

# FIVE MYTHS & PILLARS OF CURRENT PHARMACEUTICAL POLICY

## Donald Light - 2015

1. "Most new drugs are 'life-saving' and must be rushed to patients who need them."
  - a. Most new drugs not for life-threatening conditions. Perhaps 10 percent.
  - b. Independent reviewers judge about 90% new drug products as little or no better against clinical measures of improvement or less harm. Consistent pattern for 40 yrs
  - c. Therefore about 1% new drugs would be "life-saving." (10% x 10% = 1%)
  - d. Most R&D spent on developing minor variations. Most marketing spent on them.\
  - e. Inverse Benefit Law of widespread marketing that dilutes benefits and proliferates risks of harms.
2. "The FDA screens out unsafe and ineffective drugs. Approved drugs are safe and effective."
  - a. Better than placebo means new drugs may be less effective than existing ones. No useful evidence for prescribing or how new drug compares to others.
  - b. Non-inferior means new drugs are no worse than -20% the comparator drug. No useful evidence on how superior new drugs are, if they are.
  - c. Evidence on risks of harms in minimal. From company trials designed to minimize evidence of harms.
  - d. All evidence on a carefully chosen, ideal population most likely to benefit and not have adverse reactions. Real patients and real patterns of use usually less beneficial and more harmful.
  - e. Since 90% of new drug products are little or no better, they cannot be safe.
  - f. Aside from in-class choice, are the FDA and EMA flooding the market with ineffective, unsafe drugs?
3. An epidemic of harmful side effects (with few offsetting benefits).
  - a. The 4th leading cause of death. About 113,000 deaths just in hospitalized patients.
  - b. About 2.5 million serious reactions and 1.7 million hospitalizations.
  - c. About 50 million adverse reactions, mostly mild but impair performance & judgment
  - d. A major cause of falls, accidents, anti-social behaviors.
  - e. Risks of harm increase through cascade effect and take multiple drugs.
  - f. Harmful side effects generate more sales.
4. Market is flooded with new drug products of little or no advantage that consume 80% of increased pharmaceutical costs. Harmful side effects generate more sales.
  - a. A self-reinforcing syndrome: high prices, protected by government from free market competition, fund the development of these drugs and their costly marketing, which generate more revenues to develop more of these drugs.
5. "US prices have to be high to recover \$1.7 billion in R&D costs per new drug and recover what lower prices abroad do not recover."
  - a. The \$1.7 billion figure is inflated from unverifiable R&D costs which companies have strong incentives to inflate from the start. Half the "costs" are estimated profits that companies would have made if they had not invested in R&D for new products vital for their survival. Another half are costs subsidized by taxpayers. Then the \$1.7 billion estimate is based on the most costly 20 percent of new drugs but attributed to all drugs – a three-fold distortion. Just these three factors mean you divide by 12 to get \$0.14 billion. Another third of the total comes from backing in a high amount for the unknown cost of discovery. And there's more... See "Demythologizing the high costs..."
  - b. The BMJ article "Foreign free riders..." drew on data from the National Science Foundation, companies and government to conclude that companies earn back all expenses and make a profit at Canadian and European prices. US high prices simply make extra profits from government protections from free-market competition.
  - c. The USA is the primary market where drug companies raise prices each year on last year's models because they are protected from free-market competition.
  - d. Pharmaceutical companies will make solid profits under bundled payments that rein in high prices.
  - e. Cancer drugs should be relatively cheap. First, most R&D is paid for by others, not companies. Second, trials are smaller and shorter than for other drugs. Third, in most cases we have no verifiable evidence that manufacturing costs are higher. Why, then, are cancer drugs priced higher than statin drugs? Most cancer drugs cause serious harms and provide little additional benefit, with exceptions.