

# Spina Bifida Association of America

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January 21, 2000

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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Re: Comments for Proposed Medical Glove Regulation and Draft  
Medical Glove Guidance Manual (Docket No. 99D-2335)

The Spina Bifida Association of America ("SBAA") welcomes this opportunity to comment on the Food and Drug Administration's proposals on (1) the proposed medical glove rules containing latex products, and (2) the draft "Medical Glove Guidance Manual" rule, which is recognized within the proposed rule as a special control.

SBAA was founded in 1973 as a nonprofit 501 (c) (3) organization. Our mission is to promote the prevention of spina bifida and to enhance the lives of all affected. SBAA is composed of a 18-member Board of Directors, nine staff members, thousands of volunteers from 70 affiliates group members and chapters throughout the United States. SBAA is located in Washington, D.C.

SBAA represents the needs of over 25,000 individuals, consisting of persons with spina bifida, their families, and the professionals who treat and seek a means to prevent spina bifida. The SBAA provides a wide range of services including: National Resource and Information Center via our toll-free number-1-800-621-3141 and Internet access [sbaa@sbaa.org](mailto:sbaa@sbaa.org); public policy and government relations; research; education; primary prevention and secondary prevention initiatives; and member services which includes conferences, newsletters and ongoing communications. Efforts of SBAA benefits thousands of infants, children, adults, parents and professionals each year.

Over the past few years, SBAA has made very significant advances toward its mission:

1. Funded several significant research projects whose outcomes will touch the lives of those affected by spina bifida. These projects include endoscopic shunt insertion, treatment of urological conditions in persons with spina bifida, research into further understanding of hydrocephalus and an evaluative study of fetal surgery on spina bifida infants at Vanderbilt University.

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2. Played a central role in the FDA's approval of folic acid fortification of grain products to prevent spina bifida.
3. Filmed a spina bifida awareness PSA featuring First Lady Hillary Rodham Clinton for release this year.
4. Emerged as the central organization in the creation, passage and enactment of the *Agent Orange Benefits Act of 1996*, which provides Vietnam veterans' children born with spina bifida a monthly monetary allowance, lifetime health care benefits and vocational/rehabilitation training.
5. Played an instrumental role in the formulation of the National Council on Folic Acid.
6. In 1999, created the Spina Bifida Association of America Foundation (SBAAF) to focus on national research, advocacy and public awareness initiatives.

The SBAA is particularly interested in these proposed rules because a latex allergy in persons with spina bifida is a significant health care issue. Spina bifida is a defect in the spinal cord, its coverings, and the vertebrae of the spinal column resulting from the abnormal closure of the neural tube during the first month of pregnancy. This condition may cause varying degrees of paralysis and loss of feeling in lower limbs as well as bowel and bladder complications, hydrocephalus, learning disabilities and latex allergies.

The possibility of severe latex allergies in individuals with spina bifida was first raised in 1989. Since that time research studies have shown that all persons born with spina bifida are at increased risk of developing a latex allergy. The type of allergic reaction experienced can range from watery eyes and/or sneezing and coughing, to hives, to swelling of the trachea and even to life-threatening changes in blood pressure and circulation, causing anaphylactic shock. Due to the high risk of latex allergies in persons with spina bifida, strategies must be implemented to reduce overall medical exposure to latex allergens. Each year there are approximately 2,500 spina bifida babies born in the United States. There are more than 70,000 persons in the United States with spina bifida. Often the spina bifida is manageable through lifelong medical and surgical interventions, however, the secondary conditions are devastating. Latex allergies are one of these secondary conditions that affect the health and wellness of every person with spina bifida.

SBAA recommends the following for all persons with spina bifida:

***All individuals with spina bifida should be considered at HIGH RISK for having an allergic reaction to rubber and should avoid contact with rubber products, particularly during medical and surgical procedures. Only non-latex gloves and catheters should be used.***

The SBAA applauds the FDA for its commendable efforts to develop regulations pertaining to latex use in medical gloves and proper labeling. Like the ELASTIC, whose comments on these proposed rules the SBAA supports, the SBAA agrees that tougher labeling regulations and use

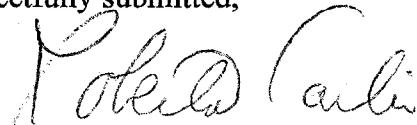
regulations is necessary in order to reduce the risk of allergic reaction to latex containing gloves.

While recognizing that the propped rules represent a very significant step toward reducing the incidence of latex allergic reactions in persons with spina bifida, the SBAA respectfully submits that the rules do not go far enough. The SBAA's concerns relate principally to three aspects of the proposed rules: (1) the statement that accompanies latex gloves should state the FDA *requires, rather than the FDA recommends* that this process contains no more than 120 mg of powder and no more than 1,200 micrograms extractable protein per glove (2) the use of medical gloves containing latex *should be phased out* within 1-2 years (3) all persons with spina bifida should be *treated proactively with non latex gloves*, even if they do not request the use of latex gloves.

To avoid duplication of authority and precedent, SBAA requests that you review the excellent sample of literature abstracts submitted by ELASTIC, which reflects the gravity of the harm created by exposure to latex containing gloves for persons with spina bifida.

In sum, the SBAA commends the FDA for its development of policies and procedures for the use of latex gloves and their handling, however, we believe these efforts can be further strengthened by clarifying and simplifying the language of the caution statements and the eventual phasing out of all latex containing gloves used in this country.

Respectfully submitted,



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SBAA Associate Executive Director