FDA and Public Health: The Last 100 Years… (and the next 10)

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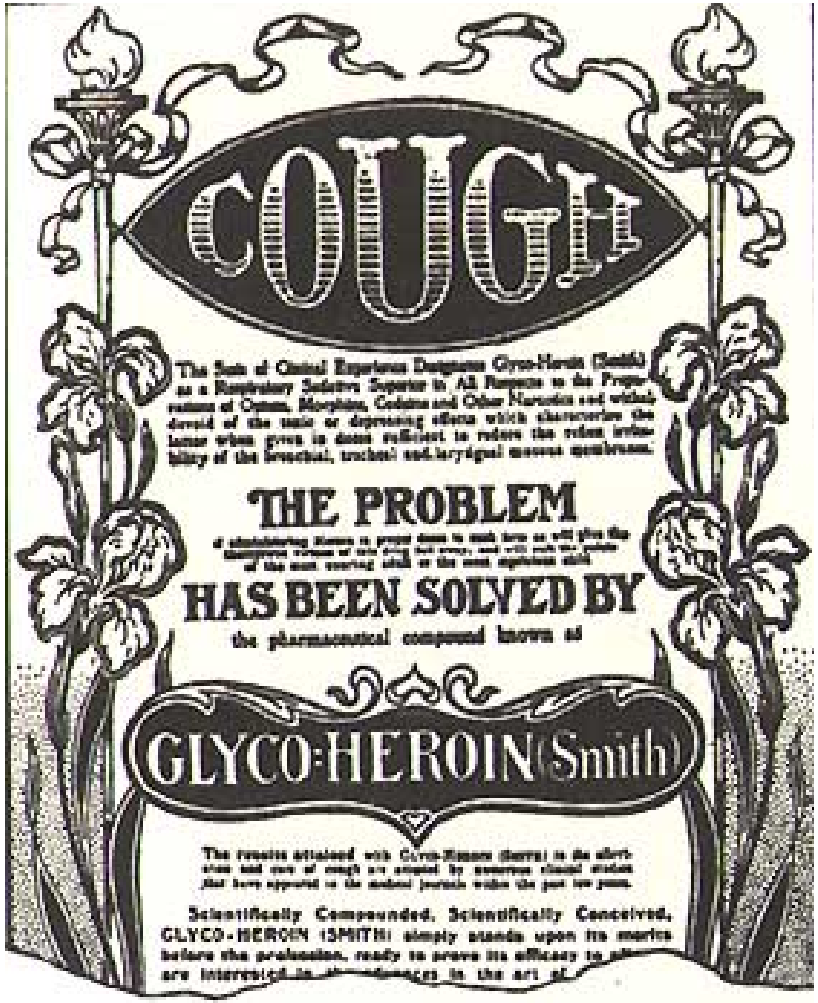
5 DARING ACTS — 210 ASTOUNDING SCENES

- 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 PROBLEM
HAS BEEN SOLVED BY
the pharmaceutical compound known as
GLYCO-HEROIN (Smith)
Scientifically Compounded, Scientifically Conceived,

- Crisis: Diethylene Glycol in Elixir Sulfanilamide
- 1938 – Food, Drug, and Cosmetic Act
  - Requires premarket review of drugs for safety
  - Eliminates most proprietary medicines


100 Tablets
KEVADON
thalidomide
25 mg. per tablet
CAUTION: New Drug—
Limited by Federal Law
to Investigational Use
Trademark "Kevadon"
Medical Research Department
THE WM. S. MERRELL COMPANY

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

U.S. Department of Health, Education, and Welfare

Food and Drug REVIEW

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PRESIDENT KENNEDY SIGNS NEW DRUG AMENDMENTS

Observers are, from left to right, Senator Thomas J. Dodd, Dr. Frances Kelsey, Commissioner Larrick, Senator Philip A. Hart, Senator Hubert H. Humphrey, Senator Estes Kefauver, Senator Olin D. Johnston, Under Secretary Ivan Nestingen, Congressman Leo W. O'Brien, and Congressman Kenneth A. Roberts.

On signing the Amendments on October 10, the President made the following statement:

"I am pleased to approve this bill, which is designed to provide safer and more effective drugs to the American consumer. Enactment of this legislation will help give the American consumer the protection from unsafe and ineffective drugs. It will also insure that our pharmaceutical industry will be even better equipped to provide us with the best possible drugs to be found anywhere.

"The Congress is to be congratulated in moving so quickly. Fortunately, prior to the revelation of the dangers posed by drugs like thalidomide, the foundation for legislative action on drugs had been laid down in exhaustive

(continued on next page)

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

Example: Buccal Fentanyl

- Physicians must be certified
- Only specific pharmacies can dispense
- Patients must be counseled
- Patient Registry

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

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

JUNE 11, 2009

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 $2 trillion in 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.[1] 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, patient and consumer groups, and others. The FDA should actively pursue opportunities to help advance science in the domains it regulates and ad-

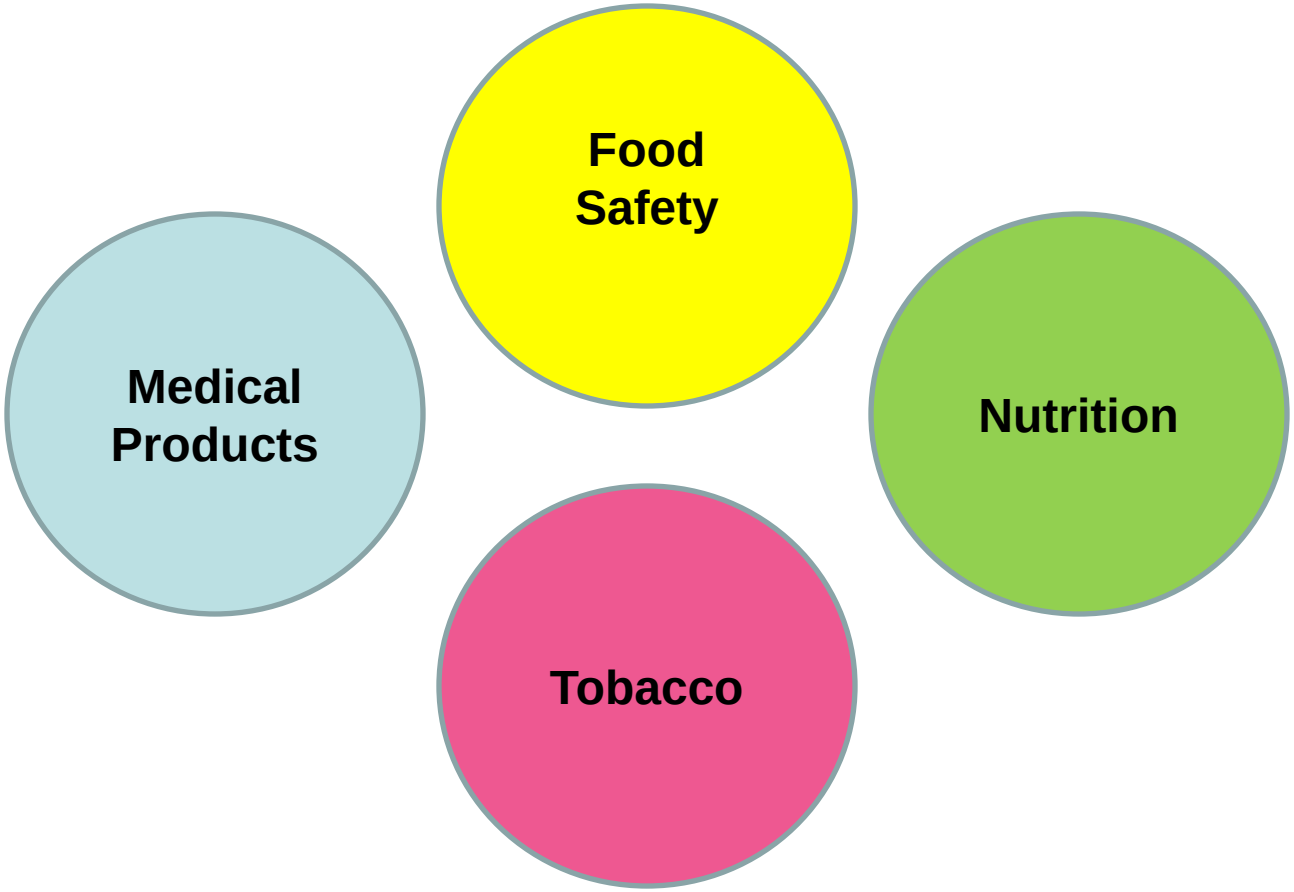
FDA's Public Health Role

- 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 for New Collaboration

- Medical Products
- Food Safety
- Nutrition
- Tobacco Control

Areas for New Collaboration



Medical Products

- Quality
- Safe use
  - Medical errors
  - Misunderstanding by patients
  - Abuse and diversion
  - Suicide
- Postmarketing safety

Why Get Involved?

- 4 million visits to outpatient settings as a result of adverse events
- As many as 10 adverse drug events per month for every 100 long-term care residents
- 2 to 6 adverse drug events per 100 hospital admissions
- 60,000 emergency department visits because of children's unsupervised ingestion of medications
- 180,000 emergency department visits for drug-related suicide attempts each year

- Outbreak response
- National food safety system
- Preventive controls

A Tale of Two Calls

- Outbreak 1
- Outbreak 2

- Front of Package labeling
- Menu labeling
- Salt


Tobacco Control

Legislation

- Mandates for industry, including:
  - No cigarettes with characterizing fruit flavors (9/09)
  - No light/low descriptors (6/09)
- Mandates for FDA, including:
  - Promulgate 1996 rule on tobacco products (6/22/09)
  - New pack labels for tobacco products (within 3 years)
  - Disclosure of ingredients and constituents (within 4 years)
- General authority for FDA, modeled on device statute:
  - Misbranding
  - Performance standards
  - Premarket approvals for new products (if not substantially equivalent)

Key Opportunities

- Epidemiological data
  - To guide standards and public health rules
- Local policy
  - FDA can take model programs national
- Direct work together
  - Enforcement contracts are a start
- Training
  - FDA expects to develop exchange program

Conclusions

- Looking back: FDA as public health agency
- Looking forward: Tremendous potential for collaboration with state and local partners to accomplish major health gains