Chevron Under Fire: What Healthcare and Life Sciences Investors Should Know

January 19, 2024

Investors in heavily regulated business sectors—particularly healthcare and life sciences—should carefully monitor several Supreme Court opinions that may make it easier for private parties to challenge federal regulations and regulatory actions in federal court. The Supreme Court heard oral arguments for these cases on January 17, 2024 and is expected to issue an opinion by this summer.

In *Loper Bright Enterprises v. Raimondo, Relentless, Inc. v. U.S. Department of Commerce* and *U.S. Food and Drug Administration v. Alliance for Hippocratic Medicine*, the Supreme Court will be considering the "*Chevron* doctrine," which requires courts to defer to an agency's interpretation of an ambiguous federal statute so long as the agency's interpretation is reasonable. In practice, this doctrine has made it challenging (although not impossible) to overturn regulatory actions that are based on a regulator's interpretation of an ambiguous federal statute.

Although it is impossible to predict the outcome of these cases with any assurance, it is anticipated that the Supreme Court will abolish or at least significantly modify the *Chevron* doctrine. Such an outcome would be unsurprising because the Supreme Court has taken steps to weaken deference to federal regulators in recent years. The Supreme Court, for example, invoked the "major questions" doctrine to invalidate certain environmental regulations issued by the Environmental Protection Agency based upon the absence of clear congressional authorization.

Ongoing litigation challenging approval by the Food and Drug Administration ("FDA") of mifepristone, a prescription drug commonly used for medication abortions, illustrates the type of litigation that may proliferate if the *Chevron* doctrine is abolished. The Fifth Circuit in *Alliance for Hippocratic Medicine ("AFHM") v. FDA* held that in 2016 and 2021, the FDA wrongfully loosened restrictions for patients seeking access to the drug in order to terminate their pregnancies. In doing so, the Fifth Circuit rejected the agency's scientific judgment that the drug is safe and effective. The Supreme Court will be reviewing the Fifth Circuit's determination that the FDA's actions were arbitrary and capricious. If the Supreme Court upholds the Fifth Circuit's decision, it would likely represent the first time that FDA approval of a New Drug Application ("NDA") was

overturned. Such an outcome may inspire other advocacy organizations to seek to overturn FDA approval of other drugs (or other FDA-approved products such as certain medical devices) that they oppose.

The potential abolition or significant modification of the *Chevron* doctrine may have differing impacts on healthcare and life science companies depending on their circumstances:

Positives: Abolishing the *Chevron* doctrine will facilitate lawsuits by regulated entities challenging agency actions on the basis that they are not authorized by the applicable statute. For example, many clinical laboratories have objected to the FDA's recent proposed rule addressing the regulation of Laboratory Developed Tests ("LDTs"), which would subject LDTs to regulation as "devices" under the Federal Food, Drug, and Cosmetic Act. Critics argue the agency lacks the statutory authority to regulate these products—a position that would be easier to litigate if the FDA's interpretation of its authorizing statute is no longer afforded discretion.

Negatives: Abolishing the doctrine could upend regulatory stability upon which regulated entities often rely. Life science companies, for example, frequently invest vast sums of money on new drug development predicated on the assumption that if the FDA approves a drug or device, that approval is unlikely to be overturned in court. The investment calculus potentially could change if such an approval could more easily be subject to a litigation challenge like the one in *AFHM v. FDA*. The *Chevron* doctrine has also helped promote stability in the administration of publicly funded insurance programs like Medicare and Medicaid, which cover nearly half the U.S. population and impact nearly every corner of the healthcare industry.

Once the Supreme Court rules, investors in regulated industries should carefully review the specific interests of target companies to determine how (if at all) the Supreme Court's opinion facilitates or harms their interests, or does some combination of both.

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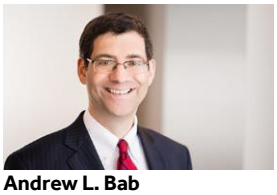
Please do not hesitate to let us know if you have any questions.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