

COLORADO COMMISSION ON AFFORDABLE HEALTH CARE
Presentation on Drug Costs
November 2015
References

COST OF DRUGS:

1. Kantarjian H, Steensma D, Sanjuna J, Elshaug A, and Light D. High cancer Drug Prices in the United States: Reasons and Proposed Solutions. *Journal of Oncology Practice* July 2014. Vol 10 Issue 4 p208. The increase in cancer drug prices in the last 15 years has many contributing factors and is harming our patients and our health care system. With OOP expenses of 20% to 30%, the financial burden of cancer treatment would be \$30,000 per year (nearly half of the average annual household income in the US). Solutions are suggested.
2. Light, D. Kantarjian, H. Market Spiral Pricing of cancer Drugs. *Cancer* Nov 15, 2013 pp3900 – 3902. The cost of cancer drugs has become staggering. What determines the escalating prices of cancer drugs? The pharmaceuticals often cite high research costs and the benefit or added value of the new cancer drug. Neither argument is well founded. The pharmaceuticals claim that the average research costs to get a drug to market is \$1.3B. This article analyzes the inflated figure. In the case of cancer drugs most basic research is done by the NCI and foundations, all free to companies. Clinical trials are smaller and shorter than for other drugs. The added value argument for unaffordable prices is not supported by objective data. Most new cancer drugs provide few or no clinical advantages over existing drugs. Only one of the 12 new anticancer drugs approved in 2012 provides survival gains that last more than 2 months.
3. Light, D. Lexchin, J. Foreign free riders and the high price of US medicines. *BMJ* (2005 Oct 22) 331 958 – 960. The US government backed by the pharmaceutical industry, wants to convince Americans that they're paying more for drugs because they're contributing more than their fair share of the costs of research and development. Not so, argue two researchers who have looked at the evidence.
4. Gagnon M. Wolfe, S. *Mirror, Mirror on the wall: Medicare Part D pays needlessly high brand-name drug prices compared with other OECD countries and with US government programs.* Public Citizen. Policy Brief July 23, 2015.
5. Fuchs, VR. *Why Do Other Rich Nations Spend So Much Less on Healthcare?* The Atlantic, July 23, 2014. Fuchs concludes that the private systems all fail and that government needs to be involved to control costs. It is further concluded that single payer would be the best solution to control costs.
6. *Health Care Cost Containment Strategies Used In Four Other High-Income Countries Hold Lessons For The United States*
7. Stabile, M. Thomson, S. Sara Allin S. Boyle, S. Busse, R. Chevreul, K. Marchildon, G. Mossialos, E. *Health Affairs*, April 2013, pp. Our review suggests that the four countries have had some success in using a variety of public policy tools and that the United States may wish to emulate their policies to reduce the growth rate in drug spending. The policies include relatively simple levers such as large-scale negotiations with pharmaceutical manufacturers and sellers as well as budget caps. Our review also suggests that the United States may wish to use more challenging tools, such as cost-effectiveness analysis that sets prices for new technologies based on the technologies' relative value and value-based user charges.

DEVELOPMENT OF PHARMACEUTICALS:

1. Keyhani S, Diener-West M, Powe N. Are Development Times for Pharmaceuticals Increasing or Decreasing? *Health Affairs* vol 25 No 2 March/April 2006. Longer clinical trial times have been described as one factor leading to higher drug prices. This study demonstrates that longer trial times are not contributing to rising prescription drug prices.
2. Light D, Warburton R. Drug R&D Costs Questioned. *Widely Quoted Average Cost to Bring Drugs to Market Doesn't Appear to Hold Up to Scrutiny.* *Genetic Engineering & Biotechnology News* Vol 31 No 13 July 2011. The average cost to bring a drug to market is \$1.3B. As a policy researcher and health economist, we discovered that this staggering R&D figure was based on companies reporting guarded numbers for their R&D costs to the pharmaceutical industry's leading policy research center. No one knows what they count as R&D costs, though bits of evidence indicate it's rather inconclusive and varies from company to company.

3. Artz K, Norma P, Hatfield D, Cardinal L. A Longitudinal Study of the Impact of R&D, Patents, and Product Innovation on Firm Performance. *J of Product Innovation Management*, vol 27 pp 725-740 (2010). Invention (new ideas) and Innovation (development of viable market products) are studied. R&D spending was positively related to patents. A negative relationship was found between patents and both return on assets (ROA) and sales growth.
4. Light, D. Lexchin, J. Pharmaceutical R&D – What do We Get for all that Money? *BMJ* (2012) vol 345 pp. 22-25. Data indicate that the widely touted “innovation crisis” in pharmaceuticals is a myth. The real innovation crisis, say Donald Light and Joel Lexchin, stems from current incentives that reward companies for developing large numbers of new drugs with few clinical advantages over existing ones.
5. DiMassi, J. Hansen R. Grabowski H. The Price of Innovation: new estimates of drug development costs. *J of Health Economics* 22 (2003) 151-185. This article is used by the pharmaceutical industry to define the cost of drug development. Multiple articles have challenged the validity of this study that defined the cost per drug to be \$802M.
6. Light, D. Lexchin, J. Will Lower Drug Prices Jeopardize Drug Research? A Policy fact Sheet. *The American Journal of Bioethics* (2004) 4(1) W1-W4. this documented fact sheet provides evidence that all drug research by large firms net of taxpayers subsidies is paid for out of domestic sales in each country, with profits to spare. Prices can be lower without jeopardizing basic research for new drugs. More exposure to global price competition would encourage more innovative research and less of the derivative me-too research that now dominates.
7. Light, D. Global Drug Discovery: Europe is Ahead. *Health Affairs* ((2009) vol 28 (5) pp 969 – 977. It is widely believed that the US has eclipsed Europe in pharmaceutical research productivity. Data demonstrates that the US never overtook Europe in research productivity, and that Europe is pulling ahead of US productivity.

DRUG QUALITY AND SAFETY:

1. Brody, H. Light, D. The Inverse Benefit Law: How Drug Marketing Undermines Patient Safety and Public Health. *Am J of Public Health* (2011) vol 101: pp 399-404. The inverse benefit law states that the ratio of benefits to harms among patients taking new drugs tends to vary inversely with how extensively the drugs are marketed. The inverse benefit law highlights the need for comparative effectiveness research and other reforms to improve evidence based prescribing.
2. Lexchin, J. Light, D. Commercial influence and the content of medical journals. *BMJ* (2006 Jun 17) 332 1444-1447. How confident should we be in the objectivity of medical journals? Do commercial biases play a part in determining what appears in print? Do financial considerations affect the content of medical journals?
3. Light, D. Lexchin, J. Darrow, J. Institutional Corruption of Pharmaceuticals and the Myth of Safe and effective drugs. *J of Law, Medicine, and Ethics*. (Fall 2013) vol 41 pp 590 – 600. Over the past 35 years, patients have suffered from a largely hidden epidemic of side effects from drugs that usually have few offsetting benefits. The pharmaceutical industry has corrupted the practice of medicine through its influence over what drugs are developed, how they are tested, and how medical knowledge is created.
4. Neumann, PJ. Cohen, JT. Measuring the Value of Prescription Drugs. *NEJM* (Nov 18, 2015) On Line first. Escalating drug prices are alarming. Consider: 1) a move to value-based frameworks for assessing drugs. 2) Whereas the governments of many countries use their regulatory and buying power to control drug prices, these US based initiatives represent private-sector solutions. 3) Value is an elusive target and there is no consensus about what dimensions should be taken into account. 4) The frameworks either ignore a drug’s overall budget impact or handle it inadequately.

HCACF SUGGESTED READINGS AND SOLUTIONS TO THE PROBLEM OF HIGH COST DRUGS

1. Five Myths & Pillars of Current Pharmaceutical Policy. Donald Light - 2015
2. Universal Health Care Financed by a Public single Payer Plan. Go to Physicians for a National Health Program website (<http://www.pnhp.org/>). In the *Articles of Interest* section one notes an entire bibliography devoted to research done related to single payer. In addition the section titled *Quote of the Day* section one reviews the most pertinent articles with editorial comment (<http://www.pnhp.org/news/quote-of-the-day>).

3. Kemp, R. Remember the MaineRx. *Applied Health Economics and Health Policy*, February 2014. Politics play an important role in health policy. In this case, pharmaceutical companies, represented by the PhRMA, were able to influence Congress to introduce a national solution to the threat of state-run PBMs and the negotiation of positive lists. The companies were instrumental in formulating Medicare Part D and lobbying for its passage. It is speculated that Medicare Part D came about to put a stop to state rebate programs such as MaineRx in fear of reduced profits for the pharmaceutical companies. Thus, Medicare Part D terminated the existence of state-run PBMs. The historical importance of MaineRx is that it was an attempt of the state trying to contain healthcare cost and expand prescription coverage. Had MaineRx been implemented, it might have been a milestone on the path to reduced healthcare cost.
4. Outterson K. Vermont's health reform law: A five part series (Vermont's Super MedPAC, Federal and ERISA plans, Pharma, Anti-trust, and Financing). *The Incidental Economist* online, May 6, 2011. Marjorie Powell is PhRMA's point person for state legislation. Vermont is one of her problem children – and not just Vermont. States in the northeast seem to love legislation that the drug industry hates. The Maine Rx program was litigated to the Supreme Court back in 2003 (PhRMA v. Walsh), with the drug industry losing 6-3. More recently, the anti-data mining statutes in Maine, New Hampshire and Vermont triggered split decisions in the First and Second Circuits and an appeal to SCOTUS earlier this year. Oral arguments were heard in April. Part of the story is that the northeast is an incubator for innovative prescription drug policy, supported in no small part by the National Legislative Association on Prescription Drug Pricing (NLARx). Their website is a cornucopia of model legislation and policy papers; what we'd expect from NCSL if it was totally free from drug company influence. (Disclosure: I've donated time to NLARx over the years). Which brings us to Vermont's single-payment system (GMC). Several items in this law will keep Marjorie and her friend busy. This not a final plan yet, but simply a framework of things drug companies don't like:
 - a. Evaluate a single state-wide drug formulary – recommendation due by Jan 15, 2012. Expect every drug-company supported patient advocacy group to testify against this. (See the excellent Pro Publica report on PhRMA support to patient advocacy groups). In any event, it is not clear that a single formulary would save money. Much more flexible formulary rules and aggressive generic & therapeutic substitution might. (Health Affairs unged).
 - b. Dramatically expand use of 340B pricing, potentially for all drugs in GMC. I don't know how this is possible – 340B was designed for low-income populations, not entire states. Expanding 340B to all eligible populations is a great idea, since the prices are quite low, but making it universal will threaten access for the free clinics that were the historic base for 340B. (I've written about price discrimination in prescription drug markets in US Senate testimony and the *Yale Journal of Health Policy, Law & Ethics*).
 - c. VT may request a full part D waiver, rolling all Part D drug purchasing into GMC. This would bypass the debate on CMS "negotiating" Part D drug prices by letting the state try.
 - d. VT will also consider buying all GMC drugs through Medicaid, with the statutory and supplemental rebates. I don't know how a state could buy drugs through Medicaid for non-Medicaid populations. This also threatens to undermine the US price discrimination scheme. In any event, PhRMA can offset the rebates by raising prices.
 - e. A single mechanism for negotiating rebates and discounts, concentrating and leveraging the state's buying power, creating a monopsony to negotiate with monopolies.
 - f. Expanding anti-datamining, gift ban, & transparency rules. Not in the legislation at present, but expect it to be added if the Supreme Court strikes down the current version of the VT anti-datamining law in *Sorrell v. IMS*.
 - g. Importation from Canada. Also missing from the list, but a perennial option frequently discussed in VT.
5. And many more

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