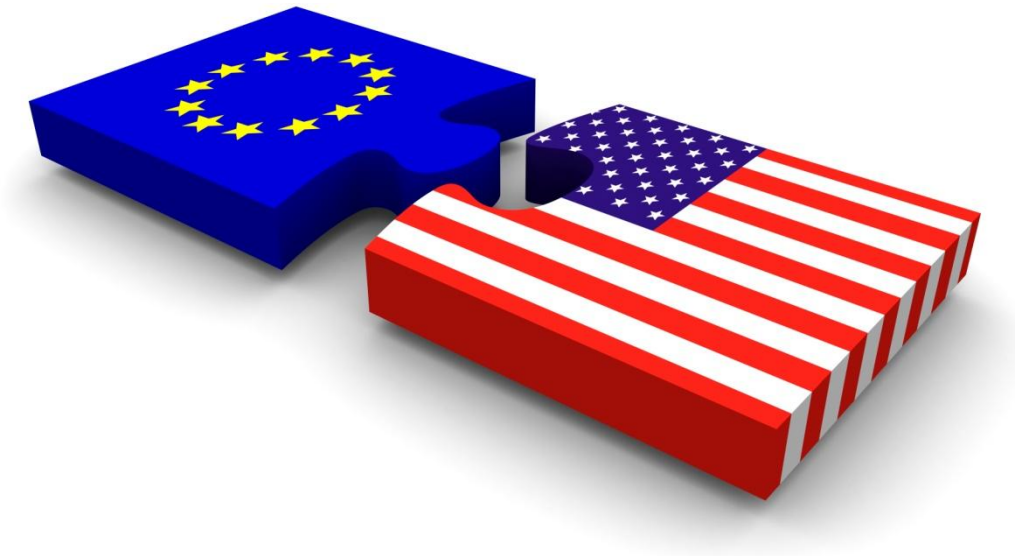
Trading Health? UK Faculty of Public Health Policy Report on the Transatlantic Trade and Investment Partnership



Trading Health? UK Faculty of Public Health Policy Report on the Transatlantic Trade and Investment Partnership

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Produced by the **UK Faculty of Public Health**

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With thanks to Dr John Middleton, Professor Martin McKee CBE; Dr David McCoy; Dr Jennifer Mindell; Professor Simon Capewell, Lindsey Stewart, Liz Skinner, Nick McKenzie, Richard Allen and Grant Fisher

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List of abbreviations used in this report

BIS	Department of Business, Innovation and Skills
BIT	Bilateral investment treaty
CEO	Corporate Europe Observatory
CETA	Consolidated Economic and Free Trade Agreement
CSDH	Commission on the Social Determinants of Health
CQC	Care Quality Commission
EC	European Commission
EMA	European Medicines Agency
EPHA	European Public Health Association
EU	European Union
EEB	European Environmental Bureau
EPA	Environment Protection Agency
EPHA	European Public Health Association
ETS	EU Emissions Trading System
FCTC	World Health Organization Framework Convention on Tobacco Control
FDA	United States' Food and Drug Administration
FET	Fair and Equitable Treatment
FoE	Friends of the Earth
FPH	UK Faculty of Public Health
FTA	Free Trade Agreement
G20	The Group of Twenty (major European governments and central banks)
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
GDP	Gross domestic product
GMB	General, Municipal, Boilermakers and Allied Trade Union
GMC	Good manufacturing practices
GWB	General Wellbeing
HFSS	High in fat, sugar and salt
HSCA	Health and Social Care Act 2012
ICESCR	United Nations International Covenant on Social and Cultural Rights
ILO	International Labour Organisation
IPR	Intellectual Property Rights
ISCID	World Bank International Centre for the Settlement of Investment Disputes
ISDS	Investor-state dispute settlement
LSE	London School of Economics

LSEE	London School of Economics Enterprise
MFN	Most Favoured Nation
MNC	Multi national corporation
MSF	Médecins Sans Frontières
MUP	Minimum unit pricing
NAFTA	North American Free Trade Agreement
NCD	Non-communicable disease
NHS	National Health Service
NICE	National Institute of Health and Care Excellence
NTB	Non-Tariff Barrier
OECD	Organisation for Economic Cooperation and Development
PHE	Public Health England
PSC	Physicians for Smokefree Canada
R&D	Research and development
RCC	Regulatory Cooperation Council
REACH	Regulatory, Evaluation, Authorisation and Restriction of Chemicals (REACH)
RED	EU Renewable Energy Directive
SBN	Seattle-Brussels Network
SPS	Sanitary and Phytosanitary Measures Agreement
TBT	Technical Barriers to Trade Agreement
TRIPs	Trade Related Aspects of Intellectual Property Rights Agreement
TSCA	US Toxic Substances Act
TTIP	Transatlantic Trade and Investment Partnership
UDHR	United Nations Universal Declaration of Human Rights
UK	United Kingdom
UKHF	UK Health Forum
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNCITRAL	United Nations Commission on International Trade Law
UNCTAD	United Nations Conference on Trade and Development
UNHCHR	United Nations Office of the High Commissioner for Human Rights
US	United States
USTR	United States Trade Representative
WHO	World Health Organization
WTO	World Trade Organization

Foreword: Trading health for profit

The UK Faculty of Public Health is concerned about the damaging potential of the Transatlantic Trade and Investment Partnership (TTIP) for public health, environmental protection and sustainability.

TTIP is being touted as a major benefit for trade between the European Union and the United States. But the means by which greater trade is to be gained is through deregulation of standards of health and safety, standards in consumer safety, environmental standards and those for public protection. The deal is also likely to further add to global climate change.

Alongside TTIP is an opaque quasi-legal instrument, operating outside of public scrutiny, known as the Investor-State Dispute Settlement mechanism (ISDS). ISDS proceedings should be a concern to all those working for better public health and the environment. The process appears to ride rough shod over national law, undermining the entitlement of states to legislate for the improved public health and protection of their citizens.

UK government ministers have not called for the NHS to be exempted from the agreement, which would be in their powers to ask for. Why would they, when the stated objectives of the Health and Social Care Act 2012 were to open up competition in the health service?

TTIP presents a much bigger threat to the public's health, bigger even than the potentially devastating impact on the NHS. TTIP threatens health and safety conditions, hard-earned workers' rights, terms and conditions and protection in employment, local and global environmental safety and controls, carbon emissions and global climate change. It also threatens to erode consumer safety standards.

FPH's current manifesto, *Start Well, Live Better*, includes major recommendations for laws designed to protect and improve the public's health. A sugar tax, minimum unit pricing (MUP) of alcohol, a statutory living wage, and reducing carbon emissions – each could fall foul of TTIP and its ISDS. If a future government chose to accept the overwhelming international and national evidence and implement MUP, alcohol companies under the TTIP agreement could demand compensation for lost profits; likewise big food, on a sugar tax.

Past evidence of major economic change suggests benefits are not delivered equally, even if the projected jobs and growth are realised. There will be big winners and therefore big losers. The narrow margin of benefit is such that gains for bankers, investors, and industrialists risks loss of money and jobs for many, widening inequalities heaped on the poor, and ending of important public health protections.

Trends towards widening inequalities in income over 40 years in the UK and globally have been accompanied by widening gaps in the ill health and life expectancy between rich and poor. In the 35 years since the seminal Black report, the reports of Whitehead, Acheson, Wilkinson and Marmot have expanded this body of knowledge. Economic inequality causes health inequalities; poverty kills. We can expect widening health inequality if this agreement is signed – and health is worse in unequal societies. GDP does not buy us happiness. We need a more sustainable people-centred economy, which supports localism.

FPH believes the TTIP agreement will damage health, create poverty and damage the environment now and in the future. It will reduce prospects for laws to protect and promote the public's health far less likely to happen in the future.

If you are not an advocate for this agreement, it is unlikely the benefits will be coming your way. It is likely to benefit only a small proportion of people in the upper echelons of societies on either side of the Atlantic or in tax havens. Anybody who is not heading a big multinational company should reject it and campaign to ensure it never becomes a reality.

Dr John Middleton
Vice President for Health Policy
UK Faculty of Public Health

Trading Health? UK Faculty of Public Health Policy Report on the Transatlantic Trade and investment Partnership – Executive Summary

Headline messages: putting profit before health

- The Transatlantic Trade and Investment Partnership (TTIP) is a comprehensive free trade agreement currently under negotiation between the EU and US.[1]
- TTIP grants the "highest levels of protection"[2] to foreign private companies, enforced by secretive, extra judicial tribunals (not by transparent process in domestic courts).
- TTIP grants states weak protections against those foreign companies, threatening their right to regulate for the public benefit, and having a 'chilling' effect on public policy.[3] [4]
- TTIP aims to "harmonise"[5] differences in important standards between the EU and US. This risks lowering key health, environmental health and hard fought for workplace health and labour standards[6]
- TTIP aims to "maximise liberalisation"[7] of access to EU public procurement and services markets – presenting grave risks to the NHS and other public services.[8]

Without urgent revision, TTIP poses a serious risk to health. It may increase tobacco related harms, particularly among young people; increase alcohol related disorders – worsening mental health and social disruption in the community; and it may restrict governments' ability to reduce consumption of unhealthy foods, associated with increased rates of obesity and related health outcomes.[9] TTIP may also increase the cost of vital medicines.

FPH therefore calls on the EU to reject the negotiating mandate for TTIP in its entirety.

Introduction

TTIP is a free trade agreement under negotiation between the EU and US since 2013. Through improved market access, regulatory cooperation and enactment of rules designed to make it easier to export, import and invest, the EU envisages that TTIP might generate

[1] European Commission. *Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America*. 2013. Accessed on 04/03/15 from http://data.consilium.europa.eu/doc/document/ST-11103-2013-DCL-1/en/pdf
[2] *Ibid.*
[3] Van Harten, G. *Why Arbitrators, not Judges? Comments on the European Commission's approach to ISDS in TTIP and CETA*. 2014. Accessed on 04/03/15 from http://eu-secretdeals.info/upload/2014/07/Van-Harten_Comments-id2466688.pdf
[4] Kent Law School. *Statement of concern about planned provisions on investment protection and ISDS in TTIP*. 2014. Accessed on 04/03/15 from http://www.kent.ac.uk/law/isds_treaty_consultation.html
[5] European Commission. *Directives for the negotiation.*
[6] London School of Economics and Political Science. *The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems and Public Health*. 2015. Accessed 04/03/15 from http://epha.org/a/6278
[7] European Commission. *Directives for the negotiation.*
[8] Royal College of Physicians. *LSE report on TTIP: RCP statement.* 2015. Accessed on 04/03/15 from https://www.rcplondon.ac.uk/update/lse-report-ttip-and-health-rcp-statement
[9] UNSW Australia. *Negotiating Healthy Trade in Australia – Health Impact Assessment of the Proposed Trans-Pacific Partnership*, 2015, Accessed on 09/03/15 from http://hiaconnect.edu.au/wp-content/uploads/2015/03/TPP_HIA.pdf

new economic opportunities for the creation of jobs and growth.[10] Yet, pursuit of economic opportunities and growth must not come at the expense of health – and are dependent on it. The focus of trade liberalisation in TTIP is on financial deregulation, investment protection, and removal of non-tariff (mainly regulatory) barriers to trade. This is deeply concerning.

The UK Faculty of Public Health (FPH) believes that ensuring the right to the highest state of physical and mental health and wellbeing is the first priority of any government towards its citizens. That is also part of international law to which the UK is signatory. FPH also believes that profound inequalities in physical and mental health and wellbeing are largely the product of avoidable social disadvantage – powerfully shaped by socio-economic policies.[11]

We therefore echo the concern expressed by NHS England and other groups that the "future health of millions of children, the sustainability of the NHS, and the economic prosperity of Britain depend on a radical upgrade in prevention and public health."[12] Thus, Public Health England has also warned that "on current trends we are going to fall short in our ambition because we face an epidemic of largely preventable long term diseases."[13]

By prioritising GDP and the profit of foreign private companies and their shareholders above the right to health, TTIP threatens to entrench and exacerbate inequalities in health for generations to come; to compromise efforts to address preventable non-communicable disease and climate change; and to safeguard the future of our NHS.[14] Little evidence has been presented to suggest that TTIP offers any benefits in addressing these most serious challenges.[15]

It is therefore important to consider that that the social costs in 2010 of alcohol consumption alone, some €156bn, outweigh the maximum estimated benefits of TTIP proposed removal of non-tariff (regulatory) barriers of €120bn.[16] As LSE point out, the value of just one public

[10] European Commission. *Directives for the negotiation*.
[11] World Health Organization Commission on the Social Determinants of Health. *Closing the gap in a generation: Health equity through action on the social determinants of health*. 2008. Accessed on 04/03/15 from http://whqlibdoc.who.int/publications/2008/9789241563703_eng.pdf?ua=1
[12] NHS England. *Five Year Forward View*. 2014. Accessed on 04/03/15 from http://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf?utm_source=NAVCA+Health+%26+Social+Care+news+-+October+2014&utm_campaign=hsc10/14&utm_medium=email
[13] Public Health England. *From evidence into action: Opportunities to protect and improve the nation's health*. 2014. Accessed on 04/03/15 from https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/366852/PHE_Priorities.pdf
[14] World Health Organization Commission on the Social Determinants of Health. *Closing the gap in a generation.*
[15] London School of Economics and Political Science. *The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems and Public Health*. 2015. Accessed 04/03/15 from http://epha.org/a/6278
[16] European Commission. *Impact Assessment Report on the future of EU-US trade relations*. 2014. Accessed on 04/03/15 from http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150759.pdf

health issue might well cancel out all the potential economic gains projected to accrue from TTIP."[17]

Why should we be concerned?

The right to regulate

The European Commission proposes to secure the highest levels of legal protection and certainty for US investors. Those investment protection standards accorded to investors are to be policed through an investor-state dispute settlement (ISDS) arbitration mechanism operating outside of domestic courts, at the level of international law, and with no effective appeal system. Furthermore, the protections afforded to investors are far stronger than the weak and ambiguous exceptions TTIP affords to States to make policy in the public interest.[18]

The international investment arbitration community, responsible for deciding the outcome of claims, has been repeatedly characterised by its failure to "police itself adequately in matters of ethics, independence, competence, impartiality, and conflicts of interest."[19] This failure has led some international lawyers to conclude that the "institutional design of investment arbitration and the decision-making process is biased against some states and investors and public interest concerns."[20]

The United Nations itself, in consideration of the extra-judicial tribunals adjudicating on sovereign policy, has drawn attention to recurring episodes of inconsistent findings, including "divergent legal interpretations of identical or similar treaty provisions and differences in the assessment of the merits of cases involving the same facts".[21] This has led to uncertainty about the meaning of key standards and lack of predictability of future application.

International lawyers have been clear in advising their clients to use ISDS as a political and financial weapon.[22] A hugely profitable arbitration industry has emerged, aggressively driving the entrenchment of the international investment regime. This regime profits from active involvement in the expansive redefinition of the parameters of investment protection standards; thus fuelling a surge in ISDS litigation against governments.

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[17] London School of Economics and Political Science. *The Transatlantic Trade and Investment Partnership.*
[18] Van Harten, *Why Arbitrators, not Judges?*
[19] Kent Law School. *Statement of concern.*
[20] *Ibid.*
[21] United Nations Conference on Trade and Development. *Reform of Investor-State Dispute Settlement: In search of a roadmap*. 2013. Accessed on 04/03/15 from http://unctad.org/en/publicationslibrary/webdiaepcb2013d4_en.pdf
[22] Transnational Institute. *Profiting from injustice: How law firms, arbitrators and financiers are fuelling an investment arbitration boom*. 2012. Accessed on 04/03/15 from http://www.tni.org/sites/www.tni.org/files/download/profitingfrominjustice.pdf

The London School of Economics Enterprise predicts that ISDS will impose meaningful economic costs on the UK, through regular invocation for governmental actions not normally challengeable under UK law. It cautions that imprecise meanings of investment protection standards may lead to risk of the UK losing arbitrations and facing significant damage awards – or strong pressure to settle defendable claims.[23]

ISDS is also likely to impose meaningful political costs on the UK, with significant risk to legitimate public policy space. Furthermore, FPH anticipates 'regulatory chill' – the abandonment, delay or modification of future preferred regulation in the public interest on account of objections (perceived or real) from US investors. TTIP's investor protection standards and institutionally biased ISDS mechanism risk limiting the hand of government to act in the public interest.[24]

This has potentially serious implications for the development of a range of important public health measures such as those outlined within FPH's manifesto, *Start Well, Live Better*.[25] These measures include alcohol minimum unit pricing (already subject to challenge at the European Court of Justice) and the standardised packaging of tobacco products, (subject to several ongoing ISDS claims). This report outlines several shocking, yet permissible, ISDS claims lodged by investors.

The National Health Service and other public services

The European Commission, through TTIP, aims to guarantee foreign investors maximum access to public procurement markets at all levels (national, regional and local), granting treatment equal to that accorded to domestic suppliers. It also aims for the highest level of liberalisation captured in existing free trade agreements in regard to trade in services – covering all sectors and modes of supply, and tackling remaining market access barriers.[26]

The UK Government has stated that it has no intention of excluding the NHS from this liberalisation, but, rather, it should be included because Britain's healthcare industry is a major exporter and would benefit from more open trade.[27] FPH considers that any reassurances presented by the government that TTIP will not open commissioning of NHS

[23] London School of Economics and Political Science. *The Transatlantic Trade and Investment Partnership*.
[24] *Ibid.*
[25] UK Faculty of Public Health. *Start Well, Live Better – a Manifesto for the Public's Health*. 2014. Accessed on 04/03/15 from http://www.fph.org.uk/start_well,_live_better_-_a_manifesto
[26] European Commission. *Directives for the negotiation.*
[27] The Independent. *TTIP trade agreement: Critics driven 'by anti-American sentiment' says minister Lord Livingston*. 2014. Accessed on 04/03/15 from http://www.independent.co.uk/news/business/news/ttip-trade-agreement-critics-driven-by-antiamerican-sentiment-says-minister-lord-livingston-9705331.html

and clinical services to further competition and private sector provision are wholly inadequate.

FPH has been unambiguous in its opposition to the Health and Social Care Act 2012, based on the grave risks to the provision of health services the Act presents.[28] FPH considers that those risks will be exacerbated by TTIP.

Furthermore, the government is clear in its ambition to "lock in liberalisation."[29] TTIP is an extension of that ambition. Increased NHS market access to foreign US investors through TTIP is likely to worsen health systems, weaken co-ordinated working across organisational boundaries and make harder efforts to ensure public health considerations are addressed across the NHS. An approach based on the highest level of liberalisation will, FPH expects, ultimately contribute to the further fragmentation of the NHS and a widening of health inequalities.[30]

Intellectual property rights

It is proposed that TTIP will, in its broad definition of 'investment', accord expansive intellectual property rights (IPR) to foreign private investors.[31] In addition, the European Commission intends to incorporate an enhanced version of a controversial IPR agreement, the *Trade Related Aspects of Intellectual Property Rights Agreement* (TRIPS). This goes far beyond the original terms of that agreement to provide so called 'TRIPS plus' provisions.[32]

Furthermore, it is these very same rights that have enabled multinational tobacco giant, Philip Morris, to file an $11bn claim against the Uruguayan Government introduction of health warnings on tobacco packets.[33] Despite the strong evidence base for this measure – in particular its protection of child health – and clear international and national law allowing Uruguay to legislate – Philip Morris has complained that the warnings have destroyed the "goodwill" associated with its trademarks, devaluing its profit.[34]

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[28] UK Faculty of Public Health. *Health and Social Care Bill: Risk Assessment Summary*. 2012. Accessed on 04/03/15 from www.fph.org.uk/uploads/Risk-assessment-Bill-FINAL.doc
[29] Department for Business, Innovation and Skills. *Trade and Investment for Growth*. 2010. Accessed on 04/03/15 from https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/228941/8015.pdf
[30] UK Faculty of Public Health. *Health and Social Care Bill: Risk Assessment Summary*.
[31] European Commission. *Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America*. 2013. Accessed on 04/03/15 from http://data.consilium.europa.eu/doc/document/ST-11103-2013-DCL-1/en/pdf
[32] *Ibid.*
[33] Investment Treaty Arbitration. *Philip Morris Brands Sàrl, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay, ICSID Case No. ARB/10/7 (formerly FTR Holding SA, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay)*. 2010. Accessed 04/03/15 from http://italaw.com/cases/460
[34] Philip Morris International. *Request for Arbitration*. 2010. Accessed on 04/03/15. http://italaw.com/sites/default/files/case-documents/ita0343.pdf

The claim arises from an investment treaty signed between Switzerland, where Philip Morris is based, and Uruguay. Yet that agreement itself stipulates that "the Contracting Parties recognize each other's right not to allow economic activities for reasons…of public health;"[35] amply demonstrating the insufficiency of such provisions to protect States against wealthy foreign investors and their legal teams. This seriously threatens states' right to regulate in the public interest.

In turn, the TRIPS agreement – claimed to uphold the long term social objective of providing incentives for future inventions and innovation, by granting multinational pharmaceutical companies strong patent protections – has been criticised by the World Health Organization (WHO) as "irrelevant for stimulating innovation in the absence of a profitable market for diseases."[36] As the CEO of Bayer has made clear, in relation to a high cost cancer drug:

> "*We developed this product for Western patients who can afford (it), quite honestly*."[37]

The 'intellectual monopoly privileges' enjoyed by giant pharmaceutical multinationals is seriously impeding the sustainable access to affordable medicine at a time of austerity, when health care systems are under intense financial strain. And, for those in the developing world, these rights not only compromise the affordability of medicines – but their existence. 90% of the global disease burden is carried by a population enjoying only 3% of R&D. [38]

TTIP not only powerfully threatens the affordability of medicines in the EU, it will also influence the policies of those developing countries in the developing world outside of the EU-US domain that are struggling to implement their own policies in the face of strong pressure from free trade agreements. The Director-General of the WHO, Margaret Chan, has condemned this situation:

> "*…something is fundamentally wrong when a corporation can challenge government policies introduced to protect the public from a product [tobacco] that kills. Member states have expressed concern that trade agreements could significantly reduce access to affordable generic medicines. If these agreements open trade yet close*

[35] International Investment Agreements. *Agreement between the Swiss Confederation and the Oriental Republic of Uruguay on the Reciprocal Promotion and Protection of Investments.*1988. Accessed on 04/03/15 from http://investmentpolicyhub.unctad.org/Download/TreatyFile/3121

[36] Oxfam and Health Action International Europe. *Trading away access to medicines – revisited: How the European Trade Agenda continues to undermine access to medicines*. 2014. Accessed on 04/03/15 from http://www.oxfam.org/sites/www.oxfam.org/files/file_attachments/bp-trading-away-access-medicines-290914-en.pdf?awc=5991_1425470207_d1512b818f7eb914e21ba88e40421e3b&cid=aff_affwd_donate

[37] Tech Dirt. *Bayer's CEO: We Develop Drugs For Rich Westerners, Not Poor Indians*. 2014. Accessed on 04/03/15 from https://www.techdirt.com/articles/20140124/09481025978/big-pharma-ceo-we-develop-drugs-rich-westerners-not-poor.shtml

[38] Martin, Greg, Sorenson, Corinna and Faunce, Thomas. *Balancing intellectual monopoly privileges and the need for essential medicines*. 2007. Accessed on 04/03/15 from http://www.globalizationandhealth.com/content/3/1/4

access to affordable medicines, we have to ask: Is this really progress at all?"[39]

Regulatory standards

80% of the claimed economic advantages from TTIP are derived from regulatory harmonisation and elimination of non-tariff barriers (NTBs).[40] These include domestic laws, regulations and practices that have an effect on investment. However, that governments often introduce such requirements in the public interest e.g. to protect human health and safety, the environment, consumers and animal and plant life, is cause for serious concern.

TTIP will impact on energy, the environment and climate change. It is therefore instructive to observe the European Commission's own impact assessment: "every scenario may increase waste and pose dangers for both natural resources and the preservation of biodiversity...changes in output in some sectors may...negatively affect their environmental impacts."[41]

TTIP could undermine crucial EU standards for environmental protection; lock in fossil fuel dependency on both sides of the Atlantic through controversial 'fracking' programmes; and remove the cornerstone of the EU's policy to combat climate change – the Emissions Trading System. TTIP's programme of regulatory harmonisation – of equivalence, mutual recognition of existing standards or obligation to change standards – may also risk the political will to develop new ones.

The US is not signatory of many of the International Labour Organisation's key provisions. TTIP therefore threatens hard fought labour standards. TTIP will also likely undermine the EU's 'precautionary principle' on which EU food regulation is built.

Despite these serious risks to the public's health, no health impact assessment has been undertaken of TTIP. A recent health impact assessment of a similar agreement for the trans-Pacific region has found potentially serious and negative health impacts.

These may result in increases in tobacco related health harms, particularly for vulnerable groups including young people; increased alcohol related disorders, worsening mental health and social disruption in the community; and potential to restrict the ability of government to

[39] World Health Organization. *Health has an obligatory place on any post-2015 agenda*. 2014. Accessed on 04/03/15 from http://www.who.int/dg/speeches/2014/wha-19052014/en/
[40] European Commission. *Directives for the negotiation*.
[41] *Ibid.*

reduce consumption of unhealthy foods, associated with increased rates of overweight / obesity and related health outcomes.[42] The same applies to TTIP.

Timescale

There are 3 main stages in negotiating a trade deal - mandate, negotiation, decision. With TTIP, we're now at the second stage - negotiation. Negotiating TTIP may take several years.[43] By way of comparison, the EU-Canada free trade agreement, on which TTIP was in part modelled, has taken approximately 10 years to arrive at a final text, which still needs to be ratified. TTIP has been under negotiation since 2013.

In the meantime, FPH urges our membership to lobby MEPs and Parliamentarians to call for the government to reject the TTIP Agreement.

Recommendations:

FPH is concerned that, without fundamental revision, the proposed TTIP agreement presents serious risk to the right to health. We propose that the UK should:

- Reject in its entirety the negotiating mandate for TTIP;
- Reject in its entirety the EU-Canada free trade agreement;
- Reject in its entirety the proposed (and any alternative) investor-state dispute settlement mechanism provisions from TTIP;
- Reject in their entirety the proposed (and any alternative) investment protection standards from TTIP;
- Explicitly exclude the NHS from TTIP (and any wider health and related services – including those at local authority and equivalent level)
- Reject in their entirety any proposed (and any alternative) intellectual property protections from TTIP;
- Reject any proposed (and any alternative) provision that liberalises the public procurement markets or those in trade in goods and services

[42] UNSW Australia. *Negotiating Healthy Trade in Australia – Health Impact Assessment of the Proposed Trans-Pacific Partnership*, 2015, Accessed on 09/03/15 from http://hiaconnect.edu.au/wp-content/uploads/2015/03/TPP_HIA.pdf
[43] European Commission, *TTIP – How well make it happen: the 3 main stages in the negotiating process*, 2015, Accessed on 09/03/2015 from http://ec.europa.eu/trade/policy/in-focus/ttip/about-ttip/process/

Chapter One: What is the Transatlantic Trade and Investment Partnership?

a. Harmonisation or de-regulation? Regulatory standards at risk

1. The Transatlantic Trade and Investment Partnership (TTIP) is a comprehensive free trade agreement under negotiation between the European Union (EU) and United States (US) since 2013. Through improved market access, regulatory harmonisation (or, as we will explore – deregulation) and enactment of rules designed to make it easier to export, import and for the free flow of private finance (and also, disinvestment); the EU envisages, through TTIP, to generate new economic opportunities for the creation of jobs and growth.[44]

2. The EU has exclusive competence to legislate on common commercial policy, including on: tariff rates, tariff and trade agreements on goods and services, commercial intellectual property rights, foreign direct investment, liberalisation, export policy and trade protection.[45] On behalf of Member States, the European Commission[46] is responsible for negotiating the final terms of the agreement with the US,[47] encompassing this broad policy and legislative portfolio.

3. At the outset, it is important to recognise that, at the time of writing – and indeed for the foreseeable future – the agreement is still under negotiation.[48] Until recently, the European Commission's "negotiating text and proposals (have been held) in confidence…(and not been) public documents."[49] Given this, a cautious approach is required in any speculative effort to analyse the possible risks and benefits that may accrue from TTIP.

4. Furthermore, regional trade and investment agreements[50] are exceptionally complex. In the example of the recently concluded (yet to be ratified) EU-Canada Free Trade Agreement, on which TTIP is partly modelled, the full text is 1,634 pages.[51] Rigorous and comprehensive analysis of the dense legalistic and technical detail, addressing provisions such as regulatory harmonisation and investment protection, is challenging.

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[44] European Commission, *Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America*, 2013, http://bit.ly/1vOSUxF
[45] Official Journal of the European Union. March 2010. *Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union: Charter of Fundamental Rights of the European Union*. http://bit.ly/1G5UOyJ
[46] The European Commission is the executive body of the European Union responsible for proposing legislation, implementing decisions, upholding the EU treaties and managing the day-to-day business of the EU
[47] Official Journal of the European Union. March 2010. *Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union: Charter of Fundamental Rights of the European Union*. http://bit.ly/1G5UOyJ
[48] Financial Times, *EU pushes back against TTIP trade agreement secrecy claims*, 2015, http://on.ft.com/1y0oLuj
[49] House of Lords European Union Committee, paper 179. 13 May 2014. *14th Report of Session 2013-14, Transatlantic Trade and Investment Partnership*. House of Lords. http://bit.ly/1wLIjIa
[50] An agreement between two nations or trading groups that gives each party favoured trade status pertaining to certain goods obtained from the signatories. The agreement sets purchase guarantees, removes tariffs and other trade barriers.
[51] European Commission, Comprehensive Economic and Free Trade Agreement, 2014,http://bit.ly/1D3HKaG

5. In fact, the European Commission itself, in consideration of the so-claimed "state-of-the-art economic modelling (used) to quantify the potential impact of several policy scenarios with differing levels of ambition" – or, in other words how beneficial TTIP is likely to be on jobs and growth – has added a caveat of its own; that "the figures are based on a model of the economy that is simplified…(and) as such they are not precise predictions."[52]

6. Indeed, the UK Parliament's EU Select Committee, in its evaluation, recommends that the Government should "deploy headline figures from economic studies commissioned…with extreme caution, lest they dent (TTIPs) credibility[53] (a view shared by the London School of Economics);[54] while an expert responsible for developing EU trade assessments has described the most realistic scenario as "trivial:" and leading trade economist, Professor Bhagwati, has dismissed the modelling as "mere opinion."[55] Indeed, LSE have noted that:

> "*In general economic assessments have drawn conclusions aligned to the aims of their sponsoring bodies…fully independent studies have been difficult to identify…while (one study) concludes that TTIP would lead to a contraction of GDP, personal incomes and employment.*"[56]

7. Even if economic growth is realised, the European Commission, while forecasting net employment gains, is clear that market liberalisation and cross-sectoral labour movement will benefit some sectors at the expense of others – "there are legitimate concerns that labour is not sufficiently mobile between sectors and States…*there could be prolonged and substantial adjustments costs*."[57] In other words – prolonged and substantial job losses.

8. In addition, LSE note that if the projected economic growth is realised, the way it is utilised is central to whether it has a positive or negative impact on living standards and health status.[58] And, while TTIP's framers provide (weak) reassurance that space is carved out for governments to regulate in the public interest; economic growth (or, specifically, private finance and investment), not health or any other public interest objective, is the underlying objective and driver of TTIP.

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[52] European Commission, *Transatlantic Trade and Investment Partnership: The Economic Analysis Explained*, 2013, http://bit.ly/15Mbvmg
[53] House of Lords European Union Committee, paper 179. 13 May 2014. 14th Report of Session 2013-14, Transatlantic Trade and Investment Partnership. House of Lords. http://bit.ly/1wLljIa
[54] London School of Economics and Political Science, *The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems and Public Health*, 2015, http://bit.ly/1Giia40
[55] War on Want. March 2014. The Transatlantic Trade and Investment Partnership: a charter for deregulation, an attack on jobs, an end to democracy. War on Want. http://bit.ly/RxmMyR
[56] London School of Economics and Political Science, *The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems and Public Health*, 2015, http://bit.ly/1Giia40
[57] European Commission, *Impact Assessment Report on the future of EU-US trade relations*, 2014, http://bit.ly/1B31bhB
[58] London School of Economics and Political Science, *The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems and Public Health*, 2015, http://bit.ly/1Giia40

9. In fact, LSE note the "absence of systematic assessment of the health impact of each relevant chapter of TTIP,"[59] and the limited specific mention of the promotion of health or societal well-being in trade agreements more generally, leading directly to the imperatives of health policy or access to medicines or tobacco control to be subject to legal challenge.[60] TTIP is no exception. And, as we explore below, health equity is a pre-requisite for growth.

10. Notwithstanding this, in June 2013 the EU's Council of Ministers[61] ratified the directives for negotiation of TTIP (the 'negotiating mandate'), based on an impact assessment report on the future of EU-US trade relations that in turn was largely informed by this modelling.[62] In this context, FPH draws attention to evidence that the way in which EU level impact assessment operates (a mandatory requirement of all EU policies) has been "fundamentally altered" by the corporate sector, towards a "business-oriented form of impact assessment."[63]

11. FPH is concerned that such impact assessments may increase the risk that EU policy advances the interests of private finance and multinational corporations and their shareholders – including those that produce products damaging to health, rather than in the interests of its citizens.[64] The same may be true of the impact assessment of TTIP, which, as this report details, has made no explicit recognition or costing of the impacts of TTIP on health inequalities.

12. While the European Commission has made no health impact assessment of TTIP, a proposed, and very similar, parallel trade agreement – the Trans-Pacific Partnership Agreement (TPP) – has been the focus of a recent health impact assessment, *Negotiating Healthy Trade in Australia*, by the Centre for Primary Care and Equity, University of South Wales, Australia.[65] FPH considers that the findings of the report are directly relevant to the TTIP Agreement, given its very similar provisions.

13. The TTP Health Impact Assessment finds considerable potential for negative impacts on the health of Australians in each of the four areas that it examined. It risks increasing the cost and availability of medicines, which may result in medical non-adherence with risks to

[59] London School of Economics and Political Science, *The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems and Public Health*, 2015, http://bit.ly/1Giia40
[60] London School of Economics and Political Science, *The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems and Public Health*, 2015, http://bit.ly/1Giia40
[61] The Council of Ministers is part of the bicameral EU legislature (the other legislative body being the European Parliament) and represents the executive governments of the EU's member states.
[62] European Commission, *Impact Assessment Report on the future of EU-US trade relations*, 2014, http://bit.ly/1B31bhB
[63] PLoS Med. 2014 March; 11(3): e1001629. Published online 2014 March 25. doi: 10.1371/journal.pmed.1001629
[64] PLoS Med. 2014 March; 11(3): e1001629. Published online 2014 March 25. doi: 10.1371/journal.pmed.1001629
[65] UNSW Australia, *Negotiating Healthy Trade in Australia – Health Impact Assessment of the Proposed Trans-Pacific Partnership*, 2015, http://bit.ly/1EJj76y

health outcomes including declining health status in the community for vulnerable population groups, increased hospitalisations and premature or preventable mortality.[66]

14. The TPP provisions also pose risks to the ability of Government to regulate and restrict tobacco advertising, which could lead to increased tobacco use and smoking prevalence, resulting in increased tobacco related harms across the community but particularly for existing vulnerable groups, such as youth.[67]

15. In turn, the report outlines that some TPP provisions have the potential to limit regulation of alcohol availability and marketing, and to restrict alcohol control measures such as pregnancy warning labels – risking increasing alcohol consumption rates and abuse, especially among younger members of the community. This may, the health impact assessment outlines, lead to an increase in alcohol related disorders, worsening mental health and social disruption in the community.[68]

16. Finally, the health impact assessment outlines serious risk that the TPP may restrict the ability of government to implement new food labelling policies limiting reductions in consumption of unhealthy foods. This is associated with rates of overweight/obesity and related poor health outcomes.[69] Given that diabetes currently costs the NHS £10bn every year, or 10% of the total NHS budget[70] – this has very serious implications for the UK.

17. FPH urges the government and European Commission to take into full consideration this very relevant health impact assessment for the TPP, and urges the European Commission to undertake an urgent health impact assessment of the proposed TTIP agreement.

18. The European Commission project that, once "fully implemented and the economies fully adjust," increased trade and efficiency will generate 0.5% GDP growth by 2027, (with EU-US goods and services exports up €187bn and US-EU imports up €159bn);[71] 2.2 million new jobs;[72] and an average family benefitting from an extra £400 per year[73] through increased

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[66] UNSW Australia, *Negotiating Healthy Trade in Australia – Health Impact Assessment of the Proposed Trans-Pacific Partnership*, 2015, http://bit.ly/1EJj76y
[67] UNSW Australia, *Negotiating Healthy Trade in Australia – Health Impact Assessment of the Proposed Trans-Pacific Partnership*, 2015, http://bit.ly/1EJj76y
[68] UNSW Australia, *Negotiating Healthy Trade in Australia – Health Impact Assessment of the Proposed Trans-Pacific Partnership*, 2015, http://bit.ly/1EJj76y
[69] UNSW Australia, *Negotiating Healthy Trade in Australia – Health Impact Assessment of the Proposed Trans-Pacific Partnership*, 2015, http://bit.ly/1EJj76y
[70] Diabetes UK, *The Cost of Diabetes Report*, 2014, http://bit.ly/11hgaua
[71] European Commission, *Transatlantic Trade and Investment Partnership: The Economic Analysis Explained*, 2013, http://bit.ly/15Mbvmg
[72] World Commercial Review, *'The Cheapest Stimulus Package you can Imagine': The EU's ambitious trade agenda*, 2013, http://bit.ly/1tieZqL

wages (0.5% for skilled and unskilled workers), increased household income and price reductions.[74]

19. TTIP's proposed "reciprocal liberalisation of trade in goods and services and rules on trade-related issues,"[75] is unprecedented given the scale of the EU market – with 500m consumers, a GDP of 12½ trillion Euros, US-EU investment three times higher than in all of Asia, EU-US investment eight times the amount of EU investment in India and China together; and over 15m people employed by EU firms in the US or US firms in the EU.[76]

20. Despite the scale outlined above, and the fact that the transatlantic relationship is already among the most open and deeply integrated in the world, worth €73.5bn to the EU in 2011, the European Commission has raised concern at the sharp decline in the relative share of the two economies' trade.[77] Former Commissioner for Trade, Karel De Gucht has criticised the failure to "*fully exploit* the potential of the relationship."[78] This report explores the practical risks of that exploitation.

b. GDP or General Wellbeing – the 'central political challenge of our times'

21. At this juncture, however, it is opportune to recall the Prime Minister's policy commitment to "focus not just on GDP but on GWB – *general wellbeing.*" As the Prime Minister rightly observed, "GWB can't be measured by money or traded in markets…improving GWB is *the* central political challenge of our times."[79] In fact, GDP is a very unreliable predictor of health and wellbeing in a population – "more important is what we do with the GDP we have."[80]

22. It is vital that we do not increase GDP at the expense of key public health protections that may reduce inequalities in health. Increased GDP at the expense of legislative and regulatory action that may address largely preventable non-communicable diseases (such as obesity, diabetes or heart disease) or the reduction in carbon emissions is simply not socially or ethically acceptable – and is in the long term economically unsustainable.

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[73] Her Majesty's Government. 2014. Government Response to the House of Lords European Union Committee's 14th Report: The Transatlantic Trade and Investment Partnership. http://bit.ly/1G3J8fJ
[74] Centre for Economic Policy Research. March 2013. Estimating the Economic Impact on the UK of a Transatlantic Trade and Investment Partnership (TTIP) Agreement between the European Union and the United States. CEPR. http://bit.ly/1m0nFNe
[75] European Commission, *Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America*, 2013, http://bit.ly/1vOSUxF
[76] World Commercial Review, *'The Cheapest Stimulus Package you can Imagine': The EU's ambitious trade agenda*, 2013, http://bit.ly/1tieZqL
[77] European Commission, *Impact Assessment Report on the future of EU-US trade relations*, 2014, http://bit.ly/1B31bhB
[78] World Commercial Review, *'The Cheapest Stimulus Package you can Imagine': The EU's ambitious trade agenda*, 2013, http://bit.ly/1tieZqL
[79] The Guardian, *David Cameron aims to make happiness the new GDP*, 2010, http://bit.ly/1ES8Sel
[80] The Guardian, *Sir Michael Marmot: consider health impacts when formulating policies*, 2013, http://bit.ly/1yRlWjf

23. This challenge is at the heart of the work of the Commission on Social Determinants of Health (CSDH), established by the World Health Organisation (WHO). CSDH provides an evidential analysis of the fundamental drivers of poor health and inequalities between and within countries.[81] FPH considers the work of the CSDH highly instructive in informing our approach to and understanding of TTIP.

24. As CSDH explains, "health and illness follow a social gradient: the lower the socioeconomic position, the worse the health."[82] Critically, much of the imbalance along this gradient is systematic. In other words – it is avoidable by practical and equitable social and economic public policy measures at the national and international level. This *health inequity*, between and within countries, CSDH avows, is a "matter of social justice."[83]

25. Health inequity has a considerable impact on a person – on their quality of life and on the risk of illness and premature death. And, as the CSDH underscores, profound variations in physical and mental health and wellbeing are connected with social disadvantage, in large part the consequence of the environment "in which people grow, live, work and age – and the systems put in place to deal with illness."[84]

26. These profound variations are moulded by socio-economic policies which have a determining impact.[85] CSDH's evidential analysis demonstrates that the social gradient in health within countries and inequities between them:

> "…*is caused by the unequal distribution of power, income, goods, and services, globally and nationally, the consequent unfairness in the immediate circumstances of peoples lives – access to health care, schools, and education, work and leisure conditions, homes, communities – and chances of leading a flourishing life*."[86]

27. Finally, CSDH draws attention to the acute impact of climate change on the global system, and its distortion of the quality of life and the health of individuals and the planet. It calls for action to merge the agendas of health equity and climate change, and concludes

[81] World Health Organization Commission on the Social Determinants of Health, *Closing the gap in a generation: Health equity through action on the social determinants of health*, 2008, http://bit.ly/1zjqSmw
[82] World Health Organization Commission on the Social Determinants of Health, *Closing the gap in a generation: Health equity through action on the social determinants of health*, 2008, http://bit.ly/1zjqSmw
[83] World Health Organization Commission on the Social Determinants of Health, *Closing the gap in a generation: Health equity through action on the social determinants of health*, 2008, http://bit.ly/1zjqSmw
[84] World Health Organization Commission on the Social Determinants of Health, *Closing the gap in a generation: Health equity through action on the social determinants of health*, 2008, http://bit.ly/1zjqSmw
[85] World Health Organization Commission on the Social Determinants of Health, *Closing the gap in a generation: Health equity through action on the social determinants of health*, 2008, http://bit.ly/1zjqSmw
[86] World Health Organization Commission on the Social Determinants of Health, *Closing the gap in a generation: Health equity through action on the social determinants of health*, 2008, http://bit.ly/1zjqSmw

that health equity must be "part of the global community balancing the needs of global socio-economic development, health equity, and the urgency of dealing with climate change."[87]

28. It is of enourmous significance that inequity is being considered not under the auspices of the WHO alone, but in many other, somewhat unexpected, fora. The head of the International Monetary Fund, speaking at the recent Davos conference, was clear that excessive inequality was not conducive to sustainable growth:

> "*If you increase the income share of the poorest, you get a multiplying effect that you do not get if you increase the income share of the richest*"[88]

29. The Chair of the Board of Governors of the US Federal Reserve System, has also expressed her "great concern" at the extent of the widening distribution of income and wealth, questioning whether this trend is "compatible with the high value Americans have traditionally placed on equality of opportunity."[89]

30. The Organisation for Economic Cooperation and Development (OECD) goes further. In recent research it demonstrates that addressing income inequality is not a matter of social justice alone – but makes economic sense, since "when income inequality rises, economic growth falls."[90] OECD recognises the Federal Reserve's concern at the widening ratio between rich and poor: in OECD countries today it is 9.5:1, compared to 7:1 in the 1980s.[91]

31. The impact of widening inequality is not felt by the bottom 10% alone. OECD, using the *Gini coefficient*,[92] notes that in OECD countries in the mid-1980s it stood at 0.29, yet had risen by 2011/12 to 0.32. This degree of income inequality, it warns, "would drag down economic growth by 0.35 percentage points per year for 25 years" a cumulated GDP loss of 8.5% by 2037,[93] or 5.1% by *2027* – the year TTIP realises its gains.[94] The Gini coefficient does not however capture the gap between the 99% and the 1%.

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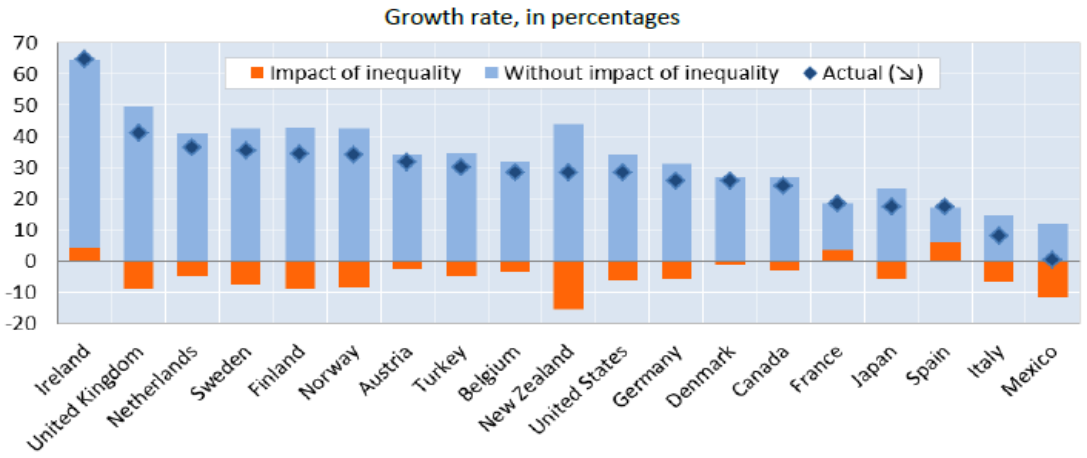
[87] World Health Organization Commission on the Social Determinants of Health, *Closing the gap in a generation: Health equity through action on the social determinants of health*, 2008, http://bit.ly/1zjqSmw
[88] The Independent, *Davos 2015: Inequality hampers growth - IMF's Christine Lagarde*, 2015, http://bit.ly/1zEnfnm
[89] Board of Governors of the Federal Reserve System, *Perspectives on Inequality and Opportunity from the Survey of Consumer Finances*, 2014, http://1.usa.gov/1sX47fQ
[90] Organisation for Economic Cooperation and Development (OECD) Directorate for Labour, Employment and Social Affairs, *Does income inequality hurt economic growth?*, 2014, http://bit.ly/1ucwjbw
[91] Organisation for Economic Cooperation and Development (OECD) Directorate for Labour, Employment and Social Affairs, *Does income inequality hurt economic growth?*, 2014, http://bit.ly/1ucwjbw
[92] The Gini coefficient is a measure of the inequality of a distribution, a value of 0 expressing total equality and a value of 1 maximal inequality. It has found application in the study of inequalities in disciplines as diverse as economics, health science, ecology, chemistry and engineering.
[93] Organisation for Economic Cooperation and Development (OECD) Directorate for Labour, Employment and Social Affairs, *Does income inequality hurt economic growth?*, 2014, http://bit.ly/1ucwjbw
[94] European Commission, *Impact Assessment Report on the future of EU-US trade relations*, 2014, http://bit.ly/1B31bhB

2. Estimated consequences of changes in inequality (1985-2005) on subsequent cumulative growth (1990-2010)



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32. For OECD the solution is clear. Efficient, targeted and evidence based redistribution is the most powerful way to reduce inequality and increase economic growth. It sees no mutual exclusivity between tackling inequity and promoting economic growth – the latter is *dependent* on the former, at least if the distribution of wealth is to be *equitable*, and not lower social mobility.[96] London School of Economics (LSE) has also observed a weakening of any link between economic growth and improved population health.[97]

33. To return to CSDH, it determines that in order to address health inequities, and inequitable conditions of daily living, it is necessary to address inequities in the way society is organised. CSDH is unequivocal in calling for "a strong public sector that is committed, capable, and adequately financed…this requires more than strengthened government – it requires strengthened governance: legitimacy, space, and support for civil society."[98]

34. And, commensurate with this aim, is the requirement for an *accountable corporate sector* – "for people across society to agree public interests and reinvest in the value of collective action. In a globalized world, the need for governance dedicated to equity applies equally from the community level to global institutions."[99] FPH considers this approach a pre-requisite to achievement the ambitions of both NHS England and Public Health England.

35. As a reminder, NHS England's *Five Year Forward View* cautions that the "future health

[95] Organisation for Economic Cooperation and Development (OECD) Directorate for Labour, Employment and Social Affairs, *Does income inequality hurt economic growth?*, 2014, http://bit.ly/1ucwjbw
[96] Organisation for Economic Cooperation and Development (OECD) Directorate for Labour, Employment and Social Affairs, *Does income inequality hurt economic growth?*, 2014, http://bit.ly/1ucwjbw
[97] London School of Economics and Political Science, *The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems and Public Health*, 2015, http://bit.ly/1Giia40
[98] World Health Organization Commission on the Social Determinants of Health, *Closing the gap in a generation: Health equity through action on the social determinants of health*, 2008, http://bit.ly/1zjqSmw
[99] World Health Organization Commission on the Social Determinants of Health, *Closing the gap in a generation: Health equity through action on the social determinants of health*, 2008, http://bit.ly/1zjqSmw

of millions of children, the sustainability of the NHS, and the economic prosperity of Britain all depend on a radical upgrade in prevention and public health."[100] It outlines a disquieting picture that far from a "fully engaged scenario…one in five adults still smoke, a third of people drink too much alcohol and almost two thirds of adults are overweight or obese." [101]

36. The Five Year Forward recognises that without action to tackle prevention, the patterns outlined above form a vicious circle, reinforcing deep health inequalities which "cascade down the generations,"[102] and at enourmous cost – e.g. NHS spending on diabetes each year, at £10bn is around 10% of the entire NHS budget.[103] These unsustainable costs are largely preventable.

37. Just as the CSDH calls for a strengthened public sector and governance, with greater policy space, so too NHS England and the Local Government Association agree that local authorities "should be granted enhanced powers to allow local democratic decisions on public health policy that go further and faster than prevailing national law – on alcohol, fast food, tobacco and other issues that affect physical and mental health."[104]

38. PHE echoes these recommendations, and is clear that "on current trends we are going to fall short in our ambition (for people to live as well for as long as possible) largely because we face an epidemic of largely preventable long term diseases."[105] It calls for a "fundamentally new approach to creating and sustaining health, mental and physical, at every stage of life and across all our communities"[106] focused on action across seven key priority areas:

- Tackling obesity
- Reducing smoking
- Reducing harmful drinking
- Ensuring every child has the best start in life
- Reducing dementia risk
- Tackling antimicrobial resistance
- Reducing tuberculosis

[100] NHS England, *Five Year Forward View*, 2014, http://bit.ly/1tkoDCo
[101] NHS England, *Five Year Forward View*, 2014, http://bit.ly/1tkoDCo
[102] NHS England, *Five Year Forward View*, 2014, http://bit.ly/1tkoDCo
[103] Diabetes UK, *The Cost of Diabetes*, 2014, http://bit.ly/11hgaua
[104] NHS England, *Five Year Forward View*, 2014, http://bit.ly/1tkoDCo
[105] Public Health England, *From evidence into action: Opportunities to protect and improve the nation's health*, 2014, http://bit.ly/ZT2t3h
[106] Public Health England, *From evidence into action: Opportunities to protect and improve the nation's health*, 2014, http://bit.ly/ZT2t3h

39. The TTIP agreement, with a focus on the interests of the corporate sector, and weak 'carve outs' for (rather than an imperative for), physical and mental health and wellbeing, is likely to make achievement of each and every one of these objectives harder. It is likely to constrain national level legislative and regulatory space, and have serious implications for the statutory responsibility of local authorities for improving the health of their people – and, related to this, for fully integrated services for patients.

40. Above, we discussed the projected economic impact of TTIP, as purported by the European Commission. It is important to note that LSE view trade liberalisation as based on a "*normative belief*" that it will bring about positive economic benefit. However, it notes that providing a "broader framework for assessing benefits realisation have proved more challenging." LSE point to the ongoing disagreement about whether the North American Free Trade Agreement has benefitted society, and whether it has caused any harms. [107]

c. From General Wellbeing and equity, to 'full exploitation'

41. In this context, it is disquieting, yet unsurprising (see paragraph 10 above), that in all 60 pages of the European Commission's impact assessment of TTIP, 'GDP' is mentioned 40 times, while by contrast there is absolutely no mention of the terms 'inequity', 'inequality', 'inequalities', or 'wellbeing' – let alone a positive statement of reinforcement of these factors.[108] Neither do the terms appear within TTIP's negotiating mandate,[109] nor all 1,634 pages of the EU-Canada Free Trade Agreement text.[110]

42. However, to use De Gucht's own words, the negotiating mandate does "*fully exploit*" the potential of the transatlantic economic relationship.[111] Integral to TTIP, and from which 80% of the claimed economic advantages are derived,[112] is a commitment to *regulatory harmonisation* and purging of *non-tariff barriers* (NTBs),[113] e.g. differences in technical regulations, standards and certification requirements.[114]

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[107] London School of Economics and Political Science, *The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems and Public Health*, 2015, http://bit.ly/1Giia40
[108] European Commission, *Impact Assessment Report on the future of EU-US trade relations*, 2014, http://bit.ly/1B31bhB
[109] European Commission, *Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America*, 2013, http://bit.ly/1vOSUxF
[110] European Commission, *EU-Canada Comprehensive Economic and Free Trade Agreement (CETA)*, 2014, http://bit.ly/1DVgVcu
[111] World Commercial Review, *'The Cheapest Stimulus Package you can Imagine': The EU's ambitious trade agenda*, 2013, http://bit.ly/1tieZqL
[112] Centre for Economic Policy Research. March 2013. Estimating the Economic Impact on the UK of a Transatlantic Trade and Investment Partnership (TTIP) Agreement between the European Union and the United States. CEPR. http://bit.ly/1m0nFNe
[113] House of Lords European Union Committee, paper 179. 13 May 2014. *14th Report of Session 2013-14, Transatlantic Trade and Investment Partnership*. House of Lords. http://bit.ly/1wLljIa
[114] World Commercial Review, *'The Cheapest Stimulus Package you can Imagine': The EU's ambitious trade agenda*, 2013, http://bit.ly/1tieZqL

43. To be absolutely clear, as is outlined within the EU's impact assessment of TTIP, NTB's include "all non-price and non-quantitative restrictions on trade in goods…*including measures flowing from domestic laws, regulations and practices that have an effect on investment*."[115] That such requirements are often introduced by sovereign governments in the public interest e.g. to protect human health and safety, the environment, consumers and animal and plant life, is cause for serious concern.

44. In this context, the European Environmental Bureau (EEB) have urged caution at the proposed development of a 'Regulatory Cooperation Council' (RCC), comprised of senior regulators and industry representatives, with the ambition of forging joint proposals on deeper regulatory cooperation. EEB note that the RCC "risks combining an EU approach to regulatory cooperation with a US approach of business being a co-writer of legislation."[116]

45. Friends of the Earth (FoE) have raised concerns that such a forum would "allow both parties to address regulatory differences in a continuous process, long after the agreement has been signed, removing regulatory cooperation from the political (and public) sphere."[117] This, FoE contends, would open the process "to business lobbying and allow weaker regulation for politically sensitive sectors, e.g. food or chemicals, with little public scrutiny."[118]

46. FPH is concerned by the history of such voluntary forums and mechanisms which have "been tried and failed around the world with depressing monotony."[119] By way of example, FPH withdrew in 2013 from the Public Health Responsibility Deal[120] (a voluntary 'deal' between the alcohol and food industry, government and the NGO sector).

47. FPH concluded that the 'deal' had not fulfilled its promise to deliver public health benefits faster and more effectively than upstream legislative action. It also failed to deliver an effective mechanism for monitoring and evaluation – and many FPH members were deeply concerned that this policy put the interests of industry ahead of improving people's health.[121]

48. The US Office of Management and Budget approach requires Federal agencies to use "voluntary consensus standards in their regulatory activities wherever possible."[122] The US

[115] European Commission, *Impact Assessment Report on the future of EU-US trade relations*, 2014, http://bit.ly/1B31bhB
[116] European Environmental Bureau, *Regulatory rollback: how TTIP puts the environment at risk*, 2014 http://bit.ly/1G5wQ6B
[117] Friends of the Earth, *Why Friends of the Earth England, Wales and Northern Ireland oppose the Transatlantic Trade and Investment Partnership (TTIP)*, 2014, http://bit.ly/1o404OJ
[118] Friends of the Earth, *Why Friends of the Earth England, Wales and Northern Ireland oppose the Transatlantic Trade and Investment Partnership (TTIP)*, 2014, http://bit.ly/1o404OJ
[119] Tob Control 1993;2:3 183doi:10.1136/tc.2.3.183
[120] UK Faculty of Public Health, *FPH withdraws from responsibility deals*, 2013, http://bit.ly/1EF3zjX
[121] UK Faculty of Public Health, *FPH withdraws from responsibility deals*, 2013, http://bit.ly/1EF3zjX
[122] United States Trade Representative, Report on Technical Barriers to Trade, 2013, http://1.usa.gov/1C4JC3N

also applies this approach within its National Technology Transfer and Advancement Act, and notes that the US Standards Strategy is strongly emphasised in free trade agreements to which the US is party, establishing a formal framework for voluntary product standards.[123]

49. The US is clear in its understanding that voluntary standard setting can "facilitate buyer-seller transactions, spur competition, increase production efficiency and unify markets."[124] It is noteworthy that the focus of US voluntary standard setting towards regulatory objectives is "cost efficiency"...and that it advocates that "responsibility for developing voluntary standards rests almost exclusively with the private sector."[125]

50. In this context, there is a serious risk that regulatory harmonisation combined with economic liberalisation will in fact result in deregulation. LSE have also drawn attention to the 'living' nature of the TTIP agreement, with structures "established to oversee on-going regulatory reform subsequent to initial ratification."[126] We now explore in greater depth how TTIP intends to approach NTBs.

Non-Tariff Barriers (NTBs) – unnecessary red tape or critical for health and wellbeing?

51. Although NTBs remain low, on average 0.5% of tariffs for trade with the US, the UK Government considers that the scale of the transatlantic relationship means dismantling them would deliver £1bn to exporters.[127] Yet, there are very important reasons to preserve many NTBs that are designed to "serve legitimate domestic purposes,"[128] including sanitary and phytosanitary standards e.g. environmental, health or food hygiene standards.

52. FPH does not share the confidence of one former Commissioner for Trade, who, appearing before the EU Select Committee, spoke of the potential to address of NTBs without putting such standards at risk through regulatory coordination via: mutual recognition of equivalent standards, harmonisation of existing safety standards and rules pertaining in different jurisdictions; and, convergence of, or joint regulatory approaches.[129]

53. International agreements at the World Trade Organization level (WTO), e.g. the

[123] United States Trade Representative, Report on Technical Barriers to Trade, 2013, http://1.usa.gov/1C4JC3N
[124] United States Trade Representative, Report on Technical Barriers to Trade, 2013, http://1.usa.gov/1C4JC3N
[125] United States Trade Representative, Report on Technical Barriers to Trade, 2013, http://1.usa.gov/1C4JC3N
[126] London School of Economics and Political Science, *The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems and Public Health*, 2015, http://bit.ly/1Giia40
[127] House of Lords European Union Committee, paper 179. 13 May 2014. 14th Report of Session 2013-14, Transatlantic Trade and Investment Partnership. House of Lords. http://bit.ly/1wLljIa
[128] House of Lords European Union Committee, paper 179. 13 May 2014. 14th Report of Session 2013-14, Transatlantic Trade and Investment Partnership. House of Lords. http://bit.ly/1wLljIa
[129] House of Lords European Union Committee, paper 179. 13 May 2014. 14th Report of Session 2013-14, Transatlantic Trade and Investment Partnership. House of Lords. http://bit.ly/1wLljIa

Technical Barriers to Trade (TBT) Agreement 1995 [130] and Sanitary and Phytosanitary Measures Agreement (SPS) 1995,[131] attempt to achieve this, and tackle perceived arbitrary technical regulation and standard setting where "an excuse for protectionism."[132] The WTO is ambitious in its efforts to remove all barriers to trade and investment for producers and exporters. Provisions of both agreements are to be embedded into TTIP, with a view, in the case of the TBT, to bring about:[133]

- greater openness, transparency and convergence in regulatory approaches and requirements and related standards development processes
- adoption of relevant international standards, as well as, inter alia, to reduction of redundant and burdensome testing and certification requirements
- promotion of confidence in our respective conformity assessment bodies and enhanced cooperation on conformity assessment and standardisation issues globally
- consideration of provisions on labelling and means of avoiding misleading information for consumers[134]

54. The question of whether a particular regulation is an 'excuse for protectionism' is controversial. The TBT Agreement clarifies what this means in the following clause:

> "*Unnecessary obstacles to trade can result when (i) a regulation is more restrictive than necessary to achieve a given policy objective, or (ii) when it does not fulfil a legitimate objective. A regulation is more restrictive than necessary when the objective pursued can be achieved through alternative measures which have less trade-restricting effects, taking account of the risks non-fulfilment would create*."[135]

55. Technical barriers to trade, within the TBT Agreement, include domestic regulatory processes to protect domestic producers – e.g. mandatory product regulations, voluntary product standards and procedures that test product conformity with these regulations and standards.[136] The TBT sets out areas of flexibility for governments, to, in theory pursue 'legitimate' policy priorities that include protection of life/health (human, animal, and plant),

[130] World Trade Organization, *Technical Barriers to Trade Agreement*, 1995, http://bit.ly/1DMjlHf
[131] World Trade Organization, The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), 1995, http://bit.ly/1znO8dH
[132] World Trade Organization, Understanding the WTO: The Agreements – Standards and Safety, 2015, http://bit.ly/1yQ7NiE
[133] European Commission, *Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America*, 2013, http://bit.ly/1vOSUxF
[134] European Commission, *Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America*, 2013, http://bit.ly/1vOSUxF
[135] World Trade Organization, Technical Information on Technical barriers to trade, 2015, http://bit.ly/1K7edVx
[136] World Trade Organization, Technical Information on Technical barriers to trade, 2015, http://bit.ly/1K7edVx

human safety, environmental protection and prevention of deceptive marketing practices.[137]

56. However, the United Nations Conference on Trade and Development (UNCTAD) has warned that "if the TBT is applied too strictly, the legitimate social policy objectives of Members will be thwarted."[138] Box A briefly outlines some of the key elements that the framers of TTIP seek to harmonise.

Box A: The WTO Technical Barriers to Trade Agreement (1995) – some definitions

Technical regulation: a document which lays down product characteristics or their related processes and production methods, including the administrative provision, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marketing or labelling requirements as they apply to a product, process or production method.

Standard: A document approved by a recognised body, that provides, for common and repeated use, rule, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marketing or labelling requirements as they apply to a product, process or production method.

Conformity Assessment Procedure: Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled…including procedures for sampling, testing and inspection; evaluation, verification and assurance; registration, accreditation and approval. This applies both to international, regional, national and local government as well as non-governmental organisations.

57. While the language is technical, is soon becomes apparent that much will be at stake that is critical to a sovereign state's ability to regulate in the interest of health, public health and the environment – not least given that approaches to complex standards and risk are often very differently taken in the EU and US.

58. In a practical sense, TTIP's framers wish to address divergences in technical standards and requirements between industry sectors that are "burdensome" to trade,[139] such as in the chemical or pharmaceutical sector; differences in approach to regulatory standards, such as

137 World Trade Organization, *Technical Information on Technical barriers to trade*, 2015, http://bit.ly/1K7edVx
138 United Nations Conference on Trade and Development, *Dispute Settlement, 3.10, Technical Barriers to Trade*, 2003, http://bit.ly/1DKeoSJ
139 European Commission, *Impact Assessment Report on the future of EU-US trade relations*, 2014, http://bit.ly/1B31bhB

related to consumer product safety or medicines; and different approaches to conformity assessment of specific products and risks, such as for electrical products or machinery.[140]

59. LSE have drawn attention to the European Committee for Standardisation and European Committee for Electrotechincal Standardisation, which have cautioned that "…not only the interpretation of convergence to international standard...(is different on both sides of the Atlantic), but also the understanding of "transparency and predictability of regulatory and standards setting processes."[141]

60. LSE observes four concerns outlined by the Center for International Environmental Law, that through regulatory convergence:

- TTIP could restrain the continued development of stronger laws in the in the EU
- TTIP may pre-empt stronger sub regional laws by Member States
- TTIP could weaken developing standards for human health, labour and the environment in both the EU and US
- TTIP could influence the development of regulations and standards outside the EU and US, including in economies in transition that have recently adopted environmental policies more similar to the European than American approaches[142]

61. It is of concern that the US Trade Representative's 2014 National Trade Estimate Report on Foreign Barriers to Trade has criticised policies that include:

- New Zealand's health programs to control medicine costs
- Australian law to prevent the offshoring of consumers' private health data
- Japan's pricing system that reduces the cost of medical devices
- Vietnam's post-crisis regulations requiring banks to hold adequate capital
- Peru's policies favouring generic versions of expensive biologic medicines
- Canada's patent standards requiring that a medicine's utility should be demonstrated to obtain monopoly patent rights;
- Mexico's 'sugary beverage tax' and 'junk food tax.'
- Japan's laws protecting the privacy of citizens' personal data[143]

[140] European Commission, *Impact Assessment Report on the future of EU-US trade relations*, 2014, http://bit.ly/1B31bhB
[141] London School of Economics and Political Science, *The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems and Public Health*, 2015, http://bit.ly/1Giia40
[142] London School of Economics and Political Science, *The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems and Public Health*, 2015, http://bit.ly/1Giia40
[143] United States Trade Representative, 2014 National Trade Estimate Report on Foreign Trade Barriers, 2014, http://1.usa.gov/1vS31Wc

62. Given that the US Trade Representative identifies such sovereign national policies as technical barriers to trade, there are clear implications for the ongoing negotiations of the TTIP agreement with regard to these and other technical barriers to trade in the context set out above – and, indeed, FPH's manifesto objectives. LSE warn of serious implications for agri-food, and achievement of public health goals in relation to reductions on NCDS.[144]

63. To illustrate this concern, LSE draw attention to the Chilean law on the Nutritional Composition of Nutrients and Their Advertising, which obliges manufacturers to ensure detailed food labelling warnings on foods that are high in fat, sugar and salt, and, in addition a requirement "for some foods to include labels advising consumers to avoid excessive intake – extended to the regulation of food advertising particularly where targeting children."[145]

64. LSE note with concern that this law was discussed during the World Trade Organization's Technical Barriers to Trade Committee – where "several member delegations expressed concerns about Chile's proposed food health regulation amendments", including the United States Trade Representative (USTR).[146]

65. Closer to home, the UK government is currently facing legal 'infraction' proceedings at the European Commission level in relation to its voluntary 'traffic light labelling scheme', with challenge led by the Italian Government, which in turn is heavily lobbied by the Italian food industry.[147] Some analysts, despite the clear evidence presented in favour of it, have concluded that it will be difficult for the UK to argue that the voluntary food labelling scheme is "for public health, which is the only reason countries can introduce something like this."[148]

66. Scottish Government legislation on minimum unit pricing for alcohol – one of FPH's key manifesto objectives – is at time of writing currently the subject of litigation at the European Court of Justice for similar reasons that are directly relevant to TTIP.[149] The Technical Standards and Regulations Directive 98/34/EC[150] is intended to eliminate trade barriers and facilitate the free movement of goods and services, operating in a similar way to that of the TBT provisions to be embedded into TTIP.

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[144] London School of Economics and Political Science, *The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems and Public Health*, 2015, http://bit.ly/1Giia40
[145] London School of Economics and Political Science, *The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems and Public Health*, 2015, http://bit.ly/1Giia40
[146] London School of Economics and Political Science, *The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems and Public Health*, 2015, http://bit.ly/1Giia40
[147] Food Navigator, Commission open infraction proceedings against UK's 'traffic light label', 2014, http://bit.ly/1vS3PKE
[148] Farmer Guardian, *Food traffic light labelling system faces EU Challenge*, 2014http://bit.ly/1Adsc0z
[149] BBC, *Minimum alcohol policy referred to European Court*, 2014, http://bbc.in/1fxQOxP
[150] Department for Business, Innovation and Skills, Technical Standards and Regulations Directive 98/34/EC: guidance for officials, 2013, http://bit.ly/17JYbz5

67. As *Addictions and Lifestyles* point out, the alcohol industry in Scotland insists that Scottish government legislation on minimum unit pricing is a technical barrier to trade.[151] The European Commission has agreed within this position.[152] The Scotch Whisky Association (with its powerful lobbying networks and links with trade associations) is also arguing that there is not a strong evidence base to support the policy, that the policy is not proportionate and that its effects could be reached by alternative means.[153]

68. The TBT Agreement is also currently being used to challenge Australian legislation on standardised packaging of tobacco products[154] (another of FPH's key manifesto objectives).[155] That a claim should be permissible under the provision of the TBT Agreement in the first instance is deeply worrying.

69. Determination of whether a social policy objective is legitimate or reasonable in light of the TBT Agreement's provisions will turn on the interpretation of several common principles.[156] As outlined in chapter three, these common principles may ultimately be interpreted by three arbitrators sitting within opaque extra-judicial tribunals operating outside of the national domestic legal system, in accordance with international law, and operating under rules set by the World Bank. In Box B below, UNCTAD highlight some of these common principles.

Box B: Common principles of the WTO's Technical Barriers to Trade Agreement (UNCTAD, Technical Barriers to Trade, 2003)

Non-Discrimination: The non-discrimination obligation has two elements: 'most-favoured-nation treatment' ('MFN treatment'), and 'national treatment'. MFN is an obligation not to discriminate between 'like products' imported from different WTO Members. 'National treatment' is an obligation not to discriminate between domestic and imported 'like products.'

Whether two products are 'like products' is one of the most difficult legal problems in the WTO Agreement. Likeness is determined on a case-by-case basis and the notion of likeness is not consistent throughout the WTO Agreement, and absolute rules are not established.

[151] Addiction and Lifestyles in Contemporary Europe Reframing Addictions Project, The struggle over Minimum Unit Pricing for alcohol has only just begun, 2012, http://bit.ly/1DuHUXs
[152] The Guardian, *Minimum alcohol price plan referred to European court by Scottish judges*, 2014, http://bit.ly/1iM0TGY
[153] The Scotch Whisky Association, *Minimum Unit Pricing*, 2012, http://bit.ly/1FNqWqf
[154] World Trade Organization, *Dispute Settlement: Australia — Certain Measures Concerning Trademarks and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, 2014, http://bit.ly/1DuUAgX
[155] UK Faculty of Public Health (lead author, Lindsey Stewart), *Start Well, Live Better – a Manifesto for the Public's Health*, 2014, http://bit.ly/1wDfDv0
[156] United Nations Conference on Trade and Development, *Dispute Settlement, 3.10, Technical Barriers to Trade*, 2003, http://bit.ly/1DKeoSJ

The Prevention of unnecessary barriers to international trade: With respect to technical regulations, the prevention of unnecessary obstacles to international trade is defined to mean that technical regulations must not be more trade restrictive than necessary to achieve a policy goal (the least-trade-restrictive measure), and must fulfil a legitimate objective, taking into account the risks that non-fulfilment would create.

With respect to standards, the prevention of unnecessary obstacles to international trade is not defined in the TBT Agreement. With respect to conformity assessment procedures, the TBT states that they "shall not be applied more strictly than is necessary to give the importing Member adequate confidence that products conform with the applicable technical regulations or standards, taking account of the risks non-conformity would create."

Legitimate Objectives: Legitimate objectives for technical regulations include: national security requirements, prevention of deceptive practices, protection of human health or safety, protection of animal life or health, protection of the environment, and other undefined objectives. Controversially, labour rights and human rights considerations are not specifically mentioned in the TBT Agreement as legitimate objectives.

Necessity: The TBT provides that technical regulations cannot be more trade restrictive than necessary to achieve a policy goal. In the Thailand - Cigarettes case a Tribunal concluded that a measure could be considered to be "necessary" only if there were no alternative measure consistent, or less inconsistent, which a contracting party could "reasonably" be expected to employ to achieve its regulatory (health policy) objective.

With respect to technical regulations and conformity assessment procedures, an "assessment" of the risks of non-performance of the legitimate objective is carried out, and the TBT delineates the elements of the risk assessment.

Reasonableness: Appellate tribunals have interpreted reasonable as requiring a "weighing and balancing process" in which an assessment is made as to whether the alternative measure "contributes to the realization of the end pursued."

Harmonisation: Harmonisation is a central pillar of the TBT Agreement. Members are encouraged to participate in the international harmonisation of standards, and to use agreed international standards as a basis for domestic technical standards, regulations and conformity assessment procedures. Members have an obligation, within the limits of their

resources, to participate in the work of international standardisation organizations with respect to products for which they have adopted or expect to adopt technical regulations or standards.[157]

70. It is important to recognise that the provisions of the TBT Agreement oblige Member States to take reasonable measures to ensure that, not only national and upstream – but local government and non-governmental bodies comply with its rules. The TBT prohibits Member States from taking measures that require any local government body to act inconsistently with the rules governing the treatment of technical regulations.[158]

71. There are thus worrying implications for the implementation of the public health functions of financially constrained local authorities and regional public health work. Local authorities, regions and cities are not equipped with the capital to take on multi-nationals. There is potential for local authorities to be constrained on many issues as a result of TTIP. FPH is concerned at the possibility that this may impact on new by laws. It is often local initiatives in public health that spark the debate for national change. The TTIP agreement has the potential to suffocate those local sparks.

72. FPH does not consider that questions of legitimacy, reasonableness or necessity in relation to the provisions of the TBT Agreement should be determined through a "weighing and balancing process"[159] undertaken outside of the already well developed, transparent and advanced judicial systems of EU member states, in extra judicial legal entities at the WTO. The WTO, exerting pressure on States, warns that: "if a country applies international standards, it is less likely to be challenged in the WTO than if it sets its own standards."[160]

73. In addition to TBT provisions, TTIP seeks to build on the WTO's Sanitary and Phytosanitary Measures Agreement (SPS) 1995. The SPS Agreement is concerned with human, animal and plant life or health. As with the TBT, SPS outlines procedural and substantive rules to ensure SPS measures are not used for protectionist purposes and…do not result in unnecessary barriers to international trade. The WTO assert that:

> "*...a myriad of regulations can be a nightmare for manufacturers and exporters*."[161]

[157] United Nations Conference on Trade and Development, *Dispute Settlement, 3.10, Technical Barriers to Trade*, 2003, http://bit.ly/1DKeoSJ
[158] United Nations Conference on Trade and Development, *Dispute Settlement, 3.10, Technical Barriers to Trade*, 2003, http://bit.ly/1DKeoSJ
[159] United Nations Conference on Trade and Development, *Dispute Settlement, 3.10, Technical Barriers to Trade*, 2003, http://bit.ly/1DKeoSJ
[160] World Trade Organization, *Agreement on the Application of Sanitary and Phytosanitary Measures*, 1995, http://bit.ly/16yMj2k
[161] World Trade Organization, Understanding the WTO: The Agreements – Standards and Safety, 2015, http://bit.ly/1yQ7NiE

74. As UNCTAD outline, the SPS agreement regulates the conditions under which national regulatory authorities may set and enforce health and safety standards that directly or indirectly affect international trade.[162] In particular, it applies to any measure, regardless of the specific form it may take, which is adopted with the aim to:

- Protect consumers and animals from food- and feed-borne risks (e.g. risks deriving from additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs), and;
- Protect consumers, animals and plants from pest- or disease-related risks[163]

75. Typical policy instruments used to achieve SPS protection are import bans, technical specifications, including process and product standards, and information tools, including labelling requirements. The SPS Agreement sets out both substantive and procedural requirements with the aim of preventing food safety and animal and plant health regulations from unnecessarily hindering international trade and from being misused for protectionist purposes.[164] The SPS imposes four principal obligations on Member States:

- The obligation that any SPS measure must be based on scientific principles and not be maintained without sufficient scientific evidence;
- The obligation to base SPS measures either on a relevant international standard (e.g. that of the Codex Alimentarius Commission for Food Safety) or on a scientific assessment of the risk;
- The obligation to apply regulations only to the extent necessary to protect human, animal or plant life or health; and
- The obligation not to arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail.[165]

76. Critically, SPS provisions require clear and unequivocal scientific foundation and evidence to identify the likelihood of risk and the means by which a particular requirement may reduce or eliminate that risk. It is important to consider this position on risk alongside the non-discrimination requirement embedded into the SPS:

> "*Members shall ensure SPS measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail…each shall avoid*

[162] United Nations Conference on Trade and Development, *Training Module on SPS measures*, 2005, http://bit.ly/1wJ5M7q
[163] United Nations Conference on Trade and Development, *Training Module on SPS measures*, 2005, http://bit.ly/1wJ5M7q
[164] United Nations Conference on Trade and Development, Training Module on SPS measures, 2005, http://bit.ly/1wJ5M7q
[165] United Nations Conference on Trade and Development, Training Module on SPS measures, 2005, http://bit.ly/1wJ5M7q

arbitrary or unjustifiable distinctions in the levels it considers appropriate in different situations, if they result in discrimination or disguised restriction on international trade."[166]

77. However, tension exists between SPS provisions for a 'free market' scientific risk assessment approach, and the more limited application within the SPS Agreement of the 'precautionary principle', or 'social market' approach to risk.[167] The latter, as LSE note, is seen as a "fundamental plank of the EU and its approach to regulation,"[168] and originated in the Rio Declaration on Development and the Environment, which outlined that a:

"…*lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation*."[169]

78. The European Commission in TTIP aims to develop 'SPS Plus' provisions that go far beyond those within the original 1995 agreement, including the requirement that each side's SPS measures are "based on international standards or scientific risk assessments"[170] with the sovereign right to appraise and manage risk in accordance with the precautionary principle "applied only to the extent necessary" – a fundamental shift in approach.[171]

79. Where the line of that extent lies will inevitably be a matter of legal determination. This is disconcerting, given that the dominant decision making methodology among EU Member States is the precautionary principle. WTO states that "if exporting countries demonstrate that measures applied to exports achieve the same level of health protection as importing countries, the importing country (must) accept its standards."[172]

80. The elimination of non-tariff barriers and achievement of regulatory coherence is complex and has very serious implications for the preservation of current standards and future policies relevant to health, public health, the environment and other important and legitimate societal interests. Combined with investment protection standards and

[166] World Trade Organization, The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), 1995, http://bit.ly/1znO8dH
[167] London School of Economics and Political Science, The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems and Public Health, 2015, http://bit.ly/1Giia40
[168] London School of Economics and Political Science, The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems and Public Health, 2015, http://bit.ly/1Giia40
[169] London School of Economics and Political Science, The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems and Public Health, 2015, http://bit.ly/1Giia40
[170] World Trade Organization, *Understanding the WTO: The Agreements – Standards and Safety*, 2015, http://bit.ly/1yQ7NiE
[171] World Trade Organization, *Understanding the WTO Agreement on Sanitary and Phytosanitary Measures*, http://bit.ly/1C4MeOQ
[172] World Trade Organization, *Understanding the WTO: The Agreements – Standards and Safety*, 2015, http://bit.ly/1yQ7NiE

enforcement mechanisms, elimination of non-tariff barriers compromises the ability of governments to promote extra-commercial investment standards e.g. for health protection.

81. FPH is also concerned that TBT and SPS measures do not impose the burden of proof upon a sovereign government to demonstrate that a particular approach is not scientifically dangerous before it may regulate, and that the balance in favour of health, public health and environmental protection is preserved and not compromised at the expense of commercial interest in the removal of non-tariff barriers to trade. Box C outlines some further key regulatory standards at risk.

Box C: Harmonisation or *de-regulation*? Regulatory standards at risk

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

* REACH legislation ensures a high protection of human health and the environment from risks posed by chemicals, promotion of alternative test methods, free circulation of substances on the internal market and enhancing competitiveness and innovation. Industry are responsible for assessing and managing the risks posed by chemicals[173]

* The US has refused to comply with REACH legislation,[174] which adds value and quality to the products produced in the EU and allows the EU to compete on a higher level. If US industries refuse to level up to vital EU health and safety standards, this will lead either to unfair competition for EU sectors which apply more positive and progressive standards and conditions or to an extremely dangerous levelling down of the standards.[175]

* On the basis of the 'precautionary principle', REACH allows the European Chemical Agency to put restrictions on how chemicals are produced, sold, and used, in order to protect public health and the environment. In contrast, US chemical rules are far leaner, with the US Toxic Substances Control Act (TSCA) conferring very limited powers to the Environment Protection Agency (EPA).[176]

* There is a serious risk from Investor-State Dispute claims, as already seen in other bilateral free trade agreements, e.g. the Vattenfall case (see below)

[173] European Commission – Enterprise and Industry, *Registration, Evaluation, Authorisation and Restriction of Chemicals*, 2013, http://bit.ly/1sGk9qU
[174] House of Lords, *European Union Sub-Committee on External Affairs: Transatlantic Trade and Investment Partnership – Written evidence volume*, 2014, http://bit.ly/16wBH3H
[175] House of Lords, *European Union Sub-Committee on External Affairs: Transatlantic Trade and Investment Partnership – Written evidence volume*, 2014, http://bit.ly/16wBH3H
[176] Seattle to Brussels Network. 2013. A Brave New Transatlantic Partnership: The proposed EU-US TTIP/TAFTA and its socio-economic and environmental consequences. SBN. http://bit.ly/1tlNCvJ

Energy (including Hydraulic Fracturing, or 'fracking')

***** A European Commission negotiating paper, circulated to the US, calls for "reinforcing free trade in raw materials and energy." Notably the European Commission include within its definition of "energy goods", "*natural gas, whether liquefied or not*."[177] Friends of the Earth (FoE) disquietingly conclude that this could "serve to lock in fossil fuel dependency on both sides of the Atlantic for decades."[178]

* SBN note that fracking is now widespread, with 11,400 new natural gas wells fracked every year. In the EU there are no more than a dozen test sites, as bans and moratoria have been introduced while the associated risks are reviewed.[179]

* SBN also underscores that US energy companies, including leading climate sceptic Exxon Mobile, have begun to eye European shale gas reserves (in Poland, Denmark and France especially) and could use TTIP to break through national bans and moratoria.[180]

* In turn, US environmental organisation, Sierra Club, has drawn attention to extensive corporate lobbying of the European Parliament, and pressure from certain Member States (UK, Poland, Romania, Lithuania, Romania and Hungary in particular) have meant the European Commission has decided not to put forward a legal framework addressing impacts of shale gas, but only non-binding recommendations.[181]

* In a move widely felt to be largely influenced by the TTIP negotiations, at the end of 2014, the European Parliament, in a vote on its Fuel Quality Directive, "scrapped a mandatory requirement to label tar sands oil as highly polluting, after years of industry" lobbying.[182] This removes discriminatory penalties against fuel derived from tar sands, despite tar sands being 23% more carbon intensive than conventional oil – thereby increasing greenhouse gas emissions and compromising EU legislation to the contrary.[183]

* Serious risk of ISDS claims (see chapter three) is presented by these developments, as has already been seen in other bilateral free trade agreements, such as the Lone Pine

[177] EU Secret Deals, *TTIP – non papers on raw materials and energy*, 2013, http://bit.ly/16vSlk1
[178] Friends of the Earth, *Stop this Trojan Horse Treaty: Why Friends of the Earth England, Wales and Northern Ireland oppose TTIP*, 2014, http://bit.ly/1o404OJ
[179] Seattle to Brussels Network. 2013. A Brave New Transatlantic Partnership: The proposed EU-US TTIP/TAFTA and its socio-economic and environmental consequences. SBN. http://bit.ly/1tlNCvJ
[180] Seattle to Brussels Network. 2013. A Brave New Transatlantic Partnership: The proposed EU-US TTIP/TAFTA and its socio-economic and environmental consequences. SBN. http://bit.ly/1tlNCvJ
[181] Sierra Club, *No Fracking Way: How the EU-US trade agreement risks expanding fracking*, 2014, http://bit.ly/1upc28q
[182] EurActiv, *Canada tar sands will not be labelled 'dirty' after all*, 2014, http://bit.ly/1x3ZqVd
[183] Friends of the Earth, *Stop this Trojan Horse Treaty: Why Friends of the Earth England, Wales and Northern Ireland oppose TTIP*, 2014, http://bit.ly/1o404OJ

case (see below)

Energy consumption

* The EU emissions trading system (EU ETS) is a cornerstone of the EU's policy to combat climate change and its key tool for reducing industrial greenhouse gas emissions cost-effectively. The first - and still by far the biggest - international system for trading greenhouse gas emission allowances, the EU ETS covers more than 11,000 power stations and industrial plants in 31 countries, as well as airlines.[184]

* The US has rejected outright the EU's emissions trading scheme (ETS), and the TTIP negotiations may therefore threaten its existence.[185]

Renewable Energy

* The EU Renewable Energy Directive (RED) requires eligible feedstock for energy-biomass meet basic greenhouse gas emissions-reduction targets and other basic sustainability criteria. US ethanol, extracted from genetically modified (GM) maize and soy fails to meet such standards, so is excluded from the same tax incentives that other fuels benefit from, and is less competitive on the EU market.

*US agribusinesses have been lobbying hard to claim that tax incentives to promote clean energy products represent a restriction to trade.[186]

* The US soy industry has worked with the US Trade Representative and the US Department of Agriculture to initiate negotiations with the EU under which producer compliance with US conservation laws would be deemed as achieving the RED's sustainability requirements. This would undermine EU efforts to minimise the damaging social and environmental impacts of the production of controversial biofuels.[187]

Food and agriculture

* EU consumers may see Genetically Modified Organisms (GMOs), hormone-treated beef and pork, and chlorine-sterilised chicken make their way back onto the shelves of supermarkets, because TTIP could lift the bans on such goods and undermine the

[184] European Commission – Climate Action, *The EU Emissions Trading System*, 2015, http://bit.ly/1ePrT2M
[185] The Guardian, *Obama fails first climate test by rejecting EU aviation carbon regime*, 2012 http://bit.ly/16TXsvu
[186] Seattle to Brussels Network. 2013. A Brave New Transatlantic Partnership: The proposed EU-US TTIP/TAFTA and its socio-economic and environmental consequences. SBN. http://bit.ly/1tlNCvJ
[187] Seattle to Brussels Network. 2013. A Brave New Transatlantic Partnership: The proposed EU-US TTIP/TAFTA and its socio-economic and environmental consequences. SBN. http://bit.ly/1tlNCvJ

'precautionary principle' on which European food regulation is built - and consumer rights rest.[188] [189]

* LSE have shown that the Sanitary and Phytosanitary Measures Agreement (SPS),[190] to be incorporated into TTIP (see below) has weakened the precautionary principle by "mandating a scientific risk assessment on all regulatory standards – allowing Canada and the US to impose sanctions to the value of $150m on the EU in 1998 in retaliation for the EU's ban on hormone treated beef imports, as there was insufficient scientific evidence to support the ban."[191]

* In addition, among the greatest increases in imports of goods through tariff reductions is anticipated to be processed foods (2.37%). As LSE outline, if existing tariffs are substantially reduced and restrictions lifted, imports into the EU of US agri-food produce could double. Any gains this may have in terms of reduced food costs may, LSE suggest, be offset by the "negative health impact of increasing the availability, uptake and consumption of unhealthy foods (high in sugar, salt and saturated fats), which are particularly price sensitive."[192]

* The same, LSE suggest, could apply to alcohol, with expected reduced tariffs and prices (and, in turn, implications for policy proposals including the minimum unit pricing of alcohol, were it subject to ISDS claims, as we will explore in chapter three). LSE warn that "TTIP clearly represents a potential challenge to alcohol control policies if its implementation results in reductions in price and increase in supply." LSE recognises concerns that TTIP "could make a regulatory response more difficult to achieve." [193]

Labour Rights

* The International Labour Organization (ILO) was established to promote social justice and internationally recognized human and labour rights. While the UK is signatory to and has enacted many of the ILO's key provisions – including the *Freedom of Association and*

[188] Seattle to Brussels Network. 2013. A Brave New Transatlantic Partnership: The proposed EU-US TTIP/TAFTA and its socio-economic and environmental consequences. SBN. http://bit.ly/1tlNCvJ
[189] London School of Economics and Political Science, *The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems and Public Health*, 2015, http://bit.ly/1Giia40
[190] World Trade Organization, The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), 1995, http://bit.ly/1znO8dH
[191] London School of Economics and Political Science, *The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems and Public Health*, 2015, http://bit.ly/1Giia40
[192] London School of Economics and Political Science, *The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems and Public Health*, 2015, http://bit.ly/1Giia40
[193] London School of Economics and Political Science, *The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems and Public Health*, 2015, http://bit.ly/1Giia40

Protection of the Right to Organise Convention and the *Right to Organise and Collective Bargaining Convention*,[194] the US has not ratified even these most basic ILO conventions.[195]

* Without these fundamental protections, the agreement risks undermining crucial European social, employment and health and safety rights and could lead to a race to the bottom in terms of standards and conditions as well as increased unemployment and mass social dumping as EU companies relocate to the US to take advantage of their weaker labour laws.[196]

* It also devalues other trade agreements in which these ILO Conventions and public procurement laws are referenced[197]

[194] International Labour Organization, *Ratifications for United Kingdom*, 2012, http://bit.ly/1LZ6lUc
[195] International Labour Organization, *Ratifications for United States*, 2012, http://bit.ly/1DqX4AE
[196] House of Lords, *European Union Sub-Committee on External Affairs: Transatlantic Trade and Investment Partnership – Written evidence volume*, 2014, http://bit.ly/16wBH3H
[197] House of Lords, *European Union Sub-Committee on External Affairs: Transatlantic Trade and Investment Partnership – Written evidence volume*, 2014, http://bit.ly/16wBH3H

Chapter Two: What is at stake? The right to the highest state of physical and mental health and wellbeing

1. The highest attainable standard of physical and mental health and wellbeing is a fundamental human right, "indispensable for the exercise of other human rights."[198] It is recognised within many legally enforceable international instruments, to which the UK is signatory;[199] international health programmes developed by the World Health Organization;[200] and through formulation of national health and public health policy.[201]

2. The United Nations' International Covenant on Economic, Social and Cultural Rights (ICESCR), at Article 12, recognises that realisation of the right is not confined to creation of conditions assuring access to health care in the event of sickness alone - and acknowledges that it "embraces a wide range of socio-economic factors that promote conditions in which people can lead a healthy life, and extends to the underlying determinants of health."[202]

3. The ICESCR outlines steps to achieve realisation of the right, e.g. those necessary for: healthy child development; a healthy environment; prevention, treatment and control of epidemic, endemic, occupational and other diseases and for healthy working conditions; and access to food, nutrition and housing.[203] In turn, the Universal Declaration of Human Rights affirms the right to work, education, life, non-discrimination, privacy, and information.[204]

4. These, and other rights and freedoms, address integral components of the right to health, and are embraced by the UK Faculty of Public Health – whose overarching mission is the promotion and protection of the health and wellbeing of everyone. At the core of the 12 priorities of our Manifesto, *Start Well, Live Better*,[205] rests a clear ambition to bridge the rapidly widening in inequalities in health – to create a fairer, healthier society.

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[198] United Nations Committee on Economic, Social and Cultural Rights, *General Comment 14, The right to the highest attainable standard of health* (Twenty-second session, 2000), U.N. Doc. E/C.12/2000/4 (2000), paragraph 1, http://bit.ly/1wRDrA8

[199] E.g. Article 5 (e) (iv) of the International Convention on the Elimination of All Forms of Racial Discrimination of 1965; Articles 11.1 (f) and 12 of the Convention on the Elimination of All Forms of Discrimination against Women of 1979; Article 24 of the Convention on the Rights of the Child of 1989; European Social Charter of 1961 as revised (art. 11); Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights of 1988 (art. 10); the Commission on Human Rights, the Vienna Declaration and Programme of Action of 1993 and other international instruments.

[200] E.g. WHO Framework Convention on Tobacco Control (2003); UN Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases (2011); WHO Global Action Plan on non-communicable diseases 2013-2020 (2013); Organisation for Economic Co-operation and Development health policies; UN Framework Convention on Climate Change (1992); the Kyoto Protocol (1998); UN sustainable development goals

[201] E.g. Children and Families Act 2014; Human Rights Act 1998; Children Act 2014; Environmental Protection Act 1990; Health and Safety at Work Act 1974; Disability Discrimination Act 1995; Mental Health Act 2007; National Health Services Act 2006;

[202] United Nations Committee on Economic, Social and Cultural Rights, *General Comment 14, The right to the highest attainable standard of health* (Twenty-second session, 2000), U.N. Doc. E/C.12/2000/4 (2000), paragraph 4, http://bit.ly/1wRDrA8

[203] United Nations, *International Covenant on Economic, Social and Cultural Rights*, (1976), http://bit.ly/J1E1V3

[204] United Nations, *Universal Declaration of Human Rights*, 1948, http://bit.ly/1wDfqbh

[205] UK Faculty of Public Health (lead author, Lindsey Stewart), *Start Well, Live Better – a Manifesto for the Public's Health*, 2014, http://bit.ly/1wDfDv0

5. These priorities align with the Millennium Development Goals adopted by United Nations member states some fifteen years ago,[206] and are reflected in the post-2015 development agenda.[207] The world is, UN Secretary General Ban Ki-moon has stressed, at an "historic crossroads – the direction we take will determine whether we succeed or fail in fulfilling our promises."[208] With our globalised economy and sophisticated technology, we can:

> "*…transform the world to better meet human needs and the necessities of economic transformation, while protecting our environment…and realising human rights*"[209]

6. In fulfilling that ambition – and fully realising their obligations in national[210] and international law – it is critical that Governments are unobstructed in exercising their right to formulate and prioritise policy interventions at the population and individual level that address the key risk factors influencing health inequalities across an increasingly steep social gradient. The National Institute of Health and Care Excellence (NICE) has emphasised that 'upstream' national or regional policy and legislation are "particularly powerful levers"[211] to effect change.

7. By way of example, NICE emphasises that "the success of legislation banning tobacco advertising and smoking in public places followed unsuccessful voluntary agreements with industry, (demonstrating) the effectiveness of national government action to improve the public's health."[212] Other legislative 'levers' identified within FPH's manifesto, include:

- the introduction of a 20% duty on sugar sweetened beverages
- stopping TV marketing of foods high in sugar, salt and fat (HFSS) before the 9pm watershed
- tightening online marketing restrictions to protect children from HFSS foods
- introducing a minimum price per unit for alcohol
- rapid implementation of standardised tobacco packaging
- giving everyone in employment and training a living wage

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[206] United Nations General Assembly, *United Nations Millennium Declaration*, 2000, <http://bit.ly/INgnuW>
[207] United Nations Economic and Social Council, *Millennium Development Goals and post-2015 Development Agenda*, http://bit.ly/1chz6gr
[208] United Nations General Assembly, *The road to dignity by 2030: ending poverty, transforming all lives and protecting the planet Synthesis report of the Secretary-General on the post-2015 sustainable development agenda*, 2014,http://bit.ly/1ycMcpC
[209] http://bit.ly/1ycMcpC
[210] Including, in the case of the UK, its obligations under the Human Rights Act 1998 http://bit.ly/1kLb3Hq
[211] National Institute for Health and Care Excellence (NICE), *Prevention of cardiovascular disease: NICE public health guidance 25*, 2010, (http://bit.ly/1DtExEM)
[212] National Institute for Health and Care Excellence (NICE), *Prevention of cardiovascular disease: NICE public health guidance 25*, 2010, (http://bit.ly/1DtExEM)

- to commit to a rapid move to 100% renewables and a zero carbon energy system[213]

8. These policies are likely to be among the most effective and cost-effective means of reducing cardiovascular disease at population level, easing the pressure on the National Health Service (NHS) and ensuring a sustainable approach to the future that includes climate change and reducing health and socio-economic inequalities. The burden of disease also adversely affects the economy and employers.

9. Analysis by the World Economic Forum and Harvard School of Public Health identifies the sizeable economic burden of non-communicable disease (NCDs) on societies, and outlines a set of "affordable, feasible and highly cost-effective strategies" that could avert millions of premature deaths and reduce economic losses by making renewed efforts to tackle NCD at the population and individual level.[214] NICE supports this perspective:

> "*Promoting good health and preventing ill health saves money…a small shift in resource towards public health prevention activity would offer significant short, medium, and long term savings to the NHS and to the taxpayer*"[215]

10. Where access to medical care is required, FPH is clear that a universal healthcare system, open to all, free to all, and funded by all through general taxation, remains not only the most equitable, but most managerially efficient and cost-effective system – delivering some of the best outcomes of any national health systems model. For that reason, in March 2012, FPH called for the withdrawal of the Health and Social Care Bill.[216]

11. FPH cautioned that reframing the mix of public-private health service delivery towards a further deregulated and competitive market, coupled with the removal of the Secretary of State's duty to secure provision of a comprehensive health service; risked fragmenting services, compromising the quality of health and social care, worsening health inequalities and removing any safety net for the most vulnerable and sick in society.[217]

12. Our membership has substantial on-going concerns about the scope and implementation of the Health and Social Care Act for England 2012, consistently rating the risks in FPH's

[213] UK Faculty of Public Health (lead author, Lindsey Stewart), *Start Well, Live Better – a Manifesto for the Public's Health*, 2014, http://bit.ly/1wDfDv0
[214] World Economic Forum and Harvard School of Public Health, *The Global Economic Burden of Non-Communicable Disease*, 2011, http://bit.ly/1iDEfzz
[215] National Institute of Health and Care Excellent, *Using NICE guidance to cut costs in the downturn*, 2009
[216] British Medical Journal, Faculty of Public Health calls for the health bill to be withdrawn, 2012 http://bmj.co/1BPILT8
[217] UK Faculty of Public Health, *Health and Social Care Bill: Risk Assessment Summary*, 2012, http://bit.ly/14BaH2u

earlier assessment[218] as still high or extreme, including those to NHS planning and delivery, e.g. loss of: insight on addressing population need; effectiveness and efficiency for NHS commissioners; service fragmentation; and poor co-ordination of care.[219]

13. FPH has called for the rejection of increased market competition for healthcare and the protection of national sovereignty over health service policy, including the protection of the NHS from trade and investment corporate laws designed to be applied to commercial activity. As outlined within this report, FPH also calls for the explicit unambiguous exclusion of ISDS and the NHS from TTIP, against the backdrop of UK Trade Minister, Lord Livingston, clarifying that there will be no such "carve out for the NHS per se."[220]

14. Beyond the general right to health as highlighted above, the UK Health Forum (UKHF) emphasises that a number of international treaties, declarations, strategies and/or action plans include measures to protect public health and the environment. UKHF have expressed deep concern that "efforts by states (Parties) to implement some of these measures and regulate in the public interest have been challenged through ISDS", including the:

- WHO Framework Convention on Tobacco Control[221]
- UN Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases[222]
- WHO Global Action Plan on non-communicable diseases 2013-2020[223]
- Organisation for Economic Co-operation and Development health policies[224]
- UN Framework Convention on Climate Change[225]
- UN Kyoto Protocol[226]
- UN sustainable development goals[227]

15. Finally, the European Commission's 'negotiating mandate' for TTIP, affirms its commitment to "enhanced (intellectual property rights) protection…in a manner that

[218] UK Faculty of Public Health, *Health and Social Care Bill: Risk Assessment Summary*, 2012, http://bit.ly/14BaH2u
[219] UK Faculty of Public Health, to be published – results of membership survey on the impact of the NHS reforms, 2014
[220] House of Lords European Union Committee, paper 179. 13 May 2014. 14th Report of Session 2013-14, Transatlantic Trade and Investment Partnership. House of Lords. http://bit.ly/1wLljIa
[221] WHO Framework Convention on Tobacco Control, 2003, http://bit.ly/1I3fFUe
[222] UN Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, 2011, http://bit.ly/OrRFmw
[223] WHO Global Action Plan on non-communicable diseases 2013-2020, 2013, http://bit.ly/1gCLUfJ
[224] Organisation for Economic Co-operation and Development health policies, http://bit.ly/1AxXNO3
[225] UN Framework Convention on Climate Change, 1992, http://bit.ly/18l0R5l
[226] UN Kyoto Protocol, 1998, http://bit.ly/1ryOcmL
[227] UN sustainable development goals, http://bit.ly/1CrZ788

complements and builds upon the World Trade Organization's (WTO) Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS)."[228] [229]

16. Through embedding within TTIP TRIPS plus provisions, the European Commission seeks to further strengthen the intellectual property rights regime in such a way as to make it harder for governments to take measures to protect health (e.g. the introduction of policies including standardised packaging of tobacco products or health warnings on alcohol products). Such intellectual property rights also threaten affordable access to medicine.

17. FPH emphasises the importance of the 'Doha Declaration on the TRIPs Agreement and public health', which states that:

> "*…the TRIPS Agreement…should not prevent Members from taking measures to protect public health. It can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.*"[230]

18. FPH recognises the ICESCR's pragmatic and sobering understanding that "for millions of people throughout the world, the full enjoyment of the right to health still remains a distant goal." It is also the case, as the ICESCR emphasises, that "formidable structural and other obstacles resulting from international and other factors beyond the control of many States parties impede full realization of article 12."[231]

19. However, as the following analysis of the proposed arbitration mechanism being negotiated by the European Commission on behalf of EU Member States demonstrates, ISDS within TTIP is not only unnecessary – but will exacerbate these structural obstacles. At stake are the provision of health care and public health; sustainable development and efforts to address climate change; and efforts to reduce health inequalities.

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[228] European Commission, *Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America*, 2013, http://bit.ly/1vOSUxF

[229] Oxfam, *Trading away access to medicines – revisited: How the European trade agenda continues to undermine access to medicines*, 2014, http://bit.ly/1x5hJTk "*TRIPS is the dominant incentive framework for the development of new medicines. Given that its incentive structure is driven by profits, the system favours commercial interests over public health concerns, and tends to prioritise short-term maximisation of returns to shareholders. It does not focus on producing medicines that actually meet public health needs (e.g. antibiotics) at a price that societies can afford in the long term. Lower-income countries lacking profitable pharmaceutical markets suffer the most from this system.*"

[230] World Trade Organisation*, Doha WTO Ministerial: Declaration on the TRIPS agreement and public health*, 2001, http://bit.ly/IXJa04

[231] United Nations Committee on Economic, Social and Cultural Rights, *General Comment 14, The right to the highest attainable standard of health* (Twenty-second session, 2000), U.N. Doc. E/C.12/2000/4 (2000), paragraph 5, http://bit.ly/1wRDrA8

Chapter Three: From investor protection to investor privilege – investment protection and investor-state dispute settlement in TTIP

1. As its title suggests, the Transatlantic Trade and Investment Partnership comprises two related elements – trade and investment. With regard to the former, as outlined in chapter one, the European Commission is focused on negotiating the removal of trade barriers for improved market access (including to public procurement markets); improved regulatory coherence; and improved cooperation on setting international standards.[232]

2. However, TTIP is not properly understood as a trade agreement alone. With regard to the latter element, investment, the European Commission proposes to use the ongoing negotiations in TTIP for a "root and branch improvement"[233] of, by its own analysis "controversial",[234] standards of international investment protection – and of the investor-state dispute settlement (ISDS) mechanisms through which those standards are enforced.

Box D: What is investor-state dispute settlement (ISDS)?

* International Investment Agreements (IIAs) often include ISDS provisions, granting private investors rights in international law to make claims against states hosting their investments
* Only foreign investors can sue states under investment treaties, and only states can be held liable to pay damages for breach of investment treaties
* 'Arbitral tribunals' take place not through the domestic court system, but through the World Bank's International Centre for the Settlement of Investment Disputes (ICSID), or other international tribunals e.g. the International Chamber of Commerce
* IIAs often provide that investors do not need to exhaust national remedies before making an ISDS claim, and so can avoid the domestic court system in its entirety
* IIAs often give flexibility for investors to choose between the rules of the UN's Commission on International Trade Law rules or World Bank's ICSID's
* ISDS claims are determined by three arbitrators (international trade and investment lawyers), appointed on an ad hoc basis
* Arbitrators decide upon the legitimacy, proportionality, reasonableness and necessity of a States' acts, often with no training in the public policy issues under scrutiny or their impacts
* Foreign investors frequently use ISDS to challenge sovereign public interest measures e.g. policies to promote social equity, environmental protection or protect public health
* ISDS proceedings can be kept fully confidential – even in cases of public interest

[232] European Commission, *The Transatlantic Trade and Investment Partnership – TTIP explained*, 2014 <http://bit.ly/1jRJQ6h>
[233] European Commission, *The Transatlantic Trade and Investment Partnership – TTIP explained*, 2014 <http://bit.ly/1jRJQ6h>
[234] European Commission. March 2014. Investment Protection and Investor-State Dispute Settlement (ISDS) in EU agreements. EC. http://bit.ly/1fo6AFD

* Arbitral decisions in the public domain have exposed recurring episodes of inconsistent findings including divergent legal interpretations of identical or similar treaty provisions
* Arbitrators decide important questions of law without a possibility of effective review where erroneous decisions are made
* An increasing number of challenges to arbitrators may indicate that disputing parties perceive them as biased or predisposed
* Multinational investment law firms, who dominate the field, have large teams of lawyers charging high rates and employing expensive litigation techniques – hard for national governments (let alone local authorities) to counter
* On average, costs, including legal fees (which on average amount to approximately 82% of total costs) and tribunal expenses, have exceeded $8 million per party per case
* Countries have faced ISDS claims of up to $114bn and awards of up to $1.77bn – exerting huge pressure on public finances and creating disincentives for public-interest regulation posing obstacles to countries' sustainable economic development
* ISDS has raised concerns of 'nationality planning', where investors structure investments through intermediary countries with the aim of benefitting from IIAs, and ISDS mechanism

3. Investment protection in bilateral and regional investment treaties (BITs) consists of standards guaranteeing that governments will uphold principles of treatment that foreign investors can rely upon when deciding to invest. It is *claimed* that these principles are merely reflected in the rights democratic governments grant their own firms (and, importantly, private finance and shareholders, who, in a globalised market operate beyond national borders): no expropriation of property without compensation, access to justice, protection against coercion, and non-discrimination. [235]

4. On this basis, as its recently declassified negotiating mandate demonstrates, the European Commission's stated aim for an investment chapter in TTIP is to secure the highest levels of investment liberalisation and highest standards of legal protection and certainty for investors, including with regard to the expropriation of property (embracing intellectual property rights) – providing a *level playing field* for US investors in EU markets, with both EU investors and national governments.[236]

5. In turn, ISDS provides a dispute resolution and enforcement mechanism for situations where questions arise about whether those protections are being provided. It allows foreign

[235] European Commission, Public consultation on modalities for investment protection and ISDS in TTIP, March 2014, <http://bit.ly/UMWM4j>
[236] European Commission, *Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America*, 2013, <http://bit.ly/1vOSUxF>

investors to file claims for compensation against a host state if they believe it in breach of treaty commitments undertaken. Critically, arbitration takes place under international law – not through the domestic legal system of the state that has hosted the investment.[237]

6. In embedding these contentious provisions in TTIP, two objectives are oft cited: creation of a positive investment climate encouraging US investors into EU markets; while affording EU investors protection against potentially discriminatory and unequal US treatment. These objectives have been justified by the assertion that "despite the solidity of…US and EU court systems, it is possible that investors will not be given effective access to justice."[238]

7. However, in this context, it is important to note that the World Bank's ranking of how conducive the international regulatory environment is, places the US and UK at 7 and 8 out of 189 – among the most conducive investment environments in the world.[239] With US-UK imports in 2011 amounting to £30bn, and UK-US exports £39bn, it is, as leading international lawyers have stated, "implausible to claim that investors have been deterred"[240] by an uncertain legal, judicial or investment environment in the EU.

8. Not only has investment not been deterred, but the Australian Government's Productivity Commission has drawn attention to research demonstrating that ISDS has "no statistically significant impact on (attracting) foreign direct investment flows into a country."[241] The London School of Economics Enterprise (LSEE) agrees: "an EU-US investment chapter is highly unlikely to encourage investment above what would otherwise take place."[242]

9. Indeed, through their political influence, foreign investors often enjoy fiscal and regulatory advantages not shared by their domestic equivalents. In practice governments of advanced democratic economies are not systemically biased against them.[243] On the other hand, ISDS provisions, the Productivity Commission cautions, "could provide additional leverage to (investors) negotiating with foreign governments, were they willing to threaten arbitration."[244]

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[237] House of Lords European Union Committee, paper 179. 13 May 2014. 14th Report of Session 2013-14, Transatlantic Trade and Investment Partnership. House of Lords. http://bit.ly/1wLljIa
[238] European Commission, Public consultation on modalities for investment protection and ISDS in TTIP, March 2014, <http://bit.ly/UMWM4i>
[239] World Bank, *Ease of doing business index*, 2014, http://bit.ly/1idj5v4
[240] Kent Law School. July 2014. Statement of concern about planned provisions on investment protection and ISDS in TTIP. http://bit.ly/1uuQJzr
[241] Australian Government, *Bilateral and Regional Trade Agreements: Productivity Commission Research Report*, 2010, http://bit.ly/1mnt7bv
[242] London School of Economics Enterprise. April 2013. Costs and Benefits of an EU-USA Investment Protection Treaty. LSE Enterprise. http://bit.ly/1vA4ihl
[243] Australian Government, *Bilateral and Regional Trade Agreements: Productivity Commission Research Report*, 2010, http://bit.ly/1mnt7bv
[244] Australian Government, *Bilateral and Regional Trade Agreements: Productivity Commission Research Report*, 2010, http://bit.ly/1mnt7bv

10. Worryingly then, the European Commission's efforts to "strengthen the balance between investment protection standards and the State's right to take measures for legitimate public policy objectives;"[245] reveal serious unresolved tensions between a rights based approach to investment, protecting health – and one that seeks to "lock in liberalisation," and "rebalance the economy from the public to the private sector, and towards increased investment."[246]

11. Chapter two demonstrated that absolutely fundamental to the effective functioning of accountable and responsible democratic societies (and their efforts to protect health) is the right for unobstructed policy space to regulate for a legitimate purpose in the public interest. A pre-requisite is the right to determine, through a government's own evidential analysis, whether a legislative or regulatory intervention is proportionate and necessary to that legitimate purpose.

12. As outlined above, that right is clearly delineated in national and international law; by contrast, clauses within investment agreements – in theory intended to reflect this right – are characterised by their ambiguous, broad (and in their practical effect contradictory) wording. This reality, recognised by the European Commission itself, creates risk that ISDS "tribunals interpret them in a manner…threatening to the state's right to regulate."[247]

13. It is then of deep concern that TTIP's investment protection standards and ISDS chapter are modelled on the EU-Canada Comprehensive Economic and Free Trade Agreement (CETA).[248] Provisions, including on fair and equitable treatment, non-discrimination and indirect expropriation, (see Box A) provide absolutely no guarantee "investment protection standards cannot be interpreted by tribunals in a way detrimental to the right to regulate."[249]

14. In fact, the proposed investor rights are far *more* expansive than those in previous investment agreements. Many analysts find this unsurprising, viewing the 'reforms' as an "echo chamber of what the business community has proposed to re-legitimise investor-state arbitration while leaving its problematic core intact."[250] The Transnational Institute has provided extensive evidence that:

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[245] European Commission, *Public consultation on modalities for investment protection and ISDS in TTIP*, March 2014, <http://bit.ly/UMWM4j>
[246] Department for Business, Innovation and Skills. February 2011. *Trade for Investment and Growth*. London: The Stationary Office. <http://bit.ly/1vZfaVO>
[247] European Commission, *Public consultation on modalities for investment protection and ISDS in TTIP*, March 2014, <http://bit.ly/UMWM4j>
[248] European Commission, *EU-Canada Comprehensive Economic and Free Trade Agreement (CETA)*, 2014, http://bit.ly/1DVqVcu
[249] European Commission, *Public consultation on modalities for investment protection and ISDS in TTIP*, March 2014, <http://bit.ly/UMWM4j>
[250] Eberhardt P, Redlin, B and Toubeau C, *Trading away democracy: How CETA's investor protection rules threaten the public good in Canada and the EU*, 2014, http://bit.ly/1IICYDl

"*Arbitration law firms and arbitrators have used positions of influence to actively lobby against reform of the investment regime…their actions, backed by corporations, have prevented changes enhancing government's policy space to regulate*"[251]

15. The European Commission itself, reflecting on its 'guarantees', has been forced to accept that "further improvements should be explored" across: protection of the right to regulate; functioning of arbitral tribunals; the relationship between domestic judicial systems and ISDS; and review of ISDS decisions.[252] When the very institution negotiating on behalf of EU Member States has no confidence in its own proposals – why should the public?

BOX E: Some key investment protection standards and why we should be concerned[253]

The 'fair and equitable treatment' standard

The fair and equitable treatment (FET) is the most relied upon and successful basis for ISDS claims. It protects investors against serious arbitrary, discriminatory or abusive conduct by host States. Yet, its vague and broad wording risk overreach of its application.

FET is applied in ISDS to restrict host-country administrative and governmental action to a degree that threatens the policymaking autonomy of that country. This arises from uncertain approaches to interpretation of FET, including the sources of law to determine the limits of discretion of interpretation. Some tribunals focus on case-by-case readings.[254]

FET raises complex issues as to the types of governmental action that can be reviewed and degree of seriousness of breach required to activate a claim. The trend is towards a less stringent reading by tribunals, increasing chances that State regulations or measures can be found to infringe FET including those that have a legitimate public purpose.[255]

An expansive approach, including overreliance on the doctrine of investors' *legitimate expectations*, poses risk of unbalanced results in determination of what is good governance, giving rise to unpredictability. This leads to undermining of legitimate State

[251] Transnational Institute, Profiting from injustice: How law firms, arbitrators and financiers are fuelling an investment arbitration boom, 2012, <http://bit.ly/1kP1vZA>
[252] European Commission, *Commission Staff Working Document: Report – online public consultation on investment protection and investor-to-state dispute settlement (ISDS) in the Transatlantic Trade and Investment Partnership Agreement*, 2015, http://bit.ly/1u249WJ
[253] The UK Faculty of Public Health fully supports the detailed analysis of the proposed investment protection standards and arbitration mechanism made by both Gus Van Harten in his report,*Why Arbitrators not Judges?* (http://bit.ly/16Cz7cT); and Kent Law School's *Statement of concern about planned provisions on investment protection and ISDS in TTIP* (http://bit.ly/1uuQJzr)
[254] United Nations Conference on Trade and Development, *Fair and Equitable Treatmnet: UNCTAD Series on Issues in International Investment Agreements II*, http://bit.ly/1DPjZUn
[255] United Nations Conference on Trade and Development, *Fair and Equitable Treatmnet: UNCTAD Series on Issues in International Investment Agreements II*, http://bit.ly/1DPjZUn

intervention for economic, social, environmental and other developmental ends. The vagueness of FET means its content is contested, impossible to narrow down.[256]

The concept of legitimate expectations has been used in arbitral decisions applying all types of FET clauses. It has been applied either on its own or in tandem with other related concepts such as "*regulatory stability*". Some awards adopt a so-called "pro-investor" approach, reading into FET an obligation to maintain a stable business framework.[257]

In CMS v. Argentina the tribunal felt FET included a "stable framework for investment". Emergency measures by Argentina in the 2000–02 Peso crisis were found to breach FET, as they dismantled tariff guarantees that induced the investor to invest. Yet, the tribunal said that "even assuming the Respondent was guided by best intentions, of which there is no doubt, there is an objective breach [of the FET standard]".[258]

The European Commission claims to have provided for a limited, or 'closed', list in the definition of FET. Yet it has not adopted obvious language to remove the arbitrators' flexibility to decide that the FET standard is not closed. It states its intent to preclude FET from being used as a stabilisation clause. Yet this is not in the Canada-EU CETA text on which it is modelled in TTIP. The European Commission has expanded the scope of the FET.[259]

The European Commission codifies *legitimate expectations*, inviting more expansiveness. Besides the failure to limit expectations to written representations on the part of the state, the concept of legitimate expectations can be used by arbitrators to frustrate or preclude legitimate changes to legislative, government, and judicial decisions.[260]

States have tried before to curtail the expansive interpretation of FET through explicitly stipulation of the customary international law minimum standard of treatment. These efforts have been fruitless in the face of ISDS insistence that FET and its connection with the stability and predictability of the business environment, founded on contractual commitments, is not different from the international law minimum standard.[261]

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[256] United Nations Conference on Trade and Development, *Fair and Equitable Treatmnet: UNCTAD Series on Issues in International Investment Agreements II*, http://bit.ly/1DPjZUn
[257] United Nations Conference on Trade and Development, *Fair and Equitable Treatmnet: UNCTAD Series on Issues in International Investment Agreements II*, http://bit.ly/1DPjZUn
[258] United Nations Conference on Trade and Development, *Fair and Equitable Treatmnet: UNCTAD Series on Issues in International Investment Agreements II*, 2012, http://bit.ly/1DPjZUn
[259] Van Harten, G. *Why Arbitrators not Judges?*,2012, http://bit.ly/16Cz7cT
[260] Van Harten, G. *Why Arbitrators not Judges?*,2012, http://bit.ly/16Cz7cT
[261] Kent Law School. July 2014. Statement of concern about planned provisions on investment protection and ISDS in TTIP. http://bit.ly/1uuQJzr

Tribunals will likely consider the doctrine of 'legitimate expectations' to flow from – and give meaning to – components of the various 'basic obligations' that the European Commission proposes, such as 'due process' and the prohibition of 'arbitrariness.'[262]

FPH is of the view that the European Commission's efforts to remove the risk of expansive interpretations and an investor's 'legitimate expectations' will have little effect.

Expropriation of property

The European Commission affirm that the right to property is enshrined in the European Convention of Human Rights; and is crucial to investors in need of protection from foreign states' expropriation, without compensation, of their investment.[263]

More complex than physical property, tribunals must assess whether a State's regulatory measures are *equivalent* to expropriation (indirect expropriation). This is of concern where regulatory measures taken for legitimate purposes are subject to claims on the grounds they were equivalent to expropriation because of their negative impact on the investment. Most agreements leave tribunals significant room for interpretation.[264]

The European Commission's approach is to suggest inclusion of a clause stating that "except in circumstances where the impact of a measure is so severe in light of its purpose that it is manifestly excessive, non-discriminatory measures, to protect legitimate public welfare objectives, are not indirect expropriations."[265]

The European Commission, in an attempt to provide reassurance, have stated that Article XX of the WTO's General Agreement on Tariffs and Trade will be incorporated into TTIP, allowing States "to take measures relating to the protection of health, the environment, consumers, etc." However, Article XX GATT also includes a *proportionality test*.[266]

This invites ISDS "tribunals to engage in discretionary proportionality analysis…with a license to substitute their own opinion for that of a democratic government on the relative

[262] Kent Law School. July 2014. Statement of concern about planned provisions on investment protection and ISDS in TTIP. http://bit.ly/1uuQJzr
[263] European Commission, Public consultation on modalities for investment protection and ISDS in TTIP, March 2014, <http://bit.ly/UMWM4i>
[264] European Commission, Public consultation on modalities for investment protection and ISDS in TTIP, March 2014, <http://bit.ly/UMWM4i>
[265] Kent Law School. July 2014. Statement of concern about planned provisions on investment protection and ISDS in TTIP. http://bit.ly/1uuQJzr
[266] Kent Law School. July 2014. Statement of concern about planned provisions on investment protection and ISDS in TTIP. http://bit.ly/1uuQJzr

importance of the purpose that the measures at issue seek to achieve, and to engage in cost-benefit analysis on whether costs imposed on investors are 'excessive.'"[267]

FPH considers the proper body for determination of this assessment to be the UK court system. Foreign investors enjoy extensive protection in democratic countries. "It is assumed absurdly that domestic courts and domestic laws systematically fail to protect foreign investors. This is incorrect even if ISDS were a fair and independent process in the manner of courts in democratic societies, which it clearly is not."[268]

16. In particular, the European Commission has failed to positively address the costs and benefits of ISDS and its implications for: democratic choice and accountability, regulatory flexibility, and market efficiency; its compatibility with judicial independence, openness, and procedural fairness; and the efficacy and role of other means – e.g. domestic and European courts, state-to-state adjudication, and market mechanisms – to protect foreign investors.[269]

17. LSEE predicts that ISDS will impose meaningful economic costs on the UK, through regular invocation for governmental actions not normally challengeable under UK law. It urges caution that imprecise meanings of investment protection standards may lead to risk of the UK losing arbitrations and facing significant damage awards – or strong pressure to settle defendable claims.[270] Box C below highlights case law under existing ISDS provisions within existing bilateral investment treaties as it relates to health.

Box F: ISDS litigation under existing bilateral investment treaties

Health policy

Achmea B.V. v. The Slovak Republic, UNCITRAL, PCA Case No. 2008-13

When the Slovakian government restricted powers of private insurance firms to extract profits from the public health system, Dutch firm Achmea eventually seized €29.5 million in public assets by way of 'compensation'. Achmea is now attempting to use the same powers to block the Slovak government from setting up a public insurance scheme that would provide health cover to all the country's citizens.

[267] Kent Law School. July 2014. Statement of concern about planned provisions on investment protection and ISDS in TTIP. http://bit.ly/1uuQJzr
[268] Van Harten, G. *Why Arbitrators not Judges?*,2012, http://bit.ly/16Cz7cT
[269] Van Harten, G. July 2014. *Why Arbitrators, not Judges? Comments on the European Commission's approach to ISDS in TTIP and CETA*. http://bit.ly/1tZOelD
[270] London School of Economics Enterprise. April 2013. Costs and Benefits of an EU-USA Investment Protection Treaty. LSE Enterprise. http://bit.ly/1vA4ihl

HICEE B.V. v. The Slovak Republic, UNCITRAL, PCA Case No. 2009-11

Dutch company HICEE, B.V, shareholder of the health insurance companies DÔVERA and Apollo, alleged violations of the bilateral agreement between the Netherlands and the Slovak Federal Republic arising out of the adoption of a number of changes and amendments to the laws on health insurance since 2007. HICEE had originally claimed damages in excess of one billion EUR.

Philip Morris Brands Sàrl, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay, ICSID Case No. ARB/10/7

Multinational tobacco company Philip Morris International has filed a complaint against Uruguay for compensation reported to be as much as $11bn, on the grounds that Uruguay's anti-smoking legislation devalues its cigarette trademarks and investments in the country and contravenes the bilateral investment treaty between Switzerland and Uruguay (Philip Morris is headquartered in Lausanne.)

Melvin J. Howard, Centurion Health Corp. & Howard Family Trust v. The Government of Canada, UNCITRAL, PCA Case No. 2009-21

The claim challenged the Canada Health Act, under which the Canadian Government ensures the provinces and territories meet certain requirements, such as free and universal access to insured health care.

Pharmaceutical policy

Eli Lilly and Company v. The Government of Canada, UNCITRAL

Eli Lilly and Company has initiated formal proceedings under the North American Free Trade Agreement (NAFTA) to attack Canada’s standards for granting drug patents, claiming that the denial of a medicine patent is an expropriation of its property rights granted by the agreement. Eli Lilly is demanding $500 million for twice failing Canada’s more stringent test for proving a patent’s utility.

Apotex Holdings Inc. and Apotex Inc. v. United States of America, ICSID Case No. ARB(AF)/12/1

Apotex Holdings Inc. and Apotex Inc., Canadian companies in the pharmaceutical industry, filed claims arising out of Import Alerts issued by the U.S. Food and Drug Administration concerning two of Apotex’s Canadian manufacturing facilities.

Apotex challenged the decision of U.S. courts not to clarify patent issues relating to its plan to develop a generic version of the Pfizer drug Zoloft when the Pfizer patent expired. Apotex sought $520 million for violations of NAFTA Articles on national treatment, most favoured nation treatment, and minimum standard of treatment.

Minimum wage

Veolia Propreté v. Arab Republic of Egypt, ICSID Case No. ARB/12/15

French company Veolia Propreté lodged a claim against the Egyptian Government on the grounds that applying a minimum wage in the country would hurt Veolia's investments and represent a violation of Egypt's commitments in the bilateral investment treaty it had entered into with France.

Environmental policy

Vattenfall AB, Vattenfall Europe AG, Vattenfall Europe Generation AG v. Federal Republic of Germany, ICSID Case No. ARB/09/6

Swedish energy utilities company Vattenfall launched international arbitration, seeking compensation from Germany for terminating its policy supporting nuclear power generation, after the Fukushima disaster – raising concerns about a state's ability to regulate its own environment, safety and energy matters without liability, in response to disasters and evolving social attitudes.

Metalclad Corporation v. The United Mexican States, ICSID Case No. ARB(AF)/97/1

Metalclad Corporation, a U.S. waste disposal company, instituted arbitration proceedings against Mexico under NAFTA's ISDS provisions, arguing that Mexico wrongfully refused to grant a permit to open and operate a hazardous waste disposal facility in San Luis Potosi, despite concerns that unstable soil at the site could pollute the community's water supply.

Lone Pine Resources Inc. v. The Government of Canada, UNCITRAL

On the basis of the North American Free Trade Agreement (NAFTA) between the US, Canada and Mexico, US company Lone Pine Resources Inc. is demanding US$250 million in compensation from Canada for the Canadian province of Quebec's moratorium on 'fracking', undertaken to assess the environmental risks

18. Appearing before the House of Lords EU Select Committee, Dr Lauge Poulsen of Oxford, has warned that the UK should expect to be subject to at least as many claims as

were filed by US investors against Canada under the North American Free Trade Agreement (which contained ISDS provisions), "given that 8 per cent of US outward foreign direct investment stock was in Canada while 13 per cent was in the UK."[271]

19. LSEE also expects ISDS to impose meaningful political costs on the UK, with significant risk to legitimate public policy space. It anticipates 'regulatory chill' – the abandonment, delay or modification of future preferred regulation in the public interest on account of objections (perceived or real) from US investors. A range of channels, including lobbying, responses to government inquiries or arbitration, are likely to be used as "bargaining tools."[272]

20. Aggressively driving the entrenchment of the international investment regime, a hugely profitable 'arbitration industry' has emerged, capitalising on and actively involved in the expansive redefinition of the parameters of investment protection standards – and fuelling a surge in ISDS litigation against governments.[273] Lawyers have also advised clients to use ISDS as a "political weapon."[274] Clyde and Co, for example suggest using the potential:

> *"…adverse publicity (of a claim) as leverage in the event of a dispute with a foreign government*;"[275] while Dentons advise that with "*40% of disputes settled before an award…starting a claim can create leverage to help reach a satisfactory result.*"[276]

21. The European Commission has condemned the international investment arbitration community for its failure to "police itself adequately in matters of ethics, independence, competence, impartiality, and conflicts of interest".[277] This failure has led some international lawyers to conclude that the "institutional design of investment arbitration and the decision-making process is biased against some states and investors and public interest concerns".[278]

22. It is difficult to reconcile this with the dismissive position the UK Government, in response to a Select Committee inquiry, has adopted, in which it stated that: "ISDS provisions are in

[271] House of Lords European Union Committee, paper 179. 13 May 2014. 14th Report of Session 2013-14, Transatlantic Trade and Investment Partnership. House of Lords. http://bit.ly/1wLljIa
[272] London School of Economics Enterprise. April 2013. Costs and Benefits of an EU-USA Investment Protection Treaty. LSE Enterprise. http://bit.ly/1vA4ihl
[273] Transnational Institute, *Profiting from injustice: How law firms, arbitrators and financiers are fuelling an investment arbitration boom*, 2012, <http://bit.ly/1kP1vZA>
[274] Corporate Europe Observatory, *Profiting from Crisis: How corporations and lawyers are scavenging profits from Europe's crisis countries*, 2014, <http://bit.ly/1tWiJil>
[275] Clyde and Co, *Managing Eurozone risk through BIT planning*, 2012, <http://bit.ly/1FFjilH>
[276] Dentons, *The latest renewables claim: Abengoa's Subsidiary Launches Investment Treaty Proceedings Against Spain*, 2013, <http://bit.ly/1C1laiN> (cited from Lexology)
[277] European Commission, *Public consultation on modalities for investment protection and ISDS in TTIP*, March 2014, <http://bit.ly/UMWM4j>
[278] Kent Law School. July 2014. Statement of concern about planned provisions on investment protection and ISDS in TTIP. http://bit.ly/1uuQJzr

themselves *only* an enforcement mechanism: the substantive (investment) protections matter most."[279] As this report will show, unelected and unaccountable arbitral tribunals wield enormous power – determining if sovereign public policy is proportionate to a legitimate aim.

23. FPH strongly disagrees with the European Commission's assertion that "the decisions of arbitral tribunals are only as good as the provisions that they have to interpret and apply."[280] Even were investment protection standards better drafted, their interpretation will be only as good as the arbitral tribunals interpreting them. Tribunals do not operate in a legal vacuum, removed from political and corporate considerations – but are intimately fused with them.

24. Yet, given this power, it is troubling that the UN Conference on Trade and Development (UNCTAD) has drawn attention to recurring episodes of inconsistent findings, including "divergent legal interpretations of identical or similar treaty provisions and differences in the assessment of the merits of cases involving the same facts". This has led to uncertainty about the meaning of key standards and lack of predictability of future application. [281]

Box G: Profiting from injustice – the Transnational Institute on the arbitration industry

The number of ISDS cases, and money involved, has surged in the last two decades
from 38 cases in 1996 to 450 known ISDS cases in 2011. In 2009/2010, 151 investment arbitration cases involved corporations demanding at least US$100m from states.

The arbitration boom has created big profits for investment lawyers from taxpayers
Legal and arbitration costs average US$8m per ISDS dispute, often exceeding US$30m.

The international investment arbitration industry is dominated by a small and tight-knit Northern hemisphere-based community of law firms and elite arbitrators
Three UK/US law firms claim to have been involved in 130 ISDS cases in 2011; 15 arbitrators, have decided 55% of all ISDS cases; they sit on the same ISDS panels, act as arbitrators and counsels and call on each other as witnesses – with conflict of interest concerns.

Investment lawyers have encouraged governments to sign investment treaties using language that maximises possibilities for litigation

[279] Her Majesty's Government. 2014. Government Response to the House of Lords European Union Committee's 14th Report: The Transatlantic Trade and Investment Partnership. http://bit.ly/1G3J8fJ
[280] Van Harten, G. July 2014. *Why Arbitrators, not Judges? Comments on the European Commission's approach to ISDS in TTIP and CETA*. http://bit.ly/1tZOelD
[281] UNCTAD, *Reform of the Investor-State Dispute Settlement: In search of a roadmap*, 2013 http://bit.ly/1KNF32I

A statistical study based on 140 investment-treaty cases shows that arbitrators consistently adopt an expansive (claimant-friendly) interpretation of various clauses, such as the concept of investment, while taking a restrictive approach to human and social rights.

Arbitrators tend to defend investor rights above the public interest

Many arbitrators have been members of boards of MNCs, including those which have filed cases against developing nations; in many public interest decisions, arbitrators only consider only claims of lost profits in rulings; arbitrators rejected proposals for more consideration of environmental and human rights law.

Law firms with ISDS departments seek out opportunities to sue countries in crisis

Encouraging use of lawsuit threats as a political weapon to weaken or prevent laws on public health or environmental protection.

There is a revolving door between ISDS lawyers and government policy-makers

Several key ISDS lawyers were chief negotiators of investment treaties (or FTAs with investment protection chapters) and defended their governments in ISDS disputes.

Investment lawyers have a firm grip on the academic discourse on investment law

Controlling on average 74% of editorial boards of the key journals on investment law, and frequently failing to disclose the way they personally benefit from the system.[282]

25. UNCTAD further observes that "arbitrators decide important questions of law without a possibility of effective review", in light of the very "narrow jurisdictional limits…existing review mechanisms operate within" – themselves created on an "ad hoc basis for the purpose of a single dispute," therefore potentially arriving at yet further inconsistent conclusions and contributing to the unpredictability of international investment law".[283]

26. The UN High Commissioner for Human Rights (UNHCHR), in turn, observes a trend that "investment liberalisation has focused on attempts to balance competing definitions of investors' rights with the right to regulate, at the expense of "articulating investor *obligations*".

[282] The Transnational Institute, *Profiting from Injustice: How law firms, arbitrators, and financiers are fuelling an investment arbitration boom*, 2012, http://bit.ly/1kP1vZA
[283] UNCTAD, *Reform of the Investor-State Dispute Settlement: In search of a roadmap*, 2013 http://bit.ly/1KNF32I

This, it contends, risks "skewing investment liberalisation in favour of investors' rights, losing sight of their conditional nature – to the detriment of the rights of other actors".[284]

27. It is then deeply disquieting that EU and US investors have initiated 64% of known ISDS disputes, challenging: "green energy and medicine policies, anti-smoking legislation, bans on harmful chemicals, environmental restrictions on mining, health insurance", and economic policy. Not least, since only 42% of known ISDS cases were decided in favour of the state, 31% the investor and 27% settled (likely to involve payments or concessions).[285]

28. In that context, it is significant that among US objectives in TTIP is expansion of "market access to (EU) government procurement contracts" – in areas including medicine – with guarantees of "predictable government conduct" and "treatment as favourable as that for domestic suppliers" sought.[286] With government procurement 15% of UK GDP,[287] it is alarming that public utilities have "proven particularly prone to (US) investment treaty claims."[288]

29. Yet, the European Commission's "maximum ambition" with regard to public procurement upholds this objective, and aims for "enhanced mutual access to public procurement markets at all administrative levels (national, regional and local), and in the fields of public utilities, covering relevant operations of undertakings operating in this field and ensuring treatment no less favourable than that accorded to locally established suppliers."[289]

30. The European Commission further states that with regard to trade in services, its intention is to ensure the "highest level of liberalisation captured in existing free trade agreements (including enhancement of regulatory rules), covering substantially all sectors and all modes of supply, while achieving new market access by tackling remaining long-standing market access barriers, recognising the sensitive nature of certain sectors."[290]

31. These tensions have led French Minister for Trade, Nicole Bricq, to unambiguously set out her Government's rejection of ISDS within TTIP. A *state-state*, as opposed to an

[284] Office of the High Commissioner for Human Rights, 5th Ministerial Conference, *Human Rights and Trade*, 2003 <http://bit.ly/1yP0Xid>
[285] Corporate Europe Observatory. October 2013. *A transatlantic corporate bill of rights. Investor Privileges in EU-US trade deal threaten public interest and democracy*. CEO. http://bit.ly/12aU0cL
[286] Office of the United States Trade Representative, *U.S. Objectives, U.S. Benefits In the Transatlantic Trade and Investment Partnership: A Detailed View*, 2014, <http://1.usa.gov/1cuSu9Q>
[287] Organisation for Economic Co-operation and Development, *Size of Procurement Market*, 2011,<http://bit.ly/MHyHba>
[288] London School of Economics Enterprise. April 2013. Costs and Benefits of an EU-USA Investment Protection Treaty. LSE Enterprise. http://bit.ly/1vA4ihl
[289] European Commission, *Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America*, 2013, <http://bit.ly/1vOSUxF>
[290] European Commission, *Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America*, 2013, http://bit.ly/1vOSUxF

investor-state mechanism, “is enough,” Bricq has insisted.[291] Brigitte Zypries, German Minister for Economic Affairs, adds that: “…from the perspective of the Federal Government, US investors in the EU have sufficient legal protection in national courts.”[292]

32. While not party to TTIP, it is also relevant that the Australian Government, subject to an egregious ISDS attack on its standardised packaging of tobacco products, has rejected ISDS in future trade agreements. It does not “support provisions conferring greater legal rights on foreign businesses than those available to domestic businesses…nor provisions constraining (its) ability to make laws on social, environmental and economic matters.”[293]

33. The European Parliament has denounced ISDS, “given the highly developed legal systems of the EU”, viewing state-to-state dispute settlement and local judicial remedies as “the most appropriate tools to address investment disputes.”[294] New European Commission President Juncker has himself remarked that he “will (not) accept that the jurisdiction of courts in the EU Member States is limited by special regimes for investor disputes.”[295]

34. If these tensions are to be resolved such that the right to health may be both realised and accorded primacy under a future TTIP agreement, it is essential that negotiations are explicitly and unambiguously reframed according to binding international treaty law on human rights, and UN resolutions with regard to globalisation, access to medicines, trade liberalisation (including on services) and intellectual property rights.[296]

35. To that end, the UN Office of the High Commissioner for Human Rights’ (UNHCHR) approach is instructive. While UNHCHR view human rights law as neutral with regard to trade liberalisation or protectionism, it locates a human rights approach to trade and investment on processes and outcomes – on how trade affects enjoyment of human rights – with their promotion and protection a key objective of trade reform.[297] FPH strongly agrees.

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[291] The Council of Canadians, *France says investor-state provision not needed in TTIP*, 2014, http://bit.ly/1At5h2d
[292] Fonds Leren en Ontwikkelen Wooncorporaties, Germany opposes EU-US investor protection scheme, 2014, http://bit.ly/1IOpXId
[293] Australian Government, *Trading our way to more jobs and prosperity*, 2011, <http://bit.ly/1z3SnZU>
[294] Eberhardt P, Redlin, B and Toubeau C, *Trading away democracy: How CETA’s investor protection rules threaten the public good in Canada and the EU*, 2014, http://bit.ly/1IICYDl
[295] Eberhardt P, Redlin, B and Toubeau C, *Trading away democracy: How CETA’s investor protection rules threaten the public good in Canada and the EU*, 2014, http://bit.ly/1IICYDl
[296] E.g.: Resolutions of the General Assembly: Globalization and its impact on the full enjoyment of all human rights (A/RES/57/205); Globalization and its impact on the full enjoyment of all human rights (A/RES/56/165); Resolutions of the Commission on Human Rights: Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria, (E/CN.4/RES/2003/29); Globalization and its impact on the full enjoyment of human rights (E/CN.4/RES/2003/239); Globalization and its impact on the full enjoyment of human rights, (E/CN.4/RES/2002/28); Resolutions of the Sub-Commission on the Promotion and Protection of Human Rights Human rights, trade and investment, (E/CN.4/Sub.2/RES/2002/11); Liberalization of trade in services, and human rights, (E/CN.4/Sub.2/RES/2001/4); Intellectual property and human rights, (E/CN.4/Sub.2/RES/2001/21); Intellectual property rights and human rights, (E/CN.4/Sub.2/RES/2000/7); Trade liberalization and its impact on human rights, (E/CN.4/Sub.2/RES/1999/30)
[297] http://www2.ohchr.org/english/issues/globalization/trade/docs/5WTOMinisterialCancun.pdf

36. However, FPH is profoundly concerned to read reports that indicate that while the EU-Canada and TTIP agreements in theory require ratification by the European Parliament and all EU governments, Greenpeace analysis indicates that the EU-Canada agreement, on which TTIP is modelled, contains sections potentially allowing the European Commission to introduce ISDS regardless of the ratification process or not.[298] According to Article X.06 3(a):

> "*This Agreement shall be provisionally applied from the first day of the month following the date on which the parties have notified each other that their respective relevant procedures have been completed.*"[299]

37. In other words, as Greenpeace's analysis suggests, "the agreement would enter into force *provisionally* as soon as the European Commission and the Canadian government have notified each other that "relevant procedures have been completed." Yet, no requirement for the "relevant procedures" to include ratification by the European Parliament or EU Member States exists.[300]

38. Scrutiny of the EU-Canada free trade agreement text reveals a further clause, Article X.07 4, under which the possibility of a decision by a Member State not to ratify the agreement is considered, as follows:

> "*If the provisional application of this Agreement is terminated and it does not enter into force, a claim may be submitted pursuant to the provisions of this Agreement, regarding any matter arising during the period of the provisional application of this Agreement, pursuant to the rules and procedures established in this Agreement, and provided no more than three (3) years have elapsed since the date of termination of the provisional application*".[301]

39. In effect, this means that should the agreement by rejected in its entirety, and the *provisional application* terminated, "claims under the ISDS chapter would still be possible up to three years afterwards for investments made during the provisional period." As Glyn Moody underscores, this is "*exactly* what happened to Russia with the Energy Charter

[298] Techdirt, *European Commission's clever ruse to introduce corporate sovereignty regardless of ratification votes In EU*, 2005, http://bit.ly/1BlptWI
[299] European Commission, *Consolidated Comprehensive Economic and Free Trade Agreement Text*, 2014 http://bit.ly/1uMnTss
[300] Techdirt, *European Commission's clever ruse to introduce corporate sovereignty regardless of ratification votes In EU*, 2005, http://bit.ly/1BlptWI
[301] European Commission, *Consolidated Comprehensive Economic and Free Trade Agreement Text*, 2014 http://bit.ly/1uMnTss

Treaty, which it never ratified – an ISDS tribunal made a $50bn claim against Russia because of the treaty's provisional application."[302]

40. And, a *provisional application* clause is, the European Commission proposes, going to be added into the TTIP agreement, which in consideration of the negotiating mandate is highly problematic, given that it states that the:

> "*…investment protection chapter of the Agreement should cover a broad range of investors and their investments, intellectual property rights included, whether the investment is made before or after the entry into force of the Agreement.*"[303]

41. As Greenpeace clarify, this would enable "corporate sovereignty provisions applying to huge numbers of existing investments to enter into force and remain there for some years even if TTIP were rejected by the European Parliament or one of the national governments."[304] If this analysis is correct, it reinforces the urgent case for the ISDS mechanism to be rejected form TTIP in its entirety.

42. Notwithstanding this, inclusion of investment protection and ISDS within TTIP is not a fait accompli. The negotiating mandate makes clear that it rests upon prior consultation with Member States and on whether a satisfactory solution is achieved. It will also be considered in view of the final balance of the agreement.[305] The 150,000 responses to the consultation has left EU Commissioner for Trade, Cecilia Malmström, with one overwhelming message:

> "*…that there is a huge scepticism against the ISDS instrument*"[306]

43. The Commissioner for Trade has called for "an open and frank discussion about investment protection and ISDS in TTIP with EU governments, the European Parliament and civil society before launching any policy recommendations in this area."[307] It is reported that

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[302] Techdirt, *European Commission's clever ruse to introduce corporate sovereignty regardless of ratification votes In EU*, 2005, http://bit.ly/1BlptWI
[303] European Commission, *Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America*, 2013, <http://bit.ly/1vOSUxF>
[304] Techdirt, *European Commission's clever ruse to introduce corporate sovereignty regardless of ratification votes In EU*, 2005, http://bit.ly/1BlptWI
[305] European Commission, Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America, 2013, <http://bit.ly/1vOSUxF>
[306] European Commission, *Press Release: Report presented today: Consultation on investment protection in EU-US trade talks*, 2015, http://bit.ly/1Abcl3r
[307] European Commission, *Press Release: Report presented today: Consultation on investment protection in EU-US trade talks*, 2015, http://bit.ly/1Abcl3r

the EU will not decide whether to include ISDS within TTIP until the final phase of the negotiations with the US.[308]

44. FPH, in responding to the European Commission's consultation on ISDS,[309] was unequivocal in our rejection of the ISDS mechanism and of investor protection standards in their entirety. FPH has also called on the European Commission to ensure the explicit and unambiguous exclusion of the NHS from the TTIP agreement. FPH now reiterates this position, on four principal grounds:

1. Inclusion of investment protection standards enforceable through ISDS is likely to lead to increased litigious activity against EU member states by US investors
2. The prospect of claims being filed is likely to create a 'regulatory chill' which stays the hand of governments to regulate in the public interest for fear of litigation
3. Foreign investors should not have access to legal remedies outside of the already established and very good domestic legal systems of EU member states
4. Investment protection provisions enforceable through ISDS are not necessary to attract foreign investment into the EU or the US

[308] EurActiv, *ISDS decision delayed to end of TTIP talks*, 2015, http://bit.ly/14RQF4r
[309] UK Faculty of Public Health, response to the European Commission Public consultation on modalities for investment protection and ISDS in TTIP http://bit.ly/1pWQMxG

Chapter four: The National Health Service

a. 'Categorical' guarantees…with some *caveats*

1. In a recent letter to Minister of State for Trade and Investment, Lord Livingston, Cecilia Malmström, new European Commissioner for Trade, wrote to "correct some of the misconceptions circulating" about the impact of TTIP on the NHS.[310] Commissioner Malmström provided reassurance on three fundamental points:

- Member States will not have to open public health services to competition from private providers, nor to outsource services to private providers
- Member States will be able to change policies and bring outsourced services back into the public sector when they choose (in a manner respecting property rights)
- It makes no difference whether a member state already allows some services to be outsourced or not.[311]

2. Commissioner Malmström further makes clear that a series of reservations in EU trade agreements ensure "EU member state governments (at all levels, from central government to local authorities) can continue to manage their public services however they see fit." This includes, for example, the right for governments to operate monopolies and grant exclusive rights for selected providers, whether public or private.[312]

3. Reassurance is also presented that Member States do not have to open up any public service market (including publically-funded health services) to private operators if they do not wish to do so, and, should they wish to do so, may reverse this decision at any point. Indeed, Commissioner Malmström affirms that "Member States have the possibility to modulate reservations according to their needs as part of EU trade negotiations."[313]

4. Finally, in regard to ISDS, Commissioner Malmström has categorically stated that "nothing in any future TTIP agreement could prevent a service being brought back into the public sector or force the payment of compensation for such an action."[314] Compensation would be

[310] Department for Business, Innovation and Skills, *NHS and TTIP: Letter from EU Trade Commissioner Cecilia Malmström*, 2015, http://bit.ly/15Oe2eK
[311] Department for Business, Innovation and Skills, *NHS and TTIP: Letter from EU Trade Commissioner Cecilia Malmström*, 2015, http://bit.ly/15Oe2eK
[312] Department for Business, Innovation and Skills, *NHS and TTIP: Letter from EU Trade Commissioner Cecilia Malmström*, 2015, http://bit.ly/15Oe2eK
[313] Department for Business, Innovation and Skills, *NHS and TTIP: Letter from EU Trade Commissioner Cecilia Malmström*, 2015, http://bit.ly/15Oe2eK
[314] Department for Business, Innovation and Skills, NHS and TTIP: Letter from EU Trade Commissioner Cecilia Malmström, 2015, http://bit.ly/15Oe2eK

available only if bringing a service back into the public sector involved nationalising property owned by foreign investors – already subject to UK law on compensation.[315]

5. Reassurance is thus provided that "deciding not to renew a contract would not give grounds for an ISDS claim." An investor, Malmström avows, has "no property at stake in the potential continuation of a contract."[316] ISDS can only be used in limited circumstances to address unfair or discriminatory treatment towards investors: e.g. if *subject to denial of justice, manifestly arbitrary treatment, or, if property is expropriated without compensation*.[317]

6. In an earlier letter to the Chair of the All-Party Parliamentary Group on TTIP, the EU's Chief Negotiator, Ignacio Garcia-Bercero, provided more detailed clarification on these positions (see 'Box E). Garcia-Bercero maintains that Member States will have complete freedom to: control access to health services markets; liberalise or de-liberalise their public procurement markets; and that ISDS would have no impact on those sovereign rights.[318]

Box H: The European Commission's position on the impact of TTIP on the NHS

NHS Services – freedom to control access to the health services market

- Health services are in principle within the scope of the negotiations – but strong safeguards will preserve the right to manage health systems according to need
- All EU free trade agreements contain a specific safeguard (GATS Article 1:3b) exempting all services supplied in the exercise of governmental authority
- EU bilateral agreements either exclude or make specific reservations for publically funded health services (depending on whether positive or negative listing is used)
- Member states do not need to provide access to their markets for foreign companies, and, if they do, they can discriminate between foreign and EU/domestic companies
- Members states can limit the access of foreign doctors to work within their health systems – and make access subject to medical manpower planning
- These protections remain valid irrespective of whether commitments are scheduled in positive or negative listing, and policy space for future restrictions is preserved
- The 'ratchet' clause – (common in negative listing) which locks in liberalisation once and forever – explicitly does not apply to measures for which policy space is reserved

[315] Department for Business, Innovation and Skills, *NHS and TTIP: Letter from EU Trade Commissioner Cecilia Malmström*, 2015, http://bit.ly/15Oe2eK
[316] Department for Business, Innovation and Skills, *NHS and TTIP: Letter from EU Trade Commissioner Cecilia Malmström*, 2015, http://bit.ly/15Oe2eK
[317] Department for Business, Innovation and Skills, *NHS and TTIP: Letter from EU Trade Commissioner Cecilia Malmström*, 2015, http://bit.ly/15Oe2eK
[318] European Commission Directorate General for Trade. July 2014. *Letter to the Rt. Hon John Healey MP, Chair, All Party Parliamentary Group on TTIP*. EC. http://bit.ly/1Kuch4c

- The EU will preserve in TTIP freedom to maintain and adopt new measures to control access to health services market by foreign suppliers, without any constraint

Public procurement – freedom to liberalise or de-liberalise

- The NHS commissioning model is decided by the UK government, not by the EU's rules on public procurement (under Directive 2004/18/EC)
- Under the directive, NHS commissioners undertaking public procurement above the given value threshold, must follow agreed basic requirements, that include:
    - Laying down the technical specifications at the start and publishing the results
    - Compliance on transparency; and treating economic operators equally and without discrimination if services are of cross-border interest
- None of the above, the EU Chief Negotiator stresses, prevent the UK from liberalising or de-liberalising the NHS – nor does the EU intend TTIP to change this

Investor-State Dispute Settlement – a guarantee of no impact on sovereign rights

- Changes to NHS policy over the past 20 years have neither been required nor indirectly affected by EU trade policy, whether bilateral or multilateral
- Changes to NHS policy over the past 20 years have not been affected by the UK's existing bilateral investment treaties, most of which include ISDS provisions
- Even if an investor demonstrates that their rights are breached, it cannot overturn national regulation nor order repeal or reversal of a government's decision related to the organisation and management of health services
- Cases are unlikely to arise in the UK since the UK already respects applicable domestic and EU law, e.g. on conditions for early termination of contracts
- The EC aims to ensure TTIP is transparent, accountable and guarantees the rights of governments to legislate in the public interest – preventing unjustified claims
- The EC can "state with confidence that any ISDS provisions could have no impact on the UK's sovereign right to make changes to the NHS"[319]

7. This confidence in the safeguards delineated above and in the negotiating mandate has led the Prime Minister to describe, at a recent G20 summit, as "bogus nonsense" and an "empty threat," any suggestion that TTIP "may damage the NHS" or the ability to regulate in the public interest;[320] and the Secretary of State for Business, Innovation and Skills to in turn unequivocally state that:

[319] European Commission Directorate General for Trade. July 2014. *Letter to the Rt. Hon John Healey MP, Chair, All Party Parliamentary Group on TTIP*. EC. http://bit.ly/1Kuch4c
[320] The Guardian, *David Cameron vows he will take the fight to unions over US-EU trade deal*, 2014, http://bit.ly/1B8wtDI

"…*there is no requirement for (any) government to open NHS services to more competition and private sector provision. There will be no change to the principle that access to NHS services is based on need, not ability to pay.*"[321]

b. Some 'grey areas' – the internal market

8. The NHS Europe Office is rather more pragmatic, stating that there can be no guarantee that the "intentions of the parties in the negotiating mandate translate into the final text." Exactly what kinds of services will be protected and reserved for Member States to regulate, the NHS Europe Office understands, will depend on the wording – and there are *grey areas* – e.g. currently private services that a future government wishes to make public.[322]

9. Given these grey areas, if, as the Prime Minister suggests, there is no cause for concern, it begs the question – why not make explicit throughout the agreement the unambiguous exclusion of NHS commissioning and service provision? Some clarity is provided by Lord Livingston, who, on one hand, affirms ability to enact legislation in a non-discriminatory way on health; yet on the other, does not "*see us having a carve out for the NHS per se*."[323] In fact, it is reported that Lord Livingston has ''said (the NHS) should be included because Britain's health care industry is a major exporter and would benefit from more open trade." [324]

10. Indeed, while organisation and provision of healthcare services is a "national competence for the democratically elected governments of the EU's member states to determine," the free movement of goods and services is a matter for the *EU's internal market*. As the NHS Europe Office affirms, healthcare services will be within the overall scope of the TTIP agreement unless specifically excluded.[325]

11. The Government notes the UK's multilateral obligations in the WTO's General Agreement on Trade in Services (GATS) Agreement. Under GATS the UK is already committed to ensuring health services are "open to overseas suppliers offering hospital services and health-related professional services through a commercial presence." It

[321] The Rt. Hon. Vince Cable MP. 2014. *Letter to all Members of Parliament: The Transatlantic Trade and Investment Partnership*. Department of Business, Innovation and Skills. http://bit.ly/1sPlPS5
[322] House of commons Business, Innovation and Skills Committee, Oral evidence: Transatlantic Trade and Investment Partnership, 2015, http://bit.ly/15fJXnW
[323] Her Majesty's Government. 2014. Government Response to the House of Lords European Union Committee's 14th Report: The Transatlantic Trade and Investment Partnership. http://bit.ly/1G3J8fJ
[324] The Independent, *TTIP trade agreement: Critics driven 'by anti-American sentiment' says minister Lord Livingston*, 2014, http://ind.pn/1qkIaWF
[325] NHS Confederation. November 2014. The Transatlantic Trade and Investment Partnership and the NHS: Separating myth from fact. NHS European Office. http://bit.ly/1Ikmp10

contends GATS does not prevent UK standards and regulations being applicable to foreign providers.[326]

c. The Health and Social Care Act 2012 – "High quality care" or "fragmented services"?

12. With regard to its "broader reform programme for the NHS," the Government maintain that it is "for NHS commissioners, not the government, to decide which providers – whether public, private or from the voluntary sectors – best meet the needs of their patients and high quality care." It is also pointed out that the Secretary of State, under the Health and Social Care Act 2012, is prohibited from discriminating in favour of the private sector.[327]

13. Notwithstanding this, the Government is by contrast also clear that it *does* want procurement to be included within a final TTIP agreement in order to ensure that "the NHS get better value for money."[328] Based on its own analysis however, FPH is absolutely clear that increased procurement and liberalisation, as has been effected under the Health and Social Care Act 2012, poses serious risks to provision of high quality care and value for money.[329]

14. FPH considers the Health and Social Care Act 2012 likely to have had a detrimental impact on NHS planning and delivery. 'Box F' outlines some specific examples of this impact:

Box I: The impact of the Health and Social Care Act 2012 [330]

- loss of insights on addressing population need
- loss of effectiveness and efficiency for NHS commissioners
- fragmentation of services and poorer coordination of care e.g. sexual health services and mental health services
- gaps in patient pathways due to multiple providers and complex commissioning arrangements
- lack of joined-up care, problems with confused accountability and disincentives to

[326] Department of Business, Innovation and Skills, Written evidence for the House of Lords European Union Sub-Committee on External Affairs Inquiry into the *Transatlantic Trade and Investment Partnership:*, 2014, http://bit.ly/1j0qfRp
[327] Department of Business, Innovation and Skills, Written evidence for the House of Lords European Union Sub-Committee on External Affairs Inquiry into the *Transatlantic Trade and Investment Partnership:*, 2014, http://bit.ly/1j0qfRp
[328] Department of Business, Innovation and Skills, Written evidence for the House of Lords European Union Sub-Committee on External Affairs Inquiry into the *Transatlantic Trade and Investment Partnership:*, 2014, http://bit.ly/1j0qfRp
[329] UK Faculty of Public Health, Health and Social Care Bill: Risk Assessment Summary, 2012, http://bit.ly/14BaH2u
[330] UK Faculty of Public Health, Health and Social Care Bill: Risk Assessment Summary, 2012, http://bit.ly/14BaH2u

take ‘up-stream’ primary preventive action

- multiplicity of service providers and commissioners resulting in increased costs
- multiple commissioners and risk averse providers meaning that no one holds the ring overall on particular pathways – with loss of patient choice (through provider exit)
- competition and the impact of procurement rules creating further obstacles
- serious risk that services currently provided by the NHS could be withdrawn and become available only via private healthcare
- insufficient attention to safeguarding responsibilities (for both adults and children)
- emergency planning resources being spread too thinly and relationships between senior officers being lost

15. At the time of writing, FPH notes with disquiet that the first private company to be put in charge of an NHS hospital has “announced plans to withdraw from its contract, hours before inspectors recommended the hospital be placed in special measures because of inadequate care.”[331] The Care Quality Commission has condemned the Trust’s inadequate service safety; inadequate level of caring services; and inadequate leadership. It further requires improvement in service efficacy and responsiveness. FPH fears similar cases are likely.[332]

16. FPH considers that reassurances presented by the European Commission that TTIP will not open commissioning of NHS and clinical services to further competition and private sector provision are a question of semantics. In the analysis of the NHS Europe Office, “on the basis of the negotiating mandate there is no intention to use TTIP to *impose* (*rather than allow*) liberalisation or privatisation publically-funded health services.”[333]

17. However, whether by design or by unintended consequence (and, in fact, FPH understands the Health and Social Care Act 2012 to be designed exactly for that imposition)[334] – unless the wording explicitly reflects the *intention*, then commissioning of publically-funded health services is at risk.

18. That existing domestic law on procurement and competition allows NHS commissioners in England to open clinical services to further competition only serves in the context of the

[331] The Independent, Circle Holdings pulls out of NHS contract hours before hospital it ran was rated 'inadequate', 2015, http://ind.pn/1ENY4Rf
[332] Care Quality Commission, *Hitchingbrooke Health Care NHS Trust*, 2015, http://bit.ly/1ziplTO
[333] NHS Confederation. November 2014. The Transatlantic Trade and Investment Partnership and the NHS: Separating myth from fact. NHS European Office. http://bit.ly/1lkmp10
[334] It seems inconceivable that the Department of Health’s White Paper, *Liberating the* NHS, published in 2010, had no connection to the Department for Business, Innovation and Skills’ own White Paper, *Trade and Investment for Growth*, also published in 2010, in which the Government outline as a “top priority” regulatory cooperation on healthcare and the environment, and through the EU-US Transatlantic Economic Council to commit to working on cross-cutting areas that include pharmaceuticals, intellectual property, energy efficiency and e-health

Health and Social Care Act 2012 and TTIP to 'lock in' further liberalisation.

19. In fact, FPH considers it difficult to understand the 'intent' as anything other than predicated on the imperative to introduce further competition and foreign private sector involvement into health (and other public services) given that this is the stated intention of the European Commission's negotiating mandate with regard to both public procurement and trade in services. With regard to the latter, the mandate aims:

> "…*to bind the existing autonomous level of liberalisation of both Parties at the highest level of liberalisation captured in existing FTAs, in line with Article V of GATS, covering substantially all sectors and all modes of supply, while achieving new market access by tackling remaining long-standing market access barriers*"[335]

20. It is in this context noteworthy that while there is no specific exclusion for health services, under pressure from the French Government with regard to its concern at the preservation of European culture – including film and digital media[336] – there is within the mandate such an exclusion for Audio-visual services.[337] By contrast, as mentioned earlier, the liberalisation of health services is a key objective of the US Trade Representative.[338]

21. Similarly, with regard to public procurement, the negotiating mandate aims for 'the maximum ambition, in terms of coverage (procurement entities, sectors, thresholds and services contracts)…and enhanced mutual access to public procurement markets at all administrative levels (national, regional and local), and in the fields of public utilities, ensuring treatment no less favourable than that accorded to locally established suppliers."[339]

22. Increased NHS market access to foreign US investors through TTIP is, given these factors, likely to worsen health systems, weaken co-ordinated working across organisational boundaries and make harder efforts to ensure public health considerations are addressed across the NHS. An approach based on the highest level of liberalisation will, FPH expects, ultimately contribute to a widening of health inequalities.

23. Notwithstanding these concerns, whatever view one adopts of the *intent* of the

[335] European Commission, Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America, 2013, http://bit.ly/1vOSUxF
[336] EurActiv, EU-US trade talks falter with France audiovisual spat, 2013, http://bit.ly/16kyhky
[337] European Commission, Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America, 2013, http://bit.ly/1vOSUxF
[338] Office of the United States Trade Representative, *U.S. Objectives, U.S. Benefits In the Transatlantic Trade and Investment Partnership: A Detailed View*, 2014, <http://1.usa.gov/1cuSu9Q>
[339] European Commission, Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America, 2013, http://bit.ly/1vOSUxF

negotiators, or whether further liberalisation is positive or negative, given the explicit confirmation that health services will remain within the scope of the agreement, (see 'Box B'), the key question is whether the "strong safeguards" that Mr Garcia-Bercero suggests will "preserve the right to manage health systems according to need",[340] are strong enough.

d. "Strong safeguards" with "little or no practical effect"

24. Mr Garcia-Bercero, in making his case, draws attention to reference made within the negotiating mandate to Article 1.3b of the WTO's General Agreement on Trade in Services (GATS).[341] GATS is designed to establish a multilateral framework of principles and rules for trade in services with "a view to progressively higher levels of liberalization."[342] At first glance, Article 1.3b does appear to protect the NHS, through the following exemption:

> "*(b) 'services' includes any service in any sector except services supplied in the exercise of governmental authority*"[343]

25. So far, so good. However, Article 1.3b needs to be read in the context of *Article 1.3c*, under which the ground on which the protections are established becomes less solid:

> "*(c) 'a service supplied in the exercise of governmental authority' means any service which is supplied neither on a commercial basis, nor in competition with one or more service suppliers.*"[344]

26. The United Nations Conference on Trade and Development (UNCTAD) has raised serious concerns with regard to Article 1.3b. By virtue of the complex mix of public-private health services in the NHS, UNCTAD caution that "difficult questions arise as to whether, by including some competition in certain aspects of…provision of health care services, the entire service (is) within the coverage of GATS."[345]

27. Some analysts view Article 1.3b as ambiguous, "rendering several interpretations possible, each with different consequences for the public sector."[346] On one hand, it may be

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[340] European Commission Directorate General for Trade. July 2014. *Letter to the Rt. Hon John Healey MP, Chair, All Party Parliamentary Group on TTIP*. EC. http://bit.ly/1Kuch4c
[341] European Commission Directorate General for Trade. July 2014. *Letter to the Rt. Hon John Healey MP, Chair, All Party Parliamentary Group on TTIP*. EC. http://bit.ly/1sbIKHy
[342] World Trade Organization, *General Agreement on Trade in Services*, 1994, http://bit.ly/10VqtU8
[343] World Trade Organization, *General Agreement on Trade in Services*, 1994, http://bit.ly/10VqtU8
[344] World Trade Organization, *General Agreement on Trade in Services*, 1994, http://bit.ly/10VqtU8
[345] United Nations Conference on Trade and Development, *Dispute Settlement: World Trade Organization, 3.13 GATS*, 2003, http://bit.ly/1yROHfP
[346] Hunt. F, *The GATS' Article I, Paragraph 3,* 2002, http://bit.ly/1GS33SH

interpreted such that in the event of a private sector challenge, the public role of the NHS as a whole may be the "overriding factor, despite the commercial or competitive nature of any of its parts, and might overturn the challenge."[347]

28. On the other hand, interpretation of the requirement that services "supplied in the exercise of governmental authority" must be "supplied neither on a commercial basis nor in competition with one or more service suppliers,"[348] may bring NHS services *within* GATS' scope, if Member States "expressly permitted competition in one of these sectors,"[349] rendering inapplicable any exception.[350]

29. This failure to provide legal clarity on this important provision creates risk that were it "narrowly interpreted by ISDS panels, the exclusion will be of little or no practical effect."[351] And, in fact, the WTO itself has agreed that those "exceptions provided in Article 1.3b *need to be* interpreted narrowly"[352] Such risk is compounded through liberalisation under the Health and Social Care Act 2012.[353] [354] A legitimate concern is presented that should a future government wish, for example, to repeal Section 75 of the Act,[355] it may face challenge.

30. It is then apparent that GATS Article 1.3b, vaunted as a *stronghold* for the sovereign right to regulate – is at best equivocal and at worst provides a *stranglehold* for arbitral tribunals, with a track record of pro-investor bias (see part one, chapter three), to determine the proportionality of sovereign democratic legislative and regulatory interventions, including provision of health services. Indeed, LSE has observed that health is "one of those areas with fewest signatories in GATS…because liberalisation in a health market may significantly distort the ability to provide services to all income groups."[356]

31. Appearing before the House of Lords EU Select Committee, Dr Lauge Poulsen has reiterated the need for better clarity on the precise clausal protections afforded to US investors. Dr Poulsen notes the "case against the Slovak Republic trying to roll back the

[347] Hunt. F, *The GATS' Article I, Paragraph 3,* 2002, http://bit.ly/1GS33SH
[348] World Trade Organization, *Uruguay Round Agreement: General Agreement on Trade in Services, Article 1.3b*, http://bit.ly/10VqtU8
[349] United Nations Conference on Trade and Development, *Dispute Settlement: World Trade Organization, 3.13 GATS*, 2003, http://bit.ly/1yROHfP
[350] Hunt. F, *The GATS' Article I, Paragraph 3,* 2002, http://bit.ly/1GS33SH
[351] Canadian Centre for Policy Alternatives, *Facing the Facts: A guide to the GATS debate*, 2002, http://bit.ly/1tdhESG
[352] World Trade Organization, *Council for Trade in Services, Report of the Meeting Held on 14 October 1998*, S/C/M/30, p. 8, No. 22 (b).
[353] The National Archives, *The Health and Social Care Act 2012*, 2012, http://bit.ly/1dCgQbZ
[354] UK Faculty of Public Health, Health and Social Care Bill: Risk Assessment Summary, 2012, http://bit.ly/14BaH2u
[355] National Archives, *Health and Social Care Act 2012 – Section 75: Requirements as to procurement, patient choice and competition*, 2012 http://bit.ly/1L8HEnX
[356] London School of Economics and Political Science, *The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems and Public Health*, 2015, http://bit.ly/1Giia40

liberalisation of the national health industry…The Slovak Republic lost about £18 million which, related to the size of the UK economy would be about £0.5 billion against the UK."[357]

32. Concern is also raised about the potential under TTIP (through GATS), with its wide ranging domestic regulation provisions and lack of effective legal certainty in regard to safeguarding; for many forms of local government regulation (see paragraph 46, Chapter one), e.g. sexual health services, waste disposal facility approvals, environmental services, planning decisions, the water supply, transport decisions and social housing; to be challenged as trade restrictive.[358]

33. The Seattle to Brussels Network (SBN) cautions that as with other WTO agreements, the aim of liberalisation of service provision may result in a reduction of government involvement in the service sector, which could mean the privatisation of public utilities, or further de-regulation of an already privatised sector. SBN contends that whatever governments believe to be the interpretation, "corporate service providers, anxious for new markets, will use all their legal might to persuade the WTO to rule in favour of liberalisation."[359]

34. FPH firmly considers that such public services should be exempt from liberalisation and privatisation and agrees with GMB that outsourcing and organisation of public services should remain firmly within accountable local authority control "as the only way to ensure public services retain high levels of quality, safety, affordability, user rights and universal access." The award of public contracts should be for the good of the public and based on quality, fairness and sustainability – and, as GMB have made clear not on the lowest costs.[360]

35. FPH further agrees with GMB that the EU must ensure that the social, environmental and sustainable development considerations currently being revised in the Public Procurement Directives become the standards for EU/US regulations on procurement. FPH notes that the US has not ratified basic International Labour Organization Conventions on labour standards, referred to in the EU Public Procurement Directives.

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[357] Dr Lauge Poulsen, University of Oxford, *Oral Evidence before the House of Lords EU Select Committee Inquiry into TTIP*, 2014, http://bit.ly/1j0qfRp
[358] Pickering, J, GATS, *public services and domestic regulation: current issues and implications for local government in Australia*, http://bit.ly/1CSq7KI
[359] Seattle to Brussels Network, *GATS and local communities: what do local decision makers need to know about GATS?*, http://bit.ly/1zd2BEx
[360] GMB, *Written evidence in response to the House of Lords EU Select Committee Inquiry into TTIP*, 2014 http://bit.ly/1j0qfRp

36. Beyond the provisions within GATS discussed above, it is also important to consider the provisions outlined by Commissioner Malmström with regard to the limitations for circumstances within which ISDS claims may be lodged. In view of the factors discussed within chapter three, FPH does not accept that the legal definitions of unfair or discriminatory treatment towards investors, manifestly arbitrary treatment, or property expropriation are sufficiently certain such as for Commissioner Malmström to make any guarantees whatsoever in this regard to the NHS and provision of wider health services.

37. In view of this, while it is impossible in the absence of the final terms of an agreement to draw any conclusions with absolute certainty, FPH is of the view that unless the NHS is unambiguously excluded from the scope of TTIP, several risks are presented which will serve to further fragment the NHS and ultimately exacerbate and indeed entrench already widening inequalities in health. These risks are recognised by the London School of Economics, through a structured and systematic evidence assessment, which identified:

> "*Risk that TTIP will require publically run health services to be opened up to competition from private sector healthcare providers; and risk that a 'ratchet clause' and negative listing in TTIP would preclude the possibility of privatised public services being returned to state operation*."[361]

38. FPH calls for the explicit exclusion from the TTIP agreement, (both within the preamble to the agreement and consistently throughout the wider agreement text), of the NHS from any procurement or competition that may arise from the terms of the TTIP agreement. FPH further calls for this to extend to the obligations of the UK, in addition to those of any NHS body, for the exemption to apply to commissioners and providers alike, and for the exemption to also expressly exclude the rights of private companies to bid for NHS contracts under TTIP.

39. FPH further calls for this exemption to apply to all services currently provided under the remit of the local authority, and in addition to exempt any private company from bidding for local authority contracts under the TTIP agreement.

[361] London School of Economics and Political Science, *The Transatlantic Trade and Investment Partnership: International Trade Law, Health Systems and Public Health*, 2015, http://bit.ly/1Giia40

Chapter five: Intellectual property – access to medicines

1. In this section, we explore the far reaching implications of inclusion within the European Commission's negotiating mandate of enhanced recognition of the WTO's *Trade Related Aspects of Intellectual Property Rights Agreement* (TRIPS),[362] for provision of sustainable and affordable access to medicines – within Europe and low and middle-income countries.

2. We will also consider the potentially undesirable impact of TTIP on EU Member States' or regulatory bodies' decisions in regard to marketing authorisation, pricing, reimbursement and medicines' data transparency; and the possibility for challenge to new EU transparency requirements through strengthened pharmaceutical control over clinical trial data.

a. 'Without discrimination' – access to medicines in international law

3. At the outset, it is important to make clear that it is incumbent on the United Kingdom to have full regard to international treaty law at the UN and EU levels to which it is signatory, and which unequivocally clarifies its obligation to ensure availability and "accessibility of health facilities, goods and services…to everyone without discrimination."[363] Article 12 of the UN International Covenant on Economic, Social and Cultural Rights outlines five factors:

> "***Non-discrimination****: health facilities, goods and services must be accessible to all, especially the most vulnerable or marginalized, in law and in fact.*
>
> ***Physical accessibility****: health facilities, goods and services must be within safe physical reach for all sections of the population, especially vulnerable or marginalized groups, older persons, persons with disabilities and persons with HIV/AIDS.*
>
> ***Economic accessibility****: health facilities, goods and services (including information) must be affordable for all. Payment for health-care services, as well as services related to the underlying determinants of health, has to be based on the principle of equity.*
>
> ***Acceptability****: All health facilities, goods and services must be respectful of medical ethics and culturally appropriate, i.e. the culture of individuals, minorities, communities, gender and life-cycle – and respect confidentiality and improve health status.*

[362] World Trade Organization, *Trade-Related Aspects of Intellectual Property Rights*, 1994, http://bit.ly/1vTBzWf
[363] United Nations Committee on Economic, Social and Cultural Rights. 2000. General Comment 14: The right to the highest attainable standard of health. http://bit.ly/1wRDrA8

***Quality**: Health facilities, goods and services must be scientifically and medically appropriate and of good quality. This requires skilled medical personnel, scientifically approved and unexpired drugs and hospital equipment, safe water and sanitation.*"[364]

4. The International Covenant also delineates the right to essential drugs, defined by the WHO Action Programme on Essential Drugs,[365] and to the "availability of relevant technologies, using and improving epidemiological surveillance and data collection on a disaggregated basis."[366]

5. In turn, the *Charter of Fundamental Rights of the European Union* clarifies that "everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices." It further states that "a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities."[367]

6. We will shortly outline FPH's serious concerns with the European Commission's rationale for inclusion of enhanced, 'TRIPS plus', provisions. At this stage, however, it is important to acknowledge the internationally agreed *WTO Ministerial Declaration on the TRIPS Agreement and Public Health* (the 'Doha Declaration'), which recognises the "gravity of the public health problems afflicting many developing countries and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics."[368]

7. The Doha Declaration, in consideration of the detrimental impact that intellectual property protection may have on pricing structures for new medicines, establishes *flexibilities* to ensure that TRIPS "does not and should not prevent members from taking measures to protect public health…and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and promote access to medicines for all."[369]

8. These flexibilities include provision that each Member State has the right to: grant compulsory licences and the freedom to determine the grounds upon which such licences are granted; determine what constitutes a national emergency or other circumstances of

[364] United Nations Committee on Economic, Social and Cultural Rights. 2000. General Comment 14: The right to the highest attainable standard of health. http://bit.ly/1wRDrA8
[365] World Health Organization, Essential medicines and health products, 2014, http://bit.ly/1z8vW35
[366] United Nations Committee on Economic, Social and Cultural Rights. 2000. General Comment 14: The right to the highest attainable standard of health. http://bit.ly/1wRDrA8
[367] Official Journal of the European Communities , *Charter of Fundamental Rights of the European Union*, 2000, http://bit.ly/1cOQRQV
[368] World Trade Organisation, Ministerial Conference, Fourth Session, Doha, Declaration on the TRIPs Agreement and Public Health, 2001, http://bit.ly/1tRJSxc
[369] World Trade Organisation, Ministerial Conference, Fourth Session, Doha, Declaration on the TRIPs Agreement and Public Health, 2001, http://bit.ly/1tRJSxc

extreme urgency; and that Member States are free to establish, *without challenge*, their own regime for exhaustion of intellectual property protections, albeit itself subject to a contentious legal caveat regarding most favoured nation and national treatment (see Chapter three).[370]

9. Finally, FPH draws attention to the recent Directive of the European Parliament and Council in regard to clinical trial data on medicinal products for human use, under which several vital provisions in relation to transparency are established.[371] In particular, the regulations provide that data included within a clinical study report should not be considered commercially confidential once:

- marketing authorisation has been granted;
- the procedure for granting the marketing authorisation has been completed, and;
- the application for marketing authorisation has been withdrawn.[372]

10. The regulations go on to establish that the main characteristics of a clinical trial, the conclusion of Part I of the assessment report for the authorisation of a clinical trial, the decision on the authorisation of a clinical trial, the substantial modification of a clinical trial, and the clinical trial results including reasons for temporary halt and early termination, in general, should not be considered confidential.[373]

11. The regulations make clear that the EU database should contain all relevant information as regards the clinical trial, presented in an easily searchable format, with related data and documents linked together by the EU trial number and with hyperlinks, e.g. linking together the summary, the layperson's summary, the protocol and the clinical study report of one clinical trial, as well as linking to data from other related clinical trials.[374]

12. All clinical trials should be registered in the EU database prior to being started. The only reasons established within the regulations for not publishing information are to protect the right of the individual to private life and the right to the protection of personal data. The objective of the regulations is to ensure that information should contribute to protecting

[370] World Trade Organisation, Ministerial Conference, Fourth Session, Doha, Declaration on the TRIPs Agreement and Public Health, 2001, http://bit.ly/1tRJSxc
[371] European Parliament and Council, Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, 2014, http://bit.ly/1sfYi9x
[372] European Parliament and Council, Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, 2014, http://bit.ly/1sfYi9x
[373] European Parliament and Council, Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, 2014, http://bit.ly/1sfYi9x
[374] European Parliament and Council, Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, 2014, http://bit.ly/1sfYi9x

public health and fostering the innovation capacity of European medical research.[375]

b. Market growth while maintaining standards?

13. The Department of Business, Innovation and Skills, in sector specific analysis of the pharmaceutical industry, anticipates that TTIP will bring about a market growth of 0.5%,[376] while at the same time provides reassurance that the "EU and US have committed to maintaining standards at the highest levels." The EU, it affirms, will retain the right to set regulatory standards "higher than internationally agreed minima.[377]

14. To achieve this growth, the European Commission presents three overarching objectives in its negotiating position on pharmaceutical products (outlined in detail in 'Box G'), to:

- End the unnecessary duplication of product testing or plant inspections
- Recognise each other's existing regulations, or bring them more closely together
- Align our respective procedures for approving or registering new products.[378]

Box J. The European Commission's position in TTIP on pharmaceutical products[379]

- Recognition of EU-US (and third country) Good Manufacturing Practices (GMP) inspections – allowing the US Food Drug Administration (FDA) and EU Member States better use of inspection resources by avoiding the overlap of inspections
- Exchange of confidential information and trade secret information between EU Member States/EU institutions and the FDA, e.g. GMP and other inspection reports and data and information on marketing authorizations applications.
- Commitment on converging systems for authorisation of biosimilars, and review of EU-US guidelines, potentially increasing approved biosimilars in the US and limiting diverging requirements to demonstrate quality, safety and efficacy of these products.
- Shaping the international approach for review/authorization of biosimilars.
- Streamlining authorisation systems for generics e.g. development or review of guidelines e.g. for bioequivalence, biowaivers and the use of reference medicines.
- Revision of guidelines on paediatrics through agreeing clinical studies design and timing (paediatric investigation plans, data collection rare disease trials, templates for

[375] European Parliament and Council, Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, 2014, http://bit.ly/1sfYi9x
[376] Her Majesty's Government. 2014. Government Response to the House of Lords European Union Committee's 14th Report: The Transatlantic Trade and Investment Partnership. http://bit.ly/1G3J8fJ
[377] Her Majesty's Government. 2014. Government Response to the House of Lords European Union Committee's 14th Report: The Transatlantic Trade and Investment Partnership. http://bit.ly/1G3J8fJ
[378] European Commission, EU position on pharmaceutical products, 2014, http://bit.ly/1qkeyEb
[379] European Commission, EU position on pharmaceutical products, 2014, http://bit.ly/1qkeyEb

information for risk assessment) and mutually accepting clinical studies.

- Harmonised terminology for pharmaceutical products, improving information flow between enterprises and regulators and regulators of both Parties.

15. To some extent, these positions have been cautiously welcomed. The NHS Confederation has recognised the potential for improving the "quality and safety of medical devices by aligning with higher surveillance standards applying in the USA."[380] Access, it suggests, to the "best diagnostic devices and innovative technologies" may be improved, while UK companies may also benefit from enhanced access to the US market. The NHS Confederation further note that standardisation of products and certification procedures may reduce unnecessary duplication of testing, while benefitting or improving patient safety.[381]

16. The European Public Health Association (EPHA) highlight possibilities for sharing clinical trial results and EU-US regulatory collaboration on inspection of companies' facilities and Good Manufacturing Practices – again, avoiding duplication while affirming medicinal quality. Collaborative working on medical and scientific initiatives, however, must be on condition of a "robust regulatory environment and information sharing."[382]

17. If secured, "faster achievements could be made to improve the therapeutic benefits of medicines coming to market" (although FPH is concerned that efforts to do so do not lower quality manufacturing standards). For example, there may be scope for the:

> *"US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) to collaborate on issues unrelated to trade and market authorisation – e.g. rare diseases, paediatrics, medicines barcoding for hospitals, and medicines shortages."*[383]

18. Some commentators have found encouraging the prominence of generic and biosimilar medicines in the TTIP negotiating position – and reflected that this underscores and may help to promote the urgent need for a "single development programme for generic medicines, especially for complex generic medicines."[384]

c. From the promotion of health to the promotion of competition?

[380] NHS Confederation, The Transatlantic Trade and Investment Partnership and the NHS Separating myth from fact, 2014, http://bit.ly/1lkmp10
[381] NHS Confederation, The Transatlantic Trade and Investment Partnership and the NHS Separating myth from fact, 2014, http://bit.ly/1lkmp10
[382] PharmaPhorum, TTIP – bringing benefits to patients or big pharma?, 2014, http://bit.ly/1w1iscC
[383] PharmaPhorum, TTIP – bringing benefits to patients or big pharma?, 2014, http://bit.ly/1w1iscC
[384] PharmaPhorum, TTIP – bringing benefits to patients or big pharma?, 2014, http://bit.ly/1w1iscC

19. Despite this, it is clear, as EPHA has stressed, that pharmaceuticals and medical devices are not, and should not be, considered equivalent to any other EU internal market product since they safeguard people's health. The true drivers of EU pharmaceuticals and health technologies are patient safety, health protection, sustainability of health systems and reduction of health inequalities,[385] as outlined in chapters one and two and section b above.

20. Given this, it is of concern – and indicative of the European Commission's approach to the relationship between health and trade policy – that President Junker has shifted competence for medical devices, health technologies and pharmaceutical policy from the health Commissioner to the Commissioner in charge of internal market and industry – mandated to promote the competitiveness of industry and the European economy.[386]

21. This shift has prompted 35 leading EU membership organisations, representing many thousands of concerned citizens, to write to President Junker, and make clear that the distinction between the imperative for health and the internal market and competition is an important one to make with "delicate issues, such as information to patients and medicine pricing, where the needs of patients can be in conflict with the interests of industry."[387]

22. It is pointed out that in 2009, responsibility for medicines and medical devices were moved into the hands of the health Commissioner to harmonise pharmaceutical governance within Member States and facilitate emergency preparedness. As the letter makes clear, "returning them to the Commissioner for Enterprise and Industry is unjustified and represents a major step back."[388]

23. The economic crisis, ageing population, technological advances, and new health threats – e.g. environmental pollution, All challenge the sustainability of EU health systems. Health inequalities between and within EU States are increasing. The European Commission plays an important role in "ensur(ing) a high level of human health protection".[389] This requires a strong vision for public health, and consistent policymaking.

24. FPH shares the Belgian Minister for Social Affairs and Public Health's call against the commercialisation of healthcare, and strongly echoes her reminder to the European

[385] PharmaPhorum, TTIP – bringing benefits to patients or big pharma?, 2014, http://bit.ly/1w1iscC
[386] PharmaPhorum, TTIP – bringing benefits to patients or big pharma?, 2014, http://bit.ly/1w1iscC
[387] European Public Health Association, *[Open Letter] to President-elect Jean-Claude Juncker on move of medicinal products and health technologies to the portfolio of the Commissioner for internal market and industry*, 2014, http://bit.ly/1w1nNAz
[388] European Public Health Association, *[Open Letter] to President-elect Jean-Claude Juncker on move of medicinal products and health technologies to the portfolio of the Commissioner for internal market and industry*, 2014, http://bit.ly/1w1nNAz
[389] Official Journal of the European Union. March 2010. *Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union: Charter of Fundamental Rights of the European Union*. http://bit.ly/1G5UOyJ

Commission, that "considering a health product a commodity puts public health at serious risk."[390] Indeed, EPHA has spoken of the move as a "direct contradiction to the need for a coherent and unified health policy within the EU,"[391] while European Parliament President, Martin Schulz, has called for the remit to be restored to 'DG Sanco.'[392]

25. It is in this context, and in view of the EU's existing trade policy focus on "extensions of monopoly protection for patented medicines, using free trade agreements and bilateral pressure;"[393] that we now explore the serious risk that by embedding 'TRIPS plus' provisions within TTIP, the European Commission may entrench the commercial interests of the pharmaceutical industry at the expense of medical innovation, affordability and sustainability.

d. TRIPS – access to medicine or access to international trade?

26. The WTOs Trade Related Aspects of Intellectual Property Rights Agreement (1994) (TRIPS), is a comprehensive multilateral agreement on intellectual property protections, and globally the "dominant incentive framework for the development of new medicines"[394] – driven by strong patent protection standards, including a 20 year minimum duration.[395] Inclusion of enhanced '*TRIPS plus'* provisions are on the negotiating table for TTIP.[396]

27. The WTO's stated objectives in pursuit of TRIPS include the reduction of distortions and impediments to international trade, promotion of effective and adequate protection of intellectual property rights (IPR), and ensuring that measures and procedures to enforce IPR do not themselves become barriers to legitimate trade.[397] TRIPS Article 7 establishes that the protection and enforcement of (IPR) should contribute to:

> "*technological innovation and transfer, and dissemination of technology, to the mutual advantage of producers and users of technological knowledge in a manner conducive to social and economic welfare, and balancing of rights and obligations.*"[398]

28. The declared philosophy underlying Article 7, to "strike a balance between the long

[390] EU Observer, *Junker defends lobby-friendly restructuring of commission services*, 2014, http://bit.ly/1BTc5H3
[391] PharmaPhorum, TTIP – bringing benefits to patients or big pharma?, 2014, http://bit.ly/1w1iscC
[392] EU Observer, *Junker defends lobby-friendly restructuring of commission services*, 2014, http://bit.ly/1BTc5H3
[393] Oxfam and Health Action International Europe, *Trading away access to medicines – revisited: How the European Trade Agenda continues to undermine access to medicines*, 2014, http://bit.ly/1s6FGZJ
[394] Oxfam and Health Action International Europe, *Trading away access to medicines – revisited: How the European Trade Agenda continues to undermine access to medicines*, 2014, http://bit.ly/1s6FGZJ
[395] World Trade Organization, *TRIPS: A more detailed overview of the TRIPS Agreement*, 2015, http://bit.ly/18N8Kvv
[396] European Commission, *Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America*, 2013, http://bit.ly/1vOSUxF
[397] World Trade Organization, *TRIPS: A more detailed overview of the TRIPS Agreement*, 2015, http://bit.ly/18N8Kvv
[398] World Trade Organization, TRIPS Part I – General Provisions and basic principles, 2015, http://bit.ly/16gqlRc

term social objective of providing incentives for future inventions and creations, and short term objective of allowing people to use existing inventions and creations"[399] – is predicated on three contentious assumptions:

- high research and development (R&D) costs (risks) necessitate strict proprietary rights which in turn incentivise knowledge production to society's benefit;
- these intellectual property rights allow both "technological progress and technology transfer";
- TRIPS "provides flexibility allowing governments to make exceptions…provided certain conditions are fulfilled".[400]

29. Industry, in turn, contends that a robust IPR regimen encourages access to medicines where accompanied by Public Private Partnerships offering discounted or donated drugs – if 'tiered pricing policies' are developed;[401] that disparity of IPR standards would inundate "markets with cheap generics or parallel imports, undermining profit"; that TRIPS increases R&D into third world diseases; and that companies have "a right to protect IP against theft".[402]

e. From intellectual property rights to "intellectual monopoly privileges" [403]

30. Yet, much criticism has been made of the failure of the incentive model to achieve an optimal synthesis between IP and user rights – a balance which, for those in the developing world, is a matter of life and death.[404] "80% of the world's population live in developing countries yet consume less than 20% of pharmaceuticals", while "90% of the global disease burden is carried by a population for whom only 3% of R&D is directed at."[405] [406]

31. The ongoing Ebola crisis which has blighted much of West Africa casts light on the sobering reality outlined above, and lack of adequate research and development, innovation,

[399] World Trade Organization, Philosophy: TRIPS attempts to strike a balance; 2015, http://bit.ly/1uWMDOj
[400] World Trade Organization, Philosophy: TRIPS attempts to strike a balance; 2015, http://bit.ly/1uWMDOj
[401] Two-tiered pricing refers to a system under which commodities for domestic use are supported at one level and those for export markets at another, lower level.
[402] Oxfam. Implausible Denial: Why the Drug Giants' Arguments on Patents Don't Stack Up, *Oxfam GB*, April 2001, <http://www.oxfam.org.uk/resources/policy/health/implausible_denial.html>
[403] Martin, Greg, Sorenson, Corinna and Faunce, Thomas. 'Balancing intellectual monopoly privileges and the need for essential medicines', *Globalization and Health,* 3:4, (June 2007), p.1
[404] Weiss, M, Tightening the ratchet – from intellectual property rights to 'intellectual monopoly privileges': Aggressive bilateralism, access to medicines and potential solutions, 2010
[405] Martin, Greg, Sorenson, Corinna and Faunce, Thomas. 'Balancing intellectual monopoly privileges and the need for essential medicines', *Globalization and Health,* 3:4, (June 2007), p.2
[406] Oxfam and Health Action International Europe, *Trading away access to medicines – revisited: How the European Trade Agenda continues to undermine access to medicines*, 2014, http://bit.ly/1s6FGZJ

and investment into treatments for rare diseases.[407] As part of a coalition of Royal Colleges and Faculties, FPH has also drawn attention to the urgent need for concerted action to reinvigorate the development of new antibiotics and their alternatives.[408]

32. Indeed, Public Health England's seven priorities for action include a strong focus on antimicrobial resistance, and warns that "across Europe…25,000 people die each year as a result of hospital infections caused by…resistant bacteria, adding, on a conservative estimate, €1.5bn to hospital treatment and societal costs."[409] The Chief Medical Officer for England, in her annual report, has described the threat posed as "catastrophic."[410]

33. Yet, Oxfam and Health Action International have underscored that the WHO has been unambiguous in asserting that intellectual property rights are "irrelevant for stimulating innovation in the absence of a profitable market for diseases affecting millions of poor people in developing countries." WHO has further stated that increased IPR will not improve this situation.[411] [412]

34. Innovation, however, is not the only casualty of the TRIPS incentive model. Long term patent protections offered under the TRIPS Agreement, applied by pharmaceutical companies to recover their investment in research and development, have the effect of disallowing the development of generic equivalent drugs, with a devastating impact on the cost, and thereby the affordability and sustainability of access to medicines.

35. Stark context to this situation is presented by the Chief Executive of multinational pharmaceutical company, Bayer, who, responding to the granting by the Indian Government of a compulsory licence to produce a generic version of Bayer's drug Nexavar, used in the treatment of a specific type of lung cancer, and which is priced at an estimated $69,000 for a year of treatment, commented: [413]

> "*Is this going to have a big effect on our business model? No, because we did not develop this product for the Indian market, let's be honest. We developed this product*

[407] UK Faculty of Public Health, *Policy Statement on Ebola*, 2014, http://bit.ly/15smiC2
[408] UK Faculty of Public Health, Royal College of Physicians, Royal College of General Practitioners, Royal Pharmaceutical Society, Royal College of Nursing, *Joint Statement on Antimicrobial Resistance*, http://bit.ly/16pDsjj
[409] Public Health England, *From evidence into action: opportunities to protect and improve the nation's health*, 2014, http://bit.ly/ZT2t3h
[410] Department of Health, *Antimicrobial resistance poses "catastrophic threat", says Chief Medical Officer*, 2013, http://bit.ly/1EkZwHQ
[411] World Health Organization, *Public Health, Innovation and Intellectual Property Rights: Report of the Commission on IP Rights, Innovation and Public Health*, 2006, http://bit.ly/1uaTf0w
[412] Oxfam and Health Action International Europe, *Trading away access to medicines – revisited: How the European Trade Agenda continues to undermine access to medicines*, 2014, http://bit.ly/1s6FGZJ
[413] Financial Times, *Buffering the Pharma Brand: Restoring Reputation, Rebuilding Trust 2013*, http://bit.ly/1l4E6c3

for Western patients who can afford this product, quite honestly."

36. UNHCHR has highlighted serious conflicts between TRIPS implementation and "realisation of economic, social and cultural rights in relation to impediments to the transfer of technology to developing countries…and restrictions on access to patented pharmaceuticals" with grave "implications for enjoyment of the right to health."[414] The Director-General of the WHO has reiterated the concerns of some Member States…:

"…that trade agreements currently under negotiation could significantly reduce access to affordable generic medicines…If these agreements open trade yet close access to affordable medicines, we have to ask: Is this really progress at all?"[415]

37. The simple answer, is no. The IPR system, encouraging members to expand IP rights but making them subject to ISDS challenge if they reduce protection, has failed to deliver compensatory trade and economic advantages and cripplingly increased pharmaceutical costs.[416] This contradicts the right to "economic accessibility of health goods;"[417] MDGs on universal access to HIV/AIDS and other disease treatment;[418] and the "right to life."[419]

38. Médecins Sans Frontières have disquietingly observed that while "following the Doha Declaration, countries can legally set patents aside, they are hesitant to do so because they are afraid of provoking the anger of the United States – the political pressure is enormous."[420] Professor Drahos, of the Centre for Commercial Law Studies, agrees, and points to the strict conditionality tied to in negotiating bilateral investment treaties.[421]

39. By way of example, Drahos draws attention to the North American Free Trade Agreement, highlighting the absence of the objectives clause and principles statement that are found in Articles 7 and 8 of the TRIPS Agreement; the more extensive application of the contentious international law principle of 'national treatment' and of copyright protection,

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[414] UNHCHR, Sub-Commission on the Promotion and protection of Human Rights, Resolution 2000/7, August 2000, at Paragraph 11, <http://ap.ohchr.org/documents/E/SUBCOM/resolutions/E-CN_4-SUB_2-RES-2000-7.doc>
[415] World Health Organization, *Director-General: Health has an obligatory place on any post-2015 agenda*, 2014, http://bit.ly/1ggv6P8
[416] Dreyfuss, Rochelle Cooper. 'TRIPS-Round II – Should Users Fight Back?' *The University of Chicago Law Review*, Vol. 71, No. 1 (2004),
[417] United Nations Committee on Economic, Social and Cultural Rights. 2000. General Comment 14: The right to the highest attainable standard of health. http://bit.ly/1wRDrA8
[418] United Nations. 'Millennium Goals', *UN*, September 2000, <http://www.un.org/millenniumgoals/aids.shtml> [Accessed January 30th 2011], 6 (b) and (c) to Combat HIV/AIDS, Malaria and Other Diseases
[419] United Nations. International Covenant on Civil and Political Rights, *United Nations*, (December 1966), <http://www2.ohchr.org/english/law/ccpr.htm>
[420] Bulletin of the World Health Organization, *Access to AIDS medicines stumbles on trade rules*, 2006, http://bit.ly/1DRCeIP
[421] Drahos, P. *Bilateralism in Intellectual Property*, 2001

combined with a more restrictive compulsory licensing provision.[422]

40. The fear that Médecins Sans Frontières (MSF) and Drahos describe above is grounded in very real, observable and aggressive pursuit of the terms of investment treaties. Indeed, MSF highlight the case of Brazil, which, since the 1990s, offered comprehensive antiretroviral drugs for the treatment of HIV/AIDS (a programme which reduced mortality by more than 50% 199-99 and saved in 2 years alone US$472m in hospital and treatment costs). It achieved this through production of ARVs under a compulsory license.[423]

41. However, in 2001, the "US took action against Brazil at the WTO Dispute Settlement Body over Article 68 of the Brazilian intellectual property law"…on the grounds that "the Brazilian law discriminated against United States owners of Brazilian patents and that it curtailed patent holders' rights." Only through strong international level NGO advocacy was the claim dropped – but the impact on other countries, fearful of the US, was profound.[424]

42. And, as the Seattle-Brussels Network outline in 'Box H' below, such cases are not confined to those countries within the developing world alone:

Box K: Eli Lilly and Company v. The Government of Canada

* In November 2012, Eli Lilly, one of America's largest pharmaceutical companies, initiated formal proceedings under the North American Free Trade Agreement (NAFTA) to attack Canada's standards for granting drug patents
* The investor privileges provisions included in NAFTA and other US free trade agreements empower private firms to directly challenge government policies before foreign tribunals comprised of three private-sector attorneys, to claim that the policies undermine investors' "expected future profits", and to demand taxpayer compensation.
* Eli Lilly's NAFTA investor-state challenge marks the first attempt by a patent-holding pharmaceutical corporation to use the extraordinary investor privileges as a tool to push for greater monopoly patent protections – which will increase the cost of medicines for consumers and governments
* As well as demanding US$100 million in compensation, Eli Lilly is effectively challenging Canada's entire legal patenting system.[425]

[422] Drahos, P. *Bilateralism in Intellectual Property*, 2001
[423] World Health Organization, *TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond*, 2003, http://bit.ly/1vbdxCe
[424] World Health Organization, *TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond*, 2003, http://bit.ly/1vbdxCe
[425] Seattle to Brussels Network. 2013. *A Brave New Transatlantic Partnership: The proposed EU-US TTIP/TAFTA and its socio-economic and environmental consequences*. SBN. http://bit.ly/1tlNCvJ

43. In a key report by the US Trade Representative (USTR), in consideration of technical barriers to trade in the context of TTIP and other free trade agreements, the USTR makes a specific focus on the interests of the US pharmaceutical industry, and is led in its own negotiations by concerns raised regarding "some EU and Member State policies affecting market access for pharmaceutical products." These include what the USTR describes as:

> *"…non-transparent procedures and a lack of meaningful stakeholder (i.e. industry) input into policies related to pricing and reimbursement, including therapeutic reference pricing and other price controls…the US pharmaceutical industry has raised concerns about the United Kingdom."*[426]

44. UNAIDS, the UN Development Programme (UNDP) and WHO have all criticised the harmful impact of TRIPS plus intellectual property protections within free trade agreements, and called on States to consider the impact on public health when adopting or implementing more extensive IPR than required under TRIPS."[427] 'Box I' outlines common TRIPS plus provisions identified by the WHO that compromise the Doha Declaration:

Box L: Common 'TRIPS plus' provisions found within free trade agreements

- limiting the grounds and conditions under which compulsory licences may be issued
- providing for the possibility of extensions of terms for individual patents beyond the 20 years required by TRIPS in order to compensate for delays in the patent-granting procedure or in marketing approval processes
- requiring drug regulatory authorities, most of which have limited expertise in patents, to consider the patent status of medicines before granting marketing authorizations to generic manufacturers
- requiring test data protection that restricts the use of clinical test data on pharmaceutical products by drug regulatory authorities for the approval of generic medicines for a certain period of time
- this prevents generic companies from relying on these data for proving the efficacy and safety of their products and thus delays the entry of such drugs on to the market
- limiting the grounds under which a patent may be revoked
- requiring countries to loosen criteria for patentability and expand the scope of

[426] United States Trade Representative, *2013 Report on Technical Barriers to Trade*, 2013, http://1.usa.gov/1C4JC3N
[427] UNAIDS, World Health Organization and the UN Development Programme, *Using TRIPS flexibilities to improve access to HIV Treatment: Policy Brief*, 2011, http://bit.ly/1C7yRuY

protection by allowing for patenting of new uses or methods of using a known product

- allowing patent-holders to restrict parallel imports, which may prevent developing countries from buying medicines from the cheapest global supplier[428]

45. In fact, UNAIDS, UNDP and WHO themselves have all expressly warned Member States that in order to retain the benefits of TRIPS Agreement flexibilities, that "countries *should avoid entering into free trade agreements that contain TRIPS-plus obligations* that can impact on pharmaceuticals price or availability."[429] FPH very strongly makes the same recommendations to Member States.

46. The European Commission seek to include within the definition of 'investment', for the purposes of investment protection standards enforceable under ISDS mechanisms, broadly worded intellectual property rights.[430] While an agreement has not been concluded, other EU bilateral investment treaties have included "monopoly extensions through data exclusivity and patent term extensions; strong IP enforcement measures; and investment measures that undermine public health policy space."[431]

47. And, even where TRIPS flexibilities are preserved, the situation is complicated by the system under which compulsory licences are granted. While in theory able to import generic drugs, countries need to navigate an impenetrable import mechanism that is "based on a drug-by drug, country-by-country and case-by-case decision making process." Exporting countries are required to amend their laws to enable production and exportation of generic drugs, and few have done so – including in the EU.[432]

48. As discussed above within part one, strong ISDS and investment protection standards (encompassing, in TTIP intellectual property), in addition to creating risk of expensive ISDS claims, also create the risk of regulatory Chill. OXFAM observe that "far reaching IP enforcement potentially 'chills' generic competition as it creates a high level of legal uncertainty for generic competitors."[433]

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[428] UNAIDS, World Health Organization and the UN Development Programme, *Using TRIPS flexibilities to improve access to HIV Treatment: Policy Brief*, 2011, http://bit.ly/1C7yRuY
[429] UN Development Programme and UNAIDS, *The Potential Impact of Free Trade Agreements on Public Health*, 2012, http://bit.ly/1A2C9Vj
[430] European Commission, Public consultation on modalities for investment protection and ISDS in TTIP, March 2014, <http://bit.ly/UMWM4j>
[431] Oxfam and Health Action International Europe, *Trading away access to medicines – revisited: How the European Trade Agenda continues to undermine access to medicines*, 2014, http://bit.ly/1s6FGZJ
[432][432] World Health Organization, *TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond*, 2003, http://bit.ly/1vbdxCe
[433] Oxfam and Health Action International Europe, Trading away access to medicines – revisited: How the European Trade Agenda continues to undermine access to medicines, 2014, http://bit.ly/1s6FGZJ

49. Against this backdrop, OXFAM have drawn attention to the worrying fact that EU public expenditure on pharmaceuticals increased by 76%, 2000-09, rising faster than many GDPs. It notes that the rise in expenditure on patented medicines is fast outpacing the savings brought through the use of generic medicines. It points out that "over 100 influential oncologists described current prices of cancer medicines as: 'astronomical, unsustainable and even immoral.'"[434]

50. Set against the context of cuts to EU healthcare budgets, TRIPS plus provisions represent a serious threat to affordable access to medicines, and risk exacerbating health inequalities. Given the lower patentability standards in the US, it is troubling that the 'harmonisation' agenda may risk introducing a greater number of patents at the expense of affordable generic products. As 'Box J' outlines, a list of demands made by the pharmaceutical industry in its lobbying of the European Commission is cause for alarm:[435]

Box M: Leaked list of pharmaceutical industry demands in TTIP

Greater regulatory convergence

- a built-in agenda allowing for progressive greater regulatory convergence over time
- a Working Group on Pharmaceutical and Medical Devices as platform to discuss implementation issues and address joint approaches to future compatibility topics.

Single development plans

- for submission in EU&US for paediatrics
- extend the current EMA/FDA parallel SA
- adopt the EMA/FDA pilot project for parallel assessment of Quality by design (QbD) application
- address duplicative clinical testing requirements (via revision of ICH E5)

Other areas of convergence

- establish harmonized list of clinical trial result data fields & agree on which may be disclosed to public (uniform protection of confidential commercial information & trade secrets)
- develop therapeutic area guidelines (beginning with specific treatment areas)
- EU and US to ensure that national/regional coding systems are based on common standards for the use of unique identifiers, developed using non-proprietary,

[434] Oxfam and Health Action International Europe, Trading away access to medicines – revisited: How the European Trade Agenda continues to undermine access to medicines, 2014, http://bit.ly/1s6FGZJ
[435] Open Medicine EU, *leaked pharmaceutical wish list for TTIP*, 2014, http://bit.ly/1AOKoTb

harmonised international standards

- add a pharmacovigilance cluster to conduct work on post-marketing testing & risk management requirements
- establish common framework & methodology for benefit-risk assessment, but retaining authority to make different risk assessment judgments
- mutual recognition of GMP inspections

Intellectual property rights

- PhRMA: seek patent term adjustments for patent office delays in the EU
- PhRMA: seek forms of patent linkage in the EU
- EU/US aligned approach re disclosure of clinical trials data (impact on commercial opportunities in third countries should also be considered)
- harmonization on the grace period
- EU/US systems should be open to further adaptation to incentivize research into unmet needs
- include commitment to shared principles regarding patentability standards
- extension of data exclusivity(DE) on biologics in EU up to 12 years (despite in US it is 4ys DE and 8ys Market Exclusivity)
- establish a benchmark for not limiting the use of trademarks other than to protect public health

Market Access & Transparency:

- P&R policies should take into account innovation
- when products are grouped for P&R purposes, it should only take into account bioequivalent products
- when external reference pricing, only countries that are similar in terms of their socio-economic level, purchasing power, populations, disease burdens and health care system should be taken into account; bailout countries while they are undergoing fiscal restructuring programmes should be excluded from any referencing
- any reimbursement controls/determinations should apply only to products dispensed and reimbursed in that Party
- to avoid that pricing & reimbursement (P&R) policies hamper trade between EU/US
- include a pharma annex on P&R policies that promote transparency principles in processes & and reward innovation
- procedural safeguard in government P&R

- specified time-limits for pricing and/or reimbursement decisions
- individual decisions containing a statement of reasons based on objective and verifiable criteria provided to applicants
- legal remedies for applicants

Other issues

- Public Procurement: building on GPA, a comprehensive chapter with rules on transparency & non-discrimination of public proc. practices at federal & sub-federal level (offensive interest for EU)
- Customs: full liberalization of tariffs and pursuit of simplified and rational RoO based on common defined chemicals & pharmaceutical processing activities
- Third countries: coordinated approach for trade policy objectives in third countries: joint principles on regulatory harmonization, transparency measures, IP and tariff elimination and coordinated approach to be leveraged at multilateral level when feasible: WTO, OECD, ICH, WIPO [436]

51. In this context, FPH draws attention to the recent European Commission consultation document on ISDS and investor protection standards. Within the consultation document, the European Commission, while proposing to exclude from the scope of ISDS compulsory licensing, conclude that this this is not a sufficient safeguard on the grounds that the:

> *"…exclusion is vaguely defined and does not take into account that Member States may use other legitimate TRIPS flexibilities (e.g., strict standards of patentability, exceptions and limitations to 5 patents) to ensure access to medicines for all. Moreover, the exclusion does not cover other limitations and exceptions to other IP rights.*
>
> *Instead, overly broad interpretations of fair and equitable treatment (FET), indirect expropriation, or national treatment and most favoured nation status can be interpreted to protect almost any alleged IP-based expectation of profit so long as IP rights are included in the definition of investment."*[437]

52. FPH has absolutely no confidence in the safeguards that the European Commission propose. FPH further is absolutely unambiguous in its contention that the TTIP agreement

[436] Open Medicine EU, *leaked pharmaceutical wish list for TTIP*, 2014, http://bit.ly/1AOKoTb
[437] European Public Health Association, The inclusion of investor-to-state dispute settlement (ISDS) in Transatlantic Trade and Investment Partnership (TTIP) would undermine public health, 2014, http://bit.ly/1BxgnIt

should include no intellectual property provisions within the definition of investment, or within any other area of the agreement. Such provisions will intensify health inequalities and will compromise access to affordable medicines.

f. Marketing authorisation, pricing, reimbursement and medicines data transparency

53. In July 2014, in response to the European Commission's consultation on ISDS and investment protection provisions, eight international organisations signed a joint statement of in which were raised serious concerns with regard to marketing authorisation, pricing, reimbursement and medicines data transparency.[438] FPH fully supports the positions made within that statement, which it now presents below in 'Box K:'

Box N: ISDS and Marketing authorisation, pricing, reimbursement and medicines data transparency

The Apotex case is demonstrative of challenges made to a governmental decision on marketing authorisation

- Apotex, a Canadian generic pharmaceutical corporation, has previously alleged that US courts wrongly interpreted federal law
- Apotex claimed that it was subject to mistreatment by the US, its agencies (particularly the US Food and Drug Administration) and its federal courts in the course of the company's efforts to market generic versions of the antidepressant medicine, sertraline, and the anti-cholesterol medicine, pravastatin, in that country
- Apotex asserted that the FDA treated other US investors and US-owned investments more favourably in not subjecting these other investors to a measure as severe as the import alert imposed on the Apotex products.
- The US objected to the jurisdiction of the NAFTA Tribunal on the grounds, inter alia, that Apotex did not qualify as an 'investor' that had made an 'investment' in the US for the purposes of NAFTA
- The Tribunal ultimately dismissed all the claims and ordered Apotex to pay the legal fees and arbitral expenses of the US, but ISDS claims can still be used to challenge routine regulatory decisions

Challenges to EU Member States' decisions on pricing and reimbursement

[438] European Public Health Association, The inclusion of investor-to-state dispute settlement (ISDS) in Transatlantic Trade and Investment Partnership (TTIP) would undermine public health, 2014, http://bit.ly/1BxgnIt

- New patented medicines introduced on the market are increasingly expensive, and rise in expenditure on patented medicines outpaces savings through use of generics
- At the beginning of the 21st century, affordability of treatment became a problem, even in developed countries, especially for serious conditions such as cancer
- To date, EU Member States have exclusive competence to determine and negotiate the price and extent of reimbursement of (new) medicines
- The organisation of their health system is, in fact, a national prerogative and the subsidiarity principle applies
- Member States can use their competence to negotiate a price and design a reimbursement scheme and procurement practices that best meets their citizens' public health needs
- For example, they can use this competence to impose price cuts and/or fixed price and reimbursement decisions based on the added therapeutic value of new drugs compared to existing medicines in the market
- Through TTIP, the Pharmaceutical Research and Manufacturers of America (PhRMA) is putting pressure for limiting the influence of European health technology assessment bodies
- PhRMA requires "that in the framework of pricing and reimbursement decisions, countries shall not duplicate the assessment conducted by regulatory agencies for market approval purposes"
- The subsidiarity of Member States may be seriously jeopardised since ISDS can be used to challenge, for instance, recent policies where Member States have cut medicine prices when faced with the need to cut public spending in times of austerity
- These challenges are particularly likely when a country adopts new measures that frustrate companies' expectations of being able to impose monopoly prices
- Pharmaceutical companies' submissions to the US Trade Representative (USTR) in the context of the Special 301 consultations show that these concerns are real.[439]

54. FPH further fully supports the position of the joint statement in regard to new EU transparency requirements and expanding pharmaceutical control over clinical data. We present those positions below in 'Box L':

Box O: EU transparency requirements and expanding pharmaceutical control over clinical data

[439] European Public Health Association, The inclusion of investor-to-state dispute settlement (ISDS) in Transatlantic Trade and Investment Partnership (TTIP) would undermine public health, 2014, http://bit.ly/1BxgnIt

- Despite adoption of a new regulation on clinical trials to improve transparency in the EU in April 2014, the pharmaceutical industry continues to strongly oppose mandatory public disclosure of detailed clinical trial results
- Two US pharmaceutical companies have sued the European Medicines Agency over its decision to grant access to clinical trial data on one of their medicines
- Despite being a public good, the industry claims that clinical trial data is commercially confidential—even a trade secret—and requires the "establishment of a harmonised list of clinical trial result data fields and agreement on which may be disclosed to the public (uniform protection of confidential commercial info and trade secrets)."
- The European Consumer Organisation (BEUC) has cautioned that the expansion of parallel scientific advice within the 'definition of commercial confidentiality' "whereby clinical trials reports could be deemed commercially confidential could stymie progression towards greater transparency"
  of clinical trial data as set out in the new Clinical Trials Directive.
- If implemented, ISDS will most likely enable companies to sue governments against their decision to grant public access to clinical trial data undermining the protection of public health [440]

[440] European Public Health Association, The inclusion of investor-to-state dispute settlement (ISDS) in Transatlantic Trade and Investment Partnership (TTIP) would undermine public health, 2014, http://bit.ly/1BxgnIt

Chapter six: Conclusion and recommendations

a. Conclusion

1. The UK Faculty of Public Health's review of the evidence shows that the Transatlantic Trade and Investment Partnership is unlikely to achieve in practice realisation of the general principles outlined within the preamble to the European Commission's *Directives for the Negotiation of TTIP*, in particular with regard to the commitments made to:

- the protection and preservation of the environment and natural resources
- the right of the Parties to take measures necessary to achieve legitimate public policy objectives on the basis of protection of health, safety, labour, consumers, the environment and the promotion of cultural diversity
- sustainable development and the contribution of international trade to sustainable development in its economic, social and environmental dimensions
- full and productive employment and decent work for all[441]

2. The TTIP Agreement risks increasing the unequal distribution of power, income, goods and services globally and nationally, and weakening the public sector and democratic national government's legitimate policy space to legislate and regulate in the public interest. TTIP is likely to impose meaningful economic costs on the UK, through regular invocation of ISDS claims for governmental actions not normally challengeable under UK law.

3. TTIP is also likely to impose meaningful political costs on the UK, with significant risk to legitimate public policy space. It will lead to the abandonment, delay or modification of future preferred regulation in the public interest on account of objections (real or perceived) from US investors. A range of channels, including lobbying, responses to government inquiries or arbitration, are likely to be used as "bargaining tools."[442]

4. It is probable that TTIP will therefore exacerbate inequalities in physical and mental health and wellbeing, and compromise efforts to ensure the realisation of the right to health in accordance with Member State's national and international obligations. Despite this, the European Commission has failed to undertake a health impact assessment of the TTIP agreement.

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[441] European Commission, *Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America*, 2013, http://bit.ly/1vOSUxF

[442] London School of Economics Enterprise. April 2013. Costs and Benefits of an EU-USA Investment Protection Treaty. LSE Enterprise. http://bit.ly/1vA4ihl

FPH agrees with the reflections made by OurNHS in its written evidence before the House of Lords European Union Sub-Committee on External Affairs Inquiry into TTIP, that:

- TTIP will restrict government's right to intervene and regulate healthcare, not only for public health and safety purposes, but also to ensure quality and equitable and sustainable financing of health care.

- TTIP could have significant detrimental impacts on the domestic regulation of health services, pharmaceutical policies, standard-setting, health promotion and health protection.

- TTIP could severely restrict the ability of the UK's national governments – to control costs and regulate outsourced health services, and the ability to bring services back in house if commercialisation fails.

- TTIP could seriously open up the risk of corporate challenges and compensation claims from legitimate public health regulation, health protection and health promotion policy measures

- TTIP, through its clauses on intellectual property and pharmaceutical policies could limit scope for using pricing and reimbursement policies, and technology assessment, to achieve better economic and clinical value from pharmaceuticals.

- TTIP could limit access to lower price or generic medicines, an issue for developed countries as much as for poorer ones, particularly in relation to high cost cancer drugs for example – especially in the context of US trade policy pressure on countries who take legitimate public policy measures to control drug costs

- TTIP, through favouring of a narrow risk assessment approach and a shift away from the broader precautionary principle that is established in the EU could restrict public health measures by national or local government – e.g. on marketing of tobacco products, on food labelling, on pesticides and chemicals, or other potentially toxic or unhealthy products

- TTIP, through the introduction of an ISDS mechanism, will create further challenges for public interest, environmental and public health regulation in other sectors. When such measures reduce future investment or profit opportunities for private companies, this could be challenged as direct or indirect 'expropriation' from the point of view of any

company operating in UK health care markets.

- The worst case scenario for the NHS would then be that commercialisation becomes "locked in", sealed by the threat of huge compensation claims by investors.

- TTIP, without appropriate exemptions, could restrict a governments' ability to regulate professional standards and qualifications. Free trade and investment agreements are not the proper forum to resolve issues on professional mobility,

- TTIP seeks to include all services on the basis of their existing legislation with a 'standstill' on any further regulation not compatible with treaty provisions. This is inappropriate for recently commercialised sectors, including, the English NHS

- TTIP appears focused on the rights of businesses, with citizens' democratic rights to protection in crucial areas like health and other public services, coming second

- TTIP could – and should – exclude health services from commitments made in relation to trade in services, investment liberalisation, government procurement and domestic regulation

- TTIP could – and should – remove both health services and other health-related regulations from investment protection parts of the agreements or substantially limit the scope and use of expropriation clauses.

Recommendations:

FPH is concerned that, without fundamental revision, the proposed TTIP agreement presents serious risk to the right to health. Accordingly, FPH proposes that the UK Government should:

- reject in its entirety the negotiating mandate for TTIP;
- reject in its entirety the EU-Canada free trade agreement;
- reject in their entirety the proposed (and any alternative) investor-state dispute settlement mechanism provisions from TTIP;
- reject in their entirety the proposed (and any alternative) investment protection standards from TTIP;
- explicitly exclude the NHS from TTIP (and any wider health and related services – including those at local authority and equivalent level)

- reject in their entirety any proposed (and any alternative) intellectual property protections from TTIP;
- reject any proposed (and any alternative) provision that liberalises the public procurement markets or those in trade in goods and services■

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