nwpen

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May 8, 2013

Members of the Pharmacy and Therapeutics Committee:

As advocates for patients with chronic illness in Oregon, we are troubled by the new guidelines being used by the state to restrict access to prescription medicines for the neediest Oregonians. The rules covering treatments of "high cost" and "marginal benefit" are a concerning step away from a science and patient-based approach.

As experience with Oregon's own Medicaid program demonstrates, access to the right treatment has a significantly positive impact on patient health. The National Bureau of Economic Research found those who received Medicaid coverage had "lower out-of-pocket medical expenditures and medical debt (including fewer bills sent to collection), and better self-reported physical and mental health than the control group." The study examined Medicaid access as a whole, but clearly access to the proper treatment and disease management are critical to these positive health results.

Additionally, there are numerous indications that overriding a doctor's preference for medicines is penny-wise and pound-foolish. The Patient Protection and Affordable Care Act specifically recognizes this connection, creating penalties for patients who return to hospital treatment soon after they have been discharged. The authors recognized that a bit of extra attention to manage illness can prevent more serious, and expensive, health problems down the road. The proposed HERC rules fly directly in the face of this commonsense provision.

Finally, many of us are encouraged by the Patient Protection and Affordable Care Act's promise of expanding Medicaid to many who previously went without care. We receive calls daily from those who cannot afford their treatments, desperate for help. Medicaid expansion holds great hope for many who are currently suffering.

Some have criticized that support, however, citing claims that PPACA contains "death panels" that will ration care and undermine the promise of increased access. Many of us have pushed back on those claims. The new HERC rules, frankly, have put us in a difficult position. Implemented in the way currently being discussed, where subjective decisions about "marginal benefit" can determine if large numbers of the poor receive the treatments they need, the proposal sounds a great deal like the warnings of PPACA opponents. These rules put us in the position of choosing between our support for PPACA and advocating for our patients and the care they need.

Providing care to those in need is our mission and all of our organizations live under strict budgets, so we understand financial constraints. We also understand that expanding access cannot mean denying treatment in a way that undermines that promise, using standards that set medical judgment aside in favor of subjective standards. We urge you to abandon this approach and use a science-based assessment of available treatments.

Sincerely,

American Cancer Society/Cancer Action Network

Northwest Patient Education Network

Caring Ambassadors

Molly's Fund

Cascade AIDS Project

Familias en Accion

Folktime

The American Lung Association of the Mountain Pacific

Hemophilia Foundation of Oregon

Cc: Governor Kitzhaber
Members of the Legislature
Health Evidence Review Commission

CITRON Roger A

From: Sumpter, Sue (OSWIM) <Sue.Sumpter@lls.org>
Sent: Monday, May 13, 2013 2:40 PM
To: 'Roger.a.citron@state.or.us'
Subject: High Cost Marginal Value Concerns

As advocates for patients with blood cancers in Oregon, we are concerned by the new guidelines being used by the state to restrict access to prescription medicines for the neediest Oregonians. The rules covering treatments of "high cost" and "marginal benefit" are a concerning step away from a science and patient-based approach.

As experience with Oregon's own Medicaid program demonstrates, access to the right treatment has a significantly positive impact on patient health. The National Bureau of Economic Research found those who received Medicaid coverage had "lower out-of-pocket medical expenditures and medical debt (including fewer bills sent to collection), and better self-reported physical and mental health than the control group." The study examined Medicaid access as a whole, but clearly access to the proper treatment and disease management are critical to these positive health results.

Additionally, there are numerous indications that overriding a doctor's preference for medicines is penny-wise and pound-foolish. The Patient Protection and Affordable Care Act specifically recognizes this connection, creating penalties for patients who return to hospital treatment soon after they have been discharged. The authors recognized that a bit of extra attention to manage illness can prevent more serious, and expensive, health problems down the road. The proposed HERC rules fly directly in the face of this commonsense provision.

Finally, many of us are encouraged by the Patient Protection and Affordable Care Act's promise of expanding Medicaid to many who previously went without care. We receive calls daily from those who cannot afford their treatments, desperate for help. Medicaid expansion holds great hope for many who are currently suffering.

The new HERC rules, implemented in the way currently being discussed, where subjective decisions about "marginal benefit" can determine if large numbers of the poor receive the treatments they need in the position of choosing between our support for PPACA and advocating for our patients and the care they need.

Providing care to those in need is our mission and all of our organizations live under strict budgets, so we understand financial constraints. We also understand that expanding access cannot mean denying treatment in a way that undermines that promise, using standards that set medical judgment aside in favor of subjective standards. We urge you to abandon this approach and use a science-based assessment of available treatments.

Sincerely,

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someday
is today

Written Testimony of the **Caring Ambassadors Program**
Lorren Sandt, Executive Director
P.O. Box 1748
Oregon City, OR 97045

Oregon Drug Use Review/Pharmacy & Therapeutics Committee
May 30, 2013

The Caring Ambassadors Program (CAP) is a national, nonprofit, advocacy organization based in Oregon City, Oregon. We respectfully submit our written testimony regarding "Therapies with Marginal Benefit and High Cost Policy".[1] The Caring Ambassadors Program (CAP) urges the P & T committee to not set up this policy thus ending discrimination based on disease or stage of disease.

Our current healthcare system is not built around prevention. An individual should not be penalized if they are diagnosed at a later stage of disease when, in general, treatments are more costly and less effective. It is the system we have of acute care. Until we have a system of prevention in place, deciding treatment based on cost, or life expectancy, is discrimination. Diseases do not discriminate therefore it is vital that the HERC/P & T committee does not discriminate against any disease state, condition, or expected length of life.

CAP still maintains that the "Therapies with High Cost and Marginal Benefit Policy" violates federal law; the anti-discrimination provision of Patient Protection and Affordable Care Act (PPACA) and the federal Medicaid rebate statute.[2,3]

If the proposed policy is going to continue, CAP proposes a change to the proposed policy subcommittee structure. It currently allows for additional members with a limit of 5 members. We recommend in each instance, you have a disease-specific, knowledgeable patient or patient advocate fill the 5th seat.

Further "marginal or clinically unimportant benefit" needs to be further defined, "marginal benefit" defined by whom? Recently, a Cochrane report question the validity of a sustained viral response in someone with hepatitis C.[4] Would you then conclude that it is of marginal benefit to cure someone of an infectious disease that can cause liver cancer or a liver transplantation? Are you really saving cost? What is the cost of not treating a disease? The emergency room visits from someone dying of liver disease can add up quickly to over a million dollars. The policy may save Oregon taxpayers money in the short-term but we will pay for it in the future with increased hospitalization cost. How will this cost analysis be done and by whom? Good policy is rational and consistent. Application of the HCBM Policy will inevitably be unpredictable and inconsistent.

Thank you for your time and consideration. CAP greatly appreciates the work you and state agencies are doing to reach the goals of the Oregon Health Authority; improved lifelong health, increased accessibility to quality care and affordable care.

Sincerely,

Lorren Sandt

Executive Director

1. OHA/DRU/Pharmacy and Therapeutics Committee HCMB Policy released May 2013
2. Patient Protection and Affordable Care Act, Public Law No. 111-148, section 1302 (2010).
3. Section 1927 of the Social Security Act
4. Interferon for interferon nonresponding and relapsing patients with chronic hepatitis C (Review), The Cochrane Library 2013, Issue 1

OREGON MEDICAL ASSOCIATION

MEMORANDUM

To: Drug Use Review/Pharmacy and Therapeutics Committee

From: Danielle Sobel, OMA Health Policy Specialist

Date: May 30, 2013

Re: Therapies with High Cost and Marginal Benefit (HCMB) Policy

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As a member-based organization whose members are impacted by the decisions of both the HERC and this committee, the OMA has strong reservations regarding the High Cost and Marginal Benefit Policy.

The OMA has followed the HCMB policy discussion closely and understands the need for the creation of a policy as well as a subcommittee. However, after reviewing the policy and constitution of the subcommittee, the OMA is concerned that the policy is written too broadly, lacks review standards and practical application guidelines as well as clinical and advocacy expertise.

The HCMB discussion originated to address principles for cancer treatment at the end of life. These guidelines are simultaneously being rewritten by a HERC workgroup as the P&T Committee is being asked to craft and expand HCMB policy to all applicable drug reviews. The OMA is concerned that too little is known about how these guidelines will be applied in practice. In addition, the practical side of dosing, a drug's efficacy and understanding every clinical exigency are not considered in this broad of a policy. To address these concerns, the OMA recommends the inclusion of an efficient and timely appeals process whereby physicians can demonstrate the efficacy and need for a drug based on the clinical situation and circumstances of the patient who is affected by the guideline. It is nearly impossible to create guidelines that address every clinical situation or use for a particular drug.

The constitution of the subcommittee in the current draft of the HCMB policy is limited by the inclusion of only one physician member with specialty training to the referred drug and lacks broader representation by those groups with knowledge and/or membership impacted by the drug under review. A poorly constituted subcommittee that lacks physician, specialty, advocate and consumer input, can lead to bad outcomes for physicians and their patients, who are often already facing their last months of life.

The subcommittee is only required to have 4 members, with up to 5 optional members that are deemed necessary. How will the committee deem members necessary? The OMA is also concerned about the availability of individual physicians (with expertise related to the referred drug) to serve on the committee. The OMA has received multiple requests from HERC staff to aid in securing expert physician witnesses for their subcommittees. The OMA supports the inclusion of a physician with

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expertise on the committee but also supports a representative of the physician or physician's professional organization or specialty society on the subcommittee. This would allow broader representation that allows for thoughtful consideration of the drug's practical application and impact on patients.

The subcommittee also lacks the interests of advocates and consumer/patient organizations. Given the importance of accounting for as many possible clinical exigencies as possible, giving voice to advocacy and specialty organizations is critical. In addition, patient voice or organizations that represent patients/health care consumers, would help the subcommittee better understand the merits of an individual's case as it relates to a particular drug.

In preparation for today's meeting, I requested feedback from our membership on the HCMB policy. From one of our members, I received a few examples of how a standardized guideline can impact a patient's health. In one of his examples, he shared the experience of a patient with severe chronic graft-versus-host disease (GVHD) who was put on steroids after fracturing her hip. The steroids led to infections twice in her hip replacement as well as diabetes. The physician tried numerous drugs to wean her off the steroids and only had success with Gleevec. Around this time, the patient became eligible for OHP benefits. Due to the prioritized list and approved drugs for OHP beneficiaries, the patient was no longer eligible for Gleevec and was forced to resume steroids. These steroids caused the patient further complications, increased costs for OHP/the state and left the physician without an appeals process to advocate for his patient and request the clinical circumstances be evaluated.

In an example that highlights the practical side of dosing and practicalities of prescribing, two similar, antifungal drugs (Voriconazole and Posaconazole) can have very different applications based on the patient's condition and toxicity profile. Voriconazole cannot be given to a patient who is delirious or experience psychosis while Posaconazole cannot be given to a patient who gastrointenstional tract is not functioning.

Thank you for your time and consideration. The OMA supports the development of this profoundly important policy and at this time, must express strong reservations about the application of this policy outside end of life cancer drugs. The OMA is more than willing to work with the P&T Committee and the HERC to improve the policy and both serve and/or recommend physician experts as this policy is adopted on a broader scale.

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I appear before you today on behalf of the Pharmaceutical Research and Manufacturers of America, PhRMA, to voice the association's strong opposition to these proceedings on "high cost marginal benefit" pharmaceuticals. Contrary to statements to the public, these proceedings are not authorized by law or the waiver, and as such, they are an abuse of the public process and a misuse of official position to serve as little more than podium from which to malign innovative medicines. This is a disservice to the scientists who use their creativity and training to develop medicines to meet unmet medical needs, and it is profoundly disrespectful of the State's poorest and sickest patients, who are held to be less worthy than the conservation of the State's fiscal resources. Although it may not alleviate the suffering of patients and their families, it is an abuse that is not without legal remedies.

Under the Medicaid Law, Prescription Medicines Are Different From Other Care. Regardless of the varying opinions about the morality of the Oregon Health Plan's twenty year-old experiment in rationing health care for the poor based on their medical condition, projected longevity and quality of life, one thing is clear – the rationing experiment did not, and does not apply to prescription medicines. Our country has federal laws that protect Americans from unsafe and ineffective medicines; these laws are implemented and enforced by the Federal Food and Drug Administration. And with the advances in scientific research, we are increasingly learning more about the unique genetic, life history, and physiological factors that make the selection of an appropriate medicine something that must be personally determined for each individual. For innovative medicines there is no such thing as "one size fits all." There is real danger to individuals from using the rationing meat cleaver to restrict the patient-physician choice of medicines. Moreover, in recognition of the fact that innovative medicines can be costly, we have federal laws that provide manufacturer-subsidized discounts to the State to defray the cost of these medicines to low income persons who depend on the Medicaid program operated by OHP, as well as low income persons with Medicare coverage. For all of its existence the Oregon Health Plan has been accepting the rebate funding from manufacturers to defray the cost of pharmaceutical care.

Remedies For Disregard Of The Federal Law. Notwithstanding the law and the subsidy paid by manufacturers to protect low-income patients' access to medically necessary care, in this proceeding, the members of the P&T Committee, in coordination with the HERC, would take it upon themselves to decide that medicines which, based on well-controlled clinical trials are approved by the government as effective for treating specific patients' conditions will not be available to the residents of Oregon who depend on Medicaid payment.

Some key facts for the record:

1. Federal Funding. The OHP rationing experiment depends on federal funding and in fiscal year 2013 OHP was supported by 62.44% federal funds.
    - Such funding is only available if the plan is implemented consistent with the scope of federal approval of the waiver of the rights of Medicaid beneficiaries;
    - If the OHP does not comply with the terms of the waiver and other applicable federal laws, the federal government could withhold its share of funding for the OHP, as the federal government has no authority to spend federal tax dollars on a state program that does not comply with federal law.
2. Medicaid Beneficiaries' Legal Rights. It is true that among the rights of Medicaid beneficiaries that have been waived is the right to use litigation to remedy the denial of access to those treatments that are covered by the waiver, provided that the service has

been assigned a ranking by HERC that is below the funding line in effect for the year. However --

- Medicaid beneficiaries retain their litigation rights with respect to any item or service that is not subject to the federal waiver.
- If necessary, legal proceedings brought by these individuals protect their access to non-waived forms of care and also ensure that the rights of other program beneficiaries are protected.

3. No Waiver Of Rights As To Prescription Drug Access. The federal approval of the OHP does not waive the rights of any beneficiary who is denied coverage of a prescribed drug for which a manufacturer has agreed to pay a rebate.
   - There is no ambiguity in this because the federal law explicitly does not provide authority to the federal Department of Health and Human Services to waive the requirements that apply to prescribed drugs (that is, section 1927 of the Social Security Act)..
   - The amendments to this federal law in 2010 make it clear that these requirements apply to prescribed drugs dispensed to beneficiaries receiving care through a Medicaid MCO or "coordinated care organization" as well as those whose benefits are reimbursed fee-for-service.
4. Although a state may use prior authorization or other utilization review techniques (for example, to prevent fraud or waste or to implement a "preferred drug list" (PDL)), no matter what its purpose, prior authorization must –
   - meet certain federal standards to assure timely access to every drug when prescribed for a medically accepted indication (i.e., 24 hour maximum response time; and the dispensing of a 72 hour supply in the event of an emergency, which may include an inability of the state to respond in 24 hours); and
   - even where prior authorization is imposed, every drug prescribed for a medically accepted use must be available with prior authorization.
5. If HERC, whether in collaboration with the Medicaid P&T Committee or otherwise, were to place a prescription drug on the prioritized list at a position on the list that fell below the funding line drawn by OHA for purposes of medical assistance, and if a Medicaid beneficiary were denied funding for the prescription based on the fact that the drug and its indication fell below the line, it would be a violation of federal law.[1] See, e.g., Weaver v. Reagan, 886 F.2d 194 (8th Cir. 1989), rehearing and rehearing en banc denied Nov. 1989.
6. Moreover, as a result of the 2010 amendments to the federal law, the same rights apply to MCO denials of prescribed drug coverage pursuant to "treatment guidelines" promulgated by HERC for use of medicines that are medically accepted treatments of a covered condition.

As these basic legal requirements have been raised previously but have been ignored by those bent on charging forward with this ill-advised process, we reiterate that we deplore the travesty of these proceedings, their potential for misleading the public, and their misuse of the public trust in its government.

In view of these key facts and rights, PhRMA, together with its member companies and their patient allies, reserves all options to protect patient access to innovative medicines, including litigation if necessary.

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[1] Note that neither the HERC process nor the procedures under discussion as part of the "coordination" with the Medicaid P&T Committee meet the strict federal requirements for a Medicaid formulary under SSA § 1927(d)(4).

National Patient Advocate Foundation
The Patient's Voice | since 1996

May 29, 2013

Members of the Pharmacy and Therapeutics Committee
Health Evidence Review Commission
Oregon Health Authority
General Services Building
1225 Ferry Street SE, First Floor
Salem, OR 97301

Re: Oregon Health Authority Therapies with High Cost and Marginal Benefit (HCMB) Policy

Dear Members,

The National Patient Advocate Foundation (NPAF) thanks you for the opportunity to provide feedback on the HCMB Policy put forth by the Oregon Health Authority Pharmacy and Therapeutics Committee (P&T) in collaboration with the Health Evidence Review Committee (HERC). In 2012, Patient Advocate Foundation, our companion organization, was contacted by 79,574 patients in Oregon, of whom 1,730 presented were cases so complex that they were referred to our professional case managers for direct assistance. NPAF appreciates the fiscal challenges faced by the Oregon Health Authority in administering the Oregon Health Plan (OHP). However, as the voice for patients seeking care after a diagnosis of a chronic, debilitating or life-threatening illness, NPAF is concerned about the overreaching guidelines being used by the P&T Committee to restrict access to prescription medications due to their "high cost" or "marginal benefit." The policy removes important health care decisions from the hands of patients and their treating physicians, who are in the best position to make such decisions. NPAF offers several suggestions for evaluating treatment that would encourage transparency and facilitate a science-based and patient-centric approach for patients in Oregon being served by the OHP.

First, NPAF recommends that the P&T Committee include on its subcommittee at least one member of the patient advocate community to represent patients in Oregon who are served by the OHP. As presently constituted, the subcommittee is not equipped to make determinations that take into account the needs of patients as determined by their treating physicians, and is not taking into account the views of this very important constituency as part of its decision-making process.

Additionally, NPAF recommends that the P&T Committee take advantage of its authority to appoint up to five additional members to the subcommittee, and include members from the state medical association and state nursing association. Input from a diverse group of state health care stakeholders would ensure that the decisions made by the subcommittee are based on science and the prevailing views of the medical community.

Nicholas J. Petrelli, MD, FACS
Medical Director
Helen F. Graham Cancer Center

Pamela S. Douglas, MD, MACC Ursula Geller
Professor of Research in
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NPAF further recommends that the subcommittee members be appointed by the Governor's office, in coordination with the state legislature. The subcommittee is responsible for health care decisions that impact the lives of Oregonians, often in life-altering ways, so such decisions should be made by officials who can be held accountable at the ballot box, to ensure that they are acting in a manner that reflects the will of the residents of Oregon, including those served by the OHP.

While we understand the fiscal challenges faced by a publicly funded program such as the OHP, it is incumbent upon those responsible for providing health care to patients served by the program to do so in a manner that allows them to receive the appropriate treatments given their health care needs. A policy through which determinations of coverage are made based on overall survival rates is not sufficient to take into account the needs of an individual patient who, despite statistics, may have been deemed by his or her physician to be comparatively well positioned to respond favorably to a particular treatment. NPAF is concerned that the current policy sets forth arbitrary coverage limitations and fails to account for the unique needs of each patient. Consequently, we advocate that the OHP respect decisions made between a patient and provider as to proper treatment, not only to extend life, but to improve its quality.

In NPAF's perspective the subcommittee's actions inappropriately remove clinical judgment in regard to appropriate treatments from the hands of the patient and health care provider. We respectfully urge the OHP to accept the consideration of context in coverage determinations and leave such decisions to those in the position to know what fits the patient's circumstance best.

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Thank you for the opportunity to provide feedback on the HCMB Policy put forth by the Oregon Health Authority. We would be happy to discuss our comments with you if you have any questions about our recommendations.

With Appreciation,

Nancy Davenport-Ennis
Chief Executive Officer and President

About NPAF

Our mission is to be the voice for patients who have sought care after a diagnosis of a chronic, debilitating or life-threatening illness. NPAF has a seventeen year history serving as this trusted voice. NPAF is also the coordinator of the Regulatory Education and Action for Patients (REAP) Coalition. The advocacy activities of NPAF are informed and influenced by the experience of patients who receive direct, sustained case management services from our companion organization, Patient Advocate Foundation (PAF).

Our comments are informed by the collective experiences of patients who have contacted PAF for assistance in accessing quality care. These experiences have been quantified in the PAF's Patient Data Analysis Report (PDAR) which illustrates the data collected across 260 variables by PAF senior cases managers. In 2011, PAF resolved 103,112 patient cases and received more than four million additional inquires from patients nationally. Many of these patients are Medicare beneficiaries.

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Oregon Bioscience Association

May 29, 2013

Dear Members of the Oregon Health Authority's Drug Use Review/Pharmacy and Therapeutics Committee:

On behalf of Oregon's 749 bioscience establishments and 13 life science research institutions, we are voicing our concern regarding the emerging "High Cost and Marginal Benefit" policy that will be discussed at your May 30 committee meeting.

Such new guidelines create grave concern regarding access to medicines among patient groups, biotechnology innovator companies and research institutions.

It is widely proven that access to the right medicine at the right time lowers overall costs, including out-of-pocket costs for patients as well as the reduction of unnecessary medical services and hospital utilization. In fact, Oregon Bioscience believes existing market driven mechanisms are working work well to bring costs down for patients and for programs, such as Medicare.

For example, in the first several years since its implementation, the costs and savings provided by Medicare Part D prescription drug benefit have already lowered program premiums more than projected. The average monthly beneficiary premium for Part D coverage is about $30 in 2013, virtually unchanged from 2012 and less than half of the $61 forecast originally. It is understood that these consistently low premiums make medications more affordable to Medicare beneficiaries. CMS officials reported that in 2011, more than 99 percent of Part D enrollees had access to a plan with a premium that is the same or lower than their 2010 premium.

Lower premiums mean lower out-of-pocket costs for patients.

Interestingly, a 2011 study published in the Journal of the American Medical Association found that implementation of the Medicare prescription drug program was followed by a $1,200 per year decrease in non-drug medical spending among those who previously had limited drug coverage. This reduction in non-drug spending achieved approximately $13.4 billion in overall savings during the first full year of Part D. Another study by Harvard researchers shows that introduction of Medicare Part D significantly reduced the probability of hospitalization for 8 conditions, leading to 4 percent fewer hospital admissions, or an estimated 77,000 fewer annual admissions nationally.

Additionally, Oregon Bio has worked for the past four years to bring concerns forward regarding P&T committee deliberations as well as determinations made by the Health Evidence Review Commission.

-continued -

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Oregon Bioscience Association

Oregon Bio and its members are concerned that the agenda delineating Thursday's discussion about the "High Cost and Marginal Benefit" policy shows the topic is to be presented among a number of policy and university members but nowhere is there inclusion of the expert opinions and analysis by those affected by such a policy, namely, patients. The consideration and implementation of such a policy must include testimony and research about the clear impact on those who are likely to be most affected.

We believe a proper health policy review must not only incorporate broad inclusion and genuine participation of industry, policy, provider and patient expertise but also:

1. Invites, considers and implements input for public and private stakeholders,
2. Considers the broadest and most current medical evidence,
3. Focuses on improving better patient outcomes, and
4. Creates committee membership positions from a cross section of public health, industry, medical practice and academia that are independent and free of conflict-of-interest concerns.

Oregon Bio also cares about innovation and access from the perspective of the efforts we're making to expand Oregon's innovation economy. We, and our members, work hard to invest, build and recruit companies to Oregon. And, those firms that are here provide jobs to 36,000 Oregonians who either work in the life science and biotechnology fields or have a job created by a bio job in Oregon.

Limiting access to medicines could have a chilling effect on the marketability of new innovative medicines and devices. We look forward the P&T committee's feedback on these important issues prior the implementation of the "High Cost and Marginal Benefit" policy.

Sincerely,

Dennis McNannay, Executive Director
Oregon Bioscience Association

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BIOTECHNOLOGY INDUSTRY ORGANIZATION

STATEMENT IN OPPOSITION OF THE PROPOSED "THERAPIES WITH HIGH COST AND MARGINAL BENEFIT POLICY" PRESENTED BY THE OREGON HEALTH EVIDENCE REVIEW COMMISSION AND THE OREGON HEALTH AUTHORITY PHARMACY AND THERAPEUTICS COMMITTEE

MAY 2013

The Biotechnology Industry Organization (BIO) is the world's largest biotechnology trade association. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial, and environmental biotechnology products. One of BIO's core missions is to ensure that patients have access to the very best care available. For this reason we oppose the proposed "Therapies with High Cost and Marginal Benefit" (HCMB) policy proposed by the Oregon Health Evidence Review Commission and the Oregon Health Authority Pharmacy and Therapeutics Committee.

As proposed, the HCMB Policy would restrict coverage of therapies deemed by the Oregon Pharmacy and Therapeutics Committee to be too expensive with little benefit to the patient. A policy decision that we believe would effectively cut physicians out of the care continuum, particularly when dealing with complex illnesses and when treating many rare or genetic conditions for which only recently has there been effective treatments developed. And all of this, we are to believe, would be accomplished with little input from the specialist physician community often tasked with making difficult and even cutting-edge decisions regarding patient care.

Comparative effectiveness information, like some of the underlying policy being debated under this proposal, can serve as a valuable tool that can contribute to improving health care delivery. As has been debated extensively at a national level, however, comparative effectiveness research should not be used as a means to contain costs. There are a tremendous number of unique benefits provided to patients by therapies that may not be accurately reflected in comparing clinical effectiveness, which could create the potential for unintended, negative effects on patients, providers and medical innovators. BIO believes that decisions regarding a patient's treatment should be made by the treating physician and the patient, not by a government committee.

Particularly as science evolves into a more personalized therapeutic environment, we see more and more that there just is no such thing as an average patient. And we continue to see that not all patients respond to treatments in the same way; particularly with respect to complex biologic medicines coming to the market targeted at many rare and otherwise untreatable conditions. Using cost as a justification for withholding coverage of a therapy discriminates against patients who do not respond to cheaper therapies. Furthermore, making determinative decisions on therapies based solely on community-wide or even cohort-level data ignores the more personalized nature of innovative biotech medicines. In effect, blanket decisions, like those being proposed under the HCMB policy, virtually guarantee that many patients in Oregon will be without an effective treatment for a particular ailment due to their own unique genetic predisposition to respond to one therapy over another notwithstanding data showing median survival and/or effectiveness momentum in a community of patients.

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What is more, basing blanket coverage decisions on immediate cost considerations or somewhat vague and perhaps even dubious determinations of "marginal benefit" ignores any long-term value that may inure from a treatment in question. Ignoring a treatment's potential to put a patient back into the workforce or keep a patient out of an inpatient setting or long-term care facility makes little sense in the overall consideration of a therapy's perceived effectiveness. And we know that many of the newest and most innovative products coming to market today do just that: help ensure patients can move on from the perils of an illness and reenter life as a productive member of society rather than a burden.

Finally, it is vitally important to consider the message a policy like the HCMB sends to both the scientific and the investment communities that are so heavily intertwined in today's market. In effect, these policies plainly discourage innovation. Instead, what we should be doing as a community is embracing policies that encourage innovation, policies that encourage the investment community to keep prodding the scientific community to search for that next effective treatment or that next disruptive-innovation that will change the way we treat a particular disease or care for a community of patients.

BIO understands that changes need to be made to many state Medicaid programs in order to ensure long-term feasibility; however the HCMB proposal will only hurt patients and may actually increase healthcare costs in other areas. Not to mention, we believe it is also likely the HCMB policy could be viewed as violating several sections of the Federal Medicaid Statute and the Affordable Care Act. **For these reasons BIO and its member companies oppose the proposed Marginal Benefit High Cost policy**. Thank you for your consideration of our comments and we are available at any time to discuss ways upon which we can work together to solve this issue.

* * * * *

Additional inquiry can be directed to:
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