

isfaction with their body image or size compared with their heterosexual counterparts.² These findings highlight the differences described by Nguyen and Margo even within the population of sexual minority males by including those with discordant identity and behaviors, as well as those who are not sure of their sexual orientation.

A broader point raised in their letter is that men are not a homogenous population with regard to body image and muscularity concerns, and specific sociocultural norms and expectations may contribute to behaviors and attitudes. Even though differences across sexual orientation and sports team involvement have begun to be addressed in the scientific literature, disparities across demographic and personal characteristics such as race, socioeconomic status, and body mass index have received only minimal attention.

For example, we found significantly higher prevalence of steroid use among males who were nonwhite, of lower socioeconomic status, or in higher body mass index categories compared with their peers who were white, of higher socioeconomic status, or of average body weight.³ Such findings further indicate the need to explore muscle-enhancing behaviors in various groups of young men in order to understand this phenomenon and identify particularly vulnerable groups, with the goal of improving prevention programs, diagnosis and treatment of body dissatisfaction, and unhealthy body change strategies across the population.

Empirical evidence is increasing that indicates a strong need to address body image issues, given the high prevalence of body dissatisfaction and the associations with problematic health behaviors and outcomes, such as unhealthy weight control practices, disturbing muscle-enhancing behaviors, and weight gain over time. Physicians need to pay attention to body image concerns in both males and females and take into account differences across subgroups in the population to ensure that needs are being addressed.

Marla E. Eisenberg, ScD, MPH
Dianne Neumark-Sztainer, PhD, MPH, RD

Author Affiliations: Department of Pediatrics, University of Minnesota, Minneapolis (Eisenberg); Division of Epidemiology and Community Health, University of Minnesota, Minneapolis (Neumark-Sztainer).

Corresponding Author: Marla E. Eisenberg, ScD, MPH, Division of General Pediatrics and Adolescent Health, University of Minnesota, 717 Delaware St SE, Minneapolis, MN 55414 (eisen012@umn.edu).

Conflict of Interest Disclosures: The authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

1. Ackard DM, Fedio G, Neumark-Sztainer D, Britt HR. Factors associated with disordered eating among sexually active adolescent males: gender and number of sexual partners. *Psychosom Med*. 2008;70(2):232-238.
2. Laska MN, VanKim NA, Erickson DJ, Lust K, Eisenberg ME, Rosser BRS. Disparities in weight and weight behaviors by sexual orientation in college students. *Am J Public Health*. 2015;105(1):111-121.
3. Eisenberg ME, Wall M, Neumark-Sztainer D. Muscle-enhancing behaviors among adolescent girls and boys. *Pediatrics*. 2012;130(6):1019-1026.

Alternative Pricing Strategies for Cancer Drugs

To the Editor Dr Bach,¹ in discussing indication-specific pricing for cancer drugs, examined the practical aspects of link-

ing the price of a drug to its benefits. However, he did not mention the Italian experience in this area, which extends more than 5 years^{2,3} and involves a total of 162 agents, most of which are oncological drugs.

In Italy, indication-specific pricing has been achieved by application of a procedure that relies on a nationwide website managed by the Italian Medicines Agency.³ All patients treated with these drugs must be registered on this website by individual hospitals. Anticancer drugs are assigned a fixed nominal price irrespective of their clinical indication, but different payback schemes for the same drug are agreed on, depending on the specific indication being treated.² These agreements are managed by the Italian Medicines Agency when reimbursement decisions are made and require acceptance by the drug manufacturer.

In the model, also known as the payment-by-results approach,⁴ each treatment is considered either a success or failure based on a predefined outcome measure (eg, progression) and a predefined timing of outcome assessment (eg, at 6 months). If a patient is classified as having experienced treatment failure, a payback goes from the drug manufacturer to the National Health System. In most cases, this payback equals the whole or partial cost of the unsuccessful treatment for the patient concerned.⁵ For example, cetuximab for the treatment of colorectal cancer is subject to a payback of 50% of the expenditure for each treatment failure for the first 8 weeks of treatment. In patients with head and neck cancer, the same drug is subject to a payback of 100% for each treatment failure for the first 6 weeks of treatment.

Overall, these paybacks have yielded savings of 10% to 20% with respect to the total expenditure for oncological agents. However, the main advantage of paybacks is that, in the presence of a fixed nominal price, different economic values can be assigned to different indications for the same drug.

Andrea Messori, PharmD
Mauro De Rosa, PharmD
Luca Pani, MD

Author Affiliations: Health Technology Assessment Unit, Regional Health Service, Firenze, Italy (Messori); Italian Society of Clinical Pharmacy and Therapeutics, Milan, Italy (De Rosa); Italian Medicines Agency, Rome, Italy (Pani).

Corresponding Author: Andrea Messori, PharmD, HTA Unit, ESTAV Centro, Regional Health Service, via San Salvi 12, 50100 Firenze, Italy (andrea.messori.it@gmail.com).

Conflict of Interest Disclosures: The authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

1. Bach PB. Indication-specific pricing for cancer drugs. *JAMA*. 2014;312(16):1629-1630.
2. Messori A. MS risk sharing scheme: outcome based schemes are more common than you think. *BMJ*. 2010;341:c3588.
3. Agenzia Italiana del Farmaco. Lista Aggiornata nuovi Registri [in Italian]. http://www.agenziafarmaco.gov.it/sites/default/files/Lista_aggiornata_nuovi_Registri_24.10.2014.pdf. Accessed October 27, 2014.
4. Garber AM, McClellan MB. Satisfaction guaranteed—"payment by results" for biologic agents. *N Engl J Med*. 2007;357(16):1575-1577.
5. Palozzo AC. New drugs—how much are they worth? the Italian registries: a model to evaluate appropriateness and effectiveness. *Eur J Hosp Pharm*. 2012;19:398-403.

In Reply Dr Messori and colleagues describe an approach to paying for cancer therapies in Italy that shares some essential features with indication-specific pricing as I discussed in a Viewpoint, but it is not the same. What the approaches share is the premise that payment should not be associated with the drug but instead with its use. Likewise, both approaches ultimately reward pharmaceutical companies more when their drugs are more effective.

Where the approaches differ is that the Italian system focuses on the results of the drug when used in a particular patient and payment levels are altered based on that. My indication-specific pricing proposal focused on paying the same amount for a drug when used in each patient with a condition, regardless of whether it was effective in that patient or not. Instead, the payment amount would be anchored to the average effect of the drug.

The payment-for-results approach described by Messori and colleagues has deep intuitive appeal. What could be better than only paying for a drug when it works? It also explicitly contemplates the reality that treatments may not work as well in the real world as they do in clinical studies. Its primary shortcoming is the administrative complexity of following patients and determining what effect the treatments have had and then financially reconciling those outcomes. From a pharmaceutical industry perspective, there are challenges as well, for instance the uncertainty introduced by not knowing if a sale can be booked or could instead need to be refunded.

What I proposed was primarily driven by the strong evidence that drugs work differently across their own indications, and therefore prices could be set more rationally if priced based on their indication-specific effectiveness. This could be done based on clinical trial data and avoid the need for follow-up of outcomes or payback schemes.

Peter B. Bach, MD, MAPP

Author Affiliation: Health Outcomes Research Group, Memorial Sloan Kettering Cancer Center, New York, New York.

Corresponding Author: Peter B. Bach, MD, MAPP, Health Outcomes Research Group, Memorial Sloan Kettering Cancer Center, 1275 York Ave, New York, NY 10021 (bachp@mskcc.org).

Conflict of Interest Disclosures: The author has completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and reported receiving speaking fees from Genentech, the Biotechnology Industry Organization, MPM Capital, Goldman Sachs, Boston Consulting Group, and McKinsey & Co; and consulting fees from Foundation Medicine.

CORRECTION

Inconsistent Units of Measure: In the Diagnostic Test Interpretation entitled "Lactate in Sepsis" published in the January 13, 2015, issue of *JAMA* (2015; 313[2]:194-195. doi:10.1001/jama.2014.13811), lactate levels were inserted in both SI and conventional units of measure. In the first paragraph, the second sentence should read "He was found to be tachycardic, hypotensive, in severe respiratory distress, and oliguric, and he had peripheral cyanosis and a lactate level of 3.1 mmol/L (reference range, 0.6-1.7 mmol/L) (27.9 mg/dL; reference range, 5.0-15 mg/dL)." The fourth sentence should read "Following admission, the patient's lactate level decreased to 1.2 mmol/L (10.8 mg/dL)." The sixth and seventh sentences should read "The following morning, his central venous pressure was 13, stroke volume variation was 7%, and lactate was 3.0 mmol/L (27.0 mg/dL). Mean arterial pressure of 60 to 65 mm Hg was achieved but lactate continued to increase to 4.2 mmol/L (37.8 mg/dL)." In the Test Characteristics section, the first sentence in the first paragraph should read "Studies in hypoxia, low flow states, and early septic shock¹ have provided grounds to conceptualize hyperlactatemia (arterial or venous blood lactate >2 mmol/L [>18.0 mg/dL]), as the manifestation of inadequate oxygen delivery and anaerobic metabolism." The first sentence in the second paragraph should read "Lactate testing is inexpensive (mean Medicare reimbursement, \$13.92) and predicts hospital mortality (likelihood ratio, 1.4-2 for ≥ 2.5 mmol/L [≥ 22.5 mg/dL]-cutoff; or 2.6-6.3 for 4 mmol/L [36.0 mg/dL]-cutoff).^{3,4}" In the Application of Test Results to This Patient section, the first sentence should read "On admission, a lactate level of 3.1 mmol/L (27.9 mg/dL) should alert the clinician to the high severity of illness." This article was corrected online.

Guidelines for Letters

Letters discussing a recent *JAMA* article should be submitted within 4 weeks of the article's publication in print. Letters received after 4 weeks will rarely be considered. Letters should not exceed 400 words of text and 5 references and may have no more than 3 authors. Letters reporting original research should not exceed 600 words of text and 6 references and may have no more than 7 authors. They may include up to 2 tables or figures but online supplementary material is not allowed. All letters should include a word count. Letters must not duplicate other material published or submitted for publication. Letters not meeting these specifications are generally not considered. Letters being considered for publication ordinarily will be sent to the authors of the *JAMA* article, who will be given the opportunity to reply. Letters will be published at the discretion of the editors and are subject to abridgement and editing. Further instructions can be found at <http://jama.com/public/Instructions-ForAuthors.aspx>. A signed statement for authorship criteria and responsibility, financial disclosure, copyright transfer, and acknowledgment and the ICMJE Form for Disclosure of Potential Conflicts of Interest are required before publication. Letters should be submitted via the *JAMA* online submission and review system at <http://manuscripts.jama.com>. For technical assistance, please contact jama-letters@jamanetwork.org.

Section Editor: Jody W. Zylke, MD, Deputy Editor.