

biologics

Scientific

**Publications** 

Garcetti v. Ceballos U.S. Sup Ct (May 30, 2006)

employees are limited in their speech about their

job-related work. The Supreme Court found this

limitation to be in the public interest. This would

Congress responded to the US Sup Court decision by

proposing new legislation to protect whistleblowers.

also apply to federally-employed biodefense

March 14, 2007 the House passed HR 985.

researchers.

The U.S. Supreme Court ruled that public

# Law, Policy and Ethics Core

Center for Biodefense. Law and Public Policy Texas Tech University School of Law



# **UPDATE:** Looking at the Law for Biodefense Researchers

Select Agents

42 CFR Part 73

Regulation

**Regulatory update** 

Federal

CFR Part 73

71 Fed Reg 6499

Request from CDC

collection for select

(Feb 8, 2006)

to OMB for

paperwork

continuation of

agent reporting

Government

Select agent Audit Guide, HHS/ OIG Office is

available (Sept 27, 2004) for compliance with 42

71 Fed Reg 32827

(Effective

June 7, 2006)

emergency

Exception from

Informed Consent for

use of medical devices

during a public health



Vaccine and Approval Processes

July 2005

This core presented recommendations for removing impediments to biodefense production by private sector vaccine manufacturers to NIH and RCE. PIs at a national RCE Presentation in Bethesda. MD.

Summer 2006

Director was consulted by Sen. Burr's office in the crafting of legislation which became PREPA.

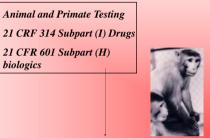
December 2005 PREPA was passed

December 2006 PAPHA was passed

Adopting recommendations from this core and creating BARDA, the Biomedical Advanced Research and Development Authority

## Purpose

The Law, Public Policy and Ethics Core (LPEC) seeks to support the areas of focus for the WRCE through research. study and analysis of policy, laws and regulations which impact research and scientists in biodefense.



**CBER** and **CDER** approve products using the Animal Rule

PRODUCTS

Approved:

**City of Boston** passed a local ordinance to regulate BSL 3, 4 Laboratories Sept 2006

Local government

HIGHLIGHTS:

-provides for local inspections

-prohibits classified research

-requires laboratory to support local public health needs

# Areas of Focus

The LPEC focuses on six areas to support the WRCE scientific program development of therapeutics, diagnostics, and vaccines for category A-C agents. The work focuses on six areas of law, ethics and policy:

International Human Subject Testing



Legal Scholars propose compensation act as a method to avoid liability for researchers and IRBs

Most recent guidelines for research in undeveloped countries 2002 CIOMS, Council for International Organizations of Medical Sciences (Available)

Intellectual Property



This core held an intellectual property clinic at the WRCE Meeting in September 2005 to provide biodefense researchers with IP advice

An Intellectual Property Brochure with Guidelines for Biodefense Researchers in Public Presentations was developed by the Core (Available)

## The Center for Biodefense, Law and Public Policy

Following a recommendation by the Texas Tech University System Task Force on Anti-Terrorism and Public Security in April 2002, the Center for Biodefense, Law and Public Policy was formally established in the fall of 2002. The Establishment of the Center is to provide an opportunity for interdisciplinary collaboration to move in the direction of solutions in the complex, and cross-disciplinary area of biodefense. A wide range of disciplines, from law to forensic pathology, are represented by the Center's 15 faculty members. Dr. Victoria Sutton, from the Texas Tech School of Law, was named the Director of the Center in September 2002.

## Contact

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