

The Emerging Role of the PHS CC Officer in Federal Regulatory Medicine



Overview of DHHS Career Experience

NIH – Research oriented with substantial regulatory responsibilities for the veterinarian

FDA – Regulatory Agency

Twenty Institutes



National Cancer Institute (NCI) Established in 1937



National Eye Institute (NEI) Est. 1968



National Heart, Lung, and Blood Institute (NHLBI) Est. 1948



National Human Genome Research Institute (NHGRI) Est. 1989



National Institute on Aging (NIA) Est. 1974



National Institute on Alcohol Abuse and Alcoholism (NIAAAA) - Est. 1970



National Institute of Allergy and Infectious Diseases (NIAID) - Est. 1948



National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) - Est. 1986



National Institute of Biomedical Imaging and Bioengineering (NIBIB) - Est. 2000



National Institute of Child Health and Human Development (NICHD) - Est. 1962



National Institute of Dental and Craniofacial Research (NIDCR) - Est. 1948



National Institute of Mental Health (NIMH) - Est. 1949



National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) - Est. 1948



National Institute on Drug Abuse (NIDA) - Est. 1973



National Institute of Environmental Health Sciences (NIEHS) - Est. 1969



National Institute of General Medical Sciences (NIGMS) - Est. 1962



National Institute on Deafness and Other Communication Disorders (NIDCD) - Est. 1988



National Institute of Neurological Disorders and Stroke (NINDS) - Est. 1950



National Institute of Nursing Research (NINR) - Est. 1986



National Library of Medicine (NLM) - Est. 1956



Seven Centers



Center for Information Technology – Est. 1964



Center for Scientific Review (CSR) - Est. 1946



John E. Fogarty International Center (FIC) - Est. 1968



National Center for Complementary and Alternative Medicine (NCCAM) - Est. 1992



National Center on Minority Health and Health Disparities (NCMHD) - Est. 1993



National Center for Research Resources (NCRR) - Est. 1962



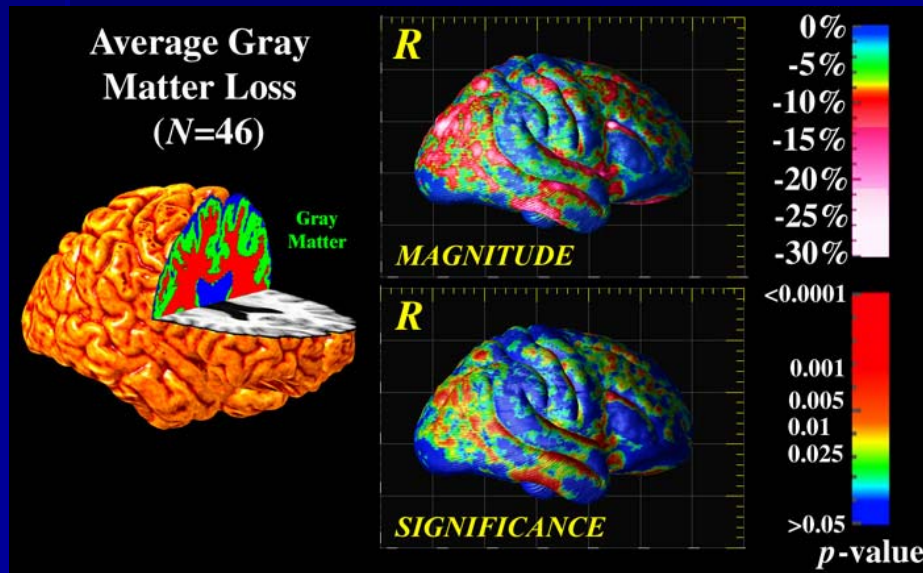
Warren Grant Magnuson Clinical Center (CC) - Est. 1953

National Institutes of Health



National Institute of Mental Health

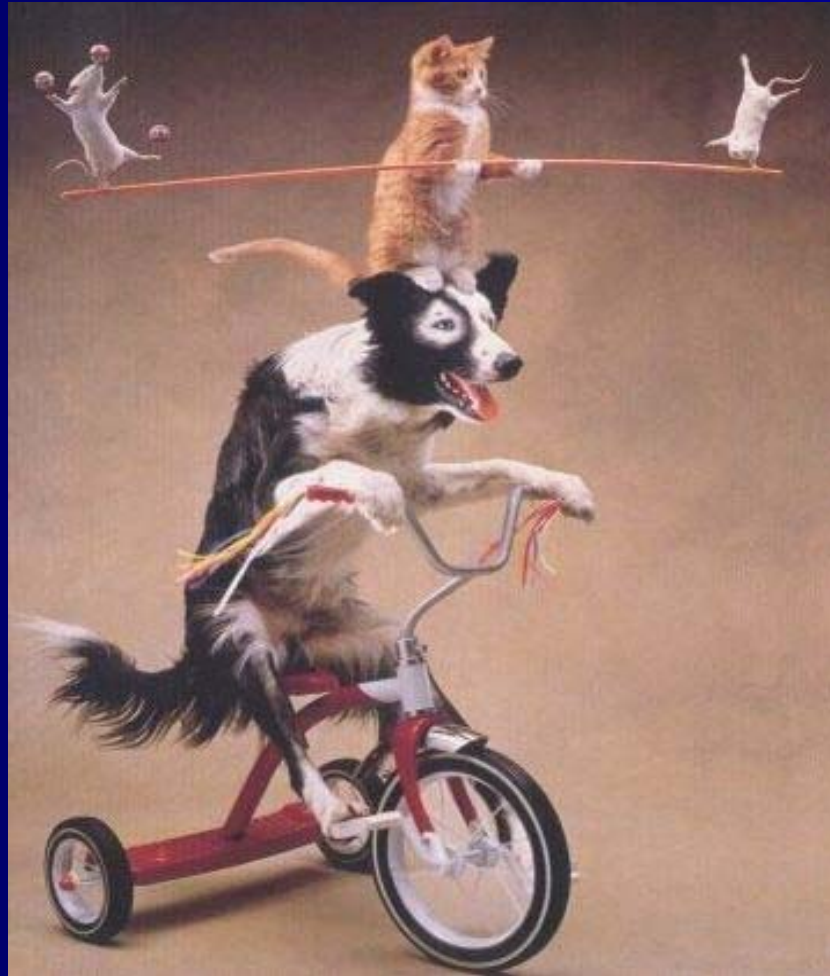
Veterinary Resources Program



- **Veterinary medical diagnostics, anesthesia surgical, and treatment services for primates**
- **Advise research community on proper restraint, care, handling, and anesthesia of primates**
- **Supervise technical personnel & animal husbandry staff**



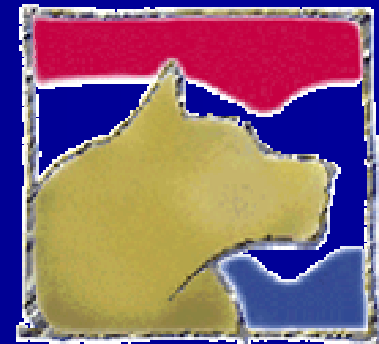
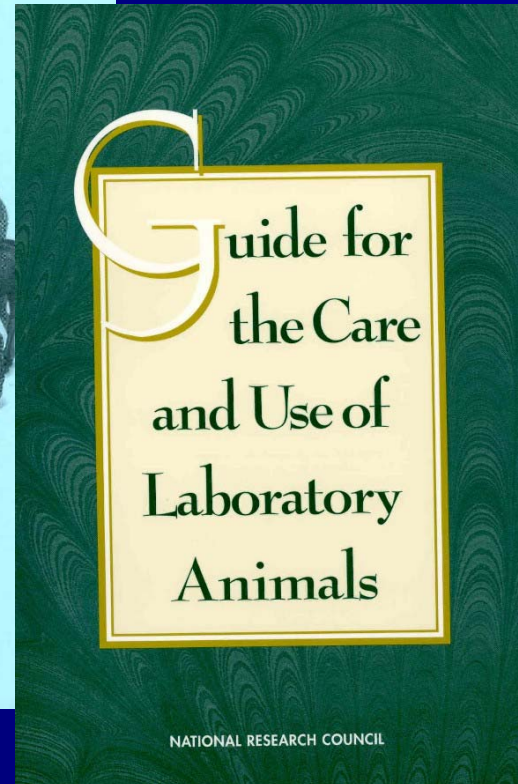
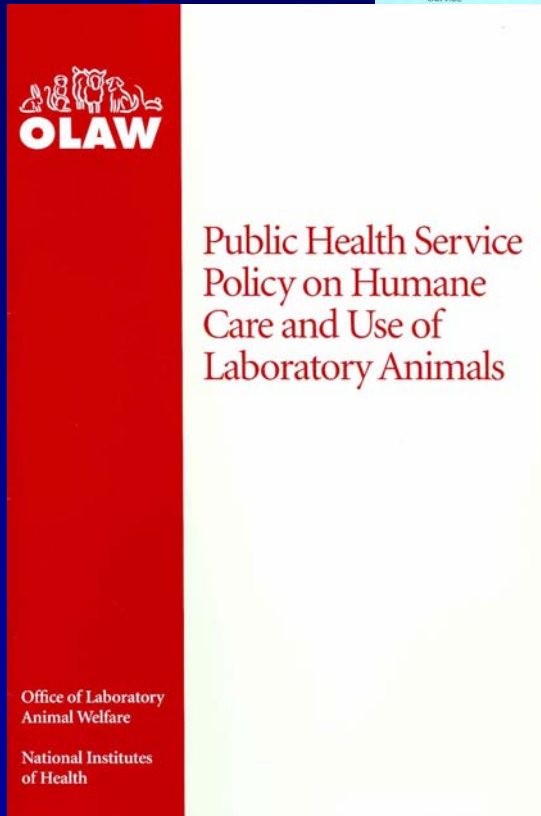
- **Veterinary clinical care of multi-species facilities (primates, ungulates, carnivores)**
- **Diagnostics, anesthesia and surgery**
- **Breeding protocols & artificial insemination**
- **Cryopreservation**



Positron Emission Tomography (PET)



- Ensure compliance with all federal policies
- Collaborative research
- Institutional Animal Care and Use Committee (IACUC)





*Protecting Consumers,
Promoting Public Health*

U.S. Food and Drug Administration

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FDA – Eight Centers/Offices

Center for Devices and Radiological Health (CDRH)

Center for Drug Evaluation and Research (CDER)

Center for Food Safety and Applied Nutrition (CFSAN)

Center for Veterinary Medicine (CVM)

National Center for Toxicological Research (NCTR)

Office of the Commissioner (OC)

Office of Regulatory Affairs (ORA)

FDA-Affiliated Organizations

Joint Institute for Food Safety and Applied Nutrition

National Center for Food Safety and Technology

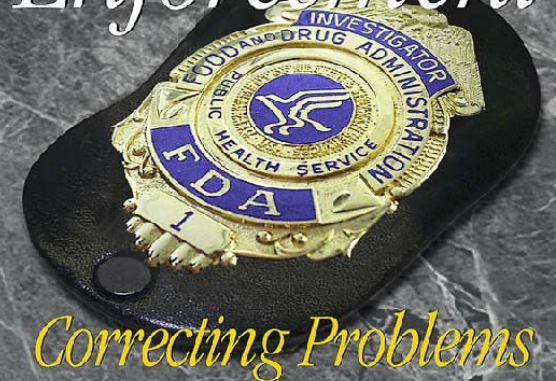
History: 1902 – The Poison Squad



Safe And Effective Animal Drugs



Enforcement



Correcting Problems

New Product Review



Keeping Watch



Safe Manufacturing
And Handling

Monitor For
New Risks

Research



Instruct GLP animal studies

Inspect laboratories and manufacturing sites





Bioresearch monitoring

Verify validity of study results

Human clinical trial monitoring



**Review of Biologic License Applications (BLAs)
Veterinary review for xenogeneic products
Investigational New Drug (IND) review**

Safe And Effective



Medicines

Biologics

Medical Devices



FDA

Proper animal modeling
Primate enrichment
Veterinary care



Safety and efficacy of new drugs

Bioequivalence determinations

Human food safety





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