



Regulators Under Fire: Could the Privilege Be Lost?



2013
Annual
Educational
Conference
Hyatt Regency at the Arch | St. Louis
Oct. 3-5, 2013



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Regulators Under Fire: Could the Privilege Be Lost?

Richard Steinecke, Steinecke Maciura LeBlanc



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Thoughts on Respect

- “Respect yourself and others will respect you.” – Confucius
- “I can win an argument on any topic, against any opponent. People know this, and steer clear of me at parties. Often, as a sign of their great respect, they don't even invite me.” – Dave Barry

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Thoughts on Respect

- “Respect is a two-way street, if you want to get it, you've got to give it.” – R. G. Risch
- Nothing is more despicable than respect based on fear. - Albert Camus
- If you have ten thousand regulations you destroy all respect for the law. - Winston Churchill

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Regulators under Fire



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Growing Distrust

- Canada is one of the last bastions of professional self-regulation in the world
- Over the past decade evidence of distrust of regulators has accelerated rapidly
- Probably not an exaggeration to say that in Ontario at least we are one major crisis away from the end of self-regulation
 - Some would say self-regulation no longer exists

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Growing Distrust - Evidence

- Toronto Star - publishing cautions series
 - What is a “caution”, and why not public?
 - January 2013
 - “The mistakes you can’t know about”
 - Over 2000 cautions in five years
 - Examples given (e.g., failing to follow up cancer diagnosis, prescribing drugs patient allergic to, saying patients will die if do not come for chiropractic care, medication errors)

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Growing Distrust - Evidence

- Toronto Star - publishing cautions series
 - Multiple requests for info - short deadlines
 - Explained value of remediation vs. shaming
 - Cited court cases that justified summary remediation on basis that no public record and no findings have been made
 - Those explanations were not reported
 - Legal uncertainty that Colleges could publish given structure of the legislation

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Growing Distrust - Evidence

- Toronto Star - publishing cautions series
 - Minister said she would talk with Colleges
 - “I do think the world is changing in terms of expectations around transparency.... I think we all expect more information and I think it’s important that colleges keep up with the expectations.”
 - Stated cautions were for “mistakes or improper behaviour”

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Growing Distrust - Evidence

- Toronto Star - publishing cautions series
 - Editorial: "... laws involving privacy and confidentiality being used as a convenient way to shield bureaucratic institutions from outside scrutiny, or prevent important information from reaching the public."

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Growing Distrust - Evidence

- Toronto Star - publishing cautions series
 - Next day article states Minister has given Colleges green light to make cautions public
 - No legislative change is required
 - Minister stated that it is "very important" that the Colleges "never lose sight that their job is to protect the public"
 - Next day opposition parties joined the fray

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Growing Distrust - Evidence

- Toronto Star - publishing cautions series
 - Profile of Toronto Star Editor:
 - It's the kind of story that gets Cooke in a froth. In his heart, he's a crusader. "It's stupid, unnecessary, arrogant secrecy," he says, his voice rising. "For me, it's not only about shining a spotlight on pompous and disgraceful behaviour, this is information you need to know to live in this city."

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Growing Distrust - Evidence

- Toronto Star - publishing cautions series
- What happened?
 - Colleges in process of considering change
 - Many think change will have negative impact on effectiveness of regulation
 - But loss of public confidence too high a price to pay
 - Similar articles have already → change
 - CPSO facility inspection results
 - OCP pharmacy inspection results

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Growing Distrust - Evidence

- Toronto Star similar series on Teachers
- Resulted in College hiring retired Justice LeSage to review their complaints and discipline process
- Resulting in changes to the process to make the process faster and fairer

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Growing Distrust - Evidence

- Increasing oversight
 - Always by courts
 - Review tribunals for complaints, registration decisions
 - Advisory councils
 - Office of the Fairness Commissioner
 - In some provinces, privacy commissioner
 - Ombudsman is requesting authority

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Growing Distrust - Evidence

One Advisory Council report in 2010:

- HPRAC also concludes that the recent actions of the [regulator] were such that it put certain interests of the profession ahead of those of the public. While the intentions might have been well meaning, the standard of practice developed did not reflect the scope of practice of the profession, and defied the 2001 direction from the Minister of Health. HPRAC agrees with the Minister's assertion that the actions of the College were troubling, and reflect on the way it serves and protects the public interest.

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Growing Distrust - Evidence

- Increased political oversight
 - Right to direct regulators on some issues
 - Sometimes with little or no consultation
 - Appointment of operational auditors
 - Past history of appointment on "consent"
 - Appointment of supervisors
 - Assurances unlikely to ever be used
 - Deanna will present on one use already
 - Increased percentage of public appointees

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Growing Distrust - Evidence

- Unilateral government action
 - AIT mobility within Canada
 - A decade ago direction to negotiate with regulators elsewhere in Canada
 - Strict criteria, most did so fairly successfully
 - 2009 enacted legislation imposing automatic recognition of qualifications without assessment across the board
 - "We don't trust you"
 - → Circumvention of requirements

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Growing Distrust - Evidence

- Unilateral government action
 - Bill 55 dealing with consumer protection
 - Includes changes to real estate industry
 - Disclosure of multiple offers
 - Compensation need not be by commission
 - Rather than working with regulator (RECO) to amend its Code of Ethics for registrants

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Growing Distrust - Evidence

- Private members' bills
 - Concept of private members' bill
 - E.g., public access to meetings of committees
 - E.g., redefining sexual abuse
 - E.g., post inspection guidelines on website
 - Frequency indicates perception on regulators

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Growing Distrust - Observations

- No one is under the radar
 - While physicians, teachers and lawyers are easy targets, others are scrutinized too
- Transparency is the easiest target
- Inexplicable decisions create traction
- Some critics are not fair

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Prognosis

- Self-regulation is still the go-to model
 - New self-professions are being created
 - Good politics to create
 - There will be a battle to remove
- But cannot be taken for granted
 - Speed at which government turns on regulators during crisis is stunning

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Prognosis

- Greater immediate risk is de facto government control
 - Informal
 - Formal (Ministerial directions, supervisors, etc.)
 - Accompanying bureaucratic paralysis while reporting to masters and awaiting direction
 - Could lose support of profession
 - i.e., quiet majority, volunteers, disheartened staff

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The Prescription

- Aggressive and trumpeted transparency
 - A hard sell to profession
- Wise and well-articulated decisions
 - Training, training, training
- Early detection systems for problems
 - Information is usually already in your files
- Good governance
 - To avoid appearance / reality of self-interest

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**Regulators Under Fire:
Could the Privilege Be Lost?**

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I will keep this Oath and this stipulation: to reckon him who taught me this Art equally dear to me as my parents, to share my substance with him, and relieve his necessities if required; to look upon his offspring in the same footing as my own brothers, and to teach them this art, if they shall wish to learn it, without fee or stipulation; and that by precept, lecture, and every other mode of instruction, I will impart a knowledge of the Art to my own sons, and those of my teachers, and to disciples bound by a stipulation and oath according to the law of medicine, but to none others.

Hippocrates, 400 BCE

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The UK regulative bargain

- The UK regulatory model is still influenced by history:
 - medieval guilds, 18th Century 'social clubs', Royal Charters
 - the 'private sector' tradition of UK professions
- UK regulation is often market-based, *laissez faire* and involves limited intervention even when it is statutory
- Many professions are wholly or largely self-regulated:
 - Engineers (Engineering Council)
 - Accountants (Financial Reporting Council)
 - Surveyors (Royal Institution of Chartered Surveyors)
 - Veterinarians (Royal College of Veterinary Surgeons)

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Statutory regulation: playing with fire



London Building Act 1667

- response to the Great Fire of London.
- minimum distances between buildings
- limits on timber content
- appointment of surveyors to verify compliance

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“Press regulation: public prefers government's plan to industry's”



Poll finds 50% back parliamentary charter while 13% support alternative drawn up by press
Guardian, 23 July 2013

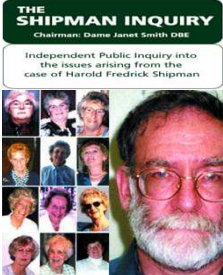


Press regulation is becoming real ...Now that the FT has signed up, Ipso is the clear frontrunner
Observer, 28 July 2013

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Health: the Shipman legacy

“The main purpose of the Health and Social Care Bill is to... reform professional regulation to enhance public and professional confidence... as part of the Government's response to the Shipman Inquiry...”



Department of Health, 2011

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“NYSE body to run Libor as City attempts to put scandal behind it”

“Libor might stand for the London interbank offered rate, but from next year the scandal-hit benchmark rate will be set by the body that runs the New York Stock Exchange in the latest attempt to clean up the City.

Libor, which is used to price \$300tn (£192tn) of financial products around the world, has been overseen until now by the British Bankers' Association (BBA). But its integrity has been questioned after banks and other financial firms were found to have rigged the rate.

The contract to run the process of setting the rate was put out to tender in April after Martin Wheatley, the boss of new City regulator the Financial Conduct Authority (FCA), concluded in a report that the BBA should be stripped of its long-running association with Libor.”

Guardian, 9 July 2013

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Clementi Review

- Regulation should promote public and consumer interests, competition and innovation, and be transparent;
- The regulatory and representative arms of the professional bodies should be separate;
- The Legal Services Board will be the overarching regulator, but the professional bodies will continue to act as front line regulators

Report of a Review of the Regulatory Framework for Legal Services in England and Wales 2004

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The 'meso-regulators'

- Legal Services Board
- Financial Reporting Council
- Professional Standards Authority for Health and Social Care
- Financial Services Authority

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'Red tape' challenge: legal services

The Justice Minister has launched plans to scrutinise, simplify or scrap more than 150 regulations that affect legal services.

The initiative is part of the Government's 'Red Tape Challenge' to simplify regulation, reduce bureaucracy for individuals and remove unnecessary red tape to reduce the burden on business to allow them to perform to their full potential.

Ministry of Justice 31 May 2013

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Health Care Professions (Indemnity Arrangements) Order 2013

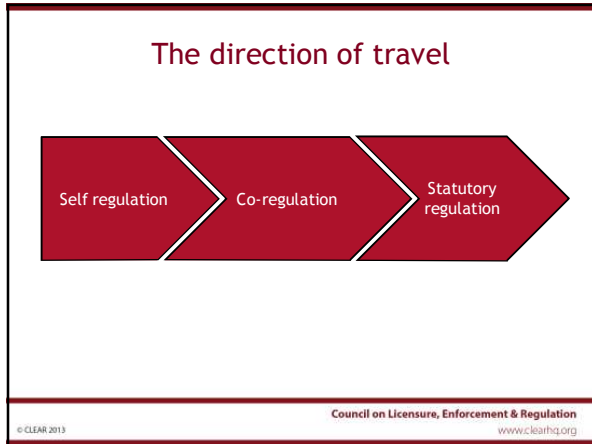
"Policy Background

There is currently **no consistency** across the eight statutory healthcare professional regulatory bodies falling within the remit of the UK Parliament, with regard to legislation or guidance on the need for individual regulated healthcare professionals to hold insurance and indemnity cover...

The four UK Health Departments believe that it is unacceptable for individuals not to have access to recourse to compensation where they suffer harm through negligence on the part of a registered healthcare professional...

...the Government believes that it is right and proper to introduce provisions which require regulated healthcare professionals to have in place indemnity cover as a condition of registration."

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Understanding the Regulatory Landscape
Compounding Tragedy: Lessons Learned
Carmen Catizone, M.S., RPh, DPh
Executive Director
National Association of Boards of Pharmacy

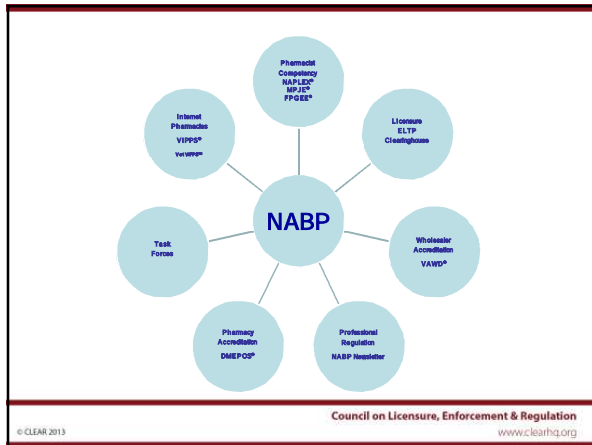
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NABP

- The National Association of Boards of Pharmacy (NABP) is the independent, international, and impartial Association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health

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Overview

- What Really Happened
- Regulatory Landscape
- Action Plan Overview
 - Identification / Information Sharing
 - Inspection Process
 - Training/Education



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Who regulates and inspects compounding pharmacies?

Each compounding pharmacy is licensed by its state's board of pharmacy, which has primary responsibility for day-to-day oversight. FDA's regulatory authority over certain compounding pharmacies is more limited than its authority over other drug manufacturers. For example, compounded drugs are not FDA approved. In addition, compounding pharmacies are not generally required to register with FDA, and therefore do not tell FDA what drugs they are making.

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What Really Happened



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FDA/Congressional Background

- Legislation -
- Hearings
- Requests
 - ✓ Senate HELP Committee
 - ✓ Committee on Commerce and Energy
- FDA Meeting December 19, 2012

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FDA Inspections/Investigations

- Investigation into New England Compounding Center (NECC)
- Risk-based model for inspections
- 52 firms inspected in 2013 (as of 7/22/13)

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FDA Inspections/Investigations

- AL, AR, AZ, CA, CO, CT, FL, GA, IL, IN, KS, LA, MA, MI, MS, MO, NV, NJ, NY, NC, OH, OK, PA, SC, TN, TX, UT, VA
- Inspections conducted with boards of pharmacy

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Regulatory Landscape

- Impact on state pharmacy boards
- Probable federal legislation
- Changes in practice
- Midwest Perspective

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Federal Compounding Legislation

- H.R. 2186 - Verifying Authority and Legality In Drug Compounding Act of 2013 ("VALID Compounding Act"), Congressman Ed Markey, (D-MA) (now Senator)
- S. 959 - The Pharmaceutical Quality, Security and Accountability Act, Senate HELP Committee Chairman Harkin (D-IA) and Ranking Minority Member Alexander (R-TN)
- Discussion Draft - Compounding Clarity Act of 2013 (not yet introduced), Congressman Morgan Griffith (R-VA)

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Action Plan Overview

- Identification of Compounding Entities Registered or Licensed as Pharmacies, but Engaged in Manufacturing Activities
- Inspections: Distinguishing Traditional Compounding and Compliance with State and Federal Laws/ Regulations and Compounding Standards
- Training and Education

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Existing NABP Infrastructure

- License Verification Services
- Disciplinary Clearinghouse - HIPDB reporting
- License Transfer for Pharmacists
- Accreditation Programs
- Contracted State Inspection Services
 - Resident
 - Nonresident

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Training/Education

- Executive Officer Forum
 - September 24-25
- Compliance Officer/Legal Counsel Forum
 - December 3-4
- Clinical IQ
 - Webinar
 - Boot camp
- Compounding Resource Guide
 - USP 797/795 checklist
 - Best practices from BOPs
 - Regulatory/policy recommendations

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**Solution: Enhance Existing Infrastructure
Verified Pharmacy Program (VPP)**

- Extrapolate the successes of the Electronic Licensure Transfer Program® and apply it to nonresident pharmacies and facilities
- Create an e-Profile for each pharmacy and link to e-Profiles for key pharmacy personnel
- Create inspection clearinghouse to facilitate sharing of inspection reports/results

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**VPP - A Unified Resource for
States**

- *Boards set uniform standards for inspections*
 - *Consistent standards that still respect unique state requirements*
- *Boards will be able to make informed licensing decisions*
- *Seamlessly integrated into Board portal*
- *No cost to boards*

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Questions



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A Precedent Set in Ontario

- The College of Denturists of Ontario
 - A Case Study...

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**Context-Professional Regulation
in Canada**

- Self-regulatory model
- Shared governance
- Autonomy- with Ministerial oversight

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Hallmarks of self-regulation

- Right to set, collect and use registrant fees
- Responsibility to set and enforce standards
- Right to investigate and adjudicate complaints, and..
- Right to discipline “own”

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Self-Regulation

- A privilege, not a right

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In Ontario

- Regulated Health Professions Act (RHPA)
 - 26 independent health regulatory colleges
 - 29 health care professions
 - Common processes and procedures
 - Profession-specific Acts
 - Increased oversight powers of Minister in 2009

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Interest and Oversight

- Increased overall
- Global not local trends
- Indication....

- In public confidence and trust

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Powers of the Health Minister In Ontario

- MOHLTC may appoint a supervisor where “necessary and appropriate”:
 - Concerns re Management, Operations
 - Administration of relevant laws
 - Performance concerns of staff, council, committees
 - Due processes lacking or inconsistent

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College of Denturists- Case Study

- In 2010, numerous concerns raised:
 - Conflicts of interest/role
 - Examinations and Registration
 - Blurring of role
 - Lack of consistency
 - Lack of communication
 - Leadership

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In 2011

- Independent audit ordered
- Conducted by PWC through 2011

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Unprecedented Action

- Supervisor appointed March 2012
- Powers broad:
 - Registrar and staff
 - Council
 - Committees* (with exceptions)

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Addressing Audit Concerns

Exams and Entry to Practice

Operating By-Laws

Ensuring Consistency and Defensibility

New Registration/QA Regulations

Financial controls and Resources

Re-building Relationships and Trust

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Where CDO is today

- New Leadership
- Privilege returned
- New operating by-law
- Consistency in all decisions, processes
- New examination for 2014

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Opportunity to Learn?

- The road to rebuilding credibility, trust and your reputation, once lost is long and difficult..

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Some Final Thoughts...

- What happens elsewhere...
- Actions of others affect us all
- Reputation is key
- Risk of losing it is real
- Embrace principles of 'right touch' regulation:
 - Doing the right things
 - Doing them right

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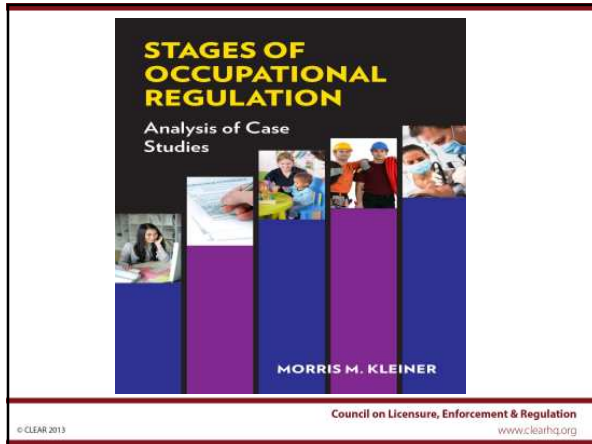
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When to License

Morris M. Kleiner, University of Minnesota



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Lessons from an analysis of case studies

- Individuals in *Licensed Occupations* gain more the longer the occupation is highly regulated
- *Attainment of a license matters* rather than being in an occupation that has some regulation or *is covered* by a licensing law (lawyers v. engineers)

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Trends in Licensing

- During the 2012-13 legislative sessions, two governors - one from Iowa and the other from Indiana - vetoed legislation from their own party's dominated legislature that would have licensed several new occupations.

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Trends in Licensing

- In Iowa Governor Terry Branstad vetoed the licensing of addictive disorder counselors and other related occupations.
- In Indiana, Governor Mike Pence vetoed the licensing of diabetes counselors and anesthesiologist assistants and dietitians.

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Trends in Licensing

- Beyond these two cases, there appears to be a trend toward reversing or at least slowing the growth of occupational licensing. In Texas, legislation was passed and signed favoring the least restrictive form of regulation, and in Utah sunrise and sunset legislation was implemented into law focusing on occupational licensing

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Trends in Licensing

- At the federal level, first lady Michele Obama challenged the states to remove licensing and credentialing barriers to Service members and veterans, and 38 states have passed laws doing so.

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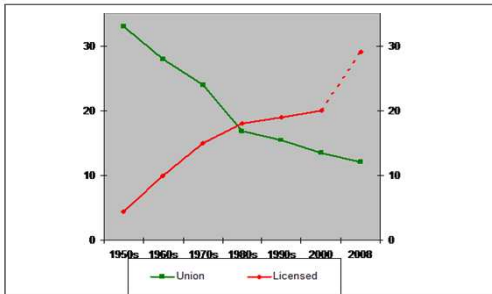
Trends in Licensing

- Internationally, Poland this year deregulated 39 occupations ranging from lawyers to surveyors.

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Trends in Two Labor Market Institutions in the U.S.



Dashed line shows the value from state estimates of licensing to the Gallup and Westat Survey results—more than 800 occupations are licensed in at least one state level according to the Council of State Governments; Union Data from the CPS

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Recommendations from Shimberg—CLEAR FOUNDER

- At a minimum, policy makers should require that representatives of the occupation seeking to become regulated state, describe, and document the physical, emotional, social, or financial consequences to the consumer that result from erroneous or incompetent practice.

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**Recommendations from
Shimberg**

- The representatives of the occupation seeking licensing should be required to describe which existing legal remedies are inadequate to prevent or redress the kinds of harm that could result from no regulation.

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**Recommendations from
Shimberg**

- They could be asked how certification, which is right to use a title, **but does not grant a monopoly**, is not sufficient and why a government legal decree is required to perform the work. Again, dealing with the unintended consequences and the labor market, they should be required to answer what is the expected impact of the proposed regulation on the existing supply of practitioners, and what percentage of current practitioners will be able to meet the proposed eligibility criteria?

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**Recommendations from
Shimberg**

- If current practitioners will be “grandparented,” the representatives of the occupations should be asked to describe how long and under what conditions. Finally, they should be asked to describe the **extent to which regulation or expansion of regulation will increase the cost of goods or services provided by practitioners and the overall cost-effectiveness and economic impact of the proposed regulation, including indirect costs to consumers.**

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**Recommendations from
Shimberg**

- Two broad categories of establishing clear criteria and data that show that being licensed would enhance the health and safety of the community and would not harm the labor market or the general economy

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**Recommendations from
Shimberg**

- A second criterion suggests that it is the burden of the state rather than the individual to show if an occupation should be licensed. Under the second set of proposals individuals would be allowed to challenge any law and show that they could perform the licensed tasks in a competent manner

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