Drug Pricing: Oncology in the United States

Ryan P. Million, Partner Trinity Partners LLC

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One of the best parts of living in New York City during the last mayoral election cycle in 2013 was discovering the wide diversity of active political parties, including the descriptively named Rent is Too Damn High party. The 2016 election cycle has kept health care in the news, but sometimes it feels like both major parties should rename themselves Drug Prices Are Too Damn High.

Despite the rhetoric, are drug prices really high? This white paper aims to parse out the real issues at play in the biopharmaceutical market and examine what dynamics are occurring by using oncology in the United States as a case study.

First, let's address the sticker shock component of drug pricing that causes reactions. Over the last few years, several new agents have launched in the US market (see table below), and their list prices expressed in price per month are all around $10,000. For consumers (and politicians looking for votes), that amount does induce a feeling of sticker shock. Really only a house or car approaches things that most people would consider purchasing at those figures. So on an emotional level, oncology drug prices feel high.

TABLE 1

Recent Approvals in Oncology: US WAC of $8-10k per Month

Drugs	Most Recent Approval Date	Indication	WAC Price per Cycle*
Keytruda (pembrolizumab)	Oct-Dec 2015	NSCLC, Melanoma	$8,500
Empliciti (elotuzumab)	Nov 2015	MM	$8,000
Portrazza (necitumumab)	Nov 2015	NSCLC	$8,000
Opdivo (nivolumab)	Mar-Nov 2015	NSCLC, Melanoma, RCC	$7,000
Tafinlar (dabrafenib)	Nov 2015	Melanoma	$9,000
Ninlaro (ixazomib)	Nov 2015	MM	$8,500
Darzalex (daratumumab)	Nov 2015	MM	$7,500
Tagrisso (osimertinib)	Nov 2015	EGFR+ NSCLC	$9,000
Cotellic (cobimetinib)	Nov 2015	Melanoma	$6,000
Yervoy (ipilimumab)	Oct 2015	Melanoma	$28,000
Onivyde (irinotecan)	Oct 2015	Pancreas	$7,000
Lonsurf (rifluridine/tipiracil)	Sep 2015	CRC	$11,000
Kyprolis (carfilzomib)	Jul 2015	MM	$8,000
Iressa (gefitinib)	Jul 2015	NSCLC	$7,000
Cyramza (ramucirumab)	Apr 2015	CRC	$10,000
Ibrance (palbociclib)	Feb 2015	HER2-	$10,000

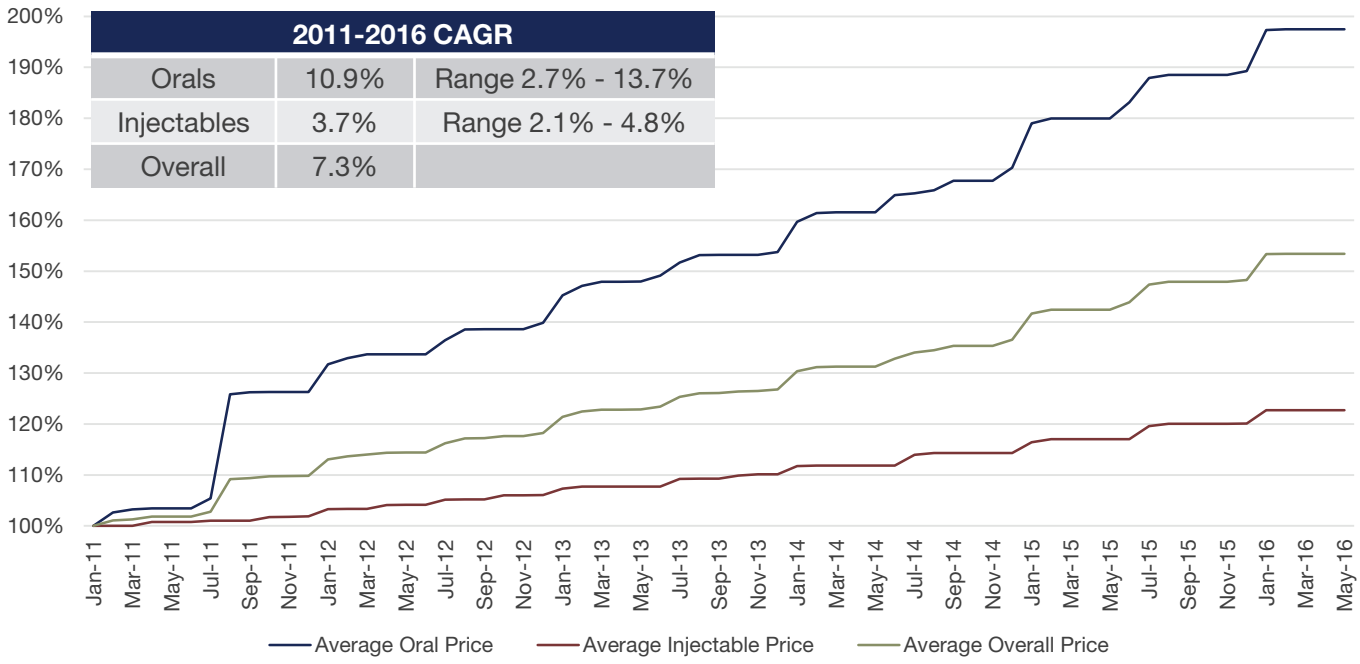
WAC = wholesalers actual cost
*Estimated price per cycle (rounded to nearest $500) calculated based on product prescribing information Sources: WAC Pricing from Redbook
Note: Select drugs approved for stated indications in 2015 (not comprehensive); original approval dates include Keytruda (Sep 2014), Opdivo (Dec 2014), Tafinlar (May 2013), Yervoy (March 2011) and Kyprolis (July 2012); Iressa is a reintroduction to the US market

Second, companies in the US market have been raising prices of oncology agents already on the market over a long period of time (see figure below) resulting in some more than tripling from the launch price. This practice in its most extreme form (e.g. Turing and Valeant) has received a lot of scrutiny in recent months, but has also received criticism from leading physicians for the most effective drugs on the market (e.g. imatinib). So another major component of the pricing environment in the US market is the ability to raise list prices, particularly of agents with an oral formulation, over the patent-protected life-span of an oncotherapeutic.

FIGURE 1

Oncology Drug Price Increases 2011-2016

Over the last five years, a sample of oncology drugs experienced ~50% increase in price; orals experienced significantly greater price increases



Market Basket	
Orals	Gleevec, Nexavar, Sutent, Tarceva, Tykerb, Xalkori, Zelboraf
Injectables	Alimta, Avastin, Erbitux, Rituxan, Vectibix

Source: RedBook data; the January 2011 price was set to equal 100% and the following monthly prices are shown relative to this first month

Third, in the US health care system patients are asked to pay for some part of drug costs, typically in the form of a copay. For oral branded drugs most commercial plans ask for a fixed copay of $50 or $100 for a one month prescription. Given multiple medicines and other non-drug medical expenses, the out of pocket cost burden can start to add up to significant figures. But the real issue of patient affordability is driven by the trend for more insurance plans and Medicare to use co-insurance instead of fixed copays. By asking patients to pay 20 or even 30 percent of the list price of a drug, cancer patients can face huge bills that they need help to pay for. Fortunately, resources do exist to help patients pay for cost sharing expenses, but the system is complex and puts a psychological burden on patients and families.

Using this framework of pricing issues, initial list price, price increases over the patent life of a drug, and patient affordability, we can now consider what value we get for our money from oncology drugs in the US. Traditionally, drug pricing has been talked about in conjunction with the research and development costs incurred to bring a new product to market. Those costs are steadily increasing; the latest figure from the Tufts Center for the Study of Drug Development is $1.4 billion in direct spending (including failures) and a capitalized amount of $2.6 billion (Science Direct). Economically, creating new drugs needs to have a healthy profit margin environment to cover these costs and encourage upfront investments; because this process is risky and unpredictable, having a market that rewards winners and offsets the losers is essential.

However, it's more difficult to justify price increases using this traditional R&D framework, especially at the rapid rate oncology drug prices have increased over the rate of inflation. After all, these drugs have already survived the highest attrition part of the drug development process so much of the uncertainty is resolved with the associated launch price decision. But there are other key benefits that come from an environment where companies can raise prices. For many drugs, the first indication is only a start of its clinical development. By continuing to increase the value of marketed assets, companies are positioned to make additional investments in life cycle management of portfolio drugs for new uses and indications.

Besides this re-investment, companies also have a fiduciary responsibility to maximize returns and make good business decisions for their shareholders. Considering this point of view, drug developers are taking price action because the US health care system allows for it and this opportunity for additional return is part of the total market at the outset for a new drug. If new regulation were put in place, such as allowing the government to negotiate drug prices as has been suggested by numerous groups, companies would adapt as they have in other markets around the world – but the financial attractiveness of investing in the space would also be adjusted downward.

Taken together, our health care system is clearly aligned to make high risk markets attractive to investment and innovation.

The health care system design is not the only way the US encourages the development of new drugs in oncology. The government has long established robust basic science support for research in the oncology space stretching from Richard Nixon's war on cancer in the 1970s, to Joe Biden's moonshot initiative today. Strong NIH and NCI budget support, patent protection laws such as Hatch-Waxman, the orphan drug act, state laws supporting access to chemotherapies, and the more recent oral parity laws, all have contributed to a pro-drug development market. The creation of these sorts of public investments and market incentives are essential in a highly regulated and risky industry. Taken together, our health care system is clearly aligned to make high risk markets attractive to investment and innovation.

Even though it appears that government and regulatory solutions aren't moving to limit the rate of price acceleration in oncology, other market forces are emerging to reshape the future landscape. First and foremost, oncologist-driven value frameworks are being created, e.g. ASCO, to determine what reasonable prices for oncology drugs actually are. In this way, the oncology market is joining forces already shaping other therapeutic areas such as HCV. Although there is no mandate to follow guidelines developed so far, physician driven decision making where cost is part of the equation is a cultural change in the approach to treating patients with cancer. Furthermore, as technology continues to advance, the barriers to education with value-based information are falling to enable more informed decision making at the point of patient care.

The key to performing well in all these value frameworks is delivering differentiated, clinical results that improve outcomes in patients. To this end, another major benefit from having growing investment and development is increased competition. Today, a record number of clinical programs (American Society of Clinical Oncology and Nature), companies of all size, and investment dollars are being focused in a wide variety of oncology indications. Large numbers of new drugs are being approved, and differentiation is harder to come by as outcomes continue to advance.

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US Drug Prices: Oncology Market Key Facts

Oncology Drug Price Trends…

- **~$10,000 per month list price** for recent launches
- **Significant price increases** of drugs already on the market
- **Increasing patient out of pocket costs** resulting in "financial toxicity"

Have Helped Drive Innovation and Investment

- **10 new drugs** approved in 2014 and **15 approved in 2015**
- Current pipeline of **over 800 programs**
- **Declining overall mortality** in several cancers

Sources: Red Book, ASCO State of Cancer Care 2015 and 2016, Nature Rev Drug Disc 11(6): 435-6

Although it may seem obvious, one major cost control is not utilizing drugs that don't deliver superior results even if their prices are on parity with other marketed agents. This is perhaps the most straightforward way that drug costs are already contained in the oncology market.

The issue of patient affordability has a less rosy picture, with one group going so far as calling this burden "financial toxicity", (Oncology). Drug manufacturers are enabled to help some patients, but too many are facing financial hardships that have broad reaching effects including sub-optimal compliance, psychological stress, and potentially negative clinical outcomes. While coverage and access remain strong, more needs to be done by all players to create a better system for oncology patients in the United States.

In summary, we've seen how the health care system provides the opportunity for robust returns, supported by government investment and regulatory incentives, can yield record setting R&D activity, innovation, and private investment. With heightened competition, new drugs must continually strive to bring more effective and differentiated products to treat patients. Innovation often unfolds in a messy, unpredictable way where great ideas crash and burn and crazy ideas turn into blockbusters after years in the wilderness. Some of these new agents seem incremental, but some are delivering strong clinical outcomes with novel approaches such as immunotherapies. And in an environment with more competition, incremental improvements are worth less than ever before as value frameworks and physician demand dictate utilization. Taken together, the oncology market has rapidly grown in total value, investment, innovation, and research programs; this has been the primary return for a market environment with strong pricing power. Whether these results are reflective of a good return on this investment will remain a hot debate topic and likely a political punchline.

As we enter ASCO of 2016 to continue the conversation on value and sustainability, one thing is clear: the legion of professionals dedicated to the war on cancer are creating the biggest effort in history against these deadly diseases.

About Trinity Partners

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Contact Us

Ryan P. Million
PhD, Partner
rmillion@trinitypartners.com

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