THE HEALTH IMPACT FUND AND CORRUPTION

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• Goal of presentation: to explore the Health Impact Fund in light of this panel’s theme of corruption concerning pharmaceuticals
HEALTH IMPACT FUND

• [http://healthimpactfund.org/](http://healthimpactfund.org/)

• An additional option for a drug company

• If a drug company chooses the HIF track for a given drug, then
  • the drug would be made available, everywhere, at the lowest feasible cost of production and distribution
  • the company would be rewarded, out of the HIF funds, according to the impact measured to be made by this drug on the global disease burden (over a period of, say, 10 years)
• Basic idea:
  • Companies are thus rewarded on the basis of their products’ impact on (global) health, rather than on the basis of sales.
ATTRACTION FEATURES OF HIF

• Responds to the problems of the present drug development (patent) regime
PROBLEMS (OF INJUSTICE AND OF INEFFICIENCY)
WITH PRESENT REGIME OF DRUG DEVELOPMENT

- Poor can’t afford the drugs that exist
  - Because sold near price determined by demand of the affluent
- Inappropriate bias in what drugs are developed:
  - Drugs for poor countries
  - Bias toward “maintenance” drugs and “me-too” drugs
- Waste:
  - *Wasted effort (and staff): multiple filing for patents; surveillance for infringement; advertising/marketing
  - “Deadweight losses”: blocked sales at intermediate price
- Counterfeiting (encouragement of fake products that are a threat to patient health and contribute to drug-specific resistance)
- Excess marketing (uncorrelated to need): distorted prescribing habits of doctors; direct-to-consumer ads
- *Last mile problem – lack of infrastructure (transport, storage, HC system)
QUESTIONS FOR THIS PRESENTATION

• (1) Can the Health Impact Fund be expected to help lessen or prevent the sorts of corruption that presently plagues our system of pharmaceutical development?
• (2) Might the sorts of processes involved in the HIF themselves be vulnerable to corruption and thus raise new problems?
PART 1: HIF’S ANTI-CORRUPTION POTENTIAL

• Ways in which the Health Impact Fund might help lessen or prevent the sorts of corruption that presently plagues our system of pharmaceutical development
STANDARD CORRUPTION ACTIVITIES’ AIMS

• Potential corruption activities carried out by drug companies so as to illegitimately
  • get FDA (regulatory) approval
  • convince physicians to prescribe
  • keep other companies from getting market share
STANDARD CORRUPTION ACTIVITIES

- **Trial design**: that biases the results in their favor
  - powering of trials, eligibility criteria, comparison treatment/dosages
- **Failure to Disclose**:  
  - data about adverse reactions or just negative results
- **Manipulative Promotion**:  
  - ghostwriting, drug reps, CME
- **Buying influence and loyalty**: payments/perks to scientists/doctors
- **Patent activity**: unjustified legal suits
TAKE AWAY MOTIVES FOR CORRUPTION: PRACTICES NO LONGER WORTH IT

• Various methods to keep the prices high
• Bias the results of RCTs submitted (to the FDA) for drug approval
• Distort knowledge of clinicians about them so as to get them to prescribe them regardless of their true efficacy
CAVEAT AND REPLY

• There can still be a motive to encourage more use of the drug
• But less
  • Because not as effective
  • Especially: it would seem that there is only a motive to increase usage if the drug really will have a positive impact on global disease burden
BETTERMENT OF HEALTH CARE SYSTEMS
PART 2: CORRUPTION IN THE ASSESSMENT PROCESS
OVERVIEW OF THE ASSESSMENT PROCESS
SOME STUDIES OR SOURCES OF INFO IN THE ASSESSMENT PROCESS

• (Randomized) Clinical Trials of the product [including “pragmatic” trials]
• Epidemiological studies [evidence of the change in the incidence in a disease, or cure rates]
• Tracing of random samples of the product to end-users
• Statistical analysis of correlations between sales data and variations in incidence of the target disease
POSSIBLE CONTROVERSY POINTS

• There are questions of **metrics** (QALYs) as well as **methods**
• There are a wide variety of studies
• Any given study raises methodological choices
• Some especially complicated cases
• It all has to be amalgamated (see EBM)
GENERIC OBJECTIVITY PROBLEM

• No knock-down argument against a particular methodological choice
• A given choice is to the advantage of a given “stakeholder”
• (and especially if this isn’t obvious to others)
RESPONSE

• We will get better at it

• Note: It’s very valuable to be able to carry out such evaluations (and get better at it) independently of the task of rewarding companies in the HIF scheme
A ROLE FOR DRUG COMPANIES?

• Different possible levels of involvement
• Reasons against leaving them out:
  • Need their cooperation?
  • Need their monetary resources?
  • Need their expertise?
A NOTE ON TRANSPARENCY

• On the face of it, we will want to make public the data from the various sorts of studies involved
• Others could then comment on this, and this could include the drug companies