

Kevin Outterson

Academic Appointments

- N. Neal Pike Scholar in Health and Disability Law (2014 – present)
- Visiting Fellow, Centre for Global Health Security, Royal Institute for International Affairs (Chatham House, London) (2014 – present)
- Visiting Professor, University of Iowa College of Law (2013)
- Professor, Boston University School of Law (2007 – present) (promoted 2013)
- Professor of Health Law, Bioethics, and Human Rights, Boston University School of Public Health (2010 – present)
- Co-director of the Health Law Program (2007 – present)
- Faculty Affiliate, Center for Communicable Disease Dynamics, Harvard University (2010 – present)
- Faculty Editor, American Journal of Law & Medicine (2007 – present)
- Editor-In-Chief, Journal of Law, Medicine & Ethics (2010 – present)
- Professor, West Virginia University College of Law (2002 – 2007) (promoted 2006)
- Lecturer, Anglia Law School, Anglia Polytechnic University, Cambridge, England (2001-2002)
- Visiting Fellow, Lauterpacht Research Centre for International Law, Cambridge, England (2001)

Education

- University of Cambridge, England (LL.M., 2002)
- Northwestern University (J.D., 1987); (B.S., 1984) *with distinction*
- University of Reading, England (Rotary Scholar, 1982-83)

Academic Leadership

- Chair, JD Curriculum Committee & Strategic Planning Committee, BU Law (2012 – 2013). Leading efforts to realign law school teaching to the changing legal marketplace for our students. Explored an accelerated JD program using executive LLM and online resources. Other projects include a significant review of grading issues, experiential learning, and online business literacy education for law students.

- Co-director of the health law program at BU Law (2007 – present), currently ranked by US News as the #5 health law program in the US. Duties include curriculum development; grant writing; overseeing the law student research program in the American Journal of Law & Medicine; marketing; recruiting health law students and Visiting Associate Professors; developing major and specialized academic conferences; and health law student job placement.
- Editor-in-Chief, Journal of Law, Medicine & Ethics, a leading peer-reviewed journal published by the American Society of Law, Medicine & Ethics (2010 – present)
- Board of Directors, American Society of Law, Medicine & Ethics (2010 – present)
- Past Chair, Section on Law, Medicine & Healthcare, Association of American Law Schools (2010-2011); Executive Committee (2008-present)
- Boston Faculty Fellowship (2008-present) (founding leadership team)
- Faculty Senate Executive Committee & University Promotion and Tenure Committee, West Virginia University (2006-2007)
- Managed teams of attorneys and large client engagement budgets; recruiting and mentoring new hires; and new client relationship development; in positions with increasing levels of responsibility, culminating as a full partner in a major law firm (1987-2001)
- Member, West Virginia Pharmaceutical Cost Management Council (2004-2008)
- Leader of several University-level academic conferences between BU and Harvard (2009-present)

Funded Research

- Associate Partner, DRIVE-AB €6,400,000 grant from the European Union's Innovative Medicines Initiative to study business models and incentives for antibiotic development (PI: Stephan Harbarth, Geneva) (2014-2017)
- Senior Technical Advisor, US HHS/FDA: *Incentives for the development of new drugs, vaccines, and rapid diagnostics for bacterial diseases*. PI – Eastern Research Group. Prime Contract No. HHSP23320095634WC, \$50,000 (2011-12)
- PI - RWJF Public Health Law Research: *Studying the public health implications of antibiotic drug regulation*. Contract 67136, \$149,996 (Dec. 2009 – May 2011)
- Consultant – Resources for the Future: *Antimicrobial conservation* (2009)
- PI – David Saul Smith Foundation: *Legal incentives & antimicrobial resistance*. \$20,000 (2010-2011)

Legal Experience

- Shareholder, Baker Donelson, Nashville, TN (1996-2002)
- Income partner, McDermott, Will & Emery, Chicago, Illinois (1989-1994)
- Associate, Lord, Bissell & Brook, Chicago, Illinois (1987-1989)
- Expert witness on corporate governance in federal and state court, including depositions and trial.

- Expert witness on FDA regulation of compounding pharmacies in federal court.
- Outside general counsel to major academic medical center (1996-2002)

Courses Taught

- Corporations
- Health Care Law
- US Corporate Law for International Lawyers
- Constitutional Health Care Litigation
- Health Care Transactions
- Food & Drug Law
- Property
- Administrative Rulemaking in Health Care

Other Teaching

- MIT Vaccine Development class (Prof. Chris Love, 2009-2011)
- Harvard School of Public Health, Biology & Epidemiology of Antibiotic Resistance (Prof. Marc Lipsitch, 2008, 2010, 2012)
- Harvard College (Prof. Dan Wikler, 2010)
- Harvard Law School (Prof. William Fisher, 2010)
- Northeastern Univ. School of Law (Corporations, fall semester 2010).

Service

- Keynote speaker at donor development events for Boston University's billion dollar capital campaign in Houston, Boston, Washington, D.C, Seattle, Los Angeles, and San Francisco (2011-present).
- Member of the Governor's Special Commission on Pharmacy Compounding (2012), created in response to the NECC compounding pharmacy disaster.
- Research and policy work on incentives for antibiotic development and conservation with Brookings, the CDC, FDA, Robert Wood Johnson Foundation, the Royal Institute for International Affairs (Chatham House) and other groups (2009-present)
- Peer Reviewer for: New England Journal of Medicine; Health Affairs; PLoS Medicine; American Journal of Law & Medicine; Journal of Law, Medicine & Ethics; Global Public Health; Australian Health Review; Jurimetrics; Bioethics; Social Science & Medicine; Health Policy & Planning; Ethics & International Affairs; Journal of World Intellectual Property; Journal of Pharmaceutical Sciences; Journal of Women, Politics & Policy; Journal of the International AIDS Society; Stanford Journal of Law, Science & Policy; Government of Qatar; Journal of the American Informatics Association.

- Ph. D. Thesis Examiner: University of Newcastle (Australia, 2009); Australian National University (2007-2008).
- *Pro bono* consultant to state governments and legislatures on health policy issues (Massachusetts, Vermont, California, West Virginia) (ongoing).

National, International & Trade Media

- Cited by the U.S. Supreme Court in *Sorrell v. IMS Health* (2010) & a primary co-author of an *amicus* brief cited in the *Florida v. HHS* (the Obamacare cases) (2012).
- Quoted in the Wall Street Journal, Economist, Atlantic Monthly, New Republic, New York Times, Nature Biotechnology, LA Times, Washington Post, Financial Times, Boston Globe, International Herald Tribune, Newsweek, CNN/Money, Scientific American, Bloomberg & The Toronto Star.
- Radio interviews for NPR's Morning Edition, All Things Considered, and Here & Now; WNYC; WGBH (Boston); BBC; New Zealand Radio; ABC Radio (Australia); Free Speech Radio Network; as well as many trade, state, and local media. Video interviews for PBS News Hour, NECN (Boston), WCVB-TV (Ch. 5, Boston) and various internet platforms.
- Blogging at www.theincidentaleconomist.com/author/mko, one of the leading interdisciplinary health policy blogs. The blog has had over 3 million visitors and about 4000 subscribers on RSS and about 4400 followers on Twitter, including health policy researchers, policy makers and journalists.

Publications and Professional Papers¹

Peer reviewed journals & law journals:

Clinical Trial Transparency – Antidote to Increased Off-label Promotion? 371 N. ENGL. J. MED. 1-3 (2014).

Analytical Framework for Examining the Value of Antibacterial Products (US Department of Health & Human Services/ASPE, April 15, 2014) (with Sertkaya et al.) http://aspe.hhs.gov/sp/reports/2014/antibacterials/rpt_antibacterials.cfm.

New Business Models for Sustainable Antibiotics, Chatham House Centre on Global Health Security Working Group Papers (London, Feb. 2014).

The Drug Quality and Security Act – Mind the Gaps, 370 N. ENGL. J. MED. 97-99 (2014).

Approval and Withdrawal of Antibiotics and Other Antiinfectives in the US, 1980-2009, 41(3) J.L. MED. & ETHICS 688-696 (2013) (with Powers, Seoane-Vazquez, Rodriguez-Monguio, & Kesselheim).

¹ All papers at <http://ssrn.com/author=340746> unless noted. Google scholar [h-index = 16](#), [i10-index = 20](#).

Plunging into Endless Difficulties: Medicaid and Coercion in the Healthcare Cases, 93 B.U. L. REV. 1 (2013) (with Huberfeld & Leonard).

Regulating Compounding Pharmacies After NECC, 367 N. ENG. J. MED. 1969 (2012).

Agents Without Principals: Regulating the Duty of Loyalty for Non Profit Corporations Through the Intermediate Sanctions Tax Regulations, 5 PEPPERDINE JOURNAL OF BUSINESS, ENTREPRENEURSHIP & THE LAW 243 (2012) (with Eisenberg CB).

All Pain, No GAIN: Need for Prudent Antimicrobial Use Provisions to Complement the GAIN Act, 30 APUA CLINICAL NEWSLETTER 13 (2012).

Deductions for Drug Ads? The Constitution Does Not Require Congress to Subsidize Direct-To-Consumer Prescription Drug Advertisements, 52 SANTA CLARA L. REV. 457-99 (2012) (with Speiser S).

Poverty Tourism and the Problem of Consent, 7 J. OF GLOBAL ETHICS 337-48 (2011) (with Whyte K & Selinger E).

Smoking and the First Amendment, 365 N. ENG. J. MED. 2351-53 (2011).

Higher First Amendment Hurdles for Public Health Regulation, 365 N. ENG. J. MED. e13 (2011). *Reviewed by the CDC Public Health Law Journal Club, Sept. 22, 2011.*

Poverty Tourism, Justice, and Policy: Can Ethical Ideals Form the Basis of New Regulations?, 14 PUBLIC INTEGRITY 39-50 (2011-2012) (with Selinger E & Whyte K).

Towards New Business Models for R&D for Novel Antibiotics, 14 DRUG RESISTANCE UPDATES 88-94 (2011) (with So AD, et al.).

Improving Antibiotic Markets for Long Term Sustainability, 11 YALE J. HEALTH POL'Y, L. & ETHICS 101 (2011) (with Kesselheim AS).

Fighting Antibiotic Resistance: Marrying New Financial Incentives to Meeting Public Health Goals, 29 HEALTH AFFAIRS 1689-1696 (2010) (with Aaron S. Kesselheim).

Questions About the 10 x '20 Initiative, 51 CLIN. INFECT. DISEASES 751-752 (2010) (with Powers JH, Gould IM & Kesselheim AS).

The Ethics of Poverty Tourism, 7(2) ENVIRONMENTAL PHILOSOPHY 93-113 (2010) (with Selinger E & Whyte KP).

The Legal Ecology of Resistance: The Role of Antibiotic Resistance in Pharmaceutical Innovation, 31 CARDOZO L. REV. 613 (2010).

How Medicare Could Get Better Prices on Prescription Drugs, 28 HEALTH AFFAIRS W832-841 (July 30, 2009, web exclusive) (with Kesselheim AS).

Death from the Public Domain?, 87 TEXAS L. REV. SEE ALSO 45 (2009).

Foreword – Will HPV Vaccines Prevent Cervical Cancers Among Poor Women of Color?: Global Health Policy at the Intersection of Human Rights and Intellectual Property Law, 35 AM. J. L. & MED. 247 (2009) (symposium editor).

Pharmaceutical Innovation: Law & the Public's Health, 37 J. L. MED. & ETHICS 173 (2009) (symposium editor).

The End of Reparations Talk – Reparations In An Obama World, 57 KANSAS L. REV. 935 (2009).

Should Access to Medicines And TRIPS Flexibilities Be Limited To Specific Diseases? 34 Am. J. L. & Med. 279 (2008).

Antibiotic Resistance and Antibiotic Development - Author's Reply. 8 LANCET INFECTIOUS DISEASES 212-214 (April 2008).

Market-Based Licenses for HPV Vaccines in Developing Countries, 27 HEALTH AFFAIRS 130 (January/February 2008) (with Aaron S. Kesselheim).

Will Longer Antimicrobial Patents Improve Global Public Health? 7 LANCET INFECTIOUS DISEASES 559-66 (2007) (with Balch Samora & Keller-Cuda).

Patent Buy-Outs For Global Disease Innovations For Low- and Middle-Income Countries, 32 AM. J. L. & MED. 159-73 (2006).

Counterfeit Drugs: The Good, The Bad, and the Ugly, 16 ALBANY L. J. OF SCIENCE & TECHNOLOGY 525 (2006) (with Smith).

The Vanishing Public Domain: Antibiotic Resistance, Pharmaceutical Innovation and Global Public Health, 67 UNIV. OF PITTSBURGH LAW REV. 67-123 (2005).

Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets, 5 YALE J. HEALTH POLICY, LAW & ETHICS 193-286 (2005).

Tragedy & Remedy: Reparations for Disparities in Black Health, 9 DEPAUL J. HEALTH CARE LAW 735-792 (2005).

Agony in the Antipodes: The Generic Drug Provisions in the Australia – US Free Trade Agreement, 2 JOURNAL OF GENERIC MEDICINES 316-326 (Spring 2005).

Free Trade in Pharmaceuticals, 181 MEDICAL JOURNAL OF AUSTRALIA 260-261 (Sept. 6, 2004).

Rapid Response to Editorial, Peter Drahos and David Henry, *The free trade agreement between Australia and the United States*, 328 BRITISH MEDICAL JOURNAL 1271 (May 2004) available at <http://www.bmj.com/rapid-response/2011/10/30/testimony-us-house-ways-amp-means-committee-australian-us-fta>.

Health Care, Technology and Federalism, 103 W. VA. L. REV. 504-539 (2001).

GP Corporatisation: Lessons Learned from the U.S. Experience, 175:8 MEDICAL JOURNAL OF AUSTRALIA 426-427 (Oct. 15, 2001).

Revenue Procedure 91-12: The IRS Launches An Information-Gathering Offensive Against International Transportation Operations, 91 TAX NOTES INTERNATIONAL 71 (1991) (with Cheung).

Taxation Without Premeditation: An Economic Analysis of The Structure, Regulation and Strangulation of the Private Activity Bond Market, 6 BOSTON UNIV. J. OF TAX L. 1-36 (1988).

Book chapters & monographs:

Combatting Antibiotic Resistance Through the Health Impact Fund (with Thomas Pogge (Yale) & Aidan Hollis (Calgary)) in THE GLOBALIZATION OF HEALTH CARE: LEGAL AND ETHICAL ISSUES (Glenn I. Cohen, ed., Oxford University Press, 2013).

Germ Shed Management in the United States, in ANTIBIOTIC POLICIES: CONTROLLING HOSPITAL-ASSOCIATED INFECTION (with Olga Yevtukhova) (Ian M. Gould and Jos van der Meer, eds., Springer, 2011).

Disease-Based Limitations On Compulsory Licenses Under Articles 31 and 31 bis, in RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY LAW AND THE WTO (Carlos Correa, ed., Edward Elgar, 2010).

Import Safety Rules And Generic Drug Markets, in IMPORT SAFETY: REGULATORY GOVERNANCE IN THE GLOBAL ECONOMY (Cary Coglianese, Adam Finkel, & David Zaring, eds., 2009) (The University of Pennsylvania Press).

Global Pharmaceutical Markets, in A COMPANION TO BIOETHICS (2ND ED.) (BLACKWELL COMPANIONS TO PHILOSOPHY) (Helga Kuhse & Peter Singer, eds.) (Blackwell, 2009) (with Donald Light).

International Pharmaceutical Issues, in THE FUNDAMENTALS OF LIFE SCIENCES LAW: DRUGS, DEVICES, AND BIOTECH (American Health Lawyers Association, 2007).

Fair Followers: Expanding Access To Generic Pharmaceuticals For Low- and Medium-Income Populations, in *THE POWER OF PILLS: SOCIAL, ETHICAL AND LEGAL ISSUES IN DRUG DEVELOPMENT, MARKETING AND PRICING* (Jillian Clare Cohen, Patricia Illingworth, and Udo Schuklenk, eds.) (London: Pluto Press, 2006).

Translated into Portuguese: *'Fair Followers': Expandindo o Acesso a Medicamentos Genéricos para a População de Baixa e Média Renda*, in *PROPRIEDADE INTELECTUAL: NOVOS PARADIGMAS INTERNACIONAIS, CONFLITOS E DESAFIOS* (Campus-Elsevier, Brasil 2007) .

Slave Taxes, in *SHOULD AMERICA PAY?: SLAVERY AND THE RAGING DEBATE OVER REPARATIONS* (Raymond Winbush, ed.) (New York: Harper Collins 2003), *reprinted in STUDIES IN THE HISTORY OF TAX LAW* (John Tiley, ed.) (Oxford: Hart Publishing 2004).

Disease Management: Legal Strategies for the Next Generation of Managed Care, 31 *JOURNAL OF HEALTH LAW* 291 (1998) (with Butler). Updated and republished as: *DISEASE MANAGEMENT AND GAINSHARING: THE NEXT GENERATION OF MANAGED CARE*, *AHLA Monograph*, 2nd ed., 1999) (with Miley and Butler).

Government testimony & legal briefs (*pro bono publico*):

Amici Curiae Brief on Behalf of the Department of Health and Human Services, Florida v. DHHS (the ACA litigation, Medicaid expansion; US Supreme Court, filing Feb. 17, 2012).

Amici Curiae Brief on Behalf of the Department of Health and Human Services, DHHS v. Florida (the ACA litigation, minimum coverage provision; US Supreme Court, filed Jan. 13, 2012).

Amici Curiae Brief on Behalf of the New England Journal of Medicine, the Massachusetts Medical Society, the National Physicians Alliance, and the American Medical Students Association in *Sorrell v. IMS Health Inc.* (US Supreme Court, filed March 1, 2011).

Amici Curiae Brief on Behalf of the New England Journal of Medicine, the Vermont Medical Society, the Massachusetts Medical Society, the New Hampshire Medical Society, the National Physicians Alliance, and the American Medical Students Association, in *IMS v. Sorrell* (2nd Cir. 2009).

Submission on Priority Watch List Treatment for Thailand and Brazil Under Section 182 of the Trade Act of 1974. Submission to the United States Trade Representative, docket number USTR-2009-0001 (Feb. 17, 2009).

Comments on the Physician Payment Sunshine Act of 2009. Submission to the U.S. SENATE COMMITTEE ON AGING (Jan. 26, 2009).

Testimony on Pharmaceutical and Medical Device Regulation: Proposed Regulation 105 CMR 970.000, Submission to the MASSACHUSETTS PUBLIC HEALTH COUNCIL (Jan. 19, 2009).

A Request for Clarification Concerning the Proper Scope of the IGWG's Work to Improve Access to Patented Medicines, Submission to the WHO IGWG (30 September 2007).

LD 838: An Act Protecting the Confidentiality of Prescription Information, SUBMISSION TO THE JOINT STANDING COMMITTEE ON HEALTH & HUMAN SERVICES, STATE OF MAINE, (March 28, 2007).

Access to Global Disease Innovation, SUBMISSION TO WHO INTER GOVERNMENTAL WORKING GROUP (15 Nov. 2006).

Advertising and Marketing of Prescription Drugs, REPORT OF THE WEST VIRGINIA PHARMACEUTICAL COST MANAGEMENT COUNCIL (Sept. 8, 2005). (Available at <http://www.wvc.state.wv.us/got/pharmacycouncil/sec/default.cfm>).

Response to Thomas C. Arthur's Testimony Before the Committee on Health, Education, Labor, & Pensions, United States Senate, HEARING ON DRUG IMPORTATION: WOULD THE PRICE BE RIGHT? (April 19, 2005).

States May Reduce Drug Prices With An Eminent Domain Process for Pharmaceutical Patents, PRESENTATION TO THE HEALTH COMMITTEE OF THE DISTRICT OF COLUMBIA (March 22, 2005).

Testimony Before the Committee on Health, Education, Labor, & Pensions, United States Senate, HEARING ON: DRUG IMPORTATION: WOULD THE PRICE BE RIGHT? (Feb. 17, 2005).

Nonrival Access To Pharmaceutical Knowledge, WHO COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH (Jan. 3, 2005).

Report of the West Virginia Pharmaceutical Cost Management Council (Sept. 15, 2004). (Available at <http://www.wvc.state.wv.us/got/pharmacycouncil/sec/default.cfm>).

The US-Australia Free Trade Agreement's Unfortunate Attack on Good Healthcare Policy (testimony submitted to the House Ways & Means Committee, June 22, 2004, in connection with the US-Australia free trade agreement).

Expert witness report on corporate governance in *FDIC v. Keystone National Bank, N.A.*, (before US District Court Judge Faber) the largest bank failure in West Virginia's history, and the fourth largest loss to date by the FDIC. (Report, April 28, 2003; testimony at bench trial June 4, 2004).

Amicus Brief on Behalf of Respondents in Gratz v. Bollinger and Grutter v. Bollinger (the Michigan affirmative action cases) on behalf of the National Coalition of Blacks for Reparations in America and the National Conference of Black Lawyers (filed with the U.S. Supreme Court Feb. 14, 2003).

Trade journals & selected other writings:

Bloggng at www.theincidentaleconomist.com/author/mko

After the deluge: Health reform without an individual mandate, KAISER HEALTH NEWS, Feb. 24, 2011, (with Frakt) available at [KHN](#).

Superbugs call for super changes in drug sale rules, Boston Globe, Nov. 15, 2010 (with Kesselheim).

Drug & Device Provisions in House Bill 3962, 15 PHRMA PRICING AND REIMBURSEMENT 1 (Dec. 2009).

From Comparative Effectiveness to Cost Effectiveness?, 14 PHRMA PRICING AND REIMBURSEMENT 126-27 (IMS Health, Cambridge, May 2009) (with Paige Goodwin).

FDA Act Creates New Incentives for Tropical Diseases, Orphan Antibiotics, 12 PHRMA PRICING AND REIMBURSEMENT 350 (IMS Health, Cambridge, Dec. 2007) (with Paige Goodwin).

New Legislative Trends Threaten the Way Health Information Companies Operate, 11 PHRMA PRICING AND REIMBURSEMENT 324-25 (IMS Health, Cambridge, Nov. 2006) (with Ilona Volker).

The Transparency Revolution in PhRMA Pricing, 10 PHRMA PRICING AND REIMBURSEMENT 4-9 (IMS Health, Cambridge, Jan. 2005).

Pharma Under George III, 9 PHRMA PRICING & REIMBURSEMENT 352 (IMS Health, Cambridge, Dec. 2004).

Resolving Dysfunctional Pharmaceutical Arbitrage and Counterfeiting through the Proposed Hubbard-Love R&D Treaty (Working Paper, Nov. 15, 2004).

Free Trade Against Free Riders?, 9 PHARMA PRICING & REIMBURSEMENT 254 (IMS Health, Cambridge, Sept. 2004).

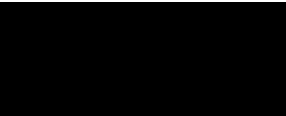
More Questions Than Answers: A Quick Response to the USTR Press Release on the AUSFTA, (July 8, 2004).

Medicare, MAJOR ACTS OF CONGRESS (Brian K. Landsberg, ed., Macmillan, 2004).

Prohibition of the Slave Trade, MAJOR ACTS OF CONGRESS (Brian K. Landsberg, ed., Macmillan, 2004).

Committee on Energy and Commerce
U.S. House of Representatives
 Witness Disclosure Requirement - "Truth in Testimony"
 Required by House Rule XI, Clause 2(g)

1. Your Name: Kevin Outterson		
2. Are you testifying on behalf of the Federal, or a State or local government entity?	Yes	No x
3. Are you testifying on behalf of an entity that is not a government entity?	Yes	No x
4. Other than yourself, please list which entity or entities you are representing: None		
5. Please list any Federal grants or contracts (including subgrants or subcontracts) that you or the entity you represent have received on or after October 1, 2011: Subcontract under Task Order No. HHSP23337004T/Contract No. HHSP23320095634WC as Michael Kevin Outterson, total payments 2011-13: \$18,250		
6. If your answer to the question in item 3 in this form is "yes," please describe your position or representational capacity with the entity or entities you are representing:		
7. If your answer to the question in item 3 is "yes," do any of the entities disclosed in item 4 have parent organizations, subsidiaries, or partnerships that you are not representing in your testimony?	Yes	No
8. If the answer to the question in item 3 is "yes," please list any Federal grants or contracts (including subgrants or subcontracts) that were received by the entities listed under the question in item 4 on or after October 1, 2011, that exceed 10 percent of the revenue of the entities in the year received, including the source and amount of each grant or contract to be listed:		
9. Please attach your curriculum vitae to your completed disclosure form. Attached		

Signature: 

Date: September 17, 2014