Conference Presentation
2018 Intellus Diagnostics Abstract

Impact of FDA Special Designations on Sales Performance & the Commercial Environment

Foster Rosenblatt

Impact of FDA Special Designations on Sales Performance & the Commercial Environment

1 Dec 2018 (Version 1)

Authors: **Thomas Foster**
Foster Rosenblatt: Managing Partner
Bernie Manente
Foster Rosenblatt: Associate Partner, Oncology

Background

The death rate from cancer in the US has declined steadily over the past 2 decades, according to annual statistics reporting from the American Cancer Society. The cancer death rate fell over 25% from its peak in 1997 to 2017, the most recent year for which data are available. This decline translates to more than 2.5 million deaths averted during this time period.

A significant portion of this improvement in human healthcare is the result of new drugs developed by the biopharmaceutical industry as well as the diagnostics that identify the patients that can most benefit from these new therapeutic innovations.

The greatest near-term opportunity to accelerate the health benefits that cancer drugs can have on our population is the earlier adoption of these therapies in the progression of oncologic disease. The industry refers to this as “stage migration,” a term referring to the improved survival of patients with cancer by either reclassifying them into different prognostic groups, recognizing more subtle disease manifestations, or by using diagnostic modalities that allow the disease to be diagnosed at an earlier stage.

This opportunity to earlier utilize the right drugs at the right time and for the right patient is heavily dependent on the better and increased use of diagnostic tools that enable the physician community to appropriately use drugs in new ways and enables payers to support such clinical practices.

Implications of the Importance of Diagnostics in Improving Health Outcomes and Key Questions

In cancer, an apparent improvement in cancer survival may be observed where a more sensitive diagnostic test is used. This may be a consequence of an examination of the cancer specimen by a more meticulous and assiduous histopathologist, may be an alternative imaging modality, or may be due to techn ological improvements.

Changes in diagnostic criteria can have the same effect, e.g. in prostate Gleason grading, some cribiform patterns were previously graded as 3, but in the modified system, would be classed as 4, resulting in stage migration.

Illustration

Consider, for example, a set of 100 Dukes’ stage A and 100 Dukes stage C colorectal cancers. Of 100 patients with stage A, 90 would be expected to be alive at 5 years compared to only 30 from among those with stage C.

If all samples are re-examined and 5 of the 100 Dukes' A cancers reveal specimens that in fact had lymph node involvement, then re-classification means that the 95 patients remaining

patients will show an improved survival (as the 5 Dukes' C patients with a poorer prognosis have been removed).

The 105 Dukes' C patients will also show an improvement, as the 5 Dukes' C patients that have just joined the group are likely to have a better prognosis than the average Dukes' C cancer ('early' Dukes' C rather than 'late' Dukes' C and more likely to go onto adjuvant chemotherapy). The assumption is that the 5 newly added patients were originally mis-classified as their histopathology appeared more favorable on initial examination.

Implications

Improvements in cancer survival may therefore not be due to improved care, but improvements in pathological examination, particularly with the advent of subspecialty interests among histopathologists.

A drug that makes it to market with a special regulatory pathway has a prima facie positive clinical impact on human healthcare. However, the impact of these special regulatory pathways is not well understood in terms of their impact on sales performance or structural commercial environment for a given drug.

Key Issues to be Explored

General

- What type of drugs and under what conditions are products obtaining these special designations?
- Does the developer/manufacturer have an impact on the likelihood of such designation?

Sales Performance

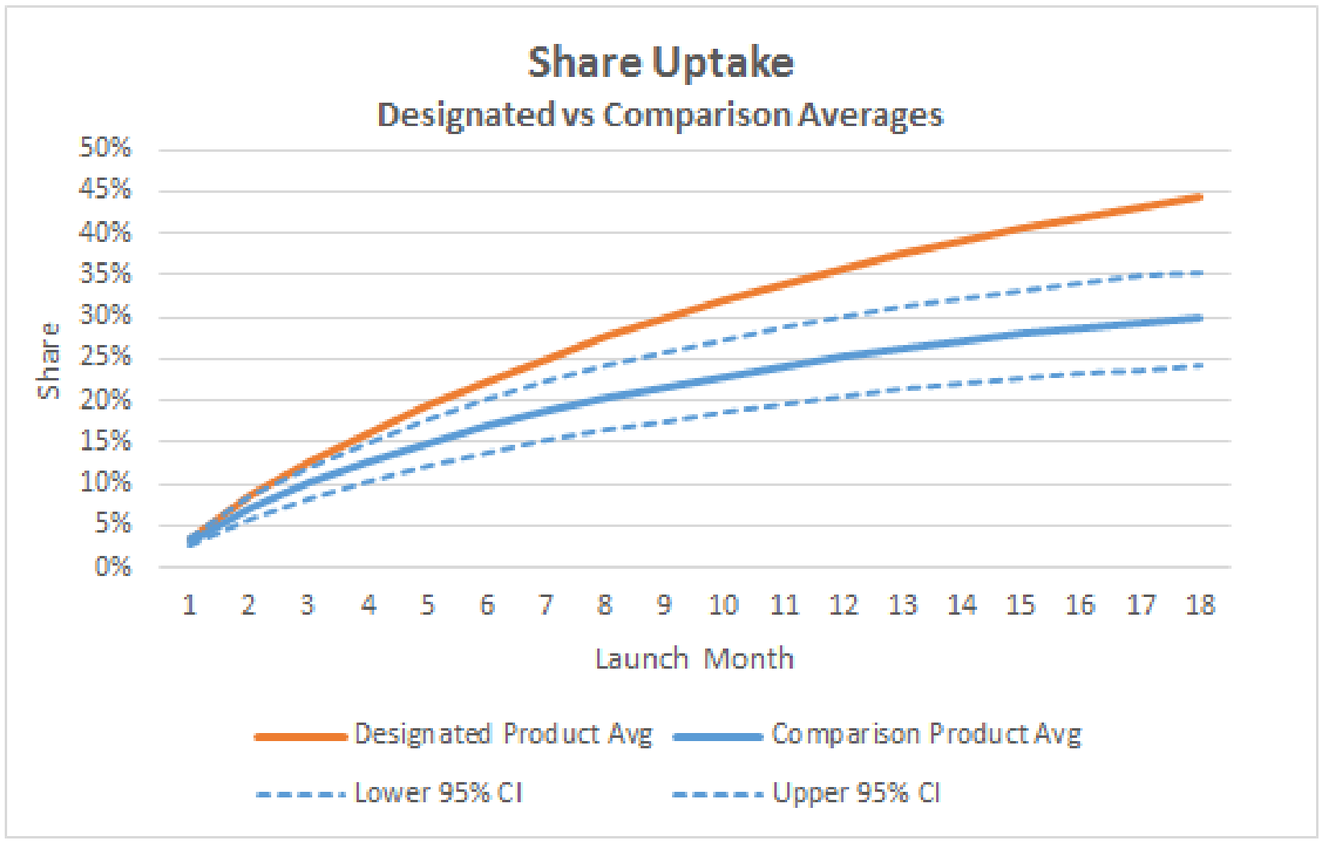
- What is the impact on launch trajectory in the US?
- What is the “halo effect” of US launch trajectory in ex-US markets?

Structural Commercial Environment

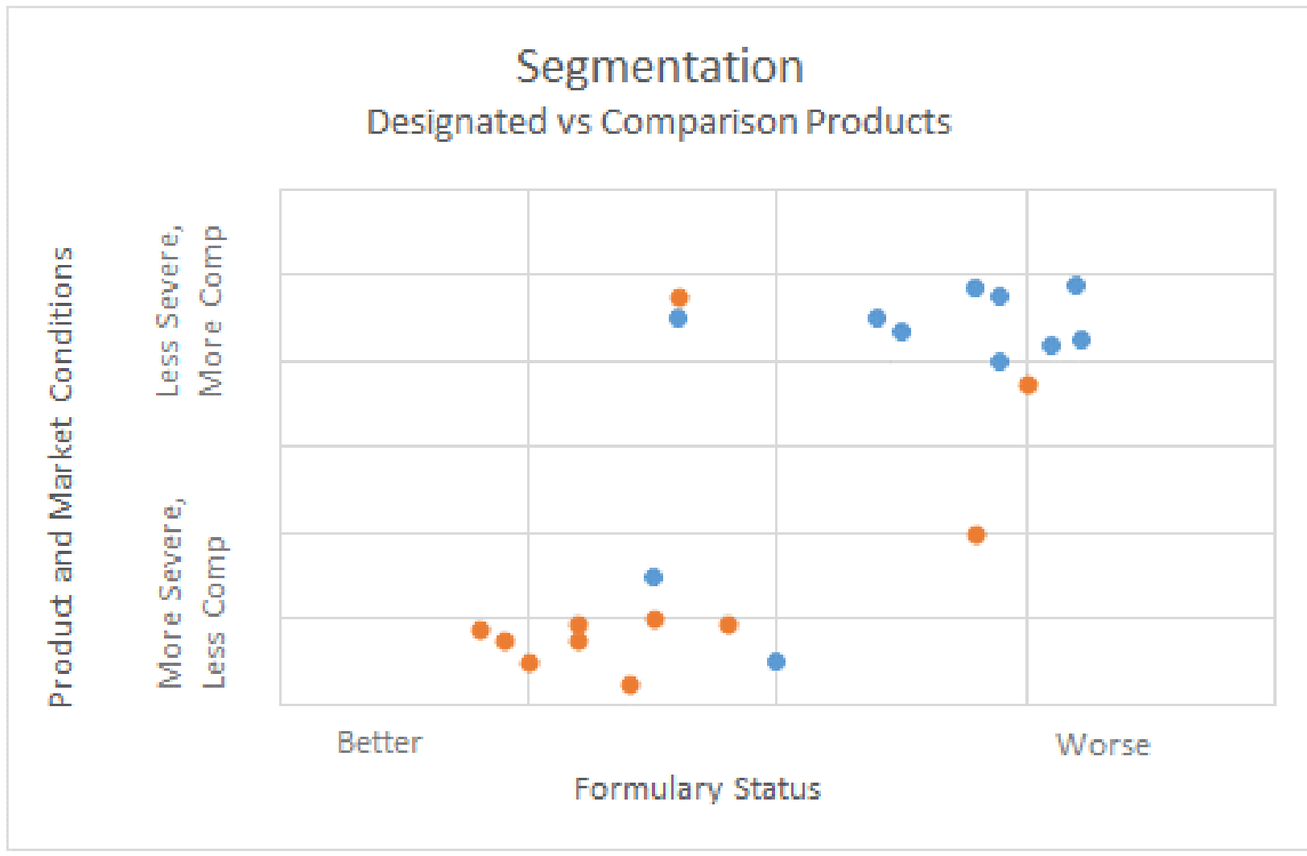
- Do special designation products receive preferred formulary positions being more available to patients?
- Is there less price elasticity of demand?
- Do these products preempt treatment algorithms or guidelines? Do they change the standard of care?
- Are specialty market product (eg., rare diseases, biologics, etc.) more likely to obtain designation than non-specialty?

Objectives and Methodology

We will answer our key questions with an analytical framework and data analyses that provide new insights into these unknown implications. First, regression analysis will be performed to determine the sales performance implications of special designation. Cross-sectional time series regression will be applied to statistically measure the impacts on both launch share and revenue uptake in the US.



This analysis will statistically compare designated products uptake over time with comparative predecessors within their markets. Both the uptake of share and revenue will be analyzed. It is important to analyze and understand both. Product launches can have market effects that underscore the share uptake. Additionally, highly differentiated pricing can have revenue effects. A similar analysis will be conducted ex-US where then products have also launched to determine if a halo effect occurs over county lines. Second, analysis will be conducted to determine the structural commercial environment impacts. The formulary position of the product will be compared to their predecessors to determine if any differences exist, and price considerations will be examined. Here, an ANCOVA comparing first twelve-month formulary position with predecessors will be completed. Similarly, the first twelve-month average wholesale price will be compared to predecessors through ANCOVA. The treatment algorithms & guidelines before and after the launch will be analyzed to understand if designated products have impacts on treatment and standard of care. Lastly, through segmentation, commonalities of launched designated products will be researched to better understand what types of products and companies receive the designation.



With these analyses, we will be able to characterize the major implications of FDA special designation on drugs as they relate to key general questions, sales performance and the structural commercial environment.

<u>Importance to Intellus Worldwide Conference Attendees</u>

This unique analysis provides a deep understanding of a largely uncharacterized but important segment of the market. This is an original approach and empirical set of applications that clarify any linkages between these important FDA regulatory pathways and a number of global sales and marketing challenges. This is a cross-functional research effort that unites data analyses from marketing research, sales analytics, marketing analytics, competitive intelligence and forecasting that drives big picture business decisions.

Foster Rosenblatt