# QUARTERLY TREND ADVISORY

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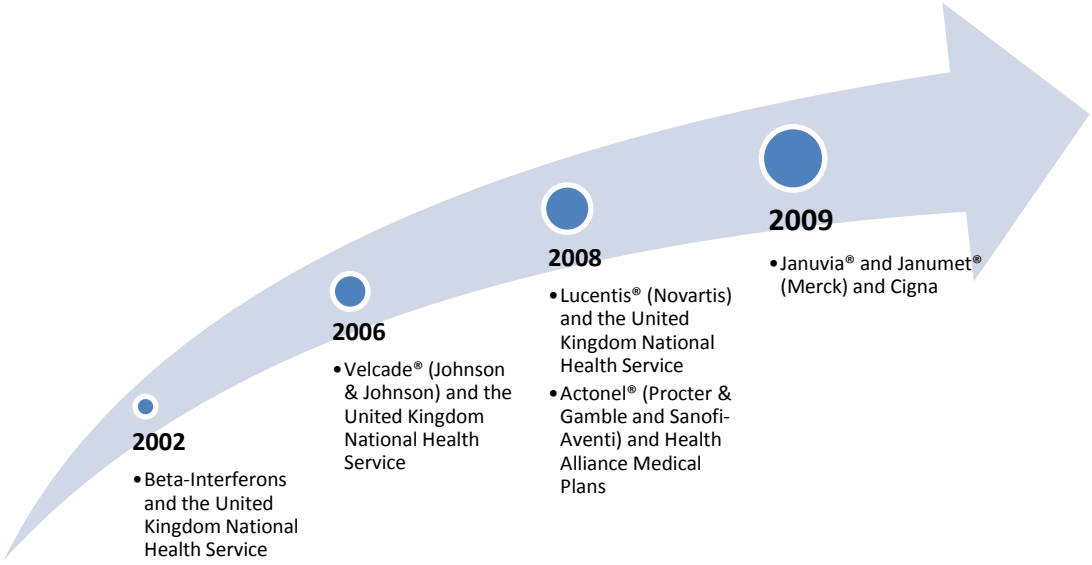
## Risk-Sharing: A Glimpse at Value-Driven Healthcare

It was recently announced that Novartis' new heart failure medication, sacubitril/valsartan (Entresto™), may be tied to a risk-sharing agreement. Risk-sharing contracts allow payers and pharmaceutical manufacturers to agree to link payment to health outcomes achieved. This is in contrast to the conventional model of linking payment to the volume of products used. The idea of paying for outcomes has been around for some time (see timeline below). The models have been referred to by different names, including: performance-based agreements, outcomes guarantees, or value-based pricing. Unfortunately, risk-sharing agreements have proven hard to implement, despite their conceptual appeal. Among other factors, one primary difficulty is getting key stakeholders to adopt the initiative because of cost and burdensome requirements. That said, expensive products with specific target populations may be suitable candidates for risk-sharing agreements. There are important things to consider when reviewing these types of contracts: 1) Successful agreements will also depend upon favorable conditions for physicians and patients; 2) Criteria must be objective, easily accessible, and provide an accurate predictor of treatment response; 3) Unintended consequences that can alter outcomes (financial and performance) should be factored in. Since Entresto has the potential to be a mega blockbuster with no near-term competition, a risk-sharing agreement may warrant a consideration.

### INSIDE THIS ISSUE



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## Keep on Your Radar: Assessing the Value of Chemotherapy

The value associated with cancer treatments, particularly chemotherapy drugs, has been a hot topic this summer, and oncologists have been leading the dialogue. Some recently approved cancer drugs are priced at more than $100,000 annually to treat one patient. Meanwhile, patient out-of-pocket costs associated with these medications have risen sharply. Oncologists are saying drug prices are increasing more than the degree of benefit they offer to their patients. According to Dr. Daniel Goldstein, "Cancer drug prices aren't linked to the benefit they provide. They're currently priced on what the market can bear." To address this question of value-based benefit, the American Society of Clinical Oncology (ASCO), recently published a proposed framework for assessing the value of cancer treatment options. Also this summer, physicians from a leading cancer hospital, Memorial Sloan Kettering Cancer Center (MSKCC), made headlines when they published an interactive online tool (http://www.drugabacus.org/) to assess the fair price of chemotherapy drugs. The tool is designed to be interactive, as it allows for individual variability in assessing some factors. For example, the value of an additional year of life can be set along a range of monetary values, while the toxicity discount can also be varied depending on the user's perception regarding the impact of the drug's side effects. Finally, another large panel of oncologists recently published a call for reforms to cancer drug pricing. These oncologists have suggested part of the solution is to allow the Food and Drug Administration (FDA) to consider value as part of the review process for new drugs. Currently, the FDA does not consider cost as part of its approval process. An additional reform called for by these oncologists is to allow Medicare to negotiate drug prices. Since the FDA does not consider cost and Medicare cannot negotiate pricing, we are "thereby essentially compelling Medicare to purchase the drugs the U.S. FDA approves at any price that a pharmaceutical company chooses to set," according to Dr. Leonard Saltz with MSKCC. While some oncologists admit to being uncomfortable talking to their patients about the cost of care, there seems to be a groundswell of approval amongst oncologists to address the rising cost of treatment and the associated impact those costs may have on patients and their families.

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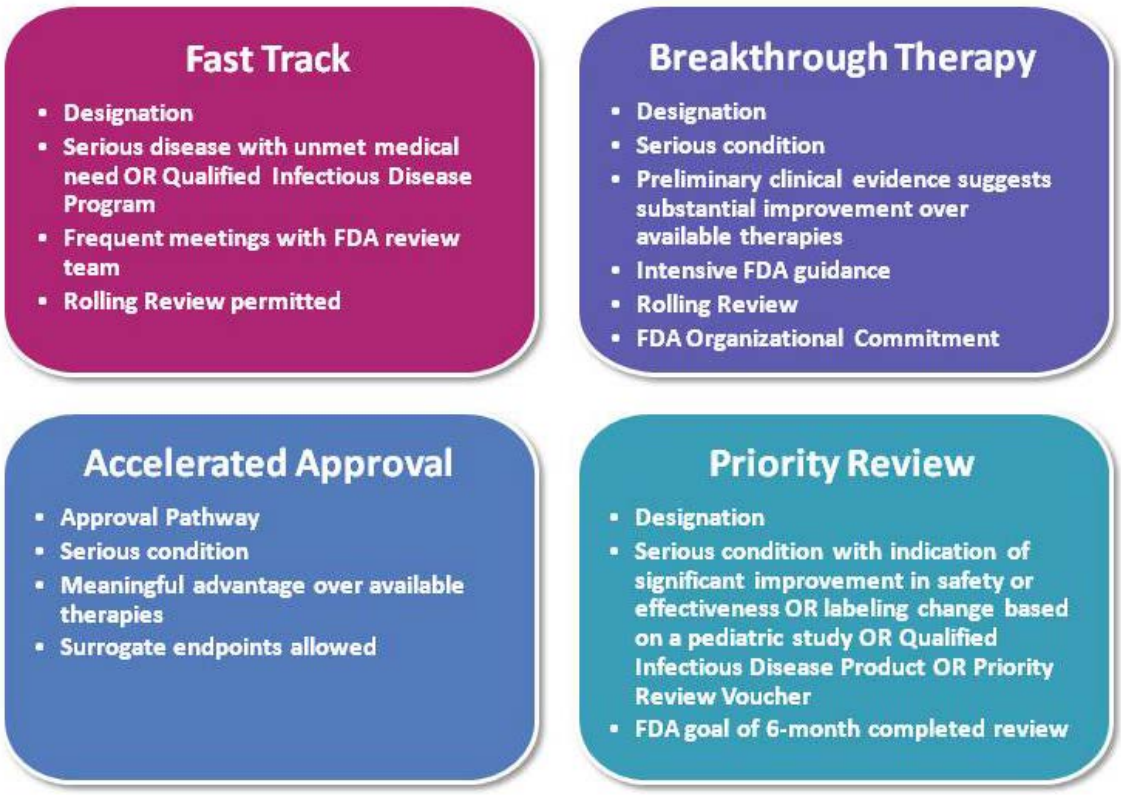
## Expedited Drug Approval Pathways: Balancing Speed with Safety

The FDA, responding to criticisms of delaying access to promising new therapies, has established four possible routes to an expedited new medication review. These four routes include *Accelerated Approval, Breakthrough Therapy, Fast Track and Priority Review*. To qualify for one of these expedited review options, the drug must be intended for the treatment of a serious disease and it must also be expected to address an unmet medical need. While there are many similarities between these four options, there are also unique advantages associated with each option. When a drug is awarded a *breakthrough therapy* designation, the FDA provides intensive and timely guidance to the drug sponsor with regard to study design ensuring data is collected as efficiently as possible. *Fast Track* and *Breakthrough Therapy* designations allow for a rolling review where the sponsor can get a "head start" by submitting portions of an application for review instead of being required to wait for the entire application to be complete before submission. Two new drugs for the treatment of hepatitis C approved in 2014, Harvoni® and Viekira Pak® were both approved via the Fast Track designation. Drugs approved via the *Accelerated Approval* pathway can be evaluated based on surrogate endpoints considered reasonably likely to predict a clinical benefit. Many new cancer drugs commonly utilize the Accelerated Approval pathway. If a drug is granted a *Priority Review*, the FDA's goal is to complete the review within six months of application acceptance. One unique aspect of Priority Review is the voucher program. Priority review vouchers may be issued by the FDA to incentivize new drug development where there is a worldwide need but little financial incentive. The awarded manufacturer may redeem the voucher in the

future themselves or they may sell the voucher to another manufacturer. In a recent auction, Sanofi purchased a priority review voucher from another company for a cost of $245 million. This is the second priority review voucher Sanofi has purchased in the last two years; they recently utilized a purchased voucher to gain priority review and approval for their PCSK9 inhibitor, alirocumab (Praluent®). The length of time it takes the FDA to review new drug applications has been reduced significantly, from an average length of 30 months in 1992 to a current standard of ten months. In addition, the option of an expedited review for select drugs can provide an advantage for both patients who gain earlier access to treatments and to the pharmaceutical companies who can get their product to market more quickly and begin to recoup the cost of developing the drug sooner.




## Did You Know? Revamping Drug Take-Back Programs

DEA Chief Chuck Rosenberg announced the need to revitalize the drug take-back initiatives in the U.S. stating, "We need you to clean out your medicine cabinet; we need you to give us the stuff in your medicine cabinet that can hurt you or your loved ones…More to come but we're going to revive that program and we're going to do it in every state in the country." The DEA has supported these programs for decades; however, the feasibility and operational costs for individual counties can be overwhelming. This is the center of a battle between small government and big pharmaceutical companies. In recent years, several bills have been introduced in state legislatures – including in New York, Washington, and California – that require pharmaceutical companies to fund state of the art take-back programs. The goal is to necessitate that manufacturers think about the life cycles of their products. A high profile case regarding this matter is an Alameda County's (California) ordinance that sought to reduce contaminants in drinking water and lower the threat of prescription drug abuse. This ordinance mandates

drugmakers to design and pay for a comprehensive drug take-back program. After the Supreme Court denied an industry request to review this ordinance, pharmaceutical companies have stated that they are not opposed to these new take-back programs; however, there is a catch 22. If pharmaceutical companies have to pay for these programs, the costs will be passed onto consumers. Without a national take-back ordinance, a Medicare beneficiary in Kentucky may have a higher cost on their medication in order to fund the take-back program in California.

## Pipeline Report: 3rd and 4th Quarter, 2015

| Drug/Manufacturer | Clinical Use | Anticipated Date | Projected Market Impact |
|---|---|---|---|
| **Select Branded Pipeline Agents: Potential New Emerging Expenses for Health Plans** | | | |
| evolocumab (Repatha™) Amgen | Hyperlipidemia | August 27, 2015 | Second entry in the new class of PCSK9 inhibitors; treatment of hyperlipidemia, given as a subcutaneous injection once or twice monthly; anticipated market price was projected to be $7,000 to $12,000 annually but alirocumab (Praluent®) entered the market in July, 2015 at a $14,600 annual price point; clinical use will likely mirror alirocumab |
| aripiprazole lauroxil Alkermes | Schizophrenia | August 2015 | Prodrug of aripiprazole administered intramuscularly monthly; will not be considered therapeutically equivalent but may compete with aripiprazole extended release injectable suspension (Abilify Maintena®), which had $174 million in sales in 2014 with current patent exclusivity until 2025 |
| patiromer for oral suspension Relypsa | Hyperkalemia | 3Q15 | Anticipated use in patients with chronic kidney disease with or without type 2 diabetes or heart failure receiving renin-angiotensin-aldosterone system (RAAS) inhibitors; competitor to sodium polystyrene sulfonate (Kayexalate®), which is used primarily in the acute setting and is associated with poor tolerability; patiromer appears to be better tolerated and may be suitable for chronic use |
| rolapitant Tesaro/OPKO Health | Chemotherapy-induced nausea and vomiting (CINV) | September 2015 | Oral (PO) and injectable (IV) long-acting neurokinin-1 (NK-1) antagonist; similar to aprepitant/fosaprepitant (Emend® PO/IV); does not appear to have any advantages over fosaprepitant which can be given as a single dose on day one of chemotherapy; will also compete with netupitant; palonosetron (Akynzeo®) |
| **Select New Generics/Patent Expirations** | | | |
| methylphenidate transdermal patch-*generic for Noven Therapeutics' Daytrana®* | Attention Deficit Hyperactivity Disorder (ADHD) | 3Q15 | Methylphenidate is well established in the treatment of ADHD; available in multiple generic dosing formulations including chewable tablets, oral solution and extended release preparations; Daytrana is the only methylphenidate transdermal patch delivery system; $103 million in sales in 2014; Actavis expected to be sole initial generic entry |
| paliperidone-*generic for Janssen's Invega®* | Schizoaffective disorder; schizophrenia | 3Q15 | Invega had U.S. sales of $537 million in 2014; Actavis expected to be first generic labeler to launch but there is no 180-day exclusivity available so other generics may launch at any time |