FDA Update:
Public Health Past and Future

Joshua M. Sharfstein, M.D.
AFDO Annual Meeting
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Upton Sinclair's

THE JUNGLE

Featuring

George Nash - Gail Kane

and the author

5 daring acts — 210 astounding scenes
• Crisis: Adulterated foods
• 1906 – Pure Food and Drug Act
  – To prevent the “manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquids.”
  – Allowed FDA to order certain products off the market
Inspectors from the Bureau of Chemistry, 1909
Cough

The symptoms of Chronic Excessive Cough are

Eradicated

With Glyco-Heroin

A Miraculous Remedy

for Cough

The Problem

has been solved by

the pharmaceutical compound known as

Glyco-Heroin

Scientifically compounded, scientifically conceived.

Eradicate the pain and discomfort of cough

with Glyco-Heroin (Smith)
• Crisis: Diethylene Glycol in Elixir Sulfanilamide
• 1938 – Food, Drug, and Cosmetic Act
  – Requires premarket review of drugs for safety
  – Eliminates most proprietary medicines
Kelsey received the President's Award for Distinguished Federal Civilian Service from President John F. Kennedy in 1962.
• Crisis: Thalidomide
• 1962 FDCA Amendments
  – Requires premarket review for safety and efficacy
  – Requirement for adequate and well-controlled clinical trials
Crisis: Unsafe Medical Devices
Response: Premarket Review

• Medical device amendments of 1976
  – Risk-based approach to device regulation
  – Higher risk devices get full review for safety and efficacy
  – Low and moderate risk devices are reviewed for substantial equivalence to existing devices
Crisis: Drug safety challenges
Response: Postmarketing authorities to make sure benefits exceed risks

• Food and Drug Administration Amendments Act of 2007 allow agency to
  – Require postmarket studies
  – Mandate label changes
  – Impose Risk Evaluation and Mitigation Strategies
Crisis: Tobacco-related Illness and Death
Response: FDA Regulation

“It's a law that will reduce the number of American children who pick up a cigarette and become adult smokers. And most importantly, it is a law that will save American lives and make Americans healthier.”

--President Barack Obama
Crisis: Food Safety Scares
Response: Preventive Controls (pending)

- Congress considering legislation to expand FDA authority over food, including:
  - Authority to mandate recalls
  - Authority to require preventive controls
The FDA as a Public Health Agency

Margaret A. Hamburg, M.D., and Joshua M. Sharfstein, M.D.

A little more than a century ago, concerned about the potential dangers of food preservatives such as formaldehyde, Congress passed, and President Theodore Roosevelt signed, the Pure Food and Drug Act. The act sought to prevent the “manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors.” The office initially charged with this responsibility was the Bureau of Chemistry of the Department of Agriculture.

Since that time, the bureau has grown into the Food and Drug Administration (FDA), an agency in the Department of Health and Human Services (DHHS) responsible for oversight of more than 17 million medical products, food, and other consumer goods. What has remained constant is the agency’s “overriding purpose,” in the words of the Supreme Court, of protecting the public health. As the new commissioner and principal deputy commissioner of the FDA, chosen by President Barack Obama, we would like to provide a broad overview of how we intend to embrace this role.

The Institute of Medicine has defined the mission of public health as “fulfilling society’s interest in assuring the conditions in which people can be healthy.” To be healthy, people need access to a safe and nutritious food supply and to innovative, safe, and effective medical products. The FDA’s job is to support this access and, in doing so, to promote health, prevent illness, and prolong life. The ultimate measures of the FDA’s success should reflect its fundamental goals and go beyond such intermediate measures as the number of facilities inspected or drugs approved.

The urgent need to develop and produce a vaccine against H1N1 influenza virus provides an illustration of the agency’s public health role. Laboratory scientists at the FDA are growing the virus and will make reagents for vaccine-potency testing. Reviewers will help to design and oversee the clinical trials, and inspectors will oversee the quality of the production process. The agency’s success will be determined by the nation’s access to a safe and effective vaccine.

The traditional tools of a regulatory agency are regulation, approval or disapproval of applications, and enforcement. As a public health agency, the FDA should always ask whether delays in approval or safety problems can be prevented — a mandate that requires extensive and creative engagement with regulated industries, patients, and consumer groups, and others. The FDA should actively pursue opportunities to help advance science in the domains it regulates and ad-
FDA’s Public Health Role

• Frequent changes in response to new challenges
• Expectation of protecting the public
• For many years, state and local collaboration largely revolving around inspections, outbreaks, and recalls
• But with increasing role, need for more work together
Areas of Public Health Focus

- Food Safety
- Medical Products
- Nutrition
- Tobacco
• Quality
  – Global marketplace
• Safe use
  – Medical errors
  – Misunderstanding by patients
  – Abuse and diversion
  – Suicide
• Postmarketing safety
• Outbreak response
  – Tale of two calls
• National food safety system
  – Labs
  – Standards
  – Training
• Preventive controls
- Front of package labeling
- Menu labeling
- Salt

**Nutrition**
Tobacco Control

- Standards and policies
  - 6/22 key date
- Inspections
- Training and coordination with states and localities
Conclusions

• Looking back: FDA as public health agency
• Looking forward: Critical role of collaboration in public health-based regulatory system of the future