**CONSEQUENCES**

* **Purity, Potency, Safety compromised**



* **FDA noncompliance**
	+ **Advisory actions**
		- **Warning letter**
			* **Could cause harm to donor or distribution of unsafe product**
			* **Continuing pattern on noncompliance**
			* **Notice of possible further action**
			* **Manufacturer has opportunity to correct deviations**
	+ **Administrative Actions**
		- **Suspension**
			* **Applied to license manufacturers only**
			* **Continuing pattern of noncompliance**
			* **Potential danger to health of donor or recipient**
			* **Manufacturer cannot engage in interstate commerce until deviations are corrected**
			* **FDA can take action quickly**
		- **Revocation**
			* **Applied to licensed manufacturers only**
			* **FDA cannot gain access to facility to inspect**
			* **Product is not safe or effective**
			* **Manufacturer cannot engage in interstate commerce**
			* **Lengthy process**

**EVEN MORE LEGAL CONSEQUENCES…**

* **Legal Actions**
	+ - **Seizure**
			* **Civil action; court order needed**
			* **Condemn violative products and remove from distribution**
			* **FDA takes possession and could dispose product**
			* **Manufacturer can contest changes**
		- **Injunction**
			* **Civil action**
			* **Health hazard due to product or collection procedures**
			* **History of uncorrected deviations; violations will continue**
			* **Manufacturer can operate while correcting deviations**
			* **Applied to both licensed and unlicensed manufacturers**
		- **Prosecution**
			* **Criminal action**
			* **Fraud, health hazards, continuing significant violations**
			* **Applied to both licensed and unlicensed manufacturers**

**THE GOOD STUFF…**

**BENEFITS**

* **Patient safety**
* **Continued operation**

**LEGAL REQUIREMENTS**

* **Licensed establishments must report to the FDA all errors and accidents that may affect the safety, purity, or potency of the biologic product.**
* **Report biological deviation ASAP but not more than 45 days from when information suggesting deviation occurred.**
* **Blood collection or transfusion related fatalities must be reported to the FDA ASAP in writing within 7 days.**



**WHAT IS REPORTABLE?**

* **Anything affecting the Safety, Purity, or Potency of a product**
	+ **Product allocated but not issued to patient**
	+ **Product issued with incorrect label**
	+ **Incorrect patient name on label**
	+ **Expired patient sample used for compatibility testing**
	+ **Expired or incorrect reagent used for testing**
	+ **Reagent manufacturer’s insert not followed**
	+ **No documentation of testing**
	+ **Issued product failed visual inspection (color, clots, hemolysis…)**
	+ **Freezer, fridge, and platelet rotator chart not changed per weekly maintenance.**
	+ **Release of:**
		- **Units that have been repeatedly reactive to viral marker testing**
		- **Units from donors whose tests results were improperly interpreted**
		- **Units from donors who are or should have been deferred due to medical history or have repeatedly reactive viral marker tests**
	+ **Units erroneously released prior to completion of all tests**
	+ **Incorrectly labeled blood components (ABO, expiration date, etc.)**