Addendum to the Preliminary Regulatory Impact Analysis of the Proposed Rule to Require a Unique Device Identification System

Docket No. FDA-2011-N-0090

Section 519(f) of the Federal Food, Drug, and Cosmetic Act requires FDA to promulgate regulations to establish a unique device identification system. Section 614 of the Food and Drug Administration Safety and Innovation Act (FDASIA) amends section 519(f) to require FDA to issue a proposed and final rule within specified timeframes, and to implement the final regulations with respect to devices that are implantable, life-saving (life-supporting), and life-sustaining not later than two years after a final rule has been published. This amendment requires FDA to modify the timeframe for implementation of the July 10, 2012 proposed rule's requirements with respect to devices that are implantable, life saving (life-supporting), or life-sustaining. Consistent with the Proposed Rule Amendment (77 Fed.Reg. 69393, November.19, 2012) of the Proposed Rule for a Unique Device Identification (UDI) System (77 Fed.Reg. 40736, July 10, 2012), we will refer to life-saving (life-supporting) as life-supporting for the remainder of this addendum.

Because the UDI requirements of FDA's July 10, 2012 proposed rule would already apply to all class III devices and to all devices licensed under the Public Health Services Act (PHS Act), the practical effect of the amendments made by FDASIA section 614 is to require a more rapid implementation of the proposed rule respecting implantable, life-supporting, and life-sustaining devices that are classified in class I or II or that have not been classified into class I, II, or III, and to require a more rapid implementation of the direct marking requirement for implantable, life-supporting, and life-sustaining class III devices.

This addendum to the preliminary regulatory impact analysis (RIA) summarizes the total costs of the proposed rule using the revised two-year implementation period for affected devices. For the proposed rule, FDA assumed that labelers of affected implantable devices would add the UDI to the device label and package and submit data to the GUDID in the first year and directly mark these devices in year three. The modified timeframe would advance the implementation dates for implantable, life-supporting and life-sustaining devices, including the requirement that these devices be directly marked. We lack sufficient information to estimate the number of establishments that label life-supporting and life sustaining devices and that would be affected by the FDASIA requirement. For this addendum, therefore, we use the simplifying assumption that labelers of all class II devices would comply with all of the UDI requirements in year two and that labelers of class III implantable devices would directly mark these devices in year two. We keep all other assumptions unchanged from the RIA. The effect of these assumptions might be to overstate the annualized costs for some labelers of class II device that would not be considered implantable, life-supporting, or life sustaining devices and to understate the annualized costs for some labelers of class I devices that would be considered life-supporting and life sustaining devices. In the latter case, affected class I device labelers would be required to comply with the rule in year 2 rather than in year 5 for the UDI requirements and in year 2 rather than in year 7 for the direct marking requirement.

The revised implementation date may create additional burdens beyond those captured in our original analysis. Having a larger share of labelers comply with all UDI requirements in year two rather than according to the original proposed implementation

dates may cause temporary inefficiencies in the device industry. We request detailed comment from labelers of implantable, life-supporting and life-sustaining devices about their expected costs to comply with the rule and request comment from all device labelers about how the two-year implementation date might affect costs.

Table 1 shows the revised undiscounted regulatory costs and the present value over 10 years at 7 percent and 3 percent for domestic labelers. The total present value of costs to domestic labelers over 10 years would equal about $540 million at 7 percent and about $608 million at 3 percent, and the annualized costs would equal $71.9 million at 7 percent and $69.2 million at 3 percent. The total increase in annualized costs to domestic labelers compared to the proposed rule is about $5.4 million at 7 percent over 10 years.

Addendum Table 1.--The Impact of the Staggered Effective Dates on the Regulatory Costs to Domestic Labelers Over a 10-Year Time Horizon (2010 dollars)

	Undiscounted Regulatory Costs of Proposed Rule by Type of Cost ($ mil)					Present Value with Discount Rate ($ mil) [1]	
	All Cost Components Except Label Redesign by Highest Device Class			Label Redesign in 1 Year			
Year	Class III [2]	Class II [3]	Class I [4]	All Classes	Total Cost by Year	7%	3%
1	$20.7			$55.2	$75.9	$75.9	$75.9
2	$16.2	$179.2		$7.6	$203.0	$189.7	$197.0
3	$4.6	$32.4		$7.6	$44.6	$39.0	$42.1
4	$4.6	$32.4		$7.6	$44.6	$36.4	$40.8
5	$4.6	$32.4	$16.8	$7.6	$61.4	$46.9	$54.6
6	$4.6	$32.4	$0.1	$7.6	$44.8	$31.9	$38.6
7	$4.6	$32.4	$15.6	$7.6	$60.3	$40.2	$50.5
8	$4.6	$32.4	$1.3	$7.6	$45.9	$28.6	$37.3
9	$4.6	$32.4	$1.3	$7.6	$45.9	$26.7	$36.2
10	$4.6	$32.4	$1.3	$7.6	$45.9	$25.0	$35.2
Total for Year 1 to Year 10					$672.3	$540.2	$608.3
Annualized Total Over 10 years ($ mil)						$71.9	$69.2

[1] Present values are calculated for each year at the beginning of the period. Present value adjusts for the time value of money with a 7 percent or 3 percent discount rate (i.e., costs incurred in future years have a lower present value than costs incurred in year 1).

[2] All labelers of implanted devices are assumed to incur UDI labeling costs in year 1. This category of costs includes the costs for direct marking of implants in year 2.

[3] Costs for labelers of affected class II devices are revised to require implementation in year 2 as required by FDASIA. However, FDA's revised estimate assumes that labelers of all class II devices that are not implants would comply in year 2.

[4] Includes the costs for direct marking of multiple-use devices in year 7.

Addendum table 2 of this document summarizes the revised total costs of the proposed rule for all sectors, assuming that in year two, labelers of implantable devices would comply with the direct marking requirements and that labelers of all class II devices would comply with all UDI requirements. The total present value of domestic costs for all affected sectors would be about $554.8 million over 10 years with a 7 percent discount rate and $625.4 million at 3 percent. The total annualized costs over 10 years would be $73.8 million at 7 percent and $71.1 million at 3 percent.

Addendum Table 2.--Summary of the Estimated Regulatory Costs of the Proposed Rule (2010 dollars)[1,2]

Affected Sectors	Total Present Value of Cost over 10 years ($ million)		Total Annualized Costs Over 10 Years ($ million)	
	3 Percent	7 Percent	3 Percent	7 Percent
Domestic Labelers	$608.3	$540.2	$69.2	$71.9
Issuing Agencies	$1.0	$0.9	$0.1	$0.1
FDA	$16.1	$13.7		$1.8
Imports	Not quantified	Not quantified	Not quantified	Not quantified
Total Domestic Cost of the Proposed Rule	$625.4	$554.8	$71.1	$73.8

[1] Present value and annualized costs calculated at the beginning of the period.
[2] Domestic costs for labelers are revised to reflect FDASIA requirement that labelers of affected devices comply in year two. However, FDA's revised estimate assumes that labelers of all class II devices would comply in year 2.

Addendum table 3 presents the revised ROCIS accounting information under the assumption that labelers of all class II devices would comply with all of the UDI requirements in year two and that labelers of class III implantable devices would comply with the direct marking requirement in year two.

Addendum Table 3.--Economic Data: Costs and Benefits Accounting Statement (2010 dollars)

				Units			
Category	Primary Estimate	Low Estimate	High Estimate	Year Dollars	Discount Rate	Period Covered	Notes
Benefits							
Annualized Monetized $millions/year					7%		
					3%		
Annualized Quantified					7%		
					3%		
Qualitative	More accurate and prompt identification of device related adverse events would lead to more rapid action to reduce the incidence of the adverse events and to more effectively target and manage medical device recalls.						
Costs							
Annualized Monetized $millions/year	$73.8	$37.6	$110.0	2011	7%	10 years	Costs to foreign labelers are not included.
	$71.1	$36.3	$106.0	2011	3%	10 years	
Annualized Quantified					7%		
					3%		
Qualitative							
Transfers							
Federal Annualized Monetized $millions/year					7%		
					3%		
From/ To	From:			To:			
Other Annualized Monetized $millions/year					7%		
					3%		
From/To	From:			To:			
Effects							
State, Local or Tribal Government: No effect							
Small Business: The proposed rule may have a significant economic impact on a substantial number of small entities that label medical devices.							
Wages: No effect							
Growth: No effect							