Title: The Drug Trial: You Be the Judge

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Abstract: How do you advise a scientist who says she has information that could be vital to the event health but sheÂ's been told to keep it a secret? In this talk Dr. Shuchman will discuss the dramatic act of blowing the whistle in science. Drawing on the extensive information in her best-selling book including interviews with whistleblowers, surveys of scientists and public testimony - and adding new material that isnÂ't in the book Â–Shuchman will outline the benefits of scientific whistleblowing over the past 40 years. Then she will describe its aftermath. In case after case, Shuchman will give audience members the information and ask their opinions of what should have happened. Miriam Shuchman is a psychiatrist with a background in medical ethics, who teaches at the State University of New York at Buffalo. Her features on ethics and psychiatry have appeared in the New York Times, the Los Angeles Times, the Washington Post and the Globe and Mail, as well as on CBC Radio and National Public Radio in the United States. Her articles on medical whistleblowers have appeared in the Annals of Internal Medicine, the British Medical Journal and the Canadian Medical Association Journal. Dr. Shuchman trained in psychiatry at the Harvard Medical School and studied ethics at Dartmouth College. Her book, Â"The Drug TrialÂ", tells the full story of the Olivieri affair, CanadaÂ's biggest science scandal, and exposes problems that should concern us all in the systems of scientific research, corporate financing and peer review. <kw> Drug trial, Miriam Shuchman, whistle blowers, Sissela Bok, Nancy Olivieri, David Kern, Cesare Maltoni, Justine Sergent, moral, responsibility, indefensible, scientists </kw>

THE DRUG TRIAL: YOU BE THE JUDGE

Miriam Shuchman, M.D.

Author, *The Drug Trial:*
Nancy Olivieri and the Science Scandal
that Rocked the Hospital for Sick Children
Random House Canada, 2005

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Disclosure Statement
Miriam Shuchman, M.D.

Financial interests: None.

Bibliography:
Available.

Affiliations:
SUNY Buffalo

ALAN CUTLER

Cutler is the procurement officer who refused to sign off on advertising contracts in 1996.

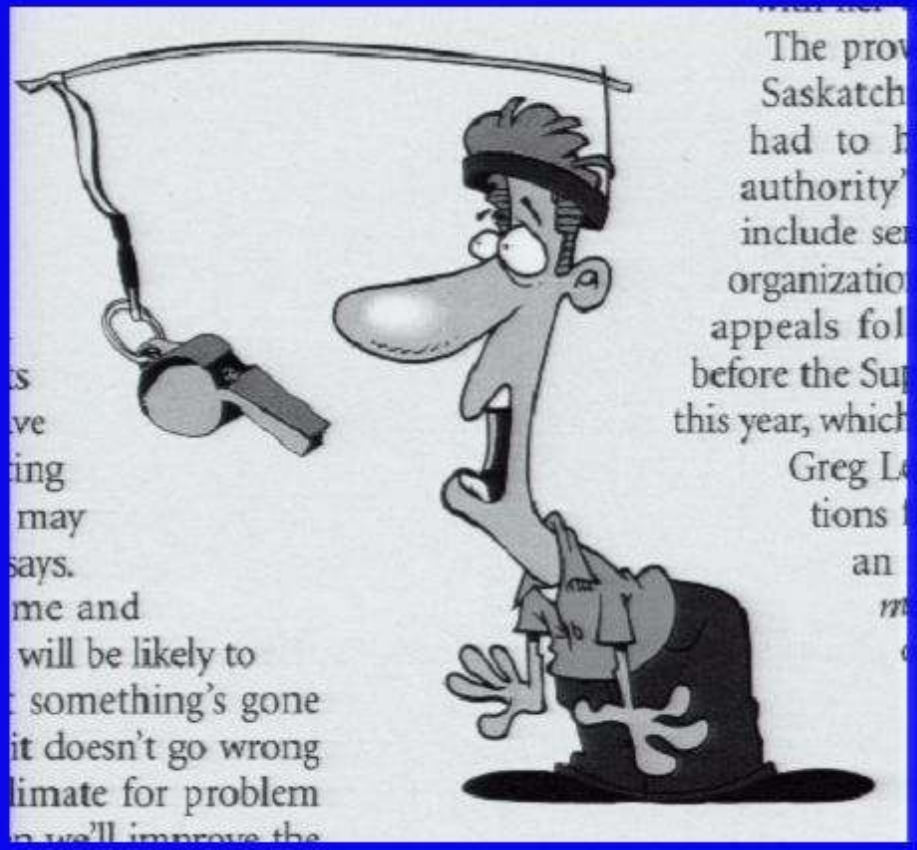
His boss, Chuck Guité declared him 'surplus'.

Pictured in Ottawa, November 1, 2005

SISSELA BOK, philosopher, Harvard University:

Whistleblowing is an act of dissent, a breach of loyalty, an accusation leveled.

Whistleblowers must think carefully about their moral responsibilities and weigh the consequences.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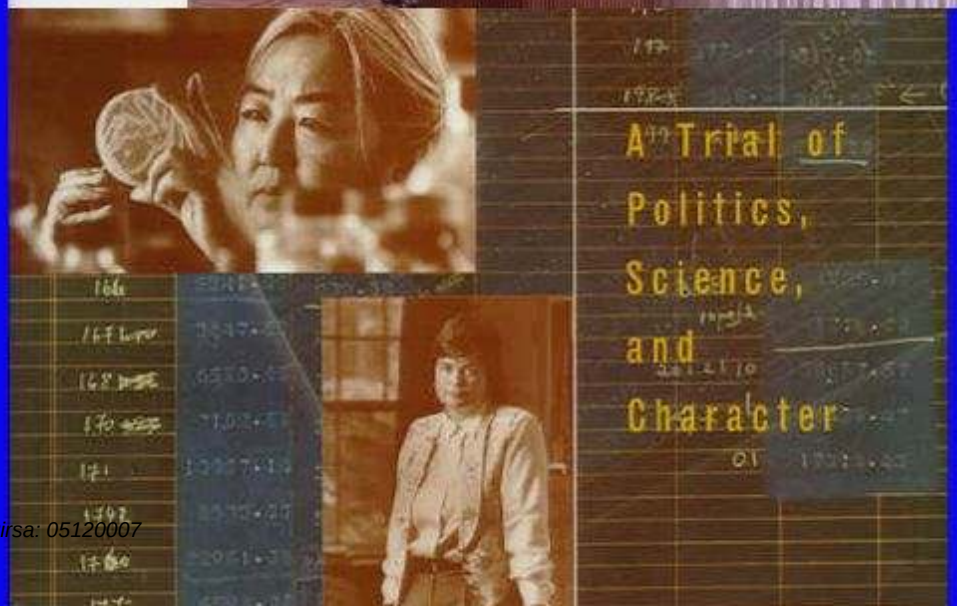
SCIENTISTS WHO BLOW THE WHISTLE



SCIENTISTS WHO BLOW THE WHISTLE

CASES TO CONSIDER

- David Kern, M.D.
- Cesare Maltoni, M.D.
- Justine Sergent, Ph.D.
- Nancy Olivieri, M.D.

David G. Kern M.D.

Microfibres®

Kern on presenting his initial findings

"Perhaps this matter had already been addressed somewhere else in the world, and there was an answer and a solution. We might be helped then, by fellow scientists and physicians.

Secondly, we wanted to warn other physicians and scientists to be on the lookout for disease of this type in this type of a work force."

YOU BE THE JUDGE

- Should Kern present?
- What is his moral responsibility as a scientist?
- What are the likely consequences?

Kern vs. the University

The Brown University News Bureau
Distributed May 21, 1997

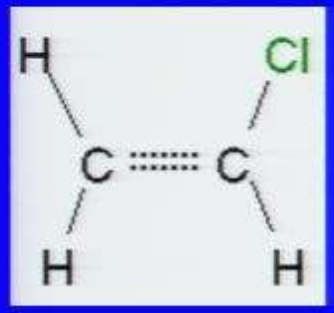
Brown University supports the academic freedom of Dr. David Kern

Fig. 1.— a) A photograph of the rotary cutter machine (grinder) used by the patient at the plant at Eurotecno, Barcelona (Spain). b) Detail of the rotary cutter blades.

Penobscot Bay, Maine

The monomer looks like this

Atom Legend
C = Carbon
H = Hydrogen
Cl = Chlorine



Any small section of the polymer looks like this:

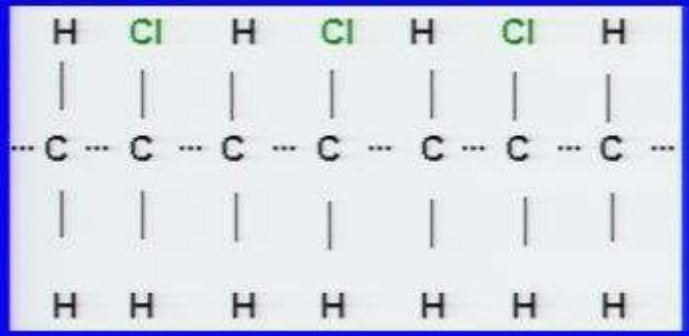
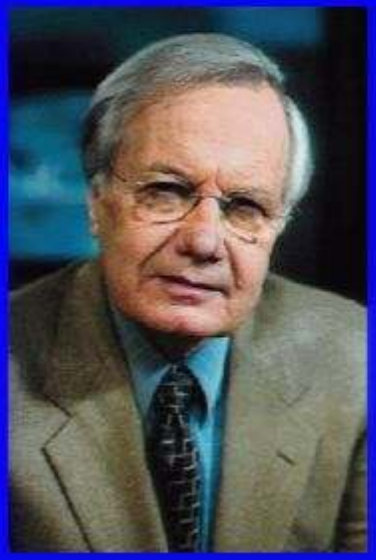


Fig. 6. Cesare Maltoni and Lanfranco Turci, President of the Emilia Romagna Region, at the symposium in Bologna in 1973

Cesare Maltoni, M.D. being introduced at a symposium: "Advances in Tumour Prevention, Detection and Characterization."
Bologna, Italy, 1973

Cesare Maltoni, Institute of Oncology sources & sponsors



- From *Trade Secrets*, a Moyers Report, PBS, 2001 and from *In Strictest Confidence* by JIM MORRIS
  © 1998 Houston Chronicle
  www.chron.com/content/chronicle/special/vinyl

- Maltoni's work was sponsored by Montedison, Imperial Chemical Industries of England, Solvay of Belgium, and Rhone Progil of France

YOU BE THE JUDGE

- Should Maltoni breach his contract with his sponsors and alert authorities in Europe and North America (NIOSH) or the public?
- What is his moral responsibility as a scientist?
- What are the likely consequences?

Vinyl chloride —> angiosarcoma

State of Alaska Epidemiology Bulletin No. 10
June 14, 1974
Angiosarcoma and Vinyl Chloride

Angiosarcoma of the liver is an exceedingly rare tumor, with an estimated annual incidence in this country of no more than 15-25 cases. The present concern stems from the recent demonstration of a possible relationship between hepatic angiosarcoma and exposure to vinyl chloride.

Cesare Maltoni

Co.	*Location*	*Product*
Dow Chemical Canada	Sarnia, Ontario	Vinyl chloride
Dow Chemical Canada	Fort Saskatchewan, Alberta	Vinyl chloride
B.F. Goodrich Canada	Niagara Falls, Ontario	Polyvinyl chloride

Nancy F. Olivieri, M.D.

The New England Journal of Medicine

13 August 1998: Long-Term Safety and Effectiveness of Iron-Chelation Therapy with Deferiprone for Thalassemia Major

Mixing and injecting Desferal

Her skin gets a little sore

Keisha uses her Desferal

- Keisha's Mom and Dad learn how to give her Desferal infusions.
- Her skin gets a little sore sometimes, but it's not as bad as she thought it would be.

THE PILL: DEFERIPRONE (Ferriprox)

The sponsor writes to the Research Ethics Board

"Spino…wrote the ethics board chair, Zlotkin, whom he knew from his time at Sick Kids, to tell him the L1 research results were in dispute.

…Zlotkin wrote Spino that the ethics board would not mediate between the company and Olivieri."

The Drug Trial, p. 151-152

Savulescu: The REB should mediate

- "One can only speculate that this whole affair may never have happened if the ethics committee in Toronto had taken a proactive and independent role in attempting to resolve the scientific dispute between Apotex and Dr Olivieri …"
- "Although one cannot expect ethics committees to have the expertise to resolve complex scientific issues, it is reasonable to expect them to manage a process, including setting up external expert review, to expedite their fair resolution."

Savulescu J. , *British Medical Journal* 328:358-359.(2004)

Gag Clauses in Clinical Trial Contracts

"Gag clauses in clinical-trial agreements prevent investigators from examining the data independently …They can also interfere with the publication of unfavorable data on safety, as it was recently alleged that Merck officials did in the company-sponsored study…"

Robert Steinbrook, New England Journal of Medicine, May 26, 2005

A pianist on the bed of a pet scanner plays a Bach concerto

The piano is suspended from a platform, the pianist is comfortable, in a study designed by neuropsychologist,

Justine Sergent, Ph.D.

- 1992: Justine Sergent publishes in *Science*: "Distributive neural network underlying musical sight-reading and keyboard performance"
- 1993: Reprimanded by the University Principal's Office.
- Enters into legal arbitration with McGill and MNI
- 1993: Not promoted.

WHY SCIENTISTS BLOW THE WHISTLE

"Whistleblowers can be divided into those acting out of genuine concern…and those acting out of discontent, malice, pique, revenge, or desire to harass or embarrass."

Herman Wigodsky, U. Texas Health Science Center in Austin, 1981

"Physicians have been concerned that … they are at the mercy of whistleblowers in their own midst or from the outside who may act in revenge or pique."

Mustokoff MM, Nelson CE. Journal of Medical Practice Management, May-June, 2005.

Montreal Researcher Commits Suicide

Montreal, Canada--April 12, 1994

A leading researcher at one of McGill University's teaching hospitals and her husband apparently committed suicide this month after press reports about an anonymous letter accusing her of scientific fraud. Scientists at the Montreal Neurological Institute were shocked by the deaths of Justine Sergent, a professor of neurology and neurosurgery, and her husband, Yves, a professor at the University of Montreal.

Indefensible whistleblowing

"I think the one thing that everyone would agree on is that whoever wrote the anonymous letter acted in a totally indefensible way. We'll probably never know who wrote that letter."

Richard Murphy, former director, Montreal Neurological Institute

Diverse whistleblower systems around the globe — and hotlines deemed illegal in France — are creating problems for companies seeking to operate uniform, global systems. Three attorneys review the issues and discuss possible solutions.
The