Public Citizen Health Research Group Comments on proposed FDA/CDRH rule to ban powdered surgeons' and patients' examination gloves as well as absorbable powder for surgeons' gloves. Docket: FDA-2015-N-5017

We support the long-standing evidence cited to justify the proposed ban but strongly disagree with how long this proposal has taken to be put forth. FDA's history of past, inexcusable and dangerous delays is cause for concern about how promptly this proposed ban will be finalized.

The following outlines the comments being filed:

1/ Evidence for ban

a/ medical/scientific evidence

b/ growing evidence of worldwide response to these dangers, resulting in banning powdered glove use in multiple U.S. hospitals going at least as far back as 1993, then in Germany,.

c/ market data showing powder-free gloves comprised the majority of U.S. glove use before 2000.

2/ Past dangerous delays using flawed excuses (lack of market availability) for not imposing this ban more than 16 years ago provide grounds for concern about the pace of finalizing the current proposal.

3/ Urgent need for a prompt process for assessing comments and issuing final rule banning powdered gloves

---

1/ Evidence for ban

a/ medical/scientific evidence

Public Citizen previously petitioned the FDA to ban powdered gloves in 1998 and again in 2011. These petitions are enclosed as attachments 2 and 3 after these comments. A summary of the evidence is as follows. It should be noted that all of these often serious adverse effects were recognized and documented well before our 1998 petition, many by the 1970's.

Harms to patients: When cornstarch is deposited in tissues at the time of surgery, it can result in foreign-body disease, resulting in the following:

• Promotion of wound infections

• Delayed wound healing;

• Granuloma formation in the peritoneal cavity, resulting in adhesions and peritonitis;

• Intestinal obstruction, pelvic pain, and infertility secondary to peritoneal adhesions;

• Endophthalmalitis;

• Post-thoracotomy syndrome;

• Meningismus after craniotomy;

• Retroperitoneal fibrosis; and

• Synovial inflammation.

For healthcare workers, the major risks are allergic reactions to latex, some of which can are serious and life-threatening. For many healthcare workers, sensitization to latex and subsequent allergic reactions results from exposure to aerosolized cornstarch powder bound to latex proteins which have been released from latex gloves. These allergic reactions include:

• Contact dermatitis and urticaria;

• Rhinitis;

• Conjunctivitis;

• Asthma; and

• Anaphylactic shock, sometimes fatal.

b/ growing evidence of worldwide response to dangers resulting in cessation of powdered glove use in multiple U.S. hospitals and Germany, at least as far back as 1993. In our 1998 petition, we noted that three hospitals - Brigham and Women's Hospital in Boston (1993), Jackson Memorial Hospital in Miami (1995), and Methodist Hospital in Indianapolis (1995-1996) - successfully transitioned to powder-free gloves in response to epidemics of allergic reactions among their healthcare workers due to use of powdered latex gloves. Since the time of our 1998 petition, the number of hospitals in the Unites States (U.S.) that have switched to powder-free gloves has dramatically increased. Jackson et al in 2000 reported identifying 70 hospitals in 21 states that had transitioned to powder-free gloves. Additional major medical centers and healthcare

systems that have eliminated the use of powdered latex gloves because of risks to their patients and employees include Kaiser Permanente, which has multiple hospitals across the country, Legacy Healthcare System in Washington and Oregon, and Geisinger Medical Center in Pennsylvania. Germany, in 1998, banned the use of powdered latex gloves and any latex gloves with high allergen content throughout the country.

c/ market data showing powder-free gloves comprised the majority of U.S. glove use before 2000. In the current proposed ban, the FDA refers to data showing that by now, more than 93% of U.S. patients' examination and surgeons' gloves are powder-free. Other data show that by the year 2000, well over half of these gloves were powder-free.

2/ Past dangerous delays, using flawed excuses (alleged lack of market availability), for not imposing this ban more than 16 years ago provide grounds for concern about the pace of finalizing the current proposal.

Although the FDA never disputed the robustness of the medical evidence concerning these serious dangers, in rejecting petitions to ban powdered gloves the almost "one note" excuse they used was the lack of "current availability" of powder-free alternatives, even after the majority available of U.S. gloves were powder-free. (see 1 c/ above). Data obtained from the Malaysian glove manufacturers, included in the FDA's 1997 Medical Glove Powder Report in 1997 (pages 23 and 24 of the current FDA proposed ban), predicted that by mid-1998 over half of the U.S. glove market would be powder-free. By 2000, based on industry data, about 2/3 of U.S. gloves were, in fact, powder-free.

3/ Urgent need for an expedited process for assessing comments and issuing final rule banning powdered gloves.

Earlier, FDA-rejected options for solving this serious health problem had included "initiate the process to ban glove powder at some predetermined time in the future and require manufacturers to convert to powder-free production."

The current proposal, belatedly acknowledging that the spurious lack of availability argument was and is not valid, states that "Once this rule is finalized, all powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's gloves must be removed from the market by the effective date provided in the final rule or the device will be deemed adulterated. Section 501(g) of the FD&C Act deems a device to be adulterated if it is a banned device." (see section IX in the proposed ban).

The key variable is when the "Proposed effective date" will be. Will the FDA yield to the marketplace again and set the effective date enough in the future for the small fraction of powdered gloves to be sold off or, in the interest of public health, will the effective date

immediately follow the expedited reading of all comments filed in response to this proposal. The reckless, almost 20-year, history of FDA's failure to ban powdered gloves mandates the latter option. The same history, however, raises concerns about holding the effective date until no more powdered gloves are available in the channels of commerce, allowing companies to sell off these dangerous products rather than facing seizure because they are adulterated.