Blocking Animal Biotech

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On January 15, the Food and Drug Administration announced “final guid-
ance” on its regulatory policy toward “genetically engineered” animals. Typical of
the agency’s current mindset, the policy tort-
tures the science and opts for the most
stringent, straining regulatory approach
among various possible choices. As a
result, the new policy threatens the health
of a promising new field: the production
of animals with novel and valuable traits.

After more than 20 years of delibera-
tion, the FDA’s Center for Veterinary
Medicine has stipulated that every geneti-
cally engineered animal will be subject to
the procedures and regulations for
drugs, such as pain relievers and anti-
tibiotics, which are used to treat ani-
mal diseases. The rationale:

The [Federal Food, Drug and Cosmetics Act] defines “articles
(other than food) intended to
affect the structure or any func-
tion of the body of man or other
animals” as drugs. A [recombi-
nant DNA] construct that is in a
[genetically engineered] animal
and is intended to affect the ani-
mal’s structure or function meets
the definition of an animal drug,
whether the animal is intended
for food, or used to produce
another substance. Developers of
these animals must demonstrate
that the construct and any new
products expressed from the
inserted construct are safe for the
health of the . . . animal and, if
they are food animals, for food
consumption.

However, the introduction of a gene
is not the same as the administration
of a drug, which makes the FDA’s rationale
questionable. And it is noteworthy that
the proposal represents a major shift in
the regulation of biotechnology that will
be hugely expensive to animal breeders
and detrimental to consumers.

What kinds of animals are we talking
about? One that has been awaiting an FDA
policy for almost a decade is an Atlantic
salmon that contains a Chinook salmon
growth hormone gene that remains turned
on all year (instead of during only the
warmer months, as in nature). This cuts
the salmon’s time to reach a marketable
adult weight from 30 months to 18. The
extra gene confers no detectable differences
in the salmon’s appearance, taste, or nutri-
tional value; it just grows faster—a tremend-
ous economic advantage to those farm-
ing the fish. There are numerous other
applications in various stages of research
and development, including livestock
with leaner muscle mass, enhanced resist-
ance to disease, and improved use of
dietary phosphorous to lessen the envi-
ronmental effects of animal manure.

ANIMALS AND DRUGS Until now, the
FDA has not regulated new lines of farm
animals or, for that matter, animals used
for what might be termed “medical pur-
poses.” For example, they do not regulate
German shepherds or golden retrievers
bred to enhance traits that make them
better seeing-eye or companion dogs. The
FDA has not even asserted its jurisdiction
over genetically engineered animals craft-
ed for research purposes, which include
hundreds of lines of rodents.

The terminology in the FDA’s policy
announcement is itself interesting. The

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mine whether or not the substance is the responsibility of the producer to deter-
new food additive is marketed, it is the producer. If the producer determines that a
additive applications for safety only if the animal is genetically engineered
salmon described above were to be the result of some sort of artifi-
cial insemination instead of recombinant DNA techniques, it would be exempt from pre-
approval evaluation. In other words, the FDA’s regulatory trigger is not the risk-related charac-
teristics of an animal, but the use of a certain technology — and the most precise and predictable one, at that. That makes no sense.

The “new drug” paradigm does not fit genetically engineered animals well. A far better model is the approach taken by another FDA unit, the Center for Food Safety and Nutrition, which places the burden of ensuring the safety of foods and food ingredi-
ents on those who produce them.

The regulations prohibit the adulteration (contamination) or misbranding (misla-
beling) of food, but the agency does not inspect or evaluate food prior to its sale in
shops, supermarkets, or restaurants. Rather, federal oversight relies on market surveillance and post-marketing regulation, and the FDA takes action if there is an apparent problem. This approach has worked quite well over many years.

The law does, however, require a pre-
marketing safety review for certain food-
related products judged to be higher-risk. These include most food additives — a class of ingredients that includes preser-
vatives, emulsifiers, spices, sweeteners, and natural and synthetic flavors or colors, among others. In general, a food additive must be pre-approved if it becomes a com-
ponent of or otherwise affects the charac-
teristics of a food and if it is “not gen-
erally recognized as safe (GRAS) by qualified experts for its intended use.”

GRAS is a critical concept. Before a new food additive is marketed, it is the responsibility of the producer to deter-
mine whether or not the substance is GRAS. The agency routinely reviews food additive applications for safety only when the substance in question has been determined not to be GRAS by the pro-
ducer. If the producer determines that a

substance is GRAS, only a notification of that decision to the FDA is necessary (which is then subject to agency review).

The FDA’s existing approach to biotechnology and to foods in general could be adapted easily to recombinant DNA-modified animals. Traditionally, the combination of two GRAS substances is still GRAS. Similarly, because adding a GRAS gene to a GRAS organism is likely to yield a GRAS outcome, an FDA pre-mar-
ket review would not be necessary for genetic constructions like the fast-grow-
ing salmon. Instead, the FDA intends to treat every new animal as though it con-
tains a “new drug,” the evaluation of which can take many years, even if there is virtually no likelihood of harm.

The FDA’s approach to “novel” foods, published in 1992, is compatible with the GRAS/food additive paradigm. It emphasizes that the Center for Food Safety and Nutrition does not impose discriminatory regulation based on the use of one technique or another, but that greater scrutiny is called for and applied only when certain safety issues are raised. These include the presence of a com-
pletely new substance in the food supply, increase in levels of a natural toxin, or the presence of an allergy where a consumer would not expect it.

Officials at the FDA’s Center for Veterinary Medicine say that a newly introduced gene expressed in an animal is analogous to the injection of a new drug, and that the genetic modification mediates the introduction of the substance synthesized under the direction of the new gene — a hormone or enzyme, for example. But this view ignores the fact that neither the FDA nor any other government agency routinely conducts pre-
market review of new genetic con-
structions that occur naturally. (We call these “mutants.”) An example is the Zucker rat, a naturally occurring mutant that is more than four times the size of its normal siblings and is available from commercial breeders for research. A more familiar exam-
ple is the mule, a horse-donkey genetic hybrid. It is also notewor-
thy that the FDA did not perform premarketing reviews of the “beefalo” when this buffalo-cow hybrid was intro-
duced into the food supply in the 1980s.

PROVE ME WRONG Why would the FDA adopt such a dubious, anti-innova-
tive, costly policy? This is an interesting story in itself, and it illustrates how far the FDA has strayed from pursuing poli-
cies that are genuinely in the public interest. In February 2008, following the publication of a couple of my articles on this subject, I received an e-mail that began thus:

Mr. Miller, my name is Joseph Grogan, Senior Policy Advisor to Commissioner Von Eschenbach at FDA. Can you name a single compa-
ny working to commercialize Transgenic [sic] animals that wants the food approach as opposed to the new animal drug approach? I note that AquaBounty and [the Biotechnology Industry Organiza-
tion, BIO] are very vocal and unani-
mous in their lobbying for a drug approach. These companies tell us the New Animal Drug Approach is essential to creating an industry here. Please tell me what these guys are missing.
I responded to him with this e-mail:

Dear Mr. Grogan:

I’m not in close touch with companies that produce transgenic animals, nor have I performed a survey of them, so I can’t tell you what their views are on the regulation of transgenic animals. Rather, I judge regulatory policy on its scientific merits and likely cost-benefit.

You note that AquaBounty and BtO are “unanimous in their lobbying for a drug approach.” I note that BtO has been on the wrong side of virtually every biotech regulatory issue for the past 20 years (documented in The Frankenfood Myth, Praeger Publishers, 2004, co-authored by Greg Conko and me). I note also economist Adam Smith’s sage observation: “People of the same trade seldom meet together, even for merriment and diversion, but the conversation ends in a conspiracy against the public, or in some contrivance to raise prices.”

The agbiotech companies did the same thing during the 1980s. They lobbied for process-based regulation that was excessive and completely unscientific and that ever since has stunted the growth of the industry and the diffusion of recombinant DNA technology to additional applications and parts of the world.

So, what are these guys missing, you ask? They’re missing the lessons of history — that what seems (and, indeed, seems) good for their own self-interest in the short-term can be a fiasco in the longer term. I’ll also tell you what they’re not missing: that an excessively regulatory, expensive approach to oversight favors big companies with deep pockets and discourages competition. Overall, though, it’s bad for the industry’s expansion, for the diffusion of the technology (especially to poorer countries that don’t have a Center for Veterinary Medicine) to perform reviews), for innovation, and for society at large.

There’s something here that I might be missing. Why should we care about the special pleading of a company and its trade association when it comes to making regulatory policy?

I’m absolutely delighted to know that this issue is on your radar screen, but I have no confidence at all that you and Commissioner von Eschenbach will make the right decisions. Please prove me wrong.

Instead, Mr. Grogan and his FDA colleagues have proved me right. Whenevrer they can, bureaucrats exhibit a tendency to arrogate new responsibilities and expand. “Dogs bark, cows moo, and regulators regulate,” FDA Commissioner Frank E. Young once quipped. Moreover, the “new drug” paradigm is the only vehicle available to the Center for Veterinary Medicine. (Recall the old adage, “When the only tool you have is a hammer, more and more problems begin to look like nails.”) But what is especially disconcerting is a senior FDA official’s ignorance about the substance of this important subject and his reliance on the views of special interests. (I never heard from Mr. Grogan again.) Even more disconcerting, of course, is the FDA’s adoption of a flawed, excessively regulatory policy that will inflate research and development costs and inhibit innovation. We taxpayers deserve better.

If animal biotech companies are to bring home the bacon, the FDA will need to revisit and revise its policy. When genetically engineered pigs can fly….

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Some government intervention in the marketplace is necessary, but it will only work if policymakers get the laws right.

For confirmation of this, we need only look at the history of banking, where laws that granted limited liability to bank ownership underwrote risk-taking that escaped all public control.

The limited liability corporation is an extremely valuable social invention. It appeared in Britain and the United States in the 1860s, and was adopted by the rest of Europe in the following decade. By saving investors from having all their wealth at stake if a business were to fail, this type of shareholding made it possible both for higher risks to be taken in investing and for the risks to be spread over portfolios. Initially, banks did not benefit from this legal innovation. In 1782, the Irish Parliament passed the first act permitting general limited liability partnerships. This contributed to a remarkable period of productive investment and prosperity in the country. Significantly, however, the privilege was explicitly denied to investors in businesses that dealt in any form of money. Banks were similarly excluded from the benefits of the first British acts that gave limited liability to shareholders in companies.

Because of this, the 1878 collapses of the City of Glasgow Bank and Caledonian Bank did not harm the depositors; it was the owners in both cases who suffered the losses because, as partners, their liability was unlimited. The same happened in 1890, when Barings Bank became overextended in South America. The Bank of England persuaded the other banks to help it provide enough liquidity to save Barings, but this was only on condition of great cost to the Barings family members who owned the bank in partnership.

RECKLESS TRADING When the law was changed to extend the privilege of limited liability to bank shares, Barings incorporated in 1905. The eventual
result was that the second time the bank could not meet its liabilities — this time in 1995, following outrageous risk-taking in the Far East — the fortunes of its owners (other than their actual shares in the bank) were protected. Instead, it was the depositors who lost. It is highly doubtful that, if the owners had still been liable for losses up to the entire limit of their wealth, they would have allowed such reckless trading with the bank’s money.

The current financial crisis is the same thing on a global scale. Limited liability was a necessary condition of the development of professional management in every industry. But in the financial sector, without any effective control from a multiplicity of shareholders, it left managers free to develop a range of instruments for the expansion of credit. In the process, they earned vast profits for their firms and correspondingly inflated bonuses for themselves, until the burst of the bubble for which they were responsible. Firms like Lehman Brothers, Bear Stearns, and Morgan Stanley survived the Great Depression of the 1930s as partnerships, but collapsed as public companies in 2008. The banking collapse was both inevitable and foreseen. In 1987, Paul Volcker argued prophetically that even a partial relaxation of banking disciplinary law “would recklessly lower loan standards and allow bad loans to be marketed to the public” — exactly what caused the subprime debacle.

**EX POST REGULATION** The traditional political and bureaucratic response to bad results of laws is to leave unchanged the laws that caused the problems, and to set up regulatory bodies to try to repair the damage. However, this is to ignore evidence that markets can only be effectively regulated ex ante, through the way we shape the laws of property on which they depend, and not by ex post interventions. There has never been greater proof of this than the catastrophic worldwide failure of regulation of financial institutions.

The phenomenon of “regulatory capture,” whereby regulators fall under the power of those they are meant to be supervising, has been well-known to economists since George Stigler. No matter what the gamekeepers are paid, the poachers can always afford to hold out. There would be no more one-way bets for managers faced only with their personal situation, one way or the other. Consequently, they can never get ahead of them, but in fact struggle to keep up.

Further, the imbalance in motivation between the parties is overwhelming. Regulators, even if people of personal integrity, are public employees, and there is no reason why they should be passionately motivated to study and understand the subject-matter of their task. Nor can outcomes have much effect on their personal situation, one way or the other. Consequently, they can never be a match for those they are supposed to regulate, the Masters of the Universe who eat, sleep, and dream their project in hand. There is no point in shooting the regulator because, even if they do their best, they can never win. They have been given a task they simply cannot perform. As long as the regulator “light touch” is apparently bringing about growth and jobs, a regulator who wanted to try to do his job properly would look in vain for support from politicians.

**GETTING IT RIGHT** Since ex post regulation is intrinsically incapable of working, we have to go back to trying to get the laws right. No matter how unacceptable it may be to the conventional wisdom and to special interests, one element of this would be to remove the shelter of limited liability progressively from financial institutions. The investment banks and similar funds should be the first to be forced to return to being partnerships, since it was they who devised the instruments of credit expansion that seduced the clearing banks and building societies. Such a move would restore responsibility at the top, because the owners would then be engaging their own wealth in its total- ity in whatever decisions they might take. There would be no more one- way bets for managers faced only with multiple and supine owners.

It is no argument against this that the financing of modern large-scale industries could not be carried on by the smaller banking units. The extraordinary economic expansion over much of the 19th century was financed by such units in the form of banking partnerships. Some of these were even able to handle flotation that would be large by today’s standards. And how much ground has the collectivist cause now made through governments having to bail out banks too big to be allowed to fail? Clearly, more than a century of going in the wrong direction cannot be reversed overnight. But the principle of getting the laws right, instead of strengthening regulation that cannot work, should nevertheless dominate the upcoming attempts to reform the international financial system.
The Small Business Administration’s Disaster Assistance loans are, collectively, the federal government’s primary disaster-relief program. The government-financed loans help not just small businesses, but also individuals, businesses of all sizes, and nonprofits to reestablish after a disaster. Unfortunately, the program’s performance has been mediocre, to say the least. Congress is now considering possible reforms, however they are modest in scope and the program will likely continue to underperform for disaster victims.

AIDING CITIES, NOT PEOPLE Congress authorizes the SBA to provide low-interest loans to disaster victims contingent upon a disaster declaration from the president or the SBA administrator, and a demonstrable ability for the recipients to repay the loans. The loans can be used to repair or replace real estate (up to $200,000) and personal property (up to $40,000), as well as to reestablish businesses and nonprofit organizations regardless of size (up to $1.5 million). Loans can be for a period of up to 30 years. The SBA has more relaxed underwriting standards than private-sector lenders, which allow it to lend money to riskier borrowers.

What restrictions should be placed on the loaned funds? Private insurers provide clients with checks after the destruction of an insured asset like a house or car, and it is left to the recipient to decide whether to purchase another car or house, or do something else with the money. In contrast, public disaster assistance mandates that the loan be used to rebuild in the same location. For example, in the wake of the devastating 2005 Gulf Coast hurricanes Katrina and Rita, policymakers momentarily considered dispensing financial aid directly to victims, to be used at their discretion. However, the possibility that many recipients would use the money to move out of the long-impoverished and hurricane-prone area resulted in the idea’s quick abandonment. The federal government’s relief effort was instead geared toward rebuilding New Orleans and encouraging its residents to stay. Because politicians gain reelection from specific places, they oppose disaster-relief policies that allow geographic mobility. They want individuals to stay and rebuild in the same area, and feel gratitude to their local representatives.
The result is inefficient location decisions, for two reasons: First, residents and businesses do not pay the full cost of their location decisions, as the loans have no risk premiums. And second, the assistance ties people to locations that typically are prone to disaster rather than allowing them to move to safer areas.

**DECLINE, WITHDRAW, AND CANCEL**

In July of 2007, the Senate Small Business Committee held a hearing to evaluate the SBA’s efforts in the wake of the 2005 Gulf hurricanes. It found that the SBA was not delivering disaster loans. Two years after Katrina destroyed New Orleans and devastated the region, the SBA still faced a huge backlog of loans, revealing its inability to process applications in a timely manner. And the SBA’s loan approval rate dropped from an average of 60 percent for previous hurricanes—including destructive Andrew—in 1992—to 33 percent.

Even among approved loans, the SBA failed to disburse the funds. Of the nearly 423,000 applications submitted, some 160,000 were approved, and yet two years after Katrina, the SBA had only fully funded 22 percent of the approved loans. According to the SBA’s inspector general, as of January 25, 2008, the SBA had withdrawn 68,456 loan applications, many of them inappropriately. The report notes, “We believe the lack of contact with applicants and hasty withdrawals occurred due to production goals set forth in a directive issued by the Director of Disaster Loan Processing. In order to meet these goals, loan officers told us they were aware that some officers would withdraw incomplete applications as doing so was easier than getting them approved.”

At the end of her testimony, Martin said, “I could go on, and on, and for hours here, but the truth is that only the

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wealthy moved through the system easily. People with credit issues, who owed money, who had lost their documents, or who just moved around, would probably not be given a loan, and if they were, they would have to fight to keep it.”

**RECENT REFORMS**

During the July 2007 Senate committee hearing, the Government Accountability Office released a report that questioned whether the SBA was prepared to handle another Katrina. Congress must not think so because it included a major overhaul of the SBA’s disaster loan program in last year’s farm bill.

The new legislation allows private-sector lenders to make short-term “bridge loans” to businesses damaged by disasters. Businesses could use bridge loans while they await processing of their regular SBA disaster loans or insurance payments. In the event of a catastrophic disaster, lenders as well as the SBA could make disaster loans. All lenders could make disaster loans to small businesses, and preferred lenders in the SBA’s 7(a) business loan program could make disaster loans to individuals.

The bill also authorizes the SBA to pay lenders to process disaster loans when applications overwhelm the agency, as was the case in 2005. The bill makes businesses anywhere in the United States eligible for disaster loans if they suffer economic injury as a direct result of the disaster, a measure similar to one enacted by Congress following the September 11, 2001 terrorist attacks. Finally, the legislation increases the maximum amount of a disaster loan from $1.5 million to $2 million and requires the SBA to create disaster response plans for various scenarios and conduct disaster simulation exercises every other year.

While the bill provides some improvements over the current system—such as stopping disaster victims from receiving payments from multiple agencies—it also contains serious flaws. First, the bill authorizes billions of dollars for use during a disaster, but the cost is not offset elsewhere in the budget. Supporters claim that most of the bill’s costs cannot be offset because no one can plan on spending disaster-related funds. But the truth is that the only obstacle to offsetting the cost of disasters is Congress. Congress chooses not to financially plan for disasters as part of its budget process. It might not know precisely when or where the next disaster will occur, but it knows that disasters will occur. Hence, Congress could and should carve out a disaster fund from the budget on the assumption that it will have to spend money on future disasters.

Second, supporters of the bill claim that the government should provide services to any and all businesses that are “adversely affected.” The problem with such language is that it places no easily defined limits on eligibility, in part because the policy is based on thinking of disaster relief as stimulus. And who could oppose more stimulus? To be sure, the money comes from taxpayers and reduces their welfare, but that loss isn’t discussed.

Third, Congress models the revised disaster loan program on the Supplemental Terrorist Activity Relief Program (STAR)—a program that is hardly an example of sound government response
to disaster. Enacted following the 2001 terrorist attacks, STAR was supposed to provide federal loans to businesses around the country that were affected by the attacks. A 2005 report by the SBA’s inspector general showed that both lenders and loan recipients abused STAR. Testifying the following spring before the Committee on Homeland Security Subcommittee on Management, Integration, and Oversight, the inspector general reported, “Most lender files did not contain sufficient information to demonstrate that borrowers were adversely affected by the September 11th terrorist attacks and their aftermath. As a result, eligibility could not be determined for 85 percent of STAR loans reviewed.”

As it turned out, lenders wrongfully advertised the loans to customers as an opportunity to receive lower interest rates rather than as a loan program intended for 9/11 victims. According to the inspector general’s report, many recipients had no idea they were receiving 9/11 loans rather than regular SBA loans. For instance, in 2002, Nevada Construction Cleanup, which removes debris that subcontractors leave at job sites, received a $1.53 million STAR loan to expand its business. David Marino, the company’s controller, told the Las Vegas Review Journal that he has no idea how Nevada Construction Cleanup landed on the list of terrorism-relief loan recipients. “This loan was way before 9/11,” he explained. Marino was unable to pinpoint a precise borrowing date, but he said his firm had had its 9/11 loan for at least 4 years. Terrorism recovery “wasn’t even a thought in anybody’s mind at that time,” he added. According to the Journal, officials with the various banks that handled the loans told investigators that they only qualified businesses for the anti-terror loans after SBA officials aggressively marketed the program to “mean that every small business could claim it was somehow impacted by the attacks, and therefore, eligible to receive a STAR loan.” The inspector general’s report supports this statement and blames top agency officials for the way the SBA promoted the program “by advising lenders that virtually any small business qualified and assuring them that SBA would not second-guess their justifications.”

The report cites other abuses of the program. A Texas golf course owner received a $480,000 STAR loan under the justification that “people were more interested in staying home and watching the attack on television than playing golf.” That the course had a different owner when the attacks took place and the justification for loan guarantees did not apply to the new owner did not prevent the lender from disbursing the loan. A Las Vegas tanning salon received a $583,500 loan on December 3, 2002. A company representative told investigators the business was not harmed by the terrorist attacks, but investigators ignored the statement because “many of the customers who use tanning salons are performers in casinos and work in various capacities in the casino industry,” and “Las Vegas tourism was hit hard by 9/11, and many casino workers lost their jobs or had their hours scaled back... This is a large part of (the borrower’s) customer base.” Better yet, according to the same report, “the lender’s credit memorandum showed the borrower experienced a 51.6 percent sales growth for 2001 and an annualized 2002 sales growth of 31.6 percent.” In the end, STAR became just another way for lenders to make money by leveraging a government guarantee. It did not serve the people it was intended to help. It is easy to see how the reformed SBA disaster loan program could suffer the same failing.

The fourth major problem with the program: they are likely to gain from it financially. But if lenders are not scrupulous in how they make disaster loans, this program could cost taxpayers dearly. Some 16–18 percent of all regular 7(a) small business loans default, and disaster bridge loans could have an even higher default rate. “An unpublished Small Business Administration report estimates that up to a quarter of Louisianans who took out SBA loans after Katrina may default on them within the next two years,” reports Reason’s Dan Rothschild. As of 2007, guarantees on SBA loans represented some $83 billion in potential taxpayer liabilities. Irresponsible lending practices increase the probability that taxpayers will pay the bills and the federal government will own many disaster victims’ homes and businesses.

CONCLUSION Disaster relief emphasizes the welfare of places rather than people because politicians represent people in specific places. Congress has never been willing to approve policies that resemble private insurance and give individuals cash after disasters. Current evidence suggests that disaster loans are best described as corporate welfare for the banks that disburse them and the clients that receive them. Those really in need receive little assistance. And recent reforms are unlikely to alter those results.