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Lobbying through science

Discussing epistemic capture in the area of chemicals regulation: ILSI and the “mode of action” regulatory concept

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Lobbying through science?

- The corporate political activity consisting in the enrolment of academic scientists and experts, to influence regulatory frameworks and norms applying to businesses

Corporate playbook regarding science

- Hiding selected science
- Funding/defunding research centers and universities
- Decredibilizing scientists in the public sphere
- Hiring scientists for product defence
- Ghost-writing
- Producing doubt and shifting the attention of publics to alternate issues
- ...

... and: creating or using 'front groups'

Creating a dedicated organization, with the appearance of a neutral, objective provider of knowledge, to alter the credibility of opponents, promote defensive messages, create or reframe controversies...

- Examples include:
 - American Industrial Health Council
 - American Council on Science and Health
 - International Life Science Institute
 - Health and Environmental Safety Institute
 - European Centre for Ecotoxicology and Toxicology of Chemicals

Three questions

- How do firms operate through such front groups and what do they achieve by lobbying through science?
- Does this qualify as capture — if not regulatory capture, can we speak of cultural or 'epistemic' capture?
- Are public policies and regulations to address the environmental crisis delayed or altogether halted, as a result of capture?

CAPTURE

From regulatory capture...

- Where regulators end up acting in the interest of regulated industries (Bernstein 1955).
- Picked up by political scientists, historians, and others, who criticized the notion:
 - An interest based reading, but interests not easy to identify and contrast
 - Opposes public and private entities, instead of looking in a more fine-grained manner at the interactions between actors in a regulatory space
 - Not easy to identify or measure (Carpenter & Moss 2013)

To cultural capture

- Carpenter and Moss 2013: « There are arguments about the cultural or social influence of repeated interaction with the regulated industry, such that the regulator begins to think like the regulated and cannot easily conceive another way of approaching its problems. »
- Contrasts with regulatory capture:
 - Knowledge-rather than interest-based view: the fact that reg and reg think alike
 - Derives from repeated, fluid interactions within the span of the networks that structure a regulatory sector
 - Diagnosed looking 'upstream' from regulatory outcomes, how regulatory frameworks are shaped

Or epistemic capture

- A situation whereby a way of knowing and addressing a regulatory problem, is shaped by concepts, methods or metrics that can be traced to regulated firms, and that tend to generate favourable regulatory outcomes when applied

ILSI & regulatory concepts for chemicals

- Operational ideas regarding how to qualify health and safety problems, based on an implicit vision of what is risky, and predefines regulatory decisions
- Examples: « acceptable daily intake », « margin of exposure », « benchmark dose », « threshold of toxicological concern » or « mode of action »...
- All exist as ideas first, and end up informing regulatory practice

ILSI

ILSI

- A non-profit, charitable (hence tax-exempted) organization created in 1978 by Coca-Cola Vice-Pdt, in the wake of the caffeine toxicity controversy
- Since the 1980s, a global organization: European branch established in 1986, alongside other regional branches

Abbott Nutrition	Loraz	Roquette
ADM	Lucasde Ribens Suntory	Sanofi-Aventis Group
Ajinomoto	Luigi Lavazza	Schwabsgroup
Arla Foods	Mars	Sensus
Banjo S&R Fratelli	Mayer-Meinof Karton	SDM EUROPE
BAF SE	Mead Johnson Nutrition	Solzaucker Group
Caolus Health	Marck	Swiss Quality Testing Services - SQTS
Cargill	Mandoliz International	Syngenta
Chr. Hansen	Monsanto Europe	Tata & Lyte
Cosucra Grovde Warcoung	Nestlé	Tereos
Danone	Nexira	Tetra Pak
Dow Europe	Onys International	The Coca-Cola Company
DSM	PepsiCo International	The Velcor Corporation
DuPont Nutrition & Health	Pfizer Consumer Healthcare	Tine SA R&D
Firmenich	Pierre Fabre Dermo-Cosmétique	Unilever
FrieslandCampina	PPG Industries	WALA Heilmittel
General Mills	Premier Foods	Yakult Europe
GlaxoSmithKline	Procter & Gamble	Yili Innovation Center Europe
Innovative Food Systems	Red Bull	
Johnson & Johnson EAME		
Kabi Fresenius		
Kao Corporation		

ILSI	40320	03-429890-29-90200-00	006209	IN189/3930	1/31/2012	THE PEW CHARITABLE TRUSTS	25,000.00
ILSI	40320	03-429890-29-90200-00	006473	IN18978510	9/30/2012	ILLINOIS INSTITUTE OF TECHNOLO	17,500.00
ILSI	40320	03-429890-29-90200-00	006400	IN18070200	11/30/2012	THE PEW CHARITABLE TRUSTS	25,000.00
ILSI	40320	01-641500-72-8410-30	006433	IN18075520	8/31/2012	KELLOGG COMPANY	10,000.00
ILSI	40320	01-641500-72-8410-30	006450	ACH08/16	8/15/2012	MARS, INC	7,667.00
ILSI	40320	01-641500-72-8410-30	006527	IN18978470	12/31/2012	AJINOMOTO CO	10,000.00
ILSI	40320	01-695112-70-8650-40	006543	IN18981210	12/31/2012	CROPLIFE INTERNATIONAL AISBL	17,500.00
							1,343,360.00
						Asia/Pacific-North	12,000.00
						Europe & Africa	36,000.00
						HESI/NA	817,381.00
						NA	201,000.00
						Outside Individual	1,545,560.00
						Grand Total	2,411,541.90
TB:						Count	888,381.00
ILSI	196,167.00					Doesn't Count - Outside	1,545,560.00
RF	2,215,774.90					Total	2,411,641.90
Total	2,411,641.90						

A vessel for direct lobbying of authorities

- One example: Top ILSI people maintained close links with officials of the CDC, and how those links were used to help articulate and deploy the strategies of Coca-Cola to counter the actions of the WHO on sweeteners (USRTK 2016a)

Are industry-funded charities promoting "advocacy-led studies" or "evidence-based science"? a case study of the International Life Sciences Institute

Sarah Steele ¹, Gary Ruskin, Lella Sarcevic, Martin McKee & David Stuckler

Globalization and Health 15, Article number: 36 (2019) | Cite this article



ILSI Response to Globalization and Health

6 June, 2019 | edited 7 November, 2019

On June 3, 2019, Dr. Sarah Steele, Department of Politics and International Studies, University of Cambridge, and colleagues published an article in *Globalization and Health* titled "Are industry-funded charities promoting "advocacy-led studies" or "evidence-based science"? a case study of the International Life Sciences Institute." Subsequently, many international media outlets have reported on this paper.

Dr. Steele's article concludes that "ILSI seeks to influence individuals, positions, and policy, both nationally and internationally, and its corporate members deploy it as a tool to promote their interests globally." **Dr. Steele's characterization of ILSI is incorrect. The following describes ILSI policies regarding lobbying, corrects claims made in the article, and provides information regarding ILSI's longstanding position on tobacco as well as recent changes to ILSI's governance.**

Key Points:

- **ILSI is a nonprofit, worldwide organization whose mission is to provide science that improves human health and well-being and safeguards the environment. ILSI and ILSI entities foster public-private scientific partnerships to address knowledge gaps to benefit public good.**
- **ILSI does not lobby, nor does ILSI seek to influence individuals, positions, and/or specific policy.** Additionally, ILSI explicitly

Networking to shape reg thinking

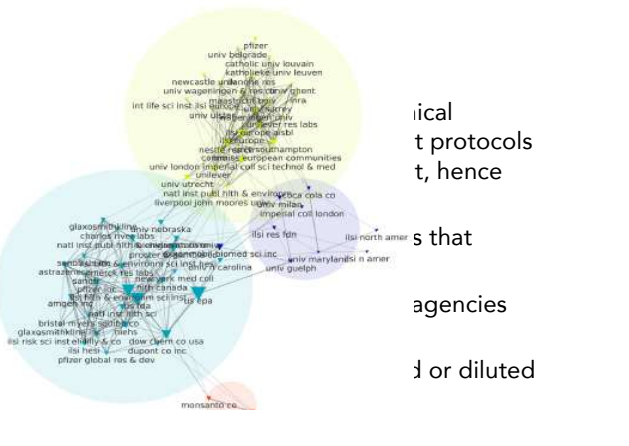


Modus operandi

- Task forces pick up ideas from firms and associated scientists, of methods that can address – or even preempt – concerns of regulators (e.g. are chemicals positive in animal tests also dangerous for humans?)
- Creates a working group, and invite a broad set of scientists and regulators, to further articulate and give credibility to the concept
- Disseminate the concept systematically through repeated publications, reports, and in meetings with regulators, to get these to apply the concepts

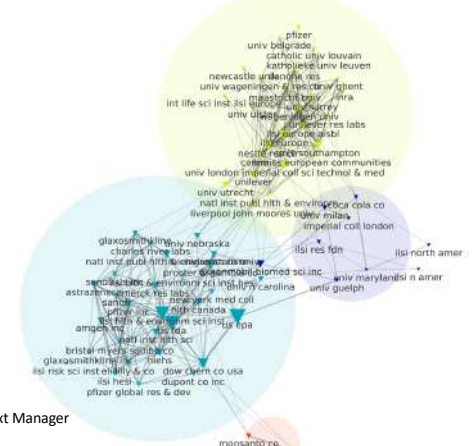
Why do

- Science-like objectivity that reduces uncertainty
- Consensus repeatedly
- Standard around the
- Links with



ical protocols, hence agencies that or diluted

Network of institutions to which co-authors of ILSI papers are affiliated



Analysis and visualization performed with Cortext Manager

Discreet but central

- ILSI does not appear as an author, sometimes not even as an affiliation of the authors of the paper.
- « *ILSI Europe has already published 12 scientific peer-reviewed publications this year. If we were to consider ILSI Europe as an individual scientist, our h-index would be 82.*»

MOA

Quick definition

- The mode of action of a chemical is the biological mechanism, described at the cellular level, by which it is presumed to cause toxicity in a given organ ('endpoint')

A toxicological paradigm

- First occurrences in the literature starting in the 1960s by the rare new university toxicology centers (e.g. Chicago, J. Doull)
- A paradigm that has unfolded and taken various conceptual forms over time:
 - « Mechanism » first
 - « modes of action » second
 - « toxicity pathways » (NRC 2007)(short-lived) third
 - And « adverse outcome pathway »

Mechanistic toxicology before ILSI

- Articulated in the 1960s in sites of gov-acad-industry collaboration (BIBRA in UK, CIIT in the US)



Instead, in 1961 Golberg became the founding Director of the British Industrial Biological Research Association (BIBRA) in London. This new organization, a joint industry-government effort, was created to investigate mechanisms underlying toxic effects of chemicals, develop new or improved toxicity tests, and give advice and information on toxicological issues. BIBRA was intended to be an impartial forum for improved communication between industry, government, and academic personnel in addressing toxicological issues of major public significance, issues that were emerging with increasing frequency and contentiousness.

Industry interest in mechanistic knowledge

- Crystallizes in the 1980s in the US, judging from scientific publications and from industry's internal correspondence
 - Working on mechanisms and modes of action= a way out of the regulatory controversies surrounding high-profile substances, and the threshold/no-threshold controversy, that animal tests do not help decide
- Takes form in R&D organization and programs in the 1990s, both in the US and in Europe

MOA research as product defence

- Firms also realized that MOA can invalidate positive results in animal tests: if you can prove the cellular mechanism does not exist in humans, positive results in animal tests may be disregarded: the 'relevance' issue
- "The original mechanistic research was asking the question what's caused these effects and would we see these effects in humans? And some of them you say, you know, if humans were exposed at the same doses, you'd get the same response and therefore that would lead to cancer, *and some you wouldn't. So that was the first sort of investigative toxicology that was done.*"

ILSI working group: (ex)EPAers and acad.



Critical Reviews in Toxicology
Volume 33, 2003 - Issue 6

285 Views
79 Citations to date
18 Abstracts

Included Reviews
The Human Relevance of Information on Carcinogenic Modes of Action: Overview
Samuel M. Cohen, M. E. (Betty) Meek, James E. Klaunig, Dorothy E. Patton & Penelope A. Farmer-Citop
Pages 591-605 | Published online: 29 Sep 2003
Cite this article: <https://doi.org/10.1080/01136960310001660371>

References | Citations | Metrics | Reprints & Permissions | [View Full Article](#)

Abstract
Risk assessment policies and practice place increasing reliance on mode of action (MOA) data to inform conclusions about the human relevance of animal tumors. In June 2007, the Risk Science Institute of the International Life Sciences Institute formed a workgroup to study this issue. The workgroup divided into two subgroups, one developing and testing a "framework" for MOA.

Related research

Funding of research on MOAs with no human relevance

> *Toxicol Sci.* 2006 Jan;89(1):51-6. doi: 10.1093/toxsci/kfj001. Epub 2005 Oct 12.

Mode of action in relevance of rodent liver tumors to human cancer risk

Michael P Holsapple¹, Henri C Pitot, Samuel M Cohen, Alan R Boobis, James E Klaunig, Timothy Pastoor, Vicki L Dellarco, Yvonne P Dragan

Enrollment of the WHO's IPCS



Regulatory Toxicology and Pharmacology

Volume 34, Issue 2, October 2001, Pages 146-152



Regular Article

IPCS Conceptual Framework for Evaluating a Mode of Action for Chemical Carcinogenesis

C. Sonich-Mullin^a, R. Fielder^b, J. Wiltse^c, K. Boetcke^c, J. Dempsey^d, P. Fenner-Crisp^e, D. Grant^f, M. Hartley^g, A. Knaap^h, D. Kroese^{g,2}, J. Mangelsdorf^b, E. Meekⁱ, J.M. Rice^j, M. Younes^o

Enrollment of other reg entities, through ILSI.eu and allied platforms

An ECETOC/ILSI RF/HESI workshop was held in 2009 to exchange views on conceptual approaches to the use of Mode of Action (MOA) in chemical risk assessment. A number of recommendations emerged, and a global Steering Group was convened by WHO/IPCS to co-ordinate implementation of an 'umbrella plan' of work, comprising experts from ECHA, EFSA, Imperial College, JRC, OECD, University of Ottawa, US EPA, ILSI/HESI, and ECETOC. The objectives of the 2013 workshop were to review progress that had been made since 2009. Specifically, these were to share experiences in applying the MOA approach in the regulatory

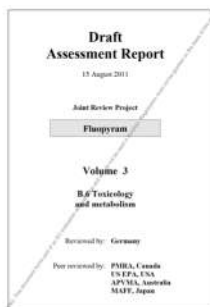
New publication based on ILSI.eu work

[Review](#) > [Crit Rev Toxicol](#). 2011 Mar;41(3):175-86. doi: 10.3109/10408444.2010.541225.

Using mode of action information to improve regulatory decision-making: an ECETOC/ILSI RF/HESI workshop overview

Neil Carmichael ¹, Melanie Bausen, Alan R Boobis, Samuel M Cohen, Michelle Embry, Claudia Frujtier-Pöloth, Helmut Greim, Richard Lewis, M E Bette Meek, Howard Mellor, Carolyn Vickers, John Doe

Relevance questions in EU reg processes



However, even if further investigation would allow the definite conclusion that the mode of action of fluopyram was very similar to PB, this would not mean that classification and labeling of fluopyram for carcinogenicity would not be warranted. In fact, the notifier referred to papers in which the receptor CAR has been shown to be less important than the PXR receptor for CYP induction in human liver (Moore et al. 2003, ASB2008-5463) and a PB-like mode of action was considered to be non-relevant to humans (Hobsapple et al., 2006, ASB2008-2112). However, molecular effects of PB are not limited to induction of CAR but also include interaction with Cx32 containing gap junctions (Moennikes et al., 2000, ASB2009-918), activation of protein phosphatases (e.g. Pusylynyak et al., 2006, ASB2009-920) and effects caused by HGF dependent signaling (Simoni-Rugiu et al. 1996, ASB2009-921; Magg-Schoeling et al. 2008, ASB2009-922). Furthermore, PB is still considered a class 2B carcinogen by the IARC (Anonym, 2001, ASB2008-5447), also due to epidemiological findings summarized by Whytner et al. (1996, ASB2008-5446). PB is consequently labeled R40 when sold as a chemical (Sigma Aldrich, 2005, ASB2009-924, SDS Phenobarbital). Accordingly, a substance that is shown to be like PB would require the same labeling in terms of tumor induction.

No mechanical benefit of MOA but...

- The effects of establishing a framework of thinking in terms of MOA and relevance, and investing in research in this area involve:
 - Raising the threshold of proof required to establish the existence of a toxicity in humans, and so delays or annuls risk assessments
 - Helping manufacture uncertainty around established mechanisms
 - Ascertaining the animal-only nature of certain mechanisms

Conclusion

- On science? Embracing the language of objectivity and evidence (replicable protocols, 'further research is needed', evidence, use of peer communities) appears decisive
- Capture? Clear strategy of diffuse intervention through the fabric of the regulatory space, with limited attributability of concepts - and of benefits.
- Environmental crisis? ILSI's concepts strengthen the focus of the reg framework on *individual chemicals*, and on the ascertaining of chemical-to-effect relationship > as much attention and time divested from measuring and acting on the overall chemical burden on populations and the biosphere.

Many thanks for your attention!

