

# Hazardous Times®



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### For More Information

If you have any questions about the information presented here, or contributions to the ongoing study of this potential exposure, we encourage you to contact your GeneralCologne Re account executive.

## Pharmaceuticals and Vaccines Draw More Claims

Pharmaceutical manufacturers have always been "deep pocket" targets for product liability litigation. DES and diet drugs prompted waves of litigation during the 1980s and 1990s, some of which is still ongoing today. There has always been significant risk inherent in producing new drugs. Even the products with tremendous benefits can have serious side effects, and those unintended and often unexpected effects bring on the lawsuits. As more drugs reach the market and more people take them, the number of lawsuits rises as well.

Childhood vaccines are the latest lightning rod for widespread pharmaceutical litigation. The attention focuses on the possible connection between a preservative once used in some vaccines, thimerosal, and an increase in the incidence of autism in children. Thimerosal contains mercury, and the lawsuits allege that the mercury in vaccines caused or contributed to autism in hundreds and potentially thousands of young children. While vaccine manufacturers have eliminated or reduced the level of thimerosal in vaccines manufactured after 2000, the

number of possible claims and affected insurance policies from past vaccinations can be enormous. The lawsuits are still in their early stages, but it is clear from the number and size of legal coalitions and class actions that the litigation is going strong.

We reviewed the vaccine litigation to see what types of insureds the new claim wave affects, and how they may fare in the lawsuits. Unlike other drug-related actions filed against a single pharmaceutical company for a single product, the thimerosal vaccine suits have already named at least 22 pharmaceutical manufacturers, distributors and chemical companies as defendants in this litigation. Although the manufacturers are the principal targets, the lawsuits add chemical manufacturers who supplied the preservative as well as distributors of the vaccines. Physicians and health care clinics that administered the vaccines are also being sued. It is too early to tell if the plaintiffs will succeed with each group of defendants, but not too early to discuss the overall exposure from these vaccines and pharmaceuticals in general.

### *Childhood Vaccines and Autism*

The basic claim in the litigation is that a mercury-containing preservative in vaccines is responsible for the dramatic increase in autism and/or other neurological disorders noted in children over the past few years. This theory is controversial and causation remains one of several hurdles for plaintiffs, but the plaintiffs' bar is actively pursuing these cases.

Autism is a neurological disorder that can hinder the development of communication skills and social interactions and in some cases cause repetitive behaviors, including repeated body movements. Some cases may also result in aggressive and/or self-injurious behaviors and some individuals may be hypersensitive to outside stimulation. According to the National Institute of Child Health and Human Development (NICHD), a Division of the National Institutes of Health, autism was once thought of as rare with only about four cases per 10,000 births. However, the incidence of autism has increased

eventually became one of the most widely used preservatives in vaccines. Exposure to thimerosal and mercury grew during the 1990s as additional vaccines were given to children and with the increased use of multi-dose vaccine vials. Twenty years ago, children generally received seven vaccines by age two. Children now receive up to 32 vaccines by that age. By 1999, over 30 vaccines marketed in the U.S. contained thimerosal, and as many as 30 million children throughout the U.S. may have been exposed to mercury from thimerosal-containing vaccines during the 1990s alone.<sup>3</sup>

Concerns about the mercury content of thimerosal did not begin to surface until the late 1990s. Many of the suits allege that the children were developing normally until they received a series of vaccines, usually around the age of two, which resulted in regressive, disintegrative, late-onset or degenerative autism. The connection, according to the suits, is mercury added to the vaccines as a preservative. The federal Agency for Toxic Substances and Disease Registry (ATSDR) has stated that the nervous system is "very sensitive to all forms of mercury" and "very young children are more sensitive to mercury than adults...Children poisoned by mercury may develop problems of their nervous and digestive systems." ATSDR also states that "Exposure to high levels of...mercury can permanently damage the brain, kidneys and developing fetus. Effects on brain functioning may result in irritability, shyness, tremors, changes in vision or hearing, and memory problems."<sup>4</sup> Some of these symptoms may be similar to those experienced by autistic children.

### *The Causation Question*

Dozens of suits filed across the United States, including class actions, now allege that these childhood vaccines—and the mercury in them—caused children to develop autism or other neurological disorders. Dozens of additional suits are in various stages of planning.<sup>5</sup> The allegations in the *Redwood v. American Home Products* case are typical.<sup>6</sup> The infant vaccines allegedly resulted in the two-month old child receiving 62.5 micrograms (mcgs) of mercury—or 625 times the EPA's

**“Thimerosal vaccine suits have already named at least 22 pharmaceutical manufacturers, distributors and chemical companies as defendants.”**

dramatically over the past few decades; estimates of the number of autism cases currently occurring in the U.S. range from 20 to 68 cases per 10,000 births.<sup>1</sup> According to annual reports given to the U.S. Congress by the Department of Education, autism cases in schoolchildren increase by about 25% annually.<sup>2</sup> The Autism Society of America estimates that up to 1.5 million Americans now suffer from some form of autism. While changes in diagnosis and reporting certainly account for some of this growth, some experts do not believe this alone could account for the large increase.

The mercury connection began in the 1930s, when vaccine manufacturers began adding the preservative thimerosal to vaccines to prevent bacterial growth. Thimerosal, which is approximately 50% mercury by weight,

allowable daily exposure of 0.1 mcg.<sup>7</sup> By the time the a child reached 18 months, the vaccines could result in a total mercury exposure of 237.5 mcgs, or 30 times the federal adult permissible exposure limit.<sup>8</sup>

Causation issues lie at the heart of the claims. Many of the suits cite a government study discovered through a Freedom of Information Act request by Safe Minds, a group formed by parents of autistic children.<sup>9</sup> This initial research conducted by the Centers for Disease Control and Prevention found that children with 62.5 mcgs of mercury in their blood were 2.48 times more likely to develop autism. The plaintiffs' attorney alleges that the inclusion of additional children under age two, which is too young to diagnose autism, watered down these results. After the inclusion of the younger children, the study found that the children were 1.69 times more likely to develop autism.<sup>10</sup>

U.S. government sources, including the FDA and the NICHD, say there is no conclusive scientific evidence that vaccines or preservatives in vaccines cause autism. However, the lawsuits cite several government actions that raise safety concerns. In 1999, the FDA reviewed the use of thimerosal in childhood vaccines and found that "infants who received thimerosal-containing vaccines at several visits may be exposed to more mercury than recommended by federal guidelines for total mercury exposure." The Institute of Medicine (IOM) went further, recommending that all thimerosal-containing vaccines be destroyed and that studies begin at once to determine whether there was a link between mercury in preservatives used in the vaccines and neurological damage to children. Subsequently, an IOM committee concluded that, while it could not accept or reject a causation link, "the hypothesis that exposure to thimerosal-containing vaccines could be associated with neurodevelopmental disorders was biologically plausible." The causation issue is alive in Congress, where four hearings on thimerosal safety were called by Indiana Representative Dan Burton whose grandson is autistic.

Vaccine manufacturers responded to the medical reports by dramatically reducing

or eliminating the levels of thimerosal and mercury in vaccines, starting around the year 2000. According to the FDA, all routinely administered pediatric vaccines currently contain less than 0.5 micrograms of mercury per dose, or are mercury-free. However, existing vaccines containing thimerosal were never recalled and in a recent survey it was discovered that approximately 5% of vaccine stocks still contained the higher doses of preservative.

Moreover, several other vaccines may still contain significant thimerosal doses. The government is urging makers of the influenza vaccine to reduce or eliminate thimerosal. These flu shots are routinely recommended for pregnant women and could possibly expose a fetus to harmful levels of mercury. Thimerosal is still used in diphtheria and tetanus vaccines, and one manufacturer's adolescent/adult hepatitis vaccine. Thimerosal has also been used in certain immune globulin preparations, antivenins, skin test antigens and ophthalmic (e.g., contact lens products) and nasal products.

The theory that any neurological disorders, including autism, may have been caused by mercury in thimerosal remains controversial. Some other theories attribute the increase in autism to the administration of live virus vaccines to pregnant women and toddlers. If this theory proved to be correct, it may be no better for the vaccine manufacturers, distributors and pediatricians who administered the vaccines than the thimerosal litigation. Exposures to environmental toxins or metabolic disturbances are also being examined to determine if they may play a role in the development of autism. It is also quite possible that there is more than one cause of autism and other neurological disorders of which mercury exposure may or may not be one.

### *The Federal Vaccine Statute*

The vaccine suits seek damages under a variety of legal theories, including strict product liability, breach of implied warranty, negligence, conspiracy, failure to warn and fraud. Suits naming pediatricians allege malpractice, including failure to warn about the risks and side effects associated with the vaccines. A key defense to many of these

claims turns on the application of a federal law, the National Childhood Vaccine Injury Act (NCVIA), and the Vaccine Injury Compensation Program (VICP) it creates.<sup>11</sup>

Under the VICP program, claims against “manufacturers and administrators” for vaccine-related injuries must first be filed through a federal administrative program before they can be pursued in civil litigation. The Act, effective in 1988, creates a federal no-fault system designed to compensate individuals who have been injured by certain childhood vaccines. A Vaccine Injury Table maintained by the U.S. Department of Health and Human Services (HHS) lists injury-causing vaccines and their effects. Claimants must show they have an injury on that list from the particular vaccine, or prove that the vaccine caused an injury not listed or aggravated a pre-existing condition not on the table. VICP awards for vaccine-related injuries currently average over \$800,000; awards for vaccine-related deaths are capped by the program at \$250,000. Autism is not currently listed on the table, which means that claimants must prove causation to receive an award.

The statute does not bar plaintiffs from going to court. Win or lose in the administrative process, plaintiffs can seek higher damages in their civil cases. The federal law does establish several defenses that may preclude many of the cases from ever reaching a civil jury. In particular, the statute requires all claims to be filed first with the VICP, so that the administrative remedy be exhausted before a civil remedy is pursued. It also requires the administrative claims to be filed within three years of the injury. The federal law goes on to deny civil liability for unavoidable side effects and the failure to provide direct warnings.

The exhaustion requirement lies at the heart of most civil suit defenses, as many claimants have not filed or completed the administrative process. Plaintiffs are seeking to avoid the NCVIA altogether by arguing it does not apply to the thimerosal claims, so that the exhaustion requirement would not bar civil suits. In particular, they contend the NCVIA does not apply to “adulterants or contaminants” by its language, and that thimerosal is an adulterant because, as a

preservative, it is not part of the basic vaccine. If this argument succeeds, the suits can go directly to court. The defendants and the VICP respond that thimerosal was intentionally added to preserve the value of the vaccine and hence is not an adulterant. If their argument succeeds, individuals must file a claim with the VICP subject to all the defenses in the federal law.

The rulings on exhaustion of VICP remedies to date are few and split. A federal court in Texas recently held that because thimerosal was intentionally added to the vaccine, it was not an adulterant or contaminant and the plaintiff must first pursue administrative relief through the NCVIA.<sup>12</sup> The decision, however, allowed civil suits against the chemical companies that supplied the vaccine makers with thimerosal to go forward. The court held that the NCVIA “only prohibits the filing of any civil action against a ‘vaccine manufacturer or administrator’ prior to the filing of a program petition;” suppliers of raw materials such as thimerosal, who do not manufacture the vaccine, can be sued without the plaintiff first having to go through the NCVIA.

Federal courts in Oregon and Washington allowed civil suits to go forward, and found either that thimerosal was an adulterant or that the law was ambiguous.<sup>13</sup> In the Washington case, the suit proceeded against a medical clinic that administered the vaccine. In contrast, a New Jersey appellate court refused to allow a civil action after the VICP dismissed the administrative claim as untimely. In that ruling, the court held that the claimants must exhaust the full VICP process before going to court.<sup>14</sup> We doubt that more cases and appeals will result in uniformity, and expect that the U.S. Supreme Court may ultimately have the final say on how the federal law works.

### *Plaintiffs’ Bar Moves Forward*

The causation and federal exhaustion issues have not slowed civil litigation or dampened interest within the legal community. The plaintiffs’ bar has formed several coalitions consisting of hundreds of attorneys that are pooling resources, sharing information and filing suits around the nation against firms

that manufactured or distributed vaccines containing thimerosal. Some of the suits also name the pediatrician who administered the vaccine. Some plaintiffs' bar attorneys have allegedly been preparing thimerosal cases for the past two years and are already representing thousands of plaintiffs.<sup>15</sup> These coalitions are actively advertising for prospective clients with autistic children. According to one plaintiffs' attorney, "As many as one-third to one-half of autistic children were injured through exposure to mercury in vaccines."

One coalition, consisting of about 30 law firms nationwide, has already filed 45 lawsuits and is currently considering 800 to 900 others. Lawsuits, including class actions, have already been filed in at least ten states including: Florida, Georgia, Louisiana, Maine, Massachusetts, New Hampshire, North Carolina, Oregon, Texas and Washington. A class-action suit has also been filed in Ontario, Canada seeking to represent thousands of children with autism and other neurological disorders allegedly caused by thimerosal.<sup>16</sup>

Companies named as defendants in thimerosal suits include: Merck & Co., Pfizer Inc. a subsidiary of Warner-Lambert, GlaxoSmithKline, SmithKline Beecham Corp., Armour Pharmaceutical Co., Wyeth-Ayerst Laboratories, American Home Products Corp., Abbott Laboratories, Dow Chemical Co., Baxter International Inc., Gallipore Inc., Aventis Pasteur Inc. (formerly Connaught), EM Industries, GDL International Inc., Uriach Corp., Emerck Inc., Sigma Chemical Co., Aldrich Corp., Johnson & Johnson, Integra Biosciences Inc., Medisca Inc., Spectrum Chemical Manufacturing, Meridian Chemical and Equipment Inc., Eli Lilly & Co. and Evergreen Pediatric Clinic. The number of manufacturers is limited, but many more suppliers, distributors, clinics and physicians will surely make the defendant list.

#### *International Implications*

Recent studies in other countries are also finding alarmingly high rates of autism. According to the National Autistic Society the incidence of autism in the United Kingdom is estimated to be up to 91 cases per 10,000 births up

from an estimated four to five cases per 10,000 births in the 1960s. A 1993 Swedish study found between 36 and 71 cases of autism per 10,000 births.<sup>17</sup> A recent Finnish study found a four-fold increase in the incidence of autism among children in their northern provinces between 1979 and 1994.

Thimerosal continues to be used in vaccines distributed in other countries. Litigation has begun overseas as well, although not with the energy seen here. Over 1,000 British families have recently joined a thimerosal lawsuit which also alleges that mercury contained in vaccines caused autism and other neurological disorders. We expect more international litigation as knowledge of the litigation spreads.

#### *Insurance Policies Affected*

It seems, for now, that most of the U.S. litigation involves children vaccinated during the 1990s. The policies issued to pharmaceutical companies during that decade may be occurrence or claims-made. If the traditional occurrence policy was issued, insurers could face some coverage issues common in toxic tort litigation, including the number of occurrences and when they took place. In many claims the vaccines were given over a several year period, and the suits allege that the cumulative effect caused injury. If claims-made forms are in place,

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there is less probability that multiple years and limits will be impacted by a single claim.

There are many other differences between the occurrence forms of ten years ago and current claims made protections. One key element is whether defense costs will reduce applicable limits, which may be found in some claims-made forms. Deductibles and limits will also be different, as well as the application of any aggregate limit. The same questions apply to medical

malpractice coverage, which may have been written on either a claims made or occurrence basis for this time period.

Given that vaccine claims are still emerging, claims-made carriers may face some difficult issues and exposures when renewing or writing new risks coverage today. At the very least, insurers can inquire about continued sale or use of vaccines with thimerosal, for children, pregnant women and other adults. Questions about any stockpiles remaining in warehouses or offices would also appear in order. They can also inquire about warnings given to patients and how the warnings measure up to the federal requirements. But the

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tougher questions concern how the coverage for vaccine manufacturers, distributors/suppliers, clinics and pediatricians will be structured. How each insurer addresses retroactive dates, exclusions and reporting provisions, as well as other provisions, may turn on its comfort with the exposure and market conditions.

Insurers should at least recognize that an injured child makes for a very sympathetic plaintiff, and hence the potential for significant damages. The costs for behavioral and other necessary therapies for treating autistic children can be significant. Some of the suits seek monitoring costs, so yet another type of expense may be involved. Defense costs might also be substantial given the potential size of the plaintiffs’ pool and the many expert witnesses for each side. Some attorneys in the plaintiffs’ bar see some cases generating awards of tens of millions of dollars per affected child.<sup>5</sup>

#### **Other Pharmaceutical Claims**

Regardless of the outcome of the thimerosal litigation, there are a number of potential causes of action lining up in the wings against the pharmaceutical industry. Some of these include:

**Polio Vaccines:** Recent lawsuits allege that millions of doses of polio vaccines contaminated with simian virus 40 (SV40) caused or may be partially responsible for certain rare forms of cancers and brain tumors. Estimates are that between 1959 and 1963 over 100 million Americans received oral and injected vaccines contaminated with SV40. Some of the suits involve vaccines administered as late as 1970. According to one plaintiff’s attorney, the cancers allegedly associated with SV40 may have a latency period of 35 to 40 years. SV40 litigation has already begun in the U.S. with four lawsuits filed against pharmaceutical industry defendants including; American Cyanamid, now a subsidiary of American Home Products, and Pfizer. Suits allege that the companies did not adequately test their products for SV40 even after required to do so by U.S. regulations. The National Cancer Institute cites several studies that “failed to detect an increased cancer risk in those likely to have been exposed to the virus;” however, they also state that “there is some evidence to suggest that SV40, unrelated to polio vaccine, may be associated with human cancer.”<sup>18</sup>

**Human Growth Hormone:** At least one French lawsuit alleges liability from the manufacture, distribution and administration of human growth hormone (hGH), a treatment once commonly used to reverse dwarfism. There are allegations that hGH infected scores of people with Creutzfeldt-Jakob disease (CJD). A 1999 French study of 1,361 people who received hGH found that 55 had contracted CJD. Latency periods between the time of injection and the onset of CJD are between nine and 12 years but may possibly take as long as 38 years. According to one French association, 81 people have died of CJD in France since 1989 due to receiving hGH. The first lawsuit alleging that CJD was caused by hGH injections has already been filed in France.<sup>19</sup>

**Baycol/Lipobay (Anti-cholesterol drug):** More than 100 law firms representing 40,000 to 50,000 plaintiffs have filed at least 668 lawsuits in the United States against German pharmaceutical maker Bayer Corp. The lawsuits allege the plaintiffs suffered serious side effects from the company’s anti-cholesterol drug Baycol/Lipobay. Plaintiffs’ attorneys

are also moving to bring suits on behalf of plaintiffs from Australia, Canada, Egypt, France, Germany and Jamaica. One German attorney has filed a class action suit in the U.S. representing some 2,000 German plaintiffs. The drug, which has been linked to more than 100 deaths worldwide, was withdrawn from the market in August 2001. Analysts have estimated that the company could be facing up to \$10 billion in claims payments.<sup>20</sup>

A recent study by Dr. Karen Lasser of Cambridge Hospital and Harvard Medical School concludes that “one in five new drugs has serious side effects that don’t show up until the medicine has been on the market for a while.” The study analyzed 548 drugs approved for use between 1975 and 1999; about 10% were later given serious side-effect warnings or removed from the market for safety reasons. When the researchers focused only on those drugs approved towards the end of the study period, the percentage that later received serious side-effects warnings or were removed from the market climbed to about 20%.<sup>21</sup>

Suits against drug makers are not new, and risks from new drugs have always been with us. What is different is how many more new drugs are introduced and, more importantly, how many more medications and vaccines are taken by more people. The exposure base is just larger than before. Even if causation hurdles are not overcome, for thimerosal or any other vaccines or drugs, the prescription is still the same: use care; pharmaceuticals are risky business.

### Footnotes

1. See the FDA website, [www.fda.gov/cber/vaccine/thimerosal.htm](http://www.fda.gov/cber/vaccine/thimerosal.htm), for a collection of research materials and studies on the topic.
2. Yazbak, “Autism 2001: The Silent Epidemic,” [www.garynull.com/Article.aspx?article=/issues/vaccines/index.htm%20&Head=issues](http://www.garynull.com/Article.aspx?article=/issues/vaccines/index.htm%20&Head=issues) (Dec. 13, 2001).
3. Durban, “Autism Out Of The Shadows,” *the Columbian* (March 20, 2002).
4. ATSDR ToxFAQs for Mercury, at [www.atsdr.cdc.gov](http://www.atsdr.cdc.gov) (April 1999).
5. Cronin, “Mercury’s Legal Morass,” *The National Law Journal* (March 18, 2002).
6. *Redwood v. American Home Products Corp.*, No. 2001V0612M, Gayette Co., Ga. Super. Ct., filed in 2001.
7. Cave, “Vaccine Controversies: Past and Present,” *Journal of the Mississippi Academy of Sciences* (April 1, 2002).
8. “Vaccines/Dental Fillings: *Way v. American Home Prods. Corp.*,” Andrews Publications, Product Liability Litigation Reporter (April 2002).
9. [www.safeminds.org](http://www.safeminds.org).
10. See Durban and Cronin articles, notes 3 and 5, for the vaccine statistics and study findings cited in this section. See also the FDA and the Safeminds websites, in notes 1 and 9, for more about the studies.
11. 42 U.S.C. 300aa-1 et. seq. (1987). The VICP website provides excellent information about the law and the administrative program, at [www.hrsa.gov](http://www.hrsa.gov).
12. “Child’s Thimerosal Claim Dismissed; Parents Can Recover,” Harris Martin Online @ [www.harrismartin.com](http://www.harrismartin.com) (May 5, 2002).
13. *King v. Aventis Pasteur*, No. CV-01-1305-AS, D.Ore., filed March 5, 2002; *Garcia v. Aventis Pasteur*, No. 02-168, W.D. Wash., filed April 22, 2002.
14. *McDonald v. Lederle Laboratories*, No. A-5032-99T2 (N.J. Super. Ct., App. Div. June 18, 2001).
15. Kay, “National Lawyer Network Gears Up for Mercury Litigation,” *Miami Daily Business Review* (April 26, 2002); also Cronin, note 5.
16. Canada News Wire via Dow Jones (May 9, 2002).
17. The National Autistic Society (UK) website, [www.nas.org.uk](http://www.nas.org.uk). See also Yazbak, note 2, and the Durban and Cronin articles, notes 3 and 5, for more about the studies.
18. Lima, “Decades Later, Suit Is Filed In Bergen County, NJ Over Polio Vaccine,” *The Record* (March 26, 2002), and Harris Martin Columns: Asbestos, “Death, Disease Rates Normal for Those Inoculated with SV40-Contaminated Polio Vaccine; Study Results Reassuring but May be Premature Given Disease Latency Periods, Researchers Say” (Jan. 2002).
19. Agence France Presse, “38 years after injection, growth hormones caused brain disease,” (May 21, 2002).
20. Jameson, “Deaths Linked to Bayer Cholesterol Drug Double,” *The Times* London (Jan. 19, 2002). See also Caruso, “Bayer among drug companies targeted by mass litigation,” *AP State and Local Wire* (April 16, 2002 ).
21. See [www.jama.ama-assn.org](http://www.jama.ama-assn.org) for more about the study; See also *The Wall Street Journal*, “Health: Side Effects of New Drugs Often Take Time to Arise, Study Says,” (May 1, 2002).

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For an investment perspective of the pharmaceutical industry, please see our financial analysis in “Competitive Position and Financial Returns on the Pharmaceutical Business,” published by GeneralCologne Re Capital in April 2002. GeneralCologne Re Capital, our asset management company, provides specialized investment management services to the insurance industry. For more information, please contact John Gilbert at via e-mail at [john\\_gilbert@grneam.com](mailto:john_gilbert@grneam.com) or by phone at 860 676 8722.



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