Expanded Requirements for Expanded Access: The 21st Century Cures Act Places New Requirements on Manufacturers and Distributors

Alan G. Minsk and Alexander B. Foster

The 21st Century Cures Act (Cures Act) makes a number of changes affecting the pharmaceutical and biologics industries, and AGG previously has written on some of these changes.[1] This update will focus on how the Cures Act impacts expanded access, also known as compassionate use. The legislation defines expanded access/compassionate use as "the use outside of a clinical trial of an investigational medical product," because either there are no ongoing clinical trials of such product or a patient is not eligible for such a trial. The Cures Act contains specific policy publicity and content requirements for pharmaceutical and biologics companies so their expanded access programs are more accessible and transparent to potential patients. The expanded access/compassionate use requirements are at §3032 of the Cures Act, amending 21 U.S.C. §360bbb.

Highlights of the Cures Act's expanded access/compassionate use requirements include:

- A manufacturer or distributor of an investigational drug must make "public and readily available" its policies on evaluating requests for expanded access, such as by "posting such policies on a publicly available Internet website."
- The policies must include:
  - Contact information for the manufacturer or distributor to facilitate communication about expanded access requests;
  - Procedures for making such requests;
  - The general criteria used by the manufacturer or distributor to evaluate such requests for individual patients, and how the manufacturer or distributor responds to such requests;
  - The length of time the manufacturer or distributor anticipates will be necessary to acknowledge receipt of such requests; and
  - A hyperlink or other reference to the information on ClinicalTrials.gov for the clinical trials of the drug for which expanded access is sought.
- These updated requirements will apply to manufacturers or distributors of investigational drugs beginning the later of 60 days after enactment of the Cures Act (which will be February 11, 2017) or the "first initiation of a phase 2 or phase 3 study . . . with respect to such investigational drug."

AGG Observations

- The expanded access/compassionate use requirements in the Cares Act addresses both patient requests for greater access to experimental medicines and concerns that drug companies make it difficult for patients and physicians to navigate the expanded access/compassionate use request process.
- While drug companies are not required to grant expanded access requests, the Cures Act requires companies to be more transparent about the publicizing of their expanded access programs as well as the content of such program information.

1 For other AGG articles about the 21st Century Cures Act, see, e.g., http://www.agg.com/Thanks-to-21st-Century-Cures-the-Sun-is-Coming-out-Tomorrow-for-Orphan-Drugs-and-Pediatric-Priority-Review-Vouchers-12-15-2016/; http://www.agg.com/21st-Century-Cures-Act-Brings-New-Research-Funding-and-Changes-to-the-FDA-12-13-2016/; http://www.agg.com/What-21st-Century-Cures-Will-Mean-For-Clinical-Trial-Sponsors-05-04-2015/..

- The new requirements will help patients seeking expanded access/compassionate use to make more informed choices about which drugs are more readily available and the criteria drug companies use to select patients requesting expanded access/compassionate use.

Authors and Contributors

Alan G. Minsk
Partner, Atlanta Office
404.873.8690
alan.minsk@agg.com

Alexander B. Foster
Associate, Atlanta Office
404.873.8598
alex.foster@agg.com

not *if*, but *how*.®

About Arnall Golden Gregory LLP

Arnall Golden Gregory, a law firm with more than 150 attorneys in Atlanta and Washington, DC, employs a "business sensibility" approach, developing a deep understanding of each client's industry and situation in order to find a customized, cost-sensitive solution, and then continuing to help them stay one step ahead. Selected for The National Law Journal's prestigious 2013 Midsize Hot List, the firm offers corporate, litigation and regulatory services for numerous industries, including healthcare, life sciences, global logistics and transportation, real estate, food distribution, financial services, franchising, consumer products and services, information services, energy and manufacturing. AGG subscribes to the belief "not if, but how.®" Visit www.agg.com.

Atlanta Office
171 17th Street, NW
Suite 2100
Atlanta, GA 30363

Washington, DC Office
1775 Pennsylvania Avenue, NW
Suite 1000
Washington, DC 20006

To subscribe to future alerts, insights and newsletters: **http://www.agg.com/subscribe/**