Support Solutions to Drug Shortages

OVERVIEW

ASCO has been working in partnership with the Food and Drug Administration (FDA) and other stakeholders to address the issue of drug shortages for the past several years.

BACKGROUND

The oncology community has been experiencing severe shortages of many critical therapies over the past few years. These shortages have been caused by a complex combination of regulatory and manufacturing problems, resulting in disruptions of care—at times, reaching crisis proportions.

Congress took action in 2012 by including an important provision in the Food and Drug Safety and Innovation Act requiring manufacturers to give the FDA six months’ notice of an anticipated drug shortage. The provision is an important first step toward addressing drug shortages.

The law also requires studies on the issue and gives the Secretary of Health and Human Services the discretion to include biologics in the required reporting. ASCO will urge the Secretary to require reporting on biologics immediately, as they are already first-line treatments for numerous cancers.

This provision has had an impact on the ongoing issue of drug shortages. Evidence shows that giving the FDA advance notice of an expected shortage has allowed the agency to find workarounds that have limited the scope of the shortage, but shortages are still a regular occurrence oncologists have to deal with.

RECOMMENDATIONS

ASCO is calling on Congress to continue to closely monitor the problem and supports the provisions included in the law as a good first step, but there are many causes of drug shortages which may not be addressed in the law.

ASCO believes Congress needs to convene a blue ribbon panel to investigate the issue and, if need be, develop comprehensive legislation to augment the drug shortage provision. The only way to ensure that all causes are examined and addressed is to convene such a panel that includes providers, manufacturers, suppliers, FDA and patients.