The Senate's S.204 vs. the House's H.R.5247

	Senate-Passed Language	House-Passed Language	Implications
Eligible Patient	Any individual diagnosed with a life-threatening disease or condition as defined in section 21 CFR 312.81.	Any individual diagnosed with "eligible illness": stage of disease in which there is a reasonable likelihood that death will occur in a matter of months OR a disease or condition that would result in significant irreversible morbidity that is likely to lead to severely premature death.	The broader definition in the Senate version could allow for the much larger chronic disease community to access this pathway, greatly shifting health policy precedent.
Exhausted Approved Treatment Options	Yes (*as certified by a physician).	Yes (*as certified by a physician).	
Participation In Clinical Trials	Must be unable to participate in those trials pertaining to the drug in question (*as certified by a physician).	Must be ineligible to participate in all trials pertaining to the condition – including if participation is not "feasible" for reasons such as geographic distance (*as certified by a physician).	
Physician Compensation	No direct compensation from the manufacturer for certifying.	No compensation for certifying.	The Senate version could allow for indirect compensation through a third party.
Informed Consent	Patient (or legal guardian as appropriate) must provide general written informed consent to be eligible.	Patient (or legal guardian as appropriate) must provide written informed consent, ***as defined by 21 CFR 50***, to be eligible.	The lack of a standard in the Senate version could allow for a dangerous variance in the quality of the informed consent.
Eligible Drugs	Completed phase 1, active development is ongoing and has not been discontinued by manufacturer or placed on a clinical hold under section 505(i).	Completed phase 1, active development is ongoing, has not been discontinued, and is not the subject of a clinical hold under the regulations implementing section 505(i) or section 351(a)(3) of the PHSA, as applicable.	
Physician Standing	Physicians must be in good standing with their licensing organization or board.	Physicians must be in good standing with their licensing organization or board.	
Profit Disallowances For Companies	21 CFR 312.7 and 312.8(d)(1) apply.	21 CFR 312.7 and 312.8(d)(1) apply.	

Reports to FDA	The manufacturer shall submit to FDA an annual summary of any use.	Manufacturers must notify FDA within 7 business days of access under alternative pathway.	In the Senate version, FDA could be unaware of access under this pathway for up to a full year.
Adverse Event Reporting	The manufacturer shall submit to FDA an annual summary of any use.	As a condition for the provision of the investigational drug, physicians must immediately notify manufacturers of adverse events. Manufacturers then must inform FDA in accordance with 21 CFR 312. (No later than 15 days to submit IND safety reports, no later than 7 days to submit unexpected fatal or life-threatening suspected adverse reaction reports.	In the Senate version, FDA could be unaware of adverse events occurring, and therefore unable to take potentially necessary action, for up to a full year.
FDA Capacity to Stop Access to Therapy	FDA can place a clinical hold on the program but has no other mechanism.	FDA can place a clinical hold on the program but has no other mechanism.	
Use of Clinical Outcomes	FDA can use data from the manufacturer's annual report if it determines that it is critical to determining the safety of the drug, or if the sponsor requests for FDA to do so.	FDA can use data from the manufacturer's annual report if it determines that it is critical to determining the safety of the drug, or if the sponsor requests for FDA to do so.	
IRB Approval	None required.	None required.	
Additional Liability Reforms	Both when providing the drug or deciding not to provide the drug, legislation guarantees that manufacturers would not be liable, and that prescribers, dispensers, or other individual entities other than the manufacturer would also not be liable except in cases of gross negligence. This language only applies to Right-to-Try, and NOT to Expanded Access.	Both when providing the drug or deciding not to provide the drug, legislation guarantees that manufacturers would not be liable. Physicians, clinical investigators, and hospitals that adhere to 21 CFR 50, 56, and 312.32 would also not be liable expect in cases of gross negligence. This language applies to BOTH Right-to-Try AND Expanded Access.	The Senate version leaves out important enforcement mechanisms relating to reporting and informed consent. The Senate version could also incentivize companies to pursue Right-to-Try rather than Expanded Access due to the differing liability rules.
Additional Public Reporting Requirements	FDA shall post an annual summary report of any use on FDA's website.	Manufacturer shall annually post, on the same website used to comply with 21st Century Cures Act, a summary of any Right to Try Access.	The Senate version places the burden of accountability entirely on FDA.