



Making Compliance/Legal a Competitive Advantage with Customers

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In the beginning . . .



What Legal does for you

- Identify minimum legal standards
- Identify risks
- Partner with compliance for execution
- Stand in the gap when the BAD THING happens





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Theranos

- 2003 Drops out of Stanford
- 2014 Valued at \$9 billion
- 2016 (Jan) CMS issues IJ letter
- 2016 (June) CMS license term letter
- 2016 (July) CMS strips lab license
- 2016 (July) **Theranos hires first**

quality, regulatory and compliance executives

- 2018 Holmes Indicted by DOJ
- 2018 Theranos Dissolved



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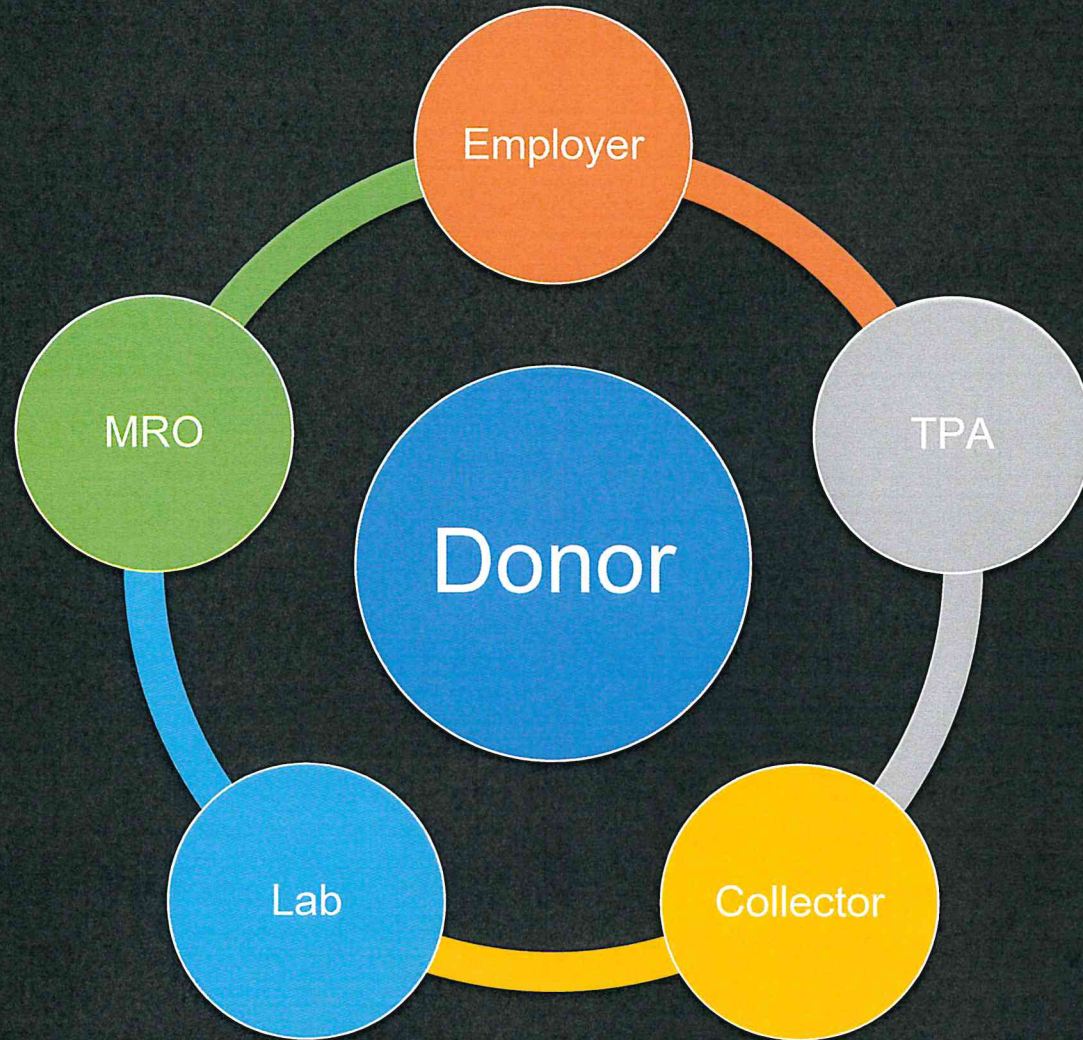
Compliance Core

- Policy – What is it we do?
- Process – How do we do it?
- Training – This is how we do it.
- Audit – Are we doing it?
- Innovate – How can we do it better and more consistently?



Compliance to Customers

- Customers EXPECT Compliance
 - Every time
 - Every situation
- The Bad Thing WILL Happen
- Compliance in the face of the BAD THING
 - Legal ?
 - Prompt, effective investigation, remediation and correction
 - Demonstrable program to detect, correct and innovate to mitigate risk

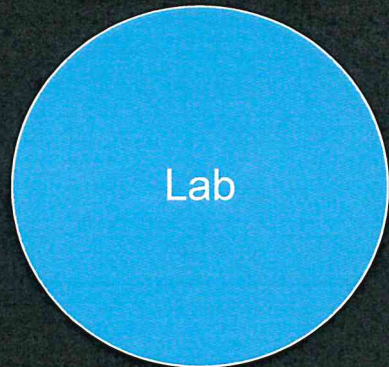




- All is going well, until . . .
 - Inadequate volume
 - No temperature
 - Something necessitates a second collection
 - The donor wishes to leave the facility



- Build a consistent, documented process
- Create guideposts for collectors
- Train to the process
- Audit to the process



- Requests for information
 - Subpoenas
 - Record requests
 - Specimen send outs



- Process for release of information
- Avoid spoliation of data, documents, samples
- Triage requests



- Medical Marijuana
 - Donor claims medical marijuana card status



- Ensure process has a decision tree
- Obtain appropriate consent
- Documentation/Reporting



- Client issues – Who has what role and where are the risks?



- I may not be responsible but I'll get sued
- Risk Assessment/Management



- Medical marijuana
 - Handling marijuana positives
 - Multistate employer



- I own the drug testing process
- I own the risk (legal & safety)
 - Know my accommodation obligations
 - Policy considerations

When The Bad Thing Happens – OR Someone Doesn't Like the Outcome

Business/Compliance

- Engage legal immediately
- Identify if there may be fault arising from your company
- Prepare to immediately resolve issue if you caused the loss
- Use the situation as a catalyst for process/production improvement



Donor

Legal

- Provide all information you would otherwise have to give
- Cooperate on everything that does not harm your case
- Look for early resolution or disposition
- Fight like crazy on everything else!

Questions?



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