Alternative gloves have not been accepted rapidly in the marketplace. "Old style" USP Absorbable Dusting Powdered gloves have largely remained the market mainstay over the past several years. FDA may therefore be unable to enforce any such dramatic shift as the proposed "powder-free" initiative, regardless of good intentions and how intensely FDA wants such a change.

FDA "social engineering" to increase use of alternative gloves and decrease use of "old style" USP Absorbable Dusting Powdered gloves may be well intentioned. However, to date all efforts to shift the market away from old-fashioned cornstarch powdered gloves have been largely ineffective. Therefore, one must assume that this dynamic change in human behavior will take longer than previously anticipated.

Likewise, an alternative pathway of gradual discrete steps away from old-fashioned cornstarch powdered gloves must be located. It is now prudent and wise for FDA to study how to fix the faulty USP Absorbable Dusting Powder device, and/or replace it with donning/lubricating powders that do not behave like USP Absorbable Dusting Powder — in binding and carrying dangerous NRL proteins.

9 *FDA also invites comments on the issue of whether the recommended limits on powder and protein proposed in this rule should be recommended limits or required limits.*

If enforcement is not forthcoming, implementation should be cancelled. If enforcement is begun, the proposed limits should be required.

10. *FDA considered allowing manufacturers to establish an initial tentative shelf-life up to a certain duration based on accelerated aging data, provided that manufacturers initiate concurrent real-time shelf-life studies to confirm and extend the tentative shelf-life. FDA has been unable, however, to determine whether any validated stability study protocols exist employing accelerated aging methodologies. The agency invites comments or information on the availability of accelerated aging stability study protocols which are predictive of glove shelf-life. If convincing information concerning such protocols is available, FDA may incorporate such an approach in a final rule.*

FDA should work with innovative manufacturers and recognized experts to design appropriate quality control procedures for all medical gloves. Manufacturers need a level playing field, and predictable enforcement expectations. Medical patients and glove users deserve the highest quality medical gloves that the market price can sustain. These elements must be expertly balanced in the final design for FDA approved quality control procedures, including shelf life date labeling.

11. *FDA considered requiring the use of a special air handling system at the point of use for those facilities using powdered surgeon's and patient examination gloves with powder levels over 120 mg per glove, regardless of glove size. FDA is seeking comments on the appropriateness of this restriction.*

If FDA intends to enforce this rule for all facilities, the rule is acceptable. Evidence is lacking that would prove that air handling alone makes much difference. On the other hand, removing or repairing USP Absorbable Dusting Powder **[cornstarch]** in medical gloves is certainly an effective step forward.

12. *FDA seeks comments as to whether a provision permitting affected persons to request exemptions or variances from the labeling requirements or restrictions on distribution and use proposed in this rule should be added.*

No delays, exemptions or variances are appropriate in these serious public health and safety matters.

FDA should move deliberately, without preference or variance, to end the required use of USP Absorbable Dusting Powder bound to NRL protein in medical gloves. Safer alternative lubricating/donning powders are available now.

Manufacturers can implement use of alternative powders much more quickly than they can eliminate donning powders (if, indeed, powder can ever be eliminated).

Thank you for this opportunity to comment.

Sincerely,

Dave Kinnaman
<LatexAllergyKills@Immune.Com>
POB 621
Vashon, Washington USA
98070-0621

Stevenson, Todd A.

From: Dave Kinnaman [kinnaman@Emissary Net]
Sent: Tuesday, May 23, 2000 7:11 AM
To: info@cpsc gov; cpsc-os@cpsc gov
Cc: Rubber@Immune Com, SusanHrn@aol.com; Mary Ann Henderson
Subject: Petition - Latex Allergy Caused By Cornstarch Lubricant "USP absorbable dusting powder"


FDADOCKET98N-0313(P).doc


CPSCPetition doc

May 22, 2000

Office of the Secretary
Consumer Product Safety Commission
Washington, District of Columbia USA
20207

Telephone (301) 504-0800
Telefacsimile (301) 504-0127
<info@cpsc.gov>,<cpsc-os@cpsc.gov>

Office of the Secretary
Consumer Product Safety Commission
Room 502
4330 East-West Highway
Bethesda, Maryland USA
20814

Dear Ms. Brown, Ms. Gall, and Mr. Brown; Madam or Sir,

As a citizen, I hereby petition the US Consumer Product Safety Commission (hereafter "Commission") to classify the primary physical offender in the cause of natural rubber latex (NRL) allergy sensitization, the allergen-protein-laden lubricant known as "USP absorbable dusting powder" [on NRL gloves and other NRL products] as a "strong sensitizer" under 15 U.S.C. 1261-1277, the Federal Hazardous Substances Act (FHSA).

The Commission has already properly labeled epichlorohydrin as a strong sensitizer under the FHSA. Now therefore be it known that the strong sensitizer epichlorohydrin is commonly (perhaps universally) required in the manufacture of the subject of this present petition: "USP absorbable dusting powder." This petition, therefore, requests that the Commission extend also to "USP absorbable dusting powder" the label "strong sensitizer" - a label that is already properly applied to one of the manufacturing precursors of "USP absorbable dusting powder," itself.

This petition to the Commission is based on well know, proven, reliable, valid, published scientific facts cited throughout. I assert, based on these facts, that the cornstarch lubricant "USP absorbable dusting powder" on NRL gloves, under current and ordinary manufacturing procedures, when aerosolized in ordinary use, is well known to sensitize life-threatening NRL allergy in individuals (both customers and workers).

A decade ago, well after the advent of near universal application of "USP absorbable dusting powder" lubrication on

These statements by scientists in authority in the US government are widely reported and have been published and publicly available on the Internet, making this information "well known" by most definitions.

Prevent Improper Consumer Diversion of Rejected "Medical" Gloves

In order to reduce and prevent the incidence of future NRL allergic sensitization, the Commission should act to declare the dangerous NRL-allergen-protein-laden lubricant "USP absorbable dusting powder" is a strong sensitizer. The Commission should also do everything in its power to appropriately limit the improper diversion into any and all consumer uses of all NRL-allergen-protein-laden "USP absorbable dusting powder," especially in products originally labeled for medical use (e.g., patient examination gloves) and subsequently rejected (detained at port of entry) by the FDA. FDA officials have communicated their disposition to cooperate in this matter in private conversations with me.

Prevalence Of Latex Allergy

Currently NRL allergically-sensitized individuals (estimated between 1% and 6% of the general population, and over 50% of spina bifida patients) must avoid all contact with NRL, including and especially "USP absorbable dusting powder" which contains and carries NRL-allergen-proteins. (8, 9) Commission action to label "USP absorbable dusting powder" may assist these currently (already) sensitized individuals to avoid NRL allergic reactions. Commission action to label "USP absorbable dusting powder" can also possibly assist already sensitized individuals in avoiding worsening (progression) of their NRL allergic symptoms, because allergy and allergic symptoms are caused by repeated exposure to an allergen. The requested labeling can assist sensitized individuals to avoid repeated exposure to the allergens which cause their allergic symptoms and that can cause the worsening of their allergy.

Therefore, I request the Commission to urgently add "USP absorbable dusting powder" in NRL products to the list of strong sensitizers so that without delay all NRL consumer products under the Commission's purview containing "USP absorbable dusting powder" will require appropriate labeling.

Thank you for promptly considering, and acting upon, this urgent petition.

Sincerely,

(signed)

Dave Kinnaman
<LatexAllergyKills@Immune.Com>
POB 621
Vashon, Washington USA
98070-0621

Lieutenant Hal Henderson Died of Latex Allergy
http://www.Immune.Com/rubber/latex.allergy.kills.html

Internet References Publicly Available Online

1- Medical Glove Guidance Manual, July 30, 1999, Center For Devices And Radiological Health, US Food And Drug Administration, Department Of Health And Human Services:
http://www.fda.gov/cdrh/dsma/135.html

2 - Elizabeth D. Jacobson, Ph.D., Acting Director, Center For Devices And Radiological Health, US Food And Drug Administration, Department Of Health And Human Services; Testimony March 25, 1999, Before The Subcommittee On Oversight And Investigations, Committee On Education And The Workforce, U.S. House Of Representatives, Re: Regulation of natural rubber latex gloves:
http://www.fda.gov/ola/latexgloves.html

3 - "Medical Glove Powder Report" September 1997, Department Of Health And Human Services, US Food and Drug Administration, Center for Devices and Radiological Health:
http://www.fda.gov/cdrh/glvpwd.html

4 - Latex Allergy: A Prevention Guide, NIOSH/Pub 98-113, 1998:
http://www.cdc.gov/niosh/98-113.html

5 - NIOSH ALERT - Preventing Allergic Reactions to Natural Rubber Latex in the Workplace, June 1997, DHHS (NIOSH) Publication No. 97-135:
http://www.cdc.gov/niosh/latexalt.html

6 - Surgeon's and Patient Examination Gloves; Reclassification and Medical Glove Guidance Manual Availability; Proposed Rule and Notice, Center For Devices And Radiological Health, US Food And Drug Administration, Department Of Health And Human Services, July 30, 1999:
http://www.fda.gov/ohrms/dockets/98fr/073099a.txt

7 - Technical Information Bulletin - Potential for Allergy to Natural Rubber Latex Gloves and other Natural Rubber Products, Occupational Safety and Health Administration, US Department of Labor, April 12, 1999:
http://www.osha-slc.gov/html/hotfoias/tib/TIB19990412.html

8 - Prevalence of Latex Allergy:
http://www.nurseweek.com/ce/1601sb2.html

9 - Latex Allergy in Pediatric Spina Bifida Patients: Incidence and Surgical
Implications
http://www.aaos.org/wordhtml/anmeet93/scipro/ppr074.htm

Additional Published References

o Tomazic VJ, Shampaine EL, Lamanna A, Withrow TJ, Adkinson, Jr. NF, and Hamilton RG: Cornstarch powder on latex products is an allergen carrier. J Allergy Clin Immunol, 93:751-758, 1994.
o McCormack B, Cameron M, Biel L. Latex sensitivity: an occupational health strategic plan. AAOHN J. 1995 Apr; 43(4): 190-6.
o Korniewicz DM, Kelly KJ. Barrier protection and latex allergy associated with surgical gloves. AORN J. 1995 June; 61(6): 1037-44.
o Beezhold D and Beck WC: Surgical glove powders bind latex

antigens. Arch Surg, 127:1354-1357, 1992.
- Tarlo SM, Sussman G, Contala A, and Swanson MC. Control of airborne latex by use of powder-free latex gloves. J Allergy Clin Immunol, 93:985-989, 1994.
- Heilman DK, Jones RT, Swanson MC, and Yunginger JW: A prospective, controlled study showing that rubber gloves are the major contributor to latex aeroallergen levels in the operating room. J Allergy Clin Immunol, 98.325-330, 1996.
- Swanson MC, Bubak ME, Hunt LW, Yunginger JW, Warner MA, and Reed CE: Clinical aspects of allergic disease: Quantification of occupational latex aeroallergens in a medical center. J Allergy Clin Immunol, 94:445-451, 1994.
- Baur X and J„ger D: Airborne antigens from latex gloves. Lancet, 335:912, 1990.
- J„ger D and Baur X: Latex specific proteins as inhalative allergens causing bronchial asthma and shock during surgery. Clin Exp Allergy, 20(abstract), 1990.
- Marcos C, L zaro M, Fraj J, Quirce S, de la Hoz B, Fern ndez-Rivas M, and Losada E: Occupational asthma due to latex surgical gloves. Ann Allergy, 67:319-323, 1991.
- Pisati G, Baruffini A, Bernabeo F, and Stanizzi R: Bronchial provocation testing in the diagnosis of occupational asthma due to latex surgical gloves. Eur Respir J, 7:332-336, 1994.
- Vandenplas O, Delwiche J-P, Evrard G, Aimont P, van der Brempt X, Jamart J, and Delaunois L: Prevalence of occupational asthma due to latex among hospital personnel. Am J Respir Crit Care Med, 151:54-60, 1995.
- Petsonk EL: Couriers of asthma: antigenic proteins in natural rubber latex. Occup Med 2000 Apr-Jun;15(2):421-30
- Lundberg M, Wrangsjo K, Johansson SG: Latex allergy from glove powder--an unintended risk with the switch from talc to cornstarch? Allergy 1997 Dec;52(12):1222-8
- Jaeger D, Kleinhans D, Czuppon AB, Baur X: Latex-specific proteins causing immediate-type cutaneous, nasal, bronchial, and systemic reactions. J Allergy Clin Immunol 1992 Mar;89(3):759-68
- Lundberg M, Wrangsjo K, Johansson SG: Latex allergens in glove-powdering slurries. Allergy 1995 Apr;50(4):378-80
- Crippa M, Pasolini G: Allergic reactions due to glove-lubricant-powder in health-care workers. Int Arch Occup Environ Health 1997;70(6):399-402
- Guin JD, Styles A: Protein-contact eczematous reaction to cornstarch in clothing. J Am Acad Dermatol 1999 Jun;40(6 Pt 1):991-4
- Seggev JS, Mawhinney TP, Yunginger JW, Braun SR. Anaphylaxis due to cornstarch surgical glove powder. Ann Allergy 1990 Aug;65(2):152-5

=== end ===

 GC
08 0191

May 22, 2000

Office of the Secretary
Consumer Product Safety Commission
Washington, District of Columbia USA
20207

Telephone (301) 504-0800
Telefacsimile (301) 504-0127
<info@cpsc.gov>,<cpsc-os@cpsc.gov>

Office of the Secretary
Consumer Product Safety Commission
Room 502
4330 East-West Highway
Bethesda, Maryland USA
20814

Dear Ms. Brown, Ms. Gall, and Mr. Brown; Madam or Sir,

As a citizen, I hereby petition the US Consumer Product Safety Commission (hereafter "Commission") to classify the primary physical offender in the cause of natural rubber latex (NRL) allergy sensitization, the allergen-protein-laden lubricant known as "USP absorbable dusting powder" [on NRL gloves and other NRL products] as a "strong sensitizer" under 15 U.S.C. 1261-1277, the Federal Hazardous Substances Act (FHSA).

The Commission has already properly labeled epichlorohydrin as a strong sensitizer under the FHSA. Now therefore be it known that the strong sensitizer epichlorohydrin is commonly (perhaps universally) required in the manufacture of the subject of this present petition: "USP absorbable dusting powder." This petition, therefore, requests that the Commission extend also to "USP absorbable dusting powder" the label "strong sensitizer" - a label that is already properly applied to one of the manufacturing precursors of "USP absorbable dusting powder," itself.

This petition to the Commission is based on well know, proven, reliable, valid, published scientific facts cited throughout. I assert, based on these facts, that the cornstarch lubricant "USP absorbable dusting powder" on NRL gloves, under current and ordinary manufacturing procedures, when aerosolized in ordinary use, is well known to sensitize life-threatening NRL allergy in individuals (both customers and workers).

A decade ago, well after the advent of near universal application of "USP absorbable dusting powder" lubrication on NRL products, the US Food and Drug Administration (FDA) recognized the dangers that NRL allergy poses, when FDA "sent a letter to manufacturers in May 1991 advising them of allergenic problems with latex devices." [1]

Further, the "USP absorbable dusting powder" lubricant on NRL gloves, under current manufacturing procedures, when aerosolized in ordinary use, is known to be a serious threat to individuals already sensitized to NRL allergy, because the "USP absorbable dusting powder" carries significant amounts of NRL allergen proteins, causing serious and life-threatening allergic reactions if sensitized individuals breathe the allergen-protein-laden "USP absorbable dusting powder" into their lungs or when the "USP absorbable dusting powder" otherwise comes into contact with mucosal tissues of these already sensitized individuals.

In order to carry out its proper duty to the public to improve and maintain public safety, I request that the Commission urgently act to declare the allergen-protein-laden lubricant "USP absorbable dusting powder," when combined with NRL products, is a strong sensitizer under the FHSA and therefore explicitly label the allergen-protein-laden "USP absorbable dusting powder" on natural rubber latex gloves, and "USP absorbable dusting powder" on all other NRL products under the Commission's jurisdiction, as a "strong sensitizer" under the FHSA.

Counter-Arguments

While some insist that NRL products (themselves, alone) are most dangerous, I instead submit that the "USP absorbable dusting powder" lubricant cornstarch powder on NRL products is the far greater danger, directly responsible for causing untold sensitization, financial loss, career loss, health loss, disability and even death through NRL allergy. I recently addressed the FDA with similar concerns, and I am attaching those comments for your information.

Other arguments commonly put forward are that latex allergy concerns should be addressed by use of alternative (synthetic) materials, or by eliminating the cornstarch lubricant powder altogether. On the other hand, synthetic gloves are implicated in Type 4 allergic sensitization to manufacturing chemicals and synthetic gloves may be more costly and much more dangerous to dispose of than natural rubber latex gloves. Similarly, elimination of "USP absorbable dusting powder" cornstarch, if not replaced with an inexpensive, effective lubricant (silicone,

their consumer-oriented pamphlet " Latex Allergy: A Prevention Guide "in 1997, saying "Is skin contact the only type of latex exposure? No. Latex proteins become fastened to the lubricant powder used in some gloves. When workers change gloves, the protein/powder particles become airborne and can be inhaled."[4]

Also in 1997, the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention said, "The proteins responsible for latex allergies have been shown to fasten to powder that is used on some latex gloves. When powdered gloves are worn, more latex protein reaches the skin. Also, when gloves are changed, latex protein/powder particles get into the air, where they can be inhaled and contact body membranes..." [5]

Again, in the Federal Register: July 30, 1999 (Volume 64, Number 146) the US FDA restated the danger, "FDA has significant concerns about the role of glove powder as a carrier of airborne allergens, because NL allergens have been shown to bind to cornstarch."[6]

Also in 1999, the US Department of Labor, Occupational Saftey and Health Administration stated, "Studies have indicated that corn starch powder, added to gloves to facilitate donning and removal, can serve as a carrier for the allergenic proteins from the NRL"[7]

These statements by scientists in authority in the US government are widely reported and have been published and publicly available on the Internet, making this information "well known" by most definitions.

Prevent Improper Consumer Diversion of Rejected "Medical" Gloves

In order to reduce and prevent the incidence of future NRL allergic sensitization, the Commission should act to declare the dangerous NRL-allergen-protein-laden lubricant "USP absorbable dusting powder" is a strong sensitizer. The Commission should also do everything in its power to appropriately limit the improper diversion into any and all consumer uses of all NRL-allergen-protein-laden "USP absorbable dusting powder," especially in products originally labeled for medical use (e.g., patient examination gloves) and subsequently rejected (detained at port of entry) by the FDA. FDA officials have communicated their disposition to cooperate in this matter in private conversations with me.

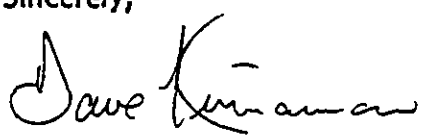
Prevalence Of Latex Allergy

Currently NRL allergically-sensitized individuals (estimated between 1% and 6% of the general population, and over 50% of spina bifida patients) must avoid all contact with NRL, including and especially "USP absorbable dusting powder" which contains and carries NRL-allergen-proteins. [8, 9] Commission action to label "USP absorbable dusting powder" may assist these currently (already) sensitized individuals to avoid NRL allergic reactions. Commission action to label "USP absorbable dusting powder" can also possibly assist already sensitized individuals in avoiding worsening (progression) of their NRL allergic symptoms, because allergy and allergic symptoms are caused by repeated exposure to an allergen. The requested labeling can assist sensitized individuals to avoid repeated exposure to the allergens which cause their allergic symptoms and that can cause the worsening of their allergy.

Therefore, I request the Commission to urgently add "USP absorbable dusting powder" in NRL products to the list of strong sensitizers so that without delay all NRL consumer products under the Commission's purview containing "USP absorbable dusting powder" will require appropriate labeling.

Thank you for promptly considering, and acting upon, this urgent petition.

Sincerely,



Dave Kinnaman
<LatexAllergyKills@Immune.Com>
POB 621
Vashon, Washington USA
98070-0621

Lieutenant Hal Henderson Died of Latex Allergy
http://www.Immune.Com/rubber/latex.allergy.kills.html

Internet References Publicly Available Online

1- Medical Glove Guidance Manual, July 30, 1999, Center For Devices And Radiological Health, US Food And Drug Administration, Department Of Health And Human Services:
http://www.fda.gov/cdrh/dsma/135.html

2 - Elizabeth D. Jacobson, Ph.D., Acting Director, Center For Devices And Radiological Health, US Food And Drug Administration, Department Of Health

And Human Services; Testimony March 25, 1999, Before The Subcommittee On Oversight And Investigations, Committee On Education And The Workforce, U.S. House Of Representatives, Re: Regulation of natural rubber latex gloves:
http://www.fda.gov/ola/latexgloves.html

3 - "Medical Glove Powder Report" September 1997, Department Of Health And Human Services, US Food and Drug Administration, Center for Devices and Radiological Health:
http://www.fda.gov/cdrh/glvpwd.html

4 - Latex Allergy: A Prevention Guide, NIOSH/Pub 98-113, 1998:
http://www.cdc.gov/niosh/98-113.html

5 - NIOSH ALERT - Preventing Allergic Reactions to Natural Rubber Latex in the Workplace, June 1997, DHHS (NIOSH) Publication No. 97-135:
http://www.cdc.gov/niosh/latexalt.html

6 - Surgeon's and Patient Examination Gloves; Reclassification and Medical Glove Guidance Manual Availability; Proposed Rule and Notice, Center For Devices And Radiological Health, US Food And Drug Administration, Department Of Health And Human Services, July 30, 1999:
http://www.fda.gov/ohrms/dockets/98fr/073099a.txt

7 - Technical Information Bulletin - Potential for Allergy to Natural Rubber Latex Gloves and other Natural Rubber Products, Occupational Safety and Health Administration, US Department of Labor, April 12, 1999:
http://www.osha-slc.gov/html/hotfolas/tib/TIB19990412.html

8 - Prevalence of Latex Allergy:
http://www.nurseweek.com/ce/1601sb2.html

9 - Latex Allergy in Pediatric Spina Bifida Patients: Incidence and Surgical Implications
http://www.aaos.org/wordhtml/anmeet93/scipro/ppr074.htm

Additional Published References

- Tomazic VJ, Shampaine EL, Lamanna A, Withrow TJ, Adkinson, Jr. NF, and Hamilton RG: Cornstarch powder on latex products is an allergen carrier. J Allergy Clin Immunol, 93:751-758, 1994.
- McCormack B, Cameron M, Biel L. Latex sensitivity: an occupational health strategic plan. AAOHN J. 1995 Apr; 43(4): 190-6.

- Komiewicz DM, Kelly KJ. Barrier protection and latex allergy associated with surgical gloves. AORN J. 1995 June; 61(6): 1037-44.
- Beezhold D and Beck WC: Surgical glove powders bind latex antigens. Arch Surg, 127:1354-1357, 1992.
- Tarlo SM, Sussman G, Contala A, and Swanson MC: Control of airborne latex by use of powder-free latex gloves. J Allergy Clin Immunol, 93:985-989, 1994.
- Heilman DK, Jones RT, Swanson MC, and Yunginger JW: A prospective, controlled study showing that rubber gloves are the major contributor to latex aeroallergen levels in the operating room. J Allergy Clin Immunol, 98:325-330, 1996.
- Swanson MC, Bubak ME, Hunt LW, Yunginger JW, Warner MA, and Reed CE: Clinical aspects of allergic disease: Quantification of occupational latex aeroallergens in a medical center. J Allergy Clin Immunol, 94:445-451, 1994.
- Baur X and Jäger D: Airborne antigens from latex gloves. Lancet, 335:912, 1990.
- Jäger D and Baur X: Latex specific proteins as inhalative allergens causing bronchial asthma and shock during surgery. Clin Exp Allergy, 20(abstract), 1990.
- Marcos C, Lázaro M, Fraj J, Quirce S, de la Hoz B, Fernández-Rivas M, and Losada E: Occupational asthma due to latex surgical gloves. Ann Allergy, 67:319-323, 1991.
- Pisati G, Baruffini A, Bernabeo F, and Stanizzi R: Bronchial provocation testing in the diagnosis of occupational asthma due to latex surgical gloves. Eur Respir J, 7:332-336, 1994.
- Vandenplas O, Delwiche J-P, Evrard G, Aimont P, van der Brempt X, Jamart J, and Delaunois L: Prevalence of occupational asthma due to latex among hospital personnel. Am J Respir Crit Care Med, 151:54-60, 1995.
- Petsonk EL: Couriers of asthma: antigenic proteins in natural rubber latex. Occup Med 2000 Apr-Jun;15(2):421-30
- Lundberg M, Wrangsjo K, Johansson SG: Latex allergy from glove powder--an unintended risk with the switch from talc to cornstarch? Allergy 1997 Dec;52(12):1222-8
- Jaeger D, Kleinhans D, Czuppon AB, Baur X: Latex-specific proteins causing immediate-type cutaneous, nasal, bronchial, and systemic reactions. J Allergy Clin Immunol 1992 Mar;89(3):759-68
- Lundberg M, Wrangsjo K, Johansson SG: Latex allergens in glove-powdering slurries. Allergy 1995 Apr;50(4):378-80
- Crippa M, Pasolini G: Allergic reactions due to glove-lubricant-powder in health-care workers. Int Arch Occup Environ Health 1997;70(6):399-402

- Guin JD, Styles A: Protein-contact eczematous reaction to cornstarch in clothing. J Am Acad Dermatol 1999 Jun;40(6 Pt 1):991-4
- Seggev JS, Mawhinney TP, Yunginger JW, Braun SR: Anaphylaxis due to cornstarch surgical glove powder. Ann Allergy 1990 Aug;65(2):152-5

January 27, 2000

Food and Drug Administration
Room. 1061
Dockets Management Branch HFA-305
5630 Fishers Lane
Rockville MD 20852-0001

Dear Madam or Sir,

These comments are in response to **Docket No. 98N-0313**

The FDA can be credited with drawing early attention to the dangers of natural rubber latex (NRL) medical gloves Sadly, FDA attention and FDA actions have been inadequate to prevent terrible damage to health care workers and others

A safe health care milieu is essential. Although the required donning powder does not originally contain NRL proteins, the donning powder now required does bind with and can carry NRL proteins after the donning powder is in contact with natural rubber inside the gloves. These NRL proteins, bound to USP Absorbable Dusting Powder, become airborne and cannot be seen or controlled, so the donning powder vector must be repaired or eliminated immediately

In health care today, during glove donning and removal, NRL protein that is already bound with USP Absorbable Dusting Powder **[cornstarch donning powder]** is released into the air NRL protein is bound to and *travels with* the airborne USP Absorbable Dusting Powder.

FDA must be responsible to regulate in a way that protects the public from airborne NRL proteins bound to USP Absorbable Dusting Powder. The glove device, when combined with the USP Absorbable Dusting Powder device, as combined in everyday use, are creating an adverse device reaction – in effect, an adverse device interaction. This unanticipated negative interaction is causing great injury in health care today. FDA should move deliberately to eliminate or fix the USP Absorbable Dusting Powder vector, or vehicle, that is now transporting breathable NRL proteins into the air to the great detriment of health care workers.

So, the cornstarch donning lubricant (USP Absorbable Dusting Powder) in powdered NRL medical gloves is NOT safe, because the cornstarch powder is known to bind with and carry significant levels of dangerous NRL protein.

The best solution is to **immediately** limit the amount of natural rubber protein present in (chemically bound to) ***medical glove donning powder***. Therefore,

FDA should rapidly acknowledge and encourage alternative glove lubrication methods, and FDA should rapidly acknowledge and encourage alternative donning powders.

A move to phase in lower levels of NRL protein in the glove itself, while probably helpful, is less important than the immediate cessation of the FDA required USP Absorbable Dusting Powder vector in surgical gloves, ***because*** the current donning powder binds with and carries NRL proteins.

Individuals allergic to natural rubber latex must continue to struggle with their disease – the least that they should be provided is access to safe and appropriate emergency medical care, and venues for safe and proper routine health care. Unless airborne USP Absorbable Dusting Powder is eliminated or repaired, the latex allergic cannot safely approach typical health care facilities.

Consequently, all proposed NRL protein limits must apply to, and must include, the NRL protein inadvertently now included in medical glove donning powder.

Protein limits must be stated either for the glove and for the donning powder, or for the both glove and donning powder devices together. Equivocation on this matter has already caused too much confusion and misinformation. The donning powder now carries significant amounts of NRL-protein, and it should not.

The proposed labeling is not adequate because it does not quantify the extractable NRL protein bound to and therefore in the donning powder The NRL protein content of the glove is false, misleading and understated *unless* the protein content in the primary airborne NRL-protein delivery vehicle, the lubricating/donning powder, is clearly identified and reported to the consumer.

Gloves in Kits

Again, I applaud the FDA for requiring gloves in kits to be precisely and accurately labeled. For public safety, all natural rubber latex items in kits, including catheters and tubes, should be labeled for NRL protein and powder content. Additionally, labeling of these devices should especially also include the NRL protein and powder content of the gloves in the kit.

So-called "Lightly Powdered" Gloves

FDA has too long ignored the widespread misbranding of "lightly powdered" labeling. Lack of enforcement of this misbranding has sown confusion and misinformation among patients, medical glove users, distributors, and manufacturers.

FDA should immediately use its enforcement powers to stop this widespread, false marketing claim ("Lightly Powdered"). Lax FDA enforcement in this matter has already caused much confusion and misinformation.

1. *FDA requests comments on the timeframe for implementation of the proposed rule considering the need for changes in production, technology, and labeling, as well as the immediate need to address adverse health concerns associated with medical gloves. Although FDA prefers a 1-year effective date, FDA is proposing a 2-year effective date based on indications from industry that the necessary changes could not be made in 1 year and that a shortage of medical gloves could result.*

FDA should implement the proposed rule immediately. Implementation without readiness to enforce, however, would be a sham. If enforcement is not promptly forthcoming, implementation should be cancelled, and the proposal should be shelved.

2. *In the proposed guidance document, FDA recommends a limit of no more than 120 mg powder per powdered glove, regardless of size, as the maximum level in order to reduce exposure to particulates and airborne allergens. FDA requests comments on the recommended limit with regard to the minimum level of powder needed for adequate donning of gloves.*

Assumptions In FDA Proposal

The proposed limit of 120 mg powder per glove <u>assumes</u> that glove donning powders are a NRL-protein (antigen) carrier, causing latex allergy incidents in those already sensitized, and causing new allergic sensitization to occur.

However, there is no evidence that any specific level (lower or higher than 120 mg.) of NRL protein or protein-bound USP Absorbable Dusting Powder will protect workers or patients from sensitization or reactions There is no known "safe" level.

Because there is no known safe level of exposure, it is all the more important to identify and label accurately and completely the actual level of NRL protein exposure caused with each glove use. The NRL-protein exposure is understated and false unless the NRL-protein bound to the USP Absorbable Dusting Powder is measured and included in the labeling.

False FDA Assumption

However, the ASSUMPTION that glove powder is the culprit, while initially satisfying, hides the further assumption that alternative glove powders are unavailable. This hidden, FALSE assumption is very dangerous.

The assumption that alternative glove powders are unavailable has clouded the air for several years now, while alternative glove powders languish in disuse. FDA has disregarded alternative lubricants and lubricating methods at great loss

FDA Therefore Again At Fault

Everyone knows that the USP Absorbable Dusting Powder, when bound to NRL protein, is dangerous beyond words, yet FDA continues to demand USP Absorbable Dusting Powder in every surgical glove. This damaging requirement should be rescinded immediately

FDA should sponsor research to identify alternative, safer donning powders. FDA should carefully investigate alternative lubrication methods and alternative donning powders. FDA should not force medical glove users, and those who inadvertently breathe the NRL-protein-laden USP Absorbable Dusting Powder vector, to continue to use dangerous powders that bind with and carry NRL proteins. FDA should sponsor research to repair this serious and perilous flaw in USP Absorbable Dusting Powder.

3. *FDA requests comments on the feasibility and desirability of additional labeling requiring manufacturers to state the primary ingredients in glove powder in the product labeling.*

Specific Labeling Is an Improvement

Increased labeling requirements have been a step in the right direction Product labeling should respond clearly and directly to specific health and safety concerns Accurate labels help to enable latex allergic individuals to protect themselves.

Accurate labels may also help enable others to avoid needless allergic sensitization, and to otherwise identify possible irritants and chemical allergens.

Accurate labeling (on primary packaging) of NRL protein content for both the glove and the donning powder, and nothing less, is required for public safety.

All labeling should be clearly visible and easy to read.

Necessary Labeling Includes

3A. No ingredients in the glove package should be optional in labeling. Donning powder now appears to be optional in labeling requirements, and donning powder SHOULD NOT BE OPTIONAL.

3B. All ingredients having recognized potential to sensitize ANY allergy MUST be labeled on the consumer glove box

3C. All ingredients that have recognized potential to irritate or disable human beings should be labeled on the consumer glove box Health care and other workers, and their patients and consumers, require the FDA to exercise this power to protect and serve the public.

3D. Specifically, the presence of these ingredients or residues MUST be labeled:

- ionically bound USP Absorbable Dusting Powder-natural-rubber-latex-protein
- magnesium oxide
- **specific** chemical accelerators MUST be labeled
- carba mix
- black rubber mix (BRM)
- quaternium-15
- mercaptobenzothiazole (MBT)
- mercapto mix
- thimerosal
- thiurams

3E. Labeling of glove donning powder as "USP absorbable dusting powder" is NOT acceptable. The actual ingredients of the powder, including the NRL protein content, magnesium oxide, etc., MUST be revealed to the consumer on the primary packaging.

Trade secret and proprietary ingredient mixes, and related manufacturing concerns, should never be allowed to prevent FDA from doing its solemn duty to protect public safety.

The proposed labeling is not adequate because it does not quantify the extractable NRL protein bound to and present in the donning powder. The NRL protein content of the glove is false, misleading and understated *unless* the protein content in the primary NRL-protein delivery vehicle, the lubricating/donning powder, is clearly identified and reported to the consumer.

4. *In the proposed guidance document, FDA is recommending no more than 2 mg powder per glove, regardless of size, as the recommended powder level for those surgeon's and patient examination gloves labeled "powder-free." FDA requests comments on the proposed limit. FDA is also seeking comments on the possible impact of this powder limit on barrier properties and shelf-life of NL gloves.*

FDA must enforce the rule on all manufacturers, for the rule to be meaningful.

5. *FDA is also considering a future requirement that all surgeon's and patient examination gloves marketed in the United States be powder-free. FDA requests comments as to whether a continued need for powdered gloves exists, and, if so, the reason for this need. Comments on the feasibility of such restrictions.*

Alternative gloves have not been accepted rapidly in the marketplace. "Old style" USP Absorbable Dusting Powdered gloves have largely remained the market mainstay over the past several years. FDA may be unable to enforce any such dramatic shift as a proposed "powder-free" initiative.

6. *FDA considered restrictions on the sale (advertising), distribution, and use of powdered surgeon's and patient examination gloves FDA is seeking comments on the feasibility of such restrictions.*

Banning USP Absorbable Dusting **[cornstarch]** Powder is appropriate and necessary because of USP Absorbable Dusting **[cornstarch]** Powder's proven propensity to bind with and carry NRL proteins Banning alternative, non-cornstarch donning powders and other lubrication methods (not so indicted) would be rash and inappropriate.

7 *In the proposed guidance document, FDA is recommending an upper limit of no more than 1,200 µg protein per NL glove, regardless of size, as the maximum level for NL surgeon's and patient examination gloves. FDA is seeking comments on the proposed recommended limit.*

This rule will be meaningless unless FDA has the ability to enforce it. Will a proposed enforcement procedure promptly go into effect?

8. *FDA's objectives in this proposed rulemaking are to reduce adverse health effects from allergic reactions and foreign body reactions by controlling the levels of water-extractable protein and glove powder on NL gloves. FDA requests comments as to whether there are feasible alternative approaches to achieve these objectives. If other alternatives or data submitted present feasible methods to protect the public health or suggest that different powder or protein levels are adequate to protect the public health, FDA may incorporate such data or approaches in a final rule.*

As emphasized throughout these comments, removing or repairing the USP Absorbable Dusting Powder donning powder is the single most promising alternative now available. Other proposed methods rely on estimates of future price economics, questionable assumptions, and social engineering. Non-cornstarch alternative lubricating powders can be much safer, equally effective in donning lubrication, and are already immediately available.

Alternative gloves have not been accepted rapidly in the marketplace "Old style" USP Absorbable Dusting Powdered gloves have largely remained the market mainstay over the past several years. FDA may therefore be unable to enforce any such dramatic shift as the proposed "powder-free" initiative, regardless of good intentions and how intensely FDA wants such a change.

FDA "social engineering" to increase use of alternative gloves and decrease use of "old style" USP Absorbable Dusting Powdered gloves may be well intentioned. However, to date all efforts to shift the market away from old-fashioned cornstarch powdered gloves have been largely ineffective Therefore, one must assume that this dynamic change in human behavior will take longer than previously anticipated.

Likewise, an alternative pathway of gradual discrete steps away from old-fashioned cornstarch powdered gloves must be located. It is now prudent and wise for FDA to study how to fix the faulty USP Absorbable Dusting Powder device, and/or replace it with donning/lubricating powders that do not behave like USP Absorbable Dusting Powder — in binding and carrying dangerous NRL proteins.

9. *FDA also invites comments on the issue of whether the recommended limits on powder and protein proposed in this rule should be recommended limits or required limits.*

If enforcement is not forthcoming, implementation should be cancelled. If enforcement is begun, the proposed limits should be required.

10. *FDA considered allowing manufacturers to establish an initial tentative shelf-life up to a certain duration based on accelerated aging data, provided that manufacturers initiate concurrent real-time shelf-life studies to confirm and extend the tentative shelf-life. FDA has been unable, however, to determine whether any validated stability study protocols exist employing accelerated aging methodologies The agency invites comments or information on the availability of accelerated aging stability study protocols which are predictive of glove shelf-life. If convincing information concerning such protocols is available, FDA may incorporate such an approach in a final rule.*

FDA should work with innovative manufacturers and recognized experts to design appropriate quality control procedures for all medical gloves. Manufacturers need a level playing field, and predictable enforcement expectations. Medical patients and glove users deserve the highest quality medical gloves that the market price can sustain. These elements must be expertly balanced in the final design for FDA approved quality control procedures, including shelf life date labeling.

11 *FDA considered requiring the use of a special air handling system at the point of use for those facilities using powdered surgeon's and patient examination gloves with powder levels over 120 mg per glove, regardless of glove size FDA is seeking comments on the appropriateness of this restriction.*

If FDA intends to enforce this rule for all facilities, the rule is acceptable Evidence is lacking that would prove that air handling alone makes much difference On the other hand, removing or repairing USP Absorbable Dusting Powder **[cornstarch]** in medical gloves is certainly an effective step forward.

12. *FDA seeks comments as to whether a provision permitting affected persons to request exemptions or variances from the labeling requirements or restrictions on distribution and use proposed in this rule should be added*

No delays, exemptions or variances are appropriate in these serious public health and safety matters.

FDA should move deliberately, without preference or variance, to end the required use of USP Absorbable Dusting Powder bound to NRL protein in medical gloves Safer alternative lubricating/donning powders are available now

Manufacturers can implement use of alternative powders much more quickly than they can eliminate donning powders (if, indeed, powder can ever be eliminated)

Thank you for this opportunity to comment.

Sincerely,

Dave Kinnaman
<LatexAllergyKills@Immune.Com>
POB 621
Vashon, Washington USA
98070-0621

U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

OFFICE OF THE GENERAL COUNSEL

Stephen Lemberg
Assistant General Counsel
Tel. 301-504-0980 ext. 2218
E-Mail. slemberg@cpsc.gov

June 15, 2000

Dave Kinnaman
P.O. Box 621
Vashon, Washington 98070-0621

Dear Mr. Kinnaman:

Your submission dated May 22, 2000 requests that the Commission issue a rule declaring "USP absorbable dusting powder" used on natural rubber latex ("NRL") gloves to be a strong sensitizer under the Federal Hazardous Substances Act ("FHSA"). As explained below, your request does not meet the Commission's requirements for petitions as set forth in 16 C.F.R. Part 1051. (A copy of these regulations is enclosed.)

A petition must identify the product or substance for which regulation under one of the Commission's statutes is sought. 16 C.F.R. § 1051.5(a)(3). You identify "USP absorbable dusting powder" as the substance at issue. You state that this powder can carry NRL proteins from gloves into the air and that sensitized individuals may breathe these proteins and have an allergic reaction to them. Thus, the substance causing the reaction would be the NRL proteins, not the USP absorbable dusting powder itself. Under the FHSA, the Commission has the authority to declare as a strong sensitizer a substance that through an allergic process "causes" hypersensitivity evident on reapplication of the substance. 15 U.S.C. § 1261(k). You do not show that USP absorbable dusting powder is such a substance. As you state, the powder binds the allergenic proteins and carries them into the air. The powder may be a vehicle for the NRL proteins, but is not the cause of any hypersensitivity. Therefore, the Commission cannot declare USP absorbable dusting powder a strong sensitizer.

Certainly, the interaction between USP absorbable dusting powder and NRL gloves is an issue the staff should consider as it prepares a briefing package for the Commission on the petition to declare NRL a strong sensitizer Therefore, the Commission will consider your submission as a comment on that petition I appreciate your sharing your concerns with the Commission.

Sincerely,

Stephen Lemberg
Assistant General Counsel

Enclosure

§§ 1034.171—1034.999 [Reserved]

PART 1051—PROCEDURE FOR PETITIONING FOR RULEMAKING

Sec.

AUTHORITY: 5 U.S.C. 553(e), 5 U.S.C. 555(e).

SOURCE: 48 FR 57123, Dec. 28, 1983, unless otherwise noted.

§ 1051.1 Scope.

(a) This part establishes procedures for the submission and disposition of petitions for the issuance, amendment or revocation of rules under the Consumer Product Safety Act (CPSA) (15 U.S.C. 2051 *et seq.*) or other statutes administered by the Consumer Product Safety Commission.

(b) Persons filing petitions for rulemaking shall follow as closely as possible the requirements and are encouraged to follow as closely as possible the recommendations for filing petitions under section 1051.5.

(c) Petitions regarding products regulated under the Federal Hazardous Substances Act (FHSA) (15 U.S.C. 1251 *et seq.*) are governed by existing Commission procedures at 16 CFR 1500.82, 16 CFR 1500.201, and 21 CFR 2.65. Petitions regarding the exemption of products regulated under the Poison Prevention Packaging Act of 1970 (PPPA) (15 U.S.C. 1471 *et seq.*) are governed by existing Commission procedures at 16 CFR 1702. In addition, however, persons filing such petitions shall follow the requirements and are encouraged to follow the recommendations for filing petitions as set forth in § 1051.5.

§ 1051.2 General.

(a) Any person may file with the Commission a petition requesting the Commission to begin a proceeding to issue, amend or revoke a regulation under any of the statutes it administers.

(b) A petition which addresses a risk of injury associated with a product which could be eliminated or reduced to a sufficient extent by action taken under the Federal Hazardous Substances Act, the Poison Prevention Packaging Act of 1970, or the Flammable Fabrics Act may be considered by the Commission under those Acts. However, if the Commission finds by rule, in accordance with section 30(d) of the CPSA, as amended by Pub. L. 94-284, that it is in the public interest to regulate such risk of injury under the CPSA, it may do so. Upon determination by the Office of the General Counsel that a petition should be considered under one of these acts rather than the CPSA, the Office of the Secretary shall docket and process the petition under the appropriate act and inform the petitioner of this determination. Such docketing, however, shall not preclude the Commission from proceeding to regulate the product under the CPSA after making the necessary findings.

§ 1051.3 Place of filing.

A petition should be mailed to: Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207. Persons wishing to file a petition in person may do so in the Office of the Secretary, at either, 5401 Westbard Avenue, (third floor) Bethesda, Maryland or 1111 18th Street, NW, (eighth floor), Washington, D.C.

§ 1051.4 Time of filing.

For purposes of computing time periods under this part, a petition shall be considered filed when time-date stamped by the Office of the Secretary. A document is time-date stamped when it is received in the Office of the Secretary.

§ 1051.5 Requirements and recommendations for petitions.

(a) *Requirements.* To be considered a petition under this part, any request to issue, amend or revoke a rule shall meet the requirements of this paragraph (a). A petition shall:

(1) Be written in the English language;

(2) Contain the name and address of the petitioner;

(3) Indicate the product (or products) regulated under the Consumer Product Safety Act or other statute the Commission administers for which a rule is sought or for which there is an existing rule sought to be modified or revoked. (If the petition regards a procedural or other rule not involving a specific product, the type of rule involved must be indicated.)

(4) Set forth facts which establish the claim that the issuance, amendment, or revocation of the rule is necessary (for example, such facts may include personal experience; medical, engineering or injury data; or a research study); and

(5) Contain an explicit request to initiate Commission rulemaking and set forth a brief description of the substance of the proposed rule or amendment or revocation thereof which it is claimed should be issued by the Commission. (A general request for regulatory action which does not reasonably specify the type of action requested shall not be sufficient for purposes of this subsection.)

(b) *Recommendations.* The Commission encourages the submission of as much information as possible related to the petition. Thus, to assist the Commission in its evaluation of a petition, to the extent the information is known and available to the petitioner, the petitioner is encouraged to supply the following information or any other information relating to the petition. The petition will be considered by the Commission even if the petitioner is unable to supply the information recommended in this paragraph (b). However, as applicable, and to the extent possible, the petitioner is encouraged to:

(1) Describe the specific risk(s) of injury to which the petition is addressed, including the degree (severity) and the nature of the risk(s) of injury associated with the product and possible reasons for the existence of the risk of injury (for example, product defect, poor design, faulty workmanship, or intentional or unintentional misuse);

(2) State why a consumer product safety standard would not be feasible if the petition requests the issuance of a rule declaring the product to be a banned hazardous product, and

(3) Supply or reference any known documentation, engineering studies, technical studies, reports of injuries, medical findings, legal analyses, economic analyses and environmental impact analyses relating to the petition.

(c) *Procedural recommendations.* The following are procedural recommendations to help the Commission in its consideration of petitions. The Commission requests, but does not require, that a petition filed under this part:

(1) Be typewritten,

(2) Include the word "petition" in a heading preceding the text,

(3) Specify what section of the statute administered by the Commission authorizes the requested rulemaking,

(4) Include the telephone number of the petitioner and

(5) Be accompanied by at least five (5) copies of the petition.

§ 1051.6 Documents not considered petitions.

(a) A document filed with the Commission which addresses a topic or involves a product outside the jurisdiction of the Commission will not be considered to be a petition. After consultation with the Office of the General Counsel, the Office of the Secretary, if appropriate, will forward to the appropriate agency documents which address products or topics within the jurisdiction of other agencies. The Office of the Secretary shall notify the sender of the document that it has been forwarded to the appropriate agency.

(b) Any other documents filed with the Office of the Secretary that are determined by the Office of the General Counsel not to be petitions shall

be evaluated for possible staff action. The Office of the General Counsel shall notify the writer of the manner in which the Commission staff is treating the document. If the writer has indicated an intention to petition the Commission, the Office of the General Counsel shall inform the writer of the procedure to be followed for petitioning.

§ 1051.7 Statement in support of or in opposition to petitions; Duty of petitioners to remain apprised of developments regarding petitions.

(a) Any person may file a statement with the Office of the Secretary in support of or in opposition to a petition prior to Commission action on the petition. Persons submitting statements in opposition to a petition are encouraged to provide copies of such statements to the petitioner.

(b) It is the duty of the petitioner, or any person submitting a statement in support of or in opposition to a petition, to keep himself or herself apprised of developments regarding the petition. Information regarding the status of petitions is available from the Office of the Secretary of the Commission.

(c) The Office of the Secretary shall send to the petitioner a copy of the staff briefing package on his or her petition at the same time the package is transmitted to the Commissioners for decision.

§ 1051.8 Public hearings on petitions.

(a) The Commission may hold a public hearing or may conduct such investigation or proceeding, including a public meeting, as it deems appropriate to determine whether a petition should be granted.

(b) If the Commission decides that a public hearing on a petition, or any portion thereof, would contribute to its determination of whether to grant or deny the petition, it shall publish in the FEDERAL REGISTER a notice of a hearing on the petition and invite interested persons to submit their views through an oral or written presentation or both. The hearings shall be informal, nonadversary, legislative-type proceedings in accordance with 16 CFR Part 1052.

§ 1051.9 Factors the Commission considers in granting or denying petitions.

(a) The major factors the Commission considers in deciding whether to grant or deny a petition regarding a product include the following items:

(1) Whether the product involved presents an unreasonable risk of injury.

(2) Whether a rule is reasonably necessary to eliminate or reduce the risk of injury.

(3) Whether failure of the Commission to initiate the rulemaking proceeding requested would unreasonably expose the petitioner or other consumers to the risk of injury which the petitioner alleges is presented by the product.

(4) Whether, in the case of a petition to declare a consumer product a "banned hazardous product" under section 8 of the CPSA, the product is being or will be distributed in commerce and whether a feasible consumer product safety standard would adequately protect the public from the unreasonable risk of injury associated with such product.

(b) In considering these factors, the Commission will treat as an important component of each one the relative priority of the risk of injury associated with the product about which the petition has been filed and the Commission's resources available for rulemaking activities with respect to that risk of injury. The CPSC Policy on Establishing Priorities for Commission Action, 16 CFR 1009.8, sets forth the criteria upon which Commission priorities are based.

§ 1051.10 Granting petitions.

(a) The Commission shall either grant or deny a petition within a reasonable time after it is filed, taking into account the resources available for processing the petition. The Commission may also grant a petition in part or deny it in part. If the Commission grants a petition, it shall begin proceedings to issue, amend or revoke the rule under the appropriate provisions of the statutes under its administration. Beginning a proceeding means taking the first step in the rulemaking process (issuance of an advance notice

Letter 58

Stevenson, Todd A.

From: walc@lycosmail com
Sent: Sunday, June 18, 2000 8 44 PM
To: cpsc-os@cpsc gov
Subject: Petition HP 00-2, Petition on Natural Rubber Latex,

To whom it may concern,

I am a mother of a four year old boy with a severe natural rubber latex allergy. You can only imagine the hazards this presents to our family; it is a way of life for us.

I'm sure you are receiving many letters describing the daily trials that people with NRLA must endure so I will not expound on them here.

I would just like to say how much safer and easier life would be if there was mandatory labelling on clothing and toys in particular advising that a product contains Natural rubber Latex.

Thank you for your consideration,

Cathy Cunningham

Votes 5

HIMA

HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

June 19, 2000

Office of the Secretary
Consumer Product Safety Commission
Washington, DC 20207
cpsc-os@cpsc.gov

Re: Petition HP 00-2, Petition on Natural Rubber Latex

Dear Sir/Madam:

I am writing to present the comments of the Health Industry Manufacturers Association (HIMA)[1] on the subject petition. Many HIMA member companies manufacture products that are either completely or partially fabricated from natural rubber latex (NRL). These products have been used for many years to both enhance and protect the public health. We believe that the CPSC will best serve the public good by rejecting the petition. At the least, the Commission should exempt medical devices from any action, because the Food and Drug Administration (FDA) already stringently regulates such products. Indeed, FDA regulates all medical devices for safety and effectiveness.

Although a limited number of adverse responses to these products has been recorded, we believe that to declare NRL a strong sensitizer in terms of the Federal Hazardous Substances Act (FHSA) would be a severe overreaction. We are also concerned that to apply the strong sensitizer label to NRL would fly in the face of both legal precedent and the currently available scientific literature.

We understand that if the CPSC were to accept the petition, further rulemaking could require labeling of products containing latex or in some cases banning of some products. Such actions could deprive our society of significant safety and health benefits bestowed by many medical devices and other products containing NRL.

CPSC Should Deny the Petition, As Natural Rubber Latex Does Not Meet the Statutory Definition of a "Strong Sensitizer."

Under the FHSA, the term "strong sensitizer" is defined as ...

> *a substance which will cause on normal living tissue through an allergic or photodynamic process a hypersensitivity which becomes evident on reapplication of the same substance and which is designated as such by the Commission. Before designating any substance as a strong sensitizer, the Commission, upon*

World Leaders in Health Care Innovation
1200 G STREET, N W , SUITE 400
WASHINGTON, D C 20005-3814
(202) 783-8700
FAX (202) 783-8750

> *consideration of the frequency of occurrence and severity of the reaction, shall find that the substance has a significant potential for causing hypersensitivity.*[1]

In enacting the FHSA, Congress did not intend that the CPSC designate as a "strong sensitizer" every substance that could potentially trigger hypersensitivity. Rather, Congress recognized that

> [s]ome portion of the population is sensitive in one way or another to almost every article that enters the household, including foods and household soap. To require precautionary labeling on all such products is not intended. Precautionary labeling would be required under this bill on any substance which affects a significant portion of the population and which may cause a strong or severe reaction [2]

Five substances have been codified as strong sensitizers:

(1) paraphenylenediamine (and products containing it) (toxic);
(2) powdered orris root (and products containing it)(highly allergenic);
(3) certain epoxy resins systems (toxic);
(4) formaldehyde (and products containing 1% or more of formaldehyde) (toxic);
(5) oil of bergamot (and products containing 2% or more of oil of bergamot) (photosensitizer).[3]

These designations were part of the original promulgation of implementing regulations under the FHSA in 1961 and nothing has been added to this list since that time [4] CPSC acknowledged Congress' intent when it rejected a request to designate permanent press clothing as a "strong sensitizer" on the grounds that permanent press clothing is not "a substance which affects a significant portion of the population and which may cause a strong or severe reaction."[5] NRL, like permanent press clothing, does not "cause a strong or severe reaction" in a "significant portion of the population." Thus, to designate it as a "strong sensitizer" would contravene both congressional intent and CPSC precedent.

In addition, to declare NRL to be "hazardous," the CPSC would have to find that it can cause "substantial personal injury or substantial illness" during or resulting from customary or reasonably foreseeable handling or use.[6] NRL is ubiquitous throughout our society, and the evidence does not support such a finding. The FDA describes the situation well in their Federal Register Notice: Surgeon's and Patient Examination Gloves; Reclassification and Medical Glove Guidance Manual; Proposed Rule and Notice.[7]

---

[1] 15 U.S.C. § 1261(f)(2); 16 C F R. § 1500.3(b)(9)
[2] Senate Report 1158, 86 Congress 2nd Session (1960) at 11 (emphasis added)
[3] 16 C.F.R. §1500.13
[4] 26 Fed. Reg. 7333, August 12, 1961.
[5] CPSC Advisory Opinion No 12 (July 26, 1973)
[6] 5 U.S C. § 1261(f).
[7] 64 Fed. Reg. 146, 41709, July 30, 1999

> Given that approximately 22 0 billion gloves (Ref. 38) were used and 2.16 billion patient visits occurred during that period (Ref. 39), the projected baseline rate of annual allergic reaction incidents to the total population (0.0001626) at current protein/powder levels does not seem unreasonable.

FDA made this observation based on data collected in its Medical Device Reporting system from August 15, 1996 - August 15, 1997, assuming that only 1% of latex allergy incidents were reported.

In further support of this position a number of studies have examined latex allergy. The studies emphasize a common confusion between a person's being sensitized and being allergic. Those in the first category are capable of producing IgE specific antigen in response to latex proteins. Although such sensitivity is a necessary condition for a person to be allergic, it is not a sufficient condition. Only a small fraction of those persons who test positive for IgE (already a small number) exhibits latex allergy. We have attached an annotated bibliography describing some of the work in this area.

If CPSC Designates Natural Rubber Latex as a "Strong Sensitizer," Medical Devices Should be Exempted.

As described above, in HIMA's view, CPSC should deny the petition. However, if CPSC grants the petition, and proceeds to issue a regulation declaring NRL and products containing NRL to be strong sensitizers, HIMA strongly urges the Commission to exclude medical devices from the scope of such regulation Indeed, to subject medical devices to FHSA labeling requirements would contradict congressional intent and would impose redundant and burdensome regulatory requirements on products that are *already* subject to extensive FDA regulation.

Under the FHSA, the definition of "hazardous substance" excludes "foods, drugs, and cosmetics subject to the Federal Food, Drug, and Cosmetic Act (FDC Act)."[8] While "medical devices" are not specifically mentioned among the list of excluded products, there is strong evidence to suggest that Congress intended to exempt all FDA-regulated products—including medical devices— from the scope of the FHSA. For example, in discussing the purpose of the FHSA, Congress observed that "articles" regulated by FDA— i.e., not merely "foods, drugs, and cosmetics"—were beyond the reach of the Act:

> The [FHSA] would supersede the Federal Caustic Poison Act of 1927, except as to articles subject to the Federal Food, Drug, and Cosmetic Act.[9]

In addition, from a public health perspective, CPSC regulation of medical devices containing NRL is unnecessary, because FDA already stringently regulates such products. Indeed, FDA regulates all medical devices for safety and effectiveness and imposes varying levels of control

---

[8] 15 U.S.C § 1261(f)(2)
[9] House Report 1861, 86 Congress 2nd Session (1960)

depending upon the agency's assessment of the risk imposed by the device. Devices whose risks outweigh their benefits cannot be legally marketed.

With regard to devices containing NRL, FDA has determined that such products may be safely marketed. However, manufacturers must comply with extensive labeling requirements. Under FDA regulations, "all devices composed of or containing, or having packaging or components that are composed of, or contain, natural rubber that contacts humans" must carry cautionary statements alerting the user that the product "may cause allergic reactions." [10] Furthermore, with respect to medical gloves containing NRL, FDA has initiated a rulemaking that would impose additional labeling requirements, including new label caution statements, recommended protein and powder limits, and expiration dating. [11]

Given FDA's comprehensive regulatory scheme governing medical devices containing NRL, CPSC regulation in this area would be redundant and burdensome, and would contravene both agencies' historical efforts to avoid duplicative regulatory initiatives. Indeed, CPSC has traditionally viewed medical devices as outside the scope of its jurisdiction and squarely within FDA's authority.[12] Thus, should CPSC grant the petition and issue a rule designating NRL and products containing NRL to be "strong sensitizers," HIMA respectfully requests that CPSC specifically exempt medical devices containing NRL. FDA regulation in this area is extensive, and additional regulatory oversight is not needed.

Sincerely,

Bernie Liebler
Director
Technology & Regulatory Affairs

Phone: 202.434.7230 Fax: 202.783.8750 *bliebler@himanet.com*

[10] 21 C.F.R. § 801.437
[11] See 64 Fed. Reg. 41710 (July 30, 1999).
[12] See, e.g., CPSC Advisory Opinion No. 222 (Sept. 10, 1975) (douching appliance was a medical device, and, therefore, under the authority of FDA, not CPSC); CPSC Advisory Opinion No. 304 (April 30, 1985) (home exercise equipment intended for medical purposes is a medical device subject to FDA regulation, not CPSC regulation).

Annotated Bibliography

1. Andrew Saxon, et al., *Prevalence of IgE to natural rubber latex in unselected blood donors and performance characteristics of AlaSTAT testing*, 84 Annals of Allergy, Asthma and Immunology 199, 203 (2000).

> Saxon found the prevalence of IgE to NRL among 3 laboratories ranged from 5.4% to 7.6%. Dr. Saxon also reviewed the rate of sensitization published in several other studies, and found the following:
>
> Grzybowski et al found that 8.8% (95% confidence interval 6.7% to 10.8%) of registered nurses has a positive AlaSTAT ELISA for anti-latex IgE. Given the 90.6% recruitment in that study, the prevalence may have been as low [as] 7.9% due to selection bias in participation by those who felt they might be reactive to NRL. Ledenbom-Mansour et al studied 996 surgical patients who were over 18 years old and found sixty-seven (6.7%) had a positive IgE to latex as measured by the AlaSTAT ELISA. ...Porri et al studied latex sensitization in 258 twenty to forty year old subjects attending a health screening in France. They found that 6 6% of subjects showed IgE to latex as determined by skin testing or the Pharmacia CAP assay to latex. A study of latex allergy in blood donors from the UK also found a very similar prevalence of latex sensitization at 7.7% as did a report that 8.6% of nursing volunteers were found to be positive for IgE to NRL prior to beginning clinical training. Given the variability for low positive results as seen in our study when even using the exact same assay and sera, all these cited studies are in a range very similar to what we detected.

2. Dennis R. Ownby et al., *The Prevalence of Anti-Latex IgE Antibodies in 1,000 Volunteer Blood Donors*, 7 J Allergy and Clinical Immunology 1188 (1996).

Ownby measured the prevalence of NRL sensitization among 1000 healthy adults by analyzing blood samples from volunteer Red Cross blood donors.[13] Using the AlaSTAT and CAP assays, Dr. Ownby found that only 6.4% of the blood samples consistently tested positive for anti-latex IgE.

3. The Centers for Disease Control and Prevention conducted the National Health and Nutrition Examination Survey (NHANES III) between 1988 and 1991. The blood from 5,325 adults was tested for NRL sensitization with the AlaSTAT assay over the period of 1988-1991. Only about one in five of individuals contained levels of latex specific IgE antibodies high enough to be considered latex sensitive.

4. Elena H. Page and Eric J. Esswein, US Department of Health and Human Services, HETA, 98-0096-2737, Exempla St. Joseph Hospital, Denver, Colorado (1999).

---

[13] Dennis R. Ownby et al, *The Prevalence of Anti-Latex IgE Antibodies in 1,000 Volunteer Blood Donors*, 7 J Allergy and Clinical Immunology 1188 (1996).

The National Institute for Occupational Safety and Health (NIOSH) conducted a health hazard evaluation at Exempla St. Joseph Hospital in Denver, Colorado in 1998 after receiving employee complaints of allergic responses suspected to be caused by NRL gloves. The NIOSH investigators compared 264 employees who wore NRL gloves on a regular basis with 255 office workers in the same hospital who did not wear NRL gloves on a regular basis. After testing for NRL sensitization with the CAP assay, NIOSH investigators found that 6.3% of those who did not wear gloves were sensitized to NRL. In comparison, only 6.1% of the healthcare workers who wore NRL gloves, as defined by NIOSH, were sensitized to NRL proteins.

5. J. Smedley et al., *Prevalence and Risk Factors for Latex Allergy: A Cross Sectional Study in a United Kingdom Hospital,* 56 Occupational Environmental Medicine 833, 836 (1999).

In a survey of 372 British hospital employees, nearly 50% of the respondents to the survey questionnaire reported symptoms typically associated with glove usage. However, when skin prick and RAST testing were performed to confirm latex sensitivity, only two employees tested positive. Moreover, of these two, one employee did not exhibit symptoms at all. Due to the lack of demonstrable cases of type I hypersensitivity to latex, the study's authors described the prevalence as comparatively "rare."

---

[1] HIMA is a Washington, D C -based trade association and the largest medical technology association in the world. HIMA represents more than 800 manufacturers of medical devices, diagnostic products, and medical information systems. HIMA's members manufacture nearly 90 percent of the $68 billion of health care technology products purchased annually in the United States, and nearly 50 percent of the $159 billion purchased annually around the world

Stevenson, Todd A.

From: Liebler, Bernie [BLiebler@HIMANET.com]
Sent: Monday, June 19, 2000 4 20 PM
To: 'cpsc-os@cpsc gov'
Subject: HIMA Comments on Petition HP 00-2, Petition on Natural Rubber Lat ex

The attached file represents HIMA's comments on the subject notice. We have also sent a hard copy via regular mail.

Bernie Liebler
Ph: 202.434.7230
Fx: 202.783.8750

60

Stevenson, Todd A.

From: Tillotson, Tom [TILLOTSON@thcnet com]
Sent: Tuesday, June 20, 2000 9 45 AM
To: cpsc-os@cpsc.gov
Subject: comments on Petition HP-00-2

June 20, 2000

Office of the Secretary
Consumer Product Safety Commission
Washington, DC 20207
cpsc-os@cpsc.gov

Re: Petition HP 00-2, Petition on Natural Rubber Latex

Dear Sir/Madam:

I am writing to present the comments of Tillotson Healthcare Corporation on the subject petition. THC manufactures gloves from natural rubber latex (NRL). These products have been used for many years to both enhance and protect the public health. We believe that the CPSC will best serve the public good by rejecting the petition. THC is a member of and supports the comments to this petition submitted by HIMA and incorporates those comments here by reference.

In addition to the HIMA comments, THC would like to point out that to declare NRL a strong sensitizer in terms of the Federal Hazardous Substances Act (FHSA) would be inconsistent with the intent of the Act to regulate specific substances. NRL is composed of a polymer of 1,4 cis-trans polyisoprene, resins, proteins and other trace materials Various means exist to modify any or all of the component materials to achieve a variety of intended outcomes. For example, enzymes can be used to digest the proteinacous materials to render them immunologically inactive. NRL is virtually never used just as it comes form the tree. Since it always undergoes various processing treatments, an overriding declaration of NRL as a strong sensitizer in terms of the Federal Hazardous Substances Act (FHSA) would be to treat a generic composite material as though it were a consistently defined single material.

Thanking you for your consideration of these comments, I am

Sincerely yours,

Thomas N Tillotson
Chairman/CEO
Tillotson Healthcare Corporation

(These comments are also being sent hard copy)

Letter 61

BDMT International Operations
21 Davis Drive / P O Box 12016
Research Triangle Park, NC 27709-2016
Tel 919-990-2250
Fax 919-990-2244

BD
Indispensable to human health

June 16, 2000

Office of the Secretary
Consumer Product Safety Commission
Washington, DC 20207
cpsc-os@cpsc.gov

Re. Petition HP00-2 to Classify Natural Rubber Latex as a Strong Sensitizer.

Dear Sir/Madam:

Becton Dickinson and Company is one of the largest producers of medical products. Our devices have been used for many years to both enhance and protect the public health, and with benefits to the consumer which clearly outweigh any hazardous risk. Because of the low severity and frequency of sensitization reaction to Natural Rubber Latex (NRL) as seen in our own experience and as reported in the published literature, and since the FDA CDRH already stringently regulates medical products for safety (including sensitization potential), the CPSC should reject the subject petition to classify NRL as a strong sensitizer. We respectfully offer the following additional comments for your consideration.

Foremost, the Federal Hazardous Substances Act (FHSA) defines the term strong sensitizer as: "a substance which will cause on normal living tissue through an allergic or photodynamic process a hypersensitivity which becomes evident on reapplication of the same substance and which is designated as such by the Commission. Before designating any substance as a strong sensitizer, the Commission, upon consideration of the frequency of occurrence and severity of the reaction, shall find that the substance has a significant potential for causing hypersensitivity." [Emphasis added]

Historically, few substances have met the criteria for strong sensitizers as defined by the FHSA. In this respect, formaldehyde ($H_2C=O$) is one example of only five substances currently codified under the FHSA as a strong sensitizer. Formaldehyde (CAS No. 50-00-0) is found in cosmetics, preservatives for hygiene products, in textiles to improve wrinkle resistance, leather, paper products, newspaper dyes, and glues and bonding agents. The chemical is well documented as being highly toxic as well as a potent sensitizing chemical. To this point, and following the extensive literature publications of formaldehydes toxic effects, OSHA issued a comprehensive regulation covering occupational

exposure to formaldehyde[1]. This rule reduced the permissible exposure limits (PELs) to 1 part formaldehyde per million parts of air (ppm) as an 8-hour time-weighted average (TWA), and established a 2-ppm 15-minute short-term exposure limit (STEL). More to the point, the comprehensive standard also included provisions for employee exposure monitoring, medical surveillance, record keeping, regulated areas, emergency procedures, preferred methods to control exposure, maintenance and selection of personal protective equipment, and hazard communication. OSHA's rule, in fact, was based on the consideration of a wide range of extensive evidence including animal bioassays and significant epidemiological evidence. Extending the same consideration to NRL, it is noteworthy that, in addition to the lack of strong epidemiologic evidence, animal studies of medical devices containing NRL consistently fail to respond positively for sensitization.

Continuing with the use of formaldehyde as an example of a strong sensitizing substance, the NTP Chemical Repository for Formaldehyde 37% Solution describes standard emergency procedures for formaldehyde exposure[2]. For example, following ingestion, skin or eye contact, a final treatment action for <u>any and all exposures</u> is to IMMEDIATELY transport the victim to a hospital. This document further notes that, with long exposure, hypersensitivity FREQUENTLY results, and lists as reference the publication by Gosselin et al[3].

Experimental and clinical evidence does exist to allow the conclusion that some chemical exposures (e.g., formaldehyde) would warrant IMMEDIATE transport to a hospital following <u>any and all exposures</u>. Similarly, experimental and clinical evidence may also allow us to conclude that some chemical substances (e.g., formaldehyde) may be capable of FREQUENTLY (a relative term) eliciting a hypersensitivity response following exposure. That formaldehyde, in fact, is classified as a toxic substance and FREQUENT strong sensitizer warranting IMMEDIATE hospital transport following <u>any and all exposures</u> is befitting of it's well-known and published toxic effects, and certainly deserving of it's codification as a strong sensitizer by the FHSA. In marked contrast, however, a ubiquitous substance like NRL cannot begin to compare to the severity or frequency of occurrence of hypersensitivity reaction, nor would the same treatment actions appear to be warranted for <u>any and all exposures</u>.

Two other codified strong sensitizers include powdered orris root and oil of bergamot. A brief review of the literature indicated that orris root (no CAS # found) is extracted from the rhizome of certain Western European flowers, contains about 85% myristic acid and has a violet-like odor. Oil of bergamot (CAS No. 8007-75-8) is extracted from the rind of a pear-shaped orange (Citrus bergamia from the Middle East, not to be confused with the wild bergamot herb of N. America]), contains about 45% linalyl acetate and has a citrus-like flavor. For many years, both orris (also used as a dusting powder) and bergamot have provided essential fragrant oils used in perfumery and, with this use, developed a substantial reporting database of hypersensitivity reactions. Ironically, bergamot

oil (which is known to have about 300 chemical constituents) has been used in the Middle East for hundreds of years for acne, boils, cold sores, eczema, insect bites, insect repellent, oily complexion, psoriasis, scabies, spot varicose veins, ulcers, wounds, sore throat, thrush, infectious disease, and depression.

p-Phenylenediamine (CAS No. 106-50-3), another codified strong sensitizer, has been used in the manufacture of azo dyes and as an accelerator in the vulcanization of rubber. The chemical is well documented for causing sensitization dermatitis[4] and has an Index of Sensitivity (to selected allergens) comparable to formaldehyde[5]. Nethercott et al[6] (see below table) listed the index of sensitivity for many common allergens in a group of 3974 individuals who were patch tested by the North American Contact Dermatitis Group. Such individuals are generally evaluated because they are already affected by contact dermatitis. Thus, the epidemiologic data generated, because it is not based on blinded cross-sectional evaluations, may not be representative of the general population. Nevertheless, such data permit recognition of allergens with high sensitizing potential. It is noteworthy that NRL was not considered to be a common allergen for inclusion in this analysis.

Index of Sensitivity to Selected Allergens*

Chemical	Response Rate (% Positive)
Nickel sulfate	10.5
Thimerosal	8.7
Neomycin sulfate	7.2
Formaldehyde	6 8
p-Phenylenediamine	6.4
Quaternium-15	6.2
Thiuram mix	5 5
Balsam of Peru	5.1
Cinnamic alcohol	4 8
Ethylenediamine dihydrochloride	3.8
Cinnamic aldehyde	3.1
Carba mix[†]	3.1
Mercapto mix[‡]	2.5
Potassium dichromate	2.4
Diazolidinyl urea	2.4
Diaminophenylmethane	2.3
Benzoyl peroxide	2.3
Rosin	2.2
Mercaptobenzothiazole	2.1
Imidazolidinyl urea	2.1
Epoxy resin	2.1
Black rubber mix[§]	2 1
Benzocaine	2.1
p-(*t*-butyl)phenol formaldehyde resin	1.6
Wood alcohol	1.5

*Adapted from Nethercott et al (1994) [†]Diphenylguanidine, zinc diethyldithiocarbamate, zinc dibutyldithiocarbamate [‡]Cyclohexyl-2-benzothiazolesulfenamide, 2,2'-benzothazyl disulfide, 4-morpholinyl-2-benzothiazole disulfide [§]*p*-Phenylenediamine congeners

The FDA recently reported on the incidence of latex sensitization in humans[7]. Out of the approximately 22.0 billion gloves used and 2.16 billion patient visits which occurred during the specified MDR period, the projected baseline rate of annual allergic reaction incidents to the total population was calculated in this FDA document as 0.0001626. No mortalities were reported during the specified MDR period. We respectfully submit that these facts reflect neither the "frequency of occurrence" nor the "severity of reaction" called for in the FHSA definition of "strong sensitizer".

NRL is ubiquitous in our society and can be found not only in life-saving medical devices, but also in a wide array of other consumer products ranging from children's toys to elastic clothing to automotive tires. Importantly, there have been no reports of widespread reactions or other symptomology in connection with the use of these products, which have provided utility to the public for many years without incident. The allegations in the petition refer to symptoms of allergy in a limited number of individuals which do not differ in either frequency or severity from the symptoms caused by the hundreds, if not thousands, of other substances which likewise constitute allergies to a very limited number in the population. Consequently, it would not be appropriate to characterize NRL as a "strong sensitizer" under the FHSA.

Upon consideration of the foregoing and further examination of the published literature, we suggest that the CPSC should NOT find that NRL has a significant potential (frequency or severity) for causing hypersensitivity. We conclude again that the CPSC should reject the subject petition to classify NRL as a strong sensitizer.

Respectfully,

Daniel E. McLain, Ph.D., DABFE, BCNS
Director, International Operations
Becton Dickinson Medical Toxicology
21 Davis Drive / P.O. Box 12016
Research Triangle Park, NC 27709-2016

Literature Citations

[1] 29 CFR 1910.1048, December 4, 1987
[2] Radian Corporation, August 29, 1991
[3] Gosselin, R.E., H.C. Hodge, and R.P. Smith. Clinical Toxicology of Commercial Products. 5th Ed. Williams and Wilkins, Co., Baltimore. 1984. P. II-187, #482; pp. III-196 to III198.
[4] NIOSH Pocket Guide to Chemical Hazards (DHHS/NIOSH 90-117, 1990) p. 178
[5]Casarett and Doull's Toxicology: The Basic Science of Poisons. 5th Ed. Chapter 18: Toxic responses of the skin, pp. 529-546. McGraw-Hill. 1996.
[6]Nethercott, J.R., D.L. Holness, R.M. Adams et al: Multivariate analysis of the effects of selected factors on the elicitation of patch test response to 28 common environmental contactants in North America. Am. J. Contact Dermatitis 5:13-18, 1994.
[7]Federal Register: July 30, 1999 (Volume 64, Number 146) Proposed Rules, 21 CFR Parts 801, 878, and 880: Surgeon's and Patient Examination Gloves; Reclassification and Medical Glove Guidance Manual Availability; Proposed Rule and Notice.

Stevenson, Todd A.

From: Daniel_E_McLain@bd com
Sent: Tuesday, June 20, 2000 3 38 PM
To: cpsc-os@cpsc gov
Subject: Comments to the Petition to Classify NRL as a Strong Sensitizer

Rich Text Format

Sir/Madam,

Comments to the above petition are attached as an MS Word file saved in Rich
Text Format (.rft). Please consider these comments as you complete your review
of this petition. A hardcopy of these comments will be forwarded by traditional
route.

(See attached file: PSA-0003 NRL.rtf)

Daniel McLain, Ph.D., DABFE, CNS
Director, International Operations
Becton Dickinson Medical Toxicology
21 Davis Drive / Post Office Box 12016
Research Triangle Park, NC 27709
T: 919-990-2250 / C: 919-349-7618 / F: 919-990-2244
Email: Daniel_E_McLain@bd.com

62

Planned Parenthood®
Federation of America, Inc.

June 20, 2000

Via Facsimile and Federal Express

Sadye Dunn, Secretary
Office of the Secretary
Consumer Product Safety Commission
Washington, DC 20207

Re Petition HP 00-2, Petition on Natural Rubber Latex: Comment

Dear Ms. Dunn:

These comments are submitted by Planned Parenthood Federation of America ("Planned Parenthood") in opposition to the Petition requesting that the Consumer Product Safety Commission ("CPSC") issue a rule declaring that natural rubber latex ("NRL") and products containing NRL are strong sensitizers under the Federal Hazardous Substances Act ("FHSA")

Planned Parenthood and its affiliates, which constitute the largest, private family planning provider in the United States, are dedicated to serving the health interests of nearly 5 million clients through medical services, advocacy, and education. Our 129 Planned Parenthood affiliates, with 875 health centers nationwide, use and/or provide a significant amount of latex products – primarily latex rubber gloves for staff and condoms for patients Planned Parenthood appreciates the seriousness of the reported increased incidence of allergic reactions to latex gloves among health workers, and we support continued research, improved manufacturing techniques, and reasonable labeling requirements. However, the intended benefit of any proposed change must be weighed against the possible negative consequences for each specific product. Specifically, Planned Parenthood is concerned that additional labeling language on condoms, declaring that latex is a "strong sensitizer" under the FHSA, is not only unnecessary, but may have the unintended, detrimental effect of deterring condom usage.

Both the public and private health sectors have worked for decades to encourage widespread condom use among sexually active people, with good reason: Condoms are the single most effective medical device to protect against the transmission of HIV, Hepatitis B and C, syphilis, gonorrhea, chlamydia, human papilloma virus, and a host of other serious sexually transmitted infections. From a public health perspective, the effectiveness of condoms obviously depends upon their widespread, consistent, and correct usage. Any new labeling requirement that would deter condom use could potentially erode vital public health efforts and increase rates of HIV infection and other serious diseases.

cont'd

June 20, 2000

Sadye Dunn, Secretary
Office of the Secretary

Planned Parenthood therefore respectfully requests that the Commission weigh the benefit of warning about a relatively small risk against the negative health consequences of alarming the entire condom-using public and deterring condom usage. While Planned Parenthood recognizes that some individuals may experience allergic reactions to latex, studies indicating high rates of allergic reactions involved people with extended exposure through wearing latex surgical gloves for their occupation. By contrast, exposure through condom use is far less extensive. Subsequently, no studies have found that latex condoms result in high allergy rates, and among those allergies due to latex condom exposure, none has been extremely serious. (Gilmore CE. In: McNeill ET, Gilmore CE, Finger WR, Lewis JH, Schellstede WP, eds. *The Latex Condom: Recent Advances, Future Directions*. Research Triangle Park, NC. Family Health International; 1998. 36-43.) In fact, three recent studies of the general population's sensitivity to latex indicate that "the prevalence of positive reactions to latex was about 1% or less." (Liss, GM, Sussman, GL. Latex sensitization: occupational versus general population prevalence [abstract] rates. *Am J Ind Med*. 1999; 35(2):196-200.Taken from Medline.)

Furthermore, the FDA already requires latex allergy warnings on all condom foil wrappers and primary packaging (21 CFR §801.437) as follows:

> Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.

This warning is appropriate and sufficient. Additional warnings that latex is a "strong sensitizer," "hazardous substance," or a "banned hazardous substance," risk alarming the public. Such dramatic warnings could be seized by individuals who are ambivalent about condom use for other social, psychological, or personal reasons, and used as an excuse or rationalization for not using condoms.

In addition, the supplemental language may not even be legible, as the condom foil wrapper already must bear numerous other FDA-required warnings and information. *See* 21 CFR §§801.435, 801.437; "Guidance for Industry: Latex Condoms for Men," U.S. Food and Drug Administration Center for Devices and Radiological Health, issued July 23, 1998 (hereinafter "Guidance"). For example, latex condoms lubricated with nonoxynol-9 currently must display 99 words of warnings and disclaimers, plus expiration date and name and address of the manufacturer. *See* Guidance, p. 12.

cont'd

June 20, 2000

Sadye Dunn, Secretary
Office of the Secretary

For these reasons, Planned Parenthood opposes the Petition and urges the Commission to seriously consider the potentially hazardous effects of undermining condom usage. If you have any questions or if we can be of any assistance, please call me at (212) 261-4701, or Carole Chervin, Esq., Assistant General Counsel at (212) 261-4330. Thank you for this opportunity to comment on this important issue.

Sincerely,

Michael S Burnhill /cic

Michael S. Burnhill, M.D., D.M.Sc.
Vice President, Medical Affairs

Planned Parenthood®
Federation of America, Inc.

LEGAL DIVISION FACSIMILE COVER SHEET

TO: Sadye Dunn, Secretary

COMPANY NAME: Consumer Product Safety Commission

FACSIMILE #: (301) 504-0127

OF PAGES (INCLUDING THIS PAGE): 4

FROM: CAROLE I. CHERVIN, Esq.
Assistant General Counsel
Telephone # (212) 261-4330
Facsimile # (212) 247-6811

COMMENTS:

Ansell Perry

June 21, 2000

VIA HAND DELIVERY

Office of the Secretary
Consumer Product Safety Commission
Room 502
4330 East-West Highway
Bethesda, MD 20814

Re: Petition HP 00-2
Petition on Natural Rubber Latex

Dear Sir or Madam:

These comments are submitted on behalf of Ansell Healthcare Products Inc. ("Ansell") in response to the above-referenced petition, notice of which appeared in the Federal Register of March 21, 2000. 65 Fed. Reg. 15133 (March 21, 2000). The petition requests the Commission Product Safety Commission ("CPSC") to designate natural rubber latex ("NRL") and products containing NRL as "strong sensitizers" under the Federal Hazardous Substances Act ("FHSA"). The CPSC has solicited comments on the petition, with comments to be submitted by June 21, 2000. 65 Fed. Reg. 33525 (May 24, 2000).

Ansell is one of the leading worldwide manufacturers of protective gloves and condoms. Products manufactured and marketed by Ansell fall into three business categories: Professional Healthcare (medical examination and surgical gloves), Occupational Healthcare (industrial and consumer gloves), and Personal Healthcare (condoms marketed in both retail and public health channels). Ansell manufactures its products in Asia, North America and the United Kingdom and markets these products worldwide in over 100 countries. The global market for medical gloves is estimated to be approximately $1.5 billion; industrial and consumer gloves approximately $3.6 billion; and condoms approximately $750 million. Ansell products are made predominantly of natural and synthetic latex.

Ansell Healthcare Products Inc. • 1875 Harsh Ave. S.E. • Massillon, Ohio 44646 • U.S.A. http://www.ansell.com
Telephone: 330-833-2811 • Toll Free: 800-321-9752 (USA only) • Fax: 330-833-5991

Ansell offers the following comments on the petition to declare NRL and NRL-containing products to be "strong sensitizers" for purposes of the FHSA

I. Natural Rubber Latex and NRL-Containing Products Are Not "Strong Sensitizers" Within the Meaning of the Federal Hazardous Substances Act and CPSC Regulations

Under the FHSA, the term "strong sensitizer" is defined as

> A substance which will cause on normal living tissue through an allergic or photodynamic process a hypersensitivity which becomes evident on reapplication of the same substance and which is designated as such by the Commission Before designating any substance as a strong sensitizer, the Commission, upon consideration of the frequence of occurrence and severity of the reaction, shall find that the substance has a significant potential for causing hypersensitivity 15 U.S.C §1261(k).

CPSC regulations implementing this statutory definition provide that, in determining whether a sensitizer is "strong" within the meaning of the FHSA, the CPSC considers a number of factors including the frequency of occurrence and the range of severity of reactions in healthy or susceptible populations, as well as other relevant data 16 C F.R. §1500.3(c)(5)(ii) Moreover, under CPSC regulations, a "significant potential for causing hypersensitivity" is a relative determination that must be made separately for each substance. 16 C.F R. §1500.3(c)(5)(iii).

In applying the "strong sensitizer" definition, CPSC has referred to the intent of Congress in concluding that the definition does not apply to every substance causing sensitization:

> In reaching this conclusion, it was acknowledged that some portion of the population is sensitive in one way or another to almost every article that enters the household, including foods and household soaps. Congress, in enacting the Federal Hazardous Substances Act, did not intend that precautionary labeling would be required on all such products (Senate Report 1158, 86 Congress 2nd Session, p. 11). A strong sensitizer must be a substance which affects a significant portion of the

> population and which may cause a strong or severe reaction. Advisory Opinion dated July 26, 1973 (emphasis added).

Applying the statutory definition, the regulatory factors, and CPSC precedents to the case of NRL leads to the conclusion that the NRL should not be designated a "strong sensitizer." Sensitization to NRL occurs in only a very small portion of the general population, approximately 1% or less, even though virtually the entire population has likely been exposed to NRL at some time in their lives. Moreover, the definition of "strong sensitizer" requires more than evidence of mere sensitization. The extent and degree of severity of allergic reaction must also be significant Only a portion of the persons sensitized to NRL will actually exhibit an allergic reaction upon contact with NRL. Most of these reactions will be mild to moderate. A much smaller percentage will have severe symptoms

By those comments, Ansell does not intend to minimize the fact that some persons are sensitized to NRL and that some sensitized persons may experience a range of reactions, including severe reactions, although this is relatively rare. Ansell concludes, however, that NRL does not meet the statutory and regulatory definition of "strong sensitizer." This conclusion is supported by the attached opinion of Dr. Jordan Fink, a nationally recognized expert in latex allergy. Dr. Jordan Fink is Professor of Medicine and Pediatrics at the Medical College of Wisconsin, Milwaukee, Wisconsin. From 1971 to 2000 he was Chief of the Allergy-Immunology Division of the Department of Medicine at that institution In addition to treating patients for NRL-related allergic symptoms, Dr. Fink has done resarch on this subject for the VA, for CDC/NIOSH, and for Ansell He received the Distinguished Service Award from the American Academy of Allergy and Immunology in 1994. A copy of Dr Fink's curriculum vitae is attached to his letter

As Dr. Fink stated,

> Approximately 1% of the population of the United States will be sensitized if exposed to natural rubber latex. Of those who are sensitized, some will have no allergic symptoms and others will have symptoms ranging from mild to severe, with only a much smaller percentage of persons having severe symptoms. Thus, less than 1% of the U.S. population will suffer any symptoms from sensitization to natural rubber latex or products containing it and much fewer will have severe symptoms. Further, infrequent, incidental contact with natural rubber latex or products containing it is extremely unlikely to result in sensitization, let alone symptoms.

Based upon consideration of the pertinent statutory and regulatory definitions and the sensitization potential of NRL, Dr. Fink concluded,

> It is my opinion that natural rubber latex and products containing natural rubber latex are not strong sensitizers within the meaning of these definitions.

II Appropriate Labeling of NRL-Containing Products Does Not Require Their Designation As "Strong Sensitizers" Under the FHSA

Designation as a "strong sensitizer" under the FHSA is not necessary to encourage appropriate labeling of products containing NRL. First, medical products containing NRL to which the healthcare worker population is exposed are regulated by FDA as medical devices Under existing FDA regulations, medical devices containing NRL – such as surgical or examination gloves and condoms – are required to bear the following label statement.

> Caution. This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions

It should be noted that in establishing this labeling requirement for medical devices under the Federal Food, Drug and Cosmetic Act, FDA did not purport to be applying the "strong sensitizer" definition of the FHSA FDA's action in no way establishes that NRL is a "strong sensitizer" under the FHSA Nevertheless, Ansell supported and continues to support the FDA-mandated labeling for medical devices, particularly in view of the likelihood of greater prolonged exposure to NRL-containing products in the healthcare worker population.

For non-medical products, Ansell believes the manufacturers should make a product-by-product determination of whether similar cautionary or informational labeling is appropriate for their particular product. Ansell has concluded that it would be appropriate for it to label its non-medical gloves manufactured from NRL with the same caution as Ansell applies to its medical gloves. For this reason, Ansell has decided to label its non-medical latex products on a voluntary basis with the FDA-mandated labeling It will do this regardless what action CPSC takes on the referenced petition. Ansell believes that this will provide useful information to its customers and is in the best interests of both its customers and the company Ansell is taking this action even though NRL is not, in its view, a "strong sensitizer" under the FHSA.

In summary, Ansell believes that NRL and products containing NRL are not "strong sensitizers" within the meaning of the FHSA but that this does not preclude appropriate cautionary or information labeling of individual products by their manufacturers

Sincerely yours,

James R Chatterton
Vice President
Regulatory Affairs/Technical

MEDICAL COLLEGE OF WISCONSIN

Kevin J Kelly, M D
Professor & Chief

Jordan N Fink, M D
Professor

Michael C Zacharisen, M D
Assistant Professor

Asnani M Chiu, M D
Assistant Professor

Michael B Levy, M D
Assistant Professor

Morton M Soifer, M D
Assistant Professor

Asthma & Allergy Center
Allergy-Immunology
Department of Pediatrics and Medicine

June 19, 2000

Mr. James R. Chatterton
Ansell Perry, Inc.
1875 Harsh Avenue, S.E.
Massilon, Ohio 44648-0550

Dear Mr. Chatterton:

As requested, this letter addresses the question of whether natural rubber latex and products containing natural rubber latex are "strong sensitizers" within the meaning of the Federal Hazardous Substances Act. I understand that you may wish to submit these views to the Consumer Product Safety Commission.

I am a physician and board certified both in internal medicine, allergy and immunology. I am a Professor of Medicine and Pediatrics at the Medical College of Wisconsin, Milwaukee, Wisconsin. Between 1971 and 2000, I served as Chief of the Allergy-Immunology Division of the Department of Medicine at the Medical College of Wisconsin My curriculum vitae is attached.

I am very familiar with the allergic and sensitization potential of natural rubber latex. In addition to treating patients suffering from natural rubber latex related allergic symptoms, I have done research on this subject sponsored both by the Veterans Administration, Centers for Disease Control/National Institute of Occupational Safety and Health and by Ansell, Inc. I have published a number of articles reporting on this research and on the problems of latex allergy generally, as listed in my curriculum vitae.

At the request of Ansell Healthcare Products, Inc., I have studied the definition of "strong sensitizer" which appears in the Federal Hazardous Substances Act and in the Consumer Product Safety Commission regulations (16 CFR § 1500.3 (b) (9)) and the supplemental regulatory definitions of "sensitizer," "strong," "severity of reaction," "significant potential for causing hypersensitivity," and "normal living tissue" (16 CFR § 1500.3 (c) (5) (i)~(v)). It is my opinion

9000 West Wisconsin Avenue
PO Box 1997
Milwaukee, Wisconsin 53201
(414) 266-6840
FAX (414) 266-6437

that natural rubber latex and products containing natural rubber latex are not strong sensitizers within the meaning of these definitions

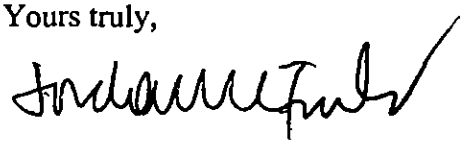
It is well known that a certain number of persons in the United States, who are exposed a number of times to natural rubber latex products, will develop contact dermatitis from exposure to these products. However, this reaction is caused by chemicals not naturally present in the natural rubber latex but used in the manufacture of natural rubber latex products. Although this contact dermatitis is a sensitization reaction, it is not caused by natural rubber latex, and is not a basis for classifying natural rubber latex as a "sensitizer" or "strong sensitizer."

Approximately 1% of the population of the United States will be sensitized if exposed to natural rubber latex. Of those who are sensitized, some will have no allergic symptoms and others will have symptoms ranging from mild to severe, with only a much smaller percentage of persons having severe symptoms. Thus, less than 1% of the U.S. population will suffer any symptoms from sensitization to natural rubber latex or products containing it and much fewer will have severe symptoms. Further, infrequent, incidental contact with natural rubber latex or products containing it is extremely unlikely to result in sensitization, let alone symptoms.

While I do not minimize the concerns with allergies associated with natural rubber latex, the level of occurrence of sensitization to natural rubber latex, as described above, and the resulting symptoms in sensitized patients having symptoms are usually not severe enough to justify classifying natural rubber latex as a "strong sensitizer " If it were so classified, it would suggest that a number of common substances with similar allergenic potential such as penicillin, milk, and house dust mite should also be so classified. Adding such substances to the list of "strong sensitizers" is not in my opinion reasonable or of benefit to the public health.

If you have any further questions about this subject, please let me know.

Yours truly,



Jordan Fink, M.D.

Professor of Medicine & Pediatrics

CURRICULUM VITAE
July 1999

Jordan N. Fink, M.D.

Home Address: 2829 West Golf Circle
Mequon, Wisconsin 53092

Office Address: 9000 W. Wisconsin Avenue
Milwaukee, Wisconsin 53226
(414) 266-6840
(414) 266-6437 Fax

Place of Birth: Milwaukee, Wisconsin

Marital Status: Married, Phyllis Mechanic, 3 children

Education: 1956 B S. University of Wisconsin, Madison, WI

1959 M.D. University of Wisconsin, Madison, WI

Postgraduate Training and Fellowship Appointments:

1959 - 1960 Intern, Mt. Sinai Hospital, Milwaukee, WI

1960 - 1963 Resident, Department of Medicine, Marquette University School of Medicine, Milwaukee County Hospital, Milwaukee, WI

1963 - 1965 NIH Fellow in Allergy-Immunology, Northwestern University Medical School, Chicago, IL

Faculty Appointments:

1965 - 1968 Instructor, Department of Medicine, Marquette University School of Medicine, Milwaukee, WI

1968 - 1970 Assistant Professor, Department of Medicine and Assistant Professor of Medicine in Microbiology, Marquette School of Medicine (formerly Marquette University School of Medicine), Milwaukee, WI

1970 - 1973	Associate Professor, Department of Medicine and Associate Professor of Medicine in Microbiology, The Medical College of Wisconsin (formerly Marquette School of Medicine), Milwaukee, WI
1971 -	Chief, Allergy-Immunology Division, Department of Medicine, The Medical College of Wisconsin, Milwaukee, WI
1973 -	Professor, Department of Medicine, and Professor of Medicine in Microbiology, The Medical College of Wisconsin, Milwaukee, WI
1994 -	Professor, Department of Medicine, Professor, of Medicine in Microbiology and Professor of Medicine in Pediatrics, The Medical College of Wisconsin, Milwaukee, WI

Hospital and Administrative Appointments:

1963 - 1965	Consulting Staff Physician, VA Research Hospital, Chicago, IL
1965 - 1996	Associate Staff, Department of Medicine, John L. Doyne Hospital (formerly Milwaukee County Medical Complex), Milwaukee, WI (Hospital closed 12/31/95)
1966 -	Associate Medical Staff, Children's Hospital of Wisconsin, Milwaukee, WI
1966 -	Consulting Staff, Department of Medicine, Mt. Sinai Hospital, Milwaukee, WI
1968 - 1998	Chief, Allergy Section, Medical Service, VA Medical Center, Milwaukee, WI
1969 -	Consulting Staff, Department of Medicine, Columbia Hospital, Milwaukee,WI
1970 -	Associate Staff, Department of Medicine, Good Samaritan Medical Center, Milwaukee, WI
1971 - 1996	Chief, Allergy Section, Dept. of Medicine, John L. Doyne Hospital, Milwaukee, WI (Hospital closed 12/31/95)
1971 -	Consulting Staff, Department of Medicine, St. Luke's Hospital, Milwaukee, WI
1973 -	Consulting Staff, Department of Medicine, St. Mary's Hospital, Milwaukee, WI

1981 -	Associate Staff, Department of Medicine Froedtert Memorial Lutheran Hospital, Milwaukee, WI

Research Appointments:

1965 -1968	Clinical Investigator, VA Medical Center, Milwaukee, WI
1978 - 1980	Chairman, Research & Development Committee, VA Medical Center, Milwaukee, WI
1978 - 1986	Member, Research & Development Committee, VA Medical Center, Milwaukee, WI
1980 - 1986	Associate Chief of Staff for Research and Development, VA Medical Center, Milwaukee, WI

Specialty Certification:

June 1966	American Board of Internal Medicine #25245
March 1967	American Board of Internal Medicine, Sub-specialty of Allergy #25245
June 1973	American Board of Allergy and Immunology. A Conjoint Board of The American Board of Internal Medicine and the American Board of Pediatrics #51
October 1977	Re-certification: American Board of Allergy and Immunology

Licensure: Wisconsin 13637, California C24793, Arizona 8181 Illinois 036-038787

Awards, Honors:

1955	Phi Beta Kappa
1959	Alpha Omega Alpha
1987	Selected in "The Best Doctors in Milwaukee"
1990	Selected in "The Best Doctors in America"
1991	Selected in "The Best Doctors in Milwaukee"
1994	American Academy of Allergy and Immunology Distinguished Service Award
1994	Selected in "The Best Doctors in America"
1996	Selected in "Top Doctors in Milwaukee"
1996	Selected in "The Best Doctors in America"

Memberships in Professional and Honorary Societies:

Association of American Physicians

American Society for Clinical Investigation

American Association of Immunologists
Financial Development Committee 1991 - 1994

American Association for the Advancement of Science

American College of Occupational and Environmental Medicine

American College of Chest Physicians

American Thoracic Society

American Academy of Allergy Asthma and Immunology
Chairman, Scientific Exhibits and Workshops Committee 1974-1975
Chairman, Research Council 1975 - 1978
Representative to the Council of Medical Sub-specialty Societies 1978 - 1981
Chairman, Continuing Medical Education Committee 1978 - 1981
Chairman, Education Council 1981 - 1984
Member, Executive Committee 1979 - 1987
Treasurer 1981 - 1983
President-Elect 1983 - 1984
President 1984 - 1985
Chairman, Related Industries Council 1984 - 1991
Chairman, Finance Committee 1986 - 1987
Endowment Research Trust Committee 1991 - 1997
Chairman, Pharmaceutically Sponsored Educational Programming Committee 1992 - 1996

American College of Allergy, Asthma & Immunology

Central Society for Clinical Research
Chairman, Allergy and Immunology Section 1984

Wisconsin Allergy Society
Secretary-Treasurer 1969 - 1971
President 1971 - 1973

Asthma and Allergy Society of Milwaukee County,
President 1986 -

International Association of Allergology and
Clinical Immunology
Finance and Audit Committee 1982 -

Collegium Internationale Allergologicum 1990 -

Editorial Boards:

Journal of Allergy and Clinical Immunology
1973 - 1978

American Review of Respiratory Diseases
1978 - 1987

Chest 1982 - 1987

Journal of Laboratory and Clinical Medicine 1987 - 1991

National Advisory Committees and/or Activities:

Ad Hoc Study Section Member, National Institute of Allergy and Infectious Diseases, National Heart, Lung and Blood Institute, National Institute of General Medical Sciences, National Institute of Environmental Health Sciences 1977 -

Member, FDA Advisory Committee on Pulmonary Allergy and Clinical Immunology 1977 - 1981

Chairman, FDA Advisory Committee on Pulmonary Allergy and Clinical Immunology 1980 - 1981

Consultant, Food and Drug Administration,
Orphan Products Development, Initial Review Group 1983 -

Member, FASEB Panel on the GRAS Status of Sulfiting Agents
1984 - 1985

Member, General Clinical Research Centers Study Section, Division of Research Resources, NIH 1985 - 1989

Participant, Workshop on Multiple Chemical Hypersensitivity, National Research Council, March 20-21, 1991

Co-Chairman, American College of Physicians MKSAP-AI
1990 - 1993

Member, Research Center in Minority Institutions Program Study Section, National Center for Research Resources, NIH 1992 - 1993

Member, Technical Advisory Group, Latex Allergy, Veterans Administration - 1997

Community Advisory Committees and/or Activities:

Camp Interlaken JCC Committee	1970 - 1983
Chairman 1979 - 1982	
Board Member, Jewish Community Center of Milwaukee	1978 - 1982

Research Grants Contracts, Awards:

VA 2825	"Hypersensitivity Lung Disease Program" $30,000 - $100,000/year, 1967 - 1986, Principal Investigator
AI 07159	"Investigation of a Hypersensitivity Pneumonitis" (NIAID) $20,000/year, 1967 - 1973, Co-Investigator
Life Ins.	"Experimental Production of Hypersensitivity Pneumonitis" Life Insurance Medical Research Fund $10,000/year, 1968 - 1971, Principal Investigator
AI 0316	"Training Grant in Allergy-Immunology" (NIAID) $35,000/year, 1969 - 1975, Principal Investigator
AI 09694	"An Experimental Model of Human Asthma" (NIAID) $14,500/year, 1970 - 1974, Principal Investigator
HL 15389	"Pulmonary SCOR: Hypersensitivity Pneumonitis" (NHLBI) $850,000/year, 1972 - 1982, Principal Investigator
AI 07006	"Training Grant in Allergy-Immunology" (NIAID), $35,000/year, 1975 - 1980, Principal Investigator
AI 15700	"Studies on the Allergens of Aspergillus fumigatus" (NIAID) $40,000/year, 1979 - 1982, Co-Investigator
AI 19104	"Asthma and Allergic Diseases Center" (NIAID) $200,000/year, 1982 - 1986, Principal Investigator
HL 29319	"Immunoregulation in Hypersensitivity Pneumonitis (NHLBI) $100,000/year, 1982-1985, Co-Investigator
AI 29327	"Studies on Environmental Allergens" (NIAID) $50,000/year, 1983 - 1985,Principal Investigator
AI 23071	"Standardized Antigens for Diagnosis of Aspergillosis" (NIAID) $80,000/year 1986 - 1989, Co-Investigator
VA 2825	"Immunoregulation in Allergic Aspergillosis" $40,000/year, 1988 - 1991, Principal Investigator
NASA 9-18492	"Effects of Stress on Immune Response to Common Airborne Fungi" $60,000, 1991-1993, Co-Investigator
ALA-WI	"Immunoregulation in Allergic Aspergillosis" $25,000/year, 1991- 1993 Principal Investigator

Ansell International, Australia	"Studies of Latex Hypersensitivity" $965,000 1992 - 1998, Co-Investigator
CCU514541	"Latex Allergy Prevention in Health Care Workers" (CDC/NIOSH) $193,000/year 1997 - 2002, Co-Investigator
AI 42349	"Aspergillus Allergen and Allergic Aspergillosis (NIAID) $125,000/year 1998 - 2001, Co-Investigator

Invited Lectures, Workshops, Site Visits:

Lectures at various hospitals and Allergy meetings in Milwaukee and other cities.

Site visits in conjunction with the NIH General Clinical Research Centers Study Section.

Medical College Committees:

1981 - 1982	Chairman, Psychiatry Department Internal Review Committee
1983 - 1987	Chairman, Psychiatry Search Committee
1986 - 1987	Chairman, Task Force on Institutes, Centers and Programs
1987 - 1990	Member, PRN Committee
1994 - 1997	Member, Faculty Welfare Committee

Hospital Committees:

1985 - 1993	Member, Medical Care Evaluation Committee, Milwaukee County Medical Complex

Medical College Teaching:

1965 -	Department of Medicine Ward Rounds
1965 -	Lectures in Allergy-Immunology, Departments of Microbiology and Otolaryngology
1965 -	Bedside teaching in Allergy-Immunology
1965 -	Bedside teaching in General Medicine
1971 -	Weekly seminars in Allergy-Immunology
1971 - 1992	Director, Allergy-Immunology Training Program
1992 - 1996	Co-Director, Allergy-Immunology Training Program

Publications:

1. Slavin RG, Fink JN, Becker RJ, Feinberg SM: Delayed responses to antigen challenge in induced delayed reactivity· A clinical and cytological study in man. J Allergy 35:499-505, 1964

2. Patterson R, Fink JN, Nishimura ET, Pruzansky JJ: The passive transfer of immediate type hypersensitivity from man to other primates. J Clin Invest 44:140-148, 1965.

3. Patterson R, Fink JN, Wennemark J, Baum J, Pruzansky JJ, Nishimura ET: The biologic consequences of the passive transfer of the immediate type of hypersensitivity from man to monkey. J Allergy 37:295-310, 1966.

4. Nishimura ET, Patterson R, Fink JN, Wennemark J: Mycocardial lesions associated with experimental passive transfer of immediate type hypersensitivity Lab Invest 15:1269-1278,1966.

5. Fink JN, Patterson R, Pruzansky JJ: The characterization of human antibody to heterologous serum protein. J Allergy 38:84-92, 1966.

6. Fink JN, Barboriak JJ, Sosman AJ· Immunologic studies of pigeon breeders' disease J Allergy 39:214-221, 1967

7. Barboriak JJ, Fink JN, Knoblock HW, Sosman AJ Precipitin reactions in hypersensitivity pneumonitides. Proc Soc Exp Biol Med 125.991-993, 1967.

8. Arkins JA, Bukosky RJ, Fink JN: The characterization of skin sensitizing antibody induced in non-sensitive dogs. J Allergy 40:50-56, 1967.

9. Fink JN, Barboriak JJ, Sosman AJ, Bukosky RJ, Arkins JA: Antibodies against pigeon serum proteins in pigeon breeders. J Lab Clin Med 71 20-24, 1968.

10. Unger JD, Fink JN, Unger GF. Pigeon breeders' disease - Roentgenographic lung findings in a hypersensitivity pneumonitis. Radiology 90:683-687, 1968.

11. Arkins JA, Schlueter DP, Fink JN: The effect of corticosteroids on methacholine inhalation in symptomatic bronchial asthma. J Allergy 41.209-216, 1968.

12. Barboriak JJ, Fink JN, Scribner G: Antigenic specificity in hypersensitivity pneumonitis. Int· Arch Allergy Appl Immunol 33:473-477, 1968.

13. Fink JN, Barboriak JJ, Kaufman L: Cryptococcal antibodies in pigeon breeders' disease. J Allergy 41:297-301, 1968.

14. Elman AJ, Tebo T, Fink JN, Barbonak JJ: Reactions of poultry farmers against chicken antigens. Arch Environ Health 17:98-100, 1968.

15. Fink JN, Sosman AJ, Barboriak JJ, Schlueter DP, Holmes RA: Pigeon breeders' disease-a clinical study of a hypersensitivity pneumonitis. Ann Intern Med 68:1205-1219, 1968.

16. Bukosky RJ, Hogan MR, Arkins JA, Fink JN: Characterization of ragweed antibodies induced in non-atopic dogs. J Lab Clin Med 72:383-391, 1968.

17. Fink JN: Treatment of urticana and physical allergy. In: *Modern Treatment.* Patterson R (ed). 5:825-836, 1968.

18. Schlueter DP, Fink JN, Sosman AJ: Pulmonary functions in pigeon breeders' disease Ann Intern Med 70:457-470, 1969.

19. Hensley GT, Garancis JC, Cherayil GD, Fink JN: Lung biopsies of pigeon breeders' disease. Arch Pathol 87.572-579, 1969.

20. Fink JN, Tebo T, Barboriak JJ: Differences in the immune responses of pigeon breeders to pigeon serum proteins. J Lab Clin Med 74.325-330, 1969

21. Fink JN: A clinical study of a hypersensitivity pneumonitis IMJ 135.157-159, 1969.

22. Hogan MR, Bukosky RJ, Fink JN, Arkins JA, Barboriak JJ: The immunogenicity of pyridine extracted alum precipitated ragweed. J Allergy 44.70-76, 1969

23. Arkins JA, Gotway CA, Hogan MR, Fink JN: The effect of 6-mercaptopurine on spontaneous canine atopy J Allergy 44.108-112, 1969.

24. Fink JN: The importance of circulating antibody in human disease. Med Times 97.140-145, 1969.

25. Fink JN, Tebo T, Barboriak JJ: Characterization of human precipitating antibody to inhaled antigens. J Immunol 103:244-251, 1969.

26. Stungis TE, Fink JN: Hypersensitivity to acrylic resin. J Prosthet Dent 22:425-428, 1969.

27. Sosman AJ, Schlueter DP, Fink JN, Barboriak JJ Hypersensitivity to wood dust. N Engl J Med 283:977-980, 1969.

28. Edwards JH, Fink JN, Barboriak JJ: Excretion of pigeon serum proteins in pigeon droppings. Proc Soc Exp Biol Med 132.907-911, 1969.

29. Banaszak EF, Thiede WH, Fink JN: Hypersensitivity pneumonitis due to contamination of an air conditioner. N Engl J Med 283:271-276, 1970.

30. Fink JN, Hensley GT, Barboriak JJ: An experimental model of a hypersensitivity pneumonitis. J Allergy 46.156-161, 1970.

31. Edwards JH, Barboriak JJ, Fink JN: Antigens in pigeon breeders' disease. Immunology 19:729-734, 1970.

32. Fink JN, Banaszak EF, Thiede WH, Barboriak JJ: Interstitial pneumonitis due to hypersensitivity to an organism contaminating a heating system. Ann Intern Med 74:80-83, 1971.

33. Fink JN: Environment and pulmonary hypersensitivity (editorial) Ann Intern Med 74:293-294, 1971.

34. Lichtenstein LM, Bernstein IL, Lowell FC, Fink JN, Levy DA, Permutt S, Slavin RG, Leskowitz S, Chase MW, Dolovich J: Sensitization to enzymes in detergents (editorial). J Allergy 47:53-55, 1971.

35. Guttman RM, Tebo T, Edwards J, Barboriak JJ, Fink JN: The immune response of the pigeon (Columba livia). J Immunol 106:392-396, 1971.

38. Fink JN, Sosman AJ, Salvaggio JE, Barboriak JJ: Precipitins and the diagnosis of hypersensitivity pneumonitis (editorial). J Allergy Clin Immunol 48. 179-181, 1971.

37. Fink JN, Resnick AJ, Salvaggio JE: Presence of thermophilic actinomycetes in residential heating systems. Appl Microbiol 22.730-731, 1971.

38. Sunthonpalin P, Arkins JA, Fink JN. Charactenzation of induced homocytotropic antibody to ragweed and timothy pollen in non-atopic dogs. Clin Exp Immunol 8:825-834, 1971.

39. Barboriak JJ, Fink JN, Scribner G: Immunologic cross-reactions of thermophilic actinomycetes isolated from home environments. J Allergy Clin Immunol 49 81-85, 1972.

40. Fink JN, Schlueter DP, Sosman AJ, Unger GF, Barboriak JJ, Rimm AA, Arkins JA, Dhalwal KS: Clinical survey of pigeon breeders. Chest 62:271-281, 1972.

41. Fink JN: Hypersensitivity pneumonitis due to organic dust inhalation. NY State J Med 72:1834-1837, 1972.

42. Schlueter DP, Fink JN, Hensley GT Wood pulp workers' disease: A hypersensitivity pneumonitis caused by Altemaria. Ann Intern Med 77:907-914, 1972.

43. Fink JN: Respiratory hypersensitivity due to molds in air conditioning units. JAMA 222.374, 1972.

44. Fink JN. Editorial expression. Chest 62.174, 1972.

45. Fink JN: Urticaria and physical allergy In: *Allergic Diseases, Diagnosis and Management.* Patterson R (ed), J B Lippincott Co., Philadelphia, 1972, pp341-354.

46. Fink JN: Hypersensitivity pneumonitis. In: *Allergic Diseases, Diagnosis and Management,* Patterson R (ed), J.B. Lippincott Co., Philadelphia, 1972, pp 532-542.

47. Fink JN: Treatment failures in urticaria. In: *Allergic Diseases, Diagnosis and Management,* Patterson R (ed), J.B. Lippincott Co , Philadelphia, 1972, pp 605-607.

48. Patterson R, Fink JN, Pruzansky JJ, Reed C, Roberts M, Slavin R, Zeiss CR: Serum immunoglobulin levels in pulmonary allergic aspergillosis and certain other lung diseases, with special reference to immunoglobulin E. Am J Med 54:16-22, 1973.

49. Seabury J, Salvaggio JE, Domer J, Fink JN Kawai T: Characterization of thermophilic actinomycetes isolated from residential heating and humidification systems. J Allergy Clin Immunol 51:161-173, 1973.

50. Fink JN: Organic dust-induced hypersensitivity pneumonitis. J Occup Med 15:245-247, 1973.

51. Barboriak JJ, Sosman AJ, Fink JN, Maksud MG, McConnell LH, Hamilton LH: Metabolic changes in exercise-induced asthma. Clin Allergy 3:83-89, 1973.

52. Fink JN, Sosman AJ: Therapy of bronchial asthma Med Clin North Am 57: 801-807, 1973.

53. McConnell LH, Arkins JA, Fink JN: Induced homocytotropic antibody to bovine serum albumin in non-atopic dogs. J Allergy Clin Immunol 52:47-54, 1973.

54. Unger GF, Scanlon GT, Fink JN, Unger JD: A radiologic approach to hypersensitivity pneumonitis. Radiol Clin North Am 11:339-356, 1973.

55. McConnell LH, Fink JN, Schlueter DP, Schmidt MG: Asthma caused by nickel sensitivity. Ann Intern Med 78:888-890, 1973.

56. Fink JN, Barboriak JJ: Precipitating antibodies in human sera (editorial). Chest 64:416-417, 1973.

57. Fink JN: Allergy rounds: Hypersensitivity pneumonitis. J Allergy Clin Immunol 52:309-317, 1973.

58. Barboriak JJ, Fink JN, Sosman AJ, Dhaliwal KS: Precipitating antibody against pigeon antigens in sera of asymptomatic pigeon breeders. J Lab Clin Med 82:372-376, 1973

59 Fink JN, Sosman AJ: Allergic lung diseases not mediated by IgE. Med Clin North Am 58:157-163, 1974.

60. Hensley GT, Fink JN, Barbonak JJ: Hypersensitivity pneumonitis in the monkey Arch Pathol 97:33-38, 1974.

61. Patterson R, Sommers H, Fink JN: Farmer's lung following inhalation of Aspergillus flavus growing in moldy corn. Clin Allergy 4:79-86, 1974.

62. Hodges GR, Fink JN, Schlueter DP: Hypersensitivity pneumonitis caused by a contaminated cool-mist vaporizer. Ann Intern Med 80:501-504, 1974.

63. Moore VL, Fink JN, Barboriak JJ, Ruff LL, Schlueter DP: Immunologic events in pigeon breeder's disease. J Allergy Clin Immunol 53.319-328, 1974.

64. Owen GC, Glassner DM, Fink JN: Allergic bronchopulmonary aspergillosis of prolonged duration. Clin Allergy 4.141-147, 1974.

65. Fink JN: Hypersensitivity pneumonitis due to organic dusts. Clin Notes on Resp Diseases 13:3-9, 1974.

66. Flaherty DK, Barbonak J, Emanuel D, Fink JN, Marx J, Moore V, Reed CE, Roberts R: Multi-laboratory comparison of three immunodiffusion methods used for the detection of precipitating antibodies in hypersensitivity pneumonitis. J Lab Clin Med 84:298-306, 1974.

67. Fink JN: Hypersensitivity pneumonitis: A case of mistaken identity. Hosp Pract 9:119-124, 1974.

68. Banaszak EF, Barboriak JJ, Fink JN, Scanlon G, Schlueter DP, Sosman A, Thiede W, Unger G: Epidemiologic studies relating thermophilic fungi and hypersensitivity lung syndrome. Am Rev Respir Dis 110:585-591, 1974.

69. Moore VL, Fink JN: Immunologic studies in hypersensitivity pneumonitis - Quantitative precipitins and complement-fixing antibodies in symptomatic and asymptomatic pigeon breeders. J Lab Clin Med 85:540-545, 1975.

70. Thiede WH, Banaszak EF, Fink JN, Unger GF, Scanlon GT: Hypersensitivity studies in Popple (Aspen tree) peelers. Chest 67:405-407, 1975.

71. Moore VL, Schanfield MS, Fink JN, Fudenberg HH: Immunoglobulin allotypes in symptomatic and asymptomatic pigeon breeders Proc Soc Exp Biol Med 149:307-310, 1975

72. Kurup VP, Barbonak JJ, Fink JN, Lechevalier M: Thermoactinomyces candidus, a new species of thermophilic actinomycetes. Int J System Bact 25:150-154, 1975.

73. Kurup VP, Fink JN: A scheme for the identification of thermophilic actinomycetes associated with hypersensitivity pneumonitis. J Clin Microbiol 2:55-61, 1975.

74. Soifer MM, Hirsch SR, Fink JN: The Wisconsin Allergy Society fee and practice survey. J Allergy Clin Immunol 56:117-126, 1975

75. Fink JN: Recurrence of childhood asthma in adult on geographic relocation. (letter) JAMA 233:1398, 1975

76. Fink JN: A new lung disease (editorial) Chest 67:254, 1975.

77. Moore VL, Hensley GT, Fink JN: An animal model of hypersensitivity pneumonitis in the rabbit. J Clin Invest 56.937-944, 1975.

78. Fink JN, Moore VL, Barboriak JJ: Cell-mediated hypersensitivity in pigeon breeders. Int Arch Allergy Appl Immunol 49:831-836, 1975

79. Phanuphak P, Salvaggio J, Fink JN, Kohler P: Incidence of serum precipitins against organic dust antigens in different populations by counter immunoelectrophoresis. Chest 68:753-758, 1975.

80. Patterson R, Schatz M, Fink JN, DeSwarte RS, Roberts M, Cugell D: Pigeon breeders' disease. I. Serum immunoglobulin concentrations; IgG, IgM, IgA, IgE antibodies against pigeon serum. Am J Med 60:144-151, 1976

81. Fink JN, Banaszak EF, Barboriak JJ, Hensley GT, Kurup VP, Scanlon GT, Schlueter DP, Sosman AK, Thiede WH, Unger GF: Interstitial lung disease due to contamination of forced air systems. Ann Intern Med 84:406-413, 1976.

82. Schatz M, Patterson R, Fink JN, Moore VL: Pigeon breeder's disease. II. Pigeon antigen-induced proliferation of lymphocytes from symptomatic and asymptomatic subjects. Clin Allergy 6:7-17, 1976.

83. Kurup VP, Barboriak JJ, Fink JN, Scribner G: Immunologic cross-reactivity among thermophilic actinomycetes associated with hypersensitivity pneumonitis. J Allergy Clin Immunol 57:417-421, 1976.

84. Schatz M, Patterson J, Fink J, Moore V, Rodey G, Cunningham A, Roberts M, Harris K: Pigeon breeders' disease. III. A study of a family exposed to doves. Clin Exp Immunol 24:33-41, 1976.

85. Santives T, Roska AK, Hensley GT, Moore VL, Fink JN, Abramoff P: Immunologically induced lung disease in guinea pigs: A comparison of ovalbumin and pigeon serum as antigens. J Allergy Clin Immunol 57:582-594, 1976

86. Soifer MM, Barboriak JJ, Chryssanthopoulos C, Fink JN, Funahashi A, Hamilton LH, Maksud MG: Metabolic changes in exercise-induced and methacholine-induced bronchoconstriction. J Allergy Clin Immunol 57:577-581, 1976.

87. Barboriak JJ, Knoblock HW, Hensley GT, Gombas OF, Fink JN. Animal model of sensitization by inhalation. Clin Exp Immunol 24:542-545, 1976.

88. Fink JN: Diseases of the lung. In: *Manual of Clinical Immunology*. Rose N, Campbell L (eds). American Society for Microbiology, Washington, D.C., 1976, pp 616-619.

89. Patterson R, Roberts M, Roberts RC, Emanuel DA, Fink JN: Antibodies of different immunoglobulin classes against antigens causing farmer's lung. Am Rev Respir Dis 114.315-324, 1976.

90. Kurup VP, Fink JN, Bauman DM: Thermophilic actinomycetes from the environment. Mycologia 68:662-665, 1976.

91. Kurup VP, Fink JN: Additional characterstics for the differentiation of Thermoactinomyces candidus and T vulgaris. The Biology of the Actinomycetes and Related Organisms 11:130-132, 1976.

92. Cunningham AS, Fink JN, Schlueter DP: Childhood hypersensitivity pneumonitis due to dove antigens. Pediatrics 56.436-442, 1976.

93. Miller MM, Patterson R, Fink JN, Roberts M: Chronic hypersensitivity lung disease and recurrent episodes of hypersensitivity pneumonitis due to a contaminated central humidifier. Clin Allergy 6:451-462, 1976.

94. Metzger JW, Patterson R, Fink JN, Semerdjian R, Roberts M. Sauna-takers disease: Hypersensitivity pneumonitis due to contaminated water in home sauna. JAMA 236:2209-2211, 1976.

95. Sampson D, Rodey GE, Fink J, Junkerman CL, Metzger J: Splenic suppressor cells in hypogammaglobulinaemia. Br Med J 1:614, 1977.

96. Schatz M, Patterson R, Fink J: Immunopathogenesis of hypersensitivity pneumonitis. J Allergy Clin Immunol 60.27-37, 1977.

97. Boren MN, Moore VL, Abramoff P, Fink JN: Pigeon breeder's disease. Antibody response of man against a purified component of pigeon dropping extract. Clin Immunol Immunopathol 8:108-115, 1977.

98. Kurup VP, Barboriak JJ, Fink JN: Indirect immunofluorescent detection of antibodies against thermophilic actinomycetes in patients with hypersensitivity pneumonitis. J Lab Clin Med 89:533-539, 1977.

99. Tebo TH, Moore VL, Fink JN: Antigens in pigeon breeder's disease. Clin Allergy 7:103-108, 1977.

100. Kurup VP, Fink JN: Extracellular antigens of Micropolyspora faeni grown in synthetic medium. Infect Immun 15:608-613, 1977.

101. Fink JN: Chronic urticaria regressing with intake of alcoholic beverages. (letter) JAMA 237:1377, 1977.

102. Fink JN, Barboriak JJ, Kurup VP, Scribner GH: Variability of extracts used in immunoprecipitin tests. J Allergy Clin Immunol 60.238-241, 1977.

103. Cohen SH, Fink JN, Garancis JC, Hensley GT, Barbonak JJ, Schlueter DP. Sarcoidosis in hypersensitivity pneumonitis. Chest 72:588-592, 1977.

104. Burke GW, Carrington CB, Strauss R, Fink JN, Gaensler EA. Allergic alveolitis caused by home humidifiers. Unusual clinical features and electron microscopic findings JAMA 238:2705-2708, 1977.

105. Cohen SH, Fink JN: Allergic patient: Guide to office evaluation. Hosp Med 13:14-31, 1977.

106. Kurup VP, Barboriak JJ, Fink JN: Comments on taxonomy of some Thermoactinomyces species. The Biology of Actinomycetes and Related Organisms 12:53-54, 1978.

107. Chryssanthopoulos C, Barboriak JJ, Fink JN, Stekiel WJ, Maksud MG: Adrenergic responses of asthmatic and normal subjects to sub-maximal and maximal work levels. J Allergy Clin Immunol 61:17-22, 1978.

108. Fink JN, Cohen SH: Classification of allergic reactions and mechanisms of the immediate allergic reaction. In: *Handbook of Clinical Laboratory Science* CRC Press, Inc., Cleveland, Ohio, 1978.

109. Schlueter DP, Banaszak EF, Fink JN, Barboriak JJ: Occupational asthma due to tetrachlorophthalic anhydride J Occup Med 20:183-188, 1978.

110. Arnow PM, Fink JN, Schlueter DP, Barboriak JJ, Mallison G, Said SI, Martin S, Unger GF, Scanlon GT, Kurup VP: Early detection of hypersensitivity pneumonitis in office workers. Am J Med 64:236-242, 1978.

111. Schwartz HJ, Chester EH, Fink JN, Payne CB, Baum GL: On respirable organic antigens, mattresses and some idiopathic lung disease Ann Allergy 40:385-386, 1978.

112. Fink JN: Hypersensitivity pneumonitis. In: *Allergy, Principles and Practice*. Middleton E, Reed CE, Ellis EF (eds). C.V. Mosby, St Louis, 1978; pp 855-867.

113. Kurup VP, Fink JN: Evaluation of methods to detect antibodies against Aspergillus fumigatus. Am J Clin Pathol 69:414-417, 1978.

114. Fink JN: Cessation of allergic asthma immunotherapy. (letter) JAMA 239:2545, 1978.

115. Fink JN, Salvaggio JE (eds): NIAID workshop on antigens in hypersensitivity pneumonitis. J Allergy Clin Immunol 61:199-239, 1978.

116. Patterson R, Fink JN, Roberts M, Kelly JF, Sommers HM: Antibody activity in sera of patients with humidifier disease. Study of the water supply as a source of antigens. J Allergy Clin Immunol 62:103-108, 1978.

117. Forman SR, Fink JN, Moore VL, Wang J, Patterson R: Humoral and cellular immune responses in Aspergillus fumigatus pulmonary disease. J Allergy Clin Immunol 62:131-136, 1978.

118. Cohen SH, Koethe SM, Kozin F, Rodey G, Arkins JA, Fink JN: Acquired angioedema associated with rectal carcinoma and its response to danazol therapy. J Allergy Clin Immunol 62:217-221, 1978.

119. Kurup VP, Fink JN, Scribner G, Falk MJ: Antigenic variability of Aspergillus fumigatus strains. Microbios 19:191-204, 1978.

120. Fink JN, Schlueter DP: Bathtub refinisher's lung: An unusual response to toluene diisocyanate. Am Rev Respir Dis 118:955-959, 1978.

121. Pagan EF, Kurup VP, Fink JN: Incidence of serum precipitins against thermophilic actinomycetes, pigeon dropping and fungal antigens in Puerto Rico. Bol Asoc Med PR 70:375-381, 1978.

122. Fink JN: The asthmatic. Am Fam Physician 28:124-127, 1978.

123. Rodey GE, Fink J., Koethe S, Schlueter D, Witkowski J, Beltonville P, Rimm A, Moore V: A study of HLA-A, B, C and DR specificities in pigeon breeder's disease. Am Rev Respir Dis 119: 755-759, 1979.

124. Schatz M, Patterson R, Fink JN: Immunologic lung disease. N Engl J Med 300: 1310-1320, 1979.

125. Kurup VP, Fink JN: Antigenic relationships among thermophilic actinomycetes. Sabouraudia 17.163-169, 1979.

126. Graves TS, Fink JN, Patterson R, Kurup VP, Scanlon GT: A familial occurrence of allergic bronchopulmonary aspergillosis. Ann Intern Med 91:378-382, 1979.

127. Kurup VP, Fink JN: Antigens of Micropolyspora faeni strains. Int Arch Allergy Appl Immunol 60:140-147, 1979.

128. Cohen SH, Yunginger JW, Rosenberg N, Fink JN: Acute allergic reaction after composite pollen ingestion J Allergy Clin Immunol 64:270-274, 1979.

129. Patterson R, Wang JLF, Fink JN, Calvanico NJ, Roberts M: IgA and IgG antibody activities of serum and bronchoalveolar fluid from symptomatic and asymptomatic pigeon breeders. Am Rev Respir Dis 120:1113-1118, 1979.

130. McGovern RR, Maron MD, Dawson CA, Moore VL, Garancis J, Schlueter DP, Fink JN: Pulmonary function in rabbits with BCG-induced lung disease. Respiration 38: 227-232, 1979.

131. Fink JN: The use of bronchoprovocation in the diagnosis of hypersensitivity pneumonitis. J Allergy Clin Immunol 64:590-591, 1979.

132. Fink JN, Cohen SH: Classification of allergic reactions and mechanisms of immediate allergic reactions, Section F: Immunology, vol 1, part 2. In: *CRC Handbook Series in Clinical Laboratory Science.* Baumgarten A, Richards FE (section eds), CRC Press, Boca Raton, 1979; pp 27-31.

133. Scribner GH, Barboriak JJ, Fink JN: Prevalence of precipitins in groups at risk of developing hypersensitivity pneumonitis. Clin Allergy 10:91-95, 1980.

134. Ganier M, Lieberman P, Fink JN, Lockwood DG: Humidifier lung. An outbreak in office workers. Chest 77:183-187, 1980.

135. Moore VL, Pedersen GM, Hauser WC, Fink JN A study of lung lavage materials in patients with hypersensitivity pneumonitis· In vitro response to mitogen and antigen in pigeon breeder's disease. J Allergy Clin Immunol 65·365-370, 1980.

136. Basich JE, Resnick A, Fink JN: Hypersensitivity pneumonitis and legionnaires' disease. Am Rev Respir Dis 121:885-887, 1980.

137. Kurup VP, Fink JN, Barboriak JJ, Scribner G. The detection of circulating antibodies against antigens from three strains of Aspergillus fumigatus. Mykosen 23:368-372, 1980.

138. Fink JN: Diseases of the lung. In: *Manual of Clinical Immunology*, 2nd ed. Rose N, Friedman H (eds). American Society of Microbiology, Washington, D.C , 1980, pp 829-832.

139. Calvanico NJ, Ambegaonkar SP, Schlueter DP, Fink JN. Immunoglobulin levels in bronchoalveolar lavage fluid from pigeon breeders. J Lab Clin Med 96·129-140, 1980.

140. Fink JN: Ventilation pneumonitis. In: Advances in Allergology and Immunology Oehling A ed Pergawon Press, Oxford 1980 pp 355-356

141. Fink JN: Shellfish sensitivity and providone-iodine use (letter) JAMA 243:2242, 1980.

142. Lutsky I, Fink JN, Arkins JA, Hoffman R, Morouse M. Skin test reactivity to dog-derived antigens. Clin Allergy 10:331-340, 1980

143. Kagen S, Fink JN, Sohnle P, Kurup VP: Aspergillus as inhalable contaminant of marijuana. N Engl J Med 304:483-484, 1981.

144. Chusid MJ, Sohnle PG, Fink JN, Shea ML: A genetic defect of granulocyte oxidative metabolism in a man with disseminated aspergillosis. J Lab Clin Med 97:730-738, 1981.

145. Fink JN, Moore VL: Experimental hypersensitivity pulmonary granulomas. In: *Basic and Clinical Aspects of Granulomatous Diseases*. Boros D, Yoshida T (eds). Elsevier North Holland, 1981, New York; pp 173-178.

146. Hirsch SR, Kalbfleisch JH, Golbert TM, Josephson BM, McConnell LH, Scanlon G, Kniker WT, Fink JN, Murphree JJ, Cohen SH: Rinkel injection therapy: A multi-center controlled study. J Allergy Clin Immunol 68:133-155, 1981.

147. Basich JE, Graves TS, Baz MN, Scanlon G, Hoffmann RG, Patterson R, Fink JN: Allergic bronchopulmonary aspergillosis in corticosteroid-dependent asthmatics. J Allergy Clin Immunol 68:98-102, 1981.

148. Banaszak EF, Fink JN: Hypersensitivity pneumonitis. In: *Pulmonary Disease in the Adult*. Gracey DG (ed). Year Book, Chicago, 1981; pp 157-172.

149. Pagan EF, Kurup VP, Cortes FM, Lotti SL, Fink JN: The prevalence of thermophilic actinomycetes in sugar cane related environments, and precipitins in the population in Puerto Rico. Bol Asoc Med PR 73:235-240, 1981.

150. Patterson R, Fink JN, Miles WB, Basich JE, Schlueter DP, Tinkelman DG, Roberts M: Hypersensitivity lung disease presumptively due to Cephalosporium in homes contaminated by sewage flooding or by humidifier water. J Allergy Clin Immunol 68:128-132, 1981.

151. Kagen SL, Fink JN, Schlueter DP, Kurup VP, Fruchtman RS: Streptomyces albus: A new cause of hypersensitivity pneumonitis J Allergy Clin Immunol 68:295-299, 1981.

152. McCormick JR, Thrall RS, Ward PA, Moore VL, Fink JN. Serum angiotensin converting enzyme levels in patients with pigeon breeder's disease. Chest 80:431-433, 1981.

153. Kurup VP, Ting EY, Fink JN, Calvanico NJ: Characterization of Micropolyspora faeni antigens. Infect Immun 34:508-512, 1981

154. Calvanico NJ, DuPont BL, Huang CJ, Patterson R, Fink JN, Kurup VP: Antigens of Aspergillus fumigatus. I. Purification of cytoplasmic antigen reactive with sera of patients with Aspergillus-related disease. Clin Exp Immunol 45:662-671, 1981.

155. Keller RH, Fink JN, Lyman S, Pedersen G: Immunoregulation in hypersensitivity pneumonitis. I. Differences in T-cell and macrophage suppressor activity in symptomatic and asymptomatic pigeon breeders. J Clin Immunol 2:46-54, 1982.

156. Kruetzer DL, McCormick JR, Thrall RS, Hupp JR, Moore VL, Fink JN Elevation of serum chemotactic factor inactivator activity during acute inflammatory reactions in patients with hypersensitivity pneumonitis. Am Rev Respir Dis 125:612-614, 1982.

157. Fink JN: Evaluation of the patient with occupational immunologic lung disease. J Allergy Clin Immunol 70:11-14, 1982.

158. Fink JN (assoc ed) Primer on allergic and immunologic diseases. Salvaggio JE (ed) JAMA 248:2579-2772, 1982.

159. Fink JN: Hypersensitivity pneumonitis. In: *Environmental and Occupational Medicine* Rom WN (ed) Little, Brown & Co., Boston, 1983; pp 215-220.

160. Kagen SL, Kurup VP, Sohnle PG, Fink JN: Marijuana smoking and fungal sensitization. J Allergy Clin Immunol 71:389-393, 1983

161. Kidd JM, Cohen SH, Sosman, AJ, Fink JN: Food-dependent exercise-induced anaphylaxis. J Allergy Clin Immunol 71.407-411, 1983.

162. Fink JN: Hypersensitivity pneumonitis. In: *Current Therapy in Allergy and Immunology.* 1983-1984. Lichtenstein LM and Fauci AS (eds). B.C. Decker, Philadelphia, 1983; pp 196-197.

163. Fink JN: Hypersensitivity pneumonitis In: *Harrison's Principles of Internal Medicine.* Petersdorf RG, Adams RD, Braunwald E, Isselbacher K, Martin JB, Wilson JD (eds). McGraw-Hill, New York, 1983; pp 1519-1524.

164. Fink JN: House dust sensitivity (letter) JAMA 249:410, 1983

165. Lutsky I, Kalbfleisch J, Fink JN: Occupational allergy to laboratory animals: Employer practices. J Occup Med 25:372-376, 1983.

166. Bar-Sela S, Shalit M, Kalbfleisch JH, Fink JN: The relative value of skin tests and radioallergosorbent test in the diagnosis of bee sting hypersensitivity. J Allergy Clin Immunol 72:690-694, 1983.

167. Kurup VP, Resnick A, Kagen SL, Cohen SH, Fink JN: Allergenic fungi and actinomycetes in smoking materials and their health implications. Mycopathologia 82:61-64, 1983.

168 Fink JN: Pigeon breeder's disease. Clin Rev Allergy 1 497-508, 1983.

169. Kurup VP, Resnick A, Scribner GH, Kalbfleisch JH, Fink JN: Comparison of antigens and serological methods in Aspergillus fumigatus antibody detection. Mykosen 27.43-50, 1983.

170. Kurup VP, Barbonak JJ, Fink JN: Hypersensitivity pneumonitis In: *Mold Allergy*. Al-Doory Y, Domson JF (eds). Lee & Febiger, Philadelphia, 1983; pp 216-243

171. Kurup VP, Ting E, Fink JN. Immunochemical characterization of Aspergillus fumigatus antigens. Infect Immun 41:698-701, 1983.

172. Laufer P, Fink JN, Bruns WT, Unger GF, Kalbfleisch JH, Greenberger PA, Patterson R: Allergic bronchopulmonary aspergillosis in cystic fibrosis. J Allergy Clin Immunol 73:44-48, 1984.

173. Fink JN: Hypersensitivity pneumonitis J Allergy Clin Immunol 74.1-14, 1984.

174. Fink JN. Allergic bronchopulmonary aspergillosis. In. *Current Therapy in Internal Medicine*. Bayless TM, Brain MC, Chemiack R. (eds) B.C. Decker, Philadelphia, 1984; pp 811-812.

175. Fink JN: Occupational asthma from inorganic chemicals. Clin Immunol Allergy 4.125-129, 1984.

176. Calvanico NJ, Fink JN, Keller RJ. Hypersensitivity pneumonitis In. *Immunology of the Lung and Upper Respiratory Tract* Bienenstock J. (ed). McGraw-Hill, New York, 1984, pp 365-385

177. Chryssanthopoulos C, Fink JN: Clinical-immunologic correlates: A differential diagnostic update. Allergic bronchopulmonary aspergillosis. J Asthma 21:41-51, 1984.

178. Fink JN: Allergy to large-pitted fruits (letter) JAMA 252: 3415, 1984.

179. Bar-Sela S, Fink JN: Recurrent dyspnea in a 35 year old female. Ann Allergy 52:73-74 (part one); 99-101 (part two), 1984.

180. Schwartz HJ, Chester EH, Fink JN: Exposures to pathogenic fungi in a voluntary hospital. J Allergy Clin Immunol 74:861, 1984

181. Keller RH, Swartz S, Schlueter DP, Bar-Sela S, Fink JN: Immunoregulation in hypersensitivity pneumonitis: Phenotypic and functional studies of bronchoalveolar lavage lymphocytes. Am Rev Respir Dis 130:766-771, 1984.

182. Fink JN: Allergic bronchopulmonary aspergillosis Chest 87 (Suppl):815-845, 1985.

183. Patterson R, Fink JN: Responsibilities of the primary care internist in the care of the allergic patient (editorial). Ann Intern Med 102:263-264, 1985.

184. Lutsky I, Fink JN, Kidd J, Dahlberg ME, Yunginger JW: Allergenic properties of rat urine and pelt extracts. J Allergy Clin Immunol 75:279-284, 1985.

185. Piechura JE, Kurup VP, Fink JN, Calvanico NJ: Antigens of Aspergillus fumigatus III. Comparative immunochemical analysis of clinically relevant aspergilli and related fungal taxa. Clin Exp Immunol 59:716-724, 1985.