



Kevin Outterson

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Academic Appointments

- Professor, Boston University School of Law (2007 – present) (promoted 2013); N. Neal Pike Scholar in Health and Disability Law (2014 – present)
- Director, Social Innovation on Drug Resistance (SIDR) Program, Boston University (2019-present)
- Associate Professor of Health Law, Policy & Management, Boston University School of Public Health (2010 – present)
- Faculty Editor, American Journal of Law & Medicine (2007 – present)
- Editor-In-Chief, Journal of Law, Medicine & Ethics (2010 – 2016)
- Associate 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, West Virginia University College of Law (2002 – 2007) (promoted 2006)

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)

Legal Experience

- Shareholder, Baker Donelson, Nashville, TN (1996-2002, transactional health care law)
- Income partner, McDermott, Will & Emery, Chicago, Illinois (1989-1994, federal and international corporate taxation)
- Associate, Lord, Bissell & Brook, Chicago, Illinois (1987-1989, tax associate)
- Expert witness on corporate governance, and food & drug law in federal and state courts, including depositions and trial (bench and jury) (2006-present)

Leadership & Awards

- Founding Executive Director, CARB-X (2016-present) CARB-X is the world's largest and most innovative antibacterial R&D accelerator, supporting 66 projects in 9 countries thus far.
- International Network for Antimicrobial Resistance Social Science (INAMRSS) (Founder & Executive Committee, 2019-present)
- G20 Global AMR R&D Hub (Appointed Stakeholder, 2019-present)

- Leadership Award, Alliance for the Prudent Use of Antibiotics (2015)
- Co-director of the health law program at BU Law (2007 – present)
- Board, American Society of Law, Medicine & Ethics (2010 – 2018), Chair (2017)
- Chair, Section on Law, Medicine & Healthcare, Association of American Law Schools (2010-2011); Executive Committee (2008-2013)
- Boston Faculty Fellowship (2008-2016) (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)

Funded Research

- Principal Investigator – CARB-X, €39,000,000 grant from the German Federal Ministry for Education and Research (BMBF) (2019-2023).
- Principal Investigator – CARB-X, \$25,000,000 grant from the Bill & Melinda Gates Foundation (2018-2022).
- Principal Investigator – CARB-X, £20,000,000 grant from the UK Department of Health and Social Care (2018-2022).
- Principal Investigator – CARB-X Award Letter from the Wellcome Trust, \$155,500,000 (2017-2021).
- Principal Investigator – CARB-X Cooperative Agreement with US HHS/BARDA (IDSEP160030-01-00) \$250,000,000 (2016-2021).
- Partner, DRIVE-AB €9,200,000 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)
- PI – David Saul Smith Foundation: *Legal incentives & antimicrobial resistance*. \$20,000 (2010-2011)

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

- Harvard School of Public Health, Biology & Epidemiology of Antibiotic Resistance (Prof. Marc Lipsitch, 2008, 2010, 2012, 2016, 2018, 2020)
- Harvard College (Prof. Dan Wikler, 2010)
- Harvard Law School (Prof. William Fisher, 2010)
- MIT Vaccine Development class (Prof. Chris Love, 2009-2011)
- Northeastern Univ. School of Law (Corporations, fall semester 2010)

Service

- 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), Dag Hammarskjöld Foundation, Duke-Margolis Center, and other groups (2009-present).
- Member of the Governor's Special Commission on Pharmacy Compounding (2012), created in response to the NECC compounding pharmacy disaster.
- 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; BMJ Global Health; Yale Journal of Health Policy, Law & Ethics.
- Keynote speaker at donor development events for Boston University's \$1.8B capital campaign in Houston, Boston, Washington, D.C, Seattle, Los Angeles, and San Francisco (2011-present).
- *Pro bono* consultant to governments and legislatures on health policy issues (Massachusetts, Vermont, California, West Virginia, US Congress).
- BU Law committees: JD (Chair); Lateral Appointments (2019-2020).

Publications and Professional Papers¹

Peer reviewed papers, law journals articles, books, book chapters & monographs:

96. Colson AR, Morton A, Årdal C, Chalkidou K, Davies SC, Garrison LP, Jit M, Laxminarayan R, Megiddo I, Morel CM, Nonvignon J, Outterson K, Rex JH, Sarker AR, Sculpher M, Woods B, Xiao Y. Antimicrobial resistance: is health technology assessment part of the solution or part of the problem? *Value in Health* 2021/6/11. Online ahead of print.

95. Outterson K, Orubu ESF, Rex J, Årdal C, Zaman MH. Patient access in fourteen high-income countries to new antibacterials approved by the FDA, EMA, PMDA, or Health Canada, 2010-2020. *Clin Inf Dis*. 2021 Jul 12;ciab612. doi: 10.1093/cid/ciab612. Online ahead of print.

94. Kållberg C, Hudson J, Blix HS, Årdal C, Klein E, Lindbæk, Outterson K, et al. The effect of generic market entry on antibiotic prescriptions in the United States. *Nat Comms* 2021;12(1):1-9.

¹ [Google scholar](#) h-index = 32, i10-index = 50.

93. Boucher HW, File TM, Fowler VG, Jezek A, Rex JH, Outterson K. Antibiotic development incentives that reflect societal value of antibiotics. *Clin Inf Dis*. 72(9):e420-e421 (2021).
92. Puzniak L, Gupta V, Kalvin CY, Ye G, Outterson K. The impact of infections on reimbursement in 92 US hospitals, 2015-2018. *Am J Inf Control* 2021.
91. Kim W, Krause K, Zimmerman Z, Outterson K. Improving data sharing to increase the efficiency of antibiotic R&D. *Nat Reviews Drug Discovery* 2021;20:1-2 doi: <https://doi.org/10.1038/d41573-020-00185-4>.
90. Minssen T, Outterson K, Van Katwyk SR, Batista PHD, Chandler CIR, et al. Social, cultural and economic aspects of antimicrobial resistance. *Bull WHO* 98(12):823 (2020).
89. Kirchhelle C, Atkinson P, Broom A, Chuengsatiansup K, Ferreira JP, Fortané N, Frost I, Gradmann C, Hinchliffe S, Hoffman SJ, Lezaun J, Nayiga S, Outterson K, Podolsky SH, Raymond S, Roberts AP, Singer AC, So AD, Sringeriyuang L, Tayler E, Van Katwyk SR, Chandler CIR. Setting the standard: multidisciplinary hallmarks for structural, equitable and tracked antibiotic policy. *BMJ Global Health* 2020 e003091.
88. Rex JH, Outterson K. Antibacterial R&D at a crossroads: We've pushed as hard as we can ... now we need to start pulling! [published online ahead of print, 2020 Jun 25]. *Clin Infect Dis*. 2020 doi:10.1093/cid/ciaa852.
87. Morel C, Alm R, Ardal C, Bandera A, Bruno G, et al. A One Health framework to estimate costs of antimicrobial resistance. (pre-print, 2020).
86. Laxminarayan R, Van Boeckel T, Frost I, Kariuki S, Khan EA, Limmathurotsakul D, Larsson DGJ, Levy-Hara G, Mendelson M, Outterson K, Peacock SJ, Zhu, Y-G (2020). The Lancet Infectious Diseases Commission on antimicrobial resistance: 6 years later. *Lancet Infect Dis*, 20(4), e51-e60. doi:[10.1016/S1473-3099\(20\)30003-7](https://doi.org/10.1016/S1473-3099(20)30003-7).
85. Outterson K, & Rex J H (2020). Evaluating for-profit public benefit corporations as an additional structure for antibiotic development and commercialization. *Transl Res*. 2020 Jun;220:182-190. doi:[10.1016/j.trsl.2020.02.006](https://doi.org/10.1016/j.trsl.2020.02.006).
84. Boucher HW, File TM, Fowler VG, Jezek A, Rex JH, Outterson K. Antibiotic development incentives that reflect societal value of antibiotics. *Clin Infect Dis*. 2020;ciaa092. doi:10.1093/cid/ciaa092.
83. Theuretzbacher U, Outterson K, Engel A, Karlen A (2019). The global preclinical antibacterial pipeline. *Nat Rev Microbiology* (epub 19 Nov. 2019).
82. Ardal C, Balasegaram M, Laxminarayan R, McAdams D, Outterson K, Rex JH, Sumpradit N (2020). Antibiotic development – economic, regulatory and societal challenges. *Nat Rev Microbiology* (epub 19 Nov. 2019).
81. Van Katwyk SR, Balasegaram M, Boriello SP, Farrar J, Giubilini A, Harrison M, Kieny M-P, Kirchhelle C, Liu J, Outterson K, Pate MA, Poirier M, Røttingen J-A, Savulescu J, Sugden R, Thamlikitkul V, Weldon I, Davies S, Hoffman SJ (2019). A roadmap for sustainably governing the global antimicrobial commons. *Lancet*, 394(10211):1788.
80. Outterson K (2019). A shot in the arm for new antibiotics. *Nat Biotechnology*, 37(10):1110-1112.
79. Rex JH, Fernandez Lynch H, Cohen IG, Darrow JJ, & Outterson K (2019). Designing development programs for non-traditional antibacterial agents. *Nat Commun*, 10(1), 1-10.

78. Huberfeld N, Weeks E, Outterson K (2018). *The Law of American Health Care* (Second Edition). Aspen Pub.
77. Årdal C, Baraldi E, Theuretzbacher U, Outterson K, Plahte J, Ciabuschi F, & Røttingen JA (2018). Insights into early stage of antibiotic development in small- and medium-sized enterprises: a survey of targets, costs, and durations. *J Pharm Policy Pract*, 11(1), 8.
76. Kallberg C, Ardal C, Blix HS, Klein E, Martinez EM, Lindbaek M, Outterson K, Rottingen JA, Laxminarayan R (2018). Introduction and geographic availability of new antibiotics approved between 1999 and 2014. *PLOS ONE*, 13(10), e0205166. doi:[10.1371/journal.pone.0205166](https://doi.org/10.1371/journal.pone.0205166)
75. Bhatti T, Lum K, Holland S, Sassman S, Findlay D, & Outterson K (2018). A Perspective on Incentives for Novel Inpatient Antibiotics: No One-Size-Fits-All. *JOURNAL OF LAW, MED & ETHICS*, 46(1), 59-65. doi:[10.1177/1073110518782916](https://doi.org/10.1177/1073110518782916)
74. Tacconelli E, Carrara E, Savoldi A, Harbarth S, Mendelson M, Monnet DL, Pulcini C, Kahlmeter G, Kluytmans J, Carmeli Y, Ouellette M, Outterson K, Patel J, Cavaleri M, Cox E, Houchens C, Grayson ML, Hansen P, Zorzet A, et al (2018). Discovery, research, and development of new antibiotics: the WHO priority list of antibiotic-resistant bacteria and tuberculosis. *LANCET INFECTIOUS DISEASES*, 18(3), 318-327. doi:[10.1016/S1473-3099\(17\)30753-3](https://doi.org/10.1016/S1473-3099(17)30753-3)
73. Ardal CO, Findlay D, Savic M, Carmeli Y, Gyssens I, Laxminarayan R, Outterson K, Rex JH (2018). Revitalizing the antibiotic pipeline: Stimulating innovation while driving sustainable use and global access. DRIVE-AB Final Report (European Commission, Innovative Medicines Initiative).
72. Theuretzbacher U, Savic M, Ardal C, & Outterson K (2017). Innovation in the preclinical antibiotic pipeline. *NATURE REVIEWS DRUG DISCOVERY*, 16(11), 744-745. doi:[10.1038/nrd.2017.195](https://doi.org/10.1038/nrd.2017.195)
71. Barlam TF, Morgan JR, Kaplan WA, Outterson K, & Pelton SI (2017). Disproportionate Exposure to Antibiotics in Children at Risk for Invasive Pneumococcal Disease: Potential for Emerging Resistance and Opportunity for Antibiotic Stewardship. *J Pediatric Infect Dis Soc*, 8(1), 63-65. doi:[10.1093/jpids/pix070](https://doi.org/10.1093/jpids/pix070)
70. Ardal C, Baraldi E, Ciabuschi F, Outterson K, Rex JH, Piddock LJV, & Findlay D (2017). To the G20: incentivising antibacterial research and development. *LANCET INFECTIOUS DISEASES*, 17(8), 799-801. doi:[10.1016/S1473-3099\(17\)30404-8](https://doi.org/10.1016/S1473-3099(17)30404-8)
69. Deak D, Powers JH, Outterson K, & Kesselheim AS (2017). The Fight Against Multidrug-Resistant Bacteria. Response. *ANNALS OF INTERNAL MEDICINE*, 166(1), 79. doi:[10.7326/L16-0582](https://doi.org/10.7326/L16-0582)
68. Outterson K, Huberfeld N, & Weeks E (2017). Teaching the Law of American Health Care. *Saint Louis University Law Journal*, 61(3), 401-410.
67. Huberfeld N, Weeks E, Outterson K (2016). *The Law of American Health Care*. Aspen Pub.
66. Outterson K, & McDonnell A (2016). Antimicrobial Resistance: The Authors Reply. *HEALTH AFFAIRS*, 35(10), 1936. doi:[10.1377/hlthaff.2016.1106](https://doi.org/10.1377/hlthaff.2016.1106)
65. Deak D, Outterson K, Powers JH, & Kesselheim AS (2016). Progress in the Fight Against Multidrug-Resistant Bacteria? A Review of US Food and Drug Administration-Approved Antibiotics, 2010-2015. *ANNALS OF INTERNAL MEDICINE*, 165(5), 363-+. doi:[10.7326/M16-0291](https://doi.org/10.7326/M16-0291)
64. Outterson , Rex, JH, Jinks T, Jackson P, Hallinan J, Karp S, Larsen J, et al (2016). Accelerating global innovation to address antibacterial resistance: introducing CARB-X. *NATURE REVIEWS DRUG DISCOVERY*, 15(9), 589-590. doi:[10.1038/nrd.2016.155](https://doi.org/10.1038/nrd.2016.155)

63. Outterson K, Gopinathan U, Clift C, So AD, Morel CM, & Rottingen JA (2016). Delinking Investment in Antibiotic Research and Development from Sales Revenues: The Challenges of Transforming a Promising Idea into Reality. *PLOS MEDICINE*, 13(6), 7 pages. doi:[10.1371/journal.pmed.1002043](https://doi.org/10.1371/journal.pmed.1002043)
62. Outterson K, & McDonnell A (2016). Funding Antibiotic Innovation With Vouchers: Recommendations On How To Strengthen A Flawed Incentive Policy. *HEALTH AFFAIRS*, 35(5), 784-790. doi:[10.1377/hlthaff.2015.1139](https://doi.org/10.1377/hlthaff.2015.1139)
61. Rex JH, & Outterson K (2016). Antibiotic reimbursement in a model delinked from sales: a benchmark-based worldwide approach. *LANCET INFECTIOUS DISEASES*, 16(4), 500-505. doi:[10.1016/S1473-3099\(15\)00500-9](https://doi.org/10.1016/S1473-3099(15)00500-9)
60. Ardal C, Outterson K, Hoffman SJ, Ghafur A, Sharland M, Ranganathan N, Rottingen JA, et al (2016). International cooperation to improve access to and sustain effectiveness of antimicrobials. *LANCET*, 387(10015), 296-307. doi:[10.1016/S0140-6736\(15\)00470-5](https://doi.org/10.1016/S0140-6736(15)00470-5)
59. Clift C, Gopinathan U, Morel C, Outterson K, Rottingen JA, So A (2015). Towards a New Global Business Model for Antibiotics: Report from the Chatham House Working Group on New Antibiotic Business Models. London.
58. Harbarth, S., Theuretzbacher, U., Hackett, J., Adriaenssens, N., Anderson, J., Antonisse, A., . . . Zorzet, A. (2015). Antibiotic research and development: business as usual? *JOURNAL OF ANTIMICROBIAL CHEMOTHERAPY*, 70(6), 1604-1607. doi:[10.1093/jac/dkv020](https://doi.org/10.1093/jac/dkv020)
57. Hoffman, S. J., & Outterson, K. (2015). What Will It Take to Address the Global Threat of Antibiotic Resistance?. *JOURNAL OF LAW MEDICINE & ETHICS*, 43(2), 363-368. doi:[10.1111/jlme.12253](https://doi.org/10.1111/jlme.12253)
56. Jaczynska E, Outterson K, Menstre-Ferrandiz J (2015). Business model options for antibiotics: Learning from other industries. Chatham House, London.
55. Outterson, K., Powers, J. H., Daniel, G. W., & McClellan, M. B. (2015). Repairing the broken market for antibiotic innovation. *HEALTH AFFAIRS*, 34(2), 277-285. doi:[10.1377/hlthaff.2014.1003](https://doi.org/10.1377/hlthaff.2014.1003)
54. Hoffman SJ, Outterson K, Rottinge JA, Cars O, Clift C, Rizvi Z, . . . Zorzet A (2015). An international legal framework to address antimicrobial resistance. *BULLETIN OF THE WORLD HEALTH ORGANIZATION*, 93(2), 66. doi:[10.2471/BLT.15.152710](https://doi.org/10.2471/BLT.15.152710)
53. Sertkaya A, Eyraud J, Birkenbach A, Franz C, Ackerley N, Overton V, Outterson K (2014). Analytical Framework for Examining the Value of Antibacterial Products (For US Department of Health & Human Services/ASPE, April 15, 2014) http://aspe.hhs.gov/sp/reports/2014/antibacterials/rpt_antibacterials.cfm.
52. Outterson K (2014). New Business Models for Sustainable Antibiotics, Chatham House Centre on Global Health Security Working Group Papers (London).
51. Outterson K (2014). AHLA Health Law Curriculum Manual. American Health Lawyers Association.
50. Outterson, K. (2014). The Drug Quality and Security Act - Mind the Gaps. *NEW ENGLAND JOURNAL OF MEDICINE*, 370(2), 97-99. doi:[10.1056/NEJMp1314691](https://doi.org/10.1056/NEJMp1314691)
49. Outterson, K. (2014). Clinical Trial Transparency - Antidote to Weaker Off-Label-Promotion Rules?. *NEW ENGLAND JOURNAL OF MEDICINE*, 371(1), 1-3. doi:[10.1056/NEJMp1402969](https://doi.org/10.1056/NEJMp1402969)
48. Huberfeld, N., Leonard, E. W., & Outterson, K. (2013). Plunging into endless difficulties: Medicaid and coercion in National Federation of Independent Business v. Sebelius. *BOSTON UNIVERSITY LAW REVIEW*, 93(1), 1-88.

47. Outterson, K., Powers, J. H., Seoane-Vazquez, E., Rodriguez-Monguio, R., & Kesselheim, A. S. (2013). Approval and Withdrawal of New Antibiotics and Other Antiinfectives in the U.S., 1980-2009. *JOURNAL OF LAW MEDICINE & ETHICS*, 41(3), 688-696. doi:[10.1111/jlme.12079](https://doi.org/10.1111/jlme.12079)
46. Pogge T, Hollis A, Outterson K (2013). Combatting Antibiotic Resistance Through the Health Impact Fund in THE GLOBALIZATION OF HEALTH CARE: LEGAL AND ETHICAL ISSUES (Glenn I. Cohen, ed., Oxford University Press, 2013).
45. Outterson, K. (2012). All Pain, No GAIN: Need for Prudent Antimicrobial Use Provisions to Complement the GAIN Act. *APUA Clinical Newsletter*, 30(1), 13.
44. Speiser, S., & Outterson, K. (2012). Deductions for Drug Ads? The Constitution Does Not Require Congress to Subsidize Direct-to-Consumer Prescription Drug Advertisements. *Santa Clara Law Review*, 52, 453.
43. Outterson, K. (2012). Regulating Compounding Pharmacies after NECC. *NEW ENGLAND JOURNAL OF MEDICINE*, 367(21), 1969-1972. doi:[10.1056/NEJMp1212667](https://doi.org/10.1056/NEJMp1212667)
42. Outterson, K. (2012). Punishing Health Care Fraud - Is the GSK Settlement Sufficient?. *NEW ENGLAND JOURNAL OF MEDICINE*, 367(12), 1082-1085. doi:[10.1056/NEJMp1209249](https://doi.org/10.1056/NEJMp1209249)
41. Eisenberg, C. B., & Outterson, K. (2012). Agents Without Principals: Regulating the Duty of Loyalty for Nonprofit Corporations Through the Intermediate Sanctions Tax Regulations. *Journal of Business, Entrepreneurship and the Law*, 5(2).
40. Outterson K, Yevtukhova O (2011). Germ Shed Management in the United States, in ANTIBIOTIC POLICIES: CONTROLLING HOSPITAL-ASSOCIATED INFECTION (Ian M. Gould and Jos van der Meer, eds., Springer, 2011).
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37. Outterson, K., Selinger, E., & Whyte, K. (2011). Poverty Tourism, Justice, and Policy. *Public Integrity*, 14(1), 39-50. doi:[10.2753/pin1099-9922140103](https://doi.org/10.2753/pin1099-9922140103)
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34. Kesselheim, A. S., & Outterson, K. (2011). Improving antibiotic markets for long-term sustainability. *Yale J Health Policy Law Ethics*, 11(1), 101-167.
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31. Outterson, K., Powers, J. H., Gould, I. M., & Kesselheim, A. S. (2010). Questions about the 10 x '20 Initiative. *CLINICAL INFECTIOUS DISEASES*, 51(6), 751-752. doi:[10.1086/655955](https://doi.org/10.1086/655955)

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29. Outterson K (2010). 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).
28. Outterson, K. (2010). Death from the Public Domain?. *Texas Law Review* (<i>See Also</i> *Online Supplement*), 87, 45-55.
27. Outterson K (2009). 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).
26. Outterson K, Light DW (2009). Global Pharmaceutical Markets, in *A COMPANION TO BIOETHICS* (2ND ED.) (BLACKWELL COMPANIONS TO PHILOSOPHY) (Helga Kuhse & Peter Singer, eds.) (Blackwell, 2009).
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