Jonathan Darrow

List of Publications by Year
in descending order

60 papers	1,547 citations	430874 18 h-index	315739 38 g-index
60 all docs	60 docs citations	60 times ranked	1488 citing authors

#	Article	IF	Citations
1	FDA Approval and Regulation of Pharmaceuticals, 1983-2018. JAMA - Journal of the American Medical Association, 2020, 323, 164.	7.4	197
2	Trends in utilization of FDA expedited drug development and approval programs, 1987-2014: cohort study. BMJ, The, 2015, 351, h4633.	6.0	143
3	Luxturna: FDA documents reveal the value of a costly gene therapy. Drug Discovery Today, 2019, 24, 949-954.	6.4	133
4	Practical, Legal, and Ethical Issues in Expanded Access to Investigational Drugs. New England Journal of Medicine, 2015, 372, 279-286.	27.0	125
5	Institutional Corruption of Pharmaceuticals and the Myth of Safe and Effective Drugs. Journal of Law, Medicine and Ethics, 2013, 41, 590-600.	0.9	112
6	New FDA Breakthrough-Drug Category â€" Implications for Patients. New England Journal of Medicine, 2014, 370, 1252-1258.	27.0	102
7	Efficacy, Safety, and Regulatory Approval of Food and Drug Administrationâ€"Designated Breakthrough and Nonbreakthrough Cancer Medicines. Journal of Clinical Oncology, 2018, 36, 1805-1812.	1.6	72
8	The FDAâ€™s Expedited Programs and Clinical Development Times for Novel Therapeutics, 2012-2016. JAMA - Journal of the American Medical Association, 2017, 318, 2137.	7.4	62
9	FDA Regulation and Approval of Medical Devices: 1976-2020. JAMA - Journal of the American Medical Association, 2021, 326, 420.	7.4	53
10	Designing development programs for non-traditional antibacterial agents. Nature Communications, 2019, 10, 3416.	12.8	46
11	The FDA Breakthrough-Drug Designation â€" Four Years of Experience. New England Journal of Medicine, 2018, 378, 1444-1453.	27.0	44
12	The <scp>US</scp> Biosimilar Market: Stunted Growth and Possible Reforms. Clinical Pharmacology and Therapeutics, 2019, 105, 92-100.	4.7	41
13	Drug Development and FDA Approval, 1938â€"2013. New England Journal of Medicine, 2014, 370, e39.	27.0	39
14	FDA Designations for Therapeutics and Their Impact on Drug Development and Regulatory Review Outcomes. Clinical Pharmacology and Therapeutics, 2015, 97, 29-36.	4.7	36
15	Speed, Safety, and Industry Funding â€" From PDUFA I to PDUFA VI. New England Journal of Medicine, 2017, 377, 2278-2286.	27.0	31
16	Precision Medicines Have Faster Approvals Based On Fewer And Smaller Trials Than Other Medicines. Health Affairs, 2018, 37, 724-731.	5.2	27
17	An Overview Of Vaccine Development, Approval, And Regulation, With Implications For COVID-19. Health Affairs, 2021, 40, 25-32.	5.2	27
18	A Method for Approximating Future Entry of Generic Drugs. Value in Health, 2018, 21, 1382-1389.	0.3	21

#	Article	IF	Citations
19	Efficacy and costs of spinal muscular atrophy drugs. Science Translational Medicine, 2020, 12, .	12.4	19
20	Incentivizing Antibiotic Development: Why Isnâ€™t the Generating Antibiotic Incentives Now (GAIN) Act Working?. Open Forum Infectious Diseases, 2020, 7, ofaa001.	0.9	19
21	Patent term restoration for top-selling drugs in the United States. Drug Discovery Today, 2019, 24, 20-25.	6.4	18
22	Existing FDA Pathways Have Potential To Ensure Early Access To, And Appropriate Use Of, Specialty Drugs. Health Affairs, 2014, 33, 1770-1778.	5.2	13
23	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.	4.7	11
24	Analysis of Supportive Evidence for US Food and Drug Administration Approvals of Novel Drugs in 2020. JAMA Network Open, 2022, 5, e2212454.	5.9	11
25	Generating Evidence from Expanded Access Use of Rare Disease Medicines: Challenges and Recommendations. Frontiers in Pharmacology, 0, 13, .	3.5	11
26	The Generic Drug Industry Embraces a Faster, Cheaper Pathway for Challenging Patents. Applied Health Economics and Health Policy, 2019, 17, 47-54.	2.1	10
27	Changing FDA Approval Standards: Ethical Implications for Patient Consent. Journal of General Internal Medicine, 2021, 36, 3212-3214.	2.6	10
28	New FDA Breakthrough-Drug Category â€” Implications for Patients. New England Journal of Medicine, 2014, 371, 87-90.	27.0	9
29	A New Approach to Treat Childhood Leukemia: Novartis' CAR-T Therapy. Journal of Law, Medicine and Ethics, 2017, 45, 692-697.	0.9	8
30	Regulation of Drugs for Early Alzheimer's Disease. New England Journal of Medicine, 2013, 369, 288-288.	27.0	7
31	Will inter partes review speed US generic drug entry?. Nature Biotechnology, 2017, 35, 1139-1141.	17.5	7
32	Pharmaceutical Advertising in Medical Journals. Chest, 2018, 153, 9-11.	0.8	7
33	Comparing Onset of Biosimilar Versus Generic Competition in the United States. Clinical Pharmacology and Therapeutics, 2020, 108, 1308-1314.	4.7	7
34	New Drug Postmarketing Requirements and Commitments in the US: A Systematic Review of the Evidence. Drug Safety, 2022, 45, 305-318.	3.2	7
35	Few new drugs deserve expedited regulatory treatment. Journal of Managed Care & Specialty Pharmacy, 2021, 27, 685-688.	0.9	6
36	Beyond The High Prices Of Prescription Drugs: A Framework To Assess Costs, Resource Allocation, And Public Funding. Health Affairs, 2021, 40, 281-288.	5.2	5

#	Article	IF	Citations
37	Integrating New Effectiveness Data Into US Food and Drug Administrationâ€“Approved Drug Labeling. JAMA Internal Medicine, 2021, 181, 897-898.	5.1	5
38	The timing of 30â€month stay expirations and generic entry: A cohort study of first generics, 2013â€“2020. Clinical and Translational Science, 2021, 14, 1917-1923.	3.1	5
39	A New Wave of Vaccines for Non-Communicable Diseases: What Are the Regulatory Challenges?. Food and Drug Law Journal, 2015, 70, 243-58, i.	0.4	5
40	Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?. Yale Journal of Health Policy, Law, and Ethics, 2015, 15, 293-347.	1.5	5
41	An export-only exception to pharmaceutical patents in Europe: should the United States follow suit?. Nature Biotechnology, 2019, 37, 21-22.	17.5	4
42	Incremental benefits of novel pharmaceuticals in the UK: a cross-sectional analysis of NICE technology appraisals from 2010 to 2020. BMJ Open, 2022, 12, e058279.	1.9	4
43	Expanded Access to Investigational Drugs. New England Journal of Medicine, 2015, 372, 1473-1474.	27.0	3
44	Approximating Future Generic Entry for New Drugs. Journal of Law, Medicine and Ethics, 2019, 47, 177-182.	0.9	3
45	Regulatory approval characteristics of antimicrobial versus non-antimicrobial products, 1984â€“2018: an evaluation of Food and Drug Administration flexibilities. Lancet Infectious Diseases, The, 2020, 20, e159-e164.	9.1	3
46	Recent Developments in Health Law. Journal of Law, Medicine and Ethics, 2011, 39, 291-300.	0.9	2
47	The Regulatory Accountability Act of 2017 â€" Implications for FDA Regulation and Public Health. New England Journal of Medicine, 2018, 378, 412-414.	27.0	2
48	Understanding when real world data can be used to replicate a clinical trial: A crossâ€sectional study of medications approved in 2011. Pharmacoepidemiology and Drug Safety, 2020, 29, 1273-1278.	1.9	2
49	Government Pharmaceutical Development to Address High Prices: Challenges Ahead. Therapeutic Innovation and Regulatory Science, 2021, 55, 1103-1105.	1.6	2
50	Strategies to Manage Drugs and Devices Approved Based on Limited Evidence: Results of a Modified Delphi Panel. Clinical Pharmacology and Therapeutics, 2022, 111, 1307-1314.	4.7	2
51	The Perils of Increasing Medicaid Rebates for Drugs With Accelerated Approval. JAMA Health Forum, 2021, 2, e213184.	2.2	1
52	Two views of cancer medicines: Imagery versus evidence. Health Marketing Quarterly, 2023, 40, 141-152.	1.0	1
53	Expertsâ€™ Views on FDA Regulatory Standards for Drug and High-Risk Medical Devices: Implications for Patient Care. Journal of General Internal Medicine, 2022, , 1.	2.6	1
54	Recent Orange and Purple Book legislation suggests a need to bridge drug and biologic patent regimes. Nature Biotechnology, 2022, 40, 167-169.	17.5	1

#	Article	IF	Citations
55	Safeguarding evidence-based decision making in the FDA for COVID-19 vaccines. Vaccine, 2021, 39, 2328-2330.	3.8	0
56	Commentary: Expedited Regulatory Review of Low-Value Drugs. Healthcare Policy, 2020, 15, 35-40.	0.6	0
57	Evidence Supporting the Value of Surgical Procedures: Can We Do Better?. American Surgeon, 2021, 87, 1352-1355.	0.8	0
58	Simplify drug labelling to show benefits clearly. Nature, 2021, 599, 181-181.	27.8	0
59	An exploration of compulsory licensing as an effective policy tool for antiretroviral drugs in India. Health Matrix, 2013, 23, 425-57.	1.5	0
60	Government Patent Use to Promote Public Health in the United States: Overcoming Nonpatent Exclusivities. American Journal of Public Health, 2022, 112, 1110-1114.	2.7	0