Malcolm Gladwell

RISK, REGULATION, AND BIOTECHNOLOGY

The big challenge for genetic engineers isn't just in the laboratory. It's in winning the public's trust and the regulators' understanding.

I t is inconceivable, of course, that one photograph could alter the direction of an entire industry, especially when it depicts nothing more than a woman walking through a strawberry patch.

And yet in the world of biotechnology, which in its short ten-year history has not always moved on the most rational of courses, the picture taken on April 24, 1987 of Julianne Lindemann walking through the strawberry fields of northern California has come to take on a strange and special significance.

On that day a small West Coast biotech firm-Advanced Genetic Sciences-became the first company ever to receive government approval to take a manmade organism out of the laboratory and release it in the open air. It was a simple experiment. A common bacteria modified by the tools of genetic engineering was sprayed on strawberry plants to protect them against frost. But coming after five years of controversy and regulatory review, after lawsuits from angry environmentalists and hostile ordinances from local city councils, it represented a milestone in the history of the biotech industry: for the first time the government had given its imprimatur to the fruits of gene manipulation. After years of being cast as mad scientists, the AGS test meant that the biotechnology industry had finally gained acceptance.

But the picture ruined everything. By some whim of the California health authority, Lindemann was made to wear what appeared to be a space suit, as if the bacteria she was spraying was radioactive, or as if the field on which she stood was the surface of the moon. Why she was made to wear such a ridiculous getup is anyone's guess, since of course if the bacteria was ruled safe

Malcolm Gladwell, former assistant managing editor of The American Spectator, is a business reporter for the Washington Post. enough to be released into the environment then it was surely safe enough to be released by a scientist dressed like a normal human being. But even today, almost two years after the fact, there are those who will say that the effect of that picture, burned into the collective consciousness the following day on TV screens and newspapers around the world, was to contradict the entire exercise, to perpetuate the superstition that gene splicing was a strange and dangerous science to be carried out only under the most extreme precautions.

And as if the injustice of the image was not enough, they will also point to the gathered crowd of reporters and onlookers just a few feet behind Lindemann in the picture, munching on donuts, sipping coffee, and snapping away with cameras without any kind of protective gear at all. In the twenty months since the Advanced Genetic Science's field test, a handful of other biotechnology companies have received the federal goahead to take their experiments out of doors. Some of the experiments have encountered the same degree of controversy as that first experiment. Some have been pulled off with a minimum of fuss. But all in some way have fallen under the shadow of that first test in a California strawberry patch.

I t is not that the biotech industry feels its attempts to seek practical applications for the products of the laboratory have been overregulated. In fact there is general agreement that the broad expanse of unexplored territory opened up by biotechnology demands some sort of close scrutiny. But there has always been a sense that in some



way the public perception of what biotechnology is, and what kind of regulations are required to control it, are out of sync with the actual risks presented by the technology itself.

Before any group of scientists can introduce some new creation into the world, they have to comply with a series of stringent and often confusing regulations involving two or even three separate government agencies. Some have had to defend their rights to conduct experiments in court against skeptical environmentalists, and at the very least to conduct extensive public relations campaigns to convince local communities that the genetically improved seeds or manmade micro-organisms conceived in a test tube will not run amok when released into the environment. Such efforts are deemed necessary in spite of overwhelming evidence that what is being created by the biotech industry is no more troubling or dangerous than the work with improving crops and chemicals that has gone on for years before. Indeed, the evidence is just as overwhelming that the toll taken by such oversight in time and money may be curtailing the growth of the industry itself.

This is true not just of the few dozen firms that have used the techniques of genetic engineering to improve crop agriculture but also those who are looking to improve livestock, to develop stronger and more useful strains of domestic animals. They too have said that their efforts have become the subject not of too much scrutiny but of scrutiny that has missed the mark. It is as if the public that has greeted the fruits of this new science and the researchers and tiny companies that have spawned it were somehow speaking in a different language.

It is as if all the industry were made to dress in space suits, even as they perform the most mundane of tasks and even as onlookers non-

chalantly sip their morning coffee and report on the brave new world of biotechnology for the evening news hour.

There are many reasons why this perceived incompatibility between the emerging field of biotechnology and the regulations that govern it should matter to Americans. The cliche that all of our lives may someday be touched by biotechnology may or may not be true, but it is certainly the case that what is now a small industry will someday be a large one, and whatever impediments are placed on the growth of U.S. firms will inevitably end up as advantages for the Japanese or the Germans or the British or whomever our competitors may someday be.

More importantly, however, how the emerging field of biotech is treated by the public and the appropriate authorities is a test case for how any new technology is greeted by society. With any new advance comes a necessary comparison of the risks presented by the new against the risks associated with the old, and the advantages of what is coming against what is already there. It is not clear that with biotechnology this has been done with any accuracy; at best it may be too soon to make that determination, as the regulatory wheels in Washington are still grinding; at worst we may have fashioned a system that both frustrates the growth of this promising technology and exposes the public to more dangers than would otherwise be the case.

ew stories better demonstrate the problems inherent in the present regulatory system than that of Gary Strobel, the Montana State University researcher who ran afoul of the public and regulatory authorities in the summer of 1987. In June of that year, Strobel independently injected a small group of elm trees on the MSU campus with a natural bacterium that has proved effective in protecting trees in the laboratory against Dutch Elm disease. Because the bacterium had been modified slightly by genetic means to make it more effective against the deadly Dutch Elm fungus, this was, for the purposes of federal authorities, a biotechnology experiment. And when the Environmental Protection Agency found out that Strobel had conducted his test without clearing it with the agency first and having its environmental impact reviewed by a panel of experts, he was sharply reprimanded and a year-long restriction on his research activities was imposed. Perhaps worse, he became the target for all those nervous about biotech's future. There were calls by some of his peers for the "book" to be thrown at him for recklessly endangering the public safety, and the clump of trees on which he performed his experiment was summarily cut down and burned.

There are several points worth making about Strobel's crime and punishment. To begin with, the rule he defied in not registering his test with the authorities is less a single standard than one part of a confusing patchwork of three separate sets of rules. Consider the questions Strobel had to answer before beginning his war on Dutch Elm disease. The Department of Agriculture has rules about outdoor true. As of the June 26, 1986 Federal Register, pages 23302-23393, the EPA has its own rules and Strobel's test fell within them. For not being familiar with that redefinition, Strobel was punished. As he would say later, "You almost have to be a lawyer before you can be a scientist."

Strobel was also punished even though almost no one believed that the bacterium he was injecting into his trees posed any general threat to the environment. As the EPA officials responsible for disciplining Strobel said, in a kind of grand bureaucratic

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tests. Did they apply to Strobel? Not so, he found out: In the case of using bacteria to control a plant disease, USDA rules apply only to test sites of over ten acres. Strobel's was smaller than that. Then there are general principles laid down by the National Institutes of Health defining what is and what is not an experiment worthy of regulation. Did they apply to Strobel? Apparently not, for his bacterium contained no manmade DNA ligations. Finally, the EPA has jurisdiction over some types of outdoor experiments. But Strobel assumed that the EPA followed the NIH's general guidelines for outdoor tests, but that is no longer

doublethink, the decision to punish him was based upon his "failure to comply with agency regulations and policies, rather than because of any adverse effect this experiment may have." To translate, he was guilty of breaking rules designed to protect the environment even though he wasn't actually endangering the environment. He was arrested for resisting.arrest.

It bears mentioning, although few bothered to at the time, that Strobel's experiment—at least in its preliminary stages—was a success. Strobel was able to cut down and burn his trees in the wake of the EPA investigation only because the bacterium with which he had



inoculated them had kept them alive. Had the experiment been a failure, there would have been no clump of trees for investigators to discover, and no evidence of Strobel's apparent crime. In what may be the ultimate irony of the sad story of the destruction wrought by Dutch Elm disease in this country, Strobel's trees, too, were arrested for resisting arrest.

Several months later Strobel was brought before the Senate to testify about his act of disobedience and about the new possibility of reform. It is impossible to read his testimony without getting a sense of his indignation. Here in a country where there are thousands of toxic waste dumps and where millions of tons of chemicals are dumped on American cropland every year in the name of better agriculture, a man had his work destroyed for trying to find a cure for Dutch Elm disease without a permit.

"Some of the scientific and technological problems that our nation faces are extremely difficult to handle," Strobel told the Senate. "On top of this we have imposed a sea of regulatory actions by a myriad of federal agencies with conflicting definitions. The entire effect is one that is absolutely impossible for a scientific researcher (especially one in a small business or academic institution) to comprehend and to follow on a regular basis.... As one who has suffered the consequences of this complex system I feel that the time has come for sweeping changes in how we think about biotechnology and how we regulate it."

iotech's regulatory problem is the B product of the extraordinary expectations that have been swirling around the industry since the first human gene was synthesized and cloned more than a decade ago. From the beginning, the highest of claims were made for the new powers that were suddenly at the disposal of scientists. This was a tool, the public was told, that would transform the world. By the time small start-up companies began to form in the early 1980s to exploit the new technologies, to discover new drugs, or to create new strains of agricultural crops, biotechnology was a magic word among investors. Random groups of biologists, thrown together by entrepreneurs without any clear idea about. what they would be producing or even when they could produce it, were able to raise millions from venture capitalists and millions more from the stock market entirely on the strength of the magical words genetic engineering.

At the same time the promises made on behalf of the new science attracted an active group of critics, regulators, environmentalists, and concerned citizens

who saw in the claims made for biotechnology a series of unanswered questions: How safe is it to introduce genetically improved, manmade organisms into an environment that has evolved over millions of years? And if this new science will someday have an impact on all of society, then shouldn't all of society have a say in how it is developed?

These questions were raised perhaps most famously in Cambridge, Massachusetts in the spring of 1976, when the city council took the scientists at Harvard University to task for conducting some of the pioneering experiments in genetic engineering without first informing the community. "This is a serious matter," said Cambridge mayor Alfred Velluci at the time. "If worse comes to worst, we could have a major disaster on our hands." Velluci, a populist type who once proposed solving the Cambridge parking problem by paving over Harvard Yard, made repeated references to Frankenstein during the debate, as a way of expressing his fears over the possible outcome of experiments then underway in the Harvard biology department to clone the human gene for insulin.

There is nothing wrong with the questions that Velluci and many since his time have raised in response to the biotechnology revolution. The problem is that the revolution itself isn't really a revolution at all, and that the claims that many of the new technology's critics have responded to have had more in common with the industry's press releases than with reality. This isn't to say that someday the ability to take natural substances, to copy them, or to manipulate their genetic makeup, or even to create new life forms entirely, won't profoundly alter American society and require stringent oversight to protect the public from undue environmental risk. But for the moment much of the furor over biotech is over a technological straw man.

I n the area of drug research, for example, biotech's big breakthrough has been to use the body as a pharmacy, locating natural human proteins with therapeutic value, cloning them, and then re-introducing them to the body as drugs. The first human protein to be identified and cloned was insulin, which was then re-administered to diabetics. But insulin cloned from humans has turned out to be only marginally more effective-and slightly more expensive-than the purified pig's insulin that had been given to diabetics previously. The same is true for TPA, another of the early biotech products, a natural anti-blood clot protein that has been copied for use in unplugging blocked arteries in heart attack victims. Billed as biotech's first blockbuster drug, TPA is in fact only slightly better and much more expensive than traditional chemical remedies for heart attacks. Other promising cloned proteins are more cost effective than insulin or TPA, but few—at this point anyway—are the miracle drugs that genetic engineering was to bring to the benefit of Americans.

In the area of agriculture, biotechnology probably will bring dramatic changes-bigger and more productive farm animals, more effective and environmentally sound pesticides, improved crop strains with larger yields. But on closer examination, the socalled agricultural revolution is no more a revolution than biotech's entry into the pharmaceutical world. In most cases, for example, the organisms being created and cloned are actually only mild variations of micro-organisms that already exist in the environment. Strobel's Dutch Elm disease vaccine was a bacterium found on various leaves around the world and modified so that it could be injected into elm saplings. A number of biotech firms have begun experiments attempting to protect corn plants from their biggest pest-a caterpillar known as the European corn borer-using modified versions of a bacterium that is already used in another form as a pesticide. Even the much ballyhooed bacterium sprayed on the California strawberry field is of a family of bacteria that have been protecting plants from frost for millions of years.

To be sure, the variations created by genetic engineering on these familiar micro-organisms are entirely new. But many scientists stress that what is new isn't necessarily harmful, although it may raise a series of legitimate and sometimes difficult questions. According to principles developed by Harvard's Bernard Davis, genetically engineered micro-organisms (GEMs), like domesticated farm species, are not particularly apt to outsurvive unmanipulated species already present in an environment. And because nature is already so diverse, GEMs will not likely add significant amounts of genetic variation to the environment.

Besides, isn't that what genetic engineers are attempting with plants and other living organisms—transferring the genes of one to another, modifying the structure of life forms to suit changing environmental conditions the same thing that has always been done by other means by scientists and farmers and indeed nature itself?

"The risks associated with the introduction of R-DNA engineered organisms are the same in kind as those associated with the introduction into the environment of unmodified organisms and organisms modified by other genetic techniques," a National Academy of Sciences panel stated in a white paper a year and a half ago.

Or, as one letter to a Cambridge newspaper on the Harvard debate put it: "We are amazed that anyone should express concern about the creation of a laboratory at Harvard to experiment with new life forms. A look around Harvard Square at nearly any time of day or night reveals life forms sufficiently grotesque to convince us it is already too late for such protest."

T he way the regulations governing biotech tests currently stand, companies and researchers must apply to the EPA first for permission to conduct a small scale, one- or two-acre experiment. And then, if that test is judged to have been ecologically acceptable—not threatening the existing eco-system or spreading beyond the target site—the EPA grants a permit for a full-scale experiment. Along the way, if their bacterium is classified by the U.S. Department of Agriculture as a "genetically engineered plant pest," they would have to get approval from that agency, as well as inform the National Institutes of Health of their activity.

To date, the biotech community has faced most of its difficulty in passing the first step of this review process. While chemical companies have for years been able to test their pesticide prototypes without government approval, two of the early proposals for tests of genetically engineered bacteria were rejected by the EPA, despite what the industry said was overwhelming evidence of the tests' safety. One biotech firm in Maryland, Crop Genetics International, was so nervous about how its applications for testing a bio-engineered corn pesticide would be treated by the authorities that it spent close to \$8 million conducting safety tests and signed former EPA Chief William Ruckelshaus, eminence

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grise Elliot Richardson, and Bush adviser Robert Teeter to a special "Committee on Social Responsibility" to convince federal regulators of their commitment to playing by the rules.

To be fair, the situation can only improve. Crop Genetics and Advanced Genetics Sciences and the other biotech firms, in requesting permission to test, so far have been pioneers, presenting the EPA with an entirely new set of questions and problems. They have had to do more than their successors will. As well, it was not until last summer that the National Academy of Sciences and the Congressional Office of Technology Assessment weighed in with reports downplaying some of the concerns that had inhibited the EPA. The OTA was particularly blunt: "None of the small-scale field tests proposed or probable within the next several years are likely to result in an environmental problem that would be widespread or difficult to control.... Small-scale field tests are likely to be the only way potential risks from commercial-scale uses of genetically engineered organisms can be evaluated."

Even the EPA itself has now suggested that at some time in the near future, the go-ahead for field tests should be given entirely by communitybased bio-safety committees, instead of being reviewed centrally by the EPA office in Washington.

Still, it is not clear that the problems that have surrounded biotech regulations are entirely over. Even as the EPA was suggesting that some oversight responsibility be delegated to local safety committees last summer, they were also drafting a new set of strict regulations covering a different category of tests involving the use of genetically engineered micro-organisms under the Toxic Substances Review Act.

What the EPA proposed was that federal oversight be extended to categories of commercial and industrial uses of micro-organisms that had not previously been covered by regulations. In some cases the proposals suggested that scientists conducting tests be required to answer no less than thirty-five questions to the satisfaction of the EPA before being permitted to go ahead with research. The rules are still under discussion and in fact prompted a fierce summer-long battle between the EPA and opponents of the rules throughout the federal bureaucracy, who claimed that the EPA was attempting to extend regulations to cover work that did not even remotely pose any safety or environmental threats.

What this says about the state of biotech regulation, however, is already painfully clear. "EPA's regulatory approach is at odds with the philosophy adopted by the FDA, USDA, National Science Foundation, and National Institutes of Health, as well as the government's position at the OECD [Organization of Economic Coordination and Development]," one of the industry's trade associations said in a statement last summer. Not even the government itself can decide what kind of risk is posed to the environment by genetic engineering.

T here are other issues that continue to plague the biotech industry. For example, the OTA and some federal authorities have given their genetically engineered pesticides match up against chemicals that contaminate groundwater and lay waste to lab rats.

But in this, the biotech industry has not always been successful. In a press release last spring, for example, Crop Genetics International, the Maryland company with a new idea for protecting corn from caterpillar infestation, pointed out that one of the advantages of a genetically engineered corn pesticide was that the chemical currently used to protect corn from caterpillars has the unintended side effect of killing 2.5 million birds annually,

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blessing to small-scale experiments. But how will regulators react when a biotech firm wants to jump from a relatively innocuous one-acre test to an experiment covering several hundred acres? And is throwing responsibility for approving tests to community-based safety committees really an advance? Some industry officials worry that this would simply make regulation more capricious, with parts of the country less convinced of the merits of biotechnology and making life worse for the industry than it was under the previous system. What would happen, after all, if Mayor Velluci and his visions of Frankenstein were on a local bio-safety committee?

The solution for biotechnology obviously must lie with more careful collection of data and gradual lifting of the regulatory umbrella as the risks become better known. There must also be a careful assessment of how the risks involved with biotechnology compare with the risks inherent in the methods and technology it replaces, how among them the endangered bald eagle.

There was nothing untruthful about the CGI press release. At worst it was impolitic, pointing out an uncomfortable truth about the environmental toll that chemically based agriculture takes on the environment. But when word of the release came back to CGI's heavyweight panel on social responsibility, Ruckelshaus and three others on the committee quit, along with the company's lawyer. There were rumors subsequently that the company that makes the pesticide had put pressure on Crop Genetics, and that some members of the committee had important ties to the chemical industry they wished to protect. But the gist of the whole affair was always crystal clear. Like so many others who have weighed in on the biotech debate over the past few years, Ruckelshaus and company's sense of social responsibility extended to making biotech safe for the world. It did not extend to making the world safe for birds.



here are other areas, beyond the L question of releasing genetically engineered organisms, where the regulation of biotechnology has appeared to turn more on emotional and political issues than on an accurate perception of risk. When the U.S. Patent Office in early 1988 first granted a patent for a genetically altered animal, the decision raised a storm of protest and calls for a moratorium on animal patents from some religious leaders, legislators, and biotechnology's traditional critics in the environmental community. But the rational connection between the group's disquiet over animal research and their calls for a patent moratorium was never clear. A patent, after all, is simply one of a number of legal tools an inventor can use to protect the fruits of his labor. Without patents, the industry made clear, the commercialization of animal research would simply go forward by other means: technological advances once made public would be kept as trade secrets, or buyers would be bound by legal contracts to respect intellectual property that the patent law would not. In short, while the arguments made by biotech's critics about the unanswered moral questions raised by pressing forward with genetic research with animals may well be sound, the expression of that concern was not. The would-be regulator had missed the mark. The industry, though clad in a ridiculous space suit, was lumbering on.

The debate about biotechnology, as essayist Lewis Thomas wrote in the New England Journal of Medicine some years ago, "has become an emotional issue, with too many irretrievably lost tempers on both sides. It has lost the sound of a discussion of technological safety, and now begins to sound like something else, almost like a religious controversy..."

There is nothing especially unique about this kind of public policy debate in American life, of course. It is news to no one that the allocation of public resources often has less to do with maximizing the health and welfare of Americans than with responding to regulatory whims and imagined threats to health and safety. Still, with biotechnology, there seems to be a special imperative to decipher just where the true risk lies, and what it is the public deserves to be protected from. At the moment the stakes are simply strawberries that survive the nip of frost and a reprieve for the country's elm trees. But there may come a time when biotechnology moves beyond these early experiments to more profound manipulation of plant and animal life. What will happen then?

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KRISTALLNACHT REFLECTIONS

by L. H. Gann

F ifty years ago, on November 10, 1938, I stood with a crowd that watched the main synagogue in Mainz as it went up in flames. The world was upside down. Far from attending to their duties, German firefighters stood around the Temple, looking sheepishly and with obvious embarrassment at a conflagration they were not allowed to extinguish. Six weeks later, my brother and I left our native city. I only returned in 1945, this time wearing the uniform of a sergeant in a British regiment.

Kristallnacht, once for me a halfsuppressed private memory, became this past November a public occasion-covered by programs on public television, sermons, concerts, panel discussions, speeches, research projects. Few events in Germany's march toward barbarism have been better documented. Yet as I watched these television programs, they were curiously remote; they seemed to describe events in another country in another world. What was missing? I can only answer according to my own recollections. distorted through fading memories, and the perusal of many books and articles published many years thereafter.

Kristallnacht was a German, as well as a Jewish, catastrophe. This is how it seemed to that crowd of onlookers who stared in bewilderment at the burning Temple. Mainz, a middle-sized Rhinish town, was not of course typical of German cities at the time. Mainz was mainly Catholic. Those citizens who had not voted for the Catholic Center party in the last semi-free elections in 1933 had included many Social Democrats. Nazi voters had formed but a minority. Mainz had a reputation for tolerance. Certainly among the bystanders in Mainz who watched the Temple burn, there was no merriment. Far from it! It was terror by order from above. The crowd, as I remember it, was not only embarrassed but incredulous and filled with gloomy forebodings. "Their temples today-our

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churches tomorrow"; such seemed to me the prevalent mood.

For German Jews, of course, Kristallnacht was more than a tale of arson, arrests, suicides, and murder. It was the end of the world. Ten years earlier, it would not have occurred to the average German Jew or so-called non-Aryan (a person of partially Jewish descent, or a Jew converted to Christianity) that a person could not be, at the same time, a Jew and a German. Kristallnacht broke the link. My father was then in England. After Kristallnacht was over, it therefore fell to my mother, a trained lawyer, a stickler for law, order, and good governance, to surrender the sword that my father had gained as a combat officer in World War I-this in compliance with that never-ending flood of official ordinances specifically designed to make life hellish for Jews. The police officer who received the sword was as embarrassed and apologetic as my mother was distressed. But what could he do?

What could he do? What could they all do? I was later asked that question many times when I went to grammar school in England, and thereafter. Television programs nowadays are apt to give a mistaken impression of contemporary moods, and to read presentday sensitivities into another era. It was not true that the whole world stood horrified at what happened in Germany. Far from it. How often did I hear, in England, observations such as the following: "You refugees whine and snivel. But why did you not defend your freedom when you had a chance? Now you tell us hard-luck stories, and expect the British Army to do your fighting for you. The British Army has better things to do." Such remarks were addressed to me not only as a Jew but also as a German. I had no answer then. I have found none since.

W hat exactly perished at Kristallnacht? What perished was a specific culture that combined German with Jewish legacies, and made a considerable impact on German intellectual life. This culture has not been recreated. West Germany's Jewry, as reconstituted after World War II, has played but a small role. And what did the so-called German-Jewish symbiosis entail? The answer is not easy to give—except that the role therein of the



In addition, Germany in 1933 contained half a million Jews, registered as such by reason of their religious affiliation. In 1933 only about 12.5 percent made their living in the public services or the professions-and most of those in a quite modest capacity, as provincial lawyers, general medical practitioners, pharmacists, nurses, teachers, and suchlike. Nearly one quarter (23.1 percent) were artisans or industrial workers. Sixty-one-point-three percent were employed in commerce-a large percentage of them as owners of small stores, or as commercial travelers, accountants, bookkeepers.

Overall, these German Jewish businessmen-small or large-had a bad press, not merely from anti-Semites but also from some Jewish critics. Zionists deplored the Jews' preoccupation with commerce, and called for a "healthier" form of occupational stratification. Radicals, from Karl Marx to Kurt Tucholsky, jeered at the merchants as philistines and humbugs, or caricatured them (as Tucholsky did in his cartoon figure of Wendriner, a comic yet repulsive Stock Exchange Jew). Yet this Jewish bourgeoisie and petty bourgeoisie deserved a better hearing than they usually got. A critique of Tucholsky on Wendriner's part would certainly have been fun to read. Wendriner and his friends in the local Liedertafel (glee club), or Turnerschaft (gymnastic association), or veterans league, or Stammtisch (the table set aside for regulars in the local pub), were better integrated into German life, and altogether more cheerful, than the

