DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Docket No. FDA-2015-N-5017

Preliminary Regulatory Impact Analysis

Initial Regulatory Flexibility Analysis

Unfunded Mandates Reform Act Analysis

Economics Staff

Office of Planning

Office of Policy, Planning, Legislation, and Analysis

Office of the Commissioner

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). The Agency believes that this proposed rule is not 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. Because this rule imposes no new burdens, the Agency proposes to certify that the final rule would not have a significant economic impact on a substantial number of small entities. 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 does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

B. Summary

The proposed rule would prohibit 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 unnecessary risk to medical workers (Ref. 1 and 2). Their results 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.

Adopting the proposed 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 internet searchers indicate that improvements to non-powdered gloves have made these products as affordable and easy to put on as powdered gloves. The ban is expected to reduce the adverse events associated with using powdered gloves. Total annual benefits are estimated to range between $26.6 million and $29.3.

II. Background and Baseline

The proposed rule would prohibit 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 (Ref. 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 completed replaced powdered radiographic gloves with non-powdered gloves (Ref. 3). Because allergic reactions reduce an individual's

quality of life, FDA proposes to expedite this process by banning these products. The ban would benefit society by reducing powder-related adverse events. It is also expected that adopting the proposed rule would not impose any new costs on society. Extensive internet searches indicate that recent improvements to non-powdered gloves have made these products as affordable and easy to put on as powdered gloves.

III. Benefits

A. Powdered Latex Gloves

The proposed 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) x (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.

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 for roughly 10 days.

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. The above 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 0.001 QALYS (=0.03 QALYS per day * (Average duration is 10 days) / (365 days per year)).

In line with HHS guidance, the average QALY value ranges between $220,000 and $1,194,000. Given these values, we estimate the average monetary amount associated with avoiding an allergic reaction to roughly range between $220 (=$220,000 per lower bound expected value associated with one QALY * 0.001 QALYs per allergic reaction) and $1,194 (= $1,194,000 per upper bound expected value associated with one QALY * 0.001 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 a primary care physician (Ref. 8). An internal

resource estimates the median cost to visit a primary care physician to roughly equal $83 (Ref. 9). Together these data indicate that the average value associated with avoiding an allergic reaction to latex ranges between $303 (= $220 + $83) and $1,277 (=$1,194 + $83).

Powdered latex products create aerosols that occasionally contain latex proteins. Exposure to these aerosols can cause sensitive individuals to develop an allergic reaction (Ref. 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 use powdered latex gloves or work with co-workers using these products. Various medical associations indicate that there are approximately 3,841,719 active doctors, nurses, dentists, and dental hygienists (Ref. 10 - 13). Given these values, we estimate that approximately 274,472 medical workers are exposed to the aerosol latex associated with using powdered latex gloves (= 3,841,719 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 an 11 in 10,000 chance, per year, of developing an allergic reaction to latex (Ref. 7 and 12). This rate assumes that the medical worker is exposed several times over the year. Given this value, we estimate that 299 medical workers develop allergic reactions to latex per year (= 274,472 medical

workers exposed to powdered products * 11 in 10,000 chance getting an allergic reaction). Furthermore, these studies also indicate that banning powdered latex gloves and other powdered products would reduce the probability of getting an allergic reaction by 76 percent. Given this value, we estimate that adopting the proposed rule would reduce allergic reactions by 226 per year (= 76 percent reduction in latex allergies * 299 latex allergies per year).

To summarize, our sources indicate that adopting the proposed rule would reduce the number of allergic reactions by 226 per year. Given that the average value to avoid an allergic reaction ranges between $303 and $1,277, we estimate that banning powdered glove products would provide annual benefits that range between $68,478 (= 226 reduction in allergic reactions per year * $303 lower bound value) and $288,602 (= 226 reduction in allergic reactions per year * $1,277 upper bound value).

B. Powdered Gloves

The proposed rule would 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 (Ref. 2 and 14). One paper tested several methods to prevent these events, which included sterilizing the glove powders, washing the gloves prior to surgery, and using powder-free gloves. The results indicated that using powder-free gloves was the most effective method to prevent powder-related adverse events (Ref. 14).

The proposed rule is expected to reduce the post-operative wound infections associated with using powdered gloves. To calculate the value, wemultiplied the expected reduction in post-operative wound infections associated with using powdered gloves by the value of avoiding these events [= (annual reduction in post-operative wound infections associated with exposure to powdered gloves) x (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 (Ref. 2, 14). 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 quality-adjusted life years (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) (Ref. 4).

The Healthcare Cost and Utilization Project estimates that patients require roughly 7 days to recover from a post-operation wound infection (Ref. 15). This value implies that the average post-operation wound infection reduces a patient's quality of life by roughly 0.005 QALYS (=0.26 QALYS per day * (Average duration is 7 days) / (365 days per year).

In line with HHS guidance, the average QALY value ranges between $220,000 and $1,194,000. Given these values, we estimate the average monetary amount associated with avoiding a post-operation wound infection to roughly range between $1,100 (=$220,000 per lower bound expected value associated with one QALY * 0.005 QALYs per allergic reaction) and $5,970 (= $1,194,000 per upper bound expected value associated with one QALY * 0.005 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 $50,852 (Ref. 15).

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 7 days, we estimate doctor visits to roughly cost $665 (= $209 + $76 x 6 days) (Ref. 15). Together, these value indicate that the value associated with avoiding a post-operation infection ranges between $52,617 (= $1,100 + $50,852 + $665) and $57,487 (=$5,970 + $50,852 + $665).

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. CDC reports that roughly 6 million patients undergo surgery involving the abdomen every year (Ref. 16). A report on medical gloves indicates that approximately 6 percent of all surgical gloves contain powder. Hence, we project that roughly 360,000 abdominal surgeries are potentially conducted using powdered gloves (= 6 million abdominal surgeries * 6 percent of all surgical gloves contain powder).

Sternlieb et al. (1977) estimate the probability that a patient develops a powder-related post-operation wound infection to approximately equal 0.14 percent (Ref. 17). 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). [1]

[1] To our knowledge, Welker et al. (1976) is the most recent study estimating this probability value.

The available data indicate that adopting the proposed rule would 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 avoid these events range between $52,617 and $57,487, we estimate that banning powdered glove products would provide additional annual benefits approximately range between $26.5 million (=$52,617 lower bound value * 504) and $29.0 million ($57,487upper bound value * 504).

Total annual benefits are estimated to approximately range between $26.6 million (= $26.5 million lower bound value for reducing post-operation wound infections + $0.06 million lower bound value for reducing latex allergic reaction) and $29.3 million (= $29.0 million upper bound value for reducing post-operation wound infections + $0.29 million upper bound value for reducing latex allergic reaction).

IV. Costs

Adopting the proposed rule could impose a 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, which suggests that banning these products would not impose a cost to these individuals beyond the transactions costs associated with switching to a new product.

V. Summary Costs and Benefits

Adopting the proposed rule is expected to provide moderate benefits to society, with the benefits accruing to medical workers with latex allergies. Estimated total annual benefits are expected to range between $26.6 million and $29.3 million. In summary, this rule proposes to ban powdered latex gloves and other powdered products. FDA anticipates that banning these products would reduce the

adverse events associated with exposure to latex products. Finally, adopting the proposed rule is not expected to impose any new costs to society.

VI. Regulatory Flexibility Analysis

FDA has examined the economic implications of the proposed rule as required by the Regulatory Flexibility Act. If a proposed 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 proposed rule would impose no new burdens on small entities, and thus would not impose a significant economic impact on a substantial number of small entities.

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