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WASHINGTON, DC

Public Interest Comment<sup>1</sup> on

The Food and Drug Administration's Proposed Rule

## National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers

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### REGULATORY STUDIES CENTER

The George Washington University Regulatory Studies Center improves regulatory policy through research, education, and outreach. As part of its mission, the Center conducts careful and independent analyses to assess rulemaking proposals from the perspective of the public interest. This comment on the Food and Drug Administration's proposed rule setting national standards for entities in the prescription drug supply chain does not represent the views of any particular affected party or special interest, but is designed to evaluate the effect of the FDA's proposal on overall consumer welfare.

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<sup>1</sup> This comment reflects the views of the author, and does not represent an official position of the GW Regulatory Studies Center or the George Washington University. The Center's policy on research integrity is available at <http://regulatorystudies.columbian.gwu.edu/policy-research-integrity>.

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## Background on Proposed Rule and Statutory Authority

On February 4, 2022, the FDA published a proposed rule that outlined national standards for the licensing of drug wholesale distributors (WDDs) and third-party logistics providers (3PLs) in the prescription drug chain. The FDA concurrently provided a regulatory impact analysis (RIA) on its website. The FDA asked for public comments to be submitted by June 6, 2022.

The FDA cites the statutory authority provided by the Drug Supply Chain Security Act (DSCSA) to issue this regulation, which was enacted as Title II of the Drug Quality and Security Act in 2013. DSCSA directed the FDA explicitly to take most of the actions contained in the proposed rule. Among other changes to previous legislation, the FDA notes that DSCSA added Section 583, requiring the FDA to establish national standards for licensing of WDDs and Section 584 which requires national standards and licensing for 3PLs in the prescription drug supply chain. DSCSA alone provides the FDA statutory authority since it explicitly requires FDA to create these national standards and take the other associated actions.

The FDA’s proposed rule states that the regulation is intended to create a uniform national standard for licenses for WDDs and 3PLs operating in the prescription drug supply chain, rather than relying on the existing system of licensure provided by distinct state governments. Much of the text of the proposed regulation outlines specifics of these standards that would be applied to these entities. The regulation also sets forth other measures related to this market, including requiring WDDs to furnish a surety bond, establishing qualifications for key personnel involved in the management of WDD or 3PL operations, and providing procedures for licensure denial, suspension reinstatement, termination, of license and more. The proposed rule also sets forth standards and requirements for approval of secondary organizations that monitor the licensure and inspection process (known as Approved Organizations).

## Assessment of Need for Regulatory Action

The proposed regulation cites the DSCSA as legislation necessitating the proposed rule, noting, “In passing the DSCSA, Congress recognized the need for national standards for the storage, handling, and transport of prescription drugs and directed FDA... to establish such standards.”<sup>3</sup> But beyond the legislative request to promulgate this regulation, the FDA also provides other reasons the proposed rule is necessary.

The proposed rule notes that the United States currently experiences a “patchwork system of governance” when it comes to entity licensure in the supply chain. The stringency of regulation

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<sup>3</sup> FDA. 2022. “National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers.” February 4, 2022, 87 FR 6708. <https://www.federalregister.gov/documents/2022/02/04/2022-01929/national-standards-for-the-licensure-of-wholesale-drug-distributors-and-third-party-logistics>.

guiding WDDs and 3PLs varies by state, and some states do not have unique licensing processes for 3PLs at all (instead licensing them under WDD licensing processes). The variation between states can lead to confusion among both regulators and market participants and may provide opportunities for regulatory arbitrage.

The FDA also states that criminal activities related to prescription drugs may occur in the prescription drug supply chain, sometimes with the assistance of 3PLs, WDDs, or subsets of their employees. The agency notes that this drug diversion can lead to deadly results for consumers.

After outlining these harms, the proposed rule provides insight into why agency action specifically may be necessary to correct them, rather than relying on market self-correction or self-policing of market participants. 3PLs and WDDs may not be economically incentivized to keep drug diversion or counterfeiting from happening. In other words, drug diversion represents a negative market externality: it poses harms to those outside the direct supply chain but imposes no direct costs to the suppliers themselves. The proposed rule also suggests there is an information asymmetry that exists between drug suppliers and consumers that keeps consumers from understanding whether they are receiving substandard (diverted) drug products. Consumers do not even realistically have the capacity to understand whether they are receiving diverted product, creating the need for another authority to make up for or correct their lack of accurate information.

The proposed rule suggests that national standards will eliminate the patchwork of regulation surrounding licensing by setting out clearly understood and consistent regulation for these entities. The consistency of regulation prevents confusion caused by inconsistent rules of different stringency across states. But the proposed rule also suggests that this action helps stem the market failures described above. If the standards and oversight put forth by the FDA are “optimal,” they can keep regulatory costs low while also lessening product diversion in the supply chain. Without sufficient regulation in licensing, the FDA suggests that unreliable stakeholders (such as corrupt 3PLs) can more easily divert prescription drugs into the hands of illegitimate entities. Through this action, in other words, the FDA suggests it is securing the prescription drug supply chain.

This commenter believes that many of the FDA’s reasons for this regulation have merit. First, there is at least anecdotal evidence that there is a market failure here in the form of insufficient self-policing by distributors.<sup>4</sup>

Furthermore, it does seem like aspects of this regulation could assist in mitigating problems present in the drug supply chain. For example, an FDA Inspector General (OIG) report released in 2020 tracked selected drug products throughout the supply chain. Officials could not trace the movement of 21 of the 44 drug products tracked and noted specifically that they “could not identify the

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<sup>4</sup> Bernstein, L., Fallis, D., and Scott Higham. “How drugs intended for patients ended up in the hands of illegal users: ‘No one was doing their job’.” *The Washington Post*. October 26, 2016.

shipping locations of trading partners (e.g., manufacturers, wholesale distributors, and dispensers) or third-party logistics providers that shipped or stored the drugs on behalf of the trading partners.”<sup>5</sup> It seems that the proposed rule, particularly running concurrently with the FDA’s efforts to create a national electronic tracking system, would eliminate this problem through its requirements that 3PLs and WDDs furnish this information. In turn, this could lead to quicker investigations of products that have been tampered with or contaminated, bolstering the FDA’s ability to uncover harmful drugs. This in turn could lead to downstream benefits to the public.

Finally, there is some evidence that states that do not sufficiently regulate WDDs and 3PLs can foment a “race to the bottom” dynamic. Some observers have noted that in some instances WDDs have crossed state borders to states with less stringent regulation; after Nevada increased its oversight of drug wholesalers in the early 2000s some wholesalers shifted most of their operations to California.<sup>6</sup>

## Unexpected Impacts and Potential Alternatives

The FDA may benefit from considering several potential impacts from this regulation, which were not raised in the proposed rule or RIA. The first is the regulation’s implications with regards to market power of particular WDDs and 3PLs. Historically, increased regulation can have unexpected or perverse consequences on market competition. Academics have noted that industry opposition to deregulation may stem from the edge they are provided over competitors by high regulatory compliance costs.<sup>7</sup> In other words, significant compliance costs can benefit large firms by stymieing the efforts of new entrants to enter the market or small competitors to grow.

It is worth considering whether uniform licensing standards would increase market power for large players in the prescription supply chain. There are two reasons such an effect seems possible. First, the FDA’s regulation suggests that its licensing requirements are stricter than the “median” state’s when it calculates that regulatory and compliance costs to WDDs and 3PLs increase post-regulation in the RIA. This may benefit larger WDDs and 3PLs who can better afford higher licensing costs. Second, certain WDDs and 3PLs may be well-placed to expand under uniform regulation—perhaps those located in states with licensing standards most similar to the proposed standards. Other WDDs and 3PLs may already have a multi-state presence, enabling them to utilize economies of scale to expand when licensing standards are uniform across states.

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<sup>5</sup> Murrin, Suzanne. “Ownership—But Not Physical Movement—of Selected Drugs Can Be Traced Through the Supply Chain.” Office of Inspector General, Department of Health and Human Services. February 2020. <https://oig.hhs.gov/oei/reports/oei-05-17-00460.pdf>.

<sup>6</sup> Flaherty, MP and G. Gaul. “Nevada gets tough with mixed results.” *Washington Post*. Oct 22, 2003.

<sup>7</sup> Levy, Martin. “When industry support for stricter regulation is good business: Considering the car rules and methane standards.” *Harvard Environmental and Energy Law Program*. April 14, 2020.

The size of these effects may be limited, and even if they are sizable, it is not necessarily worth reconsidering the proposed regulation. However, it seems problematic that they are not mentioned in the rule, RIA, or Small Entity Analysis. To build out its analysis in the final rule, FDA might consider asking for review from the competition authorities in the U.S. Department of Justice and the Federal Trade Commission.

A second unmentioned, but perhaps more socially beneficial, impact of the regulation is the possibility of more effective or coordinated state-level disciplinary action. The FDA and other parties focused on prescription supply chains have emphasized that there is currently a patchwork of regulation surrounding 3PLs and WDDs. Something that violates WDD licensing requirements in one state may not violate the law in others. This limits the incentive of states to publish or disseminate information about a business that has violated its laws across state lines—why bother when this information may not be relevant to states with different requirements? This dynamic has led to disquieting results in the past; a 2012 report prepared for congressional leaders notes that state regulators struggle to track disciplinary actions and renewals of wholesalers in other states. When North Carolina chose not to renew the wholesaler license of a company that violated drug distribution laws, the company maintained active licenses in 23 other states.<sup>8</sup>

However, with national standards for licensing, states would have greater incentive to disseminate information about violators because that violation is now likely universally applicable. The proposed regulation could make it simpler and more meaningful to track licensing-related violators across state lines because the violation in one state will almost always mean it has violated laws in other states where it operates as well. The higher returns here mean states may have higher incentive to coordinate or engage in dialogue. This rule does not purport to incentivize communications or information-sharing between states. But if the benefit outlined above seems plausible, the FDA should consider analyzing it and also might also consider issuing guidance to encourage state coordination or explore other actions to make sure this benefit is realized.

A final unmentioned impact of the proposed rule may occur through how it affects states' willingness to engage in licensing duties. Specifically, the FDA might consider whether the regulation as written leaves states likely to exit their role in licensing WDDs and 3PLs altogether. The proposed regulation reads:

Section 584(a)(1)(B) of the FD&C Act gives FDA the authority to license 3PLs directly if the State from which a 3PL conducts 3PL activities has not established a licensure requirement in accordance with the regulations... FDA intends to help

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<sup>8</sup> Oversight Committee. "Shedding Light on the "Gray Market": An Examination of Why Hospitals Are Forced to Pay Exorbitant Prices for Prescriptions Drugs Facing Critical Shortages." July 25, 2012. <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/migrated/uploads/7.25.12%20Staff%20Report%20Shining%20Light%20on%20the%20Gray%20Market.pdf>.

stakeholders understand who the appropriate licensing authority is in the 3PL's State.<sup>9</sup>

The language above clarifies that the FDA may license 3PLs in a state directly if the state does not establish a licensing process that matches the national standards. But do states have an interest in developing or operating such standards to begin with? Might they instead have incentives to “offload” licensing of 3PLs to the FDA, to relieve a financial and administrative burden on themselves?

Perhaps the FDA has processes in place that make such a scenario unlikely; states may have their own reasons to maintain control of 3PL licensing (or control of AOs who manage this licensing). But if not, the FDA should consider whether it has the resources to shoulder the management of licensing responsibilities across states itself. It might be worth determining if there is a limit to the number of states for which the FDA could serve as the manager of 3PL licenses. If so, FDA might reconsider whether it is prepared to implement the rule, as proposed, or whether changes would help it take on this role.

To address the issue above, the FDA might consider EPA’s rollout of State vs. Federal Implementation Plans to maintain the National Ambient Air Quality Standards in each state. Under the EPA regulations, states could develop their own plans to meet these standards, which must meet certain qualifications and be reviewed by EPA. EPA promulgated Federal Implementation Plans in states that failed to submit their own plans or meet minimal standards.<sup>10</sup> Uncovering more about the successes and challenges of this program could be instructive.

In the proposed rule preamble, the FDA solicits comments on a number of potential alternatives, many altering aspects of the rule but not its major provisions. One of these is whether states should be allowed to create licensing requirements above and beyond those mandated in the regulation. An earlier iteration of this proposed regulation allowed for state standards that exceeded the national standard, before the FDA revised the regulation toward one national standard because they believed this better matched congressional intent.<sup>11</sup>

The FDA states that allowing state standards to exceed the national standard would likely lower cost savings. While this may be true, since presumably compliance and monitoring costs might increase, this does not necessarily mean net benefits would also decrease as suggested in the FDA’s analysis. The effect on net benefits depends on whether more rigorous licensing standards would hinder illicit activities to a degree that is justified by the increased cost. It’s possible, for example, that more frequent licensure renewal could contribute to a culture of compliance and avoid slippage

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<sup>9</sup> 87 FR 6718

<sup>10</sup> Environmental Protection Agency. “Basic Information About Air Quality SAPs.” Updated January 15, 2022. <https://www.epa.gov/air-quality-implementation-plans/basic-information-about-air-quality-sips>.

<sup>11</sup> 87 FR 6735.

at these companies. But the FDA does not lay out assumptions needed to completely understand its calculations in tables associated with this analysis.

Furthermore, it also seems possible that by mandating exact adherence to FDA requirements, the country may lose benefits of allowing experimentation in licensing procedures. Allowing states to keep enhanced standards may allow for evaluation of whether states with enhanced licensing requirements better curb illicit behavior. Allowing states to exceed national requirements would also better embody the spirit of Executive Order 13132, which includes guidelines on how to carry out federalism. Three subsections of the Executive Order are directly relevant to this alternative:

Section 2e: The Framers recognized that the States possess unique authorities, qualities, and abilities to meet the needs of the people and should function as laboratories of democracy.

Section 2f: The nature of our constitutional system encourages a healthy diversity in the public policies adopted by the people of the several States according to their own conditions, needs, and desires. In the search for enlightened public policy, individual States and communities are free to experiment with a variety of approaches to public issues. One-size-fits-all approaches to public policy problems can inhibit the creation of effective solutions to those problems.

Section 3c: With respect to Federal statutes and regulations administered by the states, the national government shall grant the States the maximum administrative discretion possible. Intrusive Federal oversight of State administration is neither necessary nor desirable.<sup>12</sup>

This comment does not address whether the proposed rule in any way violates state sovereignty or exceeds enumerated powers of governments. But the Executive Order does encourage allowing states to function as “laboratories of democracy” when it is feasible to do so. Allowing states to experiment with different base levels of enforcement here, beyond a necessary minimum, would better embody these principles.

Furthermore, it is not impossible that states just have different landscapes with regard to drug diversion that necessitate different responses. A state heavily affected by the opioid epidemic, with a history of substantial drug diversion, might reasonably argue that it would prefer enhanced licensing standards as part of an effort to mitigate this problem. Of course, if differences in effectiveness were not tracked, it would be difficult to learn anything from allowing states to enact licensing requirements above the national minimum. Perhaps a compromise would be mandating certain reporting requirements for states that exceed national standards or instructing them to track

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<sup>12</sup> Exec. Order No. 13132. “Federalism.” Federal Register Vol. 64, No. 153, August 10, 1999.  
<https://www.govinfo.gov/content/pkg/FR-1999-08-10/pdf/99-20729.pdf>.

certain metrics. Potential methods to track success of licensing reform are discussed in more depth later in this comment.

Beyond the alternatives discussed in the proposed rule, the FDA might consider additional options. This commenter recognizes that the FDA is statutorily obligated to promulgate regulations as directed under DSCSA. However, the agency should still consider the potential effectiveness of completely different alternatives, even ones that clash with this directive. These can be used for internal analyses or to inform future suggestions to congressional stakeholders.

One alternative the FDA might consider is whether the agency has a role to play in WDD and 3PL licensing or monitoring at all, or whether such responsibilities would be better left to the DEA. It is clear that the two agencies are allowed to share data, as noted in a recent memorandum of understanding.<sup>13</sup> Perhaps there are synergies that the agencies can leverage through data gathering which the FDA might wish to pursue should it continue with the proposed rule. But a larger question is whether FDA involvement is necessary at all.

The DEA already has a major role in drug distributor management. Titles II and III of the Controlled Substances Act of 1970 (CSA) require distributors, dispensers, and others that handle controlled substances to register with the DEA.<sup>14</sup> Furthermore, one of the primary mandates of the DEA is to “prevent the diversion of controlled substances from the legitimate market;” in contrast, drug diversion is not mentioned as a primary directive in top-line summaries of FDA duties.<sup>15</sup> Given that drug distributors must already register with the DEA, and the DEA plays a major role in enforcement and monitoring, giving them sole responsibility in setting and enforcing licensing standards could simplify the monitoring process and minimize duplicative work between agencies. It might also require less collaboration and information-sharing between the FDA and DEA, lowering costs related to cooperation. Lastly, the DEA might be able to leverage existing tools and processes to inform effective licensing requirements in ways that the FDA cannot. For example, the DEA developed the Suspicious Order Reporting System database to review suspicious order reports sent by distributors of controlled substances.<sup>16</sup> Using these data could inform optimal licensing requirements or be used as a sort of “credit check” to determine whether WDDs and 3PLs are trustworthy.

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<sup>13</sup> U.S. Food and Drug Administration. “MOU 225-15-11.” July 6, 2021. <https://www.fda.gov/about-fda/domestic-mous/mou-225-15-11>.

<sup>14</sup> Office of the Inspector General. “Review of the Drug Enforcement Administration’s Regulatory and Enforcement Efforts to Control the Diversion of Opioids.” September 2019. <https://oig.justice.gov/reports/2019/e1905.pdf>.

<sup>15</sup> FDA. “MOU 225-15-11.” July 6, 2021. <https://www.fda.gov/about-fda/domestic-mous/mou-225-15-11>.

<sup>16</sup> Office of the Inspector General. “Review of the Drug Enforcement Administration’s Regulatory and Enforcement Efforts to Control the Diversion of Opioids.” September 2019. <https://oig.justice.gov/reports/2019/e1905.pdf>.

## Benefits and Costs

The FDA's RIA includes an in-depth analysis of the benefits and cost-savings associated with the regulation and an explanation of how these estimates were reached. It provides similar analysis for the costs of the regulation and breaks both benefits and costs down by the impacts on each affected stakeholder.

This analysis raises several issues. First, it is unclear that counterfeit or illicit drugs provided to consumers should be assigned a willingness-to-pay (WTP) of zero, rather than a negative value. The analysis states, "in the absence of better information about the willingness-to-pay for diverted drugs, we assume that the willingness-to-pay is zero. We welcome comments on this assumption."

Other estimates of drug diversion costs are rare, but they do exist; Pharmacy Times suggests that the annual cost of controlled prescription drug diversion/abuse for insurers is approximately \$72.5 billion.<sup>17</sup> Obviously their estimate includes drug diversion that occurs beyond WDDs and 3PLs specifically. But estimates like this suggest that rough estimates of the cost of diversion are not unreachable, and analysis included in the proposed rule's own appendix could be helpful in reaching such a figure. Even if uncovering an accurate cost to consumers is difficult, this commenter would recommend that a negative WTP be used for diverted (or counterfeit) drugs. An important component of effective prescription drug use is certainty of the drug's effects (or its range of effects). Potentially compromised drugs can cause mental damages and difficult-to-detect health effects. Additionally, the absence of crucial medication (due to replacement by ineffective diverted drugs) has its own dangers.

A different approach to estimating costs would be to divide the cost of "drug diversion" into two categories. The first category would be the cost to consumers of receiving diverted drugs (which might be expired, adulterated, ineffective or have unforeseen side effects). The second would be the cost of drugs diverted to individuals who were not prescribed them, for example the costs of addiction and long-term dependency on painkillers for those who obtain them in the black market related to 3PLs and WDDs. Once again, this is a hard cost to estimate. But it goes unacknowledged in the current RIA and should at least be considered an unquantifiable benefit in any analysis.

The proposed rule's appendix includes case studies of counterfeit drugs negatively impacting consumers. Included within this are examples of drug diversions leading to adverse events, including drugs such as Avastin, Procrit, and Xanax. As the FDA acknowledges, this has led to results such as ineffective cancer treatment and elevated side effects from drugs. It seems problematic that there is no monetization of this in cost-benefit analysis, or even an attempt to perform break-even analysis related to the human suffering caused by diverted drugs.

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<sup>17</sup> Pharmacy Times. "The High Cost of Drug Diversion." January 4, 2016.  
<https://www.pharmacytimes.com/view/the-high-cost-of-drug-diversion>.

Second, the FDA also may be leaving out benefits by not considering the rule's effects on regulatory uncertainty. Specifically, regulatory uncertainty that exists for state and business stakeholders under the status quo may be erased when the regulation is promulgated. Past regulations have suggested that reducing regulatory uncertainty is a benefit of proposed rules. For example, one EPA rule stated that it will, "reduce regulatory uncertainty by defining requirements for emission limits."<sup>18</sup>

After DSCSA passed, state agencies, WDDs, and 3PLs knew that their licensing processes would change, and that the FDA would likely play a larger role in the licensing process. But they were unsure what the FDA's role would be, and whether the standards they previously operated under would persist. One presentation by a drug law organization drives home this uncertainty. Describing Title II's effects on WDDs and 3PLs, the slide read, "experience with states varies – lack of understanding/awareness often compounds the problem, different processes (e.g., legislative vs. regulatory), as well as differences in state culture/interpretation with respect to uniformity and preemption."<sup>19</sup> Several states have also reportedly delayed updating or issuing new licensing requirements for WDDs and 3PLs since they expect federal guidance. This likely leads to suboptimal processes or general confusion.

The FDA should consider whether ending this uncertainty when the final regulation is issued should be counted as a benefit. Quantifying or monetizing the effects of regulatory uncertainty is difficult. However, some scholars have considered it in other spheres, and their methods may be useful for the FDA in considering it in the prescription drug supply chain. For example, one study has discussed regulatory uncertainty costs related to coal-fired power plants, and another discusses regulatory uncertainty's effects on investment.<sup>20</sup> Other authors have discussed monetization of regulatory uncertainty generally, which may offer insights into how the FDA could monetize the impact of regulatory uncertainty in this market.<sup>21</sup>

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<sup>18</sup> Environmental Protection Agency. "Regulatory Impact Analysis for the Proposed Standards of Performance for Greenhouse Gas Emissions for New Stationary Sources: Electric Utility Generating Units." September 2013. <https://www.epa.gov/sites/default/files/2013-09/documents/20130920proposalria.pdf>.

<sup>19</sup> Gallenagh, Elizabeth. "Title II – Licensure of Wholesale Distributors and 3PL's: Where does FDA stand, where do states stand, what about VAWD, and what can you do about it?" *Food and Drug Law Institute*. <https://www.fdli.org/wp-content/uploads/2017/11/DQSA-Hrisch-B.pdf>.

<sup>20</sup> Patiño-Echeverri D, Fischbeck P and E. Kriegler. "Economic and environmental costs of regulatory uncertainty for coal-fired power plants." *Environ Sci Technol*. 43(3):578-84. February 1, 2009. Doi: 10.1021/es800094h. PMID: 19244986.

Fabrizio, K. R. (2013). "The effect of regulatory uncertainty on investment: evidence from renewable energy generation." *The Journal of Law, Economics, & Organization*, 29(4), 765-798. April 2, 2012.

<sup>21</sup> See for example: Bloom, N. "Fluctuations in Uncertainty." *Journal of Economic Perspectives*, 28(2), 153-176. 2014 and Baker, S. R., Bloom, N., and S.J. Davis. "Economic Policy Uncertainty." *The Quarterly Journal of Economics*, 131(4), 1593-1636. 2016.

Third, FDA should make sure it considers whether unlawful behavior involving WDDs and 3PLs has increased or decreased in recent years. If either is the case, it may affect the magnitude of benefits associated with the rule's reduction of drug diversion. A 2017 report from Deloitte states that an increase in pain clinics has caused an increase in the distribution of expired or counterfeit medication.<sup>22</sup> This suggests that the opioid epidemic may have increased rates of drug diversion, although there is mixed evidence as to whether most of this diversion occurs at this point in the supply chain. On the other hand, WDD and 3PL involvement in drug diversion and other illicit activities could have declined over the years. In this case, benefits from this regulation would be reduced. To understand whether this behavior is rising or falling, it would be helpful for the FDA to develop a firm understanding of how WDDs and 3PLs conduct business today and what percent of drug diversion through 3PLs and WDDs remains unseen. Without this assessment, which is not provided in the rule or RIA, it is natural to question whether the FDA's proposed baseline is correct.

Fourth, the proposed rule should consider how the changing enforcement of prescription drug violations in other quarters may affect calculated costs and benefits. For example, OIG investigations of drug diversion increased in the late 2010s, potentially increasing scrutiny of WDDs and 3PLs and lowering their incentive to engage in unlawful behavior. The Deloitte report also suggests that combatting drug diversion has become a top law enforcement priority, noting that the DEA's budget devoted to diversion control increased by 9 percent in FY 2016.<sup>23</sup>

The DEA has also taken other steps to limit unlawful prescription drug activities. In the late 2010s the agency tried to limit unlawful prescription drug use by adjusting the quantities of controlled substances allowed to be released under its quota system. This quota system can limit the quantities of drugs flowing in the supply chain and was created partially to eliminate diversion from trade channels.<sup>24</sup> The DEA has also publicized some of its enforcement actions against wholesalers, such as a 2017 raid where agents seized 27 tractor trailer loads of opiates.<sup>25</sup> All these actions have the potential to limit the number of diverted drugs in the system or discourage WDDs and 3PLs from illicit activity.

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<sup>22</sup> Yarin, Dave. "Drug diversion enforcement on the rise, and an RX for prevention." Deloitte. 2017. <https://www2.deloitte.com/us/en/pages/regulatory/articles/drug-diversion-enforcement-on-the-rise.html>.

<sup>23</sup> Yarin, Dave. "Drug diversion enforcement on the rise, and an RX for prevention." Deloitte. 2017. <https://www2.deloitte.com/us/en/pages/regulatory/articles/drug-diversion-enforcement-on-the-rise.html>.

<sup>24</sup> Kackik, Alex. "Pharma supply chain ramps up technology to battle opioid epidemic." Modern Healthcare. September 16, 2017. <https://www.modernhealthcare.com/article/20170916/NEWS/170919916/pharma-supply-chain-ramps-up-technology-to-battle-opioid-epidemic>.

<sup>25</sup> Milenkovich, Ned. "Research Third-Party Logistics Providers Beforehand." Pharmacy Times. September 23, 2021. <https://www.pharmacytimes.com/view/research-third-party-logistics-providers-beforehand>.

Agencies are not the only entities pursuing action against businesses in the prescription drug supply chain. A coalition of hundreds of state, local and tribal governments have a suit in U.S. District Court against wholesale drug distributors and manufacturers of opioids, seeking damages from corporate actions that drove the opioid epidemic.<sup>26</sup> One wholesale drug distributor, Cardinal Health, agreed to pay a \$44 million fine to the Department of Justice as a settlement in a case involving negligence also related to the opioid epidemic.<sup>27</sup> Lastly, other federal regulations may have altered the landscape since DSCSA. One recent regulatory change is the federal Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, which requires that potentially suspicious orders be investigated thoroughly by a company within seven days.<sup>28</sup>

The FDA cannot just account for this increased enforcement by lowering potential “benefits” of uniform licensing; the regulatory landscape is more complicated than to allow for such as simple adjustment. As the GAO reported in 2020, some of the enforcement efforts of other agencies have major underlying issues, and many will focus on different parts of the drug supply chain than WDDs and 3PLs.<sup>29</sup> But the FDA should still make some effort to integrate these changing circumstances into their BCA.

Alternatively, would more effective regulation enable other agencies to devote less money and resources to fighting drug diversion (e.g., allowing the DEA to lower its vast budget devoted to drug diversion activities)? If so, then this support may no longer be necessary, and might merit consideration as a monetized cost-saving in the RIA.

## Evaluation of Outcomes

A proposed rule of this magnitude should be evaluated after implementation to determine whether it is meeting its stated aims. This can allow policymakers to determine whether more actions are required to correct market failures, or whether regulatory action is worsening conditions. The FDA proposed rule makes no mention of ex post evaluation to determine the rule’s effectiveness.

There are several potential metrics that would be useful to measure success at meeting key objectives (including implementation of national standards and lowered drug diversion). It would be useful to calculate the number of states that have implemented licensing standards and

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<sup>26</sup> Giuffre, Mark. “Drug Diversion and Loss Prevention: A Changing Landscape.” *Security Management*. September 1, 2020.

<sup>27</sup> McKeivitt, Jennifer. “Are pharmaceutical supply chains responsible for the opioid epidemic?” *Supply Chain Dive*. January 3, 2017.

<sup>28</sup> Milenkovich, Ned. “Research Third-Party Logistics Providers Beforehand.” *Pharmacy Times*. September 23, 2021. <https://www.pharmacytimes.com/view/research-third-party-logistics-providers-beforehand>.

<sup>29</sup> Government Accountability Office. “Drug Control: Actions Needed to Ensure Usefulness of Data on Suspicious Opioid Orders.” January 2020. <https://www.gao.gov/assets/gao-20-118.pdf>.

associated standards surrounding AOs and pharmacies, perhaps on an annual basis. It would also be useful to track the number of criminal incidents involving illicit behavior from WDDs and 3PLs year-over-year.

Tracking other metrics can ensure that this regulation does not interfere with other essential goals of the prescription drug supply chain. For example, a smoothly operating supply chain that allows consumers access to prescription drugs in a timely manner is also important. One metric that could be used to gauge this regulation's effects on the FDA's overall mandate is the total number of WDDs and 3PLs operational in each state before and after this proposed rule's effective date. It would also be useful to track the rate of licensure rejection or suspension year-over-year as well as the number and content of consumer complaints related to prescription drug speed of delivery, availability, or effectiveness. These metrics can help determine whether enough drug distributors exist to provide consumers with vital drugs in a timely manner and whether consumers are well-served by the resulting supply chain.

In its assessment of alternatives, the FDA mentions that it could allow enforcement discretion for WDDs for a year and extend enforcement discretion for 3PLs one additional year. The FDA suggests this could reduce compliance costs, but also delay benefits and cost savings associated with the new regulation. The FDA specifically asks for comments addressing this alternative.

If the agency expects higher costs from this rule, it may benefit from extra time to examine the effectiveness of the electronic tracking system for prescription drugs that is also being implemented. Perhaps the electronic tracking system will drastically reduce the volume of illicit supply chain activity involving prescription drugs. If this is the case, the FDA could note this to congressional authorities, and use it as evidence that the proposed regulation, given its increased cost, is no longer necessary. However, if the implementation of the electronic tracking system is dependent on, or must run concurrently with, this proposed regulation, this benefit becomes moot.

## Distributional Effects

The FDA essentially states that it expects the proposed rule to have negligible effects on international trade. It also states that the rule is unlikely to have a significant effect on the human environment, and tentatively state that it will not affect Indian tribes or their relationship with the government.

However, the FDA does directly note that it expects a significant economic impact on small entities, noteworthy because roughly 90 percent of WDDs and 66 percent of 3PLs are classified as small entities. The FDA suggests that both groups will see an annualized net cost under this rule.

It is encouraging that the proposed rule does not have disproportionate impact on most populations or the environment. But given the significant impact of this rule on 3PLs and WDDs, FDA should consider the extent of licensing requirements on an ongoing basis, keeping an eye toward

elimination of requirements that are particularly onerous for business entities while offering little to no consumer protection from diverted prescription drugs.

## Conclusions

The FDA has published a well-considered and researched proposed rule and regulatory impact analysis. Its rationale for the rule, as well as the additional analysis provided above, support the case that regulation is appropriate to correct for market failures in the prescription drug supply chain. But regulation in markets this complex can always benefit from scrutiny of their underlying assumptions, examination of their alternatives, and review of potential unintended consequences. This comment seeks to strengthen FDA analysis by offering information on each of these fronts.

The FDA should consider whether nationalizing licensing standards might have unintended effects on market power, potentially advantaging certain WDDs and 3PLs, as well as whether it will change states’ willingness to administer licenses themselves rather than deferring that responsibility to the FDA. The rule also has the potential to incentivize more positive actions, such as greater collaboration between states.

Though it must comply with the DSCSA, the FDA should also fully analyze the range of alternatives that could correct problems in the supply chain, from small adjustments to the written rule like allowing the national standards to act as a “floor” for states to major shifts such as the feasibility of making DEA the regulator primarily involved in this market. The summary of recommendations table below provides an overview of issues related to the regulation that may require greater scrutiny.

### Summary of Major Recommendations

Issue		Recommendation
Unexpected Impacts	1	Consider whether uniform licensing standards would increase market power for large players in the prescription supply chain. The FDA might perform analysis on market competition effects, receiving assistance from market competition regulators as needed.
	2	The proposed regulation could make it simpler and more meaningful to track licensing-related violators across state lines. The FDA should consider how to realize this potential benefit and issue guidance to encourage state coordination if appropriate.
	3	Consider whether the regulation leaves states likely to exit their role in licensing WDDs and 3PLs altogether. If so, the FDA should consider whether it has the resources to shoulder the management of licensing responsibilities across states itself and determine

		whether there is a limit to the number of states where the FDA could serve as the manager of 3PL licenses.
<b>Potential Alternatives</b>	4	Consider allowing states to exceed national standards if they track and report on certain metrics to evaluate efficacy, rather than banning state standards that exceed national standards altogether.
	5	Consider the benefits of sharing regulatory duties with the DEA, from general collaboration and data sharing to offloading major enforcement duties to the DEA entirely.
<b>Benefit-Cost Analysis</b>	6	Consider whether it is appropriate to assign counterfeit or illicit drugs provided to consumers a willingness-to-pay of zero. Consider alternate approaches to estimating health costs to consumers, such as performing break-even analysis.
	7	Consider whether ending “regulatory uncertainty” by enacting the proposed regulation should be counted as a benefit.
	8	Consider how changing conditions may have altered the benefits and costs of this regulation since 2013. Rates of misbehavior by entities in the supply chain, level of enforcement by other agencies, and other market volatility may have altered the benefits FDA can expect through more rigorous and uniform standards.
<b>Evaluation of Outcomes</b>	9	Establish plans to evaluate effectiveness of the proposed regulation. Metrics should determine both success at meeting key objectives (such as the number of states that have implemented licensing standards annually) and whether the regulation interferes with other essential goals of the prescription drug supply chain (such as the total number of WDDs and 3PLs operational in each state before and after this proposed rule’s effective date).
	10	Consider delaying enforcement of this rule to determine whether the electronic tracking system for prescription drugs might reduce the volume of illicit supply chain activity involving prescription drugs.