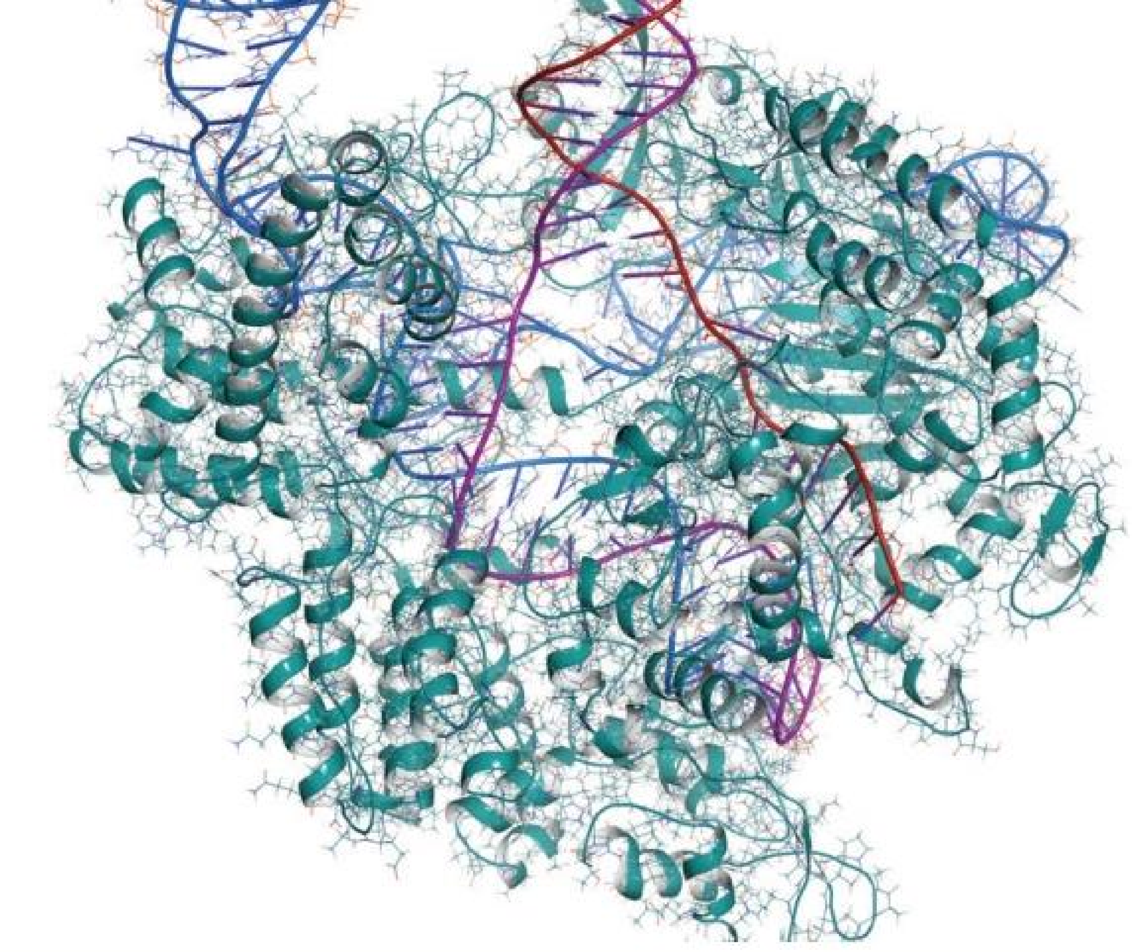

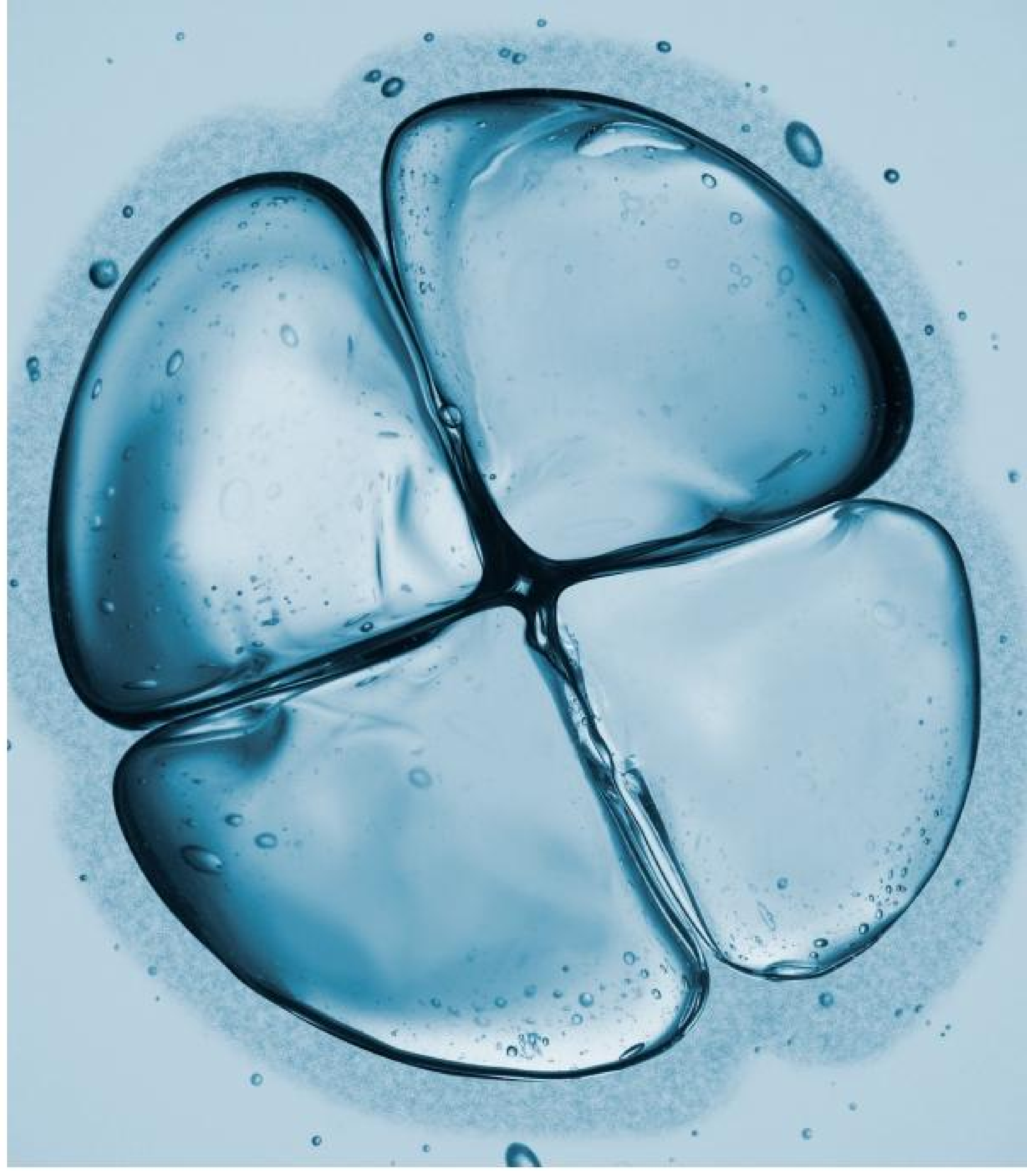

FOURTH EDITION

Introduction to Biotechnology

WILLIAM J. THIEMAN
MICHAEL A. PALLADINO

Introduction to

Biotechnology

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Introduction to **Biotechnology**

FOURTH EDITION

William J. Thieman

Ventura College, Emeritus

Michael A. Palladino

Monmouth University

Pearson

330 Hudson Street, NY NY 10013

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To my wife, Billye, the love of my life,
and to the hundreds of biotechnology graduates
now doing good science at biotechnology companies
and loving every minute of it.

W. J. T.

To my "Auntie Ro," Rosanne Hansen, who fostered in
me a love and passion for biology at an early age.

M. A. P.

About the Authors

Authors Michael Palladino and Bill Thieman

William J. Thieman taught biology at Ventura College for 40 years and biotechnology for 11 years before retiring from full-time teaching in 2005. He continues to serve as an advisor to the college biotechnology program. He received his B.A. in biology from California State University at Northridge in 1966 and his M.A. in Zoology in 1969 at UCLA. In 1995, he started the biotechnology program at Ventura College. In 1998, he added the laboratory skills course, and it was articulated as a state-approved vocational program. He identified technical skills needed for the program while serving three summer internships at Amgen, Biosource (now Invotrogen), and Biopool. The internships provided an opportunity to learn protocols, interact with lab directors, and query technicians, focusing on identifying the skills needed in these biotechnology companies. He routinely engaged his contacts at these biotechnology companies to lead lab protocols and describe their experiences to his classes.

Mr. Thieman has taught a broad range of undergraduate courses including general, human, and cancer biology. He received the Outstanding Teaching Award from the National Association of Biology Teachers in 1996 and the 1997 and 2000 Student Success Award from the California Community Colleges Chancellor's Office. The Economic Development Association presented its 1998 Program for Economic Development Award to the biotechnology training program at Ventura College for its work with local biotechnology companies. His success in acquiring grants to support the program was recognized at the 2007 Conference of the National Center for Resource Development.

Michael A. Palladino is Vice Provost for Graduate Studies, former Dean of the School of Science, and Professor of Biology at Monmouth University in West Long Branch, New Jersey. He received his B.S. in Biology from Trenton State College (now known as The College of New Jersey) in 1987 and his Ph.D. in Anatomy and Cell Biology from the University of Virginia in 1994.

Dr. Palladino has taught a wide range of courses including anatomy and physiology, biotechnology, cell and molecular biology, general biology, genetics, and endocrinology. He has received several awards for research and teaching, including the Distinguished Teacher Award from Monmouth University, the Caring Heart Award from the New Jersey Association for Biomedical Research, and the Young Andrologist Award from the American Society of Andrology. For more than 15 years he directed a laboratory of undergraduate student researchers supported by external funding from the National Institutes of Health, biopharma companies, and other agencies. He and his undergraduates studied molecular mechanisms involved in innate immunity and oxygen homeostasis of mammalian male reproductive organs.

Dr. Palladino started writing with Benjamin Cummings as a co-author of *BiologyLabs On-Line*, a series of Internet-based interactive laboratories for undergraduate students. He was Series Editor for the Benjamin Cummings *Special Topics in Biology* booklet series, and author of the first booklet in the series, *Understanding the Human Genome Project*. Dr. Palladino is a co-author on the writing team of W. S. Klug, M. R. Cummings, C. A. Spencer, and D. J. Killian for the textbooks *Concepts of Genetics* and *Essentials of Genetics*, both published by Pearson Education.

PREFACE

It is hard to imagine a more exciting time to be studying biotechnology. We began the preface with this statement in the first edition of *Introduction to Biotechnology* and this still holds true today. Advances are occurring at a dizzying pace, and biotechnology has made an impact on many aspects of our everyday lives. Now in its fourth edition, *Introduction to Biotechnology* remains the first biotechnology textbook written specifically for the diverse backgrounds of undergraduate students. Appropriate for students at both 2- and 4-year schools, *Introduction to Biotechnology* provides students with the tools for practical success in the biotechnology industry through its balanced coverage of a range of scientific disciplines, details on contemporary techniques and applications, the business of biotechnology, integration of ethical issues, coverage of important regulatory considerations, and career guidance.

Introduction to Biotechnology was designed with several major goals in mind. The text aims to provide:

- An engaging and easy-to-understand narrative that is appropriate for a diverse student audience with varying levels of scientific knowledge.
- Assistance to instructors teaching all major areas of biotechnology and help to students learning fundamental scientific concepts without overwhelming and excessive detail.
- An overview of historic applications while emphasizing modern, cutting-edge, and emerging areas of biotechnology.
- Insights on how biotechnology applications can provide some of the tools to solve important scientific and societal problems for the benefit of humankind and the environment.
- Inspiration for students to consider the many ethical issues associated with biotechnology.

Introduction to Biotechnology provides broad coverage of topics including cell and molecular biology, biochemistry, bioinformatics, genetics, genomics, proteomics, and others. We have striven to provide students with the tools and knowledge they need to understand varied and diverse areas of biotechnology.

In our effort to introduce students to the cutting-edge techniques and applications of biotechnology, we have dedicated specific chapters to constantly emerging areas such as microbial biotechnology (Chapter 5), agricultural biotechnology (Chapter 6), animal biotechnology (Chapter 7), forensic biotechnology (Chapter 8), bioremediation (Chapter 9), aquatic biotechnology (Chapter 10), and medical biotechnology (Chapter 11). Consideration of the many regulatory agencies and issues that affect the biotechnology industry are discussed in Chapter 12. In addition to the ethical issues included in each chapter as **You Decide** boxes, a separate chapter (Chapter 13) is dedicated to ethics and biotechnology.

New to the Fourth Edition

The fourth edition of *Introduction to Biotechnology* is thoroughly updated and includes several new features:

- **Case Studies—**New to this edition, each end-of-chapter question set, except for chapter 1, now concludes with a Case Study. We present an example of interesting, current research or a recent discovery related to the chapter content, provide a brief summary, and ask students to consider relevant questions. Two goals of the feature are (1) to engage students with contemporary research and (2) to ask higher order questions that require students to think critically.
- Expanded sets of end-of-chapter **Questions & Activities**, including more Internet-based exercises. Each chapter now has 20 Questions & Activities to provide a broader range of assessment options to help students learn.
- New **You Decide** entries have been added to stimulate student interest in, and critical thinking about, controversial areas of biotechnology related to legal, ethical, and social issues. We have expanded from 29 to 37 total You Decide boxes integrated throughout the chapters. Eighteen are new, and they cover topics such as the labeling

of genetically modified foods (Chapter 6), genetic screening to improve breast cancer prevention (Chapter 8), human consumption of transgenic salmon (Chapter 10), human embryo and germline editing (Chapter 11), potential FDA regulation of homeopathic remedies (Chapter 12), and potential fast track approval of genetically modified wheat to help humans suffering from gluten intolerance (Chapter 13).

- **Nearly 70 new figures and 40 new photos** help simplify and explain complex topics in biotechnology.
- **Career Profiles**—New profiles have been developed for all chapters and contributed by professionals working in biotechnology. These profiles are designed to help students appreciate the wide range of careers available in the biotechnology industry, with tips and perspectives from experts doing the work. Career Profiles are available at the Companion Website where we can keep information up to date. Each profile includes a photo and background of the individual to help personalize his or her career stories.

In addition, each chapter has been thoroughly revised and updated to provide students with current information in all areas of biotechnology. Of special note are the following changes:

- **Chapter 1: The Biotechnology Century and Its Workforce**. Includes an updated overview of key topics to be discussed in the book, organized by chapter; the current state and trends of the biotechnology industry and its workforce; biotechnology and pharmaceutical company revenues; funding sources for starting a biotechnology company; trends in drug development; and a brief future example of precision medicine. We have added new coverage of Do-It-Yourself biotechnology, an introduction to industrial biotechnology, an introduction to genome editing by CRISPR; and several new figures.
- **Chapter 2: An Introduction to Genes and Genomes.** Includes streamlined content, a new section on noncoding RNAs, and a new section titled "Immune Response Mechanism in Prokaryotes Results in Extraordinary New Technology for Editing Genes *In Vitro* and *In Vivo*," which provides an introduction to genome editing by CRISPR-Cas and its roles in biotechnology.
- **Chapter 3: Recombinant DNA Technology and Genomics**. Includes condensed content on different types of vectors, as well as streamlined or eliminated coverage of libraries, mapping, Southern blotting, and microarrays reflecting a shift from these technologies and increased use of sequencing and other applications. Updated content on the Human Genome Project includes restructured content on "After the Human Genome Project," which focuses on ENCODE and personal genomics, whole exome sequencing, and single-cell sequencing. Major content updates have been made to DNA sequencing technologies, including a new section and figure on "third-generation sequencing." Additional new content includes RNA sequencing; analyzing gene function via protein expression, gene mutagenesis, and RNAi ; gene editing via transgenics, knockouts, and CRISPR; and a new section on systems biology and synthetic biology.
- **Chapter 4: Proteins as Products**. Explains why protein drugs produced by genetically engineered living organisms have largely supplanted pharmaceutical production methods; disease discoveries that have been made using new gene canceling technologies; instrumentation improvements for protein purification and identification; detection of significant protein-protein interactions; progress in identifying protein biomarkers that can detect disease at earlier stages; and the analysis of a contemporary study of protein interaction.
- **Chapter 5: Microbial Biotechnology**. Includes new content on whole genome sequencing; metagenomics and the Human Microbiome Project; vaccine development and major targets for new vaccines; synthetic genomes; and a new section on phage therapy, including a figure on CRISPR-Cas editing to treat antibiotic resistant microbes. In addition, there's a new You Decide box titled: "'Gain of Function' Experiments and Engineering Viral Pathogens."
- **Chapter 6: Plant Biotechnology**. Recognizes the impact of biotechnology on agricultural production in the world; briefly explains contemporary methods used to produce new plant products; discusses methods for using engineered gene vectors that can transfer genes for new products and insect resistance; provides a current list of genetically modified plants including their mechanism of action; discusses the expanding use of transgenic crops in developing countries; describes newly approved crops using gene silencing technology and the effect it has had on the USDA approval process; discuses the details of the new labeling of GM foods; and provides analysis of a contemporary study of an alternative method for insect resistance. There are two new You Decide boxes: "Labeling GM Foods" and "Is Roundup Toxic to the Environment?"

- **Chapter 7: Animal Biotechnology**. Includes a shift in direction from drugs to vaccines for humans of all ages and the rationale behind it; the significance of animal testing for drugs toward treatments for animal diseases; the benefits of cell-culture testing before animal testing for regulatory approval; the first approval of a drug produced in a transgenic goat to treat a type of stroke; new method for creating animals with gene knockouts and knock-ins; and the importance of a national project to determine the function of all the genes in a rat by using knockout technology. Two new You Decide boxes are included: "Can Gene Editing in Chickens Prevent Avian Flu Transfer to Humans?" and "Humans to Pets to Humans: Will the Public Accept This Type of Animal Testing?"
- **Chapter 8: DNA Fingerprinting and Forensic Analysis**. Includes the process for comparing DNA profiles with the new CODIS markers; the exclusion process for elimination of human suspects using profile examples; improvements in "touch DNA" analysis methods; the progress in utilizing personal DNA sequence markers as a precursor to diagnosis; new examples of DNA sequences to identify certified products; and the analysis of a contemporary example of human DNA contamination in a mouse DNA profile. Two new You Decide boxes are included: "Could Genetic Screening Improve Breast Cancer Prevention?" and "Will Rapid DNA Testing at a Crime Scene Help Law Enforcement?"
- **Chapter 9: Bioremediation**. Includes updated content on genomics and GM species for bioremediation, updates on the effects of bioremediation at the *Deepwater Horizon* oil spill in the Gulf of Mexico, new content and figure on endocrine disruptors, and a new section on ocean pollution by macro- and microplastics.
- **Chapter 10: Aquatic Biotechnology**. Includes new and revised content on aquaculture, coverage of the AquAdvantage salmon as the first GM animal approved by the U.S. FDA for human consumption, bioprospecting and recently approved novel medicines from aquatic species, a new Tools of the Trade on eDNA and environmental monitoring, and a new You Decide box: "Transgenic Salmon for Human Consumption: Safe or Not?"
- **Chapter 11: Medical Biotechnology**. Because of the rapid pace of change and progress in this field, Medical Biotechnology has undergone the most significant revision of all the chapters in the book. This includes reorganized and revised content on detecting and diagnosing human disease conditions, including new content on biomarkers and cell-free DNA; prognostic and diagnostic genetic tests; updates on approaches for genetic testing, including a new section on sequence analysis of individual genomes that explores the impact of whole genome sequencing including exon sequencing, sequencing and screening fetal genes from the maternal bloodstream, and pre-conception testing; updates on personal genomics to include RNA sequencing and single-cell sequencing; and a new section and figure on genome-wide association analysis. The chapter includes a renamed and revised section, Precision Medicine and Biotechnology; new content on the Precision Medicine Initiative and examples of cutting edge approaches including nanomedicine; and a new section on immunotherapies, including recently approved FDA immunotherapies using CAR-T cells that have been highly successful. It also includes revised and new content on gene therapy approaches, including CRISPR-Cas and recent trials with therapeutic RNA; and new and updated content on regenerative medicine, including new sections on 3D bioprinting of tissues, engineered organoids and organs, and updates on stem cell technologies and regulations. Nine new figures accompany these changes along with two new You Decide boxes: "Genetics Testing: Destiny Tests?" and "Human Embryo and Germline Editing."
- **Chapter 12: Biotechnology Regulations.** Includes the USDA, EPA, and FDA regulations that pertain to biotechnology product approvals, and the USPTO regulations for patents; describes the impact that gene silencing has had on USDA approvals of genetically engineered products; describes the 21st Century Drug Act impact on the pace of drug approvals; includes progress on the use of T cell targeted drug products; compares the FDA and EMA approval process that affects genetically engineered drugs in these markets; describes patentability of gene sequences; and includes the analysis of a drug contamination event with the responsibilities of biotechnology companies and their employees. Two new You Decide boxes ask: "Should the FDA Regulate Homeopathic Remedies?" and "Will We See Fewer Blockbuster Drugs and More Biosimilars with New Patent Regulations?"
- **Chapter 13: Ethics and Biotechnology**. Includes reorganized content and an abbreviated chapter format beginning with Examples of Ethics and Biotechnology that includes new content on mitochondrial replacement therapy and so called "three-parent babies." There is new information on genome editing and germline modification,

new content on ethical issues related to gene patents and CRISPR-Cas, and six new You Decide boxes: "Should GM Wheat (for Gluten Sufferers) Be Approved Quickly?," "What Would Be the Effect of Banning GM Organisms?," "How Much Return on the Investment?," "Animal Organ Acceptance," "Regenerative Medicine: For the Rich Only?," and "Genome Hackers and 'Anonymous' Genomes Identify Individual DNA Donors."

Returning Features

Introduction to Biotechnology is specifically designed to provide several key elements that will help students enjoy learning about biotechnology and prepare them for a career in biotechnology.

Learning Objectives

Each chapter begins with a short list of learning objectives presenting key concepts that students should understand after studying the chapter.

Abundant Illustrations

Approximately 200 figures and photographs provide comprehensive coverage to support chapter content. Illustrations, instructional diagrams, tables, and flowcharts present step-by-step explanations that give students visual help to learn about the laboratory techniques and complex processes that are important in biotechnology. The new edition is enhanced by nearly 70 new figures and 40 new photos.

- **Forecasting the Future** at the beginning of each chapter briefly highlights exciting new areas of biotechnology that the authors predict will be worth watching in the future.
- **Making a Difference** at the end of each chapter spotlights particularly beneficial aspects of biotechnology applications that have had major impacts in improving the quality of life.

Career Profiles

A favorite feature of *Introduction to Biotechnology*, Career Profiles introduce students to different job options and career paths in the biotechnology industry and provide tips and information on job functions, salaries, guidance for preparing to enter the workforce, and other resources. New Career Profiles were written by different experts currently working in the biotechnology industry. For the fourth edition, all Career Profiles have moved from the book to the Companion Website where we can update profiles to provide current content and link to other relevant career resources. We strongly encourage students to refer to these profiles if they are interested in learning more about careers in the industry.

You Decide

From genetically modified foods to stem cell research, there are an endless number of topics in biotechnology that provoke strong ethical, legal, and social questions and dilemmas. **You Decide** boxes stimulate discussion in each chapter by presenting students with information that relates to the social and ethical implications of biotechnology, followed by a set of questions for them to consider. The goal of these boxes is to help them understand *how* to consider ethical issues and to formulate their own informed decisions. There are 37 You Decides integrated throughout the chapters, 18 of which are new to the fourth edition.

Tools of the Trade

Biotechnology is based on the application of various laboratory techniques or tools in molecular biology, biochemistry, bioinformatics, genetics, mathematics, engineering, computer science, chemistry, and other disciplines. **Tools of the Trade** boxes in selected chapters present modern or historically important techniques and technologies related to chapter content to help students learn about the techniques and laboratory methods that are the essence of biotechnology.

Questions & Activities

Questions are included at the conclusion of each chapter to reinforce student understanding of concepts. For the fourth edition, we expanded each chapter's question set to at least 20 questions and activities. We updated existing questions, added many new ones, and added Case Studies. Activities frequently include Internet assignments that ask students to explore a cutting-edge topic. Answers to these questions are provided in Appendix 1 at the end of the text.

Glossary

Like any technical discipline, biotechnology has a lexicon of terms and definitions that are routinely used in discussing processes, concepts, and applications. The most important terms are shown in **boldface type** throughout the book and are defined as they appear in the text. Definitions of these key terms are included in a glossary at the end of the book.

Supplemental Learning Aids

Introduction to Biotechnology **Companion Website** (**www.pearsonhighered.com/biotechnology**)

The Companion Website is designed to help students study for their exams and deepen their understanding of biotechnology. Each chapter contains learning objectives, quiz questions, flashcards, study tools, Internet and literature references, and biotech career information. For the fourth edition, **Career Profiles** have moved from the book to the website, providing engaging descriptions of various careers written by professionals working in the biotechnology industry.

Instructor Resource Center (IRC)

The Instructor Resource Center, **www.pearsonhighered.com/educator**, is designed to support instructors teaching biotechnology. The IRC is an online resource that supports and augments material in the textbook. Revised instructor supplements available for download include:

- **Computerized Test Bank:** 10 to 20 multiple-choice test questions per chapter
- **JPEG Art Files:** electronic files of all text tables, line drawings, and photos
- **PowerPoint Lecture Outlines:** a set of PowerPoint presentations consisting of lecture outlines for each chapter augmented by key text illustrations

Instructors using *Introduction to Biotechnology* can create a user account to access the Instructor Resource Center.

Acknowledgments

A textbook is the collaborative result of hard work by many dedicated individuals, including students, colleagues, editors and editorial staff, graphics experts, and many others. First, we thank our family and friends for their support and encouragement while we spent countless hours on this project. Completing each new edition brings with it a great sense of accomplishment, and a certain degree of fatigue, overshadowed by the passion we have for helping faculty teach and students learn biotechnology. Without your understanding and patience, this book would not have been possible.

We gratefully acknowledge the help of many talented people at Pearson Education, particularly the editorial staff. We thank Executive Acquisitions Editor Michael Gillespie, a pleasure to work with, and an enthusiastic champion for the project and the book's mission who provides key input and guidance for improving the text. We thank Content Producer Laura Perry for keeping us on schedule and for her attention to detail, patience, enthusiasm, editorial suggestions, and great energy for the project. Summer Giles, Editorial Assistant, helped secure and provide reviewer feedback, which is essential for writing a clear and current textbook. Margot Otway provided invaluable developmental editing and contributed greatly to the project.

We thank Production Supervisor Rose Kernan, Production Manager at Cenveo Publisher Services, for ably and calmly guiding us through the production process. We thank Artist Jim Atherton, Copy Editor Joanne Boehme, Proofreader Chris Feldman, and Indexer Maureen Johnson for their expert work in creating clear, accurate, and informative figures on complex topics. Jerilyn Bockorick delivered a fresh, innovative cover design and we appreciate her creativity as we worked through different design options.

Undergraduate students at Monmouth University read many drafts of the manuscript for each of the first three editions and critiqued art scraps for clarity and content. We thank former students in BY 201—Introduction to Biotechnology for their honest reviews, error finding, and suggestions from a student's perspective. Monmouth University students Fares Ani, April Baresi, Faith Blamon, Crystal Diaz, Briana Gayarum, Brad Henderson, Megan Hoges, Nikki Keefe, Andrew Langille, Mitchell E. Parker, Ashmi A. Patel, Priyal Patel, Stephanie Puwaslki, Joe Schuld, Danielle Trancucci, Ling Wong, and Biotechnology High School student Sanja Akula deserve special mention for making contributions to improving this edition. Our students inspire us to strive for better ways to teach and help them understand the wonders of biotechnology. We applaud you for your help in creating what we hope future students will deem to be a student-friendly textbook.

A special thank you is extended to our colleagues in a variety of areas of biotechnology who have contributed their time and expertise to develop new Career Profile entries for the website. These include Monmouth University alumni Carissa Maurin, Lawrence Perruzza, and Robert Sexton, together with Vicki Gaddy, Anne Mueller, Dean Pavlick, Richard Purcell, Daniel Rudolph, Joseph Saccente, Renee Tate, and Michiel Ultee, all outstanding professionals, highly knowledgeable and experienced in the biotechnology industry who share a passion for helping students, and gave generously of their time and expertise in contributing the Career Profiles for this edition. We are grateful to you for sharing your insights and tips to help students enter the biotechnology industry.

Finally, *Introduction to Biotechnology* has greatly benefited from the valued input of faculty colleagues who helped us in aiming for the highest levels of scientific accuracy, clarity, and pedagogical insight, offering suggestions for improvements in each chapter. The many faculty who have developed biotechnology courses and programs, and enthusiastically teach majors and nonmajors about biotechnology, provided reviews of the text and art that have been invaluable in shaping this textbook since its inception. Your constructive criticism helped us to revise drafts of each chapter, and your words of praise helped to inspire us to move ahead. All errors or omissions in the text are our responsibility. We thank you all and look forward to your continued feedback. We gratefully acknowledge your help. Reviewers of *Introduction to Biotechnology*, include:

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Brooke Yool *Ohlone College*
Mike Zeller *Iowa State University*

Whether you are a student or instructor, we invite your comments and suggestions for improving the next edition of *Introduction to Biotechnology*. Please write to us at the following addresses or contact us via e-mail at bc.feedback@pearson.com.

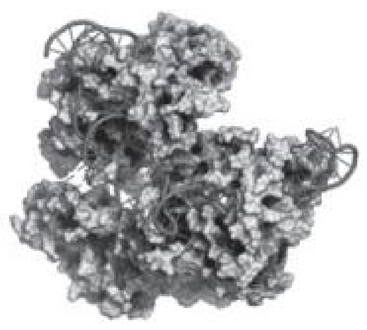
Bill Thieman
Ventura College
Department of Biology
4667 Telegraph
Ventura, CA 93003
BThieman@vcccd.edu

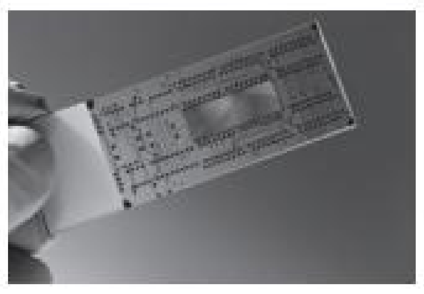
Michael Palladino
Monmouth University
Office of the Vice Provost
for Graduate Studies
400 Cedar Avenue
West Long Branch, NJ 07764
mpalladi@monmouth.edu
https://mpalladi.wixsite.com/michaelpalladino

As students ourselves, we too continue to learn about biotechnology every day. We wish you great success in your explorations of biotechnology!

W. J. T.
M. A. P.

Contents



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CHAPTER ONE

The Biotechnology Century and Its Workforce

As you will learn in this chapter, the biotechnology industry presents a wide range of exciting career opportunities for students from research scientist positions in the lab or the field to positions in sales, marketing, communications and other disciplines.

After completing this chapter, you should be able to:

- Define biotechnology and describe the many scientific disciplines that contribute to biotechnology.
- Provide examples of historic and current applications of biotechnology.
- Appreciate the range of different topics that constitute modern biotechnology and how these influence everyday life.
- Discuss how medical diagnosis is changing as a result of biotechnology and provide examples of how genome data are being used to diagnose and treat human disease conditions.
- Give an example of a new plant biotechnology crop that reached the market recently and have a basic understanding of the controversies associated with genetically modified organisms.
- Understand the basics of how a biotechnology company is started, funded, and valued, and describe the organizational structure of a typical biotech company.
- Describe career opportunities and options in biotechnology and ways to explore them.

Can you imagine a world free of diseases, where food is abundant for everyone and the environment is free of pollution? These scenarios are exactly what many people in the biotechnology industry envision as they dedicate their lives to this exciting science. This chapter was designed to provide you with a basic introduction to the incredible range of biotechnology topics that you will read about in this book. As you will see, biotechnology is a multidisciplinary science with great potential for future discoveries and many powerful applications and products.

In this chapter, we present a brief introduction and overview of many topics that we discuss in greater detail throughout the book. We begin by defining biotechnology and outlining scientific disciplines that contribute to this incredible field. We highlight both historic and modern applications and describe the different types of biotechnology that you will study in this book. At the end of the chapter, we discuss aspects of the biotechnology workforce and skills required to work in the industry.

FORECASTING THE FUTURE

The discovery and creation of new medicines is expensive and difficult. In the past 40 years, thousands of small biotech companies have attempted to prove that they can do this better and less expensively than traditional pharmaceutical companies. A review by the U.S. Food and Drug Administration (FDA) of high-priority drugs it approved from 1998 to 2012 shows that biotech companies brought the largest number of these drugs to market, and the biotech industry did this using only a fraction of the research and development money spent by the pharmaceutical industry. Specifically, pharmaceutical companies spent $5.67 billion per approved drug compared to $1.84 billion per drug by biotech companies. This kind of efficiency means biotechnology companies, and the approaches they use to develop drugs, will continue to appeal to researchers and investors.

1.1 What Is Biotechnology and What Does It Mean to You?

Have you ever eaten a nonbruising apple or potato, been treated with a monoclonal antibody, received tissue grown from embryonic stem cells, or seen a "knockout" mouse? Have you ever eaten a corn chip, sour cream, yogurt, or cheese; had a flu shot; known a person with diabetes who requires injections of insulin; taken a home pregnancy test; used an antibiotic to treat a bacterial infection; sipped a glass of wine or milk; or made bread (**Figure 1.1**)? Although you may not have experienced any of the scenarios on the first list, at least one of the items on the second list must be familiar to you. If so, you have experienced the benefits of biotechnology firsthand.

Biotechnology is broadly defined as the science of using living organisms, or the products of living organisms, for human benefit (or to benefit human surroundings)—that is, to make a product or solve a problem. Remember this definition. As you learn more about biotechnology, we will expand and refine this definition with historical examples and modern applications from everyday life and look ahead to the future of biotechnology.

You would be correct in thinking that biotechnology is a relatively new discipline that is only recently getting more attention; however, it may surprise you to know that biotechnology involves several ancient practices. As we discuss in the next section, old and new approaches to biotechnology make this field one of the most rapidly changing and exciting areas of science. It affects our everyday lives and will become even more important during this century—what some have called the "century of biotechnology."

A Brief History of Biotechnology

If you asked your friends and family to define biotechnology, their answers might surprise you. They may have no idea what biotechnology is. Perhaps they might speculate that biotechnology involves serious-looking scientists in white lab coats secretively carrying out sophisticated "cloning" experiments in expensive laboratories. When pressed for details, however, your friends probably will not be able to tell you how these "experiments" are done, what information is gained from such work, and how this knowledge can or cannot be used. Although DNA cloning, the genetic manipulation of organisms, and even cloning entire organisms are exciting modern-day techniques, biotechnology is not a new science. In fact, many applications represent old practices with new methodologies. Humans have been using other biological organisms for their benefit in many processes for several thousand years. Historical accounts have shown that the Chinese, Greeks, Romans, Babylonians, and Egyptians, among many others, have been involved in biotechnology since about 2000 B.C.

Biotechnology does not mean hunting and gathering animals and plants for food; however, the domestication of animals such as sheep and cattle for use as livestock is a classic example of biotechnology. Our early ancestors also took advantage of **microorganisms** and used **fermentation** to make breads, cheeses, yogurts, and alcoholic beverages such as beer and

(a)

(b)

FIGURE 1.1 Examples of Biotechnology are in Your Home (a) Kitchen biotechnology includes breads, cheeses, yogurts, and many other foods and drinks. These are common basic examples of biotechnology. (b) A much more sophisticated and less common example includes smartphones that monitor vital signs and blood chemistry such as blood sugar levels. Shown here is a smartphone and glucose meter application that can detect blood glucose levels in a test strip.

wine. These practices continue today. During fermentation, some strains of yeast decompose sugars to derive energy, and in the process they produce ethanol (alcohol) as a waste product. When bread dough is being made, yeast such as *Saccharomyces cerevisiae* (commonly called baker's yeast) is added to make the dough rise. This occurs because during fermentation yeast release carbon dioxide, which causes the dough to rise and creates holes in the bread. Alcohol produced by the yeast evaporates when the bread is cooked. If you make bread or pizza dough at home, you have probably added store-bought *S. cerevisiae* from an envelope or jar to your dough mix.

For thousands of years, humans have used selective breeding as a biotechnology application to improve production of crops and livestock used for food purposes. In **selective breeding,** organisms with desirable features are purposely mated to produce offspring with the same desirable characteristics. For example, cross-breeding plants that produce the largest, sweetest, and most tender ears of corn is a good way for farmers to maximize their land to produce the most desirable crops (**Figure 1.2a**).

Similar breeding techniques are used with farm animals, including turkeys (to breed birds producing the largest and most tender breast meat), cows, chickens, and pigs. Other examples include breeding wild species of plants, such as lettuces, strawberries, cabbage, and bananas, over many generations to produce modern plants that are cultivated for human consumption. Many of these approaches are really genetic applications of biotechnology. Without expensive labs, sophisticated equipment, PhD-trained scientists, and well-planned experiments, humans have been manipulating genetics for hundreds of years.

By selecting plants and animals with desirable characteristics, humans are choosing organisms with useful genes and taking advantage of their genetic potential for human benefit. As you will learn, zebrafish are important experimental **model organisms** (Figure 1.2b). Scientists at the Children's Hospital of Boston produced a transparent zebrafish named Casper. Casper was created by mating a zebrafish mutant that lacked reflective pigment with a zebrafish that lacked black pigment. Casper has also proven important for drug testing and *in vivo* (in the living organism) studies of stem cells and cancer. For example, to study how cancer cells spread, or **metastasize,** scientists injected fluorescent tumor cells into the fish's abdominal cavity and were able to track the migration of those cells to specific locations in the body.

(a)
(b)

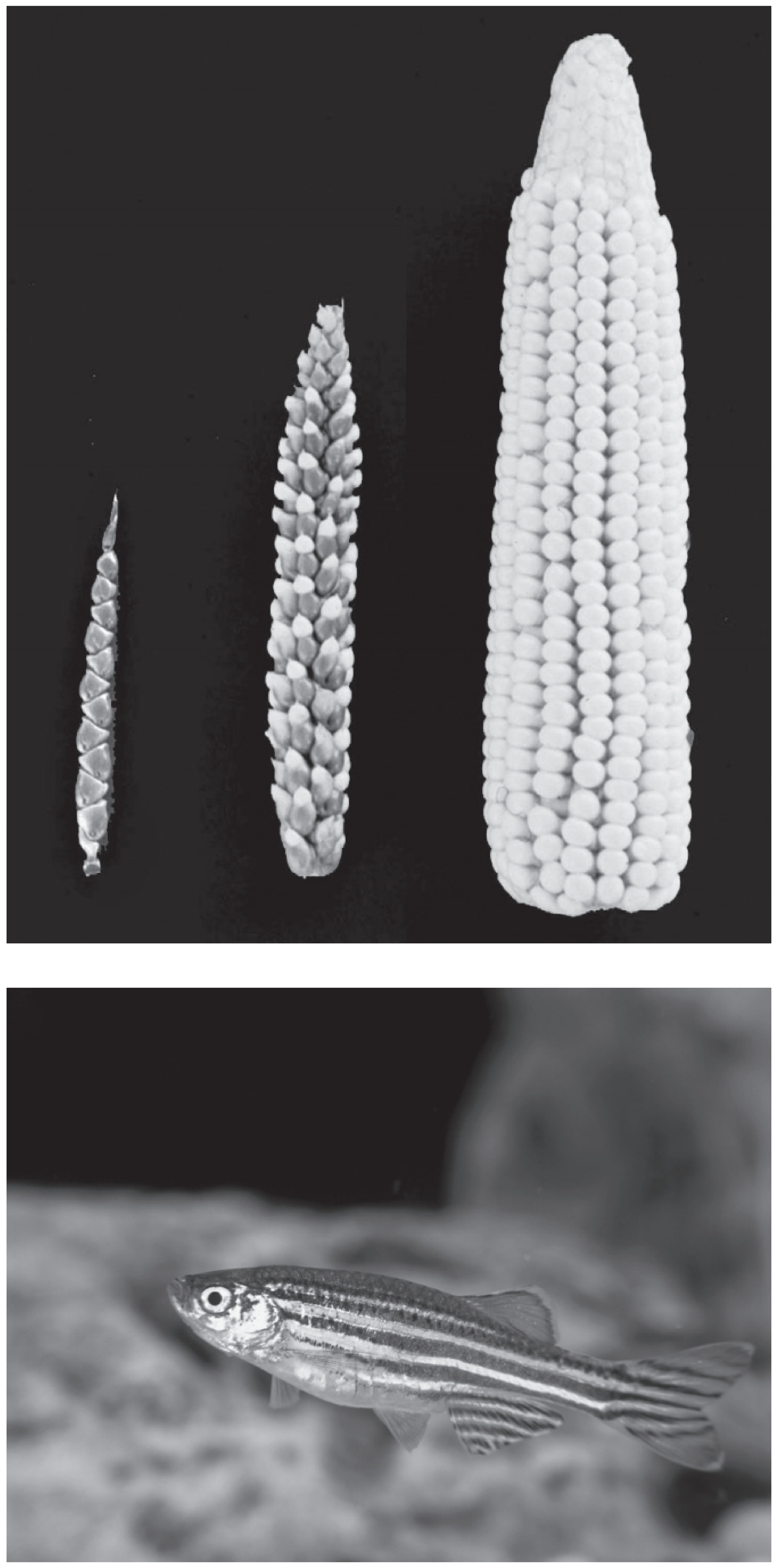

FIGURE 1.2 Selective Breeding Is an Old Example of Biotechnology That Is Still Common Today (a) Corn grown by selective breeding. From left to right is teosinte (*Zea canina*), selectively bred hybrids, and modern corn (*Zea mays*). (b) Zebrafish (*Danio rerio*).

One of the most commonly known applications of biotechnology is the use of **antibiotics,** substances produced by microorganisms that will inhibit the growth of other microorganisms. In the 1940s, penicillin became widely available for medicinal use to treat bacterial infections in humans. In the 1950s and 1960s, advances in biochemistry and cell biology made it possible to purify large amounts of antibiotics from many different strains of bacteria. **Batch (large-scale) processes**—in which scientists can grow bacteria and other cells in large amounts and harvest useful products in large batches—were developed to isolate commercially important molecules from microorganisms (explained further in Chapters 4 and 5).

Since the 1960s, rapid development of our understanding of genetics and molecular biology has led to exciting innovations and applications in biotechnology. As scientists unravelled the secrets of DNA structure and function, different laboratory technologies led to **gene cloning,** the ability to identify and reproduce a gene of interest, and **genetic engineering,** manipulating the DNA of an organism. Through genetic engineering, scientists are able to combine DNA from different sources. This process, called **recombinant DNA (rDNA) technology,** is used to produce hundreds of recombinant proteins of medical importance, including insulin, human growth hormone, and blood-clotting factors. From its inception, rDNA technology has dominated many areas of biotechnology and, as you will soon learn, many credit rDNA technology with starting modern biotechnology as an industry. You will learn that rDNA technology has led to hundreds of applications, including the development of disease-resistant plants, food crops that produce greater yields, crops engineered to be more nutritious, and genetically engineered bacteria capable of degrading environmental pollutants.

Gene cloning and rDNA technology have had a tremendous impact on human health through the identification of thousands of genes involved in human genetic diseases. Initiated in 1990 and completed in 2003, the **Human Genome Project** was the ultimate cloning project, and an international research effort with goals to identify and sequence all genes contained

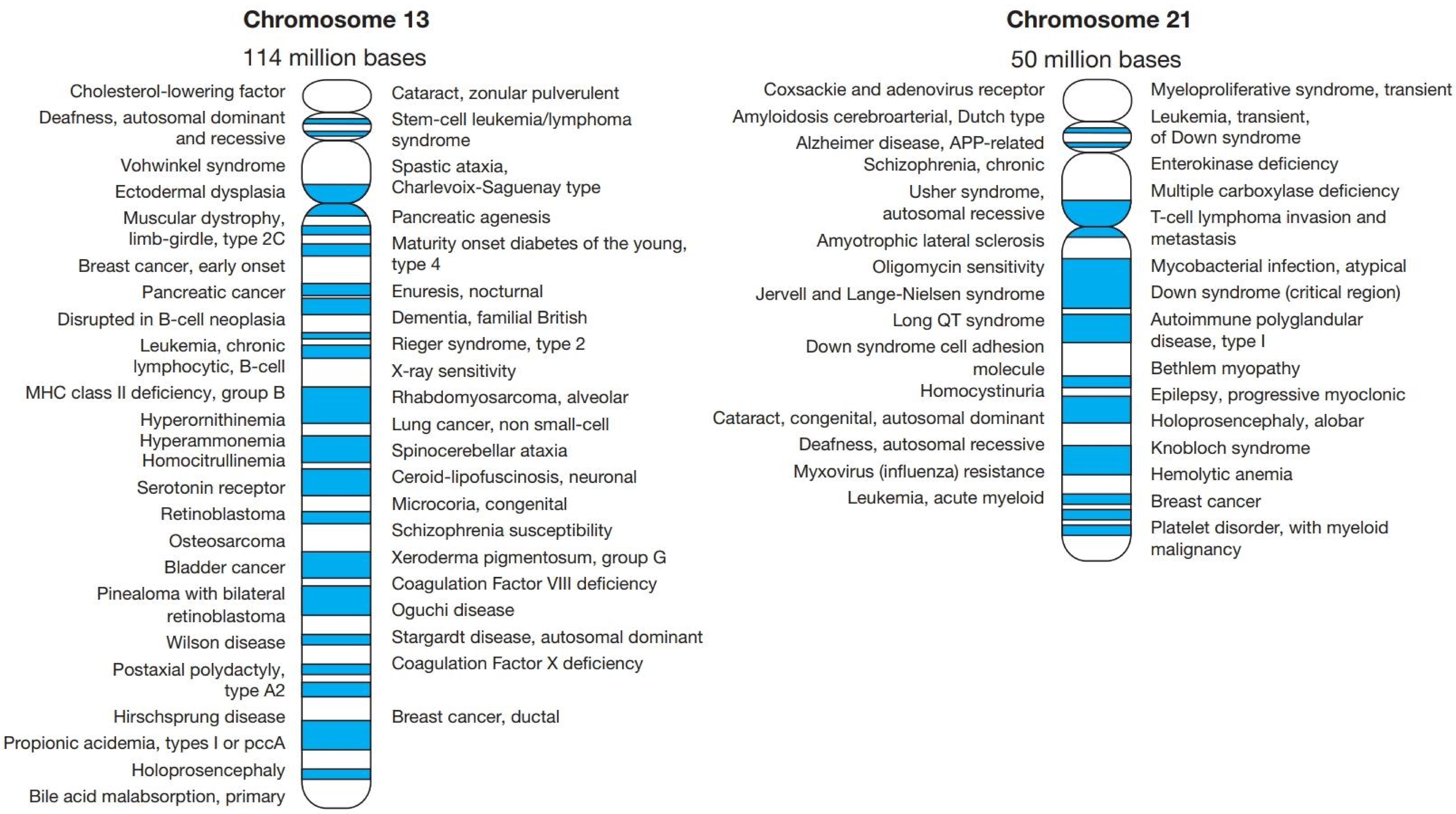

FIGURE 1.3 Gene Maps of Chromosomes 13 and 21 The Human Genome Project has led to the identification of nearly all human genes and has mapped their location on each chromosome. The maps of chromosomes 13 and 21 shown here display partial lists of genes known to be involved in human genetic diseases. Identifying such genes is an important first step toward developing treatments for many genetic diseases.

in the DNA of human cells (the **genome**) and to map gene locations to each of the 24 human chromosomes (chromosomes 1 to 22 and the X and Y chromosomes). The Human Genome Project has revealed the chromosomal location and sequence of every human gene, from genes that control normal cellular processes and determine characteristics such as hair color, eye color, height, and weight to the myriad of genes that cause human genetic diseases (**Figure 1.3**).

As you will learn, human genome data are now free and readily available in public databases. The Human Genome Project has significantly advanced the development of new diagnostic tools for detecting genetic diseases and molecular approaches for treating and curing human genetic diseases. As a result, new knowledge about human genetics is having, and will have, tremendous and wide-ranging effects on basic science and medicine now and in the near future.

The Human Genome Project ushered in an exciting new era of research in molecular biology and genetics known as **genomics** (the study of genomes), including the development of extraordinary new techniques for sequencing DNA. These techniques have made it possible to sequence the genomes of virtually any species and have resulted in the ability to sequence individual human genomes for a variety of reasons, from analyzing genetic ancestry to genetic testing and disease diagnosis. You will learn about creating **artificial** or **synthetic genomes** and the plans scientists have for these genomes. In addition, new approaches for **genome editing,** based on an exciting technology called **CRISPR-Cas,** is making it possible to correct genetic diseases and create novel genetic modification of genomes in many species—including humans. Throughout the book we extensively discuss these topics.

The Do-It-Yourself Biotechnology Movement

A movement under way called **do-it-yourself (DIY) biotechnology** moves biotechnology and related applications away from traditional research environments such as universities or established companies. The DIY movement encompasses individuals with many different backgrounds—from new doctoral students, to kitchen biologists with little formal training, to amateurs with an interest in tinkering, to entrepreneurs. Some have referred to DIY participants as "biohackers."

What DIY enthusiasts share in common is that more than 90 percent work in communal space, not garages or basements; they are mostly under 45 years old; and about 20 percent have earned a doctorate. DIY folks are not necessarily rogue, inexperienced amateurs.

DIY biotech is working much the way Apple cofounders Steve Jobs and Steve Wozniak did when they built their first circuit boards at home in their bedrooms and garages. Inexpensive instruments for amplifying DNA and diagnostic devices for detecting malaria have resulted from DIY biotechnology. However, whether any DIY discoveries will result that will have anywhere close to the impact of Apple on technology remains to be seen.

Some of the methods they are using are fairly routine now. For example, in most parts of the world you could do basic gene-cloning experiments in your kitchen. Not exactly DIY, but about 4 years ago a group of undergraduate students in a genome course at Johns Hopkins University announced they had made a synthetic version of yeast chromosome 3 incorporating only essential elements of the genome. We mention this as an example of how students with relatively little training can do this work.

DIY participants often seek crowdsource funding via online fundraising campaigns, rent space, seek equipment donations, or share lab space with others. Concern has been raised about DIY scientists working in unregulated ways and what may result from their "research." For instance, German authorities discovered pathogenic antibiotic-resistant bacteria in a CRISPR kit sent from California. The kit contained common gut microbes. German regulators declared the environmental risk of modifying these drug-resistant bacteria as insignificant but banned all such imports from the company Odin except to certified high-safety laboratories that have some governmental oversight.

Right now because there is no government funding for DIY biotechnology, participants can largely do whatever they want in an unregulated environment as long as their work is not illegal.

Biotechnology: A Science of Many Disciplines

One of the many challenges you will encounter as you study biotechnology will be piecing together complex information from different scientific disciplines. It is impossible to talk about biotechnology without considering important contributions of biology, chemistry, mathematics, computer science, and engineering, in addition to fields such as philosophy, ethics, and economics. Biotechnology is an expansive, *interdisciplinary* field. Later in this chapter, we consider how biotechnology provides a wealth of employment opportunities for people who have been trained in diverse fields.

Figure 1.4 provides a diagrammatic view of the many disciplines that contribute to biotechnology. Notice that the "roots" are primarily formed by work in the **basic sciences**—research into fundamental processes of living organisms at the biochemical, molecular, and genetic levels. Basic science research, with the help of other disciplines, can lead to genetic engineering approaches that form the core or trunk of many, but not all, biotechnology applications. At the top of the tree, biotechnology applications create products or processes to help humans or our living environment. Many future processes have yet to be developed and await the intuitive participation of people working in biotechnology today.

A simplified example of the interdisciplinary nature of biotechnology can be summarized as follows. At the basic science level, scientists conducting research in microbiology at a college, university, government agency, or public or private company may discover a gene or gene product in bacteria that shows promise as an agent for treating a disease condition. Typically, biochemical, molecular, and genetic techniques would be used to determine the role of this gene. This process also involves using computer science in sophisticated ways to study the sequence of a gene and analyze the structure of the protein produced by the gene, an example of a field called **bioinformatics**.

Once basic research has arrived at a detailed understanding of this gene, the gene may then be used in a variety of ways, including drug development, agricultural biotechnology, and environmental and aquatic applications (Figure 1.4). The many applications of biotechnology will become much clearer as we cover each area. At this point keep in mind the important concept that biotechnology is a science that requires skills from many disciplines.

Products of Modern Biotechnology

Throughout the book, we consider many cutting-edge and innovative products and applications of biotechnology. We look not only at products for human use but also at biotechnology applications of microbiology, marine biology, and plant biology, among other disciplines. More than 65 percent of biotechnology companies in the United States are involved in producing medicines for the treatment of human health conditions. Many of these medicines are **recombinant proteins** named because they are produced by gene-cloning/recombinant DNA techniques. For example, the majority of these proteins are produced from human genes inserted into bacteria to make the recombinant proteins used to treat human disease conditions. In 1982, the California biotechnology company Genentech, widely regarded as the world's first biotech company, received approval for recombinant

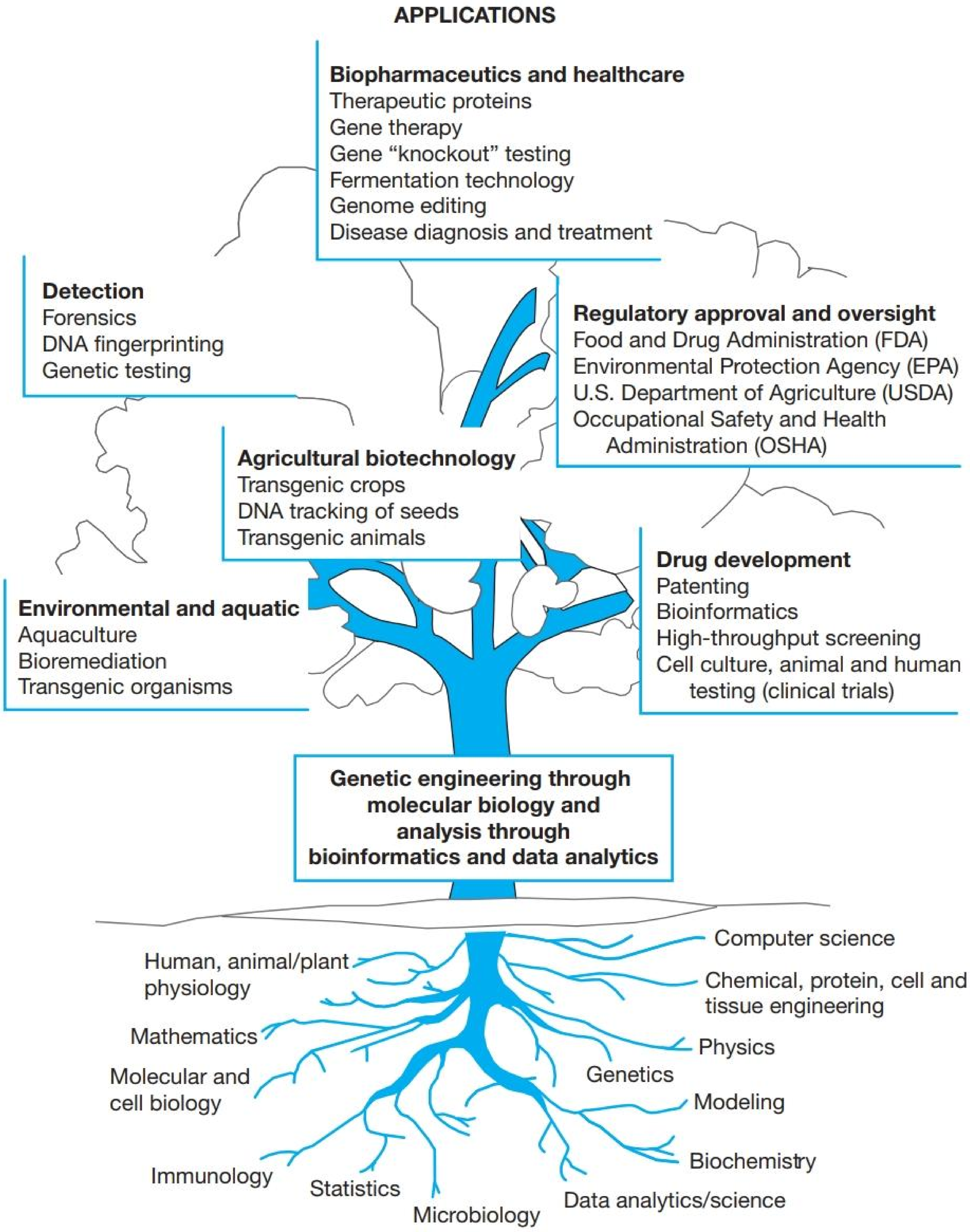

FIGURE 1.4 The Biotechnology Tree: Different Disciplines Contribute to Biotechnology The basic sciences are the foundation or "roots" of all aspects of biotechnology. The central focus or "trunk" for most biotechnological applications is genetic engineering. Branches of the tree represent different organisms, technologies, and applications that "stem" from genetic engineering and bioinformatics, central aspects of most biotechnological approaches. Regulation of biotechnology occurs through governmental agencies like the FDA, EPA, USDA, and OSHA (see Chapter 12).

insulin, used for the treatment of 3diabetes, as the first biotechnology product for human benefit (**Figure 1.5**). There are now several hundred drugs, vaccines, and diagnostics on the market, with more than 350 biotechnology medicines in development, targeting over 200 diseases.

Drug development by the biotechnology industry is focused on combating major diseases that affect humans, and over half of the new drugs in the development "pipeline" are designed to treat cancer. This focus of the industry is usually evident when reviewing types of new biotech drugs approved in the United States (a topic we discuss later in this chapter and throughout the book). For example, 2017 was a banner year for new biotech drug approvals with 46 novel drugs approved in the United States second only to 1996 when 53 biotech drugs were approved (**Figure 1.6**). As shown in Figure 1.6, cancer drugs received the most approvals.

Table 1.1 on the next page provides a brief list of some of the top-selling biotechnology drugs and the companies that developed them. Diagnosis and/or treatment of a variety of human diseases and disorders—including acquired immunodeficiency syndrome (AIDS), stroke, diabetes, and cancer—make up the bulk of biotechnology products on the market. Many of the most widely used products of biotechnology are recombinant proteins (Table 1.2, next page).

If Figure 1.6 and Tables 1.1 and 1.2 have not provided you with convincing examples of the importance of biotechnology for human health, consider that genes are being introduced increasingly into

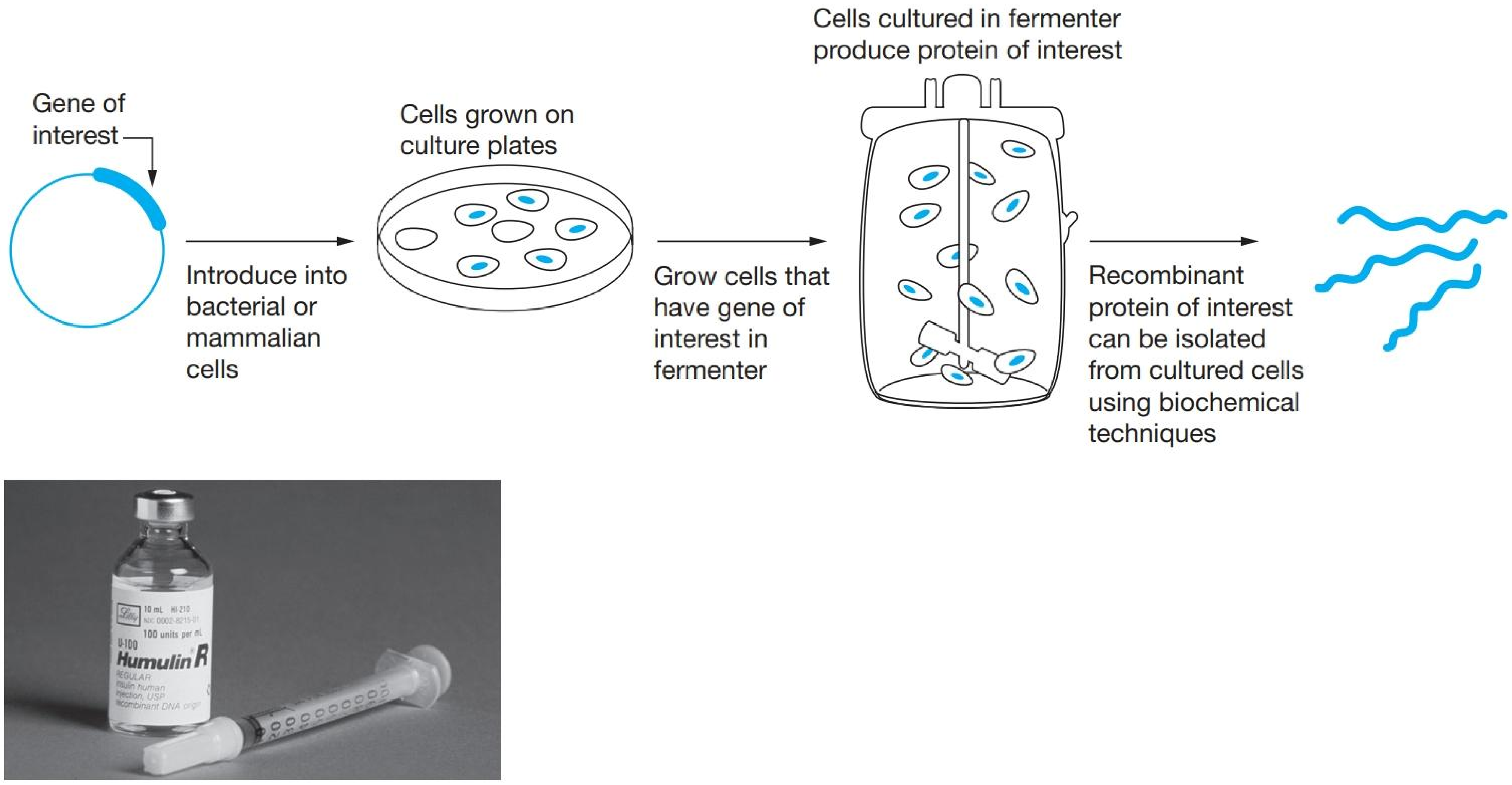

FIGURE 1.5 Using Genetically Modified Cultured Cells to Make a Protein of Interest Genes of interest can be introduced into bacterial or mammalian cells. Such cells can be grown using cell culture techniques. Recombinant proteins isolated from these cells are used in hundreds of different biotechnology applications. In this example, mammalian cells are shown, but this process is also commonly carried out using bacteria. The photograph shows a vial of human insulin produced by recombinant DNA technology.

human cells as **gene therapy** approaches are employed in attempts to treat and cure human disease conditions. Gene therapy involves delivering genes to treat or cure a genetic disorder. Genetics and tissue engineering may lead to the ability to grow organs for transplantation that would only rarely be rejected by their recipients. New biotechnology products from marine organisms are being used to treat cancers, strokes, and arthritis. There is no question that advances in modern medicine, driven by new knowledge from the Human Genome Project and biotechnology applications, will result in healthier lives and potentially increase the human life span.

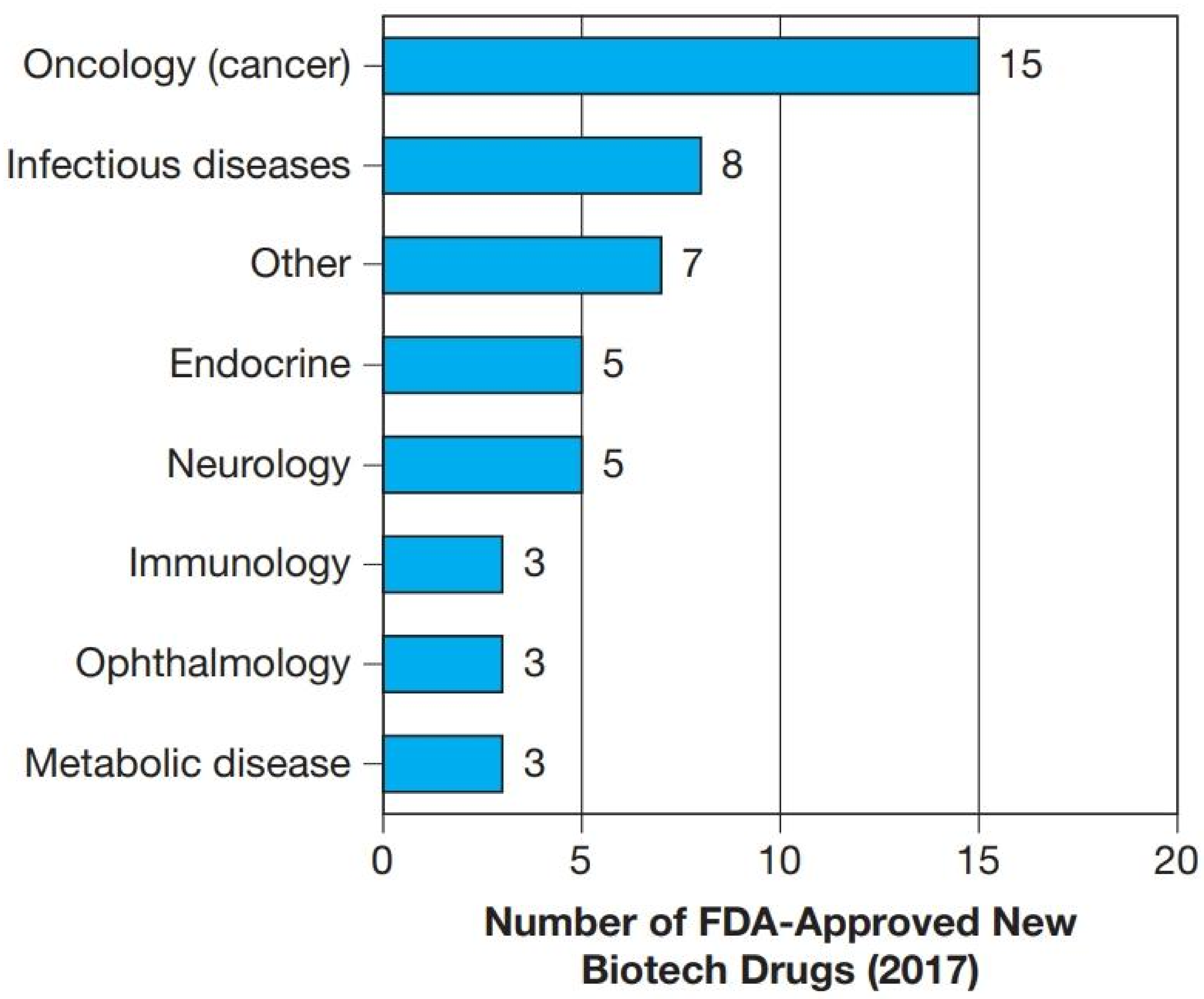

FIGURE 1.6 Investigational Biotechnology Drugs by Disease Category The production of drugs to combat cancer dominates the biotechnology industry's interest in treating human disease, with oncology-related research and treatment of infectious diseases such as the flu at the top of this list.

Ethics and Biotechnology

Just as in any other type of technology, the powerful applications and potential promise of biotechnology, including DIY experiments, raise many ethical concerns, and it should be no surprise to you that not everyone is a fan of biotechnology. A wide range of ethical, legal, and social implications of biotechnology inspire great debate and discussion among scientists, clergy, politicians, lawyers, and the general public (Figure 1.7). Throughout this book, we present ethical, legal, and social issues for you to consider.

Increasingly, you will be faced with ethical issues of biotechnology that may influence you directly. For instance, organism cloning in mammals such as sheep, cows, and monkeys has led some to suggest that human cloning should be permitted. How do you feel

TABLE 1.1 *2016—Top 10 Biotechnology Drugs (Each with Worldwide Sales over $5 Billion)

Drug Name	Developer	Drug Type	Function (Treatment of Human Disease Conditions)
Humira	AbbVie	Antibody (monoclonal)	Rheumatoid arthritis, Crohn's disease, Ulcerative colitis
Harvoni	Gilead Sciences	Small molecule	Hepatitis C
Rituxan	Roche	Antibody (monoclonal)	Non-Hodgkin's lymphoma
Revlimid	Celgene	Small molecule	Multiple myeloma
Avastin	Roche	Antibody (monoclonal)	Colorectal cancer; breast cancer; non–small cell lung cancer; ovarian, brain, and cervical cancer
Herceptin	Roche	Antibody (monoclonal)	Breast cancer, gastric cancer
Enbrel	Amgen	Recombinant protein	Rheumatoid arthritis, psoriasis
Prevnar 13	Pfizer	Vaccine	Pneumococcal (*Streptococcus Pneumoniae*) antibacterial vaccine
Lantus	Sanofi	Peptide	Diabetes mellitus types I and II
Neulasta	Amgen	Recombinant protein	Anemia (neutropenia/leukopenia)

*Data based on the most recent source available at the time of publication: Morrison C, Lähteenmäki R. Public biotech in 2016—the numbers. *Nat Biotechnol.* 2017;35:623–629.

about this? If, in the future, you and your spouse were unable to have children by any other means, would you want the opportunity to create a baby by cloning a replica of yourself? As another example, the potential for genome editing to create embryos with desired genetic characteristics has raised many ethically challenging questions.

If you choose to work in biotechnology, you will need to develop team working skills that allow for differences in opinion on many ethical issues, necessitating an understanding of the basis for the arguments supported by some of your colleagues. Look for the You Decide boxes in each chapter, in which we present scenarios or ethical dilemmas for you to consider. Realize that there are pros and cons and controversial issues associated with almost every application in biotechnology. Our goal is not to tell you *what* to think but to empower you with knowledge, and a framework for approaching ethical issues, that you can use to make your own decisions.

TABLE 1.2 Examples of Recombinant Proteins Manufactured from Cloned Genes

Product	Application
Blood Factor VIII (clotting factor)	Treat hemophilia
Epidermal growth factor	Stimulate antibody production in patients with immune system disorders
Growth hormone	Correct pituitary deficiencies and short stature in humans; other forms are used in cows to increase milk production
Insulin	Treat diabetes
Interferons	Treat cancer and viral infections
Interleukins	Treat cancer and stimulate antibody production
Monoclonal antibodies	Diagnose and treat a variety of diseases including arthritis and cancer
Tissue plasminogen activator	Treat heart attacks and stroke