

NLWJC - Kagan

Counsel - Box 022- Folder 007

FDA Issues

THE WHITE HOUSE

WASHINGTON

May 29, 1996

*kw
ok,
p*

MEMORANDUM FOR BRUCE LINDSEY

CC: JACK QUINN, KATHY WALLMAN

FROM: ELENA KAGAN *ek*

SUBJECT: FOOD AND DRUG ACT

I received the attached from Roger Ballentine of Patton Boggs, who represents ATLA. It concerns a provision in the FDA Reform Bill designed to ensure uniform federal and state "requirements" for non-prescription drugs. ATLA is concerned that this provision might be interpreted not only to preempt conflicting state regulations, but also to cut off state-law tort suits against manufacturers or sellers of non-prescription drugs.

Versions of the bill are currently pending in both House and Senate committees. There may be a mark-up in the House committee within the next couple of weeks; the Senate committee probably won't act so quickly. Ballentine thinks that there is a good chance this provision can be amended to exempt state-law tort suits. He also thinks the chances of the bill actually becoming law this year are relatively slim.

If it's OK with you, I'll contact the people at OMB and HHS dealing with this legislation and let them know we are generally concerned about this issue. Otherwise, I think we should just keep this on our radar screens.

*To Elena -
This got lost for a bit.
Where are we at it now?*

*Jack and
Kathy -*

kw

A Supreme Court decision issued in June interpreted identical language as not preempting state-law tort suits. So the consensus view is that this is no longer a problem.

Elena

Support Amending the FDA Reform Bill, S. 1477, to Avoid the Unintended Consequence of Eliminating All State Tort Law for Non-Prescription Drugs

Section 523 of S. 1477, the "Food and Drug Administration Performance and Accountability Act of 1996", seeks to provide uniform regulations on non-prescription drugs by preventing State and local governments from issuing non-prescription drug "requirements" that conflict with federal ones. Although the clear intent of the bill's authors seems to have been to provide uniform regulatory requirements, Section 523 could have the unintended consequence of preventing anyone killed or injured by a non-prescription drug from bringing a lawsuit to recover for their damages because such a lawsuit could be interpreted as a conflicting State regulatory "requirement".

In fact, the manufacturers of medical devices that can sometimes be dangerously defective have argued that nearly identical language in the Medical Device Amendments of 1976 has precisely this effect, as they have sought to dismiss claims brought against them by citizens who allege to have been injured by such devices. While the Supreme Court is currently considering the issue in the context of the Medical Device Act, *Medtronic v. Lohr*, S. Ct. Nos. 95-754, 95-886, the Senate should clarify this potential unintended consequence of the FDA reform bill by simply amending Section 523 to state that the definition of conflicting State or local non-prescription drug "requirements" does not include lawsuits brought by injured citizens.

I. Section 523 Arguably Bars All Lawsuits Involving Non-Prescription Drugs

- Unlike the Senate passed product liability bill which reformed standards of proof and placed some *limits* on damages, Section 523 could serve as an absolute ban on *any* lawsuits involving non-prescription drugs -- no matter how meritorious. Thus, Section 523 might protect: a manufacturer that obtained FDA marketing approval for its unsafe allergy medicine only by hiding information from FDA; a manufacturer that sold poisonous arthritic medicine that had been contaminated during production because of poor manufacturing practices, or a manufacturer that knew that its headache medicine caused liver damage and had failed to warn of that danger.

II. Section 523 Should be Amended to Specifically Exclude State Tort Law

- There will be two dramatic consequences if Section 523 is not amended. First, years of litigation will inevitably arise on whether Section 523 bars any lawsuits involving non-prescription drugs. Second, if Section 523 does bar such lawsuits, then those rare but notorious manufacturers of dangerously defective drugs will go unpunished.
- The Senate can avoid these unintended results of Section 523 by amending the Section to specifically provide that it does not apply to or preempt state tort liability laws.

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FAX Transmission

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Please deliver the following pages:

TO: Elena Kagen
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Our telecopier direct line is: (202) 457-6315.

OPERATOR: Jennie Barnes
OPERATOR NO.: Don't know? 457-6537

HHS A/As generally talking about this bill - this provision -
Hunt mark up in a when or so - effort to fix it probably. - prob just w/leg aware.

COMMENTS:

much - not intentional
Per phone mail message.
Medtronic 1st ctr. interrupted to preempt all.
Thank you!
Senate - Cal or curb mark up - but no del. time. Split away Deme Ken. opposes whole effort

Changes becoming less than are relatively slim.

WANTS TO SEE YOU

URGENT

RETURNED YOUR CALL

Message

would like bio for
from you for lunch on

Roy Ballentine

FDA reform bill

preempt of st cl

Operator



AMPAD
EFFICIENCY®

23-021 - 200 SETS
23-421 - 400 SETS

CARBONLESS

remedies re drugs

457-5666