Executive Summary

In the world of government regulation, the reach of government regulators frequently far exceeds the original intent of the Congress. And without a "sunset" provision, regulations stay in effect even after they have become obsolete or otherwise outdated. This paper presents ten such "Candidates for Corrections Day."

Wetlands Policy

The entire federal wetlands regulatory structure stems from a 1972 law that doesn't even contain the word "wetlands." In fact, bureaucrats have redefined "navigable waters," the phrase that actually appears in the legislation, as land that does not necessarily have any visible water on it at any time of the year.

The 60-40 Rule

Against the requests of the military and against common sense, **Congress requires that 60 percent of military maintenance be performed by federal workers.** Private companies who outsource non-core functions save 20-30 percent of costs while improving quality. Why can't the military do the same?

Off-Label Drug Use

Stifling beneficial information about off-label use of drugs probably results in needless loss of life. The FDA permits off-label use of drugs, but doesn't permit pharmaceutical companies to inform doctors about proper off-label use.

Peanut Central Planning

Why has China replaced the U.S., the inventor of peanut butter, as the leading exporter of peanuts? The federal peanut program is hindering the growth and development of the peanut industry by making peanuts more costly to produce, and keeps the price of peanuts to consumers artificially high.

FDA Turnaround Time

U.S. companies are taking their R&D to Europe because of FDA sluggishness. FDA claims to the contrary, the agency takes too long to approve new drugs and medical devices at the cost of lives being unnecessarily lost.

Superfund Sensationalism

Through exaggerated risks and community scare tactics, EPA remediation efforts are biased in favor of the most expensive and extensive option. For example, at the Glen Ridge site, an effective cleanup plan costing $20 million had to be discarded in favor of a plan costing between $253 million and $348 million.

Environmental Tobacco Smoke

Ideology is driving science to compromise and make inaccurate conclusions favoring specific political objectives concerning environmental tobacco smoke. When establishing links between substances and health risks, sound scientific principles should not be compromised in formulating public policy.

The Delaney Clause

Should coffee be banned as an additive to ice cream? The Delaney Clause states that *no measurable amount* of a known carcinogen may be found in any processed food. But when Delaney was written, residues could only be measured in parts per thousand, while today, parts per *quintillion* can be measured.

Discipline of Special Education Students

The Department of Education restricts the ability of local schools to discipline students, even a special education student carrying a loaded weapon. The inability of local schools to discipline these students undermines the teaching of acceptable behavior, and the learning environment for other students.

Toxics Release Inventory

Some FDA-approved "safe" ingredients must be reported to the EPA as a toxin. Industrial facilities must report the releases of 586 chemicals, most of which would be dropped from the list if risk assessments were conducted for these chemicals. This could save American businesses as much as $546 million.

CANDIDATES FOR CORRECTIONS DAY:
The Ten Worst Regulations of the Federal Government

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Introduction

Robert W. Kasten, Jr.

***"Government's view of the economy could be summed up in a few short phrases: If it moves, tax it. If it keeps moving, regulate it. And if it stops moving, subsidize it."* — Former President Ronald Reagan**

The cost of federal regulation[1] is staggering. According to one estimate, the gross annual cost of federal regulation is now about $500 billion and is expected to rise to about $600 billion by the year 2000 (both estimates in 1990 dollars).[2] Leon Transeau, an Interior Department official during the Reagan administration, has estimated that the public spends 12.6 billion hours annually dealing with government paperwork.[3] While during the presidency of Ronald Reagan, some progress was made,[4] today the regulatory burden on businesses and individuals is at an all-time high.

Part of the problem in the battle against excessive regulation has been framing the debate. Too often, when reformers have argued for important changes such as cost-benefit analysis or proper risk assessment, they have relied on statistics and macro-economic factoids to bolster their claims. Meanwhile, those who propose regulations have effectively used horror stories to promote government intervention. George Gilder neatly summarizes this imbalance:

> *"Every report of a defective new product, a possibly poisonous industrial waste, a vaguely carcinogenic chemical, produces headlines in the newspapers and somber commentary on television news. But the valuable products and services that are never created or marketed because of regulatory excess have no voice. When a corporate leviathan suffers a setback or retrenches its payroll—whether because of impact competition or simply obsolescence or even government policy—cameras and microphones are wheeled forward to record every whimper and complaint. But hundreds of thousands of small businesses involving millions of jobs expire annually without notice."*[5]

The Institute for Policy Innovation and the Alexis de Tocqueville Institution asked leading policy experts to write brief articles on what each saw as a good example of the worst regulations emanating from Washington. This project is not a comprehensive effort to objectively find the ten most damaging regulations; rather, these ten cases, while they all certainly have an adverse economic and human impact, throw into sharp relief the excesses of the Washington regulatory mentality. All of these regulations, from a wide variety of policy areas, would be excellent candidates for Congressional overhaul or elimination during the next "Corrections Day."

Robert W. Kasten, Jr., a former Senator from Wisconsin, is Chairman of the Center on Regulation and Economic Growth for the Alexis de Tocqueville Institution.

1. WETLANDS POLICY: The Making of a Regulatory Frankenstein

Jonathan Tolman

"It has been the agencies and the courts that have defined and enforced their own interpretation of the statute, regardless of the original intent of Congress."

No environmental issue has caused as much populist revolt as the federal government's role in regulating wetlands. But beyond all the environmental and property-rights rhetoric, few people realize that this entire regulatory scheme stems from one small section of a 20-year-old law, one that does not even mention the word "wetland."

The current regulatory apparatus has not evolved in an atmosphere of open debate and democratic voting. It has been created by the obscure memos and legal briefs of judges, lawyers and bureaucrats. It has been the agencies and the courts that have defined and enforced their own interpretation of the statute, regardless of the original intent of Congress.

The most significant part in this whole drama of wetland regulation is that virtually none of the major players have been elected officials. The changes that have taken place have never been passed by the House and Senate.

In 1972, Congress passed the Federal Water Pollution Control Act. Tucked away in a little corner of the act was a prohibition on discharging dredged or "fill" materials into navigable waters without a federal permit, known as Section 404. To those in Congress who voted for the act in 1972, this small provision must have seemed innocuous and hardly open to inventive interpretations.

At first, the Army Corps of Engineers, the agency in charge of writing permits, interpreted the passage to mean only what it obviously says—waters that could actually be navigable. Apparently, this was still a little too ambiguous, so in 1977 the Corps redefined its definition to include such things as wetlands. A wetland is just what it sounds like—land that is wet. But just because it is wet, does that mean that it is a navigable water?

"By 1987, 'navigable waters' had evolved into land that needed only to be occasionally wet."

In *U.S. v. Riverside Bayview Homes* (1985) the Supreme Court decided the question. In writing the opinion for the court, Justice Byron White observed, "it may appear unreasonable to classify land, wet or otherwise, as waters." The mere appearance of unreasonableness, however, did not stop the court.

According to Justice White, Congress knew that the EPA and the Corps had changed the definition of navigable water. The record shows that while there were numerous debates over what should be done about wetlands, Congress never passed a bill changing the definition—either to accept the new definition or to reject it. "Nonetheless," according to Justice White, "the evident breadth of congressional concern for protection of water quality and aquatic ecosystems suggests that it is reasonable for the Corps to interpret the term 'waters' to encompass wetlands…"

Other court cases following *U.S. v. Riverside Bayview Homes* granted broad discretion to the EPA and the Corps in determining what was a navigable water. By 1987, navigable waters had evolved into land that needed only to be occasionally wet. And according to the current Corps of Engineers wetland

delineation manual, it is no longer even necessary for there to be visible water in an area. It could be considered a "navigable water" if it contained the right kinds of plants and soil.

But the bureaucrats didn't stop with just changing the definition of waters—they have also focused their attentions on the definition of dredged and fill material. To settle the pending lawsuit of *North Carolina Wildlife Federation v. Tulloch*, the government has completely redefined "discharge of dredged material." The new definition includes not only the *addition* of material, but also activities such as clearing and excavation. With the deftest legal sleight of hand, subtraction has magically turned into addition. Now removing dirt from land that may have no visible water at any time during the year requires a permit.

Because of this bureaucratic morass, individual permits take an average 373 days to be completed. And even after these lengthy delays, the number of individual permits which are approved is only 30 percent. In other words, an individual can spend an entire year attempting to work with the myriad agencies and their regulations with little chance of actually obtaining the permit in the end.

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2. THE 60–40 RULE

Dr. Loren Thompson

You would think that the federal department most responsible for deterring and defeating communism during the Cold War would have a fairly well-developed appreciation for the efficiency of markets. Well, think again. The U. S. Department of Defense has for decades insisted on conducting a vast array of functions that are readily available from private-sector sources through its own internal work force. That is one reason why, when all of these functions are added up, it turns out that roughly half of the defense budget—$125 billion in 1995—is dedicated to support activities not related to the military's core competencies. For some reason, Pentagon policy makers have traditionally assumed that federal employees can do a better job than private sector workers of providing maintenance, health care, data processing, supply management, financial services, and dozens of other commercial activities.

The department has recently realized the error of its ways, and has begun to privatize support functions. But during the bad old days when the market was considered unreliable, Congress legislated a raft of protections for federal workers engaged in performing particular functions. And therein lies the genesis of the so-called "60–40 rule."

"Roughly half of the defense budget—$125 billion in 1995—is dedicated to support activities not related to the military's core competencies."

The 60–40 rule is enshrined in 10 U. S. C. 2466, which states that no more than 40 percent of the depot maintenance needs of each military service may be provided by personnel who are not employees of the federal government. Depot maintenance consists of the most complex and demanding repairs, overhauls, and modifications to major weapons systems. Such activities are typically performed in large repair facilities and shipyards run by the services and scattered across the U. S. Over 90,000 federal workers are currently engaged in depot maintenance of military systems.

As the number of workers suggests, depot maintenance is no trivial matter. In fiscal 1995, the Defense Department spent about $13 billion on such maintenance, which is more than the entire budget of some federal departments. But maintenance is important for another reason too; if modern high-tech weapons are not adequately maintained they won't work, with potentially horrendous consequences on the battlefield. So assuring a competent and reliable source of depot maintenance for major weapon systems is a serious concern.

What is not so clear is why the interests of the military and taxpayers are served by requiring that most depot maintenance be performed by federal workers. Military depots and shipyards almost never have to compete for the maintenance workloads they receive, and therefore seldom exhibit private-sector levels of productivity or performance. In fact, Pentagon studies have repeatedly demonstrated that the depots' accounting systems can't track costs and their personnel systems can't measure productivity. The result is waste on a massive scale.

Private sector companies that outsource non-core functions frequently achieve cost savings of 20-30 percent while improving quality and reliability. If similar savings could be achieved by outsourcing the roughly $9 billion in depot maintenance that the military services currently perform internally, then the department could free up $2 billion annually to apply to other purposes. And

since federal depots and shipyards do not begin to approach the efficiency of private companies that out-source, there is reason to believe that even greater savings could be achieved by giving all the maintenance work to private sector providers. Not only would private-sector sources be more efficient, but the department could shut down excess facilities, shift its cost structure from fixed to variable expenses, gain access to cutting edge commercial expertise and realize numerous other benefits.

"All of the services have urged repeal of the rule, calling it an arbitrary constraint on their ability to manage depot maintenance functions efficiently."

But none of this is possible because the 60–40 rule prevents privatization or outsourcing of most depot maintenance. Proponents of the rule in Congress contend that the government must maintain robust "organic"—i.e., internal—depot maintenance capabilities in order to assure a reliable source of services essential to peacetime readiness and wartime sustainment. But almost every legislator who vigorously supports the rule has a maintenance facility in or near his district, indicating that the 60–40 rule is really a set-aside of money for a protected political constituency.

If preserving current depots and shipyards really was essential to war fighting, then the military services presumably would support retention of the 60–40 rule or some similar provision. In reality, all of the services have urged repeal of the rule, calling it an arbitrary constraint on their ability to manage depot maintenance functions efficiently. The same view has been expressed by the Secretary of Defense, the Defense Science Board and the Commission on the Roles and Missions of the Armed Forces.

It seems clear that under the guise of advancing national security, supporters of the 60–40 rule are attempting to protect the flow of taxpayers' money to favored constituents. That subterfuge actually damages national security by forcing the military services to buy essential functions from inefficient providers, reducing the resources available for other military activities. Rather than engaging in such chicanery, Congress should repeal the 60–40 rule and allow the military to buy maintenance services from the most efficient sources.

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3. OFF-LABEL USE REGULATION

Michael Herson

One of the responsibilities of the FDA is to ensure that new drugs and medical devices are safe and effective for their intended uses before being introduced into interstate commerce. Another responsibility of the FDA is to ensure that these products are accompanied by labeling information that sets forth the uses for which the product has been found to be safe and effective. It is unlawful to introduce into interstate commerce any drug or medical device that has not been demonstrated to be safe and effective for each of the intended uses described in this labeling. "Labeling" is defined by statute to include all "written, printed, or graphic" materials "accompanying" a product, and it is well established that supplementary or explanatory information disseminated by the manufacturer of a drug or device may constitute "labeling," regardless of whether it physically accompanies the product.

"Off-label" usage refers to the use of a drug or device in a manner not approved by the FDA and not detailed in the product's labeling materials. The FDA prohibits manufacturers from marketing drugs for "off-label" uses until evidence is available, presented, and reviewed just as it would be for a new drug.

"It is now often illegal for pharmaceutical companies to send reprints of scientific articles reporting research on off-label use to physicians."

It is important to realize that there is nothing wrong with "off-label" drug use. While federal law prohibits drug manufacturers from specifying on the label any uses of the product other than the precise use approved by the FDA, doctors are free to prescribe FDA-approved products for uses other than those specified on the product label. In fact, in many areas of medicine, the majority of treatments recognized by the medical community are "off-label" uses of FDA-approved products.

While the FDA has not attempted to interfere with off-label uses of FDA-approved drugs and devices, it has taken steps to prohibit the dissemination of truthful information about these uses. It is now often illegal for pharmaceutical companies to send reprints of scientific articles reporting research on off-label use to physicians. A drug company can send reprints only if there is an unsolicited request for the information. For example, the FDA prevented a drug manufacturer from distributing to doctors an authoritative medical textbook simply because the book contained information regarding generally accepted off-label uses of the manufacturer's cancer drugs.

The FDA has also threatened severe sanctions against manufacturers who become actively involved in scientific and educational programs at which off-label uses of the manufacturer's drugs or medical devices are to be discussed. The result is that many such programs are being canceled, and doctors are not receiving information about recognized off-label uses of FDA-approved drugs and medical devices. Clearly, the FDA's actions are endangering the lives of numerous Americans who could benefit from off-label uses of FDA-approved drugs.

One egregious example of off-label use regulation is the off-label use of aspirin to reduce the risk of first heart attacks in middle-aged men. There is substantial medical evidence that shows that taking a daily dose of aspirin can reduce the risk of heart attack in middle-aged men by nearly 50 percent. The results are so

well known that a pamphlet entitled *Amazing Aspirin* that discusses this benefit is available at most grocery store supermarket checkout stands. However, neither the package for any brand of aspirin nor any advertising for it indicates this valuable use. The publishers of *Amazing Aspirin* can provide the information because the First Amendment protects them, but it appears that the FDA does not believe that the First Amendment applies to the pharmaceutical industry. By denying important information to Americans, the FDA's policies thus probably are resulting in needless loss of life.[6]

When the reports of the benefits of aspirin were first released, there were stories in the media regarding the findings. Anyone who happened to hear or see the news knew this important information, but since then, unless a consumer reads a book or magazine article containing the statistics or hears about it from a physician, they are not likely to know the facts. Consumers are unable to learn of benefits via any type of promotional material.

"FDA regulation focuses on the risks of advertising and promotion but neglects the benefits"

FDA regulation focuses on the risks of advertising and promotion but neglects the benefits. In the case of aspirin, there is a slight increased risk of a certain type of stroke for some individuals who use aspirin. However, the level of increase in this risk is not statistically significant. The reduction in risk of heart attack from taking aspirin for middle-aged males greatly outweighs the slightly increased risk of stroke. And promotion and advertising could indicate that aspirin is not a suitable drug for young females and any other group for whom the risks may outweigh the benefits.

Drug manufacturers should not be subject to penalties because they help in the distribution of truthful information about non-approved uses for their products. Of course, the FDA is authorized to prevent manufacturers from misbranding their products by including unapproved uses on product labels, but the FDA has stretched its labeling authority far beyond anything contemplated by Congress when it adopted the federal Food, Drug, and Cosmetic Act.

But leaving aside legal issues, there is a moral question here as well. What kind of bureaucratic logic drives David Kessler and his agency to suppress truthful life-saving information about aspirin or other products? By forbidding manufacturers from spreading the word, needless illnesses and deaths are occurring.

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4. SPECIAL EDUCATION: Washington vs. The Children[7]

John E. Berthoud

One of the most pernicious ways that Washington interferes with the lives of Americans is through mandates on state and local government.[8] While there are many mandates that have adverse consequences, federal rules on special education stand out as a particularly gross abridgement of states' rights and another instance of removing control of education from parents and local elected authorities. Federal control originates from the Individuals with Disabilities Education Act (P.L. 101-476) which makes federal elementary and high school aid to states contingent upon local schools providing education for children with disabilities.[9]

"Federal rules on special education stand out as a particularly gross abridgement of states' rights and another instance of removing control for education from parents and local elected authorities."

The problem for states stems from U. S. Department of Education (DoEd) rules that prevent schools from expelling special education students who have disciplinary problems. One of the biggest battles against the federal rules on special education has been waged by the state of Virginia. Under federally mandated procedures established by the state in 1988, when a local authority wishes to expel or suspend a special education student, it must convene a committee composed of people familiar with the student. The disciplinary action holds if the committee determines that:

1) the misbehavior was not related to the disability, and
2) the student had been placed appropriately in that school. Students and parents have the right to appeal.

In following these procedures since 1988, Virginia localities have been able to expel special education students, or place them on long-term suspension, without having to pay for alternative schooling. This process has led to safer schools, and educators have found that the expelled students take education more seriously, which helps them turn their lives around when applying for re-admission to a school.

Recent data describes the nature of the issue for Virginia. Between May 1994 and March 1995, 176 Virginia students with health, learning, or other disabilities were expelled or placed on long-term suspension for actions unrelated to their disabilities. Fifty-three of the students were cited for weapons violations, 24 were found to be selling or using drugs, and 52 assaulted other students or teachers.

Nonetheless, in December 1993, the U.S. Department of Education decided that Virginia must pay for and continue alternative special education for expelled special education students, and that if the state did not, the federal government would withhold $58 million in special education assistance earmarked for the state.[10]

This issue has also made headlines in California. For example, last year, a student in San Diego brought a gun to school and was suspended, but before the suspension could take effect, the student's family hired a lawyer to claim that the student was disabled and therefore could not be suspended. This claim of disability came despite the fact that he had no history of disability. The student

won his readmission. In recent years, the state has seen a doubling in the number of cases where parents and their attorneys seek referrals to special education after a student is expelled.

Virginia and California make their cases against the federal government on numerous grounds. First, the U.S. Department of Education's Office of Special Education and Rehabilitative Services did not give appropriate notice to states of its policies, causing havoc for state policy makers. In July 1994, Senator Tom Harkin (D-IA) said on the Senate floor, "The U.S. Department of Education has explained the current policy regarding disciplining children with disabilities in letters responding to individual inquiries. Unfortunately, these interpretations are not widely disseminated and therefore many educators around the country are totally unaware of the options they actually have."[11]

"Virginia educators have testified that not expelling or suspending students is often more devastating not only to the individual student in question…but also to the community and the school as a whole."

DoEd claims that it needs to make these requirements because otherwise special education students would go without any schooling after they are expelled. However, Virginia school administrators have testified that the expulsion often serves as a "wake up call" to parents who must pay for a private school for their child. Further, most students in Virginia who have been expelled re-apply, as the schools encourage students to re-enter after they make amends. In hearings on the issue, Virginia educators have testified that *not* expelling or suspending students is often more devastating not only to the individual student in question, who fails to learn community values and expectations, but also to the community and the school as a whole.

Virginia has also argued that DoEd's policy creates a double standard and promotes an anti-community "badge of honor" that schools (particularly those in the inner-city) are fighting to eliminate.[12] By getting special treatment for conduct not related to their disability, special education students are taught that they don't have to be responsible for their own behavior.

Unbelievably, these problems for states have not come about because of anything specific in the Individuals with Disabilities Education Act, since it doesn't address discipline. Rather, DoEd has simply interpreted the act to require that states must provide educational services to all special education students regardless of their disciplinary profile.

One way to resolve this dispute would be for Congress to amend the Individuals with Disabilities Education Act to read: "Neither the Individuals with Disabilities Education Act nor its regulations shall be interpreted by any federal agency to require the provision of special education services or educational services to students with disabilities expelled or suspended long-term for conduct unrelated to their disabilities, nor shall any federal agency withhold funds to any state or locality that does not provide special education services or educational services to such students." This could help begin to restore the proper balance between the federal government and states in education and help to provide a better and safer learning environment for all students in our public schools.

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5. THE U.S. PEANUT PROGRAM

Dave Juday

In terms of its overall effect on the economy, the federal peanut program and its implementing regulations don't amount to much more, as the saying goes, than "peanuts." In terms of its relative effect, however, on peanut farmers and certain food industry sectors, it is one of the most egregious examples of government interference shackling economic growth.

Like most farm commodity programs, the federal peanut program was designed to help farmers. But the peanut program has been so "generous" in its support, and so restrictive in its regulation, that the peanut industry is starting to collapse under the weight of the program. As federal policy makers and agricultural leaders consider reforms in farm policy, the peanut program is a worthy case study of how artificial barriers to competition and iron clad regulations, even when intended to help, can and will lead to an industry's demise.

"Georgia is the largest peanut producing state not because it has the best farmland for peanuts, but simply because its allotment of more than 40 percent of the peanut quota has been protected for more than 45 years."

The program provides that each December 15th, prior to the upcoming crop year, the Secretary of Agriculture must establish a poundage allotment for the U.S. peanut production "quota." That quota must be equal to the projected demand for "domestic edible, seed, and related uses" of U.S. peanuts—imported peanuts don't matter, because they are kept out of the U.S. market by import barriers.

Thus, each and every pound of peanuts produced is tracked and chronicled in order to separate out those "quota" peanuts that are bound for the domestic edible market which are supported at a higher level, and those "non-quota" peanuts which may only be sold on the export market, or for crushing for oil or meal. The Secretary's projected quota is then extrapolated first by state, then by county, then finally, farm by farm. Georgia is the largest peanut producing state not because it has the best farmland for peanuts, nor because Georgia farmers are necessarily more efficient or productive, but simply because its allotment of more than 40 percent of the peanut quota has been protected for more than 45 years.

The original purpose of the peanut program long has been lost in the abyss of bureaucratic red tape and program administration. Over the years, the results of this program have not been beneficial to farmers—in fact, 68 percent of all quota peanut producers have to pay for the right to produce peanuts, as the quotas are owned by non-farmers. Actual producers, therefore, must rent the quota allotment from the quota-holders, increasing production costs.

Moreover, farmers who try to opt out of the quota system into producing "additionals" or non-quota peanuts for the export market are similarly—perhaps even more—disadvantaged. Because of the premium for quota peanuts, quota holders—or "quota renting" farmers—have an incentive to over-produce to ensure that they meet their quota. Thus the non-quota peanut market is flooded with an artificially induced surplus.

For quota producers, the fixed costs of production are covered by participation in the program, thus surplus production for the non-quota export and oil-crushing markets is virtually windfall—even though it is not guaranteed at the higher support price. Farms not producing for quota therefore have to cover operating

expenses and still be price competitive. Furthermore, non-quota growers are—by law—forced to purchase seeds made from the more expensive quota peanuts, further increasing production costs.

This imbalance has apparently taken its toll on the total production of non-quota peanuts, squeezing out new farmers and leaving the export market to fewer quota producers who generate some over-production. In total, U.S. exports have declined by 27 percent, and last year the U.S. was displaced by China as the world's leading peanut exporter.

While the peanut program has succeeded in killing the supply of peanuts for the world market, it has also succeeded in killing the demand for peanuts in the U.S. market. The artificially high price of peanuts—the General Accounting Office estimates it is between $314 and $513 million annually[13]—has begun to shrink the domestic market for peanuts.

U.S. food manufacturers, who in 1993 launched almost 13,000 new food products, have moved away from developing and marketing products that include peanuts. Since the last farm bill in 1990, food use of peanuts has declined almost 10 percent. Snack food uses of peanuts have declined more than 11 percent, and, the All-American staple, peanut butter—the largest single food use of peanuts—has experienced a decline in production of nearly 19 percent. Moreover, of the 16 states that have at least one farm that is producing quota peanuts, 15 states lost farms between 1985 and 1993—only Missouri stayed constant with four total quota farms in 1985 through 1993.

"The artificially high price of peanuts… has begun to shrink the domestic market for peanuts."

Peanut butter was originally invented in the U.S. as a cheap source of protein that could improve the diets of low-income consumers. Today, it is an American favorite with great export potential to much of the developing world where demands for protein consumption are rising. Because of the government's peanut program—ironically designed to help the peanut industry —most of this potential to improve the incomes of U.S. farmers and the diet of those in the developing world will never be realized.

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6. MEDICAL DEVICES & DRUG APPROVAL: Has FDA Improved Its Performance?

John E. Berthoud

While the past year has been full of controversy for the Food and Drug Administration (FDA), one of the most contentious debates has been over the time it takes for the agency to approve new drugs and medical devices. Critics have long claimed that the agency takes too long and that lives are being lost because Americans don't have access to state of the art technology and medicines. Because of the FDA's delays, Dr. Keith Lurie of the University of Minnesota observes, "We don't get the equipment we need to save lives."[14]

Still, while the evidence has mounted against the agency, the FDA has fought back, claiming that it has reduced the time it takes to approve new drugs and medical devices. The General Accounting Office (GAO) has examined the FDA's record and found that despite pledges of increased efforts to lower approval times, the results have been very mixed.

"In a recent study on medical devices, the GAO found that the median time for FDA review had lengthened in all three of the key measures they analyzed."

In a recent study on medical devices,[15] the GAO found that the median time for FDA review had lengthened in all three of the key measures they analyzed.[16] The review time for 510(k) applications, the review time for original PMAs (Premarket Approvals), and the review time for PMA supplements all rose between 1989 and 1993 or 1994. The 510(k) and PMA are the two methods of review that new medical devices must go through before they can enter the marketplace, with the PMA being more stringent and usually longer. PMA supplements are applications that are not for new products but modifications to existing ones.

GAO wrote of its findings on 510(k) applications: "From 1989 through 1991, the median time between the submission of a 510(k) application and FDA's decision (total elapsed time) was relatively stable at about 80 to 90 days. The next 2 years showed a sharp increase that peaked at 230 days in 1993. Although the median review time showed a decline in 1994 (152 days), it remained higher than that of the initial 3 years."[17] GAO notes that of all the new applications submitted to the FDA over this period, more than 90 percent were for 510(k)s.[18]

While review time of medical devices trended up according to the GAO, the FDA has done a little better on approval of drugs, according to a different GAO study.[19] The GAO found that the FDA has lowered its review times on new drugs applications (NDAs).

However, the GAO left open the question of whether the improvement was because of efforts by the FDA—they note that one fifth of the time in the review process comprises activities for which new drug sponsors are responsible.[20] The GAO wrote, "With respect to time, NDAs are moving more quickly through the drug review and approval process. Whether this improvement is because of actions by FDA or the pharmaceutical industry or some other factors is an issue that is beyond the scope of this report."[21]

So overall, the record is mixed and the FDA delays remain. Julie DeFalco of the Competitive Enterprise Institute writes, "The very real regulatory delays in the

United States have increasingly led U.S. medical device firms either to abandon projects, or to do research and development overseas. No matter what the FDA does to sugarcoat its record, it cannot stop this technological exodus to Europe."[22]

DeFalco notes that evidence of this can be seen in the number of Premarket Approval applications for break-through medical devices which dropped from 84 in 1989 to 43 in 1994.[23] In a similar vein, Murray Weidenbaum writes, "U.S.-based pharmaceutical firms have introduced new drugs in Europe while waiting for the completion of Byzantine domestic regulatory procedures."[24]

These findings on FDA review times are troubling because, of course, the delays cost lives and cause needless pain and suffering. Despite concern over these delays, which one might have expected to lead to lower review times, instead (as evidenced in the GAO findings) the recent trends are mixed.

These findings also raise the issue of regulatory prioritization in all federal agencies. A recent study by Dr. Tammy Tengs and Dr. John Graham of agencies such as the Consumer Product Safety Commission, EPA and OSHA demonstrated that if federal regulators re-prioritized their efforts, 11,000 premature deaths could be avoided *annually*.[25]

Prioritization has been a particularly significant issue with the FDA. James Phillips, who left the staff of FDA Commissioner Kessler in July 1994, recently charged that the FDA has poorly prioritized its agenda and therefore "ignored other pressing needs." For example, the foreign inspection program has been overlooked and in Phillips' view is a "disaster waiting to happen." Phillips has thus stated that there needs to be a vigorous round of oversight hearings to examine FDA's priorities.

Perhaps if the FDA and these other agencies re-focused on their missions, they would be able to improve their performance on approval of all types of new medical technology and thus get back to the business of helping to save lives.

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7. GLEN RIDGE SUPERFUND SITE

Steven Milloy

Superfund is a "badly broken super scam"
—Rep. Rodney Frelinghuysen[26]

Between 1913 and 1925, a company formerly known as Radio Luminescence operated in the vicinity of the Borough of Glen Ridge, New Jersey. The company was in the radium industry and, among other things, used radium to coat watch dials and instrument panels so that they could be visible in the dark. Apparently, some radioactive waste material from the Radio Luminescence facility was disposed of in the then-rural areas around Glen Ridge. Some of the radioactive-contaminated soil is believed to have been moved from the original disposal location and used as fill material in low-lying areas or mixed with Portland cement to make concrete sidewalks or foundations. Houses were subsequently constructed on or near the radium waste disposal areas.

"The EPA tends to exaggerate site risks, frighten communities and waste public and private resources in unnecessary cleanup activities."

In 1981, the Environmental Protection Agency (EPA) and the state of New Jersey discovered elevated levels of radiation in the area and linked them back to the activities of Radio Luminescence. In 1984, the EPA and New Jersey alarmed community residents by telling them that excessive indoor radon gas readings had been measured and that ambient gamma radiation was up to 150 times normal levels. The EPA placed the Glen Ridge site on its Superfund National Priorities List. Although New Jersey started cleanup activities at twelve Glen Ridge properties in 1985, they were halted after it was discovered that the volume of contaminated soil was underestimated and potential disposal sites were unavailable. As a consequence, residents previously evacuated from their homes were unable to return, their homes were left abandoned, and the uncompleted excavation areas was left fenced off.

Pursuant to its Superfund authority, the EPA stepped in and in 1990 selected an interim remedial action that involved excavating and disposing of 323,000 cubic yards of contaminated soil and other radium-contaminated materials from the Glen Ridge site, filling the excavated areas, and environmental monitoring. The price tag for these activities was estimated to range from $253 million to $348 million, and was to be picked up by the EPA.

Based on its risk assessment of the site, the EPA concluded that as many as 36 percent of the persons exposed to the unremediated site for a lifetime would die of lung cancer caused by the elevated radon levels at the site. If true, such a risk would be very significant given that it is roughly 200 times the risk of lung cancer reported in the scientific literature for heavy smokers. However, no excess number of cases of lung cancer have been reported for residents at the site. Why not? Isn't this is very unusual given that one of every three residents is expected to die from lung cancer?

The absence of observed lung cancers associated with the site may be explained by the fact that the EPA risk assessment for the site was more driven by overly-conservative EPA risk assessment policies than science. In fact, there is no scientific consensus that ambient or residential levels of radon are harmful to

humans. That low levels of radon exposure pose a health risk is only an unsubstantiated theory propounded by regulatory officials under the guise of "better safe than sorry."

Assuming for the sake of argument that the "better safe than sorry" line of reasoning is the preferred when public health is at stake, is it really necessary to spend between $253 million and $348 million to clean up the site? Probably not. In addition to the "Cadillac" cleanup option for the site, the EPA also devised a cleanup that would cost only $20 million—probably a far more sensible alternative in tight budgetary times.

This cheaper remedy did not involve costly excavation of 323,000 cubic yards of site soils. Instead, this remedy would have involved installation of state-of-the-art systems to reduce indoor concentrations of radon, installation of shielding from indoor gamma radiation, installation of outdoor gamma radiation shielding in the form of a soil cover over the contaminated soil and relocation or redistribution of hot-spots of radium-contaminated soil on properties. Institutional controls in the form of municipal or health ordinances would also have been employed to ensure the effectiveness of the engineering controls. The EPA even stated in its record of decision for the site that this option would have been protective of the public health.

Why wasn't this effective yet much less expensive remedy selected? In part, because the Superfund law requires cleanups to meet certain standards known as "applicable or relevant and appropriate requirements" (ARARs). Although the cheaper cleanup option met the health-based ARARs, it did not satisfy the ARARs governing soil cleanup (the elevated radium levels would have been permitted to remain in the soil albeit with no adverse health impacts). However, since the application of ARARs to a site is to some extent discretionary, this was not the only reason for foregoing the less costly remedy.

The EPA also alarmed the community to the point where the Cadillac remedy was the only acceptable remedy. Between alerting the community to the otherwise non-obvious dangers of the site, forcing residents to evacuate, and promulgating its wildly exaggerated risk assessment, the EPA essentially caused the Cadillac remedy to be a foregone conclusion.

Unfortunately, the Glen Ridge site is not an atypical Superfund story. After 15 years of Superfund, the EPA has not been able to implement the statute effectively or efficiently. The EPA tends to exaggerate site risks, frighten communities and waste public and private resources in unnecessary cleanup activities. This is why Congress is attempting once again to reform the Superfund law.

Steven Milloy, President of the Environmental Policy Analysis Network, Inc., is a biostatistician, attorney and author, and specializes in health risk assessment issues.

8. ENVIRONMENTAL TOBACCO SMOKE: Ideology Before the Facts

Merrick Carey

Science has shown links between many substances and various health risks. And we as a society are better off because of it. However, sometimes ideology drives science and results in poor scientific methods being propped up to prove a political point. Environmental Tobacco Smoke (ETS) is a good case in point.[27]

The Environmental Protection Agency (EPA) has studied the effects of ETS[28] and through manipulation of the scientific method has come to conclusions about its health risk that may very well overstate the case. This is shown clearly in important studies by the Congressional Research Service (CRS), including their most recent analysis, "Environmental Tobacco Smoke and Lung Cancer Risk."

The EPA concluded that, "ETS is a human lung carcinogen, responsible for approximately 3,000 lung cancer deaths annually in U.S. nonsmokers." [29] But several scientific shortcuts were taken to reach this conclusion. In using these shortcuts, the EPA has pulled smoking into its jurisdiction by virtue of its impact on the "environment"—a tenuous conclusion made even more so by weak science.

"It is essentially an unofficial EPA policy to deny that thresholds exist for any potentially hazardous substance."

First, EPA makes an assumption about the character of the risk of ETS that is perhaps unjustified. It assumes that there is a straight-line linear relationship between dosage and effect. The size of the dosage is always proportionate to the effect. Thus, if a certain amount of nicotine causes a problem, one fifth of that amount would cause exactly one fifth of the problem.

We can see the fallacy in this by realizing that even safe substances such as salt or aspirin after a certain threshold level become unsafe for humans. There is at least a reasonably good likelihood that there is a threshold level below which ETS is not harmful. It is important to realize that this threshold issue is not unique to ETS. Kent Jeffreys notes, "It is essentially an unofficial EPA policy to deny that thresholds exist for any potentially hazardous substance. As examples, consider EPA's stance on dioxins, radon gas, or pesticide residues in the food supply."[30]

On ETS, the EPA writes, "A clear dose-response relationship exists between lung cancer and amount of exposure, without any evidence of a threshold level."[31] A substantial dose-response relationship does not rule out the possibility of a threshold, nor does it obviate EPA's responsibility to look for one.

Another problem with the EPA's analysis is that in its work it assumes that ETS is the same as "mainstream smoke" (the smoke which is directly inhaled by smokers) and makes assumptions on the effects of ETS based on the effects of mainstream smoke on smokers. However, there are significant differences, as even the EPA admits. The changes are due largely to the fact that ETS is mostly composed (85–90 percent) of sidestream smoke which differs in chemical composition and concentration from mainstream smoke.

Further, EPA uses a lower threshold than normal to determine risk. Instead of the more traditional 95 percent confidence level in their statistical tests, EPA used

only a 90 percent confidence level. If they used the more traditional 95 percent confidence interval, the results would have shown no statistically significant difference in cancer rates between those exposed to ETS and those who are not.

Indeed, a CRS survey of studies on this issue points to the inconclusive nature of the findings. Surveying 30 studies, they found that six demonstrated a small although statistically significant effect, 24 revealed no statistically significant effect, and six of these 24 showed an ETS effect opposite of the expected relationship.[32] In a November 1995 report, CRS writes, "[I]t is possible that very few or even no deaths can be attributed to ETS."[33]

The 1995 CRS study stated that, "If there are any lung cancer deaths from ETS exposure, they are likely to be concentrated among those subjected to the [highest] exposure levels… primarily among those nonsmokers subjected to significant spousal ETS."[34] But even here, CRS noted that the test results are far from definitive or certain.

Summarizing these and other problems with EPA's analysis, Gary Huber, Robert Brockie, and Vijay Mahajan write,"EPA's risk assessment is built on the manipulation of data, ignores critical chemical analyses and key epidemiological data, violates time-honored statistical principles, fails to control adequately for important confounding influences (factors other than the one studied that may affect the result or a conclusion) that provide alternative explanations for its conclusions, and violates its own guidelines for assessing and establishing risk to a potential environmental toxin."[35]

The scientific method is important for society. Its abuse must be carefully guarded against. Kent Jeffreys points out two reasons why: "First, if we debase the scientific method in pursuit of a political agenda, we are opening a Pandora's Box. Second, the ordinary dangers everyone encounters in everyday life are so numerous that if we do not carefully delineate the government's role in regulating such dangers there is essentially no limit to how much government can ultimately control our lives."[36] Jeffreys is right on the money. Whenever politics has overruled science in the 20th century, the ultimate loser has been society.

While no one disputes the fact that cigarette smokers face a serious health hazard. It seems a safe bet that you would have to be on Mars to not know the risk implications regular smoking can have on your life expectancy.

Whatever we may feel about smoking, we can't deviate from good scientific principles to achieve the findings we want. Walter Williams, in writing about the "deceitful, dishonest use of science" to achieve political objectives observes that by such methods, "tyrants never tire of tyrannizing."[37] We may achieve the result that some want in regulating ETS, but this could lead to many adverse consequences in other areas.

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9. TOXICS RELEASE INVENTORY

Steven Milloy

On December 5, 1984, an accidental release from a pesticide plant killed 2,000 people in Bhopal, India. In response to this accident, the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) was enacted into law. Administered by the Environmental Protection Agency (EPA), the purpose of EPCRA is to "establish programs to provide the public with important information on the hazardous chemicals in their communities, and to establish emergency planning and notification requirements which would protect the public in the event of a release of hazardous chemicals." This purpose was implemented in part by requiring industrial facilities to annually report their releases and transfers of chemicals listed on the *Toxics Release Inventory* (TRI).

Congress established the initial list of more than 300 chemicals subject to TRI reporting when EPCRA was enacted. Using its statutory authority, EPA added another 286 chemicals in 1994. In neither case were the decisions to add chemicals to the TRI based on the potential risks of chemical releases as determined through the process of risk assessment. If risk assessments were conducted for TRI chemicals, most, if not almost all, listings would likely not be warranted based on risks posed to human health or the environment. Only those chemicals that actually pose health and environmental threats would be subject to reporting. Unjustified listings produce no tangible public health or environmental benefits yet cause significant direct and indirect costs.

"If risk assessments were conducted for TRI chemicals, most, if not almost all, listings would likely not be warranted…"

According to the EPA, it costs a facility about $3,500 per chemical to file the required TRI annual report. In 1992, the EPA received about 80,000 reports based on the approximately 300 chemicals on the TRI at that time. The total cost of such reporting based on EPA statistics is $280 million. With the 1994 addition of another 286 chemicals, and based on 80,000 reports being filed by 23,000 facilities for 300 chemicals, another 76,000 reports could be filed annually. The annual cost of 156,000 reports costing $3,500 each is $546 million.

In addition to the direct costs of reporting, indirect costs are substantial. For example, federal storm water treatment permits costing anywhere from $2,400 to $16,250 per permit must be obtained by industrial facilities for TRI chemicals. At least ten states require pollution prevention programs for facilities that file TRI reports. The cost of these programs averages $25,500 per year per facility. Thirteen states impose taxes or fees on the use of TRI chemicals ranging from $25 to $50,000 per reporting form submitted, depending on the amount of wastes released.

Unwarranted product stigmatization and confusion of the public may result from TRI listing. For example, TRI listing may result in listing under the State of California's Proposition 65, which requires public notification of the use of toxic chemicals. Food additives and pharmaceutical products that are listed may be inappropriately characterized as dangerous when in fact these products are safe. The public may also be confused by EPA labeling of food additives and pharmaceuticals as "toxic" when the Food and Drug Administration considers them to be safe for their intended purposes.

The benefits associated with TRI listing have not been quantified, measured, or otherwise directly or empirically evaluated. Nonetheless, the EPA claims that data reported under EPCRA Section 313 can increase the public's knowledge of chemical use and releases and facilitate access to such information. Further, the EPA argues that TRI reporting can create a chain reaction of follow-on activities (*e.g.*, voluntary initiatives by industry to review processes, set goals for reductions in emissions, and institute "good neighbor" policies). These follow-on activities, in turn, may create additional benefits, such as decreased costs of treatment and disposal, lower probability of accidental releases and resulting in lower cleanup costs, reduced contamination of natural resources from decreased land disposal, improved air and water quality, and lower incidence of cancer deaths and related medical care costs.

"Chemicals should only be listed on the TRI if they are shown through the risk assessment process to pose a danger to local communities."

However, even if these claims are valid, they are not the purpose of the TRI as enacted by Congress. The purpose of TRI reporting is to enhance community knowledge of routine local releases and transfers of chemicals that may pose hazards to local communities. Toward this end, TRI reporting provides for the collection and dissemination of information to communities. It is not intended to reduce or restrict routine or permitted releases and exposures of chemicals, nor it is intended to directly reduce risks. Given the significant direct and indirect costs of TRI listing and the benefit of community information dissemination, which may be diluted by extraneous information collection, chemicals should only be listed on the TRI if they are shown through the risk assessment process to pose a danger to local communities. An information collection requirement that is limited to chemicals for which there are well-established bases for health and environmental concern will assist local communities in addressing the most important potential local hazards first.

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10. THE DELANEY CLAUSE: Nostalgia We Can't Afford

Michael Fumento

What would you say if your city's housing code dwelled at great length on the sturdiness and structure of thatched roofs? What if vehicle regulations required blinders on your automobile so that it doesn't shy when an emergency vehicle passes by? If you like those ideas, you'd love the federal Delaney Clause. The Delaney Clause prohibits any measurable residue (from, say, pesticides) that has been found to cause cancer in either animals or humans, in any processed food.

Back in 1958, when it was passed as part of the Federal Food, Drug, and Cosmetic Act, it seemed to make sense. But science has long since passed by Delaney. That's in part because back when Delaney was enacted, residues could only be measured in parts per thousand. Now they can be measured in parts per trillion and sometimes even in parts per quintillion. Let's say you detect a part per quadrillion in a plum product. That's the equivalent of one plum in 73,511,000 tons.

"Back when Delaney was enacted, residues could only be measured in parts per thousand. Now they can be measured in parts per trillion and sometimes even in parts per quintillion."

Delaney is also outdated because it greatly preceded the use of maximum tolerated dose testing in laboratory rodents which didn't get going in earnest until the late 1960s. Under such testing, about half of all chemicals—both natural and synthetic—have caused tumors, which makes them verboten under Delaney. Critics say this makes such testing useless, because it can't possibly be that half of everything is carcinogenic.

The fact that the natural world is full of rodent carcinogens makes Delaney "absurd," says Berkeley biologist Bruce Ames. "There are a thousand chemicals in a cup of coffee. Twenty-six have been tested and 19 have already proven positive, leaving about a thousand left to test," Ames says. "The FDA would be laughed at if it tried to keep coffee from being added to ice cream. But there's no reason to think it's really a hazard." In any case, decades after Delaney was passed, testing in rodents became its backbone.

In addition to allowing natural rodent carcinogens while banning synthetic ones, Delaney encompasses another double standard. First, more recent legislation does allow rodent carcinogens in unprocessed food, so long as the level is low enough under a certain formula to qualify as a "negligible risk." A fresh fruit could have a 10 parts per billion of a pesticide and be allowed but if it's turned into a sauce or juice it might have only 1 part per billion and be banned.

Because of the outrageousness of actually applying Delaney, the EPA has for the most part simply chosen not to. The agency had attempted to circumvent Delaney by establishing a *de minimus* standard relating to pesticides. But that's about to change because of a 1992 lawsuit the Natural Resources Defense Council won against the EPA, forcing strict compliance with the legislation.

Now, like it or not, the EPA has no choice but to ban 85 uses of 38 different pesticide active ingredients. According to the National Center for Food and

Agricultural Policy (NCFAP), this could result in increased annual production costs of $212 million. The crops most affected would be potatoes, apples, and sugar cane. Look for your grocery bill to go up accordingly.

NCFAP Senior Research Associate Leonard P. Gianessi observed, "the risks of the Delaney-listed pesticide uses are negligible, while the economic benefits that they provide are estimated to be $400 million per year." For example, apple growers treat 30 percent of U.S. acreage with Delaney-listed acaricides (propargite and dicofol) for control of spider mites, which feed on apple foliage. The USDA has recently estimated that if these pesticides were removed, growers would have alternatives but they would be both more expensive and less effective. Apple yields would decline 3 percent on these acres, while production costs would increase $7 million a year.

Sometimes there are no replacements for chemicals which Delaney would ban. Thus the fungicide benomyl is the only control method for a disease of citrus trees known as "post-bloom fruit drop," a problem that affects about 5 percent of Florida's citrus acreage. Without benomyl, Florida citrus growers would incur a decline in production of $14 million a year.

The Delaney Clause was always too simplistic for its own good. Explains environmentalist and University of California biologist Garret Hardin, "The Delaney Act was passed because congressmen are old men. They are afraid of cancer. Because they're scared, they wanted zero tolerance. They did not get any scientific advice. Environmentalists who are scientists would never support a zero tolerance level for anything." That's why even such ardent cheerleaders for pesticide regulation as New York Mt. Sinai pediatrician Dr. Phillip Landrigan and Senator Edward M. Kennedy (D-MA) have called for Delaney's replacement by something more workable.

Senator Richard Lugar (R-IN) has legislation, S. 1166, which would implement recommendations by the National Research Council, including a "negligible risk" standard for both processed and raw foods. This determination would be made by the EPA Administrator, assisted by a newly-created science review panel drawn from nominations made by the National Science Foundation and the National Institutes of Health.

EPA Administrator Carol Browner has already agreed in principle to such a scheme. In a recent interview she said, "What you have now, effectively, is one standard for fresh food and another standard for processed food. So a tomato that ends up in your salad is a different standard than a tomato in catsup. There should be one standard for all food. The real answer is a comprehensive rewrite of the food safety laws."[38]

Nostalgia is wonderful within limits. But when the health and safety of people are concerned, our regulations need to reflect present the latest scientific evidence, not the state of the art from 1958.

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Endnotes

1. Donald Elliott provides a good description of regulation: it, "developed as our compromise between capitalism and socialism, is a distinctively American institution. Although leaving control of the means of production in private hands, the state intervenes in more subtle ways to influence the conduct of private enterprises. The essential defining characteristic of regulation is that while preserving the nominal freedom of individuals to make private decisions, regulation attempts to alter the course of decisions in the aggregate by altering the structure of incentives individuals face when making their decisions." (Donald E. Elliott, "Regulating the Deficit After *Bowsher v. Synar*," *The Yale Journal On Regulation*, Volume 4, Number 2, Spring, 1987, Page 346.)
2. William A. Niskanen, "Reduce Federal Regulation," Chapter 5 in *Market Liberalism* (edited by David Boaz and Ed Crane), Washington, DC: The Cato Institute, Page 103. Niskanen's source is Thomas D. Hopkins, "The Cost of Federal Regulation," *Journal of Regulation and Social Costs*, March 1992, Page 25.
3. Craig Richardson and Geoff Ziebart, *Red Tape In America: Stories from the Front Line*, Washington, DC: The Heritage Foundation, 1995, Page 3.
4. William Niskanen estimates the net benefits of deregulation at $50 billion. "Reduce Federal Regulation," Page 103.
5. George Gilder, *Wealth and Poverty*, Page 241.
6. In fact, Bayer attempted to market enteric-coated aspirin, which is the kind most useful for heart attack prevention, in a "blister" pack, designed for daily use, but the FDA prevented this form of marketing.
7. Much of the original work for this section was done by Stuart Anderson. See "Discipline and Special Education: The U.S. Department of Education vs. the State of Virginia," *AdTI Issue Brief*, June 7, 1995.
8. For a discussion of the issues involved with mandates, see John Berthoud, "The Federal Mandates Scorecard: In Search of Friends of the 10th Amendment," Phoenix, AZ: The Goldwater Institute, Issue Analysis Report #134, November 1994. During 1996, the Alexis de Tocqueville Institution will be undertaking an analysis of the impact of mandates on education.
9. For a good discussion of some of other problems that many see with the Individuals with Disabilities Education Act, see *The Role of Federal Mandates in Intergovernmental Relations*, U.S. Washington, DC: Advisory Commission on Intergovernmental Relations, January 1996, Pages 11 and A-21 - A23.
10. Virginia has appealed having to pay this money. A federal hearing officer chosen by U.S. Education Secretary Richard Riley ruled against the state of Virginia in April 1995. Secretary Riley affirmed the hearing officer's decision. The state has indicated it will appeal the decision to the Fourth Circuit.
11. The *Congressional Record*, July 28, 1994.
12. The state cites a case of a Fairfax County Public School where a group of six students were involved in bringing a loaded .357 magnum handgun to school. All the non-special education students were expelled, but the sixth student had a weak writing ability and had been labeled "learning disabled." An extensive review found no relationship between the writing disability and the student's involvement with the gun. Yet the student was not expelled and later bragged to teachers and students at the school that he could not be expelled.
13. U.S. General Accounting Office, "Peanut Program: Changes are Needed to Make the Program Responsive to Market Forces," GAO/RCED-93-18, February 1993.
14. Julie DeFalco, "The FDA's Snail's Pace Approach," *The Washington Times*, December 14, 1995, Page A21.
15. "Medical Devices: FDA Review Time," GAO-PEMD-96-2, October 1995.
16. Since unclosed cases will cause the statistical mean to under-represent the length of the FDA approvals in later years, the median is a more accurate measure when looking at recent data. The GAO discussed the merits of the median versus the mean on page 12 of the study.
17. "Medical Devices: FDA Review Time," GAO-PEMD-96-2, October 1995, Page 5.
18. Ibid., Page 6.
19. "FDA Drug Approval: Review Time Has Decreased in Recent Years," GAO/PEMD-96-1, October 1995.
20. "FDA Drug Approval: Review Time Has Decreased in Recent Years," Page 11.
21. Ibid.
22. "The FDA's Snail's Pace Approach," Page A21.
23. Ibid.
24. Murray Weidenbaum, "Fast-Moving Businesses Vote With Feet," *The Los Angeles Times*, July 26, 1993.
25. "The Opportunity Costs of Haphazard Societal Investments in Life-Saving."
26. Margaret McHugh, "Lawmaker Urges 'Dumping EPA from Superfund," *The Star Ledger*, December 19, 1995, Page 25.
27. For a good discussion of this issue, see Kent Jeffreys, "Science, Economics, and Environmental Policy: A Critical Examination," Arlington, VA: The Alexis de Tocqueville Institution, 1994.
28. U.S. Environmental Protection Agency, Office of Health and Environmental Assessment, Office of Research and Development, "Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders," Washington, DC, December 1992.
29. "Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders," Page 1-1.
30. "Science, Economics, and Environmental Policy: A Critical Examination," Page 3.

31. "Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders," Page 4-1.
32. Jane Gravelle and Dennis Zimmerman, "Cigarette Taxes to Fund Health Care Reform: An Economic Analysis," Congressional Research Service, Library of Congress, March 8, 1994, Pages 46-47.
33. "Environmental Tobacco Smoke and Lung Cancer Risk," Page 55.
34. Ibid, Page 53.
35. Gary Huber, Robert Brockie, and Vijay Mahajan, "Smoke and Mirrors" The EPA's Flawed Study of Environmental Tobacco Smoke and Lung Cancer," *Regulation* (Number 3, 1993), Page 46.
36. Kent Jeffreys, "Science, Economics, and Environmental Policy: A Critical Examination," Arlington, VA: The Alexis de Tocqueville Institution, 1994, Page 1.
37. Walter Williams, "Environmental Tyrants Say Perfume is Next," *Human Events*, February 2, 1996.
38. From *The St. Petersburg* (Florida) *Times*.

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The Alexis de Tocqueville Institution was founded in 1986 to study, promote and extend the principles of classical liberalism: political equality, civil liberty and economic freedom.

In the world at large, this has meant an emphasis on the potential of U.S. diplomatic and economic leadership to help freedom take root from Russia and Poland to Latin America, Vietnam and South Africa. AdTI championed this possibility well before it was fashionable.

Believing that America is the home territory of international democracy, the Institution has always placed major emphasis on a strong American defense capability, and a coherent international economic policy.

America and its democratic allies (as a 1989 AdTI study revealed) now account for more than 80 percent of world output. Foreign policy is increasingly a matter of foreign economic policy.

External tyranny is only one threat to freedom. As early as the mid-19th century, Tocqueville warned of a second insidious force that might attack the democracies from within.

Tocqueville called this the "velvet tyranny" of democratic socialism, in which men would gradually surrender their freedoms in "small, unobtrusive increments" to an economically hegemonic state.

Such a polity, he hastened to add, might not be physically brutal or tyrannical. But it would sap the human spirit, "discourage initiative and innovation" with its high taxes, far-reaching regulations and uncontrolled spending. Government would become not a jail-keeper, but a nanny.

Accordingly, the Alexis de Tocqueville Institution regards the perfection of democracy and the extension of economic freedom in the United States as vital to the cause of freedom world wide.

AdTI studies have helped promote lower tax rates and regulatory relief, reforms in education centered on less federal intrusion and greater freedom of choice, and a coherent international economic policy based on a sound dollar and free trade.

We believe, as Tocqueville did, that the most glorious achievements of democratic capitalism lie ahead. And yet, as Edmund Burke admonished: "All that is necessary for evil to triumph is for good men to do nothing."

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