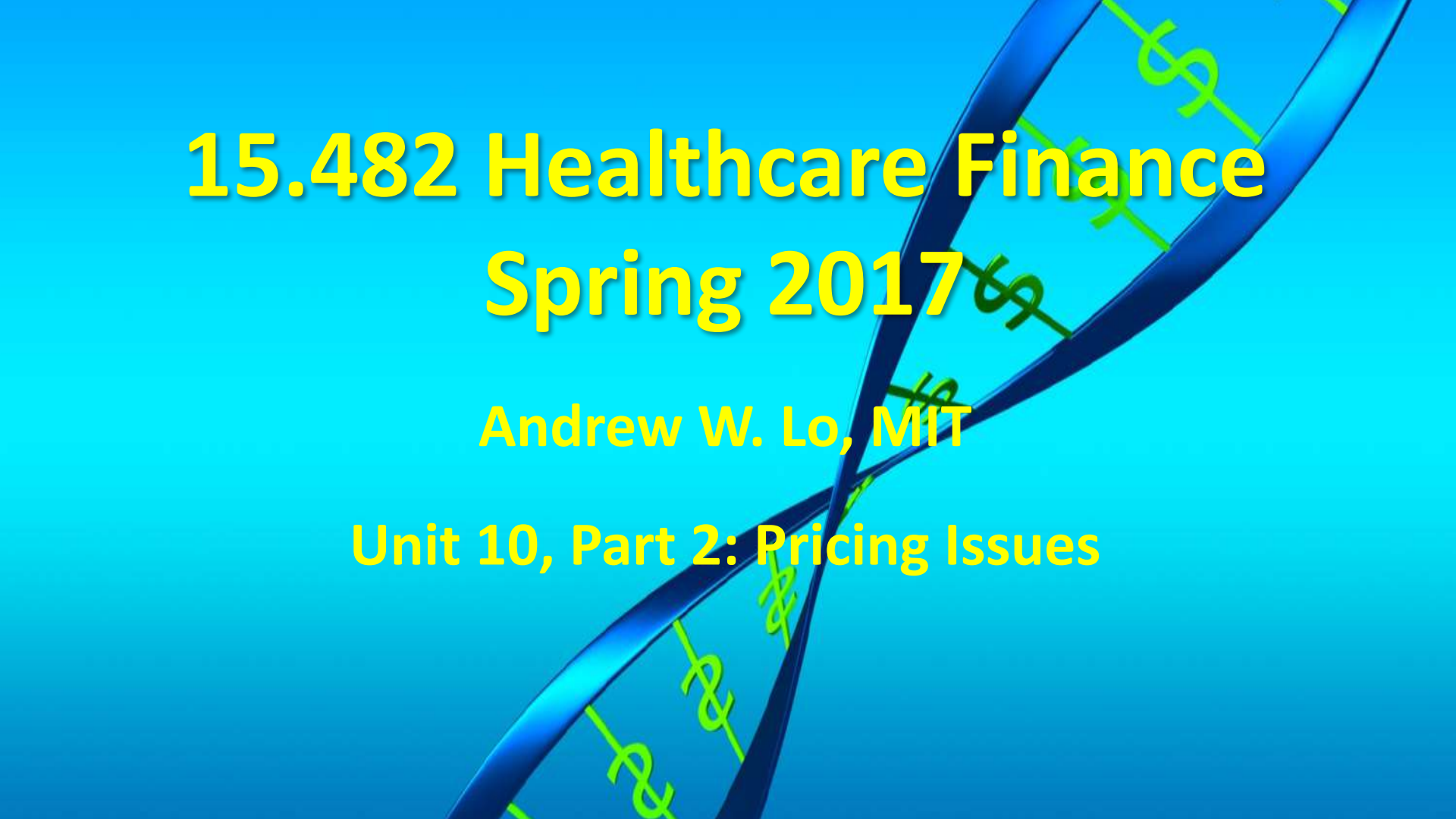
15.482 Healthcare Finance
Spring 2017

Andrew W. Lo, MIT

Unit 10, Part 2: Pricing Issues



Unit Outline

- Pricing
- Ethics
- Pricing Issues for Cancer Drugs
- Price vs. Value
- Questcor Pharmaceuticals

Pricing Issues for Cancer Drugs

MSK Says "No" To Zaltrap

The New York Times

October 14, 2012

October 14, 2012

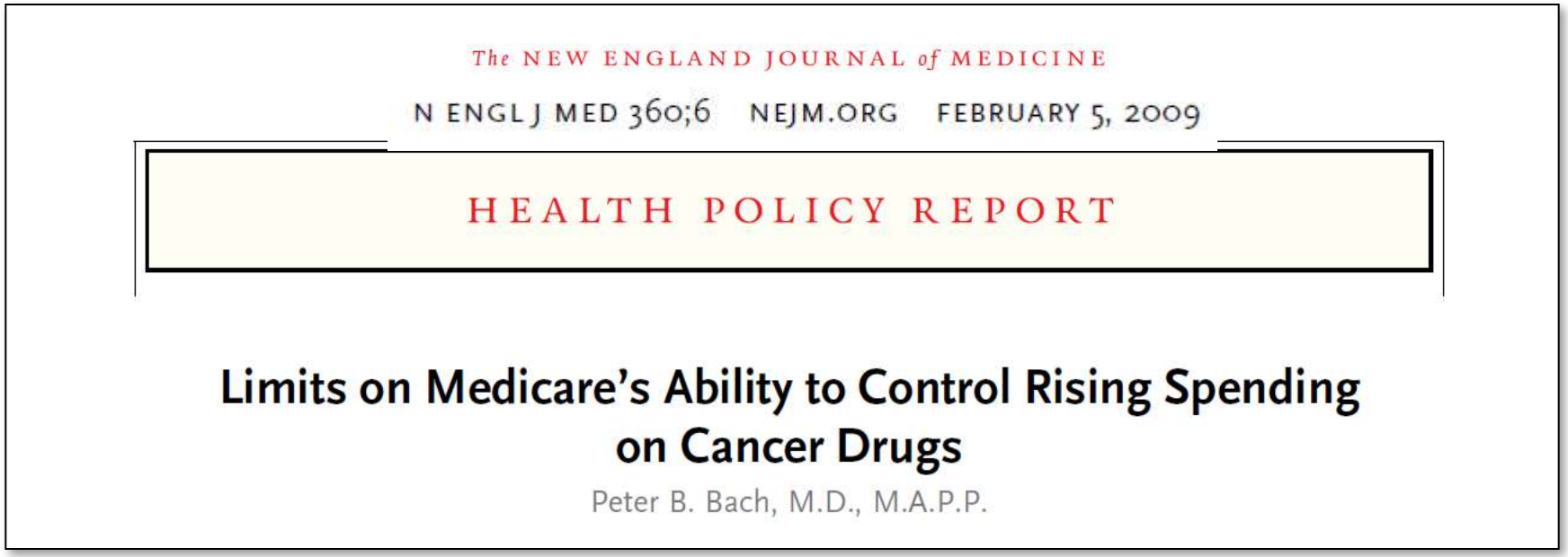
In Cancer Care, Cost Matters

By PETER B. BACH, LEONARD B. SALTZ and ROBERT E. WITTES

AT Memorial Sloan-Kettering Cancer Center, we recently made a decision that should have been a no-brainer: we are not going to give a phenomenally expensive new cancer drug to our patients.

The reasons are simple: The drug, Zaltrap, has proved to be no better than a similar medicine we already have for advanced colorectal cancer, while its price — at $11,063 on average for a month of treatment — is more than twice as high.

Medicare and Price Controls



The NEW ENGLAND JOURNAL of MEDICINE

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HEALTH POLICY REPORT

Limits on Medicare's Ability to Control Rising Spending on Cancer Drugs

Peter B. Bach, M.D., M.A.P.P.

Medicare and Price Controls

DRUG COVERAGE

Several provisions of the law address Medicare's coverage of cancer drugs, and Medicare has traditionally interpreted these as mandates that it provide coverage, thus undoing the use of coverage restrictions to limit utilization. For cancer drugs that are covered under Part B, which are generally drugs that are administered in a physician's office, the law requires Medicare to cover any drug used in an "anticancer chemotherapeutic regimen," as long as the use is "for a medically accepted indication" (Table 2). The law defines "medically accepted indication" broadly as uses approved by the Food and Drug Administration (FDA), uses listed in one of several drug compendia, and uses supported in the peer-reviewed medical literature.

For Part D drugs, which are generally oral drugs that a patient obtains from a pharmacy, the private plans that contract with Medicare to implement the program are required to include on their formularies virtually all cancer drugs that were available at the time the program was implemented in 2006.[19,24] In 2008, Congress addressed the inclusion on formularies of oral cancer drugs that came on the market after 2006, amending the law to mandate that as of 2010, Part D plans must include all drugs in certain categories in which the treated condition is "major" or "life-threatening." The prototypical example

Medicare and Price Controls

Table 3. State Legislation Affecting the Coverage of Off-Label Uses of Cancer Drugs by Private Payers.*

Requirement	States Affected	Total Population of States Affected	Percentage of the U.S. Population Affected
Mandated coverage if use is listed in either recognized compendia or peer-reviewed medical literature	AL, AZ, AK, CA, FL, GA, IL, IN, KS, LA, ME, MD, MA, MN, MS, NE, NV, NJ, NY, OH, OR, RI, SC, SD, TN, VT	174,621,577	62
Mandated coverage if use is listed in recognized compendia only	CT, NC, OK, VA	21,984,047	8
Mandated coverage if use is supported in medical literature only	MI	9,938,444	4
Mandated coverage if use is "medically necessary" (but no other requirements)†	NH	1,235,786	<1
Total mandated coverage		207,779,854	74

Medicare and Price Controls

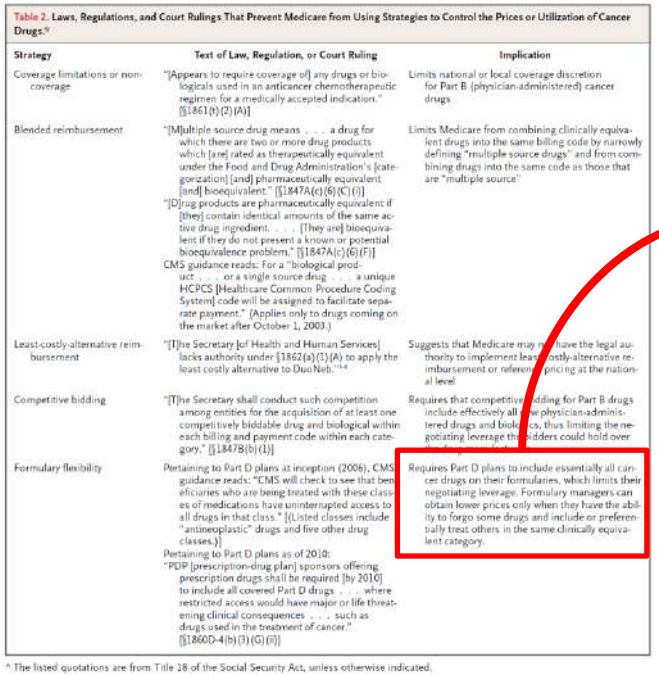

Table 2. Laws, Regulations, and Court Rulings That Prevent Medicare from Using Strategies to Control the Prices or Utilization of Cancer Drugs.*

Strategy	Text of Law, Regulation, or Court Ruling	Implication
Coverage limitations or non-coverage	"[Appears to require coverage of] any drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication." [§1861(t)(2)(A)]	Limits national or local coverage discretion for Part B (physician-administered) cancer drugs
Blended reimbursement	"[M]ultiple source drug means . . . a drug for which there are two or more drug products which [are] rated as therapeutically equivalent under the Food and Drug Administration's [categorization] [and] pharmaceutically equivalent [and] bioequivalent." [§1847A(c)(6)(C)(i)] "[D]rug products are pharmaceutically equivalent if [they] contain identical amounts of the same active drug ingredient. . . . [They are] bioequivalent if they do not present a known or potential bioequivalence problem." [§1847A(c)(6)(F)] CMS guidance reads: For a "biological product . . . or a single source drug . . . a unique HCPCS [Healthcare Common Procedure Coding System] code will be assigned to facilitate separate payment." (Applies only to drugs coming on the market after October 1, 2003.)	Limits Medicare from combining clinically equivalent drugs into the same billing code by narrowly defining "multiple source drugs" and from combining drugs into the same code as those that are "multiple source"
Least-costly-alternative reimbursement	"[T]he Secretary [of Health and Human Services] lacks authority under §1862(a)(1)(A) to apply the least costly alternative to DuoNeb."[14]	Suggests that Medicare may not have the legal authority to implement least-costly-alternative reimbursement or reference pricing at the national level
Competitive bidding	"[T]he Secretary shall conduct such competition among entities for the acquisition of at least one competitively biddable drug and biological within each billing and payment code within each category." [§1847B(b)(1)]	Requires that competitive bidding for Part B drugs include effectively all new physician-administered drugs and biologics, thus limiting the negotiating leverage that bidders could hold over
Formulary flexibility	Pertaining to Part D plans at inception (2006), CMS guidance reads: "CMS will check to see that beneficiaries who are being treated with these classes of medications have uninterrupted access to all drugs in that class." [(Listed classes include "antineoplastic" drugs and five other drug classes.)] Pertaining to Part D plans as of 2010: "PDP [prescription-drug plan] sponsors offering prescription drugs shall be required [by 2010] to include all covered Part D drugs . . . where restricted access would have major or life threatening clinical consequences . . . such as drugs used in the treatment of cancer." [§1860D-4(b)(3)(G)(i)]	Requires Part D plans to include essentially all cancer drugs on their formularies, which limits their negotiating leverage. Formulary managers can obtain lower prices only when they have the ability to forgo some drugs and include or preferentially treat others in the same clinically equivalent category.

* The listed quotations are from Title 18 of the Social Security Act, unless otherwise indicated.

Requires Part D plans to include essentially all cancer drugs on their formularies, which limits their negotiating leverage. Formulary managers can obtain lower prices only when they have the ability to forgo some drugs and include or preferentially treat others in the same clinically equivalent category.

- Cancer drugs do not trade in "free markets"

Cancer Drug Shortages

Survey of Oncologists about Shortages of Cancer Drugs

TO THE EDITOR: It is becoming increasingly difficult for patients with cancer to receive the life-saving treatments they need. Generic chemotherapy agents that are routinely used for the curative treatment of common and aggressive cancers have been vulnerable to shortages in the United States since 2006.[1] One retrospective analysis confirmed that drug substitutions forced by

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Cancer Drug Shortages

Of the 214 physicians, 82.7% were unable to prescribe the preferred chemotherapy agent because of shortages at least once during the previous 6 months. The drugs associated with the most commonly reported shortages — leucovorin (reported by 66.4% of the oncologists surveyed), liposomal doxorubicin (reported by 61.7%), fluorouracil (reported by 18.7%), bleomycin (reported by 17.3%), and cytarabine (reported by 16.4%) — are integral to curing malignant conditions such as colon cancer, breast cancer, and leukemia as well as providing palliation for patients with metastatic cancer (see the Supplementary Appendix).[4]

Table 1. Response of Oncologists to the Shortage of Chemotherapy Drugs.

Adaptation	Oncologists Reporting Modification (N = 176)
	no. (%)
Switched chemotherapy regimens	138 (78.4)
Substituted a different drug partway through treatment regimen	135 (76.7)
Delayed treatment	76 (43.2)
Excluded some patients	65 (36.9)
Omitted doses	51 (29.0)
Reduced doses	35 (19.9)
Referred patients to another practice	29 (16.5)

Cancer Drug Shortages

OCTOBER 2011

ASPE ISSUE BRIEF

OFFICE OF THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION
OFFICE OF SCIENCE AND DATA POLICY · U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

ECONOMIC ANALYSIS OF THE CAUSES OF DRUG SHORTAGES

Summary

The prescription drug and vaccine markets are characterized by sporadic shortages of individual drugs and occasional periods during which several in a class are in shortage. Currently, class-wide shortages are affecting the sterile injectables segment of the industry, particularly sterile injectable oncology products. While the existence of shortages is an unusual feature of this market, it is important to note that most drugs do not experience shortages. Even within the sterile injectable oncology segment of the market, where shortages today are most severe, only about 10% of the Medicare Part B volume of injectable oncology services in 2008 consisted of drugs that experienced any shortage at some point over the subsequent 4 years.

Sporadic and class-wide shortages of sterile injectable drugs occur because neither the quantity of these products needed by consumers nor the quantity of these products produced by manufacturers is very responsive to short term changes in price. This means that product disruptions, however caused, translate into shortages rather than simply higher prices.

The current class-wide shortages in the industry appears to be a consequence of a substantial expansion in the scope and volume of products produced by the industry that has occurred over a short period of time, without a corresponding expansion in manufacturing capacity. While several manufacturers are currently expanding capacity, most of this capacity will not become available for several years. The expansion in product scope and quantity, in turn, stems from both an increase in the overall volume of chemotherapy drugs used and an unusually high rate of patent expirations in this sector that began in 2008 and has continued through 2010. While the generic industry is highly competitive in the long run, the supply of products is constrained in the short-run, because it takes several years for new firms to enter or for existing firms to add capacity. In the short run, existing firms make strategic decisions about how to deploy production capacity among products, based on their conjectures about what choices their competitors will make.

ABOUT THIS ISSUE BRIEF

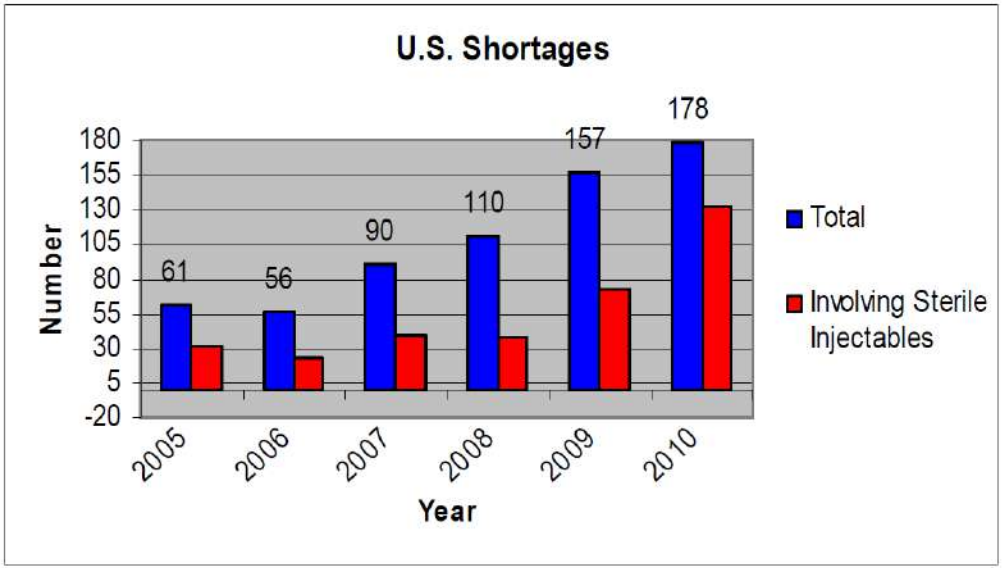
Drug shortages have been having significant impacts on patients and healthcare providers. In order to understand what is causing drug shortages and to enable evaluation of potential solutions, ASPE conducted an analysis of the underlying factors that lead to periods of shortage in the prescription drug market. This report complements the FDA's report on the current drug shortage problem, which focuses on the FDA's role in monitoring and responding to shortages.

The Issue Brief was written by Kevin Hennger, Amber Jessup, and Kathleen Koehler of ASPE's Office of Science and Data Policy.

Sherry Glied, PhD
Assistant Secretary

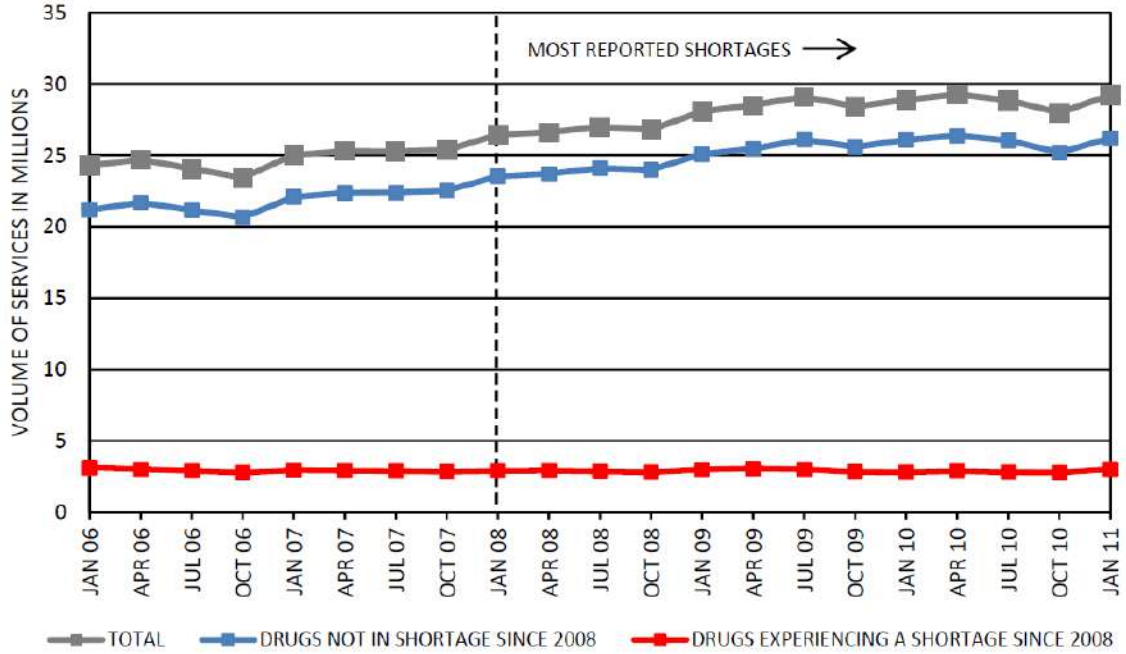
Laina Bush
Associate Deputy Assistant Secretary for Science and Data Policy

Figure 1: Drug shortages followed by FDA, by year[4]



Cancer Drug Shortages

Figure 2: Medicare Part B Volume of Services of Oncology Sterile Injectable Drugs



Note: The graph is restricted to the J9000-J9999 series of HCPCS codes with greater than 100 services in Q1 2006 and an average of more than 1,000 services annually.

Cancer Drug Shortages

Table 1: Annual Change in Medicare Part B Volume of Services of Oncology Sterile Injectable Drugs

Period	Drugs Experiencing a Shortage since 2008 (n = 44)				Drugs not in Shortage since 2008 (n = 28)			
	Number of Drugs	Change in Volume of Services over Period			Number of Drugs	Change in Volume of Services over Period		
		Mean	Median	Std. Dev.		Mean	Median	Std. Dev.
Q1 2006 to Q1 2008	44	-6.9%	-5.6%	29.6	28	11.2%	4.8%	40.5
Q1 2008 to Q1 2011	44	-2.0%	-7.6%	200.5	28	10.5%	-2.3%	59.1
Q1 2006 to Q1 2011	44	-3.0%	-16.2%	184.3	28	23.8%	-5.4%	61.7

Note: The table is restricted to the J9000-J9999 series of HCPCS codes with greater than 100 services in Q1 2006 and an average of more than 1,000 services annually. Mean and median changes are weighted by volume of services in Q1 2006.

Cancer Drug Shortages

Table 2: Annual Change in Price of Oncology Sterile Injectable Drugs

Period	Drugs Experiencing a Shortage since 2008 (n = 44)				Drugs not in Shortage since 2008 (n = 28)			
	Number of Drugs	Change in Price over Period			Number of Drugs	Change in Price over Period		
		Mean	Median	Std. Dev.		Mean	Median	Std. Dev.
Q1 2006 to Q1 2008	44	-26.5%	-21.4%	19.1	28	0.6%	2.5%	10.9
Q1 2008 to Q1 2011	44	-6.3%	-19.4%	113.7	28	2.6%	0.5%	32.0
Q1 2006 to Q1 2011	44	-27.4%	-49.1%	94.4	28	3.2%	0.3%	24.4

Note: The table is restricted to the J9000-J9999 series of HCPCS codes with greater than 100 services in Q1 2006 and an average of more than 1,000 services annually. Mean and median changes are weighted by volume of services in Q1 2006. Changes in price are based on prices in 2011 dollars.

It is expensive to hold capacity ready to make a drug and yet earn no sales from that capacity the vast majority of the time. In our current system this cost would fall on the generic drug firm that chose to build excess capacity or dual source; it would have high costs relative to its competitors. Clearly, in a competitive market, which the generic drug industry is, no firm will choose this route unless it receives a higher price in the market or other compensation.

Meanwhile…

Number of New FDA-Approved Cancer Drugs

- 2017: 6
- 2016: 11
- 2015: 21
- …