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Health Prize

Estimated Annual Pharmaceutical Revenue Loss Due to Medication Non-Adherence

Executive Summary

Medication non-adherence is one of the most serious problems in healthcare, posing a heavy financial impact on all constituencies. On the cost side, the New England Healthcare Institute estimated that medication non-adherence is responsible for $290 billion in "otherwise avoidable medical spending" in the US alone each year.[30]

On the pharmaceutical revenue side, however, the impact of medication non-adherence had yet to be accurately quantified. The market assumption relied upon to date, and quoted extensively, has been $30 billion *globally*,[8,10] which we felt was a gross underestimate—prompting this project. Our report represents the most accurate estimate of pharmaceutical revenue loss due to medication non-adherence.

According to our analysis, the US pharmaceutical industry alone loses an estimated $188 billion annually due to medication non-adherence. This represents 59% of the $320 billion in total US pharmaceutical revenue in 2011 and 37% of the $508 billion annual *potential* total revenue.

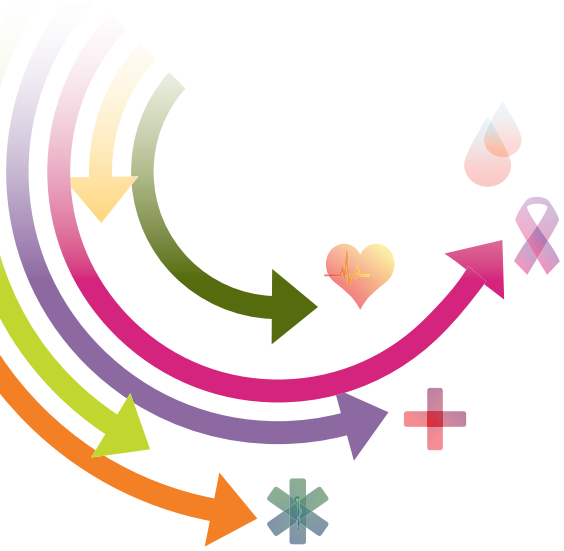
Extrapolated to the global pharmaceutical market, revenue loss is estimated to be $564 billion, or 59% of the $956 billion in total global pharmaceutical revenue in 2011 and 37% of the $1,520 billion annual *potential* total revenue.

Interventions to improve medication adherence should be top priority for the pharmaceutical industry and will prove beneficial to all stakeholders. Increasing adherence rates by only 10 percentage points would translate into a $41 billion pharmaceutical revenue opportunity in the US ($124 billion globally), accompanied by improved health outcomes and decreased healthcare spending.

Lead Authors

Thomas Forissier
Principal, Capgemini Consulting

Katrina Firlik, MD
Chief Medical Officer,
HealthPrize Technologies



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Introduction

Medication non-adherence is one of the most serious problems in healthcare, posing a heavy financial impact on all constituencies. For insurers, employers, and patients, non-adherence significantly increases healthcare costs as a result of disease-related complications. For pharmaceutical companies, pharmacies, and pharmacy benefits managers, non-adherence significantly erodes profit due to prescriptions never filled and medications not taken often enough.

Although not the focus of this report, non-adherence is also to blame for immense personal and societal costs beyond the financial, in the form of poor health outcomes, untimely death, lost productivity, and compromised quality of life. These downstream effects are particularly tragic given their preventability.

On the cost side, the magnitude of this financial impact is staggering. In 2009, the New England Healthcare Institute estimated that medication non-adherence is responsible for $290 billion in "otherwise avoidable medical spending" in the US alone each year.[6]

However, on the revenue side, prior to this report, the impact of medication non-adherence had yet to be accurately quantified. To date, the rough estimate quoted widely in industry and analyst reports, and in the pharmaceutical press, is $30 billion in lost pharmaceutical revenue per year globally, a statistic widely attributed to a 2006 report,[8] but actually originating from a 2004 report.[10] However, even a cursory "back of the napkin" calculation suggests that this number must be a gross under-representation of the problem. It clearly looms larger, given what is known about typical adherence rates, particularly for patients taking medications for chronic conditions. Our desire to set the record straight, combined with the fact that the $30 billion statistic remains widely quoted, was the impetus for this current report.

This report represents the most accurate estimate to date of annual pharmaceutical revenue loss due to medication non-adherence. Although the estimation process was driven by a set of assumptions—necessary given a lack of complete data in all therapeutic areas, both on the adherence side and on the pharmaceutical revenue side—the assumptions were carefully thought out and informed by the best and most recent intelligence available. Future estimates may be more accurate in the presence of more data, but for the time being, this report represents the most careful process to date.

The majority of modern, large-scale adherence studies—ones specifically based on objective pharmacy claims—have been focused on the United States. Given this focus, our revenue loss estimate was performed specifically for the United States market, with a simple extrapolation then extended to the global market. Although such an extrapolation is admittedly simplistic, it is likely to be reasonably accurate. According to a recent IMS report, adherence in developing countries is similar to adherence in the United States and other developing countries.[23]

Given the growing interest among pharmaceutical companies in exerting a greater influence in promoting better outcomes—and in selling wellness in addition to medication—a focus on medication adherence is a natural fit. In this setting, a more accurate estimate of the impact of non-adherence on profit can serve as further motivation to allocate resources accordingly and perhaps as stimulus for a greater sense of urgency.

Important to emphasize, pharmaceutical-industry sponsorship of adherence interventions are not simply self-serving (as in, greater adherence = greater sales), even if potentially construed in that light by a poorly informed public or press. Improved medication adherence represents a clear win-win for all constituencies in healthcare, not only for insurers and employers, but also—and most importantly—for patients.

Methods & Assumptions

For this project, we focused on medications for chronic conditions. The bulk of pharmaceutical profit loss, as well as increased healthcare spending, is due to poor adherence to medications for common chronic conditions such as hypertension, diabetes, and high cholesterol. Non-adherence to medications for acute conditions would obviously increase the estimate of annual pharmaceutical profit loss, but we cannot speculate with accuracy as to the magnitude of that incremental loss, especially given that adherence data are lacking in this area. For our analysis, then, we simply assumed that adherence to acute medications is 100%. In addition, we needed to make educated assumptions regarding what percentage of each chronic therapeutic area is self-administered on an outpatient basis (in other words, taken by the patient at home) and, therefore, subject to non-adherence.

Among chronic conditions, we examined the top 100 therapeutic areas based upon 2011 US pharmaceutical revenue data. Adherence data across these therapeutic areas were gathered from published studies in the medical literature. Although thousands of articles on medication non-adherence have been published over the past few decades, we determined that the vast majority were either unreliable in terms of methodology, out of date, or less relevant for various reasons, such as a third-world focus.

We followed a strict set of criteria for inclusion of a study in our database. First, the source of adherence data had to include pharmacy claims—objective refill data—leading to one or more of the following standard adherence measurements: medication possession ratio (MPR) or proportion of days covered (PDC). Pharmacy claims are typically accessed via a pharmacy itself, an insurance carrier, or a pharmacy benefits manager.

Given the nature of these studies and their reliance on the analysis of large-scale databases, the studies we included were relatively recent, from 2003 through 2012 (only one study was older), with the vast majority of studies published since 2008.

Study durations ranged from 6 months to 36 months, although only 2 studies were shorter than 12 months (one was 6 months and one was 8 months). Most studies included thousands of patients; some had tens of thousands. The smallest study included 267 patients with chronic myeloid leukemia.

We excluded studies that were based on patient self-reporting or on various forms of pill tracking (manual pill counts, electronic pill boxes, or other). Such studies are often compromised by shorter durations, smaller sample sizes, unreliable data, and by the fact that patients in these studies typically know that they are being observed, which can artificially raise adherence rates (the Hawthorne effect).

Studies based on pharmacy claims are more reliable in that they are a more accurate reflection of behavior in the real world (not as part of a study or intervention) and occur over longer time periods. Furthermore, contemporary adherence researchers have become increasingly sophisticated in their methodology, using techniques to control for variables that have previously led to inaccurate adherence data. Examples of such variables include patients who switch pharmacies or insurance companies or switch medications within the same therapeutic class (which may or may not be considered “non-adherence,” depending upon whether the perspective is that of a specific pharmaceutical brand or the industry as a whole).

For purposes of this project, we considered the two standard measurements of MPR and PDC to

be sufficiently equivalent and did not attempt to adjust either. Adherence researchers tend to become familiar with one or the other, and there is not yet a gold standard in the field. Technically, MPR does have a slight tendency to overestimate adherence in the event that selected patients repeatedly refill early (leading to a "double counting" of days), but this tendency is not considered—by most at least—to be of significant concern.

An important variable in estimating revenue loss is the need to include statistics regarding "primary non-adherence," otherwise known as "nonfulfillment," or "first-fill non-adherence" which means that a patient never fills even the first prescription and therefore has an adherence rate (MPR or PDC) of 0%, or a persistence of 0 months on therapy. However, given that this form of non-adherence is difficult to track in the absence of electronic prescribing (you can't track paper prescriptions), inclusion of this variable is typically lacking in adherence studies.

However, one meta-analysis recently concluded that the mean rate of primary non-adherence across studies that have been published on the topic is 17.3%,[16] and another, using a large e-prescribing database, concluded that the rate is 30.2%.[15] We decided to use the mean of both studies, for a rate of 23.8%. In both papers, primary non-adherence was also specified according to therapeutic area in a few instances, and in those instances, we used those specific data rather than the more general mean. Also, where necessary for very selected therapeutic areas such as oncology, we estimated a lower primary non-adherence rate, assuming that first fills would be higher than average.

We also assumed, based on IMS data, that new prescriptions, in general, account for 10% of the overall market, except for 10 conditions (such as diabetes and high cholesterol), for which we had more specific data. Given that, we applied the primary non-adherence rate to that same percentage of revenue, not to total revenue. Continuing prescriptions represent the majority of the market, although the correlation between percentage of new prescriptions and percentage of revenue is not exact, as new prescriptions are often newer and more expensive.

Table 1. Adherence data from published, claims-based studies

Study	Class or Medication	Secondary Adherence
	Cardiovascular	
Yeaw *et al*, 2009	Statins	61.0%
Yeaw *et al*, 2009	Antihypertensives (ARBs)	66.0%
Roebuck *et al*, 2011	Antihypertensives	59.0%
Choudhry *et al*, 2011	Statins, antihypertensives	62.9%
Cramer *et al*, 2008	Antihypertensives	67.0%
Cramer *et al*, 2008	Statins	74.0%
Shrank *et al*, 2006	Calcium-channel blockers	56.5%
Shrank *et al*, 2006	ACE inhibitors	64.9%
Shrank *et al*, 2006	ARBs	60.7%
Shrank *et al*, 2006	Statins	62.1%
	Diabetes	
Yeaw *et al*, 2009	Oral	72.0%
Roebuck *et al*, 2007	Oral	40.0%–60.0%
Cramer *et al*, 2008	Oral	71.0%
Adeyemi *et al*, 2012	Oral	44.7%
Zhu *et al*, 2011	Oral	40.0%–50.0%
Rozenfeld *et al*, 2008	Oral	81.0%
Barron *et al*, 2008	Oral	57.0%
Fabunmi *et al*, 2009	Insulin (glargine)	58.0%
Fabunmi *et al*, 2009	Insulin (exenetide)	68.0%
	Oncology	
Partridge *et al*, 2003	Tamoxifen, breast cancer	87.0%
Partridge *et al*, 2008	Arimidex, breast cancer	82.0%–88.0%
Wu *et al*, 2010	Gleevec, CML	79%
Darkow *et al*, 2007	Gleevec, CML	77%
	Antiviral	
Murphy *et al*, 2012	HIV (specialty pharmacy)	74.1%
Murphy *et al*, 2012	HIV (traditional pharmacy)	69.2%
	Central Nervous System	
Borah *et al*, 2010	Alzheimer's disease	75.0%
Davis *et al*, 2010	Parkinson's disease	58.0%
Liu *et al*, 2011	Depression (duloxetine)	38.1%
Liu *et al*, 2011	Depression (venlafaxine)	34.0%
Liu *et al*, 2011	Depression (escitalopram)	25.4%
Liu *et al*, 2011	Depression (generic SSRI)	25.5%
Barner *et al*, 2011	ADHD	47.4%
Ivanova *et al*, 2012	All MS drugs	81.1%
Reynolds *et al*, 2010	4 MS drugs	80.0%
Ettinger *et al*, 2008	Epilepsy	76.0%
Davis *et al*, 2008	Epilepsy	78.0%

Study	Class or Medication	Secondary Adherence
	Respiratory	
Mattke *et al*, 2010	Leukotriene inhibitors	39.0%
Mattke *et al*, 2010	Inhaled corticosteroids	15.0%
Stempel *et al*, 2005	Fluticasone/salmeterol combo	23.2%
Stempel *et al*, 2005	Fluticasone and salmeterol	7.3%
Stempel *et al*, 2005	Fluticasone and montelukast	7.0%
Stempel *et al*, 2005	Fluticasone	8.0%
Stempel *et al*, 2005	Montelukast	21.4%
Yu *et al*, 2011	COPD single inhaler	55.0%
Yu *et al*, 2011	COPD multiple inhalers	51.0%
Toy *et al*, 2011	COPD QD inhaler	43.3%
Toy *et al*, 2011	COPD BID inhaler	37.0%
Toy *et al*, 2011	COPD TID inhaler	30.2%
Toy *et al*, 2011	COPD QID inhaler	23.0%
	Rheumatology	
Curkendall *et al*, 2008	RA: etanercept or adalimumab	52.0%
Stempel *et al*, 2005	RA: injectable, community	60.0%
Stempel *et al*, 2005	RA: injectable, specialty	81.0%
Stempel *et al*, 2005	RA: etanercept	57.0%
Stempel *et al*, 2005	RA: anakinra	36.0%
Stempel *et al*, 2005	RA: infliximab	64.0%
Stempel *et al*, 2005	Gout: allopurinol	68.0%
	Gastrointestinal	
Kane *et al*, 2011	Ulcerative colitis: Lialda	37.2%
Kane *et al*, 2011	Ulcerative colitis: Asacol	23.5%
Kane *et al*, 2011	Ulcerative colitis: Pentasa	24.0%
Kane *et al*, 2011	Ulcerative colitis: balsalazide	24.0%
Kane *et al*, 2011	Ulcerative colitis: Dipentum	22.5%
	Osteoporosis	
Solomon *et al*, 2012	Osteoporosis	41.0%
Yeaw *et al*, 2009	Osteoporosis	60.0%
	Ophthalmology	
Gurwitz *et al*, 1993	Glaucoma	69.0%
Yeaw *et al*, 2009	Glaucoma	37.0%
	Other	
Nichol *et al*, 2009	BPH	56.0%
Yeaw *et al*, 2009	Incontinence/OAB	25.0%
Shrank *et al*, 2010	Oral contraception	54.8%

Estimate of Revenue Loss

Prior to embarking on this project, we surveyed a number of pharmaceutical executives across divisions and companies regarding their thoughts on the following: the priority level given to medication non-adherence initiatives, whether or not the industry bears a responsibility to intervene, their level of skepticism that the non-adherence problem can be significantly improved, and finally, their estimate of what the pharmaceutical industry forfeits each year in the US.

We received a range of responses to our survey. Regarding priority level, 60% felt that adherence was a "high" priority for their company, whereas 20% responded "highest" priority and another 20% respondents felt the priority level was "medium." None felt that it was "low" priority. As for whether or not the industry bears some responsibility to intervene to improve adherence, all responded "yes." One respondent stated, "I believe the pharma industry, healthcare professionals and payers all bear an equal responsibility for promoting improved adherence to medication."

Twenty percent remain "slightly skeptical" that non-adherence can be significantly improved, and 40% were "not sure," whereas 40% were either "confident" or "very confident." Regardless, one respondent stated, "It is the biggest issue affecting positive treatment outcomes for most chronic therapies."

Most interestingly, the range of estimates of revenue loss by the pharmaceutical industry due to non-adherence was very broad, from "many millions" to $100 billion.

In contrast, based on our careful review of the modern claims-based adherence literature, our estimate of revenue lost by the pharmaceutical industry each year in the US alone due to non-adherence to medications for chronic disease is $188 billion (59% of the $320 billion in actual total revenue, or 37% of the $508 billion in potential total revenue). Extrapolated to the global market, pharmaceutical revenue loss is estimated to be $564 billion annually (59% of the $956 billion in actual total global revenue, and 37% of the $1,520 billion in potential total global revenue). This is more than 18 times higher than the $30 billion globally most often quoted to date.

These large numbers, particularly the large percentages of actual revenue lost, can be surprising at first and are even more surprising when you examine specific therapeutic classes, such as respiratory agents and antidepressants, where more than 200% of total current revenues are lost due to non-adherence. How can that be? To understand this seeming paradox, it is important to consider this: The calculation of losses due to non-adherence are based on revenues that could have been earned, not actually earned.

As a simple illustration, consider a fictional medication with an adherence rate of 50%, and consider that the brand earns $100 million per year on that medication. If all patients were, instead, fully adherent (if adherence was 100% rather than 50%), revenue would double, to $200 million. However, as actual adherence is only 50%, the brand earns only half of its potential. Another way to express the same thought is this: When adherence = 50%, the ratio of revenue earned to revenue lost is 1:1. If adherence is lower than 50%, the brand actually loses out on more than it earns.

Table 2. Revenue loss by major pharmaceutical class

Non-adherence related revenue loss in the US biopharmaceutical market by major therapeutic class, 2011e, USD billion

Major Therapeutic Classes	2011 US Revenue $ Million	Revenue Lost Due to Non-adherence			% Revenues Lost (revenue lost ÷ revenue earned)
		Primary	Secondary	Total	
Respiratory Agents	$ 21,000	$ 433	$ 45,618	$ 46,051	219%
Antidepressants	$ 11,000	$ 414	$ 23,228	$ 23,642	215%
Anti-ulcerants	$ 10,100	$ 337	$ 13,611	$ 13,949	138%
Antidiabetics	$ 19,600	$ 255	$ 11,155	$ 11,410	58%
Antipsychotics	$ 18,200	$ 502	$ 10,041	$ 10,543	58%
ADHD	$ 7,900	$ 129	$ 10,310	$ 10,440	132%
Lipid Regulators	$ 20,100	$ 568	$ 9,762	$ 10,330	51%
Autoimmune Diseases	$ 12,000	$ 153	$ 6,110	$ 6,263	52%
Angiotensin II	$ 7,600	$ 120	$ 4,194	$ 4,314	57%
Hormonal Contraceptives	$ 5,200	$ 52	$ 3,903	$ 3,955	76%
Platelet Aggregation Inhibitors	$ 7,800	$ 128	$ 3,732	$ 3,859	49%
HIV Antivirals	$ 10,300	$ 103	$ 3,709	$ 3,812	37%
Oncologics	$ 23,200	$ 84	$ 2,153	$ 2,237	10%
Anti-epileptics	$ 5,900	$ 86	$ 1,436	$ 1,521	26%
Multiple Sclerosis	$ 7,100	$ 90	$ 1,222	$ 1,312	18%
Erythropoietins	$ 5,100	$ 51	$ 623	$ 674	13%
Immunostimulating Agents	$ 4,500	$ 45	$ 550	$ 595	13%
Other	$ 105,000	$ 1,024	$ 31,745	$ 32,769	31%
Narcotic Analgesics	$ 8,300	$ –	$ –	$ –	0%
Vaccines (Pure, Comb., Other)	$ 6,300	$ –	$ –	$ –	0%
Antivirals, Excl. Anti-HIV	$ 3,700	$ –	$ –	$ –	0%
Grand Total	**$ 319,900**	**$ 4,576**	**$ 183,102**	**$ 187,677**	**59%**

To further clarify this picture, a focus on one specific therapeutic area is instructive. In diabetes, for example, we examined 9 large-scale adherence studies that met our inclusion criteria. Two focused on insulin therapy and 7 focused on oral therapy. Mean MPR or PDC for oral therapy, for example, ranged from 40% to 81%, with a weighted average of 61.6%. Accounting for primary non-adherence for the 5% of the diabetes market that is dynamic in a given year—a critical factor not accounted for in any of these studies—the revised weighted average adherence rate was 60.7%. Of note, all adherence studies used for our estimate focused on type 2 diabetes, which represents the vast majority of the market and the disease variant with greater adherence challenges.

In diabetes, total US pharmaceutical revenues totaled $19.6 billion and chronic use approximately $17.6 billion. Considering an estimated mean adherence rate of 60.7% across medications, the estimate of revenue lost in this therapeutic area alone is $11.4 billion or 58% of total revenue.

Although diabetes, as a common primary care condition, is a frequent focus of the media, we would also like to emphasize that medication non-adherence is surprisingly pervasive across chronic conditions, cropping up in areas one might least expect it. Such therapeutic areas include, for example, immunosuppressant medications to prevent organ rejection after transplantation, glaucoma medications to prevent visual loss or blindness, HIV medications to prolong life, and adjuvant therapy to prevent cancer recurrence.

There are 4 main factors that make our estimate of revenue loss conservative. One, we focused only on chronic conditions, which are the target of most adherence studies and adherence interventions. Clearly, there are adherence issues with nonchronic medications, such as antibiotics or vaccines, but we excluded those categories altogether from our revenue loss calculations.

Two, the way we estimated revenue loss due to primary non-adherence (initial prescriptions never filled) was extremely conservative. For lack of better sources, the data on the relative size of the dynamic market or new patients (versus prescriptions renewed from one year to the next) that we used to calculate our baseline were measured in total prescriptions and were close to 10% of the total market. However, because new expensive drugs are generally over-represented in comparison to older, cheaper (and sometimes generic) drugs in the dynamic part of the market, the actual revenue loss due to primary non-adherence is likely to be significantly higher than our estimate.

Three, most secondary adherence studies include only patients who have filled a prescription at least twice (the initial fill, with at least one refill). However, given that the steepest drop-off in persistence typically occurs during the first 3 months on therapy, many adherence studies actually overestimate adherence by excluding the significant number of patients who fill only once. In overestimating adherence, we underestimate revenue loss.

And fourth, we did not account for the fact that in any given year, there are patients who were prescribed a medication the prior year and dropped off, but who should have remained on that medication through years two, three, and beyond. The pharma industry continues to lose out on revenue from these patients who should, based on their physicians' initial advice, be on long-term or even lifelong therapy. Because we did not add these patients to our statistics, we further overestimated adherence, thereby underestimating revenue loss.

Figure 1. Calculation of US pharmaceutical revenue loss due to non-adherence

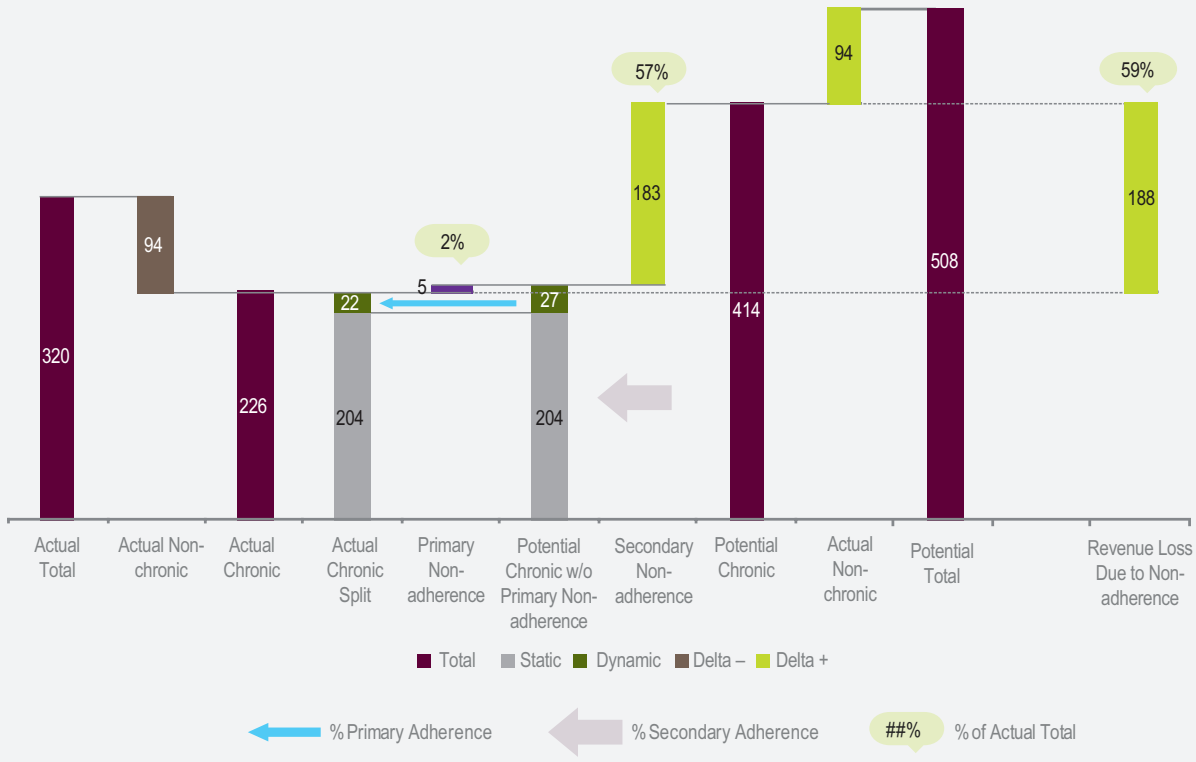
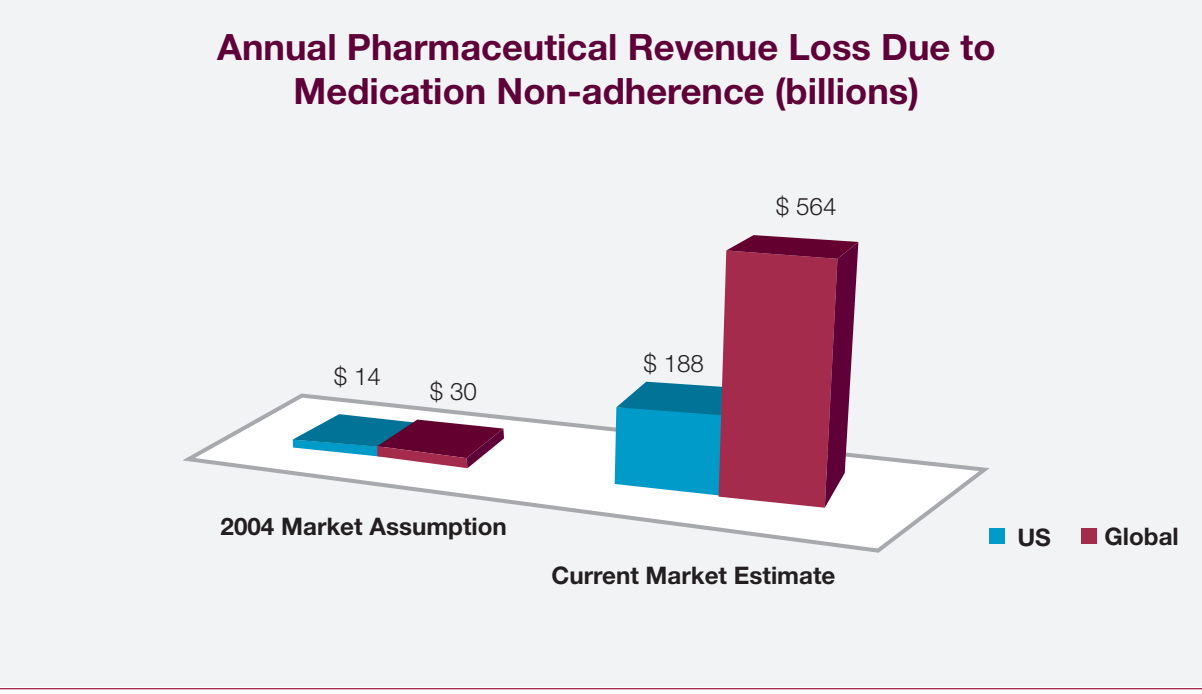


Figure 2. Current revenue loss estimate compared with previous market assumption



Implications

Our estimate of $188 billion in pharmaceutical revenue lost annually in the US alone and $564 billion globally due to medication non-adherence is the most accurate estimate to date and points to a far more significant problem than previously believed or acknowledged. Clearly, the priority level assigned to medication non-adherence should be at the highest level within the pharmaceutical industry, and a willingness to embrace more innovative solutions is imperative, given the lackluster results of historical efforts.

Although a number of pharmaceutical companies have established adherence teams, they are often underfunded, slow moving, and prone to recommending traditional tactics such as reminder programs, cost reductions, and isolated educational campaigns, which are insufficient and often do not address the root of the problem.

Interestingly, regardless of condition, cost of therapy, or demographic, a common shortcoming of human psychology is the difficulty in following through with taking a medication (or with any healthy behavior) in the present for a health-related payoff in the distant future. This is a psychological reality that tends to resist simple reminders, cost reductions, and even educational efforts.

However, even the most innovative and effective solution will not “cure” the problem. The goal is to raise adherence rates compared with baseline, not to perfect adherence, which is impossible. Given this reality, how much of the $564 billion ($188 billion US) lost each year can pharma reasonably expect to recoup in the best-case scenario? This remains unknown. However, if pharma were able to reduce the adherence gap by a tenth across the board, it would net an additional $41 billion in revenue to the US pharmaceutical industry each year. And, with this lift in adherence and revenues, a corresponding boost in clinical outcomes and decline in healthcare spending would be realized, benefiting patients and the healthcare industry as a whole.

What is clear is that the rigor applied to adherence research is bound to improve, given the growing interest in and scrutiny of the field, and the realization that some degree of standardization would go far toward more accurate meta-analysis efforts. Although our estimate was derived from the most rigorous methods possible, combined with conservative assumptions and the best publicly available data, it remains an estimate based on imperfect data. We are confident that future efforts, based on better data, will offer the industry even more accurate insights into the nature of the problem, its magnitude, and the efficacy of new interventions.

About the Authors and Contributors

If you have any questions about this report, please contact:

Thomas Forissier

Principal, Capgemini Consulting

Thomas Forissier is a Principal in Capgemini Consulting's Life Sciences Sector and co-lead of the Life Sciences Customer Experience Practice. Thomas has conducted multiple projects in the areas of customer experience and digital strategy at leading pharmaceutical companies and helped define innovative value propositions for patients and HCPs alike. Thomas has researched the area of patient adherence for the past few years. He was the lead author for Capgemini Consulting's 2011 Vision & Reality report *Patient Adherence: The Next Frontier in Patient Care*. In April 2012, he published an article in PM360 titled *Patient Adherence: Initiating the Journey toward Collaboration*. He also contributed to the FirstWord 2012 report *New Thinking on Patient Adherence*. Thomas received masters degrees in management from ESCP Europe and in political science from Science Po Paris.

Capgemini Consulting contact info: Email: thomas.forissier@capgemini.com Call: +1 646 339 6066

Katrina Firlik, MD

Chief Medical Officer, HealthPrize Technologies

Dr. Katrina Firlik is co-founder and Chief Medical Officer of HealthPrize Technologies. Prior to founding HealthPrize, Dr. Firlik was a neurosurgeon in private practice in Greenwich, Connecticut and on the clinical faculty at Yale University School of Medicine. She is also the author of *Another Day in the Frontal Lobe*, published by Random House.

HealthPrize contact info: Email: kfirlik@healthprize.com Call: +1 203 957 3402

Contributors

Kevin Qin

Senior Consultant in the Life Sciences Practice of Capgemini Consulting

Kevin Qin is a Senior Consultant in the Life Sciences Practice of Capgemini Consulting. He has an extensive background in the areas of clinical and commercial assessment and decision modeling. Kevin holds an MBA degree from the Indiana University at Bloomington, Indiana.

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