



Issue Brief 1

Drug Prices and the Emerging Majority: Should Government Negotiate Drug Prices?

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Executive Summary

More frequently than we care to admit, when national health policy is being deliberated, its implications for America's emerging majority are ignored. This omission has created a one-size-fits-all system that, by its design, provides care of unequal quality to a diverse community.

According to estimates by the U.S. Bureau of the Census, by 2020 minorities (U.S. citizens who, by descent, are American Indian or Alaska Native, Asian, black or African American, Native Hawaiian or other Pacific Islander, or Hispanic or Latino) will account for 40 percent of the population; by 2050 whites will represent about 50 percent of the country's population—down from 69 percent in 2000.* It is thus likely that by the end of this century, whites will be one of a number of distinct minorities. People who use health services, who purchase prescription drugs and devices, and who work in our health system will be drawn from a variety of ethnic and racial backgrounds.

Given the time that it takes to bring innovation to this system, it is quite possible that as the population tipping point approaches and minorities emerge as the majority in the American workforce, they will be receiving care from a system that has a history of providing them disparate care. The tendency among policy makers to consider health policy as if our society were monolithic is brought into stark relief by the debate over legislation to require government to negotiate drug prices for Medicare beneficiaries.

Virtually lost in this discussion about drug prices is any recognition that the methods used to contain drug prices could undermine the health of the emerging majority. Yet pharmacogenetic research in the past few decades has uncovered significant differences in the metabolism, clinical effectiveness, and side-effect profiles of many clinically important drugs among the minority groups that constitute the emerging majority. Historically, their needs and responses to pharmaceutical treatment have been undervalued or ignored. These differences must be taken into account in the design of cost-management policies, such as pricing, formulary management, therapeutic drug substitution, and step-care protocols. It also must be recognized that we need policies that encourage pioneers in drug

* U.S. Census Bureau, "U.S. Interim Projections by Age, Sex, Race, and Hispanic Origin," <http://www.census.gov/ipc/www/usinterimproj/>, Internet release date: 18 March 2004.

development to be more responsive to the needs of a diverse American community. We must discard anachronistic policies of the twentieth century and consider twenty-first-century solutions to twenty-first-century problems.

What is striking is that medical science is inexorably moving us toward a world of individualized care. Drugs are being designed to take advantage of our knowledge of genetic and biologic predispositions. Certainly policy makers recognize this coming age as they move to support stem-cell research, encourage investment in understanding the genome, and promote efforts to translate those new insights into medical interventions. Yet they simultaneously seek to keep our health-financing system locked in the past, hoping to control costs by denying individuality. The contradictions are manifest, and it is minorities, in both present and future terms, who will bear the immediate burden of those decisions.

Variations in Drug Metabolism

We are all different. Some of our differences translate into how we react to drugs—as individuals. Pharmacogenetic research in the past 35 years has uncovered various distributions of genetic polymorphisms in enzymes and receptors associated with drug metabolism. These polymorphisms are reflected in differences among population groups in clinical responses to drugs and in drug side effects. For example, a recent study published by the National Pharmaceutical Council and the National Medical Association found that black patients differ significantly from white patients in their responses to beta-blockers, angiotensin-converting enzyme (ACE) inhibitors, and diuretics used either alone or in combination for the treatment of high blood pressure. The study also found: “Some populations of Chinese are considerably more sensitive than whites to the effects of the beta-blocker propranolol on heart rate and blood pressure. African Americans and Chinese Americans metabolize nicotine more slowly than do whites, and genetic variations associated with slower nicotine metabolism are more common in some Asian populations.”* Certain Asian groups are more likely than some whites to require lower dosages of a variety of drugs used to treat mental illness, including lithium, antidepressants, and antipsychotics.

Our knowledge of pharmacogenetics is moving toward personalized medicine, where drugs are designed for the individual, taking into account such vari-

* Valentine J. Burroughs, Randall W. Maxey, Lavera M. Crawley, and Richard A. Levy, *Cultural and Genetic Diversity in America: The Need for Individualized Pharmaceutical Treatment* (National Pharmaceutical Council and National Medical Association, November 2002), p. 5, <http://www.npcnow.org/resources/PDFs/CulturalFINAL.pdf> (accessed 5 February 2007).

ables as age, gender, and genetic background. Current scientific limitations, which we are working hard to overcome, cause us to continue to develop and prescribe drugs according to the traditional one-size-fits-all approach: A medication is approved, and we tacitly accept that many patients will benefit from it (though dosage may vary), that others will be unresponsive, and that others will react adversely.*

The traditional method includes a major drawback for the emerging majority: Minorities are almost uniformly underrepresented in clinical trials for drug development. The failure to include adequate minority subjects in clinical trials means that while pharmacogenetic research instructs us to anticipate difference, data on drug efficacy, usage, and safety are inadequate to determine the impact of medications on minority patients. The usual practice has been to generalize from the study subjects, who are generally white males, to the rest of the population.

It is in the clinical setting that physicians, through experience, must calibrate what works and what does not for each patient. In pursuit of cost containment, our health-care financing system, without reflection on the needs of individual patients, intervenes and restricts choice. As a consequence, the health of the emerging majority is being sacrificed to achieve short-term financial benefits. The debate over government negotiation of drug prices for Medicare beneficiaries must be understood in this context.

Government Negotiation of Drug Prices

When Congress created a prescription-drug benefit for Medicare beneficiaries, it decided to prohibit the Medicare program from bargaining with pharmaceutical companies to secure lower drug prices. This was a controversial decision, taking responsibility for moderating drug prices away from government and, instead, placing it in the hands of private prescription-drug plans (PDPs).†

Opponents of government price negotiation argued that the “ability of private plans to secure low drug prices is critically important, both to America’s seniors and to taxpayers.”‡ Drug prices set by PDPs significantly affect the premiums

* Felix W. Frueh, “Personalized Medicine: What Is It? How Will It Affect Health Care?” presentation at 11th Annual FDA Science Forum, 26 August 2005, Washington, DC.

† Section 1860D-11, *Social Security Act* (42 USC 1395w-111), http://www.ssa.gov/OP_Home/ssact/title18/1860D11.htm (accessed 13 February 2007).

‡ Families USA, *Big Dollars, Little Sense: Rising Medicare Prescription Drug Prices*, Families USA Publication 06-104 (Washington: Families USA, June 2006), p. 1, <http://www.familiesusa.org/assets/pdfs/Big-Dollars-Little-Sense.pdf> (accessed 5 February 2007).

and the overall out-of-pocket costs that beneficiaries end up paying. These drug prices also have a direct effect on the burden borne by taxpayers, who pay approximately three-fourths of the costs of the Part D program.

Underlying the controversy is the assumption that lower drug prices mean greater access to these therapeutics. One year after the implementation of Part D, the House of Representatives has passed the Medicare Prescription Drug Price Negotiation Act of 2007 (HR 4)—legislation directing the secretary of the Department of Health and Human Services (HHS) to “negotiate with pharmaceutical manufacturers the prices (including discounts, rebates, and other price concessions) that may be charged to PDP sponsors and [Medicare Advantage] organizations for covered part D drugs for part D eligible individuals who are enrolled under a prescription drug plan or under [a Medicare Advantage Prescription Drug] plan.”*

Since HR 4 charges the HHS secretary with negotiating discounts, rebates, and price concessions, it is difficult to understand how the secretary can achieve those objectives effectively *without* the ability to decide how a drug will be covered (what kind of formulary treatment it may receive). This suggests that mandatory government negotiation could have the secretary replacing PDPs in determining all the terms of coverage for every drug: whether it is listed on a formulary and, if so, on which tier, at which co-payment amount, and subject to which utilization controls (such as prior authorization). Unless the secretary is willing and able to decide which drugs are covered and which are not—and on what terms—there will be little that either the secretary or the manufacturers can do to negotiate. Without real negotiating power, Congress would be directing the secretary to perform a null act. With real negotiating power, Congress would be directing the secretary to establish formularies and set price structures.

Restrictive Formularies and Minority Health

This world of restrictive formularies and preferred-drug lists (PDLs) poses many risks for minority Medicare beneficiaries. Historically these cost-containment tools have ignored the widely recognized fact that because of underrepresentation of minorities in clinical trials, we have very little understanding about the efficacy and safety of drugs that are routinely given to minority patients. Physicians need latitude to determine optimal care for these patients. The record sug-

* *Medicare Prescription Drug Price Negotiation Act of 2007*, HR 4, 110th Cong. 1st sess., http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:h4eh.txt.pdf (accessed 5 February 2007).

gests that even when the special needs of the groups constituting the emerging majority are identified, governments (both federal and state) will put cost containment over the interests of disadvantaged populations.

Given this country's history of drug development, in which drug therapeutics have been normed to the majority population, it is reasonable to assume that reducing incentives to innovate will slow progress toward a health system that is more responsive to the needs of the emerging majority. Pioneering companies need encouragement to diversify their study populations. Living in the past—with one-size-fits-all health policies that ignore minority health—will leave us ill prepared for our future. We need a twenty-first-century health system that is capable of providing quality health care to every member of the American mosaic.

The implications for the emerging majority include even more immediate consequences. Under the current system, with private-sector pharmacy benefit managers negotiating drug prices, formularies and PDLs exist, but beneficiaries have choices. Looking at their own medical needs, beneficiaries can choose among various pharmacy benefit managers. Government negotiation of drug prices would eliminate those choices, and the absence of choices would limit physicians' ability to prescribe appropriate therapy to minority patients. Because of variations in the metabolism of drugs, minority patients would be required to fail on drugs that are listed on the government PDL before prescribers could request authorization for more effective therapy. Minority patients might even find that they must produce a higher co-payment or even pay the entire cost out of pocket in order to obtain medicines that do not make the PDL.

Conclusion

Population changes will require fundamental changes in our health system. Health plans will need to anticipate that their member base will become more diverse and that this diversity could bring with it differences in disease-risk profiles and treatment modalities. Pioneering drug companies will have to determine whether to continue relying on the traditional method of developing medications to answer the requisite safety and efficacy questions when current minorities become the collective majority. As it moves to manage costs and set standards for quality, government will have to remember its responsibility to the larger American community lest it institute policies that leave us ill prepared for our future.

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Given the time that it takes to bring innovation to this system, it is quite possible that as the population tipping point approaches and minorities emerge as the majority in the American workforce, they will be receiving care from a system that has a history of providing them disparate care. The tendency among policy makers to consider health policy as if our society were monolithic is brought into stark relief by the debate over legislation to require government to negotiate drug prices for Medicare beneficiaries.

Medicare influences the rest of the health-care system. Its leverage as the largest U.S. purchaser and regulator of health care means that it can be a force in promoting minority health. Medicare provides health coverage to 43 million aged and disabled people, of whom one in five is nonwhite or Hispanic. Its reimbursement and coverage policies (including reimbursement for new medical technologies) are imitated by private insurers.

Medicare also has been instrumental in moving the health-care system toward pay for performance and an electronic payment system. In its regulatory role, Medicare influences the safety and quality of care directly, through its conditions of participation for most institutional providers, and indirectly, through its influence on the standards of private accrediting organizations.² A recent study has estimated that Medicare will buy 60 percent of all drugs purchased in the United States.³

How Medicare reimburses drug manufacturers for their products will have far-reaching implications for the American health system. A review of positions taken in the debate over price negotiation quickly reveals that it has primarily been a mechanistic discussion about the manipulation of drug prices, with some skirmishing about whether government's ability to encourage the use of particular drugs under Medicare Part D will necessarily restrict beneficiaries' access

to other drugs. Hardly mentioned are the clinical consequences that these restrictions might have for the quality of care that beneficiaries receive. Occasionally it also is observed that establishment of prices on the basis of government negotiation might undermine innovation as drug manufacturers curtail research in response to falling prices.

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ignored. These differences must be taken into account in the design of cost-management policies, such as pricing, formulary management, therapeutic drug substitution, and step-care protocols. It also must be recognized that we need policies that encourage pioneers in drug development to be more responsive to the needs of a diverse American community. We must discard anachronistic policies of the twentieth century and consider twenty-first-century solutions to twenty-first-century problems.

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Variations in Drug Metabolism

In 1892, the Canadian physician Sir William Osler observed that “if it were not for the great variability among individuals, medicine might as well be a science, not an art.” There is a tendency among some legislators and policy makers to ignore human variability and to assume that medicine is a science. When they speak of drugs, there is an assumption that these therapeutic agents work identically and equally well in all patients.

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side effects. For example, a recent study published by the National Pharmaceutical Council and the National Medical Association found that black patients differ significantly from white patients in their responses to beta-blockers, angiotensin-converting enzyme (ACE) inhibitors, and diuretics used either alone or in combination for the treatment of high blood pressure. The study also found: “Some populations of Chinese are considerably more sensitive than whites to the effects of the beta-blocker propranolol on heart rate and blood pressure. African Americans and Chinese Americans metabolize nicotine more slowly than do whites, and genetic variations associated with slower nicotine metabolism are more common in some Asian populations.”⁴ Certain Asian groups are more likely than some whites to require lower dosages of a variety of drugs used to treat mental illness, including lithium, antidepressants, and antipsychotics.

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Opponents of government price negotiation argued that the “ability of private plans to secure low drug prices is critically important, both to America’s seniors and to taxpayers.”⁷ Drug prices set by PDPs significantly affect the premiums and the overall out-of-pocket costs that beneficiaries end up paying. These drug prices also have a direct effect on the burden borne by taxpayers, who pay approximately three-fourths of the costs of the Part D program.

Underlying the controversy is the assumption that lower drug prices mean greater access to these therapeutics. Advocates of government price negotiation frequently compare Medicare Part D drug prices with those paid by the Department of Veterans Affairs (VA) and Medicaid. They argue that the VA and Medicaid have been able to achieve lower prices than those negotiated by PDPs for Medicare. They contend that “negotiating with the purchasing power of 43 million Medicare beneficiaries behind you would result in lower drug prices.”⁸ One year after the implementation of Part D, the House of Representatives has passed the Medicare Prescription

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The Congressional Budget Office has estimated that HR 4 “would have a negligible effect on federal spending because we anticipate that the Secretary would be unable to negotiate prices across the broad range of covered Part D drugs that are more favorable than those obtained by PDPs under current law.”¹⁰ It has reached this

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determination because “the bill would prohibit the Secretary from requiring a particular formulary,” and without the authority to establish a formulary, the “Secretary

would not be able to encourage the use of particular drugs by Part D beneficiaries, and as a result would lack the leverage to obtain significant discounts in his negotiations with drug manufacturers.”¹¹

The Congressional Budget Office’s reading of the legislation is rather narrow. The language does not preclude the HHS secretary from seeking to derive authority to establish a “particular formulary” from any other section of HR 4 or the other provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.¹² It also may not bar the secretary from establishing multiple national formularies (as opposed to a single or “particular” formulary), “endorsing” a formulary, or (taking a leaf from the Medicaid program) establishing one or more preferred-drug lists (PDLs). Drugs on PDLs receive more favorable administrative treatment than unlisted drugs, which are often subject to authorization and other administrative hurdles prior to prescription and administration.

Perhaps more fundamentally, it is difficult to understand how the HHS secretary can engage in

meaningful negotiations with pharmaceutical manufacturers without the ability to exert substantial influence on the creation of a particular formulary. In the current market, insurers negotiate with prescription-drug manufacturers by offering better placement on their formularies in exchange for price concessions. Manufacturers understand that if their drugs are not listed on an insurer's formulary, they will provide less of their medicines to the insured patients. Drugs that have "preferred" status on an insurer's formulary and are not subject to utilization restrictions, such as prior authorization, are more likely to be prescribed by physicians seeking to direct patients to efficacious and cost-effective treatment. Therefore, insurers bargain with manufacturers, seeking to exchange better (less restricted) formulary positions for lower prices, in the form of discounts or rebates or both.

Since HR 4 charges the HHS secretary with negotiating discounts, rebates, and price concessions, it is difficult to understand how the secretary can achieve those objectives effectively *without* the ability to decide how a drug will be covered (what kind of formulary treatment it may receive). This suggests that mandatory government negotiation could have the secretary replacing PDPs in determining all the terms of coverage for every drug: whether it is listed on a formulary and, if so, on which tier, at which co-payment amount, and subject to which utilization controls (such as prior authorization). Unless the secretary is willing and able to decide which drugs are covered and which are not—and on what terms—there will be little that either the secretary or the manufacturers can do to negotiate. Without real negotiating power, Congress would be directing the secretary to perform a null act. With real negotiating power, Congress would be directing the secretary to establish formularies and set price structures.

Restrictive Formularies and Minority Health

This world of restrictive formularies and PDLs poses many risks for minority Medicare beneficiaries. Historically these cost-containment tools have ignored the widely recognized fact that because of underrepresentation of minorities in clinical trials, we have very little understanding about the efficacy and safety of drugs that are routinely given to minority patients. Physicians need latitude to determine optimal care for these patients. The record suggests that even when the special needs of the groups constituting the emerging majority are identified, governments (both federal and state) will put cost containment over the interests of disadvantaged populations.

According to a survey by the Food and Drug Administration (FDA), blacks have participated in trials to a greater extent than other minorities; however, their participation has steadily declined, from 12 percent in 1995 to 6 percent in 1999.¹³ Researchers recently examined data on participants in National Cancer Institute (NCI) trials for breast, colorectal, lung, and prostate cancers conducted between 2000 and 2002. Comparing the demographics of participants enrolled in those trials with those of participants in similar NCI trials conducted between 1996 and 1998, they found that in 1996, blacks (who constitute 13 percent of the U.S. population) represented 11 percent of all cancer-trial participants, but by 2002 that number had dropped to just 7.9 percent; Hispanics (9.1 percent of the U.S. population) made up just 3 percent of participants in clinical trials in 2002—down from 3.7 percent in 1996.¹⁴ The editors of the *New England Journal of Medicine* have observed that "minority groups are underrepresented in most clinical trials. Often, there are insufficient data to assess the effectiveness or safety of new drugs in members of minority groups, especially blacks."¹⁵

Minorities' participation in clinical trials is poor even when these groups are at greater risk. In 2005, about two-thirds of the people in the

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United States living with HIV/AIDS were minorities.¹⁶ Pharmaceutical companies, as part of their efforts to obtain licensing approval, perform most trials of anti-HIV drugs. A recent analysis of data from the HIV Cost and Services Utilization Study found that “black race and Hispanic or ‘other’ ethnic background negatively influenced access to [HIV] clinical trials” and that pharmaceutical companies avoid “recruiting marginalized populations (such as members of minority groups, substance abusers, or homeless persons) to clinical trials because they believe that poor compliance is common in these groups.”¹⁷

The underrepresentation of minorities in clinical trials has serious implications. Clinical trials form the basis for the labeling that a successful drug obtains from the FDA. The FDA-approved label contains efficacy, safety, and usage information. Failure to include adequate minority representation in clinical trials means that there are no reliable efficacy, usage, and safety data to guide the use of most medications in minority patients. The usual practice is to generalize from the unrepresentative populations that are to be found in most clinical trials, and thus minority patients are provided with therapies that often have limited bases in science.

Clinical trials also inform clinical guidelines and quality measures for the treatment of various diseases. Unfortunately, the general absence of minority populations from clinical trials means that those guidelines and quality measures are frequently silent about their value for managing minority patients, or the more conscientious authors must warn of the clinical limitations of their guidelines when they are applied to minorities.

Obviously, policies must be implemented that encourage greater diversity in drug clinical trials. In the absence of more comprehensive clinical trials, great caution should be exercised in using restrictive formularies as cost-containment devices, because they can adversely affect minority health. There are some regulations and guidelines in place that should ensure minorities’ access to needed medications, but when we look at the

three major government health-care programs (VA, Medicaid, and Medicare), which are more sensitive to public scrutiny, we find that regulations, guidelines, and safety-net care for vulnerable populations are frequently ignored and many patients’ lives are put at risk. Government agencies seem more sensitive to costs, at the expense of their fiduciary obligation to protect their beneficiaries’ lives. They wrestle with this inherent conflict of interest—cost containment versus patient needs—and it would appear that internal review processes are not adequately deployed to prevent short-term business considerations from taking precedence over quality of care.

Controversy over recent months has made us particularly aware of one example of how these government agencies have loosely interpreted regulations to keep a specific medication off their preferred-drug lists. This medication, BiDil, provides unique benefits to black patients living with heart failure. It is instructive to review the process of inclusion and exclusion as it relates to this medication. What emerges from this review is that solid science and clear regulations do not guarantee implementation: Access to this lifesaving therapy remains in doubt.

Central to the persistent and occasionally vitriolic controversy over BiDil is the fact that its scientifically conclusive clinical trial was conducted with black subjects only. Trials that have excluded minorities have excited no such controversy, and government agencies appear willing to rely on physicians’ judgment in the clinical setting. BiDil remains excluded from a significant number of PDLs, and black patients and their providers are subjected to bureaucratic barriers, such as appeals and prior authorizations, despite the medication’s proven efficacy in this group.

Veterans Affairs Department, Minority Health, and Formulary Management

A recent communication from the NAACP to the Centers for Medicare & Medicaid Services (CMS) discusses the development and implications of restrictions on formularies

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and access to quality therapy for America's emerging majority, as evidenced by the VA's use of its formulary as a cost-containment tool to withhold BiDil from black veterans.¹⁸ Best practices in formulary management place a drug in a less preferred position only when that drug has a therapeutic equivalent that can be obtained less expensively. A therapeutic equivalent can be either a branded (still under patent protection) or a generic drug.

In the United States, the FDA regulates trial and approval of new drugs as well as of generics equivalent to existing drugs. Before the FDA can approve a drug as a generic, the patent for the existing, or branded, drug must expire. The manufacturer of the generic drug must then demonstrate therapeutic equivalence to the branded drug. A generic drug is chemically identical to its brand-name counterpart, with the same therapeutic effect and the same risk-benefit profile. To be approved by the FDA, a generic drug must contain the same amount(s) of the same active ingredient(s) as the brand-name product. The generic drug must also be the same strength, must be available in the same dosage, must have the same route of administration, and must have essentially the same labeling as the brand-name drug.

In June 2005, the FDA approved BiDil as a new drug for the treatment of heart failure in African Americans. One novel aspect of this new product was that it was a fixed-dose combination derived from two drugs—isosorbide dinitrate (ISDN) and hydralazine hydrochloride (HYD)—that already had been approved for very different clinical reasons. Although the FDA has ruled that the older, generic compounds administered separately are not equivalent to BiDil, some managers of government formularies persist in maintaining that the two generic drugs can achieve the same patient outcome as BiDil. This belief informs their decisions either to refuse to reimburse for BiDil or to restrict patient access to the medication through formulary management protocols.

Substitution of ISDN and HYD separately, however, poses a variety of challenges in the clinical setting. Physicians who service beneficiaries under these formularies evidently have not been able to overcome these challenges; it appears that they have been both unable to offer their patients BiDil and unwilling to prescribe the two drugs separately.

Heart failure is a significant problem for African Americans in part because the disease in this population has largely resisted advances in the standard treatment, which has expanded in recent years from digoxin and diuretics to include ACE inhibitors/angiotensin II receptor blockers, beta-blockers, and aldosterone antagonists. These drugs, particularly the ACE inhibitors, are not as effective in African Americans as in others. African Americans' resistance to standard treatment prompted research into the problem, which eventually led to FDA approval of BiDil.

In 2005 the American College of Cardiology (ACC)/American Heart Association (AHA) Task Force on Practice Guidelines released the ACC/AHA Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult, which cites the African-American Heart Failure Trial (A-HeFT)

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findings regarding “the adjunctive use of a proprietary formulation of isosorbide dinitrate and hydralazine” and states that “the addition of isosorbide dinitrate and hydralazine to a standard medical regimen for [heart failure], including [ACE inhibitors] and beta-blockers, is reasonable and can be effective in blacks with [New York Heart Association] functional class III or IV [heart failure].”¹⁹ In 2006, the Heart Failure Society of America (HFSA) issued an updated Comprehensive Heart Failure Practice Guideline, stating, “A strong recommendation now exists for the addition of the fixed combination of isosorbide dinitrate and hydralazine to the standard medical regimen for African Americans with [heart failure].”²⁰

In 2006 the VA decided to restrict access to this lifesaving therapy. The VA documented its

decision to limit approval of BiDil in its formulary in a National Formulary Review.²¹ The VA review assembles largely unrelated data for an analysis that

- Draws spurious conclusions.
- Usurps the FDA and asserts that there are generic drugs equivalent to BiDil,
- Sets aside the findings of A-HeFT and the cost-effectiveness study,
- Ignores the ACC/AHA and the HFSA guidelines for the management of heart failure in blacks, and
- Settles on a therapy that it conceives to be less costly, recommending that black veterans with heart failure be placed on a nitrate and HYD prescribed separately (dosage and frequency unspecified) until they fail to adhere to the medication regimen.

The review ascribes failure to noncompliance because of the pill load, but it does not acknowledge that failure may very well mean death because the patient is not on optimal therapy. The VA review exhibits a reckless disregard for the lives of black veterans living with heart failure, and a full investigation is urgently necessary to determine if this study has in any way limited the ability of black patients in the VA system to gain access to ISDN/HYD therapy.

Medicaid Formularies and Minority Health

The VA is not the only government agency that attempts to control costs by restricting patients' access to medications. Medicaid is a jointly funded federal and state health-insurance program for certain low-income and medically needy persons. Prescription-drug costs are among the largest and fastest-growing Medicaid expenditures, totaling more than \$34 billion in fiscal year 2003. These rising costs have motivated states to use the various cost and utilization controls available to them. Strategies employed by the states include aggressive use of generics, development of PDLs, and use of prior authori-

zations. Each of these approaches raises serious concerns about its impact on minority health.

CMS, the agency to which Congress has assigned oversight of state Medicaid programs, has encouraged substitution of generic drugs for brand-name equivalents as a safe and effective way for states to increase utilization of generic drugs and to reduce costs. Generic drugs are, on average, 63 percent less expensive than brand-name drugs.²² Many states have implemented policies to encourage generic substitution in their Medicaid programs.

An HHS inspector general's report found that 54 percent of all drugs dispensed by state Medicaid programs were generics and that generics were dispensed 89 percent of the time when generic substitutes were available.²³ These findings clearly indicate that when a patient has a condition that can be treated with various drugs (and the options include branded and generic drugs), the patient is usually placed on the generic drug. Generics tend to be older medications, tested in clinical trials wherein minorities were underrepresented. The physician's ability to practice the art of medicine is limited by cost controls, and the patient must fail on the generic before the physician can seek permission to put the patient on a newer, branded product that may be more effective.

The HHS inspector general's report also found that approximately 41 percent of prescriptions written for Medicaid patients were for drugs that had no generic substitutes.²⁴ In an attempt to control the cost of nongeneric drugs, at least thirty-eight states have resorted to the use of PDLs. Medicaid law limits a state's ability to restrict access to care, which is a critical protection, given the vulnerable population the program serves.²⁵

To protect patients' access to medically necessary drugs, the Medicaid statute does not permit hard formularies. With few exceptions, section 1902(a)(54) of the Social Security Act requires states to cover all approved drugs

manufactured by companies that have signed a federal drug rebate agreement with the secretary of HHS. Generally, a Medicaid PDL is a formu-

The VA review exhibits a reckless disregard for the lives of black veterans living with heart failure.

lary that comprises drugs for which the program agrees to provide reimbursement without prior authorization. A prescriber or pharmacist must obtain permission from the state before a drug that is not on the list is dispensed. By using prior authorization as the tool by which it enforces the PDL, the state creates a procedural barrier to access to nonpreferred medications. PDLs are also used as leverage in price negotiations, given that states often request supplemental rebates from manufacturers to lift prior-authorization requirements for nonpreferred drugs.

An authorized committee appointed by the governor or a state drug-utilization review board must establish Medicaid PDLs, yet it is still possible for the board or the committee to get it wrong. In the case of BiDil, for example, Medicaid review boards in Georgia and Illinois concluded that ISDN and HYD taken separately were generic equivalents to BiDil. They reached this conclusion even though the FDA has not approved a generic equivalent to BiDil, the labeling information for ISDN and that for HYD are different from the labeling information for BiDil, there are no comparable doses of ISDN and HYD, and the two drugs are administered differently. In short, these states have violated federal regulations so far with impunity, putting lives of black Medicaid patients with heart failure at risk. Their decisions underscore the lack of uniformity in the Medicaid system, the uneven federal oversight, and the tendency to prioritize cost containment over patient health.

There is evidence that PDLs can hinder Medicaid beneficiaries' access to medications, regardless of how conscientious states may be in ensuring that they are using the best possible data to construct their PDLs. Access restrictions include relatively strict lists, long wait or response times for authorization, and physicians or pharmacists who may feel overburdened and thus less able or inclined to pursue authorization. A recent study suggests that there are "unintended consequences of PDL implementation in the form of increases

in hospitalizations and office visit expenses for patients subject to PDL restrictions."²⁶

Virtually nothing is known about the effects of prior authorization on individual beneficiaries' access to appropriate, medically necessary medications.²⁷ Whatever the ill effects of access restrictions, they fall disproportionately on America's emerging majority.²⁸ Current Medicaid access restrictions—and, perhaps, future Medicare access restrictions—may pose significant obstacles for the resolution of the racial and ethnic health disparities that plague our country.

A recent nationwide survey of nearly 1,000 black elected officials conducted by the Joint Center for Political and Economic Studies revealed that they are quite concerned about the potential effects on their constituents of Medicaid restrictions on drug access, with 70 percent believing that such restrictions would make patient health worse.²⁹ A Congressional Black Caucus Foundation report acknowledges that the types of drugs offered through a formulary are very important for African Americans, because the level of responsiveness

to specific drugs can vary significantly based on racial and ethnic categories.³⁰

Health outcomes and the quality of care for African Americans could be severely compromised by formulary restrictions. It is incumbent upon policy

makers to understand the consequences of these restrictions for all of the nation's people.

Medicare

Medicare Part D differs from other federal and state drug programs, which mandate specific price discounts. Instead, private-sector pharmacy benefit managers—including such well-established firms as Medco, Blue Cross, and Aetna—negotiate with drug companies to set prices and formularies for enrolled patients. Policy makers supporting HR 4 want to use the purchasing power of the federal government to force prices below those that would be negotiated by the private sector. To achieve this goal, federal negotia-

Current Medicaid access restrictions—and, perhaps, future Medicare access restrictions—may pose significant obstacles for the resolution of the racial and ethnic health disparities that plague our country.

tors would need the power to encourage the use of particular drugs by Part D beneficiaries while they restrict access to other medications. The end product of their efforts would be some sort of PDL or formulary.

This greater willingness of federal officials to exclude drugs from formularies would lower drug prices below those that otherwise would be set by the market. This, in turn, would reduce incentives for the capital market to invest in the research and development of new medicines. It is likely that in the short run, federal price negotiations would allow some consumers to receive medicines at lower prices, or, alternatively, would yield savings for federal taxpayers. The longer-term human costs of government price negotiation, however, are likely to be large and adverse. In addition to cost reductions, this policy change portends other ancillary effects. For example, the cumulative decline in investment in research and development could yield a loss of about 200 new medicines by 2025.³¹

Given this country's history of drug development, in which drug therapeutics have been normed to the majority population, it is reasonable to assume that reducing incentives to innovate will slow progress toward a health system that is more responsive to the needs of the emerging majority. Pioneering companies need encouragement to diversify their study populations. *Living in the past—with one-size-fits-all health policies that ignore minority health—will leave us ill prepared for our future.* We need a twenty-first-century health system that is capable of providing quality health care to every member of the American mosaic.

The implications for the emerging majority include even more immediate consequences.

Under the current system, with private-sector pharmacy benefit managers negotiating drug prices, formularies and PDLs exist, but beneficiaries have choices. Looking at their own medical needs, beneficiaries can choose among various pharmacy benefit managers. Government negotiation of drug prices would eliminate those choices, and the absence of choices would limit physicians' ability to prescribe appropriate therapy to minority patients. Because of variations in the metabolism of drugs, minority patients would be required to fail on drugs that are listed on the government PDL before prescribers could request authorization for more effective therapy. Minority patients might even find that they must produce a higher co-payment or even pay the entire cost out of pocket in order to obtain medicines that do not make the PDL.

Living in the past—with one-size-fits-all health policies that ignore minority health—will leave us ill prepared for our future.

Conclusion

Population changes will require fundamental changes in our health system. Health plans will need to anticipate that their member base will become more diverse and that this diversity could bring with it differences in disease-risk profiles and treatment modalities. Pioneering drug companies will have to determine whether to continue relying on the traditional method of developing medications to answer the requisite safety and efficacy questions when current minorities become the collective majority. As it moves to manage costs and set standards for quality, government will have to remember its responsibility to the larger American community lest it institute policies that leave us ill prepared for our future.

Notes

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