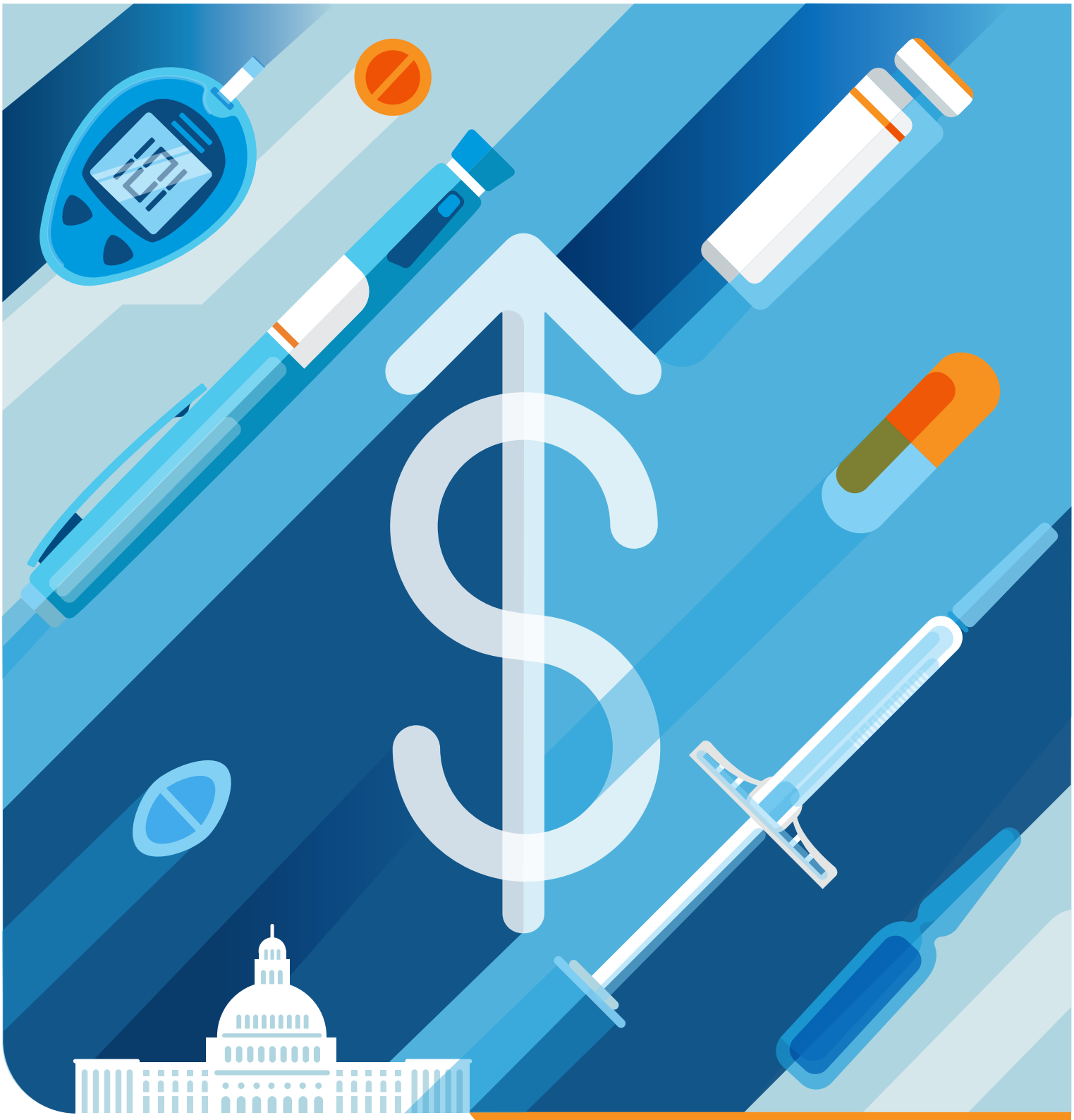

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EXPRESS SCRIPTS®

Prescription Drug Pricing: A Public Policy Analysis

Prescription Drug Pricing: A Public Policy Analysis

In 2016, the public, lawmakers and the media brought a national dialogue about drug prices to a head. Every few months, Americans learned about another egregious example of skyrocketing drug prices or a new drug coming to market with an outrageous price tag. Although accurate at the individual drug level, the headlines were inconsistent with the aggregate experience of Express Scripts clients who implemented programs to manage medication costs and experienced an average drug trend of 3.8%. However, trends emerged in our 2016 Drug Trend Report data that require a different type of analysis – one of policy, rather than economics.

Public sentiment about prescription drug prices has never been clearer – drug prices are too high. Over the summer, AARP released a survey that indicated **81% of seniors believe prescription drug prices are too high, and almost nine out of 10 want lawmakers to change public policies to make medicine more affordable.**[1] In September, 77% of Americans surveyed by the Kaiser Family Foundation found prescription drug prices unreasonable. Just five weeks before the 2016 presidential election, the candidates' platforms on healthcare issues were top of mind for two-thirds of Americans participating in one survey.[2]

Within moments of the election's conclusion, the nation came to realize that significant changes to healthcare policy were on the horizon. Already, Congress and the White House are working on legislation that could change how many Americans access the healthcare system. At the same time, federal lawmakers are considering ways to reorganize U.S. Food and Drug Administration (FDA) programs – potentially restructuring the prescription drug approval process. **Whether through federal or state legislative action, rulemaking or an executive order, prescription drug pricing is front and center for many policymakers.** We are convinced data from our Drug Trend Report will help inform the prescription-drug pricing debate.

Gain more prescription drug data and insights in the Express Scripts 2016 Drug Trend Report.

The following pages focus on five themes, each resulting from complex interactions among economic, competitive and regulatory factors. We also provide policy recommendations for consideration under each theme:

1. **Hyperinflation among brand biologics and insulins**
2. **High introductory prices for novel drugs**
3. **Hyperinflation among single-source drugs**
4. **High prices with abusive product combinations**
5. **Hyperinflation following public policy support for medicines**

1. Hyperinflation among brand biologics and insulins

Biologic medicines often are classified as specialty medications because their handling, dispensing and/or administration are more complicated than for traditional small-molecule prescription drugs. They have transformed treatments for diseases that are disabling, debilitating or life threatening. Some, such as the direct-acting hepatitis C agents, actually provide cures. These powerful medicines also have transformed how plan sponsors approach affordability of medicines, as the average specialty medication cost $9,871 in 2016 and inflation for them was 6.2%. High prices with exorbitant inflation keep these medicines top of mind for plan sponsors. Adding to the complexity are insulins, which as a result of the Biologics Price Competition and Innovation Act (BPCIA), will be re-categorized as biologics in 2020. The average cost of insulin in 2016 was $287.22 per month, with a unit cost increase of 7.2%.

Biosimilars are biological products that work like already-approved biologics. They do not have clinically meaningful distinctions in safety, purity and potency from the original biologic. For more than a decade, Express Scripts has been a vocal advocate for an expedited approval pathway for biosimilars in the United States. As the FDA has worked to build this approval pathway, we believe that both regulatory activity and legislative re-evaluation can reform the biologics market.

No provision of the BPCIA was more hotly debated than the period of time an innovator company's biologic would be free from marketplace competition from a biosimilar.

INSIGHTS AND OPPORTUNITITES

Support legislation to reduce the period of biologic exclusivity from 12 years to seven years

When Congress passed the BPCIA in 2010, none of its provisions was more hotly debated than the period of time an innovator company's biologic would be free from marketplace competition from a biosimilar. Proposed periods of exclusivity ranged from none (recommended by the Federal Trade Commission – FTC) to five years (comporting with existing law for small-molecule drugs) to 14 years (the position of innovator manufacturers). Congress ultimately settled on 12 years. Without question, Congress could not only stimulate a competitive market for biologics, but also generate savings by reducing exclusivity to seven years. Despite former President Obama's support for reducing the exclusivity provision, Congress never acted on the policy. Estimates of how much this policy change could save the federal government are as high as $16 billion over 10 years.[3]

Oppose the FDA's proposed policy for biologic naming

Among the FDA's responsibilities in the BPCIA is the naming of biologics and biosimilars. Although biosimilar manufacturers advocated for shared international nonproprietary names (INNs) in the same way that generic names for small molecule drugs are identical, manufacturers of innovator biologics argued that all biologics should have unique INNs. In essence, the innovator arguments are a red herring; as Express Scripts has long advocated, drug names are not critical to pharmacosurveillance (drug safety monitoring) systems which rely on national drug codes (NDCs) and other data points. The FDA has issued final guidance requiring all biologics (including biosimilars) sold in the United States to be renamed with a random suffix. Compliance with the FDA's regulation is estimated in the billions of dollars.[4] We believe that the FDA should remain consistent with shared nonproprietary names for both innovator and biosimilar products. Shared names will minimize provider confusion and reduce their possible reluctance to use lower cost biosimilars.

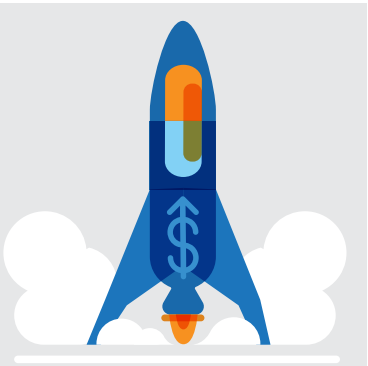
Support legislation to prevent misuse of the Orphan Drug Act

Medicines that treat small patient populations (typically 200,000 patients or fewer in the U.S.) are provided special incentives under the Orphan Drug Act (ODA). However, some drug manufacturers increasingly use ODA provisions to extend the market lives of widely used brand drugs. In some instances, a drug or biologic is first FDA approved with a limited indication to treat an uncommon condition. Subsequent to initial approval, the manufacturer seeks additional indications that expand the population to well beyond the limits established in the ODA. In other cases, a drug maker seeks orphan drug status for an already-approved brand drug toward the end of its exclusivity period, thus attempting to delay generic competition. For example, AstraZeneca sought orphan status for its blockbuster cholesterol drug, Crestor® (atorvastatin), to treat a rare pediatric genetic disorder. With Crestor's 2015 sales in excess of $8 billion[5], re-approving it as an orphan drug hardly meets the ODA's legislative intent. Potential savings from amending the ODA have not yet been estimated.

Changing the policy on biosimilars in Part D would save the federal government $800 million over 10 years.

Require manufacturers to offer biosimilar savings through Medicare Part D

As the Patient Protection and Affordable Care Act (ACA) changed key components of the Medicare Part D (Part D) program, brand drug makers offered new statutory discounts during Part D's "coverage gap" – the period requiring beneficiaries to pay full price for prescriptions. Congress decided to exempt biosimilars manufacturers from the compulsory 50% discount that innovator biologics must offer. Plan sponsors are justifiably concerned that patients in the coverage gap will be discouraged from using biosimilars. Although lawmakers considered changing the policy in 2015, no resolution was reached. Avalere Health concluded that changing the policy would save the federal government $800 million over 10 years.[6]



2. High introductory prices for novel drugs

As drug makers bring new products to market, they increasingly set introductory prices at outrageous levels. No recent drug launch is a better example than Gilead's launch of Sovaldi® (sofosbuvir), the first of a group of oral drugs that cure hepatitis C. At a list price of more than $80,000 for a 12-week course of treatment, Sovaldi's introduction shocked the pocket books of public and private payers. While academics debated competing cost-effectiveness models, policymakers were flummoxed about how to provide affordable access to the millions of Americans who have hepatitis C.

In 2016, the average new drug or biologic launched at a price of $17,727.29 per month. Even though some new drugs are introduced into competitive classes where rational market forces can temper their prices, other drugs enter underserved markets where their pricing seems limitless. Regulators, however, are not powerless to help plan sponsors create a more competitive marketplace that makes even exceptionally effective new drugs more affordable.

At a list price of more than $80,000 for a 12-week course of treatment, Sovaldi's introduction shocked public and private payers.

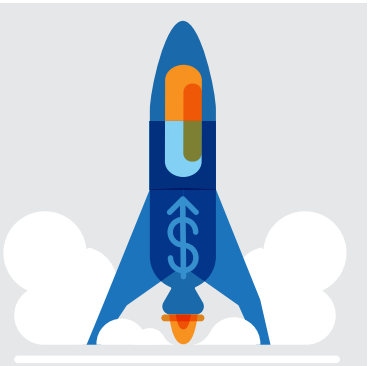
INSIGHTS AND OPPORTUNITITES

Support legislation and regulations that allow the FDA to reprioritize drug applications

For years, lawmakers have recognized that the FDA should accelerate its consideration of a new drug application (NDA) under specific circumstances. Currently, the FDA uses four programs that hasten market entry of eligible drugs. Each of the programs, however, is designed only to address unmet medical needs. The market's recent experience with novel treatments for hepatitis C clearly indicates that the FDA needs an accelerated approval program for "me too" drugs (those therapeutically similar to a product already on the U.S. market) as well. The policy's possible fiscal impacts are not readily available, but recent commercial events suggest the savings would measure in the billions.

Support legislation that prohibits drug manufacturer coupons

Recently, brand drug makers have stepped up direct-to-consumer copayment assistance via coupons that are designed to bypass plan design and benefits. While coupon programs insulate patients from costs at the point of sale, they often result in plan sponsors paying additional costs for more expensive brand products. When a generic drug is available, coupons can increase brand drug utilization by more than 60%.[7] Even in a brand-only class, the effect is significant because traditional cost-sharing tools (copayments, deductibles, coinsurance) are invalidated. Many federal programs,



including Part D, prohibit the use of coupons because costs shift to the government. Currently, lawmakers in California and several other states are considering a ban of some prescription drug coupons. If Congress enacts a federal prohibition of coupons, $32 billion could be saved over a decade.[8]

Support legislation that encourages value-based purchasing

As much of the healthcare system moves away from traditional fee-for-service (FFS) reimbursement models, some drug makers are exploring value-based purchasing agreements. More than ever, these forward-thinking manufacturers are willing to negotiate pricing based on indications and outcomes. For instance, an oncology drug that suppresses one type of cancer almost completely would command a higher price tag for that indication than it would for a different malignancy that it has little effect in controlling. Express Scripts Care Value programs have saved our plan sponsors over a billion dollars, while guaranteeing outcomes for patients. Section 114 of the Food and Drug Administration Act (FDAMA 114) allows drug manufacturers to share economic information with formulary decision makers. Some manufacturers, however, are cautious about innovative information-sharing arrangements due to potential interference with Medicare rules, Medicaid's "Best Price" requirement and other regulations. As one result, plan sponsors are spending billions unnecessarily. Medicare rules that prohibit mid-year formulary changes and protect certain classes of drugs should be repealed to promote more value for patients, plan sponsors and the government. Congress also should reconsider the application of Medicaid "Best Price" provision that frustrates drug makers' willingness to consider these novel arrangements with plan sponsors.

Express Scripts Care Value programs have saved plan sponsors over a billion dollars while guaranteeing outcomes for patients.

3. Hyperinflation among single-source drugs

No headline has grabbed more attention in the recent drug-price debate than that of the hedge fund manager, masquerading as a drug maker, who bought the rights to Daraprim® (pyrimethamine) – a decades old antiparasitic drug – and increased its price 5,000% overnight. Patients and prescribers were stunned and appropriately outraged. Similarly, patients and public-health advocates were shocked when the price of a two-pack of EpiPen® (epinephrine injection), a life-saving anti-anaphylaxis drug that is stocked in most schools, peaked at over $600. Beyond contemptible prices, these two medicines share other commonalities, including virtual monopolies in their markets.

Patients and prescribers were stunned when a hedge fund manager, masquerading as a drug maker, raised the price of Daraprim by 5,000%.

INSIGHTS AND OPPORTUNITITES

Incentivize generic drug development

Recently, some medications only available from a single manufacturer, or "single-source" drugs, have been introduced at very high prices to exploit their exclusivity. Policymakers have a wide range of tools available to encourage generic drug development. For example, earlier this year, federal lawmakers introduced the "Lower Drug Costs Through Competition Act" which encourages drug makers to seek approvals of generic competitors to single-source products. In addition to an expedited review time of six months, the sponsor of a second generic would receive a priority review voucher that the company could use to expedite a subsequent drug approval.

Support legislative and regulatory reforms to clear the FDA backlog

Generic drugs account for nearly nine in 10 prescriptions dispensed in the United States, but they represent just 28% of total drug spending.[9] The competition provided by generics increases patient access to lower-cost alternatives and provides significant savings to patients and plan sponsors. Prior to the enactment of the Generic Drug User Fee Act (GDUFA) on Oct. 1, 2012, the median approval time for generic applications ranged from 30 months to 48 months,[10] delaying vital competition from the marketplace. While the additional industry resources provided by the user-fee program have significantly reduced the approval time for new generic applications, the FDA still has a backlog of approximately 4,000 generic drug applications pending action from either FDA or the manufacturer.[11] Ensuring that the FDA has the financial and personnel resources needed to approve generic drugs in a timely manner will increase patient access to life-saving medications and give plan sponsors the ability to encourage the use of lower-cost alternatives.

Support legislation to prohibit "pay-for-delay" arrangements

In some cases, brand and generic drug makers enter into agreements that delay the market launch of a new generic drug in exchange for compensation from the brand company. In recent years, the FTC has increased enforcement activity to uncover anticompetitive effects. New legislation, the "Preserve Access to Affordable Generics Act," was introduced by Senators Klobuchar (D-MN) and Grassley (R-IA) in January. If passed, it is estimated to save the federal government between $2.9 billion and $13.6 billion over 10 years by prohibiting anticompetitive agreements between brand and generic drug makers.[12,13]

Support legislation to address misuse of Risk Evaluation and Mitigation Strategies

The FDA's Risk Evaluation and Mitigation Strategies (REMS) program provides an important protection for patient safety by ensuring that the benefits of a drug or biological product outweigh its safety risks. Certain brand manufacturers, however, have exploited a loophole in the law to prevent generic and biosimilar competition for products with and without REMS requirements. These manufacturers employ restricted distribution networks to deny generic and biosimilar manufacturers access to the product samples needed to obtain FDA approval. In fact, some manufacturers have implemented these restricted distribution programs solely to delay competition, independently from any FDA mandates. The FTC has cautioned that "this conduct may prevent the Hatch-Waxman framework from functioning as Congress intended." The Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act and the Fair Access for Safe and Timely (FAST) Generics Act would address these anticompetitive practices by closing the loophole in the law and creating a clear pathway for generic and biosimilar manufacturers to access the needed sample products needed to bring lower-cost drugs onto the market. The increased generic and biosimilar competition provided by these bills would save the federal government between $2.4 and $3.3 billion over 10 years.[14]

If passed, the Preserve Access to Affordable Generics Act is estimated to save the federal government between $2.9 billion and $13.6 billion over 10 years.

4. High prices with abusive product combinations

Policymakers have struggled with determining the appropriate level of incentives for drug makers who improve their existing prescription products. An example is producing a longer-acting dosage form that requires fewer doses per day. Many enhanced products, which usually require new FDA approvals, result in better outcomes for patients. Some manufacturers argue that their improved drugs qualify for incentives and/or treatment under the laws and regulations as new drugs. Often, though, drug product-line extensions just increase convenience, which certainly is less deserving of treatment as a novel drug under the law. Plan sponsors need the ability to manage formularies and employ prior authorization to manage the utilization of these products.

Often, drug product-line extensions increase convenience but don't improve patient outcomes.

INSIGHTS AND OPPORTUNITITES

Support laws and regulations that remove formulary and coverage requirements

Myriad laws at the federal and state levels govern formularies and utilization management tools that are essential to clinically appropriate, cost-effective prescription drug benefits. Federal "Essential Health Benefit" regulations require that plans include at least one drug per class, or the same number of drugs per class as a benchmark plan. The regulations rely on United States Pharmacopoeia's (USP) system of categories and classes as the standard, even though it was not intended as a system for formulary development, but rather to organize drugs by mechanism of action (how the drug behaves in the body). The result is shifting leverage to drug makers when negotiating for formulary position. Many states have enacted, and others are considering, broad formulary coverage and/or therapy-class specific requirements, which only add costs. Policies vary, as do their fiscal impacts, but all of them result in unnecessary coverage for medications that take unfair advantage of drug approval laws.

Support real-time electronic prior authorization

By their own admissions, physician organizations want to change public policies to reduce the amount of time spent on administrative tasks associated with utilization management. Plan sponsors, however, have a significant interest in managing inappropriate utilization of high-cost drugs through prior authorization (PA). A consortium of prescriber and provider groups, including the American Medical Association (AMA) and the American Hospital Association (AHA), have formed a coalition to frustrate PA programs.[15] Instead of discontinuing the use of this important tool, lawmakers should require the use of fully electronic PA (ePA) that minimizes administrative burdens, but maintains a plan sponsor's ability to manage utilization of high-cost drugs and services. Already mandated in four states, ePA technology has proven available, inexpensive and effective.

5. Hyperinflation following public policy support for medicines

Drug makers have a long history of promoting their medicines to public payers – federal programs, state and local governments, even local education and law enforcement authorities. However, several examples in 2016 point to manufacturers aggressively creating expanded markets for their products in the public sector while simultaneously increasing prices. Worse, many of these medicines provide emergency relief for potentially life-threatening allergic reactions or drug overdoses.

To be certain, the medicines are of great value to the public. Simply put, they save lives. We strongly support their appropriate use. Abuse-deterrent formulations (ADF) of opioids are essential to address the national epidemic of opioid abuse. Access to naloxone, a main treatment for acute overdose situations, should be expanded. But, like policymakers, plan sponsors and law enforcers, we believe that drug makers who orchestrate campaigns to sell more of their products to public payers should not escalate prices for these life-saving treatments beyond reasonable amounts. In 2016, ADF opioids (which all are brand-only) cost $102.53 more per prescription than their brand non-ADF opioid counterparts. Over the same period, the price of naloxone increased 20.3%.

Lawmakers should carefully consider unintended consequences of legislative or regulatory mandates at the behest of drug makers that require coverage for certain products. Meaningful public policies can be enacted that would help solve the opioid crisis, or other public health emergencies, by employing technology and fostering competition.

Several examples in 2016 point to manufacturers aggressively creating expanded markets for their products in the public sector while simultaneously increasing prices.

INSIGHTS AND OPPORTUNITITES

Support mandatory electronic prescribing for controlled substances

Policymakers are looking for new solutions to the opioid epidemic, as drug overdoses claimed the lives of nearly half a million Americans between 2000 and 2014.[16] Electronic prescribing (eRx) has grown significantly over the last decade, with more than a million prescribers transmitting more than 1.4 billion e-prescriptions in 2015.[17] One gap remains – electronic prescribing of controlled substances (EPCS), which allows for the safe, lawful transmission of controlled prescriptions directly from a prescriber to a pharmacy. Most electronic health records (EHRs) are capable of supporting EPCS. Between 2013 and 2015, the percentage of pharmacies capable of EPCS doubled (to more than 80%) but the percentage of prescribers capable of using the technology remained below 10%.[18] If EPCS were mandated nationwide, as it is in New York and Maine, one major contributor to the opioid epidemic – counterfeit paper prescriptions – would be eliminated. Additionally, a fully electronic mandate would allow real-time, auditable records for providers and law enforcement.

Oppose mandates to cover abuse-deterrent opioids

Over the last two years, approximately 50 pieces of legislation requiring coverage of ADF opioid products have been introduced in 20 different states. Although the bills varied, the legislation generally sought to address common objectives: Mandate preferential formulary placement for ADF products and/or prohibit utilization management tools like step therapy (ST) and PA for ADF products. The goal of these bills, reduced opioid abuse, is laudable as America faces a staggering opioid abuse crisis. This type of legislation, however, presents several problems. The success of ADF products to deter opiate abuse is mixed. The FDA fully acknowledges that these products are not abuse proof.[19] A legitimate worry is that ADF opioids will lead prescribers into thinking the products are less addictive and overprescribing patterns will continue.[20] True, ADF opioids make tampering with the product more difficult. But the reality for plan sponsors is that these products cost a lot more than their non-ADF counterparts. Required ADF legislation has been estimated to cost the state of California $4.5 million, with another $3.2 million borne by plans sponsors and patients in the state.[21] By enacting these bills, states deprive plan sponsors from exercising some of their control over formulary design. Instead of mandating first-line coverage for ADF opioids, we must remain committed to reducing opioid misuse through comprehensive, well-coordinated efforts among providers, payers, state and federal governments and law enforcement – with an emphasis on drug safety, counseling and patient support. Appropriate utilization management can ensure that patients vulnerable to abuse are prescribed ADF opioids without requiring them for every patient.

Required ADF legislation is estimated to cost California $4.5 million, with another $3.2 million borne by plan sponsors and patients in the state.

REFERENCES

[1] Sagon C. Survey shows growing worry among 50+ over drug prices. AARP. http://www.aarp.org/health/drugs-supplements/info-2016/prescription-cost-worry-older-adults.html. April 19, 2016. Accessed Feb. 21, 2017.

[2] Kirzinger A, Wu B, Brodie M. Kaiser Health Tracking poll: September 2016. http://kff.org/health-reform/report/kaiser-health-tracking-poll-september-2016/. Sept. 29, 2016. Accessed Feb. 20, 2017.

[3] Monroe-Yavneg N, Royzman I. Twelve Years, or Fewer? Two current debates on the exclusivity period for biologics. Biologics Blog. http://www.lexology.com/library/detail.aspx?g=a2e3eea6-b785-4aff-ae68-f21537796bdc. Feb. 24, 2015. Accessed Feb. 21, 2017.

[4] Kux L. Letter from National Council on Prescription Drug Programs. Attachment. https://www.regulations.gov/document?D=FDA-2013-D-1543-0189. Feb. 7, 2017. Accessed Feb. 21, 2017.

[5] IMS Health. Top 20 global products 2015. IMS Health MIDAS®. http://www.imshealth.com/files/web/Corporate/News/Top-Line%20Market%20Data/Top_20_Global_Products_2015.pdf. December 2015. Accessed Feb. 21, 2017.

[6] Avalere Health. Patient out-of-pocket costs for biosimilars in Medicare Part D. http://tinyurl.com/zmx2rb7. April 2016. Accessed Feb. 21, 2017.

[7] Dafny L, Ody C, Schmitt M. When discounts raise costs: the effect of copay coupons on generic utilization. NBER Working Paper No. 22745. National Bureau of Economic Research. http://www.hbs.edu/faculty/Publication%20Files/DafnyOdySchmitt_CopayCoupons_32601e45-849b-4280-9992-2c3e03bc8cc4.pdf. October 2016. Accessed Feb. 21, 2017.

[8] Visante. How copay coupons could raise prescription drug costs by $32 billion over the next decade. Pharmaceutical Care Manufacturers Association. https://www.pcmanet.org/how-copay-coupons-could-raise-prescription-drug-costs-by-32-billion-over-the-next-decade/. November 2011. Accessed Feb. 21, 2017.

[9] Generic Pharmaceutical Association. Generic drug savings in the U.S. Seventh annual edition: 2015. http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf. 2016. Accessed Feb. 21, 2017.

[10] http://www.raps.org/Regulatory-Focus/News/2016/09/26/25898/GDUFA-II-FDA-Looks-to-Speed-Up-Generic-Drug-Approval-Process/

[11] Brennan Z. Generic backlog at FDA: a dive into the confusing numbers. Regulatory Affairs Professionals Society. http://www.raps.org/Regulatory-Focus/News/2016/11/01/26106/Generic-Drug-Backlog-at-FDA-A-Dive-Into-the-Confusing-Numbers/. Nov. 1, 2016. Accessed Feb. 21, 2017.

[12] Congressional Budget Office. CBO Preliminary Estimate for S. 2019, the Preserve Access to Affordable Generics Act, as Introduced. (Online). October 2015. Available: https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/costestimate/s2019preliminary.pdf. Accessed: Feb. 20, 2017.

[13] Office of Management and Budget. Budget of the U.S. Government: Fiscal Year 2017. (Online). February 2016. Available: https://www.govinfo.gov/content/pkg/BUDGET-2017-BUD/pdf/BUDGET-2017-BUD.pdf. Accessed: Feb. 20, 2017.

[14] https://www.ftc.gov/news-events/press-releases/2014/06/ftc-amicus-brief-improper-use-restricted-drug-distribution. Accessed Feb. 21, 2017.

[15] Health care coalition calls for prior authorization reform [press release]. Chicago, IL; American Medical Association; Jan. 25, 2017. https://www.ama-assn.org/health-care-coalition-calls-prior-authorization-reform. Accessed Feb. 21, 2017.

[16] Rudd RA, Aleshire N, Zibbell JE, Gladden RM. Increase in drug and opioid overdose deaths – United States, 2000-2014. Morb Mortal Wkly Rep. 2016;64(50-51):1378-1382. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm?s_cid=mm6450a3_w#fig1.

[17] Surescripts. 2015 national progress report. http://surescripts.com/news-center/national-progress-report-2015/. Undated. Accessed Feb. 21, 2017.

[18] ibid.

[19] Throckmorton DC. Key facts about "abuse-deterrent" opioids. U.S. Food and Drug Administration. FDA Voice. https://blogs.fda.gov/fdavoice/index.php/2016/10/key-facts-about-abuse-deterrent-opioids/. Oct. 28, 2016. Accessed Feb. 21, 2017.

[20] Arlotta CJ. The FDA's support for abuse-deterrent opioids may not be enough. Forbes. http://www.forbes.com/sites/cjarlotta/2016/03/29/the-fdas-support-for-abuse-deterrent-opioids/#758fe42bc886. May 29, 2016. Accessed Feb. 21, 2017.

[21] AB-623 Abuse-deterrent opioid analgesic drug products. (2015-2016). Bill analysis. Assembly appropriations. https://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=201520160AB623. Undated. Accessed Feb. 21, 2017.

The policy considerations in this analysis represent several ways our nation can effectively address the issue of egregious pricing without limiting access, stifling innovation or creating disruption. As our country engages in a critical dialogue about how to provide much-needed care for millions of Americans, Express Scripts will continue to make better health more affordable, accessible and sustainable.

For more in-depth trend data and insights, download our 2016 Drug Trend Report at express-scripts.com/corporate.

To reach us directly, contact Government Affairs at governmentaffairs@express-scripts.com.

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