



Week in Regulation

Trade and Drugs Lead the Regulatory Week: September 10 – 14

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The most notable rulemaking entries in last week's Federal Register focused on trade and the approval process for certain drugs and medical devices. On trade, there was a cost-cutting measure, but another action regarding President Trump's tariffs includes a significant paperwork increase. The other notable items were a pair of proposed rules from the Food & Drug Administration (FDA) that would streamline particular requirements. Between both proposed and final rules last week, agencies published roughly \$156.3 million in net cost savings, and 582,363 hours of new paperwork. **The per capita regulatory burden for 2018 is *negative* \$18.28.**

REGULATORY TOPLINES

- New Proposed Rules: 40
- New Final Rules: 72
- 2018 Total Pages of Regulation: 46,583
- 2018 Final Rules: -\$6 Billion
- 2018 Proposed Rules: -\$543.9 Billion

The one notable burden-increasing rule comes from the Department of Commerce. The [rule](#) on "Submissions of Exclusion Requests and Objections to Submitted Requests for Steel and Aluminum" finalizes the procedure under which relevant parties can apply for an exclusion to the tariffs recently imposed on those products. While the rule does not include a full cost-benefit analysis, its requirements could impose more than 580,000 hours of new paperwork.

TRACKING REGULATORY MODERNIZATION

FDA published an interesting pair of regulatory reform proposals this week. The [first](#) would consolidate the "medical device premarket submission" filing into a single electronic submission and the [second](#) eliminates an extraneous filing for drug products sterilized by irradiation. Combined, the proposals could bring total savings of more than \$190 million. Given their proposed rule status, however, their savings do not yet apply to the regulatory budget under Executive Order (EO) 13,771.

There was one action applicable to EO 13,771 from the Department of Agriculture (USDA). The [rule](#) on “Establishing a Performance Standard for Authorizing the Importation and Interstate Movement of Fruits and Vegetables” amends how the agency clears fruit and vegetables imported from abroad as well as those transferred from Hawaii and non-mainland U.S. territories. USDA estimates that this could produce roughly \$563,000 in annualized savings due to such goods coming to U.S. markets in a more timely fashion. With two weeks left before the end of Fiscal Year (FY) 2018, USDA is on track to exceed its EO 13,771 regulatory budget goal of [\\$56 million](#) in annual savings by roughly \$12 million.

According to AAF analysis, since the start of FY 2018 (beginning Oct. 1, 2017), executive agencies have promulgated 54 deregulatory actions with quantified estimates against 12 regulatory measures, under the rubric created by EO 13,771 and the administration’s subsequent [guidance document](#) on the matter. These rules combine for net annual savings of roughly \$1.6 billion. This means that agencies have thus far surpassed the administration’s cumulative [goal for FY 2018](#) of \$687 million in net annual savings by nearly \$1 billion. According to earlier AAF projections based on the administration’s latest Unified Agenda, agencies were on track to [roughly double](#) that goal. If this current trend holds, they may well exceed that expectation too.

[Click here](#) to view AAF’s examination of the administration’s progress under the “one-in, two-out” executive order through the end of Fiscal Year 2017.

STATE OF MAJOR OBAMA-ERA INITIATIVES

Based on total lifetime costs of the regulations, the ACA has imposed costs of [\\$52.9 billion](#) in final state and private-sector burdens and 176.9 million annual paperwork hours.

Since passage, the Dodd-Frank financial reform legislation has produced more than [82.9 million](#) final paperwork burden hours and imposed \$38.9 billion in direct compliance costs.

TOTAL BURDENS

Since January 1, the federal government has published \$549.9 billion in net cost savings (with \$6 billion in net savings from final rules) and paperwork burdens amounting to roughly 10.1 million hours (including 8.2 million hours of paperwork reduced under final rules). [Click here](#) for the latest Reg Rodeo findings.

Year

☐ [Select All]

☒ 2018

☐ 2017

☐ 2016

☐ 2015

☐ 2014

☐ 2013

☐ 2012

☐ 2011

☐ 2010

☐ 2009

☐ 2008

☐ 2007

☐ 2006

☐ 2005

Total Number of
Regulations
Finalized

212

Total Finalized Cost

\$-6.0b

Paperwork Hours

-8,205,712