Right-to-Try or Right to Ask?

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Recently, the American Society of Clinical Oncology (ASCO), a prominent medical organization, announced that it does not support so called "right-to-try" laws. Right-to-try legislation, which has now gained support in 33 states, focuses on getting terminally ill patients access to experimental products still in Phase 1 testing. The movement, led by the Goldwater Institute, attempts to remove FDA from the process completely and allow doctors and patients to negotiate directly with manufacturers for expanded access to experimental products. AGG has previously written about state right-to-try legislation.[1]

In ASCO's statement, the organization explained it is "concerned that existing and proposed [right-to-try] laws do not adequately protect patients, do little to facilitate patient access to such therapies, and potentially interfere with recent reforms that are already streamlining patients' access to investigational agents."[2] ASCO is the first major medical society to take a stance on this issue that's becoming increasingly more public.

Critics of the right-to-try movement typically note two key shortcomings. First, the term "right-to-try" is a misnomer. The only right these laws really provide is the right to ask. Patients, through their doctors, can request access to experimental new drugs, but manufacturers are the ultimate gatekeepers to their own products. If the manufacturer says no, then the request ends there and FDA never gets involved. No right-to-try law can force a manufacturer to provide its investigational products to a patient.

Second, access to experimental products already exists through FDA's Expanded Access program, also referred to as Compassionate Use. FDA allows expanded access requests for seriously ill patients unable to participate in clinical trials when there is no comparable therapy available. FDA says that it has approved 99% of the requests it receives.

However, the push for increased expanded access to experimental therapies has not gone unnoticed by FDA. The recently enacted 21st Century Cures Act included an Expanded Access Policy provision. Under the new law, manufacturers and distributors must have a publicly available expanded access policy. A publicly posted policy is not a guarantee that an expanded access request would be granted, and the policy can be revised at the manufacturer's discretion. The policy must contain certain basic information:

1. Contact information for the manufacturer or distributor to facilitate communication about requests;
2. Procedures for making such requests;
3. The general criteria the manufacturer or distributor will use to evaluate such requests for individual patients, and for responses to such requests;
4. The length of time the manufacturer or distributor anticipates will be necessary to acknowledge receipt of such requests; and
5. A hyperlink or other reference to the clinical trial record containing information about the

1 http://www.agg.com/States-Seek-to-Expand-Access-to-Investigational-Drugs-Biological-Products-and-Devices-Through-Right-to-Try-Laws-06-24-2015/ (last accessed Apr. 11, 2017).

2 http://www.asco.org/sites/new-www.asco.org/files/content-files/blog-release/documents/2017-Access-to-Investigational-Drugs-Position-Statement.pdf?et_cid=39110097&et_rid=1080078963&linkid=full+statement (last accessed Apr. 11, 2017).

expanded access for such drug.

Manufacturers or distributors must publicly post their policies either at the initiation of a phase 2 or 3 study, or 60 days after enactment of the Act. 21st Century Cures was signed into law by President Obama on December 13, 2017, so the 60-day deadline has long passed. This means that manufacturers that have products currently in phase 2 or 3 studies should already have their expanded access policies publicly posted. While FDA has not taken any enforcement action against manufacturers who have not posted policies, AGG would advise manufacturers subject to the new law to draft and post their policies as soon as reasonably possible. While only the general public policy is required under the Act, AGG also suggests manufacturers develop an internal standard operating procedure for evaluating such requests for expanded access.

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