

## Day I - Impact of reform on biomedical innovation

### *Zeke Emmanuel*

- How does change, in a cost conscious environment, impact innovation?
- Main concern is not current level but cost *growth* over time
- Changes in insurance schemes have not solved the cost problem
- By any estimates, growth in healthcare costs are being driven by technology
  - 40-65% range
- Any long-term strategy has to include technology
- Technology assessment will provide information on cost effectiveness
  - Effectiveness → cost effectiveness
  - Existing data → new research
  - Advisory → linked to coverage
- Even the most conservative changes to the healthcare system will have an impact on innovation
- Insurance redesign with the goal of impacting demand (including what doctors/hospitals do)
- Care system redesign
- Real question is how will these redesigns affect innovation
- Goals
  - Reduce overuse, in cases where benefits are not greater than costs
  - Squeeze adoption and diffusion
- Heart of the talk is a chart that captures the research and development process
  - Use drugs as a paradigmatic case
  - How will devices be impacted? Similarly?
- Different effects in the various stages
- Some questions
  - Moving funds between columns
  - i.e. more money from NIH in the 18 month window

### *Mike Silber*

- Technology is a major driver of costs
  - What should be the % of cost driver coming from technology (0-1%, 2.8% ?)
- Doesn't think we should be looking as much at cost control as much as we look at cost effectiveness
  - Doesn't want to become Italy, where drugs are not discovered anymore
  - The US is one of the few countries left where we can still have pharmaceuticals developed
- We need to empower technology assessment to evaluate new technology impact and reimbursement decision
  - Need objectivity on what is new and what is valuable
- Inventions to control technology-driven costs
- It has to be all about "who cares?"

- If you are a start-up you have to convince the investor
- The costs will sort themselves out if you are able to convince providers
- Think about the consequences of what cost controls will do to innovation
  - Don't want to stamp out what is exciting and entrepreneurial
- Have to become more scrupulous as to what we get
- Where do these innovations come from?
  - There is no question that bio and Pharma have to rely on NIH funded university research
    - NIH sponsored basic research is critical
  - Entrepreneurs, start-ups are also key
    - But we see more of that go offshore to places like Israel and India, which is a concern
- New drugs, devices, or combos
  - From his experience these areas are very different
  - What is innovative for one area is not innovative in another
- Need more definition of product performance
- Innovative medicines (new molecular entities) are on the decline
  - Chart showing decline from 1996 to today
  - But that is not the whole story
- A lot of money (~40%) is made off uses that were not originally approved
  - Look at Avastin → fourth indication for use on breast cancer
- Drugs are discovered in the clinic, in the labs we discover chemicals
  - Only when you put them into humans do you discover what they are good for
- There has been a huge increase in R&D investments throughout the last three decades
  - But a decline in NME approvals → very low R&D productivity
- What are root causes of attrition?
  - Use decision analysis science
  - At each stage there is a failure
    - Toxicity, business/strategic, PK, efficacy
- Final messages
  - Really important that we are encouraging innovative technologies
  - Don't focus on cost
  - Look at unmet medical need and cost-effectiveness
    - Start-ups do this well
  - Drug development may be a useful model of innovation challenges and strategies
    - But what might be true for Big Pharma may not be true for the little guy
  - Look at the other major causes of cost increases
  - Focus on basic and translational research to drive knowledge and application of science
- There is an underlying assumption: that we are doing things as efficiently as we can. If you can shorten the approval process by a month you could decrease the costs. It doesn't have to cost \$500m, if you can decrease the costs, and get out there first.

### *Ralph Horwitz*

- Doesn't agree with the premise that cost consciousness will not have an impact on basic research
  - There is a big spillover effect on medical schools and research institutions
- There has been a huge investment in infrastructure with expectation of more funding
- There has been consolidation in NIH funding
- There will be an impact on the viability of research
- Will there be the political will to increase NIH funding?
  - There has been a recent flattening
- Cost consciousness will not leave basic science research unaffected
  - There will be a large impact on the vibrancy of those programs
- There has been a huge impact already on the career choices of young people entering the profession
- Hard to reverse in the short term
- Time is a precious commodity
- Relationship between practice of medicine and science of innovation
  - Hard to imagine that changes in system won't affect delivery
- New paradigms:
  - Deterministic biology
  - Identity
  - Away from probabilistic expectations
- Ability to make sense of personalized medicine in this cost conscious world
- Device development is not keenly aligned with drug development
  - Devices are on different timelines
  - Devices are in a constant state of evolution
  - Requirements for demonstration for approval are different
- Globalization
  - Having an impact on testing and how trials are carried out

### **Discussion**

- Drugs, devices, and other innovations are what are driving costs not necessarily the big part of underlying total costs
  - Does this discussion really make sense, it is such a small part of the total expenditure?
  - Biggest expenditure is people
  - Drugs don't matter that much, need to focus on doctors spending more time and energy on what they are prescribing and how patients are taking drugs
  - One example: Truncating a doctor's practice, and making them focus on particular patients means that acute care utilization drops by 40%
  - Bringing physicians incomes down, you save money initially but you do not save on the rate of change
- Cost-effectiveness analysis

- Cost effectiveness is too narrowly defined
  - Can't think of it only in the framework of healthcare
  - Chicken pox vaccine → cost ineffective with respect to clinical costs, but overall the benefits outweigh because of total economic costs of chicken pox
  - Look at workdays lost, etc.
- Redistributive aspects
- Measurement issues
- Depends on perspective
  - Enlightened employer will care
  - Need to shift from employer to benefit recipient
- Questions of who will be in charge: motivation, politics, leadership
- Changing the payment scheme to look at outcomes and cost will mean costs will be prioritized because outcomes take time to realize, this will be a dramatic change/effect to the healthcare system
- Data on outcomes is indecisive
- Problem with cost reduction is that sometimes a front loaded phenomenon
  - Need to create incentives to cut costs over long time
- Chronic illness issues
  - How do you cope with diseases that people have for a long period of time, lifestyle diseases?
  - Need to be thinking in terms of innovation in the context of these broader populations
  - People are managing their diseases from their homes
    - Societal nature of health and disease as opposed to medical nature
- NIH
  - Has been successful at getting funding, but that hasn't been the case as of late
  - Does not do research into devices
- Basic science research
  - Cannot isolate basic science research enterprise from other elements of the environment which are undergoing stress
  - Cross subsidization
    - Medical centers don't recover all of their investment that is necessary for basic research
- Patent system generally
  - Period of exclusivity and patent pricing but then you go off patent and others have access to your ideas
  - Huge savings when things go off patent
  - Recently there is much slower pipeline, this means that savings will be realized
  - Without patents, we'll have to resort to trade secrets and we wouldn't have the same degree of diffusion
  - Alternative schemes? None

- Universities are great facilitators of discoveries and also are able to profit from patents
- Patents and Drugs
  - Drugs are more concrete (have chemical properties that are easily described) and as a result can be thought of more as traditional property rights
  - High barriers to entry
  - Lipitor example
    - Too many people are on Lipitor, could have been on generic statins
    - No value added from Lipitor
    - Misapplication of technology
    - Marketing
  - Need to make drug development smarter
    - Upfront investment can be too high
    - Employ more cost saving measures up front so as not to invest too much to begin with
    - If you do this, you won't get the off-patent uses
- Patents and Devices
  - Patents in devices don't prevent anyone from getting in on a market
    - Low barriers to entry
  - Patents are great in the early stages for funding from VCs
  - As you move through, other companies will move into the product and infringe
  - Then you get into litigation, and basically make a bet as to who will survive
  - Someone wins the bet after 5 to 10 years
  - The litigation has little impact on innovation
  - 130,000 devices annually
  - New devices are pouring out of technology
  - Long time ago life cycle was 10 years, now it's ten months
  - Diffusion of innovation needs to be taken into account
  - There are many variations in how these things are used
  - Don't know what is the most effective
  - As of 2008 the model with VCs still works, you can still make money on devices
- Drugs and Cost effectiveness
  - Proving a drug has competitive advantage is already done, proving cost effectiveness is an additional hurdle
  - It is difficult to measure the necessary attributes
  - Cost effectiveness is NOT a binary process (consensus), inherently subjective
  - Need to look at middle ground topics, i.e. risk assessment
  - If we change system what will change for drugs?
    - One place where we are seeing changes in reimbursement is oncology
    - We used to see lots of off label use and then you would get reimbursement
    - Now you won't get reimbursement until there is FDA approval
    - You will target populations where things are effective

- The amount of money invested into R&D won't change (15-20%)
  - How you will invest that money will change based on the way people are reimbursed
- Formularies
  - Discussion about whether doctors actually do anything about them
  - They work sometimes and sometimes they don't
- Devices and Cost effectiveness
  - Device ecosystem is based on startups, \$50-70m
  - Exit strategy is to be acquired
    - Long term evidence of mortality is incompatible with this
  - Cost containment changes will have a huge impact on this ecosystem
  - The venture money and public company money will go somewhere else
  - Study what works
    - But this creates winners and losers
    - Use what you got more effectively, but If you do this will you change how or whether people innovate
  - If you prioritize cost, it is to the detriment of "science led new products"
    - Devices are generally science led
  - Example of a device that did not account for costs of integration, it is still being implemented but could have been far less costly had the researchers taken into account the costs of integrating into the existing regime, this is an example of innovation being led by science and where you could see potential cost savings
    - But can't someone make money using this device more cost effectively?
  - If you worry about costs, you won't kill innovation, you will change the pattern
    - You will have a different gizmo, but not true across the board
- Diagnostics (identifying who will respond)
  - This is not science led but customer driven
  - This is what everyone aspires to
  - Identifying patients is the most difficult problem in medicine
    - Examples from some drugs where you have a general trials, but subgroups can work
  - Critical to capture this "backflow"
- Diffusion
  - Need more standardized process for technology diffusion
- Medical centers
  - There will be an impact on medical schools because of cost consciousness (consensus)
  - If we reimburse outcomes, it will change the incentives and move money to universities away from private industry
  - Discoveries are made at universities up to a certain point, but VCs don't want to jump in at that point, there needs to be a bridge of some sort
    - A space where foundations are coming in
- Information technology

- Powerful tools at our disposal for the future
  - Adoption of IT in large organizations is difficult
  - Hospitals are 15 years behind other large orgs.
  - Who is going to know where the costs are?
    - Cost information systems are not that well developed
  - Problem is that IT spreads thanks to good marketing, not necessarily efficacy
  - Productivity and healthcare
    - There was a quite a bit of discussion in trying to find an example of increased productivity, one was found by Dr. Garber
    - Need a more balanced scorecard in terms of improving health of general population w.r.t. technology
  - Economic forecast
    - Innovation will follow the money
    - IPO exit is more difficult now because of SOX and other regulatory hurdles that make running a public company more expensive
    - Will there be a switch from VCs to Big Pharma and other institutions?
    - Big market in the future not in life extenders but in life improvement
      - Money outside of insurance will be spent on this
      - Not necessarily targeted at over 65 population
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## Day II - Health system reform

### *Samuel Their*

- Innovation however defined should support strategy
- Isolated examples of innovation defined simply by A-D may or may not support health system improvement
- Innovation in health system is almost certain not to occur on the national level
  - States and region
- Implementing innovation must address the continuing need to provide care
- Cost consciousness will alter the focus of innovation not decrease it
- Partners HealthCare System example
  - Formed at a time when managed care was wreaking havoc
  - Merger and disappearance of hospitals
  - Stated the vision
  - Who is a part of this
    - Two academic medical centers
    - Four community hospitals
    - Eight community health centers
    - Five thousand physicians
  - Shared risk between System and physicians
    - This caught on and didn't need to buy out, people joined freely
  - Continuing care division
    - Focusing on ageing in this area
  - Went over budget
  - Attempt to be a high performance healthcare system
    - Implemented Computer Provided Order Entry
    - Electronic Medical Records reaching goal
    - Transfer of key clinical data with patient discharge
    - Pay for performance on key publicly reported measures reaching 90<sup>th</sup> percentile performance for Partners hospitals
    - Using charts for prescribing
    - EMR is standard for the network
  - They have increased the prescription of generics
    - The savings are pretty huge
  - Defect free rate for 7 key items in discharge documentation is being measured and rising

### *Ralph Horwitz*

- Frustration with the definition of health, it is not merely the absence of disease
- If health becomes measured by metrics that aren't tied to health, we will have problems
  - Different set of expectations than we currently have
  - Not to say it is inappropriate goal, need to question it though
  - Points to limitations of healthcare to achieve these goals

- Relationship of social class to health is an example of the deficiencies that may not be cured by healthcare system reform
- How do you take advantage of integrated academic medical center to create larger societal health improvements?
- Emphasis of prevention throughout this discussion
  - We have moved to a system where prevention is a cure-all
- Example of aspirin study that surveyed physicians shows us that we need to pay closer attention to incremental benefits to particular subjects
- Trying to identify subgroups may in fact be problematic
- Availability of real time data in integrated systems is tremendous
  - Most centers are investing in IT
  - Few are figuring out though how to use this data well
- Need to address the question how to organize this new data
- Movement to concierge medicine has left many people without medical care in places like Palo Alto
  - It isn't just reimbursement that has made people leave
  - Medical school students are not going into primary care
- Need to fix primary care because that is a part of the system that is particularly broken
  - May not be able to replicate Boston everywhere

#### *Mike Silber*

- Partners was started with clear vision and goals
- Innovation – adding something new and valuable
  - Do we need to further define innovation
    - Only as good as how you define it
    - Very specific examples from Partners
  - Metaphor to tpp in developing drugs – performance standards
  - Disruptive changes or process improvements?
  - Innovative v. me-too products – highly subjective
- Models that have a chance of succeeding
  - Are these plans portable between regions
  - Need to make sure there is alignment between regions and the vision
- Criticality of science and its application
- Implications of the IOM report
- Emphasis on translational sciences
  - Example of synergy between academic and industry
  - Importance of IP
- Organization as key to health care reform
- Balance innovation with cost benefit
- Performance standard

#### **Discussion**

- Primary care

- Increasing the size of medical schools and adding more schools in general will not solve the primary care crisis
- People will continue to select away from primary care
- Need to think of new models
  - Different care providers on the primary care front
  - Expensive MDs are not the solutions
- Community expectations: want to see doctors
- Nurse practitioners
  - It is becoming too expensive to use them to use in primary care
  - They are being use increasingly in specialties
- Primary care is about reimbursement
  - In the UK GPs are the highest compensated doctors
  - This is what drives selection of medical specialty
- Information, infrastructure, incentives are the keys
- Fundamental way that physician groups and practices have not changed much over the last 50 years
  - The expectation that care will be the same everywhere is ubiquitous
- Personal health is something that is created by the individual, not only by the health care system
  - Blend cultural anthropology with health
  - Start with a person centric view
  - Need to have simple reports (like credit card summaries)
  - Reform needs to encompass pluralistic care
  - Need to reform medical school to account for this
  - Medical education trains people to do things on an individual basis
    - Some standardization is appropriate
    - Protocols from cancer can be a guide
- How do we generate the proper urgency on this issue?
  - Employers are simply paying it lip service
- How did people innovate at Partners?
  - Take 150 physicians on the retreat and have them talking about new ideas
  - People who were otherwise resistant, started buying in
  - Reformed payment systems
- Local/Regional vs. National
  - Hard to do this without getting Medicare on board (so this is really national)
  - You need national information standards, what is true at Partners may not be true elsewhere
  - Need a national framework / National standards
  - But you can't have application in every region
  - The infrastructure is not available relative to the kind of practice group set-ups we currently have in the US
    - How do we shift that?
    - There have to be national standards and strategies



- The problem is so hard to do with the current systems
    - Getting one hospital to do it is impossible
    - Best practices are already available, but not able to implement is too costly
  - Others think that it would be possible if it were say a billion dollars
  - Maybe there is prestige that is reward enough for this
  - As of right now, investments in IT and other service improvements are not yielding overall cost decreases (ignoring improvements in care)
    - Compare this to putting drugs out, there are incentives there
  - Compare costs in Mass General and Mayo for example
    - One reason for this is relative costs
    - Medical care is not a commodity, not BestBuy
  - It is a part of the university medical center's missions to innovate and diffuse that innovation elsewhere
  - Don't want to give patents for service improvements (consensus)
- Maryland example
  - Drive down utilization and compensate
  - Total costs went down and hospitals got more
  - More per unit of service, but provide less service
  - This was done at the hospital level
- Capacity is an issue and will drive reforms
- Incentives
  - Deliver incentives to the individual
    - Get behavioral change
  - Insurance right now is not really insurance but a prepayment system
  - Move to incentives
  - Look at the public health context
  - This is a multilayer problem
  - The employer vs. insurance dichotomy
    - Who really pays?