

Measuring the Impact of the Medicare Prescription Drug,  
Improvement, and Modernization Act of 2003 on Shortages of  
Sterile Injectable Oncology Drugs

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# Executive Summary

## **POLICY QUESTION** (p. 1)

Did the implementation of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 contribute to shortages of sterile injectable oncology drugs by capping the growth rate of reimbursements paid for Medicare Part B drugs?

## **BACKGROUND** (p. 1)

The problem of U.S. pharmaceutical drug shortages is one that has steadily grown in severity over the course of the past decade, particularly in the years since 2006. While annual shortages used to number between 50 and 100 prior to 2006, they have proliferated in the years since, with shortages reaching record levels in 2010 and 2011. While most shortages last for less than one year, approximately one quarter of all shortages last for more than one year. Many drugs subject to shortage were in shortage more than once between 2001 and 2011.

Some types of drugs have proven more susceptible to shortage than others. Sterile injectable drugs—drugs typically shipped in either liquid or powder form and that are designed to be injected into a patient—have proven in recent years to be highly susceptible to shortage, due in part to their complex manufacturing process. Data on recent drug shortages indicates that the large majority of drugs subject to shortage are sterile injectables, the majority of which are available in a generic form.

Sterile injectable drugs have been used to treat various forms of cancer since the 1940s; they have proven to be highly effective in the treatment of some cancers—such as testicular, lymphoma, and cervical cancers—while less effective in the treatment of others, such as prostate and pancreatic cancers. Shortages of cancer drugs can have a profound impact on the prognoses of patients diagnosed with cancer, as treatment options for cancer patients may be severely limited by the inability to acquire necessary drugs.

The primary concern resulting from drug shortages is whether or not patients who are in need of a critical drug will have their treatment delayed as the result of a shortage. Shortages can also lead health providers to turn to alternative drugs they are unfamiliar with, increasing the potential for errors and poor patient outcomes. Providers also spend significant amounts of time and money each year on managing shortages. Providers are sometimes forced to turn to the “grey market,” where unauthorized distributors of drugs in shortage may be selling for exorbitant prices.

Drug shortages occur due to a number of factors. Some of the oft-cited causes of shortages include:

- Disruptions in the supply of raw materials needed to produce drugs.

- Manufacturing problems related to the quality and safety of drugs in production.
- Business decisions made by drug manufacturers that can lead to the closing of a production line or production facility.
- An unstable global supply chain for drugs constrained by finite manufacturing capacities and “just-in-time” inventory systems.

Many have also blamed changes to Medicare drug reimbursement formulas resulting from the passage of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. MMA changed the formula used by the Centers for Medicare and Medicaid Services (CMS) to set reimbursement rates for Medicare Part B drugs. The new formula, which went into effect in 2005, sets rates at a drug’s average sales price (ASP) plus a 6 percent markup to cover administrative costs. Prior to 2005, CMS had reimbursed 95 percent of a Part B drug’s average wholesale price (AWP).

Many have pointed to this change in reimbursement rates as the reason for shortages of oncology drugs, calling the new formula of ASP plus 6 percent a “price control” that prevents drug prices from rising in response to market forces. Many have claimed that this new formula prevents the reimbursement rate of a drug from rising by more than 6 percent every six months.

#### **DATA AND METHODS** (p. 14)

In response to assertions that drug shortages are primarily the result of the change in the Part B reimbursement rate contained within MMA, this analysis will focus on the actual reimbursement amounts paid out by CMS over the period between 1998 and 2011. This analysis will focus on a small, nongeneralizable sample of 12 sterile injectable oncology drugs; some, but not all, of these 12 drugs have been subject to shortage during the 1998 to 2011 time period.

#### **TESTED HYPOTHESES** (p. 16)

Two hypotheses that follow from the assertion that “price controls” are to blame for shortages will be tested.

Hypothesis 1: Starting in 2005, reimbursement rates for drugs should not have risen by more than 6 percent over the course of a 3 to 6 month period.

Hypothesis 2: If the ASP plus 6 percent formula is responsible for inducing shortages, reimbursement rates for drugs in shortage should be hitting up against a 6 percent “ceiling” beyond which they cannot rise in price.

#### **ANALYSIS OF HYPOTHESES** (p. 17)

Hypothesis 1: Reimbursement rates for the sterile injectables examined here—particularly the generics—commonly rose by more than 6 percent between quarters, let alone every six months. In some cases, reimbursement rates for a number of the drugs examined here rose by hundreds or thousands of percentage points between quarters.

Hypothesis 2: Contrary to bumping up against a growth rate “ceiling,” reimbursement rates fell between 2008 and 2011 for drugs subject to shortage by an average of 22.33 percent. For drugs not subject to shortage, reimbursement rates rose by an average of 54.25 percent.

### **CONCLUSION & RECOMMENDATION (p. 23)**

Examinations of changes in reimbursement rates following the implementation of MMA indicate that, contrary to what many who have written or spoken on the topic of oncology drug shortages state, the new rate formula of ASP plus 6 percent does not appear to be capping the rate at which reimbursement rates for drugs can rise. Indeed, the MMA formula uses the “average sales price” (ASP) of a drug to set reimbursement rates; this is a market-driven formulation dictated by the actual selling price of a drug, not—as it has often been characterized—a “price control” set by the federal government.

The current reimbursement rate for a drug is based on ASP data from two quarters prior, meaning that there is a six-month delay between the market settling on a price for a drug and CMS using that market signal to calculate a reimbursement rate for that drug. Were it possible for ASPs to be submitted and rates calculated monthly rather than quarterly, a shorter delay of two months would be in effect, making CMS reimbursement rates even more responsive to market forces. While this would require a legislative amendment to MMA, as well as increased efforts on the part of both drug companies and CMS, the feasibility of such a change should be examined and considered.

## POLICY QUESTION

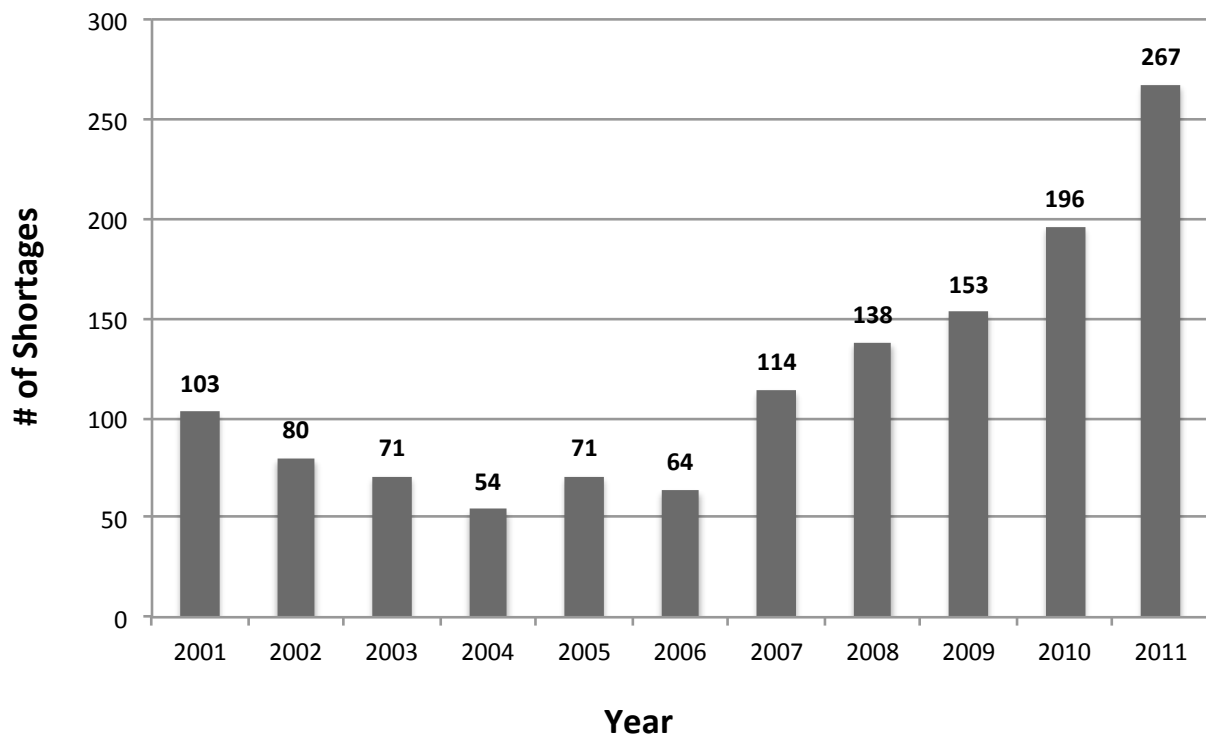
Did the implementation of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 contribute to shortages of sterile injectable oncology drugs by capping the growth rate of reimbursements paid for Medicare Part B drugs?

## BACKGROUND

*Extent of Pharmaceutical Drug Shortages in the U.S.*

The problem of U.S. pharmaceutical drug shortages is one that has steadily grown in severity over the course of the past decade, particularly in the years since 2006:

**Reported U.S. Pharmaceutical Drug Shortages, 2001 - 2011**



Source: Univ. of Utah Drug Information Service data via GAO / The Washington Post

Since 2006, the number of shortages has increased each year, growing by more than 400 percent between 2006 and 2011. The number of reported shortages reached a record level of 196 reported shortages in 2010; that record was broken in 2011 when 267 drugs were reported to be in shortage.<sup>1</sup> (For a summary of how the FDA identifies shortages of drugs, see “Appendix A - *The FDA’s Drug Shortage Program.*”)

In a 2011 report on drug shortages, the U.S. Government Accountability Office (GAO) found that approximately 64 percent of shortages—or 766 of the 1,190 shortages reported between January 2001 and June 2011—were of drugs subject to shortage more than once during this time period. These 766 shortages represented multiple shortages of 283 different drugs, with an average of 2.7 shortages per drug between January 2001 and June 2011.<sup>2</sup> GAO found that, while the large majority—74 percent—of all shortages reported between 2001 and June 2011 lasted for one year or less, 16 percent of shortages lasted for between one and two years, and 10 percent of shortages lasted for more than two years. The average length of a shortage, taking into account all reported shortages between January 2001 and June 2011, was 286 days.<sup>3</sup>

### *Sterile Injectable Drugs Particularly Subject to Shortage*

Some types of drugs have proven more susceptible to shortage than others. Sterile injectable drugs—drugs typically shipped in either liquid or powder form and that are designed to be injected into a patient—have proven in recent years to be highly susceptible to shortage. Sterile injectables subject to shortage include a number of critical anesthesia, central nervous system, cardiovascular, anti-infective, and oncology drugs. Sterile

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<sup>1</sup> Sun, Lena H. "Hospitals scramble on the front lines of drug shortages." *The Washington Post*. April 10, 2012.

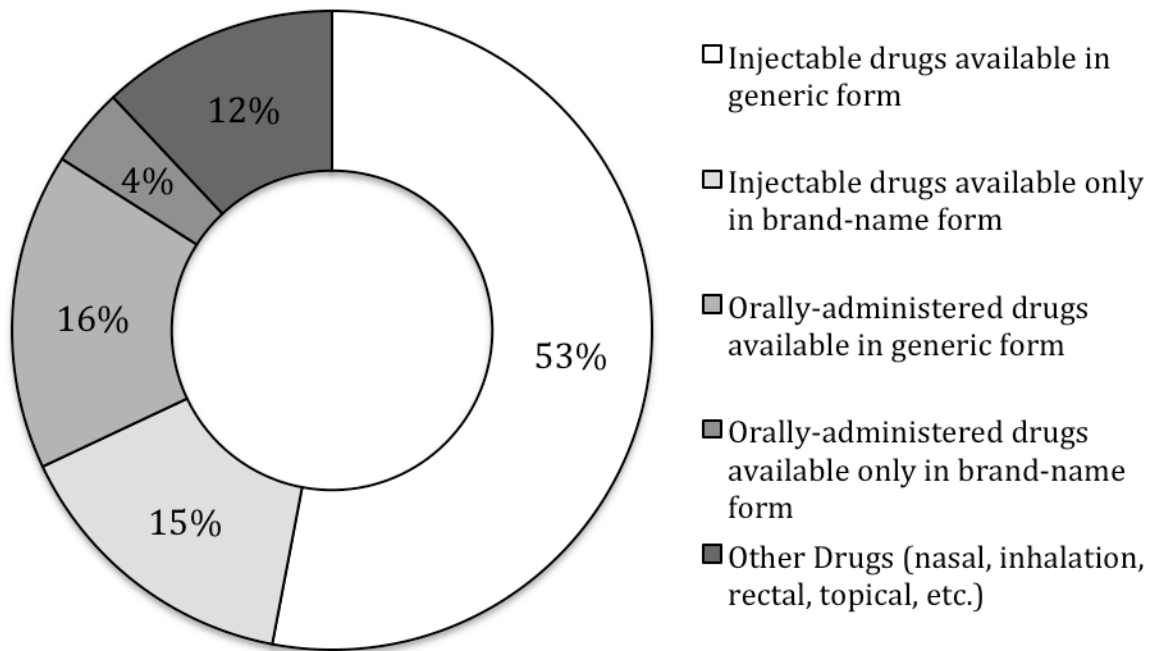
<sup>2</sup> GAO. "Drug Shortages: FDA's Ability to Respond Should be Strengthened." November 2011.

<sup>3</sup> Ibid.

injectables are particularly susceptible to shortage due in part to the fact that they can be highly susceptible to manufacturing problems, as their production process is complex and vulnerable to disruption, given that everything used to produce them must be kept sterile.<sup>4</sup>

In 2010, 74 percent of the drugs deemed by the FDA to be in short supply were sterile injectables.<sup>5</sup> Data on recent drug shortages examined by GAO found that the large majority of drugs subject to shortage are injectables, with the majority of them available in a generic form:

**Drug Shortages by Drug Type & Administration  
January 2009 – June 2011**



Source: GAO analysis of University of Utah Drug Information Service and Red Book data (GAO. "Drug Shortages: FDA's Ability to Respond Should be Strengthened." Report to Congressional Requesters, U.S. Government Accountability Office, Washington, D.C., November 2011.)

<sup>4</sup> Mullins, Tara D., and Aaron M. Cook. "Drug Shortages: Causes and Cautions." *Orthopedics* 34, no. 9 (2011): 712-714.

<sup>5</sup> Lowes, Robert. "Sterile Injectables Account for Most of Drug Shortage." September 30, 2011.

Of particular concern are sterile injectable oncology drugs, as the standard treatment regimens for a number of forms of cancer have been directly affected by shortages of key drugs. According to GAO, while only 10 percent of all shortages reported between January 2009 and June 2011 were of sterile injectable oncology drugs, the overall number of reported sterile injectable oncology drug shortages rose by more than 600 percent during this time period.<sup>6</sup> This report is focused specifically on shortages of sterile injectable oncology drugs.

### *Impact of Shortages on the Treatment of Cancer*

Sterile injectable drugs have been used to treat various forms of cancer since the 1940s. Sterile injectable oncology drugs are typically injected intravenously and are designed to kill cancer cells that would otherwise multiply rapidly; they have proven to be highly effective in the treatment of some cancers—such as testicular, lymphoma, and cervical cancers—while less effective in the treatment of others, such as prostate and pancreatic cancers.<sup>7</sup>

Shortages of cancer drugs can have a profound impact on the prognoses of patients diagnosed with cancer, as treatment options for cancer patients may be severely limited by the inability to acquire these necessary drugs. Recent survey data found that 94 percent of contacted facilities that saw cancer patients between 2010 and 2011 experienced oncology drug shortages, and that 84 percent of survey respondents said they had to modify or temporarily suspend a chemotherapy regimen—or provide a substitute drug—as the result

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<sup>6</sup> GAO. "Drug Shortages: FDA's Ability to Respond Should be Strengthened." November 2011.

<sup>7</sup> ASPE - Office of Science and Data Policy. "Economic Analysis of the Causes of Drug Shortages." 2011.

of drug shortages.<sup>8</sup> Dr. Michael Link, a professor of pediatrics at the Stanford University School of Medicine, has stated that pediatric oncologists can typically cure 70 to 80 percent of the children they see, but that, if shortages hit, “you might as well close your doors if you don’t have these drugs.”<sup>9</sup>

### *Potential Effects of Shortages*

The primary concern resulting from drug shortages, as discussed, is whether or not patients who are in need of a critical drug will have their treatment delayed as the result of a shortage. The results of a 2011 American Hospital Association survey found that 82 percent of 820 non-federal, short-term acute care hospitals reported they had delayed patient treatment as the result of a drug shortage, while more than half of surveyed hospitals were “not always able” to provide a patient with a recommended treatment.<sup>10</sup> AHA survey results also indicated that 35 percent of hospitals reported that a patient had “experienced an adverse outcome” as the result of a drug shortage.<sup>11</sup>

At the extreme—for a cancer patient fighting for their life or a patient forced to delay major surgery due to a shortage of a necessary drug—a drug shortage could mean the loss of life. Drug shortages can also affect patient care when they force doctors to seek out substitute drugs they are unfamiliar with—drugs that are often less desirable, more expensive, and unfamiliar to the doctor. When doctors are forced to resort to unfamiliar alternatives, the potential for errors and subsequent poor patient outcomes increases; treatment can also be delayed or interrupted completely while an alternative is sought, and

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<sup>8</sup> Eastman, Peggy. "Oncology Drug Shortages Worsening, Threatening Patient Care." *Oncology Times* 33, no. 15 (August 2011): 14-15.

<sup>9</sup> Ibid.

<sup>10</sup> AHA. *AHA Survey on Drug Shortages*. American Hospital Association, Chicago: July 2011.

<sup>11</sup> Ibid.

confusion over dosage amounts can arise when a drug that is similar but not identical to the drug in shortage is finally located. In other cases, a substitute drug may simply not exist, and a patient can go without a treatment altogether.

A 2010 survey performed by the Institute for Safe Medication Practices suggested that, of the 1,800 healthcare practitioners surveyed, approximately one in three reported their facility had experienced a “near miss”—an error that did not result in patient harm, but that could have—during the past year due to a drug shortage.<sup>12</sup> Approximately one in four reported actual errors during the past year, while one in five reported that an adverse patient outcome had resulted from a drug shortage. In at least two instances, ISMP survey respondents stated that patients had died as the direct result of a drug being in shortage.<sup>13</sup> One survey respondent expressed their frustration this way: “What do I tell our breast and lymphoma patients? You had a curable disease but not anymore because there is no drug available?”<sup>14</sup>

Healthcare practitioners also spend significant amounts of time and money on managing shortages. A March 2011 analysis performed by the Premier healthcare alliance, a group purchasing organization, estimated that drug shortages were costing U.S. hospitals at least \$200 million annually due to the purchase of more expensive alternative drugs, a figure that does not include the added labor and other indirect costs taken on when hospitals deploy resources in seeking to combat a shortage.<sup>15</sup> In some instances, hospitals will—in response to a shortage—turn to the “gray market,” or distributors of drugs not

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<sup>12</sup> ISMP. *Drug shortages: National survey reveals high level of frustration, low level of safety*. ISMP Medication Safety Alert, Institute for Safe Medicine Practices: September 2010.

<sup>13</sup> Ibid.

<sup>14</sup> Ibid.

<sup>15</sup> Cherici, Coleen, et al. "Navigating Drug Shortages in American Healthcare: A Premier healthcare alliance analysis." Premier Healthcare Alliance. March 2011.

approved by drug manufacturers. These third party suppliers purchase drugs and then often sell them for exorbitant prices during times of shortage. An August 2011 Premier analysis examined data from 42 acute care hospitals, finding that offers from the gray market for drugs in shortage contained an average 650 percent price markup, with the highest markups applied to drugs needed to treat critically ill patients.<sup>16</sup>

### *Potential Factors Contributing to Drug Shortages*

Drug shortages occur due to a number of factors, and no single factor is solely responsible for the problem of shortages. There are, however, a number of factors often cited as contributing to shortages, many of which have to do with the ways in which drugs are produced. These factors include disruptions in the supply of raw materials, manufacturing problems and decisions, and supply chain issues.

- Disruption in Supply of Raw Materials:

A primary factor believed to be contributing to the problem of drug shortages is the disruption of the supply of raw materials necessary for producing a drug. A raw material shortage can have a profound impact on the availability of a drug, particularly if the raw material in shortage is used in the production of multiple drugs and/or if there is only one source for the raw material.<sup>17</sup> Raw materials containing a drug's necessary active pharmaceutical ingredient (API) may come from, for example, a plant leaf or the bark of a tree, the supplies of which can be negatively impacted by environmental changes.

Additionally, the companies who acquire, store, or transport raw materials

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<sup>16</sup> Cherici, Coleen, Patrick McGinnis, and Wayne Russell. "Buyer beware: Drug shortages and the gray market." Premier Healthcare Alliance. August 2011.

<sup>17</sup> ASHP. "Understanding & Managing Drug Shortages." The American Society of Health-System Pharmacists (ASHP). December 2002.

might decide to shift their focus from the extraction of one raw material to another, or choose to exit the market altogether.<sup>18</sup> The majority of raw materials and the APIs they contain are, according to the FDA, imported from outside the U.S., meaning that trade issues and importation procedures can also impact their availability.<sup>19</sup>

- Manufacturing Problems and Decisions:

Other factors believed to be contributing to the problem of drug shortages include the problems faced—and decisions made—by drug manufacturers. Drug manufacturers may face “manufacturing problems”—such as the contamination of a plant or production line that compromises drug quality—leading to delays in production or, in some cases, recalls of a drug. These problems can be identified either by manufacturers themselves or by FDA officials during plant inspections, and are of particular concern with regard to the production of sterile injectable drugs, due to the vulnerability of the sterile manufacturing process.<sup>20</sup> Manufacturers also make business decisions that can have an impact on the availability of a drug; they may choose to cease production of one drug so as to produce another, or shut down manufacturing plants for upgrades or renovations that can place the production of a drug on hold for months or years.<sup>21</sup>

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<sup>18</sup> GAO. "Drug Shortages: FDA's Ability to Respond Should be Strengthened." November 2011.

<sup>19</sup> Ibid.

<sup>20</sup> Mullins, Tara D., and Aaron M. Cook. "Drug Shortages: Causes and Cautions." *Orthopedics* 34, no. 9 (2011): 712-714.

<sup>21</sup> GAO. "Drug Shortages: FDA's Ability to Respond Should be Strengthened." November 2011.

Especially for drugs being produced by only a handful of manufacturers, manufacturing problems and/or the shutting down of production lines or facilities can have a profound impact on the overall availability of a drug. In November 2011, drug manufacturer Ben Venue Laboratories voluntarily shut down a production plant in Bedford, Ohio, due to “significant manufacturing and quality concerns.”<sup>22</sup> The Ben Venue plant had been the sole producer of Doxil, a sterile injectable oncology drug used to treat ovarian cancer, and nationwide shortages of Doxil resulted from the plant closing. In response to the Doxil shortage, FDA officials have temporarily allowed a similar drug, Lipodox, to be imported to the U.S. from India; Ben Venue has said they may reopen the Bedford plant by the end of 2012.<sup>23</sup>

- Supply Chain Issues:

According to GAO, the supply chain for drugs is increasingly global, increasingly unstable, and vulnerable to disruption. The supply chain itself has become more cost-effective in recent years, but changes that have taken place—such as the outsourcing of certain manufacturing processes—have left participants in the pharmaceutical drug supply chain less able to respond to supply disruptions. As summarized by GAO: “As a result of the large number of entities involved in the supply chain, every individual member of the chain has

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<sup>22</sup> FDA. "Ben Venue Laboratories - Voluntary Shutdown." U.S. Food and Drug Administration. November 30, 2011.

<sup>23</sup> Harris, Gardiner. "Shipments From Abroad to Help Ease Shortage of Two Cancer Drugs." *The New York Times*. February 21, 2012.

less control, and is less able to respond to problems experienced by those on which it is dependent.”<sup>24</sup>

Additionally, manufacturers are constrained by the capacity of their facilities, and with many manufacturers seeking to trim costs by reducing manufacturing redundancies, manufacturers may keep fewer production lines active. Given this reduced capacity and the fact that some companies produce multiple drugs on the same production line, disruptions triggered by quality or safety concerns can sometimes derail the production of numerous drugs.<sup>25</sup> Finally, many manufacturers, distributors, and health care providers have implemented “just-in-time” inventory systems, whereby stored inventories of drugs are limited and are only refreshed when the supply of a drug begins to run low. This means that leaner stockpiles of drugs are ultimately kept on hand, making the impacts of shortages more quickly felt.<sup>26</sup>

*An Oft-Cited Cause of Shortages: The Medicare Prescription Drug, Improvement, and Modernization Act of 2003*

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, passed with bipartisan support in Congress and signed into law by President George W. Bush, is primarily remembered as an entitlement program created to assist Medicare beneficiaries with the purchase of prescription drugs, through a process of tax breaks and

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<sup>24</sup> GAO. "Drug Shortages: FDA's Ability to Respond Should be Strengthened." November 2011.

<sup>25</sup> Ibid.

<sup>26</sup> Ibid.

subsidies.<sup>27</sup> Portions of the act, however, have been pointed to as contributing to drug shortages, particularly with regard to generic drugs.

The 2003 act changed the formula used by the Centers for Medicare and Medicaid Services (CMS) to set reimbursement rates for Medicare Part B drugs; the new formula, which went into effect in 2005, set rates at a drug's average sales price (ASP) plus a 6 percent markup to cover administrative costs. Prior to 2005, CMS reimbursed 95 percent of a Part B drug's average wholesale price (AWP), an unregulated price that was set by drug manufacturers.<sup>28</sup> In the case of oncology drugs, the change in how the reimbursement rate was calculated effectively cut a subsidy that had been flowing from CMS to oncologists treating Medicare patients. Oncologists, unlike many other medical practitioners, purchase the drugs they prescribe, administer these drugs to their patients, and then bill Medicare or insurance companies for the cost of the drug. Prior to 2005, oncologists were being reimbursed for Part B drugs administered to Medicare patients at a rate of 95 percent of AWP, while they were typically paying between 66 and 87 percent of AWP to purchase such drugs. Thus, the change in how reimbursement rates were calculated effectively cut an estimated \$1.6 billion in annual overpayments that had previously been flowing to oncologists.<sup>29</sup>

Many have pointed to this change in reimbursement rates as the reason for shortages of oncology drugs, calling the new formula of ASP plus 6 percent a "price control" that prevents drug prices from rising in response to market forces. Oncologist and former

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<sup>27</sup> Health Policy Alternatives, Inc. *Prescription Drug Coverage for Medicare Beneficiaries: A Summary of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*. The Henry J. Kaiser Family Foundation, 2003.

<sup>28</sup> Gatesman, Mandy L., and Thomas J. Smith. "The Shortage of Essential Chemotherapy Drugs in the United States." *The New England Journal of Medicine*, no. 365 (November 2011): 1653-1655.

<sup>29</sup> Twombly, Renee. "Medicare Cost Containment Strategy Targets Several Oncology Drugs." *Journal of the National Cancer Institute* 96, no. 17 (September 2004): 1268-1270.

White House adviser Ezekiel Emanuel—in an August 2011 op-ed entitled “Shortchanging Cancer Patients” published in *The New York Times*—pointed to the change contained within MMA as the reason for oncology drug shortages:

[MMA] required Medicare to pay the physicians who prescribe the drugs based on a drug’s actual average selling price, plus 6 percent for handling. And indirectly—because of the time it takes drug companies to compile actual sales data and the government to revise the average selling price—it restricted the price from increasing by more than 6 percent every six months.

The act had an unintended consequence. In the first two or three years after a cancer drug goes generic, its price can drop by as much as 90 percent as manufacturers compete for market share. But if a shortage develops, the drug’s price should be able to increase again to attract more manufacturers. Because the 2003 act effectively limits drug price increases, it prevents this from happening. The low profit margins mean that manufacturers face a hard choice: lose money producing a lifesaving drug or switch limited production capacity to a more lucrative drug.

Dr. Emanuel, stating that “the laws of supply and demand aren’t working” because of the reimbursement rate change contained within MMA, goes on to suggest a potential “fix”:

One solution would be to amend the 2003 act to increase the amount Medicare pays for generic cancer drugs to the average selling price plus, say, 30 percent, after the drugs have been generic for three years. This would encourage the initial rapid price drop that makes generics affordable, but would allow for an increase in price and profits to attract more generic producers and the fixing of any manufacturing problems that subsequently arose.

Many public discussions of drug shortages—both in general and of oncology drugs specifically—have echoed similar sentiments, blaming “government price controls” for inducing shortages. Awi Federgruen, a professor at Columbia Business School, penned a March 2012 op-ed in *The Wall Street Journal* entitled “The Drug Shortage Debacle—And How To Fix It,” in which he wrote, “Government price controls on generic drugs limit the manufacturers’ margin to 6% in many cases . . . It is clear that the way to resolve the

shortage of critical drugs is to relax or eliminate government price controls.”<sup>30</sup> Patrick Cobb, an oncologist from Montana, stated the following during testimony delivered to the U.S. Senate Finance Committee in December of 2011: “The drug shortage problem is a direct consequence of the reimbursement system . . . It is critical that Congress move quickly to modify the Medicare reimbursement system . . . to create appropriate incentives for manufacturers.”<sup>31</sup> Senator Orrin Hatch (R.-Utah), the ranking Republican on the Finance Committee, echoed this sentiment during the same day of Finance Committee hearings, stating that, “Experts contend that federal government pricing and rebate programs are a significant contributing factor to the current drug shortage crisis,” adding that he is “working on a solution” that “addresses some of the federal price control and rebate structures that prevent the true costs of bringing these important medicines to patients from being adequately addressed.”<sup>32</sup>

In response to the growing problem of drug shortages, an executive order was issued by President Obama in October of 2011, an order that didn’t have much practical effect but that did draw attention to the issue. (For more information on the executive order, see “Appendix B - *Executive Order 13588 – Reducing Prescription Drug Shortages.*”) Additionally, Congressional legislation has been introduced in both the U.S. House and Senate. A Senate bill co-sponsored by Senators Bob Casey (D–Pa.) and Amy Klobuchar (D–Minn.) would require drug companies to notify the FDA six months in advance of an anticipated shortage. (For more information on proposed legislation, see “Appendix C – *Congressional Action.*”)

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<sup>30</sup> Federgruen, Awi. "The Drug Shortage Debacle—And How to Fix It." *The Wall Street Journal*. March 1, 2012.

<sup>31</sup> Pecquet, Julian. "Hatch blames government price controls for shortages of medical drugs." *Healthwatch: The Hill's Healthcare Blog*. The Hill. December 7, 2011.

<sup>32</sup> Hatch, Orrin. "Drug Shortages in America." *Orrin Hatch: United States Senator for Utah*. December 7, 2011.

## DATA AND METHODS

In response to assertions that drug shortages are primarily the result of the change in the Part B reimbursement rate contained within the 2003 Medicare Modernization Act (MMA), the analysis contained within this report will focus on the actual reimbursement amounts paid out by CMS over the period between 1998 and 2011. The first seven years of reimbursement history, 1998 to 2004, will consist of the reimbursement rates paid for Part B drugs according to the pre-MMA formula of 95 percent of AWP. The next seven years of reimbursement history, 2005 to 2011, will consist of the rates paid for Part B drugs according to the current MMA formula of ASP plus 6 percent.

Reimbursement rate data from 1998 to 2004 was retrieved from Drug Topics Red Books, pharmaceutical references published annually that list price data—including AWP— for tens of thousands of prescription and over-the-counter drugs. According to the publishers, Red Book data is provided and verified by drug manufacturers. As CMS does not itself make AWP data available for the pre-2005 time period, data from the annual Red Books is being used for the sake of this analysis to calculate pre-2005 reimbursement levels.

Reimbursement rate data from 2005 to 2011 was pulled directly from the CMS website. Since 2005, CMS has calculated ASP on a quarterly basis, making the ASP figures for all Part B drugs available for download.<sup>33</sup> According to CMS: “A manufacturer’s ASP must be calculated by the manufacturer every calendar quarter and submitted to CMS within 30 days of the close of the quarter.” Due to this 30-day grace period and the time needed for CMS to then calculate and update ASP data after receiving sales figures from

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<sup>33</sup> CMS. "Medicare Part B Drug Average Sales Price." *CMS.gov*. Centers for Medicare & Medicaid Services.

manufacturers, the reimbursement rate for a given quarter is dependent on the data from two quarters prior. For example, ASP figures and subsequent reimbursement rates to be paid during Q2 of 2012 are based on ASP data submitted by manufacturers for Q4 of 2011.

This analysis will focus on a small, nongeneralizable sample of 12 sterile injectable oncology drugs; some, but not all, of these 12 drugs have been subject to shortage during the 1998 to 2011 time period. These 12 drugs have been broken into three sub-groups. The first group of drugs—herein referred to as “Category 1” or “generic” drugs—are drugs that were available in generic form during the entire 1998 to 2011 time period: cytarabine hydrochloride, dactinomycin, mechlorethamine hydrochloride, and vincristine sulfate. The second group of drugs—herein referred to as “Category 2” or “brand-to-generic” drugs—are drugs that went from being available only in brand-name form to being available in generic form at some point during the 1998 to 2011 time period: vinorelbine tartrate, carboplatin, docetaxel, and epirubicin hydrochloride. Finally, the third group of drugs—herein referred to as “Category 3” or “brand-name” drugs—were available only in brand-name form for the entire 1998 to 2011 time period: porfimer sodium (Photofrin), doxorubicin hydrochloride liposome (Doxil), trastuzumab (Herceptin), and fulvestrant (Faslodex).

For the 1998 to 2004 time period, annual changes in reimbursement rates will be examined, as Red Books only supply a single AWP figure for a given year. For the 2005 to 2011 time period, both yearly and quarterly changes in reimbursement rates will be examined, as ASP is gathered and calculated quarterly by CMS, allowing for rate fluctuations within a given year to be examined.

## TESTED HYPOTHESES

In order to examine assertions that drug shortages are primarily the result of the change in the Part B reimbursement rate contained within MMA, the hypotheses that would emerge from such assertions will be tested. As Emanuel stated in his *New York Times* op-ed, “the 2003 act effectively limits drug price increases” in that it has “restricted the price [of a drug] from increasing by more than 6 percent every six months.”<sup>34</sup> This assertion, as mentioned previously, has been echoed by a number of others who have weighed in on the problem of drug shortages. Richard Epstein, a law professor at New York University, quoted Emanuel in “The Perils of Price Controls,” a piece Epstein wrote for *Defining Ideas*, a journal published by the Hoover Institution at Stanford University. Epstein, agreeing with Emanuel, cites the change in reimbursement rates contained within MMA as the reason for shortages: “. . . the law stipulates that the base price of the drug may not increase by more than 6 percent every six months . . . The only way to induce the supply is to allow prices to rise to market levels.”<sup>35</sup>

Two hypotheses that follow from these assertions will be tested using the reimbursement rate data gathered for the time periods in question:

Hypothesis 1: Starting in 2005, reimbursement rates for drugs should not have risen by more than 6 percent during the course of a 3 to 6 month period. Three month intervals will be examined because ASP data from CMS is updated quarterly; six month intervals will be examined in response to the assertions made by Emanuel, Epstein, and others.

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<sup>34</sup> Emanuel, Ezekiel J. "Shortchanging Cancer Patients." *The New York Times*, August 6, 2011.

<sup>35</sup> Epstein, Richard A. "The Perils of Price Controls." *Defining Ideas* (Hoover Institution - Stanford University), August 2011.

Hypothesis 2: If the ASP plus 6 percent formula is responsible for inducing shortages, reimbursement rates for drugs in shortage should be hitting up against a 6 percent “ceiling” beyond which they cannot rise in price.

## ANALYSIS OF HYPOTHESES

*Hypothesis 1: Starting in 2005, reimbursement rates for drugs should not have risen by more than 6 percent during the course of a 3 to 6 month period.*

When the change in the CMS reimbursement formula went into effect in 2005, reimbursement rates for all drugs in all categories dropped by approximately 40 percent, an indication that the ASP for these drugs was lower, in all cases, than the AWP:

### Drop in CMS Reimbursement Rate, 2004 – Q1 2005

| Drug Name (Dosage)                | 2004 Reimbursement Rate (AWP*0.95) | Q1 2005 Reimbursement Rate (ASP*1.06) | % Change in Rate 2004 - Q1 2005 |
|-----------------------------------|------------------------------------|---------------------------------------|---------------------------------|
| Cytarabine hcl (100 MG)           | 3.31                               | 1.68                                  | -49.40                          |
| Dactinomycin actinomycin (0.5 MG) | 13.87                              | 12.07                                 | -12.96                          |
| Mechlorethamine hcl (10 MG)       | 12.01                              | 10.45                                 | -12.96                          |
| Vincristine sulfate (1 MG)        | 24.02                              | 3.50                                  | -85.43                          |
| <b>Category 1 - Average</b>       | <b>13.30</b>                       | <b>6.93</b>                           | <b>-40.18</b>                   |
| Vinorelbine tartrate (10 MG)      | 92.47                              | 67.90                                 | -26.57                          |
| Carboplatin (50 MG)               | 155.65                             | 125.47                                | -19.39                          |
| Docetaxel (20 MG)                 | 357.91                             | 297.58                                | -16.86                          |
| Epirubicin hcl (2 MG)             | 711.71                             | 25.41                                 | -96.43                          |
| <b>Category 2 - Average</b>       | <b>329.44</b>                      | <b>129.09</b>                         | <b>-39.81</b>                   |
| Porfimer sodium (75 MG)           | 2603.67                            | 2285.15                               | -12.23                          |
| Doxorubicin hcl liposome (10 MG)  | 833.39                             | 359.63                                | -56.85                          |
| Trastuzumab (10 MG)               | 58.13                              | 52.99                                 | -8.85                           |
| Fulvestrant (25 MG)               | 448.55                             | 80.51                                 | -82.05                          |
| <b>Category 3 - Average</b>       | <b>985.94</b>                      | <b>694.57</b>                         | <b>-39.99</b>                   |
| <b>All Drugs - Average</b>        | <b>442.89</b>                      | <b>276.86</b>                         | <b>-40.00</b>                   |

Reimbursement rates are in U.S. dollars. AWP data retrieved from Drug Topics Red Books, 1998-2004; ASP reimbursement rate data from CMS “Medicare Part B Drug Average Sales Price” public database (<http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/>). Calculations made by author.

While the reimbursement rates for some drugs dropped by more than others, the average drop for all categories was virtually identical: either slightly above or below 40 percent.

Between the first and second quarters of 2005, reimbursement rates for nine of the 12 drugs fell again by an average of 8.78 percent. The rate for one drug did not change between the first and second quarters of 2005, while the rate for two other drugs rose by an average of 3.35 percent. A similar pattern continued between the second and third quarters of 2005: the reimbursement rate for ten of the drugs fell, while rising slightly for two of the drugs.

Between the third and fourth quarters of 2005, however, reimbursement rates began to rise for a number of drugs, in some cases by significantly more than 6 percent:

### Change in Reimbursement Rate, Q3 2005 – Q4 2005

| Drug Name (Dosage)                | Q3 2005 Reimbursement Rate (ASP*1.06) | Q4 2005 Reimbursement Rate (ASP*1.06) | % Change in Rate Q3 2005 - Q4 2005 |
|-----------------------------------|---------------------------------------|---------------------------------------|------------------------------------|
| Cytarabine hcl (100 MG)           | 1.02                                  | 1.44                                  | 41.38                              |
| Dactinomycin actinomycin (0.5 MG) | 12.02                                 | 12.00                                 | -0.18                              |
| Mechlorethamine hcl (10 MG)       | 10.42                                 | 10.39                                 | -0.23                              |
| Vincristine sulfate (1 MG)        | 2.59                                  | 3.60                                  | 39.00                              |
| <b>Category 1 - Average</b>       | <b>6.51</b>                           | <b>6.86</b>                           | <b>19.99</b>                       |
| Vinorelbine tartrate (10 MG)      | 40.86                                 | 42.83                                 | 4.83                               |
| Carboplatin (50 MG)               | 52.23                                 | 35.26                                 | -32.50                             |
| Docetaxel (20 MG)                 | 295.27                                | 293.64                                | -0.55                              |
| Epirubicin hcl (2 MG)             | 24.60                                 | 24.76                                 | 0.65                               |
| <b>Category 2 - Average</b>       | <b>103.24</b>                         | <b>99.12</b>                          | <b>-6.89</b>                       |
| Porfimer sodium (75 MG)           | 2150.25                               | 2464.57                               | 14.62                              |
| Doxorubicin hcl liposome (10 MG)  | 359.36                                | 364.53                                | 1.44                               |
| Trastuzumab (10 MG)               | 53.93                                 | 54.39                                 | 0.85                               |
| Fulvestrant (25 MG)               | 81.30                                 | 81.33                                 | 0.04                               |
| <b>Category 3 - Average</b>       | <b>661.21</b>                         | <b>741.20</b>                         | <b>4.24</b>                        |
| <b>All Drugs - Average</b>        | <b>256.99</b>                         | <b>282.39</b>                         | <b>5.78</b>                        |

Reimbursement rates are in U.S. dollars. ASP reimbursement rate data retrieved from CMS “Medicare Part B Drug Average Sales Price” public database (<http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/>). Calculations made by author.

As shown above, between the third and fourth quarters of 2005, reimbursement rates rose for seven of the 12 drugs, with rates for three of these seven drugs rising by far more than 6 percent. The price of cytarabine—a drug that is currently in shortage according to the American Society of Health-System Pharmacists (ASHP)<sup>36</sup>—rose by 31.38 percent. For the generic drugs in Category 1, reimbursement rates rose by an average of 19.99 percent. For all 12 drugs, reimbursement rates rose by an average of 5.78 percent.

Over the course of the entire 2005 to 2011 time period, nine of the 12 drugs experienced quarter-to-quarter changes in reimbursement rates exceeding 6 percent. Category 1 drugs were most likely to rise in price by more than 6 percent, while Category 3 drugs were least likely to do so:

### Quarterly Reimbursement Rate Rises Exceeding 6%, Q1 2005 – Q4 2011

| Drug Name (Dosage)                | # of Quarter-to-Quarter Rises Exceeding 6% | % of Quarter-to-Quarter Changes Exceeding a 6% Rise |
|-----------------------------------|--|---|
| Cytarabine hcl (100 MG)           | 9.0  | 33.3  |
| Dactinomycin actinomycin (0.5 MG) | 5.0  | 18.5  |
| Mechlorethamine hcl (10 MG)       | 4.0  | 14.8  |
| Vincristine sulfate (1 MG)        | 8.0  | 29.6  |
| <b>Category 1 - Average</b>       | <b>6.5</b>                                 | <b>24.1</b>   |
| Vinorelbine tartrate (10 MG)      | 6.0  | 22.2  |
| Carboplatin (50 MG)               | 5.0  | 18.5  |
| Docetaxel (20 MG)                 | 1.0  | 3.7   |
| Epirubicin hcl (2 MG)             | 3.0  | 11.1  |
| <b>Category 2 - Average</b>       | <b>3.8</b>                                 | <b>13.9</b>   |
| Porfimer sodium (75 MG)           | 1.0  | 3.7   |
| Doxorubicin hcl liposome (10 MG)  | 0.0  | 0.0   |
| Trastuzumab (10 MG)               | 0.0  | 0.0   |
| Fulvestrant (25 MG)               | 0.0  | 0.0   |
| <b>Category 3 - Average</b>       | <b>0.3</b>                                 | <b>0.9</b>  |
| <b>All Drugs - Average</b>        | <b>3.5</b>                                 | <b>13.0</b>   |

ASP reimbursement rate data retrieved from CMS “Medicare Part B Drug Average Sales Price” public database (<http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/>). Calculations made by author.

<sup>36</sup> ASHP. "Drug Shortages: Current Drugs." *American Society of Health-System Pharmacists*. (as of April 2012).

Contrary to the assertions made by Emanuel and others—that reimbursement rates are being prevented from rising by more than 6 percent every six months—rates for the sterile injectables examined here, particularly the generics, commonly rose by more than 6 percent between quarters. In some cases, reimbursement rates for a number of the drugs examined here rose by hundreds or thousands of percentage points between quarters. Between the second and third quarters of 2006, for example, the reimbursement rate for dactinomycin rose from \$13.93 to \$274.12, a 1,868 percent rise. By the fourth quarter of 2006, the reimbursement rate for dactinomycin had risen to \$493.43, a six-month rise in the reimbursement rate of 3,442 percent.

*Hypothesis 2: Reimbursement rates for drugs in shortage should be hitting up against a 6 percent “ceiling” beyond which they cannot rise in price.*

To examine any trends that emerge specifically for drugs that were subject to shortage between 2005 and 2011, the 12 drugs examined here have been broken into two groups. The first group consists of seven drugs, all of which have previously been or currently are subject to shortage; the second group consists of five drugs, none of which were in shortage during this time period.<sup>37</sup>

For the sake of this analysis, two time periods between 2005 and 2011 will be examined. Changes in reimbursement rates for the years between 2005 and 2007 will be assessed first, to derive a sense of the “pre-shortage” reimbursement rate trends for the sterile injectable oncology drugs examined here. Then, changes in reimbursement rates for

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<sup>37</sup> Drugs identified as having been subject to shortage between 2005 and 2011 were listed on either FDA’s or ASHP’s “Current Drug Shortages” or “Resolved Drug Shortages” web pages, or were mentioned as being in shortage in trade publications or in news articles published during these years. Drugs not appearing on either FDA’s or ASHP’s web pages—and that were not mentioned in trade publications or in news articles—were considered to have not been in shortage.

the years between 2008 and 2011 will be assessed, to derive a sense of the rate trends directly leading up to and during the 2009 to 2011 time period, when shortages of sterile injectable oncology drugs became more prevalent.

Between 2005 and 2007, reimbursement rates for five of the seven drugs subject to shortage rose, while rates dropped for two of the seven drugs:

### Change in Reimbursement Rate, Q1 2005 – Q4 2007

| Drug Name (Dosage)                   | % Change in Reimbursement Rate, Q1 2005 - Q4 2007 | Avg. Quarterly % Change in Reimbursement Rate, Q1 2005 - Q4 2007 |
|--------------------------------------|---|--|
| <b>Drugs Subject To Shortage</b>     |   |  |
| Cytarabine hcl (100 MG)              | 12.96   | 1.18   |
| Mechlorethamine hcl (10 MG)          | 1281.71   | 116.52   |
| Vincristine sulfate (1 MG)           | 106.09  | 9.64   |
| Carboplatin (50 MG)                  | -94.02  | -8.55  |
| Epirubicin hcl (2 MG)                | -21.37  | -1.94  |
| Porfimer sodium (75 MG)              | 11.88   | 1.08   |
| Doxorubicin hcl liposome (10 MG)     | 11.21   | 1.02   |
| <b>Average</b>                       | <b>186.92</b>                                     | <b>16.99</b>   |
| <b>Drugs Not Subject To Shortage</b> |   |  |
| Dactinomycin actinomycin (0.5 MG)    | 3987.05   | 362.46   |
| Vinorelbine tartrate (10 MG)         | -68.17  | -6.20  |
| Docetaxel (20 MG)                    | 5.45  | 0.50   |
| Trastuzumab (10 MG)                  | 11.47   | 1.04   |
| Fulvestrant (25 MG)                  | 1.07  | 0.10   |
| <b>Average</b>                       | <b>787.38</b>                                     | <b>71.58</b>   |

ASP reimbursement rate data retrieved from CMS “Medicare Part B Drug Average Sales Price” public database (<http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/>). Calculations made by author.

The reimbursement rate for four of the five drugs not subject to shortage rose in price between 2005 and 2007, while the rate for one of the five fell during this time. The reimbursement rate for one drug in each group—mechlorethamine, for the drugs subject to shortage, and dactinomycin, for the drugs not subject to shortage—grew by far more than the others. The rest of the drugs either dropped in price or grew by no more than 106

percent during this time period. Nevertheless, the drugs examined here were clearly not subject to a 6 percent growth “ceiling,” either during a three or six-month period, as some drugs grew by far more than 6 percent from one quarter to the next.

For the 2008 to 2011 time period—directly preceding as well as during the time when shortages of sterile injectable oncology drugs began to proliferate—the reimbursement rate fell for the majority of the drugs subject to shortage. Rates did not fall for any of the drugs not subject to shortage:

### Change in Reimbursement Rate, Q1 2008 - Q4 2011

| Drug Name (Dosage)                   | % Change in<br>Reimbursement Rate,<br>Q1 2008 - Q3 2011 | Avg. Quarterly % Change<br>in Reimbursement Rate,<br>Q1 2008 - Q3 2011 |
|--------------------------------------|---|--|
| <b>Drugs Subject To Shortage</b>     |   |  |
| Cytarabine hcl (100 MG)              | -53.96  | -3.85  |
| Mechlorethamine hcl (10 MG)          | 9.28  | 0.66   |
| Vincristine sulfate (1 MG)           | -49.16  | -3.51  |
| Carboplatin (50 MG)                  | -29.06  | -2.08  |
| Epirubicin hcl (2 MG)                | -82.19  | -5.87  |
| Porfimer sodium (75 MG)              | 17.53   | 1.25   |
| Doxorubicin hcl liposome (10 MG)     | 31.21   | 2.23   |
| <b>Average</b>                       | <b>-22.33</b>   | <b>-1.60</b>   |
| <b>Drugs Not Subject To Shortage</b> |   |  |
| Dactinomycin actinomycin (0.5 MG)    | 16.01   | 1.14   |
| Vinorelbine tartrate (10 MG)         | 8.09  | 0.58   |
| Docetaxel (20 MG)                    | 22.82   | 1.63   |
| Trastuzumab (10 MG)                  | 19.31   | 1.38   |
| Fulvestrant (25 MG)                  | 205.01  | 14.64  |
| <b>Average</b>                       | <b>54.25</b>  | <b>3.87</b>  |

ASP reimbursement rate data retrieved from CMS “Medicare Part B Drug Average Sales Price” public database (<http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/>). Calculations made by author.

Contrary to bumping up against a growth rate “ceiling,” reimbursement rates fell between 2008 and 2011 for drugs subject to shortage, by an average of 22.33 percent. For drugs not subject to shortage, reimbursement rates rose by an average of 54.25 percent.

## **CONCLUSION & RECOMMENDATION**

It was outside the scope of this analysis to clearly determine what has or hasn't been responsible for shortages of sterile injectable oncology drugs. The findings contained in this analysis were intended primarily to test the veracity of oft-cited claims made about the effect of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 on shortages. Examinations of changes in reimbursement rates following the implementation of MMA indicate that, contrary to what many who have written or spoken on the topic of oncology drug shortages state, the new rate formula of ASP plus 6 percent does not appear to be capping the rate at which reimbursement rates for drugs can rise. Indeed, the MMA formula uses the "average sales price" (ASP) of a drug to set reimbursement rates; this is a market-driven formulation dictated by the actual selling price of a drug, not—as it has often been characterized—a "price control" set by the federal government.

This is not to say that the ASP formula, as currently collected and calculated, is without its flaws. The current reimbursement rate for a drug is based on ASP data from two quarters prior, meaning that there is a six-month delay between the market settling on a price for a drug and CMS using that market signal to calculate a reimbursement rate for that drug. Were it possible for ASPs to be submitted and rates calculated monthly rather than quarterly, a shorter delay of two months would be in effect, making CMS reimbursement rates even more responsive to market forces. While this would require a legislative amendment to MMA, as well as increased efforts on the part of both drug companies and CMS, the feasibility of such a change should be examined and considered.

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## Appendix A - *The FDA's Drug Shortage Program*

The Drug Shortage Program (DSP) is part of the FDA's Center for Drug Evaluation and Research (CDER), one of five centers contained within the FDA. The CDER exists in order to ensure that safe and effective drugs are available to the American public. Prior to 1998, CDER did not have a standing drug shortage program, as the problem of chronic drug shortages has only been apparent since the late 1990s. The U.S. Food and Drug Administration (FDA) has been officially tracking and working to alleviate reported shortages since 1999, when FDA established a Drug Shortage Program.

The DSP typically receives initial reports of shortages through e-mails sent to the DSP's public e-mail account. While some reports of shortages are filed by manufacturers, there is no regulatory requirement mandating the reporting of a shortage by firms unless a shortage is the result of a discontinuation of "sole-source," "medically-necessary" drugs. A sole-source drug is one that is available only from a single provider; drugs deemed medically-necessary are those drugs "used to prevent or treat a serious or life-threatening disease or medical condition for which no other source of that product or an alternative drug is available in adequate quantities."<sup>38</sup>

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<sup>38</sup> Jensen, Valerie, Rene Kimzey, and Jouhayna Saliba. "An Overview of the FDA's Drug Shortage Program." *Pharmacy & Therapeutics* 30, no. 3 (March 2005): 174-177.

## Appendix B - *Executive Order 13588 – Reducing Prescription Drug Shortages*

In response to the growing problem of pharmaceutical drug shortages, President Barack Obama signed Executive Order 13588 on October 31, 2011. This executive order, entitled “Reducing Pharmaceutical Drug Shortages,” sets forth three approaches aimed at combating chronic drug shortages. The executive order first states that the FDA will do its best to require drug manufacturers to provide advance notice of possible drug shortages. Second, the executive order encourages the FDA to mitigate drug shortages by expanding efforts to expedite its regulatory review processes. Such processes include reviews of new drug suppliers, manufacturing sites, and manufacturing changes. Third, the executive order encourages the FDA to communicate with the U.S. Department of Justice (DOJ) with regard to any evidence that drug “gray market” participants are stockpiling drugs so as to later charge exorbitant prices for them. The DOJ is then encouraged to pursue legal action should they find that illegal price gouging is taking place.

On its own, Executive Order 13588 is unlikely to address the growing problem of pharmaceutical drug shortages in the U.S., as it does little more than encourage U.S. agencies to take actions that are already well underway. The executive order does, however, prioritize an expedited approach to FDA’s regulatory review processes, which recent reports suggest may help drug manufacturers respond more quickly to the problem of pharmaceutical drug shortages.<sup>39</sup> Additionally, the executive order draws greater attention to the issue of shortages, also indicating to the drug industry that the Obama administration is likely to be supportive of future legislation addressing drug shortages.

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<sup>39</sup> ASPE - Office of Science and Data Policy. "Economic Analysis of the Causes of Drug Shortages." 2011.

## Appendix C - Congressional Action

Proposed legislation aimed at addressing chronic drug shortages has been proposed in both the U.S. House and Senate. A Senate bill—entitled The Preserving Access to Life-Saving Medications Act of 2011 (S. 296)—was introduced in February 2011 by Sen. Bob Casey (D–Pa.) and Sen. Amy Klobuchar (D–Minn.) with the support of 28 other co-sponsors; a partner bill in the House (H.R. 2245) by the same name was introduced in June 2011 by Rep. Diana DeGette (D-Colo.) and Rep. Tom Rooney (R-Fla.) with the support of 80 co-sponsors. This legislation, if passed in its current form, would amend the Federal Food, Drug, and Cosmetic Act to require pharmaceutical companies to notify the FDA at least six months in advance of any expected drug shortages, as well as require companies to report the reason(s) for a shortage. This legislation would not, however, give the FDA any authority to compel manufacturers to continue producing a drug; in fact, language in the House bill states that the secretary of the Department of Health and Human Services “may not in any case” require manufacturers to either “manufacture a drug in the event of a discontinuance or interruption” or to “delay or alter a discontinuance or interruption.”<sup>40</sup> Some who have examined the bill worry that it could potentially lead to treatment facilities hoarding drugs once they’ve heard of the potential for a shortage.<sup>41</sup>

The Senate Committee on Health, Education, Labor, and Pensions (HELP) held a hearing on the topic of drug shortages on December 15, 2011, and the Senate Finance Committee held a hearing on drug shortages on December 7, 2011. Additionally, Sen. Hatch (R-Utah)—HELP Committee member and ranking member of the Senate Finance

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<sup>40</sup> H.R. 2245 bill text

<sup>41</sup> Emanuel, Ezekiel J. "Shortchanging Cancer Patients." *The New York Times*, August 6, 2011.

Committee—has indicated he hopes to introduce legislation aimed at combating drug shortages.<sup>42</sup> Sen. Charles Schumer (D-N.Y.) has said he will sponsor legislation that would give the U.S. Department of Justice additional authority in cracking down on “unscrupulous” gray market participants taking part in price gouging, allowing for penalties of up to \$500 million.<sup>43</sup>

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<sup>42</sup> Nocera, Kate. *POLITICO Pulse*. November 22, 2011.

<sup>43</sup> Associated Press. *Sen. Schumer introducing bill to make price gouging on drugs in short supply a federal crime*. December 6, 2011.