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# The Impact of the Ensuring Innovation Act on NCE Exclusivity

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The Ensuring Innovation Act recently became law after passing in the Senate with unanimous, bipartisan support. According to one Senator, the intent of the legislation was to “close loopholes to prevent awarding market exclusivity to products that do not present true innovation and unduly delay cheaper generic from entering the market.” Is this much ado about nothing, or much to be concerned about?

Marketing exclusivity is commonly justified as an opportunity for a drug innovator to recoup its significant investment in developing, clinically testing, and satisfying the FDA as to the safety and efficacy of a new chemical entity (“NCE”). Whether the Ensuring Innovation Act is cause for concern among drug innovators, it seems, turns on the FDA’s historical practice.

The FDA has authority to grant prescription medicines different types of marketing exclusivities, including exclusivity for new medicines that meet the definition of an NCE. The NCE exclusivity precludes the FDA’s approval of any other applications for certain potentially competing drugs for a period of five years.

Previously, an NCE designation meant that the drug’s “active ingredient” was not previously approved by the FDA. The Ensuring Innovation Act replaced the term “active ingredient” with “active moiety” in the Federal Food, Drug, and Cosmetic Act (“FD&C Act”). In short, the change to the law is consistent with the FDA’s historical interpretation of the term “active ingredient.”

Before the new law, FDA regulations interpreted the FD&C Act such that NCE exclusivity would not be granted for a minor change to the chemical structure of an active ingredient that had no therapeutic significance. Not surprisingly, the FDA's interpretation was the subject of several legal challenges, including a 2017 decision by the U.S. Court of Appeals for the District of Columbia Circuit – *Otsuka Pharmaceutical Co., Ltd. v. Price* – that upheld the FDA's interpretation. The court rejected the argument that the FDA's interpretation of the FD&C Act was inconsistent with the statute. The court cited, among other things, its prior decision in *Actavis Elizabeth LLC v. FDA*, where the D.C. Circuit upheld the FDA's position that a prodrug of a previously approved medicine would be entitled to NCE exclusivity if it contained a different active moiety.

In line with *Actavis* and *Otsuka*, Congress appears to have codified the FDA's same-moiety test, eliminating any perceived tension between the FD&C Act and existing regulations with respect to the award of NCE exclusivity.

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