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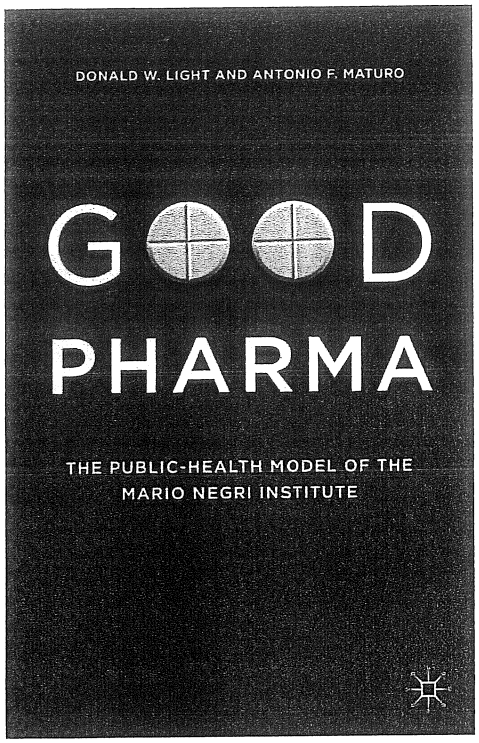

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Donald W. Light is Professor of Comparative Health Policy at Rowan University, USA and has published widely in major medical and sociological journals on ethical as well as sociological issues. Recently, he served as the Lokey Visiting Professor at Stanford University, USA and as a Visiting Fellow at Harvard University, USA.

Antonio Maturo is Associate Professor of Sociology of Health at Bologna University, Italy and Visiting Professor at Brown University, USA. He has published several books in Italian and he has edited *The Medicalization of Life* (2009, with P. Conrad) and *The Medicine of Emotions and Cognitions* (2012, with K. Barker).

Good Pharma

The Public-Health Model of the Mario Negri Institute

Donald W. Light and Antonio F. Maturo

A model of Institutional Integrity to address corruptions of research, medical knowledge, and practice

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"... combines a devastating critique of the pervasive harms of patent-driven medical research by the pharmaceutical industry with a compelling account of an alternative..."
- Erik Olin Wright, Vilas Distinguished Professor, University of Wisconsin, Past-President American Sociological Association

"... a bright light on a remarkable approach to conducting pharmacological research in the public interest... research motivated by...a social mission centered on compassion for and responsibility to the vulnerable, sick and suffering."
- Arthur L Caplan, Mitty Professor of Bioethics, New York University

About the book

Good Pharma describes a working model of institutional integrity that bypasses the many ways that commercialized research has corrupted transparent science, valid results, and trustworthy clinical practice. It is the answer to Goldacre's book, *Bad Pharma*: ethical research without commercial distortions that mislead doctors and patients.

On the basis of key concepts in sociology and management, the authors describe the history of a remarkable institute that has elevated medical research and worked out solutions to the troubling practices of commercial pharmaceutical research. This extended case history of the Mario Negri Institute describes how a brilliant young researcher, Silvio Garattini, and a boldly imaginative philanthropist, Mario Negri, conceived of an independent, ethics-based research institute to develop better medicines for patients rather than medicines better for patenting.

Drawing on its public health model, the Institute developed the first methods for founding the WHO Essential Medicines List, as well as regional and national formularies of effective, safe drugs. It was an early partner with the Cochrane Collaboration, and it campaigned to reduce secrecy and commercial influences on how drugs are approved.

The public health model of the Mario Negri Institute offers a breakthrough, already-successful way to develop better drugs at much lower prices than today's costly, wasteful drug, with few benefits for patients. An important book to provoke discussion in global public health, science and technology, history, and ethics courses.

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Patent/Profit Driven Model versus Patient- Driven, Public-health Model for Developing Better Drugs

(Table 9.3 from Light and Maturo ***Good Pharma*** Palgrave 2015)

Pharmaceutical research maximizes patents & profits (The Big Pharma Model)	Pharmacological research maximizes health of individuals and populations (The Mario Negri
Goal is to maximize number of new patented products and profits from them in government protected markets. clinical benefits to patients or populations secondary.	Goal is to develop clinically beneficial new ways to address health problems of patients or populations without considering their profitability.
Consider no promising agent that cannot be patented.	Consider all possibly helpful agents, regardless of patentability – past breakthroughs, ingredients in nature, traditional cures–.
Research directed by executives to maximize profits. Less profitable projects or teams or whole disease areas are not funded, or abandoned when profit projections fall. Priorities shift as markets or priorities shift.	Research self-directed by researchers, supported by brain-storming with colleagues.
Research funded out of high profits from protected prices as an investment in future profits. Patent everything.	Research paid in classic ways – grants, contracts – by a range of public & private funders. No patenting
Short-term research focused on patentable minor drug variations. Little basic research.	Relentless pursuit for years or decades to figure out how to solve a clinical problem.
"Innovation" measured by new molecules, best in class, or first in class, even if clinically no better or worse.	"Innovation" measured by improved clinical or population health status or reduced suffering.
Closed-science secrecy. Guard info on projects, progress, failures, successes, budgets, patenting strategies, to ward off competitors and poachers. Closely manage disclosures that sculpt research findings.	Open-science transparency, sharing, network-building. Publish all results and learn from failures. Share new solutions, methods, strategies to find effective interventions.
Ghost management or ghost writing of publications. Distorts medical knowledge.	All results published. Researchers write their own papers and publications.
Develop slightly different new drugs for large-profit conditions already treated. Occasionally, superior meds occur.	focus on finding clinically superior drugs for serious, often untreated medical conditions.
Trials designed to minimize evidence of harms & maximize evidence of benefits in artificial populations that are likely to exclude those who might experience adverse reactions and include those likely to have a positive reaction. Often exclude elderly, women and people with co-morbidities.	Trials designed to test clinical outcomes on the populations that will take the medicine. Test for superiority over current treatments, regardless of patent status. Include the natural diversity of the practice population.
Trials undertaken and designed to generate better market information and recruit doctors. Very costly, measure everything to find something.	Trials undertaken only after careful review of what is known and careful work to identify a strong end point. Clean, simple & cheap, about 1/10th the cost per patient.
Trials pay doctors and patients so well that doing or being in them is a profit stream. distorts design, data, and results.	Patients volunteer for no pay, doctors for no or modest pay for their time. Trials part of a national health care system.
Goal to maximize the number of people on as many patented drugs as possible, with few benefits to offset risks of harm. Costs to taxpayers & others about Us$1 trillion.	Goal to maximize the number of superior drugs, at low prices, while minimizing drug consumption. Would cost taxpayers & others 1/5th as much.

Pharmaceutical Company Corruption and the Moral Crisis in Medicine

By SHARON BATT

.... In *Good Pharma*, medical sociologists Donald Light and Antonio Maturo provide a startling counter-example that has been hiding in plain sight in Milan since 1963. The Mario Negri Institute (MNI) is a nonprofit center dedicated to high standards in both pharmacological research and ethics. Light and Maturo consciously play off Goldacre's title [*Bad Pharma*] and frequently reference his book, weaving a critique of the dominant for-profit system of drug development and marketing through the MNI story. Indeed, the institute has long practiced the main remedies that both Gøtzsche and Goldacre propose...

Founded by a visionary chemist-physician from a working-class background, Silvio Garattini, ...the MNI has flourished and grown while sticking to two core ethical principles: scientific excellence and integrity, and drug development dissociated from profit. The resulting culture seems thrillingly at odds with what Ben Goldacre calls the "perverse incentives" to put profits ahead of health.

MNI does not patent its discoveries. It rejects placebo-controlled trials, pursues research on toxic drug side effects, and makes public all its research results, even failures. Staff members work for modest pay, and the disparity between the highest and lowest salaries is less than fourfold; yet employees stay on because they cherish the "excitement of the work" (p. 8). Despite some dry details in the Institute's sixty-plus-year history, the book transports the reader through the looking glass to a world of drug research that seems too fantastically idealistic to be real.

HASTINGS CENTER REPORT 2016; 46 (4): 10-13

Light, D.W. and Maturo, A.F. *Good Pharma: The Public-Health Model of the Mario Negri Institute.*
Basingstoke: Palgrave MacMillan. 2015. 288pp £65 (hbk) £59.50 (ebk) ISBN 978-1-137388339

By offering a sociological perspective on the drug development process, this book presents an alternative perspective to mainstream pharmaceutical drug production focused on patenting and profit while ignoring public-health needs.... As the authors point out, the book is an answer to Goldacre's (2012) *Bad Pharma*, Light and Maturo chart the historical and social development of an independent research institute (The Mario Negri).

The book shows how personal life events and experiences collided to lead to the founding of the institute. It draws on organisation theory to explore how a culture of inclusion, and with adequate staff and community participation in organisational processes, results in successful research. Taking into account the influence that funders have on the research process and findings, the book illustrates how interdependence can be negotiated and independence achieved in the drug research process. The book further illustrates how research that is focused on improving public-health first and foremost, and not for profit or the bottom line, is actually possible....

Contrary to existing industry claims of high costs of drug production, the Mario Negri institute conducts clinical trials at a low cost, yet still ethically and with strong principles. Unlike most other organisations within the industry, their discoveries are not patented or sold for profit. The institute focuses on research that serves the public good with an emphasis on public engagement and innovation processes that engender an awareness of scientific knowledge, processes and practices among, and empowerment of, expert patients....

This book shows us that it is possible to produce cheap affordable drugs that benefit even the world's poorest populations, despite the common discourse that imbues government and mainstream pharmaceutical industry justifications for the current high costs and unequal access to medicines across the globe. The book is a welcome addition to the sociology of health and medicine and would likely appeal to those interested in critical perspectives of pharmaceuticals, health and the regulation of clinical trials.

Shadreck Mwale
University of Brighton

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doi: 10.1111/1467-9566.12469

Review of GOOD PHARMA:

Facing the unreliability of clinical trials literature

Tom Jefferson Honorary Research Fellow, Centre for Evidence-based Medicine Oxford, UK
Drug and Therapeutics Bulletin 2015;23(2) excerpt.
http://www.navarra.es/NR/rdonlyres/D0DD2C82-3B82-4EB8-A173-EEF198197F13/330071/Bit_v23n2_e2.pdf

Journal publications of randomised controlled trials ("literature") have so far formed the basis for evidence of the effects of pharmaceuticals and biologics. In the last decade, progressively accumulating evidence has shown that literature is affected by reporting bias with evident implications for the reliability of any decision based on literature or its derivatives such as research synthesis... I propose basing public health decisions and reimbursement of any important intervention on independent trials and studies following the model pioneered by the Mario Negri Institute of Pharmacological Research....

Donald Light and Antonio Maturo provide what seems a well-tested alternative solution in their book, ***Good Pharma***. It tells the story from 1961 to present of the origins and development of *the Instituto di ricerche farmacologiche mario negri*, named after its endower, a Milanese jeweler-philanthropist.

The Mario Negri Institute for Pharmacological research has a distinctive model of trial conception and delivery. The cornerstones are open science (no patenting of compounds in development and data sharing), nesting trial questions and design in an up-to-date systematic review of the topic, clinically oriented study questions and absence of surrogate outcomes of unclear link to the hard outcome.

As a physician, I do not understand brinkmanship with other people's lives in search for what is often a minimal benefit. ***GoodPharma*** is worth reading and digesting as it documents how the Negri model has produced some outstanding successes, such as the GISSI trials, and makes a strong case for viewing pharmacological research as a long-term risky investment, rather than the generator of everyday miracle breakthroughs, so lovingly portrayed by media and grant-hungry researchers.

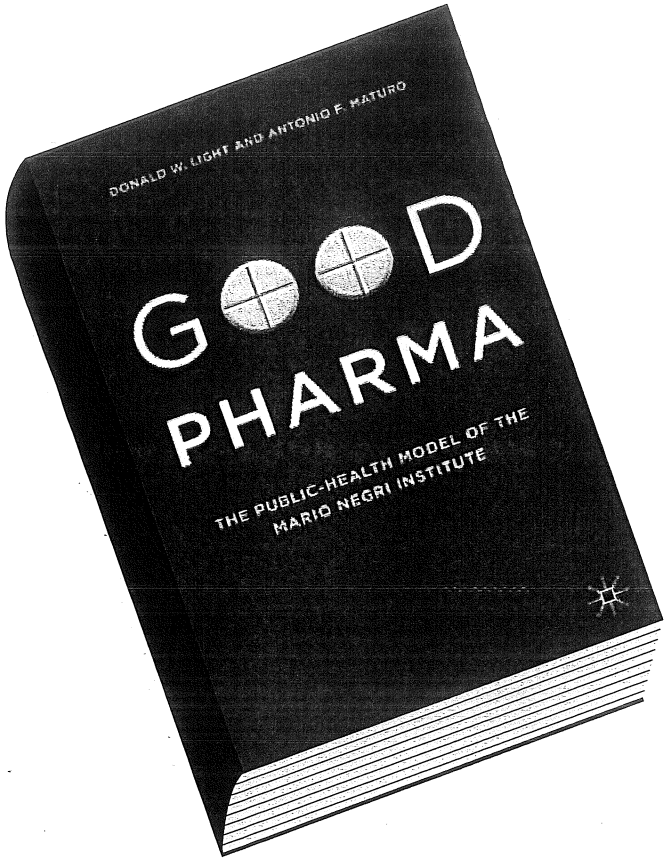
The evidence shows that the current regime of pharmaceutical regulation and licensing with its ingrained symbiosis (each benefiting from the other) is simply not amenable to reformation or change without a complete revolution, which I believe is unlikely.

Hence, the regulatory system should carry on with ever-increasing transparency. However, publicly-funded reimbursement decisions of any important intervention used by the health services (such as pharmaceuticals, imaging, diagnostics and invasive devices from which users may derive benefit) should be based only on independently- produced and analysed robust evidence. In the EU with its publicly funded national universal healthcare coverage, this principle is coherent with Beveridge philosophy.

Furthermore, the Negri Model provides a guide on how to train and develop the minds of independent researchers. Topics for research must not be restricted to drugs and must be set publicly, not influenced by private interests.

The little guy and his magic potions

Pioneering medical research in Italy has defied industry and politics for decades, says David Healy



Good Pharma: The Public-Health Model of the Mario Negri Institute
By Donald W. Light and Antonio F. Maturo
Palgrave Macmillan, 300pp, £59.50
ISBN 9781137388339 and 374332 (e-book)
Published 1 July 2015

Whatever you think of his politics, there was a certain magnificence to Yannis Varoufakis in the recent Greek crisis. Imagine if he had won. It would have been a victory straight from the pages of *Asterix the Gaul*.

Well, *Good Pharma* is straight from the pages of *Asterix*, except the little guys facing off against the imperial forces are Italian, standing up initially to the Franco-German pharmaceutical industry and latterly the Americans'. The irony is that, Ho Chi Minh-like, the little guys took their inspiration from the US way of doing transparent and egalitarian research in the 1950s, only to find themselves pitted against those they once admired.

This is the story of the Mario Negri Institute, based in a working class suburb of Milan. Mario Negri was a wealthy patron who, on his death in 1960, left a large sum of money to an upcoming researcher, Silvio Garattini, to support independent pharmaceutical research. At the time, new drugs were spilling out of the pharmaceutical industry in abundance; psychopharmacology had just come into being and Garattini played a part in its birth. New techniques to detect ever-smaller amounts of drugs, neurotransmitters and toxins were emerging, playing straight to Garattini's strengths. He and his collaborator Alfredo Leonardi set about building an institute centred on the new drugs and techniques.

As they tried to make their way in the world, they were met with bemusement at their presumption that anyone stood to gain anything from linking to them. Five decades later, after they faced down the Italian government, European regulators, GlaxoSmithKline and endless pharmaceutical companies, no one even thinks about dismissing them.

Major discoveries in cardiology have come from their organisation of some of the first mega-trials in medicine; major discoveries in chemotherapy from their pioneering research on new compounds; major discoveries in environmental toxicology from their abilities to detect toxins and drug residues in the environment. There are probably very few families anywhere whose health has not benefited from the institute's discoveries, or its resistance to industry or political efforts to cut corners or fudge data.

The institute continues to grow without ever having patented any of its many discoveries or concealing any data from experiments that didn't work out or accommodating any of their trials to industry's wishes. Reading this compelling and valuable history, it feels that if there is a sign saying conventional wisdom points left, Mario Negri has gone right, until you realise that what has happened is that what the institute does was once widely supported, and it's the field that has gone in the opposite direction.

Almost everyone has heard of the Cochrane Collaboration, the global non-profit organisation that systematically reviews clinical trials, but Mario Negri was pioneering these paths 30 years earlier, across the full range of medical disciplines. Hard-bitten ex-army-type insiders such as Tom Jefferson, who took on Roche over its claims about Tamiflu and won, view the Mario Negri operation with awe, but of course it's more than it's worth for industry to let anyone know that there is another way of doing things. If this caught on in medicine, who knows – the example might spread to the wider economy.

David Healy is professor of psychiatry, Bangor University.

Indian Journal of Medical Ethics Online First Published August 16, 2016

BOOK REVIEW

"Good pharma" is possible!

AMIT SENGUPTA

... ***Good Pharma: the public-health model of the Mario Negri Institute*** by Donald W. Light and Antonio F. Maturo, is in many senses the antithesis of Bad pharma and shows us vignettes of an alternative world where clinical research and practice are intertwined, and where medical ethics drive both....

Less expensive and more effective Researchers at the Institute receive no pay beyond their regular, modest salaries and an observer comments that it "feels like a community of graduate students". Yet today, the Institute is engaged in cutting edge research and conducts about 80 clinical trials at any one time....

The Institute is not just a centre for producing new knowledge, but also functions as a repository of knowledge and as a medium for the dissemination of knowledge. Its Rare Diseases Information Center has been gathering information on more than 1000 of the estimated 7000 rare diseases known to humankind....

The authors of ***Good Pharma*** extrapolate the approach of the Mario Negri Institute to propose a blueprint for "good pharma", as opposed to "bad pharma". In 2013, The Lancet commented on the continued lack of published or even disclosed evidence concerning the benefits, and especially the risks of harm, of new drugs and vaccines....

The authors propose that "good pharma" should be about wanting "honest researchers to work together, not separately in high-security labs, and to learn from each other's failures as well as successes while trying any active ingredient that might work, regardless of its patentability."...

Good Pharma is a fascinating story and a must read for all those who believe that something is not right about the way we incentivise medical research today. Both laypersons and specialists in the field will find something to think about in a book that is full of delectable nuggets of information interspersed in the story of Silvio Garattini and the Mario Negri Institute.