

Broad Discretion: The FDA Commissioner may prohibit the sale of a drug for human consumption when he or she determines that the drug poses an unreasonable risk of harm.

Less Discretion: The FDA Commissioner may prohibit the sale of a drug for human consumption when there exists an unreasonable risk of substantial illness or injury to those consuming the drug.

Even Less Discretion: The FDA Commissioner may prohibit the sale of a drug for human consumption when there exists an unreasonable risk of substantial illness or injury to those consuming the drug.

- A drug shall be considered as imposing a substantial risk of illness or injury if the drug increases the risk of that the individual will suffer death, a life threatening condition, an impairment that lessens the ability to perform one or more basic daily functions, or irreparable injury.
- In determining whether a drug imposes an unreasonable risk of substantial illness or injury, the FDA Commissioner shall consider the potential benefits to consumers of the drug and the percentage of consumers of the drug expected to incur a substantial illness or injury.

Narrow Discretion: The FDA Commissioner shall prohibit the sale of a drug for human consumption when the drug poses a risk of harm to at least 10% of individuals who consume the drug.

Types of Discretion

Define Vague Terms: The FDA Commissioner may prohibit the sale of a drug for human consumption when there exists an **unreasonable risk** of **substantial illness or injury** to those consuming the drug.

Explicit Authority to Set Standards: **The FDA Commissioner shall establish such standards as are necessary** to ensure that the manner in which a drug is labeled is not misleading or inaccurate, and that the drug's label provides adequate warning of all known potential risks and side effects.

HIPAA

Each [covered entity] who maintains or transmits health information shall maintain reasonable and appropriate administrative, technical, and physical safeguards

(A) to ensure the integrity and confidentiality of the information;

(B) to protect against any reasonably anticipated—

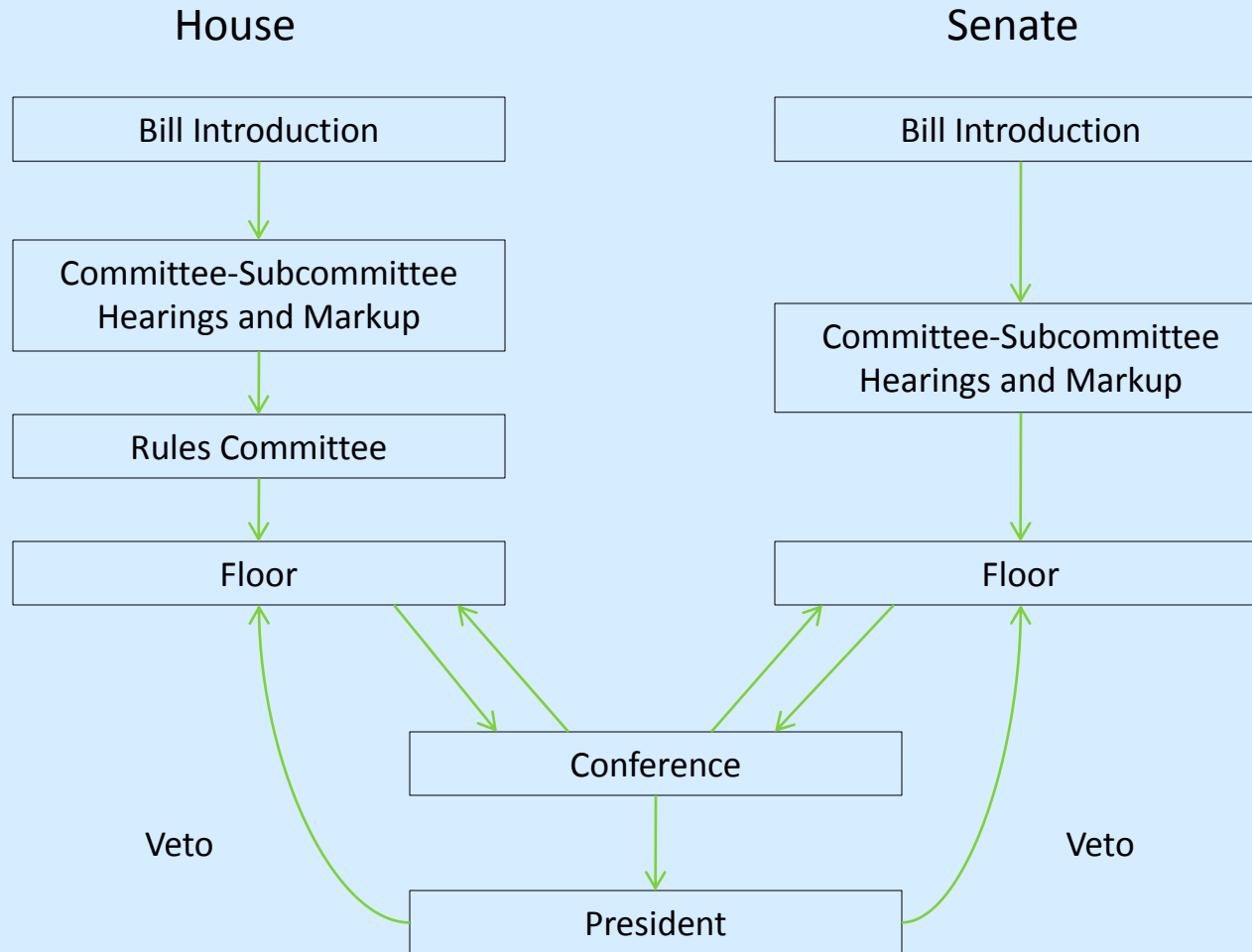
*(i) threats or hazards to the security or integrity of the information;
and*

(ii) unauthorized uses or disclosures of the information; and

(C) otherwise to ensure compliance with this part by the officers and employees of such person.

Section 1172(d)(2) of the Social Security

Legislative Process for Bills



<u>Delegate Broadly</u>	<u>Delegate Narrowly</u>
Complex issue – expertise needed	Less complex issue
Low risk bureaucratic drift	High risk bureaucratic drift
Easy to monitor agency	Monitoring agency difficult
Low political payoff for acting	High political payoff for acting
Disagreement over the details	Agreement on the details
Dodge blame for hard choices	
Committee's bill inconsistent w/ legislature's preferences	
Avoid special interest politics	