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BRIEFLY NOTED

How the FDA Virtually Destroyed an Entire Sector of Biotechnology

BY JOHN J. COHRSSEN AND HENRY I. MILLER

"Dogs bark, cows moo, and regulators regulate," former U.S. Food and Drug Administration commissioner Frank Young once quipped to explain regulatory agencies' expansionist tendencies. There may be no better example than the FDA's oversight of genetically engineered animals. This oversight misguidedly extends a regulatory regime designed specifically for the approval of new animal drugs to the regulation of the animals themselves. This sophistic and wrong-headed approach has resulted in regulatory paralysis and the near annihilation of an entire once-promising genetic engineering sector in which the United States was poised to be preeminent.

In 2009 the FDA aggressively seized control of the regulation of genetically engineered animals. That year the agency published a "guidance" that required all "genetically engineered" animals, from whales to mosquitoes, to be regulated by its Center for Veterinary Medicine. According to the guidance the animals would be regulated like "new animal drugs" such as antibiotics, pain relievers, or flea medicines. The rationale was that "intentionally altered genomic DNA" that is in a genetically engineered animal "and is intended to affect the animal's structure or function meets the definition of an animal drug."

Until that policy, no one—certainly no members of Congress or officials at other regulatory agencies—had conceived of the FDA claiming oversight of the breeding of pets, farm animals, or any other animals. For example, the FDA did not evaluate greyhounds bred by conventional techniques to enhance (DNA-mediated) traits that make them faster runners; cats that are better mousers; or even animals that have been modified with molecular genetic engineering techniques for scientific research, which includes hundreds of lines of rodents.

Fish story / Only a couple of animals have been reviewed by the FDA under the guidance, and it is no exaggeration to say that the regulators' performance has been near-catastrophic. The first was the AquAdvantage Atlantic salmon, which reaches maturity 40% faster (and consumes 25% less food) than its unmodified cohorts. We've told the story of this fish in these pages before, but it merits repeating. The genetic changes confer no detectable difference in the fish's appearance, ultimate size, taste, or nutritional value; it just grows faster, which is a tremendous economic advantage to those farming the fish in a closed-water system. Also, because the fish are sterile females and farmed inland, there is negligible possibility of any sort of "genetic contamination" of the wild salmon gene pool or other environmental effects.

Long before the FDA issued its guidance in 2009, its officials had told AquaBounty, the fish's creator, to submit a marketing approval application to the FDA, although there was no clear regulatory rationale or pathway for evaluating it. The agency delayed the application for

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approval of the salmon for almost 13 *years* before reaching a decision on how the fish should be reviewed, and then opted for the most stultifying, expensive, dilatory, and inappropriate regulatory approach among various possible policy choices. Its review of the salmon as a "new animal drug" took several more years. At the end of this two-decades-long process, the FDA concluded what had been obvious from the beginning: that no health or environmental risks or food quality concerns existed.

The FDA has determined that no special labeling is required to associate the salmon with genetic engineering because the salmon did not present any unique food safety concerns. Nevertheless, because of requirements included in spending bills, Congress has so far prevented the FDA from granting final marketing approval for the AquAdvantage salmon until the agency imposes some sort of labeling requirement. This requirement is supported by certain segments of the salmon industry that seek to discourage the acceptance of—and therefore, competition from—the AquAdvantage salmon.

Meanwhile, the sale of AquAdvantage salmon began in Canada this year. No special label is required, so consumers are making their salmon-buying choices based on quality and price. According to AquaBounty, five tons of AquAdvantage filets had been sold there by the beginning of August, and they're unable to keep up with the demand.

Mosquito woes / A delay in the availability of cheaper salmon isn't the end of the world, of course, but there are plenty of other examples. For instance, the FDA has also unnecessarily and inexplicably delayed small-scale field trials of an innovative approach to controlling the mosquitoes that transmit the Zika virus, yellow fever, dengue fever, and chikungunya: a novel, self-destructing, genetically modified *Aedes aegypti* mosquito. Biotech firm Oxitec introduced an inherited genetic defect (a conditional-lethal mutation) into the mosquitoes that causes the insects to die in the absence of a certain supplement. After the mosquitoes are released and mate, their offspring die before reaching maturity, resulting in a marked reduction in the mosquito population. The parents also soon die.

Because male mosquitoes don't bite, they present no health risk, and because the progeny die before they can reproduce, none should persist in the environment. This approach has been successfully tested in several countries, with roughly 90% suppression of the wild population of *Aedes aegypti*. Brazil's National Technical Commission for Biosecurity has granted permission for commercial releases.

The FDA's failures in policy and the actual reviews resulted from empire-building, a lack of scientific expertise, and a deference to political pressure.

The FDA took an unconscionable five years (2011–2016) to approve a single small-scale field test of this mosquito, and that came only after mounting pressure from the growing Zika threat and the consequent need to control *Aedes aegypti*. In August 2016 the FDA finally approved a field trial at one site in the Florida Keys, some 160 miles from a Zika outbreak in Miami, a trial that has yet to begin because the community has changed its mind about allowing it.

Because the FDA regulated the genetic insert in the mosquito as a new animal drug, like other "drugs" it would have to be shown to be safe and effective for the animal in order to gain government approval to be marketed. This presented a regulatory conundrum: regulators would have to conclude that the genetic material that causes a male mosquito to self-destruct after producing defective, doomed offspring is safe and effective for the mosquito. The FDA would have found itself tied up in legal knots if its ultimate approval of the insect were challenged in court by environmentalists and anti–genetic engineering activists. We pointed out this conundrum in a March 13, 2016 *Wall Street Journal* op-ed. In January 2017, the FDA ceded the regulation of mosquitoes to the U.S. Environmental Protection Agency, an agency that does have the statutory authority to regulate insecticides.

In a somewhat analogous mosquito-control innovation, the EPA has recently shown that it can efficiently review field trials with comparable nongenetically engineered strains of mosquitoes. The mosquitoes are *Aedes albopictus* males (and therefore don't bite) that have been intentionally infected with certain specific strains of *Wolbachia* bacteria. (Strains of the bacteria are present in many insect species.) When released, these males mate with female mosquitoes, but the resulting eggs fail to hatch, decreasing the biting mosquito population by as much as 80%.

Blocking innovation / The FDA's failures in both policy formulation and in the actual reviews of the genetically engineered salmon and mosquito resulted from empire-building, a lack of scientific expertise, and deference to political pressure. In contrast, the U.S. Department of Agriculture has a long history with genetically altered biocontrol agents, most notably the innovative screwworm fly produced with sterile-insect techniques that was successfully developed by the USDA more than 70 years ago to eradicate a devastating animal pest. Since then, the USDA has performed, funded, and overseen the testing and commercialization of a variety of control agents created with sterile-insect techniques. (When released in large numbers, insects made sterile—usually by irradiation—mate but don't produce progeny, and thereby reduce wild insect populations.)

Largely because of the irrationality and unpredictability of U.S. regulation, industry has been reluctant to invest in these important new approaches to the improvement of animal traits. The few companies that have, besides AquaBounty

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and Oxitec, include Recombinetics, which has produced hornless cows (an important innovation), and Genus, which has developed pigs resistant to the devastating Porcine Reproductive and Respiratory Syndrome Virus, the cause of losses to U.S. pig farmers of more than $600 million annually. The foreseeable development of chickens with genetic resistance to avian influenza will be a monumental breakthrough because there is no vaccine against it and outbreaks result in the culling of tens of millions of birds annually. These companies have the potential to create the Next Big Thing in animal husbandry—if only innovation were not strangled by unnecessary, misguided government regulation.

The arrogation of oversight over modern animal breeding by the FDA's Center for Veterinary Medicine is an exemplar of the sort of regulatory overreach and dysfunction that the Trump administration claims it wants to address. The White House Office of American Innovation, headed by Jared Kushner, was established for this purpose. However, it has not focused on biotechnology and it has a very limited staff. It will likely fall to other entities in the White House to reassign oversight of genetically engineered animals to more appropriate agencies.

The USDA has ample oversight authority over animal breeding under various statutes, and certain other agencies also may have concurrent authority over products such as pesticides (by the EPA) or particular food products (by the FDA's Center for Food Safety and Nutrition). Such a change would likely be broadly supported by academia, industry, investors, and others who have been discouraged and frustrated by the FDA's dysfunction and obstructionism.

Withdrawing the FDA's "veterinary drug" guidance and assigning jurisdiction over genetically modified animals to the USDA and EPA would be a logical and important advance for agriculture, the environment, and public health. All that is needed to get it done is resolve from the feds. It can't happen soon enough. R

Rise of the Machines?

BY PIERRE LEMIEUX

Artificial intelligence (AI) that would equal the human kind is probably as fanciful as Frankenstein's creature, but it raises fears. Elon Musk, founder of Tesla, SpaceX, and OpenAI, recently declared that AI is "summoning the demon," that "robots will be able to do everything better than us," and that "there should be some regulatory oversight, maybe at the national and international level."

Regulation of uncertain technological and economic change is an old solution. Nearly a century ago, Rexford Guy Tugwell, a progressive economist fascinated by government planning, proposed to control the rise of any new industry. "New industries will not just happen as the automobile industry did," he wrote in 1932; "they will have to be foreseen, to be argued for, to seem probably desirable features of the whole economy before they can be entered upon." (See "Total Regulation for the Greater Whole," Fall 2014.) He probably imagined committees of bureaucratic experts and assemblies of politicians exercising the "proactive regulation" that Musk is now calling for. What could go wrong?

No jobs? / The big fear for many AI critics is that robots could displace large numbers of human workers, resulting in massive unemployment and poverty. But future technological progress will probably resemble what has happened previously. Technological progress in a given industry increases labor productivity, machines incorporating the new technology partly substitute for workers, and—other things being equal—fewer of the latter are employed in the industry. However, displaced workers move to other industries, creating jobs elsewhere in the economy. Because higher productivity—producing more with the same resources—means higher living standards, more technology will generate higher incomes and wealth. Most people will benefit from technological advances, just as we have since the Industrial Revolution.

Contrary to Luddite fears, the experience thus far is that technological progress increases employment opportunities as it raises incomes. For example, close to 12 million Americans worked in agriculture in 1910 (the year when agricultural employment reached its peak), but only 2.5 million do so today. In the meantime, the total number of jobs in the American economy increased from 37 to 151 million.

More recently, the number of jobs in manufacturing dropped from its peak of nearly 29 million in 1979 to about 12 million today, while total employment in the economy increased from 99 to 151 million. Agricultural technology was a continuation of what can be called "the first machine age," which followed the Industrial Revolution; recent computer technologies in manufacturing are part of the "second machine age," as MIT economists Erik Brynjolfsson and Andrew McAfee have dubbed it. (See "Pinging the Robot Next Door," Summer 2014.)

A recent paper by David Autor (MIT) and Anna Salomons (Utrecht University School of Economics) provides more general empirical evidence that computers and robots do not threaten employment. Using a dataset covering 19 countries (the United States, Japan, and several Western European countries) over 37 years (1970–2007), Autor and Salomons find that technological progress has raised labor productivity and reduced jobs in the industries directly affected, but the resulting higher incomes in those industries generated

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offsetting jobs in other industries. They conclude that "productivity growth has been employment-augmenting rather than employment-reducing,"

They do observe that since the 2000s the "virtuous relationship" between technology and jobs seems to have weakened. In a few countries—the United States, Japan, and the United Kingdom—technology has destroyed more jobs than it has created. But they note that the 1980s were also less typical of the virtuous relationship, but then it reasserted itself. At any rate, the data for the 2000s only go up to 2007, in a period marked by "unusual economic conditions leading up to the global financial crisis." We might add that even with the 2008–2009 recession, 15 million more Americans are employed now than in 2000.

It can be shown that the main factor in employment growth is population growth. And we must not forget that income (and self-reliance or autonomy) and welfare are what's important in individuals' preferences, not jobs and sweat. Because technological progress allows people to get more by working less, it is a blessing, not a curse.

Inequality issue / It is true that the new jobs created by technological progress require more skills, mainly in terms of knowledge, than the ones that have been eliminated. As documented by Autor and Salomons, the result has been much lower growth for mid-skill (and, in most other countries, low-skill) employment than high-skill employment. One result, they remind us, is that "the real wages of less-educated workers in both the United States and Germany have fallen sharply over the last two or three decades." This polarization of the labor market has increased economic inequality.

The inequality issue, however, should not be exaggerated. Any change generates disruption, and it is not surprising that digitization, automation, and the onset of AI should have significant effects. As time passes, individuals will invest more in their education and the problem of low-skill and low-pay workers should solve itself. Progress happens through disruption. The intervention of government planners would only slow technological progress, reduce incomes (compared to what they could have been) for educated workers, reduce the incentives to invest in one's human capital, and—to borrow a mantra of social justice warriors—harm future generations.

Like any fear, the fear of robots serves as an excuse for government intervention. One proposal has recycled the idea of a "basic guaranteed income," presumably financed by a tax on robot owners and (because this proposal is very expensive) on educated and skilled workers. This would not help motivate people to invest more in their own human capital.

THE REAL PROBLEMS

As far as catastrophic scenarios go, the standard science fiction tale is that intelligent robots would control humans—like politicians and bureaucrats now do. It is not clear how government regulation would reduce alleged harms. On the contrary, decentralization and competition would foster new ideas for robot control and provide better protection if some robots turn against humans. Individuals, not the collective, should be the robots' masters.

Government intervention would only slow innovation, reduce worker incomes, reduce incentives to invest in human capital, and harm future generations.

The imagery of menacing robots with arms and legs, like in the *Terminator* movies, may sometimes hinder clear thinking on this whole topic. Some robots do have arms and legs, but they are defined by the software that runs them. Government control of robots would mean government control of software development.

The most serious danger with technological change is the possibility that the state will control the new technologies. The bureaucratic and political committees overseeing technological change could very well be captured by the elite (as so many government activities are) and abolish competition against the robot owners. Government could cap the number of robots or impose a license requirement on robot owners, using the excuse of protecting workers and consumers of course. Government intervention is more likely to create a class of robotless proletarians than to prevent it.

CONCLUSION

One specific danger requires further comment: the development of robots as machines of war (or, who knows, for federally subsidized SWAT teams). As Air Force general and current Joint Chiefs of Staff vice-chairman Paul Selva testified in a Senate Armed Services Committee hearing last July, "I don't think it's reasonable for us to put robots in charge of whether or not we take a human life ... because we take our values to war." He is right, of course, even if barbarian enemies were not to follow the same rules. But this does not require politicians and bureaucrats to take control over all robots; it just requires control over governments that use robots.

A more mundane danger is that governments use intelligent software to increase surveillance and control over their citizens. Spy agencies have already been doing this, ostensibly for our own good. Some courts use a form of AI to identify criminals who might re-offend, a process that, despite all its statistical bells and whistles, comes close to punishing pre-crimes like in Steven Spielberg's 2002 film *Minority Report*. Government control of private technological development would only compound these dangers.

In short, robots are much less scary by themselves than if they are controlled by politicians and bureaucrats. The Luddites are wrong; this new technology is no different from past innovations that they decried. And neither is the danger of government. *R*