Congressional Budget Office
Cost Estimate

May 3, 2019

H.R. 1520, Purple Book Continuity Act of 2019

As ordered reported by the House Committee on Energy and Commerce on April 3, 2019

Millions of Dollars	2019	2019-2024	2019-2029
Direct Spending (Outlays)	0	0	0
Revenues	0	0	0
Deficit Effect	0	0	0
Spending Subject to Appropriation (Outlays)	0	3	n.e.

Pay-as-you-go procedures apply?	No	**Mandate Effects**	
Increases on-budget deficits in any of the four consecutive 10-year periods beginning in 2030?	No	Contains intergovernmental mandate?	No
		Contains private-sector mandate?	Yes, Under Threshold

n.e. = not estimated.

Under current law, the Food and Drug Administration (FDA) publishes a reference guide for biological products, *Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*, commonly known as the "Purple Book." H.R. 1520 would codify publication of the Purple Book by FDA, require that the agency include more detailed information in the compendium, make the data available in a searchable electronic format, and update it every 30 days.

The Purple Book currently specifies whether a biological product licensed and marketed under section 351(k) of the Public Health Service Act (PHS) has been determined by FDA to be biosimilar to (or interchangeable with) the reference biological product. The Purple Book also includes the date a biological product was licensed for marketing under 351(a) of the PHS Act and whether FDA evaluated the biological product for reference product exclusivity. Information contained in the Purple Book is useful to health care practitioners and developers of biosimilar or interchangeable products and is updated periodically by FDA.

H.R. 1520 would require that the FDA proactively determine the reference product exclusivity for each licensed biological product listed in the Purple Book. The determination of reference product exclusivity is a complex, resource intensive assessment for the agency to make; thus, under current law it is generally made either for reasons of regulatory necessity or because the license holder that submitted the application requested the determination. The bill also would direct FDA to solicit public comments regarding the type

of information that should be contained in the Purple Book and transmit a report to the Congress within three years after the date of enactment.

Based on the cost of similar activities, CBO expects that the FDA would require the equivalent of about 5 full-time employees in 2020 to cover the increased workload to comply with the listing and reporting requirements at cost of about $300,000 per employee. CBO expects that fewer employees would be needed in later years and that by 2023, ongoing personnel-related expenses to fulfill the bill's requirements would total less than $500,000 annually. CBO estimates that implementing the bill would cost FDA about $3 million over the 2020-2024 period. Such spending would be subject to the availability of appropriated funds.

H.R. 1520 would impose a private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA) by requiring biological product manufacturers to provide the FDA with certain patent information when that information is shared with biosimilar product manufacturers. CBO estimates the cost of the mandate would fall well below the private-sector threshold established in UMRA ($164 million in 2019, adjusted annually for inflation).

The CBO staff contacts for this estimate are Julia Christensen (for federal costs) and Andrew Laughlin (for mandates). The estimate was reviewed by Leo Lex, Deputy Assistant Director for Budget Analysis.