Hogan Lovells

Crackdown coming? Draft guidance suggests FDA is looking more closely at clinical trial disclosures

September, 25 2018

On Friday, September 21, the Food and Drug Administration (FDA) published a draft guidance titled "Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank." We think this move strongly suggests that the agency may be getting serious about enforcement of the ClinicalTrials.gov regulations and may be planning to crack down on companies that fail to comply with the clinical trial registration, results posting, and certification requirements.

ClinicalTrials.gov is a government-run database of clinical trial information that is intended to increase the transparency of human subject research, help researchers find study participants, and help patients access experimental therapies. To date, we are aware of no civil money penalties being imposed or public enforcement letters being sent to companies that have failed to comply with the ClinicalTrials.gov laws. This is in spite of recently expanded requirements for studies on ClinicalTrials.gov, as we discussed here and here.

In the draft guidance, FDA states that civil money penalties may be assessed for

- failing to submit required clinical trial registration and/or results information to the ClinicalTrials.gov data bank;
- submitting false or misleading information to the ClinicalTrials.gov data bank;
- failing to submit the required certification to FDA; or
- knowingly submitting a false certification to FDA.

The statutory maximum for committing these prohibited acts is not more than US$10,000 for all violations adjudicated in a single proceeding. If a violation is not corrected within 30 days following notification of such violation, FDA may also assess penalties of not more than US$10,000 for each day that the violation continues.

Who will FDA target?

In the draft guidance, FDA said it would identify potential violations of the ClinicalTrials.gov rules through evidence collected during inspections conducted as part of FDA's Bioresearch Monitoring Program (BIMO), or as a result of trade complaints it receives. FDA said it intends to use a risk-based approach in focusing its enforcement on three areas:

- responsible parties who have failed to submit required clinical trial registration and/or results information "for higher risk applicable clinical trials or applicable clinical trials of public health importance"
- responsible parties or submitters for which there is a pattern of previous noncompliance with the requirements to submit clinical trial information and/or certifications
- applicable clinical trials for which noncompliance exists in conjunction with potential noncompliance with other statutory and/or regulatory requirements pertaining to the conduct of the trial

Steps involved in enforcement

Under the procedures outlined in the guidance, FDA will give responsible parties notice and an opportunity to cure the violation before seeking civil money penalties. More specifically,

1. FDA will send a Preliminary Notice of Noncompliance (Pre-Notice Letter) to a responsible party warning of an infraction;
2. the responsible party has 30 days to make any necessary corrections;
3. if the center determines that a responsible party failed to submit any required clinical trial information to the ClinicalTrials.gov data bank and/or submitted information that is false or misleading in any particular way, the agency will issue the responsible party a Notice of Noncompliance;
4. the responsible party will then have another 30 days to remedy noncompliance; and
5. if the center finds the noncompliance has not been remedied, it will commence legal action to seek civil money penalties pursuant to 21 CFR Part 17.

Broader significance

As noted above, we believe the publication of this draft guidance signals increased FDA scrutiny on ClinicalTrials.gov compliance and the agency's goal to put some teeth into the transparency and disclosure objectives behind ClinicalTrials.gov. If a company is found in violation of these requirements, the penalties can be considerable, especially if a violation is left uncorrected.

Of course, FDA and the Department of Justice can also criminally investigate and prosecute matters involving parties that submit false (or omit material) information to FDA. This guidance does nothing to alter that – but to the extent it indicates a potential new area of FDA enforcement – there is the possibility of additional criminal referrals for egregious cases in addition to the potential imposition of civil money penalties.

The public comment period on the draft guidance ends November 20. If you have any questions about the impact of this guidance or on clinical trial reporting obligations generally, please contact any of the authors or the Hogan Lovells lawyer with whom you commonly work.

Contacts

Robert Church
Partner, Los Angeles
T +1 310 785 4646
robert.church@hoganlovells.com

Meredith Manning
Partner, Washington, D.C./Denver
T +1 202 637 6585/+1 303 899 7385
meredith.manning@hoganlovells.com

Susan Lee
Partner, Washington, D.C.
T +1 202 637 5561
susan.lee@hoganlovells.com

Heidi Gertner
Partner, Washington, D.C.
T +1 202 637 5676
heidi.gertner@hoganlovells.com

Jodi Scott
Partner, Denver
T +1 303 454 2463
jodi.scott@hoganlovells.com

Jennifer Henderson
Partner, Washington, D.C.
T +1 202 637 5783
jennifer.henderson@hoganlovells.com

Michele Sartori
Partner, Washington, D.C.
T +1 202 637 6443
michele.sartori@hoganlovells.com

Bert Lao
Senior Associate, Los Angeles
T +1 310 785 4712
bert.lao@hoganlovells.com

www.hoganlovells.com