
Getz KA. Q&A with Jean Burns: Insights from a study volunteer. *Applied Clinical Trials Online.* Online publish date: May 28, 2014. [RS 3422]  

Lamberti MJ, Getz KA, Naik P, Costello M. Clinical supply capabilities, practices, and perceptions among investigative sites. *Applied Clinical Trials Online.* Online publish date: May 12, 2014. [RS 3421]  

http://www.mdpi.com/1660-4601/11/5/5069

http://dx.doi.org/10.1002/9781118783344.ch1

[RS 3418]  

http://dx.doi.org/10.1038/nrd4325

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http://dx.doi.org/10.4155/cli.13.134

DiMasi JA, Kim J, Getz KA. The impact of collaborative and risk-sharing innovation approaches on clinical and regulatory cycle times. *Therapeutic Innovation & Regulatory Science*. 2014; Published online before print February 5, 2014. [RS 3404]  
http://dx.doi.org/10.1177/2168479014521419


http://dx.doi.org/10.3402/jmahp.v2.23513


http://dx.doi.org/10.1371/journal.pone.0084088

http://dx.doi.org/10.1038/clpt.2013.177

http://cognoscenti.wbur.org/2013/12/18/series-prescription-drug-pipeline-sidney-wolfe-kenneth-kaitin

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http://www.appliedclinicaltrialsonline.com/appliedclinicaltrials/article/articleDetail.jsp?id=828039


http://dx.doi.org/10.1038/clpt.2013.155


http://dx.doi.org/10.1586/17512433.2013.841539

Getz KA. Leveraging pharmacists as a channel to raise clinical research literacy among patient communities. *Applied Clinical Trials*. 2013;22(10):30-33. [RS 3337]

http://www.appliedclinicaltrialsonline.com/appliedclinicaltrials/Articles/Leveraging-Pharmacists-as-a-Channel-to-Raise-ClinicalArticleStandard/Article/detail/825673


http://www.scripintelligence.com/home/Flexible-global-more-adaptive-clinical-trials-2.0-346528


http://dx.doi.org/10.1038/clpt.2013.129


http://www.appliedclinicaltrialsonline.com/appliedclinicaltrials/Articles/Lifting-Up-a-Fragmented-Study-Conduct-Landscape/ArticleStandard/Article/detail/820680


http://dx.doi.org/10.1517/21678707.2013.819289

http://dx.doi.org/10.1038/clpt.2013.117


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Getz KA. Building clinical trial awareness for patients: why not try the pharmacist? *Pharmaceutical Executive*. Published March 1, 2013 [web document] [RS 3315]

Cohen JP. Think twice about how we let overseas use of Plan B guide us [letter to the editor]. *The Boston Globe*. April 21, 2013:K8. [RS 3314]


Cohen JP, Malins A, Shahpurwala Z. Compared to US practice, evidence-based reviews in Europe appear to lead to lower prices for some drugs. *Health Affairs*. 2013;32:762-770 [RS 3312]
http://content.healthaffairs.org/content/32/4/762.abstract


http://www.sciencedirect.com/science/article/pii/S1551714413000153#

http://dij.sagepub.com/content/47/3/336


**This publication is for sale at our website  [http://csdd.tufts.edu/reports](http://csdd.tufts.edu/reports)**
Getz KA, Stergiopoulos S, Marlborough M, Whitehill J, Curran M, Kaitin, KI. Quantifying the magnitude and cost of collecting extraneous protocol data. *American Journal of Therapeutics*. 2013. [Published Ahead-of-Print; Last Updated: April 9, 2013] [RS 3307]
http://dx.doi.org/10.1097/MJT.0b013e31826fc4aa


Kaitin KI, editor. 89% of trials meet enrollment, but timelines slip, half of sites under-enroll. *Tufts Center for the Study of Drug Development Impact Report*. 2013 Jan/Feb;15(1)** [RS 3302]

http://dij.sagepub.com/content/47/1/101.full.pdf


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http://www.annallergy.org/article/S1081-1206(12)00939-8/fulltext

http://dx.doi.org/10.1634/theoncologist.2012-0235


http://link.springer.com/article/10.1007%2Fs12031-012-9803-8


Getz KA, Stergiopoulos S, Kaitin KI. Evaluating the completeness and accuracy of MedWatch data. *American Journal of Therapeutics.* 2012. [Published Ahead-of-Print; Last Updated: January 24, 2013] [RS 3232]
http://dx.doi.org/10.1097/MJT.0b013e318262316f

http://www.topra.org/regulatory-rapporteur-oct-2012

**This publication is for sale at our website  [http://csdd.tufts.edu/reports](http://csdd.tufts.edu/reports)**


Kaitin KI. Translational research and the evolving landscape for biomedical innovation. *Journal of Investigative Medicine*. 2012;60(7):995-998; doi:10.231/JIM.0b013e318268694f [RS 3228]

http://journals.lww.com/jinvestigativemed/Abstract/2012/10000/Translational_Research_and_the_Evolving_Landscape.5.aspx


http://www.expert-reviews.com/toc/erp/12/3


http://dij.sagepub.com/content/46/5/573


http://www.nature.com/clpt/journal/vaop/ncurrent/full/clpt201287a.html

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http://www.pharmafocusasia.com/research_development/


http://www.appliedclinicaltrialsonline.com/appliedclinicaltrials/Feature+Article/Outsourcing-Landscape/ArticleStandard/Article/detail/772232


http://www.landesbioscience.com/journals/mabs/ReichertMABS4-3.pdf


http://www.pharmtech.com/pharmtech/article/articleDetail.jsp?id=763940&sk=&date=&pageID=1

http://jme.bmj.com/content/early/2012/03/01/medethics-2011-100411/reply#medethics_el_3952

http://dx.doi.org/10.1016/j.nbt.2012.02.001

http://www.landesbioscience.com/journals/mabs/article/18812/


Getz KA. Profound changes in the outsourcing landscape. Pharmaceutical Executive. Published February 29, 2012. [web document] [RS 3206]

http://dx.doi.org/10.1038/nrd3677

**This publication is for sale at our website http://csdd.tufts.edu/reports**
http://dx.doi.org/10.1038/clpt.2011.338


Kaitin KI. Creating innovation nodes to meet unmet medical needs. *Pharmaceutical Technology*. 2011;35(12):27 [RS 3132]

Getz KA. Transforming legacy R&D through open innovation. *ACRP Monitor*. 2011;25(7):17-21 [RS 3131b]


**This publication is for sale at our website  http://csdd.tufts.edu/reports**


http://dx.doi.org/10.1038/tpj.2011.63

http://www.sciencedirect.com/science/journal/10983015/14/6

Reichert JM. Therapeutic fc-fusion proteins and peptides as successful alternatives to antibodies. *MAbs*. 2011;3(5):415-416; doi:10.4161/mabs.3.5.17334 [RS 3126c]
http://www.landesbioscience.com/journals/17/article/17334/ 

http://www.biopharminternational.com/biopharm/Final+Word/The-Case-for-Pediatric-Exclusivity/ArticleStandard/Article/detail/750858

Milne C-P. The case for pediatric exclusivity. *Pharmaceutical Technology*. 2011;35(9):38 [RS 3126]
http://pharmtech.findpharma.com/pharmtech/Drug+Delivery/The-Case-for-Pediatric-Exclusivity/ArticleStandard/Article/detail/738366

http://www.expert-reviews.com/doi/pdf/10.1586/ecp.11.45


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http://www.scientificamerican.com/article.cfm?id=a-dearth-of-new-meds&print=true

http://www.landesbioscience.com/journals/mabs/article/16589/


http://appliedclinicaltrialsonline.findpharma.com/appliedclinicaltrials/article/articleDetail.jsp?id=730576

Kaitin KI. 21st Century innovation: academic-industry partnerships are increasingly important in biopharmaceutical innovation. *Pharmaceutical Technology*. 2011;35(6):32 [RS 3119]
http://pharmtech.findpharma.com/pharmtech/article/articleDetail.jsp?id=724982&sk=&date=&&pageID=1

http://www.emaud.org/Doc/Market_Access_Newsletter_EMAUD_June%202011.pdf


http://www.landesbioscience.com/journals/17/article/15625/

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http://www.futuremedicine.com/action/doSearch?target=article&journal=pme&searchText=cohen+joshua&filter=single&x=25&y=10


http://appliedclinicaltrialsonline.findpharma.com/appliedclinicaltrials/article/articleDetail.jsp?id=719542&sk=9270beba3a37ef7e37f3fa5477eea1cf9%22


Kaitin KI, editor. New or modified indications for existing drugs have steadily increased in the U.S. *Tufts Center for the Study of Drug Development Impact Report*. 2011 Mar/Apr;13(2)** [RS 3111]

http://www.landesbioscience.com/journals/mabs/article/14788/

http://dij.sagepub.com/content/45/2/119.full.pdf+html

Getz KA. Low hanging fruit in the fight against inefficiency. *Applied Clinical Trials*. 2011;20(3):30-32 [RS 3109]
http://appliedclinicaltrialsonline.findpharma.com/appliedclinicaltrials/Articles/Low-Hanging-Fruit-in-the-Fight-Against-Inefficiency/ArticleStandard/Article/detail/711311?contextCategoryId=37194

http://www.nature.com/clpt/journal/v89/n2/full/clpt2010286a.html

**This publication is for sale at our website  http://csdd.tufts.edu/reports**

Getz KA. The ultimate act of appreciation of study volunteers. *Focus*. 2011;3:8-12 [RS 3106b]

http://www.landesbioscience.com/journals/mabs/article/13895/


http://www.nature.com/nrd/journal/v10/n1/full/nrd3296.html


http://www.appliedclinicaltrialsonline.com/appliedclinicaltrials/article/articleDetail.jsp?id=703033&sk=&date=&pageID=2


http://www.landesbioscience.com/journals/mabs/article/13603/

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http://www.nature.com/clpt/journal/v88/n5/full/clpt2010167a.html

http://www.nature.com/nbt/journal/v28/n11/full/nbt1110-1160.html

Getz KA. Hurry up and wait, pharma puts the brakes on strategic outsourcing partnering. Inside Outsourcing. 2010 Nov;10-16 [RS 3026b]
http://www.nxtbook.com/nxtbooks/advanstar/insideoutsourcing_201011/#/12

http://license.icopyright.net/rights/offer.act?inprocess=t&sid=13&tag=3.7442%3Dxicx_id%3D693552


Getz KA. Providing results to volunteers. Applied Clinical Trials. 2010;19(10):52-59 [RS 3023b]

Getz KA. Ominous clouds over outsourcing. Applied Clinical Trials. 2010;19(9):28-30 [RS 3023]
http://license.icopyright.net/rights/tag.act?tag=3.7442%3Ficx_id=686210

http://www.nature.com/nrd/journal/v9/n10/full/nrd3229.html

RS 3021 Vernon JA, Golec JH, DiMasi JA. Drug development costs when financial risk is measured using the Fama-French three-factor model. Health Economics. 2010;19(8):1002-1005

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http://www.appliedclinicaltrialsonline.com/appliedclinicaltrials/article/articleDetail.jsp?id=673673&sk=&date=&pageID=3


RS 3016d  Getz KA. Engaging pharmacists in research education. *Applied Clinical Trials*. 2010;19(7)30-32
http://www.appliedclinicaltrialsonline.com/appliedclinicaltrials/article/articleDetail.jsp?id=678141

http://www.nature.com/clpt/journal/v88/n1/full/clpt201086a.html

http://www.landesbioscience.com/journals/mabs/article/12369/

http://jnci.oxfordjournals.org/cgi/reprint/djq246


http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0010610

**This publication is for sale at our website  http://csdd.tufts.edu/reports**

RS 3012  Getz K. FIPNet: Pharma’s new, sexy, but not yet ready for print-time model. *Applied Clinical Trials.* 2009;Suppl:10-12,14,16


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http://www.landebioscience.com/journals/17/article/11320/

http://journals.lww.com/americantherapeutics/Abstract/2010/01000/Private_Sector_Consortiums_to_Pharma.22.aspx


http://www.nature.com/clpt/journal/v87/n3/full/clpt2009293a.html

http://www.nature.com/clpt/journal/v87/n3/full/clpt2009295a.html

http://www.landebioscience.com/journals/mabs/article/10628/?nycache=503631611

https://www.landebioscience.com/journals/mabs/article/10786/


**This publication is for sale at our website  http://csdd.tufts.edu/reports
RS 2934  Getz KA  Vogel JR.  Successful outsourcing: tracking global CRO usage.  
Applied Clinical Trials Online.  2009 Aug 17

RS 2933  Milne C-P.  Can translational medicine bring us out of the R&D wilderness?  
Personalized Medicine.  2009;6(5):543-553

RS 2932  Getz KA.  Is an investigative site shake-out imminent?  Applied Clinical Trials.  


RS 2930  Getz KA.  Assessing the downstream impact of protocol design complexity.  
Touch Briefings.  2009:93-5


RS 2924  Kaitin KI, editor.  Drug approvals for neglected diseases increased along with more R&D funding.  Tufts Center for the Study of Drug Development Impact Report.  2009 Nov/Dec;11(6)**

**This publication is for sale at our website  http://csdd.tufts.edu/reports
http://www.landesbioscience.com/journals/mabs/article/10059/?nocache=1260067508


RS2921b Getz KA. Into the aftermath of M&A. *Applied Clinical Trials.* 2009;18(9)


http://www.es.landesbioscience.com/journals/mabs/article/9675/

http://www.landesbioscience.com/journals/mabs/article/9031/


**This publication is for sale at our website  http://csdd.tufts.edu/reports**
http://www.nxtbook.com/nxtbooks/dia/druginformationjournal0709/##118


doi:org/10.4161/mabs.1.4.9076  
http://kelly-landes.org/journals/17/article/9076/


http://www.landesbioscience.com/journals/mabs/article/7645/


doi:org/10.4161/mabs.1.3.8590  
http://www.landesbioscience.com/journals/mabs/article/8590/


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RS 2903b  Cohen J  Wilson A. New challenges to Medicare beneficiary access to mAbs.  MAbs.  2009 Jan/Feb;1(1):1-11


RS2833b  Getz KA. Should physicians enroll their own patients into clinical trials?  ACRP Monitor.  2008 Dec;22(7):34-38


RS 2831  Milne C-P  Bruss JB. The economics of pediatric formulation development for off-patent drugs.  Clinical Therapeutics.  2008;30(11):2133-45

**This publication is for sale at our website  http://csdd.tufts.edu/reports


RS 2827  Kaitin KI, editor. Fast track designations more than doubled during the last five years.  Tufts Center for the Study of Drug Development Impact Report. 2008 Sep/Oct;10(5)**


RS 2826  Getz KA.  Restoring public confidence in clinical research.  ACRP Monitor. 2008 Sep;22(5):59-62


RS 2825  Getz KA.  Public confidence and trust today.  ACRP Monitor. 2008 Sep;22(5):17-21


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http://www.contractpharma.com/articles/2008/06/clinical-research-outsourcing

http://www.manhattan-institute.org/html/mpr_06.htm


RS 2815 Getz KA. Beyond outsourcing (interview by Jenefer Trevena). *Scrip Supplement Contract Research Update*. 2008;Apr;4:5-6

**This publication is for sale at our website [http://csd.tufts.edu/reports](http://csd.tufts.edu/reports)**


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http://journals.lww.com/americantherapeutics/Citation/2008/01000/Follow_On_Drugs_and_Indications__The_Importance_of.15.aspx


RS 2802 Kaitin KI. Obstacles and opportunities in new drug development. *Clinical Pharmacology & Therapeutics.* 2008;83(2):210-2
http://www.nature.com/clpt/journal/v83/n2/full/6100462a.html


RS 2729 Getz KA. In search of informed consent improvement. *Applied Clinical Trials.* 2007;16(11):42-45
http://www.actmagazine.com/appliedclinicaltrials/Clinical+Trial+Insights/In-Search-of-Informed-Consent-Improvement/ArticleStandard/Article/detail/468090

RS 2728 DiMasi JA, Grabowski HG. Should the patent system for new medicines be abolished? *Clinical Pharmacology & Therapeutics.* 2007;82(5):488-90
http://www.nature.com/clpt/journal/v82/n5/full/6100393a.html

RS 2727 Cohen JP. CEA is not a price control (letter). *Health Affairs.* 2007;26(5):1505
http://content.healthaffairs.org/cgi/reprint/26/5/1505


**This publication is for sale at our website  http://csdd.tufts.edu/reports**
RS 2723  Getz KA. Global clinical trials activity in the details. *Applied Clinical Trials.* 2007;16(9):42-44


RS 2721  Kaitin KI, editor. Despite more cancer drugs in R&D, overall U.S. approval rate is 8%. *Tufts Center for the Study of Drug Development Impact Report.* 2007 Sep/Oct;9(5)**

http://www.springerlink.com/content/f03333rv1823w611/fulltext.pdf


RS 2717  Getz KA. CRA: jack of all trades. *Applied Clinical Trials.* 2007;16(7):36-38
http://www.actmagazine.com/appliedclinicaltrials/article/articleDetail.jsp?id=439804


RS 2714  Getz KA. CRO shifts in the outsourcing market. *Applied Clinical Trials.* 2007;16(5):35-38
http://www.actmagazine.com/appliedclinicaltrials/article/articleDetail.jsp?id=424918


**This publication is for sale at our website  [http://csdd.tufts.edu/reports](http://csdd.tufts.edu/reports)**

http://www.actmagazine.com/appliedclinicaltrials/article/articleDetail.jsp?id=416536

RS 2710 Getz KA, Sergeant E, Kremidas J. Mission possible: rebranding clinical research. *Applied Clinical Trials.* 2007;16(4):35-6,8
http://www.actmagazine.com/appliedclinicaltrials/article/articleDetail.jsp?id=416537

http://www.jstor.org/pss/30033224

RS 2708 Getz K, Wenger J. High times for the CRO heavyweights. *Scrip supplements.* 2007 Mar;5-6


RS 2704 Getz KA. Drowning in the sea of regulatory compliance. *Applied Clinical Trials.* 2007;16(2):32-34
http://www.actmagazine.com/appliedclinicaltrials/article/articleDetail.jsp?id=401621


**This publication is for sale at our website  http://csdd.tufts.edu/reports**


http://www.actmagazine.com/appliedclinicaltrials/article/articleDetail.jsp?id=392454

http://classic.the-scientist.com/2006/12/1/49/1/

Cohen J Cairns C Paquette C Faden L. Comparing patient access to pharmaceuticals in the UK and US. *Applied Health Economics and Health Policy*. 2006;5(3):177-87


http://www.actmagazine.com/appliedclinicaltrials/article/articleDetail.jsp?id=382875


Getz KA. Spotting the 'new' managed site networks. *Applied Clinical Trials*. 2006;15(9):34-36
http://www.actmagazine.com/appliedclinicaltrials/article/articleDetail.jsp?id=370345

**This publication is for sale at our website  [http://csdd.tufts.edu/reports](http://csdd.tufts.edu/reports)**


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http://content.healthaffairs.org/cgi/eletters/25/2/461


**This publication is for sale at our website  http://csdd.tufts.edu/reports**


RS 2606  Getz KA. Forgotten voices in the transparency debate: online trial registries alone will not succeed at rebuilding public confidence. *Applied Clinical Trials.* 2006;15(4):42-44  


RS 2603  Kaitin KI, editor. CRO contribution to drug development is substantial and growing globally. *Tufts Center for the Study of Drug Development Impact Report.* 2006 Jan/Feb;8(1)**


RS 2601  Getz KA. The imperative to support site adoption of EDC. *Applied Clinical Trials.* 2006;15(1):38-40  


RS 2517  Getz KA. Have we pushed our PIs too far? *Applied Clinical Trials.* 2005;14(9):34-36  

**This publication is for sale at our website  [http://csdd.tufts.edu/reports](http://csdd.tufts.edu/reports)**
http://www.actmagazine.com/appliedclinicaltrials/article/articleDetail.jsp?id=172272

RS 2515  Milne C-P Kaitin KI. Down the critical path: who should lead? *Applied Clinical Trials.* 2005;14(8):56  
http://www.actmagazine.com/appliedclinicaltrials/article/articleDetail.jsp?id=172279


RS 2513  Sugarman J Getz K Speckman JL Byrne MM Gerson J Emanuel EJ  

RS 2512  DiMasi JA Hansen RW Grabowski HG. Reply: setting the record straight on setting the record straight: response to the Light and Warburton rejoinder. *Journal of Health Economics* 2005 Sep;24(5):1049-53


RS 2510  Kaitin KI, editor. Longer clinical times are extending time to market for new drugs in U.S. *Tufts Center for the Study of Drug Development Impact Report.* 2005 Nov/Dec;7(6)**

RS 2509  Reichert JM Rosensweig CJ Faden LB Dewitz MC. Monoclonal antibody successes in the clinic. *Nature Biotechnology* 2005;23(9):1073-8  


http://www.actmagazine.com/appliedclinicaltrials/article/articleDetail.jsp?id=149965


**This publication is for sale at our website  http://csdd.tufts.edu/reports**
http://appliedclinicaltrialsonline.findpharma.com/appliedclinicaltrials/article/articleDetail.jsp?id=166546


RS 2423 Milne C-P. Harbingers, or harvesters of change? *European Pharmaceutical Review Supplement (Outsourcing).* 2004 Winter:12-17


Kaitin KI. Concluding remarks:95-6

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RS 2312 Kaitin KI, editor. Switching drugs from prescription to OTC status on rise in U.S. and EU. *Tufts Center for the Study of Drug Development Impact Report.* 2003 Sep/Oct;5(5)**


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RS 2301  Kaitin KI, editor. Increased pressure on drug industry is leading to greater focus on Japan. *Tufts Center for the Study of Drug Development Impact Report*. 2003 Jan/Feb;5(1)**


RS 2218  Kaitin KI, editor. Approval times for new drugs fell by more than a year during PDUFA. *Tufts Center for the Study of Drug Development Impact Report*. 2002 Nov/Dec;4(6)**

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RS 2203  Reichert JM. Therapeutic monoclonal antibodies: trends in development and approval in the US. *Current Opinion in Molecular Therapeutics*. 2002;4(2):110-8


RS 2123  Kaitin KI. El papel de la investigación básica. [editorial]. (Original title: The quest for cures -- the role of the research-based drug industry) *La Vanguardia* (Barcelona). 2001 18 Mar*


**This publication is for sale at our website  [http://csdd.tufts.edu/reports](http://csdd.tufts.edu/reports)**
RS 2118b  Cohen J. The interaction of state, multistate, and federal initiatives to control prescription drug costs in the United States. Decision Resources. 2001 Sep;12:1-12


**This publication is for sale at our website  http://csdd.tufts.edu/reports


Kaitin KI, editor. FDA’s fast track program results in 62% approval rate after first 3 years. *Tufts Center for the Study of Drug Development Impact Report.* 2001 Jan/Feb;3(1)**


Cross-functional team focus on marketing is key to project success. *Tufts Center for the Study of Drug Development Impact Report.* 2000 Dec;2(9)

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RS 2008  Drug firms embrace pediatric study program during first 2 years of FDAMA.  *Tufts Center for the Study of Drug Development Impact Report.* 2000 Apr;2(3)


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RS 9912  Planning, independence, feedback keep global R&D projects on track. *Tufts Center for the Study of Drug Development Impact Report.* 1999 Sep;1(3)


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RS 9810 Lasagna L. Presentation of the Louis Lasagna Chair of Pharmacology and Experimental Therapeutics, Tufts University School of Medicine. *Journal of Clinical Pharmacology.* 1998;38:570-1, 575-6


**This publication is for sale at our website [http://csdd.tufts.edu/reports](http://csdd.tufts.edu/reports)**


**This publication is for sale at our website  http://csdd.tufts.edu/reports**


RS 9715  Kaitin KI. FDA reform: setting the stage for efforts to reform the agency. *Drug Information Journal.* 1997;31(1):27-33

RS 9714  Lasagna L  DiMasi JA. Let’s speed up the approval of new indications for old drugs. *Medical Marketing & Media* 1996;31(12):88-9


RS 9625  DiMasi JA. *Written testimony.* House Subcommittee on Human Resources and Intergovernmental Affairs, Committee on Government Reform and Oversight, U.S. House of Representatives. September 12, 1996

**This publication is for sale at our website [http://csdd.tufts.edu/reports](http://csdd.tufts.edu/reports)**

RS 9623 Kaitin KI. *Statement.* Hearing before the Subcommittee on Health and Environment of the Committee on Commerce, House of Representatives. The Need for FDA Reform, February 27, 1996. 104th Congress 2d Session:81-7, 100-1


RS 9618 Welling PG Lasagna L Banakar UV, editors. *The drug development process.* New York;Marcel Dekker:1996*


**This publication is for sale at our website [http://csdd.tufts.edu/reports](http://csdd.tufts.edu/reports)**


**This publication is for sale at our website  [http://csdd.tufts.edu/reports](http://csdd.tufts.edu/reports)**
RS 9506  Shulman SR, Seibring M, Manocchia M. *Letter to Hon. Judd Gregg, U.S. Senate.* Hearing before the Subcommittee on Aging of the Committee on Labor and Human Resources, United States Senate, July 13, 1995 104th Congress 1st Session: 47-8


**This publication is for sale at our website  [http://csdd.tufts.edu/reports](http://csdd.tufts.edu/reports)**
Brown JS  DiMasi JA  Gosse ME  Manocchia M  Kaitin KI  Shulman SR. Incentives for the development of drugs for AIDS and other life-threatening illnesses: points to consider. For the Public/Private Issues and Development Subcommittees of the National Task Force on AIDS Drug Development meeting, April 25, 1995


Bloom BR. The United States needs a national vaccine authority. *Science* 1994 Sep 2;265(5177):1378-80


Lasagna L. *Statement of Louis Lasagna, M.D., Dean, Tufts Sackler School of Graduate Biomedical Sciences at the National Institutes of Health CRADA forum, July 21, 1994.* Washington DC: New England Biomedical Research Coalition, 1994


**This publication is for sale at our website  [http://csdd.tufts.edu/reports](http://csdd.tufts.edu/reports)**


RS 9485  Inman WHW. Drug Safety Research Unit, University of Southampton. *PEM News*. 1993 Nov;(8)


**This publication is for sale at our website  [http://csd.tufts.edu/reports](http://csd.tufts.edu/reports)**


Shulman SR, Raiford DS. Promotional elements in educational programs: FDA attempts to wipe the slate clean. P&T. 1992;17:661-73*


**This publication is for sale at our website  [http://csdd.tufts.edu/reports]**


RS 9266  Scoville B. Shifting the burden: restructuring the drug review process. *Journal of Clinical Pharmacology and Therapeutics.* 1991;49(3):229-33


**This publication is for sale at our website [http://csd.d.tufts.edu/reports](http://csd.d.tufts.edu/reports)**


RS 9054 Shulman SR. La legislazione sulla responsabilità di produzione. *Informazioni Stampa Interesse Sanitario* (Rome) 1990 Apr 9;#15:27-8

RS 9053 Lasagna L. Le attività del Centro per lo Studio dello Sviluppo dei Farmaci. *Informazioni Stampa Interesse Sanitario* (Rome) 1990 Apr 9;#15:26

**This publication is for sale at our website [http://csdd.tufts.edu/reports](http://csdd.tufts.edu/reports)**
| RS 9052 | Inman WHW. Drug Safety Research Unit, University of Southampton, *PEM News*. 1988 Sep(5) |
| RS 9048 | Shulman SR, Raiford DS. FDA regulations provide broader access to unapproved drugs. *Journal of Clinical Pharmacology*. 1990;30:585-7 |

RS 8941 Kaitin KI. Reply to “understanding comparisons of drug introductions between

**This publication is for sale at our website [http://csdd.tufts.edu/reports](http://csdd.tufts.edu/reports)**
the United States and the United Kingdom”. *Clinical Pharmacology & Therapeutics*. 1989 Aug;46(2):146-8

RS 8940  

RS 8939  

RS 8938  

RS 8937  

RS 8936  

RS 8935  

RS 8934  
Grabowski HG. Medicaid patients' access to new drugs. *Health Affairs* 1989;7:102-14

RS 8933  

RS 8932  

RS 8931  

RS 8930  
Inman WHW. Drug Safety Research Unit, University of Southampton. *PEM News*. 1988 Sep;(5)

RS 8929  

**This publication is for sale at our website  [http://csdd.tufts.edu/reports](http://csdd.tufts.edu/reports)**


RS 8830  Shulman SR.  Drug refusal policy must include legal definition of competence.  *Hospital Formulary.* 1988 Jan;23:79

RS 8829  DiMasi JA.  The notion of "acceptable risk": comment.  *Journal of Clinical Epidemiology.* 1988;41(9):939-41


RS 8824  Wittes RE.  Antineoplastic agents and FDA regulations: square pegs for round holes?  *Cancer Treatment Reports.* 1987;71:795-806


**This publication is for sale at our website  [http://csdd.tufts.edu/reports](http://csdd.tufts.edu/reports)**

**This publication is for sale at our website [http://csdd.tufts.edu/reports]**
RS 8710  Inman WHW. Drug Safety Research Unit, University of Southampton. *PEM News*. 1987 Mar;(4)


RS 8705  Kaitin KI. Impact of generic drugs on the pharmaceutical marketplace. *Private Practice*. 1986 Sep;18:18-20 (Originally appeared as "Generic firms shun research, share rewards.")


**This publication is for sale at our website** [http://csdd.tufts.edu/reports](http://csdd.tufts.edu/reports)


RS 8601  Sharlin HI. EBD: a case study in communicating risk. Risk Analysis 1986;6(1):61-8

RS 8600  Berry CL. Unprovable verities. Human Toxicology. 1985;5(3):159-60

RS 8699  Weintraub M Northington F. Drugs that wouldn't die. Journal of the American Medical Association. 1986 May 2;255(17):2327-8


RS 8696  Inman WHW. Drug Surveillance Research Unit, University of Southampton. PEM News. 1985 Dec;(3)


RS 8694  Kitch E. Vaccines and product liability: a case of contagious litigation. Regulation. 1985 May/Jun

**This publication is for sale at our website http://csdd.tufts.edu/reports**


Walker SR Schultz E Schuppan D Gelzer J. A comparative retrospective analysis of data for short- and long-term animal toxicity studies on 40 pharmaceutical compounds. Archives of Toxicology. 1984;7:485-7


Mattison N. Sources of change affecting the U.S. pharmaceutical industry in the 1980s. Pharmaceutical Medicine. 1985;1:13-6*


**This publication is for sale at our website  http://csdd.tufts.edu/reports**


RS 8478  Lasagna L.  *Impediments to Vaccine Research, Medicine in the Public Interest Conference, Jan 9-10, 1984*.  Boston: MIPI;1984

RS 8477  Inman WHW.  Drug Surveillance Research Unit, University of Southampton,  *PEM News*. 1984 Aug;(2)


RS 8468  Hutt PB. The importance of patent term restoration to pharmaceutical innovation: will extending patent life increase drug innovation? A search for answers. *Health Affairs*. 1982;1(2):5-24


**This publication is for sale at our website [http://csdd.tufts.edu/reports](http://csdd.tufts.edu/reports)**
RS 8367 Superior Court of New Jersey, Appellate Division. Carol Ann Feldman, an infant, by her parent and guardian ad litem Harold Feldman, Plaintiffs - Appellants vs. Lederle Laboratories, a corporation, and American Cyanamid Co., a corporation, Defendants - Respondents. Nov 1983

RS 8366 Inman WHW. Drug Surveillance Research Unit, University of Southampton. PEM News. 1983 Aug;(1)

RS 8365 Covington TR. Toward a rational approach to the issue of prescribing authority for pharmacists. Drug Intelligence and Clinical Pharmacy. 1983;17(9):660-6


RS 8363 Young JH. Public policy and drug innovation. The American Institute of the History of Pharmacy. 1982;24:1-56

RS 8362 Paton WD. Animal experimentation and medical research: a study in evolution. Conquest. 1979 Feb;169:1-14


RS 8359 Diggle GE Griffin JP. Licensing times in granting marketing authorizations for medicines--a comparison between the U.K. and U.S.A. Pharmacy International. 1982;3(7):230-6


RS 8358b Zbinden G Flury-Roversi M. Significance of the LD 50 test for the toxicological evaluation of chemical substances. Archives of Toxicology. 1981 Apr;47(2):77-99

**This publication is for sale at our website  [http://csdd.tufts.edu/reports](http://csdd.tufts.edu/reports)**


RS 8260  Wardell WM Mattison N. The assessment of medical technologies using risk-benefit, cost-benefit, and cost-effectiveness analysis. In: *WMA Follow-up Committee on Development and Allocation of Medical Care Resources*. Tokyo: Japan Medical Association;1982;84-98*


**This publication is for sale at our website  [http://csdd.tufts.edu/reports](http://csdd.tufts.edu/reports)**


RS 8253b  Schweiker RS.  Remarks by the Honorable Richard S. Schweiker to the National Pharmaceutical Council Symposium. June 23, 1982


RS 8252  Shubin S.  The MAC program and advisors to the government.  *Hospital Formulary* 1981 Aug;16(8):869-79


RS 8250  Wardell WM.  *A statement on pharmaceutical patent life and innovation*.  Submitted to the Subcommittee on Investigations and Oversight of the Committee on Science and Technology, U.S. House of Representatives. Feb 4, 1982


**This publication is for sale at our website  [http://csdd.tufts.edu/reports](http://csdd.tufts.edu/reports)**
| RS 8153 | Wardell WM  Velo GP, editors. *Drug development, regulatory assessment, and postmarketing surveillance.* NATO Advanced Institutes Series, 39 (Series A: Life Sciences) New York: Plenum; 1981*


***This publication is for sale at our website [http://csdd.tufts.edu/reports](http://csdd.tufts.edu/reports)***


RS 8059  Hansen RW. *Effects of incremental costs on pharmaceutical innovation.* (Working Paper Series No. GPB-81-2) Rochester NY: Graduate School of Management, University of Rochester, Dec 1980

RS 8058  Hansen RW. *The cost of regulation in the pharmaceutical industry: economic implications of three recent studies.* (Working Paper Series No. PS 81-2) Rochester NY: Graduate School of Management, University of Rochester, Dec 1980

RS 8057  Wardell WM. Therapeutic drugs as an example of the regulation of health care: efficient and inefficient ways of utilizing resources. In: *Proceeding of the World Medical Association Follow-Up Committee Meeting on Development and Allocation of Medical Care Resources.* Tokyo: Japan Medical Association, 1980:139-50*

RS 8056  Wardell WM. Drug therapy (a response to questions on specific aspects of drug regulation). *Private Practice.* 1980 Oct:24-31*


**This publication is for sale at our website [http://csdd.tufts.edu/reports]**
RS 8052  Wardell WM  DiRaddo J.  The measurement of pharmaceutical innovation.  

RS 8051  Lasagna L.  Pharmacology's labs have moved faster than the regulators.  *Medical Tribune.* 1980 May 7;21:17


RS 8046  Hansen RW.  *Pharmaceutical development costs by therapeutic categories.*  (Working Paper Series No. GPB-80-6) Rochester, NY: Graduate School of Management, University of Rochester; Mar 1980*


**This publication is for sale at our website  http://csdd.tufts.edu/reports**


RS 8039  Letters to the editor. in re: the drug lag. Regulation. 1980 Mar/Apr;4(2):59-60


PS 8032  Merrill RA. Problems involving federal conflict of interest restrictions on members of FDA advisory committees and agency officials. Rochester, NY: Center for the Study of Drug Development; Apr 1980

RS 8031  Lasagna L. Who will adopt the orphan drugs? Regulation. 1979 Nov/Dec;(6):27-32

**This publication is for sale at our website  http://csdd.tufts.edu/reports**


RS 7939  Lasagna L. Toxicological barriers to providing better drugs. *Archives of Toxicology.* 1979;43(1):27-33

**This publication is for sale at our website [http://csdd.tufts.edu/reports]**
RS 7938  Lasagna L. Prescription drugs: the investment with the biggest dividends. 
*Private Practice.* 1979;11(5):42-3


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RS 7926b  Lasagna L.  The diseases and drug needs of the Third World. *Journal of Chronic Diseases.* 1979;32(6):413-4


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RS 7823  Wardell WM. A close inspection of the 'calm look': rhetorical amblyopia and selective amnesia at the FDA. *Journal of the American Medical Association.* 1978;239(19):2004-11


PS 7816  Landau RL. *What you should know about estrogens, or the perils of Pauline.* Rochester, NY: Center for the Study of Drug Development; Jun 1978


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