

## **Historical Developments Affecting Industry's Role in Drug Research**

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-- Kefauver-Harris Amendments, 1962: companies must demonstrate efficacy of products as well as safety before marketing, increasing drug development costs.

-- 1980s tax revolt: Public support for government spending declines; universities lose funding so less state and federal money available for research.

-- Bayh-Dole Act, 1980: promotion of "technology transfer" agreements among government, university and business.

-- Proliferation of industrial research parks like Silicon Valley and Route 128 in Boston as universities try to attract investment.

-- Industry funding leaves the academy. Early 1990s: 75% of pharmaceutical industry's research dollars went to universities. 2000: 34%.

-- Proliferation of Contract Research Organizations which operate more cheaply, faster and with fewer regulations than do university research bureaucracies.

### **Issues of Concern regarding industry-funded research**

-- Sponsor, not author, may have main responsibility for research hypothesis, study design, data collection and making inferences from data.

-- Authors often do not control the decision to findings, which interferes with the system of peer review and scientific replication.

-- Officials making decisions regarding research conduct may be on the advisory board or scientific committees of the research sponsor.

-- Projects undertaken by public universities through contracts with industry may be controversial but not subject to public and much-needed funding may dry up if unpopular topics are investigated.

-- Potential for distortion of the research foundation of evidence-based medicine.

-- Increased industry funding may erode public confidence in the objectivity of medical research.

-- Ethical justification for exposing research subjects to risks for production of knowledge that may not better society since no duty to publish?