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House Bill Proposes to Repeal the Learned Intermediary Doctrine

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On February 8, 2011, Representative Bob Filner (D-CA) introduced legislation that could dramatically change the products liability landscape for pharmaceutical and medical device manufacturers. The bill, entitled the Consumer Protection Act of 2011 (H.R. 542), would bar the use of the learned intermediary doctrine in tort claims based on products liability. The bill states:

It shall not be a defense to any tort claim in any court in the United States that a manufacturer of a product has fulfilled that manufacturer's duty of care when the manufacturer provides all of the necessary information to a learned intermediary who then interacts with the consumer of the product. (Emphasis added.)

The bill has no co-sponsors and has been referred to the House Committee on the Judiciary. Representative Filner introduced the same legislation last year (H.R. 6421), which ultimately died in the House Subcommittee on Courts & Competition Policy.

Courts in a majority of states have established the physician as a "learned intermediary" between the consumer purchasing a medical product and the manufacturer when the product is available only by prescription. Courts have reasoned that where the learned intermediary serves as the legally mandated gatekeeper, the company cannot be held liable for the customer's injury on a failure to warn theory if the manufacturer made reasonable efforts to warn the customer's physician about any potential adverse effects. In the last three years, courts in West Virginia and New Mexico, on the other hand, have expressly rejected the learned intermediary doctrine. Passage of H.R. 542 would further expose drug and device companies to liability in cases in which the learned intermediary doctrine has previously provided a defense.

We suggest you contact your U.S. Representative, industry organization, or a member of our Drug, Device & Life Sciences Industry Team.