# *Technology Transfer in the Agricultural Research Service: Implications of Federal / Private Sector, and Federal / University Partnerships to Commercialization Strategies*[1]

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America's food and agricultural producers operate in a global, diverse, and highly competitive marketplace driven by consumers. American farmers are among the most productive in the world and our food and agricultural system provides the nation with the safest, highest quality, and lowest cost food and fiber anywhere. Much of the credit for this success belongs to our public research system and its success in generating new knowledge and technologies that improve productivity and develop new markets for agricultural products.

The Department of Agriculture helps drive continuous innovation through science and technology by forming research and commercialization partnerships with other research institutions and the private sector. The Office of Technology Transfer in USDA's Agricultural Research Service (ARS) is key in facilitating these partnerships and in transferring research outcomes for broad beneficial use by the public and agricultural industries of the United States and other nations. Many of these research outcomes include patented or otherwise protectable technologies. The partnerships include private-sector corporations as well as universities (*i.e.* other public-sector institutions). The mechanisms ARS uses to

[1]Mention of product names is for identification pursposes only and does not imply endorsement by USDA.

commercialize technologies have evolved over the past 25 years in concert with federal legislation that governs federal and non-federal researchers. Federal, state, and private-sector researchers are all working toward the same goal of adopting research results and creating products and services. However, the missions, geographical scope, and accountability to their respective institutions create some real challenges.

This paper describes the "roots" of technology transfer in the United States, the culture of ARS technology transfer, and some observations on how the intersection of technology-transfer authorities has led to convergence as well as divergence among federal and non-federal agricultural researchers in the public sector. Furthermore, some metrics and successes in technology transfer in ARS—some involving partnerships, others strictly in USDA—are provided as illustrations. Finally, we offer a glimpse of what we believe is the future direction of agricultural research.

## The People's Department and the Land-Grant System

The "roots" of technology transfer can be traced to the earliest activities that can be defined broadly as "agricultural research" in the United States. Specifically, in 1819 and 1827 the Secretary of the Treasury directed consular and naval officials to transport useful seeds and plants to the United States; the subsequent western expansion during the nineteenth century resulted in the creation of the Section of Foreign Seed and Plant Introduction in 1897 (Shurtleff and Aoyagi, 2004). Frank Meyer (Figure 1) was an early explorer who made many contributions to those collections. Additionally, in 1839, the Patent Office established an Agricultural Division to conduct research. Congress designated $1,000 for "collecting and distributing seeds, carrying out agricultural investigations, and procuring agricultural statistics" [National Archives and Records Administration (RG 07-18), http://www.nara.gov/].

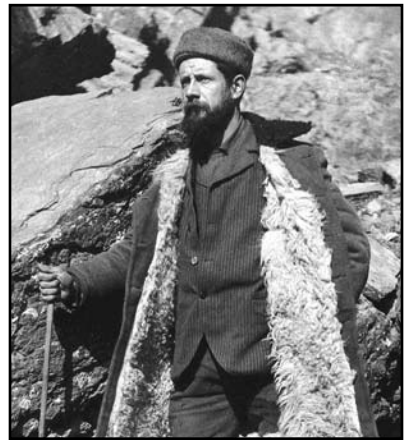

Figure 1. Frank Meyer.

Federally-financed R&D and technology transfer in agricultural research dates from May 15, 1862, when President Lincoln signed a bill that established the Department of Agriculture, or as he coined it, "the People's Department" (Figure 2). The act instructed that the *Commissioner of Agriculture…acquire and preserve…all information concerning agriculture…* Related bills enacted at the same time included The Homestead Act in 1862 and the Morrill Acts of 1862 and 1890 that led to the establishment of major state-operated agricultural research centers. State experiment stations (SAESs) were first established in Connecticut and California in 1875, based on a German model observed by American scientists. The Hatch Act of 1887 later authorized one for each state. Finally, the Equity in Educational Land-Grant Status Act of 1994 (sometimes called the Tribal Colleges Act) brought native American schools into the fold. [For a comprehensive review of the

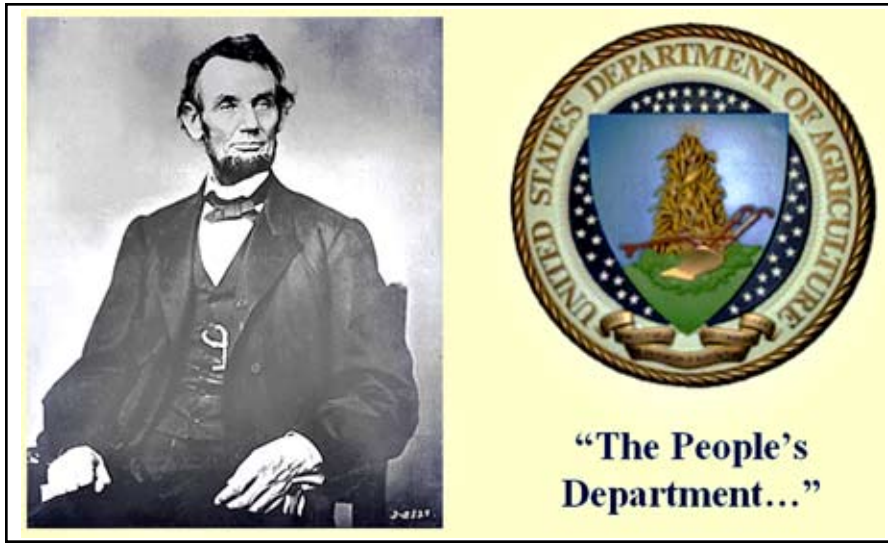


Figure 2. The USDA was established under President Lincoln in 1862.

enabling legislations cited above, see the website for the National Association of State Universities and Land Grant Colleges (NASULGC) at http://www.nasulgc.org.]

Thus, the federal government and the states established an infrastructure for publicly funded agricultural research throughout the United States to conduct research and, ultimately, to transfer results to the public. The collective results of these legislative acts created the 133 land grant colleges and universities in existence today (Figure 3). Even from their very beginnings, USDA has had a special relationship with institutions of higher education. Although USDA scientists have conducted research since the 1860s under various departmental structures, the Agricultural Research Service (ARS) was formally established in 1953. Today, many of our more than 100 ARS facilities are co-located at these institutions and we collaborate on many research projects (Figure 4).

## Management of Intellectual Property

Various legislative authorizations over the past 25 years created incentives for the government, universities and industry to work together to commercialize new technologies for the public benefit. However, how intellectual property (IP) is managed depends on the legislative authorizations that, in fact, have critical differences. *Extramural research* funded by federal appropriations are managed according to the Bayh-Dole Act of 1980 that allows institutions performing the research to take title to their inventions and to license rights to practice the inventions without constraints and without notifying the public. In contrast, inventions arising from *intramural research* conducted by federal agencies, such as ARS, are governed by the Stevenson-Wydler Act of 1980 and subsequent legislation, especially the Federal Technology Transfer Act of 1986 and other more recent legislation. (Although these references can be found at many sites, the Defense Technology Informa-

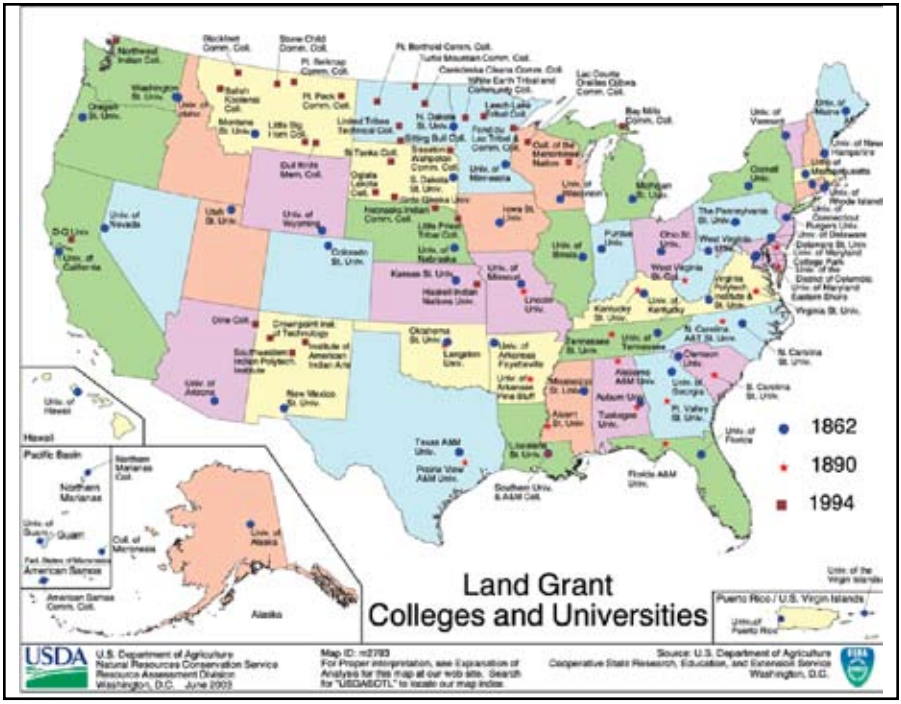


Figure 3. The land-grant network.

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tion Center has a web site that is linked to the Library of Congress Thomas file and has every conceivable legislative action taken in regard to technology transfer: http://www.dtic.mil/techtransit/refroom/laws/).

Collectively, this legislation frames the functions and actions of our Office of Technology Transfer (OTT). We coordinate the technology-transfer activities in ARS, and have the authority to develop and sign a very specific federal instrument for partnerships, specifically Cooperative Research and Development Agreements (CRADAs). We also represent the Secretary of Agriculture on IP management, and have the sole authority for licensing any inventions developed within any of the USDA agencies conducting intramural research, including the US Forest Service, the Food Safety and Inspection Service, and the Animal Plant Health Inspection Service.

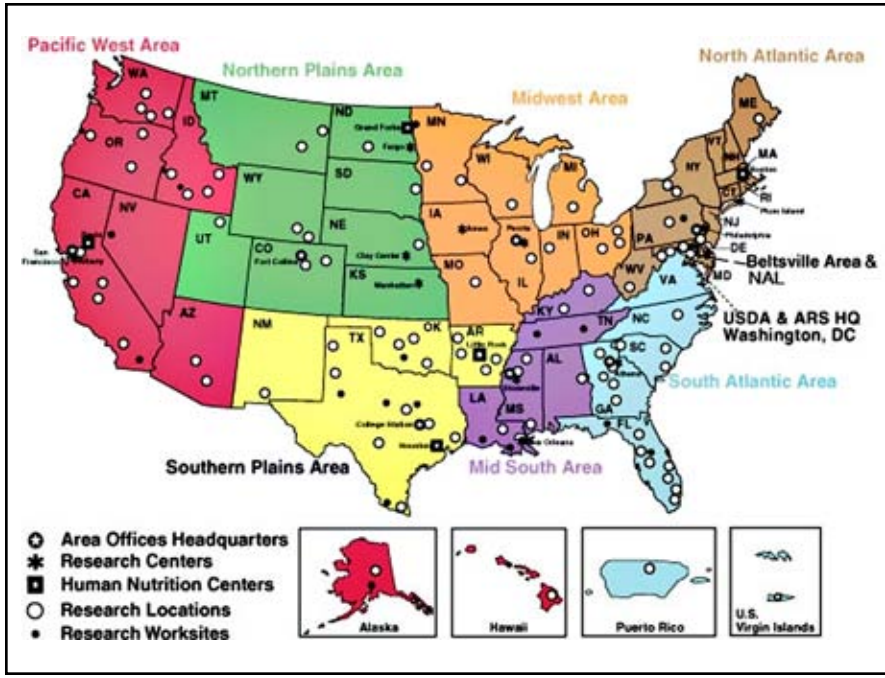


Figure 4. Locations of ARS facilities.

To evaluate the implications of the various legislative acts to our partnerships, we need to frame the context of the ARS policies of today. ARS integrates technology transfer within its research mission, protecting IP when necessary to *facilitate* technology transfer. However, we favor public releases of plant varieties, and avoid patenting "animals" or research tools, and, because we are a public research institution, we promote *further* research by permitting license-free research with any ARS technology. Consequently, the decisions we make relative to licensing federal technologies are governed largely by the goal of facilitating technology transfer for public good in support of US agricultural businesses, not a goal of generating revenue for research.

In licensing IP, two mechanisms have processes highly prescribed by federal statute. First, (also in reference to CRADA involvement) "background inventions" are those that are made by federal researchers under normal intramural research authority with Congressionally-appropriated funds. If a potential licensee requests exclusivity, then we must publish a *Federal Register* notice of our intent to license the specific patent to the applicant company. The purpose is to inform the public so that other qualified individuals or businesses who also want a license to the technology have an opportunity to object to the exclusivity. We then must address all objections. This may result in co-exclusive licenses, or exclusivity by field of use, or in rare circumstances, non-exclusive licenses to all objectors who

submit qualified license applications. All of this is prescribed in 37 CFR 404 (Licensing of Government Owned Inventions), and we are diligent in following proper procedures. Federal agencies cannot deny a license to applicants that meet minimum qualifications, except that—all other factors being equal—agencies can grant a preferential license to a small business, but cannot select one small business over any other. Thus, no technology can be preferentially licensed to a local company and denied to others elsewhere. This is a very important distinction between federal and university licensing.

The second mechanism relates to IP developed under a CRADA with a non-federal partner—almost always a private-sector company. This is also a prescribed procedure, but by statute and not by the Code of Federal Regulation (15 U.S.C. 3710a). Inventions made under a CRADA are a distinct advantage for the private-sector company for two reasons. First, the company has the first right to negotiate an exclusive license to at least one predefined field of use without *Federal Register* notice. Therefore, their competition is not only excluded, but remains uninformed. Second, federal agencies can exempt jointly developed data from Freedom of Information Act requests for up to 5 years, but, in practice, ARS rarely grants confidentiality for more than 1 year.

Thus, the laws governing activities of federal intramural research create both synergy and conflict with our partners in public-sector universities. Underlying this is the basic premise that the challenges of global agricultural markets, free trade, and diminishing research funds make these partnerships essential if we are to achieve meaningful research results.

Increasingly, however, federal agencies are often in conflict with university partners as to the goals of protecting IP. From our federal perspective, the goal is adoption of technologies to benefit the public and US industries at minimal transaction costs. We protect IP when it is necessary to achieve technology transfer, but preferred mechanisms are publication of research findings, or public release of technologies. Universities often are forced to make IP decisions on the basis of whether revenues can be generated to support research programs that are strapped by spiraling costs, and diminished federal research dollars. Unless carefully managed, these conflicts can discourage federal/university partnerships.

There is also a degree of conflict in licensing as to regional versus national accountability. Many universities have an appropriate mandate to stimulate economic development preferentially within the region or state. In contrast, federal agencies have to justify processes to the taxpayers of any given state as well as to the taxpayers of the other forty-nine.

ARS is co-located at many educational institutions, and consequently, there is a merging of intellectual capacity with universities. Co-owned inventions frequently result, and unless the federal employee has promptly reported an invention through ARS channels, the university has often moved forward before we have had the opportunity to formally consider options. This can create a problem because our policy *not* to protect certain IP may conflict with the university's policy. Consequently, should we tell the university that, regardless of their intent to issue revenue-bearing licenses, we will make the technology available free of charge, we may find ourselves in the position of spoiling opportunities for our partners.

A final area of potential conflict relates to situations when a USDA researcher uses CRADA funds to hire or contract with a university employee. If joint IP results, we discover that we truly *don't* have consolidated rights to offer exclusively to the CRADA partner (as prescribed by law), because the university has Bayh-Dole rights in the co-owned invention.

Yet, co-owned inventions are common, and we consolidate our rights, usually by licensing ours to the university. This may provide greater flexibility in the sublicensing to private-sector firms because the university may take equity as part of the licensing terms, thereby reducing upfront costs to industry, and no FR notice is required for exclusive licensing.

One disadvantage to co-owned inventions is that universities may prefer to approach licensing from a more regional, rather than a national, perspective. Appropriately, we need to be vigilant to ensure that terms are equitable to commodity groups or industries across state lines.

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Reaching consensus on policies beforehand solves joint ownership issues. When we cannot reach agreement, we may choose to go our own way, rather than to consolidate rights. Alternatively, we may prefer to in-license university rights and then license consolidated rights to industry.

There is a simple proactive solution to the issues of joint inventions made with universities under CRADAs. If ARS needs the university expertise to meet the research mission, we can establish a three-way CRADA to define disposition of IP rights by agreeing that the private-sector partner will have the right to negotiate an exclusive license to any subject invention, regardless of federal or university ownership.

## Fruitful Relationships

Despite some of the difficulties described above, these legislative acts have produced beneficial solid relationships. ARS has approximately 200 active CRADAs with the private sector, and separately, over 1,600 cooperative projects with universities where Bayh-Dole rights apply. A total of 320 active licenses are producing 100 products available to the public (Figure 5). Over 120 of these licenses are executed with universities to consolidate rights; twenty-seven of these are producing products from utility patents, plant patents, and Plant Variety Protection Certificates. Thus, there is a demonstrable benefit to the public, to the inventors, and to the publicly funded research institutions conducting the research (Figure 6).

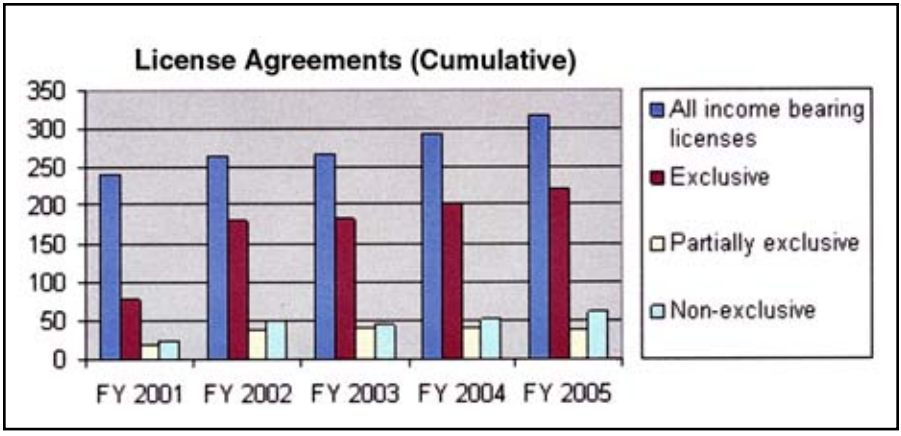


Figure 5. License metrics.

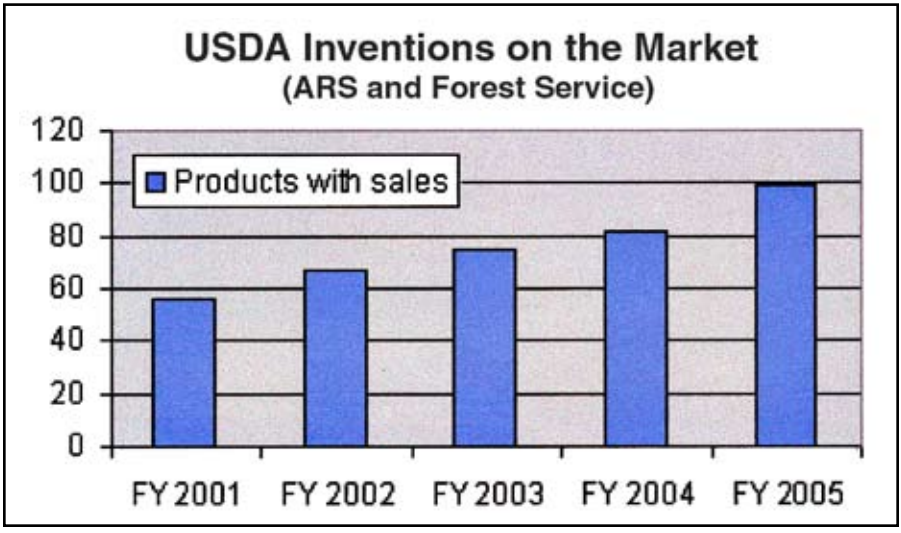


Figure 6. Commercialization of USDA products.

Recognizing that agricultural markets are characterized by thin profit margins requiring exclusivity of rights to protect investments, the majority of our licenses are exclusive. This has not changed over the past 20 years, and additionally, at least 40% of these licenses are with small businesses. Our licensees are increasingly successful at commercializing products with these exclusive rights to our inventions.

## New Products

We can illustrate a few current technologies that are on the road to success. For example, ARS developed a technology over the past several years that began reaching expanded markets in 2004. Kids' meals at McDonalds now feature "Apple Dippers," as an alternative to fried potatoes. Apple Dippers are peeled apple slices served with a cup of low-fat caramel dipping sauce. Mantrose-Hauser, a former CRADA partner and current licensee, produces the ARS-developed coating, which is used by apple processors to prevent cut fruits and vegetables from turning brown. A product under the trade name NatureSeal® is being sold commercially to grocery stores, fresh-cut producers and food-service industries. The technology has been extended for sliced avocados, celery, potatoes, carrots, and onions.

Figure 7. Apple Dippers: Dr. Dominic Wong, one of the ARS inventors of the technology sold under the name "NatureSeal" by licensee.

A grass roots effort for pear growers to add value and create new markets for their products resulted in the development of restructured fruit bars (Figure 8). ARS researchers patented and transferred technology using pureed fruit. Licensed to Gorge Delights, Hood River, Oregon, which built a manufacturing plant and created new jobs in an area with 30% unemployment. Their product line has expanded, and several grocery chains and some US military commissaries now offer these products in several hundred stores. This technology permits year-round processing of seasonal crops from puree through this intermediate "holding" step, and is expected to be used with other crops.

ARS researchers in collaboration with Red River Commodities, Fargo, North Dakota, developed a sunflower butter product—SunButter™—as an alternative to peanut butter. This is especially valuable to persons with peanut allergies. It smells, tastes, feels, and has the appearance of peanut butter. The market for SunButter is expanding to include many uses in baking formerly filled with peanut butter. In January 2004, it was made an entitlement item and added to the official list of available commodities in the National School Lunch Program, and some airlines now include the product in their snack boxes, accounting for a large boost in sales. This was a CRADA development, but there is no patent or license.

Table grape varieties represent an experiment between OTT and the California Table Grape Commission. In this era of global economic markets, a public release of new varieties makes them available to the world, not just to the US industries that provided the tax

Figure 8. Pear Bars: a snack developed by licensee using ARS technology to puree fruits.

base to support the research. Thus, the development of new varieties can inadvertently create a competitive advantage for the rest of the world who may undercut prices because of cheaper labor or unfair trade practices. Therefore, these varieties were protected, and licensed to the California Table Grape Commission (CTGC) for nominal fees to US growers. The CTGC can also sublicense to growers in other countries, thereby gaining some management of growers external to the United States, and further support the research necessary to develop new varieties that favor US growers and consumers.

ARS researchers developed a biodegradable hydraulic fluid made from soybean oil, which is now being used to power the Statue of Liberty's elevator. Until recently, mineral oil formulations derived from petroleum-based stocks were used. The National Park Service contacted ARS scientists requesting development of a biobased fluid that is environmentally friendly, produced from a renewable resource, that is economical and nonpolluting, and meets all industry standards for safety and performance including viscosity, stability, and flame-resistance. ARS researchers already had the know-how to develop this technology. Though other vegetable oils would work, soy was chosen for its low cost, chemical versatility, and availability as a renewable, home-grown resource. Soy is the nation's leading source of food-grade oil, yet only 517 million pounds—3% of the total supply—is used for industrial purposes. The invention, jointly developed with


Figure 9. SunButter™: a non-allergenic alternative to peanut butter.

Pennsylvania State University, was licensed to a start-up company that was immediately acquired by Bunge, a global food and agricultural commodity company, in early 2006; first sales were reported by mid-2006.

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The developments in technology licensing reflect how the landscape of agricultural markets has changed during the past 25 years and the growing complexity of our global food and agricultural system. Agriculture, however still must also meet the basic food and fiber needs of people. Interestingly, 70% of the active patent licenses from federal research in labs and universities are in the life sciences with products and processes that feed people,

diagnose disease, reduce pain and suffering, and save lives. This doesn't happen, however, by accident, and it is increasingly important to nurture these research partnerships. So where do public research institutes go from here and what opportunities are emerging?

## Chemurgy Revisited: Agriculture's Reinvigoration

To see the future, we need to look to the past. In the 1930s, we were using ethanol to power our cars. People like George Washington Carver were working on new uses for agricultural materials (Figure 10). In fact, Henry Ford predicted in 1937, that "… almost all cars will be made of [soy plastic]." In 1940 he installed a plastic trunk lid on one of his personal cars, demonstrating its durability with the blow of an axe (Figure 10). A year later he built an all soy plastic car which was hailed as an"…outstanding industrial achievement" (Henry Ford Museum, http://www.hfmgv.org/exhibits/hf/facts.asp).


Figure 10. George Washington Carver and Henry Ford's soy-based trunk lid.

The movement in which Ford and Carver were involved was called "chemurgy" (Finlay, 2004). Unfortunately, cheap oil sent this nation and its research capacity in another direction. In the context of 2006 issues, the times are indeed changing.

There is an urgent need to become less reliant on imported oil. Biofuels may help achieve this goal. In addition to switch grass, other crops may have potential as feedstocks for biofuels, such as gamma grass, fast-growing willows and poplars, along with biomass residues from traditional agricultural practices.

Additionally, the adoption of biobased products can "back out" petroleum usage through substitution. The federal government—through its massive procurement of goods—can play a role. Title IX of the 2002 Farm Bill put in place federal "preferred procurement" for biobased products (http://www.ers.usda.gov/Features/farmbill/titles/titleIXenergy.htm). This can have a major impact in creating market demand for biobased products and lower unit prices. In cooperation with Iowa State University, a website has been set up to serve as a clearing house for listing biobased products for purchase by federal agencies (http://www.biobased.oce.usda.gov/public/index.cfm).

Given 2006 concerns about rising petroleum prices, our nation will be increasing research emphasis to seek new crops for biotech industrial uses representing new economic opportunities for farmers. Crops that are good for the environment and for rural America and that will reduce our dependence on imported fossil fuels may become priorities. Thus, as a nation we have come full circle. "Chemurgy" has been superseded by "biobased products" and "bioenergy." There is renewed hope that with continuing agricultural research and private/public partnerships created, the products from agricultural materials will be limited only by our imagination: the most prosperous era in American agricultural history is dawning to meet the continuing and expanding needs of the public.

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As assistant administrator in ARS for technology transfer since October 2004, **RICK BRENNER** represents the Secretary of Agriculture on issues pertaining to management of intellectual property arising from USDA research. He has the delegated authority for licensing inventions developed through intramural USDA research, and is a member of the Interagency Working Group for Technology Transfer convened monthly by the Department of Commerce Office of Technology Policy.

From August 2001, Dr. Brenner served as the deputy assistant administrator for the Office of Technology Transfer, USDA-ARS, where he managed much of the daily operations on Cooperative R&D Agreements (CRADAs), patents, and licensing. From 1984, he served as an entomologist and later as a research leader for ARS in Gainesville, Florida. His research led to a number of awards, including Outstanding Senior Scientist, the USDA Award for Superior Service, the ARS the Technology Transfer Award, a Federal Laboratory Consortium Technology Transfer Award, and the *Pollution Prevention Project of the Year* award in 1999 under the Strategic Environmental Research and Development Program, jointly awarded by the Department of Defense, Department of Energy and the EPA.

Brenner has a PhD in medical entomology from Cornell University, and two degrees from the University of Illinois.