What The FDA Is Doing To Facilitate Access To New Devices Rapidly And With Assured Safety And Effectiveness — In Both The Civilian And Military Spheres

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CDRH Strategic Priorities
- Excellent customer service
- Strengthen the clinical trial enterprise
- Strike the right balance between pre-market and post-market data collection
  - Increasing emphasis on “real-world” data

How are these principles actually being applied?

Example: Emergency Medical Countermeasures (EMCM)
- FDA established a group dedicated to EMCM efforts
  - Enhanced communication and regulatory direction for relevant medical device and diagnostic projects
- Examples of cardiovascular products:
  - Tourniquets
  - Internally/externally applied hemostasis devices
  - Vascular shunts for limb salvage

Military Use of Devices for Trauma
- Important and occasionally overlooked clinical area
- Additional layers of administrative complexity
- How can FDA meet the unique needs of this particularly at-risk population?

Specific Considerations
- Military only uses devices approved for use in US
- Military strictly follows approved indications/labeling
- Differences in informed consent and follow-up
- Special conditions of use
  - Use in pre-hospital situations (e.g. battlefield)
  - Environmental factors (e.g. high altitude airlifts)
Facilitating Clinical Evaluation

- Early feasibility studies
  - Promote early-stage clinical experience in the US
  - Device design need not be final, nor does non-clinical testing need to be complete
  - Lessons learned from EFS can shape final device/study design
- Consider starting with more stable patients
  - Challenging to evaluate new technology in hemodynamically unstable patients and atypical environments
  - Move to more severely injured patients after users gain sufficient device experience and familiarity

Other Ways to Improve Access

- Shift more clinical evidentiary expectations from pre-market to post-market
  - Thoracic aortic dissections
- Alternative approaches to informed consent
  - Community-based
  - Waivers for emergency use
- Pathways for accelerated review
  - Expedited Access Pathway (EAP) program
  - DoD-expedited review timelines

Apply Benefit-Risk Principles

- What are treatment alternatives?
  - What if the patient isn’t treated at all?
- What are the magnitude/severity of the benefits/risks?
- What are appropriate risk mitigation strategies?
  - Defining appropriate patients
  - Training of healthcare providers
  - Labeling
- Use in non-military trauma cases?

Outreach

- FDA and DoD working more closely together
  - DoD Joint Hemostatics Working Group Meeting
    – January 2014
  - FDA Workshop on Hemostatic Devices for Trauma Use
    – September 2014
- Presentations at conferences such as VEITH
- Additional involvement always desired/welcomed

Summary

- FDA is working to facilitate timely access to promising devices through a variety of mechanisms
- We encourage continued dialogue among all relevant stakeholders involved in military/civilian care
  - Early/frequent communication and collaboration
  - Increase mutual understanding of our respective processes and the impact of our decisions
- Together we can enhance the quality of available care, particularly for imperiled populations

Thank You!