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# OVERSIGHT OF CLINICAL INVESTIGATORS

## Action Needed to Improve Timeliness and Enhance Scope of FDA's Debarment and Disqualification Processes for Medical Product Investigators

GAO Accountability • Integrity • Reliability

Highlights

Highlights of GAO-09-807, a report to congressional requesters

### Why GAO Did This Study

The Food and Drug Administration (FDA) oversees the clinical investigators who conduct research involving new drugs, biologics, and medical devices to ensure that their conduct does not compromise the safety of clinical trial participants or the integrity of clinical trial data. FDA can debar or disqualify investigators who have engaged in misconduct such as submitting fraudulent data. Debarred or disqualified investigators cannot engage in certain activities related to clinical research. GAO was asked to review FDA's debarment and disqualification processes. GAO examined the length of time debarment and disqualification processes have taken and factors for those time frames, and the statutory and regulatory limitations of debarment and disqualification. GAO reviewed laws, regulations, and FDA files through November 5, 2008, for (1) all investigators, study coordinators, and sub-investigators for whom FDA pursued debarment since receiving debarment authority in 1992; and (2) all clinical investigators for whom FDA pursued disqualification since FDA adopted its current process for initiating proceedings in 1998.

### What GAO Recommends

To improve its oversight, the Commissioner of FDA should pursue extending FDA's debarment authority; extend disqualification to include drugs, biologics, and medical devices; and ensure the timely completion of debarment and disqualification proceedings. FDA agreed with GAO's recommendations.

View GAO-09-807 or key components.
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### What GAO Found

More than half of the debarment proceedings in GAO's review took 4 or more years, and factors contributing to these time frames included internal control weaknesses in the debarment process and competing priorities among responsible staff. FDA has statutory authority to debar individuals who have been convicted of felonies or certain misdemeanors related to the development, approval, or regulation of a drug or biologic. For the 18 proceedings GAO reviewed, the length of time from an individual's conviction through debarment (or as of November 5, 2008, for pending proceedings) ranged from about 1 year to nearly 11 years. Factors that contributed to delays included that FDA staff faced competing priorities and FDA had not established internal controls, such as time frames for the completion of steps in the debarment process. FDA has made or planned changes that could improve timeliness (e.g., by establishing time frames in March 2009), but the effects of such actions have yet to be seen.

The time taken for disqualification proceedings varied and proceedings took longer when the investigator contested disqualification. FDA may disqualify investigators who repeatedly or deliberately failed to comply with FDA regulations or submitted false information to FDA or the sponsor of a clinical trial. For the 52 disqualification proceedings GAO reviewed, the length of time from initiation of a disqualification proceeding to its conclusion (or as of November 5, 2008, for pending proceedings) ranged from 26 days to more than a decade, with about one-third taking more than 2 years. In general, the more steps taken by the investigator to contest disqualification, the longer it took to complete the proceeding. Disqualification proceedings initiated in 1998 through 2001 generally took longer than proceedings that were initiated more recently. FDA officials told us that a lack of time frames for these proceedings—an internal control weakness—may have contributed to longer proceedings. FDA made changes to its disqualification process (e.g., by establishing time frames in June 2008 and January 2009) that could further improve timeliness, but the full effect of these changes remains to be seen.

FDA's debarment authority does not fully extend to involvement with medical devices, and its regulations do not extend disqualification for drugs and biologics to medical devices and vice versa. As a result, an individual may be debarred from involvement with drugs and biologics, but not from involvement with medical devices, regardless of the kind of misconduct in which the individual engaged. FDA's disqualification regulations allow an investigator who is disqualified for conduct related to drugs or biologics to serve as an investigator for medical devices; likewise, an individual who FDA disqualified for conduct related to medical devices remains able to serve as a clinical investigator for drugs and biologics.