RESUME
Ruben Jacobo-Rubio, Ph.D.
Economist

I. Contact

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II. Employment History

- Economist (FDA - Full Time GS14) 2014-Present
- Instructor (ABAC - Part-Time) 2016-Present
- Research Assistant at the University of Georgia (Nontenure/Part-Time) 2009-2014

III. Education

- Ph.D. Economics, University of Georgia, Athens, GA. USA August-2014
  Dissertation Tile: "Essays on the U.S. Pharmaceutical Industry"
  Committee: John Turner (chair), Jonathan Williams, David Bradford
- BBA Economics, University of Georgia, USA May-2009
  Magna Cum Laude with Minor in Statistics

IV. Experience - ABAC

- Teaching Business Statistics
- Teaching Microeconomics
- Teaching Business Finance
- Teaching Economics of Healthcare

V. Experience - FDA

- Expertise on Regulatory Impact (Benefit-Costs) Analysis work includes requirements for clinical investigators; electronic registration of establishments and listing of drug products; tanning-bed products; good laboratory practices; access to over-the-counter products in general, and regulations of sunscreens and non-sunscreen products in particular. Other regulatory work includes biologics; National Drug Code regulations, and expert advice on implications of regulations on reimbursement, prices, competition, and impact on consumers.
- Other expertise on regulation includes supporting regulatory teams through the clearance process and briefings to the Commissioner, HHS, and the Office of Management and Budget (OMB). Other compliance experience includes providing economic analyses to FDA management on the Medical Device User Fee Amendments and reporting compliance on Clinical Trials.gov.
- Additional expertise includes leading and collaborating on projects that support the FDA's priorities, including comparing pricing and availability of drug products domestically and abroad. Expertise also includes consultation to colleages, sister agencies, and other government stakeholders, on policies affecting market practices by brand drug firms to delay generic entry, and briefing FDA management on these topics.
- Collaboration with multiple economists to deliver time-sensitive analyses to FDA policy makers while balancing ongoing workload.
- Expertise on analyzing and updating several datasets of importance to the Agency in anticipation of major policies and initiatives, including the Medical Expenditure Panel Survey, the National Ambulatory Health Care Survey, the Orange Book, and pricing and sales data from private and public sources including CMS and IQVIA, a private data vendor.

VI. Awards - FDA

- Honor Team Award
  For collaboration in the Nonprescription Drug Product with an Additional Condition for Nonprescription Use Proposed Rule Fall-2023
- Honor Team Award
  For unified agenda of regulatory and deregulatory actions October-2018
- Incentive Award Nomination
  For work on international drug-price studies July-2018
- Performance Management Appraisal Program Award
  For attaining high scores in annual PMAP 2017
- Group Recognition Honor Award
  For economic models and analyses to support MDUFA IV March 2017
- Office of the Commissioner Award
  For exemplary economic analyses and client service 2016 & 2017
- CDER Award
  For assisting with the Sunscreen Innovation Act statutory deadlines 2016

VII. Trainings and Other Participation

- Quality System for Regulations (QSR) Workshops Fall-2016
- Ethics, Computer Security Awareness, Electronic Records Annual
- Federal Docket Management System for Regulations Winter-2015
- Recruiting and Interviewing for FDA Economics Staff Winter-2018
- Recruiting Co-Chair for FDA Economics Staff Winter-2015
- IQVIA-IMS Drug Products National and International Sales Data Annual
- @Risk Data Simulation with MS-Excel (FDA) January-2015
- MEPS Data Users' Workshop (AHRQ) 2014 & 2017

VIII. Active Research Interests

Pharmaceutical Industry, Health Economics, Industrial Organization

Publications

- "Estimating the Value of Market Exclusivity for First-to-File Generic Drugs" (with Aylin Sertkaya-ERG; Zeid El-Kilani-HHS; Sean Klein-HHS; Andreas Lord-ERG; and Sonal Parasrampuria-HHS). *PharmacoEconomicss, Under Review 2024.*
  Estimate the value of extending the 180-day exclusivity period granted to a qualifying first-to-file (FTF) generic entrant that successfully challenges a brand drug patent as an incentive to bring more generic drugs to market. Our analysis shows that extending the 180-day exclusivity by 30 days could result in about $877,000 in additional monthly sales during month 7 after approval, on average.

- "Authorized Generics in the US: Prevalence, Characteristics, and Timing, 2010-19" (with Jing Xu and Annabelle C. Fowler). *Health Affairs, August 2023.*
  Authorized Generic (AG) is a prescription drug launched by a branded pharmaceutical firm (or its licensee) that is identical to its brand name drug but is marketed without a brand label. The effect of AGs on competition is debated. We found that the timing of launch of AGs appears strategic, to compete with traditional generics rather than with the branded product – roughly three-fourths of the AGs were launched after approval of the first generic competitor. Further, where that first generic competitor was eligible for 180-day exclusivity, roughly 70% of the AG's were launched before or during the 180-day period.

- "The Distribution of Surplus in the US Pharmaceutical Industry: Evidence from Paragraph (iv) Patent Litigation Decisions" (with John Turner and Jonathan

Williams). *Journal of Health Economics, August 2020.*

We use pharmaceutical patent litigation decisions from 1984 to 2012 to estimate the value of entry and deterrence. We find that brand firms value deterrence at $4.6 billion while generic firms value the right to be first entrants at $236.8 million. This asymmetry in payoffs helps explain incentives for anti-competitive settlements and the decline in consumer surplus available from early entry.

Work in Progress

- "The Effect of Patent Challenges on Follow-on Pharmaceutical Innovation"

  Using data on New Chemical Entities (NCEs) from 1985 to 2016, patent challenges they face, and their follow-on innovation, I study the interplay between generic pressure and brand follow-on innovation.
- "Barriers to Generic Entry in Topical Markets" (Research Team Leader). Investigate the low rates of generic entry in topical prescription markets despite expiration of patent and exclusivity protection. Deliverables include a report on the commercial barriers to generic entry including expected profitability, cost of entry, and other scientific barriers.
- "The Effect of Generic Exit on Equilibrium Quantity and Prices: Are Price Increases an Epidemic or a Common Practice?"

  Report on prevalence and characterization of 'abnormal' price increases for prescription drugs.
- "The Evolution of the U.S. Pharmaceutical Industry Following the Hatch-Waxman Act: 1984-Present"

  I use information from every annual edition of the Orange Book (drugs, firms, patents), in combination with financial data (R&D, sales), and prescription trends (MEPS), to study the performance of brand and generic firms during the Hatch-Waxman Act.
- "International Drug Price Comparisons." (Research Co-Lead) Ongoing series of reports to senior management on price comparisons of brand, generic, a biologic drug products.

IX. Conferences and Presentations

- American Society of Health Economists -Presenter 2016-2024
- Southern Economic Association-Presenter 2013-2023
- Bates White Life Sciences Symposium (DC)-Attendee 2015-2024
- National Food Policy Conference (DC)-Attendee 2017
- FDA Brown Bag Series (Silver Spring, MD)-Presenter Spring-2015
- Society for Risk Analysis (DC)-Attendee 2015
- American Economic Association (Philadelphia, PA)-Attendee 2014
- Public Administration and Policy Department (Athens, GA)-Presenter 2012
- UGA Economics Department Seminar (Athens, GA)-Presenter 2012
- UGA Interdisciplinary Research Conference (Athens, GA)-Presenter 2010

X. Software Skills

Stata, Matlab, LaTex, SAS, Mathematica, Excel, Word, Powerpoint, PDF, OCR Extraction, @risk statistical modeling

XI. Languages

English, Spanish