US Federal Labs in the National Innovation System

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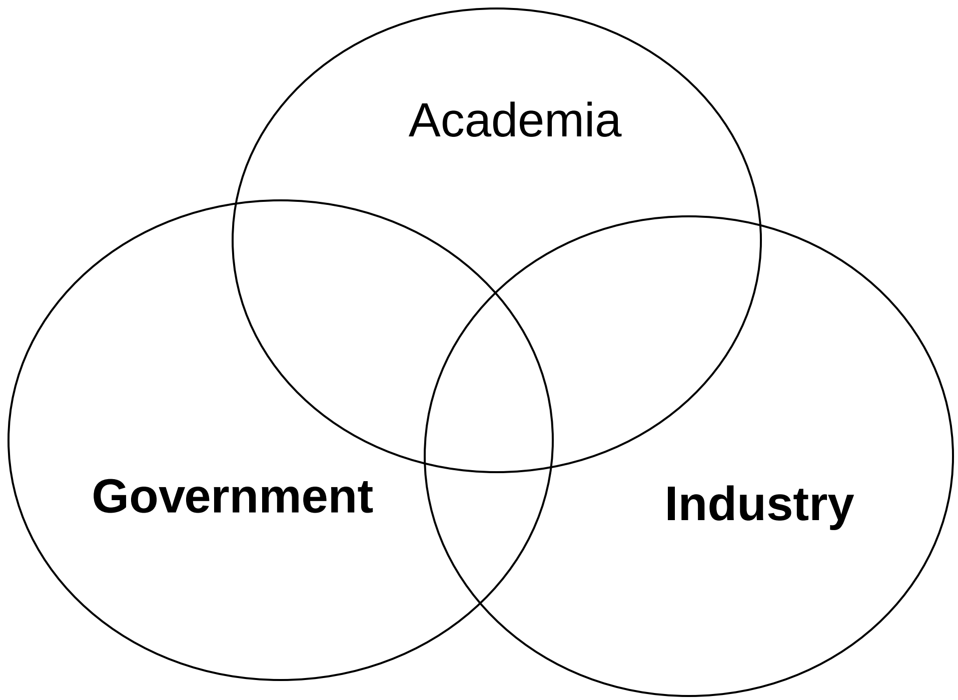
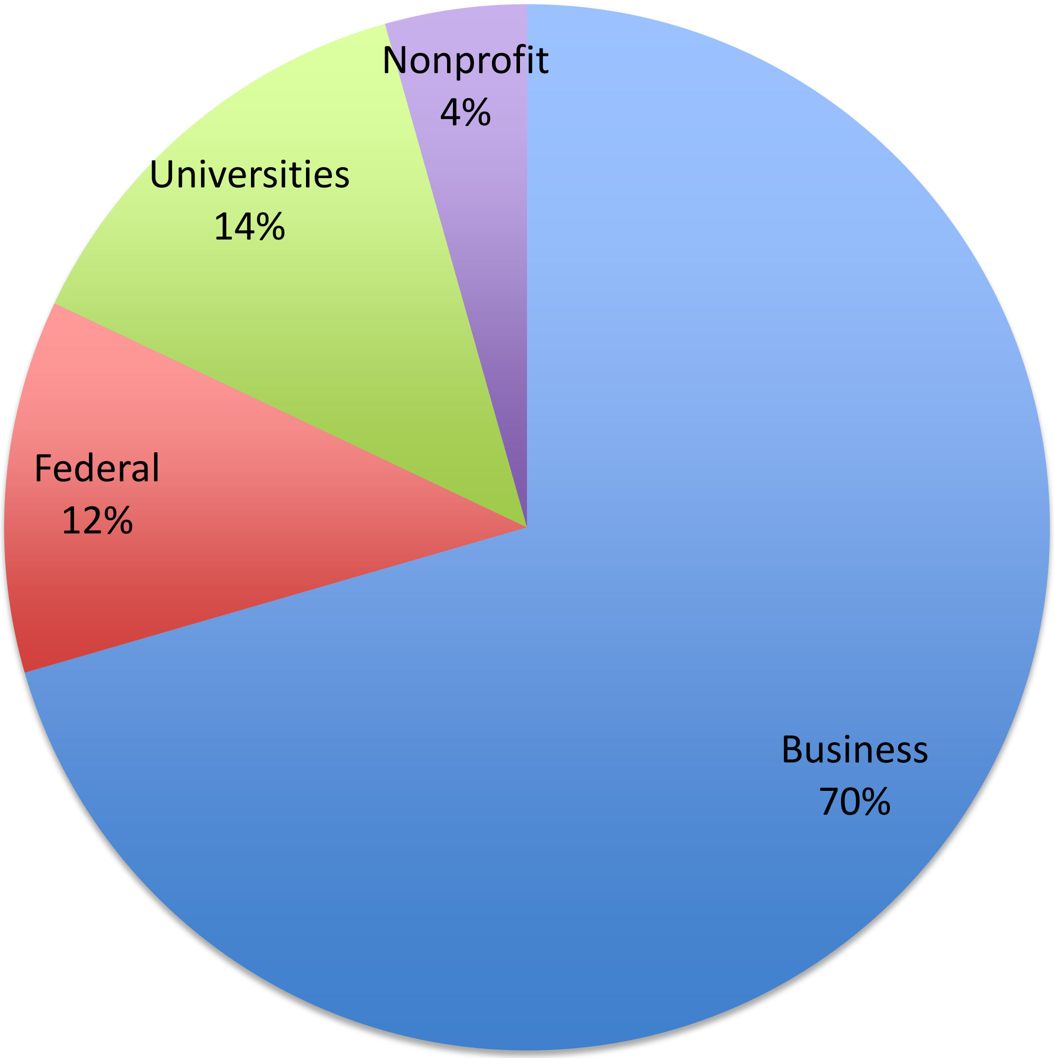
January 20, 2014

US National Innovation System



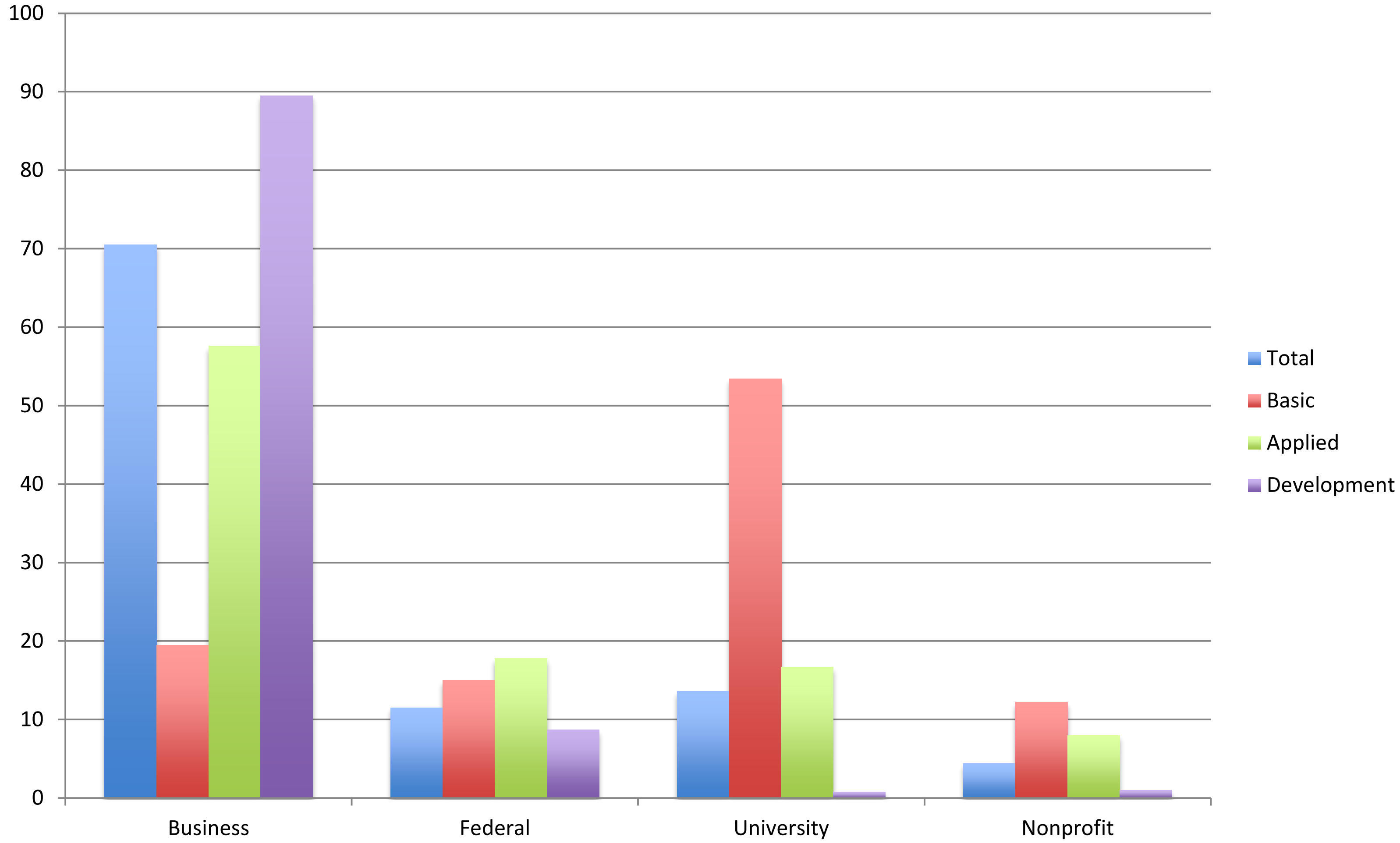
The Triple Helix Model of University-Industry-Government Relations (Etzkowitz, H & L. Leydesdorff, 2000, The dynamics of innovation: from National Systems and “Mode 2” to a Triple Helix of university-industry-government relations, *Research Policy* 29:109-123)

Share of R&D, by performing sector, US 2009



Source: NSF, SEI, 2012.

Share of R&D, by character and performing sector, US 2009



Source: NSF, SEI, 2012.

US Federal Lab System

- Federal government is major funder of R&D
- But, also conducts R&D in Federal labs
- About 700 Fed Labs, but only about 100 of significant size (Bozeman and Crow 1998) (cf. ~100 research universities in US)
  - Substantial heterogeneity in size, mission, organization, technology, commercial focus
  - Intramural v. FFRDC (DOE has most, but others also)
- Difficult to distinguish Federal from University or Industry lab. And, often find university and industry R&D personnel in the national labs.
  - In part, because providing facilities to university and industry projects is one of the functions of the labs

Key Functions of Federal Labs (Neal et al 2008)

- Support large scale research that requires significant capital expenditures, unique facilities and specialized staffing
  - Almost half of all users of DOE scientific facilities are university researchers.
- Conduct classified/sensitive research
- Support mission and regulatory function of Fed agencies
  - EPA or NIST, for example, set standards, asses risk or implement regulations aimed at protecting public good.
- Manage long-term research programs.
  - Agency labs and personnel provide continuity and institutional memory needed for such long-term projects
  - University funding often on very short cycles (2-3 years is common)

Federal Lab Examples

- DoD has a lab for each of the branches (e.g., Naval Research Lab), plus 9 FFRDCs
  - e.g. Lincoln Labs managed by MIT and Software Engineering Institute managed by CMU.
  - Also, University Affiliated Research Centers (APL at JHU).
    - Inside universities, but partner with agency to solve agency problems and receive a significant share of their support from the Fed.
    - APL operates primarily under a sole-source, cost-plus-fixed-fee contract administered by the US Navy Naval Sea Systems Command. Covers about 60% of APL budget.
- EPA has more than a dozen labs.
  - Work done in-house, rather than contract to industry, because industry may be the target of the regulations based on the research
- USDA National Seed Storage Lab (Ft Collins, CO)
  - Repository for plant seeds and also research center, to provide materials for users, and provide long-term preservation of genetic resources (diversity)

National Institutes of Health (NIH)

- Under Department of Health and Human Services
  - Mission: promote public health through biomedical research
- $28 Billion budget
  - 80% for external grants
  - ~20% for intramural researchers
  - 18,627 employees (~7000 researchers)
- 27 institutes
  - National Cancer Institute (NCI) $4.8B
  - National Institute of Allergy and Infectious Diseases (NIAID) $4.3B
  - National Heart, Lung, and Blood Institute (NHLBI) $2.9B

Department of Energy (DOE)

- Mission: research on civilian energy and nuclear weapons
- $10 Billion R&D budget
  - ~80% intramural
- Internal labs: 3 major
- DOE FFRDCs: 17
  - Operator can be university, firm, consortium, etc.
  - FFRDCs outside Civil Service regulations, so more flexibility in personnel
  - DOE's Los Alamos, Sandia, Lawrence Livermore and NASA's Jet Propulsion Lab [CalTech], each with over $1B budget, account for half of total FFRDC budget
  - In 2004 DOE announced it would make several of the lab management contracts competitive (so that different entities would bid at each renewal)

TABLE 7.1 Department of Energy National Laboratories and Technology Centers

Laboratory Name	Management	Lab Type	Contractor
Ames Laboratory	GOCO	Single program	Iowa State University
Argonne National Laboratory	GOCO	Multiprogram	University of Chicago
Brookhaven National Laboratory	GOCO	Multiprogram	Brookhaven Science Associates[b]
Fermi National Accelerator Laboratory	GOCO	Single program	Fermi Research Alliance, LLC[c]
Idaho National Laboratory	GOCO	Multiprogram	Battelle Energy Alliance[d]
Lawrence Berkeley National Laboratory	GOCO	Multiprogram	University of California
Lawrence Livermore National Laboratory	GOCO	Multiprogram/ weapons	Lawrence Livermore National Security, LLC[e]
Los Alamos National Laboratory	GOCO	Multiprogram/ weapons	Los Alamos National Security, LLC[f]
National Energy Technology Laboratory[a]	GOGO	Single program	DOE
National Renewable Energy Laboratory	GOCO	Single program	Midwest Research Institute/ Battelle Memorial Institute
New Brunswick Laboratory	GOGO	Specific mission	DOE
Oak Ridge Institute for Science and Education	GOCO	Single program	Oak Ridge Associated Universities
Oak Ridge National Laboratory	GOCO	Multiprogram	University of Tennessee/ Battelle Memorial Institute
Pacific Northwest National Laboratory	GOCO	Multiprogram	Battelle Memorial Institute
Princeton Plasma Physics Laboratory	GOCO	Single program	Princeton University
Radiological and Environmental Sciences Laboratory	GOGO	Specific mission	DOE
Sandia National Laboratory	GOCO	Multiprogram/ weapons	Lockheed Martin, Inc.
Savannah River Ecology Laboratory	GOCO	Specific mission	University of Georgia
Savannah River National Laboratory	GOCO	Single program	Westinghouse Savannah River Company
Stanford Linear Accelerator Center	GOCO	Single program	Stanford University
Thomas Jefferson National Accelerator Facility	GOCO	Single program	Jefferson Science Associates, LLC

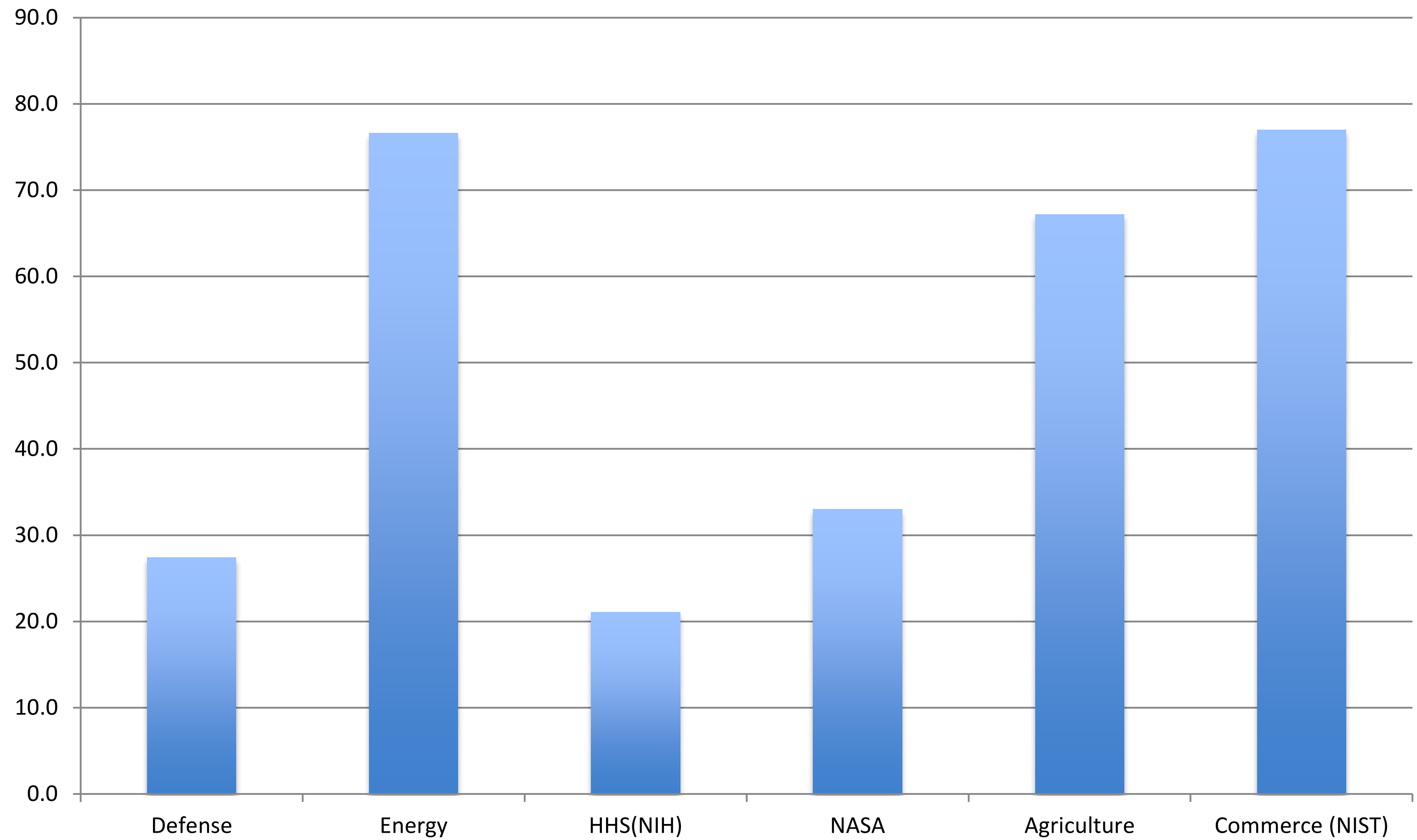
Federal Lab System

- Demographics
- Policies
- Technology Transfer
- Discussion issues

Size of Federal Labs

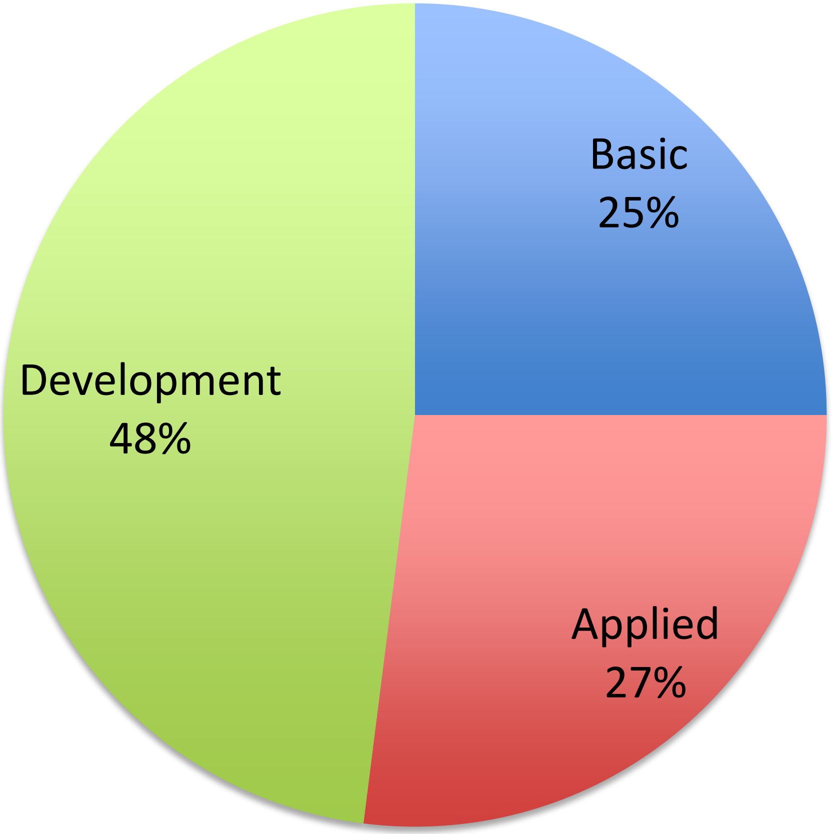
- R&D spending by federal intramural labs and FFRDCs was $46.2 billion in 2009, about 12% of all U.S. R&D (Universities about 14%)
- Of this amount, $30.9 billion was intramural and $15.3 billion was R&D by FFRDCs
- While Federal government is major funder of university research and significant source of industry R&D funding, largest performer of Federally funded R&D is the Federal Lab system (37% of total)

Share of Federal R&D funding allocated to Federal Labs, by agency, 2009



Source: NSF, SEI, 2012.

Share of Federal Lab R&D, by character, US 2009



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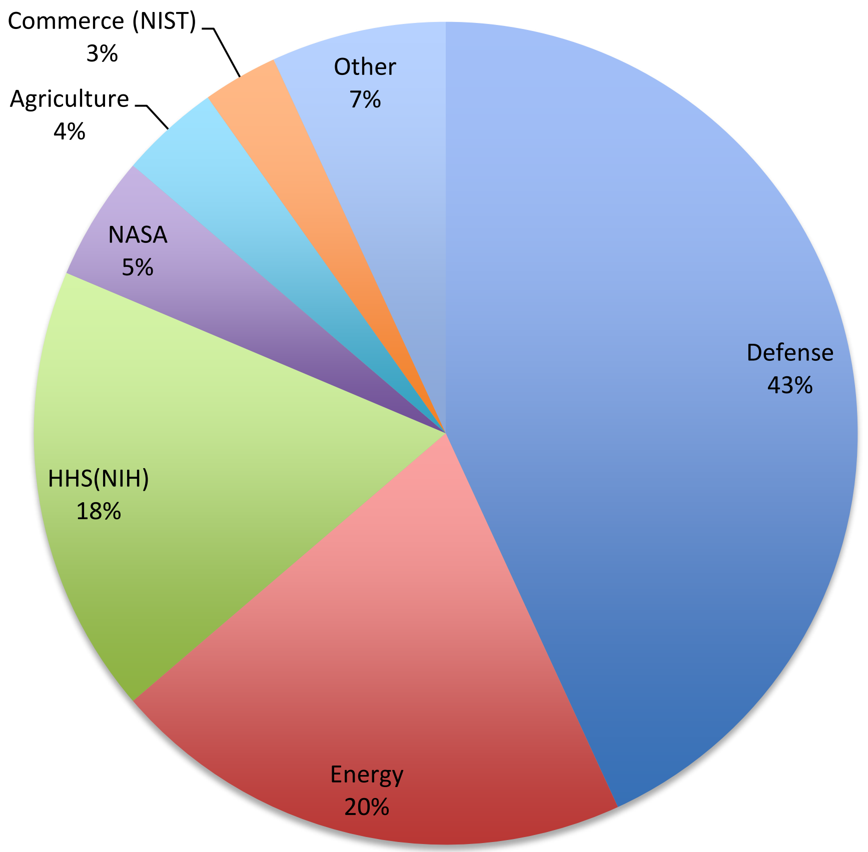
Share of Federal Lab R&D, by agency, US 2009



Source: NSF, SEI, 2012.

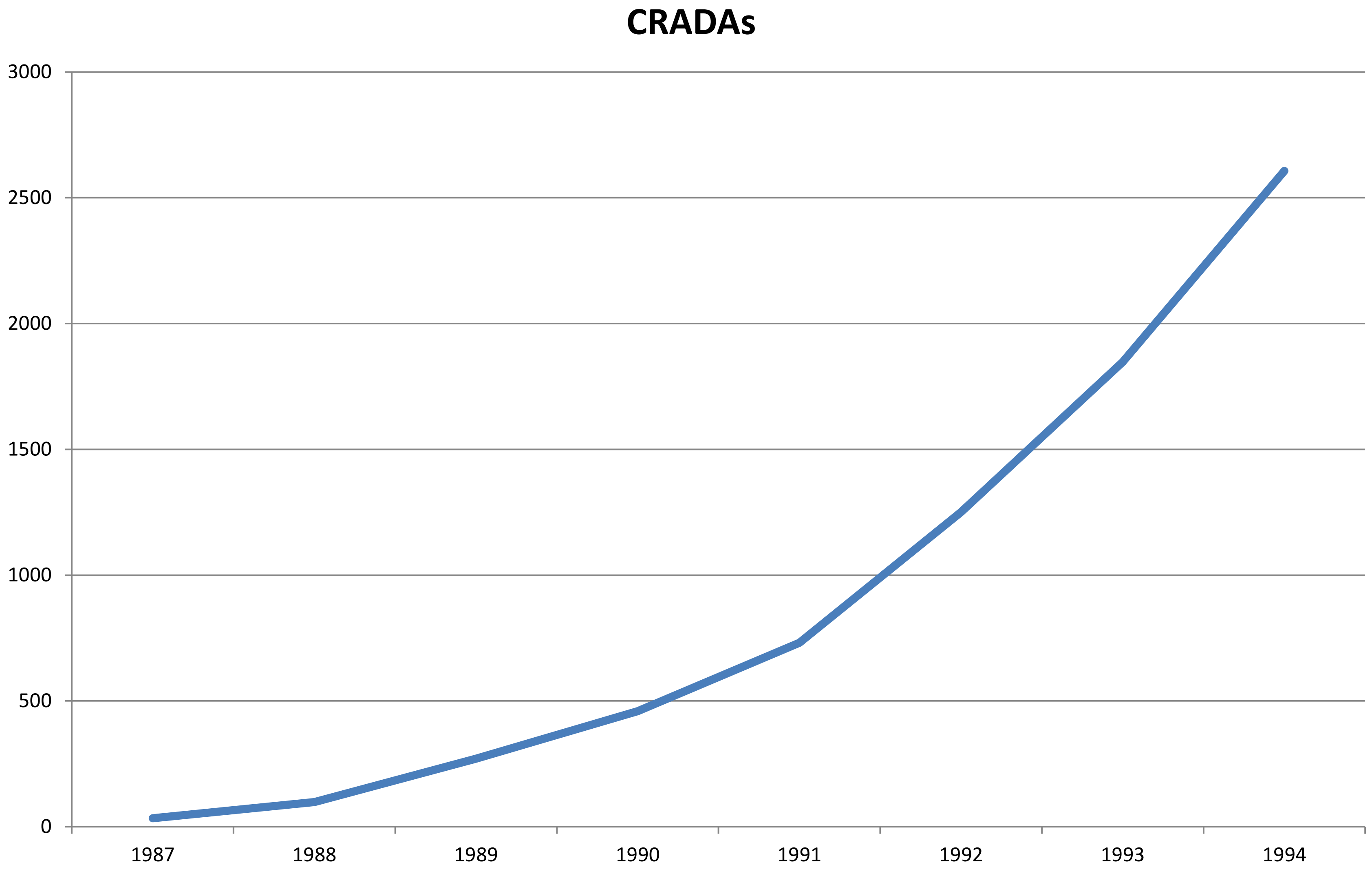
Policy Shifts Encouraging Fed Lab Technology Transfer

- *Technology Innovation Act of 1980 (Stevenson-Wydler Act)*—made tech transfer a mission of the federal labs, and dedicate 0.05% of budget to tech transfer and led to establishing tech transfer offices labs (Office of Research and Technology Applications or ORTA)
- *Federal Technology Transfer Act of 1986*—allowed cooperative research and development agreements (CRADAs) for GOGO labs, and licensing patented inventions made at the laboratory (and royalty share to inventors).
- *National Competitiveness Technology Transfer Act of 1989*—amended FTTA to include GOCO laboratories and increase nondisclosure provisions
- Share of royalty goes to inventor
  - 15% in statute (plus 100% of first $2000).
  - Argonne gave 25% (Berman 1997)
  - NIH gave 25% (Guston, 1999)
- Implementation was sluggish (Guston, 1999).

Source: NSF SEI 2012.

Additional Legislation

- *Bayh-Dole Act*—Permitted government-owned and government-operated laboratories to grant exclusive patent rights to commercial organizations.
- *Patent and Trademark Clarification Act of 1984 (Public Law 98-620)*—amended Stevenson-Wydler and Bayh-Dole Acts regarding use of patents and licenses to implement technology transfer and broadened authority for GOCOs to engage in tech transfer.
- *Executive Order 12591, Facilitating Access to Science and Technology (1987)*—sought to ensure that the federal laboratories implemented technology transfer. Delegated authority to lab directors (not centralized in agencies).
- *Omnibus Trade and Competitiveness Act of 1988)*—Directed attention to public-private cooperation on R&D, technology transfer, and commercialization and established NIST's Manufacturing Extension Partnership (MEP) program.
- *Small Business Innovation Development Act of 1992)*—increased the percentage of agency budgets devoted to SBIR, and increased the size of awards. Also established Small Business Technology Transfer (STTR) program for collaborative R&D efforts between government-owned/contractor-operated federal laboratories and small businesses.
- *National Cooperative Research and Production Act of 1993*—relaxed restrictions on cooperative production activities, which enabled working together in application of technologies jointly acquired.
- *National Technology Transfer and Advancement Act of 1995*—amended IP provisions in Stevenson-related to CRADAs, allowing non-Fed partner to choose exclusive or non-exclusive license, but also allowed Fed to negotiate third-party license for: exceptional public health or safety needs, meet Federal requirements, or if partner failed to comply with terms of agreement. Gives Fed right to certain uses of partner's employee inventions inside the CRADA.
- *Technology Transfer Commercialization Act of 2000*—broadened CRADA licensing authority to make such agreements more attractive to private industry and increase tech transfer. Established procedures for performance reporting and monitoring tech transfer.



Source: Guston, 1999. Number of CRADAs, all agencies except NASA and Social Security Administration

Tech Transfer from Federal Labs

Table 4-18

Federal laboratory technology transfer activity indicators, total and selected U.S. agencies: FY 2004 and FY 2009

Technology transfer activity	All federal labs	DOD	HHS	DOE	NASA	USDA	DOC
	FY 2009						
Invention disclosures and patenting							
Inventions disclosed	4,422	831	389	1,439	1,373	153	49
Patent applications	2,080	690	156	919	126	117	19
Patents issued	1,494	404	397	520	114	21	7
Licensing							
All licenses, total active in fiscal year	10,913	432	1,584	5,752	2,497	316	40
Invention licenses	4,226	386	1,304	1,452	504	316	40
Other intellectual property licenses	6,730	46	327	4,300	1,993	0	0
Collaborative relationships for R&D							
CRADAs, total active in fiscal year	7,733	2,870	457	744	1	233	2,386
Traditional CRADAs	4,219	2,247	284	744	1	191	77

Source: NSF SEI 2012

Tech Transfer at NIH (Guston, 1999)

- Tech transfer office established in 1988 (becomes ORTA for NIH).
- Renamed Office of Technology Transfer, covers all of HHS, including NIH, CDC and FDA
- Full-time staff: 55, 40 of which have advanced degrees
- FY97 budget: $4.1million
- Patent prosecution, technology marketing, license negotiations, and oversee and review CRADAs
- Also works with Technology Development Coordinators in each institute
- Big growth in tech transfer, although scaled back on patenting in 1996 because of concerns about time and cost of “over-patenting”

Table 9-2 Technology Transfer Activities at NIH, FY 1985–96

	Invention disclosures	Patent applications	Issued patents	Executed licenses	Royalties ($1000)
FY85	100	62	33	25	0
FY86	100	78	27	38	0
FY87	134	85	29	35	4,245
FY88	185	125	35	44	5,405
FY89	199	178	27	50	4,784
FY90	212	184	38	41	5,827
FY91	204	169	43	61	13,284
FY92	262	202	70	59	10,044
FY93	232	161	88	75	13,494
FY94	259	143	75	125	18,487
FY95	271	147	95	160	19,388
FY96	196	136	107	184	26,995
Total	2354	1670	667	897	121,953

Cooperative Research and Development Agreements (CRADAs): Berman (1997) “mid-term” review

- Generally large, R&D intensive firms participate:
- Key motivations (Berman, 1997; Guston, 1999)
  - Application of federal technology to industrial manufacturing
  - Assistance in the development of commercial products
  - Access to testing equipment in federal labs
  - Access to the expertise of federal researchers (Bozeman and Crow)
- Overall DOE negotiations seemed to take longer, because of more review for exceptions from standard CRADA
- Typically each side pays for own expenses, incl. researcher salaries and the research costs of its researchers. But, government lab prohibited from making payments to firms.
- CRADAs often require cost sharing by Feds. At DOE this can lead to delays when request exceeds lab’s pre-determined CRADA budget.
- NIH and Naval Research Lab said the high quality of their labs meant that firms often participated with minimal Fed cost sharing (firms confirm this view).
- Model agreements at NIH and DOE significantly dropped negotiation time.

Cooperative Research and Development Agreements (CRADAs): Difficulties (Berman 1997)

- US Manufacturing preference (FTTA):
  - DOE interprets strictly (and negotiations sometimes break down because of this), while DOD interprets more liberally.
- Product liability (government wants indemnification)
- Fair access (because can be seen as unfair subsidy to one firm by competing firms)
- Intellectual property.
  - Government gets nonexclusive royalty free license (which they can sublicense).
  - But, government gives 3 year (NIH) or 5 year (NIST) nondisclosure period, which can allay concerns.
- Pricing:
  - NIH CRADAs include clause giving right to request reasonable relationship among price, public investment, and health/safety needs.
  - Not yet invoked at time of Berman study, but political shifts can raise this concern
  - Dropped in 1995 (Guston, 1999)

Lab Characteristics and Tech Transfer Outcomes (Jaffe and Lerner 2001)

- Impact of policy changes (promoting tech transfer)
- Examine DOE FFRDCs
- Find that before, few patents per R&D dollar (cf. research university) but now, about par
- Some evidence that focused, rather than diversified, labs perform better in tech transfer
- And, FFRDCs run by universities seem to do better in tech transfer, perhaps due to learning from university tech transfer

Federal Labs and Technology Transfer: Discussion Issues

- Impact of Organization, and of competitive bidding on FFRDC management
- Problem of Talent: Difficult to retain top talent given much higher salaries in industry.
- Decline in discretionary funds.
  – Directors had leeway in allocation funds to pursue promising research (“laboratory directed R&D”).
  – In the past, about 6% of total budget, although significant cuts in recent years (FY2000 cut from 6% to 4% of total budget, one third cut).
- Unfair competition
  – What is role of labs compared to university or industry projects?
  – Small firm "contract R&D" businesses, want access to Fed R&D contracts.
- Adverse effects of commercialization mission (COI)?

NIH Consulting Controversy

- In-house researchers consult with industry
  - Before 1995, $25K limit on outside money from one source and $50K total
  - After 1995, relaxed rules, to make NIH more competitive with private sector
  - 200 NIH scientists (3% of staff) receive funds
  - Fulfill mission of translational research

NIH Consulting Controversy

- Hearings in 2004
  - Stevens (R-Alaska) “We have to encourage [U-I] collaboration, rather than put a taint on it.”
  - LA Times story
    - Katz, director of NIAMS, $475-620K over 10 years from drug cos
    - At same time, NIAMS conducted clinical trials for one co’s drugs and $1.7M in SBIR grants to another
    - Katz: I reported income and recused myself when appropriate
    - Other similar cases

NIH Consulting Controversy

- NIH “blue ribbon” panel, 2004
  - Recommends 500 hrs per year limit
    - “special scrutiny if consulting fees more than half of salary
  - Top officials at NIH barred from consulting
  - Joseph A. Mindell, NIH Scientist
    - I am a nascent tenure-track investigator, recently recruited to start an independent basic science lab at the NIH. As such, no one has yet shown the slightest interest in paying me for my opinions on anything. On the other hand, should a company show an actual interest, I will have an opportunity not only to share my expertise, but also to appreciate a more applied perspective from which my own work can benefit. (The Scientist 13 Apr 2004) [Mode 2?]

NIH Consulting Controversy

- Ban on consulting (2005)
  - Still able to do part time clinical practice
  - Also, divest of all stock in drug and biotech companies
  - Zerhouni, NIH Director
    - My goal here is to create a 'bright line' that is so clear thatcrossing that line will not be allowed or permitted. Nothing is more important for NIH than preserving the public's trust in our advice, our science, and in our ability to provide public health advice with no taint of conflict of interest or the appearance of conflict of interest (The Scientist, 2 Feb 2005)
- Survey of NIH scientists finds strong negative feelings about ban
  - 80% find them too restrictive
  - 90% worry it will hurt recruiting
  - 39% considering changing jobs due to rules

Questions, Comments, Suggestions?

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Comparing University and Government Labs (Bozeman, 2000)

	University	Government
Tech transfer is major mission	23%	51%
Basic research is major mission	70%	42%
Involved in tech transfer	40%	52%
%Time on publishing-related activities	44%	36%
%Time on patenting-related activities	2%	2%

Comparing University and Government Labs (Bozeman, 2000)

- Both university and government labs have a reward system heavily based on scientific publications
- In each case, commercial activity is not key criterion
- Some government labs even have “tenure track” type system
- Both are dominated by PhD researchers (though MS level researchers more common in government labs in the past)

Comparing University and Government Labs (Bozeman, 2000)

- One critical difference is universities have **students**, importance source of labor, and of tech transfer (taking knowledge and skills to firms, labs, other universities)
  – Industry labs report one motivation for ERC participation is access to students (for recruiting)
  – Some government labs have students (especially ones located inside universities, such as Ames or Lawrence Berkeley)
- Federal labs better organized for interdisciplinary projects (while universities have disciplinary legacy in organization)
- Federal labs also have expensive specialized equipment (available to university and industry researchers)