PORZIO
BROMBERG&NEWMAN P.C.
ATTORNEYS AT LAW

Pharmaceutical and Medical Device

People
Performance
Perspective

Porzio's Pharmaceutical and Medical Device Department is a Leader in its Field

For more than 30 years, Porzio has represented pharmaceutical and medical device manufacturers, from global drug makers to small specialty equipment companies. Our work has led to landmark decisions and shaped substantive law. For example:

- Our briefing and legal argument before the New Jersey Supreme Court resulted in its adoption of the "learned intermediary" doctrine in this state.
- We were intimately involved in developing the vaccine industry's strategy to defeat plaintiffs' efforts to impose market share liability.
- Our firm prevailed against plaintiffs' attempts to eliminate the state-of-the-art defense in New Jersey for pharmaceutical manufacturers.

Our litigation and regulatory compliance work in the pharmaceutical and medical device field also has drawn national attention in areas such as class action certification, protective orders for proprietary information, the exclusion of junk science, and the applicability of consumer fraud claims.

Mass Torts

Porzio is at the forefront of the industry for its success in litigating mass pharmaceutical and medical device product liability cases at the trial and appellate levels, in state and federal courts. We also have served as lead trial counsel in one of the few pharmaceutical personal injury and medical monitoring class actions tried before a jury.

Warning Labels

We litigate warning claims for pharmaceutical and medical device manufacturers. We have successfully litigated the adequacy of warning labels for both over-the-counter and prescription drugs, and claims involving over-promotion in labeling, off-label uses, and product confusion due to inconspicuous or similar labeling.

Counseling

The current business environment, coupled with intensified regulatory scrutiny in the health care field and the wide use of the Internet and other mass media to fuel plaintiffs' claims, is compounding the risks—and lawsuits—drug and device makers are likely to confront. The best defense against such matters is a good offense: Large and small companies alike have much to gain by crafting and implementing corporate compliance programs that meet regulatory guidelines before lawsuits are filed. We counsel pharmaceutical and device manufacturers on issues related to bringing new prescription drugs to market, including:

- The propriety of promotional and advertising materials, including physician, managed care and direct-to-consumer pieces.
- Continuing medical education programs with consideration to FDA regulations.
- The procurement of insurance, product liability issues and general risk management initiatives.

- FDA sampling regulations and the implementation of compliant product sampling programs.
- Direct-to-consumer advertising, revising product labels.
- Involuntary recalls due to after-market discovered side effects.

The following are among the prescription pharmaceuticals and medical devices we have defended:

Prescription Pharmaceuticals

- Anorectic drugs
- Diethylstilbestrol (DES)
- Diet drugs
- Intrauterine devices
- Hormone therapeutics
- Oral and implanted contraceptives
- Diphtheria, Pertussis, and Tetanus (DPT) vaccine
- Biologics
- Poliovirus vaccine
- Influenza vaccine
- Anticonvulsants
- Antimalarials
- Antidepressants
- Antipsychotics
- Anesthetic agents
- Non-steroidal anti-inflammatory drugs
- Tetracycline and other antibiotics

Medical Devices

- Electrosurgical generators
- Apnea monitors
- Ophthalmic and laboratory equipment
- Catheters
- Needles
- Sutures
- Latex gloves
- Medical implants
- Breast implants
- Heart valves
- Pacemakers
- Orthopedic prostheses
- Corneal tissue grafts

Over the Counter (OTC)

- PPA
- Ephedra

Porzio Pharmaceutical Services

To further serve our clients in the pharmaceutical and medical device industry, our subsidiary, Porzio Pharmaceutical Services, offers the Porzio Pharmaceutical Digest, an Internet-based searchable database. This powerful research tool is designed to provide manufacturers and sales and support companies with instant access to the statutes, regulations and pending legislation relating to distribution of drug samples, gifts and honoraria to medical practitioners.