



JOHNS HOPKINS

BLOOMBERG SCHOOL  
*of* PUBLIC HEALTH



CENTER FOR  
ANIMAL LAW  
STUDIES  
AT LEWIS & CLARK

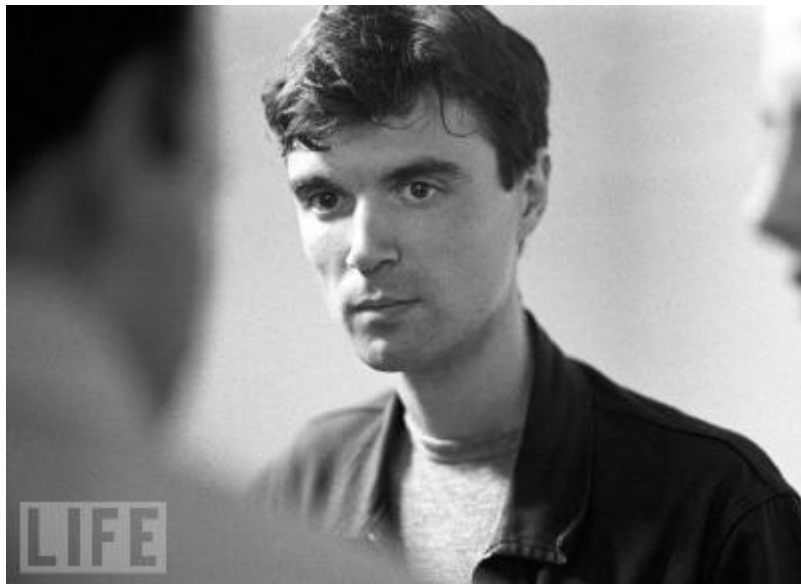
IN COLLABORATION WITH THE  
ANIMAL LEGAL DEFENSE FUND

# **Animal Testing: How can Environmental and Animal Advocates Work Together?**

Paul A Locke, MPH, JD, DrPH

# **This presentation will cover ...**

- History of product testing (abbreviated)
- Early toxicity tests – twentieth century
- A new paradigm
  - Toxicity Testing in the 21<sup>st</sup> Century (NAS report)
  - Implementation of report vision and strategy



**Who is this man?**



# Once in a Lifetime

## (The Talking Heads, c. 1980)

“And you may find yourself living in a shotgun shack;

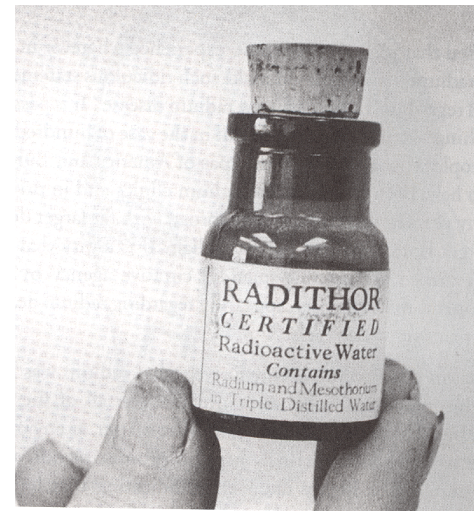
And you may find yourself in another part of the world;

And you may find yourself behind the wheel of a large automobile;

And you may find yourself in a beautiful house, with a beautiful wife

**And you may ask yourself - Well...How did I get here?”**

# Some truly wonderful products of the early 20<sup>th</sup> Century



# Elixir sulfanilimide (1937)

- Sulfanilimide effective against strep infections in powder and tablet form
- Demand for liquid form
  - Dissolved in diethylene glycol (antifreeze)
  - Bottled and distributed wo/testing
- Responsible for 100+ deaths in 15 states
  - Many children
  - Public outcry

# U. S. Races Death to Save 700 From Elixir

**Recovery of Pint Bottles Sold to Patients  
Goal as Deaths From Poison Reach 36**

By Associated Press.

CHICAGO, Ill., October 24.—A nation-wide race with death, its object recovery of more than 700 bottles, mostly pints, of a new liquid medicine, named Elixir of Sulfanilamide, which has already caused 36 verified deaths, was described today at the headquarters here of the American Medical Association.

Every agent of the United States Food and Drug Administration, said Dr. Morris Fishbein, spokesman of the Medical Association, is scouring the country to recover the bottles. By some time on Monday, said J. O. Clarke of the Food and Drug Administration, it is hoped that all of the "outstanding" shipments will be recovered.

lies in the fact that large dosages are customary with sulfanilamide preparations.

The medicine stops the kidneys. At Medical Association headquarters its effects were said to be like those of bichloride of mercury. No antidote is known yet. The "Elixir" is made of sulfanilamide and diethylene glycol, a near relative of auto antifreeze fluid. The diethylene glycol is blamed for the lethal effect, although not itself classed as a poison.

The principal shipments, said Mr. Clarke, went to the South and Midwest. But in addition consignments have been traced to the Northern Peninsula of Michigan, to a distributing house in New York City and to another in San Francisco. An



# Mascara and lash liners



*Ethel Clayton, Photoplay Star, one of the many famous American Beauties who knows the value of "MAYBELLINE"*

**The Miracle of**  
**Maybelline**  
**Makes Every Face More Beautiful**

A touch of MAYBELLINE works beauty wonders. Scant eyebrows and lashes are made to appear naturally dark, long and luxurious. All the hidden loveliness of your eyes—their brilliance, depth and expression—is instantly revealed. The difference is remarkable. Girls and women everywhere, even the most beautiful actresses of stage and screen, realize that MAYBELLINE is the most important aid to beauty and use it regularly. MAYBELLINE is unlike other preparations, it is absolutely harmless, greaseless and delightful to use. Does not spread and smear on the face or stiffen the lashes. Each dainty box contains mirror and brush. Two shades: *Brown for Blondes, Black for Brunettes*. 75c AT YOUR DEALER'S or direct from us, postpaid. Accept only genuine MAYBELLINE and your satisfaction is assured. Tear out this ad NOW as a reminder.

**MAYBELLINE CO., 4750-74 Sheridan Road, CHICAGO**





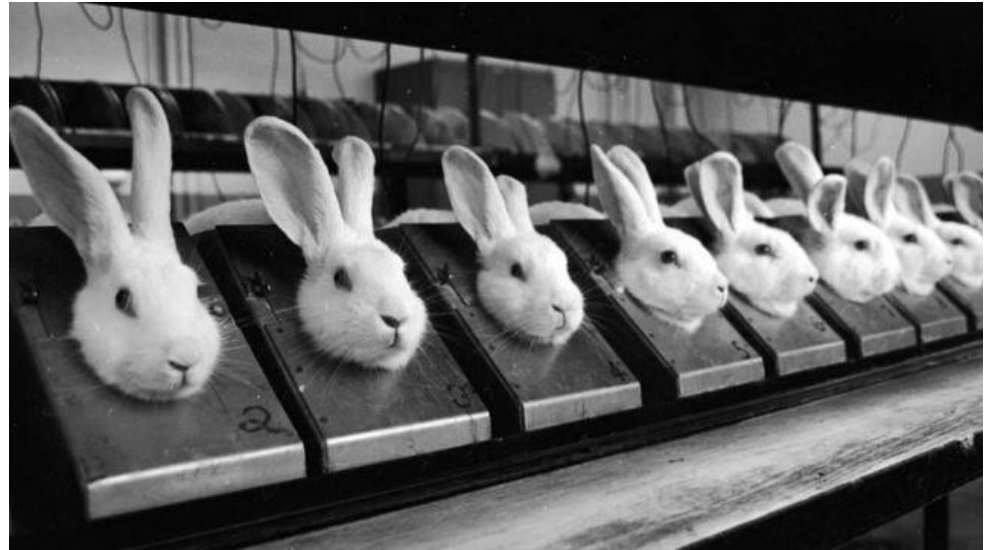

FATALITY RESULTING FROM THE USE OF LASH-  
LURE ON THE EYEBROW AND EYELASHES

S. B. FORBES, M.D., AND W. C. BLAKE, M.D., TAMPA, FLA,

JAMA 10 November 1934 103(19) p.1441 - 42

# Birth of product testing

- Demonstrated need for a system for testing cosmetics and other consumer products
  - Understanding of allergic reaction process
  - Evaluation for skin and eye irritation
- Contributed to passage of Food Drug and Cosmetic Act of 1938
- Lead to development of Draize test
  - J.H. Draize, G. Woodard, H.O. Calvery. Method for the study of irritation and toxicity of substances applied topically to the skin and mucous membranes *J Pharmacol Exp Ther*, 82 (1944), pp. 377–390



# Impact on Law

- Federalization of product testing
  - Roosevelt
  - New Deal and administrative law
- Evolution of a federal (not state) system to regulate products, pharmaceuticals and chemicals in the environment
- Evolution of a federal (not state) system about how animals are used in research and testing





# How many rabbits does Revlon blind for beauty's sake?



## WOLF AT THE DOOR

Revlon's new makeup line is a real beauty. It's the first time the company has ever introduced a line of makeup that is so good, it's almost too good to be true. The new line is called "Wolf at the Door" and it's the most beautiful makeup line ever created. It's the first time the company has ever introduced a line of makeup that is so good, it's almost too good to be true.

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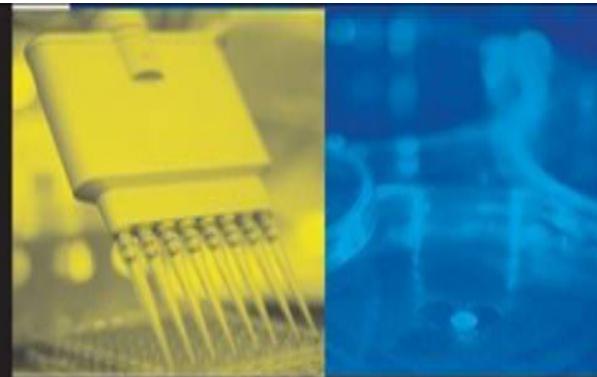
# TSCA

- Regulation of chemicals in commerce
  - Existing chemicals (at time of passage of TSCA) – no required testing
  - New chemicals and new uses for existing chemicals
    - ✓ PMN notice required, but
    - ✓ No required testing (no “base set”)
- **Toxics information gap exists**
- Law is flexible; does not create barriers to considering animal or non-animal based data
- TSCA amendment discussions underway on Capitol Hill (but bogged down in politics)

# **Toxicity Testing for Assessment of Environmental Agents**

**Interim Report**

NATIONAL RESEARCH COUNCIL  
OF THE NATIONAL ACADEMIES

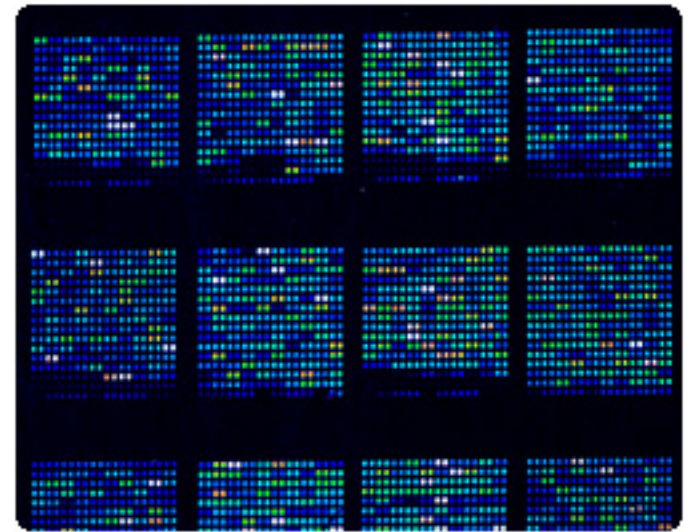
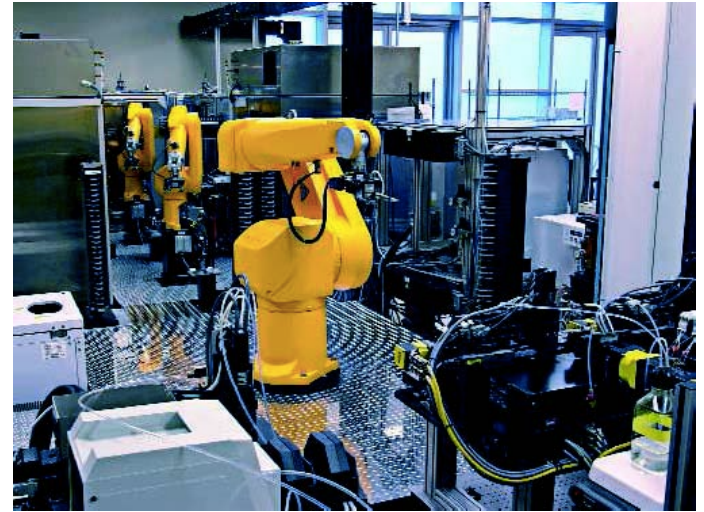
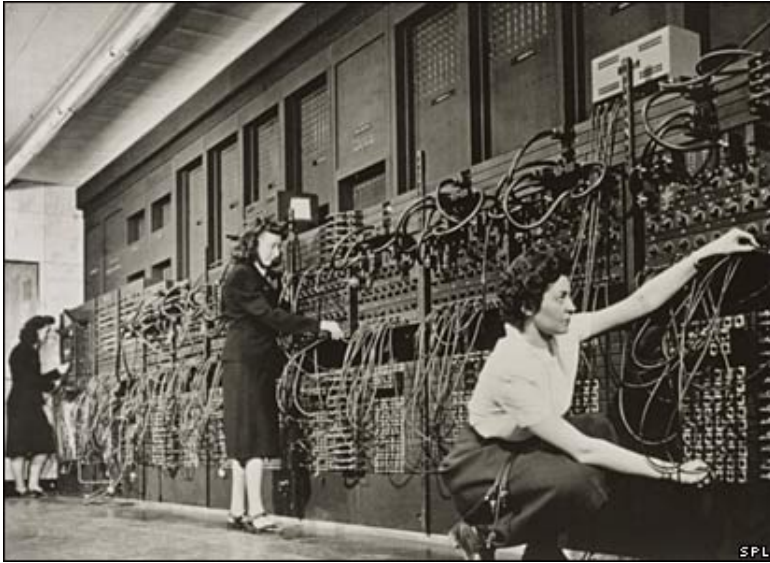


## **TOXICITY TESTING IN THE 21ST CENTURY: A VISION AND STRATEGY**



# OPTIONS FOR FUTURE TOXICITY AND SAFETY TESTING

Option I In Vivo	Option II Tiered In Vivo	Option III In Vitro/In Vivo	Option IV In vitro
Animal biology	Animal biology	Primarily human biology	Primarily human biology
High doses	High doses	Broad range of doses	Broad range of doses
Low throughput	Improved throughput	High and medium throughput	High throughput
Expensive	Less expensive	Less expensive	Less expensive
Time consuming	Less time consuming	Less time consuming	Less time consuming
Relative large number of animals	Fewer animals	Substantially fewer animals	Virtually no animals
Apical endpoints	Apical endpoints	Perturbations of toxicity pathways	Perturbations of toxicity pathways
	Some <i>in silico</i> and <i>in vitro</i> screens	<i>In silico</i> screens possible	<i>In silico</i> screens





*Please ask yourself –*

**How do we get  
here?**

*(and what should  
lawyers do to help)*

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High doses	High doses	Broad range of doses	Broad range of doses
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LIFE	Some <i>in silico</i> and <i>in vitro</i> screens	<i>In silico</i> screens possible	<i>In silico</i> screens

## CONTACT INFORMATION

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