



FDA:

1. Over 700,000 comments were received on proposed FDA regulations (millions of pages).

On previous occasions involving controversial issues (generic drug rules, nutrition labeling, etc), the FDA required 2-5 years to go through comments carefully & take them into consideration.

Understand FDA trying to "shortcut this process and issue permanent reg's in just a few months

DEMOCRATIC GOVERNORS' ASSOCIATION



STATE OF NORTH CAROLINA  
OFFICE OF THE GOVERNOR  
RALEIGH 27603-8001

JAMES B. HUNT JR.  
GOVERNOR

December 21, 1995

David A. Kessler, M.D.  
Commissioner  
Food and Drug Administration  
c/o Dockets Management Branch (HFA-305)  
Food and Drug Administration, rm. 1-23  
12420 Parklawn Drive  
Rockville, MD 20857

Dear Commissioner Kessler:

I am submitting written comments on the proposed regulations by the Food and Drug Administration, "Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents."

I am strongly in favor of limiting smoking by those under the legal age. I believe that all North Carolinians, in and out of the tobacco industry, would support a strong program to reduce access to tobacco products by those under 18. However, more big government is not the way to do it. This is one more example of Washington starting with good intentions, but piling on more regulation and bureaucracy to do the job. Instead, the focus should be on supporting states and local communities in their efforts to enforce the law and educate young people.

In these proposed regulations, the FDA subverts basic principles of federalism. In 1992, Congress affirmed the traditional role of the states through the Alcohol, Drug Abuse, and Mental Health Amendments (ADAMHA) Reorganization Act. In addition, the Congressional Research Service has warned that sweeping tobacco regulations of this nature may exceed the federal government's powers under the commerce clause of the United States Constitution. Congress also has withheld jurisdiction over tobacco from the FDA for over 80 years, choosing to regulate tobacco directly or by delegating responsibility to agencies other than the FDA.



There is no need to waste months and taxpayers' dollars fighting in Congress and the courts over whether the FDA should have jurisdiction over tobacco products. States can act now to reduce the use of tobacco products by those under 18. The most effective way to do this is for state and local governments to work with merchants, parents and communities to enforce existing laws and to educate the public about the risks associated with those under the legal age using tobacco.

North Carolina is a good example of a state that has acted in this area. The State of North Carolina prohibits anyone from knowingly selling or furnishing cigarettes, tobacco for cigarettes, smokeless tobacco or cigarette papers to minors under the age of 18 (Chapter 628, G.S. 14-313, HB 852, 1991).

In addition, a new law effective December 1, 1995 tightens existing restrictions by making it illegal to distribute, or knowingly aid, assist, or abet any other person in distributing tobacco products to minors. This new law also makes it illegal for minors to attempt to purchase tobacco in North Carolina, and requires clerks to demand proof of age from a prospective purchaser if the person has reasonable grounds to believe that the prospective purchaser is under 18 years of age. With an increasing emphasis on enforcement of these laws by state and local agencies, additional federal laws or oversight by federal agencies is unnecessary to prevent those under 18 from obtaining these products.

North Carolina has not stopped with passage of tough laws. Our state, through the Department of Human Resources, also conducts an annual, random, unannounced inspection of both over-the-counter and vending machine outlets which distribute tobacco products. These inspections measure the overall level of compliance with the state law regarding youth access to tobacco products, as required by Section 1926 of the Public Health Service Act, commonly referred to as the Synar Amendment.

North Carolina also is emphasizing merchant education. The Department of Human Resources works with local organizations to develop and distribute materials to help merchants understand and carry out their responsibilities under the law.

It is my position that the intent of these regulations, reducing teenage smoking and eliminating underage smoking, can be accomplished without intruding on the rights of adults who choose to smoke and without imposing unnecessary costs on growers, manufacturers, and distributors of tobacco products.

The costs that these regulations would impose on North Carolina are substantial. The FDA has estimated that complying with these regulations on a national level will cost manufacturers \$15 million one time, and \$150 million annually. Retail sellers will have an additional \$67 million in costs annually. These do not include costs to advertisers, vending machine operators, and organizers of popular sporting events.



If we attribute these costs within North Carolina on the basis of our share of these sectors, based on a 1992 study from Price Waterhouse on the national economic impact of the tobacco industry, complying with these regulations will cost manufacturers in North Carolina \$6.3 million one time, and \$73.1 million annually. Retail sellers in North Carolina will have an additional \$2.01 million in costs annually. These costs do not include the disproportionately large impact on those small merchants who operate in poorer neighborhoods.

The proposed tobacco regulations by the FDA represent the first step toward overall regulation of tobacco, which is an important part of North Carolina's economy and community fabric. According to the North Carolina Department of Agriculture, there are 10,000 growers in North Carolina who produce crops valued at \$942.9 million in 1994. Furthermore, there are 47,837 allotment holders, many of whom no longer grow tobacco, but are the widows or children of growers, and who derive important income supplements from these allotments.

According to the Employment Security Commission, another 15,229 North Carolinians work in the production end of tobacco, with earnings valued at \$749.8 million in 1994. Thousands of other North Carolinians depend in part on earnings from tobacco through employment in wholesale distribution, retail stores, advertising, and other sectors that derive part of their revenues from sales of tobacco products. Price Waterhouse estimated total effects of tobacco on employment from growers, auction warehousing, wholesale and retail trade, and suppliers at 102,663 in 1990. When the induced effects of expenditures on the economy are included, Price Waterhouse estimated total employment effects of 260,346.

The 1992 study by Price Waterhouse estimated the economic impact of tobacco in North Carolina for 1990, based on earnings to growers, auction warehousing, manufacturing, wholesale and retail trade, at \$1.6 billion dollars. If the earnings of suppliers to these sectors are included, the total impact of tobacco on the state economy was over \$2 billion in 1990. These direct effects do not capture the full impact of tobacco on the economy, however. Price Waterhouse estimated the total direct and indirect impacts on the economy to be \$3.7 billion in 1990.

Tobacco also pays state and local taxes. Price Waterhouse estimated state and local tax revenues at \$215.6 million in 1990, based on compensation to growers, producers, sellers, and their suppliers. If the indirect impacts of tobacco on the state economy are included, then tobacco was responsible for \$366 million in state and local tax revenues in 1990.

While North Carolina's economy is strong, there unfortunately remain poorer rural counties in our state that have not fully participated in our economic growth. For many of these counties, growing tobacco is a fundamental part of their farm economy; loss of tobacco income would be devastating to economies already under stress. For the top ten counties in per capita tobacco cash receipts, loss of farm income from tobacco



would have a per capita impact equal to from five percent to ten percent of per capita income.

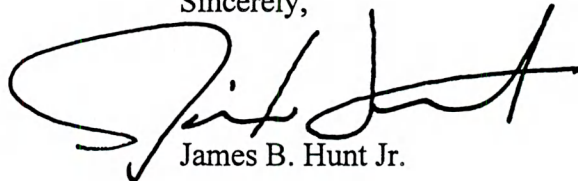
These counties, in general, have unemployment rates and poverty rates above the state average and fiscal capacity below the state average. In the 20 counties with the highest per capita tobacco receipts, cash receipts exceed \$500 per capita for 18 of these counties. Six of these counties have poverty rates at or above twenty percent, and thirteen have poverty rates above fifteen percent. Loss of tobacco income would have dramatic effects of these poor rural counties.

These economic impacts are important, but they fail to capture the full importance of tobacco in our state. Tobacco helped sustain the family farm and small rural communities long after they had disappeared in other states. Tobacco helped build our public and private universities, our much admired foundation and nonprofit institutions, and many of the public facilities across our state. The world-renowned research universities and high technology research parks that epitomize the new North Carolina would not exist without the contributions tobacco has made to the development of our state.

In summary, there is no need to waste months and taxpayers' dollars fighting in Congress and the courts over whether the FDA should have jurisdiction over tobacco products. States can act now to reduce the use of tobacco products by those under the legal age. The most effective way to do this is for government to work with merchants, parents, and communities to enforce existing laws and to educate the public about the risks associated with those under 18 using tobacco. I respectfully ask the Food and Drug Administration to reconsider its position and yield to states their proper authority to reduce use of tobacco products by those under the legal age to purchase tobacco.

My warmest personal regards.

Sincerely,

A handwritten signature in black ink, appearing to read "Jim Hunt", with a stylized flourish at the end.

James B. Hunt Jr.

**EXAMPLES OF SIGNIFICANT FDA RULEMAKINGS  
IN RECENT YEARS**

**1. Generic Drug Approval**

Implementation of Title I of the Drug Price Competition and Patent Term Restoration Act of 1984 re approval of generic drugs

07-10-89 Proposed rule (54 Fed. Reg. 28,872)

10-10-89 End of comment period

04-28-92 Final rule re certain issues (57 Fed. Reg. 17,950)

5 years 10-03-94 Final rule re remaining issues (59 Fed. Reg. 50,338)

**2. NDA Rewrite**

Comprehensive revision of regulations governing approval of new drugs and antibiotics

10-19-82 Proposed rule (54 Fed. Reg. 28,072)

12-20-82 End of comment period

2 1/2 years 02-22-85 Final rule (50 Fed. Reg. 7452)

**3. IND Rewrite**

Comprehensive revision of regulations governing investigational new drugs

06-09-83 Proposed rule (48 Fed. Reg. 26,720)

08-08-83 End of comment period

3 3/4 yrs. 03-19-87 Final rule (52 Fed. Reg. 8798)

**4. Medical Device Reporting**

Implementation of a provision of the Medical Device Amendments of 1976 re reporting of adverse events

11-18-80 Proposed rule (45 Fed. Reg. 76,183)

02-17-81 End of comment period

11-24-81 Proposal put in abeyance (46 Fed. Reg. 57,568)



05-27-83 Reproposed rule (48 Fed. Reg. 24,014)

07-26-83 End of comment period

**4 years** 09-14-84 Final rule (49 Fed. Reg. 36,326)

**5. Medical Device Reporting by User Facilities, Distributors,  
and Manufacturers**

Implementation of provision of Safe Medical Devices Act  
of 1990 re reporting of adverse events

11-26-91 Tentative final rule (56 Fed. Reg. 60,024)

01-27-92 End of comment period

09-01-93 Final rule re distributors, with opportunity  
for comments (58 Fed. Reg. 46,514)

**3 years** 12-11-95 Final rule re user facilities and  
manufacturers, with opportunity for comments  
(60 Fed. Reg. 63,578)

**6. Nutrition Labeling**

Implementation of the Nutrition Labeling and Education  
Act of 1990

11-27-91 Proposed rule (56 Fed. Reg. 60,421)

02-25-92 End of comment period

**2 years** 01-06-93 Final rule (58 Fed. Reg. 2302)

## **NEWS CONFERENCE FEBRUARY 2, 1996**

### **SPEAKERS:**

Billy Ray Smith, Commissioner of Agriculture  
Paul E. Patton, Governor  
Don Chasteen, Kentucky Medical Association  
Walker Merryman, Tobacco Institute (Representing Tobacco Companies)

### **QUESTIONS:**

### **INVITED ATTENDEES**

Stephen L. Henry, Lieutenant Governor  
Greg Ginter, ABC Commissioner  
John Morse, Cabinet for Health Services  
Dan Cherry, Justice Cabinet  
Joey Pendleton, State Senator (SB 137 Chief Sponsor)  
Eck Rose, Senate President  
Jody Richards, Speaker of the House  
Bill Sprague, Ronny Pryor, Dave Beck, Kentucky Farm Bureau  
Ron Keugel, Danny McKinney, Burley Tobacco Growers Coop  
Ray Mackey, Burley Tobacco Council  
Dan Ison, Phillip Morris  
Gene Russell, Brown & Williamson  
Joe Murray, R.J. Reynolds  
Pat Hicks, Kentucky Grocers Association  
John Hinkle, Kentucky Retailers Federation  
John Leeper, Smokeless Tobacco Council  
Morgan Bayless or Ron Cyrus, AFL/CIO  
Jesse McKnight, Senator Ford's Office  
Bob Wiseman, Congressman Baesler's Office  
Jeff Green, State Sen., Agriculture & Natural Resources Chairman  
Drew Graham, State Rep., Agriculture & Small Business Chairman  
Bill Cody, Education Commissioner  
Don Shaw, Salvation Army, Boys & Girls Club



**TOBACCO NEWS CONFERENCE  
FEBRUARY 2, 1996  
FRANKFORT**

**MANY ACTIVITIES AND PRODUCTS CAN BE BENEFICIAL OR HARMFUL TO AN INDIVIDUAL'S HEALTH.**

**WE, AS A SOCIETY, HAVE GENERALLY AGREED THAT THE GOVERNMENT HAS A RESPONSIBILITY TO DETERMINE THE POTENTIAL EFFECTS OF PRODUCTS, IN LIFESTYLES, AND ACTIVITIES AND THE RESPONSIBILITY TO INFORM THE CITIZENS OF THEIR EFFECTS, BE THEY HARMFUL OR BENEFICIAL.**

**WE ALSO BELIEVE THAT, IN GENERAL, RESPONSIBLE ADULTS SHOULD USE THIS INFORMATION AS THEY SEE FIT AND GOVERNMENT SHOULD NOT DICTATE PERSONAL CONDUCT.**

**IN MANY AREAS, WE MAKE EXCEPTIONS FOR CHILDREN, PEOPLE UNDER 18 YEARS OF AGE.**

**ONE OF THESE AREAS IS THE USE OF TOBACCO PRODUCTS.**

**IT IS ILLEGAL IN KENTUCKY AND IN ALL THE OTHER STATES FOR CHILDREN TO PURCHASE TOBACCO PRODUCTS.**

**WE IN KENTUCKY HAVE NOT BEEN SERIOUS ABOUT ENFORCING THIS LAW.**

**MANY OTHER STATES HAVE DEMONSTRATED THIS SAME ATTITUDE.**

**PRESIDENT CLINTON HAS MADE THIS A MAJOR ISSUE AND APPEARS DETERMINED TO CHANGE THIS CULTURE OF PASSIVE DISREGARD FOR THESE LAWS.**

**THE COALITION ASSEMBLED HERE SUPPORTS THE GOALS OF THE PRESIDENT'S INITIATIVE.**

**WE DISAGREE WITH HIS METHOD.**

**THE PRESIDENT HAS PROPOSED TO ACHIEVE THIS GOAL BY ALLOWING THE FOOD AND DRUG ADMINISTRATION TO CLASSIFY TOBACCO AS A DRUG AND THEREFORE ACQUIRE THE POWER TO REGULATE ITS DISTRIBUTION AND USE.**

**KENTUCKY WILL LOSE OVER \$21 MILLION IN FEDERAL FUNDS IF WE DO NOT MEET THESE REQUIREMENTS.**

**THIS GROUP SUPPORTS THE APPROACH TAKEN BY THE FEDERAL SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA) AND WE SUPPORT CHANGES IN KENTUCKY LAW TO INSURE THAT THE GOALS OF THE SYNAR AMENDMENT ARE ACHIEVED.**

**SPECIFICALLY, WE SUPPORT SENATE BILL 137 AND WE SUPPORT AN AMENDMENT TO THAT BILL WHICH WILL MAKE IT CLEAR THAT STING OPERATIONS CONDUCTED ARE NOT ILLEGAL.**

**BECAUSE OF THE SERIOUSNESS OF THIS PROBLEM, I HAVE ASKED FOR AN EMERGENCY CLAUSE BE ADDED TO MAKE THESE CHANGES EFFECTIVE IMMEDIATELY AFTER I SIGN SENATE BILL 137 INTO LAW WHICH SENATOR PENDLETON HAS ADDED TO THE BILL.**

**SENATE BILL 137 WILL:**

- 1. REQUIRE PROOF OF AGE BY ANYONE WHO THE SELLER HAS REASON TO BELIEVE IS UNDERAGE.**
- 2. PLACE MORE RESPONSIBILITY ON THE SELLER TO KNOW IF A CUSTOMER IS OF AGE BY REMOVING THE WORD "KNOWINGLY" FROM THE STATUTE.**
- 3. RAISE THE FINE ON SELLERS WHO VIOLATE THE LAW, CURRENTLY \$10 TO \$25, UP TO \$100 TO \$500.**
- 4. MAKE IT ILLEGAL FOR ANYONE UNDER AGE 18 TO PURCHASE TOBACCO PRODUCTS.**

**FINE THOSE MINORS \$50 AND 20 HOURS OF COMMUNITY SERVICE FOR THE FIRST OFFENSE.**

**FINE THEM \$200 AND 40 HOURS OF COMMUNITY SERVICE FOR SUBSEQUENT VIOLATIONS WITHIN ONE YEAR.**

- 5. REQUIRE THOSE WHO DISTRIBUTE FREE TOBACCO PRODUCTS TO REQUIRE PROOF OF AGE TO THOSE RECEIVING THE PRODUCTS IF THEY HAVE REASON TO BELIEVE THE RECIPIENTS ARE UNDERAGE AND IT ALSO RAISES THE FINE FOR GIVING FREE TOBACCO PRODUCTS TO UNDERAGE PEOPLE, CURRENTLY \$100 TO \$250 UP TO \$1,000 TO \$2,500.**



**6. RAISE FINES FOR VIOLATING LAWS REGULATING TOBACCO PRODUCTS VENDING MACHINES, CURRENTLY \$10 TO \$25, UP TO \$100 TO 500.**

**7. REQUIRE OWNERS OF RETAIL ESTABLISHMENTS TO NOTIFY ALL EMPLOYEES OF THE REQUIREMENTS OF THE LAW AND RAISES THE FINE FOR VIOLATING THIS SECTION FROM THE CURRENT \$10 TO \$25, UP TO \$100 TO \$500.**

**8. ALLOCATE ONE-TENTH OF ONE CENT OF THE EXISTING TAX ON CIGARETTES TO THE KENTUCKY DEPARTMENT OF AGRICULTURE. THIS WILL GENERATE \$500,000 TO \$600,000 FOR THE DEPARTMENT TO BEEF UP ITS ENFORCEMENT EFFORTS.**

**AGRICULTURE COMMISSIONER BILLY RAY SMITH AND ALCOHOLIC BEVERAGE COMMISSIONER GREG GINTER HAVE BOTH AGREED TO USE THIS MONEY IN A COOPERATIVE EFFORT.**

**ABC WILL ENFORCE THE LAW.**

**THE DEPARTMENT OF AGRICULTURE WILL EXPAND ITS EDUCATION EFFORTS.**

**THESE CHANGES WILL GIVE KENTUCKY, THE LARGEST BURLEY TOBACCO PRODUCING STATE IN THE UNION, ONE OF THE TOUGHEST UNDER 18 TOBACCO-PURCHASE LAWS IN THE NATION.**

**THIS IS A SIGNIFICANT FIRST STEP.**

**THIS LAW, AS STRENGTHENED, WILL BE THE LAW OF THE COMMONWEALTH.**

**THIS LAW, AS WITH ALL OTHER LAWS, CAN BE ENFORCED BY ANY POLICE OFFICER.**

**I WILL INSTRUCT SECRETARY OF JUSTICE DAN CHERRY TO ORDER HIS SWORN OFFICERS IN THE KENTUCKY STATE POLICE TO ENFORCE THIS LAW IN THE COURSE OF THEIR REGULAR DUTIES.**

**WE WILL BE NOTIFYING EVERY OTHER LAW ENFORCEMENT AGENCY IN KENTUCKY ABOUT THE CHANGES IN THE LAW AND ASKING THEM TO ENFORCE IT, AGAIN ONLY IN THE CONTEXT OF THEIR REGULAR DUTIES.**

**WE ARE SERIOUS ABOUT REDUCING UNDERAGE SMOKING IN KENTUCKY.**

**THIS UNIFIED EFFORT CONFIRMS THAT THE TOBACCO COMPANIES AND TOBACCO GROWERS ARE SERIOUS AS WELL.**

**THE TOBACCO MANUFACTURERS HAVE AGREED TO FINANCE A PUBLIC AWARENESS CAMPAIGN TO INFORM THE PUBLIC AND RETAILERS OF THESE CHANGES IN THE LAW.**

**WE ARE AGAIN ASKING PRESIDENT CLINTON TO ADOPT THE SYNAR APPROACH AND REJECT THE FDA PROPOSAL TO REGULATE TOBACCO AS A DRUG.**

**IT'S JUST PLAIN WRONG.**

**THE FACT IS, PRESIDENT CLINTON HAS, IN SOME WAYS, BEEN A FRIEND OF THE TOBACCO FARMER.**

**HIS ORDER, LIMITING THE IMPORT OF FOREIGN TOBACCO HAS BEEN THE MAJOR FACTOR STABILIZING THE TOBACCO ECONOMY.**

**IT WAS ONLY TWO YEARS AGO THAT THERE WAS TALK OF A QUOTA REDUCTION OF 30 PERCENT.**

**AND JUST WEDNESDAY, THE SECRETARY OF AGRICULTURE ANNOUNCED A 16% QUOTA INCREASE FOR THE 1996 BURLEY QUOTA.**

**THE PRESIDENT'S RECENT REMARKS TO THE EDITORIAL BOARD OF THE *COURIER JOURNAL* SHOWS HE IS NOT AN ENEMY OF THE TOBACCO FARMER.**

**HE IS, HOWEVER, IN MY JUDGMENT, MISGUIDED ON THE FDA ISSUE AND I HAVE TOLD HIM SO MANY TIMES.**

**I WILL BE DISCUSSING THIS SUBJECT WITH TOBACCO STATE GOVERNORS THIS WEEKEND AT THE NATIONAL GOVERNORS' CONFERENCE.**

**THE PRESIDENT AND FIRST LADY HAVE ASKED JUDI AND ME TO SPEND THE NIGHT AT THE WHITE HOUSE ON SUNDAY AND WE HAVE ACCEPTED.**

**I WILL USE THIS OPPORTUNITY TO AGAIN DISCUSS TOBACCO WITH THE PRESIDENT.**



**TOBACCO IS IMPORTANT TO THE ECONOMY AND CULTURE OF KENTUCKY  
AND AS GOVERNOR I WILL CONTINUE TO SUPPORT THIS IMPORTANT PART OF  
OUR SOCIETY.**

**THE WELFARE OF OUR CHILDREN IS ALSO VERY IMPORTANT TO US AND I  
WILL PURSUE THIS AND OTHER INITIATIVES TO IMPROVE THE LIVES OF OUR  
CHILDREN.**

# NEWS

KENTUCKY DEPARTMENT OF AGRICULTURE  
7TH FLOOR, 500 MERO STREET  
FRANKFORT, KENTUCKY 40601  
502-564-4696  
FAX # 502-564-6527

**COMMISSIONER OF AGRICULTURE  
BILLY RAY SMITH BRINGS TOGETHER  
PARTNERS FOR TEENS AND TOBACCO INITIATIVE**

Contact: Dee Baugh

FRANKFORT, KY (February 2, 1996) - "Today is a proud day for me, for the Department of Agriculture and for the commonwealth whose economy has long depended on tobacco as a vital component," said Commissioner Billy Ray Smith following the press conference held in the Capitol to announce Kentucky's Plan of Action for Teens and Tobacco. "Today we are bringing together two components of Kentucky's future - tobacco and children - along with some very special partners to work in the best interest of both."

The Commissioner went on to elaborate on the unique partnerships supporting the enforcement of SB 187, the tougher no sale of tobacco products to children under age 18 law enacted in a weaker, no-funded version in 1994. "The easy way for the Department to answer this legislation would have been for us to think in a traditional, bureaucratic way and just beef up our own staff and keep all the funds here in the Department," said Smith. "But the Governor challenged us to seek out the most efficient, most credible method for implementation and I firmly believe that this approach meets that challenge."

"I want to thank Farm Bureau for their continued support on this issue. I don't think I can say it any better than the public service announcements now being sponsored by the Kentucky Burley Tobacco Growers Cooperative Association: Tobacco crops and our children have a great deal in common. They're both difficult to raise and are well worth protecting. I particularly salute Danny McKinney and the Coop for this outstanding example of the type of attitudes we need to move this commonwealth forward in a positive way."

-30-



FEB-02-1996 11:01 FROM THE ASSOCIATES

WENDELL H. FORD  
SENATORCOMMERCE, SCIENCE  
AND TRANSPORTATION  
ENERGY AND  
NATURAL RESOURCES  
RULES AND  
ADMINISTRATION

## United States Senate

WASHINGTON, DC 20510-1701

January 30, 1996

Dear Governor Patton:

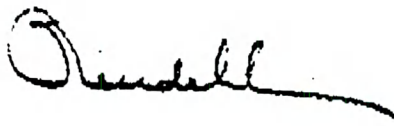
I wish to congratulate you on your efforts to stop teenage tobacco use. From what I understand about Senate Bill 137 and the enforcement changes that you have secured in conjunction with it, you have much to be proud of.

No one wants kids to smoke. The dilemma we face is, how to keep kids away from tobacco and not trample on adults' rights to use a legal product. The FDA's power grabbing, "Big Brother" proposal is absolutely not the way to address the youth/tobacco question. I believe that laws, such as the one currently making its way through the Kentucky Legislature, represent the reasonable and proper approach on this issue. All states have laws prohibiting the sale of tobacco products to minors, we must work to enforce these laws. The states need to work with the Substance Abuse and Mental Health Services Administration (SAMHSA) to devise ways to reduce teen access to tobacco in accordance with the recently announced Synar regulations.

The states working together with SAMHSA is how the Congress wanted this problem tackled. I'm glad that Kentucky, and you as its newly elected Governor, are taking the lead on this difficult issue.

Best wishes.

Sincerely,



The Honorable Paul Patton  
Governor of Kentucky  
The Capitol  
700 Capital Avenue  
Frankfort, Kentucky 40601

☐ DISTRICT OFFICE  
300 Walnut Avenue  
Lexington, KY 40504  
800-392-6364

☐ 1077 New Albany, Evansville  
Lexington, KY 40504  
800-392-6364

☐ 18 U.S. Post Office and Courthouse  
Cincinnati, KY 45211  
800-392-6364

☐ 205 Airport Building  
Cincinnati, KY 45219  
800-392-6364

PRINTED ON RECYCLED PAPER

SCOTTY BAESLER

Off. Contact  
Toll-freeAGRICULTURE  
VETERANS' AFFAIRS

Congress of the United States  
House of Representatives  
Washington, DC 20515

OFFICE:  
110 Capitol Building  
Washington, DC 20540  
CDD 225-4700  
401 West Main Street  
Suite 210  
Lexington, KY 40502  
Phone: (606) 258-1100  
FAX: (606) 258-1100  
Franklin County Courthouse Annex  
218 West Main Street  
Franklin, KY 40601

February 1, 1996

The Honorable Paul Patton  
Governor of Kentucky  
The Capitol  
700 Capital Avenue  
Frankfort, KY 40601

Dear Governor Patton:

The purpose of my letter is to voice my support for your efforts to pass legislation in the Kentucky General Assembly to prohibit the sale of tobacco products to minors. Your efforts prove that even tobacco producing states are willing to effectively deal with the issue without the need for excessive federal regulation.

Although Kentucky contains the largest burley tobacco growing regions in the country, all of us understand the wisdom of preventing children from smoking. However, we dread recent efforts aimed at giving the Food and Drug Administration regulatory responsibility for tobacco products. Such efforts are wrongheaded and would do irreparable harm to the economies of states such as Kentucky.

Indeed, studies show that even smokers don't want their kids to smoke. I am deeply concerned with the issue of teen smoking, and I think we must take strong steps to prevent them from forming this habit. At the same time, however, I am also concerned about the impact of the potential FDA regulation on Kentucky's agricultural economy.

I believe Senate Bill 137 balances these concerns. In fact, SB 137 provides a comprehensive and realistic remedy for combating teenage smoking in the Commonwealth of Kentucky. It imposes, for the first time, significant penalties and fines for the sale and distribution of tobacco products to minors. The legislation also contains a sound enforcement mechanism designed to ensure compliance. It also provides a strategy and timeframe for achieving the goal of combating youth smoking.

More importantly, SB 137 builds upon the framework outlined in the recently proposed SAMHSA (Substance Abuse and Mental Health Services Administration) regulations. I believe your legislation will serve as a national model for what states can do to prohibit the sale of tobacco products to children. It is my hope that your legislation, and similar legislation introduced by Senator Wendell Ford and myself on the Congressional level, will serve to derail efforts by the FDA to assume regulatory control over tobacco.

Thank you for taking the lead on this matter.

Sincerely,

Scotty Baesler  
Member of Congress



TO 1475213043001401

COMMITTEE ON COMMERCE  
SUBCOMMITTEE  
ON COMMERCE, TRADE AND HAZARDOUS  
MATERIALS  
HEALTH AND ENVIRONMENT

Congress of the United States  
House of Representatives  
Washington, DC 20515-1701

February 2, 1996

DEAR GOVERNOR PATTON:

The Synar Amendment, which requires states to prohibit the sale and distribution of tobacco products to minors, goes into effect next month. Senate Bill 137 and SAMHSA regulations are a constructive, constitutionally appropriate and cost-effective way to combat the problem of underage tobacco use.

At a time when American taxpayers expect, demand and deserve a more cost-effective, results-oriented government, it is unfortunate that President Clinton has encouraged the Food and Drug Administration (FDA) to propose rules that are duplicative, more costly to implement, and actually less ambitious than the final rules enacted by SAMHSA.

In spite of their inferior effectiveness and slower timetable, the FDA proposed rules will cost the taxpayers almost five times as much in annual operating costs by FDA's own admission - private accounting groups have estimated that FDA costs will be even higher. I do not understand why an agency which lacks jurisdiction over tobacco and does not have a Congressional mandate to act on youth tobacco issues should be spending a greater amount of money for inferior results when HHS has published final regulations that address the problem of tobacco use by minors.

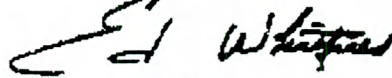
I am committed to the prevention of the sale and distribution of tobacco products to our young people. I am also committed to the Constitution, the rule of law, fiscal responsibility and effective government at every level.

Bureau Inc.  
 1000 Pennsylvania Avenue  
 Washington, D.C. 20004  
 (202) 462-1000

### INTERVIEW WITH THE RESEARCHER

The final SAMESA regulations and Senate Bill 137 go a long way toward eliminating underage tobacco use. I ask you to oppose FDA's misguided and illegal efforts to bypass Congress and use your influence to convince the Clinton Administration to stop its crusade against the tobacco farmers of Kentucky.

Sincerely,



Ed Whitfield  
Member of Congress



RON LEWIS  
SECOND DISTRICT, KENTUCKY  
AGRICULTURE COMMITTEE  
SUBCOMMITTEE  
RESOURCE CONSERVATION,  
RESEARCH, AND FORESTRY  
RISK MANAGEMENT AND  
SPECIALTY CROPS  
NATIONAL SECURITY  
COMMITTEE  
SUBCOMMITTEE  
MILITARY PERSONNEL  
MILITARY PROCUREMENT  
REGULATORY REFORM  
TASK FORCE



Congress of the United States  
House of Representatives  
Washington, DC 20515

February 2, 1996

WASHINGTON OFFICE  
111 CANNON HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515  
202-225-0501  
REPRESENTATIVE  
214 NORTH ANDERSON STREET  
CLARKSTOWN, KENTUCKY 40301  
502-466-0000  
FEDERAL BUILDING  
ROOM 8-11  
214 EAST MAIN STREET  
SOMERSET, KENTUCKY 40387  
502-466-0000  
FEDERAL BUILDING  
ROOM 8-11  
121 WESTBROOK STREET  
OWENSBORO, KENTUCKY 40301  
502-466-0000  
TOLL FREE 1-800-325-0070

The Honorable Paul Patton  
Governor  
Commonwealth of Kentucky  
Capitol Building  
Frankfort, Kentucky 40601

Dear Governor Patton:

I applaud you and the General Assembly on the efforts to address the important issue of teenage smoking.

As you know, President Clinton is proceeding with plans to allow the Food and Drug Administration to micro-manage this issue -- despite the fact that this is a matter properly left to state and local governments, and despite the fact that courts have ruled repeatedly that the FDA has no business regulating tobacco. Mr. Clinton's "FDA Job Creation Act," as it is known up here, is bad news for Kentucky.

I believe efforts like Senate Bill 137 are also preferable to legislation at the federal level designed to replicate Mr. Clinton's big-government efforts.

I believe governors, state legislators, local officials and parents are better positioned to keep children from smoking. And I am pleased that the Kentucky Farm Bureau and other industry organizations concur.

I have enclosed a cartoon concerning this issue which I have been carrying in my pocket in recent months. Please feel free to use this to help carry this important message to the public.

Please don't hesitate to ask for any help I can muster to allow Kentucky's elected officials to do their work without federal interference. That is one of my highest priorities.

Best personal regards,

RON LEWIS  
Member of Congress

### **Kentucky's Plan**

**SB 137** with emergency effective date to "jumpstart the compliance/enforcement/education effort

**Tougher provisions in SB 137 include:**

- prohibits sale to children under age 18 with fine raised from \$10 to \$25 up to \$100 to \$500

- prohibits distribution of tobacco products free of charge to children under age 18 with fines from \$1,000 to \$2,500

- requires sellers to maintain tobacco products in line of sight or under direct control of cashier (with exception of establishments from which minors are prohibited) with fines from \$100 to \$500

- prohibits sale or purchase of tobacco products through a vending machine to children under age 18 with increased fines of \$100 to \$500 up from \$10 to \$25

- requires seller to notify employees of the law and to require a signed receipt attesting that employees were so informed with fines for failure to do so from \$100 to \$500 up from \$10 to \$25

**How SB 137 will be implemented:**

- Department of Agriculture will receive the earmarking of cigarette excise taxes as provided in SB 137

- Department of Agriculture will design, in conjunction with the Cabinet for Human Resources and the Public Protection and Regulation Cabinet, a memorandum of agreement with the Alcoholic Beverage Control Commission detailing exact enforcement and compliance mechanisms in order to bring Kentucky in compliance with the Synar regulations, including permissive sting and state-out operations

- Department of Agriculture will design, in conjunction with the Kentucky Department of Education and other interested partners, a statewide program of passive enforcement consisting of education and public information campaigns designed to reach both children under age 18 and the sellers of tobacco products

- Department of Agriculture will additionally cross-train all field employees now conducting regulatory and inspection functions to allow them to include public information



distribution and monitoring of SB 137 requirements in their regular duties with complaints of possible violations to be referred to the ABC Commission

-Department of Agriculture and the ABC Commission will split funds allocated for these purposes in order to avoid duplication and to most effectively, efficiently deliver enforcement

-ABC Commission will utilize existing enforcement force, add personnel needed for a comprehensive, statewide enforcement mission, then cross-train all enforcement personnel in both functions, maximizing funds available and avoiding duplication of effort; current hearing procedures in ABC will be followed for violations of persons over age 18 and violations for children under age 18 will be referred in the usual manner to district court for subsequent referral to the proper juvenile authorities

#### **How the Kentucky Plan will meet Synar requirements:**

-Kentucky's SB 137 with emergency provisions will allow for strong, comprehensive implementation of enforcement

-Partnership of Agriculture and the ABC Commission (and other private and public entities) will ensure credible, strong, consistent enforcement and distribution of information.

-Preparation to conduct annual, random, unannounced inspections

-Developing a strategy and time frame for achieving an inspection failure rate over time (as negotiated with federal authorities) of less than 20%

#### **Partners in the Kentucky Plan:**

Governor, Lt. Governor, Cabinet for Human Resources, Public Protection and Regulation Cabinet

Commissioner of Agriculture

Kentucky General Assembly

Members of U.S. Congress

Tobacco interests from growers to manufacturers to sellers to unions representing workers to Farm Bureau

Health interests from the Department of Health Services to the Kentucky Medical Association.

**RADIO SPOTS**  
**GROWER SUPPORTS LEGISLATION**

**JANUARY 31, 1996**

Danny McKinney

Hi. I'm Danny McKinney for Kentucky's tobacco farmers.

Like everyone, we're concerned with health questions involving tobacco.

We believe personal decisions on whether or not to use tobacco should be made only with the benefit of mature judgment.

That's why tobacco farmers are working so hard to support legislation in Frankfort, designed to stop sales of tobacco products to Kentucky's youth.

Y'know tobacco crops and children are a lot alike.

They're both difficult to raise and well worth protecting.

It's Tobacco. The reason Kentucky grows.



## RADIO SPOT

Hi. I'm Danny McKinney for Kentucky's tobacco farmers.

Many of you may be aware of legislation in Frankfort designed to stop sales of tobacco products to Kentucky's youth.

Tobacco farmers and you Burley Tobacco Co-op are working hard to support this legislation.

We believe that decisions on whether or not to use tobacco are personal, but certainly should be made only with the benefit of mature judgment.

Tobacco is vitally important to our economy. The crop perpetuates time-honored values of hard work, family togetherness and pride of accomplishment.

It provides jobs. It contributes to better health resources, better schools, better roads. Better quality of life for all Kentuckians.

Sure. There'll always be tobacco in Kentucky, but we tobacco farmers want much more than just to raise our crops. We want to raise them responsibly.

Y'know, when you think about it, tobacco crops and our children have a great deal in common.

They're both difficult to raise and damn sure worth protecting.

It's Tobacco, the reason Kentucky grows.



STATE OF NORTH CAROLINA  
WASHINGTON OFFICE  
444 NORTH CAPITOL STREET, SUITE 332  
WASHINGTON, D. C. 20001  
202-624-5830

*J. O'Connor*

*cc'd: Linda*

**Memorandum**

To: Marcia Hale, White House Intergovernmental Affairs  
Doug Sosnik, White House Political Affairs

From: Debra M. Bryant, Director *DBryant*  
North Carolina Washington Office

Date: January 2, 1996

Re: FDA Regulations

Enclosed are the press release and the Governor's comments regarding the proposed FDA regulation of tobacco products.

These are provided for your information.

*This is very difficult for us!*



James B. Hunt Jr.  
Governor



State of North Carolina  
Office of the Governor

For Release: IMMEDIATE  
Date: January 1, 1996

Contact: Rachel Perry/Kim Brooks  
Phone: (919) 733-5612

**GOV. HUNT URGES FEDERAL OFFICIALS TO RECONSIDER TOBACCO REGULATION**

RALEIGH -- Gov. Jim Hunt reiterated his strong opposition to the Clinton administration's plans to regulate tobacco as a drug in a letter to federal Food and Drug Administration Commissioner David A. Kessler. The letter was sent to meet the Jan. 1 deadline for the public comment period on the Clinton administration's proposal.

Hunt's response to the proposal spells out the vital role tobacco plays to the state's economy and the livelihood of thousands of North Carolinians.

"Tobacco helped sustain the family farm and small rural communities long after they had disappeared in other states," Hunt said in the letter. "Tobacco helped build our public and private universities, our non-profit institutions and many of the public facilities across our state."

Hunt said that Congress has withheld the power to regulate tobacco from the FDA for more than 80 years, giving that power to other agencies or regulating the crop directly -- and any change could have drastic effects on the state's economy.

Estimates show that the proposed regulations will cost manufacturers \$6.3 million in one-time expenses and \$73 million annually while the proposed changes will cost retailers \$2 million annually. North Carolina is the nation's No. 1 tobacco producer, and more than 260,000 jobs rely on the crop. Tobacco has a total economic impact of \$1.6 billion in annual revenue.

While he supports finding new ways to crack down on underage smoking, Hunt believes that bringing the public and private sectors together to increase public awareness will have a greater effect than more regulations -- much like the impact of statewide public service campaigns that have reduced drunken driving and increased seat belt use.

"The most effective way to do this is for government to work with merchants, parents and communities to enforce existing laws and to educate the public about the risks associated with those under 18 using tobacco," Hunt said in the letter.

Over the last five months, Hunt has continued to fight the Clinton administration's push to regulate tobacco as a drug. Hunt has written letters, made telephone calls and flown to Washington for face-to-face meetings with top administration officials. He has also met with the president to discuss his concerns about the proposed regulations.

--30--

Governor's Press Office  
State Capitol, Raleigh, NC 27603-8001  
(919) 733-5612 - Toll Free 1-800-662-7005  
FAX (919) 733-5166

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| Fax #             |         | Fax #   |              |



STATE OF NORTH CAROLINA  
OFFICE OF THE GOVERNOR  
RALEIGH 27603-8001

JAMES B. HUNT JR.  
GOVERNOR

December 21, 1995

David A. Kessler, M.D.  
Commissioner  
Food and Drug Administration  
c/o Dockets Management Branch (HFA-305)  
Food and Drug Administration, rm. 1-23  
12420 Parklawn Drive  
Rockville, MD 20857

Re: Docket Number 95N-0253

Dear Commissioner Kessler:

I am submitting written comments on the proposed regulations by the Food and Drug Administration, "Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents."

I am strongly in favor of limiting smoking by those under the legal age. I believe that all North Carolinians, in and out of the tobacco industry, would support a strong program to reduce access to tobacco products by those under 18. However, more big government is not the way to do it. This is one more example of Washington starting with good intentions, but piling on more regulation and bureaucracy to do the job. Instead, the focus should be on supporting states and local communities in their efforts to enforce the law and educate young people.

In these proposed regulations, the FDA subverts basic principles of federalism. In 1992, Congress affirmed the traditional role of the states through the Alcohol, Drug Abuse, and Mental Health Amendments (ADAMHA) Reorganization Act. In addition, the Congressional Research Service has warned that sweeping tobacco regulations of this nature may exceed the federal government's powers under the commerce clause of the United States Constitution. Congress also has withheld jurisdiction over tobacco from the FDA for over 80 years, choosing to regulate tobacco directly or by delegating responsibility to agencies other than the FDA.



There is no need to waste months and taxpayers' dollars fighting in Congress and the courts over whether the FDA should have jurisdiction over tobacco products. States can act now to reduce the use of tobacco products by those under 18. The most effective way to do this is for state and local governments to work with merchants, parents and communities to enforce existing laws and to educate the public about the risks associated with those under the legal age using tobacco.

North Carolina is a good example of a state that has acted in this area. The State of North Carolina prohibits anyone from knowingly selling or furnishing cigarettes, tobacco for cigarettes, smokeless tobacco or cigarette papers to minors under the age of 18 (Chapter 628, G.S. 14-313, HB 852, 1991).

In addition, a new law effective December 1, 1995 tightens existing restrictions by making it illegal to distribute, or knowingly aid, assist, or abet any other person in distributing tobacco products to minors. This new law also makes it illegal for minors to attempt to purchase tobacco in North Carolina, and requires clerks to demand proof of age from a prospective purchaser if the person has reasonable grounds to believe that the prospective purchaser is under 18 years of age. With an increasing emphasis on enforcement of these laws by state and local agencies, additional federal laws or oversight by federal agencies is unnecessary to prevent those under 18 from obtaining these products.

North Carolina has not stopped with passage of tough laws. Our state, through the Department of Human Resources, also conducts an annual, random, unannounced inspection of both over-the-counter and vending machine outlets which distribute tobacco products. These inspections measure the overall level of compliance with the state law regarding youth access to tobacco products, as required by Section 1926 of the Public Health Service Act, commonly referred to as the Synar Amendment.

North Carolina also is emphasizing merchant education. The Department of Human Resources works with local organizations to develop and distribute materials to help merchants understand and carry out their responsibilities under the law.

It is my position that the intent of these regulations, reducing teenage smoking and eliminating underage smoking, can be accomplished without intruding on the rights of adults who choose to smoke and without imposing unnecessary costs on growers, manufacturers, and distributors of tobacco products.

The costs that these regulations would impose on North Carolina are substantial. The FDA has estimated that complying with these regulations on a national level will cost manufacturers \$15 million one time, and \$150 million annually. Retail sellers will have an additional \$67 million in costs annually. These do not include costs to advertisers, vending machine operators, and organizers of popular sporting events.



If we attribute these costs within North Carolina on the basis of our share of these sectors, based on a 1992 study from Price Waterhouse on the national economic impact of the tobacco industry, complying with these regulations will cost manufacturers in North Carolina \$6.3 million one time, and \$73.1 million annually. Retail sellers in North Carolina will have an additional \$2.01 million in costs annually. These costs do not include the disproportionately large impact on those small merchants who operate in poorer neighborhoods.

The proposed tobacco regulations by the FDA represent the first step toward overall regulation of tobacco, which is an important part of North Carolina's economy and community fabric. According to the North Carolina Department of Agriculture, there are 10,000 growers in North Carolina who produce crops valued at \$942.9 million in 1994. Furthermore, there are 47,837 allotment holders, many of whom no longer grow tobacco, but are the widows or children of growers, and who derive important income supplements from these allotments.

According to the Employment Security Commission, another 15,229 North Carolinians work in the production end of tobacco, with earnings valued at \$749.8 million in 1994. Thousands of other North Carolinians depend in part on earnings from tobacco through employment in wholesale distribution, retail stores, advertising, and other sectors that derive part of their revenues from sales of tobacco products. Price Waterhouse estimated total effects of tobacco on employment from growers, auction warehousing, wholesale and retail trade, and suppliers at 102,663 in 1990. When the induced effects of expenditures on the economy are included, Price Waterhouse estimated total employment effects of 260,346.

The 1992 study by Price Waterhouse estimated the economic impact of tobacco in North Carolina for 1990, based on earnings to growers, auction warehousing, manufacturing, wholesale and retail trade, at \$1.6 billion dollars. If the earnings of suppliers to these sectors are included, the total impact of tobacco on the state economy was over \$2 billion in 1990. These direct effects do not capture the full impact of tobacco on the economy, however. Price Waterhouse estimated the total direct and indirect impacts on the economy to be \$3.7 billion in 1990.

Tobacco also pays state and local taxes. Price Waterhouse estimated state and local tax revenues at \$215.6 million in 1990, based on compensation to growers, producers, sellers, and their suppliers. If the indirect impacts of tobacco on the state economy are included, then tobacco was responsible for \$366 million in state and local tax revenues in 1990.

While North Carolina's economy is strong, there unfortunately remain poorer rural counties in our state that have not fully participated in our economic growth. For many of these counties, growing tobacco is a fundamental part of their farm economy; loss of tobacco income would be devastating to economies already under stress. For the top ten counties in per capita tobacco cash receipts, loss of farm income from tobacco



would have a per capita impact equal to from five percent to ten percent of per capita income.

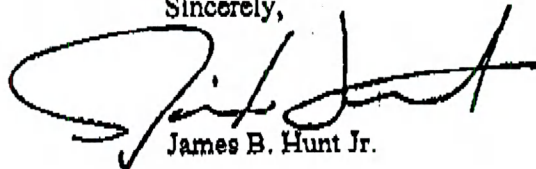
These counties, in general, have unemployment rates and poverty rates above the state average and fiscal capacity below the state average. In the 20 counties with the highest per capita tobacco receipts, cash receipts exceed \$500 per capita for 18 of these counties. Six of these counties have poverty rates at or above twenty percent, and thirteen have poverty rates above fifteen percent. Loss of tobacco income would have dramatic effects of these poor rural counties.

These economic impacts are important, but they fail to capture the full importance of tobacco in our state. Tobacco helped sustain the family farm and small rural communities long after they had disappeared in other states. Tobacco helped build our public and private universities, our much admired foundation and nonprofit institutions, and many of the public facilities across our state. The world-renowned research universities and high technology research parks that epitomize the new North Carolina would not exist without the contributions tobacco has made to the development of our state.

In summary, there is no need to waste months and taxpayers' dollars fighting in Congress and the courts over whether the FDA should have jurisdiction over tobacco products. States can act now to reduce the use of tobacco products by those under the legal age. The most effective way to do this is for government to work with merchants, parents, and communities to enforce existing laws and to educate the public about the risks associated with those under 18 using tobacco. I respectfully ask the Food and Drug Administration to reconsider its position and yield to states their proper authority to reduce use of tobacco products by those under the legal age to purchase tobacco.

My warmest personal regards.

Sincerely,

A handwritten signature in dark ink, appearing to read "Jim Hunt", with a stylized flourish at the end.

James B. Hunt Jr.

SENT BY:

1- 8-86 ; 4:12PM ; Rep. Richard Burr

;# 2/12

**Congress of the United States**  
**Washington, DC 20515**

December 15, 1995

Food and Drug Administration  
Dockets Management Branch (HFA-305)  
Room 1-23  
1420 Parklawn Drive  
Rockville, MD 20857

Re: Docket No. 95-0253, "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents" (Proposed Rule)

Dear Sirs:

We strongly believe that minors should not use or purchase tobacco products. We also strongly believe the most effective way to prevent minors from using or purchasing tobacco products lies in the strict enforcement of laws already in effect in each of the 50 states. A new federal bureaucracy, as you propose, is not needed. In fact, three years before the Food and Drug Administration (FDA) published its proposed rule Congress made a bipartisan decision that state officials, not a federal agency, are best suited to deal with the problem of underage tobacco use.

In 1992, the 102nd Congress amended the Public Health Service Act to require that each state develop and implement an effective program to keep tobacco products out of the hands of minors. This requirement is now a condition that states must meet in order to receive block grants from the Health and Human Service (HHS) Substance Abuse and Mental Health Services Administration (SAMHSA). Under this law, every state must:

1. prohibit the sale or distribution of tobacco products to anyone under age 18;
2. "enforce the law in a manner that can reasonably be expected to reduce" minors' purchase of tobacco products;
3. "annually conduct random, unannounced inspections to ensure compliance with the law"; and



SENT BY:

1- 8-96 : 4:12PM : Rep. Richard Burr→

: # 3/12

Food and Drug Administration  
Dockets Management Branch (HFA-305)  
December 15, 1995  
Page 2

4. report annually to HHS on the state's enforcement activities, its success, and future strategies for ensuring compliance with the law.

In addition to requiring every state to prevent tobacco use by underage consumers, Congress, through the Drug-Free Schools and Communities Act, provides millions of dollars for anti-smoking efforts aimed at school children. Through the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act, Congress has also put in place a comprehensive federal program regulating tobacco product advertising, promotion, labeling, and ingredient reporting.

If additional measures are necessary to stop minors from using tobacco products, Congress, not the FDA, should and will make the decision. Former FDA Commissioner Dr. Charles Edwards has said that "cigarettes recommended for smoking pleasure are beyond the federal Food, Drug, and Cosmetic Act." In testimony before the Senate Labor and Human Resources Committee this spring, Dr. Edwards reiterated that tobacco is not the responsibility of the Food and Drug Administration. Furthermore, last year FDA Commissioner Dr. David Kessler himself said with respect to whether FDA should attempt to regulate tobacco products, "it is vital in this context that Congress provide clear direction to the agency."

Congress has not given the FDA either "clear direction" or any authority to regulate tobacco. Yet the FDA has determined by regulatory fiat to assert such authority. The United States Constitution tasks Congress -- not unelected federal bureaucrats -- with responsibility for creating new law. In addition, Congress has considered and rejected numerous proposals over the years seeking to authorize FDA jurisdiction over tobacco. Indeed, Congress has considered and rejected various legislative proposals over the past several years containing most of the specific elements of the FDA's proposed rule.

The FDA's proposed rule also is objectionable because it would cause economic harm to a wide spectrum of commercial interests, including retailers, wholesalers, advertisers, manufacturers, and growers. By its own estimates, FDA regulation would eliminate 10,000 jobs nationwide.

Former FDA Commissioner Edwards testified that the FDA's tobacco initiative "divert[s] the resources of the agency" from its clear statutory mission. As a result, Americans have been denied timely access to lifesaving medical technology.

SENT BY:

1- 8-96 ; 4:12PM : Rep. Richard Burr

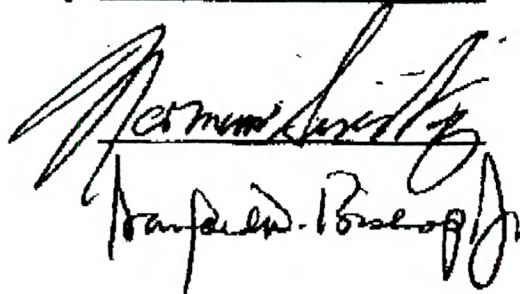
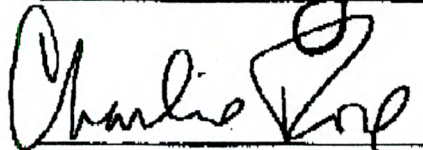
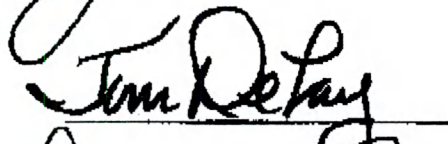
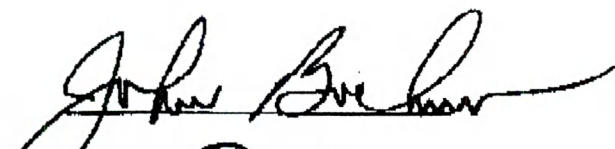
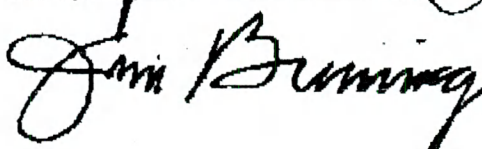
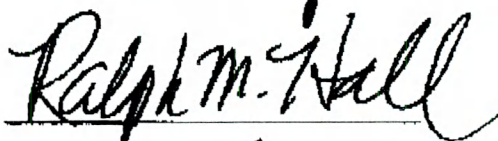
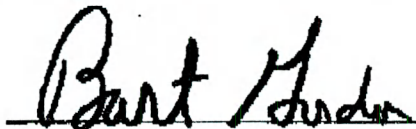
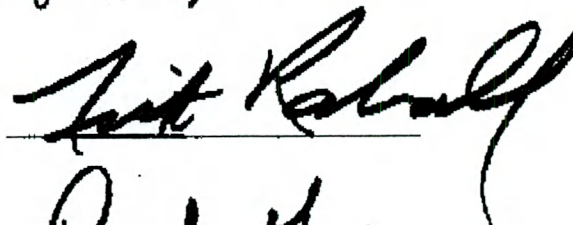
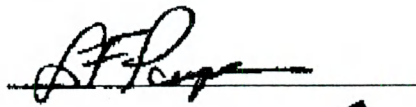
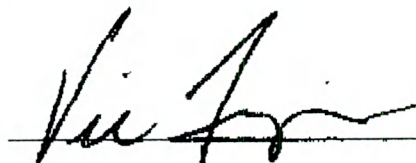
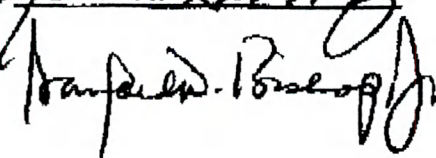
# 4/12

Food and Drug Administration  
Dockets Management Branch (HFA-305)  
December 15, 1995  
Page 3

Furthermore, the proposed FDA rule would trample First Amendment rights to advertise legal products to adults. And, it is incomprehensible that a federal regulator would seek to impose what amounts to a \$150 million a year tax on an industry with no congressional approval. Yet, the FDA's proposed rule seeks to do just that.

So, while we stand steadfastly against tobacco use by minors, we strenuously object to the FDA's effort to expand its jurisdiction and the federal bureaucracy in dealing with a problem that Congress has already designated to the states. We therefore urge that you withdraw your claim of jurisdiction and terminate your proposed rulemaking.

Sincerely,



SENT BY:

1- 3-96 : 4:13PM : Rep. Richard Burr-

# 5/12

D. A. BoucherW. D. (Bill) HefnerBlanche Lambert LurichPat AnnanKen Sum1000. 1000Joe SumMr. ClementC. J. C. C. C.E. C. C. C.Sam MumpDist. ArmyMcKinnonBarryPaul C. C.Walter B. Jones, Jr.DeafnessTom C. C.Howard ColeCarroll DillingJohn GrantBob ScottNick WardJames P. C. C.

SENT BY:

1- 3-96 ; 4:13PM ; Rep. Richard Burr-

# 6/12

Van Hilleary  
Phil Crane  
Robert Baker

Paul Hornik  
Carye P. Meek  
John O'S

Billy Jamison  
Jack Field  
Don Duff  
Hubert Bates

Sandy Montgomery  
Don Cooper

Cory Ashby  
Charles H. Doyle  
Pat Withers  
Calvin Doyle  
Barbara Lee Collins

Frank Sejda  
Barbara Vaccaro

John Myers  
Cliff Speary  
Carl Holman

R. delGans  
J.P. Hunter



SENT BY:

1- 3-96 ; 4:13PM ; Rep. Richard Burr-

# 7/12

Dick Chrysler  
Ray Schoon

Earl J. Hilliard

Ernie Callahan

Ed Bryant

Barbara Cubin

Joe Steyer  
John Peterson

Ed Whitfield

Richard Pambro

Mike Collins

Frank D. Lucas

Robert L. Ehrlich

Brian P. Bilbray

Jim Chap

Harold Rogers

Fred Henneman

Seavally

Tom Lewis

Jerry Lawdo

Jack Kingston

John Linder

James H. O'Neill

Scotty Bassler

# 8/12

Don't start  
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 1.2 number  
 Mark Linder  
 In line  
 North  
 Big  
 John N. Hottel  
 John Ennis  
 Saffy Chubb  
 Ed Whitfield



SENT BY:

1- 3-96 ; 4:14PM ; Rep. Richard Burr→

# 9/12

Jim Valant

Harold Wilkman

Ann. Jefferson

Fray Laughlin

David Gindrich

Charlie Nowood

Larry Combest

Bob Bull

Don Hastings

Therese Mantone

Wes Cooley

Aue Myrick

Jane Camp

Ken Calvert

Mike Paul

Cliff Edwards

SENT BY:

1- 3-96 ; 4:14PM ; Rep. Richard Burr-

#10/12

John Boehner  
Vic Fazio  
Tom DeLay  
L.F. Payne  
Charlie Rose  
Nick Joe Rahall  
Richard Burr  
Bart Gordon  
Bill Brewster  
Eva Clayton  
Norman Sisisky  
Ralph Hall  
Sanford Bishop  
Jim Bunning  
Rick Boucher  
Bill Hefner  
Blanche Lambert Lincoln  
Pat Danner  
Pete Geren  
Collin Peterson  
John Tanner  
Bob Clement  
Gary Condit  
Steve LaTourette  
David Minge  
Dick Arney  
Mike Flanagan  
Bob Ney  
Phil English  
Walter Jones, Jr.  
Dan Frisa  
Tom Latham  
Howard Coble  
Cass Ballenger  
John Spratt  
Bobby Scott  
Mike Ward  
Jim Clyburn  
Van Hilleary  
Gary Franks  
Phil English  
Charles Taylor  
Richard Baker  
Pat Williams  
Lee Hamilton  
Calvin Dooley



SENT BY:

1- 3-96 ; 4:14PM ; Rep. Richard Burr-

;#11/12

Carrie Meek  
Barbara Rose Collins  
Soloman Ortiz  
Frank Tejeda  
Billy Tauzin  
Barbara Vucanovich  
Jack Fields  
John Myers  
Dan Schaefer  
Cliff Stearns  
Herbert Bateman  
Curt Weldon  
Sonny Montgomery  
E. de la Garza  
Ron Coleman  
John Murtha  
Dick Chrysler  
Robert Ehrlich, Jr.  
Ray LaHood  
Brian Bilbray  
Earl Hilliard  
Jim Chapman  
Sonny Callahan  
Harold Rogers  
Ed Bryant  
Fred Heineman  
Barbara Cubin  
Sue Kelly  
J.D. Hayworth  
Ron Lewis  
Pete Peterson  
Jerry Lewis  
Ed Whitfield  
Jack Kingston  
Richard Pombo  
John Linder  
Mac Collins  
James Quillen  
Frank Lucas  
Scotty Baesler  
Bart Stupak  
Ron Klink  
Floyd Flake  
Jerry Weller  
Ed Towns  
Terry Everett

SENT BY:

1- 3-96 ; 4:14PM ; Rep. Richard Burr→

;#12/12

Floyd Flake  
Mark Souder  
Chris Cox  
Lindsey Graham  
Tom Latham (AGAIN)  
Nathan Deal  
Denny Hastert  
Bill Paxon  
Bob Goodlatte  
Mike Oxley  
Joe Scarborough  
John Hostettler  
Mark Foley  
John Insign  
Roger Wicker  
Saxby Chambliss  
Bennie G. Thompson  
Ed Whitfield (AGAIN)  
Jim Talent  
Doc Hastings  
Harold Voelkner  
Tom Manton  
William Jefferson  
Wes Cooley  
Greg Laughlin  
Sue Myrick  
David Funderburk  
Dave Camp  
Charlie Norwood  
Ken Calvert  
Larry Combest  
Mike Parker  
Harry Bonilla  
Chet Edwards



# United States Senate

WASHINGTON, DC 20510

December 28, 1991

Temifer,  
1/11  
P.L.

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
Room 1-23  
1420 Parklawn Drive  
Rockville, MD 20857

Dear Sirs:

We strongly believe that minors should not use or purchase tobacco products. We also strongly believe the most effective way to prevent minors from using or purchasing tobacco products lies in the strict enforcement of laws already in effect in each of the 50 states. A new federal bureaucracy, as you propose, is not needed. In fact, three years before FDA published its proposed rule Congress made a bipartisan decision that state officials, not a federal agency, are best suited to deal with the problem of underage tobacco use.

In 1992, the 102nd Congress amended the Public Health Service Act to require each State to develop and implement an effective program to keep tobacco products out of the hands of minors. This requirement is now a condition that states must meet in order to receive block grants from Health and Human Service (HHS) Substance Abuse and Mental Health Services Administration ("SAMHSA"). Under this law, every State must:

1. prohibit the sale or distribution of tobacco products to anyone under age 18;
2. "enforce the law...in a manner that can reasonably be expected to reduce" minors' purchase of tobacco products;
3. "annually conduct random, unannounced inspections to ensure compliance with the law"; and
4. report annually to HHS on the State's enforcement activities, its success, and future strategies for ensuring compliance with the law.

In addition to requiring every State to prevent tobacco use by underage consumers, Congress, through the Drug-Free Schools and Communities Act, provides millions of dollars for anti-smoking efforts aimed at school children. Through the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act, Congress has also put in place a comprehensive federal program regulating tobacco product advertising, promotion, labeling, and ingredient reporting.

If additional measures are necessary to stop minors from using tobacco products, Congress, not the FDA, will make the decision. Former FDA Commissioner Dr. Charles Edwards has said that "cigarettes recommended for smoking pleasure are beyond the federal Food, Drug, and Cosmetic Act." In testimony before the Senate Labor and Human Resources Committee this spring, Dr. Edwards reiterated that tobacco is not the responsibility of the Food and Drug Administration. Furthermore, last year FDA Commissioner Kessler himself said with respect to whether FDA should attempt to regulate tobacco products, "It is vital in this context that Congress provide clear direction to the agency."

Congress has not given FDA either "clear direction" or any authority to regulate tobacco. Yet FDA has determined by regulatory fiat to assert such authority. The U.S. Constitution tasks Congress -- not unelected federal bureaucrats -- with responsibility for creating new law. And Congress has considered and rejected numerous proposals over the years seeking to authorize FDA jurisdiction over tobacco. Indeed, Congress has considered and rejected various legislative proposals over the past several years containing most of the specific elements of the FDA's proposed rule.

The FDA's proposed rule also is objectionable because it would cause economic harm to a wide spectrum of commercial interests, including retailers, wholesalers, advertisers, manufacturers, and farmers. By its own estimates, FDA regulation would eliminate 10,000 jobs nationwide.

Former FDA Commissioner Edwards testified that the FDA's tobacco initiative "divert[s] the resources of the agency" from its clear statutory mission. As a result, Americans have been denied timely access to lifesaving medical technology.



The proposed FDA rule would trample First Amendment rights to advertise legal products to adults.

It is incomprehensible that a federal regulator would seek to impose what amounts to a \$150 million a year tax on an industry with no congressional approval. Yet, the FDA's proposed rule seeks to do just that.

So, while we stand steadfastly against tobacco use by minors, we strenuously object to FDA's effort to expand its jurisdiction and the federal bureaucracy in dealing with a problem that Congress has already designated to the states. We therefore urge that you withdraw your claim of jurisdiction and terminate your proposed rulemaking.

Yours truly,

|                       |                       |
|-----------------------|-----------------------|
| <u>Jesse Helms</u>    | <u>Dundell Ford</u>   |
| <u>Al M. Cunnell</u>  | <u>Went Lett</u>      |
| <u>Strom Thurmond</u> | <u>James Haincock</u> |
| <u>Cluck Boll</u>     | <u>Thad Cochran</u>   |
| <u>John Warner</u>    | <u>Fritz Hollings</u> |
| <u>Paul Thompson</u>  | <u>Bill Coons</u>     |
| <u>Bill Bond</u>      | <u>Sam Ervin</u>      |
| <u>Bob Dornan</u>     | <u>Bowell Hefner</u>  |



Jan Aoncrox

Bob Smith

Lang Presler

Frank Smith

Jim Varchle

Phil Gannon

Don Hill

Doc Doe

Alyn Kemato

Harry Reid

Ed Stevens

Sam Nunn

John Brown

Jim Clark

These are the list of signatures for the FDA docket letter:

Jesse Helms  
Mitch McConnell  
Strom Thurmond  
Chuck Robb  
John Warner  
Fred Thompson  
Kit Bond  
Rod Grams  
John Ashcroft  
Bob Smith  
Larry Pressler  
Conrad Burns  
Bennett Johnston  
Daniel Inouye  
Tom Daschle  
Phil Gramm

Wendell Ford  
Trent Lott  
Lauch Faircloth  
Thad Cochran  
Fritz Hollings  
Paul Coverdell  
Larry Craig  
Howell Heflin  
Don Nickles  
Bob Dole  
Al D'Amato  
Harry Reid  
Ted Stevens  
Sam Nunn  
John Breaux  
Jim Inhofe



United States Senate  
WASHINGTON, DC 20510

December 28, 1995

To: JOC

From: Chair

(cc'd to PDS + Jack)

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
Room 1-23  
1420 Parklawn Drive  
Rockville, MD 20857

Dear Sirs:

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-3-

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| <u>Strom Thurmond</u> | <u>Jack Faircloth</u> |
| <u>Chuck Robb</u>     | <u>Thad Cochran</u>   |
| <u>John Warner</u>    | <u>Fritz Hollings</u> |
| <u>Paul Thompson</u>  | <u>Bill Coons</u>     |
| <u>Bill Bond</u>      | <u>Long Chain</u>     |
| <u>Rod Grams</u>      | <u>Howell Hefner</u>  |



-4-

|                 |              |
|-----------------|--------------|
| John Asencio    | Sam Nill     |
| Bob Smith       | Doc Doe      |
| Lang Presler    | Alyn Vemato  |
| <del>Ed E</del> | Harry Reid   |
| James P. Smith  | John Stevens |
| William         | Sam Nunn     |
| Tom Varchle     | John Bryant  |
| Phil Gamm       | Jim Chabbe   |

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Don Nickles  
Bob Dole  
Al D'Amato  
Harry Reid  
Ted Stevens  
Sam Nunn  
John Breaux  
Jim Inhofe



RICHARD BLUMENTHAL  
ATTORNEY GENERAL



65 Elm Street  
P.O. Box 120  
Hartford, CT 06141-0180  
(860) 566-8086

Office of The Attorney General  
State of Connecticut

January 2, 1996

Dr. David Kessler  
Commissioner of Food & Drugs  
Food and Drug Administration  
Dockets Management Branch (HFA-305)  
Room 1-23  
12420 Parklawn Drive  
Rockville, MD 20857

RE: DOCKET #95N0253--Proposed Regulations Restricting the Sale and Distribution of Nicotine Containing Cigarettes and Smokeless Tobacco Products In Order to Protect Children and Adolescents.

Dear Commissioner Kessler:

The Attorneys General of Connecticut, Minnesota, Rhode Island and Washington are writing on behalf of the Attorneys General of Alaska, Arkansas, Florida, Guam, Hawaii, Indiana, Iowa, Louisiana, Maine, Maryland, Massachusetts, Michigan, Mississippi, Montana, Nevada, New Jersey, New Mexico, Puerto Rico, Texas, Utah, Vermont, West Virginia and Wisconsin, whose names appear at the end of this letter, to express our strong support for the FDA's proposed rule to regulate the sale and distribution of tobacco products. We believe that the proposed rule, which emphasizes reducing access and limiting the appeal of tobacco products to children, should be a crucial component of a national effort by federal, state and local officials to help our youngest generation of Americans avoid suffering preventable disease and premature death from the use of tobacco products.

Children who smoke are at high risk of becoming addicted. Ninety percent of smokers report that they began smoking as teenagers. The average age at which teenage smokers first begin smoking is thirteen to fourteen years, and by age eighteen, teens are smoking at a rate very near the adult rate. Studies show that, while most teenage smokers do not plan to be smokers five years from now, in fact less than ten percent will be able to quit. According to the Surgeon General, twenty million Americans try to quit smoking each year, but only three percent have any long-term success. Indeed, the December 8, 1995 Wall Street Journal reported on a tobacco company internal draft report which describes cigarettes as a nicotine delivery system; states that

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**Dr. David Kessler**

**January 2, 1996**

**Page 2**

the main reason people smoke is to get nicotine into their bodies; and calls nicotine chemically similar to such drugs as cocaine. Given this analysis by the tobacco industry itself, it is entirely appropriate and necessary for the government, through the FDA (the agency charged with the responsibility for regulating the distribution of drugs in the United States) to implement the proposed measures to regulate the sale and distribution of tobacco products.

We have been active in the national effort to protect our young people from the devastating consequences of tobacco use. In 1993, many of us participated in a working group of Attorneys General which focused on the problems associated with second hand smoke and children. The working group met with the leaders in the fast food industry to discuss the issue of second hand smoke in their restaurants. We were concerned because this industry target markets children as customers, and employs huge numbers of young workers, forty percent of whom are under the age of eighteen. Consequently, every day millions of children who spend time in these restaurants eating, playing in specially designed play areas, socializing with their teenage friends and working behind the counter are exposed to second hand smoke, a Class A carcinogen, for which no safe levels of exposure have been established. The working group issued a series of recommendations to the fast food industry to facilitate the development of smoke free restaurant environments in our report, "Fast Food, Growing Children and Passive Smoke: A Dangerous Menu." We are gratified that many fast food restaurants are now smoke free, and recognize that the effort must continue to ensure that children are not exposed to second hand smoke as a consequence of eating or working in these restaurants.

As the chief law enforcement officers of our respective states, we are especially concerned about illegal tobacco sales to minors. Although every state bans the sale of tobacco to minors, studies show that children have easy access to tobacco. In 1994, many of us participated in another working group to study this problem. The working group issued a series of recommendations for legislation and voluntary steps that retailers could take to curb illegal tobacco sales in a report entitled, "No Sale: Youth, Tobacco and Responsible Retailing."

This report takes note of the grim statistics which underscore the need to make the proposed FDA regulation a part of a cooperative federal and state effort to protect our children from tobacco addiction. These statistics include the fact that underage customers purchase over half a billion packs of cigarettes and twenty-six million containers of chewing tobacco every year. As a result, an estimated 3,100,000 American teenagers, one out of every six, are regular smokers. Tragically, each day 3,000 more children begin smoking—a process that results in over a million new underage, addicted smokers in the United States each year. As noted above, children who smoke are at high risk of becoming addicted.

Perhaps the most distressing statistic of all is that unlike adolescent use of alcohol and other drugs, adolescent smoking behavior has not declined since the early 1980's, and some studies show an increase in underage smoking. This strongly suggests to us that a cooperative federal and state regulatory approach is needed to effectively deal with youth smoking. Your agency's proposed rule would provide a strong federal complement to state and local law enforcement efforts.



Dr. David Kessler

January 2, 1996

Page 3

While we support the proposed regulations in their entirety, there are several sections of these regulations which merit particular emphasis. Specifically, we wish to express our support for Sections 879.30 and 879.32 which would restrict the advertising and marketing of tobacco products to children. As we noted in our 1994 report, the tobacco industry spent over \$4.6 billion advertising and promoting tobacco products in 1991. Much of this advertising appeals directly to children. We suspect that this explains why the three most heavily advertised brands have captured eighty-six percent of the illegal teen market, when the same brands' share of the legal, adult market is only thirty-five percent. In fact, a study published in November, 1995 concluded that each innovative tobacco marketing campaign since the 1890s has led to a major increase in the number of 14-17 year-olds who became regular smokers. This study further concluded that by the 1960s and 1970s, 14-17 year-olds had become the only age group that was responsive to tobacco marketing.

Advertisements that encourage teen smoking undermine the laws and policies of our states. While individual states can use their laws in an attempt to address tobacco advertising which targets children, it is difficult to effectively combat these sophisticated billion dollar national advertising campaigns on a state by state basis. We therefore welcome an increased federal role in controlling this threat to the integrity of state law.

We further support Section 897.34 (c), which would restrict tobacco sponsorship of sporting and entertainment events. Such sponsorship effectively has been used to avoid the federal ban on broadcast advertising, and to advertise tobacco products on the types of televised events which particularly appeal to teenagers and young adults. We also support Section 897.34 (a), which would prohibit the sale or distribution of all non-tobacco items that are identified with a cigarette or smokeless tobacco product brand name or other identifying characteristic. Studies have shown that these items, including tee shirts, hats and sporting goods have great appeal among young people. When worn by young people, these items can become "walking billboards," which can come into schools and other places where tobacco advertising is generally prohibited.

Sections 897.16 (b), (c), and (d) of the proposed rule are critical if we seriously are to reduce youth access to tobacco products. These regulations would require purchasers of tobacco products to produce positive identification before making a purchase, and would eliminate those sales and marketing practices that provide young people with easiest access to tobacco i.e. the sale of single cigarettes, sale by vending machines, self-service displays, and free samples of tobacco products. The Attorneys General working group's 1994 report made similar recommendations, and many of us have supported attempts to enact these measures into laws in our respective states. The adoption of federal regulations requiring age verification and face-to-face sales, and ending distribution of tobacco by mail order, vending machine, single cigarette ("loosies") and "kiddie pack" sales will greatly assist our efforts to enforce compliance with our state laws which prohibit the sale or distribution of tobacco products to minors.

Moreover, we strongly support Section 897.42 (a) of the proposed rule, which expressly states that the rule would not preempt more stringent state or local requirements relating to the sale, distribution, labeling, advertising or use of tobacco products that do not conflict with the



Dr. David Kessler

January 2, 1996

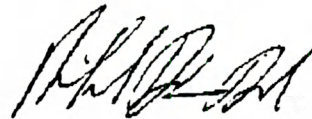
Page 4

rule. This provision reflects our collective view that a cooperative, combined effort by federal, state and local authorities is needed to reduce access and limit the appeal of tobacco products to children. In order to make this effort succeed, it is essential that state and local officials retain the ability to enact and enforce laws which they believe are most effective when actively enforced at the local level.

Finally, we wish to express our willingness to work with the FDA to implement these regulations when they are adopted. We would welcome the opportunity to discuss how existing state laws, such as those which provide for regulation of food and drugs, or those which prohibit unfair or deceptive trade practices, might be used to assist enforcement of the proposed rule.

Congratulations on offering this important regulatory proposal. Please do not hesitate to contact any of us if we may provide any further assistance to you in this most important effort.

Very truly yours,



RICHARD BLUMENTHAL

Attorney General

HUBERT H. HUMPHREY, III  
Attorney General  
State of Minnesota

JEFFREY B. PINE  
Attorney General  
State of Rhode Island

CHRISTINE O. GREGOIRE  
Attorney General  
State of Washington

RB/SRP/xx

BRUCE M. BOTELHO  
Attorney General  
State of Alaska

WINSTON BRYANT  
Attorney General  
State of Arkansas

ROBERT A. BUTTERWORTH  
Attorney General  
State of Florida

CALVIN E. HOLLOWAY, SR.  
Attorney General  
Guam

MARGERY S. BRONSTER  
Attorney General  
State of Hawaii

PAMELA FANNING CARTER  
Attorney General  
State of Indiana

TOM MILLER  
Attorney General  
State of Iowa

RICHARD P. IEYOUB  
Attorney General  
State of Louisiana

ANDREW KETTERER  
Attorney General  
State of Maine

J. JOSEPH CURRAN, JR.  
Attorney General  
State of Maryland

SCOTT HARSHBARGER  
Attorney General  
State of Massachusetts

FRANK J. KELLEY  
Attorney General  
State of Michigan

MIKE MOORE  
Attorney General  
State of Mississippi

JOSEPH P. MAZUREK  
Attorney General  
State of Montana

FRANKIE SUE DEL PAPA  
Attorney General  
State of Nevada

DEBORAH T. PORITZ  
Attorney General  
State of New Jersey

TOM UDALL  
Attorney General  
State of New Mexico

PEDRO R. PIERLUISI  
Attorney General  
Commonwealth of Puerto Rico



DAN MORALES  
Attorney General  
State of Texas

JAN GRAHAM  
Attorney General  
State of Utah

JEFFREY L. AMESTOY  
Attorney General  
State of Vermont

DARRELL V. MCGRAW, JR.  
Attorney General  
State of West Virginia

JAMES E. DOYLE  
Attorney General  
State of Wisconsin

Jen,

I asked DOJ to draft a  
response. Here it is.

Would you deal with Corresp.

Thanks.

David





## U. S. Department of Justice

Civil Division

**DRAFT**

Office of the Assistant Attorney General

Washington, D.C. 20530

John R. MacArthur  
Harper's Magazine

Dear Mr. MacArthur:

Thank you for your letter of September 5, 1996, stating that you believe that the advertising restrictions issued by the Food and Drug Administration as a part of their regulation of cigarettes and smokeless tobacco are unconstitutional.

As you know, the regulations are aimed at reducing underage smoking. I endorsed FDA's regulation because underage smoking has continued to increase over the last few years, despite the fact that all 50 states prohibit the sale of tobacco products to minors. Almost every day, 3,000 children start smoking, and 1,000 of them will have their lives shortened by smoking related diseases.

My motivation in supporting these regulations is the well being and health of our children. The message that smoking could kill you just does not seem to register with many young people because they are bombarded with advertising that glamorizes smoking. The FDA restrictions are narrowly tailored to reduce young people's exposure to such advertising without preventing tobacco companies from conveying truthful information about their products to adults.

As a former professor of Constitutional law I believe the FDA's advertising restrictions are constitutional under the Supreme Court precedents in this area. Additionally, I can assure you that before going forward with these regulations they were closely scrutinized within the government and found to be constitutional. It is not appropriate to go into greater detail since this matter is the subject of ongoing litigation, but the government's position will be spelled out in the briefs we will be filing in this action which will be publicly available.

While you may disagree with me on some of the particular restrictions the FDA has issued, I am sure you fully support the goal of those regulations, reducing underage smoking.

With my warmest, personal regards.

Sincerely

**DRAFT**