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Supplemental Table 1. Three track regulatory framework for FMT

	Track 1: Stool product from person known to patient or physician; FMT performed by physician	Track 2: FMT using stool from stool bank	Track 3: Use of modified stool-based products (drugs) with abbreviated IND
Regulator	Individual states under the "practice of medicine"	FDA will regulate stool banks and stool similarly to how it regulates tissue banks and human cells, tissues, and cellular and tissue-based products (HCT/Ps).	FDA
Allowed use	FMT for CDI can be performed under practice of medicine paradigm.	Stool from a registered stool bank can be used for CDI; other indications require an IND.	Product can be used for its indicated use as set forth in the product's New Drug Application approval (see off-label use below).
IND Requirement	Physician administering FMT for CDI with known donor not required to obtain an IND.	IND required for indications other than CDI.	Sponsor must obtain IND. Phase II and III clinical trials required (with modification of characterization requirements).
Adverse Event Reporting	Local health departments or state medical boards could require adverse event reporting.	Physician adverse event reporting to stool bank would be required similar to 21 CFR Part 1271.350(a) for certain adverse reactions related to the transplantation.	Manufacturers must follow the FDA's adverse event reporting procedures for drugs or biologics.
Registry	Local health departments or state medical boards could require physicians performing FMTs to collect data and submit it to a registry.	Stool banks must collect data on all FMT patient outcomes and report results to a national registry.	Not required.
Off-Label Use (i.e., use for unapproved indications)	IND required for new indications unless "clinical innovation."	N/A	Off-label use will be allowed as it is under current law.
Exclusivity	N/A	N/A unless stool bank receives approval for its product as a new drug.	Current FDA rules relating to exclusivity for new drugs and biologics apply (but would not exclude Track 1 or 2 FMTs).
Donor Screening/Safety	State Departments of Public Health would set screening standards for donors that are known to patient or physician.	All stool donors and donations should be tested for infectious agents and the FDA should publish a list of pathogens and testing criteria.	Manufacturer must follow all relevant regulations relating to chemistry, manufacturing and controls required for drugs by FDA.
Good Manufacturing Practices (GMPs)	N/A although state or local departments of public health could establish processes for handling.	Stool banks must follow all regulations relating to stool bank GMPs (to be developed by the FDA).	Drug manufacturers must follow all relevant FDA regulations for GMPs for drugs.
Storage and transportation	Biological material will be sourced from donors. State or local health departments may establish standards for short term storage.	FDA to set standards for storage and transporting of samples as is done for HCT/Ps.	Drug manufacturers must follow all relevant FDA regulations for storage and transportation of drugs.