No. 33211 *State of West Virginia ex rel. Johnson & Johnson Corporation, a foreign corporation, and Janssen Pharmaceutica, Inc., a foreign corporation and a wholly-owned subsidiary of Johnson & Johnson, Inc. v. The Honorable Mark A. Karl, Judge of the Circuit Court of Marshall County, Daniel W. Wilson, M.D., and Estate of Nancy J. Gellner, by Gregory A. Gellner, Executor*

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Starcher, J., concurring:

I concur with the majority's decision to not adopt the "learned intermediary" doctrine. What the majority opinion's lengthy discussion suggests, and the dissenting opinion's tenor makes clear, is that the learned intermediary doctrine is a bad public policy that is so laced with contradictions, caveats and exceptions that it is impossible to apply the doctrine fairly and consistently. The doctrine is a giant toothless tiger that causes great mischief, but accomplishes little good.

The doctrine therefore has no place in our common law. Simply because many other jurisdictions have adopted the doctrine isn't enough to say the doctrine is rational, fair, and good public policy. My mother always said to me that "just because other people are doing it doesn't mean it's the smart thing to do." There should first be a good reason before the Court adopts a major alteration to our jurisprudence; following other states off the cliff like lemmings isn't enough.

Drug companies spend years developing drugs, and more years testing the use and effect of drugs on various medical conditions, and more years being the exclusive manufacturer, marketer and distributer of drugs. In all that time, it is the drug manufacturer that has the best opportunity to discern the proper and improper uses of a drug. And in all

that time, the drug manufacturer has the best opportunity to carefully craft instructions regarding the safest uses of the product.

In a typical "failure to warn" product liability lawsuit, we say that a product is defective when the labeling, instructions or warnings didn't sufficiently warn the product's end-consumer of some hazard.

At its heart, the learned intermediary doctrine is designed to artificially shift liability away from the careless manufacturer of a product, and onto an innocent intermediary who is responsible for distributing the defective product to the consumer. The doctrine says that if the manufacturer warns an intelligent, trained middleman that the product is dangerous if used a certain way, then the manufacturer has no liability to the end-consumer if the middleman fails to pass on the warnings.

In the context of prescription drugs, the learned intermediary doctrine makes doctors the insurers of major pharmaceutical companies. Under the doctrine, the drug companies can profit by marketing their drugs directly to consumers, but they only have to give warnings of known hazards to doctors. The presumption is that patients are too simple-minded to understand the instructions and warnings, so they don't even need to know they exist. And because the doctor is "learned," then the warnings don't have to be short and simple; instead, the instructions can drone on for pages so that only the highest trained doctor with tons of free time on his or her hands will be able to decipher the safe, and dangerous, uses for the drug. The doctor becomes solely responsible for making the product safe, not the manufacturer.

I refuse to subscribe to such an archaic and parochial view of the law.

Our product liability law is motivated by many valid public policies, one of which is to improve the safety of products by improving the warnings and instructions that end-consumers receive. Adopting the learned intermediary doctrine in the context of prescription drugs impinges upon this public policy. The doctrine discourages drug companies from placing clear and succinct warnings and instructions on their products. It discourages giving any warnings to end-consumers, and discourages clear warnings to physicians. And it presumes that physicians have the training and the time to discern every potential problem that a drug may cause a consumer.

The majority opinion's rejection of the doctrine recognizes that patients should have a say in their course of treatment. Patients can read the labels, instructions and warnings, and if the manufacturer makes them clear enough, then patients can be proactive in working with their doctors to receive the best care. Patients can read the manufacturer's instructions and ask their doctors about drug interactions, or about adverse drug reactions and side effects.

And refusing to adopt the learned intermediary doctrine does nothing to alter a doctor's duty of care toward the patient. A doctor always has a duty to obtain the informed consent of a patient for a course of treatment. To me, this means that doctors have always had, and will always have, a duty to talk to their patients about the proper uses, improper uses, and risks of drugs and medical devices. Nothing in the majority opinion changes a doctor's rights and responsibilities. By rejecting the doctrine, the gist of the majority opinion

is to say that the party making all the money in this transaction – that is, the drug manufacturer – cannot escape responsibility for their actions or inactions. Just like a doctor has always done, the drug manufacturer must attempt to fully and understandably instruct the end-consumer of the proper and improper uses for the product.

There are, of course, some occasions where there is no conceivable way for a drug manufacturer to give instructions and warnings to the end-consumer. For instance, patients in the emergency room or in surgery have little ability to read warnings, and all decision-making must rest in the learned intermediary – the doctor, or the nurse, or the paramedic. And besides, the end-consumer isn't the one "using" the product in that circumstance. It is the medical care provider who is making all the decisions.

There may also be instances where the doctor chooses to prescribe a drug in an "off label" and experimental way. However, existing product liability law already holds that a manufacturer is not expected to warn of hazards caused when the product is used in unanticipated ways.[1]

But in most instances, drug manufacturers can provide warnings and instructions to the end-consumer. Labels can be placed on bottles, pamphlets tucked into boxes, and brochures packed in with the boxes of drugs or devices shipped to hospitals and

[1]If a doctor uses or prescribes a drug in an unanticipated, experimental way, then any subsequent lawsuit is likely going to be governed by standard malpractice liability law: did the doctor breach the standard of care owed to the patient? However, if a doctor uses a drug in an experimental way, but was encouraged to do so by the drug manufacturer, then under such circumstances the drug manufacturer has a duty to reasonably instruct and warn of known hazards.

doctors' offices. Samples distributed in doctor's offices can have warnings affixed to the sample boxes. Pharmacists can and already do tape warnings onto pill bottles, and often include printed instructions and warnings with any medication that is dispensed. Before or after surgery, the end-consumer could – if necessary – receive a pamphlet describing the drug or implanted medical device, instructing how it should be used and warning of known problems. And so on.

In sum, I am entirely against adopting the learned intermediary doctrine into our product liability law. Our existing law of contribution and indemnity, of contributory negligence, and of joint and several liability, serves us well in allocating fault when a manufacturer inadequately instructs and warns about the safe and dangerous uses of a product.

I therefore concur with the majority opinion.