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Product Liability - Notes [1]

Product Liability - notes + memos

THE WHITE HOUSE

WASHINGTON

May 1, 1998

Senator Slade Gorton
730 Hart Senate Office Building
Washington, DC 20510

Senator John D. Rockefeller
531 Hart Senate Office Building
Washington, DC 20510

Dear Senators Gorton and Rockefeller:

President Clinton continues to be grateful to you for your consistent efforts to craft product liability legislation that he can sign. After your meeting with White House Chief of Staff Bowles on March 13, 1998, there remained a variety of technical issues outstanding. We are pleased to transmit to you our final views on these matters.

1. Findings Language

We agree to include the findings language below. If these findings are not acceptable, we would prefer none.

SEC. 2 FINDINGS; PURPOSES

(a) FINDINGS -- The Congress finds that --

(1) although damage awards in product liability actions can encourage the production of safer products, they also can have a direct effect on interstate commerce and our Nation's consumers by, among other things, increasing the cost and decreasing the availability of products;

(2) some of the rules of law governing product liability actions are inconsistent within and among the States, resulting in differences in State laws that can be inequitable to both plaintiffs and defendants and can impose burdens on interstate commerce;

(3) product liability awards can jeopardize the financial well-being of individuals and industries, particularly the Nations' small businesses;

(4) because the product liability laws of one State can have adverse effects on consumers and businesses in many other States, it is appropriate for the Federal government to enact national, uniform product liability laws that preempt State laws; and

(5) it is the constitutional role of the national government to remove barriers to interstate commerce.

2. When to Apply the Small Business Test

As we mentioned before the last meeting, the bill does not specify the time at which a company qualifies as a small business for purposes of the cap on punitive damages. We propose language below that would clarify that the test is applied at the time the lawsuit is filed. This point is far easier to establish than when a product is manufactured, designed, or constructed or when another act occurs that could give rise to product liability.

New language added to Section 111(b)(2):

> [C] REFERENCE POINT FOR DETERMINING APPLICABILITY. In determining the applicability of this subsection, the standards in subparagraphs (A) and (B) shall be applied as of the date of commencement of any action that is subject to this title. The burden shall be on the defendant to prove the applicability of this subsection.

3. Request to Delete Section on "Defense Based on Claimant's Use of Alcohol or Drugs"

We are not willing to delete this section. However, we would be agreeable to legislative history that makes clear that this provision preempts only specific provisions establishing an intoxication defense and not state contributory and comparative negligence regimes.

4. Proposed Changes to Language on "Reduction of Damages for Misuse or Alteration"

We are not comfortable adding the new language proposed by Senator Gorton. As you know, we believe it is a slippery slope when we begin to write bill language to interpret bill language.

5. Revised Proposal on "Extension of 18-Year Statute of Repose"

Similarly, the additional language Senator Gorton proposed on extension of the statute of repose significantly confuses the statute. It ignores the aspect of the statute of limitation language that measures time from when not only the harm, but also its cause, are discovered. Similarly, it does not include exceptions in the bill to the statute of limitations provisions for a person with a legal disability or subject to a stay or injunction.

6. Proposed Changes to Workers' Compensation Subrogation Provisions

In general, we understand that the changes that Senator Gorton proposed to the workers' compensation subrogation provisions were designed by a working group of workers compensation experts to address practical considerations. Where we could be comfortable that there would not be unintended consequences, we have agreed to the changes.

a. Notification to Employer of Settlement

Senator Gorton recommended eliminating a provision in Section 113(a)(2)(B) that required the claimant to notify the workers' compensation insurer before entering into a settlement with a manufacturer or product seller. We understand that, in most cases, the claimant already has this obligation as a result of having filed a claim with the insurer pursuant to state workers' compensation law. However, in the absence of a survey of all state laws and workers

compensation claim agreements, we see no harm in retaining the language which will help ensure that the subrogation provisions work as intended. Therefore, we object to eliminating this provision.

b. Notice to Insurer By Product Manufacturer or Seller

Senator Gorton proposed changes to Section 113(a)(3)(A) that would clarify that, to seek a reduction in damages due to employer fault, the manufacturer must notify the insurer that it is raising the issue with the court. This appears to be a reasonable technical change to assure fair notice to affected parties. We have no objection to the change.

c. Reduction of Damages by Amount of Claimant's Benefits

We appreciate and support the goal of this change -- to clarify how to calculate the amount of the reduction of the damage award for workers' compensation benefits. However, everyone who read the proposed language was confused by: "amounts to be paid ... for benefits received...." Therefore, we propose language that we think more clearly accomplishes the same goal.

> "[i]f the trier of fact finds by clear and convincing evidence that the fault of the employer was a substantial factor in causing the harm to the claimant that is the subject of the product liability action ... the court shall reduce by the amount of the claimants benefits (including amounts ~~to be paid~~ obligated or received pursuant to state workers' compensation law ~~for benefits received~~ prior to the date of final judgment in the product liability action) :
>
> (I) the damages awarded against the manufacturer or product seller; and
>
> (II) any corresponding insurer's subrogation lien...."

D. Future Credit Rights

We are not comfortable with the proposed language on future credit rights. As with item #4 above, we object to adding language interpreting other language in the bill, because of the law of unintended consequences.

E. Rules of Construction

Senator Gorton proposed adding two rules of construction. We are comfortable with the first rule, as amended to clarify that by "total award received by the claimant" we mean the product liability award less the compensation insurer's subrogation lien.

> "This section, when invoked, shall not be construed to reduce the ~~total award received~~ net recovery by a claimant in a product liability action below the amount that would otherwise be received pursuant to state law."

We are not comfortable, however, with the second rule. It is unclear what the provision will do. Under current law in some states, when a manufacturer is liable for an amount that exceeds the total workers' compensation benefits, the insurer can recover all the compensation benefits paid, regardless of the employer's fault. However, under this bill, the liability of the insurer of an at-fault employer would increase (i.e., the insurer could not reduce its liability by asserting a subrogation lien). Thus, the statement seems inconsistent with the intent of the statute.

If you do not want to add the first rule of construction without the second, we would also agree to not add either.

F. Attorneys Fees

Senator Gorton proposed an amendment to give the court discretion to decide whether or not to require a manufacturer to reimburse the insurer for attorneys fees. To provide some court discretion, with a governing standard, and a presumption in favor of an attorneys fees award where the allegation was unfounded, we propose changing "may require" to "shall, unless manifest justice requires otherwise, require...."

In addition, we have noticed a drafting problem in this provision that we had not previously identified. Section 112(a)(3)(C) provides that damages are reduced and the lien is defeated only if the trier of fact finds by clear and convincing evidence that the employer's fault was in fact a cause of the injury. In Section 112(b), however, the compensation insurer's attorneys fees would be reimbursed only if the court finds that the injury was not caused by the employer's fault. Thus, Section 112(b) fails to be clear about who makes the decision, the burden of proof, and the nature of the burden of proof. While it could be read to be consistent with 112(a)(3)(C), the statute does not require that outcome. Therefore, to address all of these concerns, we believe that Section 112(b) should read:

> "(b) ATTORNEYS FEES -- If, in a product liability action that is subject to this section, a manufacturer or product seller seeks to prove that the harm to the claimant was in substantial part caused by the fault of the employer, but fails to meet its burden of proving such fault, the court shall, unless manifest justice requires otherwise, require that the manufacturer or product seller
>
> reimburse the insurer for reasonable attorney's fees and court costs, as determined by the court, incurred by the insurer in litigating the issue of employer fault."

7. Biomaterials Changes from Senator Lieberman

We have reviewed the changes proposed by Senator Lieberman to the biomaterials section. We appreciate the change that eliminates the clear and convincing evidence standard. We have no objection to any of the other changes, except the procedures for dismissal of actions against biomaterial suppliers (Section 206(a) at page 57 of the bill). The Lieberman change adds

language requiring the Secretary to complete review within six weeks of receipt of any petition for a declaration that the supplier was requied to have registered with the Secretary or include the implant on a list of devices filed with the Secretary. That timetable is impossibly short. We have asked Senator Lieberman's staff to consider revising it to allow the Secretary 120 days. We have not yet heard back.

8. Expand Biomaterials Section to Cover IVs and Catheters

We are not prepared to expand the biomaterials provisions to cover raw materials and component parts of IVs (intervenous apparatuses) and catheters, which are unlike the medical implants covered by the provisions where only a few hundred are used each year, materials suppliers face a demonstrated litigation threat, and there is a current danger of product unavailability.

9. Clarification on ADR

The current bill provides in Section 109(a) that, where state law provides for ADR procedures, the defendant shall serve notice to the claimant of the applicability of the ADR procedures. Section 109[c] provides that, after the claimant or defendant files an offer to proceed under the ADR procedures, the other party shall file a written notice of acceptance or rejection of that offer.

During the March 13th meeting, Senator Gorton sought, and the Administration agreed, to insert a provision in Section 109[c] that reads: "Such notice shall not constitute a wavier of any objection, including on grounds of jurisdiction or otherwise."

10. Definition of Alcoholic Product

We agreed to a change proposed by Senator Gorton, and concurred in by Mothers Against Drunk Driving, to change the term "alcoholic beverage" to "alcoholic product" to deal with things like alcoholic Jell-O squares. We now need a definition of "alcoholic product." After consulting with MADD, we believe it should read:

> "The term "Alcoholic Product" includes any product that contains not less than ½ of 1 percent of alcohol by volume and is intended for human consumption."

11. Coemployee

Senator Gorton proposed to delete the phrase "or coemployee" from the phrase "employer or co-employee" in a few places, because the term employer includes all employees of a company (including co-employees) and may include contractors. Referencing coemployees but not other subgroups could be misinterpreted as an intent not to include other persons within the term

"employer." We agree. The bill should be searched for all such references to ensure consistency.

12. Due Process Clause

As you recall, we did not agree to amend the Congressional "Findings" language to include reference to the Due Process Clause, on the advice of the Department of Justice. Senator Gorton asked us to provide in writing the rationale for not doing so.

If the authority for the statute rests on the Due Process Clause, the statute would be subject to challenge under the theory enunciated by the Supreme Court in City of Boerne v. Flores, 117 S.Ct. 2157 (1997). In that case, the Supreme Court declared the Religious Freedom Restoration Act (RFRA) unconstitutional. It held that Congress' enforcement power under the Fourteenth Amendment extends only to "enforcing" provisions of the Amendment, not to the power to determine what constitutes a constitutional violation. In applying this concept to invalidate RFRA, the court concluded that the statute was not designed to counteract state laws likely to be unconstitutional, was out of proportion to the supposed remedial or preventative object, and displaced laws in almost every level of government thereby constituting a congressional intrusion into states' traditional prerogatives. Invocation of the Due Process Clause as support for the product liability legislation could easily lead to a similar conclusion.

* * * * *

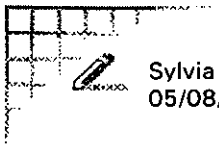
We are grateful for your efforts to work with us to reach agreement on a bill that addresses the President's concerns. We believe that this letter resolves all outstanding issues. Please feel free to call us if you have any further questions.

Sincerely,

Bruce Lindsey
Assistant to the President
and Deputy Counsel

Gene Sperling
Assistant to the President for
Economic Policy

Race init policy - crime



Sylvia M. Mathews
05/08/98 07:22:22 PM

Record Type: Record

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

cc:
Subject: Criminal Justice

Some (not all) good thoughts.

---------- Forwarded by Sylvia M. Mathews/WHO/EOP on 05/08/98 06:56 PM ----------

"Christopher Edley, Jr." <edley @ law.harvard.edu>
05/08/98 07:52:10 AM

Record Type: Record

To: Sylvia M. Mathews/WHO/EOP

cc:
Subject: Criminal Justice

Thanks for sharing Scott's draft with me. He had e-mailed me this version and an earlier one, but I took a quick look and decided not to weigh in. My bad (old) attitude. But now I have an improved (positive) attitude. Probably from our talk. Or perhaps cuz I'm in Charlotte changing planes to go to Miami for the weekend on a beach with "a friend".

1. This version is watered down from the earlier version. Reportedly, that's because Rahm was very concerned that the earlier version had controversial stuff in it that would bash cops. (Which we definitely don't want to do.) The problem is, this version misses the point of these roundtable discussions.

2. I've done these. Ogletree is a master. There's a formula for scripting and producing these disccussions. It involves: pick a couple of tough issues; understand the intellectual structure of the issue, so you know the two or three contrasting perspectives/arguments; figure out which of your discussants will articulate which viewpoints, and which hard questions to ask them in order to "move" them towards each other; conceptualize the common-ground type resolution or conclusion to which you want to lead the discussion.

3. The three issues (profiling, incarceration/sentencing, full/equal service) strike me as perfect. But they need to be fleshed out per point #2 above. Ogletree can and should do this; would be good to fly him down to listen to you or Rahm or Jose Cerda discuss this stuff. But I suggest you rely on Maria (they are friends and huge mutual fans from college) and me to be straight with him about our political concerns/needs.

4. Rahm, I suspect, is interested in emphasizing community policing and "solutions", not the controversy. This is not quite right. You have to explore the conflict to connect with people and draw them in; you can't just lay the prescriptions on them. You argue (constructively, honestly) about the problems, and then raise ideas like community policing as solutions. Lead people to the solution, don't push/lecture.

5. Trust Ogletree's advice on participants. Don't you need articulate and thoughtful people. "Ordinary" folks don't do so well at this, frankly. You aren't looking for faux authenticity. You are looking for people who can advance the ball.

Thanks for asking. Let me know if I can help with Ogletree. (I had a phone chat with him a cojple of weeks ago to encourage him to agree to do this. But I haven't spoken with him since.)

Christopher Edley, Jr.
Professor of Law
Harvard Law School
Cambridge MA 02138
617-495-4614

Message Sent To:

Richard Socarides/WHO/EOP
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Product Liability - notes + memos

MEMORANDUM

To: Product Liability Working Group
From: Sally Katzen
Sarah Rosen
Subject: Final Decisions on Gorton Proposals
Date: April 27, 1998

After the meeting between Chief of Staff Erskine Bowles, Counselor Bruce Lindsey, Counsel to the Vice President Charles Burson, Senators Gorton and Rockefeller, and staffs, on March 13, 1998, there remained a variety of technical issues outstanding. We will meet on Tuesday April 28th, in the Roosevelt Room at 11:00am to discuss the options. If you are unable to join us, please indicate your views on the option matrices below and forward them to Sarah Rosen in Room 235.

Please call Shannon at 456-2800 to comfirm attendance and give clearance information.

Outstanding Issues

1. Findings Language

We agreed to send Senator Rockefeller's staff changes to the findings language proposed by Senator Gorton. DoJ staff was of the view that some findings would be helpful in defending the Act, if challenged. ATTACHMENT A is a revised staff draft that attempts to limit any concerns that we are still conceding too much. (ATTACHMENT B is the Gorton propopsal for your reference.)

Options:
_____ **A -- Refuse to have Findings**
_____ **B -- Findings as per ATTACHMENT A**
_____ **C -- Findings as per ATTACHMENT A revised (provide recommended changes)**

2. When to Apply the Small Business Test

The bill does not specify the time at which a company qualifies as a small business for the cap on punitive damages. Should we measure the net worth, revenues, and number of employees at the time the product was manufactured or sold or at the time of the lawsuit?

To the extent that the purpose of punitive damages is to allow small companies to innovate in product design and manufacture, the time for measuring whether the company qualifies for the cap should be as close to the time of manufacture

as possible. However, a single phrase may not cover each of the steps from design, construction, storage, etc. that could give rise to product liability. DoJ staff propose instead that the test be applied at the time of sale (See ATTACHMENT C), which is far easier to establish and, in most cases, will be close to the time of manufacture. Others propose using the time of the lawsuit as the measuring point, arguing that, if the harm from a product is not discovered for many years, a large company with significant assets at the time of the suit, but which was small at the time of manufacture, should not benefit from the cap on punitive damages.

Options: _____ **A -- Time of sale (ATTACHMENT C)**
_____ **B -- Time of lawsuit**

3. Request to Delete Section on "Defense Based on Claimant's Use of Alcohol or Drugs"

Senator Gorton proposed to make the following change:

> "...[I]t shall be a complete defense if the defendant proves that the claimant ... as a result of the alcohol or drug, was more than 50% responsible for ~~such harm~~ such accident or other event."

The Administration rejected this change, arguing that product liability should only be reduced where the person under the influence was responsible for a significant portion of the harm that they suffered. We cited the following hypothetical: an intoxicated driver backs his car at 5 M.P.H. into a wall in a parking lot and the gas tank explodes. While largely responsible for the accident, the driver was only marginally responsible for the harm.

Senator Gorton then asked to delete the entire section. Apparently he wishes to avoid preempting state law in those states where the manufacturer has no liability if the plaintiff was more than 50% responsible for the accident.

Industry advocates also argue that this provision would effectively preempt some state comparative/contributory negligence regimes and have the ironic effect of providing the intoxicated individual a better result than one not intoxicated whose recovery would be governed by some state comparative/contributory negligence regimes which turn on the accident, rather than the harm. Specifically, in a state with a comparative/contributory negligence regime where damages hinge on responsibility for the accident rather than the harm, preemption for cases involving alcohol and drugs could result with a person, who was not intoxicated but was more than 50% responsible for the accident, not receiving any damages, but, an intoxicated person (50% responsible for the accident

but not 50% responsible for the harm) receiving damages.

Another approach would be to clarify in legislative history that this provision is only intended to address liability, not damages, and thus is not expected to preempt state comparative/contributory negligence regimes.

In considering whether to accede to Senator Gorton's request, we also must think first about the precedent set when, after we refuse to accept a change that is substantive in nature, we nonetheless agree to eliminate the provision, particularly a provision that is popular with the anti-drunk driving community and the public at large (to the extent they are familiar with the legislation at all). Second, if the Administration is willing to endorse a federal preemptive statute and believes that the rule established is the proper balance of responsibility for drunk drivers and accountability for product manufacturers, we should be comfortable having it preempt contrary alcohol and intoxication defenses. Any inequity that results could be viewed as stemming from the state regime's link to accident rather than harm.

Options: _____ **A -- Insist they leave it in**
_____ **B -- Agree to delete**
_____ **C -- Draft legislative history**

4. Proposed Changes to Language on "Reduction of Damages for Misuse or Alteration"

The bill's language on "Reduction of Damages for Misuse or Alteration" provides that damages shall be reduced by the percentage of responsibility attributable to use or alteration of a product contrary to adequate express warnings or involving a risk that was known or should have been known by an ordinary user. Senator Gorton had proposed language that said that damages could only be reduced after liability had been determined, but the Administration rejected that change as implicitly ordering defenses. The Senator then asked to add language in two places that reads: "Nothing in this section shall preclude consideration of misuse or alteration for purposes of determining liability."

This language does little more than what is done by Section 102(b) on preemption. ("This title supersedes a state law only to the extent that the State law applies to a matter covered by this title. Any matter that is not governed by this title ... shall be governed by any applicable Federal or State law.") The language of this section clearly speaks to damages, with no reference to determinations of liability. Arguably this is not a substantive change, nor does it raise two-way preemption issues.

However, in other places in the bill, the Administration has rejected efforts to clarify the scope of preemption.

In addition, under some state regimes, misuse or alteration is not merely a basis for reducing damages but is a basis for precluding liability, which the Administration had argued was inappropriate Federal policy. By all accounts, those state regimes will survive the current bill. By adding the language proposed by Gorton, we may appear to be endorsing that result.

Options: _____ **A -- Agree to add language**
_____ **B -- Refuse to add language**

5. Revised Proposal on "Extension of 18-Year Statute of Repose"

The legislation creates a two-year Statute of Limitations from the date on which the claimant discovered or should have discovered the harm and its cause. Furthermore, it creates a Statute of Repose (for durable goods in the workplace only) under which no product liability action may be filed after the 18-year period beginning at the time of delivery of the product to the first purchaser or lessee. Finally, the legislation explains how these two provisions interact. Specifically, it provides that, if the claimant discovers the harm from a durable good at any time within the 18-year statute of repose period, the claimant has the full two-year statute of limitations period to file the action.

After earlier changes were rejected, Senator Gorton asked whether we would consider adding language for this section that would read:

> "EXTENSION OF 18-YEAR STATUTE OF REPOSE.–If the harm leading to a product liability action described in subsection (a) occurs during the 2 years prior to the expiration of the 18-year period, then the product liability action may be commenced within two years after the harm occurs."

Staff believe that the addition of this language significantly confuses the statute. It ignores the aspect of the Statute of Limitation language that measures time from when not only the harm, but also its cause, are discovered. Similarly, it does not include exceptions in the bill to the Statute of Limitations provisions for a person with a legal disability or subject to a stay or injunction.

Options: _____ **A -- Agree to add language**
_____ **B -- Refuse to add language**

6. Proposed Changes to Workers' Compensation Subrogation Provisions

In general, the workers' compensation subrogation provisions (like most state laws) give the workers' compensation insurer of an employee a right to recover from a manufacturer or product seller any benefits paid by the insurer to the employee relating to harm from a product. However, the bill's provisions would reduce the damages recoverable by the insurer from the manufacturer or product seller, if the employer's fault was a substantial factor in the harm. Generally, this policy is thought to benefit workers, as it gives an incentive to workers' compensation insurers to motivate employers to protect workers from potential harm from products in the workplace.

Last fall, a working group of workers compensation experts (including the AFL-CIO) got together at Senator Rockefeller's request to review the workers compensation subrogation provisions in the Administration-Rockefeller agreement. The changes to these provisions proposed by Senator Gorton stem from those discussions. The Administration previously accepted two of the changes -- one deleting a provision which directed the order in which a trier of fact should consider issues and the other of which limited the reduction of damages based on employer harm to cases where that harm was a "substantial factor" in the harm. The remainder of the changes are assessed below.

The position of the AFL-CIO on these provisions and proposed changes is unclear. Although the AFL-CIO opposes product liability legislation in general, their staff initially worked with Senator Rockefeller, on the working group described above, to improve these provisions. More recently, AFL-CIO staff have recanted their support for even this section, allegedly because it would reduce the manufacturer's liability; however, it appears that they have now realized that the provisions would prevent "double recovery" which they believe does occur sometimes under current law. Senator Rockefeller's staff reports, however, that AFL-CIO President Sweeney assured the Senator that the AFL-CIO's position has not changed and that, while they do not support the legislation, they do support the workers' compensation subrogation provisions as modified by the changes described below.

a. Notification to Employer of Settlement

The Rockefeller working group recommended eliminating a provision in Section 113(a)(2)(B) that required the claimant to notify the workers' compensation insurer before entering into a settlement with a manufacturer or product seller. They argued that the claimant already has this obligation as a result of having filed a claim with the insurer pursuant to state workers' compensation law. However, no one appears to have done a survey of all state laws and workers' compensation claim agreements to be sure that this is always the case. Without such a survey, staff see a mild benefit from retaining the language which will help ensure that the subrogation provisions work

as expected.

Options: _____ **A – Insist they leave it in**
_____ **B -- Agree to delete**

b. Notice to Insurer By Product Manufacturer or Seller

The Rockefeller working group proposed changes to Section 113(a)(3)(A) that would clarify that, to seek a reduction in damages due to employer fault, the manufacturer must notify the insurer that it is raising the issue with the court . Simply raising the issue of employer fault during the trial is not sufficient. This appears to be a reasonable technical change to assure fair notice to affected parties.

Options: _____ **A – Agree to add language**
_____ **B -- Refuse to make changes**

c. Reduction of Damages by Amount of Claimant's Benefits

The Rockefeller working group proposed amending the language as follows:

> "[i]f the trier of fact finds by clear and convincing evidence that the fault of the employer was a substantial factor in causing the harm to the claimant that is the subject of the product liability action ... the court shall reduce by the amount of the claimants benefits (including amounts to be paid pursuant to state workers' compensation law for benefits received prior to the date of final judgment in the product liability action) :
>
> (I) the damages awarded against the manufacturer or product seller; and
> (II) any corresponding insurer's subrogation lien...."

In product liability cases involving harm to a worker, the workers' compensation insurer already will have paid the worker for lost wages, training and rehabilitation, and medical expenses incurred prior to the product liability award, but there may be ongoing workers' compensation benefits that will have to be paid. It is not fair to the worker to reduce the damage award by some amount expected to be paid in workers' compensation in the future, since estimates could well be wrong and the worker will end up with the damages reduced and no substitute compensation. Therefore, Senator Gorton's proposed change would reduce the claimants benefits by an amount that can be fixed at the time -- the amount of benefits already incurred. The current bill uses the amount of benefits already paid (since the definition of "claimant's benefits" only includes amounts paid). It would give the insurer an incentive to delay paying benefits,

so as to not reduce as much the amount of their subrogation lien. The working group's revised language would avoid that problem.

Options: _____ **A -- Agree to add language**
_____ **B – Refuse to add language**

D. Future Credit Rights

Under current law, an employer is not obligated to make workers' compensation payments (including payments for both lost wages and health care) to an employee who has received a judgement in a product liability action that is intended to compensate that employee for the harm caused by the workplace accident. Such payments would represent "double recovery" to the employee. Instead, what happens is that the employee continues to submit claims to the insurer, who denies payment on the basis of its "future credit rights" against the judgement in the product liability action. There has been some question raised whether the current language was intended to change these credit rights. Thus, to clarify the intention, the Rockefeller working group recommended adding new language that reads:

> "The insurer shall not lose, and this Act shall not affect, any rights to credit against future liability established pursuant to state workers' compensation law."

Although this language would be salutory, our position on this issue should be consistent with our position on item 4 above ("Reduction of Damages for Misuse or Alteration"), since in both cases we are being asked to clarify how the Federal law would interact with state laws.

Options: _____ **A -- Agree to add language**
_____ **B – Refuse to add language**

E. Rules of Construction

The Rockefeller working group proposed adding two rules of construction that they said "are completely consistent with the other provisions in this section. They are intended to assure that the provision is not misconstrued in a manner that could harm the employee or the employer as compared with current law."

The first rule provides:

> "This section, when invoked, shall not be construed to reduce the total award received by a claimant in a product liability action below the amount that would

otherwise be received pursuant to state law."

If by "total award received by the claimant" they mean the product liability award less the compensation insurer's subrogation lien, the effect is that the employee's net recovery not be reduced below the level provided for by state law. In view of the numerous differences between workers' compensation statutes of the various states, this provision could serve as a type of insurance against unintended effects of the legislation. If so, the phrase "total award received" should be replaced with "net recovery."

This rule of construction benefits employees. The second rule (discussed below), about which we have real concerns, benefits employers. If we decide to reject the second rule, Gorton and Rockefeller may reasonably argue that we should either add both or neither.

Options: _____ **A – Add rule of contruction, modified by "net recovery"**
_____ **B -- Reject rule of construction**

The second rule provides:

" This section, when invoked, shall not be construed to increase the liability of an employer above the amount that would otherwise be incurred pursuant to state workers' compensation laws."

It is unclear what this provision will do. Under current law in some states, when a manufacturer is liable for an amount that exceeds the total workers' compensation benefits, the insurer can recover all the compensation benefits paid, regardless of the employer's fault. However, under this bill, the liability of the insurer of an at-fault employer would increase (i.e., the insurer could not reduce its liability by asserting a subrogation lien). Thus, the statement seems inconsistent with the intent of the statute. The intention may be that the gross liability of the insurer not be increased above that under state law, but the language is unclear. Given the ambiguity, it may be better to reject this change unless they can propose clear language.

Options: _____ **A -- Add rule of construction, modified by "gross liability"**
_____ **B – Reject rule of construction**

F. Attorneys Fees

The Rockefeller working group proposed an amendment to the bill agreed to between the Administration and Senator Rockefeller:

"(b) ATTORNEYS FEES -- If, in a product liability action that is subject to this section, the court finds that harm to a claimant was not caused by the fault of the employer ~~(or a coemployee of the claimant)~~, the court may require the manufacturer or product seller ~~shall~~ to reimburse the insurer for reasonable attorney's fees and court costs incurred by the insurer in the action, as determined by the court."

The substantive change[1] proposed involves giving the court discretion to order reimbursement of attorneys fees, which would be mandatory under the current bill. With the workers' compensation provisions of this legislation, manufacturers may be motivated to allege employer fault to reduce their liability, potentially increasing significantly the legal expenses of workers' compensation insurers in enforcing their liens. The mandatory attorneys fees provision in the current bill mitigates this effect by encouraging product manufacturers and sellers to raise the issue of employer fault only where it is reasonably clear that the employers' fault was, in fact, a substantial factor in causing the harm. The proposed change (to discretionary award of attorneys fees) would reduce somewhat the deterrent effect of the current attorneys fee provision.

Options: ____ **A – Accept change (discretionary attorneys fees)**
____ **B -- Reject change (mandatory attorneys fees)**

DOJ staff reviewing the bill have also raised questions about the attorneys fees language in the Rockefeller-Administration agreement. They point out that Section 112(a)(3)(C) provides that damages are reduced and the lien is defeated only if the trier of fact finds by clear and convincing evidence that the employer's fault was in fact a cause of the injury. In Section 112(b), however, the compensation insurer's attorneys fees would be reimbursed only if the court finds that the injury was not caused by the employer's fault. Thus, Section 112(b) fails to be clear about who makes the decision, the burden of proof, and the nature of the burden of proof. While it could be read to be consistent with 112(a)(3)(C), the statute does not require that outcome. If we wish to reopen the language agreed to with Rockefeller, DOJ suggests the following revision:

"(b) ATTORNEYS FEES -- If, in a product liability action that is subject to this section, a manufacturer or product seller seeks to prove that the harm to the claimant was in substantial part caused by the fault of the employer, but fails to meet its burden of proving such fault, the court shall require that the manufacturer or product seller reimburse the insurer for reasonable attorney's

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[1] As noted below, changes need to be made throughout the bill to consistently eliminate references to "coemployees" because such persons are included in the definition of employer.

■

fees and court costs, as determined by the court, incurred by the insurer in litigating the issue of employer fault."

Options: ____ **A – Leave as is**
____ **B – Substitute DOJ revised language**

7. Biomaterials Changes from Senator Lieberman

In the 1996 veto message, the President said that he could not support biomaterials provisions that protected suppliers when they knew or should have known that the material they were supplying was unsuitable for the purpose intended. A new impleader section of the bill largely addressed this concern by allowing the court to bring back into the case, after final judgement, a supplier whose negligence or intentionally tortious conduct was a cause of the harm. However, the standard required that the court find, based on "clear and convincing evidence," that the negligence or tortious conduct was the actual and proximate cause of the harm and either the manufacturer's liability should be reduced because of the negligence or tortious conduct or the manufacturer is insolvent. The White House remained concerned that the clear and convincing evidence standard was too restrictive.

Senator Lieberman's staff have provided us with a set of proposed changes to the biomaterials title of the bill. (See ATTACHMENT D.) Most of the changes are beneficial or unobjectionable. The most important change is to eliminate the clear and convincing evidence standard (See Section 207(a)(1) and (2) at pages 58-59 of the bill). Instead, the court would make a finding "based on the court's independent review of the evidence...." The change accomplishes what the Administration had stated as its objective. The Administration had also sought to change the provision to allow the impleader of the supplier during trial, rather than wait until after final judgement. This change was not made by Lieberman despite our earlier request. Further requests for modifications from the Administration may not be well received.

Options: ____ **A – Accept change**
____ **B – Accept change, but attempt to reopen issue of timing of impleader**

One area where HHS will want us to resist the new Lieberman changes is in the procedures for dismissal of actions against biomaterial suppliers (Section 206(a) at page 57 of the bill). This provision says that, if a claimant has filed a petition for a declaration from the Secretary of HHS that the supplier was required to have registered with the Secretary or include the implant on a list of devices filed with the Secretary, the

court shall stay the proceedings until the Secretary has issued a final decision on that petition. The Lieberman changes add language requiring the Secretary to complete review of any such petition within six weeks of receipt of the petition.

Although we have no idea what the volume of petitions will be under this provision, the FDA believes that six weeks is impossibly short. Senator Lieberman's staff has indicated a willingness to consider a longer period. We could ask for 120 days and be prepared to accept 90 days.

Options: ____ **A -- Seek to extend time period to hear petition**
____ **B -- Accept change**

8. Lott Request to Expand Biomaterials Section to Cover IVS and Catheters

Senator Gorton asked, on behalf of Senator Lott, whether the Administration would consider amendments to the biomaterials provisions to cover raw materials and component parts of IVs (intervenous apparatuses) and catheters. There was no mention during the biomaterials hearings of a problem for IVs and catheters like the problem that exists for other medical implants -- a shortage of component parts or raw materials due to limited profits and large litigation risks.

DoJ staff asked Senator Lieberman's staff if they were aware of any evidence of such problems with these products. They replied that there are two primary manufacturers of IVs in this country, Abbot and Baxter, although there are foreign producers. (Baxter is pressing for this amendment; Abbot is not.) Baxter has a raw material supplier which was recently acquired by another firm. Although there has been no litigation against the materials supplier, the new parent has expressed some discomfort with the product and is only allowing the supplier to enter into short-term contracts. There is an alternative supplier, although Baxter would have to retool their machinery to use the other material. (See ATTACHMENT E for Baxter's talking points in support of the amendment.)

This seems to be a far different issue than heart valves or jaw implants, for example, of which only a few hundred are used each year, for which materials suppliers face a demonstrated litigation threat, and where there is a current danger of product unavailability.

Options: ____ **A -- Broaden scope to cover IVS and catheters**
____ **B -- Reject change**

Miscellaneous

9. Clarification on ADR

The current bill provides in Section 109(a) that, where state law provides for ADR procedures, the defendant shall serve notice to the claimant of the applicability of the ADR procedures. Section 109(c) provides that, after the claimant or defendant files an offer to proceed under the ADR procedures, the other party shall file a written notice of acceptance or rejection of that offer.

During the Bowles-Rockefeller-Gorton meeting, Gorton sought, and the Administration agreed, to insert a provision in Section 109(c) that reads: "Such notice shall not constitute a wavier of any objection, including on grounds of jurisdiction or otherwise." However, subsequent conversations with Rockefeller staff suggest that Gorton and others may have thought we were agreeing to his suggestion that we delete the initial notification provision in Section 109(a), which we did not intend to do. We will clarify our intent with Senator Rockefeller and Gorton.

10. Definition of Alcoholic Product

The bill excludes from preemption civil actions brought under a theory of dram-shop or third-party liability arising out of the sale of alcohol products to an intoxicated person or minor. We agreed to a change proposed by Senator Gorton, and concurred in by Mothers Against Drunk Driving, to change the term "alcoholic beverage" to "alcoholic product" to deal with things like alcoholic Jell-O squares. However, we now need a definition of "alcoholic product." After consulting with MADD, we have proposed:

> "The term "Alcoholic Product" includes any product that contains not less than ½ of 1 percent of alcohol by volume and is intended for human consumption."

11. Coemployee

Senator Gorton proposes to delete the phrase "or coemployee" from the phrase "employer or co-employee" in a few places, because the term employer includes all employees of a company (including co-employees) and may include contractors. Referencing coemployees but not other subgroups could be misinterpreted as an intent not to include other persons within the term "employer." We agree and will search the bill for all references to ensure consistency.

12. Due Process Clause

The Administration refused to agree to amend the Congressional "Findings" language to include reference to the Due Process Clause. Senator Gorton asked us to provide in writing the rationale for not doing so. DoJ staff drafted the following language:

> If the authority for the statute rests on the Due Process Clause, the statute would be subject to challenge under the theory enunciated by the Supreme Court in City of Boerne v. Flores, 117 S.Ct. 2157 (1997). In that case, the Supreme Court declared the Religious Freedom Restoration Act (RFRA) unconstitutional. It held that Congress' enforcement power under the Fourteenth Amendment extends only to "enforcing" provisions of the Amendment, not to the power to determine what constitutes a constitutional violation. In applying this concept to invalidate RFRA, the court concluded that the statute was not designed to counteract state laws likely to be unconstitutional, was out of proportion to the supposed remedial or preventative object, and displaced laws in almost every level of government thereby constituting a congressional intrusion into states' traditional prerogatives. Invocation of the Due Process Clause as support for the product liability legislation could easily lead to a similar conclusion.

ATTACHMENTS

Addressees:

Bruce Lindsey, Counsel
Charles Burson, Counsel to VP
Peter Jacoby, OLA
Michael (Buzz) Waizkin, Counsel
Maria Echaveste, OPL
Michael Deich, OMB
Alan Rhinesmith, OMB
Fran Allegra, DOJ
Pam Danner, CPSC
Ellen Seidman, OTS
Andy Pinkus, COM
Elena Kagan, DPC
Paul Weinstein, DPC

ATTACHEMENT A

SEC. 2 FINDINGS; PURPOSES

(a) FINDINGS -- The Congress finds that --

(1) although damage awards in product liability actions can encourage the production of safer products, they also can have a direct effect on interstate commerce and our Nation's consumers by, among other things, increasing the cost and decreasing the availability of products;

(2) some of the rules of law governing product liability actions are inconsistent within and among the States, resulting in differences in State laws that can be inequitable to both plaintiffs and defendants and can impose burdens on interstate commerce;

(3) product liability awards ca jeopardize the financial well-being of individuals and industries, particularly the Nations' small businesses;

(4) because the product liability laws of one State can have adverse effects on consumers and businesses in many other States, it is appropriate for the Federal government to enact national, uniform product liability laws that preempt State laws; and

(5) it is the constitutional role of the national government to remove barriers to interstate commerce.

TITLE III -- LIMITATIONS ON APPLICABILITY; EFFECTIVE DATE

SEC. 2. FINDINGS; PURPOSES.

(a) FINDINGS.--The Congress finds that--

(1) in product liability actions, excessive, unpredictable, and often arbitrary damage awards have a direct and undesirable effect on interstate commerce and our Nation's consumers by increasing the cost and decreasing the availability of products;

(2) the rules of law governing product liability actions have evolved inconsistently within and among the States, resulting in a complex, contradictory, and uncertain regime that is inequitable to both plaintiffs and defendants and unduly burdens interstate commerce;

(3) excessive, unpredictable, and often arbitrary product liability awards jeopardize the financial well-being of many individuals as well as entire industries, particularly the Nation's small businesses;

(4) the excessive costs associated with product liability actions undermine the ability of American companies to compete internationally, decrease the number of jobs and the amount of productive capital in the national economy, and add to the high cost of product liability insurance;

(5) because of the national scope of the problems concerning product liability, it is not possible for the States alone to enact laws that fully and effectively respond to those problems; and

(6) it is the constitutional role of the national government to remove barriers to interstate commerce and to protect due process rights.

(b) PURPOSES.--Based upon the powers contained in ~~clause 3 of section 8 of article I~~ Article I, Section 8, Clause 3, and the Fourteenth Amendment of the United States Constitution, the purposes of this Act are to promote the free flow of ~~goods and services~~ products and to lessen burdens on interstate commerce and to uphold constitutionally protected due process rights by--

(1) establishing certain uniform legal principles of product liability that provide a fair balance among the interests of product users, manufacturers, and product sellers;

(2) providing for reasonable standards concerning, and limits on, punitive damages over and above the actual damages suffered by a claimant;

(3) ~~ensuring~~ promoting the fair allocation of liability in product liability actions;

(4) reducing the unacceptable costs and delays in product liability actions caused by excessive litigation that harm both plaintiffs and defendants;

(5) establishing greater fairness, rationality, and predictability in product liability actions; and

ATTACHEMENT C

Add to Section 111(b)(2) --

(C) REFERENCE POINT FOR DETERMINING APPLICABILITY. In determining the applicability of this subsection, the standards in subparagraphs (A) and (B) shall be applied as of the date the product that is the subject of the action was originally sold, leased or otherwise conveyed by the defendant whose conduct gave rise to the award of punitive damages. The burden shall be on the defendant to prove the applicability of this subsection.

ATTACHEMENT D

(A) to reduce the total award received by a claimant in a product liability action below the amount that would otherwise be received pursuant to state law, or

(B) to increase the liability of an employer above the amount that would otherwise be incurred pursuant to state workers' compensation law.

(b) ATTORNEY'S FEES.- If, in a product liability action that is subject to this section, the court finds that harm to a claimant was not caused by the fault of the employer ~~or a coemployee of the claimant~~, the court may require the manufacturer or product seller ~~shall~~ to reimburse the insurer for reasonable attorney's fees and court costs incurred by the insurer in the action, as determined by the court.

TITLE II - BIOMATERIALS ACCESS ASSURANCE

SEC. 201. SHORT TITLE.

This title may be cited as the "Biomaterials Access Assurance Act of ~~1997~~ 1998".

SEC. 202. FINDINGS.

Congress find that--

(1) each year millions of citizens of the United States depend on the availability of lifesaving or life-enhancing medical devices, many of which are permanently implantable within the human body;

(2) a continued supply of raw materials and component parts is necessary for the invention, development, improvement, and maintenance of the supply of the devices;

(3) most of the medical devices are made with raw materials and component parts that--

(A) move in interstate commerce;

(B) are not designed or manufactured specifically for use in medical devices; and

(C) come in contact with internal human tissue;

(4) the raw materials and component parts also are used in a variety of nonmedical products;

(5) because small quantities of the raw materials and components parts are used for medical devices, sales of raw materials and component parts for medical devices constitute an extremely small portion of the overall market for the raw materials and medical devices component parts;

(6) under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), manufacturers of medical devices are required to demonstrate that the medical devices are safe and effective, including demonstrating that the products are properly designed and have adequate warnings or instructions;

(7) notwithstanding the fact that raw materials and component parts suppliers do not design, produce, or test a final medical device, the suppliers have been the subject of actions alleging inadequate--

(A) design and testing of medial devices manufactured with materials or parts supplied by the suppliers; or

(B) warnings related to the use of such medical devices;

(8) even though suppliers of raw materials and component parts have very rarely been held liable in such actions, such suppliers have ceased supplying certain raw materials and component parts for use in medical devices because the costs associated with litigation in order to ensure a favorable judgment for the suppliers far exceeds the total potential sales revenues from sales by such suppliers to the medical device industry;

(9) unless alternate sources of supply can be found, the unavailability of raw materials and component parts for medical devices will lead to unavailability of lifesaving and life-enhancing medical devices;

(10) because other suppliers of the raw materials and component parts in foreign nations are refusing to sell raw materials or component parts for use in manufacturing certain medical devices in the United States, the prospects for development of new sources of supply for the full range of threatened raw materials and component parts for medical devices are remote;

(11) it is unlikely that the small market for such raw materials and component parts in the United States could support the large investment needed to develop new suppliers of such raw materials and component parts;

(12) attempts to develop such new suppliers would raise the cost of medical devices;

(13) courts that have considered the duties of the suppliers of the raw materials and component parts have generally found that the suppliers do not have a duty--

(A) to evaluate the safety and efficacy of the use of a raw material or component part in a medical device; and

(B) to warn consumers concerning the safety and effectiveness of a medical device;

Because medical devices + the raw material + component parts used in their manufacture move in interstate commerce, a shortage of such raw materials + component parts affects interstate commerce,

(14) attempts to impose the duties referred to in subparagraphs (A) and (B) of paragraph (13) on suppliers of the raw materials and component parts would cause more harm than good by driving the suppliers to cease supplying manufacturers of medical devices; and

(15) in order to safeguard the availability of a wide variety of lifesaving and life-enhancing medical devices, immediate action is needed--

(A) to clarify the permissible bases of liability for suppliers of raw materials and component parts for medical devices; and

(B) to provide expeditious procedures to dispose of unwarranted suits against the suppliers in such manner as to minimize litigation costs.

Add (16) + (17) from attached

(A) to clarify the permissible bases of liability for suppliers of raw materials and component parts for medical devices; and

(B) to provide expeditious procedures to dispose of unwarranted suits against the suppliers in such manner as to minimize litigation costs;

(16) the several States and their courts are the primary architects and regulators of our tort system; Congress, however, must, in certain circumstances involving the national interest, address tort issues, and a threatened shortage of raw materials and component parts for life-saving medical devices is one such circumstance; and

(17) the protections set forth in this Act are needed to assure the continued supply of materials for life-saving medical devices; however, negligent suppliers should not be protected.

SEC. s. DEFINITIONS.

As used in this Act:

(1) BIOMATERIALS SUPPLIER.—

(A) IN GENERAL.—The term "biomaterials supplier" means an entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implant.

SEC. 203. DEFINITIONS.

As used in this title:

(1) BIOMATERIALS SUPPLIER.--

(A) IN GENERAL.--The term "biomaterials supplier" means an entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implant.

(B) PERSONS INCLUDED.--Such term includes any person who--

(i) has submitted master files to the Secretary for purposes of premarket approval of a medical device; or

(ii) licenses a biomaterials supplier to produce component parts or raw materials.

(2) CLAIMANT.--

(A) IN GENERAL.--The term "claimant" means any person who brings a civil action, or on whose behalf a civil action is brought, arising from harm allegedly caused directly or indirectly by an implant, including a person other than the individual into whose body, or in contact with whose blood or tissue, the implant is placed, who claims to have suffered harm as a result of the implant.

(B) ACTION BROUGHT ON BEHALF OF AN ESTATE.--With respect to an action brought on behalf of or through the estate of an individual into whose body, or in contact with whose

blood or tissue the implant is placed, such term includes the decedent that is the subject of the action.

(C) ACTION BROUGHT ON BEHALF OF A MINOR OR INCOMPETENT.--With respect to an action brought on behalf of or through a minor or incompetent, such term includes the parent or guardian of the minor or incompetent.

(D) EXCLUSIONS.--Such term does not include--

(i) a provider of professional health care services, in any case in which--

(I) the sale or use of an implant is incidental to the transaction; and

(II) the essence of the transaction is the furnishing of judgment, skill, or services;

(ii) a person acting in the capacity of a manufacturer, seller, or biomaterials supplier;

(iii) a person alleging harm caused by either the silicone gel or the silicone envelope utilized in a breast implant containing silicone gel, except that--

(I) neither the exclusion provided by this clause nor any other provision of this Act may be construed as a finding that silicone gel (or any other form of silicone) may or may not cause harm; and

(II) the existence of the exclusion under this clause may not--

(aa) be disclosed to a jury in any civil action or other proceeding; and

(bb) except as necessary to establish the applicability of this Act, otherwise be presented in any civil action or other proceeding; or

(iv) any person who acts in only a financial capacity with respect to the sale of an implant.

(3) COMPONENT PART.--

(A) IN GENERAL.--The term "component part" means a manufactured piece of an implant.

(B) CERTAIN COMPONENTS.--Such term includes a manufacture piece of an implant that--

(i) has significant non-implant applications and;

(ii) alone, has no implant value or purpose, but when combined with other component parts and materials, constitutes an implant.

(4) HARM.--

(A) IN GENERAL.--The term "harm" means--

(i) any injury to or damage suffered by an individual;

(ii) any illness, disease, or death of that individual resulting from that injury or damage; and

(iii) any loss to that individual or any other individual resulting from that injury or damage.

(B) EXCLUSION.--The term does not include any commercial loss or loss of or damage to an implant.

(5) IMPLANT.--The term "implant" means--

(A) a medical device that is intended by the manufacturer of the device--

(i) to be placed into a surgically or naturally formed or existing cavity of the body for a period of at least 30 days; or

(ii) to remain in contact with bodily fluids or internal human tissue through a surgically produced opening for a period of less than 30 days; and

(B) suture materials used in implant procedures.

(6) MANUFACTURER.--The term "manufacturer" means any person who, with respect to an implant--

(A) is engaged in the manufacture, preparation, propagation, compounding, or processing (as defined in section 510(a)(1)) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(a)(1)) of the implant; and

(B) is required--

(i) to register with the Secretary pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) and the regulations issued under such section; and

(ii) to include the implant on a list of devices filed with the Secretary pursuant to section 510(j) of such Act (21 U.S.C. 360(j)) and the regulations issued under such section.

(7) MEDICAL DEVICE.--The term "medical device" means a device, as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) and includes any device component of any combination product as that term is used in section 503(g) of such Act (21 U.S.C. 353(g)).

(8) RAW MATERIAL.--The term "raw material" means a substance or product that--

(A) has a generic use; and

(B) may be used in an application other than an implant.

(9) SECRETARY.--The term "Secretary" means the Secretary of Health and Human Services.

(10) SELLER.--

(A) IN GENERAL.--The term "seller" means a person who, in the course of a business conducted for that purpose, sells, distributes, leases, packages, labels, or otherwise places an implant in the stream of commerce.

(B) EXCLUSIONS.--The term does not include--

(i) a seller or lessor of real property;

(ii) a provider of professional services, in any case in which the sale or use of in implant is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill, or services; or

(iii) any person who acts in only a financial capacity with respect to the sale of an implant.

SEC. 204. GENERAL REQUIREMENTS; APPLICABILITY; PREEMPTION.

(a) GENERAL REQUIREMENTS.--

(1) IN GENERAL.--In any civil action covered by this title, a biomaterials supplier may raise any defense set forth in section 205.

(2) PROCEDURES.--Notwithstanding any other provision of law, the Federal or State court in which a civil action covered by this title is pending shall, in connection with a motion for dismissal or judgment based on a defense described in paragraph (1), use the procedures set forth in section 206.

(b) APPLICABILITY.--

(1) IN GENERAL.--Except as provided in paragraph (2), notwithstanding any other provision of law, this title applies to any civil action brought by a claimant, whether in a Federal or State court, against a

manufacturer, seller, or biomaterials supplier, on the basis of any legal theory, for harm allegedly caused by an implant.

(2) EXCLUSION.--A civil action brought by a purchaser of a medical device for use in providing professional services against a manufacturer, seller, or biomaterials supplier for loss or damage to an implant or for commercial loss to the purchaser--

(A) shall not be considered an action that is subject to this title; and

(B) shall be governed by applicable commercial or contract law.

(c) SCOPE OF PREEMPTION.--

(1) IN GENERAL.--This title supersedes any State law regarding recovery for harm caused by an implant and any rule of procedure applicable to a civil action to recover damages for such harm only to the extent that this title establishes a rule of law applicable to the recovery of such damages.

(2) APPLICABILITY OF OTHER LAWS.--Any issue that arises under this title and that is not governed by a rule of law applicable to the recovery of damages described in paragraph (1) shall be governed by applicable Federal or State law.

(d) STATUTORY CONSTRUCTION.--Nothing in this title may be construed--

(1) to affect any defense available to a defendant under any other provisions of Federal or State law in an action alleging harm caused by an implant; or

(2) to create a cause of action or Federal court jurisdiction pursuant to sectiong 1331 or 1337 of title 28, United States Code, that otherwise would not exist under applicable Federal or State law.

SEC. 205. LIABILITY OF BIOMATERIALS SUPPLIERS.

(a) IN GENERAL.--

(1) EXCLUSION FROM LIABILITY.--Except as provided in paragraph (2) or Sec. 207, a biomaterials supplier shall not be liable for harm to a claimant caused by an implant.

(2) LIABILITY.--A biomaterials supplier that--

(A) is a manufacturer may be liable for harm to a claimant described in subsection (b);

(B) is a seller may be liable for harm to a claimant described in subsection (c); and

(C) furnishes raw materials or component parts that fail to meet applicable contractual requirements or specifications may be liable for harm to a claimant described in subsection (d).

(b) LIABILITY AS MANUFACTURER.--

(1) IN GENERAL.--A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a

claimant caused by an implant if the biomaterials supplier is the manufacturer of the implant.

(2) GROUNDS FOR LIABILITY.--The biomaterials supplier may be considered the manufacturer of the implant that allegedly caused harm to a claimant only if the biomaterials supplier--

(A) (i) has registered with the Secretary pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) and the regulations issued under such section; and

(ii) included the implant on a list of devices filed with the Secretary pursuant to section 510(j) of such Act (21 U.S.C. 360(j)) and the regulations issued under such section;

(B) is the subject of a declaration issued by the Secretary pursuant to paragraph (3) that states that the supplier, with respect to the implant that allegedly caused harm to the claimant, was required to--

(i) register with the Secretary under section 510 of such Act (21 U.S.C. 360), and the regulations issued under such section, but failed to do so; or

(ii) include the implant on a list of devices filed with the Secretary pursuant to section 510(j) of such Act (21 U.S.C. 360(j)) and the regulations issued under such section, but failed to do so; or

(C) is related by common ownership or control to a person meeting all the requirements described in subparagraph (A) or (B), if the court deciding a motion to dismiss in accordance with section 206(c)(3)(B)(i) finds, on the basis of affidavits submitted in accordance with section 206, that it is necessary to impose liability on the biomaterials supplier as a manufacturer because the related manufacturer meeting the requirements of subparagraph (A) or (B) lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail.

(3) ADMINISTRATIVE PROCEDURES.--

(A) IN GENERAL.--The Secretary may issue a declaration described in paragraph (2)(B) on the motion of the Secretary or on petition by any person, after providing--

(i) notice to the affected persons; and

(ii) an opportunity for an informal hearing.

(B) DOCKETING AND FINAL DECISION.--Immediately upon receipt of a petition filed pursuant to this paragraph, the Secretary shall docket the petition. Not later than 180 days after the petition is filed, the Secretary shall issue a final decision on the petition.

(C) APPLICABILITY OF STATUTE OF LIMITATIONS.--Any applicable statute of limitations shall toll

during the period during which a claimant has filed a petition with the Secretary under this paragraph.

(c) LIABILITY AS SELLER.--A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable as a seller for harm to a claimant caused by an implant if--

(1) the biomaterials supplier--

(A) held title to the implant that allegedly caused harm to the claimant as a result of purchasing the implant after--

(i) the manufacture of the implant; and

(ii) the entrance of the implant in the stream of commerce; and

(B) subsequently resold the implant; or

(2) the biomaterials supplier is related by common ownership or control to a person meeting all the requirements described in paragraph (1), if a court deciding a motion to dismiss in accordance with section 206(c)(3)(B)(ii) finds, on the basis of affidavits submitted in accordance with section 206, that it is necessary to impose liability on the biomaterials supplier as a seller because the related seller meeting the requirements of paragraph (1) lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail.

(d) LIABILITY FOR VIOLATING CONTRACTUAL REQUIREMENTS OR SPECIFICATIONS.--A biomaterials supplier may, to the extent required and

permitted by any other applicable law, be liable for harm to a claimant caused by an implant, if the claimant in an action shows, by a preponderance of the evidence, that--

(1) the raw materials or component parts delivered by the biomaterials supplier either--

(A) did not constitute the product described in the contract between the biomaterials supplier and the person who contracted for delivery of the product; or

(B) failed to meet any specifications that were--

(i) ~~accepted by~~ accepted, pursuant to applicable law, by the biomaterials supplier ~~prior to acceptance of delivery of the raw materials or component parts;~~

(ii) (I) published by the biomaterials supplier;

(II) provided to the manufacturer by the biomaterials supplier; or

(III) contained in a master file that was submitted by the biomaterials supplier to the Secretary and that is currently maintained by the biomaterials supplier for purposes of premarket approval of medical devices; or

(iii) included in the submissions for purposes of premarket approval or review by the Secretary under section 510, 513, 515, or 520 of the Federal Food, Drug, and Cosmetic

Act (21 U.S.C. 360, 360c, 360e, or 360j), and received clearance from the Secretary if such specifications were accepted by the biomaterials supplier prior to the acceptance of delivery of the raw materials or component parts; and

accepted, pursuant to applicable law, by the biomaterials supplier; and

(2) such conduct was an actual and proximate cause of the harm to the claimant.

SEC. 206. PROCEDURES FOR DISMISSAL OF CIVIL ACTIONS AGAINST BIOMATERIALS SUPPLIERS.

(a) MOTION TO DISMISS.--In any action that is subject to this title, a biomaterials supplier who is a defendant in such action may, at any time during which a motion to dismiss may be filed under an applicable law, move to dismiss the action against it on the grounds that--

(1) the defendant is a biomaterials supplier; and

(2)(A) the defendant should not, for the purposes of--

(i) section 205(b), be considered to be a manufacturer of the implant that is subject to such section; or

(ii) section 205(c), be considered to be a seller of the implant that allegedly caused harm to the claimant; or

(B)(i) the claimant has failed to establish, pursuant to section 205(d), that the supplier furnished raw materials or component parts in violation of contractual requirements or specifications; or

(ii) the claimant has failed to comply with the procedural requirements of subsection (b).

(b) MANUFACTURER OF IMPLANT SHALL BE NAMED A PARTY.--The claimant shall be required to name the manufacturer of the implant as a party to the action, unless--

(1) the manufacturer is subject to service of process solely in a jurisdiction in which the biomaterials supplier is not domiciled or subject to a service of process; or

or rule of practice

(2) an action against the manufacturer is barred by applicable law.

(c) PROCEEDING ON MOTION TO DISMISS.--The following rules shall apply to any proceeding on a motion to dismiss fined under this section:

(1) AFFIDAVITS RELATING TO LISTING AND DECLARATIONS.--

(A) IN GENERAL.--The defendant in the action may submit an affidavit demonstrating that defendant has not included the implant on a list, if any, filed with the Secretary pursuant to section 510(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)).

(B) RESPONSE TO MOTION TO DISMISS.--In response to the motion to dismiss, the claimant may submit an affidavit demonstrating that--

(i) the Secretary has, with respect to the defendant and the implant that allegedly caused harm to the claimant, issued a declaration pursuant to section 205(b)(2)(B); or

(ii) the defendant who filed the motion to dismiss is a seller of the implant who is liable under section 205(c).

(2) EFFECT OF MOTION TO DISMISS ON DISCOVERY.--

(A) IN GENERAL.--If a defendant files a motion to dismiss under paragraph (1) or (2) of subsection (a), no discovery shall be permitted in connection to the action that is the subject of the motion, other than discovery necessary to determine a motion to dismiss for lack of jurisdiction, until such time as the court rules on the motion to dismiss in accordance with the affidavits submitted by the parties in accordance with this section.

(B) DISCOVERY.--If a defendant files a motion to dismiss under subsection (a)(2)(B)(i) on the grounds that the biomaterials supplier did not furnish raw materials or component parts in violation of contractual requirements or specifications, the court may permit discovery, as ordered by the court. The discovery conducted pursuant to this subparagraph shall be limited to issues that are directly relevant to--

(i) the pending motion to dismiss; or

(ii) the jurisdiction of the court.

(3) AFFIDAVITS RELATING STATUS OF DEFENDANT.--

(A) IN GENERAL.--Except as provided in clauses (i) and (ii) of subparagraph (B), the court shall consider a defendant to be a biomaterials supplier who is not subject to an action for harm to a claimant caused by an implant, other than an action relating to liability for a violation of contractual requirements or specifications described in subsection (d).

(B) RESPONSES TO MOTION TO DISMISS.--The court shall grant a motion to dismiss any action that asserts liability of the defendant under subsection (b) or (c) of section 205 on the grounds that the defendant is not a manufacturer subject to such section 205(b) or seller subject to section 205(c), unless the claimant submits a valid affidavit that demonstrates that--

(i) with respect to a motion to dismiss contending the defendant is not a manufacturer, the defendant meets the applicable requirements for liability as a manufacturer under section 205(b); or

(ii) with respect to a motion to dismiss contending that the defendant is not a seller, the defendant meets the applicable requirements for liability as a seller under section 205(c).

(4) BASIS OF RULING ON MOTION TO DISMISS.--

(A) IN GENERAL.--The court shall rule on a motion to dismiss filed under subsection (a) solely on the basis of the pleadings of the parties made pursuant to this section and any affidavits submitted by the parties pursuant to this section.

(B) MOTION FOR SUMMARY JUDGMENT.--Notwithstanding any other provision of law, if the court determines that the pleadings and affidavits made by parties pursuant to this section raise genuine issues concerning material facts with respect to a motion concerning contractual requirements and specifications, the court may deem the motion to dismiss to be a motion for summary judgment made pursuant to subsection (d).

(d) SUMMARY JUDGMENT.--

(1) IN GENERAL.--

(A) BASIS FOR ENTRY OF JUDGMENT.--A biomaterials supplier shall be entitled to entry of judgment without trial if the court finds there is no genuine issue concerning any material fact for each applicable element set forth in paragraphs (1) and (2) of section 205(d).

(B) ISSUES OF MATERIAL FACT.--With respect to a finding made under subparagraph (A), the court shall consider a genuine issue of material fact to exist only if the evidence submitted

by claimant would be sufficient to allow a reasonable jury to reach a verdict for the claimant if the jury found the evidence to be credible.

(2) DISCOVERY MADE PRIOR TO A RULING IN A MOTION FOR SUMMARY JUDGMENT.--If, under applicable rules, the court permits discovery prior to a ruling on a motion for summary judgment made pursuant to this subsection, such discovery shall be limited solely to establishing whether a genuine issue of material fact exists as to the applicable elements set forth in paragraphs (1) and (2) of section 205(d).

(3) DISCOVERY WITH RESPECT TO A BIOMATERIALS SUPPLIER.--A biomaterials supplier shall be subject to discovery in connection with a motion seeking dismissal or summary judgment on the basis of the inapplicability of section 205(d) or the failure to establish the applicable elements of section 205(d) solely to the extent permitted by the applicable Federal or State rules for discovery against nonparties.

(e) STAY PENDING PETITION FOR DECLARATION.--If a claimant has filed a petition for a declaration pursuant to section 205(b)(3)(A) with respect to a defendant, and the Secretary has not issued a final decision on the petition, the court shall stay all proceedings with respect to that defendant until such time as the Secretary has issued a final decision on the petition. The Secretary ✓ shall complete review of any such petition within 6 weeks of receipt of the petition.

(f) DISMISSAL WITH PREJUDICE.--An order granting a motion to dismiss or for summary judgment pursuant to this section shall be entered with prejudice, except insofar as the moving defendant may be rejoined to the action as provided in section 207.

(g) MANUFACTURER CONDUCT OF PROCEEDING.--The manufacturer of an implant that is the subject of an action covered under this title shall be permitted to file and conduct a proceeding on any motion for summary judgment or dismissal filed by a biomaterials supplier who is a defendant under this section if the manufacturer and any other defendant in such action enter into a valid and applicable contractual agreement under which the manufacturer agrees to bear the cost of such proceeding or to conduct such proceeding.

SEC. 207. SUBSEQUENT IMPLEADER OR DISMISSED DEFENDANT.

(a) IMPLEADING OF DISMISSED DEFENDANT.--A court, upon motion by a manufacturer or a claimant within 90 days after entry of a final judgment in an action by the claimant against a manufacturer, and notwithstanding any otherwise applicable statute of limitations, may implead a biomaterials supplier who has been dismissed from the action pursuant to this Act if--

(1) the manufacturer has made an assertion, either in a motion or other pleading filed with the court or in an opening or closing statement at trial, or as part of a claim for contribution or indemnification, and the court finds preliminarily, based on ~~clear and convincing~~ evidence contained in the record of the action, that under applicable law--

(A) the negligence or intentionally tortious conduct in violation of such law of the dismissed supplier was an actual and proximate cause of the harm to the claimant; and

(B) the manufacturer's liability for damages should be reduced in whole or in part because of such negligence or intentionally tortious conduct; or

(2) the claimant has moved to implead the supplier and the court finds preliminarily, based on ~~clear and convincing~~ evidence contained in the record of the action, that under applicable law--

(A) the negligence or intentionally tortious conduct in violation of such law of the dismissed supplier was an actual and proximate cause of the harm to the claimant; and

(B) the claimant is unlikely to be able to recover the full amount of its damages from the remaining defendants.

(b) STANDARD OF LIABILITY.--A biomaterials supplier who has been impleaded into an action subject to this Act, as provided for in this section--

(1) may, prior to entry of judgment on the claim against it, supplement the record of the proceeding that was developed prior to the grant of the motion for impleader under subsection (a); and

(2) may be found liable to a manufacturer or a claimant only to the extent required and permitted by any applicable State or Federal law other than this Act in an action alleging harm caused by an implant.

(c) DISCOVERY.--Nothing in this section shall give a claimant or any other party the right to obtain discovery from a biomaterials supplier defendant at any time prior to grant of a motion for impleader beyond that allowed under section 206.

TITLE III – LIMITATIONS ON APPLICABILITY; EFFECTIVE DATE

SEC. 301. FEDERAL CAUSE OF ACTION PRECLUDED.

The district courts of the United States shall not have jurisdiction pursuant to this Act based on sections 1331 or 1337 of title 28, United States Code.

SEC. 302. EFFECTIVE DATE.

This Act shall apply with respect to any action commenced on or after the date of enactment of this Act without regard to whether the harm that is the subject of the action or the conduct that caused the harm occurred before that date of enactment.

Draft

Background

In the wake of litigation and subsequent suspension of the use of most silicone breast implants, many suppliers of raw materials for healthcare products began to reevaluate their position in the market. Dow Corning's medical division represented 1% of revenues prior to the litigation and "99%" of its liability as it turns out-enough liability to force the company into bankruptcy.

It was not just implants that proved to be an unforeseen liability. Silicone supplied for one purpose was often used for another-silicone sheeting in TMJ treatment, for example-and implicated Dow Corning in liability litigation they never anticipated, involving end-use and products over which they had no control and little knowledge. They were exposed to litigation by simply supplying raw materials to medical device manufactures and, in some cases, physicians and dentists. In the end, Dow Corning announced a policy to quit supplying materials for many medical uses.

The focus of the biomaterials legislation has thus far been on implantable devices, but the reticence of suppliers has spread well beyond pure implants. Whether justified or not, suppliers of raw materials for all medical products are being much more cautious in serving customers-establishing prohibited uses, requiring indemnification, shortening the duration of contracts and raising prices for any medical use not strictly implants. All of which detract from time and resources needed to advance medical innovation.

The reluctance of manufacturers to supply basic materials for medical uses is illustrated by one large supplier's decision to classify common raw materials by their use as: prohibited, restricted, or unrestricted. These categories are arbitrary in that they are determined solely by the supplier and may all apply to the same raw material. The fact that no cases have been brought against manufacturers of IV products, for example, allows them to stay on the "restricted" but not "prohibited" use list. It only requires a change of the company/contracting policy, perhaps after the first case is filed or after the supplier's insurers refuse to cover "restricted" products, to move "restricted" to "prohibited" category.

Cleveland, Mississippi

Baxter's plant in Cleveland is one of the largest plants, employing approximately 1000 people in a rural location in the delta. The plant manufacturers a variety of health care products including plastic pour bottles, plastic caps placed over catheters when they are not in use, anesthesia trays-mostly high-volume, low-margin products. These are products which Baxter has not been sued and products for which there appears to have been no other litigation against any producer (i.e., products that would be classified as "restricted" under the system cited above).

This apparently tranquil setting and success story is marred by changes in the availability and cost of supplies. Polypropylene, a type of medical grade resin, is widely used at the plant for the majority of their products. The plant's last supplier for polypropylene was a fairly small supplier and the Cleveland plant represented a substantial portion of its business and therefore has been

reliable source for supply. A larger company recently purchased this supplier. Now Cleveland represents only about 2% of the acquirer's revenues.

Obviously, economic power has shifted. In fact, the new supplier has committed only to fulfill the remaining time (now less than 1 year) on the original supplier's commitment. The new supplier has not signaled a willingness to renew, or conditions under which, it will continue to supply Cleveland.

Cleveland's managers are obviously considering their alternatives and pursuing options. At the moment, it looks as though there is only one other supplier who could meet FDA and cost requirements. Even then, the likely alternative raw materials would require a change in the plant's manufacturing processes and, after closing the plant and retrofitting, would result in a process much less efficient than that currently employed.

The net result of all this would be a substantial increase in unit costs and therefore subject the products to more severe price competition, especially from foreign manufacturing. Even if this scenario all works out as described, and the plant survives the transition, there is no assurance the new raw material and its supplier will be any more reliable. A change in the new supplier's policy, its willingness to accept risk, the filing of a liability suit (no matter what its merits) could all cause the new supplier to retreat. In short, the supply lines are getting thinner, less reliable and more expensive.

The Imperative

So where's the "crisis?" If you define crisis as imminent disruption, there isn't one-at least not today and probably not until the end of the year. In the meantime, there are serious deleterious effects! The current situation is likely to evolve in one of several ways, none of them good. But perhaps the worst case is the status quo!

There is the obvious human cost in the uncertain outlook for the plant's employees and managers. In today's rapidly changing economy, that may not be unique. But what is unique is the vagary of availability and cost of raw materials supplies-vagary caused by the perceptions of product liability held by others, not Baxter. This plant can and does compete with anyone in the world, but only if it can get supply at reasonable cost. Under this cloud of uncertainty, there can be no plant expansion, no significant modernization that would meet fiduciary standards.

Most changes to the status quo could hardly be described as better. There could be a precipitous disruption of supply that would require the plant to close, simply by the refusal of suppliers to continue to take the risk. Perhaps more likely, current or future suppliers may increase contract demands, on price, or financial indemnification, for example, that make it uneconomical to continue operations. Many of these products are truly commodity or low-margin products, selling for pennies a unit. (It cost less to buy a liter of sterile, FDA-approved saline IV solution than a liter of Coke in your local store.) There is any number of foreign suppliers of product that, while subject to U.S. liability laws, have much less to lose financially and are willing to take the risk of closure. Foreign competition may overrun this plant for no fault of its own!

So the Cleveland plant can either die slowly, with uncertain supply preventing modernization or expansion, or it can die quickly if supplies dry up or become too expensive.

The Cure

Any change in product liability laws covering implants and medical devises, "biomaterials", must also define liability for other products used in healthcare. Supplies must be made more secure and prices more stable.

Amendment to S. 364, the Biomaterials Bill to Clarify Definition of Implant

Modify definition of implant in section 205 (5) (A) as follows:

(A) a medical device that is intended by the manufacturer of the device—

(i) to be place into a surgically or naturally formed or existing cavity of the body for a period of at least 30 days; or

(ii) to remain in contact with bodily fluids or internal human tissue through a surgically produced opening for any period of time. ~~a period of less than 30 days; or~~ and

(B) suture materials used in implant procedure; and

(C) containers and their related products to be used to collect fluids or tissue from the body in conjunction with a medical device described the above paragraph (A) to infuse or otherwise introduce fluids or tissue into the body.

Product liability - notes + memos

THE WHITE HOUSE

WASHINGTON

March 10, 1998

TO: Erskine Bowles

FROM: Gene Sperling
Sally Katzen

RE: **Product Liability Meeting**

Summary

You are scheduled to meet on Friday with Senators Rockefeller and Gorton to discuss product liability legislation. Our position remains the same as it was last fall.

- We will support the Rockefeller amendment (#1525), which was developed in consultation with the White House to address the concerns raised in the message accompanying the President's veto of the 1996 legislation.

- In addition, we will only entertain changes that are:
  - both technical and necessary; or
  - reflect a consensus view of all affected parties on a discrete issue that was not part of the initial discussions with Rockefeller (see below).

- This stance is necessary to remain consistent with the "take-it-or-leave-it" position we announced when we negotiated with Rockefeller; if we do not hold firm, we will invite others to open new issues and reopen old ones, with our ability to resist reduced.

Background

In May of 1996, the President vetoed the "Common Sense Product Liability Reform Act." Soon thereafter, we were asked by Senator Rockefeller to work with him to develop a version of the legislation that the President could support. Legislation was crafted that attempted to address all the concerns expressed in the President's veto statement.

The Administration decided to tell Rockefeller that this was our bottom line; we would not go further; but, if he could sell it as it was, the President would sign it. Even thought it was more minimal than Rockefeller's previous proposals, he agreed to run with it, provided that the Administration hold firm and not compromise further. Bruce and Gene have been called to meet with Gorton, McCain and Lott's staffs to make clear that the Administration will not move further. Rockefeller also has represented to others that this version was our final offer.

The bottom line position was reflected in an amendment (#1525), introduced by

Rockefeller on October 24, 1997, to Rockefeller's own bill.

Recent Events

Senator Gorton has developed a set of so-called "technical" changes to the Rockefeller amendment. The Product Liability Working Group met to review the proposals. We concluded that a few were not only "**technical**" but "**necessary**" changes. (These are not detailed below, as they are non-controversial.) Senator Rockefeller's staff apparently believe that a few other Gorton changes could be characterized fairly as technical and necessary. We are reserving judgement ("**reserve judgement**"). (Detailed below.)

In addition, three of Gorton's changes relate to provisions negotiated among other affected parties. We do not think that these are inconsistent with the intent of our offer; and apparently they are acceptable to Rockefeller ("**not invented here**"). (Detailed below.)

Finally, we have requested two further changes that we regard as purely technical, although Rockefeller and Gorton may not concur with that assessment of one ("**other technical and necessary**"). (Detailed below.)

The remainder of Gorton's proposals, we concluded, should be rejected, even though some may not be objectionable. It is important to avoid repeated attempts to change the Rockefeller amendment; once we begin making changes, other parties will undoubtably push on other issues that we may not be able to resist.

We have shared our categorization of these issues with Senator Rockefeller's staff, which expects to share all but the "reserve judgement" list with Senator Gorton's staff shortly before the meeting on Friday.

"Reserve Judgement"

- Senator Gorton proposed a new "findings" section that includes incendiary language such as: "excessive, unpredictable, and often arbitrary product liability awards...." We have rejected the entire section. Senator Rockefeller may suggest that some less inflammatory parts of this language can be retained. DOJ staff believe some "findings" may be helpful in any judicial challenge to the legislation.

- Exclusion of claims regarding breast implants from preemption. Section 102(a)(2)(D). Consider adding the language: "either the silicone gel or the silicone envelope utilized in a breast implant containing silicone gel shall not be subject to..." This narrows the exemption from the statute to just the class of products where problems have been greatest.

- ADR Procedures; Section 109[c] regarding written notice of acceptance or rejection of an offer to proceed using ADR. Consider inserting: "Such notice shall not constitute a waiver of any objection, including on grounds of jurisdiction or otherwise." DOJ staff believe that this is the legal effect of such notice in most states and, in any event, ensures that there is no disincentive to settlement discussions.

"Not Invented Here"

- **"Offers of Judgement"** -- The Rockefeller amendment included, at our suggestion, an "Offers of Judgement" section originally proposed by Senator Breaux. The provision permitted penalties up to $50,000 to be placed on either plaintiffs or defendants who refused settlement offers and then did not do better in court. As offered by Breaux in a stand-alone bill as an alternative to other anti-consumer, product liability legislation, the proposal had some appeal. However, when included in product liability legislation, even one less antithetical to consumer interests than the one that was vetoed, it weighs too heavily against consumer rights. Inclusion of the provision is strongly opposed by consumer advocates. Senator Gorton deleted the provision in his proposals and Senator Rockefeller does not object. We should concur.

- **Biomaterials** -- The Rockefeller amendment includes a separate title designed to ensure a continued supply of raw materials and component parts for use in lifesaving and life-enhancing medical devices by clarifying the permissible bases of liability and streamlining litigation procedures. Senator Lieberman has been meeting with key constituencies to hammer out an agreement on these provisions. Our greatest concern with earlier drafts (the requirement of "clear and convincing evidence" for successful impleader of defendant suppliers) has been eliminated. If, as we believe, the Gorton proposal incorporates the result of the Lieberman negotiations, we would accept the changes. Rockefeller's staff will confirm with Lieberman's staff.

- **Preemption of Dram Shop Act** -- All agree that actions based on a dram shop theory of liability (liability for providing alcohol to an intoxicated person or a minor) should not be covered by this bill. The bill therefore exempts such liability from its provisions. Gorton proposes technical changes to this exemption language that he reports were requested by MADD. We have calls in to MADD to confirm. If MADD believes that the changes are necessary, we would agree; however, we would suggest that two additional definitions be added for new terms introduced by the changes ("minor" and "alcoholic products").

"Other Necessary and Technical"

- **Intentional wrongdoing by product sellers -- proximate cause vs. cause in fact.** -- The legislation limits liability of product sellers (other than a manufacturer) to cases of (1) failure to exercise reasonable care; (2) failure to conform to an express warranty; and (3) intentional wrongdoing. Initially, in each case, the bill required a showing that the failure or act was the

"proximate cause" of the harm. Based on an analysis by DOJ, we argued that proximate cause was a negligence concept and did not belong with express warranties. As a result, the term "proximate" was dropped from category (2). We now make the same argument regarding intentional wrongdoing (category (3)).

cc: Bruce Lindsey

Product Liab - notes + memos

Issue - our position	Rockefeller draft/staf
Joint and several	
No change in existing law re joint and several liability for non-economic damages	Adopts our position; bill does not contain a
Punitive damages	
Full two-way preemption on punitive damages; i.e., even if a state does not currenly allow punitives, it must allow them according to federal standards	**DOES NOT INCLUDE THIS PROVISION.** Thi clear there is no wiggle room
No caps on punitive damages for big businesses; caps only for very small businesses with judicial override	Bill includes a small business cap only, but t is too generous (25 employees and annual r likely would cover over 90% of US firms). that if this is the last issue, Rockefeller will our position (10 employes and $1 million). allow judge to override.
Punitive damage standard of "clear and convincing" evidence of "conscious indifference (excluding recklessness)"	Adopts "clear and convincing"; uses "consc
Judge to decide on punitives, based on jury advice	Not included
Statute of repose	
18-year statute, which plaintiff may overcome by clear and convincing evidence of longer useful life	18-year, with no out
Covers virtually all consumer and workplace goods	Covers only durable goods in the workplace available. **Dingell wants all goods, which Ro**
Full two-way preemption	Fully preemptive for goods covered, althoug of repose in place in approximately 12 state
Allow full two-year statute of limitations to operate even if repose interferes	Intended to do this but bill is confused. Sta
Bio-medical materials	
Supplier should be brought back into action if his negligent or knowing acts caused the harm	Only covers negligent acts. Rockefeller willi Senator Lieberman agrees to. DOJ/CPSC/F alleged compromise House bill
Negligent entrustment	
Make certain statute also does not override negligence per se for guns	Staff has indicated they will accept a fix to
Bankruptcy stay issue	

Make certain statute of limitations is tolled when a bankruptcy stay is in effect	Included
Constitutional issues	
Ensure that this statute does not needlessly generate a Tenth Amendment case	There may be some problems; OLC is worki should be ready early next week.
Add-ons	
Kohl limitation on protective orders	Rockefeller will support as a separate bill bu legislation
ADR for small claims	Includes a fairly harmless ADR provision, bu offers in judgment which is probably better Amendment issue).
Affidavits and sanctions	Includes a provision that is broader than we to let us redraft; we might want to suggest Amendment issue).

Products liability : notes + memos

Ellen S. Seidman 09/10/97 09:24:33 AM

Record Type: Record

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

cc: Jennifer D. Dudley/WHO/EOP, Melissa Green/OPD/EOP, Jonathan A. Kaplan/OPD/EOP, Russell W. Horwitz/OPD/EOP

Subject: products

PRODCHT.W Here is my chart, redone to show what I believe the results of yesterday's meeting were. As you can see, there's really only one outstanding major issue (they came very close to saying they'd narrow the small business cap significantly if we agreed to no two-way preemption on punitives; I think they will if that's the last outstanding issue). We need to figure out what we do next. They strongly believe Lott wants to make certain the Senate brings this bill to the floor before the House does, and the House wants to do it in mid-October. Any time in the next several weeks, after the DC, HHS and Interior appropriations bills are done, is likely. (If there is agreement between us and Rockefeller, Rockefeller will work with Gorton to make certain the revised bill is procedurally unamendable.) So they are strongly urging a swift reaction from the President, communicated directly to the Senator. Senator Rockefeller joined the meeting briefly to remind us that he had acted in good faith, and assumed the President would too. ellen

Message Sent To:

Bruce R. Lindsey/WHO/EOP
Gene B. Sperling/OPD/EOP
John Podesta/WHO/EOP
Elena Kagan/OPD/EOP
Peter G. Jacoby/WHO/EOP

Page	Lines	Issue	Rockefeller staff response
2	8	do we want bill to provide "uniform legal principles"?	Did not discuss
2	12	"providing for reasonable limits" on punitives as a purpose inappropriate; bill only has limits on small entities	Did not discuss
3	1	"ensuring the fair allocation of liability" may be inappropriate as there's no several liability provision anymore; on the other hand, there is in effect an allocation between manufacturers and sellers	Did not discuss
3	12-14	fortunately, the "actual malice" standard is not used in the bill; the definition should be deleted	Probably will delete
5-6 7	23-5 17-22	the only times "economic" and "non-economic" damages are used is in the definition of compensatory damages, to include both. It's probably better to delete the separate definitions of economic and non-economic damages to avoid later mischief	Probably will delete
6	15on	unclear whether the definition of manufacturer includes someone who simply makes a products to someone else's specs or assembles a product; **it should**	Did not discuss
8	21-25	do not understand the tissue, blood, etc exclusion (FA - agree that this doesn't make sense)	Did not discuss
12	7-12	negligent entrustment issue needs to be extended to exclude from this bill actions for which there is strict liability under federal or state law (e.g., certain gun laws)	Will fix
15 16	11, 22 4-5	question "proximate cause" as standard for seller liability rather than "cause" (FA - has always been there on seller liability [as opposed to punitives])	Will fix the warranty provision

18	9	complete defense if alcohol or drug use by claimant was more than 50% responsible; issue of impact on non-drunk injured plaintiffs	Will make certain innocent claimants are protected; will consider substituting "harm" for "accident"; appreciated knowing that Wash state provision uses "harm"
20	3-7	question whether "reasonably foreseeable" misuse should be the defendant's responsibility	Did not discuss
20	24	is "should have discovered" in 2-year statute of limitations OK? (FA - maybe not; have to think about how toxic torts are dealt with)	Did not discuss - we will not raise
22	5-6	is workers comp requirement ("that is covered") sufficient (statute of repose), or does there need to be another requirement relating to payment under workers comp?	We internally agreed this was OK
22	9-19	interaction of limitations and repose doesn't seem to work (see also p.23, ll 16-24); given that only durable goods are now covered, do we need an extension for latent effects, toxic harm?	Agree it's a problem; have asked us to fix it; believe toxics exception is covered in durable good def, but agree it should exist
24-25	all of sec 107	this doesn't seem to accomplish the goal of a strong ADR provision for small claims, and moreover is limited to situations in which state law provides for ADR	Did not discuss
25	21	as no period for filing is described in subsection (a), reference to such a period in subsection (b) doesn't work; without some sort of judicial oversight, does this unfairly press plaintiffs to accept too-low offers (see, e.g., the situation with AT&T credit card bankruptcies)	Did not discuss

30-32	all of sec 109	this section could be a real problem in the context of the rest of this bill, including attorneys fees section	Accepted our position that this section didn't do what anyone wanted; will let us redraft
30	8-9	should "raised a defense" be added to the list of frivolous actions if "claim" is included?	See above
32	16-17	does the limitation to attorney's fees "incurred during the period preceding the disposition of the motion" box the amount in enough to not hurt plaintiffs too badly; should there be some provision for the court being able to direct the attorney to pay the fee, rather than the claimiant	See above
33	3-4	**one way preemption only on punitives**	**This is critical to Senator Gorton's support; will not budge**
33	8-9	is "conscious, flagrant indifference" the appropriate standard? (FA - no; we wanted "conscious indifference (not including recklessness)"; in particular we wanted to get rid of "flagrant")	We decided not to raise this
33	9-10	"the proximate cause" is too high a standard for punitive damages (especially when the conduct giving rise to the punitives was not aimed at the plainitiff)	They understand the issue and are actively considering changing it
34	3	small business cap is extended to businesses with "fewer than **25** full-time employees" (rather than our 10) and revenues of $10 million (rather than our $1 million). Also need to extend deeming to include parents and subs extend to revenues	Essentially said that if this is the last issue outstanding, it will be fixed

34	10 on	unsure whether bifurcation provision works with respect to admissibility of evidence, given that many states will not entertain a claim for punitives until after liability is established	Did not discuss
35-40	section 112	we didn't want workers comp subrogation, but omitted any discussion of it because we were working from 684, not last year's bill. Will need to figure out exactly why we don't want it, since logically it should reduce the number of suits (issue for Podesta)	R staff insists this is a deal AFL-CIO senior reps neg with R and if it is to be changed, they must agree
42	6-14	there seems to be little factual support for this finding of suppliers "ceasing" to supply materials	Did not discuss any of the biomed provisions; apparently Vicki Radd has negotiated some sort of deal with Lieberman; Rockefeller staff don't know what it is, and neither do I
45	24-25	probably need technical fix to deal with situation in which a professional health care service provider is also the person injured	
46	13-14	question "includes" rather than "is"	
47	15-17	this seems to include all sorts of orthodonture. Is that intended? Is there any problem?	
52	1-4	do not understand import of this section relating to defenses available under state or federal law	
56	23-24	how much of a limitation is the "to the extent required and permitted by any other applicable law" language?	
58	14-15	"proximate cause" standard	
59	18, 22	"failed to establish" is not a motion to dismiss standard, and will be virtually impossible to prove without discovery	
64 65	15-22 1-5	going to be very hard to fight dismissal without discovery	

66	18	required sanction of attorney's fees too severe	
67	13	is date of enactment the appropriate effective date?	Did not discuss
		No Kohl provision re protective orders	They just couldn't see any way to add this; will support a separate bill, which Senator Kohl is thinking of introducint; we said we wanted to work with Kohl; Peter Jacoby will follow up
		No use of judges on punitives	Did not discuss
		Doesn't pick up the negligence fix on biomed	See biomed above

Product liability -
notes + memos

September 17, 1997

MEETING ON PRODUCT LIABILITY

DATE: September 18, 1997
LOCATION: Oval Office
TIME: 4:30pm-5:00pm
FROM: Bruce Lindsey
Gene Sperling

I. PURPOSE:

For an internal meeting between you and your advisors to discuss and reach a position on Senator Rockefeller's and Mr. Dingell's separate proposals on product liability reform.

II. BACKGROUND:

Following an internal meeting on July 23, at which you established the Administration's position on this issue, we have held a series of meetings with Rockefeller and Dingell staff and, at times, the Members. On September 5, Senator Rockefeller presented us a proposal that adopts the Administration's position on several liability for non-economic damages (i.e., there is no provision); limits the statute of repose to durable goods in the workplace covered by workers' compensation; and has no large business cap on punitive damages.

On the other hand, the Senator's bill would not require punitive damages to be allowed in the seven states (including Washington state) that generally do not allow them, and has several more minor problems. In addition, Senator Rockefeller did not adopt our proposed position on limiting protective orders, the most consumer-friendly part of our proposal. While the Senator's staff has indicated he would fix most of the minor problems, including tightening the small business cap on punitives, he will not move on requiring all states to allow punitives, and is unlikely to add the protective order provision without a lot more prodding. Mr. Dingell's position is less defined, but he would include a firm 18-year statute of repose for all goods, which Senator Rockefeller will not support.

III. PARTICIPANTS

Vice President
Erskine Bowles
John Podesta
Sylvia Mathews
Bruce Lindsey
Gene Sperling
Chuck Ruff
Ron Klain
Elena Kagan
Ellen Seidman
Peter Jacoby
Tracey Thornton

IV. PRESS PLAN

Closed

V. SEQUENCE OF EVENTS

You will be meeting with your advisors to discuss product liability reform.

VI. REMARKS

None required

Product liability - notes + memos

SCHEDULE PROPOSAL DATE: July 18, 1997

_____ACCEPT _____REGRET _____PENDING

TO: Stephanie Streett

FROM: Bruce Lindsey
Gene Sperling

REQUEST: For an internal meeting between the President and his advisors to discuss and develop the Administration's position on pending product liability legislation

PURPOSE: To consider issues raised in our memo of July 3 (attached), so as to develop an Administration position on this legislation, and strategy for working with interested parties.

BACKGROUND: In 1996, the President vetoed products liability legislation, citing specific problems with the bill as passed. In May, the Senate Commerce Committee reported out a slightly revised version of that bill, which the Republicans would like to move this year. Senator Rockefeller has refused to sign on to the new bill, strongly preferring to reach an agreement with the Administration to avoid another veto. Senator Breaux and Mr. Dingell are also highly interested. At the President's request, we established and completed a two-month interagency process to develop options, which were described in our July 3 memo. The President's response to that memo, which requested a meeting, was "OK - ready to meet"

PREVIOUS PARTICIPATION: The President met with his advisors on this issue in April, which led to the establishment of the interagency process.

DATE AND TIME: Would be good to do it before Congress recesses, so as to be able to inform Senator Rockefeller of our position. He has been pressing for information.

DURATION: One-half hour.

LOCATION: Oval Office

PARTICIPANTS:	Erskine Bowles Bruce Lindsey Gene Sperling Janet Yellin Frank Raines John Hilley Ron Klain Elena Kagan Ellen Seidman
OUTLINE OF EVENTS:	Meeting
REMARKS REQUIRED:	None
MEDIA COVERAGE:	None
FIRST LADY'S ATTENDANCE:	Not required.
VICE PRESIDENT'S ATTENDANCE:	Not required.
SECOND LADY's ATTENDANCE:	Not required.
RECOMMENDED BY:	Bruce Lindsey Gene Sperling
CONTACT:	Ellen Seidman, 456-5359

Copies
Lindsey
Sperling
Seidman
COS

THE PRESIDENT HAS SEEN
7-15-97

THE WHITE HOUSE

WASHINGTON

July 13, 1997

MEMORANDUM FOR THE PRESIDENT

OK - MMM

97 JUL 13 PM 5:41

FROM: TODD STERN
PHIL CAPLAN Phil
SEAN MALONEY SM

SUBJECT: PRODUCT LIABILITY LEGISLATION

Bruce Lindsey and Gene Sperling have sent you a lengthy and detailed memo. *The memo does not seek a decision now, but simply recommends that you convene a meeting to consider three options of responding to S.648, the product liability bill voted out of the Senate Commerce Committee along party lines, and the primary legislative vehicle at this point.*

Overview. The memo arises from an eight-week interagency process and lays out three possible options: (1) deferring to recent state-law reforms by foregoing any federal product liability legislation at this time, in the absence of any national "crisis" in this area; (2) proposing an Administration bill that would reflect your priorities, even if such a bill were unlikely to pass; or (3) staking out a negotiating position that signals movement on some of your current positions, thus facilitating serious negotiations and a possible deal. *A more detailed discussion of these options follows on page 3 of this memo.*

In determining these three options, your advisors reached four general conclusions: (i) that there is no systematic, empirical evidence of reduced productivity or innovation arising from the tort system and the anecdotal evidence is mixed, with most "horror stories" relating to the pharmaceutical sector; (ii) that the states have already enacted significant, pro-defendant reforms; (iii) that federal legislation cannot be justified unless it leads to balanced, uniform national standards; and (iv) that imposing limited product liability preemption on the tort law and civil procedure of 50 states may increase, not decrease, confusion and uncertainty.

Views. Most of the primary interagency participants (NEC, DPC, Treasury, DOJ, SBA, Leg. Affairs and Counsel) favor Option 2 -- i.e., proposing your own legislation. DOJ and Counsel, in fact, prefer to see no legislation at all (Option 1), but believe such a course to be impracticable, and so support Option 2. Leg. Affairs stresses the need to consult with Rockefeller, Breaux and Dingell prior to any public announcement. Commerce and the SBA offer conditional support for Option 3 -- i.e., staking out a negotiating position. Secretary Daley recommends a deal with Rockefeller and private outreach to key business community principals and suggests grounding your position on uniform and balanced preemption as the basis for reform. Rockefeller and Dingell seek negotiations to develop a bill that will pass without a veto. Senator Breaux has developed his own bill that focuses more on reducing frivolous lawsuits than on substantive product liability reform.

Background. Last May, you vetoed a product liability bill, citing eight deficiencies: (1) interference with state tort law prerogatives; (2) "one-way preemption," whereby only pro-plaintiff measures were superseded while pro-defendant measures were not; (3) a cap on punitive damages; (4) "several" liability for non-economic (e.g., "pain and suffering") damages, under which a defendant's liability is limited to its proportionate share of fault; (5) inadequately short "statute of repose" periods, whereby manufactures are excused from liability after a specified number of years; (6) preemption of state "negligent entrustment" statutes, under which makers of dangerous goods (e.g., handguns) can be held liable for their use; (7) failure to toll statute of limitations periods during bankruptcy proceedings; and (8) the extension of biomedical material suppliers' liability limits to negligent suppliers. After the House failed to override your veto (258 to 163), the Senate abandoned any attempt to do so.

S. 648 - Brief Summary. S. 648 fixes the bankruptcy tolling problem and partially addresses the preemption of negligent entrustment statutes. S. 648 does not satisfy your concerns with respect to the extension of biomedical material suppliers' liability limits to negligent suppliers. With respect to the other major issues presented by S. 648, Gene/Bruce's memo provides a detailed discussion.

(A) One- or Two-Way Preemption. This is a "sauce-for-the-goose" issue: specifically, whether federal standards should preempt all state laws ("two-way preemption") or whether they should act merely as a benchmark, with states free to enact or retain more defendant-friendly (or plaintiff-friendly) standards ("one-way preemption"). The bill you vetoed displaced state law only when it was more favorable to consumers. S. 648 corrects these imbalances with respect to statutes of repose, but retains them with respect to punitive damages.

(B) Several Liability for Non-Economic Damages. Recent state-level tort reform has essentially done away with the traditional rule of full joint and several liability regardless of defendants' comparative fault. Both the vetoed bill and S. 648 *federally* limit a defendant's liability for non-economic damages to its percentage of fault when considered against all those responsible. In vetoing last year's bill, you cited this provision's effect of jeopardizing full compensation for injured persons and the problems created by insolvent defendants. You stressed also the equivalence of economic and non-economic damages.

(C) Punitive Damages Cap. Both last year's vetoed bill and S. 648 cap punitive damages. For larger companies the cap equals the *greater* of two times compensatory damages or $250,000. For individuals and smaller companies (i.e., those with fewer than 10 employees and $1 million in revenues), the cap equals the *lesser* of these two sums. Judges are permitted to exceed only the larger-company cap, up to the amount of the jury award, and then only after considering a lengthy, prescribed set of factors. S. 648, like last year's bill, also establishes a uniform "clear and convincing" evidentiary standard of "conscious, flagrant indifference to the rights and safety of others" that proximately caused the harm. The bill also permits parties to request a separate hearing on punitive damages to prevent evidence of a defendant's financial condition from entering the liability and compensatory damages phase of the trial.

(D) Statutes of Repose. Statutes of repose excuse manufactures from liability after their products have been in use for a specified number of years. Last year's bill contained a 15-year repose period for all products and only preempted those state laws that were less favorable to defendants. S. 648 is an improvement; it contains a fully preemptive, 18-year period for nearly all products.

Options Presented. As noted above, the memo presents three possible options for responding to the legislation moving through the Senate:

Option 1 is to take a firm and overt stance against any federal product liability legislation at this time, deferring to the considerable state-level reforms and the absence of any compelling national "crisis." This option may be difficult to square with your stated support for "limited, but meaningful" federal reform.

Option 2 is to develop an Administration bill that would reflect your priorities. The hallmarks of this option are: (a) consistency with your veto message; (b) recognition of state-level reforms; (c) fair and balanced, two-way preemption; (d) an emphasis on reducing frivolous litigation; and (e) the addition of new measures, not found in S. 648, to aid injured plaintiffs. More precisely, such a bill would contain: (i) a breachable punitive damages cap applicable only to small businesses and individuals, which would emphasize the judge's role and be fully preemptive, thereby permitting punitive awards in all jurisdictions; (ii) a narrower, rebuttable, 18-year statute of repose; and (iii) provisions to reduce frivolous law suits (e.g., good-faith affidavits and sanctions). The bill would not include joint and several liability reform with respect to non-economic damages.

Option 3 is to make a negotiation proposal. The memo warns that pursuing option 3 would require some movement away from the specifics of your veto message, and predicts a possible "negative dynamic," in which reform proponents expect a deal after meeting only some of your demands. This option would include: (a) a looser cap on punitive damages that would not preempt states that currently bar such damages (i.e., one-way preemption); and (b) a narrower, rebuttable, 18-year statute of repose. Again, no reform of joint and several liability for non-economic damages would be offered. (The memo nonetheless contains an appendix setting forth optional reforms in this area, if such proposals were deemed necessary.)

THE WHITE HOUSE

WASHINGTON

July 3, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Lindsey
Gene Sperling

SUBJECT: Product liability legislation

I. ACTION FORCING EVENT: On May 1, on a strict party line vote, the Senate Commerce Committee reported out S.648, Senator Gorton's revision of the product liability bill you vetoed last year. Senator Rockefeller not only voted against S.648, but has made it very clear that he will not join until your concerns are satisfied, and Senator Gorton understands that without Senator Rockefeller's support, the bill cannot pass. On the other hand, Senator Lott has been pushing to bring the bill to the floor, leading Senator Rockefeller (together with Mr. Dingell) to press us to negotiate changes in the bill to meet your concerns. Senator Lott may well want to move soon after the July 4 recess. Meanwhile, Senator Breaux is urging us to work with him on an alternative to the Gorton bill.

II. BACKGROUND: The 104th Congress passed product liability reform law – a part of the Contract with America -- by a vote of 259 to 158 in the House and 59 to 40 in the Senate. The bill would have partially preempted state law as to both standards of liability for sellers and manufacturers of products that cause physical harm and measures and allocation of damages. On May 2, 1996, you vetoed the bill, citing eight issues:

- Interference with state prerogatives in tort law
- One-way preemption, where pro-consumer state laws were preempted, but laws that limited consumer rights were not
- The cap on punitive damages, particularly in light of the Statement of Managers, which virtually directed judges not to use the "additur" provision included in the bill under which caps could be superseded
- Several -- not joint -- liability for non-economic damages
- A too-short (15 years), too-broad (all products) statute of repose
- Preemption of state negligent entrustment statutes, which make sellers of dangerous goods (e.g., firearms and liquor) responsible for certain actions of the buyers
- Failure to toll the statute of limitations during the period of a stay issued by a bankruptcy court
- Application of the limits on liability of biomedical materials suppliers to negligent suppliers

The House failed to override your veto by a vote of 258 to 163 to override. The House having failed to override, the Senate never took a vote.

III. CURRENT CONGRESSIONAL ACTIVITY

A. S.648

S.648 fixes the bankruptcy tolling problem, and makes an honest -- although not complete -- attempt to respond to the negligent entrustment issue. Moreover, it lengthens the statute of repose to 18 years, and establishes two-way preemption for the statute of repose, so that shorter state statutes would be lengthened (all state statutes that are set in years are shorter than 18 years). The bill does not respond to the two major problems you cited -- the cap on punitives and several liability for non-economic damages -- nor does it change the biomedical materials provision.

B. Senator Rockefeller and Mr. Dingell

Senator Rockefeller and Mr. Dingell are clearly looking for guidance on how to resolve the remaining issues (punitive damages, several liability for non-economic damages, statute of repose and biomedical materials) to meet both the concerns and fact patterns in your veto message. They have said they will engage in negotiations with us to develop legislation that will pass and will not be vetoed (clearly they do not expect to be able to accept our initial proposal). Senator Rockefeller, in particular, has said he has no interest in another veto.

C. Senator Breaux

Senator Breaux would like to deal with this issue in an entirely different way. He has developed a bill focused far more on reducing frivolous lawsuits and less on substantive product liability standards. Senator Breaux's bill would include a statute of repose that is more flexible than that in S.648, would establish uniform federal standards for punitives damages but no cap, and would do nothing to change state law concerning joint and several liability for non-economic damages.[1] His bill would also require affidavits of good faith to accompany pleadings and impose sanctions for bad faith pleadings, restrict multi-state product liability class actions, enact a very weak form of alternative dispute resolution, and require a study by the Attorney General of the product liability system. It is unclear how far Senator Breaux can get in moving Senators away from the Gorton bill without the Administration's support for his approach.

III. MAJOR ISSUES PRESENTED:

Over the past eight weeks, we have jointly run an interagency process to consider whether there are ways to alter S.648 to respond to the concerns in your veto message in a manner that could be acceptable to at least Democratic proponents of the legislation. Participants in the process

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[1] As discussed below, many states, including California, already have several liability for non-economic damages.

included: OVP, NEC, DPC, OMB, CEA, White House Counsel, White House Legislative Affairs, Justice, Treasury, Commerce, and SBA and the Consumer Product Safety Commission as an advisor. FDA is participating in the ongoing discussion of biomedical materials. The working group surveyed the law in all the states on the critical issues of punitive damages, joint and several liability and statute of repose, and developed a number of alternatives in each area that we believe could move the bill closer (and in some cases, all the way) to your goals but may have a chance of not being rejected out of hand by proponents.[2] Two meetings of the NEC principals were held, on June 24 and 26.

Although product liability has been analyzed primarily as a legal issue, with a focus on victim compensation, it can also be viewed in economic terms. As Treasury and CEA have noted, product liability essentially creates an insurance system in which consumers pay a premium in the price of the product to cover losses suffered by those injured when a product is defective. From an economic perspective, the primary question to ask in evaluating changes to product liability law is whether the system provides too little insurance, with too little incentive to produce safer products, or too much insurance, where consumers would rather have less expensive products and less protection in case they are injured.

A. Whether there should be federal legislation in this area at all

The arguments of the business community in favor of national legislation rest on three propositions:

- Concern about product liability litigation, and particularly concern about disproportionate awards for non-economic damages and punitive damages, is sapping American productivity by misdirecting management time, energy and capital, and by putting an excessive -- and frequently non-insurable tax -- on innovation. This is true even as to cases that settle, and cases that are threatened but not brought.
- In a national economy, subjecting products and manufacturers to 50 different liability regimes is not only inefficient but also -- because of the opportunities for forum shopping by plaintiffs, particularly in class actions -- unfair.
- Manufacturers are the deep pocket focus of liability suits that are in fact generated by the activities of those who repair and service products. Making manufacturer liability more limited and predictable -- as occurred when you signed the 18-year statute of repose for general aviation -- will put the burden of care of those most responsible for and able to accomplish it.

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[2] Based on discussions with the Center for Violence Policy, we have also crafted a more complete fix to the negligent entrustment provision. We believe there will be no problem getting the proponents to adopt this. A sub-group, consisting of Justice, FDA and CPSC, is working on the biomedical materials issue. We expect to have a recommendation on that shortly.

Consumer groups, as well as lawyers (the ABA as well as ATLA), argue against the need for federal legislation based on:

- The lack of any explosion of product liability suits, and in particular, excessive punitive damage awards that survive judicial remittitur, suggests there is no problem to be fixed.
- The fact that all recent proposals in this area would cut back on traditional principles of tort law that benefit plaintiffs, suggests that what the manufacturers want is not uniformity but a tilt in their direction.
- The traditional role of the states in tort law, combined with the fact that all existing proposals would only partially preempt state tort law, could lead to even more non-uniformity and uncertainty as this law is overlaid on, e.g., state medical malpractice law and state law concerning joinder and defenses.
- States have been experimenting with tort law reforms that generally favor defendants. We should give these experiments time to play out and evaluate the results before considering preemptive pro-defendant federal reform of the system.
- Plaintiff-friendly limitations that are initially included in federal product liability legislation will be vulnerable to cutbacks in future Congresses; the time to stop erosion is before it starts.

B. One-way or two-way preemption

One of the most contentious issues that runs through the legislation is whether federal standards should preempt all state laws ("two-way preemption") or whether they should function solely as a floor, with states free to establish more defendant-friendly standards ("one-way preemption"). For example, if the federal statute of repose were 18 years, two-way preemption would both lengthen shorter statutes and impose the 18-year limitation in states that have no statute of repose; one-way preemption would only shorten longer statutes and impose a limit where there was none. Similarly, if the federal government were to enact standards for awarding punitive damages, two-way preemption would both tighten the standard in states that, for example, allow punitives to be awarded for reckless behavior and require states that do not allow punitives at all to allow them according to the federal standards. One-way preemption would only tighten standards in some states, leaving others free to bar punitives entirely.

The bill you vetoed last year was almost entirely one-way preemptive. In your veto message you said, "As a rule, this bill displaces State law only when that law is more favorable to consumers; it defers to State law when that law is more helpful to manufacturers and sellers. I cannot accept, absent compelling reasons, such a one-way street of federalism." As noted above, S.648 is two-way preemptive as to the statute of repose (as well as with respect to the general standards of manufacturer and seller liability and the statute of limitations) but retains one-way preemption on punitive damages.[3]

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[3] In form, S.648 is two-way preemptive on several liability for non-economic damages. However, since it imposes the least plaintiff-friendly rule possible (totally several liability), it is

While one of the arguments manufacturers and sellers make in favor of national legislation is the desire to create uniform federal standards, which would support uniform two-way preemption, on the two issues where they have made serious headway in the states -- limitations on punitive damages and imposition of several liability -- they are far more interested in a federal floor than in uniformity. We have been told, for example, that establishing by federal law the right to punitive damages in states where it does not exist, or limiting several liability for non-economic damages where state law has established it, would be totally unacceptable.

Consumer groups argue in favor of two-way preemption, ostensibly on the ground that the only good reason to override a traditional state function with federal standards is uniformity. However, many of these same groups regularly argue that federal environmental and consumer protection standards should function only as a floor, allowing states to impose more rigorous rules. It is conceivable that the consumer argument for two-way preemption is more an effort to highlight the inconsistency in the manufacturers' position -- and perhaps to raise an insurmountable barrier to legislation -- than a firmly held constitutional principle.

C. Several liability for non-economic damages

Over the last several years, tort reform at the state level has essentially done away with the traditional rule of no comparative fault and full joint and several liability. (Only Alabama, Maryland, North Carolina and Virginia retain this combination.) Nine states[4] have full joint and several liability, but include comparative fault, thereby reducing the defendants' joint responsibility by the measure of the plaintiff's responsibility. Thirteen states[5] have pure several liability, for both economic and non-economic damages, and 24 states have various hybrid forms.

Both last year's vetoed bill and S.648 limit a defendant's responsibility for non-economic damages "in direct proportion to the percentage of responsibility of the defendant for the harm to the claimant." The trier of fact is required to assign this percentage taking into account the responsibility of all persons responsible, including those not before the court, such as settling defendants.

In vetoing last year's bill with respect to this issue, you cited the provision's general effect of preventing "many persons from receiving full compensation for injury," noting in particular the problems created by insolvent defendants. You also cited the particular impact of a several rule for non-economic damages as unfairly discriminating against "the most vulnerable members of

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effectively one-way preemptive.

[4] Arkansas, Delaware, Maine, Massachusetts, Michigan, Pennsylvania, Rhode Island, South Carolina and West Virginia

[5] Alaska, Arizona, Colorado, Illinois, Indiana, Kansas, Kentucky, North Dakota, Tennessee, Utah, Vermont and Wyoming

our society." You said, "Noneconomic damages are as real and as important to victims as economic damages."

Manufacturers assert that the problem with joint liability for non-economic damages is that such damages -- unlike economic damages -- are totally unpredictable and subject to the whim of the jury, thereby making any assessment of the risk, or the purchase of insurance against the risk, virtually impossible. They are particularly concerned about the potential for a large award against the only solvent defendant in a case in which that defendant is only marginally at fault. Opponents make the argument that non-economic damages are as real and as important -- particularly to the poor, the young and the old -- as economic damages, and should not be treated differently. Some also contend that the different state standards represent the innovation and experimentation that is the role of the states, and this should not be preempted.

D. Punitive damages

The process of awarding punitive damages and the amount of such damages have been the subject of some of the most intense controversy. Both last year's vetoed bill and S.648 cap punitive damages -- at the **greater** of two times compensatories (including non-economic damages) or $250,000 for most companies and the **lesser** of these two amounts for individuals and small businesses. Upon consideration of eight listed factors[6], a judge could award damages in excess of the large business cap (but not the small business cap), up to the amount awarded by the jury, which would not be informed of the cap.[7] The "additur" provision explicitly constitutes one-way preemption -- it does not permit additur where state law otherwise limits punitive damages.

The vetoed bill and S.648 would also: (i) establish a uniform federal standard of proof of "clear and convincing"; (ii) establish a uniform standard for award that conduct "carried out with conscious, flagrant indifference to the rights or safety of others was the proximate cause" of the

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[6] The factors are: "(i) the extent to which the defendant acted with actual malice; (ii) the likelihood that serious harm would arise from the conduct of the defendant; (iii) the degree of the awareness of the defendant of that likelihood; (iv) the profitability of the misconduct to the defendant; (v) the duration of the misconduct and any concurrent or subsequent concealment of the conduct by the defendant; (vi) the attitude and conduct of the defendant upon the discovery of the misconduct and whether the misconduct has terminated; (vii) the financial condition of the defendant; (viii) the cumulative deterrent effect of other losses, damages, and punishment suffered by the defendant as a result of the misconduct, reducing the amount of punitive damages on the basis of the economic impact and severity of all measures to which the defendant has been or may be subjected . . ."

[7] The judge would be required to hold a separate proceeding on awarding an additional amount, consider each of the items, and state the court's reasons for an award above the cap in findings of fact and conclusions of law. A separate finding on each factor is not explicitly required. The conference report on last year's bill, of course, virtually directed judges not to use this authority.

harm; and (iii) authorize any party to request that punitive damages be considered in a separate proceeding (generally so that evidence of the defendant's financial condition would not be allowed into evidence during the liability and compensatory damages phase of the trial). While these rules are meant to apply in all states that have punitive damages, they would not apply in states where punitive damages are prohibited by law.[8]

In vetoing last year's bill, you stated that you "oppose arbitrary ceilings on punitive damages, because they endanger the safety of the public. Capping punitive damages undermines their very purpose, which is to punish and thereby deter egregious misconduct." You noted that the additur provision might have mitigated this concern, but the Statement of Managers virtually directing it not be used made it ineffective in that respect.

Manufacturers assert that unpredictable and unjustifiably large (and sometimes multiple) punitive damage awards -- as well as the threat thereof -- have driven them out of markets and impinged on innovations. Consumer advocates assert that only potentially unlimited punitive damages can deter harmful misconduct by large companies. Surveys suggest that neither the award of punitives nor the amount is skyrocketing in products cases.[9] Consumer groups cite this as evidence that there is no problem; manufacturers assert it is the result of in terrorem settlements of meritless suits.

E. Statute of repose

At its starkest, a statute of repose bars litigation after a product has been in service a specified period of time. Twenty-two states and the District of Columbia currently have statutes of repose for product liability; 17 of the states and the District restrict lawsuits after a specified number of years (ranging from 5 to 15) and the remainder use some variation of "useful life" as the bar. In 1994, you signed legislation establishing a preemptive 18-year statute of repose for general aviation.

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[8] In seven states punitive damages are generally forbidden; in 16 others, they are capped in one way or another. Twenty-seven states allow unlimited punitive damages in product liability cases. Most states that allow punitive damages have adopted the "clear and convincing" evidentiary standard. While the liability standards are less uniform, only a few states allow the award of punitive damages for reckless behavior without some other aggravating factor. We have not found any state that requires that the conduct leading to the punitive damages be the "proximate cause" of the plaintiff's harm, although the words "cause" and "result" are used. Bifurcated trials -- at least on the issue of the defendant's financial condition -- are allowed or required in 15 states.

[9] A recently-released Rand study has found an increase in the number and amount of punitive damage awards in financial fraud cases, such as cases involving insurance or financial products misrepresentation. This does not appear to extend to cases involving products as defined in the bill, which is limited to physical goods.

The bill you vetoed last year included a preemptive 15-year statute of repose for all products. The statute would, however, only have preempted states without any statute of repose, or with a statute longer than 15 years. Shorter state statutes would have remained effective. Your veto message referenced the length of the statute, the fact that it was broadly inclusive (you cited handguns), and the fact that the preemption was only one way. The Senate bill from the 104th Congress had covered only durable goods in the workplace and had an 18-year one-way preemptive statute.

S. 648, as reported out of the Senate Commerce Committee on a voice vote, includes a fully (two-way) preemptive 18-year statute of repose, covering all products except: (i) motor vehicles, vessels, aircraft and trains used to transport passengers for hire; (ii) products that cause toxic harm; and (iii) products with express written warranties that exceed 18 years.

Manufacturers assert that a firm, and broad, statute of repose is necessary not only to provide them some certainty, but also to put the risk of injury from long-lived products on those most able to prevent it -- owners, upgraders and servicers. They argue that the 18-year statute of repose for general aviation you signed in 1994 has not only increased the willingness of manufacturers to produce the aircraft, but has made owners and servicers far more careful, because they understand the deep pocket of the manufacturers will not be available to bail them out.

Consumers, on the other hand, argue that injuries from long-lived products -- including those that have not been altered or do not need service -- are common, and often the manufacturer should have foreseen and prevented the problem that caused the injury. They argue it is particularly important that those injured by long-lived consumer goods (such as camping equipment and cedar chests) not be barred from court completely by a strict statute of repose. Workers, they note, at least can collect worker's compensation for injuries caused by long-lived defective goods in the workplace.

IV. ALTERNATIVES

After looking at the alternatives developed by the working group in each of the three major areas identified, your advisors concluded that the choice of alternatives really depends on another decision, whether the Administration should:

- take the position that state law developments, and the lack of strong evidence of major problems that are caused by lack of national standards, lead us to conclude that no federal legislation is appropriate at this time;
- put forward a series of proposals that are fully consistent with both your veto statement and the principle of promoting national uniformity, even if such proposals have little or no chance of leading to a bill that can be enacted; or
- put forward a series of proposals that product liability legislation proponents will regard as an acceptable place to start negotiations and that can, albeit with some difficulty, be squared with your veto message.

Some of your economic advisors believe the business community may be correct in asserting that the current tort liability system, and in particular the issues raised in this legislation, over-deter businesses in their development and production of innovative products. In our discussions with the business community, we have asked them to provide empirical evidence that innovation has been stymied by litigation in general or the issues that particularly concern us: punitive damages and several liability for non-economic damages. Unfortunately, empirical evidence is not available, and the anecdotes relate to pharmaceuticals or related products, and often to the issues raised by mass tort claims for **economic compensatory** damages, not non-economic damages or punitive damages..

As your advisors looked into the issue, we came to the following conclusions:

- While logically there might be some impact on manufacturing innovation and productivity from the tort system, the evidence is mixed
  - there is no systematic empirical evidence of reduced innovation and productivity arising from the tort system (in part, of course, because of the difficulty of developing and collecting such evidence)
  - all the anecdotal evidence is primarily from one sector -- pharmaceuticals (including vaccines) and medical devices -- but the legislative proposals are far broader
  - there is no explosion of either litigation or punitive damages
  - the economy is booming and productivity is rising
  - on the other hand, the legal system appears to be both costly and time-consuming to plaintiffs and defendants, and anecdotes suggest that the threat of litigation -- and the resulting payment of unjustified settlements -- may have a dampening effect on innovation
- Over the past several years -- indeed, even since the start of the 104th Congress -- the states have made major moves toward making the tort system more defendant-friendly, ranging from the virtual abandonment of traditional principles of joint and several liability to the imposition of caps on punitive damages
- If federal legislation is not to lead to uniform national standards, there is little justification for it; there is little or no justification for one-way preemption
- Overlaying limited product liability preemption on the tort law and civil procedure of 50 states may increase confusion and uncertainty, not decrease it

In addition, there are concerns, particularly in light of the Supreme Court's recent decision on the Brady bill in Printz v. United States (June 27, 1997), that certain provisions included in S.648, as well as the options discussed below, may invite serious constitutional challenge on federalism grounds, causing the Supreme Court to restrict further the exercise of federal power. Although the Justice Department is unaware of any cases that specifically address the constitutionality of such provisions, and although it believes reasonable arguments can be made in support of these provisions, the risk of invalidation is significant. In this regard, the Justice Department is particularly concerned that the Court would invalidate purely procedural rules (e.g., bifurcation, pleading requirements and sanctions, and the biomedical provisions) as are contained in S. 648 and some of the proposals that follow. However, Justice emphasizes that, despite what the courts

may ultimately rule, it believes acceptable constitutional arguments can be made in defense of the procedural rules in the proposals and **that it is important for the Administration not to construe the Printz decision broadly in taking a public position on product liability reform.**

Thus, while there continues to be sentiment among your economic advisors for improving the tort system, it is mild and tempered by the recognition that ongoing reform in the states weaken the need for federal action. Your legal advisors do not believe S.648 or relatively minor modifications of it should be supported. Both groups of advisors feel strongly that if there is to be any federal legislation, it should establish uniform national standards, and should -- in the areas explicitly covered -- completely preempt the field. There is no justification for one-way preemption in this area.

This position can be manifest in two ways: taking a strong position against any legislation, or developing an Administration bill that is consistent with both the veto statement and the current state of the law, even if that bill cannot be reconciled with the prime tenets of the Gorton bill.

A. Oppose federal product liability legislation at this time

One option is to take a firm and overt stance against any federal product liability legislation at this time. Recent changes in state law as well as in federal constitutional law, combined with the lack of evidence of serious widespread problems, suggest that the burden of proving that traditional state prerogatives in this area should be overruled and state law overlaid with potentially incompatible federal law has not been met. If legislation is needed in the area of pharmaceuticals (including vaccines) and medical devices, then it should be pursued on a targeted basis, taking advantage of -- and protecting and enhancing -- a strong federal regulatory system for drugs and device approval. A major disadvantage of this option is that you have stated a number of times that you support "limited, but meaningful" federal product liability legislation.

B. Develop an Administration bill we can support, consistent with both the veto statement and developments in state law

The hallmarks of this option are: (i) full two-way preemption, such that states with currently more defendant-friendly laws would be brought to a uniform national level as well as states whose laws are currently more pro-plaintiff; (ii) consistency with your veto message in all respects; (iii) tools for reducing frivolous lawsuits; and (iv) inclusion of items that were not part of either the vetoed bill or S.648 that can enhance the effectiveness of the legal system for injured plaintiffs. This option is unlikely to lead to a bill that will be enacted, but would produce an affirmative statement by the Administration of the appropriate parameters of reform.

This option does not include any provision on joint and several liability for non-economic damages. Since part of the focus of your veto message was on the unfairness of distinguishing between economic and non-economic damages, any provision that deals only with non-economic

damages cannot be fully consistent with the veto message. Moreover, we have reason to believe some proponents of legislation would be willing to put forward an alternative without any change in joint and several liability. However, we also know the business community regards this as an important issue but, given current trends in state law toward several liability, they will be extremely unlikely to accept two-way preemption in this area. Appendix A contains alternative formulations of joint and several liability for non-economic damages that were developed by the working group, together with pros and cons.

This option would consist of the following:

Punitive damages - Advisory jury opinion with judicial determination and a breachable cap for small businesses, two-way preemption

- Establish a uniform federal evidentiary standard for award of punitive damages of "clear and convincing evidence," a substantive standard "conscious indifference (excluding recklessness)," and require bifurcation of the damages determination if requested by any party
- The jury would render a solely advisory opinion on liability for and amount of punitive damages
- The actual determination of punitive damages would be made by the judge
- The judge would be required to consider the factors in S.648, and would be required to explain why the judge's award differs (either higher or lower) from the jury's advice
- The judge could allocate a portion of punitive damages to the state rather than to the plaintiff
- Punitive damages would be capped at the lesser of twice compensatories or $250,000 for firms that have 10 or fewer employees **and** annual revenues of $1 million or less. The jury would not be told of the cap (or would be told to disregard it), and the judge could award damages in excess of the cap only upon a specific finding that damages in excess of the capped amount were not only needed "to punish or deter," but also that the financial impact of the higher award had on the defendant and its employees had been explicitly considered by the judge[10]

Pros

- Is analogous to criminal law, in that the jury is involved, but the final decision on what is essentially a punishment is in the hands of the person most experienced in deciding such issues, the judge
- Since historically, punitive damage awards that seem unjustified have stemmed from jury decisions, may increase rationality in the system
- Provides some protection for truly small businesses, responding to one of the complaints about the capriciousness of punitives

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[10] CEA and CPSC argued that the case for reducing punitive damage awards for small businesses is not compelling when those awards are intended to punish willful and wanton misconduct, established with clear and convincing evidence. On the other hand, punitive damages are very rarely sought against firms this small, mainly because such firms rarely would be able to pay them.

- Since businesses of the size described are rarely assessed significant punitive damages, because in most states the defendant's financial condition is already taken into consideration and plaintiffs do not bother to litigate punitives against firms this small, there may be little practical negative effect.
- Allows the Administration to agree with some sort of cap
- By adopting the S.648 factors, may be seen as a good faith offer

Cons

- Agreeing to any cap at all breaks through a clear line we established last year of "no caps on punitives"; it may be difficult to hold the line against expansion of this cap, either to larger businesses, or by limiting the judge's discretion
- Any proposal that limits punitive damages in any way may be seen as tipping our hand -- or limiting our options -- with respect to the tobacco settlement
- Takes away from the jury what has been regarded as a traditional jury function
- While judges may determine punitive damages in many states in cases where they are the trier of fact, only Connecticut and Kansas provide for initial judicial determination (in contrast to appellate review or remittitur) where a jury has sat
- Unlikely to solve concerns of either proponents or opponents of caps; consumer groups and lawyers have not favored judicial determination
- May raise difficult Seventh Amendment issues ("no fact tried by a jury, shall be otherwise reexamined in any Court of the United States, than according to the rules of the common law")
- Making it fully two-way preemptive, thus forcing some states to allow punitive damages that do not currently do so, is likely to be regarded as both unacceptable and inflammatory by the business community

Statute of repose

- Two-way preemption of state law (as in S.648)
- 18 year statute of repose (as in S.648)
- Which a plaintiff may overcome by clear and convincing evidence that the product had a longer useful safe life (not included in S.648, and responsive to the victim of the hay-baler accident cited in the veto message and to accidents involving products clearly intended to be longer-lived, such as elevators and most firearms)
- Covering only durable goods in the workplace (narrower than S.648, retaining plaintiff rights concerning consumer goods in states without any statute of repose and responding to your concern about handguns)
- With further exceptions for toxic substances, vehicles used in transportation for hire, and express warranties (as in S.648)
- And with a provision that extends the statute to allow full benefit of the two-year statute of limitations after injury or discovery of harm in, for example, year 17 (not in S.648, but not expected to be a problem)

Pros

- By building on S.648, demonstrates good faith to proponents of that legislation

- Two-way preemption is responsive to principles of veto message, and also lengthens statute of repose in the 22 states that have them
- Number of years is longer than in any current state statute denominated in years
- Rebuttable presumption protects workers injured by products clearly intended to be longer-lived
- Bright line number of years, combined with clear and convincing standard, means manufacturers will be free from arguments about whether something was intended to have a useful life slightly longer than 18 years
- By restricting statute to durable goods in the workplace, consumers in states without statutes of repose retain their access to court for injuries from long-lived or intermittently-used consumer goods such as cedar chests and camping and baby products
- Until late last year, all formulations of this statute had been limited to durable goods in the workplace, in part because those injured in such an accident will at least have received some compensation through workers compensation
- Expands on an already-existing federal liability scheme -- workers compensation
- Exceptions protect access to court in latent defect cases

Cons

- Opponents of product liability reform will oppose any federal statute of repose as limiting plaintiffs' rights in states without such statutes
- Combination of two-way preemption and bright line (even with rebuttable presumption and limitation only to durable goods in the workplace), will restrict the access of some injured parties to court
- Proponents of S.648 may regard rebuttable presumption and limitation to durable goods in the workplace as unacceptable limitations, particularly given that they extended the statute from 15 to 18 years and made preemption two-way in response to the veto message

In addition to these proposals, we recommend that option B include items the would tend to reduce frivolous litigation and items plaintiffs believe could make a real difference in their ability to recover:

- Provision for alternative dispute resolution for small claims that both defendants and plaintiffs would find appealing
- Limitations on the use of protective orders where disclosure of the information is relevant to the public health or safety unless disclosure is clearly outweighed by a substantial interest in maintaining the confidentiality of the records
- Require affidavits of good faith to accompany pleadings and impose sanctions for bad faith pleadings
- A requirement for a study of the product liability system by the Attorney General

The first of these items might -- depending on how it is drafted -- gain the support of both plaintiffs (who cannot find lawyers to take small claims through the traditional legal system for a contingency fee) and defendants. The second (based on a bill that has been introduced by Senator Kohl) would be strongly supported by consumer groups and -- in light of the tobacco revelations -- probably could generate strong public support, but would certainly be opposed by

defendants and perhaps even by the plaintiffs' bar. The third and fourth provisions are from the Breaux draft. The class action provision may not be giving up much from the plaintiffs' perspective because of the Supreme Court's recent decision overturning the asbestos settlement.

This option is recommended by the Treasury Department, the Department of Justice, the SBA, White House Legislative Affairs, White House Counsel, DPC and the NEC.[11] Both Justice and White House Counsel emphasize that their policy preference is Option A, but they do not believe that option is viable as a practical matter. Legislative Affairs would want to discuss Option B, if chosen, with both Senator Rockefeller and Mr. Dingell (understanding they are very likely to turn it down cold) and Senator Breaux before making it public.

C. Make a proposal that has a viable chance of starting negotiations with proponents

As described in the specific pros and cons below, the items in this option cannot be completely squared with your veto statement. On the other hand, they represent real movement toward responding to your objections. However, it is critical to recognize that **once these options are on the table, negotiations may take them even farther afield, and lead to a negative dynamic in which bill supporters think they've come "most of the way" toward your position and assert that refusal to support their bill amounts to "moving the goalposts."** The danger with this option rests far less in its particular parameters than in the slippery slope it sends us down.

Again, no provision on several liability for non-economic damages is included, based on indications some proponents may be willing to move without such a provision. Appendix A contains options developed by the working group, of which only Proposal 2B is likely to be acceptable at all to the business community.

This option would consist of:

Punitive damages - Cap with easier breakthrough, one-way preemption

- Establish a uniform federal evidentiary standard for award of punitive damages of "clear and convincing evidence," a substantive standard "conscious indifference (excluding recklessness)," and require bifurcation of the damages determination if requested by any party
- Cap punitive damages at the greater of $250,000 or twice compensatories (the lesser of the two for small businesses, defined as in option B as businesses with 10 or fewer employees and not more than $1 million in annual revenue)
- Do not tell the jury of the cap
- Allow the judge to award punitive damages above the cap (for both small and large businesses) without an additional proceeding and on a finding that the capped amount is

[11] While CEA and OMB participated in the discussions, they have not chosen an alternative.

"insufficient to punish or deter," the standard in S.648, with no required consideration of specified factors
- Insist that there be no legislative history suggesting this authority is to be used more sparingly than implied by the statutory standard
- This would be two-way preemptive, except with respect to states that do not allow punitives in products cases at all

Pros
- Closest to both S.648 and earlier versions of bill, and thus likely to be most easily regarded as acceptable by proponents
- Particularly given that there are few punitive damage awards in excess of the cap and that judges now have remittitur authority, this would likely have little practical impact on actual awards
- The procedural changes may produce more uniformity across the country

Cons
- This looks like a cap on punitive damages, which you said you opposed; "no caps on punitives" has been used as a shorthand description of the Administration's firmest position
- It may actually be a cap with judges reluctant to award punitives
- Holding the line on the legislative history can be very difficult, particularly if the statute is acceptable in all other respects

Statute of repose
The proposal would be the same as under option B, which we believe will be regarded as a good faith offer to negotiate.

The primary dangers with this strategy are (i) the likelihood that opponents will not believe even the initial positions are consistent with the veto statement, and (ii) that it will be relatively easy for the other side to make what look like cosmetic changes that may in fact be quite significant. For example, deleting the plaintiff's option to breach the 18-year statute of repose by a clear and convincing showing that the useful safe life was intended to be longer -- a likely demand of the manufacturing community -- would look minor, but in fact would work a major change in that it completely shut the courtroom door on plaintiffs in the many states with no statute of repose.

Secretary Daley recommends a private attempt to reach a firm agreement with Senator Rockefeller along the lines set forth in this option, coupled with private outreach to key principals in the business community to explain the Administration's commitment to meaningful but fair reform, which justifies only limited federal action in the face of state reforms. If a deal is impossible, Secretary Daley recommends that the Administration publicly state its commitment to two-way preemption as the basis for fair and equitable reform. The SBA would also find Option C acceptable.

Several of your other advisors also believe Option C would, as a policy matter, be an acceptable endpoint. They believe, however, that legislative dynamics make it virtually impossible -- even

if Senator Rockefeller were to agree to stick to Option C -- that this would remain the endpoint. Movement away from it can be both subtle and important, and such movement would be extremely hard to explain credibly as the basis for a veto. Moreover, these advisors observe that those opposed to this legislation are strong, united and very public in their opposition. These groups will not buy the argument that Option C is acceptable even as an end point, and will assert that you have deserted your principles. Your other advisors are therefore aligned with Option B.

V. DECISIONS:

____ Please set up a meeting in the near future with the relevant principals to discuss

APPENDIX A
Options on Joint and Several Liability for Non-Economic Damages

The formulations described below reduce the negative impact of imposing several liability for non-economic damages. However, any formulation that does not guarantee the plaintiff 100% of non-economic damages (where there is any solvent and available defendant) is discriminatory against non-economic damages in those states that retain joint liability for economic damages. Assuming you do not want to put several liability for **economic** damages into play, you should be aware that all of the options described -- except pure reallocation -- have this flaw.

Informed by various state law provisions concerning joint and several liability, your advisors considered formulations for federal preemption involving the following concepts:

- Several liability with reallocation among remaining defendants (and plaintiff, if the plaintiff is at fault) in the event the amount allocated to any defendant is uncollectible (thus guaranteeing plaintiffs 100% recovery for the portion of the damage not their fault, but sparing low-fault, deep-pocket defendants the need to sue for contribution)
- Setting a level of fault below which only several liability will apply (thus responding to the concerns of low-fault deep-pocket defendants)
- Setting a threshold of fault below which several liability will apply, but with a multiplier (thereby guaranteeing the plaintiff some recovery where only the low-fault defendants are solvent)
- Guaranteeing the plaintiff a specified percentage of recovery of non-economic damages
- The extent to which plaintiff fault will be taken into account to reduce recovery for non-economic damages
- Special rules for small businesses, particularly as to responsibility for more than their share of damages
- Two-way preemption, which would be meaningful if federal law were less pro-plaintiff than some state laws

Working on the assumption that you wished us to develop proposals that include several liability for non-economic damages -- so as to be able to convince those favoring product liability of our good faith -- but that are least restrictive of the rights of plaintiffs, your advisors developed the following alternative formulations relating only to non-economic damages:

Proposal 1 - Reallocation[12]

- Joint and several if the plaintiff is fault-free

[12] This is based on the statute currently in effect in Missouri.

- If the plaintiff is at all at fault, liability is several, but if the plaintiff cannot collect from one or more defendants after a specified period of time[13], the plaintiff can petition the court for reallocation of damages not attributable to the plaintiff among the remaining defendants, but no defendant less at fault than the plaintiff may be charged with more than twice his proportionate share of damages
- This would be two-way preemptive

Pros

- Preserves balance between faultless plaintiff and defendant with any fault in favor of the plaintiff
- Is generally consistent -- or at least not less pro-plaintiff -- with the laws of most states[14]
- Where plaintiff is at fault, less culpable defendants -- even if they are deep pockets -- will have their damages limited
- Of all the potential limitations, is most likely to retain 100% recovery for non-economic damages in many cases
- By retaining joint and several liability in many situations, should encourage settlement

Cons

- May be viewed as excessively pro-plaintiff, and thus not a good-faith offer, particularly if it is two-way, thus increasing defendants' responsibility in states, such as California, with several liability for non-economic damages
- May limit plaintiff's recovery where plaintiff is at fault and there are multiple defendants
- Requires fact-finders in the 13 states that currently do not have comparative fault or several liability to assign degrees of responsibility
- Shifts from defendants to plaintiffs the responsibility for collecting from each defendant, potentially adding to delay in recovering and increased expense
- As among defendants, it is unclear why the extent of the plaintiff's responsibility should have an impact on defendants' responsibility to pay the judgment
- It is very complicated

Proposal 2A - Guaranteed recovery, two-way preemption

- Joint and several liability of any defendant who is more than 30% at fault (taking into account the fault of the plaintiff and settling defendants)
- If any defendant is less than 30% at fault, that defendant's responsibility would be limited to a maximum of twice the defendant's proportionate share of non-economic damages except where a greater multiplier was needed to ensure the plaintiff recovery of at least 50% of the assessed non-economic damages.

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[13] In Missouri it is 30 days, which may be too short to actually encourage the plaintiff to try to collect; in Connecticut it is one year, which may be too long.

[14] Only plaintiffs with some degree of fault in the four states that retain traditional no comparative fault/joint and several liability would be significantly disadvantaged; plaintiffs in the nine states with comparative fault and joint and several liability could be somewhat disadvantaged. Plaintiffs in states with any further restrictions would likely benefit.

Proposal 2B - Guaranteed recovery, one-way preemption

- Joint and several liability of any defendant who is more than 10% at fault (taking into account the fault of the plaintiff and settling defendants)
- If any defendant is less than 10% at fault, that defendant's responsibility would be limited to a maximum of twice the defendant's proportionate share of non-economic damages except where a greater multiplier was needed to ensure the plaintiff recovery of at least 60% of the assessed non-economic damages.

Pros

- Should be seen by proponents of limitation as a good-faith offer, with real limits
- Preserves joint and several liability for defendants with significant degree of fault
- Ensures that no low-fault defendant will have to pay more than 50% (or 60%, if one-way) of total non-economic damages, and that in most cases they will be limited to their proportionate share
- Although it limits responsibility of low-fault defendants, it guarantees that plaintiff will collect substantial portion of assessed non-economic damages (if there are any solvent and available defendants)
- The two-way preemption version would increase plaintiff's guaranteed level of recovery in states with several liability for non-economic damages (such as California and Illinois), and thus might be considered an acceptable tradeoff for limitation on guaranteed recovery in other states

Cons

- Setting the guaranteed recovery level at 50% or 60% (or, in fact, any level lower than 100%) may be viewed as non-responsive to both of the objections in the veto statement -- not full recovery, and discrimination against non-economic damages
- Will require fact-finders in the 13 states that don't have both comparative negligence and several liability to make additional determinations
- Defendants who view themselves as likely to be low-fault deep pockets will object that their potential for payment of non-economic damages is so high they cannot take the limitations into account in either settlement discussions or purchase of insurance
- Small degrees of differentiation of fault -- e.g., between 9% and 11% -- could have major repercussions on responsibility to pay damages