GET OUT OF JAIL FREE

How The Bush Administration Helps Corporations Escape Accountability

AMERICAN ASSOCIATION for JUSTICE

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During the Bush adminstration, several federal agencies, headed by political appointees, have embarked upon an unprecedented campaign to negate the effect of state laws that protect consumers and injured workers—in effect granting immunity to irresponsible corporations. Without any constitutional authority, and often in direct contradiction to their own prior policies, these agencies have begun claiming that their own rules preempt state laws. Preemption of state law can leave individuals with no restitution for injuries caused by irresponsible corporations and further stacks the deck against American workers and consumers. It is just one part of a campaign by big business lobbyists to emasculate state consumer protection laws, and weaken regulatory scrutiny.

The Origins of Complete Immunity Preemption

Since taking office in 2001, the Bush administration has made implementing a "get out of jail free" card for corporations one of its top priorities. The administration first attempted to do this by filing friend-of-the-court briefs on behalf of corporations in product liability lawsuits. After finding only mixed success with this strategy in the courts, the administration turned its focus to the regulatory agencies in charge of product safety oversight. The administration instructed agencies to insert complete immunity preemption language in the preambles of rules, stating that products that meet federal agency regulations are not subject to state law. This language would effectively block all product liability lawsuits from being adjudicated and would let corporations "get out of jail free" even when their products seriously injure or even kill Americans.

Freedom of Information Act Requests

To prove that the complete immunity preemption efforts by the federal regulatory agencies was actually a coordinated campaign by the Executive Office to impose its agenda on federal regulatory agencies, the American Association for Justice (AAJ) filed multiple Freedom of Information Act (FOIA) requests with the federal government. The responses show that, not only did the Executive Office direct the agencies to override state laws, it wrote the language. In effect, the Bush administration made the safety of Americans a political undertaking.

The Cozy Relationship Between Federal Agencies and the Industries They Regulate

The idea of complete immunity preemption originated with a pharmaceutical defense attorney who left his job in the private sector to become the chief counsel of the FDA in the Bush administration. The complete immunity preemption campaign spread to other agencies, which were also staffed with political appointees who had previously worked in the industries they were now charged with regulating. Many of these employees have left their government jobs and returned to industry employment.

Unprecedented Attempt to Dismantle States' Rights

The attempt to push complete immunity preemption through regulatory agencies is both unprecedented and in some cases in direct contradiction to the agencies' own prior policies. Over the last three years the U.S. Food and Drug Administration (FDA), the National Highway Traffic Safety Administration (NHTSA), the Consumer Product Safety Commission (CPSC), the Federal Railroad Administration (FRA), the Pipeline and Hazardous Materials Safety Administration (PHMSA) the Department of Homeland Security (DHS), and the Transportation Safety Administration (TSA), all broke with long-standing agency precedents to claim the authority to provide immunity from state law. Each was met with consternation from members of Congress who believe the agencies have overstepped their constitutional bounds.

Criticism of Agency Preemption

The move to allow corporations to receive complete immunity and escape accountability even when they have knowingly injured or endangered consumers with unsafe products caused dissension at the agencies involved. At the agencies, career officials clashed with Bush administration appointees over the attempt to provide complete immunity corporations when their products harm consumers.[1] Academic commentators described the preemption strategy as a "travesty" and states' rights groups described it as "nothing more than a backdoor, underhanded means by which unelected federal bureaucrats impose their will on the states."[2]

Conclusion: The Value of the Civil Justice System

Complete immunity preemption endangers the American public. The regulatory system alone does not have the resources to fully protect the public, and has long worked in tandem with the civil justice system to provide restitution to consumers injured by dangerous products. The administration has injected politics into every aspect of Americans' lives, from their medicine cabinets to their cars' brakes, at the expense of consumer safety. This report will show that this movement has nothing to do with protecting the American public and everything to do with rewarding the administration's corporate sponsors.

The Stealth Campaign to Preempt States' Rights

Corporate America has been quietly pushing complete immunity preemption as its preferred solution to litigation that might also fall under regulatory realms.[3] Complete immunity preemption leaves individuals with no restitution for injuries caused by irresponsible corporations and further stacks the deck against American consumers.

The Constitution of the United States provides that the decision to preempt state law rests entirely with the United States Congress. Where the intent of the Congress is not clear it is the responsibility of the Judiciary to interpret. However, in recent years, federal administrative agencies, led by political appointees, have engaged in a backdoor attempt to usurp states' rights.

In the past few years, carbon copy statements claiming that federal agency rules preempt state law have begun surfacing in the preambles of rules issued by the federal government. These federal rules mark an unprecedented attempt to allow corporations to escape accountability when they knowingly market unsafe products. They are unconstitutional, often in direct contradiction to their own prior agency policies, are not voted on by any Member of Congress, and in some cases not even subject to a period for public comment. As a result, states have had their authority curtailed and liabilities imposed upon them by unelected federal regulators.

The increase in efforts by federal agencies to push complete immunity preemption comes as the Bush administration increasingly focuses on rulemaking as the only way to move its agenda under a Democratically-controlled Congress. Reporting in early 2007 on the administration's push of initiatives that did not require congressional approval, *CQ Weekly* said, "the administration decision to act unilaterally through rulemaking thus has a twofold appeal because it accomplishes that task without the need to compromise with Democrats or accommodate dissenters within the GOP."[4]

Big business lobbyists have the administration's ear when it comes to changing the way government regulates industry. According to Bill Kovacs, the U.S. Chamber of Commerce vice president for environment, technology and regulatory affairs, "the change in Congress makes a big difference. Presidents have a tendency, when Congress isn't of their party, to realize that they can get just as much policy through agencies as they can through Congress."[5]

The Origins of Complete Immunity Preemption

Priority of the Bush Administration

Providing complete immunity to corporations has been the goal of the Bush presidency since day one. The administration has tried numerous legal and regulatory avenues, but has met Congressional and judicial roadblocks along its path. Both Congress and the courts have repeatedly determined that the efforts to ensure complete immunity for corporations that put dangerous products on the market violate Congressional intent. Undeterred, the administration instructed federal agencies to insert preemption language into the preambles of proposed and final rules. Because the courts had not yet conclusively determined whether preambles carry the full weight of law, corporations had a new legal theory on which they could argue in product liability cases.

A Trojan Horse at the FDA

The complete immunity preemption campaign began at the U.S. Food and Drug Administration (FDA), where a former pharmaceutical company lobbyist named Daniel Troy was serving as the agency's chief counsel. Troy's arrival at the FDA in August 2001 marked an abrupt change of course in the agency's legal philosophy. Until that time, the FDA had operated on a "presumption against preemption," a position that was reinforced by the U.S. Supreme Court decision in *Medtronic v. Lohr*,[6] where the Court ruled that FDA approval of a medical device does not preclude consumers from filing product liability claims in state courts. Troy's immediate predecessor, Margaret Porter, stated, "FDA's view is that FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection."[7]

Troy, however, was about to send the FDA in the opposite direction. The idea to have the FDA file amicus briefs on behalf of pharmaceutical manufacturers was a strategy Troy initiated, he would later tell an audience of pharmaceutical and medical device manufacturer lawyers. Troy even invited manufacturers to request the FDA file amicus briefs in their failure-to-warn litigation, telling them to "make it sound like a Hollywood pitch."[8]

"...make it sound like a Hollywood pitch."

Daniel E. Troy, December 13, 2003

The FDA's first foray into the preemption debate during the Bush administration was an amicus brief filed in *Dowhal v. SmithKline Beecham Consumer Healthcare*.[9] In 1999, Paul Dowhal filed a lawsuit against GlaxoSmithKline, alleging the company's Nicoderm and Nicorette products violated California's Proposition 65, the Safe Drinking Water and Toxic Enforcement Act.[10] The Act requires manufacturers to inform customers when their product contains one or more of hundreds of toxic chemicals.[11] The FDA-approved text for the nicotine products was not as strict as California law.

On July 18, 2002, Daniel Troy met with Michele Corash of the San Francisco law firm, Morrison & Foerster, which was representing GlaxoSmithKline in the lawsuit.[12] Just two months later, on September 12, 2002, the FDA filed a brief in support of GlaxoSmithKline. In April 2004, California Supreme Court sided with the manufacturer and the FDA, holding that California's

labeling requirements for nicotine products were preempted by the requirements already established by the FDA.[13]

Following this, the FDA filed briefs in favor of pharmaceutical and medical device manufacturers in several more cases.[14] Other agencies began copying the amicus approach.[15] The strategy continued until, according to Troy, "[i]t became very clear and very obvious that intervening on a case-by-case basis was not a very efficient way of FDA communicating its views. The briefs were being introduced in other court cases as evidence of the FDA's views and so the thought was basically to articulate this policy in a context where it was genuinely necessary and that is in the physician labeling rule."[16]

A New Line of Attack – Commandeer the Rules

The physician labeling rule Troy spoke of was originally proposed on December 22, 2000, during the last days of the Clinton administration. The proposed rule changed the labeling requirements for prescription drugs, but its preamble specifically stated that the rule would not preempt state law.[17]

However, on January 24, 2006, the FDA released its final physician labeling rule, which updated the format of drug labels to make relevant safety information easy to find. For the first time the rule included language in the preamble saying that state failure-to-warn claims would be preempted by FDA approval of the drug. The *Wall Street Journal* noted that the inclusion of preemption language in the preamble of the drug labeling rule, "sparked disagreements between FDA career officials and Bush administration appointees."[18]

Other agencies soon followed suit.[19] To date, seven federal agencies—many times without any opportunity for public comment—have issued over 60 rules with preemption language in the preamble to the rule.

Freedom of Information Act Requests

Involvement of the Executive Office in Agency Affairs

The sudden inclusion of complete immunity preemption language in the preambles of such a wide variety of rules from multiple agencies displayed all the patterns of a coordinated push by the Bush administration. To prove that federal agencies are acting on directives from the Executive Office and not on their own analysis of the best interests of Americans, the American Association for Justice (AAJ) sought to uncover documents that would prove unelected federal bureaucrats were engaged in a coordinated campaign to eliminate accountability for corporations.

During the past year, AAJ submitted numerous Freedom of Information Act (FOIA) requests to uncover proof that the Office of Management and Budget (OMB) and its Office of Information and Regulatory Affairs (OIRA) had direct involvement in the placement of complete immunity preemption language in the preambles of agency rules.

AAJ filed requests for all correspondence between OMB and selected agencies regarding preemption of state common law. OMB responded that there were no responsive documents. However, emails obtained from the agencies prove that OMB did indeed discuss preemption with agencies.

OMB's Coordinated Preemption Campaign – NHTSA

One example is a federal motor vehicle safety standard issued by NHTSA on February 6, 2007. This safety standard, which applied to door locks and door retention, was issued as a final rule, and the boilerplate preemption language included in the preamble was not subject to public comment. Emails obtained by AAJ show that, despite OMB's position that it did not discuss preemption, OMB was not only afforded an opportunity to comment, it was able to write the language itself.

Nearly three months before the final rule was published, NHTSA's Chief Counsel, Anthony (Tony) Cooke started a conversation with OMB's General Counsel, Jeffrey A. Rosen. In an email sent on November 13, 2006, with the subject line "*O'Hara v. GM*,"[20] Cooke told Rosen:

> **Jeff,**
>
> **I'm sure you've been following this case–but a Judge in the Northern District of Texas made a preemption ruling involving NHTSA's glazing standard that has been appealed to the 5th Circuit.**
>
> **I understand that Respondents briefs are due early next month. Please let me know if you'd like me to forward these to you when I get them.**
>
> **Tony**

Rosen responded later that night with the subject line deleted and John G. Knepper, OMB's deputy general counsel, copied. The body of the email said:

> **Tony, thanks–I was not familiar with this. [text redacted]**

Cooke replied to both Rosen and Knepper on November 17. The contents of the email were redacted.

Six minutes later, Rosen replied to just Cooke. The contents of the email were redacted.

On November 27, 2006, NHTSA's Anthony Cooke

sent an email with "Door Locks" in the subject line to John Knepper at OMB. The body of the email was simple and direct:

> **John,**
>
> **I understand the rule is with you on the couple of matters we've discussed. Can you tell me OMB's timing for returning this?**
>
> **Thanks, Tony**

Knepper responded within a half hour, saying,

> **We will clear shortly. I am looking at it today. Is there time pressure I need to be aware of?**

This thread shows that there was a prior discussion of the door locks rule that has not been released. It also shows that there would be a conversation in the future. In his response the next day, November 28, Cooke told Knepper:

> **John,**
>
> **I understand there has been a request by OMB for more time?**
>
> **Can you call me?**
>
> **Tony**
>
> **366-5061**

Later that afternoon, Knepper and Cooke would exchange three emails in an eight minute span. The contents of these emails were redacted by the agency. However, Knepper's last response did contain the language:

> **We're looking at another week. We may be asking for more as standard practice, but we won't need it.**
>
> **(text redacted)**

Cooke responded:

> **Thank you.**
>
> **As I mentioned last night, we would like to meet an internal deadline of next Wednesday – so anything you can do…**
>
> **Please let me know if there is anything else you need.**

On December 1, Knepper responded with:

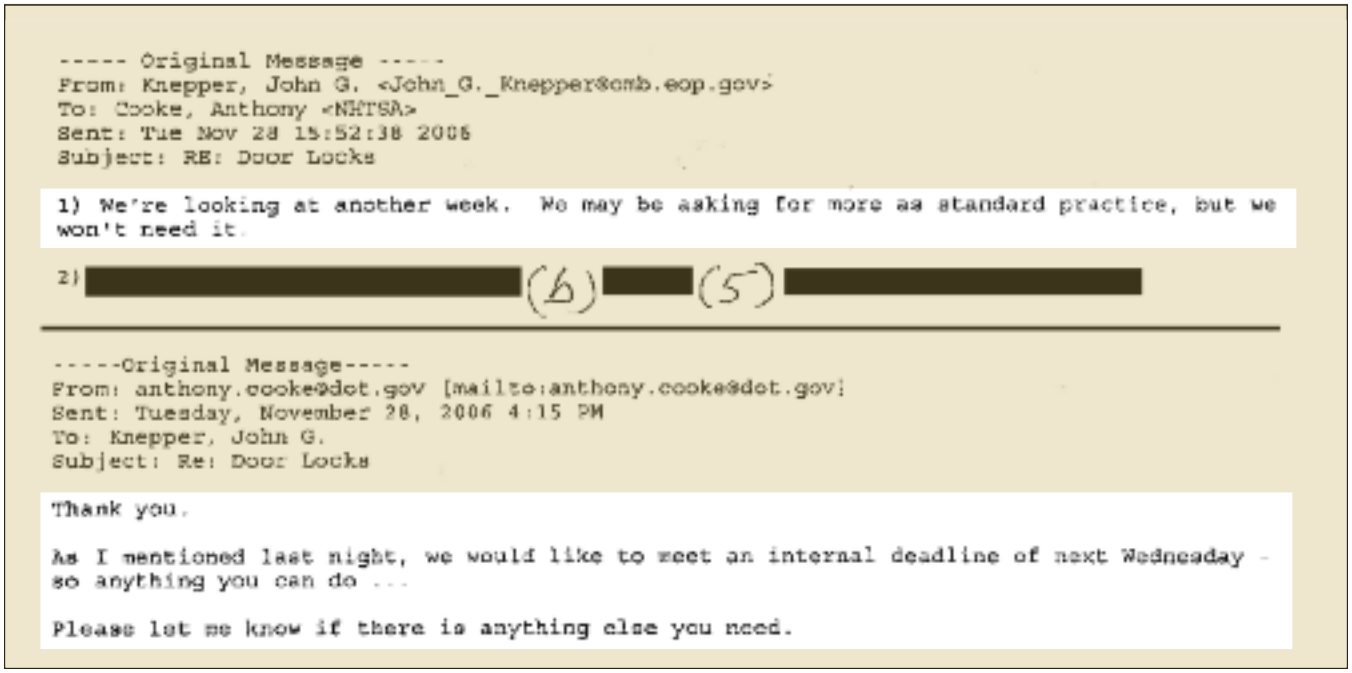
> **What is your FAX number?**

Knepper replied 15 minutes later with:

> **366-3820**

Although AAJ requested all correspondence, including faxes and phone records, these were not included in the FOIA response. Although it is known additional conversations took place, AAJ has no record of what transpired.

Emails Between NHTSA and OMB Regarding Door Locks



----- Original Message -----
From: Knepper, John G. <John_G._Knepper@omb.eop.gov>
To: Cooke, Anthony <NHTSA>
Sent: Tue Nov 28 15:52:38 2006
Subject: RE: Door Locks

1) We're looking at another week. We may be asking for more as standard practice, but we won't need it.

2) [redacted] (b) [redacted] (5) [redacted]

-----Original Message-----
From: anthony.cooke@dot.gov [mailto:anthony.cooke@dot.gov]
Sent: Tuesday, November 28, 2006 4:15 PM
To: Knepper, John G.
Subject: Re: Door Locks

Thank you.

As I mentioned last night, we would like to meet an internal deadline of next Wednesday - so anything you can do ...

Please let me know if there is anything else you need.

On November 28, 2006, Mark D. Menchik of OMB sent an email to Joanne Petrie in the Office of the Assistant General Counsel for Regulation and Enforcement at the U.S. Department of Transportation. The subject line of this email said, "NHTSA's Door Locks Final Rule (2127-AH34)" and its body contained the language:

> **Joanne,**
>
> **Today is Day 90. Although we've been making progress with the language, I think it would be a good idea to have an extension of time. Is that OK?**
>
> **Thanks.**
>
> **Mark**

Five minutes later, Petrie forwarded the email to Steve Wood, Assistant Chief Counsel for Vehicle Safety Standards at NHTSA, as an FYI.

OMB finished writing the door locks language on December 29, 2006. That day, OMB's Menchik sent an email with the subject line "Please Upload DOT/NHTSA Door Locks (2127-AH34)" to Joanne Petrie, copying NHTSA's Steve Wood, Steve Kratzke, Ronald Medford, and Tony Cooke. The email said:

> **Joanne and colleagues,**
>
> **I've gotten the green light on the EO language that's been discussed with OMB's John Knepper.**
>
> **The ROCIS [Regulatory Information Service Center and OIRA Consolidated Information System] entry is open**
>
> **Please take the rulemaking file with the agreed-upon EO language and as earlier revised in discussion with me, and make sure that it's clean,**
>
> **Have it uploaded into ROCIS.**
>
> **Let me know by ordinary e-mail, which should save a bit of time.**
>
> **Thanks.**
>
> **Mark**

A little over a month later, NHTSA would issue its final rule on door locks with complete immunity preemption language in the preamble. The complete immunity preemption language included in this rule would go on to appear as boilerplate preemption language in numerous auto safety rules promulgated by NHTSA in the next two years.

Because OMB was clearly not forthcoming in its response to the FOIA request, AAJ submitted a second request asking for all correspondence between the Office of Information and Regulatory Affairs (OIRA) within OMB and selected agencies regarding preemption. AAJ also sent requests to the agencies asking for their correspondence with OIRA on the preemption issue.

OMB's Coordinated Preemption Campaign – FRA

NHTSA was not the only agency within the Department of Transportation to collaborate with OMB in writing complete immunity preemption language. There is evidence that OMB provided both the Federal Railroad Administration (FRA) and the Pipeline and Hazardous Material Safety Administration (PHMSA) with preemption language to include in the preamble of at least one rule.

Emails obtained through a FOIA request to the FRA show that there was a debate within the Department of Transportation over the inclusion of language drafted by OMB in the preamble for a proposed rule to improve the crashworthiness protection of railroad tank cars designed to transport hazardous materials. The proposed rule was issued on April 1, 2008.

On March 24, 2008, FRA's deputy chief counsel, Michael Haley, sent an email to Brett Jortland, an attorney in the Office of the Secretary at the Department of Transportation, FRA chief counsel Mark Lindsey, FRA deputy associate administrator for safety Grady Cothen, and Mike Hilder of the Office of the Chief Counsel at PHMSA. In the email with the subject line "Preemption language for the preamble in the tank car rule," Haley told the recipients:

> **As you know, FRA and PHMSA have accepted two of the three points that OMB has asked us to include in the preamble. Attached is a slightly revised version capturing more of OMB's language on the first point damages). The draft also contains a discussion of why we are unwilling to accept the third point**

Another email was circulated on April 9, 2008. This time, Brett Jortland informed Susan Gorsky and Mike Hilder of PHMSA and Michael Haley of FRA of new preemption language in the rule. In an email with the subject line "New Preemption Language," Jortland said:

> **All,**
>
> **Let me know your thoughts on the new preemption reg text ASAP. As far as the preamble language, we don't think that it makes much sense in this context and will be speaking to OMB on that shortly.**
>
> **Thanks,**
>
> **Brett**

Michael Haley forwarded this email to his colleagues Roberta Stewart and Colleen Brennan at FRA, telling them:

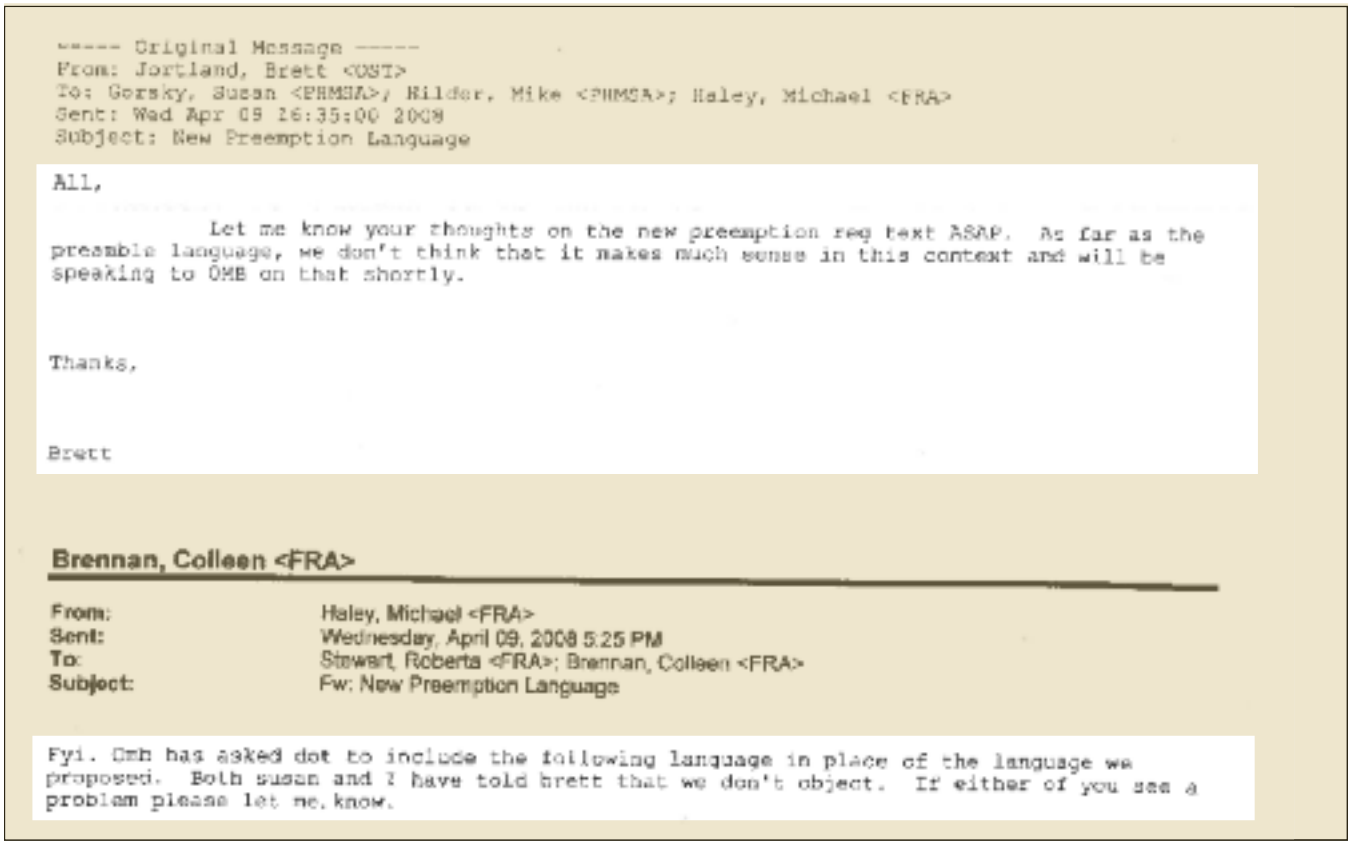
> **Fyi. Omb has asked dot to include the following language in place of the language we proposed. Both susan and I have told brett that we don't object. If either of you see a problem please let me know.**

OMB's Coordinated Preemption Campaign – FDA

The FDA responded to AAJ's request by providing the agency's rollout plan for the physician labeling rule for prescription drugs. This rule marked the first time the FDA asserted in a preamble that agency approval of a drug provides complete immunity for pharmaceutical manufacturers from failure-to-warn lawsuits brought by Americans harmed by the drug.

The FDA's rollout plan shows that the rule was originally scheduled to be released on January 18, 2006, but that the date was pushed back until January 24. An email thread provided by the FDA shows that OMB was actively involved in reviewing the physician labeling rule and did not conclude its formal review until January 17, 2006. That day, Fumie Yokota at the OMB's Office of Information and Regulatory Affairs sent an email with the subject line "RE: Physician Labeling" to several senior FDA and HHS officials. Yokota was replying to an earlier message, though that part of the thread was not supplied. In the body of the email, Yokota informed the participants that:

Emails Between FRA and OMB Regarding Preemption Language



----- Original Message -----
From: Jortland, Brett <OST>
To: Gorsky, Susan <PHMSA>; Hilder, Mike <PHMSA>; Haley, Michael <FRA>
Sent: Wed Apr 09 16:35:00 2008
Subject: New Preemption Language

All,

Let me know your thoughts on the new preemption reg text ASAP. As far as the preamble language, we don't think that it makes much sense in this context and will be speaking to OMB on that shortly.

Thanks,

Brett

Brennan, Colleen <FRA>

From: Haley, Michael <FRA>
Sent: Wednesday, April 09, 2008 5:25 PM
To: Stewart, Roberta <FRA>; Brennan, Colleen <FRA>
Subject: Fw: New Preemption Language

Fyi. Omb has asked dot to include the following language in place of the language we proposed. Both susan and I have told brett that we don't object. If either of you see a problem please let me know.

We have formally concluded review of the rule in ROCIS.

Please provide us with the final press roll-out plan and materials (including internal Q/A regarding the preemption issue).

Thank you.

Diane Sullivan responded to Yokota later that afternoon, saying:

Hi Fumie,

Attached FYI are the press materials on PLR. Please note that we are still awaiting clearance from HHS on the press release.

The rule is currently at the OFR with a request to display tomorrow morning. Thanks for all your help in getting it out.

Diane

The rollout plan shows that the FDA's Office of Policy, Planning, and Legislation (OPPL) and the Office of the Chief Counsel (OCC) were in charge of conducting outreach with legislative and state government groups, including:

- American Legislative Exchange Council
- Council of State Governments
- National Conference of State Legislatures
- National Governors Association

The OPPL and OCC were also tasked with conducting outreach to state governors. However, the agency contacted just two governors, Mississippi Governor Haley Barbour and Indiana Governor Mitch Daniels, both of whom had strong ties to the pharmaceutical industry. Barbour was a lobbyist who represented pharmaceutical manufacturers, including Amgen, Bristol Myers Squibb, and GlaxoSmithKline. Daniels had been Senior Vice President of Corporate Strategy at Eli Lilly before joining the Bush administration as Director of OMB.

OMB's Coordinated Preemption Campaign – Interest Group Connections

In the months leading up to the physician labeling rule's January 24, 2006, release, the pharmaceutical industry intensified its efforts to influence the FDA. Much of its efforts were aimed at Sheldon Bradshaw, who had succeeded Daniel Troy as FDA Chief Counsel in April 2005.

On July 19, 2005, Scott M. Lassman, Assistant General Counsel of the Pharmaceutical Research and Manufacturers of America (PhRMA) emailed Sheldon Bradshaw's executive assistant, June Stephenson, to set up a meet-and-greet with the Chief Counsel. The email, with the subject line "Meeting w/Bradshaw, Masoudi" contained the following:

Hi June,

Thanks for your call this morning. I have done some checking internally, and it looks like August 4th from 3-5 would work very well for us. August 26th will not work. Please let me know whether August 4th works for Sheldon and Gerry and whether they still want to meet downtown. I also should have a draft agenda and better idea of headcount in the next few days.

Best regards,

Scott

Stephenson followed up with Lassman later that afternoon, saying:

August 4, 3:00-5:00 is good for us. Please give me street address, room number, etc., when you send agenda and headcount. Thanks.

On August 3, 2005, the day before the meeting, Lassman again contacted Stephenson, saying:

Hi June,

We are looking forward to meeting with Sheldon and Gerry tomorrow. Do you have any idea whether other attorneys from OCC will be joining us?

Thanks, Scott

Stephenson responded three minutes later, saying:

> **Just the two of them.**

The meeting between Bradshaw, Masoudi, and PhRMA took place on August 4, 2005, at the Jefferson Hotel in Washington, D.C. A list of attendees released in the FOIA request shows that, in addition to PhRMA staffers, Bradshaw met with legal representatives from Pfizer, Wyeth, Eli Lilly, Berlex, Organon, Abbott Laboratories, Takeda, Sanofi-Aventis, Serono, AstraZeneca, Cephalon, Millenium, Eisai, Amgen, Astellas, GlaxoSmithKline, Bristol Myers Squibb, Johnson & Johnson, Novartis, Merck, and 3M.

Less than six months after this meeting between legal representatives of all the major pharmaceutical manufacturers and legal representatives of the FDA, the agency would release its final physician labeling rule, with complete immunity preemption language in the preamble, a complete about-face from the language in the proposed rule that specifically said the agency did not intend to preempt state law with the rule.

On August 5, the day after the meeting, Stephenson again emailed Lassman. Stephenson essentially allowed the pharmaceutical industry to dictate how the terms of the meeting would be published in the FDA's public calendar by writing:

> **Mr. Lassman, could you provide me with a list of attendees, or if only PhRMA members, I could designate that way on our public calendar. Thanks.**

Lassman replied eight minutes later, saying:

> **The meeting attendees were exclusively PhRMA members, so if that's easier you can designate it that way. If you need actual names, let me know and I will scan our sign-in sheet and email it to you this morning.**
>
> **Best regards,**
>
> **Scott**

Conversation Between the FDA and PhRMA

-----Original Message-----
From: Scott Lassman [mailto:SLassman@phrma.org]
Sent: Friday, August 05, 2005 9:44 AM
To: Stephenson, June
Cc: Bradshaw, Sheldon
Subject: RE: Meeting w/Bradshaw, Masoudi

The meeting attendees were exclusively PhRMA members, so if that's easier you can designate it that way. If y need actual names, let me know and I will scan our sign-in sheet and email it to you this morning.

Best regards,
Scott

Scott M. Lassman
Assistant General Counsel
Pharmaceutical Research and Manufacturers of America
1100 Fifteenth Street, NW
Washington, D.C. 20005
Phone 202-835-3470
E-mail slassman@phrma.org

This message is from a lawyer and may, together with any attachments, contain information that is confidential o legally privileged. If you are not the intended recipient, please immediately advise the sender by reply e-mail tha this message has been inadvertently transmitted to you and delete this e-mail from your system. Thank you for your cooperation.

-----Original Message-----
From: Stephenson, June [mailto:JStephen@OC.FDA.GOV]
Sent: Friday, August 05, 2005 9:48 AM
To: Scott Lassman
Subject: RE: Meeting w/Bradshaw, Masoudi

I will use PhRMA members for our calendar, but would like to have the list for our info. Thanks.

Stephenson replied four minutes later, saying:

> **I will use PhRMA members for our calendar, but would like to have the list for our info. Thanks.**

The email string ended later that morning with Lassman forwarding a list of attendees and telling Stephenson:

> **I'm attaching a list of attendees (other than Sheldon and Gerry). Thanks for your assistance organizing this. I think it was a great success.**
>
> **Scott**

Bradshaw would again meet with members of the pharmaceutical industry in October 2005. The week of October 17 was particularly busy, with Bradshaw meeting with representatives of several law firms and lobbying groups that represent pharmaceutical manufacturers. In just four days, Bradshaw held a meeting with representatives of Covington & Burling to discuss medical device regulation, had an introductory/courtesy visit with representatives of Hyman, Phelps & McNamara, participated in an introductory/courtesy meeting with APCO CEO Wayne Pines and representatives of APCO Worldwide, addressed a meeting with members of the American Bar Association Committee on Health Law Section, and held a meeting to discuss drug labeling with former FDA Chief Counsel Peter Barton Hutt and Scott Cunningham, both of Covington and Burling.

Of particular interest are the meetings between Bradshaw and Wayne Pines and representatives of APCO Worldwide. APCO is a public relations firm whose most high profile client is Philip Morris. FDA's public calendar lists the meeting as taking place at "FDA/Washington, DC." However, emails uncovered by AAJ show that Sheldon Bradshaw in fact went to APCO headquarters in Washington, D.C. to meet with pharmaceutical representatives. Bradshaw did not conduct similar courtesy visits with consumer groups.

In a September 27, 2005 email to APCO representative William Dougherty, Bradshaw's executive assistant, June Stephenson, stated:

> **Sheldon just sent me an e-mail telling me to put the 20th on the calendar, but the trail of e-mails**

Conversation Between the FDA and PhRMA

From: Scott Lassman [SLassman@phrma.org]
Sent: Friday, August 05, 2005 10:07 AM
To: Stephenson, June
Subject: RE: Meeting w/Bradshaw, Masoudi

m attaching a list of attendees (other than Sheldon and Gerry). Thanks for your assistance organizing this. I think it was a gre success.

cott

cott M. Lassman
ssistant General Counsel
harmaceutical Research and Manufacturers of America
100 Fifteenth Street, NW
/ashington, D.C. 20005
hone 202-835-3470
-mail slassman@phrma.org

his message is from a lawyer and may, together with any attachments, contain information that is confidential or legally rivileged. If you are not the intended recipient, please immediately advise the sender by reply e-mail that this message has be nadvertently transmitted to you and delete this e-mail from your system. Thank you for your cooperation.

To: Scott Lassman
Cc: Bradshaw, Sheldon
Subject: RE: Meeting w/Bradshaw, Masoudi

Mr. Lassman, could you provide me with a list of attendees, or if only PhRMA members, I could designa that way on our public calendar. Thanks.

do not say what you are doing. Please let me know and where to send him. Thanks.

Dougherty replied two minutes later saying:

Sheldon will be speaking to representatives of the pharmaceutical industry. The meeting will take place at the address that appears in my signature below and will run 12:00 to 1:30 pm on Oct. 20.

Please let me know if you have any further questions. I will be happy to answer them as best I can.

On November 7, 2005, APCO managing director Robert Schooling sent a letter to Bradshaw thanking him for attending the meeting and further detailing the cozy relationship between the regulator and the industry being regulated. The letter read:

Dear Sheldon:

Thank you so much for joining us for lunch at our offices, Given the number of issues that you have to contend with I sincerely appreciated your willingness to share your time and thoughtful remarks. I know that everyone assembled at lunch was equally grateful for your willingness to listen and share your perspective.

If I can ever be of service to you please don't hesitate to call.

Thank you again.

Sincerely,

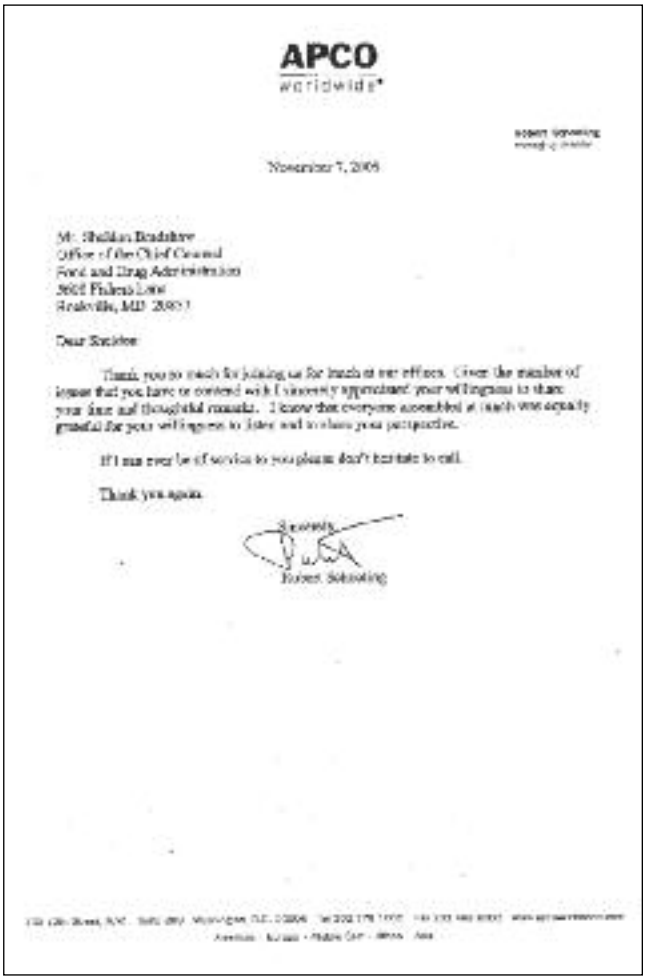
Robert Schooling

Less than three months later, the FDA would release the physician labeling rule, which provided complete immunity to pharmaceutical manufacturers whose drugs harm Americans, so long as the drug had been approved by the FDA.

These trails of emails show that across all agencies, the decision to include complete immunity preemption language in the preambles of rules had nothing to do with protecting the interests of Americans and every thing to do with rewarding the industries that helped install the Bush administration in office. The evidence that OMB was writing the complete immunity preemption language for the agencies indicates that shift toward complete immunity for manufacturers whose products meet minimum federal safety standards is politically motivated and is not grounded in established legal precedent or theories of consumer protection.

The meetings between industry representatives and agency officials are just one example of the cozy relationship between federal agencies and the industries they regulate. One of the industries' favorite tactics for ensuring its interests will be heard by the government is to send its agents and representatives through the revolving door to become the agency regulators.

Letter from APCO to the FDA

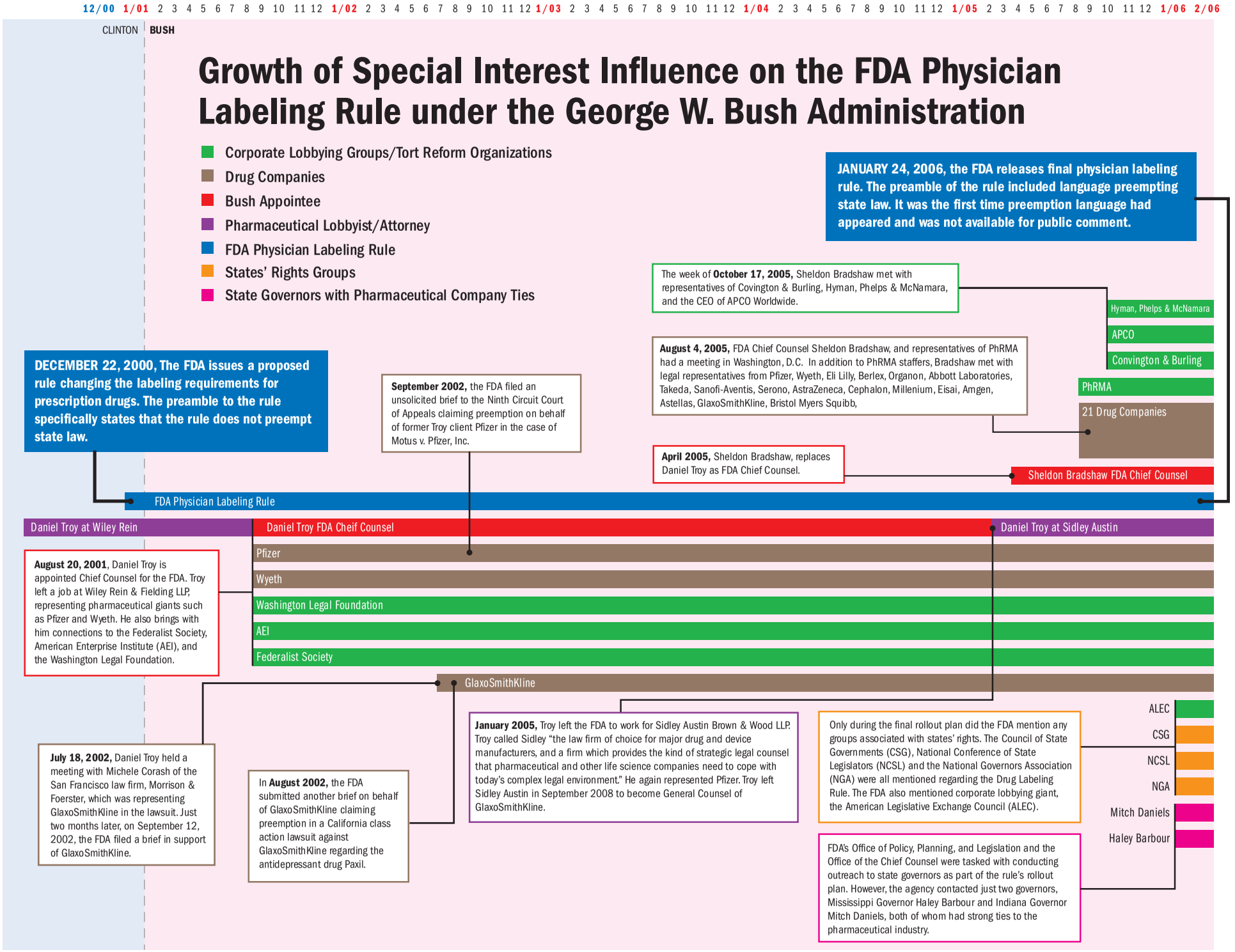


APCO
worldwide

November 7, 2005

Dear Sheldon

Robert Schooling


12/00 1/01 2 3 4 5 6 7 8 9 10 11 12 1/02 2 3 4 5 6 7 8 9 10 11 12 1/03 2 3 4 5 6 7 8 9 10 11 12 1/04 2 3 4 5 6 7 8 9 10 11 12 1/05 2 3 4 5 6 7 8 9 10 11 12 1/06 2/06
CLINTON
BUSH
Growth of Special Interest Influence on the FDA Physician Labeling Rule under the George W. Bush Administration
Corporate Lobbying Groups/Tort Reform Organizations
Drug Companies
Bush Appointee
Pharmaceutical Lobbyist/Attorney
FDA Physician Labeling Rule
States' Rights Groups
State Governors with Pharmaceutical Company Ties
JANUARY 24, 2006, the FDA releases final physician labeling rule. The preamble of the rule included language preempting state law. It was the first time preemption language had appeared and was not available for public comment.
The week of October 17, 2005, Sheldon Bradshaw met with representatives of Covington & Burling, Hyman, Phelps & McNamara, and the CEO of APCO Worldwide.
Hyman, Phelps & McNamara
APCO
Convington & Burling
August 4, 2005, FDA Chief Counsel Sheldon Bradshaw, and representatives of PhRMA had a meeting in Washington, D.C. In addition to PhRMA staffers, Bradshaw met with legal representatives from Pfizer, Wyeth, Eli Lilly, Berlex, Organon, Abbott Laboratories, Takeda, Sanofi-Aventis, Serono, AstraZeneca, Cephalon, Millenium, Eisai, Amgen, Astellas, GlaxoSmithKline, Bristol Myers Squibb,
PhRMA
21 Drug Companies
DECEMBER 22, 2000, The FDA issues a proposed rule changing the labeling requirements for prescription drugs. The preamble to the rule specifically states that the rule does not preempt state law.
September 2002, the FDA filed an unsolicited brief to the Ninth Circuit Court of Appeals claiming preemption on behalf of former Troy client Pfizer in the case of Motus v. Pfizer, Inc.
April 2005, Sheldon Bradshaw, replaces Daniel Troy as FDA Chief Counsel.
Sheldon Bradshaw FDA Chief Counsel
FDA Physician Labeling Rule
Daniel Troy at Wiley Rein
Daniel Troy FDA Cheif Counsel
Daniel Troy at Sidley Austin
August 20, 2001, Daniel Troy is appointed Chief Counsel for the FDA. Troy left a job at Wiley Rein & Fielding LLP, representing pharmaceutical giants such as Pfizer and Wyeth. He also brings with him connections to the Federalist Society, American Enterprise Institute (AEI), and the Washington Legal Foundation.
Pfizer
Wyeth
Washington Legal Foundation
AEI
Federalist Society
GlaxoSmithKline
July 18, 2002, Daniel Troy held a meeting with Michele Corash of the San Francisco law firm, Morrison & Foerster, which was representing GlaxoSmithKline in the lawsuit. Just two months later, on September 12, 2002, the FDA filed a brief in support of GlaxoSmithKline.
In August 2002, the FDA submitted another brief on behalf of GlaxoSmithKline claiming preemption in a California class action lawsuit against GlaxoSmithKline regarding the antidepressant drug Paxil.
January 2005, Troy left the FDA to work for Sidley Austin Brown & Wood LLP. Troy called Sidley "the law firm of choice for major drug and device manufacturers, and a firm which provides the kind of strategic legal counsel that pharmaceutical and other life science companies need to cope with today's complex legal environment." He again represented Pfizer. Troy left Sidley Austin in September 2008 to become General Counsel of GlaxoSmithKline.
Only during the final rollout plan did the FDA mention any groups associated with states' rights. The Council of State Governments (CSG), National Conference of State Legislators (NCSL) and the National Governors Association (NGA) were all mentioned regarding the Drug Labeling Rule. The FDA also mentioned corporate lobbying giant, the American Legislative Exchange Council (ALEC).
ALEC
CSG
NCSL
NGA
Mitch Daniels
Haley Barbour
FDA's Office of Policy, Planning, and Legislation and the Office of the Chief Counsel were tasked with conducting outreach to state governors as part of the rule's rollout plan. However, the agency contacted just two governors, Mississippi Governor Haley Barbour and Indiana Governor Mitch Daniels, both of whom had strong ties to the pharmaceutical industry.

The Cozy Relationship Between Federal Agencies and the Industries They Regulate

The inclusion of complete immunity provisions by federal agencies is not a random or haphazard occurrence. Rather, it is a coordinated campaign to eliminate accountability for negligent corporations. The campaign is enabled by the revolving door between corporations and the agencies charged with their oversight. Industries ensured that they would have the ear of the government by sending their own employees and agents to work in the agencies in charge of regulating their products. In this capacity, these employees have simultaneously attempted to loosen oversight of their products and eliminate accountability when these products injure Americans. Once they leave government service, they are often rewarded for their efforts with high-paying jobs in the industries they regulated. This phenomenon occurs across all agencies, as the following examples show.

Revolving Door at the FDA and DHHS

Daniel E. Troy

Perhaps no one represents this phenomenon better than the initiator of the preemption movement, Daniel E. Troy. Troy was a highly paid pharmaceutical company lobbyist when he joined the FDA, where he initiated the idea of complete corporate immunity through agency approval of drugs and devices. Thus, it is not surprising that after leaving the agency he became a highly-paid pharmaceutical executive.

Troy attended Columbia University School of Law in the 1980s.[21] After graduation, he clerked for Judge Robert Bork at the U.S. Court of Appeals for the D.C. Circuit.[22] Troy then spent two years at the Department of Justice before moving to private practice, first with the firm Paul Weiss Rifkind Wharton & Garrison, and later Wiley Rein & Fielding.[23] Along the way he joined the Federalist Society and became a scholar at the conservative think tank American Enterprise Institute.[24]

It was at Wiley Rein & Fielding that Troy first took an interest in the FDA. In 1993, Troy, working pro bono, filed a lawsuit for the Washington Legal Foundation, arguing that the FDA would violate the right to free speech if it were to prohibit drug manufacturers from giving doctors literature detailing unapproved uses of medications. He won.[25] He also received several hundred thousand dollars for his supposedly pro bono work on the case.[26] Pharmaceuticals are not allowed to advertise drugs for off-label uses, but once a drug is approved by the FDA, a doctor may prescribe it for any use he or she sees fit.[27]

Troy again challenged the FDA on free speech in 1998 when he represented Brown & Williamson Tobacco Corporation in a case that would determine the role of the agency in regulating tobacco.[28] The U.S. Supreme Court issued a seminal ruling in favor of Big Tobacco, keeping regulation of tobacco products out of the hands of the FDA.[29]

In 1999, Troy chastised "an overzealous FDA" for its restrictions on promoting drugs for off-label uses.[30] A year later, in 2000, again working for the Washington Legal Foundation, Troy successfully challenged the FDA's regulation that new drugs be required to undergo pediatric testing.[31]

One of Troy's clients at Wiley Rein & Fielding was pharmaceutical giant Pfizer.[32] The FDA would later defend his intervention in cases affecting Pfizer while serving as FDA Chief Counsel by saying Troy had only worked about 80 hours per year for the company.[33] However, Troy's financial disclosures showed that Pfizer paid Troy and/or his firm $415,000 over three years.[34] Commentators pointed out that "four thousand dollars an hour…has turned out to be a bargain deal for Pfizer."[35]

Bush's 2000 transition team gave Troy his choice of agencies for which he would like to work.[36] Troy chose the FDA. This was the first time an FDA chief counsel had been a political appointee since the 1980s, a fact Troy attributed to the administration's desire to exert more influence at the agency.[37] Moreover, Troy was the highest ranking official at the FDA for more than a year, because the FDA commissioner position was not filled until November 2002, when Mark McClellan joined the agency.[38] Troy essentially led the FDA, answering only to Department of Health and Human Services General Counsel Alex Azar II.

Once at the FDA Troy assumed responsibility for the warning letters FDA sent to pharmaceutical manufacturers that had violated agency regulations.[39] This task had traditionally been performed by individual departments within the FDA.[40] In 2001, 68 such letters were sent to pharmaceutical manufacturers. In 2002, the number of letters sent dropped to 27. In October 2004, when Troy announced his departure, the year's total had only reached 10.[41]

In the three years that Troy was at the FDA, he held 129 meetings with lobbyists and industry representatives. In comparison, Mark McClellan had 30 such meetings between October 2002 and March 2004. Margaret Porter, immediate past chief counsel to Dan Troy, held just one meeting between 1998 and 2001.[42] Troy did not keep notes or minutes from such meetings.[43]

One of Troy's biggest projects at the FDA was a push to get the FDA involved in failure-to-warn product liability lawsuits. Under the direction of Margaret Porter, the FDA had taken the stance that "FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection."[44] Troy's FDA abandoned that position and began filing amicus briefs in favor of pharmaceutical and medical device manufacturers who had been sued by consumers injured by these products.

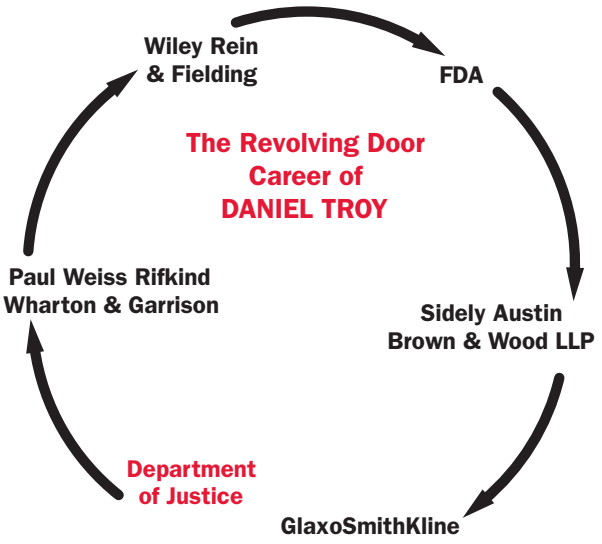
Troy announced his resignation from the FDA in November 2004, saying he was leaving to spend more time with his family.[45] In January 2005, Sidley Austin Brown & Wood LLP, a corporate law firm with more than 1,800 lawyers and offices in nine countries, hired Troy to work in its Life Sciences Practice and Appellate Litigation Group.[46] Troy called Sidley Austin "the law firm of choice for major drug and device manufacturers, and a firm which provides the kind of strategic legal counsel that pharmaceutical and other life science companies need to cope with today's complex legal environment."[47] Not surprisingly, one of his clients at Sidley Austin was Pfizer.[48]

"The preemption preamble is not a blunderbuss. I would say it is more of a rifle shot."

Daniel E. Troy, March 8, 2006

Although the government mandates a one-year "cooling off" period before former executive employees can engage in lobbying, that did little to dampen Troy's enthusiasm for the pharmaceutical industry's cause. On March 8, 2006, just weeks after the FDA released its physician labeling rule for prescription drugs, Troy boasted to the Washington Legal Foundation, that he had a hand in inserting complete immunity preemption language into the preamble of the rule.

Initially, Troy explained, the FDA had filed amicus briefs in failure-to-warn lawsuits until, "[i]t became very clear and very obvious that intervening on a case-by-case basis was not a very efficient way of FDA communicating its views. The briefs were being introduced in other court cases as evidence of the FDA's views and so the thought was basically to articulate this policy in a context where it was genuinely necessary and that is in



the physician labeling rule." The preemption preamble, he told the audience, "is not a blunderbuss. I would say it is more of a rifle shot."[49]

In September 2008, Troy left Sidley Austin to take the position of senior vice president and general counsel at GlaxoSmithKline, the pharmaceutical manufacturer currently facing Congressional and federal investigations, as well as numerous lawsuits over links between its antidepressant drug Paxil and the increased risk of suicidal behavior in some people who take the medication. Glaxo argues that these cases are preempted by the physician labeling rule.[50]

Troy was familiar with the Paxil litigation, having come to the aid of GlaxoSmithKline during his tenure at the FDA. In September 2002, the FDA filed a brief for Glaxo in In re Paxil Litigation. At a conference for pharmaceutical and device attorneys, Troy explained why he filed the brief, saying, "what prompted me to get involved in In re Paxil, was that I heard that the judge said that something could be misleading under state law, but not misleading to the FDA. That's crazy. I just had to get involved then."[51]

Alex M. Azar II

Between 1996 and June 2001, Alex Azar II worked as a partner at Wiley, Rein and Fielding, the same law firm Daniel Troy worked for when he successfully argued the seminal First Amendment cases for the pharmaceutical and tobacco industries in the late 1990s (In 2008, Bert Rein, named partner at Wiley Rein, will represent Wyeth before the U.S. Supreme Court in *Wyeth v. Levine*, where the Court will decide the merits of the industry's use of the preemption argument in failure-to-warn lawsuits).

Azar moved to the Department of Health and Human Services (DHHS) in August 2001 to serve as the department's general counsel.[52] Daniel Troy was also hired as chief counsel at the FDA in August 2001. A commissioner would not be appointed to the FDA until November 2002, leaving Troy in charge of the agency and reporting directly to Azar.

Azar was appointed deputy secretary for DHHS in 2005 and remained in that position until May 2007 when he left to become senior vice president of corporate affairs and communications at Eli Lilly.[53]

Sheldon T. Bradshaw

Sheldon Bradshaw joined the Bush administration in 2001 when he was hired by the Attorney General's Office at the Department of Justice. When Daniel Troy left the FDA, Bradshaw was tapped as his replacement. Under Bradshaw's leadership, the FDA began releasing rules with complete immunity preemption language in the preambles.

In September 2007, Bradshaw announced that he was leaving the FDA to join the Washington, D.C. law firm Hunton & Williams, where he was made partner and co-chair of the firm's Food and Drug Practice.

Revolving Door at NHTSA and DOT

Jacqueline Glassman

Jacqueline Glassman spent seven years working in the Office of the General Counsel at DaimlerChrysler before her appointment to chief counsel at the National Highway Traffic Safety Administration (NHTSA) in 2002.[54] In 1996, she was part of Chrysler legal defense team in litigation over California's "lemon law." A judge found that Chrysler had resold 119 defective cars and trucks that had been returned by consumers under the state's "lemon law."[55]

Glassman was elevated to deputy administrator at NHTSA in 2005 and took over as acting administrator later that year. Just two weeks after her appointment to deputy administrator, NHTSA issued a proposed rule on

roof crush strength with a weak standard and a preamble that explicitly preempted all state law requirements and all state tort law.

Glassman left NHTSA in 2006 to become a partner at Hogan & Hartson. Since moving to the private sector, she has been a registered lobbyist for Nissan and Hangzhou Zhongce Rubber Company, a Chinese company forced to recall over 450,000 tires that were liable to separate because of manufacturing defects.[56]

In early 2008, Glassman was rumored to be a candidate to become chairman of the perpetually troubled Consumer Product Safety Commission (CPSC).[57]

Nicole R. Nason

Nicole R. Nason was named administrator of NHTSA in 2006. Nason went to NHTSA from the Department of Transportation, where she worked as assistant secretary for government affairs.[58] Before joining the government, Nason served as government affairs counsel and was a registered lobbyist for Metropolitan Life Insurance Company.

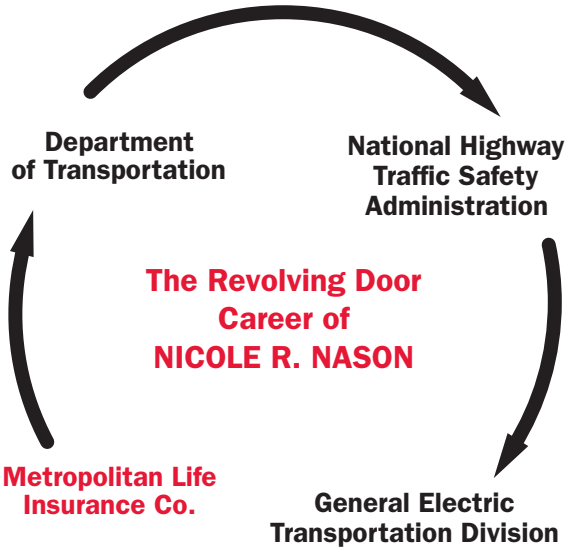
During Nason's tenure at NHTSA, the agency issued final rules on federal motor vehicle safety standards, including door locks and door retention, electronic stability control, head restraints, tire pressure monitoring, occupant crash protection, side impact protection, cargo carrying capacity, lamps, reflective devices and associated equipment, and power-operated windows, partitions, and roof-panel systems, as well as proposed rules on occupant protection standards, brake hoses, school bus passenger seating and crash protection, platform lifts for motor vehicles, child restraint systems, and windshield zone intrusion. All contained complete immunity preemption language in the preamble.

During her time at NHTSA, Nason prohibited her staff from providing information to reporters on the record. This mandate applied to everyone at the agency, including the communications department.[59]

Nason left NHTSA in August 2008 to join General Electric's transportation division.[60]

Jeffrey Rosen

Jeffrey Rosen left a senior partnership at Kirkland & Ellis to become the general counsel of the Department of Transportation in 2003. Kirkland's clients had included General Motors and the Alliance of Automobile Manufacturers.[61]



Rosen moved from the Department of Transportation to the Office of Management and Budget in 2006, where he took the job of general counsel. Later that year, Rosen exchanged emails with NHTSA's chief counsel, Tony Cooke, regarding preemption.

Revolving Door at CPSC

John Gibson Mullan

John Gibson Mullan was appointed general counsel at the CPSC in January 2004. He came from the law firm Kirkland & Ellis, where he defended such clients as General Motors and Polaris, a manufacturer of all terrain vehicles (ATVs).[62] Between 1998 and 2001, Polaris was investigated by the CPSC for failing to report safety defects in two of its products to the agency. The defects had led to numerous injuries and over a thousand consumer complaints. The company was fined $950,000 for failing to report these hazards.[63]

Not long after arriving at the CPSC, Mullan was elevated to the position of director of compliance and field operations. In this capacity, Mullan was responsible for all investigations and enforcement actions taken against manufacturers. Not long after taking this position, Mullan argued against a rule that would ban the sale of ATVs for use by children.[64]

Revolving Door at OMB

Mitch E. Daniels, Jr.

Mitch E. Daniels, Jr. left his job as the senior vice president of corporate strategy and policy at Eli Lilly, headquartered in Indiana, to become the director of the Office of Management and Budget in January 2001.

Daniels left OMB in 2003 to run for governor of Indiana. He won election and was sworn in January 2005. One year later, the FDA released its physician labeling rule. The agency's rollout plan for the rule indicated that it conducted outreach on the complete immunity preemption preamble to just two governors, even though all 50 states would be affected. Mitch Daniels, the former pharmaceutical manufacturer executive, was one of the two.

Unprecedented Attempt to Dismantle State's Rights

At the behest of these political appointees and without constitutional authority, the U.S. Food and Drug Administration (FDA), the National Highway Traffic Safety Administration (NHTSA), the Consumer Product Safety Commission (CPSC), the Federal Railroad Administration (FRA), the Pipeline and Hazardous Materials Safety Administration (PHMSA), the Department of Homeland Security (DHS), and the Transportation Safety Administration (TSA), have all broken with long-standing agency precedents to claim the authority to provide immunity from state law. Each was met with consternation from members of Congress who believe the agencies have overstepped their constitutional bounds.

Food and Drug Administration (FDA)

A 2006 FDA rule on drug labeling declaring that manufacturers of all drugs approved by the FDA would be provided with complete immunity from lawsuits was exactly contrary to the agency's long-held view on preemption.[65] In fact, when the rule was first proposed in December 2000, it had specifically stated "this proposed rule does not preempt state law."[66] There was an immediate outcry from Congress and states' groups. In a letter to the FDA, Senators Edward Kennedy and Chris Dodd, senior Democrats on the committee that oversees the FDA, criticized the agency for adding the language without allowing comments and described the assertion of preemption as "a drastic reversal of policy with…far-reaching implications."[67]

In a letter to the FDA, Representative Lee Terry (R-Neb.) stated that because the "preemption language did not appear in any earlier versions of the proposed rule FDA's response that no state or local government responded is disingenuous."[68] The National Conference of State Legislatures (NCSL) complained that "[i]t is unacceptable that FDA would not permit the states to be heard on language that has a direct impact on state civil justice systems nationwide."[69]

The FDA further weakened its mission to protect consumers in January 2008 when it issued a proposed rule regarding supplemental applications proposing labeling changes for approved drugs, biologics, and medical devices.[70] The rule was a direct contradiction of Congress' expressed intent that the duty to warn patients of newly discovered risks associated with prescription drugs rests with pharmaceutical manufacturers, which is in the best position to warn of problems, not the FDA. Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA) in response to a series of recalls and safety warnings associated with prescription drugs. In the Act, Congress asserted that drug manufacturers must update their warning labels as soon as they become aware of potential hazards the drugs may pose.

The FDA's proposed rule for supplemental applications contradicted Congressional intent by saying that drug manufacturers would have to establish a causal relationship between the drug and the hazard, instead of relying on reasonable evidence of a hazard, as has always been the policy, before a drug's warning label can be updated. Establishing a causal relationship can require years of study and review by the FDA. Under the rule, industries could claim immunity for failing to warn patients of potential hazards by arguing that a causal relationship had not been established by the FDA.

The rule sparked outrage from Congressional leaders, who intimated in a letter to the FDA that the rule appeared to have been written in part to bolster the administration's position in three preemption cases

before the U.S. Supreme Court.[71] The members of Congress noted that the release date of the proposed rule, January 16, 2008, coincided with the date of a letter by the Solicitor General, Paul Clement, to the U.S. Supreme Court supporting the drug and device industries' argument that FDA approval of their products preempts product liability lawsuits. The Solicitor General's letter cited the rule as evidence for the administration's position in the preemption cases *Riegel v. Medtronic* (06-179), *Warner-Lambert v. Kent* (06-1498), and *Wyeth v. Levine* (06-1249). The Court granted certiorari in *Wyeth* two days later.

The rule on supplemental applications was finalized on August 15, 2008, just seven months after it was initially proposed.[72] The speed with which that rule was approved prompted Rep. Henry Waxman (D-Calif.), Chairman of the House Committee on Government Oversight and Reform, to send a letter to FDA Commissioner Andrew C. von Eschenbach asking for clarification of the agency's priorities.[73] Waxman noted that the agency's process for setting priorities "appears designed to bypass normal channels," and that FDA has "put initiatives that benefit the pharmaceutical industry at the top of FDA's priority list," creating a disconnect with public health experts.

National Highway Traffic Safety Administration (NHTSA)

In 2005, NHTSA declared in preambles to proposed rules on seatbelts and roof-crush resistance that state common-law claims would be preempted by the rules. As long as the automobiles in question met the minimum federal standards, their manufacturers would have complete immunity from lawsuits even if they knew of defects that could cause serious injury to occupants. This marked the first time NHTSA had advocated preemption of state law, a concept it had specifically rejected previously.[74] Senators Arlen Specter and Patrick Leahy wrote to NHTSA criticizing the agency for claiming grounds for preemption without any Congressional authority.[75] The letter pointed out, "In the section of the Transportation Equity Act directing NHTSA to initiate rulemaking proceedings on roof resistance, we have been unable to find references to State tort law or language similar to that included in your agency's proposed rule." The letter went on, "We are interested to learn how NHTSA concluded that preemption of State law was the intent of Congress when it passed the Transportation Equity Act."

Consumer Product Safety Commission (CPSC)

The CPSC also broke with its own 33-year history by declaring in the preamble to a long-awaited rule on mattress flammability that state law would be preempted.[76]

One of CPSC's own commissioners, Thomas H. Moore, publicly questioned the decision to slip the provision in the preamble of the proposed rule at the "twelfth hour" and complained that the language was "buried in the tabs of the briefing package on our web site, [and] did not give it the public exposure it deserved."[77]

Congress has taken action to help remedy this problem. In August 2008, Congress passed the first major overhaul of the Consumer Product Safety Commission since the 1970s. The legislation recognized banned lead and certain chemicals from children's toys, added protections for whistleblowers who alert the public to safety concerns, and preserved the right of consumers who are injured by dangerous products to seek restitution from those who caused them harm. The accountability provision provides a huge incentive for manufacturers to keep dangerous products from ever coming on to the market.

Department of Homeland Security (DHS)

The DHS provided complete immunity preemption in a 2006 rule regarding chemical facility safety, despite the fact that the Senate Homeland Security and Governmental Affairs Committee expressly rejected such an approach just a year earlier.[78] Senator Joseph Lieberman, Chairman of the Homeland Security and Governmental Affairs Committee, wrote to DHS Secretary Michael Chertoff to admonish him for the failure to recognize, or even discuss, the fact that Congress never intended state laws to be preempted. "State and local protections are critical companions to our effort at the Federal level and should not be displaced," wrote the Senator. DHS, he said, "should remain silent on preemption, as Congress did and as it intended the Department to do."[79]

Federal Railroad Administration (FRA)

In 2006 the FRA proposed a rule on railroad operation.[80] The FRA referred to provisions of the Federal Railroad Safety Act (FRSA), which preempt state laws. However, in the preamble to the rule the FRA went significantly further by offering its own interpretation that state common law was also preempted. In doing so the FRA went against court interpretations of the FRSA. The U.S. Supreme Court has stated that "the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."[81] In 2006 the Supreme Court reaffirmed this presumption when it stated that the Court has "long presumed that Congress does not cavalierly pre-empt state-law causes of action."[82]

The FRA again tried to usurp Congressional authority in August 2007 when it released a proposed rule regarding passenger equipment safety standards.[83] The rule contained preemption language in the preamble that would prohibit commuter rail accident victims from pursuing legal action against railroad companies responsible for their injury or death. The proposed rule was published just days after Congress passed the Federal Rail Safety Act, which specifically protected an individual's right to hold railroad companies accountable for injuries resulting from train accidents. The FRA's attempt to claim otherwise is tantamount to an Administration declaration of the power to regulate with the force of law without regard to the will of Congress.

Criticism of Agency Preemption by the Legislative and Academic Communities

The move to provide complete immunity preemption prompted criticism from commentators and insiders alike. Professor James T. O'Reilly of the University of Cincinnati College of Law, author of a widely cited treatise on food and drug law, said "The capture of the FDA by forces favoring judicial pre-emption is a travesty."[84] According to Georgetown University law professor David Vladeck, "agencies have strayed from their proper function of applying the law as defined by Congress into the Constitutionally impermissible role of making the law on their own—untethered by guidance from Congress, unconstrained by the political process, and using backdoor means that escape serious oversight—all in an effort to eliminate state law."[85] The sudden shift toward preemption was contentious even within the agencies. The Wall Street Journal reported that the inclusion of the preemption language in the preamble of the physician labeling rule "sparked disagreements between FDA career officials and Bush administration appointees."[86]

By pushing to allow complete immunity from lawsuits for corporations, whether through legislation or agency rule, the American public pays. Injured persons will not receive restitution from the greedy corporations that sold unsafe products or the federal agencies that cut off their rights. The monetary burden is pushed onto the states. For instance, according to NSCL, while the automotive industry gets immunity from state tort claims through the NHTSA roof crush rule, the states will be forced to pick up $60 million a year in costs to support those who become permanently disabled and no longer have recourse to recoup their medical expenses.[87] According to New York State Senator Michael Balboni, a member of NCSL's Executive Committee, "Federal regulatory preemption is nothing more than a backdoor, underhanded means by which unelected federal bureaucrats impose their will on the states.[88]

Legislative Preemption

The administration's apparent dissemination of boilerplate preemption provisions through agencies was not the sum total of their attempt to immunize big business from lawsuits. The administration, supposedly committed to the belief that the federal government not impose its will on states, has consistently pushed legislation that would do just that. According to a 2006 report prepared for Rep. Henry Waxman, since 2001 the House and Senate have passed 73 separate preemption provisions, 39 of which have become law.[89]

According to Georgia Senator Don Balfour, then-chair of the NCSL's standing committees, "Federal preemption of state authority is a growing concern. These unwarranted power grabs by the federal government subvert the federal system, choke off innovation and ignore diversity among states."[90]

Conclusion: The Value of the Civil Justice System

Protecting worker and consumer safety has always required both government regulations and civil justice remedies. Regulations cannot anticipate and identify every safety problem. In the past, agencies operated under the assumption that "product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection."[91]

Even when regulations are met, there is a compelling need for the protections offered by the civil justice system, and it is these protections that are under attack. The civil justice system forced the removal from the market of tampons that were linked to toxic shock syndrome, but which had complied with FDA regulations.[92] The civil justice system uncovered the decision of Guidant executives to conceal deadly problems with their defibrillators.[93] The civil justice system forced Mega Bloks' deadly toys off the shelves even after the corporation had duped the CPSC into allowing them to remain on sale.[94]

When political appointees seek to render corporations unaccountable for their actions, the American public pays. Corporations gain immunity, consumers are left without remedy, and taxpayers are left with the financial burden of caring for the injured.

Regulations alone cannot protect the public, and negligent corporations should not be given a free pass for their actions. Federal regulatory law must work in tandem with the important safeguards of state tort law. This is why the constitutional right to fight for justice in a court of law must be preserved.

Appendices

Appendix A

What People Are Saying About Preemption

Margaret Porter, Former Chief Counsel of the FDA
"Given the harsh implications of foreclosing all judicial recourse for consumers injured by defective medical devices, FDA does not believe that Congress intended to effect so sweeping a change without even a comment. Rather, the agency believes that Congress intended to restrict preemption to positive enactments that apply to the marketing of medical devices within a state, and did not intend to preempt state tort remedies for injury to individual consumers."[95]

Professor James T. O'Reilly of the University of Cincinnati College of Law
"The capture of the FDA by forces favoring judicial preemption is a travesty."

Wall Street Journal
The Wall Street Journal reported that the inclusion of the preemption provision in the drug-labeling rule, "sparked disagreements between FDA career officials and Bush administration appointees."

U.S. Supreme Court Justice Stevens
"Nothing in [the federal statute] denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements."[96]

James M. Rosenbaum, United States Chief District Judge for the U.S. District Court of Minnesota
Judge Rosenbaum rejected the doctrine of implied preemption when he denied Pfizer's request for a summary judgment in the case *Witczak v. Pfizer, Inc.* saying; "The argument fails upon scrutiny. Federal labeling laws are minimum standards; they do not necessarily shield manufacturers from state law liability. The primary purpose of both the FDCA and the FDA's regulatory scheme is to protect the public. State-law protections reinforce and enhance this objective."[97]

National Conference of State Legislatures (NCSL)
Preemption "A Complete Disregard for Our Dual System of Government"…"a thinly-veiled attempt on the part of FDA to confer upon itself authority it does not have by statute and does not have by way of judicial ruling…This amounts to an abuse of agency process and a complete disregard for our dual system of government."[98]

Senators Arlen Specter and Patrick Leahy
"In the section of the Transportation Equity Act directing NHTSA to initiate rulemaking proceedings on roof resistance, we have been unable to find references to State tort law or language similar to that included in your agency's proposed rule."…"We are interested to learn how NHTSA concluded that preemption of State law was the intent of Congress when it passed the Transportation Equity Act."

Senator Joseph Lieberman, Chairman of the Homeland Security and Governmental Affairs Committee
"State and local protections are critical companions to our effort at the Federal level and should not be displaced,"… "[DHS] should remain silent on preemption, as Congress did and as it intended the Department to do."

Representative Lee Terry (R-NE) and the National Conference of State Legislatures (NCSL)
The FDA's drug labeling rule did not include the preemption provision in draft form. Only after the comment period had ended and the final version of the rule was issued was the preemption language publicly seen. There was an immediate outcry from Congress and states' groups. In a letter to the FDA, Representative Lee Terry (R-NE) stated that because the "preemption language did not appear in any earlier versions of the proposed rule FDA's response that no state or local government responded is disingenuous."xcix The National Conference of State Legislatures (NCSL) complained that "[i]t is unacceptable that FDA would not permit the states to be heard on language that has a direct impact on state civil justice systems nationwide."[100]

Senior National Highway Traffic Safety Administration (NHTSA) Official
The preemption issue had been handled in a way, "different from how we normally operated… [The preemption language] was dropped in from out of the blue."

CPSC Commissioner Thomas H. Moore
Commissioner Moore questioned the decision to slip a preemption provision into a mattress-flammability rule at the "twelfth hour" and complained that the language was "buried in the tabs of the briefing package on our web site, [and] did not give it the public exposure it deserved."

NCSL's Executive Committee Member and New York Senator Michael Balboni
"Federal regulatory preemption is nothing more than a backdoor, underhanded means by which unelected federal bureaucrats impose their will on the states."[101]

Georgia Senator Don Balfour, Chair of the NCSL's Standing Committees
"Federal preemption of state authority is a growing concern. These unwarranted power grabs by the federal government subvert the federal system, choke off innovation and ignore diversity among states."[102]

Georgetown Law Professor David C. Vladeck
"This is a radical restructuring of the American civil justice system,"…"If I drive my car and the brakes fail and I hit someone, I'm liable for the damage I caused,"… "Why should companies have an immunity from liability that ordinary citizens don't have? And that's what they are asking for."[103]

Appendix B

The Evolution of Unauthorized Agency Preemption

1997 – Margaret Porter, then Chief Counsel of the Food and Drug Administration (FDA), affirms agency's belief that in enacting food and drug laws, Congress "did not intend to preempt state tort remedies for injury to individual consumers."

2000 – The Supreme Court issues its decision in *Geier v. Honda Motor Co.*, 529 U.S. 861 (2000). This was a fact-specific decision dealing with a seat belt standard issued by National Highway Traffic Safety Administration. While the Court found that the state law tort suit was preempted, it went to great lengths to show that this was a unique situation based on the intent of Congress.

December 22, 2000 – The FDA issues its proposed rule changing the labeling requirements for prescription drugs. The preamble to the rule specifically states that the rule does not preempt State law. 65 Fed. Reg. at 81103.

March 25, 2002 – The FDA filed a brief in support of preemption in failure-to-warn cases in *Dowhal v. SmithKline Beecham Consumer*, which challenged the FDA's warning label on nicotine products under California's Proposition 65. During a speech at the Washington Legal Foundation in March 2006, Dan Troy emphasized that this was the first time the FDA had filed a brief over preemption.

September 3, 2002 – The FDA filed a brief in support of Pfizer in *Motus v. Pfizer, Inc*, No. 02-55372 (9th Circuit). This was the first of many briefs the agency would file in support of the pharmaceutical industry in lawsuits where the plaintiffs accused manufacturers of failing to warn of the increased risk of suicide while taking SSRI antidepressants.

September 5, 2002 – The FDA filed a brief in support of GlaxoSmithKline in In re Paxil Litigation, No. CV 01-07937. The plaintiffs sued the manufacturer over its claim that the antidepressant Paxil was non-habit forming. The FDA found this claim to be a threat to its regulation and weighed in on the side of the pharmaceutical industry.

July 18, 2003 – The FDA filed a second brief in *Dowhal v. SmithKline Beecham*. The lower court had agreed that the manufacturer could be held liable under California's Proposition 65. SmithKline appealed to the California Supreme Court, prompting the agency to file its second brief in the case.

December 12, 2003 – The FDA filed its first failure-to-warn preemption brief in a medical device case with *Murphree v. Pacesetter* (Tenn.Cr.Ct., No. 005429-00-3).

May 14, 2004 – The FDA filed a brief in *Horn v. Thoratec*, No. 02-4597 (3rd Cir.), arguing that in cases where a medical device has received pre-market approval by the agency, state tort laws are preempted by the Medical Device Amendments to the Food Drug and Cosmetics Act.

January 13, 2005 – For the first time in agency history, in the preamble to a new proposed rule regarding mattress flammability standards, the Consumer Product Safety Commission (CPSC) states that the rule preempts state tort law. Democratic CPSC Commissioner Thomas Moore issues a strong dissent. 70 Fed. Reg. at 2493. This rule takes effect March 15, 2006.

June 22, 2005 – NHTSA issues a proposed rule regarding designated seating position that contains NHTSA's first attempt to broadly preempt state common law claims. This rule went largely unnoticed by the public. 70 Fed. Reg. at 36101-02.

August 19, 2005 – NHTSA issues a proposed rule on roof crush strength with a weak standard and a preamble that explicitly preempts all state law requirements and state tort law. 70 Fed. Reg. at 49223.

August 30, 2005 – NHTSA issues a proposed rule for average fuel economy standards for light trucks for 2008-11 with brief express and implied preemption language. 70 Fed. Reg. at 51457.

September 12, 2005 – NHTSA issues a proposed rule regarding rearview mirrors which seeks to preempt all state statutes, regulations, and common law. 70 Fed. Reg. at 53768-69.

September 15, 2005 – The FDA filed an amicus brief in *Kallas v. Pfizer*, No. 2:04CV0998 PGC (D. Utah). The FDA argued that Pfizer was not liable for the death of a 15-year old girl who shot herself while taking the anti-depressant Zoloft because the agency's approval of the drug preempted failure-to-warn claims.

January 24, 2006 – In a complete reversal of its previous position, the FDA issues a final rule regarding prescription drug labeling, which contains a preamble that states the FDA intends its rule to preempt all state law requirements pertaining to a drug company's obligation to warn the public of a drug's potential side-effects. 71 Fed. Reg. at 3933-34. The labeling regulations take effect June 30, 2006.

March 29, 2006 – The FDA issues a final rule on dietary noncariogenic sweeteners with preemption language in the preamble that was not subject to notice and comment. 71 Fed. Reg. at 15563.

April 6, 2006 – NHTSA issues a final rule for average fuel economy standards for light trucks for 2008-11 with much more extensive preemption language in the preamble than was in the proposed rule. 71 Fed. Reg. at 17654-70.

May 10, 2006 – The FDA filed an amicus brief in *Colacicco v. Apotex Corp.*, C.A. No. 05-5500-MMB (E.D. Pa.), asserting that agency approval of the drug preempted state failure-to-warn claims.

May 22, 2006 – The FDA issues a final rule on soluble dietary fiber with preemption language in the preamble that was not subject to notice or comment. 71 Fed. Reg. at 29250.

July 25, 2006 – The FDA issues a final rule on raw fruits, vegetables, and fish with preemption language in the preamble that was not subject to notice or comment. 71 Fed. Reg. at 42042.

August 1, 2006 – The FDA issues a final rule on over-the-counter nasal congestion medication with preemption language in the preamble that was not subject to notice and comment. 71 Fed Reg. at 43360.

August 29, 2006 – The FDA issued a proposed rule on skin bleaching drug products with preemption language in the preamble. 71 Fed. Reg. at 51153.

September 21, 2006 – The FDA filed an amicus brief in *Perry v. Novartis Pharmaceuticals*, No. 05-CV-5350 (E.D. Pa.) but did not take a position on preemption.

October 11, 2006 – The Federal Railroad Administration (FRA) issues a final rule regarding continuous welded rail with language in the preamble seeking to expand the preemption language in the Federal Rail Safety Act (FRSA) and it was not subject to notice and comment. 71 Fed. Reg. at 59690.

October 12, 2006 – The FRA issues a proposed rule regarding railroad operating standards which contains language in the preamble seeking to expand the preemption language in the FRSA to cover common law claims. 71 Fed. Reg. at 60382.

December 4, 2006 – The FDA filed its second brief in *Colacicco v. Apotex Corp.*, No. 06-3107 (3rd Cir.) in support of preemption. The case was consolidated with a second failure-to-warn claim in an SSRI suicide lawsuit (*McNellis v. Pfizer*).

December 12, 2006 – The FDA includes what appears to be boilerplate preemption language in the preamble to its proposed rule regarding labeling of over-the-counter drugs. 71 Fed. Reg. at 74480-81.

December 13, 2006 – The FDA issues a final rule regarding the labeling of dietary supplements with preemption language that was not subject to notice or comment. 71 Fed. Reg. at 74790.

December 21, 2006 – The TSA issues a proposed rule reagarding rail transportation security which includes preemption language in the preamble. 71 Fed. Reg. at 76878-79

December 26, 2006 – The FDA issues a proposed rule that requires over-the-counter analgesics to include new warnings regarding potential risks which contain preemption language. 71 Fed. Reg. at 77345.

December 28, 2006 – The Department of Homeland Security (DHS) issues proposed chemical facility anti-terrorism regulations with extensive language seeking to preempt state tort law. 71 Fed. Reg. at 78292-93. DHS issues these regulations despite the short timeframe (statute requires regulations to be effective by April 4, 2007) and the fact that this preemption language was expressly rejected during the 109th Congress.

January 5, 2007 – The FDA issues a proposed rule on labeling claims regarding calcium which contain preemption language in the preamble. 72 Fed. Reg. at 516.

January 12, 2007 – The FDA issues a final rule that expanded use of the nutrient content claim "lean" on certain foods which contain preemption language in the preamble that was not subject to notice and comment. 72 Fed. Reg. at 1458.

February 6, 2007 – NHTSA issues the first of many final rules regarding federal motor vehicle safety standards (door locks & door retention) which include boilerplate preemption language (including cite to *Geier v. Honda Motor Co.*, 529 U.S. 861 (2000) in the preamble that was not subject to notice and comment. 72 Fed. Reg. at 5397.

March 6, 2007 – The FDA issues a final rule requiring over-the-counter dandruff products to contain a combination of 1.8% coal tar solution and 1.5 percent menthol. This rule contains preemption language in the preamble and was not subject to notice and comment. 72 Fed. Reg. at 9851.

March 29, 2007 – The FDA issues a final rule on over-the-counter laxatives with preemption language in the preamble that was not subject to notice and comment. 72 Fed. Reg. at 14673.

April 6, 2007 – NHTSA issues a final rule on electronic stability control which includes boilerplate preemption language in the preamble that was not subject to notice and comment. 72 Fed. Reg. at 17300.

April 9, 2007 – DHS issues interim final rules regarding chemical facilities, which continued to contain preemption language, despite outrage from Congress. Congress addressed this problem through the use of appropriations bills.

May 4, 2007 – NHTSA issues a final rule on head restraints which includes boilerplate preemption language in the preamble that was not subject to notice and comment. 72 Fed. Reg. at 25512.

July 12, 2007 – NHTSA issues a final rule on tire pressure monitoring which includes boilerplate preemption language in the preamble. This language was not subject to notice and comment and was not included when the earlier version of the final rule was issued two years ago. 72 Fed. Reg. at 38023-24.

July 24, 2007 – NHTSA issues a final rule on occupant crash protection which includes boilerplate preemption language in the preamble that was not subject to notice and comment. 72 Fed. Reg. at 40257.

July 27, 2007 – Congress passes legislation implementing the 9/11 Commission's recommendations. This legislation includes anti-preemption language to clarify that the Federal Rail Safety Act (FRSA) does not preempt an individual's right to hold a negligent railroad accountable for injuries resulting from a train derailment.

August 1, 2007 – The Federal Railroad Administration issues proposed rules regarding passenger equipment safety standards, which include a preamble with language seeking to preempt state tort law. 72 Fed. Reg. at 42036. This would essentially undo the progress that Congress made in interpreting the FRSA.

August 27, 2007 – The FDA issues a proposed rule regarding changes to the labels for sunscreen, which contains preamble language seeking to preempt state tort law. 72 Fed. Reg. at 49109.

September 4, 2007 – The FRA issues proposed rules regarding electronically controlled pneumatic brake systems, which include a preamble with language seeking to preempt state law. 72 Fed. Reg. at 50848-49.

September 5, 2007 – NHTSA issues a final rule regarding side impact protection which includes boilerplate preemption language in preamble that was not subject to notice and comment. 72 Fed. Reg. at 50905.

September 11, 2007 – NHTSA issues a final rule regarding side impact protection for electric powered vehicles which includes boilerplate preemption language in preamble that was not subject to notice and comment. 72 Fed. Reg. at 51953.

September 12, 2007 – Senate Judiciary Committee holds hearing titled: "Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority?"

September 17, 2007 – The FDA issues an interim final rule on dietary sweeteners with preemption language in the preamble. 72 Fed. Reg. at 52788.

September 25, 2007 – NHTSA issues a proposed rule regarding changes to its occupant protection standards which includes boilerplate preemption language. 72 Fed. Reg. at 54409.

October 9, 2007 – NHTSA issues a proposed rule regarding standards for electric-powered vehicles which includes boilerplate preemption language. 72 Fed. Reg. at 57265.

October 9, 2007 – NHTSA issues a proposed rule regarding brake hoses which includes boilerplate preemption language. 72 Fed. Reg. at 57468.

November 2, 2007 – NHTSA issues a final rule regarding occupant crash protection which includes boilerplate preemption language in the preamble that was not subject to notice and comment. 72 Fed. Reg. at 62139.

November 21, 2007 – NHTSA issues a proposed rule regarding school bus passenger seating and crash protection which includes boilerplate preemption language. 72 Fed. Reg. at 65525.

November 27, 2007 – The FDA issues a proposed rule on fatty acids with preemption language in the preamble. 72 Fed. Reg. at 66116.

December 4, 2007 – NHTSA issues a final rule regarding cargo carrying capacity which includes boilerplate preemption language in the preamble that was not subject to notice and comment. 72 Fed. Reg. at 68458.

December 4, 2007 – NHTSA issues a final rule regarding lamps, reflective devices, and associated equipment which includes boilerplate preemption language in the preamble that was not subject to notice and comment. 72 Fed. Reg. at 68265.

D**ecember 19, 2007** – The FDA issues a final rule establishing new warning statements and other labeling information for over-the-counter contraceptives with preemption language in the preamble that was not subject to notice and comment. 72 Fed. Reg. at 71783.

December 20, 2007 – NHTSA issues a proposed rule regarding platform lifts for motor vehicles which includes boilerplate preemption language. 72 Fed. Reg. at 72335.

January 16, 2008 – FDA issues a proposed rule regarding supplemental applications proposing labeling changes for approved drugs, biologics, and medical devices. This rule would effectively preempt failure to warn claims despite clear congressional intent, particularly regarding drug labeling. 73 Fed. Reg. at 2848.

January 23, 2008 – NHTSA issues a proposed rule regarding child restraint systems which includes boilerplate preemption language. 73 Fed. Reg. at 3911.

J**anuary 30, 2008** – NHTSA issues a supplemental NPRM regarding roof crush resistance which continues to preempt state tort law. 73 Fed. Reg. at 5491.

February 1, 2008 – The FDA issues a final rule on skin protectant drug products with preemption language in the preamble that was not subject to notice and comment. 73 Fed. Reg. at 6016.

February 13, 2008 – The FRA issues a final rule on railroad operating rules and responds to AAJ's comments. The FRA reiterates the language in the Railroad Preemption Clarification, which they claim renders AAJ's comments moot. 73 Fed. Reg. 8456.

February 20, 2008 – United States Supreme Court issues decision in *Riegel v. Medtronic*, stating that federal law preempts medical device claims.

February 25, 2008 – The FDA issues an interim final rule on soluble fiber with preemption language in the preamble. 73 Fed. Reg. at 9944.

April 1, 2008 – The FRA/Pipeline Hazardous Materials Safety Administration jointly issue a proposed rule to improve the crashworthiness protection of railroad tank cars designed to transport hazardous materials with preemption language in the preamble. 73 Fed. Reg. at 17852.

April 16, 2008 – The FRA/ Pipeline Hazardous Materials Safety Administration jointly issue an interim final rule enhancing rail transportation safety with preemption language in the preamble. 73 Fed. Reg. at 20755.

May 1, 2008 – The FDA publishes its final rule regarding labeling for soluble fiber which contains preemption language. 73 Fed. Reg. at 23952. This document also includes the Administration's first reference to the *Riegel v. Medtronic* decision.

May 2, 2008 – NHTSA issues its proposed rule regarding average fuel economy standards for passenger cars and light trucks for 2011-15. While the rule does not expressly state that it will preempt state tort law, it clearly preempts state regulations and prohibits a state from adopting or enforcing a law or regulation related to fuel economy, which could include the use of a court order. The rule also states that the agency has decided to ignore previous court rulings that did not support the preemption of state laws on this issue. 73 Fed. Reg. at 24478-79.

May 27, 2008 – The FDA publishes its final rule regarding labeling for dietary sweeteners which contains preemption language. 73 Fed. Reg. at 30301. This document also references the *Riegel v. Medtronic* decision.

May 29, 2008 – The FDA publishes its proposed rule regarding requirements for pregnancy and lactation labeling which contains preemption language. 73 Fed. Reg. at 30831.

June 9, 2008 – NHTSA publishes a final rule/response to petitions for reconsideration of its earlier rule regarding side impact protection, to which AAJ had filed a petition for reconsideration. NHTSA directly responded to the petitions from several automakers, but the agency did not respond to AAJ. The same preemption language was included in this version. 73 Fed. Reg. at 32481.

June 16, 2008 – The FRA issues its final rule regarding railroad operating practices (first noticed in October 2006), which contains preemption language. 73 Fed. Reg. at 33900.

July 7, 2008 – NHTSA publishes its proposed rule regarding requirements for windshield zone intrusion which contains boilerplate preemption language yet still allows the states to regulate in this area. 73 Fed. Reg. at 38373.

July 7, 2008 – NHTSA publishes a final rule (with responses to petitions for reconsideration) regarding power-operated windows, partitions, and roof-panel systems which contains boilerplate preemption language. 73 Fed. Reg. at 38338.

August 5, 2008 – NHTSA publishes a final rule on child restraint systems. The SNPRM on this issue contained boilerplate preemption language, and AAJ filed comments. For the first time in the last year and a half, NHTSA's finally deviated from its boilerplate language preempting state tort law. Instead, the agency went back to using the language it has used prior to 2005, stating that the rule did not have any impact on State and local governments. 73 Fed. Reg. at 45357.

August 15, 2008 – The FDA issues a final rule regarding soluble fiber labeling which contains preemption language and also references the Riegel decision. 73 Fed. Reg. at 47829.

August 22, 2008 – The FDA issues a final rule regarding supplemental application used to proposed labeling changes for drugs and medical devices which continues to contain language in the preamble to preempt state law claims. 73 Fed. Reg. at 49609. The text of the rule also may operate to preempt failure to warn claims, because the manufacturer can now argue it had no obligation to update its rule.

August 28, 2008 – NTHSA issues its revised final rule regarding lamps, reflective devices, and associated equipment. While the agency acknowledged that AAJ filed a petition for reconsideration, the agency only decided to extend the effective date upon reconsideration. The agency also says the boilerplate preemption language from the previous version still applies. 73 Fed. Reg. at 50730.

September 9, 2008 – Although it is after the White House's proposed "deadline" for proposed rules, the FRA issues a proposed rule regarding incident reporting requirements, which contains a new iteration of its previous language preempting state tort law. 73 Fed. Reg. at 52519.

September 12, 2008 – NHSTA issues a proposed rule removing the sunset provision for occupant crash requirements which contains boilerplate preemption language. 73 Fed. Reg. at 52941.

September 17, 2008 – NHTSA issues a proposed rule regarding motorcycle brake systems which contains boilerplate preemption language. 73 Fed. Reg. at 54034.

September 22, 2008 – NHTSA issues a final rule regarding electronic stability control systems which says that preemption is a matter for the courts to decide. 73 Fed. Reg. at 54536.

October 2, 2008 – NHTSA issues a proposed rule regarding motorcycle helmets which contains boilerplate preemption language. 73 Fed. Reg. at 57297.

October 8, 2008 – NHTSA issues a final rule regarding designated seating positions. In response to comments regarding the preamble to its proposed rule, NHTSA included language in both the text and the preamble to rule regarding the preemption of State tort law. This is the first time that any agency has taken this action. 73 Fed. Reg. at 58894.

Notes

1. Anna Wilde Mathews, "FDA Plan Would Aid Drug Makers in Liability Suits," Wall Street Journal, January 14, 2006.
2. Andrew G. Simpson, Jr., "State Lawmakers Balk at Growing Trend of Federal Preemption," *Insurance Journal*, April 10, 2006.
3. *How to Fix the Tort System*, *Business Week*, March 14, 2005.
4. Rebecca Adams, "Lame Duck or Leapfrog?" *CQ Weekly*, February 12, 2007.
5. *Id.*
6. *Medtronic v. Lohr*, 518 U.S. 470 (1996).
7. Margaret J. Porter, "The Lohr Decision: FDA Preemption and Position," *Food and Drug Law Journal* 52(1), 1997, 11. Viewed in Kerr, Kathleen, "Can FDASeal be Broken?" *Newsday*, August 11, 2004.
8. Affidavit of Jessica R. Dart, *Dusek v. Pfizer, Inc.* No. H-02-3559 (S.D. Tex. Feb. 20, 2004).
9. *Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1 (Cal. 2004).
10. Curtis, Kim, "Calif. Supreme Court OK's FDA Warning Label on Nicotine Patches," *Associated Press*, April 15, 2004.
11. *Id.*
12. U.S. Congressman Maurice Hinchey, "FDA is Placing Corporations Above Public," http://www.house.gov/hinchey/issues/fda.shtml, viewed on October 6, 2005.
13. *Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1 (Cal. 2004).
14. The FDA filed briefs in favor of pharmaceutical and medical device manufacturers in the failure-to-warn cases *Murphree v. Pacesetter, Inc.*, No. 005429-00-3 (Tenn. Cir. Ct. Dec. 12, 2003); *Horn v. Thoratec*, 376 F.3d 163 (3d Cir. 2004); In re Paxil Litigation, 212 F.R.D. 539 (C.D. Cal. 2003), and; *Motus v. Pfizer Inc.*, 358 F.3d 659 (9th Cir. 2004).
15. In *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), a group of 29 peanut farmers in Texas sued Dow Agrosciences, alleging that the company's newly-marketed "Strongarm" pesticide stunted the growth of their peanut plants. The farmers argued that they used the pesticide as directed by the label and that Dow knew Strongarm would not work as intended in the alkaline soils of west Texas. Dow argued that the farmers' claims were preempted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), because the pesticide's label had been approved by the EPA.

    After lower courts ruled that the farmers' claims were preempted by FIFRA, the farmers appealed to the U.S. Supreme Court, which heard the case in 2005. The U.S. Solicitor General, Theodore Olson, submitted an amicus brief on behalf of the Administration. In his brief, Olson sided with Dow, saying FIFRA expressly preempts state tort law claims. The Bush Administration's position in Bates was a drastic reversal of the federal government's long-held view that FIFRA does not preempt state tort claims. In a 7-2 decision the Supreme Court sided with the farmers and allowed them to proceed with their claims in state court.

    Coincidentally, the attorneys who argued *Bates* before the U.S. Supreme Court will again in a preemption case before the Court on November 3, 2008. David Frederick, who successfully argued *Bates* for the peanut farmers, will represent Diana Levine in *Wyeth v. Levine* (06-1249), while Dow's attorney, Seth Waxman, will represent Wyeth.
16. Daniel E. Troy, "FDA's Federal Preemption Policy: Implications for Drug Labeling and Product Liability," *Washington Legal Foundation,* March 8, 2006.
17. 65 Fed. Reg. at 81103.
18. Anna Wilde Mathews, *supra* note 1.
19. The National Highway Traffic Safety Administration (NHTSA), the Consumer Product Safety Commission (CPSC), the Federal Railroad Administration (FRA), the Department of Homeland Security (DHS), and the Pipeline Hazardous Materials Safety Administration (PHMSA) have all issued rules with complete immunity preemption language in the preambles.
20. The U.S. Court of Appeals for the Fifth Circuit agreed to hear *O'Hara v. General Motors Corp* 508 F.3d 753 (5th Cir.2007), where the auto manufacturer argued that it was not responsible for injuries caused to a nine-year old girl injured when she was ejected from a Chevrolet Tahoe during a rollover accident. GM

argued that because the car's windows met the federal minimum safety standard for auto glass, the family's state law claim of design defect should be preempted. The Court rejected GM's argument, ruling that the O'Hara's case could proceed.

21. Matt Fleischer-Black, "Cosmetic Advocacy," *Corporate Counsel*, October 2003, 116.
22. Michael Kranish, "FDA Counsel's Rise Embodies US Shift," *Boston Globe*, December 22, 2002.
23. Matt Fleischer-Black, *supra* note 21 at 116.
24. Thomas Frank, "Friends on the Inside," *Newsday*, October 11, 2004.
25. Matt Fleischer-Black, *supra* note 21at116; *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 62-65 (D.D.C. 1998)
26. Matt Fleischer-Black, *supra* note 21at 116.
27. *Id.*
28. Matt Fleischer-Black, *supra* note 21 at 116; *Food and Drug Administration v. Brown & Williamson Tobacco Corp.*, (98-1152) 529 U.S. 120 (2000).
29. Matt Fleischer-Black, *supra* note 21 116..
30. Thomas Frank, *supra* note 24.
31. Gary Young, "FDA Strategy Would Pre-empt Tort Suits," *The National Law Journal*, March 1, 2004; *Association of American Physicians and Surgeons v. FDA*, 226 F.Supp.2d 204 [D.D.C. 2002].
32. Thomas Frank, *supra* note 24.
33. U.S. Congressman Maurice Hinchey, "FDA is Placing Corporations Above Public," viewed at http://www.house.gov/hinchey/issues/fda.shtml. Jessica R. Dart, "Preemption Issues and Prescription Drug Litigation," *Mealey's Litigation Report*, 1(8), March 2005.
34. Jessica R. Dart, "Preemption Issues and Prescription Drug Litigation," *Mealey's Litigation Report*, 1(8), March 2005.
35. *Id.*
36. Matt Fleischer-Black, *supra* note 21 at 116.
37. Thomas Frank, *supra* note 24.
38. *Id.*
39. Matt Fleischer-Black, *supra* note 21 at 116.
40. *Id.*
41. Thomas Frank, *supra* note 24.
42. *Id.*
43. Stacy Schultz, "Mr. Outside Moves Inside," *U.S. News & World Report*, March 24, 2003.
44. Margaret J. Porter, *supra* note 7.
45. "FDA Chief Counsel Dan Troy Resigning," *FDA Week*, November 19, 2004.
46. "Former FDA Chief Counsel Dan Troy and Special Assistant Coleen Klasmeier to Join Sidley Austin Brown & Wood LLP," Sidley Austin Brown & Wood LLP Press Release, January 6, 2005.
47. *Id.*
48. Marguerite Higgins, "Vioxx Trials to Pain Industry," Washington Times, September 9, 2005.
49. Daniel E. Troy, "FDA's Federal Preemption Policy: Implications for Drug Labeling and Product Liability," *Washington Legal Foundation*, March 8, 2006.
50. Alicia Mundy, "Glaxo Braces for Probes, Hires FDA Ex-Litigator," *Wall Street Journal*, July 23, 2008, B7.
51. Affidavit of Jessica R. Dart, *Dusek v. Pfizer, Inc.* No. H-02-3559 (S.D. Tex. Feb. 20, 2004).
52. Biography, Alex M. Azar II, Eli Lilly.
53. *Id.*
54. "Jacqueline Glassman Named Chief Counsel at NHTSA," Collision Repair Industry INSIGHT, March 4, 2002.
55. Andrea Adelson, "Chrysler Curb Being Proposed In California," New York Times, June 1, 1996.
56. Adam Davison, "Recall of Chinese-Made Tires Faces Complications," *NPR Morning Edition*, June 27, 2007.
57. Annys Shin, "White House Vetting Product-Safety Candidates," Washington Post, January 26, 2008, D01.
58. Biography: Nicole R. Nason, U.S. Department of Transportation.
59. Christopher Jensen, "What's Off the Record at N.H.T.S.A.? Almost Everything," *New York Times*, August 22, 2007.
60. David Shepardson, "NHTSA Chief Hits the Road," *Detroit News*, August 27, 2008.
61. Myron Levin and Alan C. Miller, "U.S. Rules Shield Industries from Lawsuits," *Los Angeles Times*, February 19, 2006.
62. Eric Lipton, "Safety Agency Faces Scrutiny Amid Changes," New York Times, September 2, 2007.
63. Press Release: Polaris to Pay $950,000 Penalty for Failing to Report Hazards with ATVs, Consumer Product Safety Commission, January 13, 2005.
64. Eric Lipton, *supra* note 62.
65. Professor James O'Reilly, quoted in: Anne C. Mulkern, "Watchdogs or Lap Dogs? When Advocates Become Regulators," *Denver Post*, May 23, 2004.
66. *See* Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics: Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81082, 81103, proposed December 22, 2000.
67. Letter from Sen. Edward M. Kennedy & Sen. Christopher J. Dodd to Michael O. Leavitt, Secretary, Health & Human Services, February 23, 2006.
68. Letter from Rep. Lee Terry to Andrew C. Von Eschenbach, Acting Commissioner, FDA, March 31, 2006.

69. Letter from Sen. Steven J. Rauschenberger, President, National Conference of State Legislatures (NCSL) to Michael O. Leavitt, Secretary, Health & Human Services, January 13, 2006, available at: http://www.ncsl.org/programs/press/2006/060113Leavitt.htm.
70. 73 Fed. Reg. at 2848
71. Letter to the Honorable Andrew C. von Eschenbach, M.D. from Henry A. Waman et al, January 23, 2008.
72. 73 Fed. Reg. at 49603.
73. Letter to the Honorable Andrew C. von Eschenbach, M.D. from Henry Waxman, September 17, 2008.
74. See Myron Levin & Alan C. Miller, "Industries Get Quiet Protection from Lawsuits," *Los Angeles Times*, February 19, 2006; Motor Vehicle Content Labeling, 60 Fed. Reg. 47878, 47890, September 15, 1995, codified at 49 C.F.R. pt.583.
75. See Letter from Sen. Arlen Specter & Sen. Patrick Leahy to Jacqueline Glassman, Acting Director, NHTSA, November 17, 2005, available at http://dmses.dot.gov/docimages/pdf94/377136_web.pdf.
76. Stephen Labaton, "'Silent Tort Reform' Is Overriding States' Powers," *New York Times*, March 10, 2006.
77. Statement of the Honorable Thomas H. Moore on the Final Rule and Preamble for the Flammability (Open-Flame) of Mattress Sets, February 16, 2006, at http://www.cpsc.gov/cpsc.gov/cpscpub/prerel/prhtml06/06091.html.
78. Rebecca Adams, "Lame Duck or Leapfrog?" *CQ Weekly*, February 12, 2007.
79. Lieberman Expresses His Concerns About Proposed Chemical Security Regulations, Press Release of Senate Committee on Homeland Security & Governmental Affairs, February 9, 2007, available at, http://hsgac.senate.gov/public/index.cfm?FuseAction=PressReleases.Detail&PressRelease_id=c476d054-a988-4520-8cb2-5011f5e66766&Affiliation=C.
80. 71 Fed. Reg. 60372.
81. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).
82. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449, 125 S. Ct 1788, 1801 (2005).
83. 72 Fed. Reg. at 42036.
84. Gary Young, "FDA Strategy Would Pre-empt Tort Suits," *National Law Journal*, March 1, 2004.
85. Testimony of David C. Vladeck, before the U.S. Senate Committee on the Judiciary, September 12, 2007.
86. *Wall Street Journal*, 1/14/2006.
87. Andrew G. Simpson, Jr., "State Lawmakers Balk at Growing Trend of Federal Preemption," *Insurance Journal*, April 10, 2006.
88. *Id.*
89. Committee on Oversight and Government Reform (Minority Staff), "Congressional Preemption of State Laws and Regulation." Prepared for Rep. Henry Waxman, United States House of Representatives, June 2006.
90. Andrew G. Simpson, Jr., *supra* note 87.
91. Margaret J. Porter, *supra* note 7.
92. *See e.g. O'Gilvie v. International Playtex, Inc.*, 821 F.2d 1438 (10th Cir. 1987).
93. Barry Meier, "Guidant Debated Device Peril," *New York Times*, Jan. 20, 2006; Barry Meier, "Citing Flaws, Maker Recalls Heart Devices," *New York Times*, June 18, 2005.
94. Patricia Callahan, "Inside the Botched Recall of a Dangerous Toy," *Chicago Tribune*, May 7, 2007.
95. Margaret J. Porter, "The Lohr Decision: FDA Preemption and Position," Food and Drug Law Journal 52(1), 1997, 7-12. iewed in, Clune, Margaret, "Stealth Tort Reform: How the Bush Administration's Aggressive Use of the Preemption Doctrine Hurts Consumers," *Center for Progressive Regulation White Paper*, October 2004.
96. Gary Young, *supra* note 84.
97. *Wall Street Journal*, 1/14/2006.
98. *Medtronic v. Lohr*, 518 U.S. 470 (1996); *The Legal Intelligencer*, 6/27/96
99. *Witczak v. Pfizer, Inc.* 04-CV-2819
100. NCSL, 1/13/06
101. See Letter from Sen. Arlen Specter & Sen. Patrick Leahy to Jacqueline Glassman, Acting Director, NHTSA, November 17, 2005, available at http://dmses.dot.gov/docimages/pdf94/377136_web.pdf.
102. Press Release: Lieberman Expresses His Concerns About Proposed Chemical Security Regulations, Senate Committee on Homeland Security & Governmental Affairs, February 9, 2007, http://www.senate.gov/~govt-aff/index.cfm?Fuseaction=PressReleases.Detail&PressRelease_id=1413&Month=2&Year=2007&Affiliation=C.
103. Letter from Rep. Lee Terry to Andrew C. Von Eschenbach, Acting Commissioner, FDA, March 31, 2006.
104. Letter from Sen. Steven J. Rauschenberger, President, National Conference of State Legislatures (NCSL) to Michael O. Leavitt, Secretary, Health & Human Services, January 13, 2006, available at: http://www.ncsl.org/programs/press/2006/060113Leavitt.htm.
105. Myron Levin & Alan C. Miller, Industries Get Quiet Protection from Lawsuits, *Los Angeles Times*, February 19, 2006.
106. Statement of the Honorable Thomas H. Moore on the Final Rule and Preamble for the Flammability (Open-Flame) of Mattress Sets, February 16, 2006, http://www.cpsc.gov/cpsc.gov/cpscpub/prerel/prhtml06/06091.html.
107. Andrew G. Simpson, Jr., *supra* note 87.
108. *Id.*
109. David G. Savage, "Drug Makers Seek Shield from Lawsuits" *Los Angeles Times*, September 7, 2008.