



## Memorandum in Opposition

May 19, 2009

**S.3157 (MONSERRATE) / A.5201 (BRODSKY)**

### **AN ACT to Subject manufacturers of prescription drugs or medical devices who engage in direct-to-consumer advertising to liability**

On behalf of **New Yorkers for Lawsuit Reform** (NYLR), a broad based coalition of businesses, professionals, health providers, municipalities, not-for-profits, insurers and concerned citizens, we are writing to urge that this bill be HELD. Our opposition to S 3157/A5201 is based on the fact that the adoption of this proposal would lead to increased costs to businesses and consumers. The bill will unquestionably raise liability costs for makers of medicine, while potentially decreasing patient access to appropriate medication.

This bill eliminates a well-established and common-sense legal defense called the “learned intermediary doctrine” and puts New York out of step with the law in the majority of states. The learned intermediary doctrine is an exception to the general rule in torts that a manufacturer has a duty to warn the user of the risks involved with using a product. The learned intermediary doctrine recognizes that the warnings which accompany medicines and medical devices are directed to physicians, who have face-to-face interaction with patients and who are best suited to evaluate the risks and benefits associated with prescription medication.

Under the learned intermediary doctrine, a prescription medicine manufacturer’s duty to warn consumers about the dangers of a product extends only to the prescribing physician or other health care provider who acts as the “learned intermediary” between the manufacturer and patient. This rule keeps the doctor-patient relationship strong by requiring the physician to make the best medical decisions for his or her patients, not the drug manufacturer. Physicians are in the best position to present both the unique benefits and potential risks of prescription medications to individual patients.

Advertising for medicines informs patients about new therapies available for previously untreatable and difficult to treat conditions. Advertising makes consumers aware of choices in prescription medication treatments. The information is intended to help the public learn about potential treatments and is the first step leading to discussions with treating physicians. It is imperative that patients learn more about prescription medications from physicians who have training and experience in their use and who are familiar with the unique attributes of individual patient histories. In fact, advertising for medicines generally advise people to talk to their doctor. Professional medical recommendations from physicians are more custom-tailored to an individual patient than the generally stated, FDA-regulated medical risk information. Physician

recommendations help patients make better informed decisions than 30-second commercials, or magazine advertisements.

If medicine makers are "not relieved of a duty to warn consumers," then the resulting required warnings for a prescription drug would likely be required to mirror the complete, complex, highly-technical statistical warnings provided to physicians. Assuming that such information actually reached and was reviewed by a patient (let alone, understood), one likely result would be confusion, fear, and unreasonable rejection of appropriate medical treatment. This is not in the best interest of patient treatment and safety.

The learned intermediary doctrine has been sustained almost everywhere because it preserves the desirable doctor-patient relationship. Passage of this bill would result in increased lawsuits for both prescription drug manufacturers and physicians. Unjustified liability simply drives up health care costs and can deter the development or continued production of helpful medicines. If adopted this legislation will help personal injury trial lawyers and generally hurt both businesses and consumers.

Accordingly for all the foregoing reasons it is urged that this bill be held.

Respectfully submitted,

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**New Yorkers for Lawsuit Reform**