

File: Products Liability -
notes + memos

Bruce -
FYI - An update on
products.
Elena

Gene --

We just had a meeting with Dingell and Rockefeller staff. Dingell was represented by Dan Schuler and Mike(?) Quinn. Jim(?) Gottlieb, Ellen someone and another woman represented Rockefeller. Peter Jacoby, Fran Allegra (DOJ) and I were there for the whole meeting, Tracey Thornton and Elena Kagan for most of it.

The message from the Hill was (i) we're going to be forced by Lott to move this fast; (ii) you're going too slowly; (iii) we expected you to be able to negotiate with us, and expect to negotiate this out among the Admin/Rockefeller/Dingell alone; and (iv) while Rockefeller has said he wants to satisfy the President's veto message, if we don't show him how, he'll try to figure it out himself.

On the other hand, they wouldn't put any of their ideas on the table, asserting that would just be negotiating with themselves. They also explicitly said they wouldn't have any further substantive discussions until we could actually negotiate.

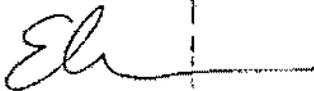
The working group is moving reasonably quickly toward having some alternatives on the three big issues -- joint and several, punitives and statute of repose -- to put before -- WHO? Deputies? Principals? The President directly? With the veto message being pretty flatfooted and it being very much a personal Presidential decision on what to do and how, I don't see how we can proceed to work with these people -- which they're insisting means we put an offer on the table -- without some direction from the President, and I think we owe it to him to (i) make it informed direction and (ii) not have different parts of the Administration wandering off in different places.

Tracey Thornton seems to think we'll be able get a few weeks' delay from Lott before he brings it up, but who knows? In the meantime, we'll try to push the process faster, but we're still more than a week away from a Presidential options memo, even assuming we don't have a formal Deputies and Principal level part of the process.

I think it was important for you NOT to be in the meeting. If there's good news in the sense of being able to move faster to deliver, you'll be better able to do it. But frankly, given that they won't put anything on the table and are demanding we move first, the only thing we could say today is we're moving, but we're not ready yet.

Probably would make sense for you and Kathy and Bruce Reed to talk to Bruce Lindsey and John Hilley to really understand where we're going and when.

Ellen



Product liability -
biomaterials



cc: Chris Jennings

Chris - We need an evaluation of this
issue by HHS. Please call me on it
ASAP. Thanks.

DOUBTS ABOUT THE "BIOMATERIALS SHORTAGE"

Elena

cc: Bruce R.

Public Citizen opposes the Biomaterials Access Assurance Act of 1997, legislation that is contained in S. 648 -- the Product Liability Reform Act of 1997. Immunity for biomaterial suppliers would remove an important financial incentive for them to properly research and test their products, as well as to warn manufacturers or the public if they suspect that their components are being used in an unsafe manner. While we all want access to life-saving medical devices, we also want biomaterial suppliers to sell the safest materials possible. Granting immunity to major corporations like Dow Chemical and DuPont, with records of wrongdoing in many other areas, is not an acceptable health and safety risk.

The bill's exemptions, such as for suppliers that violate contractual specifications, are far too limited to protect public health and safety. They do not cover situations where companies suspect that their biomaterials, as implanted, could cause serious injury or death, but do not warn the public. We agree with President Clinton, in vetoing last year's products liability bill, that such suppliers "should not receive any protection from suit."

In its campaign to obtain immunity for biomaterial suppliers, the Health Industry Manufacturers Association (HIMA) has often exaggerated facts about litigation in this area. For example, in the case of silastic shunts used for hydrocephalus (water on the brain), witnesses at an April 8, 1997 hearing before a Senate Commerce subcommittee confirmed that neither the manufacturers, nor the biomaterial suppliers, of hydrocephalic shunts have ever been sued. A review of case filings reveals two lawsuits involving defective shunts. Both were against physicians for failing to diagnose shunt malfunction, which resulted in serious mental incapacity for the patients.

In addition, assuming that biomaterial suppliers do pull out of the business, there is absolutely no guarantee that this legislation would get them back. Indeed, we have heard through members of the media that DuPont, for one, is saying privately that they will not come back into the biomaterials market even if this legislation passes.

Public Citizen's Survey Of Medical Device Manufacturers

HIMA has distributed a list of 84 medical devices that it calls "potentially affected permanent implants" due to current shortages of biomaterials. According to HIMA, this list was compiled by a HIMA staff person who called around to manufacturers who are HIMA members, and asked them what medical devices might be affected.

In response to this list, Public Citizen conducted a review of the 1997 Medical Device Register, published by *Medical Economics*, which lists every medical device registered with the FDA. The purpose of this review was to determine how manufacturers were still producing the 84 devices said to be threatened.

The survey reveals that there are still several, and often numerous manufacturers of most every permanent implant on HIMA's list. This survey is attached. (We recognize that in some cases, manufacturers of a particular device all may rely on a single biomaterials supplier, whose withdraw from the market might impact all manufacturers of that device.)

HIMA's List of Potentially Affected Permanent Implants (due to alleged biomaterials embargo)	Number of Current Permanent Implant Manufacturers (as reported in 1997 Medical Device Register)**
ACETABULAR CUPS	Category: "prosthesis, hip, acetabular": 7
ANNULOPLASTY RING	3
AORTIC/CORONARY LOCATORS	No category listed. No manufacturer could identify it.
ARTIFICIAL PANCREAS	No category listed.
BATTERIES <ul style="list-style-type: none"> <li data-bbox="159 850 406 882">• Defibrillator <li data-bbox="159 1123 391 1155">• Pacemaker 	<p data-bbox="790 850 1340 1050">No category listed. According to one defibrillator manufacturer, batteries for defibrillators are made by Panasonic and are common industrial grade batteries. There are 19 manufacturers of battery-powered defibrillators.</p> <p data-bbox="790 1123 1340 1186">No category "pacemakers, battery-powered." 1 pacemaker battery manufacturer listed.</p>
BONE CEMENT	4
BREAST IMPLANTS	10

* **How this research was conducted:** Where HIMA's description of a medical device did not correspond to a particular listing in the Medical Device Register, calls were made to manufacturers of similar devices, or to other experts, to determine other names under which the device might be listed. Devices that could not be identified are so indicated.

HIMA's List of Potentially Affected Permanent Implants (due to alleged biomaterials embargo)	Number of Current Permanent Implant Manufacturers (as reported in 1997 Medical Device Register)*
<p>CARDIAC MATERIALS</p> <ul style="list-style-type: none"> ▪ Fabrics • Felts • Mesh • Patches (vascular repair) 	<p>No category listed. No manufacturer could identify it.</p> <p style="text-align: center;">1</p> <p style="text-align: center;">8</p> <p style="text-align: center;">6</p>
<p>CATHETERS</p> <ul style="list-style-type: none"> • CAPD • Central Venous • Chest • Intra-Skomal Corneal Ring • Peritoneal Dialysis • Other 	<p>Category: "Catheter, angioplasty": 22</p> <p style="text-align: center;">16</p> <p>No category listed. According to catheter manufacturers, there is no catheter category specifically for chests. Several types of catheters are used in the chest area.</p> <p style="text-align: center;">No category listed.</p> <p style="text-align: center;">7</p> <p style="text-align: center;">There are over 50 categories of catheters listed.</p>
<p>CATHETER INTRODUCER KITS</p>	<p>Category: "introducer, catheter": 59</p>
<p>CEMENT SPACERS</p>	<p>No category listed. No manufacturer could identify it.</p>
<p>CLIPS</p> <ul style="list-style-type: none"> • Aneurysm • Ligation • Vena Cava 	<p style="text-align: center;">10</p> <p style="text-align: center;">3</p> <p style="text-align: center;">6</p>

HIMA's List of Potentially Affected Permanent Implants (due to alleged biomaterials embargo)	Number of Current Permanent Implant Manufacturers (as reported in 1997 Medical Device Register)*
COCHLEAR IMPLANT	2
CONTRACEPTIVE	No category listed. According to Planned Parenthood of Washington, D.C., there are no contraceptive devices with silicone as their main component.
DEFIBRILLATORS	27
EMBOLIC DEVICE	2
FREKOTE LUBRICANT (general)	No category listed. No manufacturer could identify it.
GENERATORS <ul style="list-style-type: none"> • Defibrillator pulse • Pacemaker pulse • Other 	<p>According to defibrillator and pacemaker manufacturers, pulse generators are components of each defibrillator and pacemaker. There are 27 defibrillator and 23 pacemaker manufacturers listed.</p> <p>Over 90 generator manufacturers listed.</p>
GRAFTS <ul style="list-style-type: none"> • A-V Access • Intra-aortic • Valve • Vascular 	<p>No categories listed.</p> <p>8</p>
IMPLANTABLE PUMPS	Category: "pump, infusion, implantable": 9
IMPOTENCE IMPLANT	Category: "penile implant": 4
INCONTINENCE IMPLANT	No category listed. No manufacturer could identify it.

HIMA's List of Potentially Affected Permanent Implants (due to alleged biomaterials embargo)	Number of Current Permanent Implant Manufacturers (as reported in 1997 Medical Device Register)*
INTRAOCULAR LENS	25
LEADS <ul style="list-style-type: none"> • Cardio • Defibrillator • Pacemaker • Vagus Nerve 	One category listed: "lead, pacemaker": 27
LEAD ADAPTORS	12
LEAD CONNECTORS	No category listed. According to a lead adapter manufacturer, lead connectors come packaged with pacemakers and adapters, and are also sold separately with leads, pacemakers, headers and connector blocks.
MOLDED COMPONENTS (Catheters, etc.)	No listed category. No manufacturer could identify it.
NASAL BUTTON	6
ORBITAL IMPLANT	4
ORTHOPEDICS <ul style="list-style-type: none"> • Finger Prosthesis • Fracture Fixation Device • Hip Joint • Knee Joint • Partial/Total Ossicular Replacement • Plug (hip fracture stem) • Shoulder Joint 	8 No category listed. Category: "prosthesis, hip": 18 Category: "prosthesis, knee": 18 4 No category listed. Category: "prosthesis, shoulder": 9

HIMA's List of Potentially Affected Permanent Implants (due to alleged biomaterials embargo)	Number of Current Permanent Implant Manufacturers (as reported in 1997 Medical Device Register)*
ORTHOPEDECS (continued) <ul style="list-style-type: none"> • Spinal Systems • Tibia Insert 	No category listed. 4
PACEMAKERS	23
PATELLAR BUTTONS	Category: "button, surgical": 4
PENILE IMPLANT	4
PLEDGETS	5
PORTS <ul style="list-style-type: none"> • Infusion • Injection • Osteoport • Vascular access • Other 	Only category listed: "ports, vascular": 17
PROSTHETIC HEART VALVES	6
SHEETING (Scar tissue prevention lining)	Category: "sheeting, silicone": 16
SHUNTS <ul style="list-style-type: none"> • CNS • Dialysis • Hydrocephalus • Peritoneal • Other 	No category listed. No category listed. 4 2 12

HIMA's List of Potentially Affected Permanent Implants (due to alleged biomaterials embargo)	Number of Current Permanent Implant Manufacturers (as reported in 1997 Medical Device Register)*
STIMULATORS <ul style="list-style-type: none"> • Bone Growth Implant • Functional Electrical • Neuro (& Accessories) 	<p style="text-align: center;">2</p> <p style="text-align: center;">23</p> <p style="text-align: center;">14</p>
SUTURES	Categories: "polybutester," "polyester," or "polypropylene": 13
TUBES <ul style="list-style-type: none"> • Myringotomy • Otological Ventilation • Vent 	Category: "tubes, myringotomy": 2. According to myringotomy tube manufacturer, otological ventilation and vent tubes are the same as myringotomy tubes, used for ear surgery drainage.
UMBILICAL TAPE	<p style="text-align: center;">6</p>
VALVED CONDUITS	No category listed. No manufacturer could identify it.
VASCULAR ACCESS DEVICE	Category: "hemostasis, vascular device": 2
VASCULAR STENTS	<p style="text-align: center;">4</p>

THE WHITE HOUSE
WASHINGTON

April 28, 1997

MEMORANDUM TO INTERESTED PARTIES

FROM: ELENA KAGAN *EK*

SUBJECT: PRODUCT LIABILITY BILL

Attached is a list of the people, mentioned by the President at our meeting last week, who attended the event at which the President vetoed the product liability bill. As described in the attachment, we used Janey Fair's case to illustrate the unfairness of the bill's joint liability provision, Jeanne Yanta's case to highlight the danger of punitive damage caps, and Carla Miller's, Lola Reinhart's, and Ruth Kamin-Nizar's cases to demonstrate the effects of the bill's statute of repose.

SARAH BRADY

On behalf of Handgun Control, Sarah Brady has been a vocal opponent of HR 956 citing concern about how the caps on punitive damages and limits on joint and several liability would apply to "negligent entrustment" cases. These are cases in which vendors knowingly sell obviously dangerous products to high risk individuals (i.e., a gun dealer who knowingly sells a firearm to a felon or minor who then injures or kills someone with that weapon). The Conference version of the bill arguably made the punitive damage and joint liability provisions applicable to such cases, through proponents of the bill contest this reading. (Attachments: Sarah Brady's Bio; Handgun Control Statement; Issue Summary)

MISSISSIPPI ATTORNEY GENERAL MIKE MOORE

The punitive damage and joint liability provisions of the bill apply to cigarettes, as they do to any other product. The Coalition on Smoking or Health believes that the punitive cap, in particular, would insulate tobacco companies from appropriate punishment for such intentional misconduct as lying to customers about the danger of cigarettes, manipulating nicotine content to hook smokers and targeting the most susceptible citizens: children. Attorney General Mike Moore's recent efforts to seek reimbursement from tobacco companies for money the state's Medicaid program paid out to treat smoking related illnesses has placed him at the forefront of the litigation debate, although his own suit is not affected by this legislation. (Attachments: Mike Moore's Bio; Issue Summary)

JANEY FAIR

Janey Fair is a Kentucky woman who lost her daughter in a defective school bus tragedy. In 1988, Shannon Fair was on a school bus with 60 other children when a drunk driver hit the bus head-on. Though everyone survived the impact, the collision ruptured the bus' fuel tank, causing it to be engulfed in flames. Twenty-seven children died in the fire along with 14 year old Shannon Fair. The Fairs filed suit against Ford and learned at the trial that Ford knew its buses had dangerous fuel-tank designs, but had successfully delayed government regulations that would have forced them to add a protective cage. This case demonstrates HR 956's unfairness in eliminating joint liability for "non-economic" losses only. In the Fair's case, the negligent acts of joint wrongdoers (the drunk driver and Ford Motor Company) combined to cause the death of Shannon Fair. Under the bill, the Fairs could not have been fully compensated for the non-economic loss resulting from Shannon's death because the drunken driver was judgment-proof (i.e., he had minimal or no assets). The death of a child generally does not involve "economic" loss because children typically have no lost wages. Further, it was the Fair's ability to bring a lawsuit against Ford and the threat of punitive damages that was instrumental in exposing the company's reckless behavior.

CARLA MILLER

Carla's 34 year old husband, James, was killed in 1990 in Blue Springs, Missouri when the 1966 Massey-Ferguson tractor he was riding hit a hidden hole and suddenly rolled over on its top, crushing him underneath. During the trial, it was discovered that this tractor was defective because it was not equipped when sold in 1966 with a "ROPS" (rollover protection system) -- a steel roll bar attached to the rear of the tractor and a seat belt which would have prevented Miller from being crushed. It was also learned that while the manufacturer did not begin equipping this model tractor with a ROPS system until 1968, it had the ability and technology to do this by 1965 and had known for many years that many people had been killed in rollover accidents involving tractors that were not equipped with a ROPS. The jury awarded Carla Miller \$2 million for her loss. Under the statute of repose section of the new legislation passed by Congress, Carla Miller and her family would have been barred from even bringing a case against the manufacturer. The bill would prohibit the filing of a suit against the maker of a defective product of this kind if that item was manufactured more than 15 years ago, which this tractor was. (Attachment: Summary of Case)

JEANNE YANTA

Jeanne Yanta is one of millions of women whose lives and health were knowingly put at risk by the manufacturer of a defective intrauterine device (IUD). Within two years of the placement of the device, Mrs. Yanta developed virulent pelvic inflammatory disease that nearly killed her. She had numerous operations and extensive hospitalizations, during which she lost a rib and was left unable to have children. At the trial, Mrs. Yanta would have presented evidence that the company manufacturing the device knowingly placed women at risk of serious infection, loss of fertility, and surgery for removal of their internal organs. The manufacturer settled on the eve of the trial. There is little doubt that punitive damage awards, which this bill caps, were largely responsible for forcing companies to remove defective intrauterine devices from the market. (Attachment: Summary of Case)

LOLA REINHART AND RUTH KAMIN-NIZAR

In 1994, Mrs. Reinhart and Mrs. Nizar entered an elevator with seven other friends (several of whom survived Nazi concentration camps) in a Cincinnati apartment building. The elevator fell to the bottom of the shaft, where one passenger died at the scene and another died several weeks later. The other seven passengers were seriously injured. The company that installed the elevator in 1972, slightly more than twenty years prior to this product failure, knowingly used a cylinder that did not meet industry specifications. The elevator lacked a protection device which the industry mandated to prevent the rapid flow of hydraulic fluid out of the cylinder in the event of a rupture. As in the Miller case, this suit could not have been brought under the bill because of the 15-year statute of repose. (Attachment: Summary of Case)