A Summary to the Paper "Information Disclosure of Clinical Trials and Drug Development Cycles"

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(a) What is the question (of the paper)?

How information transparency affects the innovative activities in pharmaceutical industry? Specifically, what are the effects of FDAAA 801 (Section 801 of the Food and Drug Administration Amendments Act of 2007)?

(b) Why should we care about it?

1. On one hand, the disclosure of one's research progress spread new knowledge, inspiring subsequent innovative activities. On the other hand, the information disclosure puts firms under the risk of being imitated or learned by potential competitors. Understanding the consequences of increasing information transparency helps governments make better related policies to improve social welfare.
2. Timely and high quality information about the development of new drugs is of the public's interests. Researchers, patients, even investors have different needs for these information. It is the government's responsibility to strike a balance between the public's interest and the firms' interests.
3. The biotech industry in Taiwan faces the same information disclosure problem. Firms find the level of required information disclosure would lower the incentives for developing new drugs.

(c) What is your (or the author's) answer?

1. FDAAA 801 speeds up clinical trials and increases suspension rates. It also decrease the frequency and likelihood of adverse event reports by approximately 50% and 15%, respectively.
2. FDAAA 801 increases the disability-adjusted life year (DALY) lost by approximately 2% in the indication group with higher suspension rates whereas it decreases DALY lost by 19% in the indication group with lower suspension rates. The result shows that FDAAA 801 may weaken the incentive of new drug developments.
3. Information of on-going or unsuccessful trails are valuable information for competitors, helping them assess the feasibility of onw researches and possible future economic performance. Therefore, if the market is highly competitive, firms would accelerate their product development and would also be more likely to abandon such product development.

(d) How did you (or the author) the there?

1. The authors use FDA project-level clinical trial phase data from the BioMedTracker (BMT) database during the period from 2002 to 2012. The sample contains 25,212 new drug project phase-year observations, including 11,066 and 14,146 clinical trial phases initiated before and after FDAAA 801, respectively. The author also use data from the FDA Adverse Event Reporting System (AERS) to analyze the social welfare and policy implications.
2. The author regression to analyze the FDAAA 801 effects. The following is a table of important variables.

Control Variable	Definition
Duration of Phase Change	The amount of time to proceed to the next phase measures the length in days of one clinical trail phase.
Suspension (Indicator)	An indicator variable that equals one if a clinical trial is suspended in a given year and zero otherwise.
FDA Competition	The total number of competitor firms that have drug projects in the same indication in a given year.
High FDA Competition (Indicator)	Indicates if *FDA Competition* is greater than the sample median from the entire sample.
Fluidity	The product market fluidity variable from Hoberg and Phillips (2016).
High Fluidity (Indicator)	Indicates if *Fluidity* is greater than the sample median.
Non-Expedited Drugs (Indicator)	Indicates if the drug project are not designated as the FDA expedited programs.