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Clinical Trial Results Will See Daylight After HHS Final Rule Is Set Aside

March 05, 2020 | Blog | By

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Some clinical trial sponsors and principal investigators will be digging through their archives soon as a result of a recent ruling in the case of *Seife v. U.S. Department of Health and Human Services*, case number 1:18-cv-11462 (S.D.N.Y. 2018). In *Seife*, the plaintiffs – an investigative journalist and a former Associate Commissioner at the Food and Drug Administration (FDA) – challenged a Department of Health and Human Services (HHS) final rule that implemented clinical trial reporting requirements mandated by the Food and Drug Administration Amendments Act (FDAAA).

Congress's goal when it enacted the FDAAA in 2007 was to address concerns that clinical trial sponsors might be misleading the public about their drugs' or devices' safety and efficacy by withholding unfavorable clinical trial results from publication. Pursuant to the relevant amendments to the law ushered in by the FDAAA, sponsors are required to submit specific clinical trial information for applicable clinical trials to the FDA for publication on **ClinicalTrials.gov**, a publicly-available website that offers information about clinical studies. In addition to information about the study design and inclusion/exclusion criteria, the FDAAA expanded the required clinical trial information to include **"basic results" data**, such as study participants' demographic information, primary and secondary outcomes, and the number of participants who dropped out of the clinical trial or who were excluded.

HHS's final rule implementing the FDAAA's expansion of the ClinicalTrials.gov reporting requirements was finalized in January 2017, and covered entities have been subject to the new regulations since April 2017. (The regulations are codified at 42 C.F.R. Part 11). However, as pointed out by the plaintiffs in *Seife*, the final rule essentially created a loophole exempting from disclosure the basic results of clinical trials for FDA-approved products if the clinical trial was completed after Congress enacted the FDAAA but before the rule's January 18, 2017 effective date – effectively excluding 10 years' worth of clinical trials from the scope of mandatory results disclosure.

The *Seife* plaintiffs argued that HHS's interpretation of the rule was contrary to the unambiguous terms of the statutory language passed by Congress and was therefore unlawful. The district court agreed, ordering the government to obtain and publicly disclose basic results of the unlawfully-exempted clinical trials. In doing so, the court highlighted that accepting HHS's interpretation and exempting study sponsors from disclosing negative clinical trial results "regardless of whether thousands of Americans use the [studied] product" would be "utterly contrary to the FDAAA's aims." To date, HHS has not stated publicly whether it will seek to appeal the ruling or how it intends to communicate with clinical trial sponsors about the need to submit to the registry results data that fall within the relevant 2007-2017 time period. The ruling is a win for transparency advocates, researchers, and pharma watchdogs, who should (sooner or later) have access to a new trove of clinical trial data.

Authors