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Innovator duty of care in the pharmaceutical industry

Does the inventor or "innovator" of a brand-name drug have a duty of care to the consumers of that drug's generic equivalent manufactured by a competitor?

The Ontario Superior Court of Justice considered this question in the recent case of *Goodridge v Pfizer Canada*[1] and determined that, for now, no such duty exists.

In that decision, the defendant Pfizer developed, manufactured and marketed the drug "Neurontin," its brand name for the drug gabapentin.

When Pfizer's patent rights in Neurontin expired, various generic manufacturers subsequently sought and obtained approval to sell a generic version of gabapentin in Canada. Pfizer was not involved in the pre-approval testing and regulatory filings, or in the post-approval manufacture, sale, marketing and distribution of any generic version of gabapentin.

A putative class action was later brought against Pfizer on behalf of all persons resident in Canada that were prescribed and ingested Neurontin or its generic equivalent gabapentin. The plaintiffs asserted, among other things, that Pfizer, as the innovator of Neurontin, had a duty of care to the consumers of generic gabapentin and that Pfizer was liable for the alleged harm caused to consumers by the generic gabapentin that was manufactured and distributed by Pfizer's competitors.

The plaintiffs' claims in *Goodridge* necessitate an understanding of the regulatory process for new drug approval in Canada. In brief, before a new drug can be approved by Health Canada it must first undergo a rigorous evaluation and approval process. The regulatory assumption is that the safety and efficacy of a new drug is adequately scrutinized during the drug's initial approval. Later generic equivalents undergo a comparatively abbreviated approval process that focuses on whether the generic drug is bioequivalent to the brand-name, original drug. As such, generic manufacturers rely to some extent on the results of the innovator's approval process. The plaintiffs in *Goodridge* implicitly suggested that this reliance could support a new duty of care between the innovator of a brand name drug and the ultimate consumer of a competitor's generic equivalent.

Pfizer opposed class certification and moved to strike certain parts of the claim. The *Goodridge* class action was certified but not with respect to the claim or common issues concerning Pfizer's liability for generic drugs manufactured by its competitors.

On this point, the Court considered whether Pfizer had a duty of care to the consumers of generic gabapentin. In conducting this analysis, Perell J. found that it was "reasonably foreseeable" to Pfizer that Neurontin would be copied

[1] 2010 ONSC 1095 [*Goodridge*].

by its competitors and that these competitors would rely on the development work and regulatory approval obtained by Pfizer in its capacity as the drug innovator.

However, the Court found no duty of care between the innovator of a drug and the consumers of subsequent generic drugs manufactured by a competitor.

The Court found that the connection between the harm alleged by the plaintiffs and the innovator was Pfizer's release of the idea for the drug. The Court then considered whether it would be fair to find Pfizer, as the innovator, liable for releasing the idea for Neurontin into the marketplace. The Court found the imposition of a duty of care in this circumstance would be unjust for two reasons. First, the Court determined that recognizing such a duty would be tantamount to imposing strict liability for harm on the innovator, which would represent a significant change in Canadian products liability law. Second, the Court found that any harm in this case would have to have arisen from releasing the idea for Neurontin without suitable warnings about how any associated product may be used and that imposing liability on Pfizer for another company's allegedly deficient warnings would be "unfair (since Pfizer) had no power to control, qualify or stop such conduct."

The Court went on to find that even if it was wrong and a duty of care existed, public policy ought to negate the scope of any such duty. Perell J. again noted that recognizing an innovator duty of care would make the innovator strictly liable for defective products, making the innovator the insurer against all harm flowing from its innovation. In addition, imposing liability on the innovator would discourage medical advances and innovative technologies, generally, and should therefore be avoided.

Goodridge demonstrates that courts are reluctant to "extend" the existing duty of care between manufacturer and ultimate consumer in the pharmaceutical industry. However, *Goodridge* may not have "closed the door" on innovator duty of care completely. The plaintiffs' common issues in *Goodridge* did not include a consideration of whether Pfizer made a negligent design choice in the development of Neurontin. The Court noted that the presence of a negligent design flaw "would be the only basis for alleging misconduct against the innovator".

However, given strong policy arguments against it, it seems unlikely that any duty of care between innovators of brand-name drugs and the consumers of generic equivalents will be recognized in the near future.

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a cautionary note

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