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# Climate Change, Environmental Laws and the Effect on Health

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*presented by*

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## Who We Are?

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## Introduction

- Presentation:
  - Will discuss the causes and effects of climate change
  - Review certain laws which address the issues that create and are created by climate change

## Climate Change and its Effect

- Access to Food
  - Desertification
  - Distribution
- Access to Water
- Natural Disaster
- Infection
  - Increase in tropical diseases
  - Increased resistance
- Migration of People
  - Access to Shelter

## Snapshot

- 5 to 6 billion pounds of insecticides, herbicides and other biocides are added to the world's environment each year, most of it never reaching a pest
- Fossil fuels account for more than 80% of our energy
- Levels of CO<sub>2</sub> are rising
- Tidal marshes, swamps and wetlands continue to disappear at about 100,000 acres per year (US)
- Estimated 40% fish species threatened with extinction, 30% of flowering plants and 10-20% for birds, mammals, reptiles and amphibians
- Are our laws working?
- The answer may not be just new laws, but systemic change and new technologies, which work with societal needs for equality and a living wages

## Legal resources will need to address Climate Change issues

- Regulation of Greenhouse gases
- Access to water and water rights
- Protection of coastlines and relocation of structures
- Immigration and migration of people
- Development, manufacture and distribution of drugs such as antibiotics and vaccines
- Regulations of animal feed and farming practices
- Human trafficking

## Clean Air Act

- *Massachusetts v EPA*
  - 12 states and several cities of the United States brought suit against the EPA to force it to regulate CO<sub>2</sub> and other Greenhouse Gases (GHGs) as pollutants in car emissions.
  - Court held that “air pollutants” includes GHGs.
  - EPA then sought to regulate stationary sources (power plants and other facilities)
  - But question was whether the regulation of GHG emissions of new motor vehicles triggered the permitting requirements for all stationary sources that emit GHGs
  - Supreme Court said “no” in 2014 but included regulation of GHGs

## Environmental Laws and Climate Change

- In *Utility Air Regulatory Group v. EPA*, the EPA's regulation of Greenhouse Gas Emissions (GHGs) under the Clean Air Act (CAA) in stationary sources was not automatically extended based on its regulation of motor vehicle emissions because the term air pollutant as applied to motor vehicle emissions is not necessarily the same definition as used elsewhere in the Clean Air Act.
- Certain Stationary Sources (power plants and factories) could be regulated for GHGs however provided they were of a certain size and being regulated for other "conventional" pollutants. US estimated this accounts for about 83% of US stationary source GHG emissions.
- Viewed as an overall "win" even with limitations.



## Worldwide GHG Emissions

- Paris Agreement
  - Goal – maximum tolerable increase in temperatures of less than 2 degrees above pre-industrial levels with a goal to 1.5 degree above pre-industrial levels
  - Failures
  - Did not lead to enforceable agreements but pledges
  - Pledges may not achieve the goal - we may be on track for a higher increase

## Climate Change and Infection

- Studies have indicated that warmer temperatures will lead to increased infectious agents in the United States and worldwide
- Recent study of effects of El Nino on infectious diseases indicated increase of vector-borne and enteric disease in the United States.
- Increase in treatment resistant bacteria
- Need for new antibiotics and vaccines

## Reason for drop in antibiotic development

- Antibiotics are expensive to develop
  - Hundreds of millions in research and testing for each new drug
  - 80% of drugs emerging from labs fail in safety or efficacy or both
  - Vulnerability to generics (especially outside US)
  - Limits on pricing (especially outside US)
  - Companies need to offset these costs
  - Antibiotics are episodic and short term and other drugs such as anti inflammatory, oncology, orphan drugs, anti depressives etc. may seem like better risks
  - Even nature is a big competitor
- Low returns +unpredictable approval pathway + high risk = few candidates

## GAIN Act

- **Provides Five Years of Exclusivity**
  - GAIN grants an **additional five years** of exclusivity for those new antibiotics designated under the law as a “**qualified infectious disease product**,” defined as “an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections.”
  - The extra five years of market protection is in addition to any existing exclusivity, including that which may be applicable under Hatch-Waxman (five years or three years), orphan drug (seven years), or pediatric exclusivity (six months).
- **Speeds Development and Review of New Antibiotics**
  - Drugs that fall under the GAIN provisions receive **fast track and priority** status and undergo an expedited regulatory approval process with FDA.

## GAIN Act

- **Requires Additional and/or Updated Clinical Trial Guidance**
  - GAIN requires FDA to issue new guidance on the development of pathogen-focused antibiotics—those that target specific bacteria. Such advice has not been available previously, leaving drug makers with no clear development pathway for these products. The agency must also review and revise other antibiotic guidance to ensure that it is up-to-date from a scientific and regulatory perspective.
- **Requires Listing of Pathogens That Pose a Threat to Public Health**
  - GAIN requires FDA to compile a list of “qualifying pathogens” that have the potential to pose a serious threat to public health and to update this list at least every five years. The agency must consult with CDC, medical care professionals, and clinical researchers in deciding which pathogens to include—taking into consideration the impact on human health and any increases in drug resistance.

## Diseases which are or could spread with Climate Change

- dengue fever
- malaria
- yellow fever
- hantavirus
- leptospirosis
- Japanese B Encephalitis
- elephantiasis
- Lyme's disease
- West Nile
- leishmaniosis
- Chagas disease
- Zika
- chikungunya
- typhus

## Not enough

- Increasing research and development of drugs but need further research and development
- Adequate manufacturing capabilities with cost effective manufacturing
- Incentives such as the GAIN Act
- Increased government support

## Food Safety and health risk

- Climate change will bring increased pressure on farming and farm practices and the use of antibiotics
- American Academy of Pediatrics (AAP) technical report says the practice of adding antibiotics and other antimicrobial drugs to the feed of healthy livestock, commonly done to promote growth and prevent disease among animals in crowded conditions, often leaves the drugs ineffective when they're needed to treat infections in people, especially the youngest among us
- More than two million people in the United States become ill with [antibiotic-resistant infections](#) every year, and more than 23,000 die from them.
- The Center for Disease Control and Prevention's Foodborne Diseases Active Surveillance Network in 2013 indicated that the highest incidence was among children under five years old



# Climate Change on Use of Drugs in Animals

- Use of antibiotics with animals is a problem
  - Domestic sales and distribution of antimicrobials approved for use in food-producing animals increased by 22% from 2009 through 2014, and increased by 4% from 2013 through 2014, including both not medically important and medically important
  - Used to treat infections and to increase growth
  - Many antibiotics are OTC for farmers
- Problems
  - Increased methane production (Climate Change link)
  - Increased resistance of pathogens
  - Increased pressure on farming with climate change
- Solutions
  - Prescription requirement
  - Diagnostics to better target diseases
  - Better farming practices

## Water Rights

- Increased scarcity of fresh water will lead to disputes which will need to be addressed legally, either through the courts or through legislation
- Technology such as desalinization and filtration/recovery will assist but are expensive

# Prior Rights

- **Prior Rights**
  - First person to take a quantity of water from a water source for "beneficial use"— agricultural, industrial or household —has the right to continue to use that quantity of water for that purpose
  - Subsequent users can take the remaining water for their own beneficial use provided that they do not impinge on the rights of previous users
  - Common in Western States
- **Riparian Rights**
  - The reasonable use of the water by a riparian owner is subject to the downstream riparian owners 'riparian right' to receive waters undiminished in flow and quality.
  - Use is proportionate to frontage on waterway
  - Common in Eastern States

# Water Rights-Equitable Apportionment

- Equitable apportionment is the doctrine of federal common law that governs disputes between States concerning their rights to use the water of an interstate stream.
- It is a flexible doctrine which calls for "the exercise of an informed judgment on a consideration of many factors" to secure a "just and equitable" allocation.
- Factors include:
  - physical and climatic conditions
  - the consumptive use of water in the several sections of the river, the character and rate of return flows
  - the extent of established uses
  - the availability of storage water
  - efficiency of current uses
  - potential benefit
  - the practical effect of wasteful uses on downstream areas, and
  - the damage to upstream areas as compared to the benefits to downstream areas if a limitation is imposed on the former
  - **Prior use not as important**

## Conservation is an important Factor

- Entirely appropriate to consider the extent to which reasonable conservation measures minimize any injury between states and what reasonable steps have been taken to minimize the amount of diversion required
- In equitable apportionment of interstate waters, it is proper to weigh the harms and benefits to competing States

## Scarcity of Water

- Will states which recognize prior rights have to change to equitable apportionment or riparian
- Will riparian rights have to adopt equitable apportionment practices
- Technology may answer, e.g., desalinization and reclamation, but water laws may have to be modified to meet most beneficial uses of water to society

## Climate Change and Effect on Laws

- Environmental Laws are not sufficient to address the wide ranged effects of climate change
- Adjustments in laws and new laws will need to be passed or addressed in order to resolve future issues which may arise.
- Questions?