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## 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.

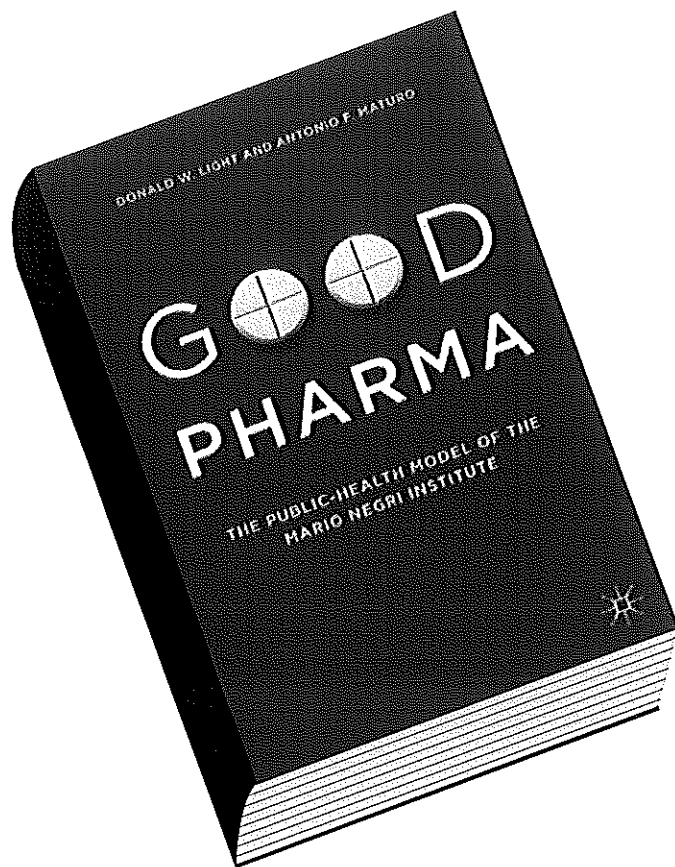
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# The little guy and his magic potions

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  
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**W**hatever 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 Ameri-

cans'. 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, GlaxoSmith-Kline 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.

**GOOD PHARMA**  
**The public health model of the Mario Negri Institute**  
**for Pharmacological Research**

Donald W. Light and Antonio Maturò  
Palgrave Macmillan New York, London 2015

...from 'patent-orientated research' to 'patient-orientated research'

Since 2000, a relentless stream of books has detailed how pharmaceutical companies manipulate research, hide evidence that their new drugs harm patients, and exaggerate their benefits. Reforms requiring all results from clinical trials and all payments to doctors to be reported help a little; but they leave unaddressed the ways that medical research gets distorted as companies pursue large profits from high prices, as detailed by Ben Goldacre in his book *BAD PHARMA*.

*GOOD PHARMA* is the first book to offer a paradigm shift from 'patent-orientated research' to 'patient-orientated research'. It tells the story of the Mario Negri Institute for Pharmacological Research in Milan, where for decades research designs and data have been controlled by investigators themselves, even when corporations fund projects; where all research results are published, whether positive or negative; where, to avoid the distorting effects of patenting on research integrity, no discoveries are patented; where clinical trials are designed to test if a new therapy is superior, to existing options judged in terms of outcomes important to patients; and where researchers reach out to the public to encourage them to learn about the risks and benefits of drugs.

*GOOD PHARMA* describes how Silvio Garattini and the multi-campus Institute that he developed became models of Italian and international science, driven by good research ethics applied to projects from conception through to analysis and publication. The Mario Negri model of research integrity and dedication to patients regards medicines, primarily, as social goods rather than as vehicles for profit. It puts 'patient-orientated research' before 'patent-orientated research'.

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**Pharmaceutical Research to Maximize  
Patents & Profits**

*The Big Pharma Model*

Goal is to maximize number of new patented products and profits from them in govt-protected markets. Clinical benefits to patients or populations secondary.

Diseases of the poor and other unprofitable diseases are not studied. Health inequities are reinforced.

Research driven by executives and high-profit goals. Less profitable projects or teams or whole disease areas not funded, or abandon them when profit projections fall. Priorities shift as markets or priorities shift.

Research funded out of high profits from protected prices as an investment in future profits.  
Priorities driven by marketing.

Short-term research for profitable results. Earlier long-term research less and less supported.

“Innovation” measured by new molecules, best in class, or first in class, even if clinically no better or worse.

Closed-science secrecy. Guard info on projects, progress, failures, successes, budgets, patenting strategies, to ward off competitors and poachers.

Closely manage disclosures. Sculpt research findings.

Ghost management or ghost writing of publications. The corporate distortion of medical knowledge.

Develop slightly different new drugs for large-profit conditions already treated. Occasional superior meds occur.

Consider no promising medicines, past breakthroughs, ingredients in nature, or traditional cure that can't be patented. Minimum or no comparing or sharing.

*Pharmacological* Research to Maximize Health of  
Individuals and Populations

*The Mario Negri Institute Model*

Goal is to develop clinically beneficial new ways to address health problems of patients or populations without considering their profitability.

All diseases, regardless of patents and profits, are considered, based on need and funding.

Research self-directed by researchers, supported by brainstorming with colleagues.

Research paid in classic ways – grants, contracts, budgets – by a range of public & private funders.  
No patenting to seek additional profits because distorts priorities, pathways, product development. Or, long arms-length patenting by host institution.

Relentless pursuit for years or decades to figure out how to help patients with a difficult problem.

“Innovation” measured by improved clinical or population health status or reduced suffering.

Open-science transparency, sharing, network-building.  
Publish all results and learn from failures. Share new solutions, methods, strategies to find effective interventions.

Researchers write their own papers and publications.

Focus on finding clinically superior drugs for serious, often untreated medical conditions.

Consider all possibly helpful medicines, past breakthroughs, ingredients in nature, traditional cures, regardless of patents. Can compare & share across companies and patent status.

Trials designed to minimize evidence of harms & maximize evidence of benefits in artificial populations that exclude those who might experience adverse reactions and include those likely to have a positive reaction. Often exclude the elderly, women, people with co-morbidities.

Trials designed to test clinical outcomes on 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 whenever better market information seems possible or prescribing doctors can be signed up. 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 1/10<sup>th</sup> 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 practice and communal.

Goal to maximize the number of people on as many patented drugs as possible, with few benefits to offset risks of harm. Costs taxpayers & others about \$1 trillion.

Goal to maximize the number of superior drugs, at low prices, while minimizing drug consumption. Would cost taxpayers & others 1/5<sup>th</sup> as much.