Think Your Drug is Safe and Effective? Not So, Says the SEC



For life sciences companies who are or are looking to become publicly traded in the U.S., one of the most frequent comments that we see from the SEC as part of their review process is the following:

You make several assertions regarding the safety and efficacy of certain of your product candidates. Safety and efficacy determinations are solely within the authority of the FDA (or applicable foreign regulators). Please revise these statements to remove statements/inferences that your product candidates are safe and/or effective. We will not object to a discussion of whether your product candidates were well-tolerated or discussion of whether trial endpoints were met.

Given the frequency with which verbiage such as “safety data” or “efficacy data” is used among drug developers, investors and even the FDA itself, this position by the SEC often catches companies by surprise. However, the SEC has consistently taken the view that such references are not appropriate in companies’ SEC disclosures. Importantly, even oblique references to “safety” or “efficacy” (for instance, forward-looking statements regarding the expected safety profile of a product candidate) will often draw an SEC comment.

Fortunately, there are typically relatively straightforward ways to resolve this comment. For instance, rather than referring to a drug’s efficacy, companies can instead refer to whether it met trial endpoints or demonstrated activity. Similarly, in lieu of referring to a drug’s safety, companies can refer to its tolerability or its adverse event profile observed to date.

While this topic is typically a point of emphasis in the IPO process, we often find that companies become less vigilant about avoiding “safety” and “efficacy” references in their subsequent Exchange Act periodic reports (not to mention their press releases and investor presentations). However, we frequently see this comment come up in SEC reviews of public company periodic reports, and proactively steering away from references to “safety” and “efficacy” can be a useful way to remove some low-hanging fruit that might otherwise draw an SEC comment.