational materials about not selling to kids. Beyond sending decals and signage to retail stores, this program was never effectively implemented. A 1992 study in the *American Journal of Public Health* found that compliance with the program was extremely low.

- In the later 1990s, to combat growing Congressional interest in the behavior of the tobacco industry, Philip Morris and its allies launched several additional programs, including "We Card" and "Action Against Access." Like previous programs, these were half-efforts at best, a point illustrated in an audit of "Action Against Access" by former U.S. Senator Warren Rudman, who found that retailers did not take the program seriously and that it was not implemented completely. Two years after the program had been in place, Philip Morris had penalized only 16 out of more than 400,000 tobacco retailers for selling to kids.

Recently released internal tobacco industry documents show that the goal of these industry programs is to deflect political pressure and avoid government regulation rather than actually protect kids:

- A 1990 Tobacco Institute memo outlined the "Helping Youth Decide" program: "The industry has in the past and must continue to defend its marketing practices. To ensure that the industry is putting forth maximum effort to meet these growing challenges, I have asked Institute staff to identify opportunities to politically and publicly reaffirm the industry's continued commitment to address the issue of youth smoking. . . *In order for this program to achieve its legislative goal*, we believe a multi-year commitment must be made up front." [Emphasis added.]

- In 1995, Philip Morris Senior Vice President Ellen Merlo wrote a memo warning her colleagues that the industry still faced a hostile climate on Capitol Hill. She warned: ". . . If we don't do something fast to project the sense of industry responsibility regarding the youth access issue, we are going to be looking at severe marketing restrictions in a very short time. Those restrictions will pave the way for equally severe legislation or regulation on where adults are allowed to smoke."

Philip Morris' new $100 million advertising campaign bears the hallmarks of the company's previous failed efforts:

The industry continues to oppose efforts to protect youth from tobacco and is still impacting kids with its marketing. Approximately 85 percent of youth who smoke choose the three most heavily advertised brands, including nearly 60 percent who smoke Marlboro. Yet, Philip Morris refuses to end such marketing. If the company was truly serious about ending youth smoking, then it would send the Marlboro Man into retirement. This is precisely what Philip Morris and other tobacco companies agreed to do in the June 20, 1997 agreement with state Attorneys General: eliminate all human and cartoon characters from their marketing. Later, the tobacco industry opposed and helped defeat the 1998 Senate tobacco control legislation, which would have ratified the agreement. Thus, it was never implemented.

What Philip Morris Says In Public

"In 1982, on behalf of the industry, the Tobacco Institute launches an ad campaign headed, 'Do cigarette companies want kids to smoke? No. As a matter of policy. No.As a matter of fact. No' "
1996 Timeline (PM#250211402)

"I have never in my job been involved with trying to get a non-smoker to smoke. ...I don't think that advertising convinces people to smoke... I have not seen statistics on when people usually begin to smoke." Ellen Merlo, June 14, 1984, testimony in Cipollone v. Liggett

"We at Philip Morris USA have long held the position that minors should not smoke and should not have access to cigarettes, and we have backed that commitment over the years with a series of concrete actions." Philip Morris President James Morgan in a 1995 memo to all Philip Morris USA Employees on the "Action Against Access" program. (PM#2046312594)

In all my years at Philip Morris, I've never heard anyone talk about marketing to youth. Geoffrey Bible, CEO of Philip Morris, Minneapolis-St. Paul Star Tribune, March 4, 1998.

What They Say In Private

"It seems to me our objective is...a 'media event' which promises a lot but produces little." Franklin Dryden, Executive Vice President, The Tobacco Institute in a 1979 memo to Senior Vice President Bill Kloepfer.

"[Pitch the industry message] to adults, not kids. After all, kids don't vote parents do." Second memo from Dryden to Kloepfer.

Marlboro's phenomenal growth rate in the past has been attributable in large part to our high market penetration among young smokers . . .15 to 19 years old . . . my own data, which includes younger teenagers, shows even higher Marlboro market penetration among 15-17-year-olds. [Philip Morris Document #1000024921/4927, May 21, 1975]

[To support Marlboro's growth, Marlboro must] *continue growth among new, young smokers...While Marlboro continues to attract increasing shares of young smokers, expected declines in the number of young people restrict future volume gains from this source.* [PM Doc. #2043440057/0112, 1985]

Thus, the ability to attract new smokers and develop them into a young adult franchise is key to brand development. [PM Doc. #2044895379/484, 1992]

What They Say In Private: Behavioral Research About Kids

It is important to know as much as possible about teenage smoking patterns and attitudes. Today's teenager is tomorrow's potential regular customer, and the overwhelming majority of smokers first begin to smoke while in their teens . . . it is during the teenage years that the initial brand choice is made. [Special Report, "Young Smokers: Prevalence, Trends, Implications, and Related Demographic Trends," PM Document #1000390803/55, March 31, 1981]

CAMPAIGN for TOBACCO-FREE Kids®

PREVIOUS AGREEMENTS ON FDA AUTHORITY AND TOBACCO MARKETING RESTRICTIONS

FDA AUTHORITY	Philip Morris-Supported June 1997 Agreement Between the Tobacco Companies and the States	FDA Provisions of 1998 Senate Tobacco Bill (S. 1415) Drafted by Senator Bill Frist
FDA authority to reduce and/or eliminate harmful components of tobacco products	Yes	Yes
FDA authority over youth access to tobacco products and tobacco advertising and marketing	Yes	Yes
FDA authority to prohibit or restrict unsubstantiated health claims about tobacco products and health claims that discourage people from quitting or encourage them to start	Yes	Yes
Tobacco industry disclosure to the FDA of all information regarding the health effects of tobacco products	Yes	Yes
FDA authority to encourage and oversee the development of products that reduce the health risk to consumers and that serve as less harmful alternatives	Yes	Yes
FDA authority to require prior testing and approval of new ingredients and additives	Yes	Yes
FDA authority to require the tobacco industry to provide the FDA with a complete list of all tobacco ingredients and additives by brand	Yes	Yes
FDA authority over health warnings on tobacco product packages and advertising, including size, location and color	Yes	Yes
Basis of FDA Authority over tobacco products	FDA's existing authority over drugs and drug-delivery devices.	New separate tobacco chapter in FDA statute.

1707 L Street, NW Suite 800 Washington, DC 20036
Phone (202) 296-5469 Fax (202) 296-5427 www.tobaccofreekids.org

Previous Agreements re FDA and Tobacco Marketing Restrictions / 2

RESTRICTIONS ON MARKETING TO CHILDREN	Philip Morris Supported June 1997 Agreement Between the Tobacco Companies and the States	FDA Provisions of 1998 Senate Comprehensive Tobacco Bill S. 1415 Drafted by Senator Bill Frist
Print Ads	Limits ads in newspapers and magazines with large youth readership to black and white text only.	Limits ads in newspapers and magazines with large youth readership to black and white text only.
In-Store Advertising	Black and white text only with limits on number and size.	Black and white text only with limits on number and size.
Internet Tobacco Ads	Banned.	Banned.
Outdoor & Transit Ads	Bans all outdoor and transit ads.	Bans all outdoor and transit ads.
Cartoons & Human Images in Tobacco Marketing	Bans all cartoons and human images, including the Marlboro Man.	Bans all cartoons and human images, including the Marlboro Man.
Tobacco Brand-Name Merchandise	Bans all tobacco brand name merchandise.	Bans all tobacco brand name merchandise.
Offers of Non-Tobacco Gifts Based on Proof of Tobacco Purchase	Banned.	Banned.
Brand Name Sponsorships	Banned.	Banned.
Use of non-tobacco brand name on tobacco products	Banned.	Banned.
Tobacco Product Placement in Movies & TV	Banned.	Banned.
YOUTH ACCESS RESTRICTIONS		
Proof of Age	Requires proof of age for tobacco purchases.	Requires proof of age for tobacco purchases.
Comprehensive Enforcement of Minimum Age Laws	Comprehensive enforcement plan established.	Comprehensive enforcement plan established.
Vending Machines	Limits vending Machines to adult only facilities.	Limits vending Machines to adult only facilities.
Self Service Displays	Banned.	Banned.
Free Samples	Banned.	Banned.
Retailer Licensing	Licenses retailers.	Licenses retailers.
"Kiddie Packs"	Bans sales in packs of less than 20.	Bans sales in packs of less than 20.
OTHER PROVISIONS		
Health Warnings	New stronger, more visible health warnings on cigarette and smokeless tobacco packages and ads.	New stronger, more visible health warnings on cigarette and smokeless tobacco packages and ads.
Youth Tobacco Use Reduction Targets	Requires youth tobacco use reduction targets with industry-wide penalties if targets not met.	Requires youth tobacco use reduction targets with industry-wide penalties if targets not met.

Tobacco
Q&A
February 29, 2000

Q: What's the Administration's response to statements by Philip Morris that the company is willing to agree to government regulation of tobacco?

A: If Philip Morris is serious about agreeing to government regulation of tobacco aimed at reducing youth smoking – and we hope they are – then they will agree to comply with the Food and Drug Administration's 1996 tobacco regulation and support the bipartisan legislation negotiated by Senator Frist and agreed to by the Senate Commerce Committee 19-1 in 1998.

Q: Do you believe Philip Morris is serious? Or is this just a public relations stunt?

A: We hope Philip Morris is serious, but only time will tell. The devil is in the details. If they are serious about reducing youth smoking, then they will agree to comply with the Food and Drug Administration's 1996 tobacco regulation and support the bipartisan legislation negotiated by Senator Frist and agreed to by the Senate Commerce Committee 19-1 in 1998.

Q: Has Philip Morris contacted the Administration to begin discussions on these issues?

A: No, they have not.

Q: Philip Morris says they are willing to agree to government regulation, but that they oppose the FDA rule. What do you think of that?

A: We need comprehensive regulation to reduce youth smoking and protect the public health. The FDA rule will help stop young people from smoking before they start by eliminating advertising aimed at children and curbing minors' access to tobacco products. These same provisions were agreed to on a bipartisan basis in the U.S. Senate in 1998. If the industry is serious about reducing youth smoking, they will agree to these rules.

Q: How exactly would the FDA rule and the Frist provisions regulate tobacco?

A: These provisions will help stop young people from smoking before they start by eliminating advertising aimed at children and curbing minors' access to tobacco products. The provisions include:

- Restricting Advertising Aimed at Children, including banning outdoor advertising within 1000 feet of schools and public playgrounds and limiting advertising in publications with significant youth readership to black-and-white text.

- Discouraging Tobacco Sales to Minors, including requiring age verification by photo ID for anyone appearing age 26 or younger and banning vending machine except in adult-only facilities.

Another critical component of effective tobacco regulation is ensuring that the FDA has sufficient authority to impose additional restrictions as future circumstances warrant.

Q: Didn't the 1998 state settlement put in place many of these advertising restrictions?

A: No. The FDA's restrictions are necessary to halt advertising and marketing aimed at children. The FDA's rules are much more comprehensive than those the tobacco companies agreed to in the 1998 settlement and will do much more to prevent youth smoking. For example, the FDA rule limits tobacco ads in newspapers and magazines with significant youth readership to black and white text, while the 1998 settlement did not limit print advertising at all. Moreover, the FDA rule banned all tobacco advertising within 1000 feet of a school, and limited all outdoor advertising to black and white text, while the state settlement allows retailers and other non-billboard ads near schools and with color ads that appeal to children.

Q: Would government regulation of tobacco include banning tobacco?

A: No. This Administration does not support a ban on tobacco products. The FDA regulation does not restrict adults' access to tobacco products – instead it is aimed at preventing underage youth from smoking by eliminating advertising aimed at children and curbing minors' access to tobacco products.

A ban on tobacco products would create a black market or cause addicted smokers to suffer sudden withdrawal of nicotine.

Q: Where does the Supreme Court case regarding the FDA rule stand?

A: The case is now pending, and we expect the Supreme Court to rule this session. The court agreed to take the case on April 26, 1999 and heard oral arguments on December 1, 1999. The case stems from challenges from the tobacco industry filed in 1996 immediately after the FDA published its tobacco regulation.

Tobacco
Q&A
March 2, 2000 -- DRAFT

Q: What's the Administration's response to statements by Philip Morris Senior Vice President Steven Parrish today?

A: My understanding is that the sponsor of the conference was experiencing technical difficulties and could not broadcast the panel including Mr. Parrish, so we don't know yet what he said. But as the President said in his statement on Tuesday, he is heartened by the reports that the nation's leading cigarette maker is now willing to accept government regulation of tobacco. If Philip Morris is ready to support the FDA provisions the industry has fought at every turn and the Congressional leadership killed just two years ago, this is an important step forward.

Q: Press reports have indicated that Philip Morris will not accept regulations as comprehensive as the FDA rule the President put in place in 1996. Is the Administration willing to negotiate with Philip Morris on a tobacco regulation that is less comprehensive than the FDA rule?

A: No, we are not. We need comprehensive and meaningful regulations to reduce youth smoking and protect the public health. The FDA rule will help stop young people from smoking before they start by eliminating advertising aimed at children and curbing minors' access to tobacco products. These same provisions were agreed to on a bipartisan basis in the U.S. Senate in 1998. If the industry is serious about reducing youth smoking, they will agree to these rules.

Q: Has Philip Morris contacted the Administration to begin discussions on these issues?

A: No, they have not.

Q: How exactly would the FDA rule and the Frist provisions regulate tobacco?

A: Throughout the life of this Administration, President Clinton and Vice President Gore have done everything they could to protect our children from the dangers of tobacco. Five years ago, we put forward a landmark rule affirming the FDA's authority to regulate tobacco products. These provisions will help stop young people from smoking before they start by eliminating advertising aimed at children and curbing minors' access to tobacco products. The provisions include:

- Restricting Advertising Aimed at Children, including banning outdoor advertising within 1000 feet of schools and public playgrounds and limiting advertising in publications with significant youth readership to black-and-white text.

- Discouraging Tobacco Sales to Minors, including requiring age verification by photo ID for anyone appearing age 26 or younger and banning vending machine except in adult-only facilities.

Another critical component of effective tobacco regulation is ensuring that the FDA has sufficient authority to impose additional restrictions as future circumstances warrant.

Q: Didn't the 1998 state settlement put in place many of these advertising restrictions?

A: No. The FDA's restrictions are necessary to halt advertising and marketing aimed at children. The FDA's rules are much more comprehensive than those the tobacco companies agreed to in the 1998 settlement and will do much more to prevent youth smoking. For example, the FDA rule limits tobacco ads in newspapers and magazines with significant youth readership to black and white text, while the 1998 settlement did not limit print advertising at all. Moreover, the FDA rule banned all tobacco advertising within 1000 feet of a school, and limited all outdoor advertising to black and white text, while the state settlement allows retailers and other non-billboard ads near schools and with color ads that appeal to children.

Q: Would government regulation of tobacco include banning tobacco?

A: No. This Administration does not support a ban on tobacco products. The FDA regulation does not restrict adults' access to tobacco products – instead it is aimed at preventing underage youth from smoking by eliminating advertising aimed at children and curbing minors' access to tobacco products.

A ban on tobacco products would create a black market or cause addicted smokers to suffer sudden withdrawal of nicotine.

Q: Where does the Supreme Court case regarding the FDA rule stand?

A: The case is now pending, and we expect the Supreme Court to rule this session. The court agreed to take the case on April 26, 1999 and heard oral arguments on December 1, 1999. The case stems from challenges from the tobacco industry filed in 1996 immediately after the FDA published its tobacco regulation. The Administration strongly believes FDA has the authority to regulate tobacco products and has urged the court to uphold the rule.

Tobacco FDA Rule — Oral arguments at Supreme Ct

Cynthia A. Rice 12/01/99 03:33:28 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP@EOP, Eric P. Liu/OPD/EOP@EOP

cc: J. Eric Gould/OPD/EOP@EOP, Eugenia Chough/OPD/EOP@EOP

Subject: Supreme Court arguments on FDA case

I hear the oral arguments went badly for our side -- many of the justices expressed skepticism about whether FDA has the authority to regulate – looks like it could be 5-4 or 6-3. There's some more detail in the wire stories below.

q&a1201 fda.doJustice and HHS OK'd these q&as if we need them.

Justices Doubt Tobacco Regulations

WASHINGTON (AP)

Several Supreme Court justices expressed doubts today about whether the Food and Drug Administration can regulate tobacco as a drug and crack down on cigarette sales to minors. Solicitor General Seth Waxman asked the court to let the FDA regulate tobacco because the nicotine it contains is a ''highly addictive'' substance that acts as a stimulant, a sedative, an appetite suppressant and is used to feed smokers' addictions. But tobacco industry lawyer Richard M. Cooper insisted the government's 1996 decision to regulate tobacco was ''lawless'' because cigarettes are not promoted as having effects on health.

76M

December 1, 1999, Wednesday 02:26 PM Eastern Time

SECTION: WASHINGTON DATELINE GENERAL NEWS

LENGTH: 789 words

HEADLINE: UPI Focus;
Court looks at future of tobacco

BYLINE: By MICHAEL KIRKLAND

DATELINE: WASHINGTON, Dec. 1

BODY:

A divided U.S. Supreme Court heard argument Wednesday on the future of tobacco.

At issue is whether the Food and Drug Administration has the authority to regulate tobacco as a drug, something the domestic industry fears could ultimately lead to the banning of its product in the United States.

A lower court has said the FDA cannot regulate tobacco either as a ''drug'' or as a ''device'' that delivers a drug, nicotine.

But the Clinton administration, acting for the FDA, has taken the case to the Supreme Court.

With the nine-member court dividing largely along ideological lines, Justice Anthony Kennedy, a moderate, appeared during Wednesday's argument to have the swing vote in any eventual decision.

The court's three genuine conservatives, Chief Justice William Rehnquist and Justices Antonin Scalia and Clarence Thomas, are expected to vote against regulation.

Rehnquist and Scalia expressed skepticism about the authority of the FDA to regulate tobacco. Though Thomas, as usual, did not speak from the bench, he consistently votes with his fellow conservatives.

All three are off-and-on smokers, though that is not expected to influence their votes.

Justice Sandra Day O'Connor, who at times holds a key swing vote though less often than Kennedy announced up front that she did not believe tobacco fit under the law governing which products are regulated by the FDA.

Kennedy, though he did not commit himself and his vote could still be up for grabs, appeared to be leaning against regulation and could make up a five-member majority in a final decision.

Even one of the four liberals expected to eventually side with the FDA, Justice David Souter, said he was convinced the agency was right on the details was still waiting to be convinced that the FDA was right on the ''totality'' of the case.

The court's remaining liberals, Justices John Paul Stevens, Ruth Bader Ginsburg and Stephen Breyer, appeared ready to side with the FDA.

Under prodding from President Clinton, the FDA first tried to regulate tobacco in 1996, placing severe

restrictions on advertising and access to tobacco by minors.

The agency considered, but ultimately rejected, an outright ban on tobacco because "the sudden withdrawal from the market of products to which so many millions of people are addicted would be dangerous," the government said in a brief to the Supreme Court. The agency also feared the effects of a black market.

The major tobacco companies and their allies immediately challenged the regulations as outside the scope of the law in federal court in North Carolina, and eventually won their case before a federal appeals court.

The companies also complained to the media and to Congress that even if the FDA did not outlaw tobacco, FDA regulation would open up the opportunity for private lawsuits that would inevitably force the agency to ban the product as a "dangerous drug."

Speaking before the Supreme Court for the FDA Wednesday, U.S. Solicitor General Seth Waxman said nicotine acts on the body in four "quintessentially drug-like ways": It is "highly addictive," and it simultaneously acts as a sedative, a stimulant and an appetite suppressant.

Waxman also rejected the argument that because a product faces the possibility of an outright ban, it should not be regulated.

Arguing for the major tobacco companies, Washington attorney Richard Cooper contended that a raft of laws passed by Congress and aimed specifically at tobacco "preclude FDA regulation."

Congress enacted the federal Food, Drug and Cosmetic Act in 1938, and President Franklin Roosevelt signed it into law. Besides eventually providing the FDA with its mandate, the act expanded the legal definition of a "drug" to include non-food "articles intended to affect the structure or any function of the body of man or other animals."

Cooper argued Wednesday that "the purpose of this statute is to regulate a product that claims to have benefits" for health or cosmetic reasons. Tobacco products have never made those claims in the marketplace, Cooper repeatedly argued, and therefore do not come under the provisions of the act.

The 1960s federal law requiring cigarettes to carry warning labels but not requiring a ban on tobacco

"shows there's more at stake than health," Cooper said, adding that there are "economic issues and issues of (personal) choice....These are beyond the FDA."

In rebuttal, Waxman argued that an industry should not be allowed to escape regulation just by not claiming that a product had "benefits." He said, "It would create the largest regulatory hole in existence."

The Supreme Court is expected to rule in the case within the next several months.

LANGUAGE: ENGLISH

LOAD-DATE: December 1, 1999

THE WHITE HOUSE

Office of the Press Secretary

Administration decides to appeal to Supreme Ct

For
Immediate Release

August 14, 1998

STATEMENT BY THE PRESIDENT

The Solicitor General has today authorized the filing of a petition in the Court of Appeals for the Fourth Circuit seeking rehearing en banc of the three-judge panel's decision regarding FDA regulation of tobacco products. I am firmly committed to the FDA's rule and its role in protecting our children from tobacco. Confirming the FDA's authority over tobacco products is necessary to help stop young people from smoking before they start by stopping advertising targeted at children and curbing minors' access to tobacco products. Almost 3,000 young people become regular smokers each day, and 1,000 of them will die prematurely as a result. If the leadership in Congress would act responsibly, it would enact bipartisan comprehensive tobacco legislation to confirm the FDA's authority and take this matter out of the courtroom.

-30-30-30-

Supreme Ct agrees to hear case

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release April 26, 1999

STATEMENT BY THE PRESIDENT

I am very pleased that the Supreme Court has agreed to take up the case regarding the Food and Drug Administration's regulation of tobacco products. Almost three years ago, the FDA put in place a regulation to protect our children from tobacco, which the tobacco companies challenged in court. Every day, 3,000 young people become regular smokers and 1,000 will have their lives cut short as a result. 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.

###

One pager on case from FDA

FDA BACKGROUNDER

CURRENT & USEFUL INFORMATION FROM THE FOOD & DRUG ADMINISTRATION

Summary of U.S. Court of Appeals for the Fourth Circuit Ruling on FDA's Jurisdiction Over, and Regulation of, Cigarettes and Smokeless Tobacco

Aug. 21, 1998

On Aug. 14, 1998, a majority of a three-judge panel of the U.S. Court of Appeals for the Fourth Circuit in Richmond, Va., ruled that FDA lacks the jurisdiction to regulate tobacco products, reversing the decision of the U.S. District Court for the Middle District of North Carolina. Because the majority found that the agency lacked jurisdiction, it invalidated FDA's Aug. 28, 1996, regulations that restricted the sale and distribution of cigarettes and smokeless tobacco to children and adolescents. Circuit Judge H. Emory Widener Jr. wrote the majority opinion. Senior Circuit Judge Kenneth K. Hall wrote a dissenting opinion.

The government will seek review of this decision by the full Fourth Circuit. Under the court of appeals' rules, unless otherwise directed by the Fourth Circuit, the effect of the decision is automatically stayed, meaning the status quo is maintained until the court has the opportunity to rule on the government's rehearing request. This means, pending the court's review, the parts of the FDA tobacco program that have been in effect since February 1997 will remain in effect.

This case involves an appeal of an April 25, 1997, decision from Judge William Osteen of the U.S. District Court in Greensboro, N.C. The district court ruled that FDA does have jurisdiction under the Federal Food, Drug, and Cosmetic (FD&C) Act to regulate nicotine-containing cigarettes and smokeless tobacco as drug-delivery devices, upholding the restrictions that involved youth access and labeling, including the two provisions that went into effect Feb. 28, 1997: a prohibition on sales of these products to persons under age 18 and a requirement that retailers check photo IDs of purchasers under age 27. Judge Osteen, however, invalidated FDA's restrictions on the advertising and promotion of cigarettes and smokeless tobacco, finding that the agency exceeded its statutory authority. Both sides then appealed.

In the Fourth Circuit, the majority opinion held that FDA's jurisdiction to regulate drugs and devices does not include cigarettes and smokeless tobacco. The court, however, did not reject FDA's conclusion that these products fall within the FD&C Act's definitions of "drugs" and "devices." Instead, the majority opinion concluded, based on several sources of evidence, that Congress did not intend the FD&C Act to apply to these products. This evidence included what the court viewed as a lack of regulatory tools in the act appropriate for the regulation of tobacco products; prior statements by FDA that it lacked authority to regulate tobacco products in the absence of express claims; congressional inaction on bills to grant FDA explicit jurisdiction over tobacco products; and tobacco-specific legislation approved by Congress such as the Federal Cigarette Labeling and Advertising Act, the Comprehensive Smokeless Tobacco Health Education Act, and the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992.

Judge Hall agreed with FDA on all issues and dissented from the majority opinion. He concluded that tobacco products fit comfortably within the FD&C Act's "drug" and "device" definitions, and that the evidence falls far short of demonstrating that Congress intended to deny FDA jurisdiction over tobacco products. He wrote that he would have found that not only does FDA have jurisdiction to regulate tobacco products, but that all of FDA's regulations, including the advertising restrictions, are within the agency's authority. He explained that how FDA has chosen to regulate tobacco products has no bearing on the question of whether the agency has the authority to regulate them at all.

As noted earlier, the access restrictions in effect since February 1997 remain in effect pending the court's review of the government's rehearing request. Therefore, FDA is continuing to enforce the age and picture ID provisions of the tobacco regulations, which prohibit retailers from selling cigarettes and smokeless tobacco to persons younger than 18 years of age, and require retailers to examine the photo ID of persons younger than age 27 before selling these products to them. FDA will continue to disseminate an advertising campaign in states where contracts for enforcement are active, and will continue to bring civil money penalty actions against retailers who violate the provisions now in effect.

BG 98-4

FDA HOME PAGE

More detailed history of case from DOJ

HISTORY OF THE FDA TOBACCO CASE

THE SOLICITOR GENERAL FILES A PETITION FOR A WRIT OF CERTIORARI WITH THE SUPREME COURT SEEKING REVIEW OF THE FOURTH CIRCUIT'S REVERSAL OF THE DISTRICT COURT'S DECISION UPHOLDING THE FOOD AND DRUG ADMINISTRATION'S TOBACCO REGULATIONS

On January 19, 1999, the Solicitor General filed a Petition for a Writ of Certiorari that requests the Supreme Court to review the August 14, 1998 decision of the United States Court of Appeals for the Fourth Circuit which reversed the decision of the United States District Court for the Middle District of North Carolina. The Tobacco Companies filed their Respondents' Brief in Opposition to Petition for a Writ of Certiorari on March 22, 1999, and on April 7, 1999, the Solicitor General filed a Reply Brief for the Petitioners.

The District Court had upheld the Food and Drug Administration's (FDA) legal authority to regulate cigarettes and smokeless tobacco products as "drugs" and "devices" under the Federal Food, Drug, and Cosmetic Act.

The Fourth Circuit's August decision struck down all of the FDA's 1996 regulations that were designed to limit the access of children under age 18 to cigarettes and smokeless tobacco and to restrict the advertising that makes those products attractive to youth.

The Solicitor General's petition argues that tobacco products fall squarely within the Act's "drug" and "device" definitions because the overwhelming evidence in the administrative record shows that they are intended to affect the structure or function of the body. The petition argues further that the Court of Appeals erroneously failed to defer to the Food and Drug Administration's reasonable interpretation of the Act, as Supreme Court precedent requires.

Filing the Petition stays the issuance of the Fourth Circuit's mandate while the Supreme Court considers the government's request. The FDA's age and identification regulations therefore remain in effect pending Supreme Court review.

CASE HISTORY

On August 23, 1996, the FDA made a final determination that it has jurisdiction over cigarettes and smokeless tobacco, and issued regulations restricting the sale and advertising of tobacco products in order to protect children and adolescents.

Tobacco manufacturers, retailers, and advertisers filed several actions in the United States District Court for the Middle District of North Carolina, challenging FDA's tobacco assess and advertising restrictions on both statutory and constitutional grounds. The cases were argued before the Honorable William L. Osteen, Sr.

DECISION BY THE DISTRICT COURT

On April 25, 1997, the District Court upheld the Food and Drug Administration's legal authority to regulate cigarettes and smokeless tobacco products as "drugs" and "devices" under the Food, Drug, and Cosmetic Act.

In doing so, Judge Osteen squarely rejected the tobacco manufacturers' argument that Congress, through enactment of the Federal Cigarette Labeling and Advertising Act and other statutes, intended to prevent FDA from exercising the jurisdiction it has now exercised. Judge Osteen, moreover, also rejected the plaintiffs' claim that prior statements by FDA officials relating to the agency's tobacco jurisdiction were binding in the face of new evidence.

Judge Osteen also upheld the FDA's application of its combination product and restricted devices provisions to these products. The Court concluded that tobacco products are "combination products," within the meaning of the FDCA, consisting of both drug and device components, and that FDA has the discretion to regulate tobacco pursuant to its device authorities. Finally, the Court concluded that the access restrictions and labeling requirements imposed by the agency were permissible exercises of its device authorities, but that the advertising and promotion restrictions were not. The regulations concerning advertising and promotion were enjoined.

Judge Osteen held, purely as a matter of statutory interpretation, that the FDA's restricted device authority (21 U.S.C. § 360j(e)) did not permit the agency to regulate tobacco advertising and promotion. Judge Osteen held that the grant of statutory authority under this provision, which allows FDA to establish "such other conditions" on the sale, distribution, and use of devices, did not allow FDA to restrict tobacco promotion or advertising. As a result of this construction of the statute, which invalidated the FDA's tobacco advertising restrictions, Judge Osteen did not reach the First Amendment issues the plaintiffs had raised.

On May 9, 1997, after Judge Osteen had issued his decision, one industry plaintiff, the Point of Purchase Advertising Institute, asked the Judge to amend his Order to say that self-service tobacco displays are advertising and promotion beyond FDA's reach, and not a means of access to tobacco products subject to FDA regulation. On June 4, 1997, Judge Osteen rejected that argument, and therefore declined to amend his Order.

TOBACCO COMPANY BRIEFS IN DISTRICT COURT

In their First Brief, filed October 15, 1996, the plaintiffs argued that FDA has no authority over tobacco products under the Food, Drug, and Cosmetic Act so long as they are sold without express medical claims, and that Congress has withheld such authority from FDA by enacting the Federal Cigarette Labeling and Advertising Act, Comprehensive Smokeless Tobacco Health Education Act, and other statutes.

In their Second Brief, filed October 15, 1996, the plaintiffs argued that tobacco products are not

"drugs" or "devices" as those terms are defined in the Food, Drug, and Cosmetic Act, and that FDA is misapplying the device laws to those products, further demonstrating that the agency does not have jurisdiction over those products.

In their Third Brief, filed October 15, 1996, the plaintiffs contended that FDA's regulations addressing tobacco advertising (which, among other things, limit most advertisements to black and white text, prohibit outdoor advertising within 1,000 feet of schools or playgrounds, and ban brand name sponsorships of sporting and cultural programs) violate First Amendment protection of commercial speech.

GOVERNMENT RESPONSE BRIEF IN DISTRICT COURT

The government filed one unified Response Brief to respond to all of the plaintiffs' briefs. The government argued:

(1) By enacting the Federal Food, Drug, and Cosmetic Act, Congress provided the FDA with the authority to regulate cigarettes and smokeless tobacco, and nothing that Congress has done in the past, either by affirmatively enacting other legislation or by inaction, has deprived FDA of that authority;

(2) FDA's finding that cigarettes and smokeless tobacco meet the Act's drug and device definitions because they are intended to affect the structure or function of the body, and its regulation of cigarettes and smokeless tobacco under the Act's device provisions, are appropriate exercises of its authority under the Act; and

(3) The restrictions adopted by FDA on advertising and other promotional activities for cigarettes and smokeless tobacco are consistent with the First Amendment.

AMICUS BRIEFS IN DISTRICT COURT

A number of states and private parties filed amicus ("friend of the court") briefs supporting or opposing FDA's regulation of tobacco. Amicus Brief 1 submitted in support of FDA by Public Citizen, National Center for Tobacco Free Kids, American Academy of Pediatrics, American Cancer Society, American College of Preventive Medicine, American Heart Association, American Lung Association, American Medical Association, American Medical Women's Association, American Public Health Association, American Society of Addiction Medicine, The HMO Group, National Association of African Americans for Positive Imagery, National Association of Elementary School Principals, National Association of Secondary School Principals, and National PTA. The groups argued that: Congress has not precluded FDA from regulating tobacco products; the Food, Drug, and Cosmetic Act authorizes FDA to regulate tobacco products; and FDA's regulations pass muster under the First Amendment.

Amicus Brief 2 of the State of Minnesota on behalf of itself and 32 other states, the territory of

Guam, and the City of San Francisco, California. The State of Minnesota argued in support of FDA's regulations that FDA's authority to regulate tobacco products is: authorized by law; not preempted; and an important part of the traditional federal and state concurrent regulation of matters affecting the public health and safety.

REPLY BRIEFS IN DISTRICT COURT

The plaintiffs, tobacco manufacturers and others, filed on December 23, 1996, three briefs in reply to the Government's Response Brief (above). Reply Brief 1, and Reply Brief 2, Reply Brief 3 reiterated the arguments made in the Tobacco Company Briefs (above).

PROCEEDINGS IN THE FOURTH CIRCUIT

The government and many of the industry plaintiffs appealed various aspects of the District Court's ruling to the Fourth Circuit Court of Appeals. The government appealed the District Court's decision that FDA lacks authority to regulate the promotion and advertising of tobacco products, and the Court's decision to enjoin certain access and labeling regulations that the Court had found to be within FDA's authority. The industry plaintiffs appealed the remainder of Judge Osteen's decision.

The government filed its opening brief on June 11, 1997. In that brief, the government argues that FDA has reasonably interpreted 21 U.S.C. § 360j(e) to authorize restrictions on advertising and promotion of tobacco products. The government also argues that there is no basis for the District Court's preliminary injunction against the access and labeling regulations.

In addition, two sets of groups filed amicus ("friend of the court") briefs in support of FDA. The State of Minnesota on behalf of itself, 37 other states, and the City of San Francisco, California filed a brief arguing that FDA's regulation of tobacco is well within its jurisdictional authority and that FDA's regulation of the advertising and promotion of tobacco products is fully consistent with the Federal Food, Drug, and Cosmetic Act.

Public Citizen, American Academy of Pediatrics, American Cancer Society, American College of Preventive Medicine, American Heart Association, American Lung Association, American Medical Association, American Medical Women's Association, American Public Health Association, American Society of Addiction Medicine, The HMO Group, National Association of Elementary School Principals, National Association of Secondary School Principals, and National Center for Tobacco-Free Kids, also filed an amicus brief in which they argue that FDA has authority to regulate tobacco products and to regulate the adverting and promotion of those products.

The industry filed its opening brief and response to the government's brief on June 27, 1997, along with supplemental briefs by the smokeless tobacco, advertising, and convenience store plaintiffs. The government filed its combined response to the industry brief and reply on July 14, 1997. The

industry's reply brief was filed on July 28, 1997.

On August 11, 1997, in Warm Springs, Virginia, a panel of the Court of Appeals for the Fourth Circuit, Circuit Judges Russell and Hall and Senior District Court Judge Michael, heard oral arguments on the issues raised by these appeals. Acting Solicitor General Walter Delinger argued for the government. Richard Cooper, of Williams & Connolly, argued for the plaintiff tobacco manufacturers. Larry Sitton, of Smith, Helms, Mullins & Moore, argued for the smokeless tobacco plaintiffs. John Oberdorfer, of Patton & Boggs, argued for the advertiser plaintiffs. William MacLeod, of Collier, Shannon, Rill & Scott, argued for the convenience store plaintiffs.

Due to the death of Judge Russell, on April 16, 1998, the Court of Appeals ordered that the case be reargued and on June 9, 1998, in Charleston, West Virginia, a panel of the Court, Circuit Judge Widener, Senior Circuit Judge Hall and Senior United States District Judge Michael, reheard oral arguments on these appeals. Gerald Kell argued for the government. Richard Cooper, of Williams & Connolly, argued for the plaintiff tobacco manufacturers. Larry Sitton, of Smith, Helms, Mullins & Moore, argued for the smokeless tobacco plaintiffs. John Oberdorfer, of Patton & Boggs, argued for the advertiser plaintiffs. William MacLeod, of Collier, Shannon, Rill & Scott, argued for the convenience store plaintiffs.

On August 14, 1998, the Court of Appeals issued its decision reversing the decision of the United States District Court. On September 25, 1998, the United States petitioned the Fourth Circuit for rehearing by the panel or by the Court en banc. In its petition for rehearing, the government noted that important public health issues were at stake and argued that the panel majority failed to follow the analytical course prescribed by the Supreme Court in Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984).

On November 10, 1998, the United States Court of Appeals for the Fourth Circuit denied the government's petition. Six judges voted against rehearing en banc (Widener, Ervin, Niemeyer, Luttig, Williams, and Traxler), three voted for (Murnaghan, M. Blane Michael, and Motz), and four did not participate (Wilkinson, Wilkins, Hamilton, and King). On November 18, 1998, in response to the government's request, the Fourth Circuit granted a 30 stay of the issuance of the mandate, and on December 17, 1998, extended the stay for another 30 days. With the filing of the government's Petition for a Writ of Certiorari, the issuance of the Fourth Circuit's mandate continues to be stayed pending Supreme Court review.

April 21, 1999
This summary, with links to referenced court briefs, is posted on the Department of Justice's web site at http://www.usdoj.gov/civil/cases/tobacco/index.htm.

About the FDA Rule

FDA Rule: Asserting its authority over tobacco products, the FDA in June 1996 issued regulations which prohibited the sale of tobacco products to minors. Specifically, the Rule establishes:

1) Youth Access Restrictions
- Sets minimum age of purchase at 18 years
- Requires age verification by photo ID for anyone 26 or younger
- Requires face-to-face sales (except for mail order sales)
- Bans vending machines and self-service displays except in facilities where only adults are permitted

2) Advertising Restrictions
- Bans outdoor advertising within 1000 feet of schools and public playgrounds
- Restricts advertising to black-and-white text only (publications, outdoor, point of purchase, direct mail, etc.), except in publications with a predominant adult readership or at adult only facilities
- Prohibits sale or giveaways of products like caps or gym bags that carry cigarette or smokeless tobacco product brand names or logos
- Prohibits brand-name sponsorship of sporting or entertainment events, but permits it in the corporate name

3) Point of Purchase Restrictions
- Prohibits sales of single cigarettes or "loosies"
- Bans free samples
- Sets minimum package size at 20 cigarettes
- Restricts all point of purchase advertising and labeling to black-and-white text only, except in adult only facilities

Comparison of FDA Tobacco Rule and 1998 Attorney General Tobacco Industry Agreement

	1996 FDA Rule	1998 Attorney General Tobacco Industry Agreement
Youth Access Restrictions	Sets 18 as minimum age for purchasing tobacco products and requires retailers to check photo ID of anyone who appears younger than 27 (implemented in Feb. 1997)	Not Required
Vending Machines	Limits vending machine sales and self service displays to places where minors are not allowed.	Not Required
Minimum Pack	Prohibits the sale of loose cigarettes and requires min. "20" packs.	Requires minimum "20" packs..
Giveaways	Prohibits free giveaways of tobacco products	Free Sampling limited to adult facilities.
Outdoor Advertising	Bans outdoor tobacco advertising within 1,000 ft. Of schools and playgrounds.	Bans billboards and transit ads but permits small signs on buildings were tobacco is sold, including near schools.
Advertising Images	Limits all outdoor advertising to b&w text only. Display advertising using color or images is allowed only insidc places minors are not allowed to enter.	Not Addressed
Print Media	Limits advertising in publications with signicant youth readerhip to b&w only.	Newspaper and magazine ads not limited
Brand Name Merchandise	Prohibits industry sales or giveaways of non-tobacco merchandise or products that carry brand names or logos.	Bands tobacco brand name merchandise, except at tobacco sposored events.
Offers of Non-Tobacco Items or Gifts Based on Proof of Purchase	Prohibits industry from giving away non-tobacco items in exchange for the purchase of tobacco.	Banned to children.
Brand Name Sponsorship	Prohibits industry from establishing brand name sponsorship of sporting or entertainment events, but permits it in the companies' corporate names.	Prohibited for concerts, events in which any contestants are under 18, or in football, baseball, soccer, or heckey; except for Kool jazz Festival or GPC Country Music Festival. Otherwise limitd to one event or series annually (i.e., Winston Cup Race Tour)
Tobacco Product Placement in Movies and on TV	Not Addressed	Banned

About FDA authority as incorporated into McCain bill (separate chapter etc) (1)

Affirming FDA Authority to Prevent Advertising and Marketing to Children

By reaffirming the full authority of the FDA to regulate tobacco products, S.1415 will prevent the tobacco industry from advertising and marketing to children, and establish tough access restrictions on tobacco products to stop sales to children.

Reaffirms 1996 Rule: Many of the measures to reduce teen smoking and protect the public health contained in S.1415 are in the 1996 FDA rule, but have not yet gone into effect because of pending litigation. The bill would put these provisions into effect immediately, protecting American children from the dangers of smoking. These provisions include: 1) banning outdoor advertising within 1000 feet of schools and playgrounds; 2) restricting advertising to black-and-white text only except in adult only facilities or publications with predominantly adult readership; 3) prohibiting the sale or giveaway of promotional products with brand names or logos; 4) prohibiting brand-name sponsorship of sporting or entertainment events; 5) setting the minimum age for purchase of tobacco products at 18 years and requiring age verification for anyone age under 27.

Creates a Separate Chapter for Regulating Tobacco: S.1415 creates a separate chapter in the Food, Drug and Cosmetic Act that gives the FDA explicit authority over access to and advertising of tobacco products, in order to ensure that FDA regulation of tobacco does not impinge on the regulation of other products.

Establishes New Standard for Regulating Tobacco: Instead of requiring tobacco products to meet the traditional safety and efficacy standard required of drugs and devices, S.1415 imposes a new standard which would require FDA regulation of tobacco products to be "appropriate for the protection of public health". This standard better meets the characteristics of tobacco products and allows the FDA to take the addiction of over 40 million Americans into account in making decisions about how to regulate these products.

Provides Necessary Flexibility: Full FDA authority to regulate tobacco products provides the agency with the flexibility it needs to protect the public health. However, any FDA effort to eliminate any particular class of tobacco products or eliminate nicotine cannot go into effect for two years in order to provide Congress with an opportunity to weigh in and vote on the measure.

Preserves State and Local Authority: S.1415 makes clear that except as expressly provided, states and localities may adopt and enforce tobacco product requirements that are in addition to, or more stringent than, requirements established under the Food, Drug and Cosmetic Act for tobacco products.

Provides Full Enforcement Authority: S.1415 provides for the same civil and criminal penalties that the agency may use in enforcing device law.

(2)

Summary of FDA Provisions in S.1415

- **Overview of FDA Provisions:** S. 1415 creates a separate chapter in the FDCA that explicitly gives FDA authority over access to and advertising of tobacco products. In nearly all respects this authority is comparable to the authority that FDA asserted in its 1996 rule, which asserted FDA jurisdiction over tobacco products on the ground that nicotine is an addictive drug and that cigarettes and smokeless tobacco products are combination drug/device products under the Federal Food, Drug and Cosmetic Act (FDCA). S.1415, however, created a separate chapter in order to respond to concerns raised by medical device companies that tobacco statutory interpretations and other policies issued under the device provisions of the FDCA could adversely affect those companies.

  The most significant difference between S. 1415 and current law is the standard that products must meet in order to be marketed. Under current law the standard is "reasonable assurance of safety and effectiveness." This standard obviously does not fit tobacco products because tobacco products are inherently unsafe. Therefore, S. 1414 adopts the standard of "appropriate for the protection of the public health," which allows FDA to take into account the fact that over 40 million Americans are addicted to tobacco in making decisions about how to regulate the product.

- **1996 FDA Tobacco Rule in Effect:** S. 1415 provides that the tobacco regulation that FDA finalized in 1996 will remain in effect as though it were issued under the new law. Because the effective date of certain portions of the regulation has been delayed due to the industry's judicial challenge to the rule, the bill would authorize FDA to establish effective dates for those provisions not yet in effect.

- **Access Restrictions:** S. 1415 authorizes FDA to establish restrictions on the sale or distribution of tobacco products. By affirming the 1996 rule's access restrictions, the bill sets the minimum age of purchase at 18 years; requires age verification by photo ID for anyone 26 or younger; requires face-to-face sales (except for mail order sales); bans vending machines and self-service displays except in facilities where only adults are permitted; prohibits the sales of single cigarettes or "loosies"; bans free samples; and sets the minimum package size at 20 cigarettes. However, S. 1415 constrains FDA from prohibiting the sale of tobacco products in face-to-face transactions by specific categories of retail stores (such as a ban on sale of cigarettes by gas stations).

- **Advertising Restrictions and Warning Labels:** S. 1415 expressly authorizes FDA to establish restrictions related to the advertising and promotion of a tobacco product. By affirming the 1996 rule's advertising restrictions, the bill bans outdoor advertising within 1000 feet of schools and public playgrounds; restricts advertising to black-and-white text only (publications, outdoor, point of purchase, direct mail, etc.), except in publications with a predominant adult readership or at adult only facilities; prohibits the sale or giveaways of products like caps or gym bags that carry cigarette or smokeless tobacco product brand names or logos; and prohibits brand-name sponsorship of sporting or entertainment events, but permits it in the corporate name.

(3)

S. 1415 also requires stronger and larger warning labels than existing law on tobacco products (to replace the "Surgeon General's warning"), and provides authority for FDA to modify the text, format, and type size requirements of these statements.

- **Submission of Health Information to the Secretary**: S. 1415 requires tobacco product manufacturers and importers, within 6 months of enactment (and annually thereafter), to submit to FDA specific categories of information relevant to FDA regulation of tobacco products.

- **Good Manufacturing Practice Requirements:** Authorizes FDA to issue regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, of a tobacco product conform to good manufacturing practice (GMPs). The bill also makes explicit that the Secretary has the authority to grant either temporary or permanent exemptions or variances from a GMP requirement.

- **Performance Standards:** S. 1415 confirms FDA's authority to issue standards for tobacco for tobacco products (for example limiting the amount of certain ingredients) if FDA determines that a standard is appropriate for protection of the public health. This authority is the same as that for devices.

  -- In issuing a performance standard, FDA must consider the health effects on tobacco users as well as potential users (such as children).

  -- In order to give Congress a chance to vote on any standard that eliminates all cigarettes, all smokeless tobacco products, or any similar class of tobacco products, or requires the reduction of nicotine yields of a tobacco product to zero, such a standard will not go into effect until two years after the President has notified Congress of such a standard.

- **Testing and Reporting of Tobacco Smoke Constituents:** S. 1415 directs the Secretary to issue regulations to require the testing, reporting, and disclosure of tobacco smoke constituents (e.g., tar, nicotine and carbon monoxide) and ingredients that "the Secretary determines should be disclosed to the public in order to protect the public health."

- **Reduced Risk Tobacco Products:** S. 1415 contains a provision that allows FDA to designate a product as a "reduced risk tobacco product" if it finds that "the product will significantly reduce harm to individuals caused by a tobacco product and is otherwise appropriate to protect the public health."

(4)

- **Preservation of State and Local Authority**: S. 1415 makes clear that except as expressly provided, states and localities may adopt and enforce tobacco product requirements that are in addition to, or more stringent than, requirements established under FDCA for tobacco products.

  -- State and local requirements related to access and advertising are not preempted by the FDCA.

  -- State and local requirements related to performance standards, good manufacturing practices, and other similar FDCA requirements, are preempted, but States and localities may apply for exemptions pursuant to procedures that parallel provisions in device law.

  -- S.1415 modifies the Federal Cigarette Labeling and Advertising Act in order to ensure that restrictions on advertising imposed under State laws are not preempted.

- **Full Enforcement Authority:** S. 1415 provides for the same civil and criminal penalties that the agency may use in enforcing the device law. The bill also provides that FDA may issue, after an administrative hearing before an Administrative Law Judge, a no tobacco sale order prohibiting the sale of tobacco products at a particular retail outlet based on repeated violations by that outlet. The bill also imposes the same requirements for the export of tobacco products that do not meet the requirements of the FDCA that apply to devices.

Museum Sues In Bid to Keep Big Meteorite

By BENJAMIN WEISER

The American Museum of Natural History asked a federal court in Manhattan yesterday to declare the museum the rightful owner of one of its oldest and most treasured exhibits, the 15-ton Willamette Meteorite, which an Indian group in Oregon is claiming as a sacred tribal object.

The Indian group, the Confederated Tribes of the Grand Ronde Community of Oregon, has requested the return of the meteorite under a federal law that allows for the repatriation of Native American cultural and religious artifacts from museums that get government money.

But the museum contends that the meteorite, which is believed to have fallen to earth 10,000 years ago from the asteroid belt between Mars and Jupiter, is not the kind of sacred object covered by the law, known as the Native American Graves Protection and Repatriation Act of 1990.

In its lawsuit filed in Federal District Court in Manhattan, the museum contended that the meteorite, which was found in the Upper Willamette Valley in Oregon, was "a natural feature of the landscape, rather than a specific ceremonial object," as described in the law.

"We feel we have a strong case under the law," said Evan A. Davis, a lawyer for the museum, which has placed the meteorite prominently in its $210 million Rose Center for Earth and Space, which opened recently to large crowds and enthusiastic reviews.

The meteorite, which sits on a steel pedestal in the planetarium's Cullman Hall of the Universe, is so big that parts of the museum had to be built around it, officials have said. The museum bought it for $20,600 in 1906 from the Oregon Iron and Steel Company, which owned the land on which it was found.

The land had been given up voluntarily by various Indian tribes in an 1855 treaty with the United States for reservation land and other considerations, the lawsuit said.

Leonard J. Bergstein, a spokesman for the tribes, said the confederation was shocked that the museum "insists on illegally keeping this sacred object, which belongs to the history and culture of the Grand Ronde people."

"The museum should do the right thing," he said, "and resolve this dispute now directly with our tribes, instead of marching us off to a court behind a squadron of attorneys."

Mr. Davis said that the museum went to court after representatives of the Indian group refused the museum's request for further negotiations, and wrote to the museum that "the only acceptable resolution of this matter will be through the unconditional repatriation of the Willamette Meteorite."

Neil deGrasse Tyson, the director of the planetarium, estimated that 40 million to 50 million people have seen the meteorite, including "untold numbers of visitors who were turned on to science because of their encounter with this meteorite."

Executive Says Philip Morris Is Open to Some Regulation

By BARRY MEIER

A top executive of the Philip Morris Companies, the nation's largest cigarette maker, said yesterday that it would no longer oppose some government regulation of the tobacco industry.

The company's senior vice president, Steven Parrish, said the company still opposed efforts by the Food and Drug Administration to classify nicotine as a drug and cigarettes as drug-delivery devices.

But Mr. Parrish said the company would be willing to talk with federal officials like those at the F.D.A. and others, including antismoking advocates, about regulating cigarettes in such areas as marketing and selling to young people, disclosing ingredients and conducting research on safer products.

Mr. Parrish's comments come as Philip Morris tries to recast its tarnished image and are the strongest indication yet that the cigarette giant would accept some government regulation.

"We believe that there should be be some discussion about what is the right way to regulate tobacco," said Mr. Parrish, who is expected to outline the company's position in a panel discussion on Thursday at a meeting of experts on smoking and health in California.

Yesterday, two antismoking advocates who were told of the company's stance expressed sharply different views.

Dr. David A. Kessler, the former head of the F.D.A., said in a telephone interview that he welcomed the step, calling it "historic."

"Of course, you need to look at this with a degree of skepticism," said Dr. Kessler, the dean of the Yale Medical School. "But the fact that Philip Morris has said that this product needs to be regulated is historic."

Matthew Myers, the executive director of the Campaign for Tobacco-Free Kids, an advocacy group in Washington, said he was highly suspect of the company's position, which he said he viewed as a pre-emptive strike.

"I think that Philip Morris believes that cigarettes will be forced to accept some form of government regulation and what they are trying to do is foreclose government action," Mr. Myers said.

At the moment, however, the major problems faced by Philip Morris and other cigarette makers are in the courtrooms rather than legislative forums.

A Miami jury is expected to award punitive damages soon against the tobacco industry in a major class-action lawsuit brought on behalf of Florida smokers.

Also, the United States Supreme Court is expected to soon decide the issue of whether the F.D.A. was given authority by Congress to regulate the tobacco industry. Arguments in that case were heard last year and most justices appeared skeptical of arguments by the government that Congress had delegated that power to the F.D.A.

Mr. Parrish said he believed it was important to begin a public discussion about the best way to regulate tobacco soon after the Supreme Court made its decision.

"We want to be an interested party with a seat at the table," Mr. Parrish said.

Mr. Parrish said Philip Morris was still opposed to regulating nicotine as a drug, but he added: "We ought to take a step. Here is a product that is addictive. So what is the right way to regulate tobacco as tobacco rather than to characterize it as something that it is not, a medical device or pharmaceutical?"

Still opposed to calling nicotine a drug, but willing to discuss other limits on cigarettes.

Opponents of smoking have long taken the position that nicotine is a drug and should be regulated as one.

The comments of the Philip Morris official are part of a recent effort by the cigarette maker to recast its image after being battered in courtrooms and public forums as the battle over cigarettes intensified in recent years.

The effort includes several initiatives intended to convince the public that the company is willing to address the problems associated with its products.

Last year, when it started a new Internet site, Philip Morris acknowledged for the first time that scientific evidence showed that smoking causes lung cancer and other deadly diseases, after decades of disputing the findings of the surgeon general.

The company also recently announced that after a decade of research it had developed a new type of cigarette paper that would reduce the likelihood of fires being started by dropped cigarettes.

The New York Times

TUESDAY, FEBRUARY 29, 2000

Clinical Trials Database for Patients Goes Online

WASHINGTON, Feb 28 (AP) — The federal government will open a database on Tuesday of all clinical trials for serious illnesses, with simple explanations of how the experiments work and what questions patients should ask before enrolling to ensure that they understand the risks.

Each study lists a phone number that can be used to call researchers about enrolling and to ask questions about the study. Less than 5 percent of American patients now enroll in such medical experiments.

"This is a single place you can go where the most important information, we hope, will be available to everybody," said Dr. Donald Lindberg of the National Library of Medicine, which is opening the registry, http://clinicaltrials.gov.

Commissioner Jane E. Henney of Food and Drug Administration advised people to seek a doctor's help in sifting through the studies, and then, when entering a study, to take along a friend or relative to hear researchers explain the risks and benefits.

"If they don't understand something, it might be that you didn't either," Ms. Henney said. Patients "are very vulnerable for information that might sound too hopeful," she said.

The free database so far contains 4,000 studies at 47,000 sites nationwide, mostly sponsored by government agencies or universities. Congress has mandated that the registry be comprehensive, so more studies, particularly drug company trials, will probably be added.

A handful of other Internet sites also are trying to list certain clinical trials; the communications company CenterWatch claims over 200,000 visitors a month check its site, www.centerwatch.com.

Clinical trials are vital to medical progress, enabling doctors to treat and understand disease better. They can offer patients access to cutting-edge therapies and, because participants are supposed to be so strictly monitored, first-rate care.

But there are caveats. Patients may not get the experimental treatment, but a placebo or standard care for comparison. And the research could be in such an early stage, or the person so sick, that the only reason to participate is to help future patients.

Or the experiment could fail or be harmful. Indeed, experts are questioning the oversight of clinical trials after an Arizona teenager died in a University of Pennsylvania gene therapy experiment. The boy's father told Congress he was misled about the risks.

Consequently, getting involved can be a hard decision.

"It was very tough," Patrick Cotter of Madison, Wis., said of enrolling his daughter Colleen, now 8, in a study of the drug Enbrel for juvenile rheumatoid arthritis. Standard medicines were helping Colleen, but they have toxic long-term effects.

"It took us three months to decide," Mr. Cotter said, but Colleen started testing Enbrel two years ago and is doing well. "It was the best thing we ever did," he said.

There is fierce competition for such patients. Pharmaceutical companies usually need about 4,000 people to test an experimental drug. Companies often pay doctors up to $2,500 for every patient they recruit.

Scientists Say Cell Treatment Can Reverse Diabetes in Mice

WASHINGTON, Feb. 28 (Reuters) — Scientists said today that they had used stem cells, "master cells" that are the source of new cells in the body, to reverse diabetes in mice.

The scientists at the University of Florida said their experiment was a first demonstration that the cells were as valuable as researchers had said they would be in treating disease.

The scientists said they had started testing human cells in the laboratory and thought that those cells would also work.

Stem cells have been the subject of much interest since their potential was discovered just over a year ago. Researchers said the cells could be used as tissue transplants, or even as a source to grow whole new organs.

Blood stem cells are routinely used to replenish the bone marrow of cancer patients when chemotherapy or radiation therapy destroys it. The other stem cells are elusive, but have been identified in the brain, muscles and other organs.

One example often cited by those who press for more stem cell research is the method's potential to treat diabetes.

Dr. Ammon Peck and the team at Florida say they have finally shown the method's value. Writing in the journal Nature Medicine, they said they isolated stem cells from the pancreases of mice, got them to grow, transplanted them into diabetic mice and showed that they worked to produce insulin.

Type-I or juvenile diabetes is caused when a person's immune system mistakenly turns against insulin-producing cells and destroys them. A person with the disease no longer produces enough insulin to control levels of blood sugar and must take insulin daily. About 10 percent of the estimated 16 million Americans with diabetes have type-I diabetes.

Scientists have tried to transplant the insulin-producing islet cells, but the method does not work well and the cells are scarce. The hope has been that stem cells could be used instead.

"To reverse diabetes, you need to either take a transplant of the whole pancreas or the islets," said Dr. Desmond Schatz, a professor of pediatrics and a diabetes expert who worked on the experiment. "Here the potential is you can take stem cells, grow them up, and they grow into islets that are capable of reversing disease."

Scientists do not really know what a stem cell looks like; they only know they produce more cells. Islet cells, Dr. Schatz's team knew, come from cells known as pancreatic ductal epithelial cells, so they took some of those cells and grew them in a culture in the hope that they would get stem cells.

Apparently, they did: in laboratory dishes the cells seemed to produce insulin in response to sugar. Those cells were then implanted in mice specially bred to develop diabetes.

'Master cells' make new cells that produce insulin.

"We were able to show a reversal" for a short period, Dr. Schatz said.

The scientists killed their mice to look at the cells, so they did not know how long the effects would have lasted.

"The next step is take this into humans," Dr. Schatz said. "In preliminary experiments it appears that we can take human pancreatic duct cells and show that they can differentiate into islet cells as well."

Dr. Schatz said the source of the stem cells was organ donors, people who have died of various causes and donated their organs.

One of the controversial sources of stem cells is early embryos, usually left over from efforts to make test-tube babies. Dr. Schatz said that if organ donors could be used as a source, "you could potentially bypass embryonic cells."

The journal article "emphasizes the enormous potential of stem cell therapy," David Sachs and Susan Bonner-Weir of Joslin Diabetes Center in Boston wrote in a commentary.

The New York Times

TUESDAY, FEBRUARY 29, 2000

A Tobacco Giant Backs FDA Role

Philip Morris Shifts Stand on Marketing

By JOHN SCHWARTZ
and MARC KAUFMAN
Washington Post Staff Writer

A1

Philip Morris Cos., the nation's largest tobacco producer, is willing to allow the Food and Drug Administration to regulate the marketing of cigarettes for the first time, a top company official said yesterday.

While the full ramifications of the announcement remain far from clear, and the details would have to be worked out in negotiations, the move marks a major shift by a company that has steadfastly resisted government regulation for decades.

"I could see at some point in the future an appropriate way to regulate tobacco products," said Steven Parrish, the company's senior vice president, in a telephone interview.

The tobacco industry only agreed in the past to some federal regulation in exchange for settling an onslaught of lawsuits by states seeking to recover the costs of treating sick smokers. But that offer was never put into effect because federal tobacco legislation aimed at implementing it failed in a bitter fight in the Senate two years ago.

The resurrection of the issue comes in the midst of a major effort by Philip Morris to rehabilitate its public image following recent revelations that the tobacco industry knew much more about the dangers and addictiveness of smoking than previously acknowledged.

Nevertheless, the move was hailed as a major advance by some of the industry's most vocal critics.

The Philip Morris statement is "a very big step—an enormous step," said former FDA Commissioner David Kessler, who led the fight to regulate the tobacco industry. "This is real progress, and there's no question but that we need to move ahead."

Philip Morris' apparent willingness to negotiate federal regulations without any promises of receiving protection from lawsuits is a significant shift that should change the political dynamics of the debate over tobacco, he said.

Bruce Reed, the Clinton administration's chief domestic policy adviser and point man on tobacco, said that he was heartened by the company's new willingness to discuss regulation. But he said the importance of the step "is in the details . . . If Philip Morris is serious about supporting the FDA provisions of the tobacco bill, that's progress."

While Parrish said he was only speaking for his own company, the turnaround could set the tone for the entire industry, since Philip Morris is by far its dominant player. Other major tobacco companies could not immediately be reached for comment last night.

Parrish said he would formally announce his proposal Thursday while speaking, along with Kessler and others, at a forum in California sponsored by Columbia University's Center on Addiction and Substance Abuse.

As Parrish described it, what is new at his company is a desire to be more open with the public and to open a "dialogue" with longtime adversaries. He had few details about how he thought tobacco should be regulated, saying, "I don't want the world to think that I or Philip Morris would be so arrogant as to say, 'Here's how we think it should be.' "

A source familiar with the company's position said Philip Morris would be willing to accept some regulation over the firm's marketing and sales activities. In addition, the company could accept some regulation of the composition of cigarettes, potentially including nicotine levels. But the company would not accept what the industry has called "back-door prohibition"—requiring nicotine levels to drop so low that it would essentially ban the product.

When the FDA first declared that it had the authority to regulate tobacco in 1995, agency officials said they had no intention of judging the safety of tobacco or pursuing a prohibition of smoking. Instead, the agency said it wanted to gain the power to regulate the industry's sales and marketing activities in the hopes of reducing smoking by teenagers.

Parrish said that his announcement would not mean that his company was accepting the FDA's logic of how and why the industry should be regulated—that the federal government should regulate cigarettes as a drug delivery system. He said that his company still believed that the agency was wrong to assert its authority over tobacco.

In addition, he said the company had no intention of giving up its suit challenging the FDA's assertion that it has the authority to regulate tobacco products. The FDA's attempt to regulate tobacco was struck down in court, but the Justice Department appealed that decision to the Supreme Court, which heard arguments in the case in December. "We're not going to give up on the case," Parrish said.

Parrish tied the company's new stance to a series of moves by Philip Morris in the last year—most notably, frank admissions on its World Wide Web site that smoking causes disease and death and a series of advertisements that attempt to show Philip Morris's good works as a corporate citizen.

"When we launched the Web site back in October, I really talked to a lot of people about what Philip Morris wants—to have a dialogue with a whole lot of different people and groups about issues surrounding our products," he said.

Matthew Myers, president of the Campaign for Tobacco-Free Kids, warned that Philip Morris had "come forward with grand-sounding proposals in the past that failed to encompass meaningful change when you look at the details."

"The critical question is, 'What does Philip Morris mean by regulation?' " he said. "Does it consent to the same kind of regulatory authority that the FDA has over other drugs and foods—including the power to require that harmful ingredients like nicotine be reduced or eliminated if that would save lives."

The Washington Post

TUESDAY, FEBRUARY 29, 2000

Dairy Group Has a Cow Over 'Milk' That Doesn't

By Cindy Skrzycki
Washington Post Staff Writer

A1

This much is undisputed: Soybeans do not lactate.

So soy producers shouldn't be calling their beverages "milk," according to the National Milk Producers Federation, which filed a complaint with the Food and Drug Administration earlier this month seeking to banish the terms "soy milk" and "soymilk" from grocery shelves and dairy cases.

The milk producers are trying to protect the distinct identity of their product, which, they point out, comes from "the lacteal secretion" of cows, compared with soybeans, which come from the ground. "Soy-based beverages are attempting to directly compete with dairy products and are inappropriately taking advantage of the familiarity and positive image of dairy terminology in their labeling," said Rob Byrne, the association's vice president of regulatory affairs. "We don't want them using milk's good name for their product."

True, sales of soy drinks are a drop in the bucket compared with those of milk, but the popularity of soy drinks has been growing, and milk producers don't like what they see—namely that soy is showing up in the dairy case of mainstream grocery stores right alongside the 2 percent and skim.

Behind the complaint lies a growing consumer health consciousness that has set the milk industry on its heels, cutting consumption by about 24 percent over the past 30 years. The pace of decline has slowed in recent years.

It wasn't that long ago that whole milk was perceived as the most healthful food around, consumed guiltlessly with cookies, cornflakes and peanut butter sandwiches. Doctors recommended it to ease the pain caused by ulcers; insomniacs drank it warm as a nightcap.

But that was before the medical establishment began warning about butterfat, cholesterol intake and calories. Suddenly whole milk was shoved to the rear of the dairy case. Two percent took over, then 1 percent, and it wasn't long before many milk drinkers became skim drinkers, imbibing mainly for the calcium and other vitamins. By 1988, the various reduced-fat varieties outsold whole milk.

Add to that trend the legions of lactose intolerant and a proliferation of people with food allergies and you have a ready-made market for soy milk, or beverages that now come in refrigerated cartons that look remarkably like milk.

Take Kathleen Bialas. She is the dairy industry's worst nightmare.

Bialas, a lawyer who lives in the District, gave up milk entirely for soy. Every morning she has a big glass of chocolate-flavored soy milk and a homemade muffin or oatmeal instead of the cereal and milk she used to have.

"I sort of have given up drinking regular milk," said Bialas, who read about the benefits of soy milk in a health magazine and thought she'd give it a try. "It tastes slightly grainy, but I like the taste of it. I like having the calcium and isoflavones. I think milk makes me congested."

Soy and soy beverages used to appeal mostly to fringe health-food devotees until the lowly legume—in the form of tofu, supplements or drinks—moved into the mainstream in the last year or so, with advocates saying it could help with everything from hot flashes to bone loss. They boast that the good things soy can do are concentrated within the soybean, not in additives.

And the federal government helped get things along. The FDA provided a big boost when it said last year that soy products could be labeled as food that helps lower cholesterol and reduce the risk of heart disease when consumed in certain quantities—a boast that many cartons now carry. The government's nutrition guidelines also list a soy-based beverage as a way to get calcium.

The biggest buyers of soy milk are women, Asians and baby boomers trying to avoid life-shortening diseases. These health-informed consumers are after the isoflavones, a type of plant estrogen that some researchers and the soy industry say can reduce cholesterol, build strong bones and ease hot flashes.

These early adopters have boosted sales from 51 million liters in 1996 to 125 million liters last year, adding up to about $300 million in sales. There are about 35 processors of soy milk, who are now jazzing it up with chocolate, vanilla, coffee, strawberry and chai flavors.

Soy milk, which has a nutty taste, is the combination of extracted whole soybean solids or other soy proteins and water.

The soy invasion comes on the heels of years of effort by the dairy industry to lure Americans back to drinking milk, spending millions promoting their products with its milk-mustache and "Got milk?" national advertising campaigns.

Dairy producers are particularly steamed because soy fluids have metamorphosed from an unrefrigerated brick package relegated to the shelves with the rice drinks to a sleek quart container displayed prominently in the dairy case. At Giant and Safeway—even Wal-Mart—you can find a variety of brands. Cases of the stuff are piled high at Fresh Fields. They offer low-fat and non-fat varieties, nomenclature associated with dairy products, and come in quarts and half-gallons.

To bolster their case against soy products, the milk producers went on a shopping spree, tossing into their carts about 10 "violative" cartons of soy drinks that either called themselves milk as part of a brand name or listed soy milk as an ingredient. They included with their complaint to the FDA the labels of such brands as Silk Plain Soymilk, Better Than Milk Vanilla Beverage Mix and Edensoy's Organic Soy Milk.

"Although some non-dairy beverages may resemble cow's milk in appearance, they are very different in nutritional value and composition from the standardized product described in the government's regulatory code," Byrne said. He said they contain half the protein per serving of real milk.

The milk producers want the FDA to take "appropriate enforcement action," from telling makers of soy milk to knock it off to removing their products from store shelves. They suggested the soy people call their product "soy beverage" or "soya drink" to reflect that it's from a "non-bovine species"—as some soy manufacturers do.

The FDA did not indicate how it might settle the dispute, but the last time the agency spoke up on this issue, it went on record stating that the use of "milk" was "inappropriate" in labeling products that are soy-based.

"We believe the terminology is not inappropriate," said Bob Callanan, spokesman for the American Soybean Association, "given it clearly states it's soy milk. It's not milk. It's soy milk."

Soy industry officials say "milk" is a generic term attached to lots of products. Just think of coconut milk and Milk of Magnesia, said Callanan: The word is in widespread use.

Furthermore, "soy milk" is not newly coined. The term was used in ancient China, the earliest reference in Europe was in 1665, and it showed up in the United States in 1896.

The product has been around for ages, too. Research by the soy industry shows that soy milk and tofu were being made in China from A.D. 25 to 220. It's assumed that soy milk at that time was being used to make tofu. It wasn't until 1866 that a Frenchman traveling in China noted that hot soy milk was a breakfast beverage.

The Soyfoods Association of North America pointed all this out to the FDA in 1996 when it filed a petition with the agency to get approval for standardized content information and labeling of soy milk products. The FDA has not acted on that petition, the association said.

Nancy Chapman, executive director of the association, said the industry is eager to have a government standard that would settle the dispute over what soy beverages should be called.

"We'll push for a standard that says 'soymilk.' One word," she said.

The Washington Post

Tuesday, February 29, 2000