

Optimization of Scientific Input to the FDA in the Regulation of Regenerative Medicine Treatments

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Introduction

- **Scope of Regenerative Medicine**
- **FDA Science Board Report Nov 2007**
- **Science Board Findings pertinent to Regenerative Medicine**
- **Recommendations**

Regenerative Medicine

- **Tissue Engineering**
 - Cells, Scaffolds, Biomolecules
 - Controlled Delivery in Space and Time
- **Individualized Medicine**
 - Transformation from treatment based on disease alone to combination of disease and characteristics peculiar to specific patient who has it



Science Board Report Findings

- **4.1.1: FDA has experienced decreasing resources in the face of increasing responsibility. The resource gap must be corrected. Emerging Science and Information Technology are two areas where this gap exists.**

Recommendations: Emerging Science

- The time interval over which efficacy is determined, and the means of determining efficacy, need reassessment
- Examples:
 - Hip systems
 - Spinal care: resection, fusion, replacement, regeneration eras

Significant Medical Device Legislation

- Kefauver-Harris Drug Amendments 1962



Recommendation: Information Technology

- The concept of population wide registries and implant retrieval systems needs discussion and implementation, both for engineering failure and success analyses.
- When Kefauver-Harris was enacted in 1962, replacement of musculoskeletal function was in its infancy.

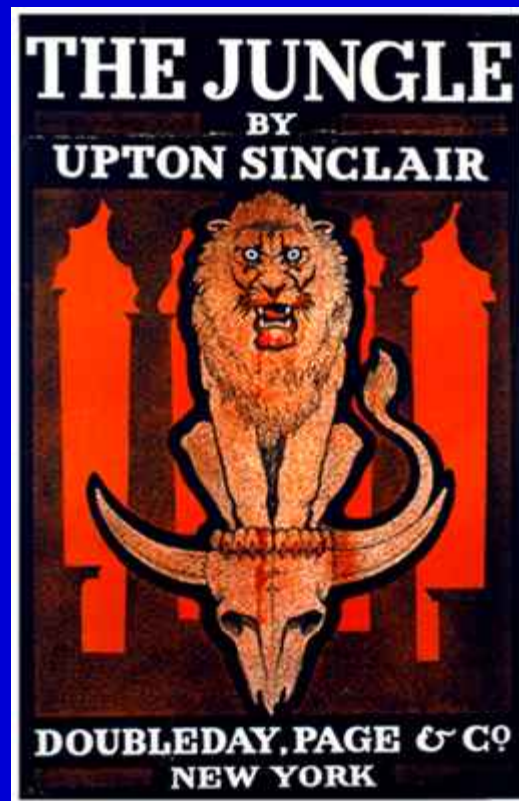


Recommendation: Increasing Scientific Input to FDA

- The conflict of interest processes for civilian consultants and panel members to the FDA need reassessment. The most knowledgeable people generally have such conflicts. A strategy of conflict management to mitigate the exclusion of experts would increase the quality of scientific input to FDA in the emerging science areas.



Federal Food and Drugs Act of 1906



Thank you.

