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To the editor

I read with great interest the blog "Avastin W" by John A. Hovanesian, whom I would like to congratulate for touching on a delicate argument that affects the quality of life of individuals affected by macular and retinal diseases.

In many countries, the incidence of blindness due to age-related maculopathy and diabetic retinopathy has been halved thanks to the efficient use of intravitreal anti-VEGF agents. On the other hand, this shift toward newer therapeutic pharmaceutical options has made eye services more costly as compared with the times in which laser was the only offer for treating macular and retinal diseases. We have entered a common "field of battle" together with oncologists and hematologists, struggling with reimbursement issues with regulatory authorities. Also, citizens are demanding higher and higher levels of health and health care even though their lifestyle often is not as rigorous as it should be. Sometimes we have the feeling that the right to life and perfect vision are undeniable whatever disease we are facing. Obviously, this has consequences on costs and affordability.

In many countries, the incidence of blindness due to age-related maculopathy and diabetic retinopathy has been halved thanks to the efficient use of intravitreal anti-VEGF agents. *Image: Adobe Stock*

The dispute between off-label bevacizumab and on-label ranibizumab has taught us more on the importance of sustainability of health care in the context of health care systems of different countries. Today, the platform of on-label medications has expanded, and newer agents such as brolucizumab and faricimab are available after the historical ranibizumab and aflibercept. More than this, in the U.S., the FDA has just approved high-dose aflibercept. Hopefully, we can now focus on extended durability with reduced burden and consequent reduced costs. Also, a number of biosimilars are now becoming available.

expensive drug by total spending for the Medicare Part B program in 2020, with more than $3 billion in annual costs, while ranibizumab was the sixth most expensive drug by total spending, costing more than $1 billion; spending on aflibercept and ranibizumab together was more than 10% of the total Medicare Part B drug spending for 2020."

Recently, an interesting article published in the journal *Ophthalmology* has taught us the "biosimilar paradox" or, in other

words, how anti-VEGF biosimilars may bring increased expenditures by both the health care system and patients. As an example, the authors cite the case of an FDA-approved bevacizumab biosimilar for ophthalmic use — actually, it would be an originator/reference drug and not a biosimilar because currently bevacizumab is not labeled for ophthalmic use — whose cost is modeled at $500 per 1.25 mg dose and $900 per 1.25 mg dose. In the two case scenarios, Medicare costs would increase by 15.2% and 29.8%, respectively.

Differently from the U.S., in Italy and many other European countries with similar universalistic national health care systems, costs of drugs are no longer a relevant issue. In the last decade, prices of on-label anti-VEGF agents have considerably decreased to a few hundred euros and are now below the maximum price to be cost-effective.

A few months ago, I contributed to two articles in *Graefe's* that highlighted the huge limitations of our Italian health care system in terms of obsolete regulations and lack of implementation of existing facilities, strategies and vision care models. As a result, although Italy was among the first countries to officially reimburse the off-label and less expensive bevacizumab for the treatment of AMD, we are not registering either improvements of visual acuity in the treated eyes or a reduction in the incidence of blindness due to AMD and diabetic retinopathy.

It is time now to ask for renovated public health systems with the aim of improving clinic efficiencies. At least in Europe, focusing on low-priced off-label bevacizumab alone is not enough to guarantee our patients the right therapy at the right point for the right time. Today, the success of intravitreal therapy programs and services depends mostly on the improvement of existing health care systems with appropriate human and technological resources.

More than for an "Avastin W," we struggle for a "National Health Care System W."

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