

## Excuses, Codes, and Cases

- Codes of ethics
- COW discussion

## Case: Childhood Leukemia, Genes & 6MP

- Treatment of childhood leukemia
  - ☑ 6 MP (mercaptopurine)
  - ☑ Effective treatment for more than 30 years
  - ☑ Toxic in some patients
- Flaws in TPMT gene, Chromosome 6
  - ☑ Gene regulated enzyme production
  - ☑ Mild reaction if flaw in one allele
  - ☑ Severe reaction if flaw in both alleles
  - ☑ 1 in 300 have severe reaction
- Test is now available for TPMT gene
  - ☑ Should the test be given to all Leukemia patients?

## Analysis of the dilemma

- Stakeholders
  - ☑ Patients and families who are directly affected
  - ☑ Physicians who are responsible for patients
  - ☑ Society, which must pay the bills (\$100 for test)
- Facts
  - ☑ There are other options for treatment
  - ☑ Cost of test is minor compared to cost treatment
- Policy decisions
  - ☑ Individual: what should physicians recommend
  - ☑ Societal: should FDA recommend/require testing

## Opposing positions

- Recommend/require testing
  - ☑ Effective way to screen for possible side effects
  - ☑ Inexpensive in comparison to the cost of treatment
  - ☑ Establish important precedent for use of genetic info.
- Do not recommend/require
  - ☑ Toxicity can be monitored, is not a problem
  - ☑ Adding genetic test could slow or undermine treatment
    - Less aggressive treatment if there is risk of a reaction
  - ☑ Adds an unnecessary expense
- FDA must make a decision

## Stakeholders reconsidered

- Pro-recommendation/requirement
  - ☑ Microarray chip manufacturers (Roche Molecular Diagnostics)
  - ☑ Some physicians have financial interest in chip and diagnostic companies
- Anti-recommendation/requirement
  - ☑ Physicians comfortable with hands-on approach
  - ☑ Government, which is looking for ways to trim costs
- Off-license drug users/prescribers
  - ☑ 6x more use as anti-inflammatory drug
  - ☑ Not officially approved for this purpose

## Food & drug regulation

- Changing government role
  - ☑ 19th C, USDA, Chemical Laboratory
  - ☑ 1906 Food and Drug Act (under agriculture)



## 1930s, New Deal



- ☑ 1938 Food, Drug & Cosmetic Act (USDA)
- ☑ 1950s, food additive amendments (under DHEW)

## Current regulation

- Reach of the FDA
  - ☑ Cover 25 cents of every dollar spent
    - Food and food products
    - Medicines
    - Medical devices
    - cosmetics
- FDA approves drugs and regulates advertising/sale

## How does FDA make decisions?

- Science based
  - ☑ Gather scientific facts
  - ☑ Assemble panel of experts (Review Panel)
  - ☑ Make recommendations
  - ☑ FDA Commissioner accepts/rejects
  - ☑ Courts/Congress/President can intervene
- Science cannot answer all questions
  - ☑ Evidence is sometimes not conclusive
  - ☑ Does not say what to do with facts
- Enter bioethics

## Bioethics

- Definitions:
  - ☑ **Bioethics** – the critical study of the moral problems associated with biomedical and behavioral sciences and its application to health care decision-making.
  - ☑ **Research Integrity** – the use of honest and verifiable methods in proposing, performing and evaluating research and in reporting research results, with particular attention to adherence to rules, regulations, guidelines and commonly accepted professional codes or norms.
  - ☑ **Responsible Conduct of Research (RCR)** – conducting research in a way that fulfills the professional responsibilities of scientists and contributes to the perpetuation of science as a social endeavor held in high repute.
- Last 30 years developed into a [professional field of study](#)

## Bioethics & Codes of Ethics

- The critical study of the moral problems associated with biomedical and behavioral sciences and its application to health care decision-making
- Source of guidance, codes of ethics
- Best known in medicine is [Hippocratic Oath](#)

## World War II

- New guidelines were written after WW II to deal with war-related crimes
- Nazis had conducted medical experiments on Jewish prisoners
- Widely agreed that human experimentation had to be regulated
- Conference in Nuremberg Germany produce the [Nuremberg Code](#)
- Expanded/modified in [Belmont Declaration of Helsinki](#), 1964

### **Post WW II problems**

- Early 1970s, focus of activity shift to government
- Public attention raised by a number of reported abuses of human subjects
  - ☑ *Tuskegee experiment - syphilis study begun in 1930s*
  - ☑ *Willowbrook experiment*
  - ☑ *Radiation testing*

### **Government response**

- Congressional response, beginning mid 1970s, leads to two key sets of guidelines
  - ☑ *Belmont Report (1979)*
  - ☑ *Common Rules (45 CFR 46) (1981)*
- [Belmont Report](#) (1979)
- [Common Rule](#) (1990)

### **Cow**

### **Genes and criminal behavior**

- Duty to individuals:
  - ☑ I believe it is the duty of our society to help anyone succeed.
  - ☑ I believe it is the individual's responsibility to deal with the lot they've been cast.
- Application

### **Increasing supply of organs?**

- Although some reservations have been raised about organ transplants, I assume most of the class would not vote to make transplants illegal. You also understand that there are not nearly enough organs to go around. This leads to two policy questions that raise ethical dilemmas:
  - ☑ 1. if supplies are low, should society take steps to increase supplies?
  - ☑ 2. if steps should be taken to increase supplies, what steps?

### **Poll response**

- Question 1
  - ☑ 89% yes
  - ☑ 11% no (based on objection to use of stem cells)
- Question 2 (yes only answers)
  - ☑ 95% grow organs from stem cells
  - ☑ 1% xenotransplants
- Is this an ethically responsible policy option?

### **Justice in a databank society**

- A suspect has been arrested for a violent crime. Subsequent to the reading of his/her Miranda rights, the arresting officer takes an involuntary cheek swab to be processed in identity testing.
- The suspect has now been cleared and is released into society. However, in the process of interrogations, it was discovered that this individual may be participating in other criminal activities. Thus, the state wishes to retain the DNA sample.
- Again, all charges against the suspect have been dropped, but the state wishes to turn the DNA sample over to research facilities for anonymous testing.

### **Testing for susceptibility to cancer**

- If you could take a test that would tell you if you were at risk for a type of cancer that had a fifty percent chance of killing you, but doctors did not know when you would die, and there would be no treatment, would you still take the test?
  - Hypothetical #1 If the insurance companies could not find out because it was free?
  - Hypothetical #2 If you could pass it on to your progeny?
  - Hypothetical #3 If you got benefits from being labeled with that disease?
- What societal decisions does this question raise?