ANTHROPOLOGY | SOCIOLOGY

THE PHENOMENAL GROWTH of global pharmaceutical sales and the quest for innovation are driving an unprecedented search for human test subjects, particularly in middle- and low-income countries. Our hope for medical progress increasingly depends on the willingness of the world's poor to participate in clinical drug trials. While these experiments often provide those in need with vital and previously unattainable medical resources, the outsourcing and offshoring of trials also create new problems. In this groundbreaking book, anthropologist Adriana Petryna takes us deep into the clinical trials industry as it brings together players separated by vast economic and cultural differences. Moving between corporate and scientific offices in the United States and research and public health sites in Poland and Brazil, *When Experiments Travel* documents the complex ways that commercial medical science, with all its benefits and risks, is being integrated into local health systems and emerging drug markets.

Providing a unique perspective on globalized clinical trials, *When Experiments Travel* raises central questions: Are such trials exploitative or are they social goods? How are experiments controlled and how is drug safety ensured? And do these experiments help or harm public health in the countries where they are conducted? Empirically rich and theoretically innovative, the book shows that neither the language of coercion nor that of rational choice fully captures the range of situations and value systems at work in medical experiments today. *When Experiments Travel* challenges conventional understandings of the ethics and politics of transnational science and changes the way we think about global medicine and the new infrastructures of our lives.

"This thoughtful and reflective book offers us a sobering account of the spread of clinical research in a world without borders and often without norms. Based on careful comparative anthropological research, it both casts light on a gray zone where research, medicine, and capitalism merge, and provides a first-rate example of how an anthropology for the twenty-first century can contribute to our understanding and to the public good."
—Paul Rabinow, author of *Marking Time*

"This superb book provides the best overview of the pharmaceutical industry's rush to move clinical trials to developing countries, and the intensely troubling moral, political, economic, and cultural issues this effort raises. Petryna's argument is balanced and compelling, and her case studies are riveting."
—Arthur Kleinman, M.D.,
HARVARD UNIVERSITY

"This is a very important book, notable for its novel subject, innovative approach, and seriousness. A singular contribution to the anthropology of science and medicine."
—Veena Das, JOHNS HOPKINS UNIVERSITY

Adriana Petryna is associate professor of anthropology at the University of Pennsylvania. She is the author of the award-winning *Life Exposed: Biological Citizens after Chernobyl* (Princeton) and the coeditor of *Global Pharmaceuticals: Ethics, Markets, Practices*.

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WHEN EXPERIMENTS TRAVEL

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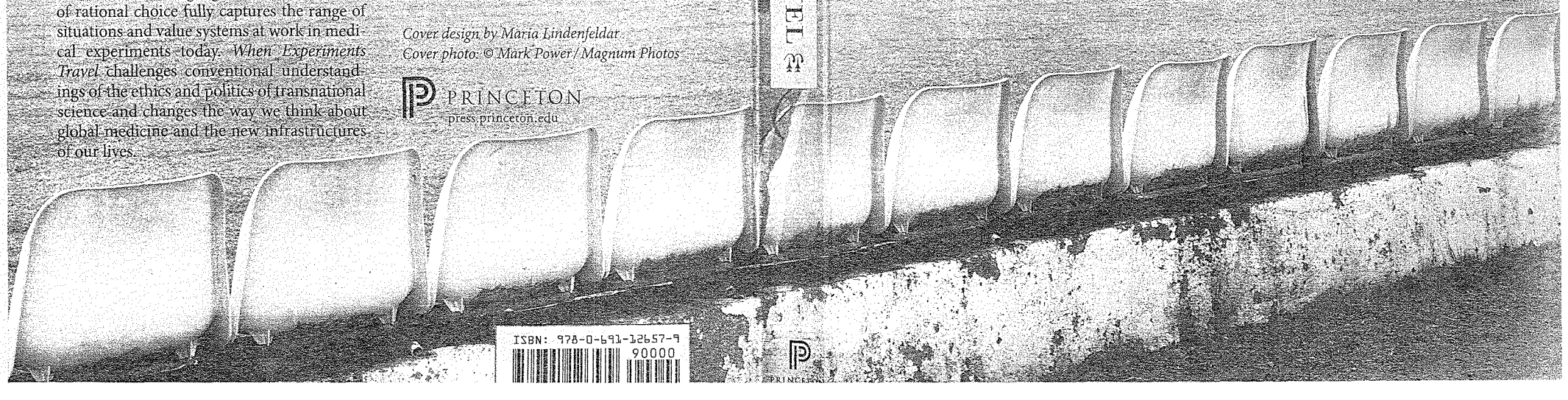
ADRIANA PETRYNA



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For João and Andre

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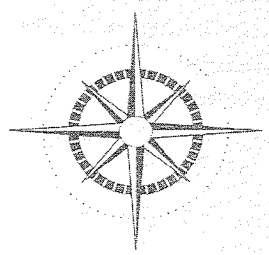
ABBREVIATIONS

ACHRE	Advisory Committee on Human Radiation Experiments
ANVISA	Agência Nacional de Vigilância Sanitária (Brazilian National Health Surveillance Agency)
BMIS	Bioresearch Monitoring Information System File (FDA)
CONEP	Comissão Nacional de Ética em Pesquisa (Brazilian National Committee on Research Ethics)
CRO	contract research organization
EMEA	European Agency for the Evaluation of Medicinal Products
ERT	enzyme replacement therapy
FDA	U.S. Food and Drug Administration
FDAMA	Food and Drug Administration Modernization Act
GCP	Good Clinical Practice
GFHR	Global Forum for Health Research
HEW	U.S. Department of Health, Education and Welfare
HHS	U.S. Department of Health and Human Services
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICMJE	International Committee of Medical Journal Editors
ICTRP	International Clinical Trials Registry Platform
IND	investigational new drug
IOWH	Institute for OneWorld Health
IRB	institutional review board
NDA	new drug application
NIH	U.S. National Institutes of Health
OHRP	Office for Human Research Protections (HHS)
OIG	Office of Inspector General (HHS)
PEPFAR	President's Emergency Plan for AIDS Relief
PIH	Partners In Health
PT	Partido dos Trabalhadores (Brazilian Workers Party)
R&D	research and development
RCT	randomized controlled trial

SMO	site management organization
SUS	Sistema Único de Saúde (Brazilian national health system)
TRIPS	trade-related aspects of intellectual property rights
WHO	World Health Organization
WTO	World Trade Organization

WHEN EXPERIMENTS TRAVEL

INTRODUCTION



EXPERIMENTAL FIELDS

The Search for Human Subjects

If I drive two miles down the road that takes me to the supermarkets and retail shops of the midwestern town where I grew up, I will pass the local branch of Across-the-Globe-Research (AGR). A freestanding office space, newly built, with a redbrick exterior and white casement windows, the building is surrounded by a parking lot. The AGR facility looks like a standard suburban medical practice, but it is not quite that. It is an investigative research site that conducts clinical trials for the pharmaceutical industry. Clinical trials are studies designed to systematically evaluate new drugs or new ways of using known treatments in humans. They are a way to meet the requirement that the safety and effectiveness of drugs or treatments be established before they enter the market. Yet trials are imperfect and, at times, biased instruments that may or may not yield the most complete evidence about a drug's benefits and risks.

Inside AGR, one spring day in 2005, a bedraggled patient-volunteer, accompanied by an escort who appeared to be his caregiver, sat waiting for his name to be called by a physician who was standing behind a glass pane—much like a bank teller, I thought. The physician asked the patient whether he had experienced any side effects from taking an experimental drug. The answer was no, and the doctor passed him a new dose. The patient left. He would return regularly over a prescribed period. According to the research protocol, some visits were brief, like this one. Others involved more detailed