Feedback for FDA staff prior to PDUFA reauthorization

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My Perspective

Health economist at Duke University (my own views)

Lead author of paper proposing priority review voucher

Regular user of FDA data

Thank You

FDA plays a vital role and does it well

- FDA has managed priority review voucher program well
 - Program is imperfect but FDA doing its best
 - Priority reviews have been consistently 6 months
 - Voucher user fees are sensible (\$2M in 2020, was \$5M in 2012)
 - Criteria for adding tropical diseases are sensible
- FDA shares many useful data sets
 - For example, NME data shared in February 2020
 - But much more to do on data transparency

Positive Example: NME Data

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🗕 Drug 🗸	Approval	s and	Databases
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Compilation of CDER New Molecular Entity (NME) Drug and New Biologic Approvals



- NME & BLA data for 1985 to 2019
- Excel format
- Released in February
- Dr. Kathleen Miller involved

Negative Example: Shortages Data

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Negative Example: Shortages Data

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Mallinckrodt 5 Customer Service: 1 (800) 325-8888 1	NDC 00406- 121-01; 1000s - NDC 00406- are	strengths of ethylphenidate and ER tablets e expected to be ailable by mid-		Manufacturing Revise delays 5/18/20	12		APP 1-888-386-1300 4.2% 2.5 mEq, 5 mL (NDC 63323-0026-05)	Increased demand		-ordered and expects a ase check wholesalers fo	Reverified 4/24/2012	
	NDC 00406- his	ne to meet storical demand.	0				Hospira, Inc. Customer Service: 1-877-946-7747 4%: 5 mL vial (NDC	Manufacturing delay; Other manufacturer shortages/market withdrawal.	Product 4%; 5 mL via 0409-6609-02): next Product 0.5 mEq/mL Abboject (NDC 0409	t delivery May. ; 10 mL	Revised 5/2/2012	
Company/Products Meda Pharmaceuticals	Reason		Information	lesaler for available			0409-6609-02)	windrawai.	delivery May. Product 0.9 mEg/mL	: 50 ml		
Inc.: 732-564-2200 50 mg (bottles of 100) - NDC 68220-055-10	to Active Pharmaceutical Ingredient (API)	: due Please check with your wholesaler for available inventory. Meda cannot estimate a release date for additional supplies.					0.5 mEq/mL; 10 mL Abboject (NDC 0409-5534-34)		Abboject (NDC 0409 delivery May. Product 1 mEq/mL; (NDC 0409-6625-02			
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Company/Products	Reason		information				1 mEq/mL; 50 mL vial		May. Product 1 mEg/mL; 1	10 ml Abboiect		
Hospira Inc. 1-877-946-7747 50,000 units/mL, 2 mL ampule (NDC 61703- 418-07)	Change in manufacturing si		nticipates next de	livery in 1Q 2012.			(NDC 0409-6625-02) 1 mEq/mL; 50 mL Abboject (NDC 0409-6637-34)		(NDC 0409-4900-34 April. Please check with yo for available inventor): next delivery our wholesaler		
					NO DATA		1 mEq/mL; 10 mL Abboject (NDC 0409-4900-34		<u></u>	NES		

Source: leff Jones & David Ridley

Negative Example: Shortages Data

- Accessed through (non-gov.) Internet Archive
- Occasional snapshots with months in between
- Posted in html format with format changing
- Inconsistent headers and tables within tables
- Cannot be read by machines

Data Transparency: Proposal

- Post data in a data base, not just html table
- Post data, even if imperfect, with caveats
- Create data czar reporting to Commissioner
 - Evaluated on new data availability

Data Transparency: Concerns

If data errors, could be sued

- Response: include caveats and contact info.
- Iterative process to refine data that benefits all
- It's commercially sensitive
 - Response: much of data has been public but poorly formatted

Data Transparency: Benefits

Benefits FDA

refine data and interact with people that improve it

crowd source assignments from Congress

Benefits society

- provide information about problems and solutions
- example: which companies and drugs have frequent shortages

Conclusions

► FDA is doing good work

- FDA should improve data access & sharing
- FDA should create a high-level job for data access