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## The signaling effects of incremental information: Evidence from stacked US Food and Drug Administration designations

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### ABSTRACT

The US Food and Drug Administration offers multiple designations for drugs under development, such as the fast-track designation (for drugs that treat serious conditions with unmet medical need) and the orphan drug designation (for drugs that treat rare diseases). In this study, we look at whether a stacked designation (a fast-track designation with a prior orphan designation) provides stronger positive signaling effects to investors than an unstacked designation (a fast-track alone). We examine differences in average cumulative abnormal returns (CARs) following “stacked” and “unstacked” announcements using daily stock data for individual firms and the S&P 500 Composite Index for the period of 1998–2015. Results show a substantial decline in average CARs over the study period for both stacked and unstacked designations. We hypothesize that this decline could be caused by the increased availability of information caused by the growth of the internet over the study period: as more information is more readily available, the value of each piece of incremental information may decrease. We also find evidence of substantially larger average CARs for small firms than large firms for both stacked and unstacked designations. We believe that this evidence supports the conclusion that there is a strong “dilution effect” for incremental information, as large pharmaceutical firms make more frequent announcements than smaller firms.

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### 1. Introduction

This study examines whether the receipt of two designations on a single drug, known as a stacked designation, provides a stronger signal to investors than a single, or unstacked, designation. Specifically, we investigate whether there is a greater difference in stock price following the announcement of a fast-track designation for a drug with a prior orphan designation (stacked designation) than with the announcement of a fast-track designation without a prior orphan designation (unstacked designation). The stacked designations may provide important incremental information for investors, and we expect that the presence of both designations will result in a stronger perceived signal by investors (captured by higher abnormal returns for the stacked designations).

The US Food and Drug Administration (FDA) grants many types of designations on new drugs under development. Most of these designations indicate that the drug will provide a meaningful benefit to patients if it were to be approved. All of the designations must be applied for by the firm, and come with specific, publicly disclosed, criteria that a drug must meet in order to be designated. These designations are therefore important to investors because they convey both a known signal (that the drug meets the mandated criteria), and are given by a neutral, third-party that will eventually determine whether the drug is ever approved.

We treat the fast-track designation as the stacked, or second, designation because it is typically conferred later than an orphan designation. Therefore, adding a fast-track designation to an existing orphan designation is the most common method of stacking, and should yield the largest sample size for the study.

We perform three main analyses. First, we investigate whether there are differences in stock price changes between stacked and unstacked designations. Second, we analyze whether there have been changes in stock price reactions over time for the stacked and unstacked designations. Over the study period, 1998–2015, the size and speed of information on the internet has increased significantly. This may have led to changes in the value of incremental information: as more information on these drugs has become more

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readily available over time, the value of the information may be decreasing. Lastly, we investigate whether there are differences in stock price changes by firm size. It is possible that incremental information may be less valuable to larger firms, because they are releasing new information more frequently than their smaller counterparts (due to the different number of drugs that each has under development, or that are approved). We therefore may see differences in the stock price change between large and small firms, due to the differences in value of each piece of incremental information.

Results show a substantial decline in average CARs over the study period for both stacked and unstacked designations. We also find evidence of substantially larger average CARs for small firms than large firms for both stacked and unstacked designations. We believe that this evidence supports the conclusion that there is a strong “dilution effect” for incremental information.

## 2. Background

FDA designations available to pharmaceutical firms include the fast-track designation and the orphan drug designation.<sup>3</sup> The fast-track designation was created in 1998 to decrease the development and review time for clinically needed drugs. In order to receive the designation, a firm needs to show that a drug is for a serious or life-threatening condition, and meets an unmet medical need (Food and Drug Administration, 2014).

The orphan designation was created in 1983 to promote drug development for rare diseases. To receive an orphan designation, a firm needs to show that the drug is intended to treat a rare disease, which in the US is defined as affecting fewer than 200,000 patients (Haffner, Whitley, & Moses, 2002). A drug can receive both types of designations, and it can also receive multiples of each designation (on each disease that the drug is being tested to treat). Between 1998 and 2015, the FDA has granted approximately 1250 fast-track and 2790 orphan designations (Food and Drug Administration, 2016a, 2016b; Miller, Nardinelli, Pink, & Reiter, 2017).

Some previous work has looked at the effects of fast-track and orphan designations alone. Several studies have estimated the magnitude of investors' reactions to the fast-track designation; two event studies of the first years of the designation found that the stock price of a firm rose 9–10% after the announcement of the receipt of the designation (Alefantis, Kulkarni, & Vora, 2004; Anderson & Zhang, 2010). In a more recent analysis, Miller et al. (2017) found that between 1998 and 2015, the stock price of a firm increased an average of 6 percent after the announcement of the designation. Additionally, the authors found that the magnitude of this increase decreased by almost fifty percent over time; from approximately 9% in 1998–2004 to 5% in 2005–2015.

One study has investigated the firm-level stock reactions to the orphan designation, and found an average increase of approximately 3% after the announcement (Miller, 2017). While this increase is substantially less than the average increase seen for a fast-track designation, it is still a large average stock reaction. Additionally, the strength of this signal did not appear to decrease over the length of the study period (1983–2015). It appears then, that the value of an orphan designation has retained its value over time much better than the fast-track designation.

While the potential market for many orphan drugs might be small, the prices that companies are able to charge for them can

be much higher than for drugs that treat a more common disease, leading to potentially similar total annual sales. In recent years, the annual cost of some of these treatments has run to hundreds of thousands of dollars (Tripple & Sidney, 2017). Additionally, if these drugs are eventually approved for other, common, indications, the sales of the drug can reach blockbuster status (grossing \$1 billion a year or more in sales) (Divino, DeKoven, Kleinrock, Wade, & Kaura, 2016). It therefore appears reasonable to assume that an orphan designation should provide a positive boost to the signal of a fast-track designation, although the magnitude may be not be large, and this increase should be approximately uniform across the entire study period.

Although the practice of seeking stacked designations is common, we are not aware of another study that examines whether the incremental information given by the receipt of a fast-track designation following an orphan designation increases the signaling effect beyond a fast-track designation only. We address this gap in the literature by analyzing and comparing the market returns of both stacked and unstacked designations to determine the signaling effects of this incremental information.

## 3. Signaling framework and hypothesis development

Drug development is inherently risky, both for firms that develop drugs and for the investors that provide equity capital to those firms. Unlike other types of consumer products, such as cellular phones, pharmaceuticals cannot immediately enter the market once product development is finished. There are significant barriers to entry in the market: drugs must undergo strenuous clinical testing to ensure their safety and efficacy, and then must be approved by a federal regulatory body, the FDA, before being marketed.

Additionally, while some drugs receive marketing approval and go on to become blockbusters (grossing greater than \$1 billion per year in sales), most drugs fail during development and never reach the market (Aitken, Berndt, & Cutler, 2009; Debnath, Al-Mawsawi, & Neamati, 2010; DiMasi, 2001; Kola & Landis, 2004). It has been estimated that only 32% of biologics (large molecule) and 13% of pharmaceutical drugs (small molecule) that initiate clinical development are ever approved (DiMasi, Feldman, Seckler, & Wilson, 2010). This makes investment in the space inherently uncertain; if a drug fails, investors will lose their capital and not realize any profits.

Risks are compounded further because investors in publicly traded pharmaceutical firms are unable to observe the information known to pharmaceutical firms that might help predict a drug's approval outcome. This information asymmetry between investors and firms occurs primarily because publicly traded pharmaceutical firms are unable to provide proprietary information regarding the drugs to investors, for fear of assisting their competition (Aboody & Lev, 2002; Janney & Folta, 2003; Thomas, 2002).

One way pharmaceutical firms can reduce these unknowns for investors is to use signals, such as the public announcement of a firm-level event. The concept of signaling is well described in the economics and finance literature (Connelly, Certo, Ireland, & Reutzel, 2011; Kirmani & Rao, 2000; Spence, 1973, 1976). A signal conveys to investors some piece of knowledge associated with a drug's likelihood of success, without having to divulge any proprietary information, thereby potentially reducing the riskiness of the investment. One potential signal that pharmaceutical firms can use is the public announcement of the receipt of an FDA drug designation.

FDA designations can be an important signaling tool for pharmaceutical firms. Firms provide the FDA with the data necessary to make a decision regarding granting the designation, which allows the FDA to review otherwise proprietary data. And because the FDA

<sup>3</sup> The FDA has other designations available to firms, such as the Breakthrough Therapy designation, the Qualified Infectious Disease Product (QIDP) designation, and the rare pediatric disease designation, but these are recently created programs (all were created through congressional legislation in 2012) and therefore do not yet have the sample size needed for analysis.

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