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Perspective of Medical Product Sponsor in Disaster Research Response

Presentation to IOM/NIH Workshop

June 13, 2014

Key Points

- **Requirements under the Animal Rule**
- **Role of a pharmaceutical company**
- **Opportunities for collaboration**
  - **before/during/after an event**

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Animal Rule*

*** 21 CFR 314.600 (drugs)**
21 CFR 601.90 (biologics)

Approval Subject to 3 requirements

- Post-market studies
  - Part of application for approval, plan/approach to:
    - verify/describe clinical benefit
    - assess safety
- Restrictions to ensure safe use
  - Commensurate with product specific concerns
    - certain facilities, HCPs with special training
    - performance of special medical procedures/follow-up
- Information to be provided to patient recipients
  - Part of label
    - explains that approval based on animal studies alone
    - indications, directions for use, contraindications, AE, interactions, benefits/risks, etc.

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Role of the pharmaceutical sponsor

Role

- Sponsor studies/use data from others
- Assemble dossier and submit application to/seek approval from FDA
- Develop post-event study protocols/patient labelling
- Provide/maintain product for the Strategic National Stockpile
  - pre-specified amount
  - surge capacity should needs outstrip initial supply
  - inventory cycled through to retain maximum remaining shelf life and availability 24/7

Capabilities/Assets

- Analytics particular to the product
  - may not be generally available to researchers/academic institutions
- Data on product parameters
  - pharmacokinetics/pharmacodynamics
  - genetic testing/susceptibility, biomarkers
- Data from clinical trials
  - other indications/treated populations
    - comparators, historical controls

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Opportunities for Collaboration

Before, during and after

- Study protocol development
  - IRB approved studies
  - roles and responsibilities defined
- Forging relationships with networks
  - clinical researchers and research centers
- Analytic role
  - FDA will be turning to sponsors for data on benefits/safety
- Patient communications
  - prepared and available

Conclusion

- Immediate response to an event will be managed by public health, medical, law enforcement and disaster response infrastructure
- Sponsor's role extends beyond supply of medication to:
  - Post-event study protocol development
  - Contribution of unique capabilities
  - Partner in the conduct/analysis of studies