

*Beginning the Next 100 Years
of FDA Regulation
(There Have Been a Few Changes Since 1906)*



*The Second Annual FDA Regulatory and
Compliance Symposium*

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Education: Quality Engineering, Science, & Technology

Agenda



- A Brief History
- Where are we?
- How did we get here?
- Where are we going?

A Brief History

- With the passage of the Federal Food and Drugs Act of 1906 regulatory authority was added to the research responsibilities of USDA's Bureau of Chemistry. This began the modern era of the FDA.
- In 1927 the research responsibilities were transferred elsewhere and in 1930 the name was changed to the Food & Drug Administration.

A Brief History

- In 1940 FDA was moved from the USDA to the Federal Security Agency.
- In 1953 FDA was moved from the FSA to the Department of Health Education and Welfare.
- FDA became part of the Public Health Service (within HEW) in 1968.

A Brief History

- In 1980 congress removed education from HEW, forming the Department of Health and Human Services where FDA remains today.
- Food and drug regulatory history actually began within the states. A 1785 law in Massachusetts included fines, imprisonment, and standing in the pillory and “binding to the good behavior” as punishment for sale of “diseased, corrupted, contagious, or unwholesome provisions”.

A Brief History

- More importantly, FDA history has been driven by problems and attempted solutions.
- Prior to 1906, the USDA Division of Chemistry was primarily focused on adulteration of foods and drugs, usually as economic cheats. Later the Poison Squad was formed to evaluate the effects of some “preservatives”.

A Brief History

- The impetus for the 1906 Food and Drugs Act was the public outcry over the publicized use of poisonous preservatives and dyes in foods and cure-all claims for worthless and dangerous patent medicines.
- The law has been amended dozens of times to address deficiencies in wording, legal interpretations, and to extend its scope.

A Brief History

- In 1937 Elixir of Sulfanilamide, containing the poisonous solvent diethylene glycol, killed 107 people, many of them children, publicly dramatized the need to establish drug safety before marketing and was a key to congressional passage of a pending food and drug law.

A Brief History

- The Federal Food, Drug, and Cosmetic (FDC) Act of 1938
 - Extended control to cosmetics and therapeutic devices
 - Required new drugs to be shown safe before marketing-starting a new system of drug regulation
 - Eliminated the Sherley Amendment requirement to prove intent to defraud in drug misbranding cases

A Brief History

- The Federal Food, Drug, and Cosmetic (FDC) Act of 1938
 - Provided that safe tolerances be set for unavoidable poisonous substances
 - Authorized standards of identity, quality, and fill-of-container for foods
 - Authorized factory inspections
 - Added the remedy of court injunctions to the previous penalties of seizures and prosecutions

A Brief History

- In 1962, Thalidomide, a new sleeping pill, was found to have caused birth defects in thousands of babies born in western Europe. News reports on the role of Dr. Frances Kelsey, FDA medical officer, in keeping the drug off the U.S. market, aroused public support for stronger drug regulation.

A Brief History

- The response – 1962's Kefauver-Harris Drug Amendments were passed to ensure drug efficacy and greater drug safety. For the first time, drug manufacturers are required to prove to FDA the effectiveness of their products before marketing them. The new law also exempts from the Delaney clause animal drugs and animal feed additives shown to induce cancer but which leave no detectable levels of residue in the human food supply.

Where Are We?

- An Agency much the size it was in 1974 with dramatically more responsibility and visibility
- Commissioner – a political appointment since 1988
- Major funding from “user fees”

Where Are We?



- Political Problems
 - Industry influence/committee presence, etc.
 - Lack of permanent commissioner/leadership
 - Large number of political appointees
 - Loss of expertise and experienced staff
 - Plan B and other political pharmaceuticals
 - Drug Re-importation

Where Are We?



- Political Problems
 - Increases in costs of medicine
 - Increases in costs of medical insurance
 - FDA stance and capability relative to terrorism
 - Regulations under attack
 - Reliance on “industry standards”, “consensus standards”, “industry guidance”

Where Are We?



- Political Problems
 - Buzzwords – “Risk”, “Science Based”, etc.
 - Political pressure (real or perceived) on scientists for “correct” decisions and approvals
 - Total lack of enforcement (real or perceived)
 - “Stacking” the Agency
 - Unresponsiveness to public requests (FOI, meeting attendee lists, etc.)

How Did We Get Here?



- Ever increasing political influence over the past 20 years
- Lack of oversight by congress and the people
- Lack of adequate funding
- User fees

Where Are We Going?



- Various views
 - 100 years is long enough – start over
 - Rebuild with what we have
 - If it ain't broke ...
 - Evolve (not to survive, to improve)

Where Are We Going?



- 100 years is long enough – start over
 - New, more modern laws and approaches to enforcement
 - Innovative funding
 - Better responsiveness
 - New leadership
- Not likely!

Where Are We Going?



- Rebuild with what we have
 - Energize congress and the people to support a modernization of the FDA
 - Change the funding model
 - Rebuild Agency credibility
 - Remove from political influence
- This will take 100 years!

Where Are We Going?



- If it ain't broke ...
 - Continue as it is
 - I like politics
 - If it's good enough for ... It's good enough for the American people!
 - FDA will become an advertising agency for its "paying customers"
- Hard to tolerate ... a disaster will happen!

Where Are We Going?



- Evolve (not to survive, to improve)
 - Requires recognition of the issues
 - Requires long-term commitment and goals
 - Requires oversight, funding, and management
 - Requires removal from politics and a real science base, not just words
- Slow!

What?

Me worry?