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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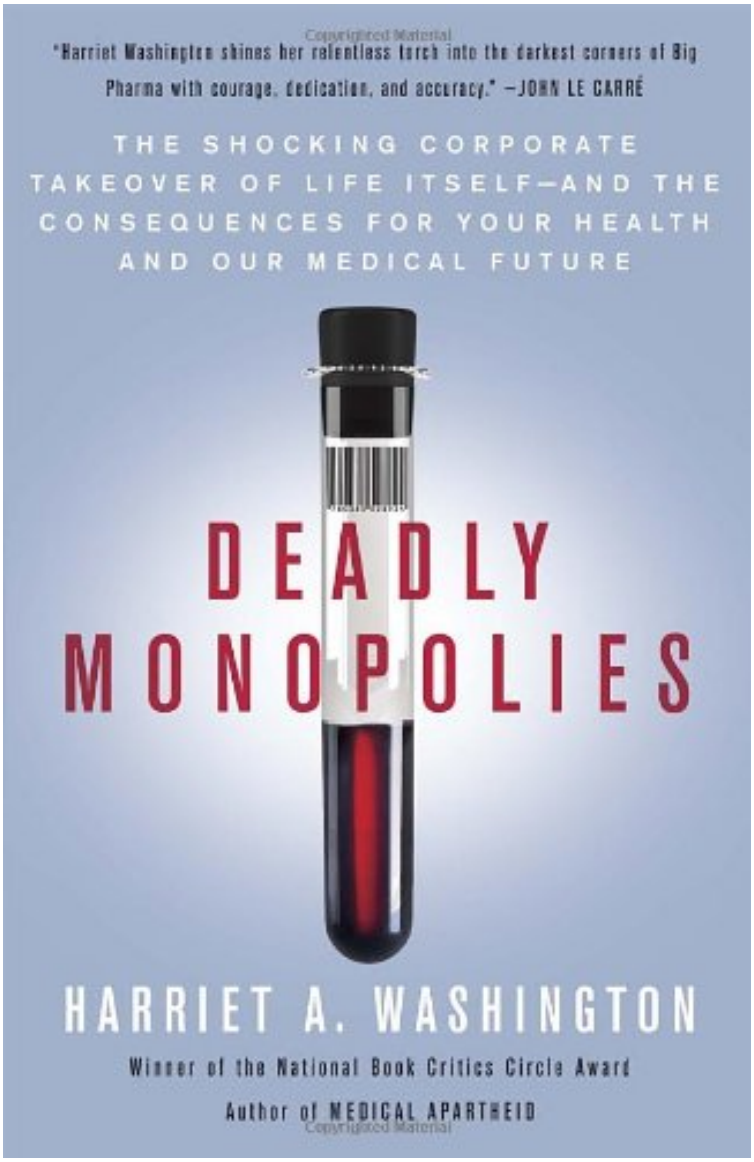

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Harriet A. Washington : Deadly Monopolies: The Shocking Corporate Takeover of Life Itself--And the Consequences for Your Health and Our Medical Future before purchasing it in order to gage whether or not it would be worth my time, and all praised Deadly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

the Consequences for Your Health and Our Medical Future:

2 of 2 people found the following review helpful. You'll need a dictionary tooBy sean carterAlthough this book was informative, Washington used elevated language appropriate for her peers, not the audience who needs to hear about it. The book felt drawn out and repetitive after a while.0 of 0 people found the following review helpful. Most peoplenot ready to know these truthsBy marilynmouReally good very informative0 of 1 people found the following review helpful. You Don't Say....By Big Sistah PattyI 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 expos of the rush to own and exploit the raw materials of lifeincluding 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. Like the bestselling The Immortal Life of Henrietta Lacks, it reveals in shocking detail just how far the profit motive has encroached in colonizing human life and compromising medical ethics.

Praise for Harriet A. Washington'sDeadly Monopolies: Important. . . . Humane. . . . An extraordinary achievement. . . . Deadly Monopolies explores contentious issues in modern biomedical research that have been aggravated by the fields commercial emphasis. . . . Washington offers an overarching framework that enables readers to see connections that are often obscured. The books brilliance lies in the compassionately told narratives of individuals whose lives have been affected by the increasing corporate control of scientific research. The American ProspectHarriet Washington shines her relentless torch into the darkest corners of Big Pharma with courage, dedication and accuracy. John le CarrHarriet 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 drugseven 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 MedicineBig Pharma is not going to like Deadly Monopolies one bit, but you probably willespecially if, like most Americans, youre 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 worlds 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 AttacksPatents, were 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 expos of whats 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[Washington] adeptly details the wide-ranging repercussions ofthis monopolistic research model andrecounts chilling anecdotes that reveal a pattern of shady practices by biotech and pharma companies. . . . The author clearly presents data to elucidate these complexissues, and cogently argues that there are opportunities to reinstate transparency, collaboration and altruism in drug development and disbursement. A gripping, revelatory account. Kirkus s (starred review)About the AuthorHarriet 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. Reprinted by permission. All rights reserved.Chapter OneA NEW LEASE ON LIFE: The Patent in American Medical CultureHow 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. 4,438,032In 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.3Some 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 fils 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 protecting the rights of "innovators" sounds ironic considering that Kimbara, who discovered the gene, was being assailed for exercising her rights to it.In fact, the only rights that immediately accrued to the duo were the Miranda rights read to them while being taken into custody in La Jolla. Sitting in the La Jolla jail, the researchers learned that they faced up to twenty-five years in prison and at least $750,000 in fines.9In the subsequent hearing, the FBI and Harvard made a highly unusual request for a six-month delay. Then Harvard announced that Medical and Biological Laboratories, the Japanese company, had cooperated fully and returned all research data and products to Harvard Medical School.After Zhu and Kimbara made bail, they were indicted by a grand jury, but there was no trial. Following a July 11 arraignment,10 all charges were dropped, prompting their lawyers to respond: "The indictment returned today abandons any claim that our clients stole trade secrets or attempted to commercialize them, recognition that there was never any truth to those charges."As the pair left the courthouse, they were mobbed by Japanese reporters, whose intensive coverage of their case came not only because Kimbara was a Japanese national and a Japanese firm was involved, but also because the life patent was then foreign to Japanese scientific culture. Japan, unlike the United States, had refused to patent life-forms or to bolster a U.S.-style university- corporate symbiosis.The Japanese bewilderment over bitter patent litigation that spilled over into criminal courts continued. In May 2001, the Cleveland Clinic similarly prosecuted researchers over monopolistic patent rights and Japanese journalists thronged its courtrooms as well, to convey the bizarre spectacle of scientists on trial over corporate property rights based on a patent. Today Japan is a major center of drug and biological design and treasures scientific innovation, but, in the words of Science magazine, "The Japanese are ill equipped to deal with stricter US laws on intellectual property."11A Medical Sea ChangeBy contrast, Americans seemed unfazed by the interstate pursuit of medical research scientists on charges of the sort normally reserved for Ponzi scammers and mafiosi. For many of us, used as we are to accrimonious turf battles over intellectual property, the salient question turns on whether the Zhu-Kimbara team was guilty, not whether they should have been legally pursued.But for the purposes of our present discussion, this event is important for a different reason: it dramatizes how the landscape of university medical research has changed in the United States. Medical- research culture has been transformed from a milieu of collegial public-goods resources devoted to the health of the community to a product governed by patents and other monopolies. Once a collaborative haven for independent inquiry and pure research, the university medical-research center is today just another arena of commercial corporate endeavor that takes competition seriously enough to deal harshly with disloyalty and raiding, to the point of seeking to send former colleagues to prison.How did we get here, and what does the change augur for patients, medical consumers, and other everyday Americans? This acerbic exchange between Harvard and its former researchers was triggered by the potential loss of a lucrative patent that would enable someone- Harvard and its corporate partners, or another institution-to profit from the couple's research. It illustrates a face of the patent at odds with the very American values of ingenuity and independence upon which medical research has always relied.However, the contentious climate of the patent gold rush has led to far more than mere turf squabbles, and these issues are the subject of this book. Biological patents, or "life patents," are those obtained for monopolies on living things such as pathogens, plants, animals, or portions of our own bodies, including, but hardly limited to, our genes. The requirement that U.S. patents be issued only on truly novel substances would seem to preclude U.S. biological patents on things that are commonly found in nature. So might the prohibition against patents on "laws of nature" or naturally occurring

material. But the U.S. Patent Office has often issued patents on naturally occurring living things, as long as researchers have "purified," "isolated," or otherwise "transformed" the patented version into a new entity that, they argue, is not found in nature. Life patents, patents on products of nature, and related pharmaceutical patents on medications are now rife, highly profitable, and the frequent subjects of legal tugs-of-war between corporations.From the Hardcover edition.