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Federal Court Decision Increases Reporting for Clinical Trial Sponsors, But Enforcement Subject to Agency Resources and Discretion

While the U.S. Department of Health & Human Services (HHS) is currently working to contain the spread of the COVID-19 outbreak, some agencies within the department may soon be asked to divert resources towards collecting and reporting significant swaths of previously unpublished clinical trial data.

This requirement follows from a recent order issued by Judge Naomi Buchwald of the District Court for the Southern District of New York, finding that HHS misinterpreted key provisions under Section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) relating to publication of data for certain applicable clinical trials (ACTs). Judge Buchwald's decision indicated that the misinterpretation has resulted in a 10-year "gap" in clinical trial data held by clinical trial sponsors, which now must be retroactively collected and published to the HHS ClinicalTrials.gov database.

The order in that case, captioned *Seife v. HHS*, held that the FDAAA unambiguously requires ClinicalTrials.gov to include certain clinical trial results for ACTs—referred to statutorily as "Basic Results"—if the ACT was completed before the implementing rule's effective date of January 18, 2017 *and* if it studied a product that was approved, licensed, or cleared by the U.S. Food & Drug Administration (FDA) at any time after the ACT completion date. Referred to as "pre-Rule, pre-approval ACTs," the HHS implementing rule previously interpreted the FDAAA to allow an exemption from publication via ClinicalTrials.gov for such data. Now, drug and device companies and other institutions that sponsor ATCs will need to determine if they submitted Basic Results for clinical trials conducted between the effective date of the FDAAA in September 2007 and the effective date of the HHS implementing rule in January 2017. If sponsors did not

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previously submit to HHS the Basic Results of pre-Rule, pre-approval ATCs, the order now compels them to do so for public reporting on ClinicalTrials.gov.

Clinical trial sponsors should be aware that HHS has not yet announced whether it will appeal the district court's order with the U.S. Court of Appeals for the Second Circuit. If appealed, interested parties may be able to participate by seeking leave to intervene or by filing an amicus brief in support of either side.

If the order stands, however, clinical trial sponsors should also be aware that Section 801 of the FDAAA provides for civil penalties including monetary fines and other adverse actions for failure to submit required clinical trial registration or results information. Still, HHS has not yet indicated a deadline for retroactive submission of pre-Rule, pre-approval ATC data nor issued other guidance to industry regarding implementation of the order. Since compliance determinations and penalty assessments are generally left to the discretion of HHS, it remains to be seen how current events will affect implementation and roll-out by the Agency.

Michael Best & Friedrich has a wealth of experience in FDA and HHS regulatory processes including sponsorship and clinical trials of drugs and medical devices. For more information about the business and legal implications of this order, please contact your Michael Best attorney.

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