U.S. FOOD & DRUG ADMINISTRATION

FDA FACT SHEET

Right to Try

What is Right to Try?

- Right to Try is one pathway for patients diagnosed with life-threatening diseases or conditions who have exhausted all approved treatment options and are unable to participate in a clinical trial to access certain drugs that have not been approved by the Food and Drug Administration (FDA).
- Right to Try allows eligible patients to request access to certain investigational drugs (including biologics[1]) that have not yet been approved by the FDA.
- Under Right to Try, patients and their doctors work with a company that is developing a drug or biologic to request access without involving FDA in the process.
- The FDA does not review or approve Right to Try requests.

How do I know if I am eligible to request access to a drug or biologic under Right to Try?

Patients who are eligible under the Right to Try Act[2] meet the following criteria:

- You have a life-threatening disease or condition.
- You have exhausted approved treatment options and are unable to participate in a clinical trial involving the drug or biologic, as certified by your doctor.
- You (or your legally authorized representative) have given written informed consent to the doctor regarding the investigational drug.

How do I know if a drug or biologic is available under Right to Try?

- The Right to Try Act sets forth specific criteria for a drug or biologic to be eligible for this pathway, such as a drug or biologic being under clinical trial investigation.
- The Right to Try Act does not require a manufacturer or sponsor to provide access to drugs or biologics. Further, FDA cannot require a manufacturer or sponsor to provide access to drugs or biologics under the Right to Try Act.

[1] A biologic is a product that is made from a living thing or its products. Some examples include vaccines, allergy shots, blood, genes, tissues and cells.

[2] The Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017.

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- Talk to your doctor. You or your doctor can then consult with the manufacturer or sponsor to request access for the drug or biologic.
- Manufacturers or sponsors may provide information about whether their drug or biologic is eligible under the Right to Try Act and whether they are willing to make their drugs or biologics available to patients who qualify to request access under the Right to Try Act.

What else do I need to know about Right to Try?

- Through the Investigational New Drug (IND) application process, the FDA typically reviews the safety of each proposed use of an investigational new drug before it can be provided to patients. While the Right to Try Act requires drugs to meet specific criteria in order to be eligible to be provided to patients under the Right to Try pathway, drugs that are provided through the Right to Try pathway are generally exempt from these IND reviews.
- Drugs and biologics available under Right to Try have not been approved by the FDA. This means that:
    - *Safety*: The FDA has not determined whether drugs and biologics made available under Right to Try are safe and if there could be serious risks or side effects.
    - *Effectiveness*: The FDA has not determined whether drugs and biologics made available under Right to Try can lead to any improvement in disease or symptoms.
- Discuss the potential benefits and risks of receiving drugs through Right to Try with your doctor.

For more information:

- **Right to Try:** https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try
- **Clinical Trials:** https://www.fda.gov/patients/clinical-trials-what-patients-need-know
- **FDA's Drug Review Process:** https://www.fda.gov/drugs/drug-information-consumers/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective

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