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Axinn FDA Update: Insights on the MODERN Labeling Act

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On November 17, 2020 the U.S. House of Representatives passed the MODERN Labeling Act of 2020 (H.R. 5668, the "Act") with bipartisan support. The Act amends the Food, Drug and Cosmetic Act to permit the Food and Drug Administration (the "FDA") to identify drugs "for which updates would provide a public health benefit" and propose and order labeling changes. The Act directs FDA to use this authority to identify products for which generic drugs are on the market but the branded drugs have either been withdrawn or discontinued for reasons other than safety and efficacy, in which case the brand manufacturer with the primary responsibility to update the label is no longer reporting information about post-approval adverse events.

After identifying drugs whose labels need to be updated, the Act would permit FDA to enter into cooperative agreements with public and private entities to review the currently available scientific evidence for such drugs and seek public comment, including regarding whether clinical practices reflect the approved label. If, based on this evidence, FDA determines that labeling changes are appropriate, it must provide notice summarizing the evidence and "provid[ing] a clear statement regarding the additional, modified, or supplemental information for such labeling." Within 30 days, the generic manufacturer must then agree to the proposed labeling changes or notify FDA that it does not believe the changes are warranted and submit a statement detailing why.

While the Act generally describes that FDA may determine that a drug's label needs to be updated based on "the available scientific evidence," the Act specifically states that it does not limit FDA's determination "solely based on the availability of new safety information." Further, the Act does not provide criteria that FDA must follow to decide whether labeling changes are appropriate. If a generic manufacturer opposes FDA's proposed changes, the Act does not describe what happens in the event an "agreement" cannot be reached between the opposing parties and FDA. Based on the Act's final approval structure, however, in the event an

agreement cannot be reached, FDA will likely use its discretion and experience to order changes, and if so, the specific changes. Once FDA reaches its final decision, if it orders labeling changes, the generic manufacturer must (1) “update its paper labeling for the drug at the next printing of that labeling,” (2) “update any electronic labeling for the drug within 30 days of such order,” and (3) “submit the revised labeling through the form, ‘Supplement—Changes Being Effected.’”

The Act has been sent to the Senate and referred to the Senate Committee on Health, Education, Labor, and Pensions. Although the Act must still pass the Senate, given its bipartisan support in the House, it is possible that we will see similar support in the Senate. If so, generic manufacturers will need to adjust to this new requirement and be ready to respond to FDA actions on labeling going forward.