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[Submitted electronically via verticalmergerguidelines@ftc.gov and verticalmergerguidelines@usdoj.gov]

The Honorable Joseph J. Simons
Chairman
Federal Trade Commission (FTC)
600 Pennsylvania Ave., NW
Washington, DC 20580

The Honorable Makan Delrahim
Assistant Attorney General
U.S. Department of Justice (DOJ)
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

Re: Draft Vertical Merger Guidelines for Public Comment

Dear Chairman Simons and Assistant Attorney General Delrahim:

The American Pharmacists Association (“APhA”) is pleased to submit these comments regarding the new draft 2020 “Vertical Merger Guidelines” (hereinafter “Draft Guidelines”) that describe how the federal antitrust agencies review vertical mergers to evaluate whether the mergers violate antitrust law.

We also submitted joint comments with four other national pharmacy organizations (Alliance for Pharmacy Compounding, American Society of Consultant Pharmacists, National Alliance of State Pharmacy Associations, and National Community Pharmacists Association) recommending:

- The agencies closely evaluate vertical consolidation in healthcare, as it has yielded significant anticompetitive effects without promised improvements in cost or quality.
- A reinvigorated and reimagined antitrust enforcement policy rather than a continuation of the status quo.
- The agencies account for anticompetitive harm to healthcare access, quality, and service in vertical merger enforcement policy as it relates to the healthcare sector.
- The agencies rigorously scrutinize claimed efficiencies from vertical mergers, including whether any efficiencies will be passed on to consumers.
APhA, founded in 1852 as the American Pharmaceutical Association, represents 60,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians’ offices, hospitals, specialty pharmacies, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services. APhA promotes patient access and coverage for pharmacists’ quality patient care services.

I. General Comments

APhA appreciates your agencies updates to the decades-old statement regarding the practices and policies of the federal enforcement agencies in this critical area. A comparison of the Draft Guidelines to the previous 1984 DOJ Non-Horizontal Merger Guidelines displays a noticeable focus on the distinct considerations of vertical mergers impacts that substantially lessen competition. This update is necessary to keep up with the wave of recent multi-billion dollar vertical mergers between pharmaceutical be benefit managers (“PBMs”) and health insurers and other healthcare vertical mergers and their harm to the drug supply chain, consumer choice, prices and access to health care products and services. While the DOJ has traditionally reviewed consolidations involving health plans, the FTC has taken on the responsibility of reviewing deals involving retail pharmacies and PBMs. It is heartening to see both agencies focused on improving enforcement of your oversight authority authorized under Section 7 of the Clayton Act which prohibits mergers “in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly.” We also appreciate the clarity of the Draft Guidelines that “[t]his provision applies to vertical mergers, as Congress made plain in the 1950 amendments to the Clayton Act.”

As stated by a former FTC official, “[c]onflicts of interest raise severe concerns in the health care system. Where a payor is also a provider they can manipulate the relationship to raise health care costs. That is why, when pharmaceutical manufacturers obtained PBMs in the 1990’s, the FTC acted to eliminate those conflicts of interest. The FTC challenged the acquisition of PCS by Lilly and Medco by Merck, because of the concern that having a manufacturer own a PBM would be giving the “fox the keys to the hen house door”—and would lead to higher prices for consumers.”¹ We urge DOJ and the FTC to take similar action with the recent flurry of healthcare vertical mergers.

A. Action from the DOJ/ FTC is Necessary to Keep Up with the Recent Wave of Healthcare Vertical Mergers

APhA is pleased to see your agencies renewed focus on unlawful vertical transactions and DOJ’s recent challenges to such vertical mergers.² Some vertical acquisitions can be anticompetitive. Vertical mergers can create or raise entry barriers that lead to higher prices or

lower quality or innovation for consumers. For example, in industries with extensive networks, many firms already have market power through their ownership of established networks or installed bases involving huge sunk costs. Vertical mergers can, in certain instances, increase those barriers to entry even more, raising costs and reducing innovation and quality for consumers.³ APhA remains hopeful the new Draft Guidelines will assist your agencies’ oversight of the highly concentrated PBM marketplace where in 2018, about three-quarters of all equivalent prescription claims were processed by only three vertically merged companies: CVS Health (including Caremark and Aetna), Express Scripts (Cigna), and the OptumRx business of UnitedHealth. For clarification, the top six PBMs handle more than 95% of total U.S. equivalent prescription claims.⁴ Theoretically, these PBMs are designed to lower drug prices; however, there is ample evidence to counter these claims which clearly shows that consolidation of PBMs has led to increases in patient’s drug prices at the pharmacy counter through utilization of direct and indirect remuneration (“DIR”) fees and other “clawback” mechanisms, delaying prescribed treatments through patient steering and prior authorization, and limiting options for patients by controlling access to insurance networks. These PBM practices have also led to increases in PBM profits rather than reduced drug prices to such an extent the Administration has released two proposed rules by both the Office of Inspector General (“OIG”)⁵ and Centers for Medicare and Medicaid Services (“CMS”)⁶ to require issuers to give these discounts to patients at the point-of-sale rather than PBMs.

As stated in the separate comments we submitted with other pharmacy organizations, “[u]nfortunately, the Draft Guidelines largely restate conventional analytical approaches that have failed to protect competition and healthcare consumers” and “we urge the agencies to account for anticompetitive harm to healthcare access, quality, and service in vertical merger enforcement policy as it relates to the healthcare sector.” Since none of the recent multi-billion dollar PBM-health insurer vertical mergers were prohibited by the antitrust regulators at the FTC and the DOJ, in 2019, APhA’s House of Delegates proactively approved official policy on the “Consolidation within Health Care,” to clarify the position of pharmacists on mergers and consolidation in the health care marketplace. APhA’s policy states:

“1. APhA advocates that health care mergers and acquisitions must preserve the pharmacist-patient relationship.
2. APhA supports optimizing the role of pharmacists in the provision of team-based care following health care mergers and acquisitions in order to:
   • Enhance patient experience and safety,
   • Improve population health,
   • Reduce health care costs, and
   • Improve the work life of health care providers.”

3. APhA asserts that the scope of review by federal agencies must have a focus on the impact of health care mergers and acquisitions on patient access and the provision of care to ensure optimal patient outcomes. Therefore, APhA calls for:

- Reform of the pre-health care mergers and acquisitions process;
- Implementation of an ongoing post-health care mergers and acquisitions evaluation process to preserve patient choice and access to established patient-pharmacist relationships; and
- Continuous transparent dialogue among stakeholders throughout the process.

4. APhA calls for the Federal Trade Commission (FTC) to develop a task force to monitor health care mergers and acquisitions activity.

In formulation of this policy, APhA noted that while the current oversight of the FTC includes the “quality of goods or services,” the review of this subject as it relates to a health care setting may not be comprehensive or transparent and could be limiting a patient’s access to care. APhA also noticed in our review of the charges of the FTC regarding merger review that neither the 1984 DOJ Non-Horizontal Merger Guidelines nor the Draft Guidelines are available for reference on FTC’s merger review webpage. We urge your agencies to elevate the scrutiny of vertical mergers in your resources related to assist stakeholders and the FTC throughout the merger review process.

B. Universal Agreement Among Health Care Providers Healthcare Vertical Mergers Increase Barriers to Market Entry and Foreclose Competitors

As the nation’s largest group representing pharmacists in all practice settings, we are not alone in our significant concerns regarding the inaction of DOJ and FTC to prohibit any of the recent PBM-health insurer mergers. For example, in regards to the CVS-Aetna merger, the American Medical Association’s (“AMA”) analysis found the proposed merger would likely increase barriers to market entry and foreclose competitors, stating “[t]here is every indication that extensive vertical integration resulting from the proposed merger would raise prices, reduce choice and stifle innovation in markets for PBM services, health insurance, retail pharmacy, and specialty pharmacy.” The AMA also urged the DOJ to beware of vague and speculative efficiency claims that would not outweigh the anticompetitive effects of the proposed merger. As an example, the AMA analysis noted the alleged consumer benefits from combining CVS’ pharmacy data with Aetna’s medical data. AMA pointed out that Aetna already performed its own core PBM functions and already integrates pharmacy and medical data. According to the AMA analysis, “the alleged principal efficiency justification for the merger is nonexistent.”

C. Healthcare Vertical Mergers Restrict Patent Access to Community Pharmacies and Damage the Pharmacist-Patient Relationship

Community pharmacies are faced on a daily basis with the impact of the PBM’s disproportionate market power. Community pharmacies routinely must agree to “take it or leave

it contracts” from the PBMs just to continue to serve their longstanding patients. Such contracts often include blind price terms and onerous obligations that disadvantage community pharmacies. However, from a business standpoint, community pharmacies cannot just walk away from these contracts—because if they did, they would lose patients/customers given the large share of covered lives these PBMs represent. From a patient care and consumer services standpoint, if a community pharmacy drops a PBM contract—they also “drop” their patients. Community pharmacies across the country have been built on a philosophy of community service. However, these one-sided PBM contracts have forced community pharmacies to provide pharmacy services at unsustainable rates, often at a financial loss.  

In some cases, even if a pharmacy is willing to accept onerous contract terms, the PBM will exclude certain pharmacies from their networks altogether, limiting patient choice and access. For example, Aetna, for which CVS Caremark administers the pharmacy benefit, had already engaged in this practice as the 2018 plan year marked the second consecutive year that Aetna excluded independent pharmacies from the opportunity to bid for preferred status in its Part D pharmacy networks. Having the opportunity to be a part of a plan's preferred network is critical, as nearly all Part D plans in 2018 included preferred networks that offer lower co-pays to beneficiaries in exchange for lower reimbursement to the pharmacy.

D. Healthcare Vertical Mergers Restrict Formulary/ Prescription Drug Access

Another issue is formulary exclusion lists, which are a PBM-industry standard. In 2017, 37% of denials for treatment for chronic illnesses were due to formulary exclusions. Since 2012, on PBM more than quadrupled the number of treatments it does not cover. It was the first PBM to exclude some cancer medications. Other market-dominant PBMs soon followed. An updated 2018 study found that the number of drugs included on two major PBMs’ formulary exclusion lists increased from 132 in 2014 to 244 for 2018, an increase of more than 160%. The authors suggest that patients with cancer may be required to switch to generic treatments and low-income minority patients with diabetes are hit especially hard by formulary exclusion lists. There is no competition when PBMs simply remove a medication from a formulary which can create serious issues for patient access to necessary medications. Clearly, these practices have prohibited free market principles and created a no-win situation for pharmacists and patients which warrants greater scrutiny of new healthcare vertical mergers and a re-evaluation of previous PBM mergers and their determined impact on patients (consumers) and marketplaces.

II. Recommendations

With the introduction of the new Draft Guidelines, APhA provides the following recommendations for your agencies to consider in a re-/new evaluation of recent and future healthcare vertical mergers:


A. Increase FTC Scrutiny of Anti-competitive Healthcare Vertical Mergers

APhA strongly urges the agencies to increase FTC enforcement of healthcare vertical mergers. The FTC is the nation’s premier antitrust enforcer and in some respects a model of sound government enforcement. However, as stated by a former FTC official, FTC’s track record(s) is concerning when it comes to PBMs:

- The FTC permitted Express Scripts to acquire Medco creating a PBM with over 40% of the market for large firms. It created the largest specialty drug pharmacy. (The Commission deadlocked 2-2 on whether to remedy concerns in the specialty market). The failure to take actions was in spite of extensive consumer, employer and union advocacy opposing the merger and concerns raised by over 70 Congressmen.
- Despite spite of calls for a review by Commissioner Julie Brill in Congressional testimony in 2013, the FTC declined to review the impact of its decision to determine whether it was right or wrong.
- State legislatures have tried to fill the regulatory vacuum. Yet, when states or the Department of Labor (a fellow federal agency) have considered sound legislation or regulation to address the ongoing consumer protection or competition problems the FTC has opposed that regulation. In some cases, the FTC has opposed transparency in spite of the fact that consumer groups, employers and unions all called for greater transparency, an essential component of health care reform.

B. Develop a DOJ/ FTC Task Force to Monitor Healthcare Vertical Mergers and Acquisitions Activity

As described above, it is clear from the anticompetitive impacts of healthcare vertical merger models that your agencies should immediately establish a joint Task Force to monitor healthcare vertical mergers and acquisitions activity. The Task Force could follow the FTC’s successful Merger Litigation Task Force, launched in 2002 that reinvigorated the FTC’s hospital merger program, which includes a review of, and potential challenge to, consummated transactions that may have resulted in anticompetitive price increases. More recently, the FTC’s Bureau of Competition has formed a Task Force to Monitor Technology Markets investigating any potential anticompetitive conduct in those markets, and taking enforcement actions when warranted. Increased scrutiny is needed as the three largest PBMs collectively control 85-89% of the market, and the four largest commercial health insurers account for more

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21 NCPA CVS/Aetna Comment.
than 80% of the country’s commercial health insurance business, with the majority of local markets dominated by no more than two insurers controlling over 70% of the market.\textsuperscript{22}

\textit{C. Add Section that Demonstrates Consideration that Merger is in the Public Interest}

The Draft Guidelines do not acknowledge the subsequent opportunity for oversight and scrutiny that might be afforded pursuant to the Tunney Act, which establishes post-settlement procedures for a court to determine whether the FTC/DOJ final judgment “is in the public interest.”\textsuperscript{23} APhA strongly urges your agencies to clearly reference compliance considerations in the Draft Guidelines with the Tunney Act and provide justification and documentation of why the merger would be in the public interest.

\textbf{III. Specific Comments on the Draft Guidelines}

APhA offers the following specific comments on the Draft Guidelines:

\textbf{Section 5. Unilateral Effect}

Vertically integrated companies may be able to increase the costs of its rivals in either the upstream or downstream market. Such foreclosure effect can raise prices or reduce quality or innovation to consumers downstream. Ultimately, such a foreclosure effect may require that firms seeking to enter one of the markets must enter both markets, significantly increasing the difficulty of entry. An increasing consolidated vertically merged healthcare marketplace led to the big three vertically merged PBM-insurer companies of today which is encouraging additional mergers in this space to add new market entrants that will be able to compete in the PBM/insurer space. It also discourages new market entrants as the big three PBM-insurers control such high market share.

\textit{a. Foreclosure and Raising Rivals’ Costs}

Under the Draft Guidelines, “[t]he merged firm could also refuse to supply rivals with the related products altogether (“foreclosure”). We strongly urge your agencies to reference the above section I. D. Healthcare Vertical Mergers Restrict Formulary/Prescription Drug Access. Vertically merged PBM-health insurers are simply refusing to give pharmacies and patients in their networks access to certain prescription drugs with limited formularies. While merged PBMs/insurers use restrictive formularies to negotiate with manufacturers for lower prices under certain categories of drugs, they are simply removing and denying enrollees’ access to prescribed medications and inserting themselves as health care providers, which is outside of their scope and clearly disrupts the physician-pharmacist-patient relationship.


Section 6. Elimination of Double Marginalization

It is vitally important that your agencies evaluate how healthcare vertical mergers under Section 6 would eliminate double marginalization to benefit from both margins (upstream and downstream). For example, one pharmacy who recently vertically merged with a health insurer, has used its in-house PBM to slash reimbursements for medications sold to their patients on Medicaid. At the same time, the PBM was reimbursing its pharmacies at much better rates. In 2018, the Arkansas Pharmacists Association found the following:

- For a Fentanyl Patch 100, the merged entity’s pharmacies were reimbursed $400.65 while community pharmacies were reimbursed $75.74.
- For Amoxicillin, the merged entity’s pharmacies were reimbursed $35.92 while community pharmacies were reimbursed $12.21.
- For even something as simple as Ibuprofen, the merged entity’s pharmacies were reimbursed $5.86 while community pharmacies were reimbursed $1.39.26

Section 7. Coordinated Effects

The Draft Guidelines refer to Section 7 of the Horizontal Merger Guidelines which describes how the Agencies evaluate coordinated effects. “In particular, Section 7.1 notes that the Agencies are more likely to challenge a merger on the basis of coordinated effects when the relevant market shows signs of vulnerability to coordinated conduct, and the Agencies have a credible basis on which to conclude that the merger may enhance that vulnerability.” The Horizontal Merger Guidelines state “[p]ursuant to the Clayton Act’s incipiency standard, the Agencies may challenge mergers that in their judgment pose a real danger of harm through coordinated effects, even without specific evidence showing precisely how the coordination likely would take place. The Agencies are likely to challenge a merger if the following three conditions are all met: (1) the merger would significantly increase concentration and lead to a moderately or highly concentrated market; (2) that market shows signs of vulnerability to coordinated conduct (see Section 7.2); and (3) the Agencies have a credible basis on which to conclude that the merger may enhance that vulnerability. An acquisition eliminating a maverick firm (see Section 2.1.5) in a market vulnerable to coordinated conduct is likely to cause adverse coordinated effects.”27 In short, a vertical merger may involve the purchase of a particularly disruptive downstream buyer. By eliminating a buyer who played one upstream firm off of another, such a merger may facilitate collusion in the upstream market. As stated above, three major companies handle the vast majority of prescription claims. Following many of these PBMs’ vertical mergers with insurers they have practiced coordinated efforts for a highly concentrated and vulnerable marketplace that denies patient’s choice of the pharmacy of their choosing to the detriment of the government and other payers. For example, Cigna’s recent acquisition of Express Scripts, the largest unaffiliated PBM in the country with large market share clearly removes a “maverick firm” from the marketplace. For reference, Express Scripts claimed 23% of the PBM market share by total equivalent prescription claims managed in 2018. However, this does not account for all of the Cigna claims that will transition to Express Scripts

by 2020. It also acts as a deterrent to smaller PBMs and community pharmacies’ use of a Pharmacy Services Administrative Organization or a PSAO to contract on their behalf. These PSAOs are no match for the PBMs. In 2013, the Government Accountability Office (“GAO”) conducted a study on the role and ownership of PSAOs and stated that “over half of the PSAOs we spoke with reported having little success in modifying certain contract terms as a result of negotiations. This may be due to PBMs’ use of standard contract terms and the dominant market share of the largest PBMs. Many PBM contracts contain standard terms and conditions that are largely non-negotiable.”

Thank you for your consideration of our comments and your commitment to transparent antitrust enforcement, market competition, and ultimately the welfare of American consumers. If you have any questions or require additional information, please contact, Michael Baxter, Director of Regulatory Affairs, at mbaxter@aphanet.org or by phone at (202) 429-7538.

Sincerely,

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

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