Week in Regulation

A Well-stuffed Week

DAN GOLDBECK | NOVEMBER 27, 2023

Despite the Thanksgiving holiday, last week saw plenty of activity in the pages of the Federal Register. There were 16 rulemakings with some measurable economic impact and both costs and paperwork burdens increased significantly. The main item as it pertains to costs was an Environmental Protection Agency (EPA) proposed rule regarding component chemicals in flame retardants. Across all rulemakings, agencies published $5.7 billion in total costs and added 11.6 million annual paperwork burden hours.

REGULATORY TOPLINES

- Proposed Rules: 27
- Final Rules: 65
- 2023 Total Pages: 82,655
- 2023 Final Rule Costs: $118.6 billion
- 2023 Proposed Rule Costs: $526.2 billion

NOTABLE REGULATORY ACTIONS

The most consequential rulemaking of the week, at least from a cost perspective, was the proposed rule from EPA regarding “Decabromodiphenyl Ether and Phenol, Isopropylated Phosphate (3:1); Revision to the Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under the Toxic Substances Control Act (TSCA).” The proposal focuses on revising the regulatory standards on the use of “decabromodiphenyl ether” or “phenol, isopropylated phosphate” in the production of myriad other products (the agency includes a list of potentially affected sectors here). EPA estimates that implementing these new standards will impose roughly $416 million in annualized costs, or $5.2 billion in present value over the 30-year analytical window.

TRACKING THE ADMINISTRATIONS

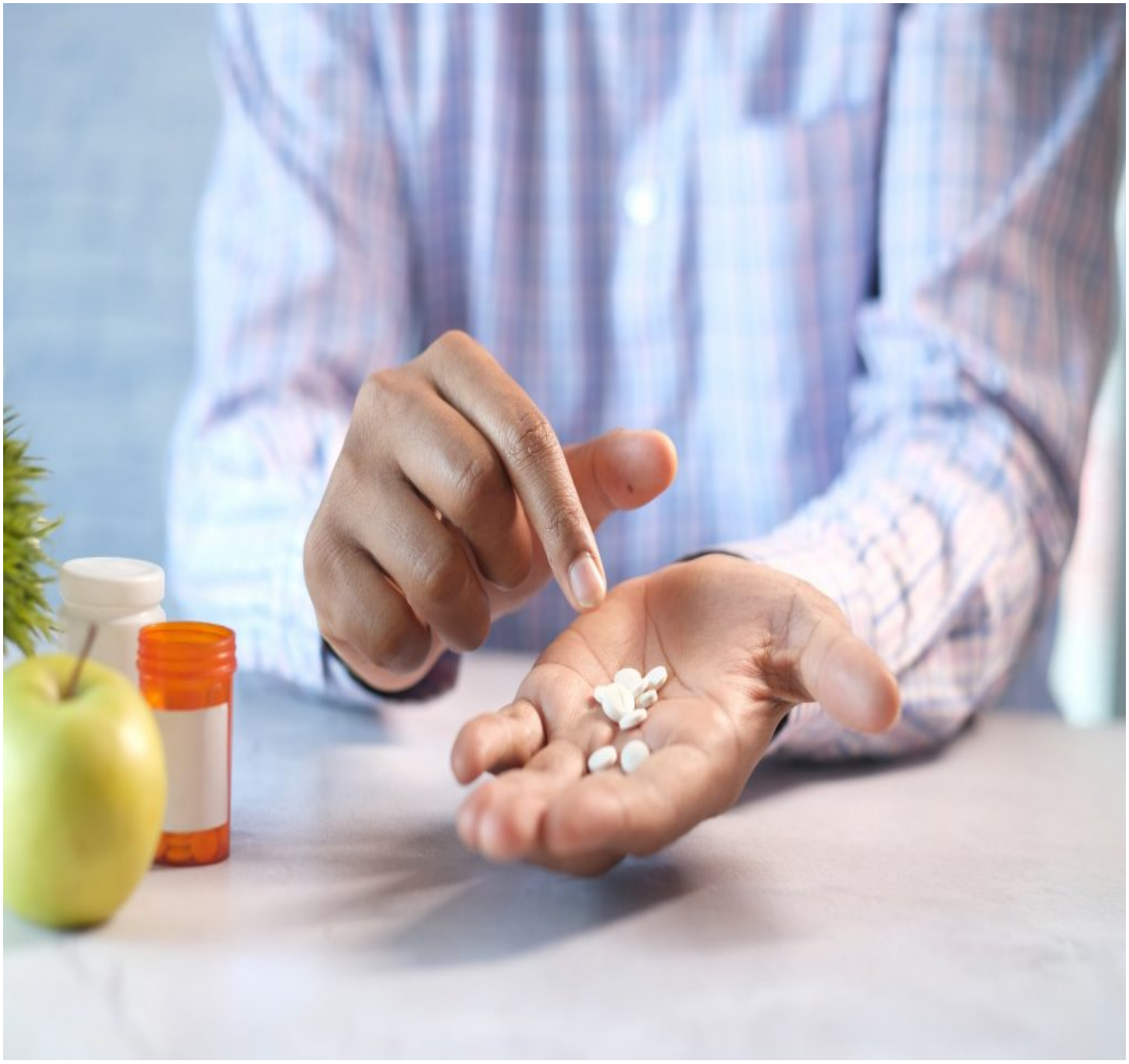
As we have already seen from executive orders and memos, the Biden Administration will surely provide plenty of contrasts with the Trump Administration on the regulatory front. And while there is a general expectation that the current administration will seek to broadly restore Obama-esque regulatory actions, there will also be areas where it charts its own course. Since the AAF RegRodeo data extend back to 2005, it is possible to provide weekly updates on how the top-level trends of President Biden’s regulatory record track with those of his two most recent predecessors. The following table provides the cumulative totals of final rules containing some quantified economic impact from each administration through this point in their respective terms.

While the week's main cost action came from the proposed rule side, there were some substantial shifts in the Biden Administration's final rule stats. Costs increased by $471 million and paperwork shot up by 11.3 million hours. A Department of Labor rule was the primary reason for the latter trend with its nearly 10.7 million hours of new paperwork. Yet that increase could have been orders of magnitude greater if the erroneous estimate in the proposed version of the rule had stood. Neither of the other two administrations saw such notable shifts. The most significant trend was a $214 million cost increase under the Trump Administration, due primarily to a data

reporting rule for defense contractors.

THIS WEEK'S REGULATORY PICTURE

This week, the Food & Drug Administration (FDA) makes some changes to its standards for everyone's favorite: pharmaceutical advertisements.



Source: Photo by Towfiqu barbhuiya on Unsplash

Most readers are likely familiar with the phrase: "possible side effects include…." Despite the relative ubiquity of this portion of a pharmaceutical ad, FDA has apparently found the need to prescribe further parameters for

how drug companies convey information about their products. Last Tuesday, FDA published a final rule entitled "Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, and Neutral Manner in Advertisements in Television and Radio Format."

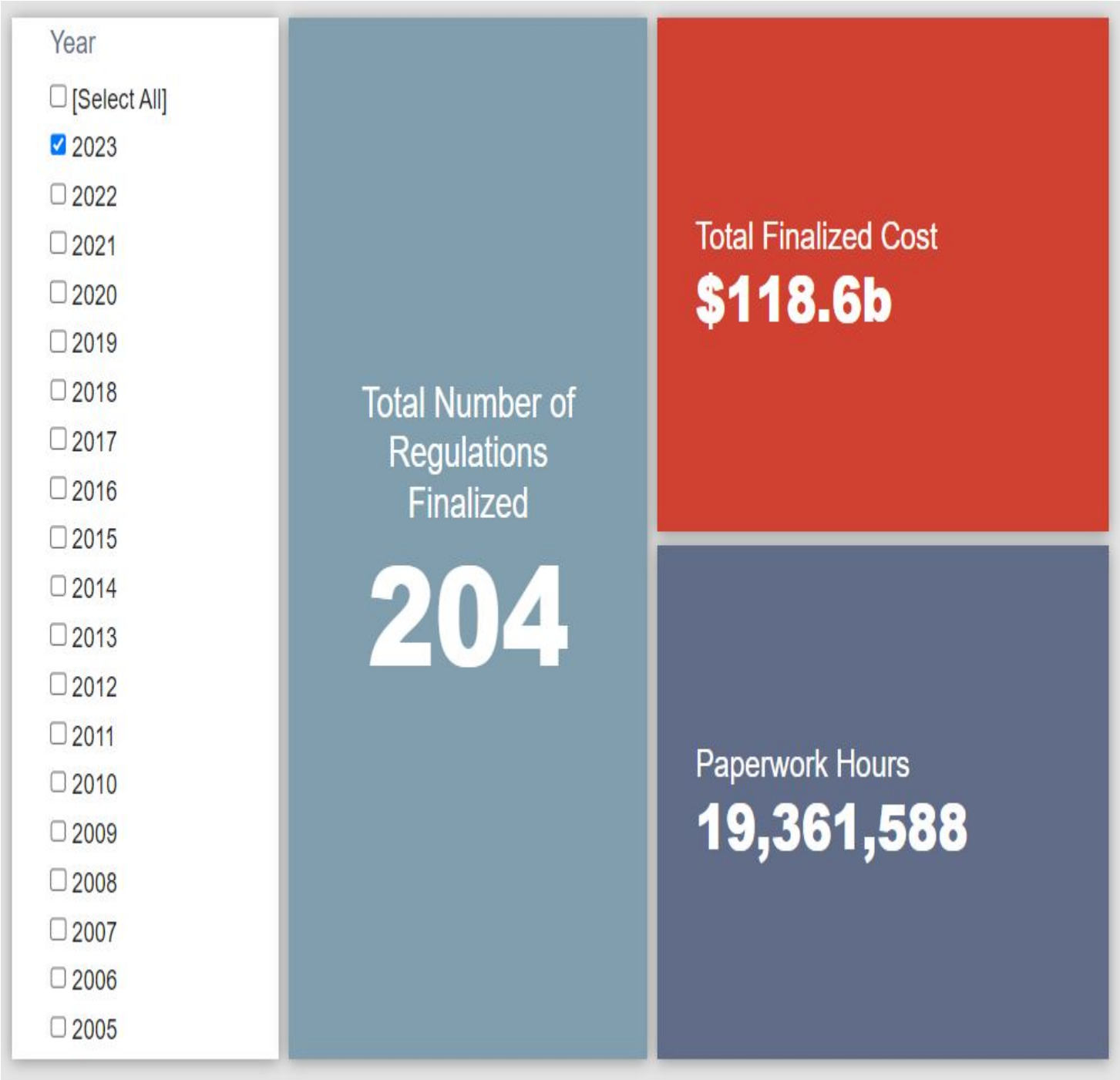
The rule builds from a proposed rule from all the way back in 2010 to establish five new standards for how affected companies present "the major statement in DTC television or radio advertisements (or ads) relating to the side effects and contraindications of an advertised prescription drug." FDA summarizes the new standards thusly:

> The final rule establishes that the information must be presented in consumer-friendly language and terminology that is readily understandable. The audio information in the major statement must be at least as understandable as the audio information presented in the rest of the ad. In ads in TV format, the information presented in the audio portion of the major statement must also be presented concurrently in text for a sufficient duration to allow it to be read easily. In ads in TV format, the information in text must be formatted such that the information can be read easily. The ad must not include audio or visual elements during the presentation of the major statement that are likely to interfere with comprehension of the major statement.

FDA only provides a qualitative discussion of the rule's potential benefits, focusing on how these updated standards will "help ensure that consumers are better informed when they participate in healthcare decision making." The agency was able to produce a quantitative analysis of potential costs, however, finding that it will involve roughly $218 million in total costs (or $31.1 million on an annualized basis). Per the rule's Regulatory Impact Analysis, most of the costs come from the direct costs of changing ads to comply with the new standards and the opportunity cost of devoting marginally more time to the "major statement" than to other aspects of the advertisement. The compliance date for these new standards is November 20, 2024.

TOTAL BURDENS

Since January 1, the federal government has published $644.8 billion in total net costs (with $118.6 billion in new costs from finalized rules) and 203.1 million hours of net annual paperwork burden increases (with 19.4 million hours in coming from final rules).


Year
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2023
2022
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2008
2007
2006
2005
Total Number of Regulations Finalized
204
Total Finalized Cost
$118.6b
Paperwork Hours
19,361,588