Aerosol anatomy:

Aerosol product litigation-Part 1

This two-part series focuses on strategies that can be used to provide accurate verification that an aerosol product is developed, manufactured and tested to specific principles that meet "adequate standards of care."



One of the first lines of defense is to implement or upgrade a thorough record-keeping process during the product development program.



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his could be one of your worst nightmares: you are in a room, under oath, in front of a video camera, and the lawyer for the plaintiff, who is suing your company says, "So, you are in the technical department of your company and you worked on the development of Brand X aerosol. When you developed this product- which you know to be dangerous to the

knew to be dangerous to the public based on a record of

consumer complaints-what exactly did you do to improve the safety parameters of this-inherently dangerous-aerosol product?"

This scenario can unfold, unfortunately, as a result of today's litigious society. Aerosol products-due to their pressurized product form, the possible inclusion of flammable components and their potential for consumer misuse—are a prime ttarget for legal actions. I have participated as an expert witness in a dozen legal cases, and I have learned

that the best defense is provided by companies who have implemented robust systems of procedures and documentation, which span product development, manufacturing, quality control and customer service. Such systems provide the basis for a sound defense, and potentially mitigate judgments and settlements when cases do arise.

Obviously, the time to prepare to answer the question posed in the first paragraph, whether it is posed in six months or six years, is now. To begin, this can be done by auditing (and upgrading where necessary) your internal systems so that you can provide robust answers to this potential line of questioning in the future. This exercise will, in all likelihood, also add more detail, thoroughness and reproducibility to your current systems.

The intention of this two-part article is to suggest strategies, procedures and methods, which may be useful in mitigating your company's legal exposure, in the event a lawsuit emerges. Think of this as installing preventative measures for future damage control; it is, in effect, a kind of insurance. That said, I will quickly add that each aerosol manufacturing company is unique, and this article cannot address the wide variety of situations and complexities that exist in our industry. However, what I will do is share some basic general strategies and recommendations.

In Part 1, I will set the stage by introducing some of the basic legal techniques used by the plaintiff's attorneys in the pursuit of a product liability lawsuit and how those tools are employed to extract information, which is then used to build a case for the plaintiff. In addition, I will begin to look at possible strategies for upgrading manufacturers' R&D efforts to specifically prepare for intense probing from opposing counsel.

Part 2 continues with a review of manufacturing and quality assurance systems, an exploration of

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the consumer complaint and subsequent corrective action processes, from the manufacturers' viewpoint. This is the process that can be used to "flag" what may be more serious complaints (potentially leading to future lawsuits).

Throughout these two articles, the focus will be on strategies, methods and procedures that are used to provide accurate and thorough verification that your aerosol products

are developed, manufactured and quality tested to standards that not only meet or exceed industry standards, but also meet what the legal profession calls "adequate standards of care."

While this all sounds quite reasonable and obvious, I am still surprised today at the "holes," which can exist in the complex and interrelated systems involving the creation and production of aerosol products. Unfortunately, it is too late to address these potential gaps in the system when the inevitable lawsuit occurs. So, let's begin with the legal mechanisms used to build a case from the plaintiff's perspective.

Investigative legal tools

In the course of a lawsuit, opposing lawyers can learn a great deal about your company through a legal process called discovery. Discovery is part of the pre-trial litigation process during which each party requests relevant information and documents from the other side in an attempt to learn pertinent facts, which are used to build a case. This process is intended to probe the other side's version of the facts, find out what witnesses know and uncover other evidence for potential use at trial. Common discovery devices include:

- Deposition: a proceeding in which a witness, under oath, is asked to answer questions orally. Lawyers from both sides are present and the witness' testimony is recorded by a court reporter. The process may be videotaped.
- Interrogatories: written questions sent by one party to the other party for the latter to answer in writing (and under oath). These are answered under penalty of perjury.
- Request for admission: a written request whereby one party asks the opposing party to admit that certain facts are true. One party sends the other a request for admission so that basic iissues the parties agree upon can be resolved and not have to be proven if the parties go to trial.
- Request for production of documents: a request to a party to deliver certain specific documents to the opposing party for review and possible use at trial.
- Request for inspection: a request by a party to look at tangible items in the possession or control of the other party,

such as an aerosol can that exploded and injured the plaintiff. Items requested may include virtually any physical item.

• Subpoena: a legal order requiring a witness to appear in court or at a deposition. A subpoena is issued by the court, and if the witness fails to comply, he/she can personally be held in contempt of court. In some states, a law enforcement officer must personally serve the subpoena, while in others, service can be issued by mail or by telephone call.

Obviously, the amount and type of information that companies may be ordered to produce are quite extensive and span R&D, manufacturing, quality assurance and customer service; literally all areas of the company are "fair game" for opposing attorneys to probe.

I'm often asked why customer service is included on the list. Actually, there is a wealth of information here: customer service is typically the first layer of contact point for problems or potential problems. From an opposing counsel's point of view, this is where the records of previous complaints are located, as well as a record of what your company did-or did not do-early in the process to acknowledge and correct potential problems. The actual investigation and corrective actions may, of course, be led by othet groups-quality assurance, for example; however, the "top layer," where the problems are initially addressed and the complaint information captured, is often the customer service department.

Back to the beginningproduct R&D

A prime area that plaintiff lawyers often probe is the research and development effort, which led to the development and manufacture of the product involved in a lawsuit. As discussed above, opposing counsel has at their disposal a wide array of discovery tools that allow them to probe all aspects of product development, including interviewing personnel via the deposition

process, reviewing confidential lab notebooks and test reports via requests for documents.

Obviously, the first line of defense is to implement, or possibly upgrade, a thorough record-keeping process during the product development program. This may include handwritten lab notebooks, which are signed and counter-signed daily, as well as electronic data tracking and database management systems.

Data captured include test procedures and results; reports; summaries of meeting notes; and information supplied by third party sources, such as component vendors. Due to the nature of electronic information, a robust system of back-up and archiving is essential.

The continuity of historical project record-keeping must be maintained as personnel changes occur.

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This is often overlooked. One system requires that all notebooks and project data files be catalogued in a central data collection archive so that a logical project trail can be found in the future.

Beyond record keeping, a robust R&D effort involving the development of aerosol products might include routine evaluations of alternative chemical ingredients and propellant systems, as well as

Quick Takes:

Comprehensive systems that document development, manufacturing, QC and customer service provide the basis for a sound defense-and potentially mitigate judgments and settlements when cases do arise.

Internal systems for processing complaints and implementing corrective actions can serve as the "early warning system" for potential trouble areas in terms of product liability. Thorough efforts to identify and address problem areas early can substantially reduce potential future liability exposure.

alternative packaging. This is done with the specific focus of improving, if possible, the safety of the aerosol product under development. When considering these possibilities, documentation is essential. It is understood that in many cases these efforts will lead to dead-ends due to: unreasonably high costs; component availability issues; or other technical issues, such as incompatibility within the aerosol system that may prohibit alternative choices.

However, routinely exploring and documenting research in these areas will, in the course of aerosol product development, yield a more complete R&D effort, and, occasionally, may provide you with a technical or marketing advantage over the competition.

Additionally, all supplier contact-as well as all final formula and packaging decisions-should be documented in notebooks or electronic files that are permanently archived. Some companies use a Supplier Contact template to cap-

ture key discussion and decision points when dealing with suppliers.

When combined, the processes described above will provide a clear and thorough accounting of the R&D effort directed at developing an aerosol product, which may be utilized in the future in a number of ways, including demonstrating your company's efforts to deliver a safe and effective aerosol product.

In Part 2, we will examine strategies relating to quality control during the manufacturing process. In addition, we will look into internal systems for processing complaints and implementing corrective actions. These procedures serve as the "early warning system" for potential trouble areas in terms of product liability. Thorough efforts to identify and address problem areas early can substantially reduce potential future liability exposure. SPRAY

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