

Comparison of Clinical Trial Oversight in China and the U.S.

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Introduction



- The regulator
- How are clinical trials regulated
- Enforcement actions
- Other considerations
- Conclusions

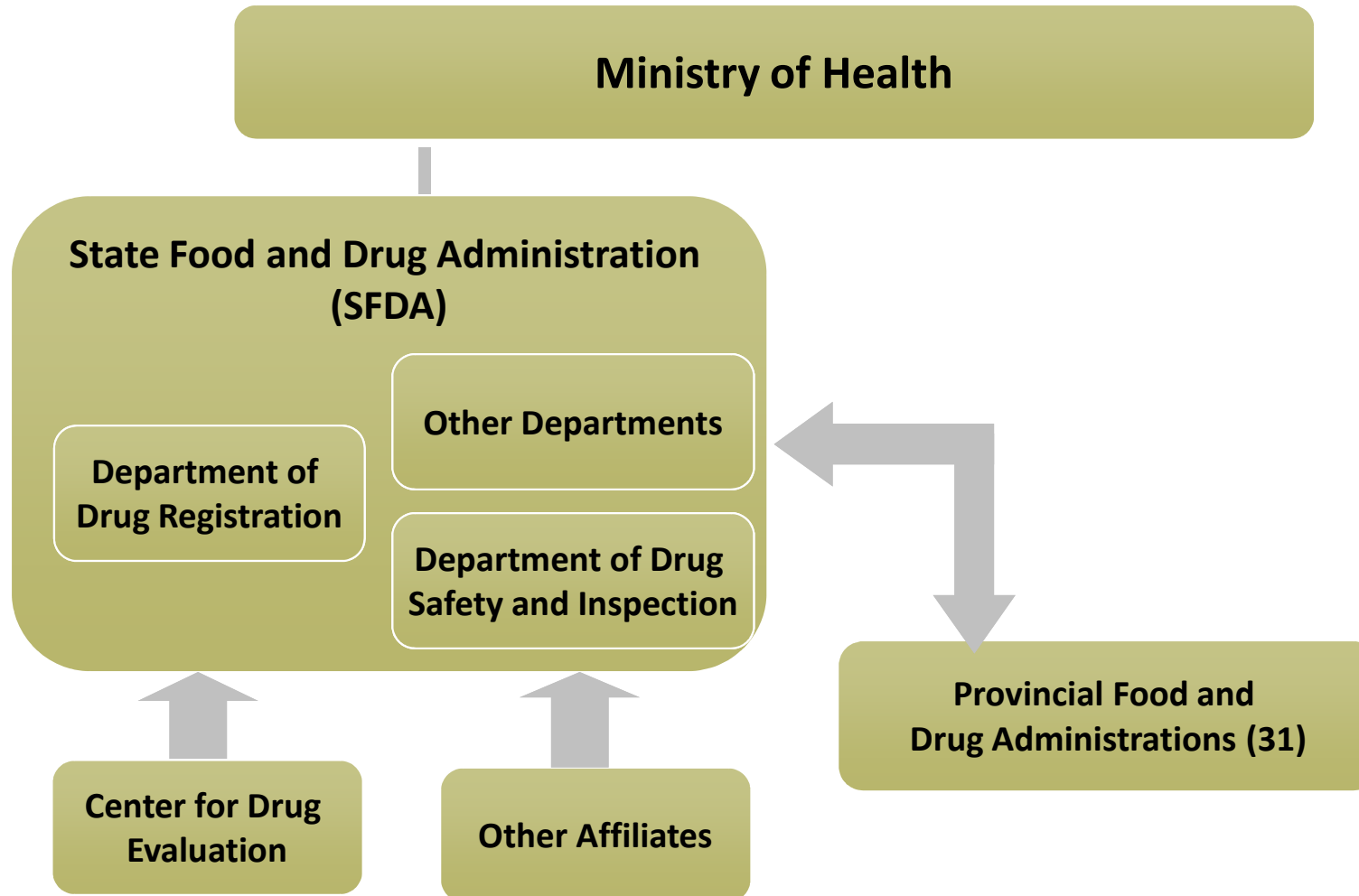
The Regulator

Regulator



FDA vs. SFDA

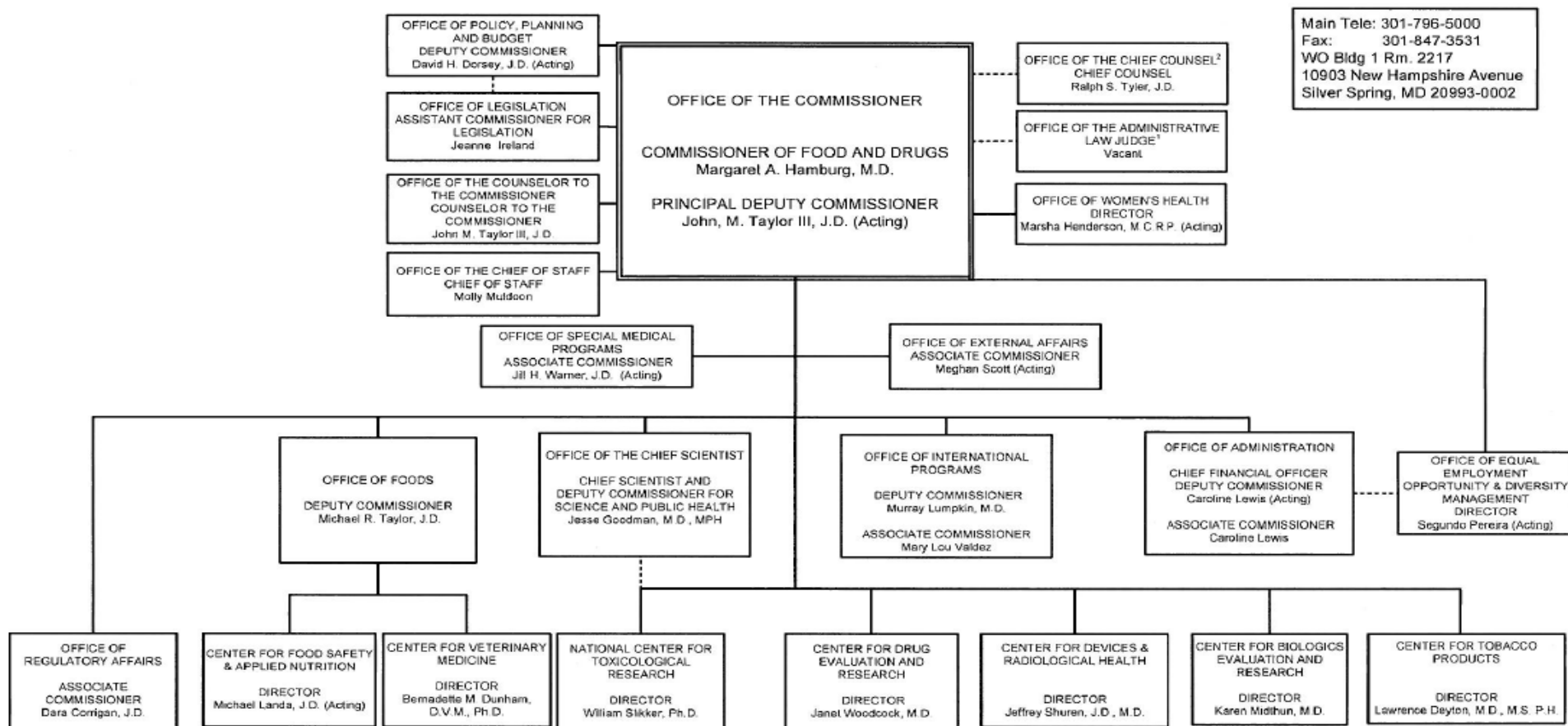
SFDA



FDA



DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION



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 10903 New Hampshire Avenue
 Silver Spring, MD 20993-0002

¹ Reports Directly to the Secretary, HHS
² Reports to the General Counsel of the HHS, advises the Commissioner of Food and Drugs

Vanessa Stans 5/9/11
 Approved by the FDA Reorganization Coordinator and Principal Delegation Control Officer

SFDA vs. FDA



- The Role of the Chief Counsel in FDA
- CDE vs. CDER & CBER
- Transparency
- Procedural rules

Regulating Clinical Trials

Approval for clinical trials



China: Clinical Trial Approval

U.S.: Investigational New Drug

Investigators



China: Only accredited institutes

U.S.: No such a mechanism

GCP



China: GCP

- Sponsor's liabilities
- Reporting
- IRB

U.S.: GCP

- Sponsor's liabilities
- Reporting
- IRB

Inspections



China:

- Inspection for approval
- Regular compliance inspections
- Inspections for cause

U.S.:

- Regular compliance inspections
- Inspections for cause

Enforcement Actions

Enforcement Actions



China:

- Warning and Request for Correction
- Administrative fines
- Suspension of production or operation
- Revocation of licenses
- Rejection of application for CTA
- Disqualification for three year
- Criminal prosecution

China

- Ambiguity of law
- Sanctions available not deterrent enough
- Need more procedural rules and guidance
- Transparency
- Improving

Enforcement Actions



U.S.:

- Untitled letters
- Warning letters
- Disqualification
- Rejection of site data
- Termination of IND
- Criminal prosecution

Enforcement Actions



U.S.: Case study

Other Considerations



- Legal system
- Sponsor's legal liabilities
- Congress
- Media

Conclusions

Questions?



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