This document contains:

- Course description
- Class reading assignments & focus questions for each day
- Course syllabus
- Research paper topics
Law, Healthy Lifestyles & Business Regulation

(Week 1 of Spring Term, 2017)

Course description

This course is about legal responses to tobacco use, obesity, poor diet, harmful use of alcohol and sedentary lifestyle – the leading causes of preventable disease in the United States, in high-income countries generally, and increasingly, in developing economies. Cancer, heart disease, stroke, diabetes and tobacco-related diseases (known as “non-communicable diseases” or NCDs) are society’s greatest killers, but what can law do – and what should it be doing – to prevent and control them?

Unlike other global health threats, NCDs and their risk factors are partly caused by patterns of consumer choices and transactions lived out every day across the country. The challenge of creating healthier lifestyles cannot be separated, then, from the debate about how best to regulate those business that all too often have a vested interest in unhealthy lifestyles.

Although the law’s relationship with the lifestyle-related risk factors for NCDs is complex and contested, governments around the world are experimenting with a wide range of legal strategies to prevent their impact and to create healthier societies. This course places U.S. developments in an international context, and offers frequent comparisons with legal strategies for encouraging healthier lifestyles in Australia and other countries.

During the course, we will confront some important over-arching questions. What are the global determinants of NCDs, and to what extent are global solutions needed? What do global solutions look like? To what extent should law intervene to influence the behavior of populations – as distinct from treating lifestyle-related risk factors as the personal responsibility of each individual? Does a regulatory approach to the prevention of NCDs imply coercion? Does it signal the emergence of the “nanny state”? Does progress necessarily depend on motivating people to consciously improve their habits and lifestyles? Is it possible to regulate business without micro-managing or dictating commercial decisions and “mandating the recipe for tomato ketchup”?

The overall aim of this course is to give students the conceptual skills to think powerfully about law’s role in the prevention of NCDs, and to participate effectively in debates about appropriate and workable, legal interventions.
The class runs from 9.00-12.20pm each day. Each module contains “focus questions”. Please do some reading in advance and come to class ready to share your thoughts on these questions.

Monday, January 9, 2017

**MODULE 1: Frameworks for thinking about law, and environments that support healthier lifestyles**

**FOCUS QUESTION:**
1. Why is a model which conceptualises of law’s role in terms of (1) seeking to inform individuals so that they can make healthier choices; or (2) constraining individual choices – an *inadequate model* when it comes to chronic, non-communicable diseases (NCDs) and their risk factors?

**CLASS ACTIVITY: “SHOW & TELL”**
- A number of the items in the course materials in Module 1 are marked with this symbol: Ø. In preparing for class, familiarise yourself with two or three of these items and see if you can identify how each item relates to the conceptual framework that will be presented in the first class. See Module 1 for more details about this activity.

Tuesday, January 10, 2017

**MODULE 2: Global health governance and the prevention of non-communicable diseases**

**FOCUS QUESTION:**
1. Review the WHO’s *Global Action Plan for the Prevention and Control of Non-communicable Diseases 2013-2020* (A66/10, 26 May 2013). What are the key themes and messages from this document? What are the most important concepts in the action plan that are most critical to its success. Explain why.
2. In light of the Malone chapter (above), read the *Guidelines for Implementation of Article 5.3 of the FCTC* (above) and identify a particular issue or topic or question in them that interests you. Be prepared to present this to the class in 5 short sentences. Also, ask yourself whether there are any law reform implications that arise from the issue you have chosen.

**Wednesday, January 11, 2017**

**MODULE 3: Tobacco control: where to from here?**

**FOCUS QUESTIONS: on US federal tobacco control**
1. What is the “Final Rule” and what are its most important provisions?

2. What actions is the FDA prevented from taking under the FSPTCA? (There are at least 8 significant restrictions).

3. To what extent has the FDA used its regulatory powers to regulate menthol in tobacco products? Can it regulate menthol?

4. What criteria does the Act instruct the Secretary to apply in: (1) adopting tobacco product standards; (2) assessing applications for approval to market a “new tobacco product”; and (3) making an order approving the commercial marketing of “modified risk tobacco products”?

**FOCUS QUESTIONS on tobacco harm reduction**

1. What is the status of the FDA’s attempts to regulate electronic cigarettes?

2. What do your instincts, and what does current research tell you about the promotion of smokeless and other “reduced exposure” forms of tobacco, as a harm reduction strategy? Consider the Gartner (*Lancet*) and Mejia (*Lancet*) articles.

**CLASS ACTIVITY: “SHOW & TELL”**
- A number of the items in the course materials in Module 1 are marked with this symbol: Ø. Choose one or two items and come to class ready to talk about the significance and relevance of this item. What is its relevance to (potential) future tobacco control strategies?

**Thursday, January 12, 2017**

**MODULE 4: Obesity, public health nutrition & active living**
FOCUS QUESTIONS:
1. What is performance-based regulation? How might it be applied to regulatory approach to obesity prevention and/or public health nutrition?

CLASS ACTIVITY: “SHOW & TELL”
- Every student is asked to come to class prepared to briefly present one concrete legal intervention that could be implemented at either federal, state or city/local level to improve diet, increase physical activity, or to prevent and reduce obesity. You are welcome to choose examples or initiatives mentioned or extracted in the reading materials, or from the list of further reading. It doesn’t have to be an American example: every country can learn from a comparative approach. You should also be able to briefly explain the mechanism or process through which the intervention would improve diet (or achieve its other aims).
Course description:

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Unlike other global health threats, NCDs and their risk factors are partly caused by patterns of consumer choices and transactions lived out every day across the country. The challenge of creating healthier lifestyles cannot be separated, then, from the regulation of those businesses that all too frequently have a vested interest in unhealthy lifestyles.

Although the law’s relationship with the lifestyle-related risk factors for NCDs is complex and contested, governments around the world are experimenting with a wide range of legal strategies to prevent their impact and to create healthier societies. This course places U.S. developments in an international context, and offers frequent comparisons with legal strategies for encouraging healthier lifestyles in Australia and other countries.

During the course, we will confront some important over-arching questions. What are the global determinants of NCDs, and to what extent are global solutions needed? What do global solutions look like? To what extent should law intervene to influence the behavior of populations – as distinct from treating lifestyle-related risk factors as the personal responsibility of each individual? Does a regulatory approach to the prevention of NCDs imply coercion? Does it signal the emergence of the “nanny state”? Does progress necessarily depend on motivating people to consciously improve their habits and lifestyles? Is it possible to regulate business without micro-managing or dictating commercial decisions and “mandating the recipe for tomato ketchup?”
The overall aim of this course is to give students the conceptual skills to think powerfully about law’s role in the prevention of NCDs, and to participate effectively in debates about appropriate, workable, legal interventions.

**Contact details:**

- Professor Roger Magnusson, Sydney Law School, University of Sydney

**When contacting me, please use my Sydney Law School email, which is:**

- [Email redacted]

**Lecture Times**

- Week 1 of Spring Term (Mon 9, Tues 10, Wed 11, Thurs 12 Jan, 2017, 9am-12.20pm.
- Venue: Hotung 1000.

**Assessment**

This course will be assessed by research paper. A range of topics for papers will be made available. Students may also propose their own topics.

Proposed word length is 3,000 words (3,500 words max), excluding footnotes.

**Plagiarism and Academic Honesty**

Georgetown University Law Center’s policies on plagiarism and academic honesty can be found at in the appendix to the student disciplinary code, at: [http://www.law.georgetown.edu/registrar/bulletin/conduct_policies/sdc.cfm#appendix](http://www.law.georgetown.edu/registrar/bulletin/conduct_policies/sdc.cfm#appendix)

**Books & Recommended Materials:**

**There are no prescribed texts for this course.** A comprehensive set of materials will be made available. Students are requested to have these materials available for rapid reference during class, either in hard copy (which might be easier) or, at least, in soft copy.
The following texts are of general relevance:


You may also find the following helpful:

Some useful websites:

- Public Health Law Program at CDC: [http://www2.cdc.gov/phlp/](http://www2.cdc.gov/phlp/)

**Course summary**

Module 1: Frameworks for thinking about law, and environments that support healthier lifestyles (Day 1-2)

Module 2: Global health governance and the prevention of non-communicable diseases (Day 2)

Module 3: Tobacco control: where to from here? (Day 3)

Module 4: Obesity prevention, public health nutrition and active living (Day 4)

For further reference:

Module 5: Personal responsibility, risk factors, and regulation
Module 1: (Day 1-2)

Frameworks for thinking about law, and environments that support healthier lifestyles

Aims of this module
In this module you will be:

• Encouraged to develop a framework to better understand the law’s potential role in the prevention and management of risk factors for disease.
• Locate and make sense of specific legal initiatives by relating them back to a broader framework for health protection, and disease prevention.

1. The age of chronic disease: healthy lifestyles and the challenge of public policy that addresses lifestyle risk factors

• CDC, National Health Report Highlights 2014 (selected pages): http://www.cdc.gov/healthreport/

2. A conceptual framework for thinking about law & non-communicable diseases (NCDs)

Personal responsibility is an excellent change strategy for individuals, but is that the only way to improve the health of populations?
• Howard M. Leichter, “‘Evil Habits’ and ‘Personal Choices’: Assigning Responsibility for Health in the 20th Century” (2003) 81 The Milbank Quarterly 603-626. [JSTOR] Do you agree with the extent to which Leichter would assert that America is, as a whole, responsible for the state of its collective health?

Q: FOCUS QUESTION:
2. Why is a model which conceptualises of law’s role in terms of (1) seeking to inform individuals so that they can make healthier choices; or (2) constraining individual choices – an impoverished model when it comes to chronic, non-communicable diseases (NCDs) and their risk factors?

The determinants of health and disease:

- **Australian Institute of Health & Welfare (AIHW),** extracts from *Australia’s Health 2014* (Canberra: AIHW, 2014) pp 4-7 [WWW (scroll to pg 4 of the PDF)], and *Australia’s Health 2008* pp 42-51[WWW (scroll to pg 42 of the PDF)]. This extract provides a nice outline of a “determinants of health” approach to thinking about public health, in which individuals (with their physical, psychological and genetic makeup) interact with a series of other systems and factors to create a dynamic health pathway for each individual, and for the population as a whole.

What are some of the implications of a “determinants of health” approach – for public health law?

The population health approach:


3. What can governments – and what can law – do?

Gostin, Perdue et al, and Magnusson (in the “further reading”) provide three somewhat different ways of categorising the strategies law can deploy in responding to risks for chronic disease:


Enhancing law’s role: look out for these important themes as we progress through the course:

(i) An “all-of-government approach”?


• Executive Order 13544 of June 10, 2010 establishing the National Prevention, Health Promotion, and Public Health Council (under §4001 of the *Patient Protection and Affordable Care Act* (PL 111-148). [WestlawNext]

• **Executive Order S-04-10** of California Governor Arnold Schwartzenegger, 23 February 2010, establishing the Health in All Policies (HiAP) Task Force. [LexisAdvance] [WWW]

What are some examples of laws that facilitate a cross-sectoral (inter-departmental) or even an all-of-government approach?

(ii) Pre-emption


(iii) Performance-based regulation

More “command and control” regulation, or is it time for something completely different: performance-based regulation?

• Ø **Stephen Sugarman**, “No More Business as Usual: Enticing Companies to Sharply Lower the Health Costs of the Products they Sell” (2009) 123 *Public Health* 275-279. [ScienceDirect]

(iv) The role of local government


4. Applying the framework: time for you to get involved!

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<th>Time for show &amp; tell</th>
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Students will be divided into small groups and asked to consider the document in the materials that contain this sign: Ø.

The aim of this exercise is to identify the relevance of the document in terms of the framework. Ask yourself questions like: what principle or legal initiative or issue does this document illustrate? What part of the legal framework does it relate to? How can I make sense of this document in the context of the challenges of chronic disease and the role of law in seeking to prevent them?

Prepare to briefly describe the significance of each document to the class.


• Ø Mississippi Legislature, Senate Bill No. 2687 (2013). [WWW]

• Ø General Assembly of North Carolina, Session 2013; House Bill 683. [WWW]


• Ø Steve Holt, “California Soda Warning Label Bill Dies as Research Suggests Efficacy”, 14 January 2016. [WWW]


• Ø Food Standards Amendment (Truth in Labelling – Palm Oil) Bill 2009 (Cth), Second reading Speech, 23 November 2009. [WWW] [This Bill was not passed] AND Rachel Gordon, “Supes Back Posting of Cell Phone Emission Levels” San Francisco Chronicle 16 June 2010 [WWW]; AND Ordinance Amending the San Francisco Environment Code by Adding Chapter 11 (Sections 1100 through 1104) to Require Retailers to Disclose Specific Absorption Rate Values for Cell Phones (26 January 2010). [WWW] [Consider these three items together]

• Ø The Synar Amendment: 42 USC § 300x-26. [WWW] What kind of strategy does this provision illustrate?

• Ø Bill to establish the California Healthy Places Act of 2008. [LexisAdvance]

• Ø Quit Smoking Incentive and Opportunity Act of 2003 (Bill introduced into the House of Representatives, July 24, 2003 [HR 2876; never passed]. [WWW]

• Ø California Legislature, Bill AB-2539, introduced February 19, 2016; as amended March 30, 2016: http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520160AB2539 (requiring the establishment of an occupational safety and health standard for fashion industry models in California, to prevent exploitation of models, eating disorders and excessive thinness).

• Ø Extracts from British Columbia’s Public Health Act [SBC 2008] Ch 28 (entered into force 31 March 2009). [WestlawNext]

• Ø Extracts from the South Australian Public Health Act 2011. [WWW] What is the most significant and potentially broad provision extracted here?

• Ø United States v Philip Morris USA, U.S. Court of Appeals for the District of Columbia, 22 May 2009 [WestlawNext] (upholding virtually all of Judge Kessler’s judgment in the
DOJ case under the RICO Act). Selected extracts relate to the issuing of corrective statements to prevent future fraudulent conduct.

- Ø *Alcohol (Minimum Pricing) (Scotland) Act* 2012 [WWW]
These references are not part of the course, but the list is worth scanning because some may be relevant to your research paper topics.

- Susan Mayor, “Non-communicable diseases now cause two thirds of deaths worldwide” *BMJ* 2016; 355:i5456.
- Derek Yach, Samuel Calitz, “New Opportunities in the Changing Landscape of Prevention” (2014) *JAMA*, published online 17 July 2014. [JAMA]
- Kristin Madison, Harald Schmidt, Kevin Volpp, “Smoking, Obesity, Health Insurance and Health Incentives in the Affordable Care Act” (2013) 310 *JAMA* 143-144. [JAMA]
• Roger Magnusson, “Using a Legal and Regulatory Framework to Identify and Evaluate Priorities for Cancer Prevention” (2011) 125(12) Public Health 854-875. [ScienceDirect]


  o The Annual Status reports which the Council is required to publish can be found at: http://www.healthcare.gov/center/councils/nphpphc/index.html


• Center for Public Health and Tobacco Policy, Tobacco Retail Licensing: Local Regulation of the Number, Location and Type of Tobacco Retail Establishments in New York, October 2010, Bostin: The Center for Public Health & Tobacco Policy at New England Law www.tobaccopolicycenter.org


• Abdesslam Boutayeb, “The Double Burden of Communicable and Non-communicable Diseases in Developing Countries” (2006) 100 Transactions of the Royal Society of Tropical Medicine and Hygiene 191-199. [ScienceDirect]

• NCDeNet: http://www.who.int/ncdnet/en/


• M. McNally, J. Downie, "The Ethics of Water Fluoridation" (2000) 66 Journal of the Canadian Dental Association 592-593. [WWW]


Module 2: (Day 2)

Global health governance and the prevention of non-communicable diseases (NCDs)

— What are the global determinants of NCDs?
— What are the structures, processes & governance “architecture” for reducing and preventing NCDs at the global level?
— Who is providing leadership?

Aims of this module

In this module you will be:

• Introduced to the global processes that are driving changes in lifestyles and lifestyle risk factors
• Introduced to the major instruments that comprise the “global governance” of NCDs and their risk factors at the population level
• Introduced to some the key issues and debates about the global governance of NCDs

1. The evolving global governance of NCDs

A good summary of the global burden of NCDs can be found at:

• **Roger Magnusson, David Patterson**, “Role of Law in Global Response to Non-communicable Diseases” (2011) 378 Lancet 859-860. [ProQuest]
For noting:

- **Roger Magnusson, David Patterson**, “The Role of Law and Governance Reform in the Global Response to Non-communicable Diseases” *Globalization and Health* 2014; 10: 44: [http://www.globalizationandhealth.com/content/10/1/44](http://www.globalizationandhealth.com/content/10/1/44) (open access; not extracted in the materials).

Why is there a need for “global health governance” when it comes to chronic disease? Why is it not purely a domestic matter for national governments?

**The global context of chronic disease:**

“Today, noncommunicable diseases (NCDs), mainly cardiovascular diseases, cancers, chronic respiratory diseases and diabetes represent a leading threat to human health and development. These four diseases are the world’s biggest killers, causing an estimated 35 million deaths each year - 60% of all deaths globally - with 80% in low- and middle-income countries.

These diseases are preventable. Up to 80% of heart disease, stroke, and type 2 diabetes and over a third of cancers could be prevented by eliminating shared risk factors, mainly tobacco use, unhealthy diet, physical inactivity and the harmful use of alcohol.

Unless addressed, the mortality and disease burden from these health problems will continue to increase. WHO projects that, globally, NCD deaths will increase by 17% over the next ten years. The greatest increase will be seen in the African region (27%) and the Eastern Mediterranean region (25%). The highest absolute number of deaths will occur in the Western Pacific and South-East Asia regions.

We have the right vision and knowledge to address these problems. Proven cost-effective strategies exist to prevent and control this growing burden. However, high-level commitment and concrete action are often missing at the national level....in all low and middle-income countries and by any measure, NCDs account for a large enough share of the disease burden of the poor to merit a serious policy response.”

**Dr Ala Alwan** (Assistant Director-General, Noncommunicable Diseases and Mental Health, World Health Organization), foreword to WHO, *2008-2013 Action Plan for the Global Strategy on the Prevention and Control of Noncommunicable Diseases*, p 5. [WWW](http://www.who.int)

**2. The trans-national determinants of disease and “global health governance”**

The model of health determinants and of health law you have been introduced to in this course recognises the role of trans-national determinants and their impact on the health of national populations (and indeed on global health). Why is there a need for “global health
governance” when it comes to NCDs? Why is it not purely a domestic matter for national governments?

Case study: food & nutrition:

Case study: tobacco:
- **WHO**, *Guidelines for Implementation of Article 5.3 of the Framework Convention on Tobacco Control* (Protection of public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry). [WWW]

**Q: FOCUS QUESTION:**

3. Review the WHO’s *Global Action Plan for the Prevention and Control of Non-communicable Diseases 2013-2020* (A66/10, 26 May 2013) [WHO.int]. What are the key themes and messages from this document? What are the most important concepts in the action plan that are most critical to its success. Explain why.

4. In light of the Malone chapter (above), read the *Guidelines for Implementation of Article 5.3 of the FCTC* (above) and identify a particular issue or topic or question in them that interests you. Be prepared to present this to the class in 5 short sentences. Also, ask yourself whether there are any law reform implications that arise from the issue you have chosen.

“That a product that is so destructive and so expensive to society remains on the market, sold in every convenience store and, until recently, in almost all pharmacies and hospital gift shops, is due to the ability of the tobacco industry to adapt to challenges, constantly repositioning itself in order to feed upon the social body as mosquitoes feed upon their victims.” (Ruth Malone, “The Tobacco Industry” (citation above, p 159.)


**3. The Impact of WTO Rules and International Trade and Investment Agreements on Global Governance of NCDs**
WTO rules and bilateral investment treaties (BITs) impose obligations on WTO members states, and on parties to BITs, respectively.

Case study: United States – Measures Affecting the Production and Sale of Clove Cigarettes


[REFERENCES FOR RESEARCH PAPERS]

These references are not part of the course, but the list is worth scanning because some may be relevant to your research paper topics.


- **Emilie Aguirre, Olivery Mytton, Pablo Monsivais**, “Liberalising agricultural policy for sugar in Europe risks damaging public health” *BMJ* 2015; **351**:h5085.


- **Helen Walls, Richard Smith**, “Rethinking Governance for Trade and Health” *BMJ* 2015; 351:h3652. [BMJ](http://www.bmj.com)


• **Andy Haines et al.**, “Towards a Comprehensive Global Approach to Prevention and Control of NCDs” *Globalization and Health* 2014; 10:74. [WWW]

• **C. Angkurawaranon et al.**, “Urbanization and non-communicable disease in Southeast Asia: A review of Current Evidence” *Public Health* 2014; 128:886-895. [ScienceDirect]


• **Keats S, Wiggins S., Future Diets: Implications for Agriculture and Food Prices**. Overseas Development Institute, 2014 (http://www.odi.org.uk/future-diets (Chapter 2 explores changes to diets through time and the factors influencing those changes; chapter 3 reviews policies to improve diet).


• WHO, Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013-2020 (A66/9, 6 May 2013). This very useful document contains very useful appendices. Appendix 2 summarises the global monitoring framework for NCDs adopted by the WHA in May 2013. Appendix 3 sets out priority interventions for the prevention and treatment of the leading NCDs. Appendix 5 gives examples of cross-sectoral interventions, including legal interventions, to reduce the major risk factors for NCDs. [WHO.int]


• S Kleiman, S Ng, B Popkin, “Drinking to Our Health: Can Beverage Companies Cut Calories While Maintaining Profits” (2012) 13 Obesity Reviews 258-274 (beverage companies follow different strategies in different countries). [Wiley]


• Deborah Gleeson, Sharon Friel, “Emerging Threats to Public Health from Regional Trade Agreements” (2013) 381 Lancet 1507-1509. [ProQuest]


• Barry Popkin, Linda Adair, Shu Wen Ng, “Global Nutrition Transition and the Pandemic of Obesity in Developing Countries” Nutrition Reviews 2012; 70; 3-21. [Wiley]


• Roger Magnusson, “Global Health Governance and the Challenge of Chronic, Non-communicable Disease” (2010) 38 Journal of Law, Medicine & Ethics 490-507. [HEIN]


• Derek Yach, “Nutritional Change is Not a Simple Answer to Non-communicable Disease” (2011) 343 *British Medical Journal* d5097. [BMJ]


• Ronald Labonte, Katia Mohindra, Raphael Lencucha, “Framing International Trade and Chronic Disease” *Globalization & Health* 2011; 7:21 (online, open source). [WWW]


• Robert Beaglehole et al., “UN High-Level Meeting on Non-communicable Disease: Addressing Four Questions” (2011) published online 13 June 2011. [ProQuest]


• **George Alleyne, David Stuckler, Ala Alwan**, “The Hope and the Promise of the UN Resolution on Non-communicable Diseases” *Globalization and Health* 2010; 6:15. [WWW]


• **Roger Magnusson**, “Rethinking Global Health Challenges: Towards a ‘Global Compact’ For Reducing the Burden of Chronic Disease” (2009) 123 *Public Health* 265-274. [ScienceDirect]


• Framework Convention on Tobacco Control (FCTC) website: http://www.who.int/fctc/en/

• Food Secure Pacific website: http://www.foodsecurepacific.org/
Module 3: (Day 3)

Tobacco control: where to from here?

Aims of this module

There is not sufficient space in this course for anything resembling a coherent review of tobacco control law – in any jurisdiction. The module will begin, however, with a brief review of federal tobacco regulation in the US. This provides the general background for the focus of this module:

In this module you will be:

- Given the opportunity to analyse, discuss and debate specific legal strategies for tobacco control.
- Be encouraged to critically evaluate “harm reduction”, as applied to tobacco, and the public health significance of snus, e-cigarettes and other products delivering nicotine.
- Encouraged to think about the kind of laws that would separate a country (such as the USA) where around 20% of the population smoke daily, from one where less than 5% of the population smoke.
- Be encouraged to think about the tension between civil rights, economic rights, and public health in the context of tobacco control law.

You may find the following website on global tobacco laws helpful:

http://www.tobaccocontrollaws.org/

“Manufacturers’ worldwide profits of about $50 billion in 2012 (approximately $10,000 per tobacco-attributable death) yield enormous political influence.....a substantial increase in specific excise taxes on tobacco [is] the single most important intervention against noncommunicable diseases...”


1. Law & tobacco control: where are we now?

Table summarising selected aspects of federal tobacco control law in the United States

You are expected to browse the *Family Smoking Prevention and Tobacco Control Act* (FSPTCA), Public Law No. 111-31: [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_public_laws&docid=f:publ031.111.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_public_laws&docid=f:publ031.111.pdf)


**Discount Tobacco City & Lottery Inc. V United States**, United States Court of Appeals for the Sixth Circuit, 19 March 2012 (edited extract). [WestlawNext] This case dismissed challenges to the FDA’s new graphic health warnings, but upheld the challenge to the provision that would have restricted tobacco advertising to “black text on a white background.

**R.J. Reynolds Tobacco Co. v Food & Drug Administration**, U.S. Court of Appeals for the District of Columbia, 24 August 2012 (No 11-5332) [extracts – upholding challenges to the FDA’s new graphic health warnings] [WestlawNext].

You are expected to browse §102 of the FSPTCA, as well as the Final Rule restricting the sale, distribution and use of cigarettes and smokeless tobacco issued by the FDA, at: [http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/RegsRestrictingSale/default.htm](http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/RegsRestrictingSale/default.htm)


“...without branding, future generations will grow up never having seen category A carcinogens packaged in attractive packs... (Simon Chapman, “Why the tobacco Industry Fears Plan Packaging” (2011) 195(5) *Medical Journal of Australia* 255.)

“Short of some currently unanticipated development, the annual smoking-produced death toll in the United States alone will continue to number in the hundreds of thousands for decades to come,...[W]e must find novel means of rejuvenating the spirit and creativity that have made tobacco control a sparkling jewel in the crown of public health”. (Kenneth Warner et al., “Impact of Tobacco Control on Adult per Capita Cigarette Consumption in the United States” (2014) 104 *American Journal of Public Health* 83-89, 89 [ProQuest]

**Q: FOCUS QUESTIONS**

5. What is the “Final Rule” and what are its most important provisions?

6. What actions is the FDA prevented from taking under the FSPTCA? (There are at least 8 significant restrictions).
7. To what extent has the FDA used its regulatory powers to regulate menthol in tobacco products? Can it regulate menthol?

8. What criteria does the Act instruct the Secretary to apply in: (1) adopting tobacco product standards; (2) assessing applications for approval to market a “new tobacco product”; and (3) making an order approving the commercial marketing of “modified risk tobacco products”?

2. Regulation, corporate social responsibility and the global tobacco business

What does the tobacco industry most want from government?

- **World Health Organization**, Guidelines for Implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control [WHO.int] – on the protection of public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry (Decision FCTC/COP3(7) (November 2008) [Module 2 above]

“...we are convinced that the remaining policy differences can be resolved through mutually respectful discussions that seek resolution rather than vilification. I hope very much that, together, we can bridge the divide and achieve our common goal”


“I think it’s fair to say that there is some number of people who are and will continue to smoke, and want to buy cigarettes. And the question I think people have to ask themselves is who do you want selling those cigarettes? Do you want companies that are unwilling to listen to their critics, or do you want people who do it who are trying very hard to meet or exceed expectations and change the way they’ve done business in the past?”

(William S. Ohlemeyer, Vice President and Associate General Counsel, Altria Group Inc, speech entitled “Litigation: An Inefficient Means of Changing Corporate Behavior”, 18 July 2003, from the Altria website).

3. E-cigarettes, snus, and other tobacco products

**Q: FOCUS QUESTION**

3. What is the status of the FDA’s attempts to regulate electronic cigarettes?
Effective 8 August 2016, FDA finalised its “deeming rule” in order to bring all tobacco products under FDA regulatory control, including e-cigarettes, all cigars, hookahs, pipe tobacco nicotine gels, and dissolvables.

- **FDA**, The Facts on the FDA’s New Tobacco Rule, 16 June 2016: [http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm506676.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm506676.htm)

Q: **FOCUS QUESTIONS on tobacco harm reduction**

4. What do your instincts, and what does current research tell you about the promotion of smokeless, and e-cigarettes, as a harm reduction strategy? Consider the Gartner (*Lancet*) and Mejia (*Lancet*) articles.

- **Adrienne Mejia**, Pamela Ling, Stanton Glantz, “Quantifying the Effects of Promoting Smokeless Tobacco as a Harm Reduction Strategy in the USA” (2010) 19 *Tobacco Control* 297-305. [BMJ](http://www.bmj.com/content/340/cd3739)

4. **Other opportunities for tobacco control**

<table>
<thead>
<tr>
<th>Time for show &amp; tell</th>
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<tr>
<td>We may not have sufficient time to consider this in detail, so pick one of the items marked by a Ø and come prepared to present this item to the class, illustrating very briefly its relevance to future tobacco control strategies</td>
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</table>
In identifying future opportunities and frontiers for tobacco control in the United States, a comparative approach is useful:

- Table summarising tobacco control laws in Australia.
- Selected extracts from the Public Health (Tobacco) Act (NSW). Are any of these approaches applicable to the United States?

Smoke-free laws: how far should they go?

- George Thomson et al., “Should Smoking in Outside Public Spaces Be Banned?” (2009) 338 British Medical Journal 76-77 [yes and no cases, respectively] [BMJ]
[REFERENCES FOR RESEARCH PAPERS]

These references are not part of the course, but the list is worth scanning because some may be relevant to your research paper topics.

- **Clare Dyer**, “Tobacco Companies Take UK to Court Over ‘Standardised Packaging’ Regulations” *BMJ* 2015; 351: h6751.
- **Adam Leventhal et al.** “Association of Electronic Cigarette Use with Initiation of Combustable Tobacco Product Smoking in Early Adolescence” *JAMA* 2015; 314:700-707. [JAMA]
- **Nancy Rigotti**, “e-Cigarette Use and Subsequent Tobacco Use by Adolescents” *JAMA* 2015; 314:673-674. [JAMA]


• **Deborah Khoo, Yvonne Chiam, Priscilla Ng**, “Phasing-out Tobacco: Proposal to Deny Access to Tobacco for those Born from 2000” (2010) 19 Tobacco Control 355-360. [BMJ]


• Shanta Dube et al., “Pro-Tobacco Influences and Susceptibility to Smoking Cigarettes Among Middle and High School Students – United States, 2011” Journal of Adolescent Health 2013; 52:S45-S51. [ScienceDirect]


• **CDC**, State Laws Prohibiting Sales to Minors and Indoor Use of Electronic Nicotine Delivery Systems – United States, November 2014. MMWR Dec 12, 2014; 63(49):1145-1150. [EBSCO]
• Jennifer Duke et al., “Exposure to Electronic Cigarette Television Advertisements Among Youth and Young Adults” Pediatrics 2014; 134:e29-e36. [WWW]
• Adrian Dowd, “Doctors criticize new advertising rules that allow celebrities to endorse e-cigarettes”, BMJ 2014; 349:g6180. [BMJ]
• Smoking Everywhere Inc v U.S. Food and Drug Administration, United States District Court for the District of Columbia, 14 January 2010 (opinion of Judge Richard Leon; this case is relevant to FDA jurisdiction to regulate e-cigarettes). [WestlawNext]
- C Bullen, C Howe, M Laugesen et al., “Electronic Cigarettes for Smoking Cessation: A Randomised Controlled Trial” (2013) 382 *Lancet* 1629-1637. [ScienceDirect]
- P Callahan-Lyon, “Electronic Cigarettes: Human Health Effects” *Tobacco Control* 2014; 23:i36-i40. [BMJ]
- CDC, “Teen Smokers Turn to Flavored Cigars” (2014) 311(3) *JAMA* 236. [JAMA]
- M McCarthy, “New York City Considers Raising Legal Age for Buying Tobacco to 21” *British Medical Journal* 2013; 346: f2698. [BMJ]
• Kristin Madison, Harald Schmidt, Kevin Volpp, “Smoking, Obesity, Health Insurance and Health Incentives in the Affordable Care Act” (2013) 310 JAMA 143-144. [JAMA]
• Tobacco Control 2013; vol. 22(3) contains a special issue on tobacco endgame scenarios. [BMJ]
• Nasser BinDihm, Becky Freeman, Lyndal Trevena, “Pro-Smoking Aps for Smartphones: the Latest Vehicle for the Tobacco Industry?” Tobacco Control, 22 October 2012: http://tobaccocontrol.bmj.com/content/early/2012/10/01/tobaccocontrol-2012-050598
• Jonathan Gornall, „Electronic Cigarettes: Medical Device or Consumer Product” British Medical Journal 2012; 345:e6417. [BMJ]
• Vol 125 (issue 12) December 2011 of Public Health (Journal of the Royal Society for Public Health, UK), is a special issue entitled: Can law improve prevention and treatment of cancer? This symposium includes a number of articles on tobacco control [ScienceDirect]
• Ron Borland, “Electronic Cigarettes as a Method of Tobacco Control” (2011) 343 British Medical Journal d6269. [BMJ]
• Andrew Waylen et al., “Cross-sectional Association Between Smoking Depiction in Films and Adolescent Tobacco Use Nested in a British Cohort Study” (2011) 66 Thorax 856-861. [BMJ]
• Simon Chapman, Matthew Farrelly, “Four Arguments Against the Adult-Rating of Movies with Smoking Scenes” (2011) PLoS Medicine, vol 8, issue 8, e1001078. [WWW]
• **Sorrell v IMS Health Inc.**, United States Supreme Court, April 26, 2011 [recent commercial free speech case]. [WestlawNext]


• **Menthol cigarettes and public health: review of the scientific evidence and recommendations.**


• **Center for Public Health and Tobacco Policy**, *Tobacco Retail Licensing: Local Regulation of the Number, Location and Type of Tobacco Retail Establishments in New York*, October 2010, Bostin: The Center for Public Health & Tobacco Policy at New England Law www.tobaccopolicycenter.org


• **Physicians for a Smoke-Free Canada**, “Future Options for Tobacco Control: Performance-Based Regulation of Tobacco, June 2010, at: http://www.smoke-free.ca/eng_research/psrcsearch_papers.htm


• **Dorothy Hatsukami, Kenneth Perkins, Mark LeSage et al.**, “Nicotine Reduction Revisited: Science and Future Directions” (2010) 19 *Tobacco Control* e1-e10. [BMJ]


• **Jonathan Samet**, “Smoking in Movies; When will the Saga End?” (2010) 19 *Tobacco Control* 173-174. [BMJ]
• W. Hall, C. Gartner, “Supping with the devil? The role of law in promoting tobacco harm reduction using low nitrosamine smokeless tobacco products” (2009) 123 Public Health 287-291. [ScienceDirect]
• Joe Nocera, “If it’s good for Philip Morris, Can it also be Good for Public Health?” New York Times Magazine, 18 June 2006. [ProQuest]
Module 4: (Day 4)

Obesity prevention, public health nutrition and active living:

Aims of this module

In this module you will be:

• Introduced to the epidemiological context of the obesity epidemic;
• Introduced to some legal responses to obesity;
• Encouraged to evaluate arguments about law and obesity and to think creatively about how law can control and prevent obesity at the population level;
• Encouraged to draw your learning in this unit together and to identify priorities for law in responding to NCDs and their behavioral risk factors.

1. Population weight gain: how did we get this way?


2. Frameworks for understanding opportunities for law & regulation in improving the food and physical activity environments


Q: FOCUS QUESTION
2. What is performance-based regulation? How might it be applied to regulatory approach to obesity prevention and/or public health nutrition?

3. Case studies of legal strategies for improving nutrition and reducing obesity


Case-study 1: U.S. federal spending and how it influences children’s nutrition

• Healthy, Hunger-Free Kids Act of 2010 (P.L. 111-296) ss. 201-204, 208, 243. [HEIN]
• Department of Agriculture, Nutrition Standards in the National School Lunch and School Breakfast Programs, 7 CFR (Code of Federal Regulations) Parts 210 and 220 (as amended, 26 January 2012; not included in the materials; be aware of their existence only; http://www.fns.usda.gov/cnd/governance/regulations.htm).
• Extracts from the Consolidated and Further Continuing Appropriations Act, 2012 (PL 112-055). [HEIN]
• Letter from the National School Boards Association to the Hon. Tom Visack, Secretary, U.S. Department of Agriculture, 24 February 2011. [WWW]

Case study 2: New York City’s soda ban
• Department of Health and Mental Hygiene, Board of Health. Notice of adoption of an amendment to §81.53 of the New York City Health Code.
• New York Statewide Coalition of Hispanic Chambers of Commerce v New York City Department of Health and Mental Hygiene, New York Court of Appeals, No 134, 26 June
2004 (upholding the decisions of the NY State Supreme Court, Appellate Division (30 July 2013) [WestlawNext], and of trial judge (Milton Tingling JSC, 11 March 2013). Not extracted but will be briefly discussed.

Case study 3: front-of-pack nutrition labelling in Australia, the UK and USA

- **FDA**, Proposed Changes to the Nutrition Fats Label: http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm385663.htm
- **Letter from FDA to General Manager, Smart Choices Program, August 19, 2009** (from the FDA website): http://www.fda.gov/Food/LabelingNutrition/LabelClaims/ucm180146.htm
- Extracts from blog, http://nourishedkitchen.com/smart-choices-program

Case study 4: advertising of energy-dense, non-core foods to children:

- **Interagency Working Group on Food Marketing to Children, Food for Thought** (Preliminary Proposed Nutrition Principles for Marketing Foods to Children Ages 2-17), April 2011. [WWW]
- **What did industry lobbying do to the Interagency Working Group’s voluntary principles?**
- **Bob Roehr**, “US Efforts to Limit Marketing of Unhealthy Food to Children are Delayed” *British Medical Journal* 2012; 344: e3340. [BMJ]

“Conditions that are highly prevalent and broadly reaching within a population may appear less like a crisis requiring legal interventions and deserving legal analysis. Neither the common cold nor breast cancer is the subject of coercive police power regulations. Consequently, there are no books, nor any law school classes, on the law surrounding these diseases. But both diseases cause significant, widespread morbidity. And in both cases, we do not know the role that law has played in shaping the disease’s epidemiology or the role that law might play in reducing the disease’s incidence. The relationship of law to nonstigmatized, or “normalized” conditions, remains largely unexplored” (Parmet, in further reading, Module 1, at 608).

4. Time for you to get involved!

Pick one of the items marked by a Ø below and come prepared to present this item to the class, illustrating very briefly its relevance to the framework for understanding law’s role in preventing obesity and improving diet. The aim of this exercise is to build our understanding of the range of legal interventions that are arising across different jurisdictions in the US and beyond.

The items below illustrate some of the wide range of laws that national state and local/city legislatures are introducing, debating, litigating:

• Ø Benjamin Mueller, Michael Grynbaum, “New York City Health Board Backs Warning on Menu Items with High Salt” New York Times, 9 September 2015. [ProQuest] [WWW]
• Ø Lydia O’Connor, “Nation’s First Soda Tax Passes in Berkeley, Fails in San Francisco” The Huffington Post, 5 November 2014. [WWW]
• Ø Jamie Morton, “Fizzy drinks banned in council buildings” New Zealand Herald, 5 August 2016. [WWW (mobile ver.)] [WWW]
• Ø Sam Frizell, “Big Soda Sues San Francisco Over Beverage Warnings” Time 27 July 2015 [WWW]
• Ø Food, Environmental and Economic Development in the District of Columbia Act of 2010 (D.C. Code § 2-1212.01 ff [LexisAdvance]; § 47-3801ff [LexisAdvance]).

Ø Patient Protection and Affordable Care Act (P.L. 111-148) §4202. [HEIN]

Ø San Francisco County, California, Resolution No. 95-25A6 (the Commercial Free Schools Act). [WWW]

Ø Public Health and Wellbeing Act 2008 (Vic) ss 26-27 [this Act from the State of Victoria, in Australia, requires local councils to prepare municipal public health and wellbeing plans]. [WWW]

The Nutritional Requirements for Food and Drink in Schools (Scotland) Regulations 2008. [WWW] Schools are a critical setting for improving nutrition. Although many States in the US have used law to improve school nutrition, this example is from Scotland. NB also The Education (Nutritional Standards and Requirements for School Food) (England) Regulations 2007 (England): http://www.legislation.gov.uk/uksi/2007/2359/contents/made


Ø Stephanie Strom, “Toys Stay in San Francisco Happy Meals, for a Charge”, New York Times, 30 November 2011. [ProQuest] [WWW]

Ø State of New York, Senate Bill No. 3597, 2011-2012 session, introduced 28 February 2011, Senator Adams. [WWW]


REFERENCES FOR RESEARCH PAPERS

These references are not part of the course, but the list is worth scanning because some may be relevant to your research paper topics.

Broad reviews, including reviews of legal strategies for responding to obesity and NCDs:

- Christina Roberto et. al., “Patchy Progress on Obesity Prevention: Emerging Examples, Entrenched Barriers, and New Thinking” Lancet 2015; published online 18 February 2015 [first in Lancet’s 2nd Obesity series] [ProQuest]
- Boyd Swinburn et. al., “Strengthening of Accountability Systems to Create Healthy Food Environments and Reduce Global Obesity” Lancet 2015; published online 18 February 2015 [6th paper in Lancet’s 2nd Obesity series] [ProQuest]
• International Association for the Study of Obesity, Policy Briefing, The Prevention of Obesity and NCDs: Challenges and Opportunities for Governments, January 2014 (edited by T. Lobstein, H. Brinsden). [WWW]

• Keats S, Wiggins S., Future Diets: Implications for Agriculture and Food Prices. Overseas Development Institute, 2014 (http://www.odi.org.uk/future-diets (Chapter 2 explores changes to diets through time and the factors influencing those changes; chapter 3 reviews policies to improve diet).

http://www.wcrf.org/index.php (contains a very nice discussion of the barriers to using law)


• JT Winkler, “Brutal Pragmatism on Food” British Medical Journal 2013; 346:f3728. [BMJ]


• Vol 125 (issue 12) December 2011 of Public Health (Journal of the Royal Society for Public Health, UK), is a special issue entitled: Can law improve prevention and treatment of cancer? Includes a number of articles on obesity prevention [ScienceDirect]

• Roger Magnusson, “Using a Legal and Regulatory Framework to Identify and Evaluate Priorities for Cancer Prevention” (2011) 125(12) Public Health 854-875. [ScienceDirect]


• Jennifer Pomeranz, Stephen Teret, Stephen Sugarman, LainieRutkow, Kelly Brownell, “Innovative Legal Approaches to Address Obesity” (2009) 87 The Milbank Quarterly 185-213. [JSTOR]


• The *Australian and New Zealand Health Policy* published a special issue called “Obesity: should there be a law against it?” at [http://www.anzhealthpolicy.com/series/1743-8462-Aso](http://www.anzhealthpolicy.com/series/1743-8462-Aso)

• Volume 37, Supplement 1 of the *Journal of Law, Medicine & Ethics* contains a symposium on obesity prevention & control. [HEIN]


**Other resources on food, diet, obesity; papers on specific legal interventions:**

• **Melissa Mialon et. al.**, “Analysis of the Corporate Political Activity of Major Food Industry Actors in Fiji” *Globalization and Health* 2016; 12:18.


• **Ian Simpson**, “District of Columbia Approves ‘Yoga Tax’ as Part of Budget” Reuters, 24 June 2014. [WWW]


• **Caitlin Caspi et al.**, “The Local Food Environment and Diet: A Systematic Review” (2012) 18 *Health & Place* 1172-1187. [ScienceDirect]


• **Lawrence Gostin, Belinda Reeve, Marice Ashe**, “The Historic Role of Boards of Health: New York City’s Soda Portion Case” *JAMA* 2014; 312(15):1511-1512. [JAMA]

• **Michael Grynbaum**, “New York’s Ban on Big Sodas is Rejected by Final Court” *New York Times*, 26 June 2014. [ProQuest] [WWW]


• Simon Capewell, “Sugar Sweetened Drinks Should Carry Obesity Warnings” *British Medical Journal* 2014; **348**: g3428. [BMJ]


• Lisa Powell, Jennifer Harris, Tracy Fox, “Food Marketing Expenditures Aimed at Youth: Putting the Numbers into Context” (2013) 45(4) *American Journal of Preventive Medicine* 453-461. [ScienceDirect]

• C. Mitchell, G. Cowburn, C. Foster, “Assessing the Options for Local Government to Use Legal Approaches to Combat Obesity in the UK: Putting Theory into Practice” (2011) 12 *Obesity Reviews* 660-667. [Wiley]


• Stephen Sugarman, ‘Enticing Business to Create a Healthier American Diet: Performance-Based Regulation of Food and Beverage Retailers’ (2013) 36 *Law & Policy* 91-112. [Wiley]

• C. Mitchell, G. Cowburn, C. Foster, “Assessing the Options for Local Government to Use Legal Approaches to Combat Obesity in the UK: Putting Theory into Practice” (2011) 12 *Obesity Reviews* 660-667. [Wiley]

• Anne Barnhill, Katherine King, “Ethical Agreement and Disagreement About Obesity Prevention Policy in the United States” *International Journal of Health Policy and Management* 2013; **1**: 117-120. [UHPM]

• S Kleiman, S Ng, B Popkin, “Drinking to Our Health: Can Beverage Companies Cut Calories While Maintaining Profits” (2012) 13 *Obesity Reviews* 258-274. [Wiley]


• John Cawley, “The Economics of Child Obesity” (2010) 29 *Health Affairs* 364-371. [Health Affairs]


Marlene Schwartz, Amy Usjanauskas, “Food Marketing to Youth: Current Threats and Opportunities” (2012) 8(2) Childhood Obesity 85-88. [ProQuest]

Oliver Mytton, Dushy Clarke, Mike Rayner, “Taxing Unhealthy Food and Drinks to Improve Health”, British Medical Journal 2012; 344:e2931. [BMJ]


• L Murtagh, D Ludwig, “State Intervention in Life-Threatening Childhood Obesity” (2011) 306 JAMA 206-207. [JAMA]


• Institute of Medicine, Local Government Actions to Prevent Childhood Obesity, Report Brief, September 2009. [WWW]

• ShadiChamany, Lynn Silver, Mary Bassett, Cynthia Driver et al., “Tracking Diabetes: New York City’s A1C Registry” (2009) 87 The Milbank Quarterly 547-570. [JSTOR]


• Laura Bond, Mike Daube, Tanya Chikritzhs, “Selling Addictions: Similarities in Approaches Between Big Tobacco and Big Booze” (2010) 3(6) Australasian Medical Journal 325-332. [WWW]


Module 5: (Days 1-2)

Personal responsibility, risk factors, and regulation

This module is for further reference.

Aims of this module

In this module you will be:

- Encouraged to think deeply and critically about the extent to which assumptions about personal responsibility and the role of the state interact with our understanding of law’s role in public health.
- Encouraged to think critically about the extent to which law should hold individuals responsible for their behaviours, habits and choices, and for their state of health, and whether this should limit the role of the State in responding to behavioural risk factors.
- Encouraged to recognise that law can influence and improve population health without those improvements being mediated through the conscious efforts of individuals.

1. What are the limits of my responsibility for my health?

Case study: Christopher Hitchens’ crime spree in New York City

- **Christopher Hitchens**, “I Fought the Law”, *Vanity Fair*, February 2004, pp74-9. [ProQuest] No need to read in great detail; you get the idea: US-based, British journalist Christopher Hitchens goes on a one-man crime spree in NY City, breaking as many laws as he can. In an era where “personal responsibility” has come back with a vengeance, are public health advocates (and legislators) thrust into the role of nannies?
- **Roger Magnusson**, “Bloomberg, Hitchins, and the Libertarian Critique” (2014) 44(1) *Hastings Center Reports* 3-4 [WWW] (and see pp 4-8 for other perspectives on Bloomberg’s legacy) [pp 4-6] [pp 6-7] [pp 7] [pp 8].
- **AAP**, “Hitchens Hit with Throat Cancer” *Sydney Morning Herald*, 1 July 2010. [WWW]

Ruth Limbaugh explains...

Perspectives on the appropriate boundaries for public health law:

- **Lawrence O. Gostin**, “General Justifications for Public Health Regulation” (2007) 121 Public Health 829-834. [ScienceDirect]

2. Regulation, public health, and freedom

In this segment we consider the question: Is regulation possible without being coercive or overly intrusive on individuals, and businesses?

The focus of a population health approach is not individuals, but the factors (determinants) that are responsible for changes or trends in behaviour at the population level. In many cases, by focusing on the broader environment (frequently, on business activity), regulation can avoid targeting individuals. However, this raises debate about the “nanny state”, and ultimately, the idea that the state should defer to the market and be agnostic about the health of the population.

[REFERENCES FOR RESEARCH PAPERS]

These references are not part of the course, but the list is worth scanning because some may be relevant to your research paper topics.

- **Jonathan Gornall**, “Under the Influence: Scotland’s Battle Over Alcohol Pricing” *British Medical Journal* 2014; g1274. [BMJ](http://bmj.com)
- **Ken Harvey**, “I want to consume this product; should public health experts stop me? Yes” (2011) 195(7) *Medical Journal of Australia* 378.
- **Michael Keane**, “I want to consume this product; should public health experts stop me? Yes” (2011) 195(7) *Medical Journal of Australia* 379.

Research paper topics

Expected research paper topics:

1. How are noncommunicable diseases (NCDs) “governed”, globally, in 2017? Identify and discuss the key documents, resolutions, concepts and governance structures for the global response to NCDs.
2. What are the priorities for the law of chronic disease prevention (and its risk factors, including tobacco use, obesity and sedentary lifestyle) in the United States (or another country if you wish)? Against the background of the current state of the law, identify the legal components or dimensions of the interventions/strategies you identify. How might they lead to improve health outcomes?

3. Schroeder and Warner argue:

“If no additional progress is made in reducing smoking-initiation rates and increasing cessation rates, the prevalence of smoking in the United States will decline only to 16.7% by 2020 and will stabilize at 13.5% shortly after mid-century, and millions of people will die prematurely” (Steven Shroeder, Kenneth Warner, "Don’t Forget Tobacco" (2010) 363(3) New England Journal of Medicine 201-204, at 201). [WWW]

What are the priorities for tobacco control in the United States, and what is law’s role exactly? In your paper, briefly review current regulation, and make an evidence-based case for priority initiatives for the future.

4. Review the legal mandate of the Food and Drug Administration (FDA) with tobacco control, and discuss current controversies and regulatory challenges as the FDA moves forward on matters within its jurisdiction.

5. To what extent has the Obama administration so far been successful with its attempts to regulate tobacco, including the regulation of tobacco packaging, tobacco advertising and non-smoked tobacco products? Discuss, with reference to the Family Smoking Prevention and Tobacco Control Act (Public Law No. 111-31), the “Final Rule” issued under it, recent court decisions and other relevant materials.

6. Review the status of efforts to regulate e-cigarettes in the United States. How should e-cigarettes be regulated? Evaluate the competing arguments that e-cigarettes are, respectively, a threat to public health, or an opportunity for reducing the burden of disease from combustable tobacco products.

7. Explore the role that law and regulation might play in responding to child and adolescent obesity? In your discussion, include reference to laws and developments in the United States.

8. Can self-regulation, including voluntary codes and standards developed by industry, work effectively for improving nutrition and reducing obesity? Discuss, including case studies from the United States. (Alternatively, you might like to focus on Britain and to include a review of the literature evaluating the Public Health Responsibility Deal).

9. The Guidelines on Article 5.3 of the Framework Convention on Tobacco Control recommends that governments should “limit interactions with the tobacco industry and ensure the transparency of those interactions that occur”. Within the public health community, big tobacco is almost uniformly seen as the enemy of public health. To what extent should governments and public health groups work with the alcohol and processed food industries, both at the global level (for example, through interactions with WHO and with international public health groups), and at national level (for example, through interactions with governments and national health NGOs). Discuss.
10. Discuss how constitutional human rights provisions can be used to accelerate progress in tobacco control. You may wish to consider case studies from a country or countries to illustrate your analysis.

11. To what extent should an individual’s health remain entirely a matter of individual responsibility? Discuss, with references to non-communicable diseases, and possibilities for shifting liability on to third parties (including governments, and corporations) for an individual’s state of ill-health. Relate these to case studies or relevant contests over the use of law or regulation to reduce risk factors for NCDs.

12. Review the legislative basis, scope and current status of federal nutrition support programs.

13. Review the merits and options for seeking to reduce sugar-intake in the United States by taxing or otherwise regulating sugar-sweetened beverages.

14. Review the merits of regulating menthol under the Family Smoking Prevention and Tobacco Control Act. Review the status of efforts to review menthol, within the broader context of patterns of use of menthol cigarettes, their health impacts, and U.S. federal tobacco control law.

15. Is tobacco regulation a useful model for understanding the challenges of reducing diet-related risk factors? Discuss, taking account of the food industry’s preference for self-regulation, and its attitude to legal regulation. To what extent are self-regulation, and public/private partnerships a viable alternative to regulation?

16. Is the United States using law to reduce dietary-risk factors? If so, how? What should the priorities for the use of law be?

17. Explain the legal basis and policy challenges of improving health and nutrition in school settings in the United States, including discussion of nutrition programs supported in the Healthy Hunger-free Kids Act of 2010 (the Child Nutrition Reauthorisation Bill), and local school wellness programs. [The Healthy, Hunger-free Kids Act of 2010 (P.L. 111-296) expired on 30 September 2015. However, further funding for nutrition support programs – till 30 September 2016 – was contained in the Consolidated and Further Continuing Appropriations Act of 2015 (P.L. 113-235).] At the time of writing, the intention of Congress with respect to funding in 2017 is not clear.

18. Read Duff Wilson and Janet Robert’s analysis of food industry resistance to legal and regulatory efforts to improve diet and prevent obesity in the United States: http://www.reuters.com/article/2012/04/27/us-usa-foodlobby-idUSBRE83Q0ED20120427. Document these and any other relevant case studies of legal and regulatory efforts to improve diet and prevent obesity, updating as necessary. What are the prospects for using law as a public health tool successfully in this area?


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20. Do we have an adequate conceptual model for understanding how law can improve the public’s health? Critically review existing models, and give examples of their advantages and limitations, with specific reference to legal strategies for reducing risk factors for NCDs.

21. Are States leaders in using law to reduce smoking and dietary-risk factors? Discuss, comparing actions (or lack thereof) taken at the federal level with actions at State level (e.g., in California, New York, or another appropriate State).

22. Taking New York City as an example, explore recent city-based strategies for improving health, including reducing obesity and tobacco use. Were the public health initiatives of the Bloomberg administration justified? What role should local and city governments play in improving public health?

23. Review the draft Protocol to Eliminate Illicit Trade in Tobacco Products. To what extent is US law already in compliance with its (likely) provisions?

24. Is there a law of public health nutrition in the United States? Should there be? Discuss, and put forward some specific proposals for improving nutrition at the population level that would take the form of law, as distinct from being based in health promotion, voluntary industry initiatives etc.

25. If you wish to submit a proposal for a different research topic, please submit a 1-page proposal setting out the main questions and themes, and the general sources you intend to consult.