REPORT 2 OF THE COUNCIL ON MEDICAL SERVICE (I-15)
Pharmaceutical Costs
(Resolution 207-I-14 and Resolution 228-I-14)
(Reference Committee J)

## EXECUTIVE SUMMARY

At the 2014 Interim Meeting, the House of Delegates referred two resolutions on the issue of pharmaceutical costs. Resolution 207-I-14 asked that our American Medical Association (AMA) advocate for prescription drug cost containment, and communicate concerns about the rapidly rising cost of generic prescription drugs to the US Food and Drug Administration. Resolution 228-I-14 asked: (1) That our AMA advocate for a comprehensive federal government study of the development and pricing practices of the pharmaceutical industry and inform the Congress of the United States if any questionable pricing practices are discovered; (2) That our AMA explore the rapidly escalating cost of generic drugs that are years past developmental costs; and (3) That our AMA report back to the House of Delegates at the 2015 Annual Meeting.

The most recent National Health Expenditure projections showed that prescription drug spending was estimated to have increased by 12.6 percent to $305.1 billion in 2014, the highest rate of growth in the sector since 2002. While annual price increases for prescription drugs are expected to average three percent from 2014 to 2024, some drugs have experienced significant price increases.

The Council on Medical Service believes that the AMA has a strong policy foundation on the issue of pharmaceutical costs, and therefore recommends reaffirmation of policies promoting market-based strategies to achieve prescription drug affordability, opposing "pay-for-delay" arrangements, and encouraging the development of methods that increase choice and competition in the development and pricing of generic prescription drugs. In addition, the AMA should encourage Federal Trade Commission actions to limit anticompetitive behavior by pharmaceutical companies attempting to ensure extended exclusivity for drugs and reduced competition from generic manufacturers through the filing of multiple patents on a single drug.

Recent mergers and acquisitions in the pharmaceutical industry have reignited concerns that a consolidated pharmaceutical marketplace has the potential to increase drug prices. As such, the Council believes that our AMA needs to monitor pharmaceutical company mergers and acquisitions, as well as the impact of such actions on drug prices. In addition, patent reform continues to be a key area to engage in as policy-makers evaluate barriers to greater market-based competition. Finally, while market exclusivity periods are important in ensuring pharmaceutical industry innovation, the Council recommends shortening the market exclusivity period for biologics to facilitate entry of biosimilar competition in the marketplace.

The pricing of prescription drugs impacts state Medicaid budgets, Medicare spending, insurance premiums and prescription drug tiers, and most importantly, patient access to these medications and medication adherence. To spur additional pricing restraint in generic drugs, the Council believes that generic drug manufacturers should be required to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation. In addition, the promotion of transparency in prescription drug pricing and costs will help patients, physicians and other stakeholders understand how drug and biologic manufacturers set prices. If there is greater understanding of the factors that contribute to prescription drug pricing, then the marketplace can react appropriately.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 2-I-15

Subject: Pharmaceutical Costs
(Resolution 207-I-14 and Resolution 228-I-14)

Presented by: Robert E. Hertzka, MD, Chair

Referred to: Reference Committee J
(Jeffrey P. Gold, MD, Chair)

---

At the 2014 Interim Meeting, the House of Delegates referred two resolutions on the issue of pharmaceutical costs. The Board of Trustees assigned these items to the Council on Medical Service for a report back to the House of Delegates at the 2015 Interim Meeting. Resolution 207-I-14, "Generic Pharmaceutical Pricing," introduced by the Idaho Delegation, asked:

> That our American Medical Association (AMA) advocate for prescription drug cost containment, and communicate concerns about the rapidly rising cost of generic prescription drugs to the US Food and Drug Administration.

Resolution 228-I-14, "High Cost of Drugs," introduced by the Organized Medical Staff Section, asked:

> (1) That our American Medical Association (AMA) advocate for a comprehensive federal government (e.g., CMS, etc.) study of the development and pricing practices of the pharmaceutical industry and inform the Congress of the United States if any questionable pricing practices are discovered; (2) That our AMA explore the rapidly escalating cost of generic drugs that are years past developmental costs; and (3) That our AMA report back to the House of Delegates at the 2015 Annual Meeting.

This report provides background on prescription drug spending and pricing; highlights contributors to drug pricing; assesses the impact of drug pricing on health plans, payers, physicians and patients; outlines relevant ongoing legislative activity; summarizes relevant AMA policy; and presents policy recommendations.

## BACKGROUND

The most recent National Health Expenditure projections showed that prescription drug spending was estimated to have increased by 12.6 percent to $305.1 billion in 2014, the highest rate of growth in the sector since 2002.[1] Drivers behind the high rate of growth in prescription drug spending include new specialty drugs, including those for hepatitis C, as well as increased utilization of prescription drugs. The projected annual growth in prescription drug spending is expected to average 6.3 percent from 2015 through 2024. Contributions to future growth in spending in the prescription drug sector include modifications in benefit management to improve drug adherence for individuals with chronic diseases, expected changes to clinical guidelines supporting drug therapies at earlier stages of treatment, identifying new drug targets and therapies

based on expanded knowledge of genetic contribution to health and disease, and improving economic conditions.[2]

On the whole, prescription drugs account for more than nine percent of total health spending, and specialty drugs make up one-third of drug spending. Over the past five years, spending on specialty drugs, including biologics, has contributed to 73 percent of the overall growth in drug spending. In 2014 alone, spending on new brands increased by $20.2 billion, which included four new hepatitis C treatments.[3] The two hepatitis C treatments that have received significant attention over the past year due to their price include Sovaldi, which has an average wholesale price of $1,000 per pill, amounting to $84,000 per treatment regimen, and Harvoni, which has a list price of $95,000 for a 12-week course of treatment. Outside of hepatitis C drugs, drivers of specialty spending growth include drugs for autoimmune diseases and oncology. The trend in growth in specialty drug spending is expected to continue, with 42 percent of the late-stage research and development pipeline consisting of specialty drugs.[3] Many health plans and pharmacy benefit managers are concerned with the potential cost and impact of another new biologic which is a monoclonal antibody that inactivates a specific protein (proprotein convertase subtilism kexin type 9, or PCSK9) in the liver, dramatically reducing the amount of harmful LDL cholesterol circulating in the bloodstream. At the time that this report was written, two PCSK9 inhibitors had been approved by the Food and Drug Administration (FDA), and had estimated annual wholesale acquisition costs between $14,000 and $15,000.[4] Comparatively, evolocumab costs $6,800 per year in the United Kingdom, $8,200 per year in Austria and $8,800 per year in Finland.[5] Unlike Sovaldi and Harvoni, which are time-limited treatments, patients could potentially take PCSK9 inhibitors for the duration of their lives. In addition, the target patient population for PCSK9 inhibitors could be significant.

Overall, annual price increases for prescription drugs are expected to average three percent from 2014 to 2024.[1] In 2013, the retail prices for 97 percent of the 227 most widely used brand name prescription drugs by older Americans increased. Prices for 96 percent of these drugs increased faster than the rate of inflation, with 87 percent of these drugs having annual retail price increases of more than three times the rate of inflation. Eighty-five of the 227 most widely used brand name drugs by older Americans had annual retail price increases of 15 percent or more.[6]

Approximately 4.3 billion outpatient prescriptions were dispensed in the US in 2014. Eighty-eight percent of prescriptions were dispensed as generics, an increase of two percent over 2013.[3] Generic drugs, due to their historically significant savings over their brand-name counterparts, have contributed to health system savings over the past decade. However, there have been concerns whether savings from generics will continue to be achieved. There was a $9.5 billion increase in generic drug spending in 2014. Recent patent expirations resulted in a $11.9 billion reduction in drug spending in 2014, the lowest impact in five years.[3] The average annual retail price of therapy for the most widely used generic drugs by older Americans was $283 in 2013, approximately 78 cents per day. Twenty-seven percent of the 280 most widely used generic drugs by older Americans had price increases in 2013. Eleven of these generic drugs had price increases of 30 percent or more in 2013. From 2012 to 2013, doxycycline hyclate 100 mg capsule experienced a price increase of 1,961.5 percent, methotrexate 2.5 mg tablet had a 213.4 percent price increase, and divalproex sodium 500 mg tablet extended-release 24-hour experienced a 193.3 percent price increase.[7]

## CONTRIBUTORS TO DRUG PRICING

### *Generic Drugs*

Price increases for generic drugs may result from many factors, including drug shortages, supply disruptions, limits in manufacturing capacity, and generic drug industry mergers and acquisitions. In addition, generic drug companies may transition to manufacture drugs recently off patent to gain early market share, while others have chosen to manufacture generic drugs that have been on the market for some time and no longer have ample competition. To spur competition and expedite FDA review of generic drug applications, Congress passed the Generic Drug User Fee Amendments (GDUFA) of 2012. Effective October 2014, the GDUFA outlined new timelines for review of generic drug applications, the funding of which is supplemented by industry user fees. By 2017, the goal is for the FDA to take regulatory action on 90 percent of new generic drug applications within 10 months of submission. FDA's Office of Generic Drugs also expedites generic drug applications determined to be critical to public health or alleviate drug shortages. During the first three quarters of calendar year 2014, approximately 100 generic abbreviated new drug or supplemental applications had expedited review.[8]

### *Brand-Name Drugs*

Several factors contribute to the pricing of brand-name drugs, including the number of individuals expected to use the drug, development costs, and competition in the marketplace. Brand-name drugs have 20 years of patent protection from the date of filing, and also enjoy a period of market exclusivity, depending on the type of drug. Orphan drugs – drugs to treat rare diseases or conditions affecting less than 200,000 individuals in the US, or affecting more than 200,000 individuals but for which there is not a reasonable expectation that the sales of the drug would recover the costs – have seven years of market exclusivity. Drugs deemed to be innovative products that include an entirely new active ingredient – a new chemical – have five years of market exclusivity. Six months of exclusivity are added to existing exclusivity periods once studies on the effects of a drug upon children are submitted for FDA review and meet the statutory requirements.[9]

Brand-name drug manufacturers have also used various techniques to delay competition in the marketplace or lengthen patent protection. In reverse-payment patent litigation settlements, also known as "pay-for-delay" settlements, a brand-name drug manufacturer pays a potential generic competitor to abandon its patent challenge and delay offering a generic drug product for a number of years. Pay-for-delay settlements do not always involve a direct cash payment to the generic manufacturer. For example, if a generic drug manufacturer agrees to delay its introduction of a generic drug into the marketplace, a brand-name manufacturer can agree not to offer an authorized generic to compete with the generic competitor. In the case *Federal Trade Commission v. Actavis*, the US Supreme Court held that pay-for-delay settlements can violate antitrust laws.

Brand-name manufacturers can also attempt to effectively extend the term of patent protection for a single product by creating a patent portfolio, composed of patents with staggered terms for modified forms of the same drug, new delivery systems for that drug, or other variations of the original product, a practice known as "evergreening." Examples of evergreening include reformulating a drug as extended release or changing the mix of chemical isomers. In situations where a newer version of an existing brand-name drug enters the marketplace, brand-name manufacturers can also choose to take the older drug off the market or restrict access to the older drug, including by limiting its distribution through select specialty pharmacies.

*Biologics*

Biologics include a range of products including vaccines, antitoxins, blood components, serums, allergenic extracts, and recombinant therapeutic proteins. Overall prices for biologics are higher resulting from the high risk and expense of manufacturing these products, the special handling and administration required, and an overall lack of competition in the marketplace. Currently, biologic manufacturers have 12 years of market exclusivity for innovator products. Innovator biologics also have additional patent protection that generally exceeds the market exclusivity period by a few years.

The Biologics Price Competition and Innovation Act (BPCIA), part of the Affordable Care Act, provided an expedited biosimilars approval pathway. In the case of biologics, biosimilar manufacturers do not have to show bioequivalence to the reference product. Instead, it needs to show that it is biosimilar; such products must be "highly similar to the reference product notwithstanding minor difference in clinically inactive components and exhibit "no clinically meaningful differences" in terms of safety, purity, and potency."[10] In order to meet the higher standard of interchangeability, the sponsor must demonstrate that the product "produces the same clinical result as the reference product in any given patient" and that switching between the reference biologic and the biosimilar does not result in additional risk in safety or efficacy for patients using only the reference biologic.[11] In March of this year, the FDA approved the first biosimilar in the United States, Zarxio, which is biosimilar to Neupogen (filgrastim).[12]

## IMPACT ON HEALTH PLANS, PAYERS, PHYSICIANS AND PATIENTS

Health plans, payers, employers, physicians and patients are facing the increasing financial burden posed by prescription drugs, both brand name and generic. In the Medicare program, over the past eight years, Part D spending has seen an annual growth rate of approximately 6.5 percent, and amounted to $78.1 billion in 2014.[13] Under Medicare Part B, spending on covered prescription drugs was more than $19 billion in 2013, with the drugs with the highest part B spending being biologics. Generic drugs accounted for 81 percent of all prescriptions filled in Part D in 2012.[14] Medicare Parts B and D have also had to absorb the cost impact of the trend towards biologic products and specialty drugs. Specialty drug spending has been concentrated in conditions more prevalent in the Medicare population, including cancer, rheumatoid arthritis and multiple sclerosis. However, there has been a more limited use of specialty drugs among Part D beneficiaries thus far, as most plans have specialty tiers that require between 25 and 33 percent cost sharing. With the high reliance on generic drugs among Part D enrollees, the recent generic drug price increases can substantially impact the rate of growth in spending in Part D. In fact, the estimated average annual increase in spending for Part D is 10.9 percent over the next five years.[13]

Prescription drug costs are also consuming a greater share of Medicaid budgets, and state budgets overall. Under the Medicaid drug benefit, drug manufacturers pay rebates to states in return for Medicaid reimbursement for their prescription drugs. Drug manufacturers are required to pay an additional rebate amount if the average manufacturer price (AMP) for a brand-name drug rises faster than inflation. Medicaid spending on prescription drugs is projected to have increased by more than 23 percent in 2014.[15] High growth in Medicaid drug spending is expected due to the increase in cost and utilization of specialty drugs; increases in enrollment; and fewer generic drugs entering the marketplace. Between 2010 and 2012, approximately one-quarter of total Medicaid drug spending before rebates was on specialty drugs, despite specialty drugs accounting for only two percent of total prescriptions. Overall, 28 percent of total Medicaid spending in 2012 was on specialty drugs.[16] With the entrance of hepatitis C treatments including Solvaldi and Harvoni into

the marketplace, specialty drugs are expected to consume a greater share of Medicaid budgets in future years.

Employer-sponsored health plans as well as health plans sold in the individual market have also had to absorb the higher costs of prescription drugs, which may translate to higher premiums, higher prescription drug cost-sharing, and additional prescription drug tiers to accommodate the higher costs of specialty and certain generic drugs. In 2014, 80 percent of employees were enrolled in plans with three, four or more cost-sharing tiers for prescription drugs.[17] Like private health plans, Medicare Part D sponsors have started to move toward a five-tier formulary structure, placing higher-cost generics on a nonpreferred generic tier.

The higher costs of prescription drugs are expected in part to be passed down to health plan enrollees. Nonpreferred generic tiers in many cases have higher copayments than patients have become accustomed to for generic medications. In addition, plans with specialty drug cost-sharing tiers oftentimes require coinsurance amounts of 25 to 33 percent, versus requiring a fixed copayment. Considering the costs of many specialty medications, patients could quickly reach their deductibles and out-of-pocket maximums. The increased use and cost of specialty drugs in Medicare has the ability to cause the number of Part D enrollees who reach the out-of-pocket threshold to grow substantially, resulting in increases in Medicare spending for individual reinsurance and low-income cost sharing.

Increasing patient cost-sharing is associated with declines in medication adherence, which in turn can lead to poorer health outcomes.[18,19,20] The higher costs of drugs and biologics can also impact the ability of physicians to place their patients on the best treatment regimen, due to the regimen being unaffordable for the patient, or being subject to coverage limitations and restrictions by the patient's health plan. In the worst-case scenario, patients entirely forego necessary treatments involving drugs and biologics due to their high cost.

The cost of drugs and biologics can also impact physicians participating in alternative payment models. For example, under the Oncology Care Model (OCM) developed by the Center for Medicare and Medicaid Innovation and starting in 2016, Medicare will continue to pay for Part B drugs administered within episodes of care at Average Sales Price plus six percent.[21] However, bundled payment models also have the potential to pay physicians the same fee for drug administration regardless of the drugs administered to patients. Also, as providers under a bundled payment approach are paid a single payment amount for all services related to an episode of care, if the costs of care exceed the bundled payment, the providers assume financial liability. As such, if patients of physicians participating in shared savings models require higher cost drugs and biologics, the treating physicians may be portrayed as higher cost providers. The Council underscores that alternative payment models need to ensure that physicians and their patients can choose the drugs and biologics that are best for the individual patient. It is also important for physicians participating in alternative payment models to have the ability to change an episode's treatment regimen as new evidence on drug and biologic efficacy becomes available.

## LEGISLATIVE ACTIVITY

There has been legislative activity on the state and federal levels addressing several of the factors contributing to the prices of generic and brand-name drugs, as well as biologics. On the state level, there have been bills introduced in states including California, Massachusetts, New York, North Carolina, Oregon and Pennsylvania to require prescription drug cost transparency. These bills propose to require pharmaceutical companies to disclose certain information, including development, manufacturing, marketing and advertising costs; a history of price increases; and the

profit attributable to the drugs. Some state legislation would allow insurers and states to act on the information disclosed, ranging from allowing insurers to refuse to pay for a drug if its manufacturer did not file the required disclosure, to giving a state commission the authority to set a maximum price of a drug if the manufacturer's price was deemed to be too high after considering a range of factors.[22] Legislation has also been introduced to cap the co-payments or coinsurance that patients could be required to pay for prescription drugs. In addition, state legislation has been introduced addressing state prescription drug discount programs, adverse drug tiering, as well as Medicaid and private insurer coverage of certain prescription drugs.

On the federal level, H.R. 6, the 21st Century Cures Act, sponsored by Representative Fred Upton (R-MI) passed the House of Representatives. H.R. 6, as passed in the House, would extend the marketing exclusivity period for drugs approved for a new indication that is a rare disease or condition, also known as orphan drugs, by six months. The bill also has provisions to support antibiotic drug development, and provide grants for studying continuous drug manufacturing. H.R. 6 would also make several revisions to the drug approval process, including allowing the FDA to expedite the development of certain drugs by relying upon data previously submitted for a different purpose, establishing a streamlined data review process for approving drugs for additional indications, and allowing patient experience data to be considered in the benefit-risk assessment of a new drug.

Patent reform legislation, including S. 1137, the PATENT Act and H.R. 9, the Innovation Act, has been introduced, which has the potential to impact pharmaceutical pricing practices as well as competition in the prescription drug marketplace. Perennial legislation has also been introduced on such topics as prescription drug price negotiation in Medicare and prescription drug importation.

The Obama administration, in its fiscal year 2016 budget proposal, also proposed shortening the market exclusivity period for biologics from 12 to seven years, which would require legislation. In addition, the budget included a proposal to stop companies from making anti-competitive deals intended to block or delay patient access to generic medications. The administration estimated that these proposals would save $16 billion over 10 years.[23]

AMA POLICY

At the 2015 Annual Meeting, the House of Delegates adopted Policy H-110.988, which states that the AMA will:

- Work collaboratively with relevant federal and state agencies, policymakers and key stakeholders (e.g., the FDA, the US Federal Trade Commission [FTC], and the Generic Pharmaceutical Association) to identify and promote adoption of policies to address the already high and escalating costs of generic prescription drugs;
- Advocate with interested parties to support legislation to ensure fair and appropriate pricing of generic medications, and educate Congress about the adverse impact of generic prescription drug price increases on the health of our patients;
- Encourage the development of methods that increase choice and competition in the development and pricing of generic prescription drugs; and
- Support measures that increase price transparency for generic prescription drugs.

Policy H-110.998 urges the pharmaceutical industry to exercise reasonable restraint in the pricing of drugs. Policy D-110.993 states that our AMA will continue to meet with the Pharmaceutical Research and Manufacturers of America to engage in effective dialogue that urges the

pharmaceutical industry to exercise reasonable restraint in the pricing of drugs. Policy H-110.992 states that the AMA will monitor the relationships between pharmaceutical benefits managers and the pharmaceutical industry and will strongly discourage arrangements that could cause a negative impact on the cost or availability of essential drugs. Policy H-110.997 supports programs to contain the rising costs of prescription drugs that meet certain criteria, and encourages physicians to consider prescribing the least expensive drug.

Policy H-155.962 opposes the use of price controls in any segment of the health care industry, and continues to promote market-based strategies to achieve access to and affordability of health care goods and services. However, AMA policy makes a departure from its market-based approach to pharmaceutical pricing in Policy D-330.954, which supports federal legislation that gives the Secretary of the Department of Health and Human Services the authority to negotiate contracts with manufacturers of covered Part D drugs. The policy also states that our AMA will work toward eliminating the Medicare prohibition on drug price negotiation.

Policies H-110.997 and H-110.996 support increasing physician awareness about the cost of drugs prescribed for their patients. Related, Policy H-125.979 supports physicians having accurate, real-time formulary data at the point of prescribing, as well as requiring insurance carriers making formulary information available to patients by October 1 of each year and forbidding insurers from making formulary deletions within the policy term. Policy H-110.990 supports physicians and patients being able to determine the actual price and out-of-pocket costs of individual prescription drugs prior to making prescribing decisions. The policy also states that cost-sharing requirements for prescription drugs should be based on considerations such as the unit cost of medication; availability of therapeutic alternatives; medical condition being treated; personal income; and other factors known to affect patient compliance. Policy H-185.953 supports complete transparency of health care coverage policies related to specialty pharmaceuticals, including co-payment or co-insurance levels and how these levels are determined. Policy H-165.846 states that mechanisms must be in place to educate patients and assist them in making informed choices, including ensuring transparency among all health plans regarding covered services, cost-sharing obligations, out-of-pocket limits and lifetime benefit caps, and excluded services.

Policies H-100.980 and H-125.984 support a strong and adequately funded FDA to support effective drug approval processes. H-100.980 also states that our AMA will continue to work with the FDA on controversial issues concerning drugs, biologics and pharmaceuticals to try to resolve concerns of physicians. Policy D-110.994 states that the AMA will continue to monitor the implementation of the newly enacted reforms to the Hatch-Waxman law to see if further refinements are needed that would prevent inappropriate extension of patent life of pharmaceuticals, and work accordingly with Congress and the Administration to ensure that AMA policy concerns are addressed. Policy H-125.978 states that our AMA will raise awareness among physicians of the strategy that could be used to limit the value to manufacturers of forced switching of brand formulations of prescription drugs; and advocate that the FDA and Congress ascertain the pervasiveness of this practice and advance solutions that strike an appropriate balance between innovation incentives and competition in order to support patient access to the newest treatments as well as those that are cost-effective. Policy H-110.989 supports the FTC in its efforts to stop “pay for delay” arrangements by pharmaceutical companies and federal legislation that makes tactics delaying conversion of medications to generic status, also known as “pay for delay,” illegal in the US.

DISCUSSION

The Council notes that AMA policy has long supported market-driven mechanisms to control pharmaceutical costs, as outlined in Policy H-155.962. However, policy also recognizes that improvements need to be made to ensure that the pharmaceutical marketplace operates efficiently and effectively, as evidenced in Policy H-110.989, which calls for making "pay-for-delay" agreements illegal, as well as Policy H-110.988, which encourages the development of methods that increase choice and competition in the development and pricing of generic prescription drugs. The Council believes that steps need to be taken to ensure that "evergreening" practices of brand-name drug manufacturers are not anticompetitive in nature. In that light, the AMA should encourage FTC actions to limit anticompetitive behavior by pharmaceutical companies attempting to ensure extended exclusivity for drugs and reduced competition from generic manufacturers through the filing of multiple patents on a single drug. Using controlled distribution channels for pharmaceuticals by limiting distribution through specialty pharmacies is sometimes necessary for reasons including safety considerations. However, the Council recognizes that controlled distribution can also be used to restrict patient access to a pharmaceutical, as well as limit market competition. As such, the AMA should also encourage Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition.

Recent mergers and acquisitions in the pharmaceutical industry, especially in the generic drug industry, have reignited concerns that a consolidated pharmaceutical marketplace has the potential to increase drug prices. As such, the Council believes that our AMA needs to monitor pharmaceutical company mergers and acquisitions, as well as the impact of such actions on drug prices. In addition, patent reform continues to be a key area to monitor as policy-makers evaluate barriers to greater market-based competition. Brand and generic manufacturers are disputing whether the current statutory and regulatory framework for adjudicating patent disputes is adequate. Finally, while market exclusivity periods are important in ensuring pharmaceutical industry innovation, the 12-year exclusivity period currently enjoyed by biologics unduly delays entry of biosimilar competition in the marketplace. As such, the Council recommends that the market exclusivity period for biologics be shortened.

While AMA policy continues to promote market-based strategies to achieve the affordability of prescription drugs, policy also urges the pharmaceutical industry to exercise reasonable restraint in the pricing of drugs. The pricing of prescription drugs impacts state Medicaid budgets, Medicare spending, insurance premiums and prescription drugs tiers, and most importantly, patient access to these medications and medication adherence. To spur additional pricing restraint in the generic drug arena, the Council believes that generic drug manufacturers should be required to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation, as is currently required of brand-name drug manufacturers. The Council recognizes that the promotion of transparency in prescription drug pricing and costs will help patients, physicians and other stakeholders understand how drug and biologic manufacturers set prices. If there is greater understanding of the factors that contribute to prescription drug pricing, including the research, development, manufacturing, marketing and advertising costs borne by pharmaceutical companies, then the marketplace can react appropriately.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 207-I-14 and Resolution 228-I-14, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) reaffirm Policy H-155.962, which opposes the use of price controls in any segment of the health care industry, and continues to promote market-based strategies to achieve access to and affordability of health care goods and services. (Reaffirm HOD Policy)

2. That our AMA reaffirm Policy H-110.988, which supports efforts to ensure fair and appropriate pricing of generic medications. (Reaffirm HOD Policy)

3. That our AMA reaffirm Policy H-110.989, which supports the Federal Trade Commission (FTC) in its efforts to stop "pay for delay" arrangements by pharmaceutical companies and federal legislation that makes tactics delaying conversion of medications to generic status, also known as "pay for delay," illegal in the United States. (Reaffirm HOD Policy)

4. That our AMA reaffirm Policy H-110.992, which states that our AMA will monitor the relationships between pharmaceutical benefits managers and the pharmaceutical industry and will strongly discourage arrangements that could cause a negative impact on the cost or availability of essential drugs. (Reaffirm HOD Policy)

5. That our AMA reaffirm Policy D-330.954, which states that our AMA will support federal legislation which gives the Secretary of the Department of Health and Human Services the authority to negotiate contracts with manufacturers of covered Part D drugs, and work toward eliminating Medicare prohibition on drug price negotiation. (Reaffirm HOD Policy)

6. That our AMA encourage Federal Trade Commission actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives. (Directive to Take Action)

7. That our AMA encourage Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition. (Directive to Take Action)

8. That our AMA monitor the impact of mergers and acquisitions in the pharmaceutical industry. (Directive to Take Action)

9. That our AMA continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system. (New HOD Policy)

10. That our AMA encourage prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies. (New HOD Policy)

11. That our AMA support legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation. (Directive to Take Action)

12. That our AMA support legislation to shorten the exclusivity period for biologics. (Directive to Take Action)

13. That our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens. (Directive to Take Action)

14. That our AMA generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients, and report back to the House of Delegates regarding the progress of the drug pricing advocacy campaign at the 2016 Interim Meeting. (Directive to Take Action)

Fiscal Note: Less than $5000.

REFERENCES

[1] Keehan, S; Cuckler, G; Sisko, A; Madison, A; Smith, S; Stone, D; Poisal, J; Wolfe, C; Lizonitz, J. National Health Expenditure Projections, 2014−24: Spending Growth Faster Than Recent Trends. Health Affairs, July 2015.
[2] Centers for Medicare & Medicaid Services. National Health Expenditure Projections 2014-2024: Forecast Summary. Available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/proj2014.pdf.
[3] IMS Institute for Healthcare Informatics. Medicines Use and Spending Shifts. April 2015.
[4] Institute for Clinical and Economic Review. PCSK9 Inhibitors for Treatment of High Cholesterol: Effectiveness, Value, and Value Based Price Benchmarks - Draft Report. September 8, 2015. Available at: http://cepac.icer-review.org/wp-content/uploads/2015/04/PCSK9_Draft_Report_0908152.pdf.
[5] O'Riordan, M. PCSK9 Inhibitors Not Cost-effective at Current Price: ICER Review. Medscape. September 9, 2015. Available at: http://www.medscape.com/viewarticle/850715.
[6] Schondelmeyer, S, Purvis, L. Rx Price Watch Report: Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans 2006 to 2013. November 2014. Available at: http://www.aarp.org/content/dam/aarp/ppi/2014-11/rx-price-watch-report-AARP-ppi-health.pdf.
[7] Schondelmeyer, S, Purvis, L. Trends in Retail Prices of Generic Prescription Drugs Widely Used by Older Americans, 2006 to 2013. May 2015. Available at: http://www.aarp.org/content/dam/aarp/ppi/2015/trends-in-retail-prices-of-generic-prescription-drugs.pdf.
[8] US Food and Drug Administration. Report to Congress: Second Annual Report on Drug Shortages for Calendar Year 2014. Available at: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM443917.pdf.
[9] US Food and Drug Administration. Frequently Asked Questions on Patents and Exclusivity. Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm.
[10] 42 U.S.C. 262(i)(2)(B).
[11] 42 U.S.C. 262(I)(3).
[12] US Food and Drug Administration. FDA approves first biosimilar product Zarxio. March 6, 2015. Available at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm436648.htm.
[13] Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. The 2015 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. July 22, 2015. Available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2015.pdf.
[14] Medicare Payment Advisory Commission. Report to the Congress: Medicare and the Health Care Delivery System. June 2015. Available at: http://www.medpac.gov/documents/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0.
[15] National Health Expenditure Projections 2014-2024 Tables. July 2015. Available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2014tables.zip.

[16] Bruen, B,Young, K. What Drives Spending and Utilization on Medicaid Drug Benefits in States? December 2014. Available at: http://files.kff.org/attachment/brief-what-drives-spending-and-utilization-on-medicaid-drug-benefits.
[17] Kaiser Family Foundation and Health Research & Educational Trust. Employer Health Benefits: 2014 Annual Survey. Available at: http://files.kff.org/attachment/2014-employer-health-benefits-survey-full-report.
[18] Eaddy, M, Cook, C, O'Day, K, Burch, S, Cantrell, C. How Patient Cost-Sharing Trends Affect Adherence and Outcomes: A Literature Review. Pharmacy and Therapeutics. 2012;37(1):45-55.
[19] Iuga, A, McGuire, M. Adherence and health care costs. Risk Management and Healthcare Policy. 2014;7:35-44.
[20] Roebuck, M, Liberman, J, Gemmill-Toyama, M, Brennan, T. Medication Adherence Leads To Lower Health Care Use And Costs Despite Increased Drug Spending. Health Affairs, 30, no.1 (2011):91-99.
[21] Center for Medicare & Medicaid Innovation, Centers for Medicare & Medicaid Services. Oncology Care Model Frequently Asked Questions. June 15, 2015. Available at: http://innovation.cms.gov/Files/x/ocmfaqs.pdf.
[22] Pollack, A. Drug Prices Soar, Prompting Calls for Justification. The New York Times. July 23, 2015. Available at: http://www.nytimes.com/2015/07/23/business/drug-companies-pushed-from-far-and-wide-to-explain-high-prices.html.
[23] Office of Management and Budget. Fiscal Year 2016 Budget of the U.S. Government. Available at: https://www.whitehouse.gov/sites/default/files/omb/budget/fy2016/assets/budget.pdf.