DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Banned Devices; Ban Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove

Docket No. FDA-2015-N-5017

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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Table of Contents

I. Introduction and Summary

A. Introduction

We have examined the impacts of the final 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 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us 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). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule imposes no new burdens, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "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 $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

The final rule prohibits marketing of powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating surgeon's gloves. The rule does not cover or include powdered radiographic gloves.

In the past, powdering gloves was a popular method to make the gloves easier to put on and remove. However, recent studies indicate that these powders pose an unreasonable and substantial risk to medical workers (Refs. 1 and 2). The results of these studies note that these powders carry the latex material on latex gloves. As a result, medical workers that are sensitive to latex are occasionally exposed to enough latex to develop an allergy.

The final rule is expected to provide a positive net benefit (estimated benefits minus estimated costs) to society. Banning powdered glove products is not expected to impose any costs to society. Extensive searchers of glove distributor pricing indicate that improvements to non-powdered gloves have made these products as affordable as powdered gloves. The ban is expected to reduce the adverse events associated with using powdered gloves. The Agency estimates maximum total annual net benefits to range between $26.8 million and $31.8 million.

The present discounted value of the estimated benefits over 10 years ranges from $228.9 million to $270.8 million at a 3 percent discount rate and from $188.5 million to $223 million at a 7 percent discount rate.

C. Comments on the Preliminary RIA and Our Responses

FDA's proposed rule "Banned Devices; Proposal to Ban Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove" (81 FR 15173; hereinafter the proposed rule) was published on March 22, 2016, and its comment period ended June 20, 2016. Although the Agency received approximately 100 comment letters, few comments addressed our preliminary regulatory impact analysis (PRIA). We describe and respond to the comments we received on the PRIA in the paragraphs below. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value, importance, or the order in which it was received.

(Comment 1) Five comments oppose the proposed ban on powdered patient examination gloves and powdered surgeon's gloves due to their expectation that users will ultimately have to pay more for medical gloves once the ban is finalized because the cost of non-powdered gloves is currently higher than the cost of powdered gloves

(Response 1) We do not find any evidence to support the claims that current prices of non-powdered gloves are significantly higher than powdered gloves. As we stated in the PRIA, extensive searches of glove distributor pricing indicate that non-powdered gloves have become as affordable as powdered gloves. Our searches also revealed that the market is saturated with alternatives to powdered gloves, resulting in downward pressure on the prices of non-powdered gloves. In addition, the share of powdered medical gloves sales has been declining since at least 2000 while total sales of all disposable medical gloves increased (Ref. 3). We would not expect this trend to be occurring without regulatory action if users of disposable medical gloves faced significantly higher prices for switching to non-powdered gloves. We therefore do not find it necessary to update our analysis based on these comments.

(Comment 2) We received one comment that disagrees with our determination that the availability of examination and surgical gloves would not be reduced.

(Response 2) We do not find any evidence to support these claims. As we stated in the PRIA, research shows only 7 percent of total sales of examination and surgical gloves to medical workers were projected to be from powdered gloves in 2010 (Ref. 3). Global Industry Analysts (GIA) projected the share of powdered disposable medical gloves sales to decrease to 2 percent in 2015, while total sales of all disposable medical gloves continue to increase (Ref. 3). We would not expect this trend to be occurring without regulatory action if there were a reduction in the availability of disposable examination and surgical gloves. We therefore do not find it necessary to update our analysis based on these comments.

(Comment 3) Three commenters suggest there would be a loss in consumer utility due to the preference some medical workers may have for powdered gloves due to comfort and ease of use.

(Response 3) We stated in the PRIA that the remaining 7 percent continuing to use these powdered gloves may experience utility loss from the removal of powdered gloves from the market (Ref. 3). The potential loss in consumer utility would be due to the perceived loss in comfort from powdered gloves users switching to non-powdered gloves. However, as the GIA report shows, there has been a downward trend in total sales of powdered disposable medical gloves since at least 2000 while total sales of all disposable medical gloves has increased (Ref. 3). We would not expect this trend to be occurring without regulatory action if the loss in consumer utility to current medical workers were substantial. Korniewicz et al. reported no loss in consumer satisfaction in a sample of operating room staff switching to non-powdered surgical gloves (Ref. 2). We have not estimated this potential burden, but the evidence listed above suggests that any burden would not be substantial. Further, even having considered that some degree of consumer comfort may be lost by banning powdered gloves, FDA continues to believe that this benefit is considerably outweighed by the numerous risks posed by powdered gloves.

D. Summary of Changes

While we do not make changes to the regulatory impact analysis that are directly related to the comments we received, review of the submitted comments and updated data has led us to re-estimate several benefits. The estimated range of annual benefits in the PRIA is $26.6 million to $29.3 million. The estimated range of annual benefits in the PRIA is $26.8 million to $31.8 million. The small change in values is a result of

1) updating all dollar values to 2015 US dollars;
2) an updated estimate of active doctors, nurses, dentists, and dental hygienists;
3) using a range for the estimate of the likelihood of a medical worker developing an allergic reaction to latex rather than an average;
4) an update on the cost of treating a post-operation wound infection; and
5) an update of the estimate on the average number of days a patient needs to recover from a post-operation wound infection.

II. Final Regulatory Impact Analysis

A. Background and Baseline

The rule prohibits the marketing of powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating surgeon's gloves. The rule does not include nor cover powdered radiographic protective gloves. In the past, medical providers preferred powdered gloves because they were cheaper and easier to put on than non-powdered gloves. However, as recent as 2010, 93 percent of medical providers have switched to non-powdered gloves (Ref. 3). Researchers attribute the switch to emerging reports on medical workers developing allergic reactions to glove powders (Refs. 1 and 2). Glove powders occasionally carry latex proteins, resulting in medical workers sensitive to latex to develop allergic reactions when they are exposed to too much powder.

A recent report indicates that it could take 10 or more years for natural market forces to completely replace powdered gloves with non-powdered gloves, with the exception of powdered

radiographic gloves where natural market forces appear to have completely replaced powdered radiographic gloves with non-powdered gloves (Ref. 3). Because allergic reactions reduce an individual's quality of life, FDA is pursuing banning these products through rulemaking to expedite this process. The ban will benefit society by reducing powder-related adverse events. It is also expected that adoption of the rule will not impose any new costs on society. Extensive searches of glove distributor pricing indicate that improvements to non-powdered gloves have made these products as affordable as powdered gloves.

B. Costs of the Rule

The rule could impose minimal cost to the remaining 7 percent of medical workers that use powdered gloves. These workers could be more comfortable with powdered products, or believe that they perform better with them. However, there is no empirical or anecdotal evidence to support these claims. Korniewicz et al. (2003) reported no loss in consumer satisfaction in a sample of operating room staff switching to non-powdered surgical gloves (Ref. 2).

It is possible that healthcare workers cannot find non-powdered gloves at a similar price to the powdered gloves they are currently using. However, we believe because the market is saturated with non-powdered gloves and healthcare workers have been moving away from powdered gloves there is not a significant difference between the prices of these gloves. Extensive searches of glove distributor pricing indicate that there is no difference in the average current prices of powdered and powder-free gloves.

C. Benefits of the Rule

1. Powdered Latex Gloves

The rule is expected to reduce the allergic reactions associated with using powdered latex gloves. To calculate this value, we would multiply the expected reduction in allergic reactions associated with using powdered latex gloves by the value of avoiding these events (= annual reduction in allergic reactions associated with using powdered gloves * value associated with avoiding an allergic reaction to latex).

The value associated with avoiding an adverse events roughly equals the amount an individual is willing-to-pay to avoid the event. Because willingness-to-pay measures are unavailable, we indirectly measure this value using the medical costs to treat the adverse event plus the amount an allergic reaction reduces an individual's quality of life (i.e., ability to participate in activities that they value, such as working or enjoying leisure). We measure the latter value using the average monetized value of avoiding a decrease in quality-adjusted life years (QALYs) attributed to an allergic reaction to latex. The full QALY loss represents the reduction in health-related quality of life associated with the time the condition lasts. A QALY captures an individual's quality of life for an entire year.

We estimate this value by multiplying the expected gain in QALYs attributed to avoiding an allergic reaction to latex with the average monetary value corresponding to one QALY. The Cost-Effectiveness Analysis Registry (CEA Registry) reports health-related quality of life

reductions associated with various adverse events. The index values range from 0 to 1; 0 is equivalent to death, while 1 is equivalent to perfect health. Values lower than 1 represent a reduction in quality of life.

The CEA Registry indicates that the average health-related quality of life index value associated with a generic allergic reaction roughly equals 0.84 (Ref. 4). To estimate the QALY gains associated with avoiding an allergic reaction, we subtract the average individual's health-related quality of life value by their health-related quality of life when experiencing an allergic reaction. Recent studies indicate that the average individual's health-related quality of life value is roughly 0.87 (Refs. 5 and 6). Hence, we estimate that avoiding an allergic reaction is expected to increase an average individual's health-related quality of life index roughly 0.03 QALYs (= 0.87 – 0.84).

The values indicate that the average allergic reaction results in a modest reduction in health-related quality of life. Academic studies examining allergic reactions to latex support this result (Refs. 2 and 7). These studies indicate that almost every medical worker that developed an allergic reaction experienced mild symptoms, such as minor skin irritation, asthma, or fever. These studies indicate that the average duration associated with an allergic reaction is roughly 10 days (Refs. 2 and 7). These values imply that the average allergic reaction reduces a patient's quality of life by roughly 0.0008 QALYs (= 0.03 QALYs per day * [10 days / 365 days per year]).

In line with HHS guidance, the average QALY value ranges between $226,000 and $1,226,000 in 2015 dollars. Given these values, we estimate the average monetary amount associated with avoiding an allergic reaction to roughly range between $185 (= $226,000 per lower bound expected value associated with one QALY * 0.0008 QALYs per allergic reaction) and $1,010 (= $1,226,000 per upper bound expected value associated with one QALY * 0.0008 QALYs per allergic reaction).

An allergic reaction to latex also incurs medical expenses. A study indicates that almost every reaction to latex results in mild, short-term contact dermatitis, and that the medical expenses associated with such a reaction usually includes only a single visit to an urgent care facility (Ref. 7). A recent report from the Agency for Healthcare Research and Quality estimates the 2013 average expense for an office-based physician visit to be $228 (Ref. 8). This amount is equivalent to $234 in 2015 dollars. Together these data indicate that the average value associated with avoiding an allergic reaction to latex ranges between $419 (= $185 + $234 per doctor visit) and $1,244 (= $1,010 + $234 per doctor visit).

Powdered latex products create aerosols that occasionally contain latex proteins. Exposure to these aerosols can cause sensitive individuals to develop an allergic reaction (Refs. 1 and 2). Hence, using powdered gloves poses a risk to the user, their co-workers, and their patients. Although it is possible for patients to develop allergic reactions, previous studies indicate that these adverse events are rare because patients are usually not exposed to enough aerosols. On the other hand, medical workers are exposed to these aerosols, in tight enclosed spaces, several times a day, for weeks to months, and thus are substantially more likely to develop an allergic reaction (Ref. 1 and 2).

FDA has no data on the expected annual reduction in allergic reactions associated with working in environments that use powdered gloves. To calculate this value, we multiply the total expected number of medical workers working in environments using powdered products by the probability that they develop an allergic reaction as a result of working in such an environment. In 2010, approximately 7 percent of medical workers either used powdered latex gloves or worked with co-workers who used these products (Ref. 3). The Bureau of Labor Statistics indicates that there are approximately 3,811,300 active doctors, nurses, dentists, and dental hygienists in 2014 (Refs. 9-12). Given these values, we estimate that approximately 272,300 medical workers are exposed to the aerosol latex associated with using powdered latex gloves (= 3,811,300 active medical workers * 7 percent medical workers work in an environment using powdered latex gloves). Our estimate assumes that there is one exposure per use of powdered gloves.

Recent studies indicate that medical workers working in an environment that uses powdered latex gloves have between a 0.01 percent chance and a 1 percent chance, per year, of developing an allergic reaction to latex (Ref. 7). This rate assumes that the medical worker is exposed several times over the year. Given these estimates, we calculate that between 27 (= 272,300 exposed medical workers * 0.01 percent) and 2,723 (= 272,300 exposed medical workers * 1 percent) medical workers may develop allergic reactions to latex per year.

Furthermore, these studies also indicate that banning powdered latex gloves and other powdered products would reduce the probability of getting an allergic reaction by approximately 76 percent (Refs. 7 and 13). Given this value, we estimate that the rule will reduce the total number of allergic reactions between 20 per year (= 76 percent reduction in latex allergies * 27 latex allergies per year) and 2,058 per year (= 76 percent reduction in latex allergies * 2,723 latex allergies per year).

To summarize, our sources indicate that the rule may reduce the number of allergic reactions between 20 and 2,058 per year. Given that the average value to avoid an allergic reaction ranges between $419 and $1,244, we estimate that banning powdered glove products may provide annual benefits that range between $8,380 (= 20 fewer allergic reactions per year * $419 lower bound value) and $2,560,000 (= 2,058 fewer allergic reactions per year * $1,244 upper bound value).

2. Powdered non-Latex Gloves

The rule will also prohibit the sale of other powdered gloves. The literature indicates that this action would further reduce the adverse reactions associated with exposure to glove powders (e.g., a post-operation wound infection, such as starch peritonitis). These events primarily occur in patients receiving surgeries involving the abdomen. In rare instances, enough aerosol powders enter the patient's abdomen to trigger a post-operative wound infection (Refs. 2, 14-16).

The rule is expected to reduce the post-operative wound infections associated with using powdered gloves. To get an estimate of the potential value, we multiplied the maximum expected reduction in post-operative wound infections associated with using powdered gloves by the value

of avoiding these events (= anticipated annual reduction in post-operative wound infections associated with exposure to powdered gloves * value associated with avoiding an post-operative wound infections).

Powdered gloves pose a particular risk to patients undergoing surgeries involving the abdomen where aerosol powders can enter, resulting in a post-operative wound infection, such as acute peritonitis (Refs. 2, 14-16). Like an allergic reaction, a post-operative wound infection reduces an individual's quality of life. Because willingness-to-pay measures are unavailable, we indirectly measure these values using the average monetized value of avoiding a decrease in QALYs.

The CEA Registry indicates that the average health-related quality of life index value associated with a post-operation wound infection roughly equals 0.61, which implies that avoiding this event is expected to increase an average individual's health-related quality of life index roughly 0.26 QALYs (= 0.87 – 0.61) (Refs. 4-6).

The Healthcare Cost and Utilization Project estimates that patients with a post-operation wound infection will need an average of approximately 6.6 days to recover (Ref. 17). This value implies that the average post-operation wound infection reduces a patient's quality of life by roughly 0.0047 QALYs (= 0.26 QALYs per day * (Average duration is 6.6 days) / (365 days per year).

In line with HHS guidance, the average QALY value ranges between $226,000 and $1,226,000 in 2015 dollars. Given these values, we estimate the average monetary amount associated with avoiding a post-operation wound infection to roughly range between $1,062 (= $226,000 per lower bound expected value associated with one QALY * 0.0047 QALYs per allergic reaction) and $5,762 (= $1,226,000 per upper bound expected value associated with one QALY * 0.0047 QALYs per allergic reaction).

A post-operation infection also incurs medical expenses. Because these infections develop under inpatient care, patients tend to remain hospitalized while they are treated. Hence, the medical expenses associated with treating these conditions tend to include the costs associated with hospitalization and any separate medical costs that occur during hospitalization, such as daily doctor visits.

An internal model recommends estimating the costs associated with hospitalization using hospitalization charges. The Healthcare Cost and Utilization Project estimates that the average hospitalization charge associated with treating a post-operation wound infection, such as acute peritonitis, is roughly $51,557 (Ref. 17).

An internal resource estimates the median cost to visit a primary care physician during hospitalization to roughly equal $209 during the initial visit and $76 every subsequent visit. Given that the average length of stay is 6.6 days, we estimate doctor visits to roughly cost $635 (= $209 initial cost + [$76 daily cost * 5.6 days]) (Ref. 17). Together, these estimates indicate that the value associated with avoiding a post-operation infection ranges between $53,254 (= $1,062 + $51,557 + $635) and $57,954 (= $5,762 + $51,557 + $635).

To estimate the expected reduction in powder-related wound infections, we multiply the annual amount of abdominal surgeries that were conducted using powdered gloves by the probability that a patient develops peritonitis due to their exposure to aerosol glove powders. Recent CDC data shows that roughly 6 million patients undergo surgery involving the abdomen every year (Ref. 18). A report on medical gloves indicates that approximately 6 percent of all surgical gloves contain powder (Ref. 3). Hence, we project that roughly 360,000 (= 6 million abdominal surgeries * 6 percent of all surgical gloves contain powder) abdominal surgeries are potentially conducted using powdered gloves.

Data from Sternlieb et al. (1977) suggests that the probability a patient develops a powder-related post-operation wound infection is approximately 0.14 percent (Ref. 19). A caveat to this study is that it might overestimate the contemporary probability associated with this relationship because it was conducted during a period where medical workers were largely unaware of the potential hazards of powdered gloves. Because awareness probably grew over time, it is possible that rising awareness resulted in changes to standard operating procedures intended to mitigate powder-related wound infection (such as washing gloves prior to surgery).

The available data indicate that the rule will reduce the number of patients developing powder-related wound infection by, at most, 504 per year (= 360,000 abdominal surgeries potentially conducted using powdered gloves * 0.0014 chance of developing post-operation wound infection). Given that the average benefit of avoiding these events range between $53,254 and $57,954, we estimate that banning powdered glove products would provide additional annual benefits ranging between approximately $26.840 million (= $53,254 lower bound value * 504 powder-related wound infections) and $29.194 million (= $57,954 upper bound value * 504 powder-related wound infections).

Total annual benefits are estimated to approximately range between $26.8 million (= $26.840 million lower bound value for reducing post-operation wound infections + $0.008 million lower bound value for reducing latex allergic reaction) and $31.8 million (= $29.209 million upper bound value for reducing post-operation wound infections + $2.56 million upper bound value for reducing latex allergic reaction).

D. Summary of Costs and Benefits

In summary, this rule bans powdered latex gloves and other powdered products. FDA anticipates that banning these products will reduce the adverse events associated with exposure to latex products. The rule is not expected to impose any new costs on society. Adopting the rule will provide moderate benefits to society, with the benefits accruing to medical workers with latex allergies. Estimated maximum total annual benefits are expected to range between $26.8 million and $31.8 million.

III. Final Small Entity Analysis

FDA has examined the economic implications of the rule as required by the Regulatory Flexibility Act. If a rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. This rule will not impose any new burdens on small entities, and thus will not impose a significant economic impact on a substantial number of small entities.

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