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The Drug Shortage Crisis: What Happens When Generic Manufacturers "Just Say No"

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THE DRUG SHORTAGE CRISIS:
WHEN GENERIC MANUFACTURERS “JUST SAY NO”

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INTRODUCTION

Jenny Morrill, a mother and former arts administrator has been battling ovarian cancer since 2007.1 When she recently went to the hospital for her scheduled chemotherapy treatment, she was greeted with both good news and bad. The good news was that she was responding very well to the prescribed chemotherapy drug, Doxil. The bad news was that due to nationwide shortages, the hospital had no more Doxil to give her. Ms. Morrill said her “jaw dropped.”2 In describing her health predicament, Ms. Morrill said, “A lot of things can go wrong when you’re in cancer treatment - your white count can go down, you can become too frail to get treatment, the chemo can stop working. One of the things you never consider is that treatment might just not be available. It’s like you’re out in the ocean and the guy on the lifeboat says, ‘Sorry, they ran out of life rings.’”3

This scenario is playing out with increasing frequency, as Ms. Morrill and thousands of other cancer patients cannot get access to life-saving medications. Doxil shortages began in 2011, when the manufacturer temporarily halted production to address Food and Drug Administration (“FDA”) manufacturing and sanitation issues.4 The facility’s remediation efforts continued over the next two years. During that time, the facility produced only 17 of 65 expected batches of Doxil.5 Claiming required upgrades to restore full operation were too costly, the owner of the facility shut down production in 2013. The facility was the sole

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2 Id.
3 Id.
5 Id.
supplier of Doxil. Adding to Ms. Morrill’s health predicament - the Doxil shortage will continue at least through 2014.

In the past five years, the number of drug shortages in the United States has nearly quintupled. The majority of shortages involve generic sterile injectables used to fight infectious diseases and treat cancer. These complex drugs are produced in a concentrated market consisting of only a few generic manufacturers. Any disruption in their supply can result in shortages that leave patients without access to life-saving drugs. In some cases, the drugs are the only treatment for their condition. These shortages have been the result of many factors, including product quality concerns, discontinuation of product lines, changes in supply and demand, and manufacturing problems.

In response to the serious effects shortages have on the public’s health, recent federal legislation attempts to address the drug shortage problem by focusing on manufacturers’ notification responsibilities. This legislation authorizes the FDA to require manufacturers of life-saving and life-supporting drugs to alert the Agency of impending shortages. While this requirement may alleviate some of the factors associated with drug shortages, the FDA receiving advance notice of shortages fails to address the underlying causes.

Despite reoccurring drug shortages, manufacturers have not increased production of these life-saving medicines. Using generic manufacturers as the lens, this Article explores the confluence of regulatory constraints and market forces behind the shortages. As noted in the Doxil example, shortages have occurred among branded pharmaceuticals; however, over 80% of drugs in short supply are generic injectable medications. Understanding the unique aspects of the generic drug industry is critical to ending shortages.

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7 Palmer, note 4.
8 Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products, 78 Fed. Reg. 65,905, 65,906 (Proposed Nov. 4, 2013) [hereinafter Discontinuance or Interruption].
11 Id.
12 Discontinuance or Interruption, supra note 8.
14 Food and Drug Administration Safety and Innovation Act (“FDASIA”), Pub. L. No. 112-144, 126 Stat. 993 (2012); FDC Act §506 C (a) as amended by FDASIA § 1001(a)
15 Id.
Part I of this Article provides an overview of current drug shortages and their impact on patient care and healthcare providers. Part II offers an economic analysis of the root causes of the drug shortages. Specifically, Section A provides background on the manufacturers who produce many of the drugs in shortage. This section also examines how these drugs’ complex production processes affect manufacturers’ ability to meet increases in demand. Section B looks at unique features of the healthcare drug market and examines their influence on traditional notions of supply and demand. Section C explores the role market consolidations and healthcare reimbursement rates play in current shortages. This section also expands the analysis to examine how Group Purchasing Organizations’ (“GPOs”) contract practices influence generic manufacturers’ production decisions. Section D focuses on the FDA’s role in current shortages. According to the FDA, a leading cause of drug shortages is quality problems at manufacturing sites that precipitate production disruptions. This section challenges that notion. After examining FDA policy decisions, this section posits that poor Agency execution has helped to transform manageable facility improvements into the current drug shortage. Part III analyzes current legislative, regulatory, and industry efforts to address drug shortages. While these approaches may mitigate shortages, this section concludes they do not go far enough. Part IV acknowledges that shortages will continue until it is profitable for generic manufacturers to maintain production levels sufficient to meet patient demand. Accordingly, this section offers a multi-pronged approach that balances patient needs, regulatory safeguards, and manufacturer incentives in a manner sufficient to end drug shortages.

I. OVERVIEW OF THE DRUG SHORTAGE CRISIS

A. The Current State of Drug Shortages

According the FDA Drug Shortage Index, there is a “shortage” of over 105 medically necessary drugs. The FDA defines a “drug shortage” as a situation in which the total supply of all clinically interchangeable versions of a FDA-regulated drug is inadequate to meet the current or projected demand at the patient level. Some may be surprised to learn that notwithstanding the United States’ free market economy and robust patient demand for life-saving medicines, drug shortages are neither new nor decreasing. In 2005, there were 61 reported new drug shortages. By 2011, that number had quadrupled to more than new 250 shortages.
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shortages, however, typically continue for extended periods so the actual number of shortages at any point in time is often higher.22 While the number of new shortages decreased in 2012, more than 300 shortages remained active by the end of the year.23

The majority of drug shortages have been concentrated among older generic sterile injectables.24 In 2011, the FDA published a study of 127 long duration drug shortages that had significant public health implications.25 The study revealed that the three most common classes of drugs in shortage were oncology (28%), antibiotics (13%), and electrolyte nutrition drugs (11%).26 Recent shortages have been documented in “crash cart” medicines, which can be life-saving drugs needed in emergency ambulatory centers while waiting for emergency medical staff to arrive.27 There are also ongoing shortages in outpatient chemotherapy drugs that must be administered within rigid timeframes of a few days or weeks to provide maximum patient benefit.28

In 2011, the American Hospital Association (“AHA”) released a survey that found 99.5% of the 820 hospitals surveyed had experienced at least one drug shortage during the last six months.29 Forty-four percent reported having experienced 21 or more shortages during this same time, and 64% indicated that the shortages created significant patient risks.30 In a 2012 survey conducted by the American Society of Anesthesiologists, 98% of the 3,063 members surveyed reported current shortages of at least one anesthetic.31 Of those, 96% indicated having to use an alternative drug, 50% had to change an anesthetic procedure because of the shortage, 7% had

of Health System Pharmacists (“ASHP”) has a broader definition of drug shortage than the FDA. The ASHP takes into account all instances in which “a supply issue . . . affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribes must use an alternative agent.” Erin R. Fox et al., ASHP Guidelines on Managing Drug Product Shortages in Hospitals and Health Systems, 66 AM. J. HEALTH-SYST. PHARM. 1399, 1400 (2009) (ASHP reported 211 drug shortages in 2010 compared to the FDA’s finding of 178).

22 FDA 2013 Plan, supra note 9, at 8 (74% of the drugs reported to the Drug Shortage Program in 2010 were sterile injectables).
23 Id.
25 Id.
26 FDA 2011 Review, supra note 10, at 4
28 Id.
29 American Hospital Association, AHA Survey on Drug Shortages, 2, available at www.aha.org/content/11/drugshortagesurvey.pdf
30 Id. at 5-8; see also Institute for Safe Medicine Practices, Drug Shortages: National Survey Reveals High Level of Frustration, Low Level of Safety, 15 MED. SAFETY ALERT!, 1, 3 (2010) [hereinafter ISMP 2010 Survey], available at www.ismp.org/newsletters/acute-care/articles/20100923.asp
to postpone treatment, and 4% had to cancel procedures. Finally, the group purchasing organization (“GPO”) Premier Healthcare Alliance conducted a survey of 311 pharmacy experts representing 228 hospitals. Of those surveyed, 89% reported drug shortages that may have caused a safety issue or medical error and 80% reported that a drug shortage resulted in delay or cancellation of a patient care intervention. Behind these statistics are patients who are in need of drugs to treat life-threatening diseases such as cancer, to provide required parenteral nutrition, or to address serious infections.

**B. Effect of Drug Shortages on Patient Care and Healthcare Providers**

Drug shortages have had serious and immediate effects on patients and healthcare providers. The unavailability of life-saving treatments has resulted in providers prescribing second-line alternatives. Providers prescribe a specific drug for a number of reasons. In their medical opinion, the ordered drug is the most effective, has the fewest side effects, and is compatible with other medication the patient is taking. When healthcare providers are forced to use second-line alternatives, which may not be as effective as the first-line option, the risk of adverse reactions and errors increase. Shortages require healthcare providers to redirect their therapeutic efforts from applying the optimum course of treatment to searching through alternative drugs to determine proper dosages and interactions with other medications. Sixty-nine percent of the AHA survey respondents indicated that shortages resulted in patients receiving a less effective drug and 35% reported that patients have experienced adverse outcomes as result of this treatment.

When healthcare providers are unable to use an alternative treatment option because the specified drug is the only available treatment for a particular illness, patients forgo treatment and hospitals must ration the supplies they have. According to the AHA survey, 78% of respondents reported rationing or restricting drugs. As one physician noted, when there is no alternative to a life-saving drug,

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32 Id.
34 Id.
36 Id.
38 Id.
40 Maryn McKenna, Hospital Pharmacists Scrambling Amid Vast Drug Shortages: Emergency Physicians Between a Rock and a Hard Place, 56 ANN. EMERGENCY MED. 13A (2011).ac
“I guess patients just have to die.”  

In addition to the toll shortages have taken on patient care, an American Society of Health Pharmacists (“ASHP”) survey has estimated the financial toll of these shortages to the health care system. Pharmacists and pharmacy technicians reported devoting on average nine and eight hours a week, respectively to drug shortages. This translates into estimated labor costs of $216 million per year. Added to these expenses is the higher prices hospitals and healthcare providers pay for alternative drugs, as well as shipping costs to ensure the drug arrives in time.

As a result of drug shortages, some hospitals have resorted to purchasing life-saving drugs on the gray market. This market consists of distributors who offer their short supply drugs to healthcare providers at exorbitant prices. The average markup is 650% above normal prices. The cost for drugs used to treat critically ill patients and those needing anesthesia for surgery can be even higher. In a 2011 Buyer Beware Report, a vendor offered to sell the generic antihypertensive drug Labetalol for $1200. This is a 4533% markup from the drug’s customary cost of $25.90 per dose.

It is predicted that over the next year, U.S. hospitals will spend almost half a billion dollars in enhanced labor and inflated pharmaceutical costs to combat shortages.

In addition to paying exorbitant prices, hospitals acquiring drugs through the gray market have no guarantee of the drug’s quality. Diverted drugs sold through the gray market may be diluted, expired, contaminated, or relabeled with the wrong information. In a study by the Institute for Safe Medication Practices, a patient

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42 ISMP 2010 Survey, supra note 30, at 1, 4.
44 Id.
48 Cherici C. et al., supra note 46.
50 Cherici C. et al., supra note 46.
51 Hearing, supra note 35 (statement of Michael Alkire, Chief Operating Officer Premier Health Alliance).
53 Gray Market, Black Heart: Pharmaceutical Gray Market Finds a Disturbing Niche During the
safety group, more than half of the 549 U.S. hospitals acknowledged that they had purchased one or more prescription drugs from gray market vendors. 54 Seven percent reported side effects or other problems attributable to the gray market supplied drug.55

There are several conflicting theories as to the cause of drug shortages. However, in the end, there is agreement on one key fact. Drug shortages persist in part, because generic manufacturers are either unable or unwilling to supply drugs sufficient to meet current patient and provider demand. The next section explores some of the reasons for the shortages.

II. THE ECONOMICS OF THE DRUG SHORTAGES

A. Role of Generic Manufacturers

More than 80% of all drug shortages involve sterile generic injectables.56 To understand why shortages are so frequent in this area necessitates a closer examination of sterile injectable generic manufacturers and their production processes. The generic sterile injectable market is highly concentrated with seven manufacturers producing the vast percentage of all the drugs.57 In fact, the majority of the production of a given sterile injectable is done by three or fewer manufacturers.58 A 2010 study of 33 injectable oncology drugs shows that for 28 of the drugs, at least 90% of the total production unit sales were done by three or fewer manufacturers.59 If one refines the analysis down to specific drug classes, the concentration order increases. In 2008, Teva Pharmaceutical Industries, LTD held a 68% market share of Bleomycin, a cancer drug. In the same year, Bedford Laboratories®, held a 62% market share of Cytarabine, a chemotherapy agent.60

To produce sterile injectables, each of these manufacturers operates a small number of highly specialized facilities to produce the drugs.61 Production must take place in a “clean room” environment to assure that the drugs are sterile. In this context, sterile drugs are free of contamination from all microorganisms and visible matter.62 Many of these sterilized products require dedicated lines and

54 Id.
55 Id.
56 Characterization of Products, IMS Institute for Health Informatics website (Oct. 7, 2011), available at http://www.imshealth.com/portal/site/ims/menuitem.748f6639e159b2ab41d84b903208c22a/?vgnextoid=8db6a9876493310VgnVCM100000ed152ca2RCRD
57 FDA presentation at the FDA Drug Shortage Workshop (Sep. 26 2011).
59 Id.
60 IMS Health, IMS National Sales Perspective (2008), Data extracted June 2012.
61 ASPE ISSUE BRIEF, supra note 58.
specialized manufacturing equipment. As a result, there is limited production fungibility within the facilities. The production time for these drugs ranges from hours to weeks.

Given the highly specialized facilities required to produce sterile injectables, companies have chosen to meet growing demand by increasing production levels rather than expanding their manufacturing infrastructure. Manufacturers justify this production approach by balancing the cost of building redundancy into their facilities against the purported slim profit margins available in the injectable generic market. This has created an industry in which facilities are on tighter schedules. Any need for facility repairs or equipment maintenance could cripple a manufacturer’s ability to maintain sufficient output levels to prevent a shortage.

Inspection reports from key manufacturing sites indicate that several facilities experiencing current production shortages have been in continuous operation since the 1960s. These reports note that some facilities’ manufacturing lines have undergone only limited upgrades during that time while operating 24 hours a day, seven days a week. In summary, much of the market for generic injections is highly concentrated and composed of manufacturers who have opted, in several cases to meet demand by running aging production equipment at high capacity. Against this backdrop, we examine the economic underpinnings and generic manufacturers’ role in the current drug shortage.

B. Underlying Conditions of the Shortage

1. Market Forces – Inelasticity of Demand and Supply

The unique nature of the healthcare market makes it particularly susceptible to drug shortages. In the majority of markets, shortages are rare because prices change to maintain equilibrium between the quantity of products supplied and the quantity demanded. For example, when a supply disruption reduces the availability of a product, prices increase and consumer demand recalibrates.

By contrast, the prescription drug market is relatively inflexible and constrained in

64 Id. ( nature article)
66 Id.
67 Id.
68 Woodcock, et al., supra note 64.
69 Id.
70 Id.
71 72 ASPE ISSUE BRIEF, supra note 58, at 3.
its ability to react effectively to demand and supply changes. Patient demand for these drugs is often unaffected by changes in price for two reasons. First, a majority of these drugs are medically necessary, which suggests that there are few substitutes. Insufficient supplies generally do not precipitate a reduced demand for drugs because patients cannot control what illnesses they will suffer and the specific medications they require. Second, manufacturers are prevented from raising prices to influence demand because patient health insurance contracts typically pay providers using pre-negotiated payment rates. These pre-set rates do not allow manufacturers to alter prices during the contract term.

Price inelasticity is present on the supply side as well. Here, low price responsiveness influences manufacturer inventory decisions. If a manufacturer has a surplus of a particular oncology drug, there may be no market for it even at a highly discounted price. Drugs have a limited shelf life and holding excess inventory is costly. As noted in a recent industry report, this produces a scenario where “... manufacturers face an asymmetry of incentives. There is minimal cost of producing too little of a drug, and a potentially high cost of producing too much.” Rather than carry excess product, manufacturers commonly use “just in time” inventory practices. Using this approach, facilities manufacture drugs in amounts calculated to satisfy current demand. While efficient from a manufacturing perspective, any sudden change in supply or demand could render a drug vulnerable to shortage.

Another feature of the sterile injectable market is that high front-end costs, dedicated production lines, and strict regulatory requirements prevent new manufacturers from quickly entering the market to increase supply. It generally takes 2 to 3 years for a manufacturer to get FDA approval for a new production facility. In addition, raw materials for production are often difficult to source.

75 Haninger, *supra* note 66, at 1.
76 *Id.*
77 ASPE ISSUE BRIEF, *supra* note 58, at 4.
79 ASPE ISSUE BRIEF, *supra* note 58 at 6; *see also* Woodcock, et al., *supra* note 64 at 170-176 (while contracts generally place a penalty for failure to supply product, that penalty structure as the difference between the contracted rate and the rate that a provider have to pay for an alternative source. Drug shortages and generally not trigger these clauses because there is often no alternative source).
81 *Id.*
must be validated by manufacturers, and require regulatory approvals. As a result of these factors, it generally takes years for the industry to expand capacity in response to an increase in demand. Moreover, if the increase in demand is expected to be temporary (i.e. a shortage due to a production line disruption) investments in increased capacity are unlikely to occur.

In the sterile injectable market, maintaining excess production capacity to meet unanticipated demand is an uneconomical business approach. It would result in a generic manufacturer having high costs relative to its competitors. In the highly competitive generic drug market, no generic manufacturer would choose this strategy unless it could receive a higher price in the market. As discussed in the following section, Medicare Modernization Act (“MMA”) price controls forestall that possibility.

2. Legislative Constraints

The MMA has a significant effect on the profit margins for generic sterile injectable drugs. In pertinent part, the law changed the reimbursement system for physician administered drugs under Medicare Part B. The MMA capped provider reimbursement at the actual average sales price (“ASP”) recorded in the market place plus a 6% markup, which is intended to cover the drug cost, overhead, staff and materials. Prior to the MMA, providers received 95% of the average wholesale price (“AWP”) for each covered drug. Despite the name, the AWP was not actually the average wholesale price, but rather, the manufacturer’s suggested list price. In 2001, a Government Accounting Office (“GAO”) and Centers for Medicare and Medicaid Services (“CMS”) joint report found the AWP system resulted in Medicare overpaying for Part B drugs by over 1 billion dollars a year. Congress addressed the overpayment issue by including provisions in the MMA to change the Medicare reimbursement system.
In 2005, Medicare converted to the ASP-based reimbursement system. This had the practical effect of limiting manufacturer price increases for generic drugs to no more than 6% every six months (because raising the price more than that would cause reimbursement for the drug to be less than the actual selling price). Economists note that the ASP cap leaves little flexibility for prices to adapt to supply and demand. This hurts manufacturers because in the generic market drug prices can decrease quickly. As noted by former health-care advisor to the Obama administration, physician Ezekiel Emanuel:

The first two or three years after a cancer drug goes generic, its price can drop by as much as 90% 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 of the 2003 act effectively limits drug price increases, it prevents this from happening.

Because traditional notions of supply and demand do not apply to cancer drugs, the market cannot self-correct to address shortages. Typically, the market would respond to increased demand with increased prices. The Medicare payment system, however, makes it difficult to raise prices. This creates a situation that for low cost drugs with dwindling profit margins there is little incentive for continued production. This theory along with a Department of Health and Human Services (“DHHS”) study that reviewed Medicare Part B volume of service data suggests that drug shortages are likely to occur when a drug’s price falls. The study found that within “the group of drugs that eventually experienced a shortage, average prices decrease in every year leading up to that shortage. In contrast, the average prices of drugs that never experienced the shortage over this period did not change . . . .”

The ASP reimbursement system also exerts price pressure on generic manufacturers because it incentivizes physicians to prescribe costly brand-name

95 The MMA applied to all drugs administered in a provider setting. Link, Michael P., Karen Hagerty, and Hagop M. Kantarjian, Chemotherapy drug shortages in the United States: genesis and potential solutions, 7 J. CLINICAL ONCOLOGY 30, 692-693 (2012).

96 Id.


98 Id.

99 Id.

100 Id.

101 Id.

102 Link, et al., supra note 96.

103 Haninger, et al., supra note 66.

104 Id. (The study found that 44 drugs with declining sales in 2006 – 2008 were in shortage in subsequent years, and 28 drugs with increased sales in 2006 – 2008 were never involved in a shortage. The study also found that the prices of 44 drugs in shortage had steadily decreased, while the prices of the 28 drugs to supply was adequate did not change significantly).
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drugs over generics. Physicians who prescribe drugs that are more expensive receive a higher dollar amount than those who prescribe generics. For example, 6% of the cancer drug, Abraxane, which sells for $5,824, yields a much higher payment for a provider than 6% of the generic Paclitaxel, priced at $312.

For nearly a decade, the MMA’s reimbursement system has applied a steady downward pressure on sterile injectables drug prices. In the short run, these falling prices are favorable to patients and payers. However, when the cost of a drug falls below a certain price, patients can run the risk of manufacturers abandoning production in favor of more lucrative product lines. Consider the long-term viability of producing a $1 sterile injectable cancer drug from a manufacturer’s perspective. Faced with diminishing returns from low prices, the incentive to remain in the market is reduced. As recent market activity suggests, fewer manufacturers choose to produce these drugs. With a limited number of manufacturers, any production line disruption magnifies the impact on the supply of product. Currently, providers treat patients with life-saving cancer drugs that cost less than a can of soda. In the end, this pricing scheme may not be economically viable for generic manufacturers.

C. Exacerbating Economic Factors

1. Business Decisions and Market Consolidations

The MMA reimbursement policies and market forces described above influence generic manufacturers’ decisions regarding not only how much to produce but to where to sell their products. Some generic manufacturers have made the business decision to sell their products abroad rather than in the U.S. market. Medicare type reimbursement caps do not exist in Europe and generic drugs prices are higher. As a result, generic drugs manufactured in the U.S. can be sold abroad at a higher profit. When manufacturers decide to focus on more profitable markets, needed drugs are diverted to foreign countries. These business practices, in turn, contribute to drug shortages in the U.S.

High production costs and comparatively low profit margins associated with sterile injectables have prompted generic manufacturers to reduce or discontinue

106 Id.; CMS 2012 Files, supra note 89.
107 Gatesman, et al., supra note 105.
108 Haninger, et al., supra note 66.
109 Id.
110 Id.
111 Haninger, et al., supra note 66.
113 Link, et al., supra note 96.
114 Chabner, et al., supra note 112.
115 Sharona H., supra note 73, at 7.
production. In 2000, vaccines used against diphtheria and tetanus were in shortage because one manufacturer, citing low revenues, decided to discontinue production. In the case of the cancer drug Leucovorin, a generic manufacturer recently decided to stop production because a brand-name version with a higher profit margin became available. For over seventy years, several manufacturers have produced the cancer drug. In 2008, the FDA approved a patented active L-isomer of the drug. Though the brand name drug was no more effective than the generic, it was 58 times more expensive than the $32 per dose generic. Eight months after FDA approval of the branded version, there were reports of a shortage of the less costly generic. The high manufacturing costs and insufficient financial return made it no longer in generic manufacturers’ business interests to continue production.

Industry consolidations have also affected the availability of drugs. When generic manufacturers combine, the merged entity often streamlines or transfers product lines to new facilities. These actions can result in discontinuations or delays in the manufacturing process of drugs. In addition, consolidation between two companies with similar product lines often results in single-source productions. Decreases in the number of manufacturers producing a drug, in turn, decreases resiliency in the supply chain. The net result is that those drugs become more vulnerable to shortages.

Recent consolidations within the generic drug industry include Teva’s acquisition of Barr Pharmaceuticals, and Mylan Pharmaceuticals’ acquisition of Merck’s KGaA generics. Mergers of this type often result in competing financial interests within an organization that can affect availability of lower priced pharmaceuticals. A DHHS report indicates that mergers could have a significant contribution to drug shortages “if consolidations result in closures of manufacturing facilities that reduced production capacity.” As noted by

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117 ASHP 2009 Guidelines, supra note 47 at, 1399,1401.
118 Sharona H., supra note 73, at 6.
119 Id.
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121 Gatesman, et al., supra note 105.
122 Sharona H., supra note 73, at 6.
123 Id.
124 Gatesman, et al., supra note 105.
125 Koh testimony.
126 ASHP 2009 Guidelines, supra note 47, at 1399,1401.
127 Sharona H., supra note 73, at 6.
128 Id.
129 ASHP 2009 Guidelines, supra note 47 at, 1399,1401.
131 Canonsburg, P, Mylan Laboratories Inc. 2006 Annual Report. ;
132
133 ISSUE BRIEF, supra note 58 at 6; see also Woodcock, et al., supra note 64.
Industry consolidation has also contributed to the drug shortage problem . . . when a firm has a manufacturing or quality problem they will often voluntarily suspend production so they can identify and address the root cause of the product quality problem. . . . Consolidation has led to fewer firms making these drugs and the firms have a limited number of manufacturing lines. When one firm experiences a quality problem which results in production holds or slowdowns, the remaining firms are usually not able to make up the shortfall due to capacity constraints.  

2. The Role of GPOs

Currently, the GAO is investigating the extent to which GPOs contribute to ongoing shortages. GPOs are purchasing intermediaries that leverage the buying power of their members and negotiate contracts with manufacturers and vendors. In the healthcare setting, GPOs negotiate contracts with drug manufacturers on behalf of hospital groups and healthcare organizations. As the intermediary between manufacturers and hospitals, GPOs create value by reducing transaction costs and negotiating lower prices than could be achieved by a single hospital. GPOs derive a majority of this value (and their operating revenue) by charging drug manufacturers for contracting services. Referred to as “contract administrative fees,” these payments are on a percentage of each drug manufacturers’ GPO-negotiated contract sales. By law, this fee should not exceed 3%, but in special cases, GPOs have charged higher fees. GPOs can charge these fees through a “safe harbor” amendment to the Social Security Act’s Anti-Kickback Statute.

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139 Government Accountability Office 2003 Group Purchasing Organizations: Use of Contracting Processes and Strategies to Award Contracts for Medical-Surgical Products GAO-03-998T, Washin
gton, D.C. (July 16, 2003).

140 Hu, et al., supra note 137.

141 GAO-03-998T, supra note 139.

142 The Anti-Kickback statute prohibits the knowing or willful solicitation, receipt, offer, or payment of fees, or other remuneration, to induce the purchase of an item or service for which payment may be made under a federal health care program. See 42 U.S.C. § 1320a-7(b) (2006).
In 2011, over 90% of all hospital purchases were made through GPO contracts.\textsuperscript{143} In the same year, the two largest GPOs, Novation and Premier, negotiated contracts worth approximately $70 billion.\textsuperscript{144} The consolidation of GPO purchasing power has raised several policy concerns. In particular, contract provisions frequently used when negotiating with generic manufacturers have raised the specter of anti-competitive foreclosure.\textsuperscript{145} Most recently, these practices have been linked to drug shortages.

GPO contracts are structured to take advantage of large economies of scale in drug production.\textsuperscript{146} In the sterile injectable market this results in only a few large manufacturers producing each medication.\textsuperscript{147} GPOs tend to favor large manufacturers because they have a wider variety of products and are financially capable of paying the contract fees.\textsuperscript{148} In exchange for the administration fees, GPOs offer drug manufacturers a variety of contractual incentives that limit competition among sources of supply to their member hospitals.\textsuperscript{149} A recent GAO report indicates that GPOs frequently use sole-source contracts.\textsuperscript{150} In such contracts, a GPO grants a generic manufacturer the exclusive right to offer its drugs to the GPO member hospitals.\textsuperscript{151} Other GPO contracts offer minimum volume purchase requirements to specific drug manufacturers.\textsuperscript{152} GPOs set the volume requirements at levels that essentially block smaller generic manufacturers from competing for these contracts.\textsuperscript{153} GPOs also offer select manufacturers bundling arrangements.\textsuperscript{154} In these contracts, GPO member hospitals can purchase combinations of products from specific manufacturers. The manufacturer benefits from these arrangements through increased sales from items that may not generate adequate revenue as standalone items.\textsuperscript{155} As noted in the GAO report, in each of these instances there is a tendency for one manufacturer to thrive while rivals are either marginalized or excluded entirely from the market.\textsuperscript{156}

\begin{footnotesize}
\begin{itemize}
  \item \textsuperscript{143} Blair, Roger D., and Christine Piette Durrance, \textit{Group Purchasing Organizations, Monopsony, and Antitrust Policy}, MNANGERIAL & DECISION ECONOMICS (2013).
  \item \textsuperscript{144} \textit{Id.}
  \item \textsuperscript{145} Frech, Ted, \textit{Some Thoughts on Bundled Rebates and Exclusionary Policies}, 6 ANTITRUST CHRONICLE (2008).
  \item \textsuperscript{146} Blair, \textit{supra} note 143.
  \item \textsuperscript{147} Committee on Government Oversight and Reform: Report on FDA’s Contribution to the Drug Shortage Crisis, \textit{Staff Report H.R.}, 112\textsuperscript{th} Cong. (June 15, 2012) [hereinafter CGOR 2012 Report]
  \item \textsuperscript{148} Blair, \textit{supra} note 143.
  \item \textsuperscript{149} \textit{Id.}
  \item \textsuperscript{150} GAO-03-998T, \textit{supra} note 139.
  \item \textsuperscript{151} Blair, \textit{supra} note 143.
  \item \textsuperscript{152} CGOR 2012 Report, \textit{supra} note 147.
  \item \textsuperscript{153} \textit{Id.}
  \item \textsuperscript{154} \textit{Id.}
  \item \textsuperscript{155} \textit{Id.}
  \item \textsuperscript{156} GAO-03-998T, \textit{supra} note 139.
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In 2012, a House Committee on Oversight and Government Reform (“House Committee”) report indicated that these GPO practices contribute to the current shortage of generic injectable medications. Because GPO networks are a guaranteed source of demand, drug manufacturers compete aggressively for GPO contracts. As previously noted, GPOs favor drug manufacturers who can produce drugs in high volume because economies of scale in drug manufacturing results in declining average costs as the amount of production increases. This intense manufacturer competition to win GPO contracts drives prices down. As a result, however, the House Committee report notes, “companies that cannot produce a drug at large enough output levels to take advantage of the economies of scale . . . will stop producing the drug or will neglect to enter the market.” These practices contract the market. In contracted markets dominated by single source suppliers, drugs are more vulnerable to shortage.

Critics contend that these exclusive contracting provisions have given GPOs monopolistic control over the industry and jeopardize market competition. In response to these concerns, six senior members from the House of Representatives have asked the GAO to investigate whether GPO contracts practices and safe harbor administration fees are a “driving cause” of drug shortages. The GAO report is due out in 2014.

D. The FDA’s Role in Drug Shortages

According to a report published by the FDA, quality problems at generic manufacturing facilities that resulted in supply disruptions of life-saving medicines caused current drug shortages. The report further notes that while product disruptions and other root causes of drugs “lie outside the purview of FDA,” the Agency is currently working with manufacturers to prevent and mitigate such shortages. The FDA report, however, mischaracterizes both the leading cause and the Agency’s role in the origins of current drug shortages.

The root cause of current shortages can be traced back to 2009, when President Obama appointed Dr. Margret Hamburg Commissioner of the FDA. Her appointment came soon after contaminated batches of a sterile injectable, Heparin,
were linked to over 80 deaths in the U.S. during 2007 and 2008.\textsuperscript{167} As the new commissioner, Hamburg made taking greater action to prevent contaminated drugs a top priority.\textsuperscript{168} Specifically, she announced, “the FDA’s fortunate to receive significant funding increases for the current and next fiscal year that will be devoted to additional inspection and compliance activities that will support the elements of an effective enforcement strategy that I have outlined.”\textsuperscript{169}

As a result of the FDA’s intensified inspections, four of the U.S.’ five largest generic injectable manufacturers simultaneously began remediation efforts.\textsuperscript{170} As part of addressing issues raised in FDA warning letters, all the recipients temporarily halted production.\textsuperscript{171} When explaining these concurrent production stoppages to Congress, the FDA stated that they were “voluntary manufacturer decisions.”\textsuperscript{172} However, given the explicit threat contained in FDA warning letters, “[f]ailure to promptly correct these violations may result in legal action without further notice including, without limitation, seizure and injunction,” one could question the ‘voluntariness’ of such action.\textsuperscript{173}

By February 2012, 58\% of the drugs in short supply were manufactured by one or more of the facilities that had received a warning letter from the FDA and were undergoing remediation efforts.\textsuperscript{174} Under Hamburg’s direction, FDA agents increased their efforts in conducting facility inspections and issuing citations.\textsuperscript{175} According to the House Report, these field agents did not believe it was their responsibility to consider the implications of their increased enforcement action.

\begin{itemize}
\item \textsuperscript{167} Barry Matt, Medicare Price Controls Worsen Drug Shortages, Boost Gray Market.” (2012), (quoting Linking Medicare Price Controls to a Surge in Drug Shortages Ed Silverman, Congress Widens Probe into Heparin Scandal, PHARMA LOT, (June 30, 2011)).
\item \textsuperscript{168} Remarks by FDA Commissioner Margaret A. Hamburg on, Effective Enforcement and Benefits to Public Health, FOOD & DRUG LAW INST., (Aug. 6, 2009), available at: http://www.fda.gov/NewsEvents/Speeches/ucm175983.htm
\item \textsuperscript{169} Id.
\item \textsuperscript{170} Id.
\item \textsuperscript{171} An FDA warning letter is a: “[A] correspondence that notifies regulated industry about violations that FDA has documented during its inspections or investigations. Typically, a Warning Letter notifies a responsible individual or firm that the Agency considers one or more products, practices, processes, or other activities to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act), its implementing regulations and other federal statutes. Warning Letters should only be issued for violations of regulatory significance, i.e., those that may actually lead to an enforcement action if the documented violations are not promptly and adequately corrected. A Warning Letter is one of the Agency’s principal means of achieving prompt voluntary compliance with the Act.” FOOD & DRUG ADMIN., “Procedures for Clearing FDA Warning Letters and Untitled Letters,” (Dec. 2010), available at: http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM176965.pdf.
\item \textsuperscript{173} CGOR 2012 Report, supra note 147.
\item \textsuperscript{174} Id.
even if it resulted in production disruptions, facility closures, and eventual shortages.\textsuperscript{176}

A troubling aspect of the FDA’s heightened enforcement strategy was that in some instances, it is questionable whether allegations contained in the warning letter were valid. The FDA conducted three separate investigations of a Sandoz manufacturing plant in Québec during 2011.\textsuperscript{177} In November, the Agency issued a warning letter citing possible contamination of some of Sandoz’s sterile injectable drugs.\textsuperscript{178} The Canadian drug authority conducted a separate inspection soon thereafter and identified no problems.\textsuperscript{179} Faced with possible FDA sanctions, however, Sandoz decided to scale back production of several drugs while addressing Agency concerns.\textsuperscript{180} Sandoz’s experience, of having no identifiable problems, is not uncommon. During the House Committee’s investigation of the FDA’s role in drug shortages, it found no evidence that any products produced at the facilities undergoing remediation had harmed anyone beyond typical side effects associated with any type of medication.\textsuperscript{181}

The House Committee’s finding do not dispute that many of the facilities were older and the upgrade to certain production lines was desirable.\textsuperscript{182} In addition, the committee agreed that FDA should maintain regulatory oversight to ensure that contaminated drugs such as those responsible for the deadly outbreak of fungal meningitis and other infections do not occur.\textsuperscript{183} However, as pointed out by former Deputy Commissioner of the FDA and Senior Policy Advisor to CMS, Dr. Scott Gottlieb, the FDA has largely contributed to the drug shortage crisis with inflexible and outdated policies:

> With its vigilance heightened, the FDA has required manufacturers to undergo major plant renovations, suspend facilities or stop shipping goods from suspect production lines. The FDA and the manufacturers often don’t understand the drug-production processes well enough to detect the root cause of problems. Instead of calling for targeted fixes of troubled plants, the Agency has often required manufacturers to undertake costly, general upgrades to facilities.\textsuperscript{184}

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\textsuperscript{176} Id.
\textsuperscript{177} Id.
\textsuperscript{179} Generic Licensing, supra note 178.
\textsuperscript{180} CGOR 2012 Report, supra note 147.
\textsuperscript{181} MDs 2013 Blame, supra note 162.
Between fiscal years 2009 and 2011, the number of FDA-issued warning letters increased by 250%. Compliance with the warning letters essentially required all U.S. manufacturers of sterile injectables to remediate their facilities at the same time. The simultaneous remediation reduced available capacity at these facilities by 30% relative to capacity in 2009. This created a vacuum in the generic drug market which, due to the highly complex manufacturing processes, could not be filled immediately. For facilities with genuine manufacturing problems, the FDA could have directed facilities to make targeted improvements carried out over a timeframe that would have significantly diminished the public health crisis the country is now facing from drug shortages.

Perhaps in recognition that its enforcement strategy was contributing to drug shortages, the FDA revised its warning letters. The letters now include the following directive:

If as a result of receiving this warning letter or in general, you are considering making a decision that will result in a decreased number of finished drug products or active pharmaceutical ingredients produced by your manufacturing facility, FDA requests that you contact CDER’s Drug Shortages Program immediately, as you begin your internal discussions, . . . in order to ensure that your action(s) does not adversely affect the public health.

III. THE NEED FOR A NEW APPROACH

A. Current Administrative and Legislative Solutions to the Drug Short Crisis

This section examines current legislative, regulatory, and private sector approaches to mitigate and prevent drug shortages. These efforts will ameliorate some of the effects of drug shortages. As the analysis shows, however, in several critical areas, these approaches are insufficient.

1. Executive Order 13588 - Reducing Prescription Drug Shortages

On October 31, 2013, President Obama issued an Executive Order in response to the rising number of drug shortages and their impact on healthcare in the United States. The order directs the FDA to take steps to prevent future disruptions in the supply of life-saving medicines. An important element in that process is “ensuring that the FDA and public have advance notice of shortages whenever

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185 CGOR 2012 Report, supra note 147.
186 Id.
187 FDA 2009 letter, supra note 173.
189 CGOR 2012 Report, supra note 147.
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possible.”¹⁹¹ To that end, the order tasks the FDA with a two-part directive. The first part instructs the Agency to require drug manufacturers to provide advance notice of production interruptions that could lead to shortages of certain drugs.¹⁹² The second requires the FDA to expand and expedite its regulatory reviews of new drug suppliers and manufacturing facilities.¹⁹³

2. FDASIA

   a. Expanded Notification Requirements

In July 2012, President Obama signed the Food and Drug Administration Safety and Innovation Act ("FDASIA") into law.¹⁹⁴ The Act amends existing FD&C drug shortage notification requirements and adds new notice provisions.¹⁹⁵ Title X of the Act (1) expands drug supply disruption and reporting requirements; (2) directs the FDA to take specific actions to prevent or mitigate shortages; (3) creates a mechanism for tracking drug shortage data and sharing that information with key stakeholders; and (4) establishes a task force to analyze the causes of drug shortages and devise strategic plans that address the shortages.¹⁹⁶

The FDASIA substantially revises the scope of drug shortage reporting requirements. The Act’s notice requirements now apply to all manufacturers of medically important approved and unapproved drugs.¹⁹⁷ Previously, only sole manufacturers of approved drugs were required to alert the FDA of a drug shortage.¹⁹⁸ Title X also expands the scope of drugs subject to shortage notification to include drugs used during emergency medical care or surgery.¹⁹⁹ Prior FD&C notice provisions applied only to drugs that were life-supporting, life-sustaining, or intended for use in the prevention of a debilitating disease or condition.²⁰⁰

The Act requires all manufacturers to alert the FDA of a permanent discontinuance or a production interruption that is likely to lead to a meaningful disruption in the availability of that drug in the United States.²⁰¹ Manufacturers must also include in

¹⁹¹ *Id.*
¹⁹² *Id.*
¹⁹³ *Id.* In response to the Executive Order’s instruction to address the growing number of drug shortages, the FDA published an interim final rule (IFR) that required sole manufacturers of certain drugs to provide FDA with six months’ notice before discontinuing production. Because IFR is superseded by the Food Drug Administration Safety and Innovation Act (FDASIA) this article does not substantively address the IFR
¹⁹⁴ amends the FFDCA to better manage and track drug shortages and threatened shortages
¹⁹⁵ FFDCA § 506(c), as amended by Title X of FDASIA Pub. L. 112-144, 126 Stat. 993 (2012)).
¹⁹⁶ FFDCA § 506C(a), as amended by Title X of FDASIA Pub. L. 112-144, 126 Stat. 993 (2012)).
¹⁹⁷ *Id.*
¹⁹⁸ FDASIA § 1001(a).
¹⁹⁹ *Id.*
²⁰⁰ FFDCA § 506C(a)(1).
²⁰¹ FDASIA § 1001(a).
the notice the reasons for the disruption.\textsuperscript{202} Previously, manufacturers only had to alert the Agency only of permanent drug discontinuances.\textsuperscript{203} Manufacturers are required to give the FDA 6 months’ notice before permanently discontinuing a drug.\textsuperscript{204} The FDASIA extends this requirement to product interruptions that could lead to a meaningful disruption in the supply of the drug within the U.S.\textsuperscript{205} The Act defines meaningful disruption as “a more than negligible change in production that affects the manufacturer’s ability to fill orders or meet expected demand.”\textsuperscript{206}

The FDASIA requires the FDA to issue letters of noncompliance to manufacturers who fail to notify the Agency of a product discontinuance or interruption within a specified timeframe.\textsuperscript{207} The Act also authorizes the FDA to investigate, and make available, instances of noncompliance.\textsuperscript{208} In addition to increasing manufacturer notification requirements, the FDASIA also expands the Agency’s notification responsibilities to the public. The FDA is required to create a process for entities to communicate information regarding shortages to the Agency.\textsuperscript{209} The FDA is also responsible for maintaining a publicly available list of drugs currently in shortage.\textsuperscript{210} Finally, in terms of expanding FDA reporting requirements, the Act formalizes existing Agency practices aimed at preventing shortages. It is now mandatory for the FDA to consider the potential impact a warning letter may have on the supply of a drug before taking enforcement action.\textsuperscript{211} Any Agency enforcement action that could have an adverse impact on a drug’s supply must be vetted by the appropriate FDA Center.\textsuperscript{212}

b. Strategic Plan

Perhaps in tacit recognition that the FDASIA may be insufficient to prevent future shortages, the Act creates two mechanisms for continuing drug shortage research and strategic planning.\textsuperscript{213} The Act requires the Agency establish a task force to develop and implement a strategic plan to prevent and mitigate shortages.\textsuperscript{214} Part of the strategic plan must examine whether to establish a Qualified Manufacturing Partner Program.\textsuperscript{215} Manufacturers in the program would have ability and capacity to quickly supply drugs in, or anticipated to be in, shortage.\textsuperscript{216} The FDA is also tasked with determining if incentives would be necessary to encourage

\begin{footnotes}
\item[202] Id.
\item[203] FFDCA § 506C(b).
\item[204] FFDCA § 506C(h)(3) as amended by FDASIA §1001(a).
\item[205] FFDCA § 506C(b) as amended by FDASIA §1003.
\item[206] Id.
\item[207] Id.
\item[208] FFDCA § 506E(a) as amended by FDASIA §1004.
\item[209] FFDCA § 506D(b)-(c) as amended by FDASIA§1003.
\item[210] Id.
\item[211] FDASIA §1003.
\item[212] Id.
\item[213] FDASIA § 1003.
\item[214] FFDCA § 506D(a)(1)(C), as amended by FDASIA §1003.
\item[215] Id.
\item[216] Id.
\end{footnotes}
manufacturers to participate in the program. Finally, the FDASIA requires the Comptroller General to examine the causes of drug shortages and submit to Congress by January 9, 2014 recommendations regarding how to prevent or alleviate them.

B. Current Regulatory Solutions to the Drug Shortage Crisis

1. FDA Proposed Rule Implementing FDASIA

The proposed rule would amend FDA regulations to implement the FDASIA drug shortage notice provisions. The proposed rule contains broad definitions of several key terms which give maximum effect to the FDASIA notice requirements. The proposed rule refers to “product” as a specific strength, dosage form, or route of administration. If a manufacturer may experience disruption that relates to only one strength of a particular drug, the FDA must be notified, even if other strengths are available. The FDASIA requires manufacturers to alert the Agency of manufacturing interruptions that are likely lead to a “meaningful disruption in supply of that drug in the United States.” According to the proposed rule, manufacturers must report interruptions that will likely lead to a meaningful disruption in their own supply. In other words, manufacturers must notify the FDA even if the manufacturer has such a small market share that its disruption is unlikely to affect the market as a whole.

Consistent with FDASIA’s intent, these notification requirements expand the FDA’s access to information regarding drug discontinuances and interruptions. According to the FDA, this information will allow the Agency time to work with manufacturers to resolve production disruptions, or find alternative producers. It is arguable whether the Agency has the capacity to analyze and react to the volume of notifications the proposed rule will generate. The Agency acknowledges that 6 months’ advanced notice of a manufacturing interruption is purely aspirational. The proposed rule notes that often only a few days advance notice is practicable. Further, the FDA acknowledges that in some cases notice may even postdate the production disruption. In the proposed rule, the Agency expresses concern regarding the expanded definition of the types of drugs subject to notice

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217 Id.
218 FDASIA §§1008. As of the writing of this article the Comptroller Report was not available.
219 Discontinuance or Interruption, supra note 8.
220 Id.
221
222 Id.
223
225 Discontinuance or Interruption, supra note 8, at 65,914.
226 Id.
227
requirements.\textsuperscript{228} Perhaps mindful of its limited resources, the FDA seeks public comment on whether the definitions may have the effect of “unintentionally broadening[ing] the scope of reporting to such an extent that the Agency is ‘over-notified.’”\textsuperscript{229} Interestingly, the FDA’s ability to enforce the notice requirements is limited to issuing public noncompliance letters.\textsuperscript{230} Generally, the FDA’s ability to publicize violations is one of its most powerful enforcement tools. Most recently, the Agency used this “name and shame” approach and published noncompliance letters of companies who failed to conduct federally required parenteral studies.\textsuperscript{231} Stronger enforcement provisions were included in draft legislation. Both the House of Representatives and Senate drug shortage bills contained fines for noncompliance. The House of Representative bill authorized the FDA to levy fines up to $10,000 a day.”\textsuperscript{232} No such provisions were included in the FDASIA. Perhaps they were omitted because fines or other punitive measures have the potential to exacerbate shortages. There would always be the risk that a manufacturer subject to a large fine could decide to simply shut down a facility rather than remediate it.

2. FDA Drug Shortage Task Force

The FDASIA required the FDA to create a Task Force to develop a Strategic Plan to mitigate and prevent drug shortages.\textsuperscript{233} Released October 31, 2013, the Strategic Plan outlines ways to improve the FDA’s response to manufacturer shortage notifications.\textsuperscript{234} Task Force recommendations include: (1) streamlining FDA internal processes, (2) clarifying roles and responsibilities of various groups within the FDA, (3) improving communications with the public and healthcare providers regarding actual or potential shortages, and (4) collaborating with manufacturers on remediation efforts.\textsuperscript{235}

The FDA identifies quality and production deficiencies and manufacturing facilities as the leading causes of drug shortages. The Strategic Plan includes a blueprint of Agency actions to strengthen its effort to address shortages.\textsuperscript{236} As part of the plan, the FDA will create an Office of Pharmaceutical Quality.\textsuperscript{237} The Agency will develop a risk-based approach to detect manufacturing problems

\textsuperscript{228} Discontinuance or Interruption, supra note 8, at 65909.
\textsuperscript{229} \textit{Id. at} 65917.
\textsuperscript{231} Preserving access to life-saving medications act, H. Art. 2245, 112 Cong. (2011)
\textsuperscript{233} \textit{Id.}
\textsuperscript{234} \textit{Id.}
\textsuperscript{235} FDA 2013 Plan, supra note 9, at 12-17.
\textsuperscript{236} \textit{Id.}
\textsuperscript{237} \textit{Id.}
that could result in shortages. According to the plan, the FDA will also increase collaborations with industry and other stakeholders. By working together, the Task Force believes the FDA can gain a better understanding of shortages and strategies to prevent them.

Notwithstanding these measures, the Strategic Plan notes that “shortages cannot be resolved until one or more manufacturers commit to fill in for lost production.” The Strategic Plan recommends manufacturers consider building redundant manufacturing capacity or increasing inventory levels to lower the risks of shortages. The FDA notes that it lacks the authority to require or regulate such practices. The Task Force also mentions that the FDA is exploring ways to develop positive incentives to improve prioritizing manufacturing quality.

The Strategic Plan seems to represent a nascent proposal rather than a fully developed approach to mitigating and preventing shortages. Two years ago the FDASIA directed the FDA to create an Office of Pharmaceutical Quality. The Strategic Plan indicates that the FDA is still “implementing” such a proposed office and provides no specifics as to when it will begin operations. The FDA was also instructed to explore whether a qualified manufacturing partner program would help mitigate future drug shortage. In response to the FDA’s request for public comments, the Agency received substantial industry input specifically addressing the viability of such a partner program. In addition, the Agency had access to a potential model in the Biomedical Advanced Research and Development Authority (“BARDA”) program and data from the partnership model used in mitigating Doxil shortages. Nevertheless, the Task Force states that it still needs more industry input on feasibility. As a result, the Strategic Plan contains no information regarding whether it will actually create such partnership program.

In crafting the Strategic Plan, the FDA also requested public comment regarding how manufacturers use quality metrics to monitor production and select contract manufacturers. In response, manufacturers and trade associations submitted comments describing several different industry standards and quality assurance approaches. This input provided the Task Force a range of reporting material
that purchasers and manufacturers identified as helpful in assessing quality. However, the Task Force does not appear to consider these or any other system to standardize and consolidate quality reporting information. Rather, the Strategic Plan indicates that purchasers should rely on already published data.\footnote{Id.} The FDA eschews its responsibility to create useful quality metrics by stating “buyers ultimately decide how or whether they will use this data when they make purchasing decisions.”\footnote{Id.} The Strategic Plan makes no reference to increasing the availability of quality information to the public or presenting the already available information in a more usable format for purchasers.

The Strategic Plan does make passing reference to shortage-related issues it considers outside of the FDA’s direct control. On the issue of manufacturing incentives, the Strategic Plan indicates that the FDA’s “ability to offer financial or other economic means to promote innovation and quality manufacturing is limited.”\footnote{Id.} This inert statement misses the point. No one expects the Agency to mete out cash rewards for quality improvements. As evident in several industry responses, the FDA has the ability to offer valuable several noneconomic incentives. For example, the Agency could offer expedited review of new facilities for manufacturers exhibiting exemplary quality standards.\footnote{Id.} The Agency could expedite product reviews for manufacturers who voluntarily invest in state of the art production technologies. Yet, the Strategic Plan does not analyze, or include, any quality-based incentives.

Despite some shortcomings, the Strategic Plan could have a positive effect on mitigating shortages. As enacted however, it is questionable whether the Task Force will have sufficient time to entrench itself within the market and regulatory system sufficiently to have any lasting effect. Pursuant to FD&C Section 506(f) the structure and purpose of the Task Force end in 2017. This sunset provision means that even if the Strategic Plan’s initiatives begin to succeed, the Task Force will cease operations at the end of five years.\footnote{Id.} Sunset provisions are not uncommon in legislative acts. Given the severity of the drug shortages, however, such a short timeframe does not give the Task Force much time to assert itself before losing its mandate.

\section*{C. Current Industry Solution to the Drug Shortage Crisis}

The Generic Pharmaceutical Association (“GPhA”) and a subset of member companies have collaborated with the FDA to develop and implement a program to address potential drug shortages.\footnote{GPhA Receives Positive FTC Advisory Opinion on Accelerated Recovery Initiative, available at \url{http://www.gphaonline.org/gpha-media/press/gpha-receives-positive-ftc-advisory}.} Under the Accelerated Recovery Initiative
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(“ARI”), generic companies share manufacturing information about drugs in short supply with the FDA and a third party.\textsuperscript{258} As of April 2013, five generic manufacturers had agreed to participate.\textsuperscript{259}

The ARI consists of voluntary confidential communications among the FDA, IMS, and stakeholders involved in the manufacturing and distribution of generic drugs currently in shortage.\textsuperscript{260} The goal of the initiative is to use real-time supply and distribution information to expedite Agency efforts to mitigate shortages.\textsuperscript{261} The multi-stakeholder approach also will use manufacturers’ production and release forecasts to assist Agency staff in preventing shortage.\textsuperscript{262} The FDA and GPhA are also currently working to identify four to eight generic sterile injectables that have at least two manufacturers to cooperate in meeting market production needs.\textsuperscript{263}

A key element of the ARI is the agreement among drug manufacturers to pool competitively sensitive production information about shortage drugs. To avoid anti-trust concerns, the GPhA requested FTC review.\textsuperscript{264} The FTC concluded that safeguards built into the process are sufficient to prevent collusion and unfair competition among the participants.\textsuperscript{265} For example, the ARI requires that an independent third party collect and transmit the data to the FDA. No other party will have access to the information or any analysis derived from it.\textsuperscript{266} The initiative also requires ARI participants to sign a binding commitment not to use the program for anti-competitive ends.\textsuperscript{267}

\textbf{D. Things Left Unsaid . . . Additional Deficiencies in the Current Approach}

The measures discussed above attempt to mitigate drug shortages through advanced agency notification, increased industry communication regarding drug supply levels, and task force efforts aimed at increasing manufacturing quality. These are positive steps. However, they focus on the symptoms, rather than the causes, of drug shortages. The underlying cause for generic manufacturers’ decision to stop producing certain categories of drugs lies in simple economics. Advanced notification requirements or increased industry communications will not replenish drugs in situations where slim profits and market imbalances have

\textsuperscript{258} Id.
\textsuperscript{260} Id.
\textsuperscript{261}
\textsuperscript{262} Id.
\textsuperscript{263} Id.
\textsuperscript{265} Id.
\textsuperscript{266} Id.
\textsuperscript{267} Id.
resulted in manufacturers leaving the market. Until there is increased elasticity of
demand and or supply, shortages will continue. Yet, the solutions implemented
thus far fail to acknowledge this fact.

Admittedly, the FDA’s ability to end shortages is constrained. The Agency does
not have the legal authority to compel manufacturers to produce drugs. Nor does
the FDA possess the manufacturing ability to produce drugs itself. The FDASIA,
the proposed rule, and the Strategic Plan fail to address the imbalance of market
forces in the current system. To date, no legislation has been passed that offers a
solution to the root causes of manufacturers’ inability or unwillingness to meet
current drug demands. What follows is a multi-party approach that addresses the
economic underpinnings of drug shortages. This section offers legislative,
regulatory, and private industry solutions aimed at motivating generic
manufacturers to produce safe, adequate quantities of affordable generics that are
currently in short supply.

IV MULTI-PRONGED APPROACH TO END DRUG SHORTAGES

A. Regulatory Solutions

1. Manufacturer Incentives

It is difficult to conceive of a viable approach to ending shortages without
manufacturer incentives. The Task Force acknowledges that incentives are a key
element in its prevention strategies. However, the Strategic Plan contains no
Agency specific proposals. Instead, the drafters encourage unnamed “others” to
explore means to incentivize manufacturing innovation and quality. Setting
aside the Agency’s self-imposed limitations, there are several incentives the FDA
could offer that would have an economic impact on manufacturers’ willingness to
both remain in and enter the market to produce critical life-saving drugs.

The Agency could offer targeted tax incentives in exchange for generic
manufacturers building extra capacity into their facilities. Infrastructure
redundancy measures could include manufacturers establishing and maintaining
alternate production lines or facilities. The Agency could offer tax rebates
offered for programs that identify and maintain alternate active ingredient
pharmaceutical (“API”) suppliers. Manufacturers who create risk management
programs that include extra manufacturing capacity dedicated to prevent shortages

268 FDA 2013 Plan, supra note 9, at 22.
269 FTC Opinion, supra note 264.
270 PDA Responses to Docket No. FDA-2013-N-0124: FDA Drug Shortages Task Force
Strategic Plan (March 14, 2013) [hereinafter PDA 2013 Responses], available at
http://www.regulations.gov/#/documentDetail;D=FDA-2013-N-0124-0063
271 Id.
272 Id.
273 Id.
could similarly be eligible for tax rebates. In return for increased manufacturing capacity, the FDA could also waive user fee requirements and streamline the approval process for redundant facilities at single-source manufacturers.

Improving quality in the manufacturing process is another core element in preventing shortages. Currently, drug price is the primary consideration in purchasing decisions. This can lead manufacturers to prioritize reducing costs over quality. Agency incentives that encourage better manufacturing processes could help reorient the industry. Agency actions could include reduced oversight for manufacturers who maintain good compliance histories and effective risk remediation plans. Reduced oversight could include downgrading filing categories for site transfers and assay improvements. The FDA could consider granting manufacturers who consistently maintain high quality manufacturing standards additional exclusivity for products in the same therapeutic areas as the drugs in shortage.

The FDA could also consider implementing a scoring system to encourage manufacturers to focus on quality. The FDA could post on its website the names of manufacturing facilities who received high quality scores during Agency inspections. This FDA “stamp of approval” could favorably influence the supplier selection. It could also improve the market value of these publicly held companies. Another approach would offer incentives to manufacturers who successfully adopt the Pharmaceutical Quality Manufacturing Guidelines contained in the International Conference on Harmonization (“ICH”). The ICH provisions cover risk management as well as maintaining quality in the pharmaceutical sector. The Agency could also award these manufacturers with the FDA “stamp of approval.”

Finally, the FDA could consider financial incentives patterned after the Orphan Drug Act. Under the Act, the Agency offers tax credits for clinical research and a seven-year period of exclusive marketing to developers of drugs for rare diseases. Since the Act’s passage in 1983, the FDA has approved more than

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275 Id.
277 Id.
278 Id.
279 Id.
280 Link, et al., supra note 96, at 692-694.
281 Letter from Blair Childs, supra note 276.
282 Id.
283 Orphan Drug Act 21 CFR 316.
1,000 orphan products for rare diseases.\textsuperscript{285} Prior to this incentive based Act, only a handful of orphan drugs were on the market.\textsuperscript{286} As noted by Abbey Meyers, President of the National Organization for Rare Disorders, “the Act has been very successful in attracting companies.” A similar tax-based incentive could help attract new entrants to the market by countering the low profit margins manufacturers associate with producing certain critical drugs.

2. Improved FDA Communication

A primary goal of the FDASIA is averting drug shortages through improved communication and notification. A critical component to achieving that goal is the Agency’s ability to quickly disseminate information. The FDA should maintain a real-time map that allows healthcare providers see where critical drugs can be found and in what quantities.\textsuperscript{287} The FDA’s website should include timelines regarding how long the Agency expects a shortage to last.\textsuperscript{288} The expected duration of the shortage would help manufacturers provide guidance to hospitals regarding appropriate steps to take to minimize the impact of the shortage.\textsuperscript{289} The FDA website should also post the compliance status of manufacturing sites and products.\textsuperscript{290}

The FDA maintains an index of all drug shortages.\textsuperscript{291} This system relies on manufacturer-supplied information regarding their current drug supply levels.\textsuperscript{292} While helpful in providing the public information regarding drug availability, the system could be improved. The Agency should consider creating a template for manufacturers to submit drug index information.\textsuperscript{293} A streamlined approach would increase efficiency and ensure that the information is submitted in a uniform format by the reporting manufacturers.\textsuperscript{294}

There are reportedly more than 2000 generic applications in the queue for FDA approval.\textsuperscript{295} The median wait time is 30 months.\textsuperscript{296} It is critical that the FDA

\begin{itemize}
\item \textsuperscript{285} Id.
\item \textsuperscript{286} Id.
\item \textsuperscript{288} Id.
\item \textsuperscript{289} Letter from Blair Childs, supra note 276.
\item \textsuperscript{290} Letter from Thomas K. McInerny, supra note 287.
\item \textsuperscript{291} Id.
\item \textsuperscript{292} Letter from David R. Gaugh, senior vice president for science, It and regulatory affairs GPhA to division of dockets management, food and drug administration (Mar, 14, 2013) (on file with the author), available at http://www.regulations.gov/#/documentDetail;D=FDA-2013-N-0124-0087
\item \textsuperscript{293} Id.
\item \textsuperscript{294} Id.
\end{itemize}
devote the necessary resources to expedite approvals and eliminate this backlog. Shorter approval times allow more lifesaving medications into the market. Reducing the 30-month approval timeframe also would give the Agency more generic options within the 6-month manufacturer provided notice of an anticipated drug shortage. Increasing the number of FDA approved entrants would also reduce the presence and influence of gray market suppliers.

3. Quality Metrics

Opacity in the pharmaceutical drug production process provides purchasers limited information about manufacturing quality. Purchasers often base their knowledge on press reports or personal experiences. As a result, they may be unaware of potential variation in pharmaceutical product quality and assume all facilities use high manufacturing standards to produce drugs. In this environment, price is often the sole determinant in deciding which generic drug to purchase. These facts, and the FDA’s goal of increasing manufacturing quality require the Task Force revisit its approach to quality metrics.

The Strategic Plan cannot adequately address production quality concerns without including some type of metrics for purchasers. Access to quality metrics such as the number and level of recalls, inspection irregularities, and production line maintenance reports would help purchasers and prescribers balance price with quality. Manufacturing quality metrics should be as readily available to purchasers as price when ordering sterile injectables. Changing the purchasing dynamics would encourage manufacturers to focus on quality. Nursing homes, restaurants, and other settings have successfully used this approach where it is difficult to observe or interpret quality.

As noted previously, quality metrics should also be available to manufacturers choosing a contract provider. The FDA solicited and received several industry examples regarding useful metrics to evaluate contract manufacturers. Identified metrics include: employee turnover rates, inspection history, ability to meet the contract giver’s quality system requirements, facility maintenance reports, and the availability of alternate suppliers. These metrics have high industry acceptance as reliable ways to assess manufacturing quality.

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296 Id.
297 Id.
298 Link, et al., supra note 96, at 692-694.
299 Woodcock, et al., supra note 64.
300 Id.
301 Id.
302 Letter from David R. Gaugh, supra note 292.
303 Id.
304 Id.
305 Id.
306 Id.
The Agency also solicited and received comments on metrics the industry relies on to assess internal quality. According to comments submitted by Pharmaceutical Manufacturers of America (“PhRMA”) and the GPhA pharmaceutical companies regularly monitor error rates to assess quality. High error rates are considered evidence of poor process control, poor training of operators, lax oversight by supervisors, poorly maintained equipment and facilities, or poor product and process characterization. Comments submitted by the Parenteral Drug Association (“PAD”) note that yield analysis, inspection outcomes, and contingency plans for act-of-God situations such as pandemics are commonly used quality metrics. PAD comments also state that companies use similar metrics when selecting contract manufacturers.

Based on these industry suggestions, the FDA should adopt standard nationwide metrics to assess all manufacturing quality. To increase transparency, the FDA could then use these metrics to issue quarterly trend analysis on how manufacturers have performed. The FDA should also provide manufacturers a clear policy statement on what the Agency reviews during facility inspections. Finally, the FDA should consider revising its Form 483 facility inspection report. A more user-friendly format would allow non-manufacturers to better assess the level of concern the FDA has regarding a facility.

4. International Imports

The FDA has approved a limited number of imports from Europe to help mitigate shortages. In 2010, the Agency permitted import of the unapproved anesthetics agent Propofpl to address shortages. The Task Force should expand the scope of the Strategic Plan to include a mechanism that allows for the timely import of approved drugs from foreign markets. International imports are referenced in the Strategic Plan’s appendix. However, they are an underdeveloped aspect of the Task Force’s approach to mitigate shortages. The FDA could also consider adapting the tentative approval process the Agency has used to approve anti-HIV medications for purchase. For more than a decade the FDA has approved

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307 Id.
309 FDA 2013 Responses, supra note 271.
310 Id.
311 Id.
312 Letter from Blair Childs, supra note 276.
313 Id.
315 Id.
316 Id.
317 FDA 2013 Plan, supra note 9.
foreign drugs as part of the President’s Emergency Plan for AIDS Relief.\textsuperscript{319} This plan allows for the review and approval of high quality medical products made in foreign countries and develops mechanisms to permit their purchase and domestic use when shortages occur.\textsuperscript{320}

\textit{B. Congressional Solutions}

1. Hatch-Waxman Act Revisions

Revising certain Hatch-Waxman Act requirements for generic manufacturers may help address the shortage crisis. In general terms, the Hatch-Waxman Act established a streamlined approval process for generic drugs.\textsuperscript{321} Under the Hatch-Waxman Act, generic manufacturers file Abbreviated New Drug Applications (“ANDA”) with the FDA to receive marketing approval.\textsuperscript{322} Congress could amend the Hatch-Waxman Act’s ANDA process to require manufacturers include present projections for product demand and plans for meeting those demands.\textsuperscript{323} Borrowing from the legislative approach used for patented drugs, the amendment could also require manufacturers build redundancy into their production facilities.\textsuperscript{324} This proposal could diminish the impact of production disruptions on overall market supply. Such an amendment would likely face legislative opposition.

The 10\textsuperscript{th} Circuit recently affirmed that the FDA does not have the authority to regulate or control manufacturer decisions regarding quality or production.\textsuperscript{325} In addition, accurate production forecasts may be difficult given the limited control manufacturers have over the supply of raw materials used in their medications.\textsuperscript{326} Approximately 80 percent of the raw materials used in manufacturing drugs are imported.\textsuperscript{327} Many of these imports are from countries where political instability or problems with product contamination are common.\textsuperscript{328} Industry stakeholders would similarly oppose legislation that penalizes manufacturers for not meeting product goals due to events that were outside their control.

A slightly different approach would grant the FDA authority to revoke market

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\textsuperscript{319} Id.
\textsuperscript{320} Letter from Mark Harrington, treatment action group to build and drug administration drug shortages task force and strategic plan public comment (Mar. 14, 2013) (on file with the author), available at http://www.regulations.gov/#/documentDetail;D=FDA-2013-N-0124-0116
\textsuperscript{321} 21 U.S.C. §355(j)
\textsuperscript{322} Id.
\textsuperscript{323} Chabner, et al., supra note 112; Sharona H., supra note 73.
\textsuperscript{324} Sharona H., supra note 73.
\textsuperscript{325} Id.
\textsuperscript{327} Id.
\textsuperscript{328} Id.
approval if a manufacturer consistently fails to meet stated production levels.\footnote{Id.} This too would likely face fierce opposition. Legislation authorizing the FDA to require manufacturers to include redundancy capabilities and revoke market approval of drugs in short supply seems to run counter the FDASIA’s intent.

2. MMA

Some politicians commonly refer to the MMA’s reimbursement system as one of the primary economic causes of drug shortages. Recently, members of Congress introduced “The Patient Access to Drugs in Shortage Act,” which aimed to increase generic injectable production by recalibrating the Medicare rate to more accurately reflect the value of those drugs.\footnote{H.R. 6611--112th Congress: Patient Access to Drugs in Shortage Act of 2012 (Feb. 7, 2014), available at http://www.govtrack.us/congress/bills/112/hr6611} The legislation proposed amending the Social Security Act to exempt generic sterile injectables with three or fewer active manufacturers from the ASP-based reimbursement pricing method.\footnote{Id.} The proposed legislation died in committee.\footnote{Id.} However, its approach of eliminating disincentives to production posed by the Medicare reimbursement system may be a necessary component to any long term approach to end drug shortages. To date, no other potential solution directly addresses manufacturers’ profit margin concerns.

An alternate solution is to establish a minimum price for generics based on comparable brand name drugs.\footnote{Link, et al., supra note 96, at 692-694.} If a brand name drug costs $70,000 per year, the generic version could be priced at 5% to 10%, or $3500 - $7000 per year.\footnote{Id.} Another suggestion is to establish a payment system based on disease management fees rather than drug sales.\footnote{Id.}

These more robust reimbursement rates could provide the economic incentive for generic drug manufacturers to enter and remain in the market. Enacting such a proposal, however, would be challenging. In fact, recently deliberated proposals aimed at reducing the deficit recommended the opposite.\footnote{The U.S. oncology network, health policy report (Nov. 10, 2011), available at https://ex.democracydata.com/213278093BDCEAE05CA9FC1F62FC3D4C5EC6424/799bd1ed-4e64ae3-a48f-ef549b94c160.pdf} A super committee of six Republicans and six Democrats reported considering reducing the Medicare Part B drug reimbursement formula from ASP +6% to ASP +3%.\footnote{Id.} The MMAs reimbursement system illustrates the classic tension between a public program’s goal of cost containment and manufacturers’ need to maintain profit margins sufficient to justify continued production.

\footnotesize{329 Id. \\
331 Id. \\
332 Id. \\
333 Link, et al., supra note 96, at 692-694. \\
334 Id. \\
335 Id. \\
336 The U.S. oncology network, health policy report (Nov. 10, 2011), available at https://ex.democracydata.com/213278093BDCEAE05CA9FC1F62FC3D4C5EC6424/799bd1ed-4e64ae3-a48f-ef549b94c160.pdf \\
337 Id.}
3. GPOs and Safe Harbor Provisions

Over the past two decades, GPOs’ effect on competition and innovation has been the subject of inquiry. As previously discussed, some have theorized that GPO anticompetitive business practices are a major contributor to current shortages. GPO contract practices have been scrutinized in numerous Senate Antitrust Subcommittee hearings and GAO investigations. In 2005, members of Congress introduced a draft discussion bill to eliminate GPO contract administration fees by repealing the Medicare anti-kickback safe harbor provisions. Supporters of the bill argued that GPO administrative fees create a “pay to play” mechanism that inhibits free market competition. The bill died in subcommittee. Two years ago, Congress asked the GAO to investigate GPO business practices. Specifically, lawmakers are concerned that GPO contract provisions limit competition among manufacturers and contribute to drug shortages. No action, however, appears to have been taken on this request.

GPOs’ role in the healthcare supply system remains controversial. To assess accurately whether substantive changes should be made to safe harbor provisions to ensure competition and innovation among generic manufacturers, more information is needed. One approach is to use various governmental agency tools to compel the necessary information. The Executive Branch could direct the Department of Justice and the FTC to investigate GPO business practices. These agencies can subpoena documents, compel testimony and seize property. Additionally, they have the authority to prosecute if they find anti-competition violations.

In 2004 Congress asked the GAO to investigate the impact of GPO administrative fees on generic manufacturers’ ability to upgrade their facilities and conduct quality control. A 2012 GAO report notes the DHHS OIG has the authority to compel production of this information. For over 10 years, the OIG has failed to obtain the information. The FDA should prevail upon the DHHS to demand that GPOs immediately produce the data. The DHHS should also make the information available to the public on the OIG website. The FTC could exercise its antitrust enforcement authority to investigate GPO antitrust allegations. Shortly after the President’s Executive Order directing the FDA to end drug shortages, five

339 Id.
340 Id.
341 Id.
342 Id.
343 Id.
344 Id.
345 Id.
346 Id.
347 Id.
348 Id.
U.S. senators made such a request to FTC Chairman Jon Leibowitz. The Commission has not made any public statement regarding the investigation. The Executive Branch could consider directing the FTC to make its finding public. To the extent appropriate, the FTC should also exercise its authority pursuant to Healthcare Statement 7 and “halt anti-competitive contracting practices” that are involved in GPO business practices.

**C. Industry Solutions**

Ending drug shortages requires a multi-party approach. Congress and the FDA play significant roles in addressing shortages. Their efforts will fail, however, unless generic manufacturers agree to increase drug production. The Strategic Plan highlights the Agency’s need to collaborate with manufacturers to develop new strategies as a key feature to address shortages.

One potential solution involves manufacturers collaborating with the FDA to establish voluntary production and quality levels in exchange for customized incentive packages. The FDA cannot compel manufacturers to meet certain capacity levels, nor can the Agency prevent a manufacturer from exiting the market to pursue other more profitable production lines. However, in return for facilities building in extra capacity to meet pre-set production levels, the FDA can provide a variety of economic and noneconomic incentives that manufacturers could select to suit their individual business needs.

For manufacturers, this approach is appealing because unlike other solutions, it offers a flexible approach for manufacturers to create their own incentives. Generic manufacturers have different priorities depending on whether they are considering entering the market or whether they are already producing a drug in shortage. As a result, some incentives will be more attractive than others based on manufacturers’ individual business plans and strategies. Manufacturers in the final stages of drug development may value a voucher for expedited FDA product review over a tax rebate.

In exchange for a customized incentive package, manufacturers would commit to increasing capacity while maintaining quality. While the FDA could offer this option on an individual manufacturer basis, an industry-wide approach is preferable. As discussed previously, one manufacturer building redundancy into its operations results in higher production costs compared to others in the market. To avoid that production cost differential, all manufacturers would need to commit to infrastructure improvements sufficient to meet the established capacity levels. In addition to ending shortages, this approach eliminates the downstream effects of

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351 FDA 2013 Plan, supra note 9, at 22.
CONCLUSION

While there are several causes to drug shortages, the common effect is the risk to patient care. The number and frequency of shortages have risen dramatically over the past five years. The repercussions of shortages adversely affect hospitals and other healthcare providers’ ability to treat patients. The unavailability of certain drugs has required healthcare providers to cancel interventions, administer less effective second-line alternatives, and purchase drugs through the gray market.

To date, administrative, legislative, and industry approaches to address shortages have focused on the symptoms. The FDA’s revised manufacturer notice requirements and the multi-stakeholder ARI initiative to share drug production information may aid in addressing shortages. However, these measures will not address the root cause.

The solution to ending shortages lies in removing the economic and regulatory obstacles that prevent manufacturers from achieving profit margins sufficient to produce certain needed medicines. Legislative action to restructure the MMA’s reimbursement system is necessary. Government agencies should conduct a thorough investigation of GPO contract activities. If appropriate based on the findings, Congress should repeal the safe harbor provisions to ensure free market competition among manufacturers. Manufacturers should build on the multi-party industry collaboration that created the ARI to approach the FDA about working together to develop customized incentive packages in exchange for manufacturer commitments to meet certain production and quality levels. The appeal of this approach is it has the potential to provide what has been largely absent – willing manufacturers.

The United States government spends trillions of dollars a year subsidizing healthcare so more people can receive medical treatment. Advancements in chemotherapy and other drugs allow physicians to treat and cure several types of diseases that a few years ago would have been fatal. The most pernicious aspect of drug shortages is that they jeopardize, and in some cases, eliminate patients’ access to those life-saving drugs. This Article proposes solutions to ensure patients have access to the right medicine at the right time.