

# POZNÁMKY

## 1. kapitola: Chýbajúce údaje

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30. Na tento problém ako prvý upozornil Jamie Heywood z Patients-LiekMe, ktorý strávil dlhý čas nad mnohými pokusmi a omylmi pri zdrojoch, aby replikoval výskumné zistenia v inej oblasti medicíny. Pri poslednom stretnutí sme hovorili o zapísaní jeho myšlienky, že pravdepodobnosť, že je nejaké tvrdenie pravdivé, je priamo úmerná

nákladom vynaloženým na jeho prezentovanie a naopak nepriamo úmerná nákladom vynaloženým na jeho vyvrátenie. Neurobili sme to a dokiaľ to neurobíme, bude popis našej konverzácie jediným dôkazom tejto zaujímavej myšlienky.

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  50. Toto je jeden z mnohých príbehov, kde odporúčam ponoriť sa do hrozných podrobností, ak vás to zaujíma. Dobrým miestom, kde začať, je blog prof. Davida Colquhouna na túto tému s mnohými odkazmi: <http://www.dcsceience.net/?p=193> a tento článok v *BMJ* napísaný právnikom, aby som im urobil radosť, keď čítajú túto knihu: Dyer C. Aubrey Blumsohn: *Academic who took on industry.* *BMJ.* 2009 Dec 15; 339 (dec15 1):b5293–b5293.
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63. Dobrý, aj keď stručný prehľad o tom, ako sa pokúsiť a získať informácie z neakademických zdrojov, je tu: Chan A.-W. Out of sight but not out of mind: how to search for unpublished clinical trial evidence. *BMJ*. 3. január 2012; 344(jan03 2):d8013–d8013.
64. Listy aj správu si môžete prečítať on-line. Ide o pútavé čítanie s mnohými zaujímavými a ohavnými podrobnosťami, takže vám vrelo odporúčam prečítať si to: Medicines and Healthcare products Regulatory Agency (MHRA) [www.mhra.gov.uk](http://www.mhra.gov.uk/GSK%20investigation%20concludes). GSK investigation concludes [Internet]. [citované 29. apríla 2012]. Dostupné na: <http://www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON014153>
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73. Tento príbeh je popísaný v rôznych publikáciách od Cochraneovho tímu a dané vysvetlenie je prevzaté z ich práve publikovaných odpovedí Roche a diskusií s Cochraneovým tímom. Najlepšie miesto, kde sa dozviete prvú polovicu tohto príbehu, je nasledujúci článok: Doshi P. Neuraminidase inhibitors – the story behind the Cochrane review. *BMJ.* 2009; 339. A na druhú polovicu odporúčam voľne dostupný článok: Doshi P., Jefferson T., Del Mar C. (2012) The Imperative to Share Clinical Study Reports: Recommendations from the Tamiflu Experience. *PLoS Med* 9(4): e1001201. doi:10.1371/journal.pmed.1001201 <http://bit.ly/HIbwqO>
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75. To všetko pochádza z: Jefferson T., Doshi P., Thompson M., Heneghan C., Group CARI. Ensuring safe and effective drugs: who can do what it takes? *BMJ.* 11. január 2011; 342(jan11 1):c7258–c7258.
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80. Pokiaľ vás tento príbeh zaujíma, všetky odkazy na primárne dokumenty sú tu: Diabetes drug ‘victory’ is really an ugly story about incompetence. Ben Goldacre, *The Guardian*. 17. júl 2010 [citované 2. mája 2012]; Dostupné na: <http://www.badscience.net/2010/07/pharmaco-epidemiology-would-be-fascinating-enough-even-if-society-didnt-manage-it-really-really-badly/>
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83. Ide o siahodlhý príbeh, ktorý sa dostatočne rozpráva inde. Začnete tu: Curfman G. D., Morrissey S., Drazen J. M. Expression of concern reaffirmed. *N. Engl. J. Med*. 16. marec 2006; 354(11):1193.
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85. Yaleský projekt otvoreného údajového archívu alebo YODA je dobrým príkladom toho, ako by to raz mohlo vyzerať.

## **2. kapitola: Odkiaľ sa berú nové lieky?**

1. Odporúčam klasickú učebnicu pre medikov „Rang and Dale“: Rang & Dale’s *Pharmacology*. 6th ed. Churchill Livingstone; 2007. Ale tiež túto prácu o regulačnom procese okolo raného vývoja liekov: Friedhoff L. T. *New Drugs: An Insider’s Guide to the FDA’s New Drug Approval Process for Scientists, Investors and Patients*. 1st ed. PSPG Publishing, 2009.



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13. DRUG TESTING GOES OFFSHORE – 8. august 2005 [Internet]. [citované 11. februára 2012]. Dostupné na: [http://money.cnn.com/magazines/fortune/fortune\\_archive/2005/08/08/8267653/index.htm](http://money.cnn.com/magazines/fortune/fortune_archive/2005/08/08/8267653/index.htm)
14. Thiers F. A., Sinskey A. J., Berndt E. R. Trends in the globalization of clinical trials. *Nature Reviews Drug Discovery*. Január 2008; 7(1):13–4.
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- and the Global Search for Human Subjects. 1st ed. Princeton University Press; 2009.
16. Ethical and Scientific Implications of the Globalization of Clinical Research Seth W. Glickman, M.D., M.B.A., John G. McHutchison, M.D., Eric D. Peterson, M.D., M.P.H., Charles B. Cairns, M.D., Robert A. Harrington, M.D., Robert M. Califf, M.D., a Kevin A. Schulman, M.D. *N Engl J Med* 2009; 360:816–823. 19. február 2009.
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  22. Depeša WikiLeaks: Pfizer ‘used dirty tricks to avoid clinical trial payout’ – Business – The Guardian [Internet]. [citované 11. februára 2012]. Dostupné na: <http://www.guardian.co.uk/business/2010/dec/09/wikileaks-cables-pfizer-nigeria>
  23. Depeša amerického veľvyslanectva, pondelok 20. apríla 2009, 16:00, Abuja 000671 ‘Pfizer reaches preliminary agreement for \$75m settlement’ [citované 11. februára 2012]. Dostupné na: <http://www.guardian.co.uk/world/us-embassy-cables-documents/203205>
  24. Depeša WikiLeaks: Pfizer ‘used dirty tricks to avoid clinical trial payout’ – Business – The Guardian [Internet]. [citované 11. februára 2012]. Dostupné na: <http://www.guardian.co.uk/business/2010/dec/09/wikileaks-cables-pfizer-nigeria>

25. Jonathan Kimmelman, Charles Weijer a Eric M Meslin, 'Helsinki dis-cords: FDA, ethics, and international drug trials,' *The Lancet* 373, č. 9657 (3. január 2009): 13–14.
26. Goodyear M. D. E., Lemmens T., Sprumont D., Tangwa G. Does the FDA have the authority to trump the Declaration of Helsinki? *BMJ*. 21. apríl 2009; 338(apr21 1):b1559–b1559.

### **3. kapitola: Podivná regulácia liečiv**

1. Royal College of Physicians, London UK. INNOVATING FOR HEALTH. Patients, physicians, the pharmaceutical industry and the NHS. Február 2009. Správa pracovného tímu.
2. Ak máte zmätok ohľadom Európskej agentúry pre liečivá britského MHRA a toho, aký vzťah medzi sebou vlastne majú, je to úplne jedno-duché. MHRA schvaľoval lieky skôr, EMA ich schvaľuje teraz. Niektorú miestnu prácu však odovzdala starším národným regulátorom, obzvlášť dohľad a komunikáciu, rovnako ako časť schvaľovacieho personálu.
3. Odporúčam prácu Johna Abrahama, stiahnuteľnú na:<http://www.sussex.ac.uk/profiles/6>
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32. NICE, 'CG17 Dyspepsia: full guideline,' Guidance/Clinical Guidelines, <http://guidance.nice.org.uk/CG17/Guidance/pdf/English>. Ak by vám smernice NICE a jeho odkazy nestačili (pochádzajú z roku 2004), venujte prosím hodinku svojho času štúdiu ďalších novších výskumov. Zistíte, že na Esomeprazole nebolo nájdené nič magické.
  33. <http://www.nytimes.com/2004/10/12/business/media/12drug.html>
  34. [http://www.mediapost.com/publications/?fa=Articles.showArticle&art\\_aid=92473](http://www.mediapost.com/publications/?fa=Articles.showArticle&art_aid=92473)
  35. <http://www.forbes.com/forbes/2010/0412/opinions-healthcare-nexium-hmo-prescriptions-heads-up.html>
  36. Tu by som mal priznať svoj záujem: sedím vo finančnej rade, ktorá rieši presne túto otázku každé štyri roky pre program NHS „Hodnotenie zdravotníckej technológie“. Tento prúd financovania je špeciálne určený na odhalovanie výskumov, ktoré je potrebné urobiť, ale ktoré nebude financovať žiadna firma, na porovnanie jedných liekov s inými. Ak ste si vedomí nejakých významných oblastí, kde nevieme, ktorý z dvoch známych liekov je lepší, mali by ste si tu podať žiadosť (alebo ak ste leniví, napíšte mi e-mail).
  37. Ak vás veľmi zaujíma táto téma, v tomto detaile spočíva vážny problém. Medzinárodná spoločnosť bulletinov o liekoch, ktorá zastupuje akademikov a farmaceutov vytvárajúca prívetivé zhrnutie údajov pre lekárov, počas piatich rokov viedla kampaň za to, aby získala prístup k niečomu menom Signal, publikácii WHO, ktorá hovorí o otázkach bezpečnosti lieku, ktoré vzišli z nespracovaných údajov z kazuistik. WHO neustále odmietala a trvala na tom, že správu môžu vidieť len „národné zdravotnícke úrady“, ale v roku 2012 zmenila názor a teraz plánuje širší prístup aj pre iné nezávislé skupiny. Tým však sága bohužiaľ nekončí. Farmaceutickým firmám sa stále povoľuje prvotný prístup, aby mohli „čítať a komentovať“ pred publikáciou. A Signal je len publikácia popisujúca výsledky, nie jednotlivé prípadové štúdie, ktoré sú zhromaždené v tzv. VigiBase, ktorá naďalej zostáva tajná. Údaje z UK a USA sú ľahšie dostupné, ale údaje EÚ, ako asi čakáte, nie. Viac si môžete prečítať v tlačovej správe a na webovej stránke ISDB: <http://www.isdbweb.org/publications/view/pharmacovigilance-data> ('Broadening access to signal is a positive step, but access to VigiBase is also needed', ISDB, 15. február 2012).

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## **5. kapitola: Väčšie a jednoduchšie výskumy**

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## **6. kapitola: Marketing**

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