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Federal Biotechnology Policy: The Perils of Progress and the Risks of Uncertainty

Al Gore
United States Senate

FEDERAL BIOTECHNOLOGY POLICY: THE PERILS OF PROGRESS AND THE RISKS OF UNCERTAINTY

Senator Al Gore*

Americans have a schizophrenic view of science and technology. Some of our greatest heroes have been technological pioneers—from the Wright brothers to Lindbergh to Chuck Yeager. Until recently, we expressed unmitigated adoration for the scientists and engineers who put man in space. Yet at the same time, many Americans are generally uneasy about the triumph of technology in their own lives. One does not have to be a Luddite to rail against computers every now and then.

In deciding how to allocate precious public resources in an era of limits, legislators must take public perceptions of science very seriously. Unfortunately, the public can prove to be quite fickle in these matters. It is not easy to keep funding a scientific project when the American people keep changing their minds about it.

Nuclear power once had almost universal support as a safe, environmentally superior source of energy. It still has many supporters—but the public perception of nuclear technology has changed dramatically over the past two decades.

Minds can change quicker still, as the Challenger accident sadly demonstrated. For years, NASA was worshipped by Congress, the press, and the American public. The Challenger tragedy transformed the image of the space program almost overnight. Now NASA must confront an atmosphere of skepticism, mistrust, and intensive scrutiny. America still supports space exploration and research, and Congress will continue to fund it—but not without a host of difficult questions.

America may never write a blank check like that again. The fate of science and technology in the next hundred years will

* Senator from Tennessee; member of Armed Services; Commerce, Science, and Transportation; and Rules Committees; Vice-Chairman of the Congressional Biomedical Ethics Board. Senator Gore graduated with Honors from Harvard College in 1969 with a Bachelor of Arts degree in Government. He attended law school and divinity school at Vanderbilt University before coming to Congress in 1977.

depend largely on the public perception of what scientists intend to do with it. The more scientists can do to establish a steady, forthright, and reasonable relationship with the public, the better off all of us will be. With care and cooperation, the scientific community can help assure that Luddites will not rule the twenty-first century.

No field illustrates the inevitable tensions, as well as the potential for cooperation, better than molecular biology. In the century since Gregor Mendel's death, we have not only come to understand the intricacies of genetics, but we are on the verge of being able to use it to change the basic forms of life itself.

Not since we learned to split the atom has man seen so powerful a technology with such tremendous implications. Biotechnology presents us with the ability to change and reshape the world as we know it. We will be able to study human blueprints and correct their architectural flaws. Soon we may learn to develop new and better strains of crops and livestock; to create new miracle drugs; to treat and cure human diseases that have long seemed incurable; to fight hazardous wastes safely and at reasonable expense; and to diminish our dependence on chemical pesticides. The economic potential is virtually unlimited, and the medical applications may well be miraculous.

In November 1982, I chaired hearings on the ethics of human genetic engineering.[1] It became clear at those hearings that we are beginning to unlock the mystery of human life itself.

To show how much our knowledge has advanced in this area, one witness compared it to a satellite photographing the earth. Our early knowledge of the human genome was likened to photographs of the continents. We could see the broad outlines, but we did not know the specifics of the terrain. As the technology developed we have been able to "zoom in" on those continents until we could see cities, then streets, then houses, and now mailboxes. Soon, we will even be able to tell whether the flag on the mailbox is up or down—whether a gene is turned on or off.

The implications of this knowledge are enormous. We already know that many serious diseases—sickle cell anemia, Tay Sachs, Lesch Nyhan Syndrome, cancer—have genetic bases. Genetic explorers have found possible gene markers for Huntington's disease, Alzheimer's disease, cystic fibrosis, and manic depression. This can be hard work—one researcher said it was like searching

1. *Human Genetic Engineering Hearings Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology*, 97th Cong., 2d Sess. (1982) [hereinafter *Human Genetics Engineering Hearings*].

for a house in a city without knowing the street address. In some areas, progress may seem distant. But without gene therapy, the chance of curing a disease like cystic fibrosis is nil.

I. THE PERILS OF PROGRESS

For every use of biotechnology there is a potential misuse. For every benefit, there is a possible hazard. Our challenge is to know when we are about to go too far. Unless we are prepared to deal rationally with this newfound power, we will realize none of its real benefits and find ourselves saddled with all of its problems. The nuclear arms race demonstrates the hazards of a technology developed with neither foresight nor planning. If we had taken more time to comprehend the implications of nuclear technology when it was created, we might have developed a keener appreciation for those choices before us. We might even have found a way to avoid the dilemma we have created.

The science of genetic engineering presents amazing possibilities, but it also holds the potential for enormous hazards. As these amazing possibilities come within our grasp, we must also consider potentially serious adverse consequences. Some new crops and livestock we develop may have no natural enemies and will be genetically superior to their predecessors. Like kudzu, starlings, and gypsy moths, these new organisms could get out of control. So could new microorganisms being created to "eat" hazardous waste. As we discover the genetic bases for many diseases, we are also beginning to understand the biological essence of what makes us human. We must struggle to use that knowledge wisely.

In the process of manipulating plant life for the better, we can so easily make things worse—perhaps through the catastrophic release of unknown pathogens into the environment. Just as we are learning to alter somatic disease cells, we are also figuring out how to manipulate gamete cells—giving us the power nobody wanted, to tamper with the genetic makeup of a generation yet unborn.

Genetic screening is another example. In the workplace, employers could use screening to protect employees from danger. But at what point does protection become discrimination? When does the employer's wish to avoid even the remote possibility of a personal injury lawsuit override concern for the employee's

well-being? In several hearings I chaired on this issue,[2] I discovered that some companies were already using this technology to screen employees, and many others had considered it.

An even more difficult ethical question involves the use of genetic engineering to intervene in the human genome. By genetically engineering gametic cells, we could keep defective, disease-causing genetic traits from being passed on to future generations.

As wonderful as it would be to wipe out certain diseases forever, the same technology will give us the power to make dramatic changes in individuals that may not be so desirable. Although no one objects to curing disease, the ability to custom-order our children is something else again.

We are beginning to understand how to manipulate the genes that determine our basic physical characteristics—height, hair color, and so on. We are learning more and more about human growth genes, and we have already been able to influence physical traits in animals, such as fruit flies and mice. It is not hard to imagine that someday we will have the ability to influence such traits in our children.

Genetic makeup appears to determine our mental and psychological characteristics as well. Unlocking the mystery of these genes could enable us to cure a host of illnesses, from manic depression to retardation. Yet from there it would only be a short step to trying to soup up our brains.

Rapid development of genetic engineering could turn out to be a mixed blessing unless we also develop a means to cope with it. Researchers are on the verge of replicating Creation, and we have scarcely given thought to the design.

II. THE GENE REVOLUTION: SHARING THE WEALTH

Of course, there is also the possibility that biotechnology will work all too well. Its potential impact on the food supply, for example, is enormous. Few expect that by accident we will set loose some genetically defective "Andromeda Strain." Given our past record in dealing with agriculture, we are far more likely to drown ourselves in a sea of excess grain. The Green Revolution made America the world's breadbasket, but it has also brought

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2. *Genetic Screening and the Handling of High-Risk Groups in the Workplace: Hearings Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology*, 97th Cong., 1st Sess. (1981).

on an age of intractable overproduction. Unless we plan more carefully, the Gene Revolution could do the same—on an even grander scale.

What is the price of progress? Will the "supercow" trample the small dairy farmer? Could the family farm be genetically altered out of existence? Meanwhile, will biotechnology help to feed the starving millions—or will the Third World be left behind?

The biggest threat is overproduction. These are hard times down on the farm—and if anything, the prospects are worse. We live in an age of excess capacity. From the standpoint of the small farmer, even the Green Revolution has been a mixed blessing. Increased agricultural efficiency forced many family farms out of business, and left others hostage to the increasing volatility of glutted commodity markets.

How can the small farmer possibly survive the Gene Revolution? The effect of genetic advances on production will dwarf the triumphs of the past two decades. Bovine growth hormones already can make cows produce up to forty percent more milk.[3] Scientists are working on "supercows," "superpigs," even "supersized salmon." Other experiments have led to multiple births, more rapid growth, and higher resistance to disease. Unless we can somehow find a way to create very hungry Superhumans, each of these advances may produce nothing but glut.

In the next few years, our capacity to expand the food supply will grow at an unprecedented rate. The Gene Revolution will do for animal products what the Green Revolution did for crop yields. Much to the farmers' chagrin, it will have the same effect on food prices as well. Robert Kalter, an agricultural economist at Cornell University, predicts that "the unparalleled speed and magnitude of the expected productivity gains" will flood commodity markets.[4] As prices fall, he fears that the cost of maintaining price supports will rise so rapidly that the government may have to abandon the program.

For the average farmer, most of these new developments in biotechnology will be out of reach. A quarter of a million family-sized farms in this country, already on the ropes, will be hard pressed to afford biotech's high start-up costs. After the ruinous

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3. Rogers, Copeland & Hager, *Tinkering with Nature*, NEWSWEEK, May 26, 1986, at 54, 55.

4. Gabor, *Fresh From the Labs, A Farming Revolution*, U.S. NEWS & WORLD REP., Nov. 25, 1985, at 74.

expansion of farm debt in the 1970's, banks may be more reluctant to lend small farmers money for expensive new investments—and quicker to foreclose on them if anything goes wrong. Only the large farms will be able to afford a new technology which, if it works, could drive their smaller competitors out of business. Biotechnology will be a hollow victory for science and for society if only the big boys survive to divide the spoils.

It does not have to be that way. With the right planning, biotechnology could be the salvation of the family farm rather than the death of it. One way or another, biotechnology will become a cornerstone of our future prosperity. The challenge is to make sure it will help those who need it—from the wheat grower in west Tennessee to the starving peasant farmer in west Africa.

We can turn this revolution into the common man's revenge by changing our approach to agricultural research. In our all-out rush to boost total production during the Green Revolution, we stopped worrying about producers. We almost forgot the small farmer, who needed cost-effective *applied* technology. The yield on a large farm in Iowa is forty times that of a subsistence farm in Nigeria not just because American farmers are more efficient, but also because the world has yet to develop agricultural techniques that work on a small scale. Traditionally, ninety-five percent of all agricultural research has been geared toward agribusiness, to ever greater efficiencies of scale.

Today we are paying for that policy of bigger is better—with bigger farm debts, a bigger price-support program, and big troubles for all but the biggest farms. We cannot afford to make that mistake again. Biotechnology can and ought to be a Great Equalizer, making a miraculous yield possible on even a small plot of land.

That should be an important goal of our research. Instead of rewarding agribusiness interests or distributing academic pork barrel, government grants should target the individual farmer. Perhaps we will never see another USDA study on how long Americans take to cook breakfast. We should worry instead about what Americans *eat* for breakfast and how the farmer can provide a cheap, tasty, and nutritious product.

Unless we consciously steer progress toward the little guy, it will trickle down too late to do much good. A Biotechnology Extension Service, for example, could offer technological assistance in agricultural areas. Biotechnology will bloom and grow only if it is affordable and easy to understand.

The government might also consider a Rural Development Bank to give small farmers low-interest loans on appropriate

biotechnology. Eventually, we could apply our success in the Third World, so the areas that need progress most do not just fall further behind.

Here at home, we can use our technological research to target the individual consumer. One biotech company now produces healthy snacks, like carrots that are extra-sweet and popcorn that tastes buttery without adding butter. Instead of continually trying to change people's diets, we may someday be able to take the dietary risk out of high-risk foods.

The Gene Revolution is still young and full of possibilities. It can bring on a brave new era—or just much more of the same old thing. We can sit back and watch the gap widen between rich and poor, North and South, agribusinessman and family farmer—or we can use this fabulous opportunity to leap ahead together.

III. UNCERTAIN RISKS AND THE RISK OF UNCERTAINTY

Biotechnology is about to pose some very direct challenges to our sociopolitical institutions. For the field to go forward, it will need the faith of the American people behind it.

Despite its considerable promise, this new technology got off to a rocky start. The manipulation of recombinant DNA was unpopular from the outset. When news leaked out in the mid-1970's that certain laboratories wanted to experiment with genetic manipulation of various bacteria, the idea met with considerable controversy. Cambridge, Massachusetts, actually banned such experimentation within the city limits, for fear that some unforeseen bacterium might slip out and wreak havoc in Harvard Yard.[5] At the same time, some members of Congress introduced legislation to restrict or even ban such research outright.[6]

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5. *Cambridge Council Bids Harvard Delay Its Gene Research*, N.Y. Times, July 8, 1976, at 12, col. 6.

6. In the Senate, Senator Edward Kennedy introduced a bill that would have created a permanent national commission to regulate and monitor all recombinant DNA research in the United States. *See Recombinant DNA Regulation Act, 1977: Hearings on S. 1217 Before the Subcomm. on Health and Scientific Research of the Senate Comm. on Human Resources*, 95th Cong., 1st Sess. (1977). In the House, several bills intended to regulate DNA research were introduced. For the text of these bills, see *Recombinant DNA Research Act of 1977: Hearings on H.R. 4759 and H.R. 4849; H.R. 3191, H.R. 3591, H.R. 3592, and H.R. 5020; H.R. 4232; and H. Res. 131, Before the Subcomm. on Health and the Environment of the House Comm. on Interstate and Foreign Commerce*, 95th Cong., 1st Sess. (1977). For a discussion of the scientific community's reaction to these

Fortunately, the controversy had a sober and happy ending. The National Institutes of Health adopted guidelines that accommodated the interests of both researchers and the public.[7] Research was able to continue.

Yet government and society are being tested once again in this field, on several fronts. Our ability to deal with these new controversies will set the tone for social and scientific cooperation in the years to come.

Back in 1983, the Subcommittee on Investigations and Oversight concluded that the gravest danger associated with the release of genetically altered organisms was not necessarily the release itself, but our inability and failure to make risk assessments.[8] Four years later, we still have not developed adequate standards for risk assessment. As a result, important experiments like the use of genetically engineered microbes to fight frost formation (ice-minus) have been stalled, even though their benefits seem to far outweigh their possible dangers.

Our subcommittee did not call for a new biotechnology bill or agency, concluding instead that government should encourage this new science, not stand in its way. But we did see the need for an interagency committee to sort out the conflicts and gaps in agency jurisdiction, and to coordinate the federal effort in research and regulation. Yet those conflicts have only multiplied. The constant uncertainty has hurt industry and regulators alike—and the picture is not likely to clear up any time soon.

In 1983, we predicted that the biggest and most difficult hurdle for biotechnology would be to develop a broad public consensus for the science. The debate is just getting started, and the public still knows next to nothing about biotechnology. Soon the industry and the scientific community must realize that public perceptions will set the agenda for biotech regulation, research funding, and consumer support. No matter how important future applications could be, they will not happen unless the public is convinced that the science is safe, sound, and worthwhile.

In fact, the American public may be the most overlooked element in our current risk assessments. The debate over deliberate release has centered on the potential risks involved, but ultimately the public perception of those risks will determine the

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bills, see Schmeck, *Scientists Seek to Influence Legislation on Gene Research*, N.Y. Times, July 6, 1977, at 15, col. 1.

7. *See Goodbye to Guidelines*, NATURE, Feb. 4, 1982, at 356.

8. STAFF OF HOUSE SUBCOMM. ON INVESTIGATIONS AND OVERSIGHT, TRANSMITTED TO THE HOUSE COMM. ON SCIENCE AND TECHNOLOGY, 98TH CONG., 2D SESS., THE ENVIRONMENTAL IMPACTS OF GENETIC ENGINEERING (Comm. Print 1984).

future of the experiments. Look at the changing fortunes of Tylenol. Over the years, millions of Americans have taken Tylenol Extra-Strength Capsules. More people have probably died from accidental overdose or allergic reactions to Tylenol than from tampered pills. Yet after two dramatic episodes of poisoning, Johnson & Johnson decided that it could no longer market the drug in capsule form.

It is up to the industry whether biotechnology will go the way of Tylenol Extra-Strength Capsules. The most important lesson of recent events is to level with people, and not to play down the risks in the hope that they will never materialize. Sooner or later, an accident will happen—and it could devastate the industry if the public is unprepared or feels betrayed. The Bhopal catastrophe shows what can happen when people do not understand the risks involved in what they are doing. We must not let the same wishful thinking poison biotechnology.

The ice-minus stalemate was an example of the industry's failure to recognize the importance of public perception. Advanced Genetic Sciences (AGS), the company that makes ice-minus, forgot about the people of Monterey County, where the first test of the product was set to take place. When local residents learned of the company's plans, they got scared. The area depends on agriculture, and people there did not want any highfalutin' scientists coming in and jeopardizing their livelihood. The people convinced the Monterey County Board of Supervisors to place a moratorium on the project.[9] Had AGS taken the time to educate the public, the snafu might never have happened.

IV. THE REGULATORY MUDDLE

So biotechnologists must be patient with democracy. Meanwhile, all of us in government must work to speed the democratic process along. These issues are tremendously complicated, and they are bound to get more so. But that is no reason for government to sit on its hands and wonder what to do next. We need a way to sort out the regulatory mess, so that the world's largest biotech community will not have to spend all its time fighting the world's largest judicial system.

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9. Rhein, *The EPA Locks Gene-Splicers in the Lab*, BUS. WK., Apr. 7, 1986, at 42. To add to AGS's woes, the EPA revoked a test permit when it discovered that AGS had initiated tests of ice-minus bacteria on an open rooftop nine months before receiving EPA approval for tests outside the laboratory. The EPA also fined the company $20,000. Rogers, Copeland & Hager, *supra* note 3, at 55.

Right now, the only federal effort to clear up this muddle is the administration's proposed Biotechnology Science Coordinating Committee (BSCC). Although some kind of interagency committee is necessary, I do not believe an interagency "discussion group" can do the job. The BSCC has no vested authority to resolve disputes or to come up with a common policy that eliminates confusion and overlap.

We will need to do better than that in order to resolve the tough questions that lie ahead. Will our regulatory system be able to keep pace? What will happen, for example, when scientists find a way to produce a drug genetically for less than it costs to produce it by conventional means? Should the FDA regulate it as a new drug? The USDA will face the same dilemma with genetically altered seeds—what constitutes a new crop?

We need a group with the power to settle disputes that arise. If the administration continues to be unable to provide such a group, this is one area where I would consider introducing legislation.

Perhaps more importantly, we need to get our regulatory act together because our ability to compete depends on it. Unnecessary delays in review and approval could fritter away our lead in biotechnology research and development. With a trade deficit of $170 billion in 1986,[10] the United States cannot afford to jeopardize its long-term competitive strengths.

A recent cartoon summed up the frustrations of our research community. The drawing portrayed scientists' first close look at a molecule: in small print, it says "Made in Japan." It often seems that American inventors do all the work while cut-rate foreign imitators reap the profits. We must not let that happen to biotechnology. As our manufacturing industries lose ground, sophisticated value-added sectors like biotechnology will become critically important to the American economy.

To preserve our vital technological edge, government must maintain a strong commitment to research and development. Scientists are understandably concerned about the level of basic research in a time of limited resources. Trying to save a little on research today could cost us a lot more tomorrow. Gramm-Rudman-Hollings or not, we simply cannot afford to eat our seed corn. In fact, the federal government should start expanding its research base if it hopes to regulate biotechnology effectively in the future.

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10. In 1986, the trade deficit amounted to $166.3 billion. Auerbach, *U.S. Trade Deficit Balloons*, WASH. POST, Apr. 15, 1987, at A1, col. 1, A18, col. 4.

In these competitive times, industry and government will have to cooperate as best they can. Ideally, agencies and biotech companies will get together to set the research agenda. We may need some kind of research consortium to pool government and industry efforts. More cooperation will be required to make sure that biotechnology products reach the market quickly. At the same time, intellectual property and patent rights can be strengthened to protect researchers, and other impediments to international trade can be removed. Eventually, we can hope to develop international standards and guidelines for the biotechnology industry.

V. THE ETHICS OF GENES

The new technology is developing so rapidly that it is out-running the ability of our social, ethical, and legal institutions to deal with it. Biotechnology presents myriad new challenges that can no longer be ignored.

The last thing we need is some new form of heavy-handed regulatory structure that would hinder the development of biotechnology. The government should help guide biotech, but it must not control it. We must be careful not to burden the biotech industry with an uncertain climate.

Even so, the human applications of genetic engineering pose profoundly difficult issues. The November 1982 hearings on human genetic engineering[11] convinced me that our society is woefully unprepared to grapple with the serious ethical choices the new technology will raise. Unless we are careful, we may well stumble across the hazy line between good and bad, desirable and undesirable, ethical and unethical. The challenge we face is to know where that line falls, and to keep from crossing it.

Scientists and government officials cannot find that line on their own. Our society will need a collective effort to understand the technology and its dilemmas. We must create a new body of ethics—a body of "genethics"—to help us make the difficult choices that lie ahead.

It is not enough simply to declare a new technology safe and hope that the public will go away. If there is public concern over safety, then government and the scientific community had better work together to address it. The stakes are too great and public support is too vital to ignore. What we need is a well-defined

11. *See Human Genetic Engineering Hearings, supra* note 1.

process to satisfy public concerns so that scientists can get on with their work.

Scientists cannot resolve these troubling questions by themselves. These issues touch the core of our existence. Whether or not one endorses such biological adventures, it is vital that we resolve their implicit moral dilemmas.

In bioethics, at least, we have begun to lay the groundwork for extensive public debate. I proposed legislation in the last Congress that has created a Biomedical Ethics Board to bring together scientists, public officials, and laymen.[12] Through such a forum, science and society can resolve these issues to everyone's satisfaction. The Biomedical Ethics Board is designed to anticipate future challenges to our political institutions and our ethical beliefs. It will be able to advise Congress and other branches of government on sound guidelines and reasonable standards.

Our society will keep pace with science as long as scientists take the time to calm our fears and hear our concerns. We are running out of time. The technology is developing rapidly, and we must start making decisions soon. In 1982, a witness testified at my hearings that human gene therapy experiments were a decade away.[13] But it appears that the first such tests will be conducted any day now.

We are in the midst of a biotech boom. Scientists at Cold Springs Harbor Laboratory in New York have just launched a program to teach genetic engineering to students *in high school.* Without a coherent set of scientific and ethical guidelines, events may simply overtake us. Our experience with nuclear technology shows that hindsight does very little good.

Developing the necessary consensus will require the cooperation of all participants in the debate. No group is more crucial to the success of this effort than the scientific community. Those of us in government rely tremendously upon scientists for the assessments we need to make reasoned judgments and formulate rational strategies. Scientists also set an important example. As one member of French Anderson's gene team said recently, when asked about the race to use gene therapy in a human pa-

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12. The Health Research Extension Act of 1985, Pub. L. No. 99-158, § 11, 99 Stat. 820, 883-85 (codified at 42 U.S.C.A. § 275 (West Supp. 1987)). The members of the Biomedical Ethics Board in the 100th Congress are Rep. Willis Gradison (R-Ohio), Chairman; Sen. Albert Gore, Jr. (D-Tenn.), Vice-Chairman; Representatives Thomas Bliley (R-Va.), Thomas Luken (D-Ohio), J. Roy Rowland (D-Ga.), Thomas Tauke (R-Iowa), and Henry Waxman (D-Calif.); and Senators Dale Bumpers (D-Ark.), David Durenberger (R-Minn.), Gordon Humphrey (R-N.H.), Edward Kennedy (D-Mass.), and Lowell Weicker (R-Conn.).

13. *See Human Genetic Engineering Hearings, supra* note 1.

tient: "You're dealing with people. It's important not only to be first, but to be *right*."

If biotechnology is to proceed in this country, our society must believe that it is right, and that its benefits outweigh its drawbacks. That means we must approach the technology with care, and develop a consensus about its appropriate applications.

We always assume that somehow science will work everything out for us and everything will come out all right in the end. But that will not happen by itself—not if we let the march of technology overwhelm us. We must make an effort to choose the good effects and reject the bad.

We cannot predict the future, but we can create it. Science and technology have always been the engines of human progress. Together we can make sure that over the next hundred years they drive humanity forward—and in a direction we have chosen.