REGULATORY REPORT CARD | January 2015

MERCATUS CENTER
George Mason University

AGENCY

Food and Drug Administration

Rule title
Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products

RIN	0910-AG88
Publication Date	November 4, 2013
Comment Period Closing Date	January 3, 2014
Stage	Proposed rule

REGULATORY SCORING

	SCORE
1. Systemic Problem: How well does the analysis identify and demonstrate the existence of a market failure or other systemic problem the regulation is supposed to solve?	**2**/5
2. Alternatives: How well does the analysis assess the effectiveness of alternative approaches?	**2**/5
3. Benefits (or Other Outcomes): How well does the analysis identify the benefits or other desired outcomes and demonstrate that the regulation will achieve them?[1]	**3**/5
4. Costs: How well does the analysis assess costs?	**3**/5
5. Use of Analysis: Does the proposed rule or the RIA present evidence that the agency used the Regulatory Impact Analysis in any decisions?	**1**/5
6. Cognizance of Net Benefits: Did the agency maximize net benefits or explain why it chose another alternative?	**2**/5
Total Score	**13**/30

SUMMARY

The goal of the proposed regulation is to prevent shortages of drugs and biological products. It would require manufacturers to notify the FDA six months in advance of when there is an expected permanent discontinuance or interruption in manufacturing or as soon as possible. The legal authority for this regulation comes from the recently passed law called the Food and Drug Administration Safety and Innovation Act (FDASIA). The FDA's primary estimate suggests that the net benefit is between $25.749 and $25.859 million annually. The regulation would impose $31.306 million in costs annually. The benefit is between $57.055 and $57.165 million annually. The regulation has weak economic reasoning and fails to conduct any serious investigation of alternatives or why the market fails to deal with the shortages.

The Regulatory Studies Program at the Mercatus Center at George Mason University issues Regulatory Report Cards scored by a team of economists for economically significant proposed regulations. For more information about the program, scorers, other scores, and scoring conventions, see www.mercatus.org/reportcard.

MERCATUS CENTER
George Mason University

1. Systemic Problem: How well does the analysis identify and demonstrate the existence of a market failure or other systemic problem the regulation is supposed to solve?	**2**		
Does the analysis identify a market failure or other systemic problem?	2	1A	The analysis does not clearly identify a market failure. The FDA simply states that drug and biological product shortages may result in delays or interruptions in patient treatment and suboptimal patient care. The FDA does not entertain the possibility that ongoing market shortages might stem from government policies that influence prices and may hamper the ability of the market to remove market shortages. If this is the case, the problem would be correctly labelled a government failure.
Does the analysis outline a coherent and testable theory that explains why the problem (associated with the outcome above) is systemic rather than anecdotal?	1	1B	The FDA does not develop a theory as to why shortages exist or continue, but simply states that shortages occur, with little to no explanation as to why this reflects a systemic problem in private markets.
Does the analysis present credible empirical support for the theory?	1	1C	The analysis presents no theory, and hence no empirical support; however, empirical support is shown for the number of shortages that occur, but it is not clear how exactly the FDA got its numbers.
Does the analysis adequately address the baseline? That is, what the state of the world is likely to be in the absence of federal intervention not just now but in the future?	2	1D	The baseline is the old regulation, which was based on an executive order. The new rule is based on law (RIA, 7). From two years' worth of data, the FDA projects what will happen in the future to notifications. This method of using just two years of data and "staff predictions" about the future leaves room for error. No discussion on a purely market-based drug regime is provided.
Does the analysis adequately assess uncertainty about the existence or size of the problem?	2	1E	The FDA acknowledges some estimates are uncertain since they are based on nonrepresentative studies. The FDA also states there is uncertainty surrounding a possible change in behavior from industry that would result in notifications that are not meaningful (e.g., due to different interpretation of words such as "life supporting," and "life sustaining" drugs) and yet would still result in additional FDA review costs.
2. Alternatives: How well does the analysis assess alternative approaches?	**2**		
Does the analysis enumerate other alternatives to address the problem?	4	2A	Alternatives to the proposed rulemaking include: (1) no change in regulation (staying with the regulation that is based on the executive order); (2) publish additional guidance encouraging voluntary notifications; (3) require notification from all manufacturers, not just those affected by this current rule (a stricter standard).
Is the range of alternatives considered narrow (e.g., some exemptions to a regulation) or broad (e.g., performance-based regulation vs. command and control, market mechanisms, nonbinding guidance, information disclosure, addressing any government failures that caused the original problem)?	1	2B	The range of alternatives is fairly narrow in scope since they do not represent significant departures from the status quo. The FDA acknowledges that it is required by law to issue a regulation implementing the new drug shortage provisions of FDASIA, and so this makes alternatives to publishing guidance not viable. There is no discussion of using a price system to eliminate shortages, which is the typical policy an economist would suggest to remove a market shortage.

Does the analysis evaluate how alternative approaches would affect the amount of benefits or other outcome achieved?	1	2C	The focus here is on the law requiring the FDA to act, hence choices 1 and 2 are not considered. The FDA feels choice 3 would have greater benefits, but the costs would be great as well. This is mentioned, but no calculations are done. Option 3 would probably require additional authority from Congress.
Does the analysis identify and quantify incremental costs of all alternatives considered?	0	2D	There is no quantification.
Does the analysis identify the alternative that maximizes net benefits?	2	2E	The net benefits of the proposed rule are estimated; none are estimates for alternatives.
Does the analysis identify the cost-effectiveness of each alternative considered?	1	2F	There is no discussion of cost-effectiveness of alternatives, other than for the alternative "Require Notifications from All Manufacturers." The FDA simply states, "This alternative would increase costs associated with notifications, but may also increase benefits."
3. Benefits (or other Outcomes): How well does the analysis identify the benefits or other desired outcomes and demonstrate that the regulation will achieve them?	**3**		
Does the analysis clearly identify ultimate outcomes that affect citizens' quality of life?	5	3A	Yes, the analysis identifies ultimate outcomes clearly: expensive alternative treatments are avoided; the number of patients affected by shortages declines; reduced premature deaths and other, nonfatal adverse events are identified (RIA, 12ff).
Does the analysis identify how these outcomes are to be measured?	4	3B	The analysis assumes to measure benefits of life years gained using willingness to pay measures, avoiding expensive treatments, and managing shortages as benefits.
Does the analysis provide a coherent and testable theory showing how the regulation will produce the desired outcomes?	3	3C	The theory is basically the idea that if the FDA knows of any interruptions or discontinuance in manufacturing, then it can be managed for better future outcomes. The solution for the FDA seems to be to encourage manufacturers to ramp up production and to work with the FDA to come up with an action plan; further, the FDA hopes that reputational concerns would induce manufacturers to avoid shortages.
Does the analysis present credible empirical support for the theory?	2	3D	The analysis's support for the theory is mostly anecdotal. The FDA cites a survey of 245 oncologists where 92 percent indicated that their patients' treatments were affected and 83 percent said they were unable to prescribe standard chemotherapy to their patients because of a shortage in an oncology drug. This survey found that respondents switched regimens (79 percent), substituted a drug partway through therapy (77 percent), delayed treatment (43 percent), chose among patients (37 percent), reduced doses (20 percent), and referred patients to other practices (17 percent) in response to a drug shortage. A separate survey of anesthesiologists showed that respondents said patients experienced longer recovery times (52.8 percent), and a less optimal outcome (66.7 percent) due in part to increases in risk of medication errors and adverse events because providers might be unaware that the alternative product may vary in strength, dosage, time to onset of action, and duration of action.

Does the analysis adequately assess uncertainty about the outcomes?	2	3E	Uncertainty is mentioned due to the fact the FDA's calculations don't include certain factors, such as nonfatal adverse events. They use anecdotal evidence in some areas. They use unrepresentative measurements in some cases (RIA, 17). They present high and low estimates.
Does the analysis identify all parties who would receive benefits and assess the incidence of benefits?	4	3F	The gain to consumers is measured. The gain to hospitals and manufacturers is calculated (RIA, 21).
4. Costs: How well does the analysis assess costs of the regulation?	**3**		
Does the analysis identify all expenditures likely to arise as a result of the regulation?	4	4A	The report identifies the costs to manufacturers for reporting to the FDA and the responses they have to take. The report also identifies the costs to the FDA to mitigate and prevent shortages (RIA, 17ff).
Does the analysis identify how the regulation would likely affect the prices of goods and services?	3	4B	Shortages have resulted in cases of drug prices going up 650 percent and 4,533 percent. This would be mitigated by this regulation (RIA, 7). However, encouraging manufacturers to longer shifts increases marginal costs, which would also have to be recouped by higher prices of products (RIA, 13), which the FDA is unable to quantify at this stage.
Does the analysis examine costs that stem from changes in human behavior as consumers and producers respond to the regulation?	2	4C	The FDA assumes 100 percent compliance from industry since noncompliance would be publicized, hence changes in behavior in response to regulation is not foreseen.
If costs are uncertain, does the analysis present a range of estimates and/or perform a sensitivity analysis?	3	4D	The analysis has a primary estimate and then a low and a high estimate of the regulation due to uncertainties in calculating costs and benefits. A sensitivity analysis is not performed.
Does the analysis identify all parties who would bear costs and assess the incidence of costs?	3	4E	Small business calculations are completed. Impact on manufacturers are completed. Costs to the FDA are calculated. Price elasticity needs to be discussed. The impacts on wages and on growth were not estimated (918).
5. Use of Analysis: Does the proposed rule or the RIA present evidence that the agency used the analysis in any decisions?	**1**	5	The RIA seems more like a formality performed because OMB identified this regulation as economically significant (RIA, 3). The proposed rule appears to simply meet the demands of executive order 13588 directing the FDA to take steps necessary to prevent or mitigate disruptions in the supply of lifesaving medicines. There is no discussion of what an optimal rule might look like, and there are no viable alternatives presented or examined.
6. Net Benefits: Did the agency maximize net benefits or explain why it chose another alternative?	**2**	6	Net benefits of the proposed rule are estimated, but not necessarily the maximum, since no other alternatives were assessed.