

**NLWJC - Kagan**

**DPC - Box 052 - Folder-010**

**Tobacco-Settlement: Preemption &  
Penalties**

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Record Type: Record

To: Elena Kagan/OPD/EOP

cc:

Subject: Tobacco Bill

In my previous life, I did a fair amount of work on tobacco regulation. So, here's a thought about the legislative situation for what it's worth..

If we end up with a narrow bill and we are looking to good things to add to it, one possibility is a provision overturning the preemptive effect of the 1969 Cigarette Act. That would have two effects. First, it would allow tort actions to proceed on a failure to warn theory. We have already seen that Cipollone will create difficulties for private tort plaintiffs. And, I'm afraid it could be a tremendous barrier to the success of the state suits, at least in many cases. Second, and more importantly, it would allow states and localities to regulate marketing.

A year ago, I would have said that it is unthinkable that more than a handful of Republicans would go along with eliminating preemption. But they are obviously looking for something to do, and there may be some appeal to the idea of returning power to the states. So there may even be Rep. leadership interest in doing it.



Penalties/Preemption 7/7/97

1. Penalties - generally unclear - not clear what's being ~~added~~ replaced + what's not. Replace or add??  
- part of prob: not clear what states will do + what feds will do.

Where issues  
may be  
suppld  
(specif)  
(issues)

Retailers - more lenient than should be -  
10 times in 2 yrs!

Protocol - what does it mean?

- Need to maintain existing auths -  
Nothing explicit about FDA maintaining auth.

Schultz - key - what we're losing

1. Retailer
2. Effect on crim. auth -
3. St preemp issues - intending to limit st. abil to enforce
4. Provision - concurrent decrees. may be interpreted to restrict abil to enforce

Pros -

Ability to revoke license

Need: explicit lang - not  
need to replant.  
+ abil to revoke license

sep from that - st. licensing  
laws w/ penalties.

- floor w st structure?

Dithin headlines  
low signs/missives.

Lookback - "gd faster" too low  
a standard.  
alternative state -  
current FDCA std -  
(has to be apt each individual)

Preemptive -

FDA wants to do as little as possible in  
way of preemptive  
We can live w/ where we are - don't want  
more preemptive (of st. reg)

Need to make clear  
that tort suits are not  
preempted.

1. Make clear - doesn't preempt st tort actions
2. Don't make preemptive - more likely.  
• don't make it more difficult to petition  
in state

p. 26 v. p. 32 - seems contradictory

Should FDA reg set law?? - They don't YUW.

Not preempting states in areas of advert + promotion ???  
What would be left??

DRAFT

At the 11:00 a.m. meeting on July 7, we were asked to draft proposed legislation providing that (1) state-law tort suits relating to tobacco products would not be subject to preemption; (2) the scope of FDA's authority to exempt state and local requirements from preemption under 21 U.S.C. 360k(b) would be preserved; and (3) the adoption of federal requirements relating to tobacco products should not foreclose states and their political subdivisions from adopting more stringent requirements. The draft legislation appears below.

Preemption.

(a) Neither Section 521(a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 360k(a), nor any provision of this legislation, shall be construed to preempt any state-law tort action relating to tobacco products.

(b) Nothing in this legislation alters the scope of the Secretary's authority under 21 U.S.C. 360k(b) to exempt any state or local requirement with respect to tobacco products from preemption under 21 U.S.C. 360k(a).

(c) Neither Section 521(a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 360k(a), nor any provision of this legislation, shall be construed to prohibit any State or political subdivision of a State from establishing or continuing in effect any requirement with respect to tobacco products that is more stringent than any federal requirement applicable to such products.

tobacco-settlement - preemption +  
penalties

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**TODAY'S DATE: July 9, 1997**

**THIS FAX IS FOR: Elena Kagan**

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**FROM: Bill Schultz/Judy Wilkenfeld**

**NUMBER OF PAGES W/O FAX COVER: 3**

**COMMENTS: Attached is the assignment from  
Monday's regulation meeting.**

## Other Preemption Issues

In addition to the preemption issues specifically covered by the proposed settlement, other preemption issues are raised by statutes that directly regulate tobacco products and by express exclusionary provisions found in the enabling statutes for various federal agencies.

### **The Federal Cigarette Labeling and Advertising Act, 15 U.S.C. 1331**

The main focus of the Cigarette Act is the requirement that four specific rotating health messages be displayed on package labels and in advertising of cigarettes. One of the stated policies of this act was to

establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby \* \* \*

(2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations ....

To further this purpose, the Act provides that no statement relating to smoking and health, other than the proscribed four rotating warnings shall be required on any cigarette package and

No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.

The first preemption issue, that forbidding any federal or state entity from requiring any warnings on packages in addition to the four required warnings, is addressed directly in the proposed settlement and is a legitimate concern. New warnings are provided and FDA is granted authority to change the messages at a future date. This provision covers both packaging and advertising.

The second preemption issue, that forbidding state entities from enacting any regulation of advertising and promotion predicated on a smoking and health basis, is not addressed in the proposed settlement and presumably therefore still pertains. The Supreme Court has interpreted this provision as precluding certain common law damage actions, in addition to positive enactments by a state legislature.<sup>1</sup> In Cipollone v. Liggett Group, 505 U.S. 504

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<sup>1</sup> In two subsequent actions, the Supreme Court has let stand state regulation of tobacco advertising ostensibly based on justifications other than smoking and health. Mangini v. R.J. Reynolds Tobacco Co. 875 P.2d 73 (Cal. en banc), cert. denied, 115

(1992), the Court found that common law damages actions were preempted by the Cigarette Act because such actions constituted "requirements or prohibitions" within the meaning of the preemption provision.

[C]ommon law damages actions ... are premised on the existence of a legal duty and it is difficult to say that such actions do not impose "requirements or prohibitions." 505 U.S. at 522.

This second preemption serves no useful purpose and prevents those states which wish to provide additional protections in regulating advertising or in enabling persons to bring tort actions, from enacting legislation or making court action available to their citizens.

There is no similar problematic preemption provision in the Comprehensive Smokeless Tobacco Health Education Act of 1986, 15 U.S.C. 4401. The two preemption provisions in that Act provide that no statement relating to the use of smokeless tobacco products and health, other than the required statements, shall be required by any Federal agency, or State or local statute or regulation to appear on any package or in any advertisement of a smokeless tobacco product. Finally, the Act states that nothing in the Act will relieve any person from liability at common law or under a state's statutory law.

#### **The Consumer Product Safety Commission**

The Consumer Product Safety Act, 15 U.S.C. 2051, states that its purpose is to protect the public against unreasonable risks of injury associated with consumer products. It authorizes the CPSC to promulgate consumer product safety standards for a consumer product when such standards are "reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product." 15 U.S.C. 2056. However, the definition section of the statute expressly excludes tobacco and tobacco products from the definition of "consumer products." 15 U.S.C. § 2052(a)(1)(B).

The Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261, also administered by CPSC and which prohibits the introduction into commerce of any misbranded hazardous substance, similarly excludes tobacco products. This later exclusion resulted from congressional amendment of the FHSA to exclude cigarettes following a court ruling that CPSC had the power to regulate high-tar cigarettes under the FHSA. The stated congressional reason for excluding tobacco products was to save CPSC from "exhaust[ing] its resources and ...[thus, being] unable to address the other safety issues with which it must be concerned." S. Rep. No. 251, 94th Cong., 2d Sess. (1976).

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S. Ct. 577 (1994) and Penn Advertising of Baltimore, Inc. v. Mayor and City Counsel 63 F.3rd 1318 (4th Cir. 1995), vacated, 116 S. Ct. 2575 (1996), aff'd on remand, 101 F. 3rd 332 (4th Cir. 1996), cert. denied, 117 S. Ct. 1569 (1997).



Although these exclusions may prevent potentially conflicting regulation of tobacco products in the area of warning labels concerning the health of the smoker, they have also prevented CPSC from enacting final standards for the testing and mandating of more fire-resistant cigarettes. In 1984 (The Cigarette Safety Act of 1984 , P.L. 98-567) and again in 1990 (Fire Safe Cigarette Act of 1990, P.L. 101-352), Congress charged CPSC with the responsibility to oversee the development and design of a performance standard to reduce cigarette ignition propensity. In 1993, CPSC reported to Congress that it had concluded "that it is practicable to develop a performance standard to reduce cigarette ignition propensity..." ( Overview, Practicability of Developing a Performance Standard to Reduce Cigarette Ignition Propensity) However, CPSC lacked jurisdiction to implement its recommendation and require that cigarettes be tested to determine their fire hazard. Elimination of one or both of the relevant exclusions would permit CPSC to complete its work on this project and allow it to explore what, if any, other consumer hazards exist.

### **Toxic Substances Control Act and Controlled Substances Act**

Two other statutes contain explicit exclusion of tobacco from their Acts' coverage, the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 and the Controlled Substances Act (CSA), 21 U.S.C. 801. Under the TSCA, the Environmental Protection Agency is authorized to regulate hazardous chemical substances, excluding tobacco.

The CSA prohibits the manufacture, distribution or dispensing of a controlled substance. FDA, as part of the Department of Health and Human Services, independently reviews drugs with abuse potential and makes recommendations to the Drug Enforcement Administration (DEA) on whether, and to what extent, substances should be controlled under the various schedules. Controlled substances are thus subject to special requirements under DEA's jurisdiction. In addition, FDA retains jurisdiction to regulate the research and marketing of these products. However, because the CSA excludes tobacco products, these additional controls are not available.