NLWJC - Kagan
DPC - Box 069 - Folder-007

Biomaterials

Ron Greene - Wilmer Telecon 8/26/96

HIMA - who w/ Cong. Burman - (D) - sent last wk
He had concerns like BL's. lang.
Have some language - formative stages
Hope - reach final ag w/ him.
Then try to move bill in September.
2 amendments - our 4 discussions:

1. provide exception for br. implant cases.
silicon gel

2. More difficult as drafting mtg -
designed to deal w/ prob 4 supplier who
falsely rep'ed safety 4 mat'l or had
knowl 4 potential hazard for use in
implant.
On verge of language
Prob - and need to adjud under summary
procedures.
And can't be so open-ended to allow
use 4 this exception always.
Trick - allow kids for these cases -
but provide defense for case where
supplier has expressly disclaimed any rep
as to safety or suitability

[what as to supplier who did know
but disclaimed?]
RG thinks could be construed either
way

Ron Greene 9-5-96

Biomaterials –

stuff sent - discussions w/ Burman
Those have flundered
Not succeeded in reaching agr.
Breast implant provision OK
Fraud. misrep - logrolheads.

Current Thoughts by strategists:
<u>Omit</u> so That vote
go back to McCain/Lieberman
see if They'd agree to attach The bill
w/ b.i. amend – but not otherwise –
to some piece of leg. – at end of
session.
Discussions now going on – whether b.i.
can vote
If successful, put on State bill –
Then come around The other way.

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Date: August 26, 1996

For:	Elena Kagan	**Facsimile Number:**	(202) 456-1647
Company:		**Main Number:**	(202) 456-7594
From:	Ron Greene		

COMMENTS:

In accordance with our conversation today.

We are beginning to send a communication of 4 pages (including this cover sheet). If transmission is interrupted or of poor quality, please notify us immediately by telephone at (202) 663-6712.

August 2, 1996

AMENDMENT TO H.R. 3468

Page 7, line 18, strike "or" and in line 21 strike the period and insert"; or".

Page 7, add after line 21 the following:

(iii) a person alleging harm caused by either the silicone gel or the silicone envelope utilized in a breast implant containing silicone gel, provided that this exclusion from the definition of the term "claimant" shall not be construed in any civil action (including a civil action to which this Act is not applicable) to constitute a finding by Congress concerning whether harm may or may not result to a person from the use of either silicone gel or silicone envelopes in silicone gel breast implants.

DRAFT
August 23, 1996

AMENDMENT FOR FRAUDULENT MISREPRESENTATION

Insert as section 5(e):

(e) LIABILITY FOR FRAUDULENT MISREPRESENTATION--A raw material or component part will be deemed not to constitute the product described in the contract between the biomaterials supplier and the person who contracted for delivery of the product for purposes of section 5(d)(1)(A) if the biomaterials supplier--

(1) knew at the time the buyer contracted for delivery that use of the raw material or component in the implant at issue would likely cause the harm allegedly suffered by the claimant and concealed such knowledge from the person who contracted for delivery of the product; or

(2) with the intention that the buyer rely on the misrepresentation, fraudulently, expressly, and affirmatively misrepresented to the person who contracted for delivery of the product that the raw material or component part would be safe for use in the manufacture of the implant that allegedly caused the harm suffered by the claimant or similar devices.

A biomaterials supplier shall not be found liable under this subsection if he expressly disclaimed any knowledge or representation concerning the suitability or safety of the raw

material or component part for use in the manufacture of implants or medical devices.

Insert in section 6(d)(1)(A) after "BASIS FOR ENTRY OF JUDGMENT.--":

"Except as set forth in subparagraph (C) . . ."

Insert as section 6(d)(1)(C):

(C) LIABILITY FOR FRAUDULENT MISREPRESENTATION.--A biomaterials supplier shall be entitled to entry of judgment without trial in any case in which the claimant alleges liability under section 5(e) unless, solely on the basis of affidavits submitted and discovery permitted under this section, the claimant (i) demonstrates by clear and convincing evidence all the elements of liability under section 5(e), and (ii) presents clear and convincing evidence rebutting any defense raised by the biomaterials supplier under section 5(e). The preponderance of the evidence standard included in section 5(d) shall not apply to claims governed by this subsection.