Appendix D

Individual Characteristics of Mass Torts Case Congregations

A report to the Mass Torts Working Group

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Contents

Introduction and analysis

At its inception in February 1998, the Mass Torts Working Group (MTWG) asked the Federal Judicial Center to assist it by identifying the major mass torts that courts had faced in modern times and looking at the individual characteristics of such cases to see if any patterns emerge. This report responds to that challenging assignment by examining 50 sets of cases—we call them case congregations—dating from the modest-sized Thalidomide and MER/29 cases of the late 1950s and early 1960s up to the contemporary Fen/phen/Redux, latex glove, and synthetic stucco cases. For each case congregation we present information in a single format about the shape of the litigation (individual, consolidated, MDL, class, bankruptcy), the number and type of claimants and defendants, the number and dispersal of cases in the federal and state systems, maturity as shown by the number and amounts of verdicts and settlements, causation and injuries, research and testing, length of any latency period, length of exposure and extent of individual exposure, and current status of the litigation.

Overview

In this introductory section, we concentrate on personal injury cases that arose out of the sale of an allegedly dangerous or defective product for a substantial period of time, usually more than a year. We do not analyze or discuss in any depth the personal injury cases that resulted from a single incident or a toxic emission at a single site, but we present information about such cases in a following section. Property damage cases are treated similarly. Our assumption—which seems to be borne out by the information we collected—is that single event and property damage mass torts do not pose the kinds of difficulties that led to the creation of the MTWG.

In part we present the analyses in the section to illustrate how the interested reader might use the information that follows to analyze each of the individual characteristics for each of the three major groups of mass torts: personal injury, personal injury based on a single event, and property damage. Cross-sectional analyses of all of the characteristics of all of the groups is beyond the scope of this project.

Following this introduction and analysis is a detailed tort-by-tort summary of some of the major characteristics of mass torts that federal and state courts have experienced to date. Part 1-A summarizes, one by one, the 26 major product-based mass injury case congregations, such as asbestos, breast implants, Dalkon Shields, and Fen/phen/Redux. Part I-B summarizes 15 personal injury case congregations that arose from a single event (e.g., an airplane crash or a hotel fire), a single toxic waste site (e.g., Stringfellow Pits, Times Beach), or a single distribution of a batch of contaminated products (e.g., salmonella in milk, albuterol). Part I-C summarizes 9 product-based property damages claims (e.g., the Audi transmissions, GM gas tanks),

including one that was based on a single event, the oil spill that followed the 1989 grounding of the Exxon Valdez.

Methods

Case congregations were selected for inclusion based on a review of the literature on mass torts and suggestions from Judge Anthony Scirica, Professor Francis McGovern, and other members of the Mass Torts Working Group. The project team gathered information primarily from public sources, such as case reports, legal newspapers, law journals, and other periodicals. In addition, for a number of active personal injury case congregations, a draft summary was faxed to a number of lawyers experienced in handling that type of litigation. Many responded and we changed the drafts to address their comments. We are, of course, both grateful for the assistance of those attorneys and responsible for the final product. In addition, Cathy Maida, Acting Clerk of the Judicial Panel on Multidistrict Litigation, supplied up-to-date information on the number of cases that had been transferred and the number that remained pending as of December 31, 1998.

The object of collecting these individual case congregations is to examine characteristics across case types to see if any patterns have developed. In this section we focus on the following characteristics: the number of claims, the number exposed to the products, the maturity of the litigation, dispersion of cases among the courts, number of defendants, MDL and class action activity, clarity of the product's capacity to cause injuries, identifiability of the product in relation to those injuries, and the ability of defendants to pay. By presenting these characteristics in tables, we can compare congregations and identify subsets of cases that used different procedures or faced different problems.

The characteristics we address necessarily intrude into the merits of the litigation. As much as possible, we attempt to base any considerations relating to the merits on the consensus of parties and observers or on past judgments by the courts. We have attempted to indicate where issues are disputed, especially in pending litigations, but may not have been totally successful. We specifically disclaim any ability or intent to resolve disputed issues, and any statements in these charts should not be used for such purposes, particularly in pending litigation.

Table 1 (see next page) presents a synopsis of current information on the number of claims, number of individuals exposed to potential harm, and maturity. For each case congregation, we indicate directly under the title whether the information came exclusively from published sources or whether we had the benefit of an attorneys' review. In either event, our estimates are based on information derived from secondary sources and should be treated as rough estimates, not as scientific or statistical analyses.

Table 1
Estimated number of claimants, numbers exposed, claims-to-exposure rates, and maturity levels for individual personal injury mass tort case congregations (other than case types based on a single event)

(1) Mass tort congregation	(2) Estimated number claimants	(3) Estimated number exposed	(4) Claims-to-exposure rate (col. [2] divided by (3)]	(5) Current status	(6) Maturity
Tobacco	50,000,000-class	50,000,000	1.0	Open	Variable
Breast implants	440,000	2,000,000	.22	Open	Mature
Asbestos	300,000–700,000	21,000,000 plus	.01–.03	Open	Mature
Dalkon Shield	300,000	2,800,000 (U.S.)	.107	Closed	Post-maturation
Norplant	30,000–50,000	800,000–1,000,000	.04–.05	Open	Moderately mature
Radiation-HRE	23,000-class	23,000	1.0	Open	Immature
Benzene	22,000	Varies	Not available	Open	Moderately mature
Radiation fallout	21,192 (3 cases)	Not available	Not available	Closed	Moderately mature
Agent Orange	15,000	600,000–2,400,000	.0006–.02	Closed	Pre-maturation
Heart valves	12,000	40,000	.30	Closed	Post-maturation
Orthopedic screws	6,000–10,000	100,000	.06–.10	Open	Moderately mature
HIV-blood	6,000-7,000-class	10,000	.60-.70	Open	Post-maturation
DES	6,000	1,500,000	.004	Open	Mature
Swine flu vaccine	4,000	40,000,000	.0001	Closed	Post-maturation
Fen/phen/Redux	3,000 plus	6,000,000	.0005	Open	Immature
Computers/RSI	3,000	180,000–46 million	.02–.00006	Uncertain	Uncertain
TMJ implants	2,300	25,000	.09	Closed	Post-maturation
Bendectin	2,100	10,000,000 plus	.0002	Closed	Post-maturation
MER/29	1,500	400,000	.004	Closed	Post-maturation
Lead	1,000+ (thousands)	12,000,000	.0002–.0007	Open	Moderately mature
Penile prostheses	750	300,000	.002	Open	Moderately mature
J-pacemaker leads	500	3,000–5,000	.10–.16	Open	Pre-maturation
Felbatol	235	110,000	.002	Closed	Pre-maturation
Tampons	100+ (hundreds)	Unclear	Not available (low)	Closed	Post-maturation
Latex gloves	100+ (hundreds)	950,000	.0002–.009	Open	Moderately mature
Thalidomide	17	20,0000	.008	Closed	Post-maturation

Number of claimants (Table 1, column 2)

Table 1 is arranged according to the estimated number of claimants in each type of litigation in descending order. When we look at the various litigations this way a distinct pattern emerges: three mass torts—asbestos, Dalkon Shield, and silicone gel breast implants—far outpace all other case congregations. Each of those three congregations had hundreds of thousands of claims. Tobacco has the potential for an even larger number of claims, but individual cases have not generally been successful.

The above numbers distort the uniqueness of asbestos. In the Dalkon Shield and silicone gel breast implant litigations, the vast majority of claims were filed in response to bankruptcy and class action notices; most claimants had not previously filed a lawsuit. Asbestos remains unique in the number of lawsuits filed individually and in the number of defendants involved in defending those cases.

Other mass torts typically have had hundreds or thousands of claims. A few (Agent Orange, benzene, heart valves, orthopedic screws, and radiation cases) have had 10,000 or more claims, most of which arose during a claims process or an aggregated proceeding and do not represent individual lawsuits clogging the courts. Of these mid-sized case congregations, only orthopedic screw cases are dispersed throughout either the federal or state courts (and that dispersal is taking place after an MDL consolidation).

Thus, we see that there have been three "mega-mass torts" and a host of sizeable but smaller—we hesitate to say "run-of-the-mill"—mass torts. Of the mega cases, asbestos is unique in the number of claims filed independently, without prompting by notices in a class settlement or bankruptcy proceeding.

Number of claims by number exposed (Table 1, column 4)

First of all, several caveats are in order. The figures in column 4 of Table 1 are derived from estimates divided by estimates. While the final figures look very precise, the decimal places mask their imprecision. We present these figures only to identify large differences. We emphasize that the denominator, the number of people exposed, does not represent the number of people injured by the product. Accordingly, the claims-to-exposure rate we present should not be confused with a claims-to-injury rate. Without a reliable epidemiological study we would have no way of estimating the number of injuries related to a product, and there are few products for which epidemiological studies are available.

It is useful to compare congregations with claims-to-exposure rates above 0.10 (10%) (excluding radition-HRE and tobacco litigation where the estimated number of claimants comes from a class action context and thus equals 100%) to cases with claims-to-exposure rates far below 10%. Were congregations with the higher claims-to-exposure rates associated with being treated in an aggregated procedure, either a class action or bankruptcy, employing classwide notices that may have at-

tracted more claimants? All of the case congregations with a claims-to-exposure rate above 10%— albuterol, Dalkon Shield, HIV-contaminated blood, "J" leads, orthopedic screws, silicone gel breast implants, and TMJ implants—were in fact treated in an aggregated fashion (see Table 2, columns 5 & 6, below). This is not to say that the aggregation caused the high claims-to-exposure rate. It might be that cases with a potentially high claims-to-exposure rate are more likely than other cases to be treated in an aggregated fashion. In addition to their class action or bankruptcy status, all the high claims-to-exposure litigations had been consolidated by the MDL panel. The heart valve litigation is the only case with a high claims-to-exposure rate that did not have MDL status, and it was the subject of an approved settlement class action. In that case, the class notice and claims process accounted for most of the claims.

This discussion is not meant to imply that a high claims-to-exposure rate is necessarily a negative attribute. Where the ability of a product to cause injuries has proven to be clear, as with asbestos and Dalkon Shield, some would argue that a high claims-to-exposure rate better serves the tort system's goals of compensation and deterrence than a low rate that fails to include meritorious claims. On the other hand, most would agree that a high rate that reflects attracting cases that do not warrant compensation is not desirable.

All of the high claims-to-exposure rate cases were certified as class actions during some stage of their life. Many of the high claims-to-exposure rate cases had multiple forms of aggregation, such as MDL and bankruptcy (Dalkon Shield) or MDL and class action (all except Dalkon Shield).

Aggregation procedures, however, do not guarantee a high claims-to-exposure rate. Both asbestos and Bendectin litigation have experienced various aggregated treatments, including nationwide class certifications, but have claims-to-exposure rates far below 10%. The low claims-to-exposure rates in those instances seem to be a product of having a high level of exposure, each above the 10 million level.

Maturity (Table 1, column 6)

When we look at the maturity factor in each case congregation, a number of patterns emerge. We divided the cases into open and closed categories (Table 1, column 5). Of the closed cases, a couple have closed without going through the maturation process of generating individual verdicts and settlements before establishing an equilibrium of case filings and terminations. These "pre-maturation" mass torts include Agent Orange and albuterol, each of which were litigation class actions that resulted in global opt-out settlements.

Other closed cases were resolved after individual verdicts and settlements emerged. Of the mega-mass torts, only Dalkon Shield appears to be at or very near to a conclusion. That the Dalkon Shield claims were primarily against a single defendant

and were resolved through a bankruptcy reorganization are factors that undoubtedly contributed to the closure of that mega-mass tort.

Some closed mass torts, such as Bendectin, came to a conclusion after a substantial number of defense verdicts discouraged plaintiffs from pursuing further litigation. Computer keyboards may be in this category as well, depending on recent filing trends.

Other closed cases appear to have come to a conclusion because there was a defined and relatively small number of potential claims, perhaps because a product was modified or removed from the market relatively quickly. Such cases include the Bjork-Shilely heart valve, MER/29, swine flu vaccines, tampons, thalidomide, and TMJ implants. These modest-sized mass torts seem to have been contained because a limited number of individuals were exposed to the product during a brief marketing period.

Open cases exhibit various levels of maturity. Only asbestos, DES, and breast implants can be called fully mature. Again, asbestos shows its uniqueness in the fact that many cases remain in the courts and do not automatically settle despite relatively well-established case values. The threat of bankruptcy and the dynamics of insurance coverage—together with the uncertainty of specific causation—seem to provide incentives for a few asbestos defendants to litigate individual issues. Other mature mass torts seem to settle routinely, and most asbestos cases settle routinely with all but a few defendants.

A number of other open case congregations can be said to be moderately mature. Some, such as benzene and lead cases, represent a scattered and disaggregated set of cases that deal with the same basic substance but allege claims against different defendants. Other open case congregations such as orthopedic screws, latex gloves, and penile prostheses have had a few verdicts or settlements, but values seem not to have stabilized.

A substantial number of recently filed cases have to be classified as immature. Fen/phen, felbatol, human radiation experiment cases, and Telectronic "J" pacemaker leads fit this category.

Tobacco litigation, with its changing shape over time, seems to be a rolling wave of immature litigation. Cases brought by the states for medical payments now seem moderately mature, despite the absence of verdicts or judgments, because settlement values appear to be relatively fixed.

Table 2 [next page] repeats the information on number of claimants from Table 1 and, like Table 1, rank-orders the case congregations by number of claimants. Table 2 adds summary information about the estimated number of defendants, the extent to which cases were dispersed among a number of federal and state courts across the country, whether MDL treatment was used, and whether class actions were used in a way that resulted in the disposition of a significant number of claims. Each of these factors can be expected to be related to the degree of difficulty that cases pose for the courts and litigants.

Table 2
Estimated number of claimants, number of defendants, dispersal among courts, MDL transfer, and use of class action to terminate cases for individual personal injury mass tort case congregations (other than case types based on a single event)

(1) Mass tort congregation	(2) Estimated number claimants	(3) Estimated number of defendants	(4) Dispersal among courts	(5) MDL transfer	(6) Class action used to terminate all or part
Tobacco	50,000,000-class	10 manufacturers	Yes	No	Partial
Breast implants	440,000	7-8	Yes	Yes	3- 2(b)(1)s & 1(b)(3)
Asbestos	300,000-700,000	Up to 2400	Yes	Yes	Partial, (b)(1)*
Dalkon Shield	300,000	2	Yes	Yes	Partial, (b)(1)
Norplant	30,000-50,000	1	No	Yes	Denied, (b)(3)
Radiation-HRE	23,000-class	5 primary	No	No	No
Benzene	22,000	22 (diff. cases)	No	Yes	No
Radiation fallout	21,192	5	No	No	2- (b)(1)(A) & (b)(2)
Agent Orange	15,000	7	No	Yes	(b)(3)
Heart valves	12,000	2	No	No	(b)(3)
Orthopedic screws	6,000-10,000	3 primary	Yes	Yes	Partial, (b)(1)
HIV- blood	6,000-7,000	4	Yes	Yes	(b)(3)
DES	6,000	60	Yes	Denied	No
Swine flu vaccine	4,000	1	Moderately	Yes	No
Fen/phen/Redux	3,000 plus	14 drug cos.	Moderately	Yes	Partial, (b)(1)*
Computers/RSI	3,000	57	Moderately	Denied	No
TMJ implants	2,300	6 primary	No	Yes	Partial, (b)(3)
Bendectin	2,100	2	No	Yes	Decertified, (b)(1)
MER/29	1,500	2	Unknown	No	No
Lead	1,000+ (thousands)	Numerous	Yes	No	No
Penile prostheses	750	4	Moderately	Denied	Decertified, (b)(3)
J-pacemaker leads	500	4	No	Yes	Partial, (b)(1)*
Felbatol	235	2	Yes	Yes	Decertified
Tampons	100+ (hundreds)	6	Yes	Denied	No
Latex gloves	100+ (hundreds)	19-20	Yes	Yes	No
Thalidomide	17	1	No	No	No

Note: * = pending

Estimated number of defendants (Table 2, column 3)

To examine this factor we estimated the number of defendants based on reports from published cases, newspaper articles, law review commentary, and, in some instances, information provided by attorneys. As Table 2 shows, seven of the twenty-six congregations have more than ten defendants.

In those seven case congregations, there are dozens or even hundreds of defendants who have been sued. In most instances, defendants are the manufacturers or distributors of a product in question and they are sued separately when their product is involved in a given case. In two congregations, however, this is not the case. In DES litigation, multiple manufacturers of a generic product are often sued because there are few records of a plaintiff's mother having purchased any particular defendant's product. In asbestos litigation, multiple manufacturers and distributors are often sued because plaintiffs were exposed to multiple products. A single asbestos case often includes two dozen or more defendants, each of whom may be liable to the plaintiff. This feature adds to the unique overall difficulty of resolving asbestos cases.

Dispersal among courts (Table 2, column 4)

We made judgments about dispersal based on reports from published cases. If there were more than ten federal districts or states with one or more cases, we labeled that congregation as "moderately" dispersed. If there were more than twenty federal and state courts with reported cases, we considered that case to be fully dispersed. Even under this relatively moderate threshold, nine of twenty-six case congregations were considered fully dispersed and three were considered moderately dispersed. One of the nine dispersed sets (MER/29) preceded the creation of the Judicial Panel on Multidistrict Litigation. Of the remaining eight, half (asbestos, Dalkon Shield, silicone gel breast implants, and orthopedic bone screw) were consolidated by the JPML at some stage of the litigation and also had cases resolved via the class action mechanism (Table 2, column 5). The other four groups (lead, tampons, tobacco, and DES) were not consolidated by the judicial panel and only tobacco has experienced class action settlements.

MDL status (Table 2, column 5)

Nine case congregations (e.g., Agent Orange, HIV blood) were not considered to be dispersed because federal cases had been consolidated by the panel. Fifteen of the twenty-six case congregations were consolidated by the panel. Aside from the relationship with claims-to-exposure rates discussed above, there seems to be no clear or consistent pattern shown by the MDL consolidations. Some cases that have matured as mass torts in which plaintiffs have had some success—DES and the heart valve litigation are prime examples—were not consolidated by the MDL panel. As-

bestos litigation matured before the MDL consolidation. On the other hand, as the Bendectin and Norplant cases illustrate, MDL consolidation has been no guarantee of success for plaintiffs.

In the computer keyboard cases, defendants vigorously opposed MDL consolidation or any other form of aggregation. Some claim that resisting MDL treatment was a key factor in preventing the growth of such cases into a mass tort. Those claims are discussed further in Appendix C to the MTWG final report (Thomas E. Willging, Mass Torts Problems and Proposals).

Class action terminations (Table 2, column 6)

Settlement appears to have been the primary function served by the class action device in mass tort litigation. Ten case congregations have had class action settlements affecting all or part of the litigation and two of them ("J" pacemaker leads and Fen/phen) currently have settlement class actions that are pending approval. Nine of the ten class action settlements that have been approved (including the *Ahearn* asbestos settlement that awaits Supreme Court action) came from the top half of Table 2, that is they are from the thirteen most numerous congregations.

Despite all the discussion one hears about litigation class actions, apart from settlement there has been little effect of litigation classes in mass torts. In asbestos, a district-wide class action certified and tried by Judge Robert M. Parker (5th Cir.), then sitting as a district judge in E.D. Tex. (*Cimino v. Raymark*) was the only mass tort trial that led to court-ordered class relief, and that judgment was overturned on appeal. In asbestos (*Jenkins v. Raymark)* and albuterol, class trials proceeded for a substantial length of time before terminating in settlements. In the Masonite and breast implant litigations, there were single issue class action verdicts reached in state courts. In Fen/phen/Redux, statewide class actions for medical monitoring have been conditionally certified in two states, but it is too soon to assess the effects of those actions.

Table 3 (next page) adds three characteristics that some hypothesize as accounting for the growth and development of a mass tort: causation, identifiability of the link between a product and plaintiff's injuries, and the ability of defendants to pay judgments.

Table 3
Estimated number of claimants, clarity of general causation, identifiability of product, and ability of defendants to pay for individual personal injury mass tort case congregations (other than case types based on a single event)

(1) Mass tort congregation	(2) Estimated number of claimants	(3) Clarity of general causation	(4) Identifiability of product causing injuries	(5) Defendants' ability to pay
Tobacco	50,000,000-class	Clear	Identifiable	High
Breast implants	440,000	Mixed	Mixed	High as to some Ds
Asbestos	300,000-700,000	Clear	Identifiable	High as to some Ds
Dalkon Shield	300,000	Clear	Highly identifiable	High, but limited
Norplant	30,000-50,000	Disputed	Difficult to identify	High
Radiation-HRE	23,000-class	Clear	Difficult to identify	No information
Benzene	22,000	Clear	Difficult to identify	High as to some Ds
Radiation fallout	21,192	Clear	Difficult to identify	Limited-govt. immunity
Agent Orange	15,000	Unclear	Not identifiable	High
Heart valves	12,000	Clear	Highly identifiable	High
Orthopedic screws	6,000-10,000	Disputed	Highly identifiable	High as to some Ds
HIV-blood	6,000-7,000-class	Clear	Identifiable	No information
DES	6,000	Mixed	Difficult to identify	High as to most Ds
Swine flu vaccine	4,000	Disputed	Difficult to identify	Limited by statute
Fen/phen/Redux	3,000 plus	Disputed	Mixed	High as to most Ds
Computers/RSI	3,000	Unclear	Difficult to identify	High as to most Ds
TMJ implants	2,300	Clear	Highly identifiable	Low
Bendectin	2,100	Unclear	Difficult to identify	High
MER/29	1,500	Clear	No information	High
Lead	1,000+ (thousands)	Clear	Difficult to identify	High as to some Ds
Penile prostheses	750	Disputed	Mixed	High
J-pacemaker leads	500	Clear	Highly identifiable	Settled
Felbatol	235	Clear	No information	Not an issue
Tampons	100+ (hundreds)	Disputed	Identifiable	High
Latex gloves	100+ (hundreds)	Mixed	Difficult to identify	High
Thalidomide	17	Clear	Identifiable	High

Causation (Table 3, column 3)

The general capacity of a product to cause the alleged injuries is the sine qua non of achieving mass tort status. All of the mass tort congregations have arguable claims that general causation exists. Fourteen had clear claims and general causation is no longer disputed in those cases. Three (Bendectin, computer-repetitive stress injuries, Agent Orange) had unclear general causation even after substantial litigation, and this factor accounts for the failure of those congregations to become mature mass torts. Six congregations remain active, including the silicone gel breast implant litigation. The lack of clarity, of course, may get resolved in favor of either side of the litigation. In silicone gel, the causation issues are somewhat mixed. Clearly, implants are associated with local injuries relating to rupture, contraction, and compaction of the implants and the need to remove them surgically, but it remains unclear as to whether they are associated with systemic injuries to the immune system or with connective tissue diseases. Several closed congregations with unclear or disputed general causation ended in settlements (e.g., Agent Orange, L-Tryptophan, tampons), but none reached mature mass tort status.

Identifiability of product causing injury (Table 3, column 4)

In classifying groups on this factor, we attempted to distinguish between those cases in which identification of the product in relation to the injury is generally not problematic and those in which it is. Only the highly identifiable congregations (medical devices) are relatively free of problems in that regard. Even plaintiffs experiencing the asbestos-related signature diseases of mesothelioma and asbestosis have to identify specific products to which they were exposed. All of the other groups require proof, often epidemiological evidence, to link the product with the injuries claimed. We divided the latter group into "identifiable" and "difficult to identify" groups. In the latter it is difficult to distinguish the injuries claimed from injuries that might be experienced by people who were not exposed to the product in question.

A plausible hypothesis is that cases where the linkage between the product and the injury is difficult to identify will not be successful as a group. That appears to have been the case for Bendectin, computers, lead, and benzene cases. Congregations involving products that are difficult to identify and that require proof on a case-by-case basis may never become mature mass torts like asbestos and DES. Some of these groups, such as the HIV-blood cases, have settled on an aggregate basis, perhaps reflecting the fact that they cannot support the transaction costs of case-by-case adjudication. Identification, however, can become routinized as information accumulates during the course of mass litigation.

Only asbestos causes injuries associated with signature diseases, that is, diseases exclusively or predominantly caused by a single product. DES cases involve injuries that plaintiffs claim to be linked with signature diseases, but defendants dispute

such claims. It may not be coincidental that asbestos and DES are also two mature ongoing mass torts. Both, of course, also involve latent claims. As symptoms of those injuries become manifest, the cases are routinely filed and, apparently, settled. For the medical devices cases (heart valves, "J" leads, TMJ implants, and orthopedic screws) the device is always identifiable. If the capacity of the device to cause the injury is clear, those cases too become routine. Medical device cases, however, tend to be more containable than other mature mass torts because the injury generally occurs soon after the device is used.

Defendants' ability to pay (Table 3, column 5)

Having one or more defendants with an ability to pay judgments is a necessary but not sufficient condition for creating the volume of cases necessary for mass tort status. Of the twenty-two case congregations for which we had some information, nineteen had at least one defendant with sufficient assets to be rated as having a high ability to pay. In the TMJ litigation, the principal defendant had a low ability and filed for liquidation under Chapter 7 of the Bankruptcy Code. Another defendant with a much deeper pocket was able to avoid liability in the TMJ litigation by successfully invoking a raw materials supplier defense.

Three groups of cases were identified as limited, but one (swine flu) was limited only because of budgetary limits set by Congress and the President, and another (Dalkon Shield) was limited to the multi-billion dollar value of the company. In all cases, at some stage of the litigation there was a defendant who evidently had an ability to pay substantial judgments.

The following are summaries of the individual characteristics of mass tort types. As indicated before, they are divided into three groups: (A) personal injury claims arising from an allegedly defective or dangerous product that has been sold over a substantial period of time, at least more than one year; (B) personal injury claims arising from a single event, such as an airplane crash, or from short-term distribution of a contaminated batch of an otherwise safe product, such as salmonella-infected milk products; and (C) property damage claims arising from the sale or use of an allegedly defective product, such as polybutylene pipes or synthetic stucco. Within each group, the summaries are arranged in alphabetical order.

Part I-A
Individual characteristics of personal injury mass tort case congregations (not based on a single event)

Product: Agent Orange (personal injury claims relating to a chemical herbicide used extensively by the U.S. military during the Vietnam War)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. Ultimately, fewer than 300 opt-out plaintiffs pursued their individual claims. Judge Jack B. Weinstein (E.D.N.Y.) dismissed individual suits brought by claimants who had opted out of the settlement class action.

Consolidated cases. None reported.

MDL pretrial referral. In 1979, the JPML transferred all federal cases to E.D.N.Y. A total of 596 cases had been referred as of Dec. 31, 1998.

Litigation class action. Approximately 600 suits filed by more than 15,000 named individuals were certified as an opt-out class action for compensatory damages and as a mandatory class for punitive damages.

Settlement class action/mandatory. None reported.

Settlement class action/opt-out. Judge Weinstein approved an opt-out class settlement under which corporate defendants paid $180 million into a settlement fund.

Bankruptcies. Nothing reported.

Estimated number of claimants. Approximately 15,000.

Estimated number of future claimants. Unknown. The settlement allows future claimants to submit claims as their disability or disease becomes manifest, or results in death.

Estimated number of defendants. There were seven companies that manufactured Agent Orange for the U.S. military. The U.S. government was originally named as a defendant, but was found not to be liable.

Ability of defendants to pay judgments. Overall, high.

Estimated number of federal cases. One consolidated set of cases.

Estimated number of state cases. No reported state cases.

Estimated number of federal courts with one or more cases. One.

Estimated number of state courts with one or more cases. None.

Maturity of litigation. Some contend that the litigation settled and was decided on summary judgment before it had a chance to mature.

Estimated number and amounts of damage awards including punitive damages. None.

Estimated number and amounts of settlements. One settlement for $180 million.

Capacity of product to cause injuries (general causation). This was unclear at the time of the settlement, but the judge ruled in the opt-out cases that there was not

sufficient evidence to prove that Agent Orange was capable of causing the injuries plaintiffs alleged. He applied an epidemiology threshold, holding that animal studies were not sufficient to prove causation.

The settlement relieved veterans of the burden of proving general causation, which they could not have done at that time. All the claimants have to prove is that they served in Vietnam during 1961 to 1972, and that they were in an area where it was "probable" that they had been exposed to Agent Orange.

Types of injuries. Injuries ranged from a serious skin ailment (chloracne) to liver disease, lymphoma, soft tissue sarcoma, other cancers, neurological disorders, birth defects in the children of veterans, and death.

Identifiability of causative agent. It was difficult to identify levels of exposure to Agent Orange as well as its relationship to specific diseases.

Description of premarket research or testing. Some claim that Agent Orange was not adequately tested.

Alleged suppression of research/testing/safety information. Nothing reported.

Length of exposure (marketing/sales) period. About 11 years (1961 to 1972).

Length of latency period (time from exposure to injury). Variable, depending on the injury alleged.

Estimated number of users exposed to potential harm. Between 600,000 and 2.4 million, including Vietnam veterans and their families.

Trends/current status. There are a few new filings, but cases are generally dismissed on grounds that the claims are precluded by the settlement. Three cases are pending according to JPML statistics as of Dec. 31, 1998.

Product: Asbestos (personal injury claims relating to natural mineral fibers used for insulation and other purposes in a wide variety of industrial, commercial, and consumer products)

Information for this report was obtained from published sources supplemented by information from one or more attorneys who represented clients in the litigation.

Individual cases. Estimates of the number of asbestos cases filed since the 1970s vary widely, ranging from 200,000 to 350,000. Estimates of the total number of expected cases up to the year 2050, including those filed to date, also vary widely ranging from 300,000 to 700,000.

Consolidated cases. Generally cases have been consolidated at least for pretrial purposes in both federal and state courts. Some courts have consolidated hundreds and even thousands of cases for trial in New York, Texas, West Virginia, and Baltimore, Maryland. Some courts have used combinations of Rule 42 consolidations and Rule 23 class actions to try large groups of cases. Other state have more ad hoc, informal consolidated procedures.

MDL pretrial referral. After declining consolidation several times, the JPML re-

ferred all federal asbestos claims to E.D. Pa. in 1992 (MDL 875). A total of 79, 883 cases have been transferred to E.D. Pa. As of Dec. 31, 1998, 22,224 cases were pending according to statistics maintained by the Judicial Panel.

Litigation class action. In two cases in E.D. Tex., class action/consolidation trials were commenced. In *Jenkins* (1986), the case settled before verdict. In *Cimino* (1990) the court of appeals overturned judgments based on extrapolations from jury verdicts.

Settlement class action/mandatory. In *Ahearn*, the court of appeals affirmed a mandatory class settlement based on a finding of a limited fund. The Supreme Court decided to review the case and arguments were heard on Dec. 8, 1998.

Settlement class action/opt-out. In *Amchem*, the Supreme Court rejected a "sprawling" class that included present and future claimants with a wide range of medical conditions.

Bankruptcies. There have been approximately twenty asbestos-related bankruptcies, mostly Chapter 11 reorganizations, but also several liquidations. About five to seven of the reorganizations involved major defendants with substantial assets. These reorganizations have produced multiple claims facilities to which often the same individual claimants must submit claims (sometimes using the same claims form). Many of the bankruptcies involved companies with relatively few assets.

Estimated number of claimants. Between 300,000 and 700,000, between 1970 and 2050.

Estimated number of future claimants. Estimates have ranged up to 2 million. In 1994, Judge Jack B. Weinstein (E.D.N.Y.) estimated that 300,000 to 600,000 claims could be expected by 2050.

Estimated number of defendants. There are generally dozens of defendants in each litigation and the cast of characters has expanded over the past two decades. One attorney claims to have counted 2,400 defendants involved in one or more asbestos cases. Of these, a relatively small number, estimated at between twenty and fifty, are national companies with a significant number of cases.

Ability of defendants to pay judgments. Varies considerably. After their insurance coverage ran out, a number of companies have reorganized under the bankruptcy laws and created trusts to compensate asbestos claimants. In several instances the claimants' trust, in effect, owns the company. Plaintiffs report that a financial analysis of companies that participate in the Center for Claims Resolution shows a very high aggregate ability of those companies to pay judgments from earnings.

Estimated number of federal cases. Administrative Office statistics show that 104,423 original or removed asbestos cases have been filed in the federal courts between 1976 and June 30, 1998. This figure includes a large number of maritime cases, estimated as about 30,000, that were filed and dismissed summarily.

Estimated number of state cases. Overall estimates range from 100,000 to 250,000. Accurate statistics are not available.

Estimated number of federal courts with one or more cases. Currently, one. In the past, it is likely that all federal districts have had asbestos cases.

Estimated number of state courts with one or more cases. All.

Maturity of litigation. Asbestos has senior status as a mature mass tort.

Estimated number and amounts of damage awards including punitive damages. Total damages have been estimated to be as high as $90 billion and as low as $21 billion. The latter estimate includes defense costs as well as verdicts and settlements.

Estimated number and amounts of settlements. As has been the case for more than a decade, almost all cases settle, especially when scheduled for trial.

Capacity of product to cause injuries (general causation). Epidemiological evidence established that exposure to asbestos is associated with a variety of serious physical injuries.

Types of injuries. Mesothelioma is a cancer generally affecting the lining of the lung or abdomen. Other than exposure to asbestos, there is no known cause for this deadly disease. Lung cancers, especially among smokers, and other cancers have also been linked to asbestos. Non-malignant diseases include asbestosis, an interstitial fibrosis or scarring within the lung that is, by definition, caused by asbestos fibers. Localized abnormalities around the lungs are called pleural plaques, which rarely cause any functional impairment. Because pleural plaques result from an invasion of the pleural membrane by asbestos fibers, there continues to be considerable controversy among counsel for plaintiffs and defendants about whether unimpaired claimants with pleural plaques should be compensated. Many, perhaps most, states have permitted compensation for such injuries, but the U.S. Supreme Court, in *Metro-North Commuter R.R. v. Buckley,* held that unimpaired asbestos claimants have no cause of action under the FELA.

Identifiability of causative agent. Despite the presence of the signature diseases of mesothelioma and asbestosis, identifiability of the specific cause of an individual's injury is not always clear. There are a variety of opportunities for exposure to asbestos. Proof of exposure to a particular product is required and, while routinely handled in most cases, can pose difficult factual issues. There are a variety of other causal agents, such as smoking, for some of the diseases associated with asbestos, particularly lung cancer. Again, accounting for such variations, while routinely handled in most cases, can pose difficult factual issues.

Description of premarket research or testing. Evidence of research on the effects of asbestos and suppression of the results of such research, starting in the 1930s along with evidence of suppression of worker injury claims during that period, was obtained in discovery. Such evidence has led to punitive damage awards against a number of major defendants. Suppression by some defendants was well documented and has become an oft-told tale.

Alleged suppression of research/testing/safety information. Suppression of testing and safety information became known through discovery and appears to be a major factor in large compensatory and punitive damage awards and large settlements.

Length of exposure (marketing/sales) period. From the turn of the century (and before) until the mid-1970s, with continuing exposure to asbestos in public and private buildings and among the growing asbestos removal industry. Use increased dramatically in the 1940s (in shipyards) and in the 1950s and 1960s, especially in building products.

Length of latency period (time from exposure to injury). Mesothelioma generally has shown latency periods in the 20- to 40-year range, but there is some evidence of its appearance both within 10 to 15 years of exposure and more than 40 years after exposure. Pleural plaques may appear as early as 5 to 10 years after exposure.

Estimated number of users exposed to potential harm. Experts have estimated that more than 21 million American workers have been exposed to significant amounts of asbestos since 1940. Exposure through contact with relatives who have worked with the products or through contact with asbestos fibers in buildings (home, office, school) or in the environment add an indeterminate number.

Trends/current status. Very mature and expected to continue to be very active until 2010 to 2020 (about 40 to 50 years after use of asbestos was sharply curtailed).

Product: Bendectin (child deformity claims relating to a pharmaceutical prescribed for morning sickness during pregnancy)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. Early Bendectin litigation consisted of individual lawsuits pursued in different forums, beginning in 1980. At first, defendants preferred to litigate individual trials in Bendectin cases. After the MDL consolidation in 1985, about 300 individual Bendectin suits were brought against Merrell Dow, and about 26 of these cases actually went to trial. As the litigation developed, most cases were disposed of by summary judgment for the defendant.

Consolidated cases. Plaintiff claims in federal court were consolidated after a mandatory settlement class certification had been vacated. Bendectin claims were consolidated for a "common issues" trial. Consolidation was mandatory for Ohio cases and voluntary for all others. A jury verdict for the defendant in 1985 disposed of more than 1,200 claims in 800 cases.

MDL pretrial referral. In 1982, the JPML transferred the Bendectin litigation to the U.S. District Judge Carl Rubin (S.D. Ohio) (deceased) for consolidated pretrial proceedings. During the course of the litigation 1,189 cases were transferred to Judge Rubin.

Litigation class action. None reported.

Settlement class action/mandatory. In 1984, the district court for S.D. Ohio certified a mandatory temporary settlement class under Rule 23(b)(1), consisting of all present and future claimants nationwide, for $120 million. Opponents of the settlement obtained a ruling from the Sixth Circuit Court of Appeals that the trial judge lacked the authority to certify a mandatory Bendectin class, because the limited fund requirement had not been satisfied.

Settlement class action/opt-out. None reported.

Bankruptcies. None reported

Estimated number of claimants. As of 1992, more than 2,100 Bendectin claims had been brought against Merrell Dow, most (about 1,700) by children who claim damages related to a wide variety of birth defects caused by their mothers' ingesting Bendectin during pregnancy.

Estimated number of future claimants. None expected (short latency period).

Estimated number of defendants. Two: Merrell Dow Pharmaceuticals, Inc., manufacturer of Bendectin, and Dow Chemical, the purchaser of Richardson-Merrell.

Ability of defendants to pay judgments. High.

Estimated number of federal cases. Almost all Bendectin claims were in federal courts.

Estimated number of state cases. Thirteen state court cases were identified.

Estimated number of federal courts with one or more cases. At least six federal courts had reported claims: D. Md., S.D. Ohio, D.D.C., D. Tenn., E.D. Pa., and D. Mass.

Estimated number of state courts with one or more cases. At least one.

Maturity of litigation. Litigation matured slowly as post-marketing scientific testing developed.

Estimated number and amounts of damage awards including punitive damages. Since 1977, there have been about 30 trials litigating the question of whether Bendectin causes birth defects in the offspring of women who took the drug. Of these cases, only one verdict (adjusted to $450,000 against Merrell) has been returned in favor of the plaintiff and survived appeal.

Estimated number and amounts of settlements. Mandatory class action settlement for $120 million was vacated on appeal.

Capacity of product to cause injuries (general causation). General causation is widely disputed. In *Daubert v. Merrell Dow Pharmaceuticals,* Merrell Dow's expert witness asserted that none of more than 30 published studies indicated that Bendectin was a teratogen. Plaintiffs rebutted with the testimony of eight expert witnesses who concluded that Bendectin could be a teratogen, based on in vitro and in vivo studies (test tube and animal studies), chemical structure analysis, and reanalysis of epidemiological studies. Plaintiffs' experts claimed that Bendectin inhibits limb bud mesenchyme cell differentiation. Also, evidence suggests that Bendectin's antihistamine component may have some adverse effects on embryonic cell development, but there

is relatively little research on this, and the findings are not clear-cut. There is no generally accepted biological theory as to how Bendectin produces its alleged effect.

Types of injuries. Birth defects (such as limb reduction and other defects) in children of women who had ingested Bendectin during pregnancy.

Identifiability of causative agent. Bendectin does not have a "signature" disease.

Description of premarket research or testing. Before Bendectin was marketed in 1957, each of its ingredients (dicyclomine hydrochloride, doxylamine succinate, and pyridoxine hydrochloride) had been prescribed separately, and each alone had no recorded adverse effect on humans. Apparently, no pre-marketing tests were conducted on the combination, and some allege that Bendectin was an inadequately-tested product. They claim that Merrell Dow resisted conducting relatively straightforward studies on the long-term safety of Bendectin. Plaintiffs emphasized Merrell Dow's failure to test the drug's long-term safety before marketing the drug, claiming that Merrell Dow failed to perform any meaningful reproductive testing of Bendectin until the late 1970s.

Alleged suppression of research/testing/safety information. Nothing reported.

Length of exposure (marketing/sales) period. About 27 years (1956–1983).

Length of latency period (time from exposure to injury). Ten months or less.

Estimated number of users exposed to potential harm. Tens of millions of women had ingested Bendectin during pregnancy.

Trends/current status. Litigation appears to be history. No cases are pending in the MDL transfer.

Product: Benzene (separate personal injury litigations relating to different uses of this carcinogenic chemical agent)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual trials. About twelve individual cases were identified, four of which involved exposure to benzene in the work place. One concerned bottled water contaminated with benzene and two concerned benzene exposure to pollution resulting from, in one case, a chemical plant explosion and, in another case, a spill. Most verdicts favored the defendants, but in the chemical plant explosion case, summary judgments in favor of seven plaintiffs were affirmed by the Fifth Circuit.

Consolidated trials. The *Miller* case in E.D. Tex. comprised two similar benzene actions that had been consolidated.

MDL pretrial referral. A total of 16 involving claims that Perrier water was contaminated with benzene were transferred to D. Conn. in 1990 (MDL # 844).

Litigation class action. Three were certified and one more is expected to be certified in *Gant v. Ingram*.

Settlement class action/mandatory. None reported.

Settlement class action/opt-out. None reported.

Bankruptcies. None reported.

Estimated number of claimants. Total of about 22,000 (multiple incidents and locations).

Estimated number of future claimants. Not available.

Estimated number of defendants. More than 22 in various litigations. A number are oil or chemical companies.

Ability of defendants to pay judgments. Apparently high, at least as to some.

Estimated number of federal cases. Three federal cases reported.

Estimated number of state cases. Twenty-five reported.

Estimated number of federal courts with one or more cases. Two

Estimated number of state courts with one or more cases. Five (New Jersey, New York, Louisiana, and two unidentified states).

Maturity of litigation. There have been two jury verdicts for defendants, one jury verdict for plaintiffs, two summary judgments for defendants, one summary judgment for plaintiffs, one reversal of trial court's grant of summary judgment for defendants.

Estimated number of damage awards including punitive damages. In one case, a jury awarded the plaintiffs $9.5 million in medical monitoring. Conoco, the defendant, settled for $36 million before the jury returned its decision on punitive damages.

Estimated number and amounts of settlements. In the chemical explosion case, defendant settled with 4,000 claimants for an undisclosed amount. In another case, Conoco settled for $36 million before the jury returned its decision on punitive damages.

Capacity of product to cause injuries (general causation). Benzene has been accepted as a carcinogenic agent, and classified by the EPA as a "Group A" carcinogen (same category as asbestos). In 1978, the EPA published a study linking the inhalation of benzene in the workplace to the development of leukemia among exposed workers.

Types of injuries (range/severity). Acute myelogenous leukemia (AML), chronic myelogenous leukemia (CML), blood disorders, chromosomal abnormalities, stomach and liver cancer, cancerous brain tumor, other cancer, and various other health problems, such as nausea, rashes, and nosebleeds.

Identifiability of causative agent. In *Wells*, the jury did not find a causal link between benzene exposure and the plaintiff's leukemia. In *Sutera*, the judge found that plaintiff produced no reliable evidence that his leukemia was more likely than not caused by his consumption of Perrier containing benzene.

Description of premarket research or testing. None reported.

Alleged suppression of research/testing/safety information. In a case involving a chemical spill, plaintiffs alleged misrepresentation and concealing conditions at the port terminal. Plaintiffs claimed that defendants destroyed a memo from a port chemist stating that he had found high levels of benzene in the area. In a work place exposure case, plaintiffs alleged failure to warn.

Length of exposure (marketing/sales) period. Thirty-three years was the longest exposure period reported.

Length of latency period (time from exposure to injury). Not reported, but one would expect a long latency period for leukemia and other cancers.

Estimated number of users exposed to potential harm. Varies by the individual case.

Trends/current status. No solid information. It seems that these cases appear episodically, responding to occurrences such as an oil spill or gasoline leak. There were no cases pending in the MDL consolidation as of Dec. 31, 1998.

Product: Computer keyboards (repetitive stress injury (RSI) claims arising from use of computers)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. According to one report, thousands of individual cases have been filed throughout the country.

Consolidated cases. Judge Jack B. Weinstein (E.D.N.Y.) ordered 44 cases consolidated and future cases were to be added as they were filed. The Second Circuit reversed the consolidation.

MDL pretrial referral. The MDL panel declined to consolidate the computer keyboards cases for pretrial proceedings.

Litigation class action. None reported.

Settlement class action/mandatory. None reported.

Settlement class action/opt-out. None reported.

Bankruptcies. None reported.

Estimated number of claimants. More than 3,000 plaintiffs reportedly filed cases.

Estimated number of future claimants. It is estimated that more than 180,000 American workers suffer from repetitive motion injuries.

Estimated number of defendants. Fifty-seven, according to one report, including many major computer and office machine manufacturers.

Ability of defendants to pay judgments. Very high.

Estimated number of federal cases. Unknown.

Estimated number of state cases. Unknown.

Estimated number of federal courts with one or more cases. Nine federal districts were identified in an electronic search: E.D.N.Y., N.D.N.Y., S.D.N.Y., W.D.N.Y., D.N.J., D.R.I., D. Md., S.D. Tex., N.D. Ill.

Estimated number of state courts with one or more cases. Three were identified in an electronic search: Minnesota, Texas, and New York.

Maturity of litigation. Immature, perhaps ending. New filings have not appeared.

Estimated number and amounts of damage awards including punitive damages. There have been about twenty verdicts, the vast majority of which favored the defendants. In a consolidated trial, one plaintiff was awarded $5.3 million (which was set aside), another $306,005 (which was reversed on appeal), and a third $278,000 (which was set aside on statute of limitations grounds). In another case, a verdict for plaintiffs for $6 million was partially reversed on appeal. In a consolidated trial of nine cases, including retrials of some of the above cases, a jury returned defense verdicts in all cases.

Estimated number and amounts of settlements. Two settlements of unknown amounts were identified, one by Apple Computers and another by IBM.

Capacity of product to cause injuries (general causation). Disputed. Epidemiological studies apparently find no specific causal connection between computer keyboards and the injuries claimed. Still, many doctors and others believe that some computer keyboards can cause injuries in the absence of warnings or proper training.

Types of injuries. Repetitive stress injuries (RSI) and cumulative trauma disorder (CTD). These terms include virtually any disorder of the musculoskeletal system of the upper torso, from the fingers to the lower back. Severe forms include carpal tunnel syndrome, characterized by swelling that narrows the small sheath in the wrist through which nerves pass from the lower arm into the hand. Other RSI/CTD injuries include tenosynouitis, emicondylitis, pronator nerve injuries, Rayneud's phenomenon, pain and swelling in hands, arms, and shoulders (ranging in severity), nerve entrapment, nerve transfer, radial tunnel syndrome, and tendinitis.

Identifiability of causative agent. Uncertain. Other factors, such as working conditions, job stress, hobbies, posture, and diet, may partially or totally cause some or all of the alleged injuries.

Description of premarket research or testing. Plaintiffs allege that the computer keyboard industry aggressively marketed its product despite being aware of some health risks.

Alleged suppression of research/testing/safety information. In at least one case plaintiffs alleged that manufacturers warned their own employees but not purchasers.

Length of exposure (marketing/sales) period. Decades.

Length of latency period (time from exposure to injury). Varies by individual. In the cases identified, the shortest exposure period was 4 to 5 years and the longest exposure period was 15 years

Estimated number of users exposed to potential harm. The Bureau of Labor Statistics in 1990 estimated that 180,000 American workers have repetitive stress symp-

toms, and that more than 46 million American workers use a computer for work. The Bureau of Labor Statistics also stated that the number of new RSI/CTD cases doubled between 1989 and 1993, from 147,000 to 302,000.

Trends/current status. New filings not found.

Product: Dalkon Shield (reproductive and other personal injuries related to using an intrauterine contraceptive device)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. There were approximately 50 trials before A.H. Robins filed for Chapter 11 bankruptcy protection. An estimated 15,000 cases had been filed against Robins by that time. Even after the settlement trust, women who had refused the first offering in the settlement of their claims sued A.H. Robins individually.

Consolidated cases. There were numerous consolidations of cases for pretrial and trials in various state courts and federal districts, including D. Minn. and E.D. Va.

MDL pretrial referral. In MDL # 211, the JPML transferred a total of 1,136 cases to D. Kan. for discovery and pretrial proceedings. Cases were later transferred back to their original districts.

Litigation class action. Judge Spencer M. Williams in N.D. Cal. certified an opt-out class and a mandatory class for punitive damages, but was reversed on both counts by the court of appeals. Later, Robins moved a second time for certification of a mandatory class for punitive damages, but their motion was denied.

Settlement class action/mandatory. Judge Robert A. Merhige, Jr., approved a mandatory class settlement against Aetna, Robins's insurer, and that settlement was approved by the court of appeals.

Settlement class action/opt-out. None reported.

Bankruptcies. A.H. Robins Co., the sole manufacturer and distributor of the Dalkon Shield, filed for Chapter 11 bankruptcy protection in 1985 in E.D. Va. District Judge Robert A. Merhige, Jr., and Bankruptcy Judge Blackwell N. Shelley presided jointly over many aspects of the reorganization. As a result of the reorganization process, the Dalkon Shield Claimants Trust was established with the $2.475 billion proceeds of the sale of the company.

Estimated number of claimants. More than 300,000 individuals filed claims with the Dalkon Shield Claimants Trust and approximately 200,000 were not disqualified.

Estimated number of future claimants. The Dalkon Shield Claimants Trust provided for future claimants, potentially tens of thousands. A representative for future claimants had been appointed in the reorganization proceedings.

Estimated number of defendants. Two: A.H. Robins Co. (the sole manufacturer and distributor of the Dalkon Shield) and its insurer, Aetna Insurance.

Ability of defendants to pay judgments. The estimated number of claims exceeded the value of the company and its insurance coverage.

Estimated number of federal cases. Most of the estimated 15,000 cases that were filed before the Chapter 11 filing were federal cases.

Estimated number of state cases. There were a significant number of state cases as well. Two $6 million to $7 million punitive damage awards were from cases in Kansas and Colorado state courts.

Estimated number of federal courts with one or more cases. Injuries and claimants are widely dispersed throughout most, if not all, federal districts.

Estimated number of state courts with one or more cases. Injuries and claimants are widely dispersed throughout most, if not all, states.

Maturity of litigation. Mature. Discovery was complete and there had been a substantial number of verdicts and settlements before Robins filed its Chapter 11 petition.

Estimated number and amounts of damage awards including punitive damages. Verdicts for plaintiffs kept escalating, beginning with an award of $85,000 in 1975 to a verdict of more than $9 million in 1985.

Estimated number and amounts of settlements. Not found.

Capacity of product to cause injuries (general causation). There was no real doubt about the causal relationship between the Dalkon Shield and the injuries attributed to it. Causation became well documented in the scientific literature and in numerous cases.

Types of injuries. Nearly all women fitted with the Dalkon Shield suffered from pelvic inflammatory disease. Some also reported infertility, pelvic infections, and the possible need for reproductive surgery. Other women may suffer injuries, including reproductive disorders, that may take time to manifest. Psychological suffering is also a major consequence of using the device. Reproductive disorders resulting from the use of Dalkon Shield include ectopic pregnancy, septic abortion, spontaneous abortion, sterility, and various other serious afflictions. It is reported to be possible that the Dalkon Shield will contribute to birth defects in the offspring of women who have used the product. At least 15 American women died from Dalkon Shield-related septic abortions.

Identifiability of causative agent. No signature diseases, but use of the Dalkon Shield is identifiable.

Description of premarket research or testing. There seems to be a consensus that the Dalkon Shield was not adequately tested. According to one commentator, A.H. Robins resisted conducting relatively straightforward studies on the long-term safety of the Dalkon Shield. Reportedly, A.H. Robins' primary strategy was to avoid safety research on the Dalkon Shield and to disclose only the positive results of its limited testing.

Alleged suppression of research/testing/safety information. Corporate concealment of adverse testing results was reported. In one case, evidence indicated that A.H. Robins "commissioned studies on the Dalkon Shield which it dropped or concealed when the results were unfavorable" and that Robins "consigned hundreds of documents to the furnace."

Length of exposure (marketing/sales) period. About 13 years (1971–1984) worldwide; about three years (1971–1974) in the United States.

Length of latency period (time from exposure to injury). The latency period for the inflammatory diseases was usually not long, but some reproductive injuries have taken a longer time to appear.

Estimated number of users exposed to potential harm. By the time the product was withdrawn from the market, A.H. Robins had distributed approximately 2.8 million Dalkon Shields in the U.S. and 1.7 million overseas. Approximately 3.6 million women worldwide actually used the Dalkon Shield.

Trends/current status. The Claimants Trust has completed its review of claims. A smattering of court cases filed by individuals who rejected the outcome of the claims process continue to appear in published reports. There were no cases pending on the MDL docket as of Dec. 31, 1998.

Product: DES (cancer and reproductive injury claims related to diethylstilbestrol, a pharmaceutical often prescribed to address complications of pregnancy)

Information for this report was obtained from published sources supplemented by information from one or more attorneys who represented clients in the litigation.

Individual cases. All of the more than 2,000 DES suits terminated to date were disposed of individually, either by verdict, dispositive motion, or settlement.

Consolidated cases. Consolidation of cases has typically been rejected, but cases have been consolidated for purposes of pretrial administration and discovery in a few jurisdictions, e.g., E.D.N.Y. and the N.Y. Supreme Court.

MDL pretrial referral. In 1976, in an unpublished order, the Judicial Panel decided not to consolidate DES cases.

Litigation class action. In *Payton v. Abbott Laboratories*—a statewide opt-in class action—was certified as to issues of liability, but decertified after rulings on preliminary issues of law.

Settlement class action/mandatory. None reported.

Settlement class action/opt-out. None reported.

Bankruptcies. Emons Industries, Inc., filed for Chapter 11 bankruptcy in March 1984 and its plan of reorganization was confirmed in December 1986. A bankruptcy court recently ruled that DES plaintiffs who did not know of a bar date for filing

claims against Emons Industries, Inc. may not pursue their claims in full against the company because the reorganization plan provides for their compensation. That issue is on appeal.

Estimated number of claimants. More than 600 lawsuits brought by more than 6,000 named plaintiffs were reported by the mid-1980s. A continuous stream of filings is anticipated.

Estimated number of future claimants. Alleged injuries may not manifest themselves for decades. While there have been some claims on behalf of grandchildren of women who had ingested DES, the N.Y. Court of Appeals has held those claims to be too remote to support liability.

Estimated number of defendants. DES had been manufactured by about 300 companies between the 1940s and 1971. Of those, about 60 have been defendants, and about 25 are served and brought into the litigation on a regular basis. DES was generally sold in a generic format and it is often difficult to identify a specific seller. Some of the defendants are major pharmaceutical companies. Plaintiffs have alleged concert of action among manufacturers.

Ability of defendants to pay judgments. In the aggregate, the ability of defendants to pay seems high. For some, the ability to pay is very high. Under market share or other alternative liability theories, courts may find that liability is separate and that a defendant is liable for only its share of the market.

Estimated number of federal cases. In the past, many federal courts had DES cases; currently DES case filings appear to be filed in E.D.N.Y. and La.

Estimated number of state cases. In the past, many state courts had DES cases; currently DES case filings appear to be filed in New York, D.C., Florida, Ohio, Pennsylvania, and Washington.

Estimated number of federal courts with one or more cases. Many.

Estimated number of state courts with one or more cases. Many.

Maturity of litigation. DES is considered a mature mass tort. DES litigation has a long history and track record, and the value of individual claims of disease and injury is well known.

Estimated number and amounts of damage awards including punitive damages. Few verdicts have been reported. In the late 1970s and the 1980s, verdicts in the $500,000 to $1,000,000 range were reported. In *In re New York County DES Litigation,* a jury found for plaintiffs and awarded damages for 11 plaintiffs, ranging from $125,000 to $12 million each, and totaling about $42 million.

Estimated number and amounts of settlements. Almost all DES cases settle. Aggregate settlements and global agreements were routinely accepted by Judge Jack B. Weinstein. In E.D.N.Y., Special Master Kenneth Feinberg was appointed to help facilitate settlement in cases before Judge Weinstein.

Capacity of product to cause injuries (general causation). DES's general ability to cause clear cell cancer does not appear to be disputed. Its ability to cause other

cancers, reproductive deformities, infertility, and various other injuries continues to be disputed, as does specific causation of all claims.

Types of injuries. Plaintiffs allege and defendants dispute that DES has been a proven cause of clear cell adenocarcinoma, a vaginal cancer, breast cancer, testicular cancer, other kinds of cancer, infertility, adverse pregnancy outcomes (e.g., premature birth), reproductive tract injuries (e.g., vaginal lesions, T-shaped uterus, incompetent cervix, and testicle abnormalities), and autoimmune diseases. DES is alleged to cause such injuries in the offspring of women who ingested the drug. Plaintiffs also allege that they suffer psychological harm in the fear and anticipation that such conditions may develop. Defendants dispute all of the above claims.

Identifiability of causative agent. Plaintiffs allege that clear cell adenocarcinoma and the T-shaped uterus condition are signature diseases linked with DES exposure, and defendants dispute such allegations. Specific causation is often difficult to show because the product was generally sold in a generic form. At least four states have adopted a market share theory of liability. A number of other states have found liability based on concert of action or other alternative liability theories. At least six states have required strict product identification.

Description of premarket research or testing. DES allegedly was an inadequately tested drug. Plaintiffs allege that there was no testing for use during pregnancy or of the effects on fetuses. According to some accounts, manufacturers resisted conducting relatively straightforward studies on the long-term safety of DES. There were claims of concerted action among manufacturers. The N.Y. Ct. App. in 1982 upheld a $500,000 verdict based on parallel activity in filing an FDA application. Other courts have held that the DES manufacturers did not act jointly in regard to gaining FDA approval to use DES for treatment of problem pregnancies.

Alleged suppression of research/testing/safety information. As noted above, there have been claims of concert of action among DES manufacturers in gaining FDA approval. Plaintiffs allege that the question of harm to the fetus was raised by prior research that was not fully reported to the FDA.

Length of exposure (marketing/sales) period. About 25 years, from about 1947 to 1971 when the FDA banned the use of DES during pregnancy.

Length of latency period (time from exposure to injury). Very lengthy. Alleged injury may not occur until decades after exposure. Alleged DES injuries manifest themselves in the offspring of women who had ingested the drug. Some estimate that new cases will continue to appear for approximately 40 years from 1971, when it was no longer prescribed for use by pregnant women.

Estimated number of users exposed to potential harm. It is estimated that DES was prescribed for millions of women between 1947 and 1971. There are 1.5 million potential litigants, i.e., the children of the women who took the drug.

Trends/current status. No recent reported cases, but cases seem likely to continue

to be filed in a steady stream. Defendants assert that many of the DES cases currently being filed are time-barred.

Product: Felbatol (personal injury claims related to a pharmaceutical used to treat epilepsy)

Information for this report was obtained from published sources supplemented by information from one or more attorneys who represented clients in the litigation.

Individual cases. As of October 1996, Carter-Wallace had been named in 45 actions in state and federal courts alleging injury due to the use of Felbatol, in addition to two federal court cases filed as class actions.

Consolidated cases. MDL only.

MDL pretrial referral. MDL-1048. The MDL panel had consolidated pretrial proceedings in all federal Felbatol cases and transferred them to N.D. Cal. A total of 41 cases have been transferred and one is listed by the MDL clerk as pending as of Dec. 31, 1998. Attorneys for plaintiffs and defendant, however, indicate that there are no pending cases.

Litigation class action. The Felbatol class action was filed before individual lawsuits. The class was certified in N.D. Cal. but then decertified by the Ninth Circuit in *Valentino v. Carter-Wallace*. After the class certification was vacated and remanded, the parties negotiated for about six months and settled more than 200 individual cases. Another class action (*Bryan*) was filed in E.D. Pa. and transferred to N.D. Cal., but not certified.

Settlement class action/mandatory. Nothing reported.

Settlement class action/opt-out. Nothing reported.

Bankruptcies. Nothing reported.

Estimated number of claimants. Approximately 235 Felbatol users asserted claims.

Estimated number of future claimants. None are anticipated.

Estimated number of defendants. Mainly, two: Carter-Wallace, Inc. (manufacturer of Felbatol) and Wallace Laboratories (a division of Carter-Wallace). In some cases, doctors and other health care providers not affiliated with Carter-Wallace were also named.

Ability of defendants to pay judgments. Nothing reported, but not an issue.

Estimated number of federal cases. The two class actions were in federal court, and about 33 individual actions were filed in federal court.

Estimated number of state cases. Approximately 18 actions have been filed in state court.

Estimated number of federal courts with one or more cases. Twenty-five, including those courts in which cases were filed before transfer to the MDL court.

Estimated number of state courts with one or more cases. 17.

Maturity of litigation. Most cases were settled in a group without any prior individual verdicts or settlements, but settlement took place after extensive document discovery and settlement negotiations.

Estimated number and amounts of damage awards including punitive damages. None.

Estimated number and amounts of settlements. After the Ninth Circuit decertified the *Valentino* class, the parties reached a settlement with respect to 184 Felbatol user claims consisting of (1) all the individual claims of the representative plaintiffs in the *Valentino* and *Bryan* classes; (2) certain other individual complaints coordinated in MDL-1048; and (3) other potential claimants represented by plaintiffs' counsel who had not filed cases in federal court. In addition, settlements have been reached in approximately 10 other federal court cases and 10 other state court cases.

Capacity of product to cause injuries (general causation). The FDA required Carter-Wallace to warn doctors in August 1994 of an association between Felbatol and aplastic anemia and in September 1994 of an association between Felbatol and liver disease. A "black box" warning was also required in the package insert provided to the patient.

Types of injuries. Felbatol has been associated with a rare form of anemia (aplastic anemia) in some patients, which can be severe to fatal (12 deaths reported). Felbatol has been associated with liver failure in some patients as well.

Identifiability of causative agent. Nothing reported.

Description of premarket research or testing. Felbatol is used in the treatment of epilepsy. The drug was first marketed in August 1993 following preclinical testing and clinical studies and after FDA approval. The Felbatol package insert listed adverse reactions that were observed during the clinical studies. Carter-Wallace indicated that it received reports in 1994 that some Felbatol users had developed liver failure and aplastic anemia while taking the drug.

Alleged suppression of research/testing/safety information. Plaintiffs accused Carter-Wallace of marketing Felbatol without proper premarket testing. Carter-Wallace claimed that its premarket testing was proper. Plaintiffs also claimed that Carter-Wallace had failed to notify the medical community promptly when it gained information about serious side effects. Carter-Wallace denied this accusation and asserted that it had promptly notified the FDA after hearing reports of the side effects that sometimes developed for patients taking Felbatol.

Length of exposure (marketing/sales) period. The drug was released in August 1993, and Carter-Wallace indicated that reports of aplastic anemia and liver failure first came to its attention in 1994.

Length of latency period (time from exposure to injury). Plaintiffs' attorneys indicate that the latency period is probably 2-6 months. One report indicated that the latency period may be as long as a year.

Estimated number of users exposed to potential harm. At the time of peak use, in July 1994, there were 110,000 patients who had used or were then using Felbatol. After the warning, use reportedly has tapered down to about 10,000 to 13,000 individuals.

Trends/current status. No recent cases have been reported. One case was pending on the MDL docket as of Dec. 31, 1998. A state court case involving aplastic anemia was reportedly pending in Arizona at the end of 1998.

Product: Fen/phen/Redux (claims of heart valve damage and pulmonary hypertension related to use of diet drugs)

Information for this report was obtained from published sources supplemented by information from one or more attorneys who represented clients in the litigation.

Individual cases. Thousands of individual cases have been filed, and thousands more are expected.

Consolidated cases. At least three states (California, New Jersey, and New York) have consolidated their cases for pretrial management.

MDL pretrial referral. In December 1997, the MDL panel consolidated all federal products liability cases against manufacturers of fenfluramine (fen), phentermine (phen), and dexfenfluramine (Redux) in E.D. Pa. for purposes of discovery and pretrial management. As of Dec. 31, 1998, 792 cases have been consolidated in MDL-1203, and 754 of those cases were then pending.

Litigation class action. Litigation class actions for medical monitoring of Texas and Washington state residents were conditionally certified. Similar classes were denied certification in New Jersey and Arkansas. As of September 1998, there were 137 separate class action complaints pending. The MDL transferee judge ordered further efforts to coordinate those cases and to identify common issues and differences.

Settlement class action/mandatory. A proposed limited fund settlement involving Interneuron has been preliminarily approved and scheduled for notice and further hearing. The Plaintiffs' Management Committee filed under seal a motion for (b)(1)(B) certification regarding ten phentermine defendants, but the PMC has indicated that most or all limited fund allegation may be withdrawn without prejudice.

Settlement class action/opt-out. Nothing found.

Bankruptcies. One defendant has filed for bankruptcy.

Estimated number of claimants. Over 3,000.

Estimated number of future claimants. Some surveys have suggested that about one out of every three users of fen-phen-Redux may wind up with heart valve problems—about 2 million potential claimants. Other studies suggest the incidence to

be significantly lower. As noted below, there is no latency period associated with the drugs, and the number of claimants should become known within the applicable limitations periods.

Estimated number of defendants. There are four classes: (1) manufacturers, (2) physicians, (3) pharmacies, and (4) commercial weight loss centers. Within the manufacturers' class, there were at least twelve who produced phentermine (six brand names and six generic) and at least two that produce fenfluramine. Some lawyers are reportedly considering suing the FDA for approving Redux and for allowing fenfluramine and phentermine to be taken together.

Ability of defendants to pay judgments. For some, very high.

Estimated number of federal cases. 673 have been joined in the MDL.

Estimated number of state cases. Thousands

Estimated number of federal courts with one or more cases. One (MDL).

Estimated number of state courts with one or more cases. At least six reportedly have substantial numbers of cases (New Jersey, Pennsylvania, New York, Florida, Texas, and California).

Maturity of litigation. Immature, very young.

Estimated number and amounts of damage awards including punitive damages. No awards found.

Estimated number and amounts of settlements. There have been five or fewer cases settled individually as they came up for trial. Settlement amounts are confidential.

Capacity of product to cause injuries (general causation). A Mayo Clinic study found valvular heart disease in 24 women treated with fen-phen who had no history of cardiac disease. As increasing numbers of these patients with certain levels of cardiac valve regurgitation were identified, researchers reported that there appeared to be an association between these features and fen-phen therapy.

*Types of injur*ies. Heart valve damage, primary pulmonary hypertension (PPH—a lung reaction that is fatal in about half of the reported cases), brain damage, death. Causation of brain damage and death is disputed.

Identifiability of causative agent. The combination of fenfluramine with phentermine appears to be particularly problematic. Fen-phen affects serotonin release and uptake. Some believe that the effects of serotonin include severe regurgitant cardiac valvular disease and pulmonary hypertension.

Description of premarket research or testing. Separately, fenfluramine & phentermine were approved by the FDA over twenty years ago. For a number of years, reports apparently have linked use of anorexigens with primary pulmonary hypertension (PPH).

Alleged suppression of research/testing/safety information. Some plaintiffs assert failure to warn, the making of false statements, fraud, and conspiracy to hide the truth.

Length of exposure (marketing/sales) period. Redux was on the market for about a year. The Fen/phen combination was popular for about three years before it was recalled, but had been used by some practitioners for about ten years. On average, there was a twelve month exposure period for the individuals in the Mayo Clinic study.

Length of latency period (time from exposure to injury). Latency does not appear to be a significant factor in this litigation.

Estimated number of users exposed to potential harm. About 6 million people. Before fenfluramine and Redux were taken off the market, some 18 million prescriptions were written for them.

Trends/current status. Cases were filed recently and are in the pretrial stage.

Product: Heart valve (Bjork-Shilely) (wrongful death and personal injury claims related to a medical device designed to replace a human heart valve)

Information for this report was obtained from published sources supplemented by information from one or more attorneys who represented clients in the litigation.

Individual cases. Before the class settlement, a number of individual suits were brought. At least 27 courts had awarded summary judgment to defendants on the grounds that plaintiffs may not recover for emotional distress alone.

Consolidated cases. None identified.

MDL pretrial referral. No.

Litigation class action. The federal case that was certified for settlement was originally filed as a litigation class action. An earlier federal class action had been denied certification in California. A statewide class action had been filed but not certified in Pennsylvania.

Settlement class action/mandatory. None identified.

Settlement class action/opt-out. Yes, including what has been termed a "back-end opt-out," in which the choice of compensation or suit does not have to be made until after an injury occurs. Under the terms of the settlement, a victim of heart valve fracture could receive somewhere between $500,000 and $2 million, according to a formula that reflected age, income, and family status. All heart valve users were eligible to receive a modest cash sum for emotional distress. Class members retained the right to reject the settlement's formula for a cash award payment and then sue for damages in court, or to opt for binding arbitration to determine fair compensatory damages.

Bankruptcies. None identified.

Estimated number of claimants. Approximately 12,000 individuals filed claims.

Estimated number of future claimants. At the time of the settlement there were an

estimated 40,000 living heart valve recipients and approximately ten percent or fewer might be expected to have claims.

Estimated number of defendants. Two: Pfizer, Inc. and its subsidiary, Shiley (manufacturers of heart valves).

Ability of defendants to pay judgments. High.

Estimated number of federal cases. Most of the 27 summary judgments were in federal courts.

Estimated number of state cases. At least five cases had been filed in state courts.

Estimated number of federal courts with one or more cases. At least three.

Estimated number of state courts with one or more cases. At least two.

Maturity of litigation. Fear of fracture cases were relatively mature at the time of the settlement (most summary judgments for defendants; no plaintiffs awards). Fracture cases were routinely settled for undisclosed amounts.

Estimated number and amounts of damage awards including punitive damages. No reported awards for emotional distress or fracture.

Estimated number and amounts of settlements. All fracture cases settled.

Capacity of product to cause injuries (general causation). Clear that a defective valve can cause serious injuries. Plaintiffs alleged design and manufacturing defects generally, but defendants claimed that their artificial heart valves were no less safe than others on the market.

Types of injuries. Failure of a heart valve is life-threatening and absent emergency surgery will cause death. Some 300 deaths have been reported as a result of heart valve fractures. Emotional distress claims are linked to fear and anxiety arising from the risk of heart valve fracture.

Identifiability of causative agent. Highly identifiable.

Description of premarket research or testing. One commentator reported that despite the occurrence of strut fractures during clinical trials, the FDA approved the Bjork-Shiley heart valve after a short premarket approval process.

Alleged suppression of research/testing/safety information. It has been alleged that Pfizer / Shiley made false statements to the FDA to obtain market approval and later to keep defective Bjork-Shiley mechanical heart valves on the market.

Length of exposure (marketing/sales) period. 1979–1986.

Length of latency period (time from exposure to injury). Basically, the lifetimes of the recipients.

Estimated number of users exposed to potential harm. At the time of the settlement there were an estimated 40,000 living heart valve recipients.

Trends/current status. Settlement approved. Little visible activity.

Product/Service: HIV contaminated plasma derivatives (claims that blood-clotting therapies/substances sold to hemophiliacs were contaminated with the HIV virus)

Information for this report was obtained from published sources supplemented by information from one or more attorneys who represented clients in the litigation.

Individual cases. Hundreds of individual negligence suits involving about 1000 HIV positive claimants were filed nationwide against the four major processors of blood-clotting plasma derivatives.

Consolidated cases. Nothing found other than the MDL consolidation.

MDL pretrial referral. MDL-986. The JPML consolidated 249 products liability claims asserted by or on behalf of hemophiliacs against pharmaceutical companies that allegedly produced blood products contaminated with the HIV virus. The cases were consolidated before Judge John F. Grady (N.D. Ill.) for pretrial proceedings.

Litigation class action. Judge Grady certified a class action on the issue of negligence, with individual liability and damages issues to be resolved on a case-by-case basis. The court of appeals issued a writ of mandamus prohibiting that course of action.

Settlement class action/mandatory. None.

Settlement class action/opt-out. The parties submitted an opt-out settlement class after the court of appeals prohibited the litigation class from going forward.

Bankruptcies. None.

Estimated number of claimants. The class was estimated to include as many as 6,000-7,000 HIV positive hemopheliacs. Approximately 500 opted out of the settlement.

Estimated number of future claimants. Unknown, but a small number because there have been no new primary infections since 1985; there have been a small number of secondary infections (e.g., of sexual partners of HIV positive hemophiliacs).

Estimated number of defendants. There were four major defendants.

Ability of defendants to pay judgments. No information found.

Estimated number of federal cases. There have been about 250 federal cases involving about 500 HIV positive claimants. Currently, there are about 50–75 federal opt-out cases involving as many as 150 claimants.

Estimated number of state cases. There have been about 250 state cases involving about 500 HIV positive claimants. Currently, there are about 100 state opt-out cases involving as many as 200 claimants.

Estimated number of federal courts with one or more cases. Before the MDL consolidation, about 50.

Estimated number of state courts with one or more cases. Before the class settlement, about 50 in about 40 states.

Maturity of litigation. Relatively mature. The first cases were filed in 1985 and

there have been 16 cases tried to verdict, 14 of which were defense verdicts. Two plaintiffs verdicts for $2 million were settled for a smaller, undisclosed amount on appeal. Many more cases have been resolved by settlement and summary judgment (e.g., on statute of limitations grounds).

Estimated number and amounts of damage awards including punitive damages. Two plaintiffs' verdicts for $2 million were settled for a smaller, undisclosed amount on appeal.

Estimated number and amounts of settlements. In the class action settlement, payment of $100,000 per infection was approved by the court. About 6,000 claimants opted in and about 5,800 have been paid as of the end of 1998.

Capacity of product to cause injuries (general causation). General causation does not appear to have been disputed. The issues were whether defendants could have protected against contamination by the HIV virus and whether plaintiffs could prove how and when they were injured and by what defendant's substance.

Types of injuries. HIV, AIDS, death.

Identifiability of causative agent. This would seem to be an issue because there are clearly other causes of HIV infection, and not every lot of the plasma factor was infectious.

Description of premarket research or testing. Plaintiffs alleged that defendants had not screened for and inactivated the hepatitis B virus. Had they done so, they would have, serendipitously, also killed the HIV virus.

Alleged suppression of research/testing/safety information. Nothing found.

Length of exposure (marketing/sales) period. Several years.

Length of latency period (time from exposure to injury). Could be as long as a decade or more.

Estimated number of users exposed to potential harm. In 1995, the number exposed was estimated to be about 10,000.

Trends/current status. Active, but winding down. Opt-out cases are in the process of being remanded from the MDL court to their original courts. State opt-out cases are proceeding. As of Dec. 31, 1998, MDL records indicate that 243 of 249 MDL consolidated cases were pending.

Product: "J" pacemaker leads (personal injury cases related to tendency of polyurethane insulation to break and allow lead wire to puncture heart or aorta)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. At least 456 individual cases in MDL consolidation.

Consolidated cases. See MDL.

MDL pretrial referral. MDL-1057. All federal suits (456 as of Dec. 31, 1998) were

consolidated for pretrial purposes and transferred to Judge S. Arthur Spiegel (S.D. Ohio).

Litigation class action. The transferee court certified a class action, decertified, then recertified a nationwide class with subclasses for claims of medical monitoring, negligence, strict liability, and punitive damages.

Settlement class action/mandatory. In August 1998, Judge Spiegel preliminarily approved a $57.2 million mandatory national class action settlement. The settlement provides up to $1 million for persons who died because the pacemaker leads broke or because of removal or replacement surgery and also provides for medical monitoring costs to patients with leads.

Settlement class action/opt-out. A Canadian opt-out class action settled.

Bankruptcies. None reported.

Estimated number of claimants. At least 456 individual claims have been filed.

Estimated number of future claimants. Up to about 4,500.

Estimated number of defendants. Four, the manufacturing company and its holding company, and two Australian companies.

Ability of defendants to pay judgments. Settled.

Estimated number of federal cases. 456.

Estimated number of state cases. None reported.

Estimated number of federal courts with one or more cases. One.

Estimated number of state courts with one or more cases. None reported.

Maturity of litigation. Immature, but settled.

Estimated number and amounts of damage awards including punitive damages. None reported.

Estimated number and amounts of settlements. A mandatory $57.2 million class settlement has been reported, and a fairness hearing has been scheduled. A class action settlement in Canada reported provided $23.1 million to approximately 1,005 class members; 96 class members opted out.

Capacity of product to cause injuries (general causation). Apparently not disputed. A defective lead bends and can break through the polyurethane insulation of the pacemaker and penetrate the heart or blood vessels. (Telectronic has recalled all unsold leads, set up a program to identify fractures as early as possible, and offered to compensate individuals with fractures.)

Types of injuries. Serious injuries to the heart or blood vessels or, at best, the need for often risky surgery to remove a defective pacemaker.

Identifiability of causative agent. The fractured lead is very identifiable.

Description of premarket research or testing. None found.

Alleged suppression of research/testing/safety information. None found.

Length of exposure (marketing/sales) period. 1988–1994.

Length of latency period (time from exposure to injury). Uncertain.

Estimated number of users exposed to potential harm. There have been 25,000 in-

dividual with "J" wires implanted. The fracture rate is estimated at between 12% and 20%, so the number potentially harmed is expected to be between 3,000 and 5,000.

Trends/current status. Active. All but one of the 456 MDL cases are pending as of Dec. 31, 1998. A fairness hearing on the mandatory class settlement is pending.

Product: Latex gloves (claims that repeated use creates allergic reactions in health care workers)

Information for this report was obtained from published sources supplemented by information from one or more attorneys who represented clients in the litigation.

Individual cases. One article cited 50 individual latex glove cases.

Consolidated cases. There are coordinated proceedings in New Jersey and California state courts. Reports indicate that a block of cases have been set for trial in California in June 1999. In Milwaukee County Circuit Court, there were 34 pending suits against Baxter Healthcare and Smith & Nephew, either individually or together. The parties involved agreed to try a single case before proceeding with the others, which resulted in a $1 million jury verdict for plaintiff.

MDL pretrial referral. In re Latex Glove Prod. Liab. Litig. (MDL No. 1148) consolidated 150 cases in E.D. Pa. for pretrial purposes. As of Dec. 31, 1998, 250 cases had been transferred to that district and 241 were pending.

Litigation class action. A California court denied certification of a statewide litigation class of California healthcare workers who claimed damages resulting from allergic reactions to latex gloves. The court found that individual fact issues predominated. Individual cases were dismissed by the parties.

Settlement class action/mandatory. None reported.

Settlement class action/opt-out. None reported.

Bankruptcies. None reported.

Estimated number of claimants. Not certain, but appears to be at least in the hundreds.

Estimated number of future claimants. No estimates are available. Potential claimants include 950,000 health care workers who are reported to have developed sensitivity to latex gloves and some of whom *may* develop symptoms of allergy.

Estimated number of defendants. There have been 19-20 latex glove manufacturers named as defendants, but a number of defendants obtained dismissal from individual cases during the discovery phase of the MDL proceedings. Baxter HealthCare is the nation's largest latex glove maker.

Ability of defendants to pay judgments. High.

Estimated number of federal cases. The MDL proceedings have involved 250 transferred cases as of the end of 1998.

Estimated number of state cases. There are over 100 state latex glove allergy cases pending.

Estimated number of federal courts with one or more cases. One.

Estimated number of state courts with one or more cases. Courts in 18 states (CA, FL, GA, HA, IA, IL, ME, MI, MN, NJ, NY, OH, OR, PA, TN, TX, WA, and WI) have one or more cases.

Maturity of litigation. Immature, but gaining maturity as cases move through the system.

Estimated number and amounts of damage awards including punitive damages. In a Wisconsin case, plaintiff was awarded $1 million: $34,000 for past medical expenses; $42,000 for future medical expenses; $90,000 for lost earnings; $250,000 for lost future potential earnings; and $584,000 for pain and suffering. A defendant, Smith & Nephew, won a verdict against a single plaintiff in a New Jersey state court. Defendants were granted summary judgment in at least two cases in which plaintiff failed to prove that their products were implicated. A motion to impose a form of market share liability has been denied without prejudice in California.

Estimated number and amounts of settlements. There have been reports of a couple confidential settlements filed under seal in individual cases.

Capacity of product to cause injuries (general causation). Plaintiffs primarily are healthcare workers who allege that they have developed a latex allergy, in some cases severe, as a result of exposure to defendants' natural rubber latex gloves used in their work. Plaintiffs allege that they have been sensitized to and developed latex allergies from exposure to certain proteins in latex gloves which act as allergens.

Types of injuries. Some plaintiffs allege severe allergic reactions. At least 16 fatalities due to latex exposure have been reported to the FDA, but all 16 were related to exposure to barium enema catheters that had some latex components, not to latex gloves. Injuries range from rashes and skin lesions to more serious respiratory ailments, even potentially fatal anaphylactic shock.

Identifiability of causative agent. Exposure allegedly creates severe allergy in some people; however, there are more than 40,000 household products that contain latex, so uncertainty exists over what is causing the sensitivity to latex. In some cases, it is difficult or impossible for a plaintiff to identify which particular latex gloves were used at his or her particular worksite.

Description of premarket research or testing. Nothing reported.

Alleged suppression of research/testing/safety information. In one case, plaintiff's expert alleged that latex allergy had been documented and recognized since 1979 and that severe reactions had been reported in medical literature since 1986. In another case, plaintiff claimed that defendant knew of reactions to latex proteins and had a duty to warn. In the MDL proceedings, some plaintiffs alleged that Health Industry Manufacturers Association (HIMA) played a coordinating role in a con-

spiracy on the part of defendants to obstruct the FDA from intensifying regulation of the manufacture, sale, and labeling of latex gloves.

Length of exposure (marketing/sales) period. Latex gloves have been on the market for decades and are still on the market.

Length of latency period (time from exposure to injury). Definitive latency periods do not seem to have been documented. In one case, exposure for 3 to 4 years was reported before symptoms allegedly appeared; in another case, 13 years elapsed between exposure and alleged injury.

Estimated number of users exposed to potential harm. According to one study, an estimated 950,000 health care workers have developed sensitivity to latex. Another study from the American Academy of Allergy, Asthma and Immunology estimates that latex sensitivity may affect 6% of the U.S. population (about 18 million people). It is important to note that there is a difference between latex sensitivity and latex allergy. A person can become sensitized to latex and begin to produce latex allergen antibodies but never have any symptoms of an allergy. Only an unknown percentage of those who become sensitized ever develop clinical symptoms, such as a rash, and could be considered to have a latex allergy.

Trends/current status. Active. As of Dec. 31, 1998, MDL records indicate that 241 of the 250 transferred cases are pending.

Product: Lead (claims that lead in paint caused injuries, primarily to children, based on effects of lead on their central nervous systems)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. Most lead paint cases were brought as individual law suits.

Consolidated cases. Nothing found.

MDL pretrial referral. None.

Litigation class action. Class actions have been filed against housing authorities and paint and pigment manufacturers, but no successful class actions have been found.

Settlement class action/mandatory. Nothing found.

Settlement class action/opt-out. Nothing found.

Bankruptcies. Nothing found.

Estimated number of claimants. Thousands.

Estimated number of future claimants. Potentially millions, the majority of whom are young children.

Estimated number of defendants. Numerous. Mostly local property owners and landlords, lead paint manufacturers, and local governments.

Ability of defendants to pay judgments. Varies. Some have insurance.

Estimated number of federal cases. Several thousand.

Estimated number of state cases. Several thousand.

Estimated number of federal courts with one or more cases. Cases are dispersed, with some concentration in older cities in the eastern U.S.

Estimated number of state courts with one or more cases. Cases are dispersed, also with some concentration in eastern states.

Maturity of litigation. Relatively mature. Individual cases seem to have established stable values.

Estimated number and amounts of damage awards including punitive damages. Verdicts in individual cases vary markedly. For example, in one case a jury awarded an 8-year-old girl $150,000; in another, a jury awarded an 8-year-old girl $7.8 million; in another, a jury awarded a 12-year-old boy $10 million.

Estimated number and amounts of settlements. Out-of-court settlements are reported to average approximately $500,000 per injured child. In one case, a $2 million settlement was reported. These settlements, of course, may be more visible because of their large amounts. Lower levels of lead poisoning have led to settlements in the $8,000 to $30,000 range.

Capacity of product to cause injuries (general causation). General causation is not disputed. The effects of lead on children have been known for almost 100 years. Lead is a neurotoxin, which can affect a young child's developing central nervous system. It travels throughout the blood stream and is then distributed throughout the bones and soft tissue of the body.

Types of injuries. Lead poisoning, particularly in young children, encephalopathy, convulsions, decreased stature and growth, decreased hearing acuity, decreased fine motor coordination, lowered IQ scores, impaired neurobehavioral development, learning disabilities, and death.

Identifiability of causative agent. Lead levels in a child's blood stream are measurable, but it is difficult to determine where the lead came from because there are multiple sources of lead in the environment. One state has a presumption that high lead levels in children are caused by any lead paint present in the child's current home.

Description of premarket research or testing. Nothing found.

Alleged suppression of research/testing/safety information. Misrepresentation of safety is one of the common claims in lead paint cases.

Length of exposure (marketing/sales) period. More than 100 years.

Length of latency period (time from exposure to injury). Nothing found.

Estimated number of users exposed to potential harm. It has been estimated that approximately 12 million children under the age of five have been exposed to potentially toxic lead levels. One out of every six preschool children has a dangerous level of lead in his or her blood. Lead paint is found in about 57 million occupied private housing units built before 1980. Of that number, 14 million units are be-

lieved to have dangerous peeling and chipping paint, and 3.8 million of those units are occupied by young children.

Trends/current status. Individual cases seem to be ongoing, especially in Boston, New York, and Baltimore. A recent CDC study shows that children's lead levels have been declining in recent years.

Product: MER/29 (miscellaneous personal injury claims related to use of a cholesterol-reduction drug distributed in the early 1960s)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. After voluntary pretrial coordination, cases were resolved through individual trials and settlements in the state and federal courts in which they were filed. Eleven cases were tried; the vast majority were settled.

Consolidated cases. Plaintiffs and defendants both resisted consolidated trials, even intradistrict consolidations. In a number of courts, all of the MER/29 cases were assigned to the same judge, but none consolidated the cases for trial.

MDL pretrial referral. MER/29 suits arose before there was a federal MDL panel.

Litigation class action. None reported.

Settlement class action/mandatory. None reported.

Settlement class action/opt-out. None reported.

Bankruptcies. None reported.

Estimated number of claimants. At least 5,000 people were reportedly harmed by MER/29, and more than 1,500 suits were filed.

Estimated number of future claimants. None anticipated.

Estimated number of defendants. Two: Richardson-Merrell, Inc., and its subsidiary, Merrell.

Ability of defendants to pay judgments. High.

Estimated number of federal cases. Fewer than 750 cases (less than half).

Estimated number of state cases. More than 750 cases (more than half).

Estimated number of federal courts with one or more cases. Not found.

Estimated number of state courts with one or more cases. Not found.

Maturity of litigation. This litigation developed maturity through individual trials.

Estimated number and amounts of damage awards including punitive damages. There were eleven trials. The first three resulted in verdicts for Merrell, but the later cases tended to favor the plaintiffs, prompting Merrell to settle most of the remaining cases. Merrell ultimately paid more than $200 million in damages. MER/29 litigation resulted in the first award of punitive damages in a product liability case, an award of $250,000 in a California state court action.

Estimated number and amounts of settlements. During and after the first eleven

trials, the vast majority of MER/29 cases settled. The total cost of the litigation to defendant was more than $200 million, but the amount of that allocated to settlements is not known.

Capacity of product to cause injuries (general causation). General causation was not disputed.

Types of injuries. Potential side effects discovered in 1961 included cataracts, baldness, and severe dermatitis.

Identifiability of causative agent. Not reported.

Description of premarket research or testing. Between 1956 and 1959, tests were conducted on laboratory animals (rats, dogs, and monkeys) and humans to explore the therapeutic and toxicological effects of MER/29. MER/29 has been criticized as an inadequately-tested product.

Alleged suppression of research/testing/safety information. An FDA investigation in 1962 concluded that Merrell had provided inaccurate animal data to the FDA. Specifically, the company had not told the FDA that two laboratory dogs had developed cataracts even though this fact was noted on their autopsy sheets. In addition, company scientists had altered the results of tests on monkeys and presented falsified data to the FDA. Merrell, its parent company, Richardson-Merrell, and three of Merrell's scientists were indicted under the Federal False Writing Statute for withholding such data from the FDA. The defendants, including Dr. Evert van Maanen, Merrell's director of biological sciences, entered nolo contendere pleas. The firms (Merrell & Richardson-Merrell) were fined a statutory maximum of $80,000, and the scientists received suspended sentences.

Length of exposure (marketing/sales) period. About two years.

Length of latency period (time from exposure to injury). Not long.

Estimated number of users exposed to potential harm. By December 1961, MER/29 had been used by approximately 400,000 individuals.

Trends/current status. Closed. This was one of the first "mass torts." All cases have settled.

Product: Norplant (personal injury claims related to using an implanted long-term contraceptive device)

Information for this report was obtained from published sources supplemented by information from one or more attorneys who represented clients in the litigation.

Individual cases. For the most part, cases have proceeded on an individual or consolidated basis. Since 1993, only one Norplant products liability action has gone to the jury (defense verdict), and 14 cases have resulted in summary judgment for the defendant. One bellwether case involving 5 individual plaintiffs resulted in summary judgment for the defendant and is pending on appeal in the Fifth Circuit.

Consolidated cases. State courts in Alabama, Illinois, Indiana, New Jersey, and Texas have consolidated cases on a statewide or countywide basis.

MDL pretrial referral. Originally, 168 federal lawsuits were consolidated in MDL No. 1038 and assigned to Judge Richard A. Schell (E.D. Tex.). As of Dec. 31, 1998, 3,929 Norplant cases, on behalf of more than 30,000 claimants, had been filed in the MDL and 3,399 of those were pending.

Litigation class action. Class certification was denied in the MDL proceedings in August 1996. State courts in Pennsylvania (1997), New Jersey (1996), Illinois (1996), and California (1994) have denied class certification motions. In January 1998, a West Virginia circuit-court judge decertified a statewide class of Norplant users that he had certified only three weeks earlier (reportedly without briefing or notice to defendants). Louisiana is the only state in which certification issues were reported to be pending.

Settlement class action/mandatory. None found.

Settlement class action/opt-out. None found.

Bankruptcies. None found.

Estimated number of claimants. Reportedly, a total of 53,375 women have sued in federal and state courts. There are more than 3,730 Norplant suits pending in state and federal courts; 8,100 claims have been dismissed, and others have been withdrawn. Approximately 70 of the cases were filed as class actions.

Estimated number of future claimants. Not applicable because there has been no indication that any of the symptoms arguably attributable to Norplants are latent or that they persist for a substantial time after removal of the device.

Estimated number of defendants. Basically, one: American Hope Products Corp. & Wyeth-Ayerst Laboratories, a division of AHP, is the only company that manufactures and sells Norplant systems. Some suits also name the health care providers who inserted the implant, or the Population Council, a non-profit organization that began development of Norplant in 1966 and has tested the device over the next two decades, or Dow Corning France, S.A., which makes the silicone capsules in the original Norplant system, or Leiras Oy, which fills the capsules with the active ingredient (levonorgestrel).

Ability of defendants to pay judgments. High.

Estimated number of federal cases. 3,900.

Estimated number of state cases. 180.

Estimated number of federal courts with one or more cases. One (after consolidation).

Estimated number of state courts with one or more cases. Twenty-six states and the District of Columbia.

Maturity of litigation. There has been one trial: verdict and judgment were for defendant.

Estimated number and amounts of damage awards including punitive damages. None found.

Estimated number and amounts of settlements. None found.

Capacity of product to cause injuries (general causation). Norplant consists of six flexible matchstick-sized, silicone-coated rods that are inserted under the skin of the upper arm and release a synthetic hormone (which has been used in birth control pills for more than 20 years) that prevents pregnancy for up to 5 years, but may be removed at any time. Plaintiffs claim the contraceptive device causes a wide range of adverse side effects. According to defendants, the vast majority of cases focus on routine hormonal side effects, such as headache and weight gain, that are not serious or life-threatening. Claims of more serious effects, such as strokes and blindness, were infrequent. Defendants argue that the side effect commonly alleged are clearly warned about in the package insert and labeling; that doctors who prescribed Norplant were aware of the potential side effects about which plaintiffs complain; and that plaintiffs' symptoms may have been caused by many factors other than Norplant.

Types of injuries. (1) Norplant's alleged side effects cover a wide range, including menstrual irregularities, false menopause, dizziness, nausea, mental depression, nervousness, hair loss, hirsutism, dermatitis, acne, changes in appetite, blood vessel abnormalities, carpal tunnel syndrome, vomiting, blood loss resulting in anemia, increased hemoglobin concentrations, weight gain, fatigue, ovarian cysts, mood swings, anemia, skin discoloration, enlargement of the ovaries or fallopian tubes, headaches, & infection of the implantation site. The most serious claims include blindness, strokes, heart attacks, and brain tumors. Dozens of side effects were listed on the product labeling that was approved by the FDA.

(2) Removal/explantation difficulties include claims of pain, scarring, and nerve damage.

(3) Silicone coating of capsules. Initially there were some claims that Norplant users suffered from the same autoimmune reactions as women who had silicone breast implants. These claims appear to have receded in the face of expert opinion that the small amount of silicone in Norplant had no bearing on alleged injuries. The silicone tubing used for Norplant had previously been used for decades in various medical applications, including hydrocephalus shunts.

Identifiability of causative agent. At this time, causation has not been shown.

Description of premarket research or testing. According to Wyeth, beginning in 1975, Norplant was tested for more than 20 years in at least 55,000 women in 46 countries (including hundreds in the U.S.) before being marketed in the U.S. Testing was done under the direction of the Population Council, a nonprofit organization. Norplant's active ingredient—levonorgestrel—had previously been tested and used, in higher doses, in oral contraceptives. The FDA approved Norplant in 1990.

In 1995 the FDA investigated reports of adverse reactions and found no basis for questioning its safety and effectiveness when used as directed. In 1996 an NIH panel found Norplant safe and effective.

Alleged suppression of research/testing/safety information. None found, although plaintiff attorneys have suggested that Wyeth tried to keep adverse information from potential users by targeting Hispanic women. Defense attorneys dispute that such targeting occurred and note that Wyeth had printed warnings in both Spanish and English.

Length of exposure (marketing/sales) period. Norplant was first sold in the US in 1991. The device is inserted under the skin of the upper arm for up to five years and then surgically removed.

Length of latency period (time from exposure to injury). Adverse reactions, if related to the implant tend to occur soon after they are inserted. The hormone is reportedly out of the system within approximately 96 hours. Both sides agree that even the most serious side effects tend to subside after the device is removed.

Estimated number of users exposed to potential harm. According to Wyeth-Ayerst, about 1 million women in the United States have used Norplant since it was first sold in this country in 1991. Defendants have indicated that more than 800,000 Norplant systems were prescribed and inserted during 1991–1993.

Trends/current status. As of Dec. 31, 1998, 3,399 Norplant cases were pending in the MDL. The litigation appears to be on hold while the Fifth Circuit considers an appeal from Judge Schell's 1997 order granting summary judgment in favor of the defendants in the first bellwether case.

Product: Orthopedic bone screws (personal injury claims related to medical devices used to support spine after surgery)

Information for this report was obtained from published sources supplemented by information from one or more attorneys who represented clients in the litigation.

Individual cases. It is estimated that more than 4,000 lawsuits have been filed against various manufacturers of pedicile bone screws in state and federal courts.

Consolidated cases. A large number of cases have been consolidated in a Tennessee state court.

MDL pretrial referral. In August 1994, the JPML assigned all federal cases to Judge Louis C. Bechtle (E.D. Pa.) who presided over all pretrial discovery. A total of 3,052 cases have been transferred to Judge Bechtle as of Dec. 31, 1998.

Litigation class action. Judge Bechtle denied plaintiff's motion to certify a litigation class action.

Settlement class action/mandatory. Judge Bechtle approved a limited fund class action settlement with Acromed Corp. for $100 million.

Settlement class action/opt-out. None.

Bankruptcies. None.

Estimated number of claimants. In the first motion for class certification, plaintiffs estimated that there were 10,000 claimants. At the settlement approval hearing in 1997, plaintiffs' counsel reported that there were more than 6,000 claimants.

Estimated number of future claimants. None (no latency period).

Estimated number of defendants. There were multiple defendants in "omni" complaints that alleged conspiracy and other claims against all manufacturers of pedicile screws and against a number of doctors and medical societies. Acromed's liability for such claims was included in the settlement class.

Ability of defendants to pay judgments. Limited fund for one defendant. Others are insured.

Estimated number of federal cases. Approximately 3,000

Estimated number of state cases. Many, but number unknown.

Estimated number of federal courts with one or more cases. The Acromed settlement involved claims for about 3,200 plaintiffs, from 85 district courts in 46 states.

Estimated number of state courts with one or more cases. Unknown.

Maturity of litigation. Somewhat mature (not immature).

Estimated number and amounts of damage awards including punitive damages. There were four federal verdicts, two for plaintiffs and two for defendants, averaging $561,500.

Estimated number and amounts of settlements. In October 1997, Judge Bechtle approved a $100 million settlement offered by Acromed for the claims of about 3,200 plaintiffs. Acromed agreed to pay up to $100 million depending on the number of claims actually filed. Before the class settlement, there were 44 settlements involving Acromed, averaging $131,000.

Capacity of product to cause injuries (general causation). Disputed. Plaintiffs claim that screw have broken, causing excruciating pain and further damage to the spine. Defendants claims that preexisting conditions cause the injuries.

Types of injuries. Damage to bones and spinal column, and pain.

Identifiability of causative agent. Screws are implanted during surgery. Product and victim both clearly identifiable from medical records.

Description of premarket research or testing. Acromed claimed that it did not approve of the use of the pedicile screws for the type of surgery involved in the litigation, that it was approved by the FDA for other purposes and was being used by surgeons without the FDA's or Acromed's approval. Plaintiffs alleged that defendant marketed the screws for the surgical uses that caused the injuries. Apparently it was not tested for the uses involved.

Alleged suppression of research/testing/safety information. No.

Length of exposure (marketing/sales) period. Uncertain.

Length of latency period (time from exposure to injury). No longer than four months.

Estimated number of users exposed to potential harm. More than 100,000 Americans had bone screws implanted in the pedicles of their spines by 1994.

Trends/current status. MDL judge approved settlement against one defendant, which has become final. The MDL clerk's office reports that 1,041 cases remain pending as of Dec. 31, 1998. Cases against other defendants are being remanded to transferor courts.

Product: Penile prostheses (products liability and medical malpractice claims related to penile implants)

Information for this report was obtained from published sources supplemented by information from one or more attorneys who represented clients in the litigation.

Individual trials. Approximately 715 individual cases were filed against American Medical Systems, Inc. (AMS) in the last two years. In addition, more that a dozen individual case rulings were identified through published reports. Most reported cases have resulted in summary judgments for the defendants, often on statute of limitations grounds, but in at least one instance on the failure of plaintiff to establish a prima facie case. Several courts have denied summary judgment based on preemption grounds, following *Medtronic v. Lohrs,* but there are no reports of the outcomes of those cases.

Consolidated trials. One group of summary judgments in a single court (E.D. La.) were reported together, and counsel indicates they were consolidated solely for pretrial administration. In Minnesota state court, the judge randomly selected 60 of the 715 cases for full discovery, including plaintiff and spouse depositions, and expert and medical provider depositions. From that 60, the parties selected a total of 20 cases. After full discovery, the cases were to be tried one by one.

MDL pretrial referral. The MDL panel denied plaintiffs' motion to consolidate pretrial proceedings in Sept. 1994 (MDL No. 1020).

Litigation class action. A class action against American Medical Systems, Inc. (AMS) and Pfizer, Inc., was certified in S.D. Ohio on behalf of 15,000 to 120,000 purchasers of AMS penile prostheses, but the Sixth Circuit decertified it. Courts in four other courts (N.D. Cal., E.D. La., and S.D. Ind.) denied class certification, and a motion for class certification has been briefed but not decided in D.D.C.

Settlement class action/mandatory. None reported.

Settlement class action/opt-out. None reported.

Bankruptcies. None reported.

Estimated number of claimants. Outside of the unsuccessful class actions, the number of individual plaintiffs appears to be in the hundreds.

Estimated number of future claimants. Not applicable. There have been no reports of latent defects.

Estimated number of defendants. American Medical Systems, Mentor, Bristol-Meyers Squibb, and Dacomed have been named as defendants in penile prostheses litigation.

Ability of defendants to pay judgments. No information.

Estimated number of federal cases. There are about 15 cases in federal court involving AMS penile prostheses.

Estimated number of state cases. After litigation class actions were denied, class counsel filed a large number of cases in Minnesota state court. There are approximately 25 cases involving AMS prostheses in other state courts. Four cases were reported to be from state courts in California, Pennsylvania, and two unidentified states.

Estimated number of federal courts with one or more cases. About twelve.

Estimated number of state courts with one or more cases. Four or five.

Maturity of litigation. Moderately mature. There have been relatively few trials in the 25 years that AMS has been marketing penile prostheses. AMS has won 5 federal trials and lost 2 and has won 10 state court trials and lost 3. Reported cases show two plaintiffs' verdicts and numerous summary judgments for defendants.

Estimated number of damage awards including punitive damages. There are only two reported damage awards, both of which appeared to involve questions of medical malpractice in removing allegedly defective implants. One award was for $300,000 in Los Angeles in 1993, based on severing of a nerve during surgery to remove a displaced tube, resulting in total sexual dysfunction. The other award was for $1.75 million in Philadelphia in 1995 to a man who underwent six surgeries due to infections and hematomas related to the device.

Estimated number and amounts of settlements. None reported. (In one case, plaintiff reportedly settled for $85,000 but refused to release future claims relating to immune disorders.) There are reports that the lawyers have reached a global agreement regarding settlement of the Minnesota cases, but that agreement is subject to acceptance by the 715 individual plaintiffs.

Capacity of product to cause injuries (general causation). Appears to be highly disputed. Injuries that were compensated were surgical. Plaintiffs have claimed that the silicone used in penile prostheses can cause systemic injuries. DefendantS claim that the *solid* silicone elastomer used in penile prostheses is not comparable to the silicone *gel* used in breast implants. They assert that the FDA recognized the distinction between silicone gel and a solid silicone elastomer when it removed silicone gel breast implants from the market but permitted solid silicone elastomer prostheses—including penile prostheses and saline breast implants encapsulated in a solid silicone elastomer—to remain on the market.

Types of injuries (range/severity). The injuries that were compensated were surgical and they resulted in total sexual dysfunction. Aside from complications relating to surgical implantation of the devices, products liability claims appear to assert that defective products cause physical pain and may have to be surgically removed. Several claimants have alleged autoimmune disease and connective tissue disorders related to the exposure to silicone. One court recently found that a plaintiff's claim was not supported by reliable data and expert testimony and granted summary judgment, which is now on appeal. Other claims have related to infections, abscesses, osteomyelitis, necrosis (one case), and shortening of the penis.

Identifiability of causative agent. Generally not applicable if the implant is the culprit. If silicone is the culprit, it is probably not readily identifiable, but no court has held that the silicone in penile implants, which is in a solid silicone elastomer, is capable of causing systemic diseases.

Description of premarket research or testing. Nothing reported.

Alleged suppression of research/testing/safety information. None reported directly. Sometimes plaintiffs allege a failure to warn about dangers allegedly associated with penile prostheses.

Length of exposure (marketing/sales) period. The products have been on the market for about 25 years.

Length of latency period (time from exposure to injury). No claims of latent injuries due to exposure to a toxic substance have been accepted in court.

Estimated number of users exposed to potential harm. The district court in S.D. Ohio in certifying a class (later decertified by the court of appeals) found that there were between 15,000 and 200,000 purchasers of penile prostheses who might claim damages. A San Francisco newspaper article in 1994 estimated that 300,000 men have undergone penile implant surgery since 1973. It has been estimated that AMS has sold 120,000 products.

Trends/current status. One plaintiffs' attorney reported that most cases do not have sufficient damages to support individual litigation and that denial of class certification nationally and in some states effectively ended the litigation. A large block of cases appear to be close to settlement, leaving a sprinkling of individual cases in the courts.

Product: Radiation (unconnected cases claiming personal injuries resulting from nuclear testing fallout)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. No individual nuclear fallout cases were identified.

Consolidated cases. In *Allen v. United States,* 24 representative plaintiffs had trials that were used to resolve 1,192 claims.

MDL pretrial referral. None.

Litigation class action. For fallout exposure, cases that have been certified as class actions include *In re Fernald Litig., Day v. NLO, In re Three Mile Island, Boggs v. Divested Atomic Corp.,* and *Cook v. Rockwell International Corp.* The first two cases dealt with the alleged negligent release of tons of uranium dust at the Fernald plant in southern Ohio. *In re Fernald,* which was settled in 1989 on behalf of a class of local residents, was certified under Rule 23(b)(1)(A). *Day v. NLO, Inc.* involved a class of former employees, contractors, and frequent visitors to the Fernald plant. It was certified under Rule 23(b)(2) as a medical monitoring class and settled in 1994, with relief in the form of damages and medical monitoring.

Settlement class action/mandatory. None, but note that both litigation class actions were mandatory and ended up as settlements.

Settlement class action/opt-out. Nothing reported.

Bankruptcies. Nothing reported.

Estimated number of claimants. There were 1,192 claims in the *Allen* case. In *Fernald,* the class was estimated as including 14,000 residents. In *Day,* the class was estimated as including 6,000 claimants.

Estimated number of future claimants. Nothing reported.

Estimated number of defendants. The United States was the primary defendant in the *Allen* case. On appeal, the United States was held not to be liable because the testing was deemed to be a discretionary function. In other fallout radiation exposure cases, defendants have included government contractors, such as NLO, Inc., Divested Atomic Corp., Cotter Corp., and Rockwell International Corp. In the *Fernald* settlement, the Department of Energy was the real party in interest.

Ability of defendants to pay judgments. High, at least as to some.

Estimated number of federal cases. At least six.

Estimated number of state cases. Nothing reported.

Estimated number of federal courts with one or more cases. For fallout cases, at least two.

Estimated number of state courts with one or more cases. Nothing reported.

Maturity of litigation. The issue of liability for releasing high levels of radiation seems mature. The question is not quite applicable because these are separate litigations based on different incidents or patterns of radiation fallout.

Estimated number and amounts of damage awards including punitive damages. The original verdict in *Allen v. United States* was in favor of 10 of the 24 bellwether plaintiffs. Awards averaged $295,000 but were reversed by the court of appeals on governmental immunity grounds. In 1998, Congress created a compensation program that provided up to $50,000 for people living downwind from test sites, up to $75,000 for Nevada bomb test site workers, and up to $100,000 for Navajo uranium miners.

In *Fernald*, a jury in a nonbinding summary jury trial awarded $136 million to plaintiffs.

Estimated number and amounts of settlements. In re Fernald Lititg. settled for $73 million, an average of about $5,000 per class member (if all the estimated members submitted claims). *Day v. NLO* settled for $15 million plus medical monitoring costs (estimated at about $5 million).

Capacity of product to cause injuries (general causation). The capacity of large doses of radiation to cause injuries is not disputed.

Types of injuries. Cancer, leukemia, seriously shortened life expectancy, bone marrow failure or suppression, nausea, vomiting, burns, severe and permanent pain, and emotional distress.

Identifiability of causative agent. According to one commentator, radiation exposure as causative agent of an injury is sometimes not easy to prove. The linear energy transfer of a form of radiation is a factor in assessing its potential for causing injury. The higher the frequency, the greater the energy associated with radiation.

Description of premarket research or testing. Not applicable.

Alleged suppression of research/testing/safety information. We did not pursue this highly complex question.

Length of exposure (marketing/sales) period. We did not pursue this highly complex question.

Length of latency period (time from exposure to injury). Not specified, but may be lengthy.

Estimated number of users exposed to potential harm. We did not pursue this issue for the six fallout cases.

Trends/current status. The cases described are settled or closed. New cases may arise from time to time based on different exposures.

Product:

Radiation: Human radiation experiment (HRE) (personal injury cases based on federal experiments testing the effects of radiation on humans)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. At least three radiation exposure cases that have been filed and ruled on individually.

Consolidated cases. Nothing reported.

MDL pretrial referral. Nothing reported.

Litigation class action. In 1994, a proposed class action suit was filed against research doctors, the University of Cincinnati, and the City of Cincinnati.

Settlement class action/mandatory. Nothing reported.

Settlement class action/opt-out. Nothing reported.

Bankruptcies. Nothing reported.

Estimated number of potential claimants. Plaintiffs allege that there were more than 23,000 subjects.

Estimated number of future claimants. Not specified.

Estimated number of defendants. Defendants include the U.S. government, physicians involved in the experiments, private institutions (such as MIT, Pacific Northwest Research Foundation, University of Cincinnati, and University of Rochester), as well as state and local officials who may have been involved in the experiments (such as the City of Cincinnati).

Ability of defendants to pay judgments. Nothing reported.

Estimated number of federal cases. Three cases have been filed.

Estimated number of state cases. None reported.

Estimated number of federal courts with one or more cases. Three.

Estimated number of state courts with one or more cases. None.

Maturity of litigation. Immature.

Estimated number and amounts of damage awards including punitive damages. None.

Estimated number and amounts of settlements. There was a government settlement for $4.3 million, which would pay $36,000 to $66,000 to each family of cancer patients who were given large experimental radiation doses during the Cold War.

Capacity of product to cause injuries (general causation). General causation is not disputed.

Types of injuries. Primary effects of radiation exposure: Cancer, leukemia, seriously shortened life expectancy, bone marrow failure or suppression, nausea, vomiting, burns, severe and permanent pain, and emotional distress.

Identifiability of causative agent. According to one commentator, radiation exposure as causative agent of an injury is sometimes not easy to prove. The linear energy transfer of a form of radiation is a factor in assessing its potential for causing injury. The higher the frequency, the greater the energy associated with radiation.

Description of premarket research or testing. Federal officials, concerned about the exposure of workers to radioactive materials, were reported to have ordered secret radiation tests on the effects of such materials on human metabolism.

Alleged suppression of research/testing/safety information. These allegations concerned radiation experiments conducted on people who were unaware of the fact that they were participating in an experiment involving serious risks.

Length of exposure (marketing/sales) period. HRE allegedly went on for nearly 30 years, beginning in the mid-1940s.

Length of latency period (time from exposure to injury). Not specified, but may be lengthy.

Estimated number of users exposed to potential harm. More than 23,000 subjects

of the HRE. This number does not include the hundreds of "initial radiation releases," in which radioactive substances were emitted into the environment to test human responses.

Trends/current status. One case settled. Reports were not available regarding other cases.

Product: Silicone gel breast implants (varied claims related to product defects, including claims of local injuries as well as systemic injuries)

Information for this report was obtained from published sources supplemented by information from one or more attorneys who represented clients in the litigation.

Individual cases. In addition to the 27,000 MDL cases, there have been thousands of individual actions filed in state courts.

Consolidated cases. Cases in a number of states, including California, New York, and New Jersey have been consolidated for pretrial purposes. In remands of opt-out cases from the MDL transferee court, federal courts in Oregon, Georgia, and New York have consolidated cases. In Oregon, the court entered a tentative ruling for the defendants on causation issues after receiving reports from court-appointed technical advisers and conducting a modified Daubert hearing. That ruling is to be reconsidered after the deposition of the national science panel members, scheduled for April 1999.

MDL pretrial referral. The JPML consolidated the federal cases and transferred them to N.D. Ala. (MDL 926) in 1992. A total of 27,190 have been transferred, and 20,909 are currently pending.

Litigation class action. A Louisiana litigation class action against Dow Chemical went to partial verdict in favor of the plaintiffs, after which the class was decertified.

Settlement class action/mandatory. There has been one limited fund settlement class action approved in the MDL proceedings, and a motion to certify another limited fund settlement class action has been set for hearing on January 11, 1999.

Settlement class action/opt-out. An opt-out class settlement was approved by the MDL transferee judge in 1994, but had to be revised in light of the number of claims that were filed. A revised settlement program, consisting of unilateral offers to settle by three defendants, replaced the original settlement in late 1995.

Bankruptcies. Dow Corning filed for Chapter 11 reorganization after the 1994 class action settlement failed. A proposed joint reorganization plan has been submitted by Dow Corning and the Tort Claimants Committee. Another defendant, Bioplasty, also filed for Chapter 11 reorganization and its reorganization plan has been approved and is being administered.

Estimated number of claimants. The 1994 opt-out settlement attracted in excess

of 400,000 claims, far exceeding the number of anticipated claims which were the basis for establishing payment schedules.

Estimated number of future claimants. Uncertain.

Estimated number of defendants. About seven or eight corporate defendants, plus parent or subsidiary corporations, manufactured silicone gel breast implants and have been named in various cases.

Ability of defendants to pay judgments. Mixed. Two Chapter 11s and two limited fund class action settlements have occurred. Courts have split as to whether Dow Chemical, the parent of Dow Corning is liable for its role in the premarket testing of silicone gel.

Estimated number of federal cases. The MDL panel has counted 27,190 federal cases transferred to N.D. Ala.

Estimated number of state cases. Thousands. California alone was reported to have had 1,800 cases.

Estimated number of federal courts with one or more cases. Consolidated in one court, but now being remanded to a number of other federal districts.

Estimated number of state courts with one or more cases. Uncertain, but concentrations have been reported in California, Texas, New York, and New Jersey.

Maturity of litigation. Relatively mature. Values seem established.

Estimated number and amounts of damage awards including punitive damages. A verdict for $6.5 million in punitive damages and $840,000 in compensatory damages was returned in 1991. Several other multi-million dollar verdicts followed. Combined with an FDA moratorium on breast implants in 1992, these verdicts triggered a substantial outpouring of litigation. A number of more modest verdicts have been returned since then, as have a number of verdicts for defendants. A verdict for $10 million in compensatory damages was returned in Jan. 1999 by a jury in D.C. federal court; post-trial motions and appeals are expected. In December 1998, the Nevada Supreme Court affirmed a verdict for $4.1 million in compensatory damages and reversed an award of $10 million in punitive damages in the same case.

Estimated number and amounts of settlements. There have been a number of major settlements. The first "global" settlement was for $4.225 billion. The limited fund settlements were for $25.8 million and $31.5 million. The term sheet for the July 1998 settlement in the Dow Corning Chapter 11 reorganization was $3.2 billion. Current individual settlements for systemic injuries are reported to be at modest levels.

Capacity of product to cause injuries (general causation). General causation of "systemic" injuries (see below) is highly disputed. In late November 1998 a panel of court-appointed experts in the MDL proceedings concluded that existing scientific data show no consistent association between silicone gel implants and any known

connective tissue disease or other autoimmune or rheumatic conditions. Plaintiffs contend that some studies show statistically significant associations that support their liability claims. Some plaintiffs also claim an atypical disease that is linked specifically to silicone gel.

Types of injuries. Two types of injuries are alleged, "local" and "systemic." Local injuries include encapsulation or capsular contraction, scarring, inflammation, pain, and deformity of the breast. Systemic injuries include changes in the immune system and connective tissue diseases such as rheumatoid arthritis, scleroderma, and lupus. There have also been claims of esophageal dysfunction in children fed by mothers with silicone gel breast implants. Atypical disease claims include those based on symptoms of joint and muscle pain, fatigue, impaired mental concentration, and bowel and urinary problems.

Identifiability of causative agent. Local injuries are directly traceable to the implants. Systemic injuries may have a host of normal causes, raising scientific issues concerning whether the SGBI more likely than not cause such injuries.

Description of premarket research or testing. Plaintiffs and some commentators assert that the premarket testing of silicone gel during the 1940s and 1950s was inadequate. The implants were marketed beginning in 1964.

Alleged suppression of research/testing/safety information. There have been allegations that Dow Corning withheld safety-related information from the FDA. In 1991, a jury in California entered a $7.3 million verdict, consisting mostly of punitive damages. In 1998, the Nevada Supreme Court reversed an award of $10 million in punitive damages against Dow Chemical.

Length of exposure (marketing/sales) period. Approximately 28 years (1964-1992).

Length of latency period (time from exposure to injury). Nothing found on this time.

Estimated number of users exposed to potential harm. Approximately 2 million women, about 20% for postsurgical reconstruction and 80% for cosmetic purposes.

Trends/current status. Major pieces of the litigation seem to be nearing a conclusion. The science panel members are expected to give videotaped depositions in April 1999, and those depositions will be available for use in any pending cases.

Product: Swine flu vaccine (claims of injuries related to the vaccine)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. More than 150 individual actions were brought in federal court. Early in the swine flu litigation, individuals claiming injury were required by statute to proceed through an administrative process already established for claims against the United States government under the Federal Tort Claims Act. Approximately 4,000 claims were filed administratively. The government rejected 2,707 of these

claims and failed to act on most of the other claims within the statutorily required six-month period.

Consolidated cases. MDL consolidation only.

MDL pretrial referral. In 1978, twenty-six federal cases were consolidated and transferred by the JPML panel to D.D.C. for pretrial proceedings. A total of 1,605 cases were ultimately transferred.

Litigation class action. Plaintiff in a swine flu action in S.D. Fla. sought to represent a class consisting of all individuals who have contracted Guillain-Barre Syndrome as a proximate result of having been inoculated with swine flu vaccine.

Settlement class action/mandatory. Nothing reported.

Settlement class action/opt-out. Nothing reported.

Bankruptcies. Nothing reported.

Estimated number of claimants. More than 4,000.

Estimated number of future claimants. Not applicable (no latency period).

Estimated number of defendants. One, the United States, in all but two cases. In those two cases, four pharmaceutical manufacturers and a New York hospital were named. The National Swine Flu Immunization Program of 1976 (42 U.S.C. § 247b(j)–(l)) provided that the United States would assume exclusive liability, with certain limitations, for all personal injuries and/or deaths resulting from the manufacture, distribution, or administration of vaccine under the swine flu program.

Ability of defendants to pay judgments. The Swine Flu Vaccine Program provided some funds for liability; however, by 1985, the cost of settlements and suit judgments was approaching $100 million, far exceeding the budget allotted for the program.

Estimated number of federal cases. At least 1,605.

Estimated number of state cases. Four state cases were identified through an electronic search.

Estimated number of federal courts with one or more cases. At least seven (D.D.C., N.D. Ala., N.D. Cal., E.D. Cal., S.D.N.Y., D. Minn., and D. Hawaii).

Estimated number of state courts with one or more cases. At least four (Michigan, New York, Texas, and California).

Maturity of litigation. Became mature and is now finished.

Estimated number and amounts of damage awards including punitive damages. Unclear; most verdicts or judgments were for the defendants, but there were a few reported cases in which plaintiffs were awarded verdicts.

Estimated number and amounts of settlements. At least 398 cases were settled through the statutory administrative process.

Capacity of product to cause injuries (general causation). Disputed. There was a noticeable increase in the incidence of Guillain-Barre Syndrome (GBS) in the aftermath of the swine flu vaccine; however, plaintiffs had a difficult time proving causa-

tion. An expert testified in one case that the swine flu vaccine can have a demyelinating effect on the sciatic nerve, which can in turn cause drop foot or other paralysis. Another expert conducted several studies concerning the effect of the swine flu vaccine on the immune system and found that 66% of the GBS patients who had been vaccinated demonstrated a positive reaction to both the nerve antigen and the vaccine, whereas only 8% on the non-GBS patients evidenced two positive reactions. This expert also testified that these test results were preliminary and inconclusive. In a Tenth Circuit case, a panel of experts was appointed to assist the trial court in understanding complex neurological and epidemiological issues. *See Gates v. United States*, 707 F.2d 1141 (10th Cir. 1983).

Types of injuries. Guillain-Barre Syndrome, drop foot, paralysis, loss of sensation, and death.

Identifiability of causative agent. Plaintiffs had difficulty proving that the vaccine was the cause of their injuries.

Description of premarket research or testing. Plaintiffs claimed that the swine flu vaccine was an inadequately tested product.

Alleged suppression of research/testing/safety information. Nothing reported

Length of exposure (marketing/sales) period. 1976–1977.

Length of latency period (time from exposure to injury). Short.

Estimated number of users exposed to potential harm. During the winter of 1976–1977, more than 40 million individuals were inoculated with the swine flu vaccine by federal, state, and local authorities and by private physicians as part of a national immunization program initiated by the federal government.

Trends/current status. Finished. There are no pending MDL cases.

Product: Tampons (products liability claims toxic shock syndrome related to using highly absorbent tampons)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. The vast majority of the tampons suits were brought individually. More than 100 individual suits were brought.

Consolidated cases. None identified.

MDL pretrial referral. In 1982, the MDL panel denied motions filed by two groups of plaintiffs to consolidate ninety-two federal cases.

Litigation class action. In 1996, 15 years after tampon use was first associated with Toxic Shock Syndrome, a putative national class action was filed in D. Kan. to deal with the handful of pending cases. Class certification was denied.

Settlement class action/mandatory. None identified.

Settlement class action/opt-out. None identified.

Bankruptcies. None identified.

Estimated number of claimants. Hundreds.

Estimated number of future claimants. None identified.

Estimated number of defendants. At least six tampon manufacturers in the United States and abroad were sued. One magazine was sued unsuccessfully in relation to an advertisement for tampons.

Ability of defendants to pay judgments. High.

Estimated number of federal cases. More than 100.

Estimated number of state cases. Eight were identified in electronic searches.

Estimated number of federal courts with one or more cases. Sixteen were identified in an electronic search.

Estimated number of state courts with one or more cases. Not examined.

Maturity of litigation. This litigation matured enough for cases to settle, but did not grow for some reason despite a number of large verdicts including punitive damages. One theory is that defendants changed their practices as a result of the litigation, cutting off the flow of new cases, given the short latency period.

Estimated number and amounts of damage awards including punitive damages. Most early cases resulted in summary judgment for defendants. In 1983, a verdict for $300,000 was affirmed; in 1986, a California verdict for $100,000 in compensatory and $1 million in punitive damages was affirmed; and in 1987 a verdict for $1.5 million in compensatory and $10 million in punitive was affirmed.

Estimated number and amounts of settlements. None identified, but presumably many of the remaining cases were settled.

Capacity of product to cause injuries (general causation). Disputed. Many courts have accepted that the use of tampons is a substantial factor in occurrence with toxic shock syndrome, but that theory is disputed.

Types of injuries. Toxic Shock Syndrome (TSS). Symptoms include abnormally low blood pressure, fever, nausea, vomiting, reddening of skin, accelerated heartbeat, disquamation, swollen tonsils, and abnormally functioning liver and kidneys. TSS can be fatal.

Identifiability of causative agent. With highly absorbent tampons, it has been shown that the total bacterial count in the interior of the vagina drops markedly during the first days of menstruation (indicating that the tampon absorbs bacteria). When such a tampon is removed, small fibers are sometimes left behind, causing injuries.

Description of premarket research or testing. Super absorbent tampons that caused TSS were reported to be inadequately tested products. For example, before one product was put on the U.S. market, the following "patch test" was conducted: The material from the tampon was put on skin to see if there was any reaction. This was done to 25 female panelists and tested for 72 hours, and the testers concluded that there was no skin irritation. Until a substantial verdict was rendered against it, one major manufacturer reportedly had conducted no studies to ascertain whether the

use of a tampon was in any way related to vaginal infection. By the early 1980s, the first verdicts against tampon manufacturers apparently led to changes, including warnings and the use of more natural fibers—that drastically reduced the number of women stricken with TSS.

Alleged suppression of research/testing/safety information. In a case that resulted in an award of $10 million in punitive damages, the court found that the defendant had deliberately disregarded medical reports and studies linking high-absorbency tampon fibers with toxic shock syndrome while other manufacturers withdrew or modified their high-absorbency products as a result of the information.

Length of exposure (marketing/sales) period. About ten years (mid-1970s to mid-1980s).

Length of latency period (time from exposure to injury). Not long.

Estimated number of users exposed to potential harm. Unclear.

Trends/current status. No current signs of activity.

Product: Temporomandibular joint ("TMJ") implants (injury claims that teflon jaw implants fragmented and caused severe pain and bone and tissue damage)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. More than 250 cases were filed against DuPont/Dow Corning. Thousands had been filed against Vitek.

Consolidated cases. None identified.

MDL pretrial referral. In MDL-1001, a total of 387 federal cases were consolidated in D. Minn.

Litigation class action. None identified.

Settlement class action/mandatory. None identified.

Settlement class action/opt-out. A class action for all Proplast implant recipients was filed in S.D. Tex. against Methodist Hospital, where the developer of Proplast had worked. The hospital agreed to settle the case for $30 million.

Bankruptcies. Dow Corning was responsible for the silicone in TMJ implants and filed a second plan of bankruptcy. Dow Corning agreed to pay up to $2.4 billion over 16 years to resolve all of its personal injury claims, including the TMJ implant claims. Vitek, the manufacturer of problematic TMJ implants, filed for Chapter 7 bankruptcy.

Estimated number of claimants. More than 2,300.

Estimated number of future claimants. Could be as many as 25,000 who have had such implants.

Estimated number of defendants. Vitek, manufacturer of the problematic implant, filed for bankruptcy liquidation. Dow Corning filed for bankruptcy reorganization.

Plaintiffs have sued DuPont, manufacturer of raw materials (teflon) in implants, Dow Chemical, parent of Dow Corning, Methodist Hospital (where the developer of Proplast had worked), Duke Hospital, and many independent physicians and medical centers.

Ability of defendants to pay judgments. Vitek, the manufacturer of TMJ implants, ran out of assets and insurance coverage and went bankrupt. The inventor of TMJ implants lives in Switzerland. Plaintiffs sued teflon supplier DuPont, whose ability to pay judgments is high.

Estimated number of federal cases. The MDL consolidation included 387 cases.

Estimated number of state cases. About 15 state cases were identified through an electronic search.

Estimated number of federal courts with one or more cases. One.

Estimated number of state courts with one or more cases. Courts in Texas, Missouri, New Mexico, and Georgia have published cases.

Maturity of litigation. Never matured. Aside from claims against Vitek, most cases have been dismissed on legal grounds.

Estimated number and amounts of damage awards including punitive damages. The MDL transferee judge dismissed all TMJ suits against DuPont, claiming that the "raw material defense" precludes DuPont's liability and dismissed all suits against Dow Chemical. The court also dismissed claims against other parent corporations because plaintiffs could not "pierce the corporate veil." The 8th Circuit affirmed both decisions.

Estimated number and amounts of settlements. One reported: Methodist Hospital's $30 million class action settlement distinguished two types of claims. Category A included class members who probably would be time barred under Texas law. They received payments of $1,500 each. Category B included all other class members. They received payments ranging from $15,000 to $100,000 each.

Capacity of product to cause injuries (general causation). TMJ implants, made out of teflon, were reportedly almost certain to break due to the weakness of the teflon. Once broken, they disintegrated into fragments, worsening the condition of TMJ and leading to further jaw bone deterioration.

Types of injuries. Irritation of human tissue, painful tissue irritation, foreign body response, progressive bone degeneration, severe pain, and further jaw bone deterioration.

Identifiability of causative agent. Highly identifiable by the nature and location of the product and the location of the injuries.

Description of premarket research or testing. This was an inadequately tested product. Teflon was not strong enough to keep TMJ implants in place. Reportedly, Dr. Homsy, founder of Vitek, invented Proplast material (used in TMJ implants) in 1968 using DuPont teflon. Dr. Kent studied Proplast for years and declared it a suc-

cess in 1982. DuPont sent Vitek a policy statement that Teflon was not intended for medical devices and that Vitek should proceed with caution. DuPont informed the manufacturer that teflon was tested only for industrial use. Further, DuPont warned Vitek of a study that reported that teflon caused harm when used in hip replacements on dogs. Vitek acknowledged this study and concluded that it was inapplicable to Proplast.

Alleged suppression of research/testing/safety information. Plaintiffs claimed that DuPont failed to warn users about dangers posed by the use of teflon in medical implants.

Length of exposure (marketing/sales) period. 1983-1991.

Length of latency period (time from exposure to injury). Seven years was the longest reported latency period.

Estimated number of users exposed to potential harm. More than 25,000 people had received teflon TMJ implants produced by Vitek, Inc.

Trends/current status. Appears to be finished. There are no cases pending in the MDL consolidation.

Product: Thalidomide (claims that a pharmaceutical sedative increased the risk of birth defects when taken during pregnancy)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. Thirteen individual thalidomide suits were brought in the United States.

Consolidated cases. Nothing reported.

MDL pretrial referral. Thalidomide suits were brought before the MDL panel existed.

Litigation class action. In Japan, thalidomide plaintiffs brought class actions against two drug manufacturers and the Ministry of Health and Welfare. Defendants ultimately admitted liability.

Settlement class action/mandatory. Nothing reported.

Settlement class action/opt-out. Nothing reported.

Bankruptcies. Nothing reported.

Estimated number of claimants. At least 17 babies in the United States were born with defects attributable to thalidomide. Merrell reached settlements on all suits brought against it.

Estimated number of future claimants. Not applicable.

Estimated number of defendants. One in the United States—Merrell, later Merrell Dow Pharmaceuticals (manufacturer). Others in Germany, Great Britain, and Japan.

Ability of defendants to pay judgments. No reported problems.

Estimated number of federal cases. Not found.

Estimated number of state cases. Not found.

Estimated number of federal courts with one or more cases. At least two.

Estimated number of state courts with one or more cases. At least two.

Maturity of litigation. Cases settled without apparent need for jury verdicts.

Estimated number and amounts of damage awards including punitive damages. Richardson-Merrell was charged with distributing thalidomide in the United States, leading a California jury to award punitive damages in a total verdict of $2.75 million. The trial judge had ordered a remittitur, and the two parties eventually settled for $600,000.

Estimated number and amounts of settlements. Merrell reached settlements in all of the thalidomide suits brought against it in the United States. Some settlements were as high as $1 million, and most were for $100,000 or more. One commentator estimates that Merrell may have paid as much as $50 million in thalidomide settlements.

Capacity of product to cause injuries (general causation). General causation was not disputed.

Types of injuries. Severe birth defects, including arm and leg deformities, missing and deformed limbs, and limb reduction (phocomelia). Thalidomide also affected the development of a number of organs, including the heart, kidney, and digestive tract. Other side effects included peripheral neuritis, constipation, nausea, dizziness, tingling, numbness, weakness, or muscular pain in limbs.

Identifiability of causative agent. Because it was a prescribed drug, a mother's use of thalidomide was highly identifiable and its linkage to specific injuries seems to have been undisputed.

Description of premarket research or testing. By most accounts, thalidomide was an inadequately tested product. Early animal tests failed to detect the teratogenic effects of thalidomide, in part because they used species of animals unaffected by the drug. Harmful effects on human fetuses were not apparent in the animal testing. Several children were born with birth defects in the United States during a clinical testing program.

Alleged suppression of research/testing/safety information. Chemie Gruenthal, the German company that manufactured and marketed thalidomide, reportedly denied all causal connection between thalidomide and peripheral neuritis, tried to conceal the number of injuries that had been reported to the company, tried to suppress publication of reports about thalidomide-induced peripheral neuritis and to obtain favorable reports of thalidomide.

Length of exposure (marketing/sales) period. About five years (1957-1961).

Length of latency period (time from exposure to injury). No more than ten months.

Estimated number of users exposed to potential harm. Richardson-Merrell had sent out about 2.5 million thalidomide pills to more than 1,200 American physicians throughout the United States (and particularly in California), for what it described as testing on about 20,000 patients. Thalidomide was widely marketed in Europe, but the FDA had not approved it for sale in the United States. As a result of their mothers having ingested thalidomide during pregnancy, an estimated 7,000 to 12,000 babies with serious birth defects were born worldwide.

Trends/current status. Closed. No current cases.

Product: Tobacco (claims for personal injuries, addiction, medical monitoring, and health care reimbursement based on use of tobacco products)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. Tobacco litigation began in the late 1950s. During the late 1950s to early 1960s, more than 100 individual personal injury/product liability suits against tobacco companies were filed and resolved in favor of the defendants. Tobacco litigation subsided for a while, but a new wave of individual action arose again in the 1980s.

Consolidated cases. Forty-one states have sued the tobacco companies seeking reimbursement of money spent treating sick smokers. A number of these cases have come up for trial and have settled.

MDL pretrial referral. None.

Litigation class action. Numerous litigation class actions have been filed. Several have been certified, but none to date have survived appellate review.

After the decertification of the *Castano* class, plaintiffs filed statewide class actions throughout the country and joined forces with attorneys general and governmental authorities in an increasing number of states to assert equitable and injunctive claims for restitution and disgorgement of profit against the tobacco companies. The tobacco companies have attempted to remove most, if not all, of these state court actions to federal court. Class certification status is mixed. Most cases have not been certified as class actions; three cases in Florida, Maryland, and Louisiana have certified class actions. Trial began in Oct. 1998 in the Florida class action.

Settlement class action/mandatory. A proposed national settlement required action by Congress which does not appear likely.

Settlement class action/opt-out. In Florida, a class action settlement was approved in a case brought on behalf of current and former flight attendants who suffered exposure to secondhand tobacco smoke in airline cabins.

Bankruptcies. None.

Estimated number of potential claimants. The *Castano* class would have consisted of an estimated 50 million people alleged to be nicotine-dependent.

Estimated number of future claimants. Unknown.

Estimated number of defendants. About ten, including the seven largest tobacco companies in the United States (American Tobacco Co., Liggett Group, Inc., Brown & Williamson Tobacco Corp., R.J. Reynolds Tobacco Co., Philip Morris & Co., Lorillard, Inc., and RJR Nabisco), the Tobacco Institute, the National Association of Manufacturers, and US Tobacco Sales & Marketing Co. In addition, there are various holding groups and parent corporations that are sued, as well as local distributors of tobacco products.

Ability of defendants to pay judgments. Very high.

Estimated number of federal cases. Hundreds. Much of the tobacco litigation has taken place in federal courts, but after *Castano* there appears to be a shift towards more state litigation.

Estimated number of state cases. At least 100, including the statewide class actions filed after Castano.

Estimated number of federal courts with one or more cases. At least 30.

Estimated number of state courts with one or more cases. At least 14, including Alabama, California, District of Columbia, Florida, Illinois, Indiana, Louisiana, Maryland, Minnesota, Mississippi, New Jersey, New York, Ohio, Tennessee, and Texas.

Maturity of litigation. Novel theories seem to have created a continuing wave of immaturity, as shown in the Castano court's holding regarding claims of addiction. With a few exceptions, individual injury trials have resulted in verdicts for defendants.

Estimated number and amounts of damage awards including punitive damages. In two verdicts won by tobacco litigation plaintiffs, one awarded the plaintiff $400,000, but this amount was set aside on appeal. In another case a jury awarded the plaintiff $750,000.

Estimated number and amounts of settlements. In early 1998, the tobacco industry agreed to settle a Texas lawsuit for $15.3 billion over the next 25 years. Also in 1998, the tobacco companies agreed to settle cases with 41 attorneys general and create a compensation fund worth $300 billion to $375 billion over a 25-year period, but the requisite congressional enactment has not materialized. State cases for health care costs have been settled as they arise. As noted above, the flight attendants class action was settled.

Capacity of product to cause injuries (general causation). Evidence of carcinogenicity of tobacco is strong. Thousands of tobacco company internal documents that became available in 1994 provided support for plaintiffs' assertion that tobacco is an addictive drug.

Types of injuries. Smoking-related injuries include lung cancer, throat cancer, other cancer, emphysema, Buerger's disease, birth defects in offspring, and death. The *Castano* plaintiffs asserted economic loss related to the injury of nicotine addiction.

Identifiability of causative agent. Identifying which particular brand of cigarettes caused a particular plaintiff's injuries is difficult, especially with respect to second-hand smoke and with respect to plaintiffs who have been exposed to other agents which cause similar injuries, such as asbestos.

Description of premarket research or testing. Not applicable.

Alleged suppression of research/testing/safety information. Thousands of tobacco company internal documents became available in 1994 and provided support for plaintiffs' assertion that tobacco is an addictive drug. Plaintiffs allege that the tobacco companies attempted to suppress documents implicating the tobacco companies in an effort to conduct, control, and ultimately suppress the results of systematic research into the addiction-producing characteristics of nicotine, and to manipulate nicotine levels to maintain and increase cigarette sales and profits. Very recently, it was asserted that the tobacco industry paid thirteen scientists more than $156,000 for writing letters and manuscripts to discredit studies linking second-hand smoke to lung cancer, including a 1993 EPA report.

Length of exposure (marketing/sales) period. More than 100 years.

Length of latency period (time from exposure to injury). Varies, but is usually fairly lengthy.

Estimated number of users exposed to potential harm. Estimates are that approximately 50 million persons in the United States are nicotine-dependent, and that at least 350,000 Americans die each year from smoking-related injuries.

Trends/current status. Ongoing group litigation, mostly statewide actions for health care costs and addiction class actions. An undetermined number of individual claims seem to be proceeding on a regional basis.

Part I-B
Individual characteristics of personal injury mass tort case congregations based on a single event or location

Event: Air Crash at Chicago's O'Hare Airport in 1979 (wrongful death and personal injury claims)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. There were about 22 individual trials. There appear to have been 16 verdicts on the state level and about 6 on the federal level, but it is unclear how many MDL cases resulted in a trial, and the number above could be somewhat larger.

Consolidated cases. Whether California consolidated its cases for pretrial proceedings is unclear.

MDL pretrial referral. The Judicial Panel transferred a total of 170 cases to N.D. Ill. in August 1979.

Litigation class action. None.

Settlement class action/mandatory. None.

Settlement class action/opt-out. None.

Bankruptcies. None.

Estimated number of claimants. There were close to 300 claimants: 281 passenger and crew members died in the crash. Two persons on the ground were killed and several others were seriously injured. In addition, the crash caused substantial property damage. The scope of that damage and the number of claimants is unknown.

Estimated number of future claimants. Not applicable. It is highly unlikely there will be any future claimants because of the contained nature of the event.

Estimated number of defendants. Usually at least two parties were sued, American Airlines and McDonnell Douglas, but the number varied and California cases generally included parts manufacturers.

Ability of defendants to pay judgments. High.

Estimated number of federal cases. There were a total of 170 cases in the MDL proceedings.

Estimated number of state cases. There were at least 70 cases and probably more at the state level.

Estimated number of federal courts with one or more cases. At least two (N.D. Ill. and S.D.N.Y.). Other federal courts may have had cases remanded back from the MDL court; in all, 45 cases were remanded.

Estimated number of state courts with one or more cases. Only one state court, the Superior Court of Los Angeles, was found to have had cases.

Maturity of litigation. Closed after full maturation.

Estimated number and amounts of damage awards including punitive damages.

There were at least 16 verdicts in state court and 4 in the federal courts. Two awards, for $250,000 each, were not contested. The remainder of the awards either went through remittitur or were appealed. The final amounts could not be determined. For example, an award of $3 million dollars was reversed and remanded for a new trial on damages. A trial judge ordered a $4.15 million award remitted to $3.15 million to bring it into line with other verdicts in similar cases. The 7th Circuit barred punitive damages for federal cases based on a choice of law ruling. In addition, many plaintiffs waived their right to claim punitive damages in exchange for defendants' stipulation of liability.

Estimated number and amount of settlements. There were between 200 and 300 settlements. Most federal cases were settled. At least 107 cases in the Northern District of Illinois were known to have settled, and there were indications that the majority of transferred cases settled. No state settlements was reported.

Capacity of product to cause injuries (general causation). The National Transportation Safety Board found that the airline improperly maintained the aircraft. There was a crack in the assembly that lead to the left engine falling off during takeoff. In addition, the NTSB found that McDonnell Douglas defectively designed the airplane.

Types of injuries. Plaintiffs' claims included wrongful death, pain and suffering, loss of decedent's society, and bodily injury (for those on the ground).

Identifiability of causative agent. The causes of the crash were limited to two identifiable defendants. The NTSB found both negligence on the part of the airline and defective design on the part of the manufacturer.

Description of premarket research or testing. Nothing was found on this point.

Alleged suppression of research/testing/safety information. Nothing was found on this point.

Length of exposure (marketing/sales) period. Nothing was found on this point.

Length of latency period (time from exposure to injury). Not applicable.

Estimated number of users exposed to potential harm. Around 300, including passengers, crew members, and people on the ground.

Trends/current status. Closed. The MDL clerk's office reports that there were no cases pending as of the end of 1998.

Event: Air Crash—Detroit Metropolitan Airport-1987 (wrongful death and personal injury claims)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. Several individual cases were filed in state courts, and 160 individual actions were filed in four federal courts against Northwest Airlines and McDonell-Douglas Corp. (MDC), the manufacturer. There were various third and

fourth party complaints for indemnification and contribution, especially between MCD and Northwest. There was also a claim by Northwest that National Car Rental was liable for placement of a lamppost in violation of FAA regulations. The estate of a flight officer sued National Car Rental on the same theory and included a claim against Wayne County Michigan for allowing the lamppost to obstruct the flight.

Consolidated cases. See MDL, below.

MDL pretrial referral. One hundred and sixty federal actions were consolidated, transferred, and assigned to Judge Julian Abele Cook, Jr. in E.D. Mich. (MDL No. 742). Before trial, Judge Cook granted a motion to transfer for trial in his court all MDL cases originating in other districts. Cases filed later would be permitted to "opt-in" to the joint trial. The trial plan called for three stages: (1) a joint liability trial involving claims of all nonsettling plaintiffs against Northwest and MDC, (2) damages trials to set compensation for individual plaintiffs, and (3) a second liability trial to determine the third-party claims.

Litigation class action. None.

Settlement class action/mandatory. None.

Settlement class action/opt-out. None.

Bankruptcies. None.

Estimated number of claimants. 170, including estates of 156 who died in the crash, one survivor, and a number of bystanders.

Estimated number of future claimants. None. Not applicable.

Estimated number of defendants. The two main defendants were Northwest and McDonnell Douglas. Texas Instruments, National Car Rental, the United States, and Wayne County were also named as defendants in one or more cases.

Ability of defendants to pay judgments. Very high.

Estimated number of federal cases. Between 156 and 170.

Estimated number of state cases. Judge Cook mentioned in an opinion that there were "several" state cases.

Estimated number of federal courts with one or more cases. Before the MDL, four. After MDL transfer, Judge Cook granted a motion to transfer all cases to his court for trial.

Estimated number of state courts with one or more cases. Nothing found on point.

Maturity of litigation. Cases settled before trial verdict on liability, but value of injury claims in air crashes has been determined in other airplane crash litigation.

Estimated number and amounts of damage awards including punitive damages. All individual cases settled before verdict. The jury held that Northwest had been negligent and granted subrogation rights to MDC.

Estimated number and amount of settlements. Judge Louis C. Bechtle (E.D. Pa.) served as a settlement judge in the MDL proceedings. Before trial, Northwest entered into "damage only" settlements with sixty passengers. The airline agreed to

stipulate liability and the plaintiffs agreed not to seek punitive damages. Sixteen other cases in which Northwest had a special defense (i.e., Warsaw Convention, Workmen's Compensation, and exculpatory provisions) were settled as well. The final amounts are unknown. MDC also reached an agreement with these special defense parties for $25 million. However, MDC sought and received $21 million in indemnity from Northwest for those claims. Finally, on the threshold of trial, Northwest settled with eighty remaining claimants for an estimated amount that ranged between $150 and $200 million. MDC settled with the same claimants in the midst of trial but did not seek contribution and indemnity from Northwest. Those amounts are also unknown. A newspaper report at the time said that payments ranged from $500,000 to $4,000,000, the latter being for the sole survivor, who was four years old at the time of the crash, and the former for the estate of a Phoenix Suns basketball player. The average award was estimated at $1.5 million per passenger, much higher than the averages in similar cases.

Capacity of product to cause injuries (general causation). The jury found that the plane crashed because of the flight crew's negligence. The crew failed to follow checklists mandated by the FAA and Northwest. As a result, the flaps were not properly set for takeoff. The crew also had disconnected the power to a system that could have warned the crew about the flaps.

Types of injuries. Death for 154 passengers and 2 bystanders. Physical and emotional injuries for the sole survivor and the other bystanders.

Identifiability of causative agent. Expert testimony was required to determine whether the airline, the manufacturer, or some other entity caused the crash.

Description of premarket research or testing. Not applicable.

Alleged suppression of research/testing/safety information. Nothing found.

Length of exposure (marketing/sales) period. Not applicable, given the jury determination that the crew's negligence caused the crash.

Length of latency period (time from exposure to injury). None.

Estimated number of users exposed to potential harm. Approximately 170.

Trends/current status. The last case, an individual claim against National Car Rental and Wayne County, was resolved on July 7, 1997, when the court granted summary judgment for the defendants. As of Dec. 31, 1998, there were no cases pending in MDL 742.

Event: Airline Crash—Everglades, 1972 (wrongful death and personal injury claims)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. Two cases were scheduled for trial on the federal level. On the eve of trial, Eastern Airlines admitted liability and the rest of the cases settled. It is unclear how many cases were filed in state courts.

Consolidated cases. Nothing found regarding state consolidation.

MDL pretrial referral. A total of 65 cases were consolidated in S.D. Fla. by the Judicial Panel on Multidistrict Litigation. Several cases were transferred from S.D.N.Y.

Litigation class action. Nothing found.

Settlement class action/mandatory. Nothing found.

Settlement class action/opt-out. Nothing found.

Bankruptcies. Nothing found.

Estimated number of claimants. Claims were filed by 191 passengers and crew members aboard the plane. More than 150 of claimants participated in the civil actions held in federal court. The remaining claimants were involved in the state action. (See Fifth Circuit opinion)

Estimated number of future claimants. It is highly unlikely there will be any future claimants because of the limited nature of the event and the fact that all passengers and crew members or their families filed claims.

Estimated number of defendants. Two, Eastern Airlines and Boeing Corp.

Ability of defendants to pay judgments. High.

Estimated number of federal cases. More than 150.

Estimated number of state cases. Approximately 40.

Estimated number of federal courts with one or more cases. One

Estimated number of state courts with one or more cases. One or two.

Maturity of litigation. Post-mature. Claims settled without need for trials.

Estimated number and amounts of damage awards including punitive damages. None reported.

Estimated number and amounts of settlements. Around 191. No information on the amounts of the settlements was found.

Capacity of product to cause injuries (general causation). Not an issue. Airline conceded liability after discovery.

Types of injuries. The civil actions were based on wrongful death and personal injuries. No further information on the severity of the injuries was found.

Identifiability of causative agent. Not an issue in this case, at least not after discovery.

Description of premarket research or testing. Nothing found.

Alleged suppression of research/testing/safety information. Nothing found.
Length of exposure (marketing/sales) period. Not applicable.
Length of latency period (time from exposure to injury). Virtually none.
Estimated number of users exposed to potential harm. 191.
Trends/current status. Case closed. Initial cases were resolved within a year.

Product: Albuterol (wrongful death and personal injury claims relating to a contaminated batch of an allergy drug)

Information for this report was obtained from published sources supplemented by information from one or more attorneys who represented clients in the litigation.

Individual cases. A large number of individual cases were identified in addition to the major class action suit against Copley Pharmaceuticals.

Consolidated cases. One state case had eight plaintiffs.

MDL pretrial referral. In June 1994, the JPML consolidated about 85 federal cases brought against Copley Pharmaceuticals, Inc., and transferred them to Judge Clarence A. Brimmer (D. Wyo.). As of Dec. 31, 1998, a total of 115 cases had been transferred.

Litigation class action. Judge Brimmer certified the cases to proceed as a class action as to certain issues.

Settlement class action/mandatory. None reported.

Settlement class action/opt-out. A class settlement was announced 42 days after the trial began in August 1995. Copley agreed to pay out a minimum of $65 million and a maximum of $150 million to settle the class action (although they did not admit liability); close to 2,000 claimants opted out of the class after certification and before the settlement was announced. A substantial number of those claimant opted into the class after the settlement.

Bankruptcies. None reported. One insurer declared bankruptcy but had issued a letter of credit to cover its layer of liability.

Estimated number of claimants. The total claims against the settlement are estimated to be up to 5,600.

Estimated number of future claimants. No estimates available, but future claims are unlikely. Injuries were based on bacterial contamination.

Estimated number of defendants. Copley Pharmaceuticals was the only defendant in the class action, but various vendors were named in separate lawsuits. Claims against vendors are released as part of the class settlement.

Ability of defendants to pay judgments. All but 15% of the settlement was covered by Copley's insurance. Copley and its insurers presented letters of credit sufficient to cover their maximum obligations under the settlement.

Estimated number of federal cases. All federal lawsuits were consolidated under *In Re Copley Pharmaceuticals.*

Estimated number of state cases. Two additional state cases were reported.

Estimated number of federal courts with one or more cases. One.

Estimated number of state courts with one or more cases. Two.

Maturity of litigation. Closed before maturation. There was a $65–150 million settlement approved by the federal district court between *In Re Copley* and thousands of claimants. No prior verdicts were found. At least one settlement of a lawsuit was indicated as were hundreds of settlements of claims made directly to the company or its insurers.

Estimated number and amounts of damage awards including punitive damages. No verdicts reported either before or after the class settlement.

Estimated number and amounts of settlements. The class settlement was valued at up to $150 million, depending on the number of claims. Before the class settlement, the company had settled a number of claims that were not filed in court. These claimants became members of the class, with their prior settlement acting as an offset against their claim to a share of the class settlement.

Capacity of product to cause injuries (general causation). Although Copley believes that contamination of several lots of the asthma medication was restricted and relatively harmless, plaintiffs claimed that the bacteria in the contaminated albuterol made them sick and in some cases was fatal.

Types of injuries. Injuries alleged were pneumonia, bronchitis, and exacerbation of asthma or chronic obstructive pulmonary disease; 400-500 death claims were presented in the class settlement.

Identifiability of causative agent. Several batches of albuterol produced by Copley were found to be contaminated with bacteria; Copley recalled 4 million vials of the drug.

Description of premarket research or testing. Not applicable.

Alleged suppression of research/testing/safety information. Copley alleges that it promptly recalled millions of vials of the drug upon discovery of widespread contamination.

Length of exposure (marketing/sales) period. Contaminated batches of albuterol were found in Nov. 1993, confirmed in Dec. 1993, and an initial recall was begun in Dec. 1993. The recall was completed in Jan. 1994.

Length of latency period (time from exposure to injury). The settlement established a threshold of a diagnosis within 14 days of purchase of the product.

Estimated number of users exposed to potential harm. Copley said contamination of their albuterol was limited to 118,000 vials of the 4 million recalled.

Trends/current status. The class settlement was approved, and settlements with all but two or three of the opt outs have been completed. The J.P.M.L.'s clerk's office reports that 96 of the 115 transferred cases remain pending as of Dec. 31, 1998, but that appears to be because the parties have not filed the papers to dismiss the cases.

Initial payments of $10,000 were made, pending the disposition of internal appeals. Second payments are being made as of Jan. 1999.

Product: Hyatt Skywalk cases (personal injury cases related to the collapse of hotel skywalks in 1981)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. After the collapse and prior to consolidation, there were more than 140 individual lawsuits filed involving claims for both compensatory and punitive damages. Individuals who opted out from the final class action settlement also brought individual suits.

Consolidated cases. The state court cases were consolidated and assigned to one judge, as were the federal cases.

MDL pretrial referral. Nothing reported.

Litigation class action. In 1981, a Missouri district court certified a class of all persons injured by the collapse of two Hyatt skywalks in Kansas City, Mo. In 1982, however, this certification was overturned by the Eighth Circuit.

Settlement class action/mandatory. Nothing reported.

Settlement class action/opt-out. The Hyatt Skywalk cases were ultimately settled by means of opt-out settlement class actions in state and federal courts.

Bankruptcies. Nothing reported.

Estimated number of claimants. Estimates of the number of claimants in the federal class action ranged from 1,500 to 2,500. Approximately 2,000 to 2,500 persons were present in the Hyatt lobby at the time the two skywalks collapsed.

Estimated number of future claimants. Not applicable.

Estimated number of defendants. Eleven, including several major corporations and a number of local architects and building contractors.

Ability of defendants to pay judgments. Some defendants had enough assets and insurance coverage to pay the judgments. Others asserted in the federal class action that their net worth was minimal or negative.

Estimated number of federal cases. By the end of 1982 and prior to consolidation, there were 18 cases filed in district court.

Estimated number of state cases. By the end of 1982 and prior to consolidation, there were approximately 120 cases filed in state court.

Estimated number of federal courts with one or more cases. One.

Estimated number of state courts with one or more cases. One.

Maturity of litigation. Closed after maturation. Single incident; cases matured in tandem.

Estimated number and amounts of damage awards including punitive damages. No reports of jury verdicts prior to the class settlements were found. Subsequent to the

settlements, two opt-out plaintiffs reportedly received verdicts of $4 million and $15 million.

Estimated number and amounts of settlements. Prior to class certification, 123 claims had been settled for a total of $18.5 million. Under the opt-out class action settlement, the defendants were willing to settle any plausible claim for at least $1,000. Approximately $150 million was committed to the payment of compensatory damages. In addition, Hallmark (owner of the Kansas City Hyatt) agreed to pay a minimum of $6.5 million to charity for four years, and Crown Center agreed to create a fund of $3.5 million for the payment of supplemental compensation to those class members who arbitrate or try their damage claims, and for attorneys' fees and expenses. State court cases were settled for $20 million in punitive damages to be apportioned among all the plaintiffs and compensatory damages to be worked out for each victim in subsequent negotiations.

Capacity of product to cause injuries (general causation). Not applicable. Plaintiffs alleged negligence in design, construction, and inspection of the skywalks.

Types of injuries. There were reports that 114 people were killed and 269 others injured in various ways.

Identifiability of causative agent. No direct information found.

Description of premarket research or testing. Not applicable.

Alleged suppression of research/testing/safety information. Not applicable.

Length of exposure (marketing/sales) period. Not applicable.

Length of latency period (time from exposure to injury). Not applicable.

Estimated number of users exposed to potential harm. Approximately 2,000 to 2,500 persons were present in the Hyatt lobby at the time of the collapse.

Trends/current status. Litigation concluded in the mid-1980s.

Product: Kepone (personal injury, environmental, and economic loss claims relating to a pesticide allegedly dumped into James River)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. The federal government brought three separate criminal cases. In the main case, filed in May 1976, Allied Chemical Corp. was charged with 940 violations of the Refuse Act and the Federal Water Pollution Control Act for discharging kepone and two other chemicals (TAIC and THEIC) into the James River between 1971 and 1974 without a permit.

Hundreds of personal injury and other damage claims were filed against Allied. Claims of Life Science employees, their families, and others sought about $85 million. Approximately 400 fishers, alleging that their livelihood was impaired by the closing of the James River and Chesapeake Bay, filed claims for $24 million.

Consolidated cases. Some of the claims summarized above appear to have been consolidated.

MDL pretrial referral. None found.

Litigation class action. A class action suit was brought against Allied on behalf of some 10,000 fishers and some 500 others in marine-related businesses, claiming damages of $25 billion was filed as a litigation class, but later settled. Plaintiffs included commercial fishers, marinas, seafood wholesalers, and the like. A group of stockholders sued Allied's board of directors, claiming it had violated its responsibilities in its handling of the kepone matter.

Settlement class action/mandatory. None found.

Settlement class action/opt-out. None found.

Bankruptcies. Life Science Products Co., the company that produced kepone for Allied Chemical in 1974–1975, became insolvent after the state of Virginia ordered it to close down its kepone plant.

Estimated number of claimants. About 10,500 persons alleging to have been harmed by the kepone incident sought damages in excess of $25 billion.

Estimated number of future claimants. None found.

Estimated number of defendants. Primarily four: Allied Chemical Corp., Life Science Product Corp., and the two owners of Life Science Product Corp. Also Allied's insurer, The Travelers Indemnity Co., and Hooker Chemicals & Plastic Corp., a patent owner and producer of the chemical substance HCP, the essential toxic raw material for kepone, were involved.

Ability of defendants to pay judgments. Allied Chemical had net sales of $2.33 billion in 1975 and was able to pay damages and voluntarily decontaminate the Life Science site (at a cost of nearly $1 million); moreover, Allied had insurance to cover many of the claims. Life Science, however, became insolvent when the Virginia Health Department ordered its plant closed, and it was financially incapable of remedying the consequences of the kepone incident (it had only $32 in assets).

Estimated number of federal cases. Three.

Estimated number of state cases. Several dozen.

Estimated number of federal courts with one or more cases. One (E.D. Va.).

Estimated number of state courts with one or more cases. One (Virginia).

Maturity of litigation. There were no civil jury verdicts. Civil liability apparently flowed from the evidence used to support the criminal proceedings which resulted in nolo contendere and guilty pleas.

Estimated number and amounts of damage awards including punitive damages. None found.

Estimated number and amounts of settlements. Allied Chemical reportedly settled dozens of lawsuits brought by workers & neighbors (including local commercial fishers, marina owners, restaurant owners, etc.) with total payments amounting to

more than $15 million. In addition, Allied settled for $5,250,000 (in addition to nearly $1 million it had spent to clean up the LSP plant site) all the claims of the Commonwealth of Virginia and the City of Hopewell for kepone-related costs that these governments had incurred, including penalties. Allied also set up an $8 million fund to alleviate other damages.

Capacity of product to cause injuries (general causation). (1) Health: At the time of the James River dumping, kepone was recognized as a contact and nerve poison capable of being absorbed through the skin or cuticle. Today kepone is known as a carcinogen, neurotoxin, and hepatotoxin (causing liver damage) and is believed to harm reproductive and immune systems.

(2) Environmental damage: Kepone is lipophilic (fat-soluble) but insoluble in water; it accumulates in fatty tissues of fish and other animals. Kepone residues contaminated fish, oysters, sediments, and waters of the James River and its tributaries, resulting in the closing of almost 100 miles of the James River to fishing. Kepone remains embedded on the river bottom. The only available technique to remove it (dredging at an estimated cost of at least $2 billion) has been considered potentially even more destructive to the natural resources than the kepone has been. Expert estimates of the length of time the kepone will remain in the river sediment range from decades to centuries.

(3) Economic loss to interests dependent on the natural environment (e.g., fishers, marina/charter boat owners, seafood industry) occurred as a result of kepone's damage to the James River and Chesapeake Bay ecology.

Types of injuries. The results of contact include loss of control over muscular coordination, convulsions, DDT-like tremors, and possibly death.

Identifiability of causative agent. Because it accumulates in fatty tissues, kepone exposure is identifiable in humans as well as fish.

Description of premarket research or testing. Kepone was invented in the later 1940s by an Allied chemist. Allied's initial testing showed kepone to be highly toxic to all species tested and to cause cancer, liver damage, and reproductive system failure, and to inhibit growth and muscular coordination in fish, mammals, and birds. Allied subsequently withdrew its petition to the FDA for establishment of kepone residue tolerances for agricultural products, ensuring that kepone would not be used in the United States. During its development and manufacture of the pesticide, Allied prepared detailed operating instructions for internal use and submitted studies to the USDA. The manuals developed for internal use evidence a substantial knowledge of the dangers of contact with human skin, cuticle, lungs, and other organs.

Alleged suppression of research/testing/safety information. Despite documented adverse effects of kepone on animals and the fact that Allied's operating manuals called for the use of respirators and gloves by kepone handlers as well as showers and change of clothing before leaving the plant, Allied apparently discounted the

possibility that human exposure to kepone might cause acute poisoning. A witness for the United States at the federal trial testified that Allied should have suspected "that the same symptomology would be induced in man if exposed to kepone."

Life Science either failed to follow or ignored safety precautions required for the safe manufacture and handling of kepone.

In addition, Allied and LSP failed to report the discharge of kepone as required by federal water-pollution legislation. An Allied memo obtained in discovery strongly implied that kepone had been omitted in Allied's application for permits for the discharge of effluents because of fears that the company would be required to install expensive water-treatment equipment or to suspend production.

Length of exposure (marketing/sales) period. Allied Chemical produced kepone in commercial quantities at its Hopewell, Va., facility and secretly discharged kepone and other chemical wastes directly into the James River from 1966 until 1974.

Length of latency period (time from exposure to injury). Serious medical problems (including sterility and tremors) appeared within 16 months or less of serious human exposure in the early 1970s. Medical researchers estimate that, as a carcinogen, Kepone has a latency period of two to three decades.

Estimated number of users exposed to potential harm. In addition to the approximately 70 employees at the Life Science Products plant, approximately 700 people resided within a one-mile radius and 24,000 resided in the City of Hopewell. Some 30,000 commercial fishers, marina owners, boat, tackle and bait shop, seafood wholesalers, retailers, processors, distributors and restauranteurs suffered commercial and economic losses as a result of environmental damage to the James River and the Chesapeake Bay.

Trends/current status. Closed. No recent activity.

Event: L'Ambiance building collapse during construction—April 1987 (personal injury and wrongful death claims)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. More than eight months after the building collapsed, fewer than 10 state and federal lawsuits had been filed, but observers expected that in 1988 more than 200 additional state and federal lawsuits and more than 1,000 crossclaims, counterclaims, and other causes of action would be instituted by more than 80 parties.

Consolidated cases. In January 1988 a settlement mediation panel was formed and all state and federal pending lawsuits were stayed and transferred to the mediation panel "for settlement purposes only." U.S. District Judge Robert C. Zampano and Connecticut Superior Court Judge Frank S. Meadow were the mediators. Motions to lift the stays were denied, no additional lawsuits were commenced, and even

the OSHA administrative hearings in Boston came to a halt. The panel apparently, though, sought to mediate claims that had not been formally filed.

MDL pretrial referral. Nothing reported.

Litigation class action. Nothing reported.

Settlement class action/mandatory. Nothing reported.

Settlement class action/opt-out. Nothing reported.

Bankruptcies. Texstar Construction Corporation, the subcontractor hired to install the floor, filed for bankruptcy. However, it unclear the nature of the bankruptcy. TMPI/Macomber, the general contractor, eventually went out of business but apparently did not file for bankruptcy.

Estimated number of claimants. There were 44 personal injury claimants, representing 28 dead and 16 injured construction workers, who could file personal injury actions. Apparently, only 10 claimants filed suit before all claims were settled 19 months after the accident.

Estimated number of future claimants. None.

Estimated number of defendants. While the initial number of defendants named in the ten cases was only six, 70 potential defendants participated in settlement discussions. The mediation panel divided defendants into three groups to assist in allocating contributions to the settlement fund. Group I included the parties primarily responsible for the collapse (owner/partnership, general contractor, Texstar, the architects, the suppliers of concrete, Fairfield Testing Lab, the city of Bridgeport and the Connecticut Housing Finance Authority). This group contributed insurance coverage as well as some personal assets. Group II represented those parties who could possibly be liable for the collapse. Its contribution was a percentage of total policy limits. Group III consisted of those with no potential liability. Its contribution was limited to estimated defense costs based on the likelihood they would be brought into future litigation.

Ability of defendants to pay judgments. As noted, the general contractor and a subcontractor went into bankruptcy. Other defendants had insurance coverage and the panel limit assessments

Estimated number of federal cases. About five.

Estimated number of state cases. About five.

Estimated number of federal courts with one or more cases. One.

Estimated number of state courts with one or more cases. One.

Maturity of litigation. Settled pre-maturation, without any verdicts.

Estimated number and amounts of damage awards including punitive damages. No awards.

Estimated number and amount of settlements. A settlement of $34,809,528 was reached for the 44 workers or their estates. The amount exceeded $41 million, including the equity of the building, when the commercial claims were settled.

Capacity of product to cause injuries (general causation). Not disputed.

Types of injuries. Death, physical injuries, and emotional distress.

Identifiability of causative agent. In constructing the building, concrete slabs, designed to serve as flooring, crashed onto the lower floor when the spearheads, an anchoring device, failed to support the 1,000-ton slabs as they were being lifted into place. When the slabs fell, the walls of the building collapsed and crushed the workers. The "lift-slabbing" method is not the standard method in the construction business in installing concrete floors. The general method is to pour concrete slabs at their final position instead of creating the floor sections on the ground and then hoisting them into place. The lift-slabbing method in comparison to the standard method, however, is cheaper. OSHA determined that the main cause was that the spearhead had been over-stressed by an excess load. In addition, contributing to the building's collapse was failure to anchor the jacks, inadequate bracing, and the use of substandard material. Others theorized that the collapse was due to faulty engineering design. Still others blamed the accident on excessive water beneath the soil. Finally, one other theory was based on the weakness of the concrete. The mediation panel, due to all these alternative theories, concluded that there were multiple causes.

Description of premarket research or testing. Not applicable.

Alleged suppression of research/testing/safety information. Two months before the accident, concrete slabs slipped from the anchors because of overburdened or failed spearheads. The contractor repaired the problem but failed to seek out the cause of the mishap. In addition, at another site operated by the same contractor a year before, a falling slab almost caused the same chain reaction of the L'Ambiance disaster. Fortunately, one of the overburdened spearheads jammed against the slab, preventing a free fall that would have created the same chain-reaction collapse.

Length of exposure (marketing/sales) period. The collapse of the building took less than ten seconds.

Length of latency period (time from exposure to injury). Not applicable.

Estimated number of users exposed to potential harm. 44, all the people who were working in the building when injured.

Trends/current status. The cases were settled a little more than 19 months after the building collapsed. The global settlement included workers' compensation, OSHA, commercial, insurance, and individual personal injury claims in federal and state courts.

Product: L-Tryptophan (wrongful death and personal injury claims relating to a dietary supplement containing an alleged chemical contaminant)

Information for this report was obtained from published sources supplemented by information from one or more attorneys who represented clients in the litigation.

Individual cases. There were many individual lawsuits. Most of the federal cases wound up being consolidated by the JPML and many of the state cases did also. One L-Tryptophan distributor sued its supplier (Showa Denko) for the cost of pulling the products from circulation. There have also been reports of L-Tryptophan arbitration proceedings.

Consolidated cases. All the L-Tryptophan cases in Minnesota have been consolidated before a single judge. In California, plaintiffs successfully fought overall consolidation of the state cases. In most California counties, the cases were "coordinated" for purposes of discovery. Twenty-five claimants filed a consolidated lawsuit against forty-eight defendants in state court in Cleburne, Tex.

MDL pretrial referral. MDL-865. All 951 federal cases were consolidated for pretrial proceedings in D.S.C. before District Judge Matthew J. Perry.

Litigation class action. One plaintiff 's lawyer tried to get a class certified, but failed.

Settlement class action/mandatory. None.

Settlement class action/opt-out. None.

Bankruptcies. None.

Estimated number of potential claimants. Approximately 1,500 cases of illness and at least 38 deaths allegedly resulting from L-Tryptophan use were reported to the Centers for Disease Control.

Estimated number of future claimants. As of 1992, only a few claimants known to Showa Denko America, a defendant, had not filed suit in any court.

Estimated number of defendants. More than 300 defendants were included in the MDL consolidation. Showa Denko had an estimated 60–70% market share in the production of L-Tryptophan. Other defendants included Solgar Co., GNC, Twin Labs, Walgreen Co., Triarco Corp., Revco Drug Stores, Bio-Energy Inc., Contract Pharmacal Corp., Windmill Natural Vitamin Co., Garden State Nutritionals, Pharnavite Corp., Naturite Products, Inc., and Fred Meyer.

Ability of defendants to pay judgments. The one final judgment in a California state court has been paid. Virtually all other cases have been dismissed, arbitrated, or otherwise settled.

Estimated number of federal cases. Probably at least 1,000. As of 1992, approximately 1,800 lawsuits had been filed in state and federal courts in at least 43 states, including D.C, and Puerto Rico.

Estimated number of state cases. Probably at least 2,000. As of 1992, approximately

1,800 lawsuits have been filed in state and federal courts in at least 43 states, including D.C. and Puerto Rico.

Estimated number of federal courts with one or more cases. D.S.C. had the consolidated cases from about 50 districts.

Estimated number of state courts with one or more cases. More than 40.

Maturity of litigation. Post-mature. A small number of cases have been filed in recent years.

Estimated number and amounts of damage awards including punitive damages. A California state court jury awarded $1.05 million against Showa Denko to a woman who became seriously ill after taking L-Tryptophan. Another California state jury rendered a defense verdict. No punitive damages have been awarded in any proceeding. An arbitration panel ordered Showa Denko to pay $2 million to four claimants. Approximately 15 cases have been arbitrated.

Estimated number and amount of settlements. Nothing reported.

Capacity of product to cause injuries (general causation). Disputed. Center for Disease Control studies have indicated that there is a cause and effect relationship between L-Tryptophan and a serious blood disorder (EMS). Plaintiffs have cited epidemiological studies that linked L-Tryptophan to EMS. However, defendants assert that no one has been able to identify the precise cause of the disease.

Types of injuries. Eosinophilia-Myalgia Syndrome (EMS) is the main set of injuries, which can be fatal. Symptoms include severe muscle pain, a marked thickening of the skin, fatigue, dyspnea, and blood counts well out of the normal range. Most of the 38 reported fatalities resulted from pulmonary hypertension or ascending polyneuropathy.

Identifiability of causative agent. In the trial verdict reported above, plaintiffs used statistical evidence to link the product to plaintiff's injuries.

Description of premarket research or testing. L-Tryptophan was marketed for decades and generally thought to be safe. The Showa Denka product was tested in animals and exceeded the recognized analytical standards for purity. In the fall of 1989, doctors in New Mexico reported a possible association between the ingestion of L-Tryptophan and the onset of a series of medical conditions, later defined as EMS.

Alleged suppression of research/testing/safety information. Nothing reported.

Length of exposure (marketing/sales) period. 1974–1989.

Length of latency period (time from exposure to injury). Nothing reported.

Estimated number of users exposed to potential harm. It was estimated that by late 1989 approximately 5 million persons were taking L-Tryptophan on a regular basis.

Trends/current status. A small number of late-filed cases remain pending in the MDL proceedings and in state courts. As of Dec. 31, 1998, there were 9 cases pending in the MDL consolidation.

Product: MGM Grand Hotel Fire in 1980 (personal injury and wrongful death claims)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. In the early stages of the litigation, individual lawsuits were filed across the United States, in numerous federal and state courts.

Consolidated cases. MDL (below) was the only consolidation found.

MDL pretrial referral. MDL-453. In May 1981, the JPML transferred all federal court actions to D. Nev., consolidated them for pretrial purposes, and assigned them to Judge Louis C. Bechtle (E.D. Pa.). The panel referred a total of 429 separate actions during the course of the litigation.

Litigation class action. Nothing found.

Settlement class action/mandatory. Nothing found.

Settlement class action/opt-out. Nothing found.

Bankruptcies. Nothing found.

Estimated number of claimants. At least 1,357.

Estimated number of future claimants. None.

Estimated number of defendants. 118.

Ability of defendants to pay judgments. High.

Estimated number of federal cases. 1,357.

Estimated number of state cases. Unknown.

Estimated number of federal courts with one or more cases. One (MDL transferee court).

Estimated number of state courts with one or more cases. Two (California and Nevada).

Maturity of litigation. Closed after maturation. Matured through aggregate settlement negotiations, including reviews of individual claims by district judge and special master's mediation on a defendant-by-defendant basis.

Estimated number and amounts of damage awards including punitive damages. Nothing reported

Estimated number and amounts of settlements. Nothing reported prior to "global settlement" of $134 million in 1983.

Capacity of product to cause injuries (general causation). Not disputed at a general level, but individual defendants disputed claims that they contributed to the injuries and damages.

Types of injuries. As a result of the fire and heavy smoke and gases, eighty-four persons died in various locations in the casino and hotel. More than 1,000 persons suffered injuries due to smoke inhalation and hundreds of others suffered sprains, broken bones and lacerations in escaping the fire.

Identifiability of causative agent. Disputed. Multiple causes included available fuels, building arrangement, and the lack of adequate fire barriers.

Description of premarket research or testing. Not applicable.

Alleged suppression of research/testing/safety information. Nothing found.

Length of exposure (marketing/sales) period. Not applicable.

Length of latency period (time from exposure to injury). None or very short.

Estimated number of users exposed to potential harm. An estimated 3,400 guests plus a number of employees were in the hotel when the fire broke out.

Trends/current status. Completed. There were no MDL cases pending as of Dec. 31, 1998.

Product: Salmonella-contaminated ice cream (personal injury claims)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. Twenty-five individual lawsuits were filed around the country. The company (Schwan) also sued its supplier and transporter.

Consolidated cases. None found.

MDL pretrial referral. None found.

Litigation class action. Three were filed, in California, Illinois, and Minnesota. The Minnesota case was certified and an opt-out settlement was approved.

Settlement class action/mandatory. None found.

Settlement class action/opt-out. See litigation class, above.

Bankruptcies. None found.

Estimated number of potential claimants. 28,000 (which may include 4,600 customers who reportedly declined to make claims).

Estimated number of future claimants. Few expected. Of 219 opt-outs, few filed claims immediately, but the statute of limitations for negligence is six years in Minnesota.

Estimated number of defendants. One.

Ability of defendants to pay judgments. No problems indicated. Defendant was insured.

Estimated number of federal cases. None.

Estimated number of state cases. Twenty-nine.

Estimated number of federal courts with one or more cases. None.

Estimated number of state courts with one or more cases. At least three.

Maturity of litigation. Closed before maturation. Cases were resolved for actual damages or a minimal payment, without waiting for trials or verdicts.

Estimated number and amounts of damage awards including punitive damages. None.

Estimated number and amounts of settlements. About 28,000. Approximately 14,600

claims or potential claims were settled for a total of $3.55 million by claims representatives or the insurer without litigation. Many settled for $25. The remaining 13,000+ claims were received in the class action and payments will range from $80 to $75,000 plus medical expenses and lost earnings.

Capacity of product to cause injuries (general causation). Stipulated. The company admitted that a batch of its ice cream was contaminated.

Types of injuries. Mostly diarrhea and nausea. A few people reported more serious injuries, including a few miscarriages, a number of leukemia patients who became very ill, and several people who were hospitalized for up to 20 days.

Identifiability of causative agent. Stipulated. In addition, the product was generally delivered to the home, so the identity of potential claimants was known for the most part.

Description of premarket research or testing. Company had a contingency plan for dealing with such a crisis, including prompt warnings, product recalls, and cooperation with public health officials in uncovering the cause of the contamination (a delivery tanker that had previously delivered raw, unpasteurized eggs).

Alleged suppression of research/testing/safety information. None found.

Length of exposure (marketing/sales) period. A few weeks, and many of those products were recalled and replaced with certificates.

Length of latency period (time from exposure to injury). Nothing found, but presumably brief for the most common injuries such as diarrhea and nausea.

Estimated number of users exposed to potential harm. There were an estimated 32,000 people in Minnesota alone. Many thousands more in other states were exposed to the contaminated ice cream.

Trends/current status. No recent activity reported. Most of the litigation was settled within 13 months of the incident, which occurred in October 1994.

Product: Salmonella-contaminated milk (personal injury claims)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. Numerous individual claims were filed prior to the class action, and a number opted out of the class settlement.

Consolidated cases. All cases appear to have been consolidated in an Illinois state court.

MDL pretrial referral. Nothing found.

Litigation class action. An Illinois court used an opt-opt class action for punitive damages (*In re Salmonella Litigation*). The case resulted in an opt-out class settlement with Jewel Companies Inc.

Settlement class action/mandatory. Nothing found.

Settlement class action/opt-out. See litigation class action, above.

Bankruptcies. Nothing found. The dairy that supplied the milk was closed permanently about three months after the outbreak.

Estimated number of claimants. Approximately 15,800

Estimated number of future claimants. None. Opt-out class defined number of claims.

Estimated number of defendants. One.

Ability of defendants to pay judgments. No apparent problems.

Estimated number of federal cases. None reported.

Estimated number of state cases. About 15,800 individual claims were consolidated in one court and treated as a class.

Estimated number of federal courts with one or more cases. None.

Estimated number of state courts with one or more cases. One (Illinois).

Maturity of litigation. Closed before maturation. Claims settled with few trials.

Estimated number and amounts of damage awards including punitive damages. There was one reported award of $490,000 for a family of three. No other awards were found.

Estimated number and amounts of settlements. Most of the 15,800 claims settled.

Capacity of product to cause injuries (general causation). There is no question that salmonella can cause dysentery and other temporary intestinal injuries. Defendant stipulated as to liability for such injuries. There were 78 claims for reactive arthritis; the company disputed causation for those injuries, which it described as rare.

Types of injuries. Dysentery, joint pain, reactive arthritis.

Identifiability of causative agent. Stipulated as to minor injuries.

Description of premarket research or testing. Nothing found.

Alleged suppression of research/testing/safety information. Nothing found.

Length of exposure (marketing/sales) period. About two months (March to April 1985).

Length of latency period (time from exposure to injury). Apparently quite short.

Estimated number of users exposed to potential harm. An estimated 120,000 people became ill after drinking tainted milk, but reportedly only about 10% sought medical treatment.

Trends/current status. Closed; no recent activity found.

Event: San Juan Hotel Fire—December 31, 1986 (personal injury and wrongful death claims)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. On Jan. 5, 1987, the first individual complaint related to this matter was filed. A number of individual lawsuits had been filed before MDL con-

solidation. The judge used trial of twelve representative cases to establish values for the other cases.

Consolidated cases. There were more than 2,500 parties involved in this litigation. Because of the great number of parties, a consolidated discovery procedure was instituted in the district court (D.P.R.).

MDL pretrial referral. MDL-721. In May 1987, the MDL panel consolidated more than 270 cases arising out of the San Juan Dupont Plaza Hotel fire. In all, a total of 286 cases were consolidated and transferred to Judge Raymond L. Acosta (D. P.R.).

Litigation class action. Nothing reported.

Settlement class action/mandatory. Nothing reported.

Settlement class action/opt-out. Nothing reported.

Bankruptcies. Nothing reported.

Estimated number of claimants. Ninety-seven people were killed and 100 injured in the blaze. There were nearly 1,000 guests in the hotel. Overall, the number of claims has been estimated at 2,300.

Estimated number of future claimants. None.

Estimated number of defendants. More than 200, including the hotel, insurers, carpet and drapery suppliers, and other contractors.

Ability of defendants to pay judgments. Nothing reported.

Estimated number of federal cases. More than 270.

Estimated number of state cases. No information found.

Estimated number of federal courts with one or more cases. Complaints were filed in a large number of federal courts, but ultimately transferred to D. P.R.

Estimated number of state courts with one or more cases. One.

Maturity of litigation. Injury cases may have been mature in other contexts.

Estimated number and amounts of damage awards including punitive damages. There were as least two trials in the MDL consolidation. A Phase I trial, which involved complex alter-ego theories regarding the interests and liability of various entities, ended in a settlement during its ninth week. The products and services defendants liability was addressed in Phase II trial; 9 of 89 defendants went to verdict and a jury found 4 of the 9 liable for damage claims presented by 10 of 12 representative plaintiffs. The balance of the cases settled before the damages trials of the remaining 2,300 plaintiffs began.

Estimated number and amounts of settlements. A total settlement fund of approximately $220 million was established. Judge Louis C. Bechtle (E.D. Pa.) served as a settlement judge.

Capacity of product to cause injuries (general causation). The immediate cause of the fire seems clear. Three hotel employees pleaded guilty in April 1987 to a federal charge of "arson that interfered with interstate commerce" by setting the San Juan Hotel fire. They allegedly set the fire with canned fuel. Claims against the defen-

dants related to products and designs that might have retarded the spread of the fire.

Types of injuries. Primarily personal injuries and death from burns and smoke inhalation.

Identifiability of causative agent. Secondary causes are many and may be difficult to distinguish.

Description of premarket research or testing. Nothing found.

Alleged suppression of research/testing/safety information. Nothing found.

Length of exposure (marketing/sales) period. Not applicable.

Length of latency period (time from exposure to injury). None. Not applicable.

Estimated number of users exposed to potential harm. There were nearly 1,000 guests.

Trends/current status. Although the cases appears to have been settled and closed, MDL records indicate that 279 of the 286 transferred cases remain pending as of Dec. 31, 1998.

Product: Toxic waste disposal at the Stringfellow site in Glen Avon, Riverside County, California (wrongful death and fear of cancer claims)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. Seventeen individual test cases were consolidated into one trial.

Consolidated cases. Seventeen individual test cases were consolidated into one trial.

MDL pretrial referral. None found.

Litigation class action. None found.

Settlement class action/mandatory. None found.

Settlement class action/opt-out. None found.

Bankruptcies. None found.

Estimated number of claimants. Approximately 4,000–5,000 residents of Glen Avon, the town principally affected by the toxic waste site, were part of the consolidated litigation.

Estimated number of future claimants. Some portion of the claimants could have additional claims if they develop cancer or other latent diseases as a result of their exposure.

Estimated number of defendants. There were twenty-six defendants, including the State of California (which designed, licensed, and supervised the facility), the operator of the site, and twenty-four companies that disposed of waste at the facility.

Ability of defendants to pay judgments. No apparent problems.

Estimated number of federal cases. There was one related federal case, a suit by the

United States and the State of California against operator and users of the site seeking contributions to the cost of cleaning up the site.

Estimated number of state cases. There was one consolidated case.

Estimated number of federal courts with one or more cases. One.

Estimated number of state courts with one or more cases. One.

Maturity of litigation. Closed after maturation. All of the cases have settled against all of the defendants.

Estimated number and amounts of damage awards including punitive damages. All but two defendants settled before trial. California and one small manufacturer-defendant remained for the trial. The jury found California liable and assessed damages at $159,148. No punitive damages were awarded. There were seventeen verdicts, nine in favor of the plaintiffs and eight in favor of the defendants. As a result of the verdicts, the state settled with the remaining plaintiffs.

Estimated number and amounts of settlements. Overall, the state settled for $13.5 million and the twenty-four other defendants settled for $95 million.

Capacity of product to cause injuries (general causation). Plaintiffs alleged that between February 1982 and February 1983, the concentration of trichlorethylene (a suspected human carcinogen) tripled in the ground water located between the Stringfellow site and the town of Glen Avon.

Types of injuries. Plaintiffs claimed that 27 wrongful deaths occurred between 1982 and 1986, that numerous bodily injuries occurred, and that plaintiffs were entitled to recover for fear of cancer.

Identifiability of causative agent. The relationships between the deaths and the toxic materials was not clear.

Description of premarket research or testing. No information found.

Alleged suppression of research/testing/safety information. No information found.

Length of exposure (marketing/sales) period. The waste disposal site operated between 1956 and 1972. Chemical wastes were reportedly dumped between 1968 and 1972. The exposure to groundwater contamination

Length of latency period (time from exposure to injury). No information found.

Estimated number of users exposed to potential harm. 5,000.

Trends/current status. We found no recent cases or claims. Insurance coverage litigation followed the settlements and the CERCLA (Superfund) litigation.

Product: Toxic waste—Times Beach, Missouri dioxin contamination (personal injury claims relating to cancer and other injuries)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. Numerous cases were filed but almost all were settled. Three

cases, at least two of them consolidations, reached trial. The EPA filed a CERCLA (Superfund) action against Syntex.

Consolidated cases. A consolidated trial involving 184 plaintiffs ended in a defendants' verdict. Another consolidated trial involving 5 plaintiffs resulted in a hung jury.

MDL pretrial referral. Nothing found.

Litigation class action. Nothing found.

Settlement class action/mandatory. Nothing found.

Settlement class action/opt-out. Nothing found.

Bankruptcies. One defendant, Independent Petrochemical Corp., filed for bankruptcy.

Estimated number of claimants. About 2,200, the population of Times Beach (which was evacuated). Other areas may have been affected.

Estimated number of future claimants. Unknown.

Estimated number of defendants. Four (Syntex USA, Syntex Agribusiness, Northeastern Pharmaceutical, and Independent Petrochemical Corp.).

Ability of defendants to pay judgments. Syntex had little problem paying the settlements because of its insurance coverage. The financial status of Northeastern Pharmaceutical is unclear. Independent Petrochemical's filed for bankruptcy protection.

Estimated number of federal cases. One, a CERCLA (Superfund) case in E.D. Mo.

Estimated number of state cases. Numerous cases, but exact number of separate lawsuits could not be found.

Estimated number of federal courts with one or more cases. One.

Estimated number of state courts with one or more cases. One (St. Louis Circuit Court).

Maturity of litigation. Post-mature. There is no evidence of any continuing litigation.

Estimated number and amounts of damage awards including punitive damages. No damage awards. One defendants' verdict in a case with 184 plaintiffs.

Estimated number and amounts of settlements. Syntex has settled with more than 1,800 claimants for $22 million. We were unable to find any information about settlements with Northeastern Pharmaceutical or Independent Petrochemical. The Superfund case settled for a split between EPA and Syntex of the $200 million cost of cleanup.

Capacity of product to cause injuries (general causation). Dioxin was mixed with waste oil and spread on dirt roads to control dust. Dioxin has been linked to cancer and other ailments in animals, but its effects on humans was being debated when the last cases were settled in November 1992.

Types of injuries. Cancer and other unspecified ailments. Plaintiffs claimed reck-

less endangerment and negligent handling of the dioxin, causing "health problems and other personal tragedies."

Identifiability of causative agent. Blood levels of dioxin can be measured, but it is difficult to get an adequate baseline measure for people who have been exposed over a period of time. Even in an individual with elevated blood levels of dioxin, causation remains uncertain.

Description of premarket research or testing. Nothing found. Allegation of reckless endangerment suggests an alleged lack of testing before use of the dioxin on the roads.

Alleged suppression of research/testing/safety information. Nothing found.

Length of exposure (marketing/sales) period. Eight to ten years.

Length of latency period (time from exposure to injury). Uncertain, but could be lengthy.

Estimated number of users exposed to potential harm. At least 2,200.

Trends/current status. Closed. No recent activity found.

Product: Toxic waste—Tennessee chemical waste landfill (*Sterling v. Velsicol*) (cancer and other personal injury claims)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. There were eight separate cases.

Consolidated cases. The largest case included 42 plaintiffs.

MDL pretrial referral. Nothing found.

Litigation class action. The trial judge consolidated seven individual civil actions, containing fourteen litigants, into the larger lawsuit by certifying a class action. A bench trial was held on the claims of five class representatives selected by plaintiffs' counsel.

Settlement class action/mandatory. Nothing found.

Settlement class action/opt-out. Nothing found.

Bankruptcies. Nothing found.

Estimated number of claimants. 128.

Estimated number of future claimants. The contamination was limited to a three-mile radius of the landfill, so future claimants should be somewhat limited.

Estimated number of defendants. One.

Ability of defendants to pay judgments. High.

Estimated number of federal cases. Eight, combined into one class action.

Estimated number of state cases. One was removed from state to federal court.

Estimated number of federal courts with one or more cases. One.

Estimated number of state courts with one or more cases. One.

Maturity of litigation. Post-mature. All claims appear to be resolved.

Estimated number and amounts of damage awards including punitive damages. After a bench trial, the district court entered a judgment for each of the five class representatives. The district court awarded $5,273,492.50 in compensatory damages, $8,964,973.25 in prejudgment interest dating back to 1965, and $7,500,000 in punitive damages. The court of appeals, however, disagreed with some of the lower court's conclusions, especially the damages calculations. The appeals court also held that certain plaintiffs failed to show to a reasonable medical certainty that particular injuries were caused by the contaminated drinking water. An awards for risk or susceptibility of future disease was denied, and damages for fear of cancer and other diseases were reduced. The court of appeals also held that the district court used improper criteria for assessing punitive damages and remanded for a recomputation.

Estimated number and amount of settlements. At least 27 cases had settled before the class trial. Presumably, the remaining claims settled after the remand.

Capacity of product to cause injuries (general causation). Highly disputed. The district court relied on expert testimony, scientific studies, and extensive literature. The court received testimony from treating physicians, medical specialists, scientists, psychiatrists, clinical psychologists, engineers, and hydrologists. Carbon tetrachloride and chloroform are known carcinogens, but their presence in plaintiffs' drinking water during the relevant period was disputed.

Types of injuries. Plaintiffs were found to have cancer, liver and kidney damage, central nervous system injuries, nervousness, fatigue, and skin irritation as a result of their exposure.

Identifiability of causative agent. There were no signature diseases.

Description of premarket research or testing. Defendant was found not to have conducted any hydrogeological studies to assess the soil composition under the site, the water flow direction, or the location of the local water aquifer before dumping chemicals at the site.

Alleged suppression of research/testing/safety information. The court found that defendant doubled the size of its waste disposal site in 1967, after a U.S. Geological Survey report indicated that chemicals had migrated and damaged the environment.

Length of exposure (marketing/sales) period Approximately 14 years, from 1964 until access to well water was prohibited in 1978.

Length of latency period (time from exposure to injury). Uncertain and variable.

Estimated number of users exposed to potential harm. At least 128 claimants.

Trends/current status. Apparently closed. No recent activity found.

Part I-C
Individual characteristics of property damage mass tort case congregations

Product: Asbestos in buildings (property damage claims related to costs of removal of friable asbestos)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. There are three types of building cases: those dealing with public schools, other public buildings, and private buildings. School cases were brought in the early 1980s on an individual basis. A class action was certified in 1984 for school cases, but a number of school districts opted out and pursued cases on an individual or districtwide basis. Public building cases have generally been brought on a statewide basis, but some may be grouped by other political subdivisions. Private building cases have generally been pursued on an individual basis.

Consolidated cases. Generally, public building cases have been consolidated by joining all cases related to the political entity (state, county, municipality, school district) that filed the action. Some observe that property damage cases are more susceptible to consolidated treatment than personal injury cases because damages have less individual variation.

MDL pretrial referral. Nothing found.

Litigation class action. In the school asbestos litigation, Judge James McGirr Kelly in 1984 certified a nationwide class action of claims by school districts to recover the cost of removing asbestos from their buildings. The opt-out class action was affirmed by the Third Circuit and proceeded as a litigation class until it was settled.

Settlement class action/mandatory. Judge Kelly also certified a mandatory class of punitive damages claims on the grounds that it satisfied the "limited fund" rationale of Fed. R. Civ. P. 23(b)(1)(B), but the court of appeals reversed that decision. Judge Kelly denied a motion to certify a mandatory class under Fed. R. Civ. P. 23(b)(2).

Settlement class action/opt-out. None.

Bankruptcies. As discussed under the asbestos personal injury cases, above, there have been approximately twenty asbestos-related bankruptcies, mostly Chapter 11 reorganizations. In some of the five to seven reorganizations involving major manufacturers with substantial assets, the reorganization plan included funds to create a property damage trust fund.

Estimated number of claimants. Complete information is not available. Overall, the EPA projected in 1988 that 733,000 public and private buildings contain asbestos and that the cost of abatement would exceed $51 billion. Approximately 30,000 to 35,000 school districts were reported to have friable (i.e., dry, tending to crumble and release airborne fibers) asbestos in their buildings. A 1985 GAO report esti-

mated that it would cost as much as $3 billion to remove friable asbestos from school buildings.

Estimated number of future claimants. Future claims do not present the same problems as in the personal injury cases because statutes of limitations and repose operate differently in relation to property damages claims because the injury latency period is not applicable.

Estimated number of defendants. See also asbestos personal injury, above. There are between twenty and fifty national companies involved in a significant number of cases.

Ability of defendants to pay judgments. Varies considerably. See asbestos personal injury, in Part 1-A, above. A number of reorganized companies have established trusts to settle property damage claims.

Estimated number of federal cases. Unknown, probably in the hundreds.

Estimated number of state cases. Unknown, probably in the hundreds.

Estimated number of federal courts with one or more cases. School cases were concentrated in E.D. Pa., but other public and private building cases are believed to be widely dispersed.

Estimated number of state courts with one or more cases. Many, perhaps most, states have asbestos property damage cases. Cases have been noted in California, Louisiana, Massachusetts, New Jersey, New York, Ohio, South Carolina, and Texas.

Maturity of litigation. Very mature.

Estimated number and amounts of damage awards including punitive damages. Not found.

Estimated number and amount of settlements. The nationwide school asbestos case settled in 1994 for $200 million

Capacity of product to cause injuries (general causation). There is no dispute that friable asbestos can be dangerous. Parties have disputed whether it is safer to contain the asbestos than the remove it and whether the danger of small quantities of asbestos represents a serious health risk. Public health agencies have not established a minimum threshold amount of asbestos that is safe.

Types of injuries. The injuries are either the cost of removal or the diminution in value of a building containing asbestos. These issues may be disputed.

Identifiability of causative agent. There may be issues related to identifying specific products in specific buildings.

Description of premarket research or testing. See asbestos personal injury, above. Premarket research was conducted as early as the 1930s, but results of such research was suppressed.

Alleged suppression of research/testing/safety information. See asbestos personal injury, in Part 1-A, above. Suppression of safety information seems well-documented.

Length of exposure (marketing/sales) period. Asbestos has been used in buildings

for decades, primarily as insulation but also to serve a variety of functions. Use tapered off sharply in the early to mid-1970s.

Length of latency period (time from exposure to injury). Not applicable.

Estimated number of users exposed to potential harm. Estimated at 733,000 public and private buildings.

Trends/current status. School cases have settled. Other types of asbestos in building cases continue to be active.

Product: Audi 5000 transmissions (claims that a defective transmission caused sudden acceleration, resulting in personal injuries and diminution in property values)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. There have been a handful of individual personal injury sudden-acceleration cases. For example, the Supreme Court in 1989 left intact $100,000 in punitive damages to a family whose basement apartment was rammed by an Audi 5000 car, even though the family received only $14,000 for actual injuries.

Consolidated cases. None found.

MDL pretrial referral. Nothing found.

Litigation class action. Perona et al. v. Volkswagen of America, Inc., a class action of plaintiffs who purchased Audi 5000 automobiles during model years 1983 through 1987, was originally filed in March 1987 and is still pending. Plaintiffs claim that their Audi 5000s have lost their resale value as a result of continuing alleged defects. In August 1997, an Illinois appeals court affirmed the trial court's dismissal of the Uniform Commercial Code and Magnuson-Moss claims, but reversed the trial court's dismissal of state consumer fraud statutory claims insofar as they were based on Audi's concealment of material facts regarding the Audi 5000's safety risk. In May 1988 a settlement agreement was executed that would have provided rebates of $300–$2,000 toward the purchase of a new Audi. In August 1988, a Cook County Circuit Court judge vacated the settlement, calling it "unfair" to all car buyers involved. After the settlement was vacated, Audi announced that it would not try to reach further out-of-court settlements.

Settlement class action/mandatory. None found.

Settlement class action/opt-out. None found.

Bankruptcies. None found.

Estimated number of potential claimants. 250,000 to 350,000

Estimated number of future claimants. Not applicable.

Estimated number of defendants. Three: Volkswagen of America, Inc. (the importer and distributor of Audis in the US), Audi A.G. (the Audi manufacturer), and Volkswagen A.G. (the parent corporation of Audi A.G. and Volkswagen of America).

Ability of defendants to pay judgments. High.

Estimated number of federal cases. At least four.

Estimated number of state cases. About 150 (all personal injury except for one economic loss class action).

Estimated number of federal courts with one or more cases. Four.

Estimated number of state courts with one or more cases. At least three.

Maturity of litigation. No verdicts on economic loss.

Estimated number and amounts of damage awards including punitive damages. No verdicts on economic loss. There were a number of verdicts on personal injury claims.

Estimated number and amount of settlements. Reportedly there were several settlements for personal injury claims, but not for diminution of resale value claims.

Capacity of product to cause injuries (general causation). Plaintiffs claimed that Audi 5000 sedans with automatic transmission have lurched into full-throttle acceleration just after drivers shift the automatic transmissions out of park or reverse. Audi blamed the incidents on driver error—drivers mistakenly pressing the accelerator pedal rather than the brake pedal as they shifted into drive or reverse. After a year-long study, the National Highway Traffic Safety Administration in 1988 concluded that the most likely cause of the unexpected acceleration was driver error ("pedal misapplication"), adding that the problem may have been "aggravated by vehicle design." In its final report, issued in July 1989, however, the NHTSA said there was no evidence that the 5000's cockpit configuration was in any way related to "pedal misapplication." NHTSA dismissed theories that faulty cruise control or electronic idle speed control systems caused the problems.

Types of injuries. In addition to the personal injury cases, plaintiffs claimed depreciation or total loss of cars' resale value. In 1988 the Center for Auto Safety claimed that the 1985 Audi 5000 sedan had retained only 47% of its original value.

Identifiability of causative agent. See "general causation," above.

Description of premarket research or testing. There were no reports of premarket testing. Audi sent recall letters to its customers in April 1982, September 1983, and January 1987, recalling Audi 5000s for repair, advising the owners of the problem, and instructing the drivers about certain vehicle safety procedures. In addition, Audi issued two press releases regarding the unintended accelerations.

Alleged suppression of research/testing/safety information. Nothing alleged on this point.

Length of exposure (marketing/sales) period. Model years 1983 through 1987.

Length of latency period (time from exposure to injury). Not applicable.

Estimated number of users exposed to potential harm. There were an estimated 350,000–390,000 owners/lessees/lessors of Audi 5000s manufactured during model years 1983 through 1986.

Trends/current status. Based solely on published materials, it appears that the class litigation has been dormant for ten years.

Product: Bronco II sports utility vehicle (economic injury claims relating to the purchase and resale as affected by alleged tendency of vehicle to roll over)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. In the MDL proceeding, the transferee judge denied certification of a class action and addressed many claims individually on motions for summary judgment. There have been no trials for economic injuries.

Consolidated cases. None found except MDL consolidation. The transferee judge appears to have grouped and ruled on the MDL cases according to their state of origin.

MDL pretrial referral. Between June and August 1993, six class actions were filed in various courts asserting that the 1984–1990 Bronco II had design defects causing an unreasonable propensity to roll over under certain driving conditions and seeking economic damages relating to those defects. In February 1994, the JPML transferred five pending putative class actions to Judge Morey L. Sear (E.D. La.) for consolidated pretrial proceedings. Three other actions were subsequently consolidated as "tag-alongs."

Litigation class action. Judge Sear denied a motion to certify a class action.

Settlement class action/mandatory. None found.

Settlement class action/opt-out. Two separate attempts at settlement were rejected by Judge Sear in March 1995 and January 1997. The first would have provided plaintiffs with a utility vehicle video, a sun-visor warning sticker, a utility vehicle Owners Guide Supplement, and an inspection of their vehicles. Judge Sear rejected the proposed settlement because the amount of plaintiff attorney fees sought ($4 million) was excessive in view of the limited amount of discovery conducted by counsel, and the arrangement, in relation to the recovery afforded the class, suggested collusion. The second proposed settlement would have provided Bronco II owners with free inspections and educational materials as well as up to $200 for suspension system parts and repairs. Judge Sear rejected it on grounds that it was not sufficiently fair, reasonable, and adequate, noting that "collusion problems remain."

Bankruptcies. None.

Estimated number of potential claimants. There were approximately 650,000 owners of Bronco IIs at the time of the litigation, according to the parties' estimate.

Estimated number of future claimants. Not applicable.

Estimated number of defendants. One, Ford Motor Co.

Ability of defendants to pay judgments. High. In a November 1992 financial filing,

Ford disclosed that it had set aside $421 million to handle pending personal injury claims. A spokesman said the amount reflects what plaintiffs have asked for in suits and does not necessarily reflect what the company expects to pay out.

Estimated number of federal cases. Five class action cases for economic injuries were filed in federal courts, as were two "tag-along" actions. There were at least 200 personal injury cases dispersed among federal and state courts.

Estimated number of state cases. One class action for economic injuries was certified in Alabama. There were at least 200 personal injury cases dispersed among federal and state courts.

Estimated number of federal courts with one or more cases. At least seven courts had economic-injury cases that were consolidated in one MDL court.

Estimated number of state courts with one or more cases. Only one state court had an economic-injury case.

Maturity of litigation. Settlements were proposed without verdicts in economic-injury cases; amounts at stake in individual cases would not have supported trials.

Estimated number and amounts of damage awards including punitive damages. There were no verdicts for economic loss. There were as many as a dozen verdicts in personal injury/wrongful death cases. Judge Sear found in 1995 that Ford had paid $113.4 million to settle 334 claims (an average of $339,477 per claim).

Estimated number and amounts of settlements. See Settlement Class Action/opt-out, above.

Capacity of product to cause injuries (general causation). Plaintiffs contend that all Ford Bronco IIs suffer from "a substantially increased and unacceptable propensity to roll over during normal operation" and that this defect has diminished the resale value of the vehicle. They attribute this stability problem to the vehicle's "high center of gravity and short, narrow wheelbase." Ford maintains that not all Bronco IIs are substantially the same and that the high incidence of rollovers was overwhelmingly due to driver error, environmental factors or unsafe conditions, or after-market modifications made to the vehicles and differences in vehicle maintenance.

In the class action, the causation issue is more narrowly focused on the impact of bad publicity about the Bronco II and related litigation on the vehicle's resale value. Ford has maintained that the Broncos' resale value has not been adversely affected. One plaintiffs' attorney was quoted in the Wall Street Journal as saying that the difficulty with the lawsuit was proving that current Bronco II owners suffered damages. "Our survey of the market shows that Bronco II resale values are about the same as other sport-utility vehicles. The value hasn't really gone down," he said. Judge Sear referred to these public statements as "disturbing."

Types of injuries. Plaintiffs allege economic injury to resale values and also claims that they paid "inflated prices for their Bronco IIs—i.e., prices which do not reflect that the vehicle suffered from an unreasonably dangerous defect."

Identifiability of causative agent. Not applicable.

Description of premarket research or testing. According to the *Wall Street Journal* article, Ford was aware of bad publicity about the dangers of similar off-road vehicles. In addition, it was concerned that the Bronco II tended not only to tip but to roll over completely at relatively moderate speeds. Ford formed a special Bronco II committee—including senior engineers, safety specialists, and an in-house attorney—to monitor test procedures, analyze results, and address safety concerns. Ford reportedly knew in 1981, two years before the Bronco II was first marketed, that it could stabilize the vehicle considerably by switching to a much wider chassis, but rejected such a design change because it would defeat much of the purpose of the smaller model and cause Ford to fall behind in a race to market with General Motors Corp.'s S-10 Blazer.

Alleged suppression of research/testing/safety information. Plaintiffs maintain that Ford withheld information about the Bronco's rollover propensity from the public and investigating agencies, citing allegations concerning what Ford knew about the alleged defect during the production of the Bronco II. In June 1998, Judge Sear determined that the plaintiffs have offered no evidentiary support for these allegations.

Length of exposure (marketing/sales) period. Marketed between 1984 and 1990.

Length of latency period (time from exposure to injury). Not applicable.

Estimated number of users exposed to potential harm. Ford sold approximately 680,000 Bronco IIs. As of early 1997, about 650,000 were still registered for use in the U.S.

Trends/current status. In June 1998, Judge Sear declared his role in the litigation to be at an end and issued a "suggestion of remand" to the JPML. He recommended that five remaining cases be transferred to S.D. Miss., from which they had been transferred. All other cases had been dismissed and class certification had been denied.

Event: Exxon-Valdez Oil Spill (property damage, fishing rights, and other environmental damage claims arising of the oil spill on March 24, 1989)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. It is estimated that more than 330 separate civil suits, many of them class actions, were filed against Exxon and its affiliates in state or federal court. Plaintiffs included commercial fishers, fish processors & distributors, union workers laid off by processors after the spill, local businesses that supplied equipment/services to the fishing industry, tour operators, recreational users, state & local governments, & Native American corporations. In addition, there were a sizable num-

ber of individual plaintiffs who opted out of class litigation (e.g., 700 of 3,620 Alaskan native claimants opted out). Exxon filed a coverage action against its insurers in state court in Texas and some insurers filed a declaratory judgment action against Exxon in federal court in New York.

Consolidated cases. District Judge H. Russel Holland (D. Alaska) consolidated the majority of federal actions. Alaska state judge Brian Shortell consolidated the state actions, which consisted mainly of suits filed by 6 American Indian groups and 6 municipalities. The two judges ordered the attorneys to formulate a joint discovery plan, which was subsequently adopted by both courts. The plan called for joint depositions and joint appointment of a special discovery master.

MDL pretrial referral. On Feb. 2, 1990, the JPML declined to consolidate cases.

Litigation class action. Civil cases related to the economic claims of fishers proceeded as a class action in three trial phases. In Phase I (liability), the jury determined that Exxon and its captain each had acted negligently and recklessly and that such reckless conduct caused the Exxon Valdez to run aground. In Phase II (compensatory damages), the same jury delivered a verdict of $286,700,000 to approximately 10,000 commercial fishers. In Phase III (punitive damages), the same jury determined that Exxon was liable for $5 billion and Captain Hazelwood for $5,000 in punitive damages. That verdict was appealed to the 9th Cir. on June 19, 1997.

Another litigation class action, filed by representatives of 130,000 Alaskan sports fishermen—consolidated with similar actions filed by environmental groups—sought damages and injunctive relief for loss of use of the public lands affected by the oil spill. The district court dismissed the cases on res judicata grounds, deciding that a $1 billion settlement reached in 1991 among Exxon and federal and state agencies covered damages for all losses of natural resources. A panel of the U.S. Court of Appeals for the Ninth Circuit unanimously affirmed that decision.

Settlement class action/mandatory. None.

Settlement class action/opt-out. None found.

Bankruptcies. None found.

Estimated number of claimants. As many as 52,000 plaintiffs (including commercial fishers, local business owners, state & local governments, & Native American corporations) were reportedly involved in individual and class claims for economic injuries. The two major plaintiff classes were commercial fishers and Alaska natives. The Alaska native class consisted of 3,620 claimants, about 700 individuals opted out. In addition, 130,000 sports fishers and numerous environmental users were represented in class actions.

Estimated number of future claimants. No future claims are expected.

Estimated number of defendants. There was four principal defendants: Exxon Corp., Exxon Shipping Co., Exxon Pipeline Co., and Alyeska Pipeline Service Co., a consortium of oil companies that operates the trans-Alaska pipeline at Valdez.

Ability of defendants to pay judgments. Very high. In 1990, Exxon reported that it had internally generated more that $100 billion in cash over the previous ten years.

Estimated number of federal cases. See above, individual, consolidated, and class action cases. Most of the cases appear to have been brought in federal court.

Estimated number of state cases. The number of cases brought in state court is not clear, but claims by the Native Alaskan corporation and Alaska municipalities appear to have been brought in state courts. A number of economic injury claims were brought originally in state court and removed to federal court. Exxon's insurance coverage action was filed in state court in Texas.

Estimated number of federal courts with one or more cases. Two. All federal cases except one insurance coverage case were filed in D. Alaska.

Estimated number of state courts with one or more cases. Two. All state cases except one insurance coverage case were filed in Alaska courts.

Maturity of litigation. Cases were consolidated or certified as classes before maturing. Values in the major economic damages class action were established through a trial.

Estimated number and amounts of damage awards including punitive damages. In 1994, a federal jury awarded $286.8 million in compensatory damages and $5 billion dollars in punitive damages to a class of approximately 10,000 commercial fishers. In 1994, a state court jury awarded 6 Native Alaskan corporations and the Kodiak Island Borough $9.7 in compensation for land damage and archeological claims.

Estimated number and amount of settlements. There were a number of different settlements over time. In Sept. 1991 Exxon agreed to pay almost $1.05 billion (including $150 million in criminal fines) to state and federal governments for damages to public lands. Alyeska entered into a settlement agreement with the various plaintiffs, which Exxon opposed, to pay $98 million for all claims. In 1994, Exxon agreed with Native Alaskans to pay $20 million for replacement costs of lost subsistence crops, fish, seals, kelp, and other food gathered from the sea and coastline. In addition, in 1991 Exxon entered a secret pretrial arrangement with 7 Seattle fish processors, settling their claims with Exxon for $70 million. Under the deal, the processors were required to pursue a share of the punitive damages to be paid by Exxon and then return it to Exxon. The agreement came to light when the processors challenged the process for distributing punitive damages funds to the plaintiffs in 1996. Judge Holland called the deal a "startling affront to the jury system."

Phase IV of the commercial fishers' class litigation involved a settlement of various individual claims, including claims of commercial fishers for species other than salmon and herring, and personal injury claims. Approximately 29,681 claimants were involved. In June 1996, the court granted final approval. Exxon apparently had made earlier payments—which exceeded the amount of the Phase IV settlement—that were then setoff against the settlement.

Capacity of product to cause injuries (general causation). It is undisputed that on March 24, 1989, the Exxon Valdez, a supertanker (more than 300 yards long) owned and operated by Exxon, ran aground in Prince William Sound, causing a spill of about 11 million gallons of crude oil in Alaska's territorial waters, contaminating over 1,275 miles of shoreline.

Types of injuries. The commercial fishers claimed damages related to reduced harvests, diminished prices, and diminished permit values. The native subsistence cases related to reduced harvests, diminished valuation due to a fear of contamination, and devalued rights to fish and gather marine resources. The verdicts and settlements focused on claims of direct economic loss.

Judge Holland dismissed or granted summary judgment excluding a number of indirect or noneconomic losses, except to the extent that their losses result from physical injury to a proprietary interest caused by the spill. Such claims included Alaska natives' claims that the disaster harmed their traditional lifestyles, businesspersons' claims that they suffered indirect losses from the spill, and miscellaneous claims such as hedonic or emotional distress, price diminishment in fisheries that were not oiled, diminished value of fishing permits or fishing vessels absent a sale of the permit or vessel, damages to unoiled land, diminution of market value owing to fear or stigma, the claims of seafood wholesalers, processors, cannery employees, and tender boat operators, and claims of plaintiffs who are not commercial fishers or Native subsistence harvesters.

Identifiability of causative agent. Causation was disputed, especially claims that the captain was the sole cause of the spill. The jury found both the captain and Exxon liable.

Description of premarket research or testing. Nothing found.

Alleged suppression of research/testing/safety information. Nothing found.

Length of exposure (marketing/sales) period. Not applicable.

Length of latency period (time from exposure to injury). The spill had an immediate impact on environment and livelihoods of local fishers, businesses. Latent injuries are not expected.

Estimated number of users exposed to potential harm. No good estimates found. More than 50,000 filed some form of claim, but hundreds of thousands of potential users of the public lands and waterways also filed class actions.

Trends/current status. The commercial fishers' verdict, including punitive damages, is on appeal. Other settlements and verdicts appear to be final.

Product: GM pick-up gas tank (claims for economic damages as affected by alleged dangers related to location of gas tanks)

Information for this report was obtained from published sources supplemented by information from one or more attorneys who represented clients in the litigation.

Individual cases. Prior to the formation of class actions, more than 100 individual personal injury lawsuits included property value loss as an ancillary claim. In addition, some individuals filed objections to the class-action settlements claiming that their interests were not properly represented.

Consolidated cases. None found.

MDL pretrial referral. Yes. Approximately 300 representative plaintiffs, including both individual and fleet owners, were consolidated in a total of 26 cases under the MDL and assigned to E.D. Pa.

Litigation class action. All class actions were certified only for settlement.

Settlement class action/mandatory. None found.

Settlement class action/opt-out. In the MDL settlement, an opt-out class was certified for settlement purposes only. Approximately 5,200 owners opted out of the national settlement. The settlement was approved by the district court, but reversed by the court of appeals. A revised version of the settlement was approved by a Louisiana trial judge, but that decision was reversed by Louisiana's First Circuit Court of Appeals in June 1998. A Texas trial judge approved a statewide class settlement, but that decision was reversed by an intermediate appellate court, and the Texas Supreme Court affirmed the reversal. In February 1996, the Texas Supreme Court remanded the case for further hearings on class certification and on attorneys' fees. We were unable to find further information about the status of the remand.

Bankruptcies. None found.

Estimated number of potential claimants. Between 1973 and 1991, GM produced approximately 6.3 million GMC and Chevy trucks with sidesaddle gas tanks placed outside of the main frame of the vehicle. Residents of Texas, which did not participate in the national class action, had approximately 645,000 of these vehicles in 1993.

Estimated number of future claimants. Future claimants—except those who opted out—would be bound by the proposed class action settlement, if approved. When a vehicle is sold, the future owner would absorb any property loss.

Estimated number of defendants. The only defendant is General Motors.

Ability of defendants to pay judgments. High.

Estimated number of federal cases. One MDL case.

Estimated number of state cases. Approximately 100 personal injury suits were filed that named property loss as ancillary claims.

Estimated number of federal courts with one or more cases. One.

Estimated number of state courts with one or more cases. At least two.

Maturity of litigation. The proposed settlement was reached without the benefit of any verdicts on the property damage issues. The settlement was criticized as being unfavorable to consumers and has not been adopted on a national level.

Estimated number and amounts of damage awards including punitive damages. None found.

Estimated number and amounts of settlements. National settlements have been rejected by courts of appeals in the Third Circuit and in Louisiana. The Texas Supreme Court found the settlement to be fair, but remanded the case with instructions to issue clearer notice of proposed attorneys' fees and to conduct a plenary hearing on class certification and on the fairness of the settlement. Under the proposed settlements, vehicle owners were to receive a coupon (to be used within 15 months) for $1,000 toward the purchase of a new GM truck or van. Transferability of the coupons was restricted. There were limited options to have a vehicle repaired. The lawyers were to receive approximately $30 million in fees. GM also paid $51 million to settle a administrative claim with the United States Department of Transportation to avoid a recall of the trucks that GM claimed would have cost approximately $1 billion.

Capacity of product to cause injuries (general causation). There is disagreement as to whether the sidesaddle gas tanks caused injury to the property value of the vehicle.

Types of injuries. Plaintiffs asserted that the location of the gas tanks reduced the marketability and the resale value of the pickups. Defendant argued that there was no injury because the Kelley Blue Book and other guides indicated a greater value for GM pickups than for comparable vehicles. Plaintiffs, however, argued that the value increase would have been greater without the sidesaddle gas tank.

Identifiability of causative agent. The location of the gas tank is, of course, absolutely identifiable.

Description of premarket research or testing. Some have suggested that GM hid documents regarding their early knowledge of the problem. GM denies the allegation. The government acknowledges that GM met the minimum government safety requirements in the design.

Alleged suppression of research/testing/safety information. See above, next item.

Length of exposure (marketing/sales) period. Trucks were marketed with sidesaddle gas tanks from 1973–1986 for GM truck models "C" and "K" series, and from 1987–1991 for truck models "R" and "V" series.

Length of latency period (time from exposure to injury). Not applicable. No personal injuries involved.

Estimated number of users exposed to potential harm. At time of suit, approximately 6 million GM vehicles with sidesaddle gas tanks were registered nation wide

Trends/current status. This controversial settlement appears to remain in limbo while the Louisiana Supreme Court reviews the appellate court reversal of the approval of the settlement. There are no cases pending on the MDL docket as of Dec. 31, 1998.

Product: Masonite siding (property damage claims relating to allegedly defective siding used in home construction)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. No reported individual trials or other dispositions.

Consolidated cases. Nothing reported.

MDL pretrial referral. In April 1996, the JPML consolidated 24 federal Masonite hardwood siding product liability cases for pretrial purposes and assigned them to Judge Martin L.C. Feldman (E.D. La.).

Litigation class action. A national class action was certified in Alabama state court, and the first phase of the trial resulted in a jury verdict that Masonite hardwood siding is defective. A motion to certify a class in federal court in E.D. La. was denied because the action did not satisfy predominance and superiority requirements.

Settlement class action/mandatory. None.

Settlement class action/opt-out. None.

Bankruptcies. Nothing reported.

Estimated number of potential claimants. The class action was brought on behalf of an estimated 4 million homeowners.

Estimated number of future claimants. Nothing reported.

Estimated number of defendants. At least 15.

Ability of defendants to pay judgments. Nothing reported.

Estimated number of federal cases. Nine cases were consolidated by the JPML.

Estimated number of state cases. One case found.

Estimated number of federal courts with one or more cases. Originally, four; consolidated into one.

Estimated number of state courts with one or more cases. One found.

Maturity of litigation. Settled before maturation. No individual verdicts found. The manufacturer of a similar siding had settled national litigation for $275 million.

Estimated number and amounts of damage awards including punitive damages. In the first phase of a class trial, a jury in Alabama state court found the products to be defective.

Estimated number and amounts of settlements. A national class action settlement

was announced by Masonite Corp. on July 14, 1997. The settlement calls for the company to pay as much as $197.5 million to homeowners on an individual basis. Louisiana-Pacific Corp., which makes a similar siding, settled a lawsuit over its product in April 1996 for $275 million.

Capacity of product to cause injuries (general causation). In dispute. Plaintiffs contended that the limited durability and relative weakness of the bonds between individual wood fibers in the Masonite board leads to problems with moisture cycling and allows water to seep into the siding. Defendants, however, claim that installation and finishing, as well as poor building design and construction, cause the problems. Defendants also contend that many builders fail to follow the detailed instructions that Masonite sends out with the siding. Plaintiffs respond that any siding product so sensitive to installation is per se defective.

Types of injuries. Masonite siding allegedly could not withstand normal weather conditions. Moisture intrusion resulted in premature deterioration, rotting, discoloration, cracking, warping, splitting, delamination, and swelling. Many plaintiffs have had to replace the siding on their homes and businesses. Some claim a loss in property value due to their siding's poor appearance and constant need for maintenance. Repair costs are estimated at $1,000 to $10,000 per house.

Identifiability of causative agent. Plaintiffs used expert testimony to link the product to their property damage. Plaintiffs' expert contended that limited durability and the relative weakness of the bonds between individual wood fibers in the board causes problems with moisture cycling and allows water to seep into the siding. The siding allegedly absorbs water and deteriorates.

Description of premarket research or testing. Nothing reported.

Alleged suppression of research/testing/safety information. Plaintiffs contended that defendants knew of and concealed the above problems with the Masonite hardwood siding.

Length of exposure (marketing/sales) period. 1980 through 1997.

Length of latency period (time from exposure to injury). Nothing reported.

Estimated number of users exposed to potential harm. Since 1980, Masonite Corp. has produced more than 6 billion feet of hardboard siding for as many as 4 million homes in every state in the U.S.

Trends/current status. Settled, but the MDL clerk lists 7 cases as pending as of Dec. 31, 1998.

Product: Plywood (fire-retardant) (property damage claims that plywood sued in town house roofs deteriorates at moderate temperatures)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. Individual litigation preceded consolidation of cases in New Jersey.

Consolidated cases. In 1990, trial judges and attorneys for plaintiffs and defendants agreed that consolidation management of FRT plywood cases was appropriate to reduce costs and delays and to maintain consistency of judicial rulings. Prior to the statewide consolidation that results, cases were dispersed across the state.

MDL pretrial referral. Nothing found.

Litigation class action. A nationwide litigation class action in federal court in Oregon resulted in a settlement for up to $375 million to be paid to more than 10,000 customers of Louisiana-Pacific.

A statewide litigation class action in Maryland against an FRT plywood manufacturer was dismissed and the dismissal was affirmed in 1995 by the highest court in the state. The Maryland court dismissed all of the plaintiffs' claims for relief because Maryland law does not recognize strict liability claims against manufacturers for purely economic loss. A statewide class action in Florida resulted in a settlement. Other state class actions have been mentioned in reports.

Settlement class action/mandatory. Nothing found.

Settlement class action/opt-out. Nothing found.

Bankruptcies. Nothing found.

Estimated number of claimants. The class action against Louisiana-Pacific was reported to have had more than 10,000 claimants. The National Association of Home Builders has estimated that up to a million homes in the eastern United States have been affected by the FRT plywood problem.

Estimated number of future claimants. Generally not a problem because the condition manifests itself rather quickly

Estimated number of defendants. At least a half dozen manufacturers of FRT plywood have been named in lawsuits, including Louisiana-Pacific, Georgia Pacific, Osmose Wood Preservation, Ply-Gem Industries, Hoover Treated Wood Products, Inc., and Hoover Universal, Inc.

Ability of defendants to pay judgments. No information found.

Estimated number of federal cases. Three found.

Estimated number of state cases. Many cases were found in NJ. A class action was dismissed in MD. Other cases were found in FL, VA, and MI.

Estimated number of federal courts with one or more cases. Three found.

Estimated number of state courts with one or more cases. Five.

Maturity of litigation. No trial verdicts found. Two major settlements indicate that values may be known.

Estimated number and amounts of damage awards including punitive damages.

Estimated number and amount of settlements. The national Louisiana-Pacific case settled for up to $375 million to be paid to more than 10,000 customers. A Florida case settled for $2.82 per square foot to repair or replace damaged panel siding and $3.40 per square foot for lap siding.

Capacity of product to cause injuries (general causation). Plaintiffs claim that the chemicals in the fire retardant plywood activate at lower temperatures than intended (130–140 degrees Fahrenheit instead of 180 degrees). These temperatures are regularly reached when temperature and humidity are high, conditions that occur frequently in southern and eastern states. The chemical reaction that is intended to retard the spread of fire allegedly causes the premature deterioration of the plywood.

Types of injuries. Economic loss associated with the alleged deterioration of plywood in the roofs of homes. Plaintiffs seek to recover damages for the cost of replacing these roofs.

Identifiability of causative agent. Product is highly identifiable.

Description of premarket research or testing. Nothing found.

Alleged suppression of research/testing/safety information. Nothing found.

Length of exposure (marketing/sales) period. The product has been developed in the last decade to meet the requirements of building codes for fire retardant materials.

Length of latency period (time from exposure to injury). Reportedly brief. The Florida settlement allowed claims for up to five years.

Estimated number of users exposed to potential harm. As stated above, the National Association of Home Builders has estimated that up to a million homes in the eastern United States have been affected by the FRT plywood problem.

Trends/current status. Little activity reported in 1998.

Product: Polybutylene pipe (property damage claims related to plumbing pipe's defective performance after substantial exposure to chlorine)

All information for this summary was obtained from published sources: case reports, newspapers, and journals.

Individual cases. There was a considerable amount of individual or non-class group litigation for a decade before the nationwide class settlement. For example, in a Texas case, attorney represented a group of 65,000 individually listed plaintiffs; in a California case, a condominium association and individual property owners joined in litigating claims regarding allegedly defective pipes and fraudulent marketing practices.

Consolidated cases. Many individual cases described above were filed with a large number of individual plaintiffs and administered on a group basis. In the Texas case, plaintiffs were represented by a single law firm.

MDL pretrial referral. In May 1995 the JPML entered a minute order indicating that the question of pretrial referral was moot.

Litigation class action. Before a nationwide class action settlement was approved in *Cox v. Shell* in Tennessee, there were overlapping nationwide classes certified by courts in Texas and Alabama and a putative mobile homeowner class that had been filed in California. The *Cox* court also indicated that there were many uncertified class actions pending around the country.

Settlement class action/mandatory. None found.

Settlement class action/opt-out. None found.

Bankruptcies. U.S. Brass Corp. sought Chapter 11 protection. The *Cox* settlement provided that any settlement from the U.S. Brass reorganization would be added to the settlement fund and administered by the claims facility set up to administer *Cox*.

Estimated number of claimants. More than 195,000 homeowners requested settlement class claim forms before the opinion approving the settlement was issued in November 1995. Notices were sent by first class mail to more than 5.6 million people and the court described a worst case scenario as one involving 6 million claims. As of Sept. 1998, it appears that approximately between 115,000 and 285,000 had been received and $567.5 million paid in claims.

Estimated number of future claimants. There could have been as many as 6 million claimants in the nationwide class action settlement. Payment of future repairs and replacement specifically continues until the year 2009 in the *Cox* settlement, and the settlement requires a comprehensive notice program every three years. A class settlement in Alabama (*Spencer*) provided that homeowners were to undertake repairs of interior leaks by Aug. 20, 1999.

Estimated number of defendants. There have been dozens, including E.I. DuPont, Hoechst-Celanese Corp., Royal Dutch Shell, Shell Chemical Co., Shell International Chemical Co., Shell International Trading Co., Shell Oil Co., and U.S. Brass Corp. Plumbers and other contractors are often included as defendants.

Ability of defendants to pay judgments. Very high as to some defendants.

Estimated number of federal cases. Unknown, but probably in the hundreds.

Estimated number of state cases. Unknown, but probably in the thousands.

Estimated number of federal courts with one or more cases. Unknown, but probably dispersed.

Estimated number of state courts with one or more cases. At least seven states were identified. All but California are in the east, but cases were probably widely dispersed.

Maturity of litigation. Mature. Two nationwide settlement occurred after about a decade of individual and group litigation.

Estimated number and amounts of damage awards including punitive damages. There were dozens of damage awards, almost all in favor of plaintiffs. In a California case, 20-34 homeowners recovered $222,282 in damages (14 had no damages because there was no evidence of leaks).

Estimated number and amount of settlements. There were three major settlements. In *Cox*, a nationwide class settlement between homeowners and Shell Oil Co. and Hoechst Celanese Corp. provided a minimum of $950 million to provide repairs, replacement, and compensation for property damage to a class of homeowners with polybutylene pipe. Attorneys fees were paid in addition to the $950 million. During the first three years of operation, the average claim per home in the settlement has been $4,000-$5,000. The average claim for a mobile home is $2,000. In *Spencer*, plaintiffs and Dupont settled their claims on a national basis. In a Texas, 65,000 homeowners settled, with Dupont, Shell, and Hoechst Celanese agreeing to replace leaky pipes and provide $170 millions for damages and attorneys' fees.

*Capacity of product to cause injuries (general causation).*The product consists of resin-based plumbing pipes that were widely used in mobile home and other sited-home construction. General causation does not seem to be disputed. The problem appears to be that the pipes become brittle and crack when exposed to chlorine—a chemical commonly found in drinking water. Cracking in turn leads to leaks that can directly lead to additional property damage.

Types of injuries. There are two basic types of injuries: defective pipes need to be replaced and water leakage can cause damage to other parts of the home.

Identifiability of causative agent. The product and the cause are highly identifiable.

Description of premarket research or testing. Nothing found.

Alleged suppression of research/testing/safety information. Nothing found.

Length of exposure (marketing/sales) period. The pipes were first installed in 1978 and were marketed for at least ten years until the litigation began.

Length of latency period (time from exposure to injury). Depending on the type of structure, it takes between 2 to 16 years from the time of installation to the appearance of the defects.

Estimated number of users exposed to potential harm. One estimate is that the allegedly defective pipes have been installed in three million mobile homes and an estimated four to five million site-built homes.

Trends/current status. Settled. The Consumer Plumbing Recovery Center has been paying claims for at least three years.

Product: Synthetic stucco (housing property damage attributed to Exterior Insulation and Finish System (EIFS))

Information for this report was obtained from published sources supplemented by information from one or more attorneys who represented clients in the litigation.

Individual cases. There are an estimated 400 cases pending in North Carolina and another 150 or so in the rest of the U.S. Cases were first filed in 1993, but the litigation began to grow in the summer of 1995.

Consolidated cases. None found, other than the MDL.

MDL pretrial referral. In Oct. 1996, the JPML transferred 11 cases to Judge W. Earl Britt (E.D.N.C.). Ten of the cases transferred to Judge Britt included class action allegations.

Litigation class action. In the MDL court, in August 1997, Judge Britt found that common questions did not predominate because of variations in negligence standards and other aspects of state law and denied national class certification. As part of the consolidation, the panel conditionally transferred a class action from a federal court in Illinois to E.D.N.C., but plaintiffs' counsel in that case objected and a hearing is scheduled on that issue for Jan. 29, 1999, before the panel.

Putative state class actions are reported to have been filed in North Carolina, Louisiana, Texas, and Alabama. A statewide class action in North Carolina has been certified and is proceeding against the manufacturers, but defendants expect to file motions to add third parties, such as builders and installers, and to decertify the class. Defendant-manufacturers assert that the state judge certified the class ex parte before papers were served on them. Motions to certify have not been filed in several class actions pending in Alabama, Louisiana, and Texas. In Georgia, a judge denied class action status in a product liability suit in September 1998. In another Georgia case, a motion to certify a class has not been filed. Reports of class action litigation in South Carolina and Florida could not be confirmed.

Settlement class action/mandatory. None found.

Settlement class action/opt-out. In September 1998, a North Carolina trial court approved a $20 million class action settlement proposed by Senergy, Inc. a synthetic stucco manufacturer that was one of nine defendants in the NC class action. The settlement involved residential structures only and provides $20 million, with a "soft cap." If claims exceed $20 million, Senergy can either provide additional money or be subject to court action by claimants who have not been compensated.

Bankruptcies. None found.

Estimated number of claimants. At least hundreds and probably thousands. There are an estimated 400–800 lawsuits in North Carolina alone.

Estimated number of future claimants. No estimate of the rate of claims is available. There are an estimated 125,000 to 250,000 houses in the U.S. covered with

EIFS. Defendants indicate that the problem is concentrated in areas of the country with hot, humid climates and large amounts of rainfall, mostly in the southeast and Oregon and Washington, suggesting that problems are relatively infrequent outside of those areas. Cases have also been filed in other states, including Kansas, Texas, California, Tennessee, Ohio, Illinois, and Pennsylvania.

Estimated number of defendants. Possibly hundreds. Many companies make or distribute the barrier stucco system. Sixteen were named in the E.D.N.C. case. Sto Corp., Senergy Inc., Parex Inc., and Dryvit Systems are among the top manufacturers. Dryvit is the largest, reported to have roughly 41% of the national market. Producing EIFS is apparently labor intensive, requiring little capital investment. Homeowners are also suing their building contractors, who in turn are suing manufacturers and subcontractors who installed flashing, sealant, windows, and other building components that could have been the source of leaks.

Ability of defendants to pay judgments. According to an attorney for homeowners, none of the manufacturers could cover a settlement without help from their insurance carriers, based on a four-month examination of their financial records. Manufacturers and contractors are "not Fortune 500 companies," according to that attorney. The Senergy settlement was financed primarily by insurers. All the manufacturers have reportedly been in litigation with their insurers.

Estimated number of federal cases. One MDL court, but a motion to remand is pending as to another case.

Estimated number of state cases. Hundreds.

Estimated number of federal courts with one or more cases. One.

Estimated number of state courts with one or more cases. Sixteen.

Maturity of litigation. In denying class certification, Judge Britt (E.D.N.C.) called the litigation an "immature tort" and noted the lack of history of prior litigation over EIFS.

Estimated number and amounts of damage awards including punitive damages. There have been two verdicts reported, one for the defendant in Tacoma, Wash., in July 1997; the other a November 1998 verdict awarding $187,000 for plaintiff against a builder in Greensboro, N.C. There was no claim against a manufacturer in that action. Motions are pending to overturn the verdict or reduce the award. There are also reports of jury verdicts against builders and subcontractors in Florida, Pennsylvania, and South Carolina.

Estimated number and amounts of settlements. In the North Carolina class action, Senergy agreed to pay homeowners $4 per square foot for water damage attributed to EIFS siding and a five-year limited warranty on repairs. Homeowners who repaired their stucco but sold their houses before May 18, 1988, when the agreement was negotiated, were eligible for up to $1,000. Senergy's insurance company will pay

as much as $20 million to settle the suit, but Senergy may also have to contribute if claims exceed $20 million.

Reportedly, over 200 cases have been settled after the parties participated in mandatory mediation under North Carolina court rules. An attorney for EIFS manufacturers reported that mediation outcomes known to him averaged approximately $52,000, with manufacturers paying approximately $16,000 of that amount. We do not know how many of the mediation results were not known to the attorneys or whether the number known are typical of the whole group. Other estimates have been reported, indicating that a typical settlement ranges from $60,000 to $70,000.

According to reports, United States Gypsum, a Fortune 500 company with a small portion of the synthetic stucco market (about 1200 homes during 2.5 years of production), has withdrawn its product from the market and agreed to pay about 50% of the cost of repairing the homes while its installers, distributor, and home builders cover the remaining expense.

Capacity of product to cause injuries (general causation). Barrier EIFS is a sandwich of plywood sheathing, vapor barrier wrap, foam, fiberglass mesh, and two coats of synthetic stucco attached directly to the wood framing of residential homes. Manufacturers claim that EIFS itself is waterproof and that claim does not appear to be disputed. The main type of injury alleged is structural damage caused by water leaking through other parts of a building, such as windows or flashing, and getting behind the EIFS. Plaintiffs claim barrier EIFS traps moisture in the wall cavities of EIFS-clad homes, causing wood sheathing or structural wood to rot. Defendants claim that faulty installation and/or maintenance is to blame. Plaintiffs contend that manufacturers should have anticipated the faulty installation and designed a product with a drainage system to dispose of water that might enter behind the EIFS. Defendants claim that their products work as intended and, if properly installed, will not allow water leakage to occur.

Types of injuries. In addition to structural damage through rotting of the wooden frame, as described above, plaintiffs claim diminution in market value of housing ("stigma damage"). The North Carolina Real Estate Commission requires that realtors disclose whether a house contains or once contained synthetic stucco even if no problems have occurred.

Identifiability of causative agent. While there should be no difficulty in identifying whether EIFS was used in the house, there remains an issue of whether installers, distributors, and home builders are liable for any damage.

Description of premarket research or testing. Defendants contend that the building industry is heavily regulated and that the EIFS product has been extensively tested under conditions of proper installation. Plaintiffs contend that they have discovered evidence that premarket testing revealed problems with the alleged tendency of EIFS to trap water.

Alleged suppression of research/testing/safety information. In the E.D.N.C. putative class action, plaintiffs claim that defendants failed to remove EIFS from the market and take other remedial action while knowing of and after learning of the defective nature of EIFS. Specifically, plaintiffs contend that HUD requested one or more manufacturer to redesign the product to deal with trapped moisture and that the manufacturers' response was to not use the product in HUD housing.

Length of exposure (marketing/sales) period. EIFS has been used in the United States for nearly 30 years, primarily in commercial construction (where EIFS is attached to steel, not wood). It has been used in residential construction for more than 10 years, becoming popular during the building booms of the 1980s and early 1990s, particularly on more expensive homes. The problems that precipitated the current wave of litigation became widely known as a result of problems that were reported in 1995 in Wilmington, North Carolina.

Length of latency period (time from exposure to injury). Water damage has been reported in EIFS homes that are less than two years old, but the average of homes affected is reportedly six years. According to one North Carolina-based inspection company that specializes in synthetic stucco homes, rotting can begin again in eight to twelve months after repairs.

Estimated number of users exposed to potential harm. Possibly hundreds of thousands (primarily in the southeast and northwest, but also in Pennsylvania, Maryland, California, and other states).

Trends/current status. Active. Discovery is ongoing. According to the clerk of the JPML, two of the eleven cases transferred to E.D.N.C. remained pending as of Jan. 13, 1999.