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Incentivizing R&D for New Products for Use in Food Animal Agriculture

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Defining Terms

- "New products"
  - Products developed by the pharmaceutical industry or outside of traditional pharma
    - Includes: New antibiotics and other products that would enable the lessening of use of antibiotics in shared classes (shared by humans and animals)
- HP = human pharma
- AP = animal pharma
  - Shorthand to include industry elements that are not drugs

Literature On Incentivizing New AP

- Very little
- Great deal of academic work on incentivizing HP (theoretical and empirical)
- Government programs have been adopted to incentivize HP (practical)

ERS Work in This Area

- White paper (in progress)
  - At behest of Under Secretary of Agriculture Catherine Woteki
  - Utilizes…
    - » Interviews with industry stakeholders
    - » What research is available
    - » Data from a variety of sources
    - » Economic analyses (theoretical)

- Workshop: R&D for New Antimicrobial Drugs and Alternatives to Antibiotics for Use in Food Animals
  - March 17-18, 2016, Washington, DC
  - Brought together animal pharma companies, start-ups, government agencies, and academics

TODAY: MAJOR QUESTIONS

1. Is there a government role for incentivizing new products for use in food animal production?
2. What are some relevant differences between HP and AP that would impact incentive programs?
3. Can programs to incentivize HP development be leveraged for AP development? ("Ride-on programs")
4. How would separate incentive programs for AP compare to HP program? ("Separate programs")
5. What about non-monetary changes to incentivize AP?

GOVERNMENT ROLE? (1)

- Argument: Food animal products are a market good and therefore the government should not play a role in developing technologies to improve productivity in this sector
  - E.g., if antibiotics can no longer be used in food animals, food may become more expensive, but there is no market failure

- Response: Consider antibiotic efficacy as a common pool resource
  - All use detracts from the common pool resource
  - No single user faces full cost of use
  - Getting some users to reduce use supports maintenance of resource

GOVERNMENT ROLE? (2)

- So why not just regulate or tax use in agriculture?
  - Regulation or taxes may work in regions with well-functioning institutions
  - May not work in less developed countries without well-functioning institutions
    - These are also the regions expected to increase antibiotic use

- Why care about new products for use in food animals?
  - Maintain/improve animal and/or human health
  - Reduce antibiotic resistance pool
  - Can reduce use of AB without reliance on well-functioning institutions

- Why care about incentivizing new products for use in food animals?
  - Same reasons as incentivizing human products
    - Time between research and market may be long
    - Market incentives may only appear when there are significant public health problems

Relevant Connections Between HP and AP (1)

- R&D process is very similar and may be directly connected
  - AP products often “discards” from HP
  - Portions of testing may overlap
- Same companies
  - 7 companies comprising 73% of AP market are divisions of HP companies or recently spun off from HP (Zoetis)

Relevant Connections Between HP and AP (2)

- Lack of R&D for new human antibiotics may mean less R&D for animal antibiotics
- Use of antibiotics by humans may mean they are restricted for use in veterinary applications
  - Even “bad” antibiotics for human use may eventually serve as last resort measure
    - Increases uncertainty in AP development

Relevant Differences Between HP And AP (1)

- Size of market

Human versus Animal Pharmaceutical Industry			
		Human	**Animal**
Total (2014)			
	Global	$1,057.1B	$23.9B
	North America	$406.2B	$7.9B*
Antibacterials (2013)			
	Global	$40.3B	$4.7B*

Sources: IMS Health, IFAH
*Estimate

Relevant Differences Between HP And AP (2)

- Even if part of one company, may have separate research departments
- Drug testing costs significantly higher in human pharma due to human clinical trials
- Differences in testing procedures
  - Human drug testing:
    - Safe and effective for humans
  - Animal drug testing:
    - Safe and effective for target species
    - Safe for humans to consume in end product
    - Additional protocols for new antibiotics

Relevant Differences Between HP And AP (3)

- Animal drugs often applicable to multiple species/drug label claims/dosages/routes of administration
  - Approval in multiple species necessary for ROI
  - Approval therefore extended in time

Relevant Differences Between HP And AP (4)

- No third-party payer in AP
- Food animal industry produces a market good
- Food animal industry has acceptable death loss above 0%
- Specifics of the livestock industry strongly relevant for whether HP would be similarly useful in AP
  - Ex. 1: Preventive products only used narrowly in humans, much more broadly in livestock production
  - Ex. 2: Diagnostics need to be nearly instantaneous in livestock to maintain current production methods

Can incentives to develop new HP be leveraged for AP?

RIDE-ON PROGRAMS (1)

- Depends on connections between animal and human drugs
  - Same research department?
  - Same company?
- Would incentivized candidates deemed not suitable for human use be considered for animal use?
- Could this become a provision in programs designed for HP development?
- Could funds in these programs ever be directed to AP?

Ride-on Programs (2)

- Two broad examples that might be amenable to “Ride-on”:

1. Grant programs for early R&D
   – Similar molecules may have similar effects in humans and animals
2. Prizes that place resulting platform technologies in public sphere
   – AP tends to apply insights already discovered in HP

Ride-on Programs (3)

- Challenges
  - HP programs target new classes of AB likely to be “effective in humans,” not “effective in animals but toxic to humans”
  - HP programs unlikely to target specific AP needs

Can similar incentives suggested for HP be used for AP?

Separate Program For AP (1)

- Some non-directed funding for basic R&D, but no government programs for AP like those seen for HP
  - E.g., BARDA, IMI
- Because of similarities between HP and AP, strengths and weakness of various incentive mechanisms are often similar

Separate Program For AP (2)

- Pertinent differences between AP and HP likely impact efficacy and efficiency of different incentive types
- Broad example 1:
  - Prizes that place research results in public domain help production of new products when the major barrier is basic research, not translation of research to market product
    - Ie., there is a strong generic sector
  - When the major obstacle is bringing product from research to market, then prizes would theoretically not work as well
  - In AP, the generic sector is comparatively not as strong, making these types of prizes conceivably less effective

Separate Program For AP (3)

- Broad example 2:
  - Patent are more effective than prizes when the social and market values of a good are highly correlated
  - In HP, social and market values may be highly divergent
  - In AP, social and market values may be more closely aligned (as animal products are market goods)
  - Ergo, a patent may be more effective than a prize in AP than HP

Non-monetary Policies

- Reducing Regulatory Uncertainty
  - Novel types of products
  - International Harmonization
  - Long-term stability: are further restrictions on AB coming?
- Information Asymmetries
  - Many small firms develop products for HP that do not succeed, but might succeed in AP if they knew how to enter the market.
  - Market is small enough that this can be challenging

Concluding Thoughts

- HP is very large, relative to AP
  - Drives research into new drugs
  - Drives research about drug development incentives
  - Dominates policy development
- AP may be able to leverage HP
  - Overlap in biology and economics
  - HP drug development may be a pipeline for some AP drugs
- Significant differences remain
  - AP less studied
  - Case for prize-like programs may be weaker
  - AP specific needs may not be met by HP programs