BEFORE TEE UNITED STATES HOUSE

OF REPRESENTATIVES

Sub-Committee on Telecommunications, Trade, and Consumer Protection of the House Commerce Committee

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Commentary on the Reasonability of Proposed Changes in Tort Law Regarding Bio-materials and Related Topics

Testimony of Andrew F. Popper

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Executive Summary of the Testimony of Andrew P. Popper

Over the past 15 years, different groups have come forward asking for immunity or other forms of special treatment. These requests are accompanied by a carefully orchestrated presentation which has an irresistible message: protection is nccded to avert unthinkable disaster of the economic or more personalized sort.

Today it is the bio-material producers who have managed to catch your ear with a blunt form of rhetoric: Pass this legislation or 7.5 million people will die leaving bio-material production to the unsuited, the foreign, the back alley. It is essential to look beyond assertions designed to terrify, not to inform. No body or law or precedent affirms the threat of a bio-material crisis, characterized by massive human suffering and economic ruin. Thereforc, based on concerns of health and safety, it is essential that the tort system continue to be applied.

The guest of the bio-material industry seems not to be about reducing exposure by creating a sympathetic set of rulcs, but rather a more indefensible quest to be permitted to function outside of the entire tort system. They have not made a casc for this. They ask you to embrace a regime of immunity and unaccountability, to contort the rules of civil procedure, to do a hatchet job on pre-trial process just so that select, successful, bio-materials providers are at peace. This is wrong.

This Committee must avoid scrupulously the mis-characterizationn that have been put forward regarding bio-materials. Press kits and news releases must not be the tools of legislative and jurisprudential debate.

Given this testimony one might assume that the companies making these proposals are callous. irresponsible entities. To the contrary, the vast majority of market participants in this industry are well-regarded, valuable, productive enterprises that seek only one thing: certainty. All these companies want from you is to know their exposure, with some level of certainly, so that they can calmly, cooly, and precisely breed into the price of the products they sell the projected cost of tort liability. In that moment, the public safety incentive value of the tort system is lost. Free from liability they could proceed with impunity, not bound by the rules that challenge every other American producer to not only excel but to excel with optimum safety. This is hardly the kind of incentive that should be set in stone by the Congress.

My name is Andrew F. Popper. I am a professor of lav at American University Washington College of Law. I appreciate the opportunity to address this Subcommittee on various proposed changes in tort law.

over the past 15 years, different groups have come before this as well as other committees in the Congress, asking for immunity Or other forms of special treatment on the promise that their industry cannot survivc if state tort law is applicablc to the products they produce or the services thcy provide. Invariably, these requests are accompanied by a carefully orchcstratad presentatlon which has an irresistible message: protection is needed to avert unthinkable disaster of the economic or more personalized sort.

In the last few years, the airline industry, the whole of the pharmaccutical industry, and similar entities have made this pitch, either for a private bill in thc nature of a civil pardon or as part of a broader bill which is mysteriously labeled as reform legislation, despite thc fact that these bills have never qiven the American consumer any protection not presently in existence.

Today it is the bio-material producers who have managed to catch your ear. They have come forward with a blunt form of rnctoric that feels somewhat likc quilt based extortion: Pass this legislation or 7.5 million people will dic and major product and research providers will go under, leaving bio-material production to the unsuited, the foreign, the back alley.

This threat is powerful, and it is not true. while truth has not always played a major role in the tort reform debate, I urge you to look beyond these violent assertions. They arc dcsiqned to terrify, not to inform. For year-s, we heard how there would no longer be a domestic airline production industry, a pharmaceutical industry, an athletic equipment manufacturing industry, and even sufficient doctors to treat an ailing public if such 'civil pardons" were not qranted. 'Today we knav those threats were false.

Following the well worn path of those who came before seeking special treatment, the bio-materials producers contend that a crisis looms, replete with bankruptcies, bale-outs and uncontrolled jury verdicts. I am unaware of any convincing evidence to show that the current threat of a bio-material crisis, characterized by massive human suffering and economic ruin, is any more true than those similar threats made by other industries that employed this heavy-handed argumentative device in the past. This is simply another legislative assault to benefit raw parts producers, manufacturers, product sellers, and insurance entities.

Admittedly, there is precedent for the relief sought by the bio-materials industry. In a few, limited instances where a documented, severe, irreparable disaster was at hand, narrow, carefully conceived, legislative has been used. Such is not the case here. An industry that has thus far prospered mightily in the marketplace, with the Wall Street Journal, The Washington

Post, and the Journal of Medical Economics extolling the economic and investment virtues of bio-materials and related companies in the last few months', an industry that comes to you with its primary damage being its fear of litigation costs but no history of substantive decisions against then, an industry that has dozens of stable companies and many nev market entrants', an industry that produces products that are untestable by consumers or their physicians placing a high burden on all involved in production to "get it right', an industry that has enjoyed regulatory inaction from the FDA more than it is "checked" by the FDA, hardly qualifies as an industry in crisis.

Parenthetically, while this Sub-committee has not asked for data on the FDA, the bio-material industry argument that federal regulation, specifically the FDA, provides an adequate force to insure safety in this area is suspect. Three years ago, an oversight committee looking into the question of the FDA's effectiveness in regulating bio-materials and their downstream products gave the FDA low marks, finding, inter alia, that the FDA had allowed a product on the market 'that actually killed patients... and that may have been ineffective in treating life-

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[1]Tanouye, Three Drug Companies Post Hefty Earnings Increases, B4 January 30, 1997; Journal Medical Economics, Why Medical Device Stocks Belong in Your Portfolio," p. 55, January 13, 1997), Washington Post (To Alexine Clement Jackson. It Matters We're Investing a Record $19 Billion in Pharmaceutical Research, February 4, 1997.

-E.g. Baxter International, Pfizer, Inc., Medtronic, DuPont. Dow, Sigma Aldrich, 3M, Abbott Labs, Hoechst Celanese, Cordis, Inc., Bio-Pace Technology, Cardiac Control Systems, Inc., Ela Medical, Intermodicr, Inc., Novacon, Siemens Pacesetter, Alcon. Inc., DGR. Inc., Hymedix International, Inc.,...and on and on.

threatening diseases."

Sadly, there are other FDA approved products that proved tragically flawed, such as the Bjork-Shiley heart valve, certain types of implant materials, and the Copper-7 IUD. These stand as evidence of the inadvisability of permitting the FDA to be the sole external legal agent compelling excellence in this field. Although the FDA has become more active in the last few years, the simple fact is that biro-materials and 'medical devices have not been subject to the same rigorous pre-market clearance procedures that govern the marketing of prescription drugs." Accordingly, it is essential that the tort system continue to be applied in these areas as an effective and necessary complement to the questionable regulatory force of the FM.

The Tort System. The force of the tort system, although uncomfortable and periodically harnh, has proved throuqh our history to be one of the best and most efficient mechanisms to ferret out dangerous and defective products. To delete tort law from the landscape at this time, relying on the FDA as the bio-material producers suggest, subjects the public to risk of harm and even death without recourse.

While a sensitivity to the tort system is fundamental to the

Less Than the Sum of Its Parts: Reforms Needed in the Organization, Management, and Resources of the FDA's Center for Devices and Radiological Health," Report of the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, U.S. House of Representatives, May, 1993.

'Schwartz, Prescription Productions and the Proposed Restatement Third, 61 Tenn. L. Rev. 1357, 1391 (1994).

task of those in Conqress charged with considering any 'tort reform' proposals (translation: liability and court access limiting), understanding the details of the application of current tort law to bio-material providers is equally important. Several af the proposals under consideration involve a clear distinction between component part providers who produce and sell raw or processed material to others, and manufacturers who assemble, package, distribute, warn, advertize and ultimately sell products for use in the human body.

The law reqarcling manufacturers is not different in any significant way from tort law applicable to most entities in the business of product sales. As to component part providers (broadly defined) the lav is extremely restrictive. Outside of a situation involving a company that was negligent, in classical terms, it is just about impossible to find tort liability against a component part producer. New Jersey, the state that gave birth to the most expansive product liability theory in history (absolute liability) rejects component part liability outside of negligence. The state Supreme Court recently found that outside of negligence, 'no public policy can be served by imposing on a manufacturer of specialized parts...when...the parts were created in accordanco with . ..specifications.'[1]

Ten years earlier, an appellate court in Massachusetts, having surveyed a number of states, rejected an implied duty to warn findinq, 'the majority of jurisdictions . ..hold that a

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[1] Zaza v. Marquess, 675 A2d. 620(1996).

supplier of a component part...has no duty to warn...of any danger that may arise after the components are assembled." Federal courts also follow the restrictive liability rules regarding component part providers.[1] In light of the law in this area, the quest of the bio-material industry seems not to be about reducing exposure by creating a sympathetic set of rules, but rathcr a morc crass and indcfanoible guest to be permitted to function outside of the entire tort system on the premise that the system produces more costs than is justified.

Inherent in the asscrtions of the bid-material plea is the premise that the tort system is a beast with an Insatiable appetite that will devour them if left unchecked. This is, of course, not so. Contrary to the assertions of the bio-material producers, as legal scholar Carl Bogus recently commented, 'the *common* law has receded in importance..." a particular loss if that includes product liability law since it, 'has become an essential participant in promoting public safcty."[3] Bogus notcs that an extreme risk exists in terms of the survival of a viable product liability system if the "common law is underappreciated by legislators....' Id, at 70.

Other scholars who have studied the tort and product liability system for decades echo these concerns. Michael J.

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[1] Mitchell v. Sky Climber, Inc., 487 N.E.2d 1374, 1376(Mass. 1986).

[2] Sperry v. Bauermeister, 4 F.3d 596, 599(8th Cir, 1993).

[3] Bogus, The War on the Common Law: The Struggle at the Center of Products Liability, 60 Missouri L. Rev.1,86-87 (1995).

Saks, Faculty Scholar and Professor of Law at the University of Iowa fears that there is a" unawareness that the tort system is 'doing a better job as a deterrent than it usually receives credit for.' After completing a thorough empirical study of the tort system (which determined that existing studies are insufficient to permit global characterizations of the way the system functions) Professor Saks draws several limited conclusions: a 'tiny fraction' of injuries actually end up in contested litiqation, most claims appear to be actually "under-compensated' at the *end* of the process, jury awards are "remarkably predictable," the system as a whole is *efficient and effective as a deterrent.' and there is an unfortunate likelihood that 'reforms will produce effects contrary to the intentions of their makers; indeed, some already have."

If it seems to you that this is really a limited, highly focused, innocuous legislative agenda, think again. *First*, if the real problem is the potential liability of raw product bio-material producers who have little control over how their products are used, the tort system has created at pattern of defenses available in every state to resist such claims outside of those situations where the bio-product is itself defective. Based on research performed in the days prior to this hesrinq. so

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'Saks, Do We Really Know Anything About the Behavior of the Tort Litigation System- And Why Not?" 140 U. Pa. L. Rev. 1147, 1286-1289 (1992).

'"See Putenson v. Clay Adams, Inc., 12 Cal.App.3rd 1062 (1970) for an example of the negligent producer scenario.

case regarding 'bio-materials was found which actually got to a trial on the merits and was reviewed in an appellate court where these defenses failed, outside of those situations where the bio-product itself was defective. The defenses include the conventional bulk supplier defense, the learned intermediary and sophisticated user defense, and the law of intervening cause.!'

Second, history teaches that this type of legislative strategy is a predicate to systemic legislation if passed would Open the door to the destruction of critical individual rights and obliterate essential market incentives.

Third, if this problem is as narrow as some would have this Sub-committee believe, i.e., protection of "innocent" upstream bio-material providers who produce products in conformity vith the manufacturers specificstiona, adoption of either broad scale federal tort reform which abolishes the law in all 50 states and incites unimaginable legal mischief that will take decades to sort out, or the passage of a narrow 'Rio-materials Producer Relief Act" art? unnecessary and border on the ridiculous. if the goal is singular protection of a component parts provider. Any participant in the American marketplace that uses component parts, whether bio-materials Or wooden wheel spokes, is aware of the uniform use of contractual indemnification that protects such parties. To the extent that indemnification is incomplete, it is

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[11] See Comment, An Analysis of the Potential Liabilities and Defenses of Bulk Suppliers of Titanium Bio-materials, 32 Gonzaga L. Rev. 195 and Haig and Caley, Successfully Defending Products Liability Cases, 4 No. 15 Mealey's Litigation Rep.: Toxic Torts 23 (1995).

only in those situations where the 'assembler' of the component parts is bankrupt or otherwise unavailable for suit.

The answer to this problem was and is insurance for such eventualities, either through private sources, or if need be through state pools. To embrace a regime of immunity and unaccountability or contort the rules of civil procedure by doiny a hatchet job on pre-trial process just so that select, financially successful, bio-materials providers aro sated is obscene, particularly with other doctrinal protections of their interests abounding in the legal system.'

Fourth, the case for the necessity of a sharply focused bill protecting suppliers of bio-matcriala is suspect. You have heard much of the Woes of DuPont and its travails with the Vitek jaw implant. On February 20, 1997, only six weeks ago, the Court of Appeals of Texas affirmed summary judqements that had been granted in favor of Dupont.[1] After nnalysing strict liability and conventional negligence claims the court determined that there was no basis to go forward. From a consumer perspective, this is an unfortunate rulinq, but from the perspective of the bona fides of the claim of the blo-materials producers, these case5 demonstrate that the current tort law in the United States works to protect the producers, not to harm them. and certainly not to create a 'crisis' sufficient to take away citizen access to the courts.

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[1] Cason v. DuPont, 1997 WC 69858 (Tex. App.-Hous. (1 Dist.)); Doll et. al. V. DuPont, 1997 WL 69862 (Tex.App.-Hous. (1 Dist.)). The court found that DuPont, 'did not have a duty to warn," (p. 9 slip op.).

The case law and literature in this field, as is the case in many areas of tort law, has shifted in the direction of producers and manufacturers, not in the direction of injured plaintiffs. On precisely the issue of the difficulties plaintiffs face when they seek relief against bio-materials suppliers, the case law is clear: the formula for a successful Claim is nowhere to be found." As "component parts" producers, the bio-materials producers have been almost uniformly successful at the stato law level (the forum for tort action) and the trend seems nothing but positive, at least from their perspective.

In Texas, for example, a state with a history of forceful consumer oriented product liability law, the Court of Appeals recently declared that a component part manufacturer producing a product that conforms with the purchaser's specifications cannot be liable in strict liability, outside of a demonstrated defect in the component part."' Cases of this nature coincide with both the 'tort reform" (meaning tort limitation) legislation enacted in 80% of the states and with the apparent goal of the authors or the Restatement (Third) of Torts, (Tentative Draft, 1997): limiting the ability of injured consumers to pursue civil justice.

AS the substantive law continues to recede in terms of its

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[3] See e.g.: Kealoha V. Dupont, DC Hawaii, No. 92-00282, February 24. 1994, affirmed 82 F.3d 894 (9th Cir. 1395) and Bond v. DuPont, Colo. Ct. hpp., No. 92CA0624, June 3, 1994.

[4] Molina v. Kelco Tool & Dies, 904 S.W. 2d 857, 861 (Tex. App Houston, 1 Dist., (1995)).

capacity to redress the harms of injured persons and, thereby, lessens the incentives to produce optimal goods and services, so to do the procedural components of this body of law seem to turn away from the plaintiff's side of the arena. On point is Daubert v. Merrell Dow Pharmaceuticals,[9] where the Supreme Court limited the capacity of plaintiffs to use expert testimony if such testimony is based on statistical and empirical evidence unless the plaintiff can satisfy a fairly strict test reqarding 'scientific' validity. The Court obligates trial judges to exclude testimony unless certain gate-keeping factors are met including whether the expert evidence is based on clear scientific knowledge, has been subject to peer review, is capable to independent testing, and has an established error analysis pattern pa-trial.

Daubert expands the preclusionary impact of Rule 702 of the Federal Rules of Evidence, compounding the challenges plaintiffs face in bio-material cases where there is a qood chance that the totality of the plaintiffs case will rest on empirical data only available through expert testimony. With Vitek, the best evidence of the products failure was that virtually every TMJ implant had to be removed or repaired, fairly strong empirical data, but arguably problematic asadmissible evidence under Daubert.[10]

Predictably, a recent bio-materials case, Cabrera v.

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[9] 509 U.S. 579 (1993).

[10] (See infra, Statement of The Honorable Theodore Weiss,).

Cordis,[17] blocked the use of all four expert witnesses proposed by the plaintiff, based on Daubert, rendering the plaintiffs case a nullity. As these measures mature at the state level, there is at least the hope that the states, the faithful laboratories of tort law, vi11 restore balance to the system. Adopt federal legislation that destroys the ability of consumers to pursue legitimate claims either narrowly in the bio-materials context or with more broad tort reform law, and the possibility af forceful and essential consumer protection could end.

One further word on the Vitck implant is needed. The Vitak jaw implant, a centerpiece of the bio-materiala producers cry for relief from state tort law, is not exactly the kind of product that demonstrates the great success and safety associated with bio-materials, a demonstration you must demand, as a matter of public safety, if you are contemplating relieving these companies from the 'incentives to safety' pressure of the tort system. In 1990, the FDA, in one of its better moments, ordered Vitck to inform oral surgeons that the implant had a tendency to fragment. The FDA subsequently recalled the product. Congressional hearings held thereafter concluded with the following finding: 'There is evidence that the overwhelming majority of qrafts and implants will fail if they haven't already.""

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[17] 945 F. Supp. 209 (D. Nev. 1996).

[18] Statement of the Honorable Theodore Weiss, Human Resources and Intergovernmental Relations Sub-Committee, Committee on Government Operations, U.S. House of Representatives, June 4, 1992.

Although no specific legislation is currently before this Sub-committee, both a narrow 'bio-materials-specific' bill and a broad tort limitation bill are under consideration this term. Adoption of either form of legislation would have an untoward effect: Pass either type of bill, and through the amendment process, in future quiet sessions attracting nowhere near this level of attention, the federalization of tort law and the disassembly of consumer protection Will become an annual function of this and other Committees in our Congress.

There is no systemic crisis that would Justify the disassembly of state law inherent in these proposals. The "tort crisis" predicate cannot possibly be based on compensatory damaqe cases. First, there have been no compensatory damages paid. Second, no draft thus far nas even addressed compensatory damages in a significant way. Third, not one credible empirical juried study of bio-material production has taken placc. Fourth, the major back ground noise in this field for ycars has been that horror of horrors, punitive damaqes. Every juried independent study of punitive damages rejects flatly the idea that there is, in any industry, a punitive damaqe crisis.

This Committee must avoid scrupulously the mis-characterizations that have been put forward regarding bio-materials. Press kits and news releases must not be tho tools of legislative and jurisprudential debate. An ABF study concludco: "Horror stories and their implications are presented as if they are

representative of what is typical, describing a system run amuck and in need of fundamental and immediate change. Such vivid stories typically distort the actual facts of situations described."[19]

As with all 'tort reform' arguments, the bio-material producers have raised the 'America First" flag, urging you to be aware of the threats of foreign providers. First, this is utter nonsense since there is not only a viable but a thriving domestic market. Second, it is incredible to assert that a system that condemns defective products and services produced in a negligent or grossly negligent manner is destructive of our competitive posture.

A companion invalid justification involves the diversion of assets away from research and development. There is only a miniscule real dollar loss from tort litigation involving bio-materials, and based on available data prior to this hearing nonc of that loss actually comes from a plaintiff prevailing in a tort action! More generally, even the most conservative commentators have come to understand that the financial burden of the tort system (specifically referring to punitive dames) is negligible.[20] For bio-materials, the loss is so insignificant that investors in the medical community are urged to invest in

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[19] Steven Daniels & Joanne Martin, The Myth and Reality in Punitive Damages, ABF Working Paper 8911, American Bar Foundation Res. J 63 1990 at 29.

[20] Landes and Posner, New Light on Punitive Damages, 10 Req. 33 (Sept./Oct 1986); Daniels and Martin, supra.

companies producing bio-materials and research funds flow freely."[1]

A several years ago, an Office of Technology Assessment study on competitiveness evaluated four factors needed to improve the posture of American businesses in international markets. Notably, modification of tort and product liability law was not part of that recommendation. It bears noting that report was completed before 'tort reform' (read tort limiting) legislation was passed in a dozen states. Thus, even during a period where the exposure of producers was greater than today, the research arm set up to assess independently the claim that there is a tort crisis requiring action found none.:"

The law that you would create, were you to accede to the pleas of the bio-material crowd, would abolish tne judgments of state courts. It will turn on its head leqislation passed by state legislatures. This is federal legislative self-righteousness of the highest order. The policy prefercncos that would be reflected are no wiser, just, or equitable than the policy preferences underlying the laws adopted in tho various states. In many ways the proposals look a qood deal like draft legislation passed, rejected, or pending in many states. For the entire history of this country, the question of a private

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[1] (See, Tanouye, Three Drug Companies Post Hefty [redacted] Increases, Wall Street Journal, supra, and "To Alexine Clement...." Washington Post, supra.)

[2] U.S. Congress, Office of Technology Assessment OTA-ITE 443, Making Things Better: Competing in Manufacturing (February, 1990).

citizens right to access to the courts and civil justice has been a matter for the states, barring circumstances that demand destruction of the rights to the states to determine the well-being of their citizens. This is not such a case.

Another justification for this destruction of federal/ state relations involves the desire to establish a uniform tort system. First, the very nature of the our republic of 50 states implies that uniform state law is not a dominant federal objective, outside of ovcrwhelminq circumstances that are not present here.

Second, rather than uniformity, this type of legislation will create a g-rosa discrimination between plaintiffs in bio-materials cases and all other plaintiffs in product liability, tort, or any other civil actions, creating a procedural morass in complex litigation situations. What an ironic event it vould be if Congress were to muck up civil procedurc and destroy consumer rights in a setting whore the potential defendants are profiting greatly from tne sale of their products, vnere those same defendants have not been, generally speaking, at the losing and of any litigation, where consumers arc completely helpless to test products, where consumers arc not protected in a meaningful way throuqh FDA regulation, where consumer-e are in life and death risk situations.

Third, as has always been the case in these tort reform proposals, the legislation that is contemplated is written in such a way that it requires state court interpretation of virtually every one of its major sections, giving lavyers and law

professors much to work on, but hardly creating uniformity.

Some have argued that this legislation is needed to protect raw material producers on the premise that they are far removed from the final product sale. Do not take the bait. Producers currently have an incentive to develop means to inspect and test products or create such opportunities in part because they are subject to liability in tort. Further, producers ore a gigantic economic force in this industry, shaping the actions of those who follow them in the chain of production. Their exposure compels a critical level of caution regarding their products, a pressure that would be lost were you.to grant them the requested pardon. The huge companies involved directly or through their subsidiaries in this industry exert a powerful influence on product quality. No consumer or consumer organization is as powerful. Despite the obvious desire on tho part of the producers to be absolved of any losses resulting from the sale of their products, there is nothinq other than corporate peace of mind, granted at the expense of the public, that will result from this type of legislation.

Plaintiffs in product liability cases are victims in desperate circumstances and are a part of families whose expectations have been shattered by traumatic injury, illness, or death. Families and victims find the legal system complex and emotionally devastating. Depositions require parents to relive the most horrible and tragic moments of their lives. Some are so

overwrought by the process that they become incapable of going forward, and those who do go forward find the process deeply painful. Their pain is continuous, their sorrow chronic. To impose on people in these circumstance an absolute bar against the entity that produced the product that harmed them is just plain wrong.

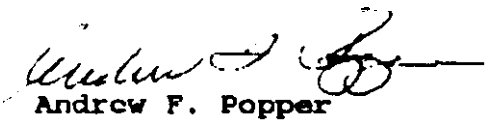
In light of the criticism of the proposed leqislation that has been set forth one might assume that the conpanics making these proposals are callous, irresponsible entities. Far from it; the vast majority of market participants in this industry are well-regarded, valuable, productive enterprises that seek only one thing: certainty. This entire debate, in the end, is about nothing else. All these companies want from you is to know their exposure, with some level of certainly, so that they can calmly, cooly, and precisely breed into the price of the products they sell the projected cost of tort liability. In that moment, the public safety incentive value of the tort system is lost. Give them that and you destroy a system that has, at a remarkably low national cost, pushed (sometimes uncomfortably) American industry to qreatness.

I am very aware of the specter of human suffering the proponents suggest is on the horizon if you do not act. Let me suggest to you a different scenario. Free from liability of any kind, the producers might continue as they are today. Alternatively, vith little incentive to develop product testinq

or new products, thoy would be in a position to secure top dollar for products in high demand without being in any way accountable_ Unlike most other entities in this country. thny can proceed with impunity, not bound by the rules that challenge every other American producer to not only excel but to excel with optimum safety. This is hardly the kind of incentive that should be set in stone by the Congress.

For these reasons, I urge this Sub-Committee to maintain current tort liability.

Respectfully submitted,



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