To the Editor:

The mischaracterization of biologic naming policies in your December editorial[1] is both surprising and disappointing. Biologic naming policies have longstanding scientific basis and are an important topic that deserves balanced consideration where they are discussed and reviewed. Amgen (Thousand Oaks, CA), as both a biologics innovator and a biosimilars developer, endorses distinguishable names for biosimilars as a means of manufacturer accountability.

Currently, there is a shortfall in companies following the existing World Health Organization (WHO; Geneva, Switzerland) International Nonproprietary Name (INN) rules for glycosylated proteins. With the single exception of epoetin zeta, mentioned in the editorial, biosimilars on the market in Europe have not followed WHO INN rules. In response to this breakdown of the existing INN system, the WHO is actively considering a mechanism for distinguishable nonproprietary identification of all biologics, not just biosimilars. The approach under discussion would not change the INN naming policies but would include the use of an identifier to help product-level traceability on a global level[2].

Experience in other countries with distinguishable names for biosimilars supports this policy. Japan and Australia have adopted distinguishable names for biosimilars, and biosimilars continue to be a viable and important option for patients and physicians. Additionally, in a recent survey, 80% of US and European Union (EU; Brussels) physicians surveyed want distinguishable or unique names for biologics[3].

Amgen is seeking distinguishable nonproprietary names for our biosimilar products and supports the use of an identifier for all of our biologic medicines. Simply put, distinguishable nonproprietary names are an easily implemented and reliable means of advancing accurate product identification. We share this perspective with many in our industry[4].

Importantly, this simple measure could help increase confidence in biosimilars and support their continued success in Europe[5] as well as providing consumer confidence when they are introduced in the United States.

COMPETING FINANCIAL INTERESTS
The author declares competing financial interests: details are available in the online version of the paper (doi:10.1038/nbt.2817).

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To the Editor:

During my time as its president and CEO, the Biotechnology Industry Organization (BIO; Washington, DC) has consistently called for open, transparent and science-based dialogue regarding biosimilars. More recently, we played a leading role in the effort to establish a pathway for the approval of biosimilars. Many of our members are global leaders in the development and commercialization of biosimilars.

We are deeply concerned that the arguments offered in your December editorial[1] disregard fundamental scientific considerations at the heart of the debate regarding biosimilars—scientific considerations that have important implications for the appropriate use of all biologics, whether innovative or biosimilar.

We agree that one consideration in any debate around the naming of biosimilars is access to medicines at competitive prices. However, as leading scientific and regulatory authorities around the world have universally determined, treating biosimilars like generic drugs is inappropriate because biosimilars are not the same as their reference biologics.

Thus, the introduction of biosimilars into the marketplace raises novel and complex questions of science and law, and requires the updating of legal and regulatory frameworks to ensure, among other things, accurate product identification. A naming convention that ensures distinguishable product identification will help to prevent inappropriate substitution, facilitate pharmacovigilance (postmarket surveillance of drug safety), ensure accurate attribution of adverse events to the right product and support tracing of products in the event of the need to recall.

The existing International Nonproprietary Name (INN) system, which *Nature Biotechnology* recognizes to be a 'generic' name system, must be updated to achieve these goals. I would like to respond to four specific points raised in the editorial:

Commercial success. BIO strongly disagrees that assigning distinguishable nonproprietary names (or identifiers) for all biological products will compromise the ability of biosimilars to succeed in the marketplace. In fact, we believe it is possible to craft a naming convention that both contributes to patient safety through enhanced product identification and improves access to medicines at competitive prices. We have proposed that a distinct name could consist both of a common stem to permit science-based associations among products and a qualifier to permit identification. With appropriate education, such a naming system would introduce in the mind of the prescriber not uncertainty, but rather clarity and greater confidence in prescribing. Existing biosimilar markets that use distinguishable brand and nonproprietary names, within the International Conference on Harmonization (ICH) regions, are proving robust on both a time to peak sales and an overall market share basis.

Product drift. *Nature Biotechnology* argues that 'product drift' does not necessarily result in an INN change for a branded biological product, and that this fact supports the assignment of the same INN to both a reference product and all its biosimilars. To the contrary, the reality of product drift in fact supports the need for distinct naming to ensure that prescribers and patients are informed that biosimilar products are not the same as the reference product, both at the time of approval and throughout the products' life cycles. Additionally, in the event that multiple biosimilar or interchangeable products are available for a single reference product, the need for distinguishable names for all biological products becomes even greater because biosimilarity or interchangeability will generally have been designated between one reference product and one other product, not among all biosimilars or interchangeable products.

Comparability and similarity. The demonstration of comparability before and after a manufacturing change is a contextually different exercise from the establishment of similarity between two products made by different manufacturers using different cell lines, manufacturing processes, facilities and equipment. A comparability assessment for