QUESTION PRESENTED:

1. Whether, under the conflict preemption principles in Buckman Co. v. Plaintiffs’ Legal Comm., 531 U.S. 341 (2001), federal law preempts state law to the extent that it requires the fact-finder to determine whether the defendant committed fraud on a federal agency that impacted the agency’s product approval, where the agency—which is authorized by Congress to investigate and determine fraud—has not found any such fraud, and thus—as in Buckman—the state requirement would interfere with the agency’s critical functions.

2. Whether, under the conflict preemption principles in Buckman, federal law preempts the provision in a Michigan statute that allows a product liability claim to be maintained against a manufacturer of an FDA approved drug where, without an FDA finding of fraud on that agency, the fact-finder is required to make a finding under state law as to whether the manufacturer committed fraud-on-the-FDA and whether, in the absence of that fraud, the FDA would not have approved the drug.