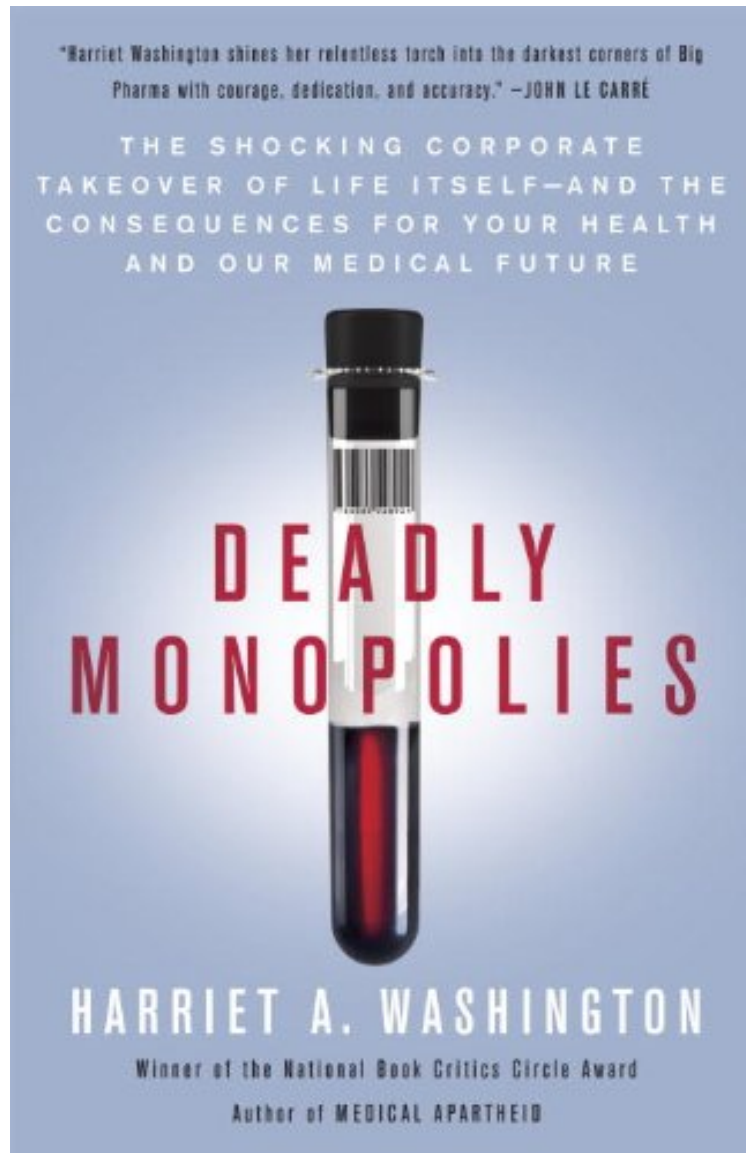


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Deadly Monopolies: The Shocking Corporate Takeover of Life Itself--And the Consequences for Your Health and Our Medical Future.

Harriet A. Washington

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Harriet A. Washington : Deadly Monopolies: The Shocking Corporate Takeover of Life Itself--And the Consequences for Your Health and Our Medical Future. before purchasing it in order to gage whether or not it would be worth my time, and all praised **Deadly Monopolies: The Shocking Corporate Takeover of Life Itself--And the Consequences for Your Health and Our Medical Future.**:

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I highly recommend this book be read by all functionally literate humans. I underlined and made so many notes in my copy of the book, it could not possibly be re-sold to anyone. A lot of what I read was "you don't say." However, when I read about presumed consent and how in most states it is legal to harvest your body and or organs without consent, had steam coming from my ears (figuratively, of course). I want choke a doctor and his/her co-conspirators.

From the award-winning author of *Medical Apartheid*, an expose of the rush to own and exploit the raw materials of life—including yours. Think your body is your own to control and dispose of as you wish? Think again. The United States Patent Office has granted at least 40,000 patents on genes controlling the most basic processes of human life, and more are pending. If you undergo surgery in many hospitals you must sign away ownership rights to your excised tissues, even if they turn out to have medical and fiscal value. Life itself is rapidly becoming a wholly owned subsidiary of the medical-industrial complex. *Deadly Monopolies* is a powerful, disturbing, and deeply researched book that illuminates this "life patent" gold rush and its harmful, and even lethal, consequences for public health. It examines the shaky legal, ethical, and social bases for Big Pharma's argument that such patents are necessary to protect their investments in new drugs and treatments, arguing that they instead stifle the research, competition, and innovation that can drive down costs and save lives. In opposing the commodification of the body, Harriet Washington provides a crucial human dimension to an often all-too-abstract debate. Like the bestseller *The Immortal Life of Henrietta Lacks*, *Deadly Monopolies* reveals in shocking detail just how far the profit motive has encroached in colonizing human life and compromising medical ethics. It is sure to stir debate and instigate change.
From the Hardcover edition.

Praise for *Deadly Monopolies*: "*Deadly Monopolies* explores contentious issues in modern biomedical research that have been aggravated by the field's commercial emphasis.... Though she is not the first to raise many of these concerns, Washington offers an overarching framework that enables readers to see connections that are often obscured. The book's brilliance lies in the compassionately told narratives of individuals whose lives have been affected by the increasing corporate control of scientific research. Rather than simply writing another book about biomedical wrongdoing, Washington with her journalistic approach provides a more humane account of the problems tied to the for-profit nature of today's research industry. In doing this, Washington accomplishes what has thus far escaped previous authors. She makes the case for a broader political consciousness of science and technology.... This is precisely the conversation an important book starts in order to challenge readers to see the world differently so that they connect the disparate dots. *Deadly Monopolies* is an extraordinary achievement in this and many other regards." —Osagie K. Obasogie, *The American Prospect*
"A searing look at the medical-industrial complex and its ability to patent genes and other biological products, resulting in an opportunistic and powerful pharmaceutical industry that often ignores the most pressing global-health issues in order to make a profit. National Book Critics Circle Award winner Washington (*Medical Apartheid: The Dark History of Medical Experimentation on Black Americans from Colonial Times to the Present*, 2007, etc.) begins with the controversial 1980 Bayh-Dole Act, which allowed the commercialization of medical inventions based on government-funded patents, including those on living things. As a result, an unprecedented collusion between universities, researchers and private pharmaceutical and biotechnology companies spawned an era in which many vital medicines are too expensive or inaccessible to average consumers, or rushed to market before being adequately tested. Despite the fact that taxpayers largely fund medical research and development, pharma companies include that cost in their purported expenses, therefore using disingenuous figures to justify the skyrocketing costs of patented drugs. The author adeptly details the wide-ranging repercussions of this monopolistic research model and recounts chilling anecdotes that reveal a pattern of shady practices by biotech and pharma companies. These firms often display a lack of respect for patients' rights in a ruthless pursuit of "blockbuster" drugs without regard for helping those who need it most. As of 2009, only 10 percent of the more than \$70 billion spent per year on medical research addresses diseases that cause 90 percent of the world's health burden. In addition, minorities and poor populations are often exploited for their genetic material yet not compensated for their contribution. Thousands of people die from preventable causes simply because it's not profitable to save them. The author clearly presents data to elucidate these complex issues, and cogently argues that there are opportunities to reinstate transparency, collaboration and altruism in drug development and disbursement. A gripping, revelatory account." —Kirkus (starred)
"Harriet Washington has written an important and compelling book. She shows how recent changes in patent law have caused drug prices to soar, while reducing innovation by drug companies to near-zero. Well-documented, yet highly readable, the book paints a vivid

picture of an industry that now exploits monopoly rights to patients' genes, and relies on taxpayer-funded NIH research for its few novel and important drugs— even as it turns out an endless stream of trivial variations of top-selling old drugs.” — Marcia Angell, M.D., author of *The Truth About the Drug Companies* and former editor of the *New England Journal of Medicine* — Harriet Washington shines her relentless torch into the darkest corners of Big Pharma with courage, dedication and accuracy. — John le Carre: “Big Pharma is not going to like *Deadly Monopolies* one bit, but you probably will— especially if, like most Americans, you’re finding the co-pay on your drugs too much to handle. Washington correctly reminds us that, as hard as high drug costs are in the USA, they are lethal for the world’s poor. Brava Harriet Washington!” — Laurie Garrett, Pulitzer Prize-winning writer and author of *I Heard the Sirens Scream: How Americans Responded to the 9/11 and Anthrax Attacks* — Patents, we’re repeatedly told, are crucial to fostering innovation. *Deadly Monopolies* reveals how the privatization of medical science is retarding research, putting patients at risk, and making what cures we have exorbitantly expensive. This book is a meticulously documented expose of what’s gone wrong with our medical innovation system, and a roadmap for change.” — Merrill Goozner, author of *The \$800 Million Pill: The Truth Behind The Cost of New Drugs* — Praise for Harriet A. Washington’s *Medical Apartheid*: “An important book. The disgraceful history it details is a reminder that people in power have always been capable of exploiting those they regard as ‘other.’” — *New York Times* — A fresh account of the Tuskegee study, including new information, lies at the center of Harriet A. Washington’s courageous and poignant book. Washington sheds light on how our understanding of what constitutes medical research requires broadening in the face of new developments in genetic science.” — *Washington Post Book World* — *Medical Apartheid* is fascinating and compelling . . . The book’s analysis challenges the reader to question established paradigms in the history of medicine.” — Dr. Marius Turda, Oxford Brookes University, in *Social History of Medicine* — Groundbreaking . . . Washington is a great storyteller, and in addition to giving us an abundance of information on ‘scientific racism,’ the book, even at its most distressing, is compulsively readable . . . Paints a powerful and disturbing portrait of medicine, race, sex, and the abuse of power.” — *Publishers Weekly* (starred review) — One of [Washington’s] goals in writing this book, aside from documenting a shameful past, is to convince [African Americans] that they must participate actively in therapeutic medical research . . . while remaining ever alert to possible abuses . . . Sweeping and powerful.” — *Kirkus* (starred review) — About the Author Harriet A. Washington is the author of *Medical Apartheid*, which won a National Book Critics Circle Award, the 2007 PEN Oakland Award, and the 2007 American Library Association Black Caucus Nonfiction Award. She has been a fellow in medical ethics at the Harvard Medical School, a senior research scholar at the National Center for Bioethics at Tuskegee University, a fellow at the Harvard School of Public Health, and the recipient of a John S. Knight Fellowship at Stanford University. Excerpt. copy; Reprinted by permission. All rights reserved. Chapter One A NEW LEASE ON LIFE: The Patent in American Medical Culture How does it feel to be patented? There was a sense of betrayal. I mean, they owned a part of me that I could never recover. I certainly have no objection to scientific research . . . but it was like a rape. In a sense, you’ve been violated, for dollars. My genetic essence is held captive. — John Moore, the subject of u.s. patent no. 4,438,032 In 1982, the mother of Japanese biotechnology scientist Dr. Heideaki Hagiwara was suffering from cervical cancer. 1 When he learned that Dr. Ivor Royston at the University of California at San Diego was developing cell lines to treat cancer, he asked to join the laboratory and, once there, convinced Royston to use tumor cells from Hagiwara's mother's lymphatic system to create a therapeutic cell line. A cell line is a community of cells, usually animal or human, that grows continuously in the laboratory, proliferating indefinitely under glass in precise, artificially maintained conditions, where it is used in research. In a warm living body, with its genius for homeostasis, every cell receives ample oxygen and nutrients in a dynamic environment tailored to its needs. But cells exiled to the cold, sterile prisons of unresponsive glassware tend to die quickly without the most assiduous coddling, although cancer cells live somewhat longer. Cell culture is the meticulous process by which optimal temperature, gas concentrations, and nutrients, which vary with the type of cell being cultured, are maintained, often with great difficulty. Carefully tended cell cultures boost medical research by providing living human material for risk-free testing of the effectiveness and safety of drugs. But cell cultures can also host viruses and other pathogens, permitting them to be prepared in quantity for the manufacture of vaccines. Polio, measles, mumps, rubella, and chickenpox viruses are currently produced in cell cultures. In the early twentieth century, Ross Granville Harrison of Johns Hopkins University established the technique of maintaining cells in vitro and dubbed it tissue culture. 2 Because cancer cell lines are somewhat more long-lived than those of “normal” human cells, many extant cell lines are derived from cancers. By the mid-1900s, cell cultures were commonly used in laboratories. 3 Some cell lines retain the characteristics of and produce substances that are peculiar to their cells of origin. Royston was working on a cell line that he hoped would treat cancers by producing antibodies that attack cancer cells. Hagiwara suggested that he use lymph cells from his sick mother, and Royston did so, fusing Hagiwara's mother's cells to the line. UCSD researchers soon agreed that this particular cell line possessed unique cancer-fighting properties, so Royston patented the promising cells. Hagiwara then returned to Japan, surreptitiously taking with him a sample of the cell line, which he used to treat his mother, who rallied but ultimately

succumbed to her cancer. Months later, Hagiwara gave the cell line to his father, Dr. Yoshide Hagiwara, who was also a biomedical researcher, for use in the family firm, the Hagiwara Institute of Health in Osaka. He claimed patent rights to the cell line and the antibodies it produced because it emanated from his mother's body, entitling his family, he said, to a financial interest in the cell lines. The U.S. Office of Technology Assessment disagreed and sued Hagiwara for taking the patented cells without permission.⁴ Hagiwara argued that despite the UCSD patent, the fact that the cell line had originated with his mother's tissues gave his family rights to the cells as well. Hagiwara won these rights in a 1983 settlement with the university that gave the Hagiwaras the sole license to the patent throughout Asia.⁵ Patented entities can be licensed in an exclusive or a nonexclusive manner, and they can be licensed for specific geographic regions, and even for specific uses.⁶ In this case, the Hagiwaras' agreement with UCSD permitted them to use the line in research, but not to license it commercially elsewhere. Twenty years later, another family affair was handled quite differently when FBI agents tracked down, arrested, and jailed Dr. Jiangyu Zhu, thirty, of China and Dr. Kayoko Kimbara, thirty-two, of Japan on June 19, 2002, in La Jolla, California. The married couple were former fellows of Harvard Medical School who had resigned to pursue new research positions. But their time at Harvard had been very fruitful: from November 1998 through September 1999, Kimbara identified two genes that block the action of calcineurin, an enzyme that signals the immune system to reject transplanted organs. This was a potentially lucrative discovery that could transform organ transplantation by leading to immunosuppressive drugs, medicines that drastically lower the risks of organ rejection. It also was a potential treatment for several diseases that affect the cardiovascular, immune, and nervous systems, which multiplied its commercial potential. Then, on October 22, 1999, Harvard filed a provisional patent on the two genes and their products. On December 13, 1999, Zhu and Kimbara accepted university research positions at the Institute of Biotechnology at the University of Texas, San Antonio, and when they left Harvard, they took some materials and notes with them, as researchers are wont to do. They were to begin on January 15, and by early January 2000 they shipped some additional materials from Harvard to their new lab. But the university's complaint says that in direct violation of the participation agreement signed by both Zhu and Kimbara, Zhu emailed Medical and Biological Laboratories of Nagoya, a biochemical company in Japan,⁷ indicating that he intended to collaborate with a researcher there to commercialize the antibodies suggested by his Harvard gene research after he left Boston. Harvard says that Zhu also sent three other genes to Japan without its knowledge. Harvard officials angrily accused Zhu and Kimbara of violating the terms of their agreement by sneaking into the lab in the wee hours to remove contested material, and of lying about having done so. The duo denied this, and the facts were never established in court. But according to the university's complaint, the Japanese company did succeed in producing antibodies against two of the three genes and then shipped them to Zhu at the University of Texas, where he now ran his own lab. Removing materials is not a crime and is certainly not prosecuted unless the materials are alleged to be the property of the university, not the researcher. Even removing university property is acceptable if the amounts are not excessive and the researcher has appropriate permission. If the accusations of having lied about the removal of large quantities of university property are true, the couple become less sympathetic. But it is important to evaluate such actions in the context of research culture: researchers typically remove materials from their laboratories when they leave for other institutions and sometimes do not ask permission to do so. There is no question that Heideaki Hagiwara, for example, had violated the spirit and the letter of the agreements he signed, yet he and UCSD were able to come to an amicable arrangement that recognized his contribution and shared the rights in the contested cell line. Therefore, many in the research community felt that Harvard overreacted when the university decided to play hardball. Moreover, given that they were sued by Harvard, an academic behemoth of sterling reputation, it is also easy to overlook that Zhu and Kimbara steadfastly denied having taken disputed materials with them and that Harvard's very public accusations of theft were never publicly backed up with copies of agreements or evidence of wrongdoing. The school brought criminal charges, and the two were charged with conspiracy, theft, theft of trade secrets, and (since they had left Texas and were now ensconced in new labs in San Diego) interstate transportation of stolen property.⁸ The case was investigated by the Federal Bureau of Investigation in New England. The Department of Justice press release, titled "Pair Charged with Theft of Trade Secrets from Harvard Medical School," focused on the fear of corporate competition, speculating that the two shared an "intention of profiting from such information by collaborating with a Japanese company in the creation and sale of related and derivative products." "Because any attempt to develop drugs from the pair's Harvard discovery threatened Harvard's own ability to patent calcineurin and sell the rights to a biotechnology company or corporation, this was a turf battle between Harvard and Medical and Biological Laboratories as well as between it and its erstwhile fellows. Unlike UCSD, Harvard did not seem inclined to share patent rights with the Japanese firm. The school and the FBI's public statements, however, focused on Zhu and Kimbara. "Prosecuting people who steal the intellectual property of individuals and institutions is a very high priority for the Department of Justice," declared U.S. attorney Michael J. Sullivan. "Congress has enacted a series of laws to assure that innovators get credit for their inventions and if people steal the ideas that belong to someone else and try to use those ideas for their own economic benefit, they will be prosecuted. Protecting cutting-edge ideas is crucial to the creation of new products and our economy as a whole." "Discovering the genes was Kimbara's achievement, but the patent "ownership" was governed by her signed agreement with the school, which was never made public. As a

research fellow at Harvard Medical School myself, I was required to sign an agreement ceding patent rights for any discovery to the "President and Fellows of Harvard College," but this was years after the Zhu-Kimbara incident and may not reflect agreements they made. I can't help reflecting that the oft-voiced virtue of the patent as a means of protect...