Aaron S Kesselheim

List of Publications by Year in Descending Order

534 papers	10,384 citations	50 h-index	80 g-index
581 ext. papers	12,995 ext. citations	16.6 avg, IF	7.43 L-index

#	Paper	IF	Citations
534	Reporting bias in clinical trials: Progress toward transparency and next steps.. *PLoS Medicine*, **2022**, 19, e1003894	11.6	1
533	Differences in Diabetic Prescription Drug Utilization and Costs Among Patients With Diabetes Enrolled in Colorado Marketplace and Medicaid Plans, 2014-2015.. *JAMA Network Open*, **2022**, 5, e2140371	10.4	0
532	Medicaid Spending on Drugs Marketed Without US Food and Drug Administration Approval in 2020.. *JAMA Internal Medicine*, **2022**,	11.5	1
531	Extending Drug Monopolies by Patenting Safe Drug Use.. *JAMA Internal Medicine*, **2022**,	11.5	2
530	Competition law and pricing among biologic drugs: the case of VEGF therapy for retinal diseases.. *Journal of Law and the Biosciences*, **2022**, 9, lsac001	4.1	1
529	The characteristics of patents impacting availability of biosimilars.. *Nature Biotechnology*, **2022**, 40, 22-25	44.5	0
528	Patient and Caregiver Experiences With and Perceptions of Risk Evaluation and Mitigation Strategy Programs With Elements to Assure Safe Use.. *JAMA Network Open*, **2022**, 5, e2144386	10.4	2
527	Experts' Views on FDA Regulatory Standards for Drug and High-Risk Medical Devices: Implications for Patient Care.. *Journal of General Internal Medicine*, **2022**, 1	4	0
526	A New Way to Contain Unaffordable Medication Costs - Exercising the Government's Existing Rights.. *New England Journal of Medicine*, **2022**,	59.2	2
525	Indication-Specific Generic Uptake of Imatinib Demonstrates the Impact of Skinny Labeling.. *Journal of Clinical Oncology*, **2022**, JCO2102139	2.2	
524	New Drug Postmarketing Requirements and Commitments in the US: A Systematic Review of the Evidence.. *Drug Safety*, **2022**,	5.1	0
523	Recent Orange and Purple Book legislation suggests a need to bridge drug and biologic patent regimes.. *Nature Biotechnology*, **2022**, 40, 167-169	44.5	
522	Aducanumab and Accelerated Approval: Where Do We Go From Here?. *Clinical Pharmacology and Therapeutics*, **2022**,	6.1	1
521	Anticipated efficiencies, real costs: Medicaid managed care organizations and the pharmacy benefit.. *Journal of Managed Care & Specialty Pharmacy*, **2022**, 28, 354-361	1.9	
520	Updating the Bayh-Dole Act: March-in Rights and Transparency.. *JAMA - Journal of the American Medical Association*, **2022**,	27.4	1
519	Switching to Over-the-Counter Availability of Rescue Inhalers for Asthma.. *JAMA - Journal of the American Medical Association*, **2022**,	27.4	1
518	QALYs In Health Resource Usage Decisions: The Authors Reply.. *Health Affairs*, **2022**, 41, 610	0	

517	Therapeutic Value Assessments of Novel Medicines in the US and Europe, 2018-2019.. *JAMA Network Open*, **2022**, 5, e226479	10.4	2
516	Risks to the 340B Drug Pricing Program Related to Manufacturer Restrictions on Drug Availability.. *JAMA - Journal of the American Medical Association*, **2022**,	27.4	3
515	Use of Extrapolation in New Drug Approvals by the US Food and Drug Administration.. *JAMA Network Open*, **2022**, 5, e227958	10.4	3
514	Medicaid Expenditures and Estimated Rebates on Line Extension Drugs, 2010-2018.. *Journal of General Internal Medicine*, **2022**,	4	3
513	Unwanted Advice? Frequency, Characteristics, And Outcomes Of Negative Advisory Committee Votes For FDA-Approved Drugs.. *Health Affairs*, **2022**, 41, 713-721	0	0
512	Analysis of Supportive Evidence for US Food and Drug Administration Approvals of Novel Drugs in 2020.. *JAMA Network Open*, **2022**, 5, e2212454	10.4	2
511	Improving the quality of US drug patents through international awareness.. *BMJ, The*, **2022**, 377, e068173	3.9	1
510	Variations in Generic Combination Opioid Use Across State Medicaid Programs. *Journal of General Internal Medicine*, **2021**, 36, 3240-3242	4	
509	Promoting Competition in Drug Pricing: A Review of Recent Congressional Legislation.. *Journal of Law, Medicine and Ethics*, **2021**, 49, 683-687	1.2	
508	Views from Academia, Industry, Regulatory Agencies, and the Legal System **2021**, 73-111		
507	Medicare Spending on Drugs With Accelerated Approval, 2015-2019. *JAMA Health Forum*, **2021**, 2, e213937	2.7	1
506	Trends in Medicare Part D Inhaler Spending: 2012-2018. *Annals of the American Thoracic Society*, **2021**, 18, 548-550	4.7	4
505	Frequency of First Generic Drug Approvals With "Skinny Labels" in the United States. *JAMA Internal Medicine*, **2021**, 181, 995-997	11.5	2
504	Non-warfarin oral anticoagulant copayments and adherence in atrial fibrillation: A population-based cohort study. *American Heart Journal*, **2021**, 233, 109-121	4.9	9
503	FDA approval standards for anticancer agents - lessons from two recent approvals in breast cancer. *Nature Reviews Clinical Oncology*, **2021**, 18, 397-398	19.4	2
502	Paying for Prescription Drugs in the New Administration. *JAMA - Journal of the American Medical Association*, **2021**, 325, 819-820	27.4	3
501	Identifying potential prescription drug product hopping. *Nature Biotechnology*, **2021**, 39, 414-417	44.5	2
500	Public funding and the importance of reasonable pricing for buprenorphine. *Drug and Alcohol Dependence*, **2021**, 221, 108643	4.9	

499	A Multi-modal Approach to Evaluate the Impact of Risk Evaluation and Mitigation Strategy (REMS) Programs. *Drug Safety*, **2021**, 44, 743-751	5.1	3
498	Characteristics of Postmarketing Studies for Vaccines Approved by the US Food and Drug Administration, 2006-2020. *JAMA Network Open*, **2021**, 4, e218530	10.4	2
497	Substitution of Generic Drugs and Biosimilars-Reply. *JAMA Internal Medicine*, **2021**, 181, 568	11.5	
496	Assessment of Coverage in England of Cancer Drugs Qualifying for US Food and Drug Administration Accelerated Approval. *JAMA Internal Medicine*, **2021**, 181, 490-498	11.5	15
495	Frequency Of Generic Drug Price Spikes And Impact On Medicaid Spending. *Health Affairs*, **2021**, 40, 779-785	7	1
494	Correlation Between Changes in Brand-Name Drug Prices and Patient Out-of-Pocket Costs. *JAMA Network Open*, **2021**, 4, e218816	10.4	2
493	Evaluation of Aducanumab for Alzheimer Disease: Scientific Evidence and Regulatory Review Involving Efficacy, Safety, and Futility. *JAMA - Journal of the American Medical Association*, **2021**, 325, 1717-1718	27.4	60
492	Integrating New Effectiveness Data Into US Food and Drug Administration-Approved Drug Labeling. *JAMA Internal Medicine*, **2021**, 181, 897-898	11.5	1
491	The timing of 30-month stay expirations and generic entry: A cohort study of first generics, 2013-2020. *Clinical and Translational Science*, **2021**, 14, 1917-1923	4.9	2
490	Diabetes Drugs: List Price Increases Were Not Always Reflected In Net Price; Impact Of Brand Competition Unclear. *Health Affairs*, **2021**, 40, 772-778	7	0
489	Association of California's Prescription Drug Coupon Ban With Generic Drug Use. *JAMA - Journal of the American Medical Association*, **2021**, 325, 2399-2402	27.4	1
488	Estimating Rebates and Other Discounts Received by Medicare Part D. *JAMA Health Forum*, **2021**, 2, e210626	10	10
487	Factors Associated With Generic Drug Uptake in the United States, 2012 to 2017. *Value in Health*, **2021**, 24, 804-811	3.3	2
486	Continual learning in medical devices: FDA's action plan and beyond. *The Lancet Digital Health*, **2021**, 3, e337-e338	14.4	14
485	Federal Spending on Off-Patent Drugs That Lack Generic Competition. *Journal of General Internal Medicine*, **2021**, 36, 821-823	4	1
484	Market Exclusivity Length for Drugs with New Generic or Biosimilar Competition, 2012-2018. *Clinical Pharmacology and Therapeutics*, **2021**, 109, 367-371	6.1	8
483	Reply to Boucher et al. *Clinical Infectious Diseases*, **2021**, 72, e422-e423	11.6	
482	Public funding for transformative drugs: the case of sofosbuvir. *Drug Discovery Today*, **2021**, 26, 273-281	8.8	2

481	An Overview Of Vaccine Development, Approval, And Regulation, With Implications For COVID-19. *Health Affairs*, **2021**, 40, 25-32	7	14
480	Changes in Erythropoiesis Stimulating Agent Use Under a Risk Evaluation and Mitigation Strategy (REMS) Program. *Drug Safety*, **2021**, 44, 327-335	5.1	2
479	Factors Affecting Buprenorphine Utilization and Spending in Medicaid, 2002-2018. *Value in Health*, **2021**, 24, 182-187	3.3	2
478	The Wrong Cure: Financial Incentives for Unimpressive New Antibiotics. *Journal of Infectious Diseases*, **2021**, 223, 1506-1509	7	1
477	Assessment of Variation in State Regulation of Generic Drug and Interchangeable Biologic Substitutions. *JAMA Internal Medicine*, **2021**, 181, 16-22	11.5	10
476	INTRODUCTION: Public Sector and Non-Profit Contributions to Drug Development - Historical Scope, Opportunities, and Challenges. *Journal of Law, Medicine and Ethics*, **2021**, 49, 6-9	1.2	2
475	A correlation analysis to assess event-free survival as a trial-level surrogate for overall survival in early breast cancer. *EClinicalMedicine*, **2021**, 32, 100730	11.3	4
474	Buprenorphine for opioid use disorder: The role of public funding in its development. *Drug and Alcohol Dependence*, **2021**, 219, 108491	4.9	3
473	ASHP Foundation Pharmacy Forecast 2021: Strategic Planning Advice for Pharmacy Departments in Hospitals and Health Systems. *American Journal of Health-System Pharmacy*, **2021**, 78, 472-497	2.2	1
472	The Future of Drug-Pricing Transparency. *New England Journal of Medicine*, **2021**, 384, 489-491	59.2	3
471	Associations Between Copays, Coverage Limits for Opioid Use Disorder Medications, and Prescribing in Medicaid, 2018. *Medical Care*, **2021**, 59, 266-272	3.1	
470	Prospects for Enforcing Prohibitions on Off-Label Drug Promotion after United States v. Caronia: An Analysis of Litigated Cases. *Journal of Health Politics, Policy and Law*, **2021**, 46, 487-504	2.6	1
469	Why France Spends Less Than the United States on Drugs: A Comparative Study of Drug Pricing and Pricing Regulation. *Milbank Quarterly*, **2021**, 99, 240-272	3.9	0
468	Fulfilling the Mandate of the US Food and Drug Administration's Accelerated Approval Pathway: The Need for Reforms. *JAMA Internal Medicine*, **2021**, 181, 1275-1276	11.5	16
467	Public-sector Contributions to Novel Biologic Drugs. *JAMA Internal Medicine*, **2021**, 181, 1522-1525	11.5	0
466	Assessing the Impact of US Food and Drug Administration Breakthrough Therapy Designation Timing on Trial Characteristics and Development Speed. *Clinical Pharmacology and Therapeutics*, **2021**, 110, 1018-1024	6.1	3
465	Cost to Medicare of Delayed Adalimumab Biosimilar Availability. *Clinical Pharmacology and Therapeutics*, **2021**, 110, 1050-1056	6.1	2
464	FDA Regulation and Approval of Medical Devices: 1976-2020. *JAMA - Journal of the American Medical Association*, **2021**, 326, 420-432	27.4	9

463	Barriers To US Biosimilar Market Growth: Lessons From Biosimilar Patent Litigation. *Health Affairs*, **2021**, 40, 1198-1205	7	6
462	Will Ending the Medicaid Drug Rebate Cap Lower Drug Prices?. *JAMA Internal Medicine*, **2021**, 181, 1034-1035	11.5	4
461	Market Exclusivity and Changes in Competition and Prices Associated With the US Food and Drug Administration Unapproved Drug Initiative. *JAMA Internal Medicine*, **2021**, 181, 1124-1126	11.5	1
460	Revisiting FDA Approval of Aducanumab. *New England Journal of Medicine*, **2021**, 385, 769-771	59.2	40
459	Discovery and Development of Pregabalin (Lyrica): The Role of Public Funding. *Neurology*, **2021**, 97, e1653-e1660	8.5	0
458	Analysis of Launch and Postapproval Cancer Drug Pricing, Clinical Benefit, and Policy Implications in the US and Europe. *JAMA Oncology*, **2021**, 7, e212026	13.4	14
457	A Court Decision on "Skinny Labeling": Another Challenge for Less Expensive Drugs. *JAMA - Journal of the American Medical Association*, **2021**, 326, 1371-1372	27.4	2
456	Characteristics of US Patients and Prescribers Using Hydroxychloroquine During the COVID-19 Pandemic. *Journal of General Internal Medicine*, **2021**, 36, 3918-3921	4	
455	Reimagining Pharmaceutical Market Exclusivities: Should the Duration of Guaranteed Monopoly Periods Be Value Based?. *Value in Health*, **2021**, 24, 1328-1334	3.3	3
454	Controversy Over Using Quality-Adjusted Life-Years In Cost-Effectiveness Analyses: A Systematic Literature Review. *Health Affairs*, **2021**, 40, 1402-1410	7	0
453	International reference pricing for prescription drugs: a landscape analysis. *Journal of Managed Care & Specialty Pharmacy*, **2021**, 27, 1309-1313	1.9	0
452	Regulatory and clinical consequences of negative confirmatory trials of accelerated approval cancer drugs: retrospective observational study. *BMJ, The*, **2021**, 374, n1959	5.9	13
451	Repurposing existing drugs for new uses: a cohort study of the frequency of FDA-granted new indication exclusivities since 1997. *Journal of Pharmaceutical Policy and Practice*, **2021**, 14, 3	3.2	12
450	Over-the-Counter Monograph Safety, Innovation, and Reform Act.. *Journal of Law, Medicine and Ethics*, **2021**, 49, 321-327	1.2	1
449	Raising Medicaid Rebates For Drugs With Accelerated Approval. *Health Affairs*, **2021**, 40, 1935-1942	0	1
448	A qualitative study of biosimilar manufacturer and regulator perceptions on intellectual property and abbreviated approval pathways. *Nature Biotechnology*, **2020**, 38, 1253-1256	44.5	6
447	Development of a National Public Pharmaceutical Research and Development Institute. *Journal of Law, Medicine and Ethics*, **2020**, 48, 225-227	1.2	
446	Need for Transparency and Reliable Evidence in Emergency Use Authorizations for Coronavirus Disease 2019 (COVID-19) Therapies. *JAMA Internal Medicine*, **2020**, 180, 1145-1146	11.5	11

445	Estimating The Cost Of Delayed Generic Drug Entry To Medicaid. *Health Affairs*, **2020**, 39, 1011-1017	7	2
444	Regulatory approval characteristics of antimicrobial versus non-antimicrobial products, 1984-2018: an evaluation of Food and Drug Administration flexibilities. *Lancet Infectious Diseases, The*, **2020**, 20, e159-e164	25.5	1
443	Specialty Drugs - A Distinctly American Phenomenon. *New England Journal of Medicine*, **2020**, 382, 2179-2181	59.1	6
442	False Negative Tests for SARS-CoV-2 Infection - Challenges and Implications. *New England Journal of Medicine*, **2020**, 383, e38	59.2	520
441	Evaluating the evidence behind the surrogate measures included in the FDA's table of surrogate endpoints as supporting approval of cancer drugs. *EClinicalMedicine*, **2020**, 21, 100332	11.3	33
440	Rates and Costs of Dispensing Naloxone to Patients at High Risk for Opioid Overdose in the United States, 2014-2018. *Drug Safety*, **2020**, 43, 669-675	5.1	5
439	Using real-world safety data in regulatory approval decisions: Sotagliflozin and the risk of diabetic ketoacidosis. *Pharmacoepidemiology and Drug Safety*, **2020**, 29, 1322-1324	2.6	1
438	Generating comparative evidence on new drugs and devices before approval. *Lancet, The*, **2020**, 395, 986-997	40	28
437	Decision Making Under Uncertainty: Comparing Regulatory and Health Technology Assessment Reviews of Medicines in the United States and Europe. *Clinical Pharmacology and Therapeutics*, **2020**, 108, 350-357	6.1	16
436	Lessons From The Impact Of Price Regulation On The Pricing Of Anticancer Drugs In Germany. *Health Affairs*, **2020**, 39, 1185-1193	7	12
435	Comparing Onset of Biosimilar Versus Generic Competition in the United States. *Clinical Pharmacology and Therapeutics*, **2020**, 108, 1308-1314	6.1	4
434	FDA Approval and Regulation of Pharmaceuticals, 1983-2018. *JAMA - Journal of the American Medical Association*, **2020**, 323, 164-176	27.4	104
433	Estimation of Medicare Part D Spending on Insulin for Patients With Diabetes Using Negotiated Prices and a Defined Formulary. *JAMA Internal Medicine*, **2020**, 180, 597-601	11.5	8
432	Internet Searches for Unproven COVID-19 Therapies in the United States. *JAMA Internal Medicine*, **2020**, 180, 1116-1118	11.5	53
431	Prices and clinical benefit of cancer drugs in the USA and Europe: a cost-benefit analysis. *Lancet Oncology, The*, **2020**, 21, 664-670	21.7	55
430	Using Data From Routine Care to Estimate the Effectiveness and Potential Limitations of Outcomes-Based Contracts for Diabetes Medications. *Value in Health*, **2020**, 23, 434-440	3.3	1
429	Insulin access and affordability in the USA: anticipating the first interchangeable insulin product. *Lancet Diabetes and Endocrinology,the*, **2020**, 8, 360-362	18.1	3
428	Prescribing systemic steroids for acute respiratory tract infections in United States outpatient settings: A nationwide population-based cohort study. *PLoS Medicine*, **2020**, 17, e1003058	11.6	5

427	Increasing Access to FDA Inspection Reports on Irregularities and Misconduct in Clinical Trials. *JAMA - Journal of the American Medical Association*, **2020**, 323, 1903-1904	27.4	6
426	Response Rates and Durations of Response for Biomarker-Based Cancer Drugs in Nonrandomized Versus Randomized Trials. *Journal of the National Comprehensive Cancer Network: JNCCN*, **2020**, 18, 36-43	7.3	11
425	Preferences for and experiences with pill appearance changes: national surveys of patients and pharmacists. *American Journal of Managed Care*, **2020**, 26, 340-347	2.1	0
424	Generic Competition for Drugs Treating Rare Diseases. *Journal of Law, Medicine and Ethics*, **2020**, 48, 789-795	1.2	0
423	New drug approvals in oncology. *Nature Reviews Clinical Oncology*, **2020**, 17, 140-146	19.4	12
422	US Food and Drug Administration Recommendations on the Use of Surrogate Measures as End Points in New Anti-infective Drug Approvals. *JAMA Internal Medicine*, **2020**, 180, 131-138	11.5	3
421	FDA and EMA Biosimilar Approvals. *Journal of General Internal Medicine*, **2020**, 35, 1908-1910	4	3
420	Confidentiality Orders and Public Interest in Drug and Medical Device Litigation. *JAMA Internal Medicine*, **2020**, 180, 292-299	11.5	2
419	Novelty of Active Ingredients in High-Cost Brand-Name Drugs. *Journal of General Internal Medicine*, **2020**, 35, 2219-2221	4	0
418	Potential Medicare Savings on Inhaler Prescriptions Through the Use of Negotiated Prices and a Defined Formulary. *JAMA Internal Medicine*, **2020**, 180, 454-456	11.5	3
417	Getting the Right Evidence After Drug Approval. *Frontiers in Pharmacology*, **2020**, 11, 569535	5.6	5
416	Implementing U.S. Covid-19 Testing: Regulatory and Infrastructural Challenges. *Journal of Law, Medicine and Ethics*, **2020**, 48, 606-612	1.2	1
415	Clinical Development Times for Biosimilars in the United States. *Mayo Clinic Proceedings*, **2020**, 95, 2152-2154	6.1	1
414	Association between FDA and EMA expedited approval programs and therapeutic value of new medicines: retrospective cohort study. *BMJ, The*, **2020**, 371, m3434	5.9	22
413	Projected spending for brand-name drugs in English primary care given US prices: a cross-sectional study. *Journal of the Royal Society of Medicine*, **2020**, 113, 350-359	2.3	1
412	Revisiting the National Institutes of Health Fair Pricing Condition: Promoting the Affordability of Drugs Developed With Government Support. *Annals of Internal Medicine*, **2020**, 172, 348-350	8	4
411	Clinical benefit and cost of breakthrough cancer drugs approved by the US Food and Drug Administration. *Cancer*, **2020**, 126, 4390-4399	6.4	7
410	US Spending Associated With Transition From Daily to 3-Times-Weekly Glatiramer Acetate. *JAMA Internal Medicine*, **2020**, 180, 1165-1172	11.5	4

409	Drug Prices, Rebates, and Discounts. *JAMA - Journal of the American Medical Association*, **2020**, 324, 399	27.4	4
408	Missed Opportunities on Emergency Remdesivir Use. *JAMA - Journal of the American Medical Association*, **2020**, 324, 331-332	27.4	12
407	Accounting for US public funding in drug development: how can we better balance access, affordability, and innovation?. *BMJ, The*, **2020**, 371, m3841	5.9	3
406	Understanding when real world data can be used to replicate a clinical trial: A cross-sectional study of medications approved in 2011. *Pharmacoepidemiology and Drug Safety*, **2020**, 29, 1273-1278	2.6	0
405	Regulatory Decision-making on COVID-19 Vaccines During a Public Health Emergency. *JAMA - Journal of the American Medical Association*, **2020**, 324, 1284-1285	27.4	17
404	Up Is Down - Pharmaceutical Industry Caution vs. Federal Acceleration of Covid-19 Vaccine Approval. *New England Journal of Medicine*, **2020**, 383, 1706-1708	59.2	7
403	Transferrable Market Exclusivity Extensions to Promote Antibiotic Development: An Economic Analysis. *Clinical Infectious Diseases*, **2020**, 71, 1671-1675	11.6	7
402	Incentivizing Antibiotic Development: Why Isn't the Generating Antibiotic Incentives Now (GAIN) Act Working?. *Open Forum Infectious Diseases*, **2020**, 7, ofaa001	1	10
401	The evidence landscape in precision medicine. *Science Translational Medicine*, **2020**, 12,	17.5	11
400	Prescribing systemic steroids for acute respiratory tract infections in United States outpatient settings: A nationwide population-based cohort study **2020**, 17, e1003058		
399	Prescribing systemic steroids for acute respiratory tract infections in United States outpatient settings: A nationwide population-based cohort study **2020**, 17, e1003058		
398	Prescribing systemic steroids for acute respiratory tract infections in United States outpatient settings: A nationwide population-based cohort study **2020**, 17, e1003058		
397	Prescribing systemic steroids for acute respiratory tract infections in United States outpatient settings: A nationwide population-based cohort study **2020**, 17, e1003058		
396	Prescribing systemic steroids for acute respiratory tract infections in United States outpatient settings: A nationwide population-based cohort study **2020**, 17, e1003058		
395	Promoting Pediatric Drug Research and Labeling - Outcomes of Legislation. *New England Journal of Medicine*, **2019**, 381, 875-881	59.2	11
394	Assessing the Justification, Funding, Success, and Survival Outcomes of Randomized Noninferiority Trials of Cancer Drugs: A Systematic Review and Pooled Analysis. *JAMA Network Open*, **2019**, 2, e199570	10.4	8
393	Patients' Knowledge of Key Messaging in Drug Safety Communications for Zolpidem and Eszopiclone: A National Survey. *Journal of Law, Medicine and Ethics*, **2019**, 47, 430-441	1.2	6
392	Surrogate Endpoints and Drug Regulation: What Is Needed to Clarify the Evidence. *Journal of Law, Medicine and Ethics*, **2019**, 47, 381-387	1.2	1

391	Challenges and Opportunities for Biomarker Validation. *Journal of Law, Medicine and Ethics*, **2019**, 47, 357-361	1.2	7
390	Implementation of a Health Plan Program for Switching From Analogue to Human Insulin and Glycemic Control Among Medicare Beneficiaries With Type 2 Diabetes. *JAMA - Journal of the American Medical Association*, **2019**, 321, 374-384	27.4	18
389	Tepid Steps on Drug Pricing. *JAMA Internal Medicine*, **2019**, 179, 439-441	11.5	4
388	Physicians' Perspectives on FDA Approval Standards and Off-label Drug Marketing. *JAMA Internal Medicine*, **2019**, 179, 707-709	11.5	11
387	Pre-market development times for biologic versus small-molecule drugs. *Nature Biotechnology*, **2019**, 37, 708-711	44.5	16
386	Characteristics of trials and regulatory pathways leading to US approval of innovative vs. non-innovative oncology drugs. *Health Policy*, **2019**, 123, 721-727	3.2	3
385	Assessment of the Clinical Benefit of Cancer Drugs Receiving Accelerated Approval. *JAMA Internal Medicine*, **2019**, 179, 906-913	11.5	114
384	Changes in Price for Generic Drugs in the USA, 2008-2016. *Journal of General Internal Medicine*, **2019**, 34, 1677-1679	4	6
383	Approximating Future Generic Entry for New Drugs. *Journal of Law, Medicine and Ethics*, **2019**, 47, 177-182	1.2	1
382	Pharmaceutical Protections in U.S. Trade Deals - What Do Americans Get in Return?. *New England Journal of Medicine*, **2019**, 380, 1993-1995	59.2	2
381	Experiences With and Challenges Afforded by Expedited Regulatory Pathways. *Clinical Pharmacology and Therapeutics*, **2019**, 105, 795-797	6.1	4
380	New Drug Formulations and Their Respective Generic Entry Dates. *Journal of Managed Care & Specialty Pharmacy*, **2019**, 25, 218-224	1.9	4
379	US Food and Drug Administration Approval of New Drugs Based on Noninferiority Trials in Oncology: A Dangerous Precedent?. *JAMA Oncology*, **2019**, 5, 607-608	13.4	6
378	Comparative effectiveness of generic and brand-name medication use: A database study of US health insurance claims. *PLoS Medicine*, **2019**, 16, e1002763	11.6	26
377	Assessment of the Role of Niacin in Managing Cardiovascular Disease Outcomes: A Systematic Review and Meta-analysis. *JAMA Network Open*, **2019**, 2, e192224	10.4	25
376	Effect of Lawyer-Submitted Reports on Signals of Disproportional Reporting in the Food and Drug Administration's Adverse Event Reporting System. *Drug Safety*, **2019**, 42, 85-93	5.1	3
375	Patent term restoration for top-selling drugs in the United States. *Drug Discovery Today*, **2019**, 24, 20-25	8.8	10
374	The Generic Drug Industry Embraces a Faster, Cheaper Pathway for Challenging Patents. *Applied Health Economics and Health Policy*, **2019**, 17, 47-54	3.4	7

373	Why Are Biosimilars Not Living up to Their Promise in the US?. *AMA Journal of Ethics*, **2019**, 21, E668-678	1.4	28
372	Landscape of Cardiovascular Device Registries in the United States. *Journal of the American Heart Association*, **2019**, 8, e012756	6	3
371	Potential Medicare Savings From Generic Substitution and Therapeutic Interchange of ACE Inhibitors and Angiotensin-II-Receptor Blockers. *JAMA Internal Medicine*, **2019**, 179, 1712-1714	11.5	5
370	Impact of State Laws Restricting Opioid Duration on Characteristics of New Opioid Prescriptions. *Journal of General Internal Medicine*, **2019**, 34, 2339-2341	4	13
369	Orphan Drug Designation and Exclusivity for "Same Drugs". *Journal of Law, Medicine and Ethics*, **2019**, 47, 347-349	1.2	0
368	Price Increases of Protected-Class Drugs in Medicare Part D, Relative to Inflation, 2012-2017. *JAMA - Journal of the American Medical Association*, **2019**, 322, 267-269	27.4	8
367	Multimodal Analysis of FDA Drug Safety Communications: Lessons from Zolpidem. *Drug Safety*, **2019**, 42, 1287-1295	5.1	10
366	Reforming the Orphan Drug Act for the 21st Century. *New England Journal of Medicine*, **2019**, 381, 106-108	59.2	19
365	Public Approval of Exception From Informed Consent in Emergency Clinical Trials: A Systematic Review of Community Consultation Surveys. *JAMA Network Open*, **2019**, 2, e197591	10.4	9
364	Competition and price among brand-name drugs in the same class: A systematic review of the evidence. *PLoS Medicine*, **2019**, 16, e1002872	11.6	21
363	The Impact Of Price Regulation On The Availability Of New Drugs In Germany. *Health Affairs*, **2019**, 38, 1182-1187	7	10
362	Characteristics of Recent Generic Drug Approvals by the US Food and Drug Administration. *JAMA Network Open*, **2019**, 2, e1913029	10.4	1
361	Transparency on Prescription Drug Research Expenditures **2019**, 121-131		
360	Physician Perceptions of Step Therapy Prescribing Requirements. *Journal of Managed Care & Specialty Pharmacy*, **2019**, 25, 1210-1224	1.9	2
359	Prescription Opioid Epidemic and Trends in the Clinical Development of New Pain Medications. *Mayo Clinic Proceedings*, **2019**, 94, 2437-2443	6.4	2
358	Randomized Study of Providing Evidence Context to Mitigate Physician Misinterpretation Arising From Off-Label Drug Promotion. *Circulation: Cardiovascular Quality and Outcomes*, **2019**, 12, e006073	5.8	2
357	The U.S. Insulin Crisis - Rationing a Lifesaving Medication Discovered in the 1920s. *New England Journal of Medicine*, **2019**, 381, 1793-1795	59.2	30
356	Pharmacoepidemiology and the Law **2019**, 140-163		

355	Public sector financial support for late stage discovery of new drugs in the United States: cohort study. *BMJ, The*, **2019**, 367, l5766	5.9	17
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