NIHCM’s Report on Pharmaceutical Innovation: Fact vs. Fiction
A Preliminary Report by PhRMA
June 11, 2002

On Tuesday, May 28, 2002, the National Institute for Health Care Management (NIHCM) issued a report, “Changing Patterns of Pharmaceutical Innovation,” purporting to demonstrate that the pharmaceutical industry is less innovative now than it has been in the past. Newspapers around the country reported these results. Unfortunately, while NIHCM insists that it conducts “objective” research, it misinterpreted the facts regarding pharmaceutical innovation and the role of pharmaceuticals in quality health care.

NIHCM’s report never discloses its sponsorship. Eleven of its twelve Board members are CEOs of Blue Cross and Blue Shield plans. This is a material fact that should be disclosed to readers of the report. Even a superficial review of the NIHCM report shows that the biases of NIHCM’s membership, governance and funding substitute for meaningful analysis. NIHCM pulled the wool over your eyes. Here’s how:

I. Shortcomings in Recent NIHCM Report, “Changing Patterns of Innovation.”

NIHCM Arbitrarily Excludes All Vaccines and Biotech Drugs From its Purported Objective Analysis

NIHCM Quote: “This report characterizes the level of innovation of all the new branded medicines that entered the U.S. market from 1989 to 2000, excluding vaccines and other biologics products.”

REALITY:

NIHCM identified 153 drugs that it labels “highly innovative.” Its analysis focuses primarily on these drugs. At the same time, NIHCM arbitrarily excludes through brief references in the text and a footnote all vaccines and other biologic products from its report. NIHCM buries in footnote number 3 of the Introduction an admission that by doing so it eliminates more than 130 new medicines approved by FDA during the report period. This exclusion, by itself, undermines the entire premise and “analysis” of the report. It is, of course, easy for NIHCM to report any results supporting a conclusion it desires to produce by arbitrarily excluding large numbers of innovative medicines from all of the data it presents.

It is impossible to discuss pharmaceutical innovation fairly without referencing one of the most important and promising areas of pharmaceutical research and development (R&D) –production of complex, large molecule drugs derived from biological material. By excluding biotech drugs and vaccines, the report did not count drugs such as Herceptin, which is a remarkable breakthrough treatment for breast cancer. Among the other medicines excluded was Enbrel, a medicine to treat the debilitating effects of rheumatoid arthritis. With these, and many other,
exclusions, the study incompletely and inaccurately portrays pharmaceutical innovation.

Among the vaccines and biotechnology drugs excluded from NIHCM’s report are:

- ReoPro – A monoclonal antibody for treatment of complications accompanying angioplasty.
- Havrix – First Hepatitis A vaccine.
- Varivax – First chicken pox vaccine.
- RespiGAM – First biologic to aid in the prevention of respiratory syncytial virus in children under 24 months of age.
- BeneFIX – First recombinant clotting factor for treatment of hemophilia B.
- Neumega – First biologic drug that promotes production of body’s platelet supply in cancer patients undergoing chemotherapy.
- Regranex – First prescription biologic to stimulate the body to grow new tissue to diabetic ulcers.
- Rituxan – First monoclonal antibody approved for therapeutic use in cancer.
- Zenapax – First monoclonal antibody to help prevent kidney transplant rejection.
- Herceptin – A monoclonal antibody for the treatment of breast cancer.
- Remicade – A monoclonal antibody for the treatment of Crohn’s disease.
- Simulect – A monoclonal antibody for prevention of acute rejection episodes in kidney transplant patients.
- Prevnar – A vaccine for protection against pneumococcal disease in infants and children.
- Synagis – First monoclonal antibody for the treatment of respiratory syncytial virus (RSV).
• Ontak – A biologic for treatment of persistent or recurrent cutaneous T-cell lymphoma.

• PEG-Intron – Treatment of chronic Hepatitis C.

• Xigris – Monoclonal antibody for the treatment of severe sepsis.

**NIHCM Misuses FDA’s Priority Review Classification System**

**NIHCM Quote:** “From 1989 to 2000, the FDA gave a priority review to 24% of NDAs, which appeared to provide clinical improvement over the products available at the time of the application. It assigned the remaining 76% to the standard review track, indicating that these drugs did not appear to provide significant clinical improvement over marketed products in of the four recognized ways mentioned above. Using the FDA characterizations of NDAs based on chemical type and therapeutic potential, it is possible to rank all new drugs from most to least innovative.”

**REALITY:**

NIHCM’s analysis centers on counting the number of medicines (exclusive of vaccines and biologics) accorded “priority” review by the FDA compared to those drugs receiving “standard” review and suggesting that only those drugs receiving priority review status represent true innovation or clinical value for patients. FDA’s Manual of Policies and Procedures (MAPP) notes that priority designation is assigned to products with the potential for providing significant preventive or diagnostic therapeutic advance as compared to standard applications. However, NIHCM—which states that it offers “objective” analysis—never tells the reader that the FDA’s Manual of Policies and Procedures also states that “The priority determination does not take into consideration any information or estimate of price and is based on conditions and information available at the time the application is filed. It is not intended to predict a drug’s ultimate value or its eventual place in the market.” (MAPP 6020.3 – Priority Review Policy, italics added).1

“Priority review” is an FDA management tool—it should not be surprising that only a limited number of applications are granted this status. If priority were routinely granted, the concept would lose its meaning as a management tool. Thus, just because an application is subjected to a standard review does not mean it is not an important innovation or valuable addition to physician’s treatment options. It is noteworthy that the NIHCM report cites this FDA Manual but never discloses or discusses this qualification. Moreover, as experience referenced elsewhere in this report demonstrates, many medicines not accorded priority review offer significant clinical benefit to patients.

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1 MAPP 6020.3 is available at the FDA website, [www.fda.gov](http://www.fda.gov).
Additionally, while NIHCM proclaims that “standard rated medicines are those that the FDA views as providing no significant improvement over marketed products,” it fails to inform the reader that, according to the FDA’s annual Report to the Nation: Improving Public Health Through Human Drugs for years 1999, 2000 and 2001, there were many drugs that the FDA identified as “Notable new drug approvals.” These included approvals that benefited people with rare disorders, cancer, diabetes, HIV infection, heart disease, disorders of the circulatory and nervous systems, and other disorders. The list of notable new drugs published by the FDA included both priority-reviewed drugs and standard-reviewed drugs.

Below are drugs that the FDA considered “notable new drug approvals” during 1999-2001 but that were not “priority-reviewed” drugs:

**Notable 2001 Standard Reviewed New Drug Approvals**

- **Natrecor**: Treatment for acute decompensated congestive heart failure. The drug, which was developed with the use of recombinant DNA technology, is a synthetic version of a human hormone that dilates veins and arteries.
- **Geodon**: Drug for the treatment of schizophrenia, a life-long illness that strikes men and women in their late adolescence or early 20s, often with multiple relapses and impaired daily functioning.
- **Reminyl**: For the treatment of mild to moderate Alzheimer’s disease.
- **Invanz**: A long-acting injectable antibiotic for treatment of adults with moderate to severe bacterial infections, including complicated intra-abdominal infections, complicated skin and skin structure infections, community-acquired pneumonia, complicated urinary tract infections and acute pelvic infections.

**Notable 2000 Standard Reviewed New Drug Approvals**

- **Trelstar Depot**: A drug for the palliative treatment of advanced prostate cancer. According to the FDA, “It represents a new alternative for patients with prostate cancer in whom orchiectomy or estrogen administration is not indicated or is unacceptable.”
- **Acova**: An anticoagulant for the prevention or treatment of thrombosis (abnormal blood clotting) associated with heparin-induced thrombocytopenia, a serious immune disorder caused by heparin, a common anticoagulant used to prevent blood clots.
- **Colazal**: A drug for the treatment of mild to moderately active ulcerative colitis, a chronic and debilitating inflammatory disease of the gastrointestinal tract.

**Notable 1999 Standard Reviewed New Drug Approvals**
- **Tequin**: A new type of quinolone antibiotic for treating community-acquired respiratory tract infections such as pneumonia, acute exacerbation of chronic bronchitis and acute sinusitis.
- **Aciphex**: A once-a-day proton pump inhibitor to heal duodenal ulcers and erosive gastroesophageal reflux disease.

**NIHCM Report Ignores Benefits of Standard Review Drugs**

**NIHCM Quote**: “Thus, standard rated medicines are those that the FDA views as providing no significant improvement over marketed products.”

**REALITY:**

Again, while NIHCM claims to be “objective,” it leaves important information out of its report. While paying lip service to the possibility that standard review drugs (which often include drugs that are not the first in a class) offer clinical benefits, its entire analysis is premised on its notion that standard review drugs provide no significant clinical improvement for patients. Additionally, it never meaningfully discusses the value of multiple drugs within a therapeutic class, despite a wealth of data available for it to consider.

One of the most important reasons for having multiple drugs within a therapeutic class is that patients often respond differently to similar drugs and similar drugs may differ in their clinical benefits and side effects. For example, for diseases of the central nervous system, overall response rates are often 50% or less.\(^2\) Patients who fail to respond to one drug will often respond to another drug in the class. Examples of widely used drug classes associated with great variation in patient response are the selective serotonin reuptake inhibitors (SSRIs) and the non-steroidal anti-inflammatory agents (NSAIDs). In patients treated with SSRI agents for depression, 26% of non-responders to fluoxetine did respond to sertraline.\(^3\) Conversely, another study reported that 63% of patients who failed to respond to sertraline did respond to fluoxetine.\(^4\)

The NSAIDs also differ greatly with respect to efficacy and patient tolerance. Often, multiple drugs must be tried before success is achieved. For example, in one two-year study of patients on NSAIDs, 49% of patients were switched to

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another NSAID; 20% were switched two times or more; and 7% received four or more different NSAIDs.  

The currently available beta-blockers offer differences in potency, cardioselectivity, effects on the nervous system, pharmacokinetic properties (which determine appropriateness for patients with impaired kidney or liver function), additional pharmacological benefits, potential for interaction with other drugs, efficacy in specific racial groups, complexity of the dosage regimen and adverse effects profile. The array of differences among these drugs allows for customized treatment for patients. Another clear advantage for having multiple drugs in a therapeutic class is that undesirable side effects in an individual patient often may be avoided by switching to another drug in the class.

There are many examples of drugs assigned by the FDA to “standard” review that were important innovations by being first in a therapeutic category (and note that drugs that are first in a category are not the only drugs that are innovative or that hold significant clinical value for patients; as discussed above, later drugs in a category can add important clinical benefits for many patients). Examples of such drugs that were first in their therapeutic category but accorded a standard review by the FDA and thus counted as non-innovative/lacking in clinical improvement by NIHCM are:

- Cozaar – First in a class of new antihypertensive agents that block angiotensin-II receptors.
- Accolate – First leukotriene receptor antagonist for asthma treatment.
- Elmiron – First oral medication approved for use in interstitial cystitis.
- Remeron – First in a new class of antidepressants.
- Vistide – First in a new class of antivirals called nucleotide analogues for treatment of cytomegalovirus retinitis in AIDS patients.
- Detrol – First medication approved for bladder control in more than 20 years.
- Provigil – First non-amphetamine therapy for narcolepsy approved in 40 years.

• Tasmar – First in a new class of drugs called COMT (catechol-O-methyltransferase) inhibitors for the treatment of Parkinson’s disease.

• Zemplar – First vitamin D analog to be approved for suppression of parathyroid hormone in chronic renal failure.

**NIHCM Ignores New Medicines in Development**

In its report, NIHCM never tells readers about the large number of drugs in late stage clinical trials, or any other stage of development. Many of these drugs are intended to treat conditions for which there currently are few treatments, or treatments with limited success, or to provide improvements to currently available medicines. This information is easily available to NIHCM from PhRMA’s New Medicines in Development series, which describes the pipeline for various populations and diseases. This information can be obtained by NIHCM or any member of the public at PhRMA’s web site, www.phrma.org.

**REALITY:**

**98 New Medicines In Development For AIDS**
- Including 38 antivirals, 15 AIDS-related cancers, 14 vaccines, 8 immunomodulators, 7 anti-infectives, and 6 antifungals.

**400 New Medicines In Development For Cancer**
- Including 68 for lung cancer, the leading cause of cancer death in the U.S; 59 for breast cancer, which strikes one out of every 10 American women; 55 for colon cancer, which has the third highest incidence of any cancer site for American men; 52 for skin cancers including melanoma, the deadliest form, whose incidence has grown 4 percent a year since the 1970s, and 52 for prostate cancer, which kills 37,000 men a year.

**200 New Medicines In Development For Children**
- Including 21 vaccines; 19 for cardiovascular disease; 16 for infectious bacterial diseases; 14 for psychiatric disorders; 13 for cystic fibrosis, a genetic disease that affects 30,000 children and young adults in the U.S; 13 for asthma, the most common chronic disease of childhood that affects 5 million American children and is on the rise; 9 for skin disorders; 8 for genetic disorders; 8 for neurologic disorders, and 7 for AIDS and AIDS-related diseases.

**120 New Medicines In Development For Heart Disease And Stroke**
- Including 18 for stroke; 18 for congestive heart failure; 12 for peripheral vascular disease; 11 for hypertension; 11 for adjunctive therapies; 10 for hyperlipidemia, and 9 for heart attacks.

**176 New Medicines In Development For Neurologic Diseases**
- Including 41 for pain; 34 for brain tumors; 24 for Alzheimer’s disease; 17 for Parkinson’s disease; 16 for multiple sclerosis; 14 for stroke, and 10 for migraine headaches.

**780 New Medicines In Development For Older Americans**
- Including 44 for respiratory/lung disorders, the fourth leading cause of death among the elderly; 23 for diabetes, the sixth leading cause of death among people 65 and older; 22 for rheumatoid arthritis; 21 for Alzheimer’s disease – which afflicts 4 million Americans – and dementias; 20 for depression, which affects about 2 million older adults or about 6 percent of that age group; 19 for gastrointestinal disorders; 18 for pain; 16 for skin conditions; 15 for osteoporosis, which affects 10 million Americans; 14 for bladder/kidney disorders, and 13 for Parkinson’s disease, which affects 1.5 million Americans, including 1 of every 100 people over 60.

**NIHCM Report Claims But Does Not Demonstrate Changing Pattern of Pharmaceutical Innovation**

**NIHCM Quote:** Title of the report is, “Changing Patterns of Pharmaceutical Innovation.”

**REALITY:**

The title of the latest report by NIHCM, “Changing Patterns of Pharmaceutical Innovation,” as well as the content of its report, suggest that pharmaceutical innovation is changing away from “highly innovative drugs – medicines that contain active ingredients and also provide significant clinical improvement,” as NIHCM defines innovative drugs, to less innovative, less risky and less time consuming “standard-rated” medicines.

Despite the assertions in NIHCM’s report, the number of new molecular entities (NMEs), or drugs containing new active ingredients, has remained relatively constant over the past twenty years.

![New Molecular Entity Approvals 1980-2001](source: FDA)
The NIHCM report provides no benchmark to compare the level of innovation of new branded medicines from 1989 to 2000 to previous decades in pharmaceutical history. Moreover, even in NIHCM’s own (flawed) terms, no pattern of declining innovation is evident when we trace priority approvals throughout the 1990s.

**NIHCM Report Ignores Evidence Indicating Multiple NME’s in a Class Does Lead to Price Competition**

NIHCM Quote: “This pattern suggests that when there are several new NME’s [New Molecular Entities] in a therapeutic class, price competition among them is limited.”

**REALITY:**

In its report, NIHCM suggests that having several NMEs in a therapeutic class does not lead to price competition. However, a study by Dr. Joseph A. DiMasi of Tufts University found that new drugs in a class are often priced lower than existing drugs in the class. DiMasi examined the pricing of new entrants to drug classes and subclasses in eight therapeutic categories accounting for half of total retail prescription drug expenditures in 1999. The study found that the majority of new drug entrants he examined were launched at discounts (sometimes substantial) relative to both the class price leader and to the average price in the class. (Of the 20 drugs examined, 13 were priced at discounts of at least 5%--and often at much larger discounts; five were introduced essentially at parity with existing prices; and two entered the market at a premium to the weighted mean price in the class but at a discount relative to the price leader in the class. It is extraordinary that this important research by respected academic researchers on a key topic would not even be mentioned in a report by an organization that describes itself as generating “objective” research, while it states its own opposing conclusion without in-depth analysis.

**Insurers Often Cover Standard Review Drugs And Sometimes Do Not Cover Priority Review Drugs**

Crosswalking California health plan formularies--available at [www.ca.mcodrugs.com](http://www.ca.mcodrugs.com)-- with standard review drugs reveals that these health plans cover many of the standard review drugs that NIHCM deems as providing no significant improvement over marketed products and as raising costs, but do not cover every priority review drug that NIHCM considers innovative. Moreover, plans indicate that they carefully select drugs to include on their formularies. For instance, Blue Cross of California states that “Formulary revision is based on objective evaluation of the efficacy, safety, and value of reviewed medications,” but does not indicate that it gives any consideration to

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whether a drug received a standard or priority review by the FDA. Do these coverage patterns and criteria mean that the NIHCM report is wrong about the clinical value and economics of new medicines, or does it mean that health plans are making the wrong formulary decisions?

**NIHCM Report is Self-Contradictory in its Critique of Pharmaceutical Innovation**

**NIHCM Quote:** “Drug manufacturers patent a wide range of inventions connected with incremental modifications of their products, including minor features such as inert ingredients and the form, color, and scoring of tablets. In some cases, these patents may discourage generic companies from trying to develop a competitive product.”

**REALITY:**

While on the one hand, NIHCM accuses the pharmaceutical industry of attempting to stifle competition, at the same time it criticizes the industry for focusing too much effort on incremental improvements to drugs and follow-on drugs in a class. By definition, however, incrementally improved drugs and later drugs in a class treat the same disease through similar chemical pathways to those already on the market and as such compete with those drugs. It is unreasonable to simultaneously criticize the pharmaceutical industry for stifling competition and for developing medicines that compete with one another. Moreover, different products offer important treatment choices – differing side effects, indications, contraindications, and dosing regimens.

In addition, NIHCM fails to acknowledge that companies develop new formulations for specific patient populations. For instance, many supplemental NDAs (mistakenly counted as NDAs in the NIHCM study) are submitted on new formulations for children. Children may need different, age-appropriate formulations of medicines for accurate and compliant administration. For example, an oral liquid may be needed for young children (sometimes different concentrations for newborns), perhaps chewable tablets for somewhat older children, still unable to swallow pills or capsules.

**NIHCM Report Misleads by Blaming Standard-Rated Medicines for Cost Increases**

**NIHCM Quote:** “New standard-rated medicines – those providing no significant clinical improvement over existing products – accounted for $29.3 billion or 67% of the increase associated with new drugs, and 44% of the total increase in spending.”

**REALITY:**

NIHCM’s analysis seemingly implies that spending would have been lower if new drugs had been confined to “priority” drugs. But this would be true only if all of the patients taking the second or third drug in a class would have gone untreated—particularly in light of the fact that tens of millions of patients remain
untreated for serious illnesses. Additionally, competition among drugs in a class is often the basis for health insurers cost containment techniques, such as according preferred status to one drug over another. With only drug per class, these techniques would not be viable.

NIHCM Report Focuses on Price of New Drugs, Not Their Value to Patients

NIHCM Quote: “In 2000, the average price per prescription varied widely by the age and class of the drug (see Figure 9). Older medications, including a mix of branded and generic drugs, cost much less than products approved in 1995 or later. New priority-rated drugs commanded the highest prices. However, new standard drugs were also significantly more expensive than older medicines.”

REALITY:

Much of the second half of NIHCM’s report focuses on the price implications of the various research categories created by NIHCM. However, the report does not provide any context for this price discussion in regard to benefits conferred by these innovations. The report concludes that new drugs cost more than older drugs, but there is no discussion as to what benefits are derived from these new drugs.

For example, the type of discussion that is omitted from the report is as follows: in one study, health care costs for patients with congestive heart failure (CHF) treated with the original loop diuretic furosemide were compared with costs for patients treated with a newer loop diuretic, torasemide, which is better absorbed. Although torasemide is more expensive, the patients taking it experienced fewer hospitalizations, which translated to a net savings in hospital costs of $536 for CHF admissions and $1027 for all cardiovascular admissions. The authors projected a net annual savings in hospital costs of $700,000 for CHF admissions and $1.3 million for all cardiovascular events if the newer drug was used for all CHF patients at the hospital. This is but one example from a large and growing body of research.

Modifications to Existing Drugs Does Not Preclude Generic Competition on Older Invention Once its Patent Expires, Contrary to NIHCM’s Suggestion

NIHCM Quote: “According to IMS Health, blockbusters accounted for 48% to 80% of the total prescription drug sales of the five largest pharmaceutical firms in 2001. As these drugs approach patent expiration, their manufacturers may be able to thwart generic competition by modifying them.”

REALITY:

According to the NIHCM report, modifying existing older products allows brand name drugs to delay the entry of generic competitors. This is not true. A later patent on a new and improved version of the original invention does not preclude a generic company from copying the old invention once its patent(s) expire. For example, if a brand name company creates a new once-a-day version of a medicine and the U.S. Patent and Trade Office (PTO) grants a patent on the new invention, a generic drug manufacturer is not precluded from making the older version of the drug. By continuing to refine a product, a manufacturer may discover a new use for the drug or a less complicated dosing regimen, both of which benefit the patient. Modifying a drug from four times a day to a once-a-day drug, for example, has been shown to improve compliance. Lack of compliance is a critical problem in achieving efficacious medical care. In addition, the costs of non-compliance are great. According to an article in the Journal of Research Pharmaceutical Economics, 5.5 percent of all hospital admissions are due to non-compliance, which results in $8.5 billion annually in unnecessary hospital expenditures, plus another $17-$25 billion in estimated indirect costs.⁹

In addition, if innovator companies are truly making only small improvements over existing drugs, chances are the new and improved drug will not succeed in the market against the older drug or other competitors in the class. Numerous incentives exist in managed care today to encourage the use of generics and “preferred brand” drugs. These tools used to influence which medications patients receive may include: payment incentives that are linked to prescribing and dispensing patterns; formularies, which typically are structured in part based on financial considerations; variable patient cost-sharing arrangements for medicines, again based in part on financial considerations; therapeutic interchange; and prior authorization.

Conclusion

The NIHCM report fails any reasonable test of objectivity, notwithstanding NIHCM’s declaration that it conducts objective research. From conducting an analysis that excludes vaccines and biologics, to basing that analysis on the flawed premise that standard review drugs provide no significant improvement over marketed products, to failing to note that the FDA’s Manual of Policies and Procedures states that priority review “is not intended to predict a drug’s ultimate value or its eventual place in the market,” the NIHCM report takes every opportunity to develop ceaselessly negative analyses of the pharmaceutical

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industry. This clear agenda should be considered carefully when assessing the credibility of this and future NIHCM reports.

NIHCM claims to focus on health care management. However, its specialty increasingly is producing reports critical of the pharmaceutical industry while virtually ignoring meaningful patient care issues that involve its own industry.

For instance, while NIHCM reports complain about pharmaceutical utilization, it has elected not to accord similar attention to apparent undertreatment of patients in its own member health plans. For example, the California Office of the Patient Advocate issues a health maintenance organization (HMO) report card that includes Blue Cross HMO – CaliforniaCare, which is part of one of the NIHCM member companies. One measure of this report card provides a “quality score on making sure that children, adolescents and adults with asthma get the right medicine.” The measure shows the percentage of each group with asthma having a “prescription for anti-inflammatory medicine to reduce the severity of asthma symptoms and avoid asthma attacks”. Also according to the explanation of the scores posted on the Office of the Patient Advocate’s web site:

Good asthma care means seeing that patients use medicines – called anti-inflammatories – regularly to reduce the effects of asthma including wheezing, coughing and shortness of breath. These medicines are part of the daily efforts of people with asthma to avoid the pain, anxiety or even death that results from asthma.

On this measure of “making sure that children, adolescents and adults get the right medicine,” Blue Cross HMO – CaliforniaCare, received 48% for children, 51% for adolescents, and 58% for adults, on a scale of 0% (worse) to 100% (best). Of course, if and when this underutilization is addressed and many more children,

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10 According to its website, since February 1999, NIHCM has released 7 separate publications on pharmaceuticals. All can fairly be described as critical of the pharmaceutical industry. During the same time period, NIHCM has issued no publications on Medical Necessity, Medicaid, Medicare, Rural Issues, State Health Care Reform and Individual Market Reform—all of which were the topic of reports prior to February 1999. The 16 non-pharmaceutical publications issued since February 1999 include 12 documents on children’s health issues (as noted on its website, NIHCM is under a five-year cooperative agreement with the U.S. Health Resources and Services Administration Maternal Child Health Bureau to produce these documents, most of which are quite brief) and four “Expert Voices” publications, which according to its website are “Essays on Trends, Innovative Ideas and Cutting-Edge Research in Health Care.” The topics of these four essays, which also are brief, were: Paying Doctors, Racial and Ethnic Disparities in the U.S., Chronic Conditions and Evidence-Based Medicine. Other than publications on child health, which NIHCM is under contract to produce, no other single health care issued has garnered as much attention from NIHCM as pharmaceuticals.

11 For a statement of the importance of inhaled corticosteroids, see National Institutes of Health, Expert Panel Report 2, “Guidelines for the Diagnosis and Management of Asthma.” Thus, EPR-2 continues to emphasize that the most effective medications for long-term control are those shown to have anti-inflammatory effects. For example, early interventions with inhaled corticosteroids can improve asthma control and normalize lung function, and preliminary studies suggest that it may prevent irreversible airway injury.”
adolescents and adults get the right asthma medicine, it will show up as an added expense in NIHCM’s reports critical of the pharmaceutical industry.\footnote{12}

Likewise, according to the National Committee for Quality Assurance 2001 Quality Compass, on a national basis, only 51% of adults 46 to 85 years old diagnosed with hypertension (high blood pressure) had their blood pressure controlled consistent with current guidelines from the U.S. Preventive Services Task Force. Effective treatment of high blood pressure, which often requires use of pharmaceuticals, reduces mortality from heart disease, stroke and renal failure.

Also according to the National Committee for Quality Assurance 2001 Quality Compass, approximately 55% of diabetic patients (on a national basis) had not achieved lipid control consistent with current guidelines and approximately 42% of diabetic patients had poor HBA1c control according to current guidelines. Much of the disability from diabetes – amputations, blindness, renal failure and premature death – can be prevented if diabetes is properly managed.

PhRMA looks forward to collaborating with health plans intent on solving these problems. Addressing the epidemic of uncontrolled asthma, diabetes and hypertension would help control health care costs while allowing patients to lead longer, healthier, more productive lives.

\footnote{12 For the California Office of Patient Advocate HMO report card, see \url{www.opa.ca.gov/report_card}. In addition to the asthma measure discussed above, the report card also includes data on controlling diabetes and hypertension, among other measures.}