Improving the Affordability of Prescription Medications for People with Chronic Respiratory Disease: An Official American Thoracic Society Policy Statement

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ABSTRACT

Background: Mounting evidence indicates that out-of-pocket costs for prescription medications, particularly among low- and middle-income patients with chronic diseases, are imposing financial burden, reducing medication adherence, and worsening health outcomes. This problem is exacerbated by a paucity of generic alternatives for prevalent lung diseases such as asthma and COPD as well as high cost medicines for rare diseases such as cystic fibrosis. Affordability and access challenges are especially salient in the U.S, as citizens of many other countries pay lower prices for and have greater access to prescription medications.

Methods: The American Thoracic Society convened a multidisciplinary committee comprising experts in health policy, pharmacoeconomics, behavioral sciences and clinical care, along with individuals providing industry and patient perspectives. The report and its recommendation were iteratively developed over a year of in-person, telephonic, and electronic deliberation.

Results: The committee unanimously recommended the establishment of a publicly funded, politically independent, impartial entity to systematically draft evidence-based pharmaceutical policy recommendations. The goal of this entity would be to generate evidence and action steps to ensure people have equitable and affordable access to prescription medications, to maximize the value of public and private pharmaceutical expenditures on health, to support novel drug development within a market-based economy, and preserve clinician and patient choice regarding personalized treatment. An immediate priority is to examine the evidence and make recommendations regarding the need to have essential medicines with established clinical benefit from each drug class in all Tier 1 formularies, and propose recommendations to reduce barriers to timely generic drug availability.

Conclusions: By making explicit, evidence-based recommendations, the entity can support the establishment of coherent national policies that expand access to affordable medications, improve the health of patients with chronic disease, and optimize the use of public and private resources.

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EXECUTIVE SUMMARY

Rising healthcare costs are leading to higher out-of-pocket (OOP) expenses for patients such that one-quarter of families report health spending imposes a significant financial burden. This burden is especially high among individuals with low and middle incomes who have chronic respiratory conditions and is magnified by the limited availability of generic medicines within many drug classes. Even when generics are available, their prices are unexpectedly high due to lack of competition. Rising medication costs increase stress and fear while cost-related non-adherence worsens health status and leads to unnecessary hospitalizations. Other economically developed countries have taken greater steps than the U.S. to establish policies to protect patients from unmanageable prescription medication expenses. There is a pressing need in the U.S. to establish more consistent and rational pharmaceutical policies at the national level.

The current market for prescription medications is complex and contains numerous government and private entities that regulate, develop, distribute, dispense and purchase prescription medications. Recommendations addressing affordability must acknowledge the diverse roles these entities play in making medications available to patients. The National Academies of Science, Engineering and Medicine and others recommend important reforms based on careful and objective examination of available evidence. Given the difficulty of crafting and implementing evidence-based policies in a complex and dynamic pharmaceutical supply chain, a system is needed to monitor long-term outcomes and adapt to changing circumstances.

The following policy recommendations are designed to address the long-term challenges facing the nation as a whole, in order to better serve all patients in need of prescription medications, not just those with respiratory disease:

- The U.S. government should establish and financially support a politically independent, impartial expert advisory committee tasked with making critical, evidence-based recommendations on pharmaceutical policy. Their overarching goals would be to ensure affordable access to life-

111 preserving medications, while retaining consumer choice, promoting future innovation and
112 respecting our market-based economy.

- 113
- 114 • An immediate priority of the aforementioned committee is to examine the evidence and make
115 strong recommendations to have essential medicines with established clinical benefit from each
116 drug class in all Tier 1 formularies, and reduce barriers to timely generic drug availability.

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BACKGROUND

Prescription medication spending has garnered notable attention in the U.S. because rising expenditures are straining government and patient finances. Demand for prescription medications is high given 50% of adults have at least one chronic condition and 25% have two or more (1). Sixty percent of the population and 90% of Medicare beneficiaries have taken at least one prescription medication in the past month (2). While prescription medication spending accounts for 22% of all expenditures devoted to treating individual medical conditions, it accounts for 28% among those with chronic respiratory conditions and 58% among those with asthma, a highly prevalent disease (3-4). Prescription medications are critical to the effective management of respiratory disease, which is reflected in increased spending. However, rising healthcare costs are passed on to patients through higher out-of-pocket (OOP) expenses resulting in one-quarter of families reporting a significant financial burden (5). This burden is greatest among individuals with low and middle incomes who have a chronic condition, with OOP spending doubling between zero and one condition, and between two and multiple conditions (6).

Higher OOP medication costs imposes a financial burden on families that is known to increase stress and fear, and to induce cost-related non-adherence--- an adaption that affects nearly one-third of adults with chronic conditions, worsens health status, and leads to unnecessary hospitalizations (7-9). Among economically developed countries, cost-related non-adherence is highest in the U.S (10). Cost-saving tactics includes taking smaller doses, skipping doses, delaying refills and borrowing medicines from others (11). Transferring medication costs from third-party payers to patients may burden patients without yielding corresponding savings if non-adherence leads to increased health care utilization in other service settings (e.g., hospital admissions).

The high cost of prescription medications coincides with increases in all forms of health care spending (12). While health spending is highest in the U.S., all economically developed nations struggle to ensure their health expenditures are fiscally sustainable (12). Other economically developed countries have taken greater steps than the U.S. to use national policies to curb health spending and

protect patients from OOP expenses. Because these mechanisms rely heavily on government regulation, negotiation, and price-setting, they have gained little favor in the U.S.

Pharmaceutical policy in the U.S. is not hampered by a lack of expert recommendations (13-15), but rather by lack of political will to act upon them on a scale that could benefit the nation as a whole. For example, the National Academies of Science, Engineering and Medicine recently outlined a series of evidence-based recommendations to improve medication affordability (16). While the task force provided actionable guidance to federal agencies who have legal authority to implement specific recommendations, two factors act to reinforce the status quo: 1) the approach for reform remains fragmented, and 2) the pharmaceutical market is an evolving and complex endeavor for which continued and careful examination of evidence is needed to evaluate the success (and failure) of policy recommendations.

More coherent and consistent pharmaceutical policies are needed at the national level to ensure Americans have equitable access to affordable prescription medications. The ATS supports policies that give people the best available resources to manage their health, including affordable access to pharmaceutical therapies while also supporting innovation in the development of new efficacious treatments. To meet these challenges, this ATS policy statement recommends the establishment of a publicly funded, politically independent, impartial entity to systematically draft evidence-based pharmaceutical policy recommendations at the national level. This statement outlines key features of the pharmaceutical supply chain that impact people with chronic respiratory conditions, highlights international examples of how those features can be better managed, and concludes with our rationale of how such an entity can be integrated into our unique political system to provide impactful regulatory guidance.

DESCRIPTION OF COMMITTEE COMPOSITION AND ACTIVITY

A multidisciplinary expert committee developed this policy statement. A full working group was recruited at the initiation of the project, comprising experts in health policy, pharmaceutical policy and pharmaco-economics, behavioral and translational science, pediatric and adult respiratory medicine,

industry, and patients. Conflicts of interest were vetted and managed according to the policies and procedures of the ATS. This policy statement was developed through an iterative, consensus-based process that included face-to-face meetings, electronic polls and correspondence, and teleconferences. The full committee participated in topic-focused writing committees, and provided expertise on various sections of the statement. A writing committee consisting of the co-chairs drafted the initial policy statement. The statement was reviewed by the full committee on multiple occasions and ultimately approved by the ATS Board of Directors.

THE PHARMACEUTICAL SUPPLY CHAIN IN THE UNITED STATES

The current market for prescription medications is complex and contains numerous government and private entities that regulate, develop, distribute, dispense and purchase prescription medications. Recommendations addressing affordable access to pharmaceutical therapies must acknowledge the diverse roles that these entities play in making medications available to patients. We highlight the contributions of and structural challenges facing manufacturers, distributors, insurers, and prescribers as they seek to control growing pharmaceutical costs for patients with chronic lung disease.

Manufacturers and Patent Laws

Pharmaceutical manufacturers engage in drug research, development, evaluation, licensing and marketing with the aim of distributing therapies for a range of diseases. Pharmaceutical manufacturers are an important entity ensuring that innovative therapies are made available to the public. Although physician marketing and direct-to-consumer advertising are often a focus of scrutiny when it comes to examining costs, one of the most costly investments made by manufacturers includes the complex clinical trials required to evaluate efficacy, inform safety, and meet regulatory requirements (16).

A number of legal protections including regulatory and patent-related exclusivity prolong the life-span of branded therapies, allowing patient cost of medications to be influenced by the wholesale price set by manufactures (14). While patent exclusivity is intended to reward novel drug development, it can

also protect profits at the expense of lower prices for respiratory medicines, particularly those delivered by inhalation. For example, the U.S. FDA banned the production and sale of all chlorofluorocarbon (CFC)-based albuterol inhalers in 2008 in response to an international agreement to reduce environmental contaminants that were depleting the ozone layer. As an unintended consequence, generic CFC inhalers were replaced by more expensive, patented hydrofluoroalkane inhalers prompting higher OOP costs for patients, especially those privately insured (17). At this time, there are still no marketed generic albuterol inhalers. In addition to this unusual circumstance, respiratory medicines delivered by inhalation are more protected from generic competition than orally ingested medications because of the complexity of patent law involved in proprietary pump designs, delivery systems, formulations and production processes that hinder generic competition when the active ingredient may no longer be patent-protected. Oversight provided by a patient-oriented, politically independent, entity could help detect and mitigate unintended consequences of regulatory actions that sustain high prescription medication prices.

Distribution Channels and Insurers

Prescription medications are made available to patients only after passing through several intermediaries. Most recently, Pharmacy Benefit Managers (PBMs) have become influential intermediaries that secure prescription medications from manufacturers on behalf of health plans and employers. While pharmacies often provide patients with direct access to prescription medications, PBMs exist behind the scenes to develop and maintain formularies, sell medications and provide rebates to pharmacies, negotiate discounts and obtain medications from drug manufacturers, and process prescription drug claims on behalf of insurers. Three large PBMs serve 75% of the U.S. market (14). Although there is some consistency for public payers, like Medicaid, prices paid by private insurers are highly variable and typically lack price transparency. As a result, the prices paid insurers, pharmacies, and individual patients varies widely (18). Numerous intermediaries exist between manufacturers and patients; accordingly, each step in the supply chain is associated with mark-ups

such that \$1 out of every \$5 spent on prescription drugs feeds profits in the distribution system (19). In Europe, the price that such suppliers can charge is limited to a fixed percentage cost of the medication being supplied.

Many insurance policies impose substantial cost-sharing requirements that impact OOP prescription drug spending including general medical deductibles, copayments and coinsurance. These requirements vary depending on whether the health insurance is publically or privately sponsored. For instance, high deductible private plans often require thousands of dollars in spending before subsidizing prescription medication costs. Alternatively, public plans, like Medicare, tend to impose smaller deductibles but lack an annual expenditure cap exposing some beneficiaries (e.g., those undergoing cancer chemotherapy) to high OOP spending owing to co-insurance payments above the Medicare Part D catastrophic spending threshold. More routinely, Medicare patients with common chronic respiratory diseases like COPD may pay up to \$1200 annually to cover single maintenance inhaler treatment, a striking 79% of the total drug cost (20). Until the “donut hole” is phased out, those who use >2 inhalers will almost certainly reach this coverage gap where they are responsible for up to one-third of the drug costs until the catastrophic limit is reached, at which point they are responsible for 5%. By federal regulation, Medicare patients cannot receive any copayment assistance from the pharmaceutical company marketing the product.

Prescribers

Pharmaceutical company relationships with physicians have long been scrutinized for their impact on prescribing more expensive, branded medicines (21). Over the last decade, many policies have been enacted to reduce product detailing (22) in an attempt to reduce branded prescribing when generic alternatives are available (23). An unintended consequence is the deceleration of the adoption of new therapies (24). This is especially concerning for novel therapies for patients with rare diseases where delayed uptake could deprive these patients of clinically beneficial therapies.

Over time, more prescribers have come to recognize that treatment costs can impact adherence with treatment recommendations and/or place undue financial burden on patients (25-26). For many lung diseases, such as asthma and COPD, few suitable generics are available. Prescribing branded medications in these circumstances forces patients to pay more because these medications are typically placed in higher formulary tiers with larger copayments. Thus, prescribers are placed in a catch-22 where prescribing efficacious treatments may not offer the expected benefits owing to greater non-adherence as a result of cost.

Prescribers often lack adequate information or training to prescribe in a cost-conscious manner to improve affordability. Given large heterogeneity between health insurance formularies, costs for the same treatments are highly variable between patients. Formularies change frequently making it even more challenging for prescribers to address affordability for individual patients. Because hospitals have unique formularies, patients may be prescribed one type of medication prior to hospitalization, given a different one during the hospitalization, and then be prescribed that inhaler at discharge—meaning patients may, at times, be purchasing duplicative medications.

PHARMACEUTICAL SUPPLY CHAIN IN THE INTERNATIONAL CONTEXT

In an effort to ensure the safety, availability and access to health promoting pharmaceutical products worldwide, the World Health Organization (WHO) released evidence-based guideline to assist national policy-makers and other stakeholders to manage pharmaceutical prices (27). Recommendations included greater regulation of mark-ups in the pharmaceutical supply chain, tax exemptions for pharmaceutical products, use of external reference pricing, promotion of generic medicines, and greater use of health technology assessments (27). These recommendations are widely used by high income countries, but not the US.

Outside of the US, the European Union (EU) comprises the second largest concentration of pharmaceutical industries and suppliers of patented medications. For over two decades, EU countries have been focusing on containing pharmaceutical expenditures and ensuring affordable access to

medicines (29). Although, prescription medication prices are higher in the US than any other advanced nation, prices in the EU have been rising (28) for many years as well (14). Several features of EU countries help explain their lower prices. In general, the EU has a greater commitment to fulfill a right to health care and essential medicines for its citizens (29). They also work to ensure that health policies in member nations do not disrupt the goals and operation of the internal EU market-- a larger EU objective (29). Thus EU pricing reflects that overarching goal. While individual countries have some leeway in price setting, all member nations must comply with EU provisions governing transparency, regulation, and approval. One common approach for individual EU countries is to use external reference pricing-- that is, setting their prices based on comparison prices in other member nations, often adopting the lowest price. Canada has also adopted reference pricing using EU member nations as common comparators. The European Commission, an elected group represented by each member country that maintains the general interests of the EU and can propose legislation, has been examining many of the same issues that face the U.S. in pharmaceutical policy reform. Examples of these issues include adequate generic supply and the pharmaceutical lobby.

Many countries with universal healthcare and/or multi-payer systems have national organizations responsible for conducting health technology assessments that generate evidence to support reimbursement decisions and price setting, including Australia, Canada, Germany, Ireland, and the United Kingdom. Organizations adopt a range of review criteria including clinical, comparative, and cost-effectiveness evidence to drive decision-making. In the U.S., these same approaches have been undertaken by non-governmental organizations such as the Institute for Clinical and Economic Review and individual physician and patient advocacy groups; however, these efforts are isolated, underfunded and their work is not widely used in practice.

RECOMMENDATIONS

297 **Recommendation 1: The U.S. government should establish and financially support a politically**
298 **independent, impartial expert advisory committee tasked with making evidence-based**
299 **recommendations on pharmaceutical policy. Their overarching goal would be to ensure**
300 **affordable access to life-preserving medications while retaining consumer choice, promoting**
301 **future innovation, and respecting our market-based economy.**

302 Without a single entity to coordinate and/or regulate the activities of the various parties comprising
303 the pharmaceutical supply chain in the US, broad adoption of evidence-based policies has fallen behind
304 that of other economically developed nations. Accordingly, patients are unduly burdened by high
305 treatment costs, and as a result, experience greater morbidity due to cost-related non-adherence. Over
306 the past decade, numerous entities have proposed policies to curb the rise in prescription medication
307 prices including encouraging greater price transparency, changing patent law and adopting value-
308 based purchasing (16). However, lacking any clear standing, these recommendations have been
309 largely ignored. The National Academies of Science, Engineering and Medicine recently recommended
310 numerous, targeted, evidence-based reforms based on the best available evidence to address
311 inefficiencies in the pharmaceutical supply chain (16). While our committee is supportive of many of
312 these recommendations, we intentionally refrained from championing any particular strategy owing to
313 our belief that adopting highly targeted policies in a piece-meal fashion will not sufficiently address the
314 long-term challenges posed by a complex, ever-evolving system (16).

315 Instead, the problem calls for a permanent entity with sufficient standing to confront entrenched
316 stakeholders and adapt to changing circumstances. To address this long-term need, we unanimously
317 recommend that the U.S. government establish and financially support an independent expert advisory
318 committee tasked with making recommendations on pharmaceutical policy. The fact that 75% of
319 Americans already favor the creation of an independent group with specific focus on the costs of
320 prescription medicines lends credence to the acceptability of our recommendation (30).

321 One may view this recommendation as a “punt” by failing to make specific, targeted
322 recommendation affecting obvious inefficiencies in the current pharmaceutical market. However, the
323 committee concluded that there are two necessary requisites to realize pharmaceutical policy reform in
324 the U.S: impartiality and capacity. Due to close financial relationships between industry and the medical
325 profession it is impossible for organizations like the ATS to manage the actual or perceived conflicts of
326 interest that exists between its members and industry. This makes it difficult for professional societies to
327 make independent and objective recommendations with suitable traction to bring about meaningful
328 change. Second, individual professional societies lack the capacity to shoulder the long-term burden
329 needed to reform pharmaceutical policy. While such societies should inform and influence policy, their
330 voice alone is insufficient to realize the substantial changes that are needed.

331 Given the magnitude of the challenge, only the federal government is positioned to facilitate, fund
332 and organize this effort. However, public distrust in government and hyper-partisanship would invariably
333 threaten the impartiality of such an entity without a high degree of independence from political forces.
334 Therefore, we propose the creation of an independent entity for pharmaceutical reform be modeled
335 after the successful example of the United States Preventive Services Task Force (USPSTF). This
336 entity, supported by the Agency for Healthcare Research and Quality, has served in an independent,
337 impartial advisory capacity since 1984 (31).

338 The example of the USPSTF demonstrates how the federal government can effectively advance
339 health policy formulation independent of partisan influence. The USPSTF is comprised of an
340 independent group of national experts in prevention and evidence-based medicine that works to
341 improve the health of all Americans by making evidence-based recommendations about clinical
342 preventive services. Because its recommendations are not subject to government approval, they are
343 highly respected by the general public, public officials, health care entities and clinicians. A notable
344 example of how the USPSTF has exerted tangible impact on national health policy is reflected by the
345 Affordable Care Act requirement that all public and private insurers must provide recommended
346 preventive services without patient cost-sharing. Admittedly, this provision only had incremental impact

on our health system, but as recently pointed out, “incremental change is not necessarily inconsequential change” (32).

Other similar organizations exist that operate independently in order to support evidence-based practice and policy, and their operating procedures could be considered as models for the proposed entity, including the Medicare Payment Advisory Commission (MedPAC), and the Congressional Budget Office.

Structure of an independent expert advisory committee

An independent, expert advisory committee would be comprised of national pharmaceutical policy experts representing a broad range of stakeholders including clinicians, pharmacists, researchers, public health practitioners, patient advocates, industry and legal experts, and economists. Like the USPSTF, individuals would be publicly nominated. Members would be appointed to serve fixed terms, and screened to ensure that they have no substantial conflicts of interest that could impair the scientific integrity of the entity’s work. Similar to MedPAC, members would ultimately be confirmed by the Comptroller General. A clear set of conflict of interest protocols would be established to monitor and manage conflicts.

The newly proposed entity would be tasked with making evidence-based recommendations regarding the myriad of factors that influence access to affordable prescription medications. Their overarching goals would be to make recommendations that if implemented, would likely result in improved access to life-preserving medications, while retaining consumer choice, promoting future innovation and respecting our market-based economy. The entity would require an appropriate infrastructure to conduct evidence reviews. They would necessarily seek feedback from professional societies, advocacy groups, and expert consultants as needed. This would provide an important avenue for ATS to shape important policy recommendations that impact patient affordability of respiratory therapies. Recommendations would contain detailed information about the primary evidence behind it, and how to implement the recommendation. Like the USPSTF, when there is not enough evidence to support a recommendation, the entity would make a clear call for needed research. The

entity would have at least two annual required reports to the U.S. Congress, who along with government agencies with legislative authority, would ultimately enforce and implement recommendations. Reports would make clear recommendations to government agencies (e.g FDA) with definitive legislative authority or to the U.S. Congress to grant legislative authority where necessary (16).

This paper, the National Academies of Science, Engineering and Medicine report on making medicines more affordable (16), and others (14-15) have identified several key areas for further examination to inform evidence-based pharmaceutical policy reform that this new entity can draw from to initiate their scope of work- including value-based pricing, transparency, and uniform negotiation. Table 1 highlights priorities in pharmaceutical policy reform in the U.S. to support the ATS mission and patient affordability and access.

Recommendation 2: An immediate priority of the aforementioned committee is to examine the evidence and make recommendations to have essential medicines with established clinical benefit from each drug class in all Tier 1 formularies, and to reduce barriers to timely generic drug availability.

A critical issue for patients with respiratory disease are the high out-of-pocket costs of inhalers owing to lack of low-cost generic availability and variation in coverage on insurance formularies. Advair for example, a commonly prescribed medicine for asthma and COPD, had its U.S. patent expire in 2010, but a generic version has yet to enter the market at the time of this writing. As previously mentioned, generic availability of Albuterol has also faced challenges. If the proposed entity had been around at the time generic CFC inhalers were replaced by patented, hydrofluoroalkane inhalers, they would have been equipped to anticipate the lack of availability of albuterol generics as a result of the change and the anticipated cost consequences. Their work could have therefore addressed the issue and perhaps avoided the untenable situation we are in now. Despite the established clinical benefit of both Advair and Albuterol in mitigating respiratory symptoms and exacerbations, these therapies are

398 not guaranteed on Tier 1 formularies of all insurance plans where out-of-pocket costs would be the
399 lowest for patients compared to other tiers. Although the ACA established an essential benefits list that
400 includes prescriptions, there are not specific protections for certain medicines, or specific guidance or
401 incentives around formulary tiering. A re-examination of essential prescription lists are needed with
402 more uniformity in how insurance plans cover medicines from each drug class at minimal cost to
403 patients.

404 Entry of generic medicines into the market has historically shown that the price of previously
405 patented medicines can drop substantially as a result of increased competition among manufacturers.
406 However, delays in generic entry of medicines and the rising costs of generics in general due to fewer
407 suppliers have created a situation that requires intervention. Key issues that an established entity would
408 provide evidence review and recommendations on would include industry practices to extend patent
409 exclusivity, FDA backlogs of safe generic entry onto the market, and increasing availability of
410 manufactures and their ability to compete (16).

411 **CONCLUSION**

412 The ATS supports policies that improve the health and well-being of patients with chronic lung
413 disease. At present, pharmaceutical costs of common therapies are burdensome for many patients and
414 a major barrier to medication adherence. As other countries have demonstrated, this burden can be
415 mitigated. We recommend the federal government establish and fund an independent, impartial entity
416 to spearhead U.S. pharmaceutical policy reform and prioritize the availability of low-cost generic
417 medicines with proven clinical benefit. This entity would shape pharmaceutical policy reform by
418 developing evidence-based policies that are congruent with international best practices yet consistent
419 with our unique national values. We believe that an independent, impartial entity dedicated to tackling
420 the complex issues involving the development, manufacture, distribution, and sale of pharmaceutical
421 products would be best-positioned to improve our patients' access to affordable, life-preserving and life-
422 enhancing therapies long-term. Such an entity represents a best first step for incremental, yet
423 meaningful, reform of U.S. pharmaceutical policy.

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525

526 **Table 1. Priorities in pharmaceutical policy reform in the U.S. to support the ATS mission and**
 527 **patient affordability and access^{16, 14}**

Expand flexibility of formulary design to mitigate cost burdens to patients. Essential respiratory medicines with established clinical benefit should be available in Tier 1 formularies
Reduce barriers to timely generic drug availability and foster competition to ensure continued affordability
Promote expeditious market entry of international providers of generic and novel medicines.
Establish uniform and meaningful negotiation with producers and suppliers of medicines in the pharmaceutical supply chain
Establish price transparency of financial flows through the pharmaceutical supply chain
Establish a cost-effectiveness research agenda and action plan that develops value metrics for therapies and a uniform pharmaceutical value framework
Expand value-based pricing and benefit design, including demonstration projects to test alternative payment models on outcomes and costs
Incentivize development of truly new medicines
Ensure that financial incentives for the prevention and treatment of rare diseases are not extended to widely sold drugs
Expand stock albuterol programs in schools within all 50 states
Establish an infrastructure for ongoing examination of patient affordability, and availability and access to assistance programs
Define a list of essential medicines and routinely examine this list
Establish policies to reduce academic detailing, lobbying, direct-to-consumer drug advertising, and anticompetitive deals
Examine expenses and processes between NIH and small-industry supported early stage drug development research and that of large pharmaceutical manufacturers
Modify requirements for the award and extension of exclusivity rights