DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

General and Plastic Surgery Devices: Restricted Sales, Distribution, and Use of Sunlamp Products

Docket No. FDA-2015-N-1765

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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Office of the Commissioner

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Submit either electronic or written comments on the proposed regulatory impact analysis by March 21, 2016.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2015-N-1765 and RIN 0910-AH14 for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided.

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I. Introduction and Summary

A. Introduction

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). OMB has determined that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. We believe this proposed rule would result in a significant impact on a substantial number of small entities, but the impacts are uncertain.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA expects this proposed rule, if finalized, to result in a 1-year expenditure that would meet or exceed this amount.

B. Summary of Costs and Benefits

The proposed rule would restrict the use of sunlamp products to individuals aged 18 years and over and require all users to read and sign a risk acknowledgement certification before use (unless the prospective user has previously signed the certification within the preceding 6 months). The social benefits from this proposed rule stem from a potential reduction in the incidence of skin cancer. The social costs of the proposed role are associated with the value of time spent by users and tanning facility operators on the risk acknowledgement certifications and verifying proof of age, as well as other compliance costs. As discussed later in this document, analyzing the impact of the proposed rule is difficult because of the uncertainty of how users would be affected by reading and signing the risk acknowledgment certification and how not using tanning beds when under 18 affects later adult use. Because of this uncertainty, we use a 1 to 10 percent range in the response rate to both the risk information and age restriction. Under these scenarios, assuming a discount rate of 7 percent the annualized cost over 10 years would range from $104 million to $114 million; annualized benefits would range from $70 to $115 million. With a 3 percent discount rate the annualized cost over 10 years would range from $122 million to $144 million; annualized benefits would range from $151 to $248 million. .

In addition to the social costs, the proposed rule would likely generate distribution effects from the reduced demand for tanning services. The annualized reduction in indoor tanning revenues would range from about $500 million to $820 million at a 7 percent discount rate over 10 years and from about $500 million to $825 million at a 3 percent discount rate.

Table 1: Summary of the Impact of the Proposed Rule* ($ millions)

	7% Discount Rate, 5%	7% Discount Rate, 1%	7% Discount Rate, 10%	3% Discount Rate, 5%	3% Discount Rate, 1%	3% Discount Rate, 10%

	Impact	Impact	Impact	Impact	Impact	Impact
Present Value over 10 Years						
Benefits	632.9	491.7	806.8	1,657.3	1,284.4	2,115.7
Costs	763.4	732.2	801.7	1,126.4	1,043.3	1,228.6
Net Benefits	-130.5	-240.5	5.1	530.9	241.1	887.1
Lost Revenue	4,532.9	3,527.2	5,770.4	5222.4	4287.4	7040.7
Annualized Value over 10 years						
Benefits	90.1	70.0	114.9	194.3	150.6	248.0
Costs	107.2	104.2	114.1	132.1	122.3	144.0
Net Benefits	-18.6	-34.2	0.7	62.2	28.3	104.0
Revenue Loss	645.4	502.2	821.6	647.4	502.6	825.4

* The impacts are tied to the acknowledgement certification and changing habits, which we interpret as the effect of age restrictions in disrupting the development of a habit for indoor tanning.

II. Regulatory Impact Analysis

A. Background and Purpose

This proposed rule, when finalized, would restrict the use of sunlamp products to individuals age 18 and over and help to ensure that those 18 and over are aware both of the risks of exposure to UV radiation prior to use and of proper use of the devices. Recent studies have cited peer reviewed articles that examine the effects of legislation on indoor tanning use and concluded that an age restriction or ban would be far more effective at reducing youth indoor tanning than other potential actions such as parental consent (Ref. 14, 15, 27). The risk acknowledgement certification, among other things, would warn users of the health risks

associated with UV exposure. Some users may not incorporate this information into their decisions to use sunlamp products. One study found that as many as 95 percent of sunlamp product users exceed FDA's recommended exposure limits (Ref. 16), and the body of literature, in general, shows non-compliance with state regulations relating to sunlamp product use (Ref. 6, 21, 23). One reason product users exceed recommended exposure rates may be attributable to failing to follow recommended exposure schedules (Ref. 21). Younger people (16 to 25), in particular, routinely use sunlamp products in a manner inconsistent with labeled instructions (Ref. 20, 22). This improper use is probably not attributable to not knowing the risks, as college students who are frequent tanning bed users often use sunlamp products despite awareness of the long-term risks (Ref. 20). Individuals appear to be discounting whatever risk information they are receiving or may have difficulty incorporating the information into their decision making. By presenting this information in a risk acknowledgement certification and restricting product use to those 18 and over, we would help ensure that users understand the underlying health risks of indoor tanning and would protect a subpopulation that is particularly vulnerable to the harmful effects of tanning and can have difficulty making decisions involving known public health risks (Ref. 4, 7, 12, 15, 23, 26).

The risks of indoor tanning and UV exposure in general are well known. Exposure to UV radiation can cause skin cancers including melanoma, burns to the skin and eyes, actinic keratoses, premature skin aging, and other health problems. The social costs associated with skin cancer alone are in the billions of dollars, so even a small percentage reduction in incidence would result in substantial benefits (Ref. 31).

The proposal would affect the millions of indoor tanners and the commercial facilities they patronize. Under this proposal, those under 18 wishing to get an indoor tan using a UV

emitting device at any commercial establishment would no longer be able to do so. Those 18 and older visiting a tanning facility would be given a risk acknowledgement certification to read and sign. The tanning facility would have to retain the certification for one year and provide a copy of the signed certification to the user. By restricting indoor tanning to adults and helping to ensure that users know the underlying health risks of indoor tanning, we would reduce exposure to UV radiation from indoor tanning and potentially the incidence of skin cancer and other public health problems associated with UV radiation exposure.

There are also requirements in the proposed rule on providing the sunlamp product manual to users and tanning facility operators. Upon request, a tanning facility operator would be required to provide a sunlamp product user or prospective user a copy of the user manual or the name and address of the 510(k) holder of the equipment so the user could request the manual. The 510(k) holder would be required, upon request from a tanning facility operator, sunlamp product user or prospective user, to provide a copy of the user manual.

B. Number of People and Businesses Affected

To estimate the number of indoor tanners affected by the proposed rule, we used the 2010 National Health Interview Survey (NHIS), the 2011 Youth Risk Behavior Survey (YRBS), and population data from the 2010 Census. Table 2 shows the population of tanners by age group in thousands. Because the age brackets in the surveys and the census were not the same, we made some accommodating adjustments to the percentages of tanners by age groups. Between the ages of 15 and 64, there are 14.5 million users of indoor tanning devices. Adjusting each age group for the 10 percent of indoor tanning taking place in the home or non-commercial facilities (Ref. 10), there are 13.1 million users of commercial devices.

The 2010 NHIS found the average frequency of tanning is 19.6 visits per year or 260

million visits when projected to the entire indoor tanning population. These numbers differ from the indoor tanning industry estimates of 30 million people and 300 million annual visits (Ref. 17). The Indoor Tanning Association (ITA) claims that 10 percent of the population tanned indoors, while the 2010 NHIS found 5.7 percent of the adult population tanned indoors. We analyzed the costs and benefits of the proposal using the NHIS and YRBS surveys because they were designed to reflect a representative sample of the US population. We also did a separate calculation using industry's estimates as an upper bound.

Table 2: Indoor Tanning Population by Age Group

U.S. Population (2010) age groups	Resident Population* (000)	Percent indoor tanners**	Indoor-tanning Population (000)	Commercial tanning pop. (000)	Commercial Sessions per year (000)
15 to 19 years	22,040	14.8%	3,262	2,936	60,183
20 to 24 years	21,586	12.3%	2,265	2,390	48,986
25 to 29 years	21,102	9.3%	1,962	1,766	36,208
30 to 34 years	19,962	5.9%	1,178	1,060	18,126
35 to 39 years	20,180	5.9%	1,191	1,072	18,323
40 to 44 years	20,891	5.9%	1,233	1,109	25,736
45 to 49 years	22,709	5.9%	1,340	1,206	27,975
50 to 54 years	22,298	2.9%	647	582	9,370
55 to 59 years	19,665	2.9%	570	513	8,263
60 to 64 years	16,818	2.9%	488	439	7,067
Total	207,250		14,525	13,072	260,238

*2010 U.S. Census; **NHIS 2010; the estimated number of 18-19 year-old tanners is 40 percent of the 15-19 total.

Most indoor tanning takes place at 18,000 to 19,000 professional indoor tanning salons and 15,000 to 20,000 health clubs, spas, and other commercial establishments that offer tanning services in addition to their primary source of revenue (Ref. 10). Although most of these other facilities are within the personal care service sector, some facilities offering indoor tanning services do not have a primary business affiliated with the personal care service sector.

C. Behavioral Effects

There are three types of behavioral effects we anticipate if the proposed rule is finalized. The first effect, which we refer to as the restriction effect, would impact the population of tanners younger than eighteen years of age. This would have the biggest effect because the demand for indoor sunlamp tanning services would decline because of the restriction on youth access. We refer to a second effect as the acknowledgement effect. This describes the potential changes in behavior because of an improved appreciation of health risks that would occur when signing the acknowledgment documents required by the rule. We anticipate a third effect that we refer to as the habit effect. This describes the potential long-term changes in habits among adults as persons denied access when under age 18 become less likely to use indoor tanning as adults.

We estimate the reduction in the use of sunlamp products based on (1) the reduction in use by those under the age of 18 due to the restriction effect, and (2) the reduction among those 18 and over due to the acknowledgement and habit effects. We estimate the reduction in users under 18 as equal to the current number. The reduction in tanning among those aged 18 and over cannot be estimated as easily. We nominally identify the reduction in adult use of tanning to the effects of the risk acknowledgement certification, but in fact it is likely the combined effects of:

- The risk acknowledgment certification, which makes the risk salient and has some informational value;
- The continued effects of the restriction on underage tanning because – as table 2 demonstrates – tanning rates decline steadily as a cohort ages. One implication is that those who start young may continue to tan, but use steadily drops off. A smaller young tanning cohort could in fact lead to declines at all ages later on.
- The spillover effect of restrictions placed on those under 18 could affect persons at later

ages, who either take it as a signal or find that the restriction on young tanning, plus the risk acknowledgement certification, make the risk more salient.

The more difficult question is how large the effect will be. Many current tanners now recognize the risk and accept it. Others however will be amenable to signals and messages that will change behavior. Tanning itself is not a lifetime activity for most. As table 2 shows, between ages 15 and 50, the tanning participation falls 3 to 9 percent per year, similar to the range we estimate as the combined effects of the disclosure policy. Without direct estimates of the effects cited above, we rely on general results on public health and FDA warnings, as well as more general findings on disclosure and other information policies (Ref. 2, 8, 9, 36).

There is evidence in the regulation of alcohol, tobacco, and indoor tanning that laws prohibiting adolescent access may curtail use of these products (Ref. 12, 13, 37). Some evidence from literature on tobacco and alcohol use indicates that reduced use as adolescents carries over into adulthood by disrupting the formation of habit, but the size of the impact is difficult to ascertain (Ref. 12, 37). One study on alcohol consumption found a 10 percent decline in alcohol consumption among adolescents that carried over into college alcohol consumption behavior; however, the effect due to habit accounted for only 40 percent of the carryover (Ref. 37). Grucza et al. (Ref. 13) estimated a 14 percent reduction in lifetime smoking for women and a 29 percent reduction in heavy smoking for those who ever smoked. Indoor tanning generally starts at an early age, and public health experts believe that, as with tobacco and alcohol age restrictions, there could be a carryover effect (Ref. 15). A survey by Poorsatter and Homung (Ref. 28) of college-age students who used tanning beds found that 71 percent had started indoor tanning before age 18. While there could be a carryover effect due to the proposed age restriction, we do not know the size. For this analysis we assumed a 5 percent impact, but estimate a range of 1 to

10 percent because of the uncertainty. We request comment on this assumption.

1. Restriction Effect

Individuals under 18 could no longer use sunlamp products at commercial facilities. Of the 22.0 million individuals, ages 15 to 19, 14.8 percent, or 3.3 million are indoor tanners (U.S. Census 2010: YRBS 2011). Assuming 90 percent of these users go to commercial indoor tanning facilities and an equal distribution of users 15 to 19 (a simplifying assumption for calculation purposes), the age restriction would remove up to 1.78 million individuals from tanning (1.78 mil=(2.9 mil / 5 age groups) x 2 age groups), leaving 11.3 million adult patrons (see Table 3A).[1] Should the rule become final, the decrease in users would vary across facilities depending on existing state restrictions and on the percentage of a facility's clientele that are under the age of 18. Forty states have some type of age restrictions on indoor tanning with 11 states now restricting indoor tanning for those under age 18 (Ref. 25). Because some of these state restrictions are recent, some are not effective yet, and the survey data were obtained before these state restrictions were enacted, our analysis assumes that all individuals under 18 now have access to indoor tanning facilities. The rule's impact would be less because of these pre-existing state restrictions. Also, if illegal tanning operations aimed at minors come into being in response to this rule, then the reduction in tanning would be less.

Table 3A: Restriction Effect on Underage Population

U.S. Population (2010) age groups	Commercial tanning population (000)	Decline in commercial tanning population (000)	Average number of visits per year[1]	Decline in number of commercial-tanning visits (000)

[1] The 1.78 million represents an upper bound in the sense that we assume full compliance with the age restriction. Should facilities fail to comply or individuals under 18 years old circumvent the requirement, the impact on the industry would be less and the cumulative benefits would also be lower.

15 years[2]	587	587	20	11,512
16 years[2]	587	587	20	11,512
17 years[2]	587	587	20	11,512
18 years[2]	587	0	20	0
19 years[2]	587	0	20	0
20 to 24 years	2,390	0	20	0
25 to 29 years	1,766	0	20	0
30 to 34 years	1,060	0	20	0
35 to 39 years	1,072	0	20	0
40 to 44 years	1,109	0	20	0
45 to 49 years	1,206	0	20	0
50 to 54 years	582	0	20	0
55 to 59 years	513	0	20	0
60 to 64 years	439	0	20	0
Totals	**13,072**	**1,762**		**34,535**

Note: Population numbers are expressed in thousands. Although population younger than fifteen may also be commercial indoor tanners, we do not know the population of such tanners, their frequency, or distribution.

[1] Average number of visits per year from 2010 NHIS (19.6 visits per year)

[2] We assume a uniform distribution of 15-19 year old cohort (587=2,936 / 5).

2. Acknowledgment Effect

Requiring that users sign a risk acknowledgment certification prior to use of a sunlamp product would help to ensure that users over age 18 know the underlying health risks of indoor tanning and proper use of these devices. The risk acknowledgment certification is intended to provide warnings regarding sunlamp products as well as information regarding the proper use of the devices. By making this information available to users in a direct and accessible manner, the certification would better enable consumers to make informed decisions about their use of sunlamp products. The information could counteract false or misleading information that sunlamp product users may have received regarding the risks of indoor tanning. The FDA 2010 Advisory Committee referred to in the preamble of this proposed rule recommended the risk acknowledgment certification be signed (Ref. 34). We expect that reading and signing the risk acknowledgement certification would reduce the demand for indoor tanning. Although there is

ample evidence that risk information given at time of purchase can affect consumer behavior, we are not aware of any evidence predicting the size of the consumer reaction to this proposed requirement (76 FR 36628, 36712; Ref. 11, 2). We therefore expect an effect, but the size is uncertain.

As discussed in the analysis of another recent FDA rule to add calorie information on restaurant menus, numerous studies have tried, with mixed results, to measure the impact of providing nutrition and calorie information at point of purchase on current and future purchase decisions (Ref. 35). While the cues and consequences for food consumption decisions are quite different from those for indoor tanning, the studies provide some quantitative measures of the effect of point of purchase information on purchase decisions. The studies differed in sample size and method but found effects ranging from a 3 percent increase to a decrease of 15 percent in caloric consumption (Ref. 35, Appendix A).

Requiring a signature on the risk acknowledgement certification should increase the attention that the user devotes to reading the information. Research indicates that signing one's name on a contract or honor code leads to greater adherence even when there are no economic or legal consequences if they did not (Ref. 19).

For our analysis, we assume that as a result of the proposed risk acknowledgement certification, the number of adult users would fall by 5 percent, but we also estimate the effects for declines as small as 1 percent and as large as 10 percent. Table 3B shows our estimate of the acknowledge effect. To calculate the first cohort (18 to 19 years) we use the estimated number of commercial tanners from Table 2 (2,936 in thousands), and assume a uniform distribution of tanners across ages 15 to 19. Thus, the cohort 18 to 19 year olds has 1,174 thousand tanners (587 multiplied by 2 one-year cohorts). In estimating the decrease in commercial-tanning users, we

apply a range of potential percentages of attrition, 1%, 5%, and 10%. Therefore, we estimate that the total decrease from the acknowledgement effect ranges from 113 to 1,131 thousand potential commercial-tanning facility users.

Table 3B: Acknowledgement Effect on Tanners Eighteen and Older

U.S. Population (2010) age groups	Commercial tanning pop age 18+ (000)*	Decrease in users from risk acknowledgement 5% (000)	Decrease in users from risk acknowledgement 1% (000)	Decrease in users from risk acknowledgement 10% (000)
18 to 19 years	1,174	59	12	117
20 to 24 years	2,390	119	24	239
25 to 29 years	1,766	88	18	177
30 to 34 years	1,060	53	11	106
35 to 39 years	1,072	54	11	107
40 to 44 years	1,109	55	11	111
45 to 49 years	1,206	60	12	121
50 to 54 years	582	29	6	58
55 to 59 years	513	26	5	51
60 to 64 years	439	22	4	44
Total	11,311	566	113	1,131

Note: *See Table 2. Population numbers are expressed in thousands.

A user base of 11.3 million experiencing a 5 percent decline would lose 566,000 users, leaving a user base of 10.7 million indoor tanners. With a 1 to 10 percent range of uncertainty, the decline could range from 113,000 to 1.13 million, so we also consider a range of 10.2 million to 11.2 million users after accounting for the impact of the age restriction (Table 3A) and the communication of the risk information (Table 3B). We welcome comments on these assumptions and this approach.

3. Habit Effect

Over time, the user base may fall further because of potential changes in habits induced by the rule. Individuals who do not use sunlamp products as minors may be less likely to use them upon turning 18 (Ref. 3). As discussed above, we have limited information on this

question, so to project the long-term changes in behavior; we assume that an adult would be 5 percent less likely to use sunlamp products if he were restricted from doing so when under 18. Because many users initiate indoor tanning while young (Ref. 14, 15), this change would alone eventually reduce adult tanning rates, assuming that tanning habits are less likely to emerge after age 18. We consider a range from 1 to 10 percent to account for the uncertainty around the estimate. The impact on the population of indoor tanners would likely be gradual. In our model, the 18 and 19-year-old cohort of sunlamp products users is 1.12 million after accounting for a 5 percent effect from the risk acknowledgement certifications.

Table 3C: Habit Effect on Commercial-Indoor Tanners Upon Becoming Eligible to Tan

Year	Decrease in commercial tanners from 5% habit effect (000)	Decrease in commercial tanners from 1% habit effect (000)	Decrease in commercial tanners from 10% habit effect (000)
1	0	0	0
2	27.9	5.8	52.8
3	50.6	10.5	95.9
4	22.7	4.7	43
5	22.7	4.7	43
6	22.7	4.7	43
7	22.7	4.7	43
8	16.8	3.5	31.8
9	16.8	3.5	31.8
10	16.8	3.5	31.8
Total decrease from habit effect over 10 years	220	46	416
Average annual decrease from habit effect	22	5	42

Note: Decrease represents individuals in thousands. Year represents the beginning of each year relative to when the rule is first implemented.

In year 1 of our analysis, 18 year-olds were able to obtain indoor tans as 17 year-olds and there is no effect. In year 2, the new 18 year-olds could not use sunlamp products as 17 year-

olds and the number of those using sunlamp products falls by 5 percent. As our above cohort includes 18 and 19 year olds, we consider a decline to the cohort of 2.5 percent, or 28,000. In year 3, both the 18 and 19 year-olds had not used sunlamp products as 17 year olds, so we consider a decline of 5 percent and we model a 1 percent decline in the 20-24 age cohort, for a combined drop of 50,600 users. There are 2.27 million 20-24 year olds, so the user base falls by 22,700 in year 4. There would be additional 1 percent drops of 22,700 in years 5 through 7. In model years 8-10, there would be 1 percent drops in the 1.68 million users ages 25-29. By year 10, there would be 220,000 fewer indoor tanning users because of the potential change in habits, leaving 10.5 million users. Considering an uncertainty range of declines from 1 to 10 percent from potential change in habits, the decline would range from 45,800 to 416,100 users.

4. Total Effects

Table 3D summarizes the total change in tanning as a result of the rule. The restriction effect, which accounts for an annual estimated decline of 1,762 thousand potential tanners, does not vary across different scenarios because this effect would be a direct outcome of the rule. The acknowledgement effect ranges from a decline of 113 to 1,131 thousand users because we incorporate three different percentages of responses as a result of active tanners becoming aware of the health risks and reacting to such information. The total habit effect in this table ranges from 46 to 416 thousand individuals, and it is relatively small compared to the restriction and the acknowledgement effects. Thus, variations in assumptions in estimating the range of habit effects (Table 3C) would not have large effects on the total estimated effect of the rule which ranges from 1,921 to 3,309 thousand individuals over a ten year horizon.

Table 3D: Summary of Effects and Estimated Declines in Population of Commercial Tanning Users Over a Ten-Year Horizon

	Decline under the 5% response	Decline under the 1% response	Decline under the 10% response	Source Table

	scenario (000)	scenario (000)	scenario (000)	
Baseline	13,072	13,072	13,072	2
Total restriction effect	1,762	1,762	1,762	3A
Total acknowledgment effect	566	113	1,131	3B
Total habit effect	220	46	416	3C
Grand Total	2,547	1,920	3,309	

Note: population decline measured in thousands. Numbers may not sum due to rounding.

D. Costs

The proposed rule would generate social costs associated with amount of time users and tanning facility operators spend reading, signing, and processing the risk acknowledgment certifications and verifying proof of age and records. The number of certifications and identity checks processed per year would depend on the impact that the proposed rule would have on the demand for indoor tanning services. Although these time costs would be significant, from the standpoint of the indoor tanning industry, the primary costs of the proposal would stem from the revenue loss from loss of the adolescent sector and potential reduced visits from the adult population. We estimate the social cost as well as the lost tanning revenue in this section.

1. Costs Associated with Risk Acknowledgement Certification.

In the proposal, a user would be required to sign a risk acknowledgment certification and the certification would be valid for 6 months. The tanning facility would be required to maintain the record for one year or until a more recent document is signed. The tanning facility operator would also have to provide the user a copy of the risk acknowledgement certification. Estimating the incremental increase in costs from this proposed requirement is difficult because the industry is subject to varying state requirements. The proposed rule would preempt state laws with respect to providing risk information that are different from these requirements. Industry sources indicate that keeping customer records is standard business practice in the

personal care industry and because 85 percent of the tanning population is in states that regulate the indoor tanning industry, which often have customer record keeping requirements, we assume that the facilities have the administrative infrastructure in place to make the adoption of the proposed risk acknowledgement certification requirements a negligible cost.[2] We do not include incremental increases in tanning facility operator time to comply with the age restriction because most states have some form of age-based requirements now and the saving from no longer needing to comply with state requirements that are duplicative of these federal requirements would offset these costs if the rule becomes final. Although the necessary actions to comply with the risk acknowledgement certification may satisfy some existing states' requirements, we do not adjust the incremental costs of administering the risk acknowledgement certification to account for any savings on state compliance costs; we also assume that the federal and state procedures are taking place one at a time when in fact the compliance steps could often be combined for significant time savings.

We estimate that the first time a user visits a tanning facility after the date the proposed requirements become effective, a tanning facility operator would take an extra 30 seconds explaining to the user the purpose of the certification and the facility's policy regarding its implementation. The user would need 2 minutes to read and sign the certification and the tanning facility operator would need about 15 seconds to process or file the signed certification.[3] After the initial visit, the signing of the risk acknowledgment certification would require 2 minutes of the user's time and about 135 seconds of the tanning facility operator's time every 6 months. The other visits during the year could also require an incremental increase in time in

[2] An Internet search on July 15, 2014 using the terms "operating tanning salon" suggested that software specific to tanning salons is available and preferred over other POS software for tracking both machines and customers.
[3] Time to read is based on the length of the risk acknowledgement certification (406 words) and a reading speed of 250 words per minute.

order for the tanning facility operator to verify age or check the status of the records. We estimate that this could require about 15 seconds of both the tanning facility operator and user's time.[4] In year 1, the cost to verify records would require about 787,000 hours[5] and cost industry about $17.3 million (ranging from 745,000 to 821,000 hours and $16.4 million to $18.1 million) (Table 4). In the first year, there would be 21.5 million risk acknowledgement certifications signed resulting in 806,000 hours of worker time.[6] For the time of the tanning facility operator, we use a fully loaded wage of $22, including supervision and overhead. The year one cost for tanning facilities to process the risk acknowledgement certifications is $17.7 million. There will also be recurring costs to print the risk acknowledgement certification and provide a copy to the users of the sun lamp products. Printing costs vary by size of order, the larger the order the lower the per page cost to print. We assume most facilities will not order quantities large enough to get significant discounts, and estimate that it will cost $0.25 per certification (includes copy for operator and user).[7] Table 4 lists the cost for the printed pages, in the first year the costs would range from $5.1 to $5.6 million. The total year one incremental costs for the supplying, obtaining the signature, and retaining the risk acknowledgement certification would be $40.4 million.

There would also be one-time costs associated with training tanning facility operators on the new procedures. We estimate training to take about 15 minutes per employee. Industry employment ranges from 120,000 to 160,000 (Ref. 17, 18), assuming a loaded wage rate of

[4] Time estimated is time required to check id (8.3 seconds rounded to 10) from 61 FR 44396, 44594 plus 5 seconds to review date of signature.
[5] Hours were calculated as the number of tanning sessions per year minus the sessions when the certification would be signed multiplied by time.
[6] To calculate time to administer the risk acknowledgment certification in the first year the time for initial and subsequent signing were added together and multiplied by the number of users. For subsequent years it was calculated as 2 x the number of users x time to sign certification.
[7] An internet search on printing costs (7-8-14) yielded costs ranging from $0.025 per page for fewer than 100 copies to $0.20 per page. We assumed about $0.10 per double-sided printed page, 2 pages for each certification, and added $0.05 to account for each facility ordering more certifications than they would use.

$22the one-time cost to train tanning facility operators would range from $660,000 to $880,000 (Table 5).[8] The one-time costs to explain the risk acknowledgement certification would range from $1.9 million to $2.1 million and require 89,540 to 93,310 hours.

Table 4: Recurring Industry Cost to Administer Risk Acknowledgement Certification over Time ($ million)

		Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
5% impact from acknowledgement and habit	Administer Certification 2 times each year	17.7	17.7	17.6	17.6	17.5	17.5	17.4	17.4	17.4	17.4
	Check Records	17.3	17.3	17.2	17.2	17.1	17.1	17.1	17.0	17.0	17.0
	Cost of Printed Certification	5.4	5.4	5.3	5.3	5.3	5.3	5.3	5.3	5.3	5.3
	Total	**40.4**	**40.3**	**40.1**	**40.1**	**40.0**	**39.9**	**39.8**	**39.7**	**39.7**	**39.6**
1% impact from acknowledgement and habit	Administer Certification 2 times each year	18.5	18.5	18.4	18.4	18.4	18.4	18.4	18.4	18.4	18.4
	Check Records	18.1	18.1	18.0	18.0	18.0	18.0	18.0	18.0	18.0	18.0
	Cost of Printed Certification	5.6	5.6	5.6	5.6	5.6	5.6	5.6	5.6	5.6	5.6
	Total	**42.1**	**42.1**	**42.1**	**42.1**	**42.0**	**42.0**	**42.0**	**42.0**	**42.0**	**42.0**
10% impact from acknowledgement and habit	Administer Certification 2 times each year	16.8	16.7	16.6	16.5	16.4	16.3	16.3	16.2	16.2	16.1
	Check Records	16.4	16.3	16.2	16.1	16.0	16.0	15.9	15.9	15.8	15.8
	Cost of Printed Certification	5.1	5.1	5.0	5.0	5.0	5.0	4.9	4.9	4.9	4.9
	Total	**38.3**	**38.1**	**37.7**	**37.6**	**37.4**	**37.3**	**37.1**	**37.0**	**36.9**	**36.7**

[8] Wage derived from 2010 Bureau of Labor Statistics Occupation Employment Statistics Survey, occupation code NAICS 812100 Personal Care Service, Occupation Code 39-9099. Mean wage is $10.59 multiplied by 2 to account for fringe benefits and overhead.

Table 5: One-Time Industry Costs Under Various Scenarios

	Total hours	Total cost
One-time to train employees		
Employment = 120,000*	30,000	$660,000
Employment = 160,000**	40,000	$880,000
One-time to explain procedure		
5% impact from acknowledgement and habit	89,540	$1.97 million
1% impact from acknowledgement and habit	93,310	$2.05 million
10% impact from acknowledgement and habit	84,830	$1.87 million
Total one-time - employment = 120,000		
5% impact from acknowledgement and habit	119,540	$2.63 million
1% impact from acknowledgement and habit	123,310	$2.71 million
10% impact from acknowledgement and habit	114,830	$2.53 million
Total one-time - employment = 160,000		
5% impact from acknowledgement and habit	129,540	$2.85 million
1% impact from acknowledgement and habit	133,310	$2.93 million
10% impact from acknowledgement and habit	124,830	$2.75 million

*International Tanning Association (ITA) Press Release 1-28-2011 (www.theITA.com); **ITA FAQs (www.theITA.com) (Ref. 17, 18)

2. Cost to Supply Sunlamp Product User Manual Upon Request.

Section 878.4635(c)(2) of the proposed rule would require, upon request by a user, tanning facility operators to provide a copy of the user manual for the sunlamp products; or the facility operator could supply the name and address of the manufacturer or distributor from whom a user could request a copy of the manual. The 510(k) holders of sunlamp products would have to, upon request, supply tanning facility operators, users, and potential users, copies of their operating manuals. We believe the incremental compliance costs to tanning facilities would be

negligible because facilities already receive the user manual with the equipment and use the information to train their employees. Requests from users would not be frequent and the tanning facility need only supply the name and address, which could be an e-mail address, of the 510(k) holder.

The 510(k) holders would have to develop standard operating procedures (SOP) for responding to requests. In our experience, it would take a company about 5 hours of management time to develop the SOPs and set up a system for response. Most 510(k) holders would satisfy this proposed requirement by making the manuals available on the internet so recurring costs to satisfy requests for the user manual should be negligible. Many companies already make user manuals available online but for those who do not, it may take up to 10 hours of a computer programmer's time to modify the company's web site and to upload the manuals for both current and past models that could still be in use. About 20 firms manufacture and distribute sunlamp products that could be affected by these proposed requirements. Because we do not know how many of them have user manuals online, and all would have to modify their web pages so product users could find the manuals, we are assuming all firms will incur one-time costs of 5 hours for SOPs and 10 hours to modify their web pages. Using an average wage of $122[9] for management and $78[10] for a computer programmer, the one-time cost to 510(k) holders to supply user manuals for their sunlamp products would be $27,800 ([($122 x 5 hours) + ($78 x 10 hours)] x 20 firms). We did not assume any recurring costs for this requirement because adding new manuals, which are prepared electronically, should be negligible because it will be part of the process of bringing a new product to market. We request comments on these

[9] Wage is mean hourly wage of $61.21 from May 2013 BLS Occupational Employment Statistics, SOC 11-000 general management; multiplied by 2 to account for fringe benefits and overhead (122.42) and rounded to $122.
[10] Wage is mean hourly wage of $38.91 from May 2013 BLS Occupational Employment Statistics, SOC 15-1131 Computer Programmers; multiplied by 2 for fringe benefits and overhead (77.82) and rounded to $78.

assumptions.

3. Decline in Revenue due to Fewer Users.

Although not a social cost, the decline in revenue due to fewer users would have a greater economic impact on the indoor tanning industry than the cost to administer the risk acknowledgement certification. The age restriction would reduce the number of users by 1.78 million individuals from indoor tanning, which represents a decline in revenue of $471 million assuming an annual indoor tanning frequency of 19.6 sessions (NHIS 2010) at a cost of $13.50 per session.[11] This would be a 13.6 percent decline in indoor tanning revenues from the baseline.

The risk acknowledgement certification requirement may reduce the number of users by 113,000 to 1.13 million individuals and further reduce annual revenues by about $30 million to $300 million, assuming 19.6 sessions per person per year, $13.50 per session, and a response rate ranging from 1 to 10 percent. By year 10, the decrease in annual revenue because of a change in habit would range from $12.1 million to $110.1 million.

The combined decline in users from the baseline number of 13.1 million is 2.55 million in year 10 due to the age restriction, the risk acknowledgment certification, and the potential change in habits, with an uncertainty range of 1.92 million to 3.31 million. The decline in baseline revenue by year 10 would range from $508.1 million to $875.5 million in current dollars (Table 6).

The lost revenue would be expected to be used to purchase other consumer products, the substitutes for indoor tanning. FDA is unable to predict what substitutes would be purchased.

[11] There is no source for average cost of an indoor tanning session. Most salons have a single visit cost that varies by type of equipment in addition to many promotional prices from number of tans per package to unlimited tanning for a flat rate. Plus, some gyms and health spas provide indoor tanning as part of the membership fee. The price, $13.50, was the midpoint of the most common single visit prices ($10 to $17, for a basic tan found on an internet search of the phrase “cost of indoor tanning session”).

There are many reason people engage in indoor tanning including cosmetic, sensual pleasure, and relaxation. Product and services with those characteristics might therefore be possible destinations for the expenditures shifted away from indoor tanning. Most indoor tanning facilities offer other services in addition to indoor tanning, such as spray-on or other forms of sunless tans, which if seen as a substitute, would mitigate some lost revenue.

Table 6: Decline in Revenue from Baseline from Proposed Risk Acknowledgement Certification Requirement Over Time and Under Different Scenarios

Year	5% impact from acknowledgement and habit ($million)	1% impact from acknowledgement and habit ($million)	10% impact from acknowledgement and habit ($million)
1	-615.7	-496.0	-765.4
2	-623.1	-497.6	-779.4
3	-636.5	-500.3	-804.7
4	-642.5	-501.6	-816.1
5	-648.5	-502.8	-827.5
6	-654.5	-504.1	-838.9
7	-660.5	-505.3	-850.2
8	-665.0	-506.3	-858.7
9	-669.4	-507.2	-867.1
10	-673.8	-508.1	-875.5
Present Value at 7% discount	-4,532.9	-3,527.2	-5,770.4
Lost Producer Surplus at 7%	-113.3	-88.2	-144.3
Present Value at 3% discount	-5,522.4	-4,287.4	-7,040.7
Lost Producer Surplus at 3%	-138.1	-107.2	-176.0

Over 10 years, the present value of the cumulative loss in revenue from the three impacts would range from $3.5 billion to $5.8 billion at a 7 percent discount rate and $4.3 to $7.0 billion at a 3 percent discount rate. As stated previously, should the rule become final, the decrease in users and revenue will vary across facilities depending on existing state restrictions and on the

percentage of a facility's clientele that were under 18 years old.

4. Lost Producer Surplus.

While lost revenue is largely a transfer, some social costs could accompany the decline. If the resources used to produce tanning services earn rents (a difference between the opportunity costs and payments) there will be producer surplus lost as the marketplace contracts. In addition, falling revenue also leads to transition costs from reduced output that would be included in the social cost of the rule. The loss in producer surplus would be small because we do not expect that the behavioral changes induced by the rule would have a significant impact on price; we very roughly estimate the lost producer surplus and transition cost as 2.5 percent of lost revenue. Lost producer surplus would range from $88.2 million to $144.3 million at a 7 percent discount rate and from $107.2 million to $176.0 million at 3 percent (Table 6). We welcome comment on this proposed measure.

5. Costs for Users

Users who continue to use commercial indoor tanning devices will incur a loss equal at least to the opportunity cost of the time it takes to read and sign the risk acknowledgement certification and to wait while records are verified. In the first year, there will be a one-time loss of 30 seconds per unique user on their first visit while the new risk acknowledgement certification requirement is explained to them. There would be a one-time cost for the 84,800 hours to 93,300 hours for explaining the new requirements to users at a cost between $1.8 million to $2.0 million assuming a value of time of $21.4 per hour.[12] They would be required to also read and sign the risk acknowledgement certification every 6 months, which we estimate

[12] Source: BLS Employment, Hours, and Earnings from the Current Employment Statistics survey (National) Average Hourly Earnings Of All Employees, December 2014. Mean all employees wage and salary $24.6 adjusted for taxes (0.87) = $21.4 per hour.

will require 2 minutes, and they will have to wait 15 seconds while records are checked during other visits. The annual recurring cost from time spent reading and signing the risk acknowledgement certification twice each year would range from 678,630 to 746,500 hours the first year, which represents a cost of $14.5 million to $16.0 million (Table 7). The time waiting during records checks during subsequent visits would range from 746,490 hours to 821,140 hours and valued at $16.0 million to $17.6 million assuming 19.6 visits annually and $21.4 per hour of time.

We also indirectly estimate the value of the utility lost by users who, as a result of this proposed rule, do not use sunlamp products. In our estimate of the value of lost utility, we assign no utility loss for persons under the age of 18 who would be prohibited from indoor tanning. Although it is simplistic to assume that the value of decision-making suddenly changes upon an individual's 18th birthday, standard practice assigns zero utility loss or gain for the revealed preferences of minors over commodities. (Whittington and MacRae 1986). Children under 18 of course experience utility from their choices; the question is whether to count it. We assign value to many parental choices for their children, especially with respect to investments in human capital. To the extent that revealed preferences of children are ratified or directed by adults, it can be argued that they should be included. In some states, minors are only allowed to tan with the permission of parents, indicating parental endorsement of this preference. Persons over 18 who, as a result of this proposed rule, would choose not to indoor tan would lose utility; however, if consumption of tanning services is characterized by myopia, time inconsistency, incomplete information about long-term health hazards, or other intrapersonal market failures, the value of the reduced risk to dissuaded consumers necessarily exceeds this cost. We can estimate lost utility as a fraction of the value of the health gains to persons 18 and over, who

account for more than 90 percent of consumers. Without any direct evidence, we assume that value of lost utility is 25 percent of the willingness-to-pay for the reduced risk. That yields an estimated utility loss of 22.5 percent of the value of the health gains (value of lost utility = 25 percent x 90 percent). Using the value of expected cancers averted discussed later in this document, the loss in consumer utility would range from about 15 million to 23 million at a 7 percent discount rate the first year and from 32 to 50 million at a 3 percent discount rate (Table 7). (If we were to include lost utility for minors, the estimated consumer surplus loss would rise by about 11 percent, leading to total costs of 2-4 percent higher than in Table 8.) We welcome comments on this calculation.

Table 7: Recurring Consumer Time Cost from Risk Acknowledgement Certification and Lost Consumer Utility (millions)

		Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
5% impact	Read and Sign Certification twice year plus records check	32.2	32.1	32.0	31.9	31.8	31.8	31.7	31.6	31.6	31.5
	Lost consumer utility 7%	18.6	19.0	19.6	20.0	20.4	20.8	21.1	21.5	21.8	22.2
	Lost consumer utility 3%	39.8	40.7	42.0	42.8	43.6	44.5	45.3	46.0	46.8	47.5
	Total cost to consumers, 7 percent	50.8	51.1	51.6	51.9	52.2	52.5	52.8	53.1	53.4	53.7
	Total cost to consumers, 3%	72.0	72.8	74.0	74.7	75.5	76.2	77.0	77.7	78.4	79.1
1% impact habit	Read and Sign Certification twice year plus records check	33.5	33.5	33.5	33.5	33.5	33.5	33.4	33.4	33.4	33.4

	Lost consumer Utility7%	15.0	15.2	15.4	15.6	15.8	16.0	16.2	16.3	16.5	16.7
	Lost consumer utility 3%	32.1	32.5	33.0	33.4	33.8	34.2	34.6	35.0	35.4	35.7
	Total cost to consumers 7 percent	48.5	48.7	48.9	49.1	49.3	49.4	49.6	49.7	50.0	50.1
	Total cost to consumers, 3%	65.6	66.0	66.5	66.9	67.3	67.7	68.1	68.4	68.8	69.2
10% impact from acknowledgement and habit	Read and Sign Certification twice year plus records check	30.5	30.3	30.1	29.9	29.8	29.7	29.5	29.4	29.3	29.3
	Lost consumer utility 7%	23.1	23.8	24.8	25.4	26.0	26.6	27.2	27.8	28.3	28.9
	Lost consumer utility 3%	49.6	51.0	53.2	54.4	55.7	57.1	58.4	59.5	60.7	61.8
	Total cost to consumers' 7 percent	53.6	54.1	54.9	55.3	55.8	56.3	56.8	57.2	57.7	58.1
	Total cost to consumers, 3%	80.1	81.3	83.2	84.4	85.5	86.7	87.9	89.0	90.0	91.1

E. Costs: Summary

The total social costs of the proposed rule, which include lost time to industry, training costs, the value of consumers' time, and lost tanning utility, are presented in Table 8. The annualized costs over 10 years at a 7 percent discount rate range from $104.3 million to $114.1 million; at 3 percent annualized costs range from $122.3 million to $144.0 million. We do not include the loss of revenue to the industry in the societal cost of the rule because it is a transfer cost to the industry but not a loss to society, as users will use the money for other services and

resources associated with indoor tanning. We do include an estimate of lost producer surplus as a percent of lost revenue.

Table 8: Total Costs: Different Behavioral Response Scenarios ($millions)

Discount Rate	7%, 10 years	7%, 10 years	7%, 10 years	3%, 10 years	3%, 10 years	3%, 10 years
Scenario	*5% Impact*	*1% Impact*	*10% Impact*	*5% Impact*	*1%*	*10% Impact*
Consumer time costs	223.7	235.1	209.7	271.5	285.5	254.4
Consumer utility loss	142.4	110.6	181.5	372.9	289.0	476.0
Industry time costs	283.9	298.3	266.2	343.9	361.6	322.2
Lost producer surplus	113.3	88.2	144.3	138.1	107.2	176.0
Total costs	763.4	732.2	801.7	1,126.4	1,043.3	1,228.6
Annualized total costs	108.7	104.3	114.1	132.1	122.3	144.0

F. Benefits

This proposal would reduce UV exposure from indoor tanning, which would lead to a reduction in the incidence of certain negative health effects. UV radiation can cause acute injuries such as sunburns and eye irritations (e.g. photo keratitis). Long-term UV exposure has been associated with skin cancer (including squamous cell carcinoma, basal cell carcinoma, and melanoma), skin aging, and cataracts. We limit our monetized benefits in this analysis to reductions in cases of melanoma, melanoma in situ, and other forms of skin cancer, making our estimate conservative.

The projected numbers of new melanomas and deaths from melanoma in 2014 are 76,100 and 9,710, with 63,770 new occurrences of melanoma in situ (Ref. 1). The two most common

forms of skin cancer are basal cell carcinoma and squamous cell carcinoma, usually combined in cancer statistics and referred to as NMSC. The incidence of these cancers is somewhat uncertain, as they are not reported to major cancer tracking registries, such as the National Cancer Institute Surveillance Epidemiology and End Results (SEER) database. The estimated number of new NMCS treated in 2013 is 2.2 million with about 3,170 deaths (Ref 1).

Estimating willingness to pay to avoid a case of skin cancer. To calculate benefits, we would ideally use a measure of society's willingness to pay to avoid a case of melanoma or NMSC but could not find any suitable direct measures in a search of the literature. To value the willingness to pay to avoid a fatal case we therefore used the value of a statistical life (VSL) approach. A VSL is a summary measure for the dollar value of small changes in mortality risk experienced by a large number of people. For fatal cases we used the recommended VSL of $9.1 million (in 2014 dollars) to value reduced mortality. To derive the values for nonfatal cases we used a variety of sources to estimate treatment costs weighted by level of treatment, and estimates for other human health-related costs, including intangible costs.

Societal cost to treat NMSC. For an estimate of the medical cost to treat a case of NMSC we used data from a study by Chen et al. (Ref. 5) where the authors estimated the cost of treatments by office setting. The authors estimated an average treatment cost for NMSC, weighted by setting (where the procedures was performed), of $588 per episode of care. In order to capture the indirect and intangible costs per episode we used data from a study by the Lewin Group, Inc. (Ref. 32) on the burden of skin disease. Indirect costs estimated in the Lewin study are the costs not directly attributable to treatment, predominately lost productivity, and include patient and care giver lost work days, losses due to restricted activity during recovery, and lost future earnings due to premature death. The intangible costs are the diminished quality of life

and were measured as the willingness to pay to alleviate symptoms in the Lewin study. Assuming that the relationship between the estimates of the total burden of NMSC primary and intangible costs would be the same on an average per case basis, we calculated the ratios between the totals of treatment costs to other costs reported in the Lewin study. We then applied these factors to our estimate of per case direct medical treatment costs. The cost estimates in the Lewin study included a measure of lost future earnings. Because we are using a VSL approach, which incorporates this value, we needed to remove lost future earnings from Lewin's cost variable before calculating our ratios. The relevant data from the Lewin study and how we applied it to create our estimate of total social cost per case of NMSC are listed in Table 9. There is very little mortality risk due to NMSC. To determine the mortality value, we used the ratio of annual deaths to new incidence (0.0014) and applied it to the VSL. The mortality-adjusted total cost per case (mortality cost plus other costs) of NMSC was $14,167.

To the extent that issuance of this proposed rule would reduce the incidence of skin cancers, the benefits of the reduction would be delayed because of the latency periods between exposure and diagnosis. We do not know the latency periods precisely, but have obtained some information from published research. The latency period between first exposure to therapeutic ionizing radiation and the appearance of NMSC is estimated to be at least 20 years (Ref. 25). For this analysis, we assume a 20-year lag attributable to latency between issuance of this regulation and any public health benefits. Discounting for 20 years, the monetary value of an averted case of NMSC is $3,661 at a 7 percent discount rate and $7,845 at 3 percent.

Table 9: Calculation of Social Cost per Case NMSC

Measurement	Value	Line	Calculation	Notes
Annual direct costs (2005 $) Annual indirect costs less value of future earnings Annual intangible costs	$1,451 million $ 65.5 million $130.0 million	A B C		Lewin (Ref. 32) and Chen et al. (Ref. 5) $48 million lost wages of patient and caregiver during treatment; $17.5 million lost wages patient during recovery
Ratio indirect to direct costs Ratio intangible costs and direct costs	0.045 0.090	D E	B/A C/A	Assuming the ratio of direct, indirect, and intangible costs for total burden of NMSC will be the same on a per case basis
Direct treatment costs (2001 $)	$586	F		Chen (Ref 5)
Direct treatment costs (2014 $)	$930	G		Updated with CPI for medical costs
Indirect treatment costs	$42	H	G x D	
Intangible costs	$84	I	G x E	
Total social cost to treat one case	$1055	J	G+H+I	
Cost per mortality (VSL) (2014 $)	$9,100,000	K		Current HHS recommended value for a statistical life
2013 Estimate new incidence 2013 Deaths Deaths to new incidence	2,200,000 3,170 0.0014	L M N	 M/L	ACS (Ref. 1)
Mortality cost per case	$13,112	O	K x N	
Total cost per case	$14,167	P	O+J	
Total cost per case with latency of 20 years at 7% discount	$3661		P x 0.2584	
Total cost per case with latency of 20 years at 3%	$7,845		P x 0.5537	

Societal cost to treat melanoma and melanoma in situ. To estimate the direct cost to treat a new case of melanoma we used data on treatment costs by disease stage at diagnosis from a study by Tsao et al. (Ref. 33) and incidence rates by stage from SEER (see Table 10). We used the same method we used for estimating the cost to treat NMSC to estimate the indirect and intangible costs of treating melanoma. We did not have data on the cost to treat melanoma in situ; we assumed it would be the same as treating Stage I melanoma but we used the factors developed for estimating indirect and intangible costs for NMSC to estimate those variables. Although treating melanoma in situ would be more expensive than an average NMSC treatment, the morbidity and lost work time would be far less than that of invasive melanoma and there is no mortality associated with melanoma in situ. The cost per case in current dollars is $2,844 (Table 11). Assuming 20-year latency, the cost is $735 per episode of melanoma in situ when discounted at a 7 percent rate.

The calculation of the social cost to treat melanoma is presented in Table 12. The mortality-adjusted value per episode is about $1.2 million. We used a 20-year latency period when calculating the benefit of an averted case because a study found that those who have received extensive UV therapy for psoriasis have a 5-fold increase for the rate of melanoma beginning 15 years after treatment and 10-fold increase after 25 years of follow-up (Ref. 29). With 20-year latency at a 7 percent discount rate, the societal cost of melanoma is $304,703 per episode; at a 3 percent discount rate, the societal cost of melanoma is $652,921 per episode.

Table 10: Calculation of the Cost to Treat a New Incidence of Melanoma (1997 $)

Stage of development	Share of new incidence*	Cost per case**	Weighted cost	
Stage I and unknown	65%	$1,350	$852	
Stage II	23%	$3,299	$759	
Stage III	8%	$41,670	$3,334	
Stage IV	4%	$42,410	$1,696	
Total weighted cost to treat new case of melanoma				$6,640
Cost to treat in situ melanoma***				$1,350

Source:*SEER years 2003-2009 (Ref. 24); ** Tsao (Ref. 33); *** assumed equal to cost to treat Stage I

Table 11: Calculation of Social Cost per Case of Melanoma in Situ

Measurement	Value	Line	Calculation	Notes
Factor indirect costs to direct costs	0.045	A		Assume same factor as calculated for NMSC
Factor intangible costs to direct costs	0.090	B		Assume same factor as calculated for NMSC
Cost to treat melanoma in situ	$2,506	C		Used CPI medical costs to inflate estimated 1997 $ to 2014 $
Indirect costs to treat	$113	D	C x A	
Intangible costs to treat	$226	E	C x B	
Total cost per case	$2,844	F	D+E+F	No mortality costs with melanoma in situ
Total cost per case with latency of 20 years at 7% discount	$735		F x 0.2584	
Total cost per case with latency of 20 years at 3% discount	$1,575		F x 0.5537	

Table 12: Calculation of Social Cost per Case of Melanoma

Measure	Value	Line	Calculation	Notes
Annual direct costs (2005 $) Annual indirect costs less value of future earnings Annual intangible costs	$291 million $758 million $367 million	A B C		Lewin Group, Inc. (Ref. 32) Lewin estimate less estimated future earnings per mortality ($364,000)
Factor indirect to direct costs Factor intangible costs to direct costs	2.60 1.26	D E	B/A C/A	Assuming the ratio of direct, indirect, and intangible costs for total burden of NMSC will be the same on a per case basis
Direct Treatment costs melanoma (2014 $)	$12,324	H		Value calculated in table inflated using CPI medical goods 1997 to 2014
Indirect treatment costs	$32,043	I	H x D	
Intangible costs	$15,529	J	H x E	
Total treatment costs	$59,896	K	H+I+J	
Cost per mortality (VSL)	$9,100,000	L		Current HHS recommended value for a statistical life
2013 Estimate new incidence 2013 Deaths Deaths to new incidence	76,790 9,480 12.3%	M N O	 N/M	ACS (Ref. 1)
Mortality cost per case	$1,119,300	P	L x O	
Total cost per case	$1,179,196	Q	K+P	
Total cost per case with latency of 20 years at 7%	$304,704		Q x 0.2584	

discount				
Total cost per case with latency of 20 years at 3% discount	$652,921		Q x 0.5537	

Estimation of Benefits

To calculate benefits, we needed a measure of the difference between the number of cancers expected in the baseline population and the potentially reduced population if the rule became final. We first discuss how we calculated the number of cancers averted and then our estimate of annual benefits.

Estimate of Cancers Averted. To estimate the number of potential cancers that would be averted if the proposed rule became final we used methods developed by RTI to estimate the health and economic burden of sunlamp products (Ref. 30). RTI used the variable Population Attributable Risk (PAR) to estimate the number of expected cancers in a subpopulation of interest. In our case, the subpopulations were the baseline tanning population that would be affected by the proposed rule and the estimates of the affected population under the different impact scenarios. Table 13 lists the variables we used to calculate PAR for the baseline population. The PAR is calculated as [share of the population – (relative risk – 1)] ÷ [[share of population – (relative risk – 1)] + 1]. The relative risk is the proportion of the indoor tanning population that develops skin cancer divided by the proportion to the population not exposed to indoor tanning developing skin cancer. We used the same relative risks of skin cancer as used by RTI; they are listed in Table 13 along with the baseline PAR. The value of PAR over time under the differing impact scenarios are listed in Table 14. To obtain the expected number of skin cancers in our affected population at the baseline and at the different impact assumptions,

the incidence of cancers in the total population is multiplied by PAR. Table 15 presents the estimated number of cancers averted (Baseline projection – Impact projection).

Table 13: Population Attributable Risk (PAR) for Affected Population

Measure	Type	Value	Notes
US Population between 15 and 64 Baseline Indoor Tanning Pop		207,250,000 13,072,000	2010 US Census Table: 2 6.3% total pop
Number of new Skin Cancers in the US	Melanoma	76,256	RTI (Ref. 30)
	Melanoma in situ	55,560	
	Basal Cell	1,761,434	
	Squamous Cell	444,359	
Relative Risk	Melanoma	1.20	RTI (Ref. 30)
	Melanoma in situ	1.20	
	Basal Cell	1.29	
	Squamous Cell	1.67	
PAR at Baseline	Melanoma	1.25%	PAR= (percent pop – (relative risk – 1) / [(percent pop – (relative risk - 1)) + 1]
	Melanoma in situ	1.25%	
	Basal Cell	1.80%	
	Squamous Cell	4.50%	
Expected Occurrence in Baseline Population	Melanoma	950	Occurrence in total population x PAR of affected population
	Melanoma in situ	692	
	Basal Cell	31,640	
	Squamous Cell	17,855	

Table 14: Change in PAR as Indoor Tanning Population Declines

	year	Base year	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
5% impact from acknowledgement and habit	Indoor tanning pop.	13,072	10,745	10,718	10,667	10,644	10,622	10,599	10,576	10,559	10,543	10,526
	Tanning pop. as % of total pop.	6.31%	5.18%	5.17%	5.15%	5.14%	5.12%	5.11%	5.10%	5.09%	5.09%	5.08%
	PAR melanoma		1.03%	1.02%	1.02%	1.02%	1.01%	1.01%	1.01%	1.01%	1.01%	1.01%
	PAR melanoma in situ		1.03%	1.02%	1.02%	1.02%	1.01%	1.01%	1.01%	1.01%	1.01%	1.01%
	PAR basal cell		1.48%	1.48%	1.47%	1.47%	1.46%	1.46%	1.46%	1.46%	1.45%	1.45%
	PAR squamous cell		3.36%	3.35%	3.33%	3.33%	3.32%	3.31%	3.31%	3.30%	3.30%	3.29%
1% impact from acknowledgement and habit	Indoor tanning pop.	13,072	11,198	11,192	11,181	11,177	11,172	11,167	11,163	11,163	11,156	11,156
	Tanning pop. as % of total pop.	6.31%	5.40%	5.40%	5.40%	5.39%	5.39%	5.39%	5.39%	5.39%	5.38%	5.38%
	PAR melanoma		1.07%	1.07%	1.07%	1.07%	1.07%	1.07%	1.07%	1.07%	1.07%	1.07%
	PAR melanoma in situ		1.07%	1.07%	1.07%	1.07%	1.07%	1.07%	1.07%	1.07%	1.07%	1.07%

	PAR basal cell		1.54%	1.54%	1.54%	1.54%	1.54%	1.54%	1.54%	1.54%	1.54%	1.54%
	PAR squamous cell		3.49%	3.49%	3.49%	3.49%	3.49%	3.48%	3.48%	3.48%	3.48%	3.48%
10% impact from acknowledgement and habit	Indoor tanning pop.	13,072	10,180	10,127	10,031	9,988	9,945	9,902	9,859	9,827	9,796	9,764
	Tanning pop. as % of total pop.	6.31%	4.91%	4.89%	4.84%	4.82%	4.80%	4.78%	4.76%	4.74%	4.73%	4.71%
	PAR melanoma		0.97%	0.97%	0.96%	0.95%	0.95%	0.95%	0.94%	0.94%	0.94%	0.93%
	PAR melanoma in situ		0.97%	0.97%	0.96%	0.95%	0.95%	0.95%	0.94%	0.94%	0.94%	0.93%
	PAR basal cell		1.40%	1.40%	1.38%	1.38%	1.37%	1.37%	1.36%	1.36%	1.35%	1.35%
	PAR squamous cell		3.19%	3.17%	3.14%	3.13%	3.11%	3.10%	3.09%	3.08%	3.07%	3.06%

Table 15: Expected Decline in Occurrence of Skin Cancers Over 10 years

		Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
5% impact from acknowledgement and habit	Melanoma	167	169	173	175	176	178	180	181	182	183
	Melanoma in situ	122	123	126	127	128	130	131	132	133	133
	NMSC	8,619	8,723	8,911	8,996	9,080	9,165	9,249	9,312	9,374	9,437
1% impact from acknowledgement and habit	Melanoma	135	135	136	136	137	137	137	137	138	138
	Melanoma in situ	98	98	99	99	100	100	100	100	100	100
	NMSC	6,937	6,958	6,998	7,015	7,033	7,050	7,068	7,068	7,094	7,094
10% impact from acknowledgement and habit	Melanoma	208	212	219	222	225	228	231	234	236	238
	Melanoma in situ	152	154	159	162	164	166	169	170	172	174
	NMSC	10,726	10,924	11,281	11,442	11,602	11,763	11,924	12,042	12,161	12,280

The projected numbers of cancers averted as a result of the requirements in the proposed rule were multiplied by the present value of the cost per case by type of cancer, (see bottom of Tables 10 – 12 for present values). The benefits are presented in Table 16. To account for increasing costs we inflated the total benefits by one percent per year. The annualized benefits discounted over 10 years are presented in Table 17 and range from $70 million to $114.9 million at a 7 percent discount rate and from $150.6 million to $248 million at a 3 percent discount rate.

Table 16: Benefits from Reduced Occurrences of Skin Cancers Over 10 Years with 20-year Latency ($ million)

		Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
5% impact from acknowledgement and habit	20 year latency discounted 7%	82.6	84.5	87.1	88.8	90.5	92.2	94.0	95.5	97.0	98.6
	20 year latency discounted 3%	177.1	181.0	186.7	190.3	194.0	197.7	201.4	204.7	208.0	211.3
1% impact from acknowledgement and habit	20 year latency discounted 7%	66.5	67.4	68.4	69.3	70.1	71.0	71.8	72.5	73.5	74.1
	20 year latency discounted 3%	142.5	144.4	146.7	148.5	150.3	152.1	153.9	155.4	157.4	158.9
10% impact from acknowledgement and habit	20 year latency discounted 7%	102.8	105.7	110.3	112.9	115.6	118.3	121.1	123.5	125.8	128.2
	20 year latency discounted 3%	220.3	226.6	236.3	242.0	247.8	253.6	259.5	264.5	269.6	274.8

Table 17: Total and Annualized Benefits after 10 Years ($ millions)

		7% Discount	3 % Discount
5% impact from acknowledgement and habit	Total	632.9	1,657.3
	Annualized	90.1	194.3
1% impact from acknowledgement and habit	Total	491.7	1,284.4
	Annualized	70.00	150.6
10% impact from acknowledgement and habit	Total	806.8	2,115.7
	Annualized	114.9	248.0

G. Net Benefits of Proposed Rule

Table 18 summarizes the total costs and benefits of the proposed rule under the various potential impacts of the risk acknowledgement certification and habit.

The scenarios show mixed results depending on the discount rate. Because the costs incur immediately and the health effects on average would occur with a lag of 20 years in the future, the net benefits are highly sensitive to the rate at which we discount future events. At the 7 percent rate discounted over 10 years, there would be a net loss of $130.5 million with a 5 percent impact; at the 3 percent discount rate, there would be a net benefit of $530.9 million

Table 18: Summary of Benefits and Costs of Proposed Rule under Different Scenarios Present Value over 10 years (*$ million)

	7% discount rate 5% impact	7% discount rate 1% impact	7% discount rate 10% impact	3% discount rate 5% impact	3% discount rate 1% impact	3% discount rate 10% impact
Total benefits	632.9	491.7	806.8	1,657.3	1,284.4	2,115.7
Total costs	763.4	732.2	801.7	1,126.4	1,043.3	1,228.6
Net benefits	-130.5	-240.5	5.1	530.9	241.1	887.1

H. Additional Sensitivity Assessment

We have built sensitivity analyses into this cost-benefit analysis, showing the how the effects change with a 1 to 10 percent range in the response rate to both the risk information and the age restriction. We also calculated the regulatory impact of the proposed rule using the ITA estimate of 30 million people indoor tanning and 300 million visits per year. We distributed the 30 million tanners using the percent of population tanning from the NHIS and YRBS surveys and assumed all of the users visited commercial tanning facilities. Under this assumption, both the costs and benefits are higher because there are more people visiting tanning facilities and a larger number of expected cancers averted in the larger population. The benefits rise more than costs, so we find large net benefits at both 7 and 3 percent rates of discount. At a 7 percent discount rate, the total cost would be $1.26 billion and total benefit would be $1.39 billion. At the 3 percent discount rate, the total cost would be $1.96 billion and total benefit would be benefit of $3.65 billion.

III. Regulatory Flexibility Analysis

One alternative to the proposed rule would be to require users to sign the risk acknowledgement certification every time they tanned or not requiring a signature on the acknowledgement certification. We did not assess any alternatives without the age restriction because parental awareness of the risks, educational campaigns, and parental consent to the risks, on their own, have been shown to be insufficient in reducing indoor tanning in young age groups (Ref. 7, 20, 23).

Requiring a signature every time a user tanned would increase the cost to administer the requirement about 10-fold (assuming that users carefully read the certification each time) without a correspondingly large increase in benefits. The signing of the certification would become routine and the message might then have little effect on the user's behavior; the user would likely stop reading the certification after the first couple of times and the signature would become routine. The real cost per visit would rise but the additional informational effect could be negligible. The potential for the certification to serve as a risk reminder or behavioral cue would also likely be small. To calculate the cost of this alternative, we assumed a user would read the certification carefully at least a couple of times each year, which would require 2 minutes of the user's time and 135 seconds of the employee's time. We assumed the user would sign the certification without reading it during additional visits, which would require 20 seconds of the user's time and 35 seconds of the employee's time because the employee would have to file the record. This scenario would increase costs and possibly decrease the estimated benefits. For the analysis, we assume that benefits do not fall; with this assumption, net benefits for alternative 1 would be -$434.6 million at the 7 percent discount rate and 161.4 million at the 3 percent rate.

The second alternative would be the same as the proposed rule except that users would

not be required to sign the acknowledgement certification. Under the second alternative, the user would not be compelled to read the risk acknowledgement certification and could consider it part of the promotional materials provided by the tanning facility. If users do not voluntarily read the risk information, there would be no effects from the risk acknowledgement certification. Under this alternative, the decrease in the number of users would be due to the age restriction and any additional decrease due to habit only. There would be reduced costs to the tanning facilities, which would only need to distribute the forms every visit, but benefits would decline because there would be fewer cancers averted. Net benefits for alternative 2 would be -$35.4 million at the 7 percent discount rate and $489.6 million at the 3 percent rate.

Table 19: Summary of Benefits and Costs of Proposed Rule and Alternatives at the 5 Percent Level ($ millions)

	7% Discount Rate over 10 Years	7% Discount Rate over 10 Years	7% Discount Rate over 10 Years	3% Discount Rate over 10 Years	3% Discount Rate over 10 Years	3% Discount Rate over 10 Years
	Proposed Rule	Alternative 1: Sign Every Visit	Alternative 2: Receive Information	Proposed Rule	Alternative 1: Sign Every Visit	Alternative 2: Receive Information
Benefits	632.9	632.9	487.9	1,657.3	1,657.3	1.279.2
Costs	763.4	1,067.5	523.3	1126.4	1,495.8	789.7
Net benefits	-130.5	-434.6	-35.4	530.9	161.4	489.6

Small Entity Analysis

There are 18,000 to 19,000 indoor tanning salons and 15,000 to 20,000 other facilities that offer indoor tanning services. Tanning salons and most of the other establishments who

offer commercial tanning services are classified as Other Personal Care Services under the North American Industry Classification System (NAICS 812199). The Small Business Administration considers an entity small if it has revenues of $7 million or less. We do not have information on the size distribution of this industry but most, if not all, entities are small businesses. Using the industry trade association's estimate of $5 billion in sales and the low end of the number of tanning salons, sales would average $278,000 per salon.

The impact of the proposal on individual firms would depend on the number of users and frequency of visits plus the regulatory environment of their state. Firms in states where persons under 18 years old could indoor tan would now lose the revenue from that cohort and all would lose revenue from potential decreased use by adults and the added cost of administering the risk acknowledgement certification. In our analysis, we treat the majority of the loss in revenue, the largest impact, as a cost to industry but from a societal perspective it is mostly a transfer cost and the money not spent on indoor tanning may be spent on other services the salon offers such as spray-on tans, other personal care services, or products or services outside the personal care industry. We estimate the loss in revenue from indoor tanning services to range from 15 to 23 percent, the majority of that, almost 70 percent, from the age restriction. There could also be a loss in sales of products sold in the salons associated with sunlamp products because there would be less traffic. We did not try to predict this impact as it is secondary to the impact of the proposed rule and represents a transfer payment. Using the estimate of $278,000 for the average revenue per salon, the loss in sales would range from about $42,000 to $64,000.

By dividing the industry incremental cost to administer the risk acknowledgement certification by the total number of sessions annually, the costs to administer the risk acknowledgement certification would add about $0.10 per tanning session, which assuming a

cost of $13.50 per session, is about 0.7 percent of revenue.

The proposed rule would have a significant impact on a substantial number of small entities due to the loss of revenue. The revenue loss is generated by the same effect – reduced indoor tanning – that generates the public health gains. Moreover, the relationship between revenue loss and public health gain is direct. The direct relationship between the revenues of small businesses and the public health gains from the proposed rule greatly limits the options for regulatory relief. Exempting small businesses, for example, would virtually negate the rule. Increasing the compliance period would delay the effects on both revenues and public health.

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