

Gluten in pharmaceutical products

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The Notes section welcomes the following types of contributions: (1) practical innovations or solutions to everyday practice problems, (2) substantial updates or elaborations on work previously published by the same authors, (3) important confirmations of research findings previously published by others, and (4) short research reports, including practice surveys, of modest scope or interest.

Notes should be submitted with AJHP's manuscript checklist. The text should be concise, and the number of references, tables, and figures should be limited.

Celiac disease, also known as sprue, is a gluten-sensitive enteropathy elicited by an autoimmune response to the ingestion of wheat, rye, and barley¹ and possibly oats.² The treatment is lifelong total abstinence from gluten,¹ the alcohol-soluble peptides responsible for triggering the hypersensitivity. Gluten in all forms and amounts must be excluded from food,¹ drugs,^{1,3} and nutritional products³ ingested by people with celiac disease.

Celiac disease is more common than most health care providers realize. In several European countries, the prevalence is approximately 1 in 300.⁴⁻⁷ Preliminary studies in the United States indicate a similar prevalence.⁷ Classic symptoms include diarrhea, abdominal distention, weight loss, and asthenia; nongastrointestinal symptoms also often occur.^{6,8} Consequences of untreated celiac disease can include malnutrition, osteoporosis,^{9,10} malignancy,^{4,5,11,12} anemia, and infertility.^{4,5} Total permanent exclusion of gluten allows rejuvenation of the small bowel and reso-

lution of symptoms, and complications are prevented or curtailed.^{4,5,9-13}

Optimal care of the celiac disease patient requires that the pharmacist and other members of the health care team have accurate information about the gluten content of pharmaceutical and nutritional products. The objective of this study was to identify pharmaceutical companies with an established policy of producing only gluten-free products and to identify specific gluten-free and gluten-containing products produced by companies without such a policy.

Methods. We designed a six-item survey to update and extend the findings on gluten-free pharmaceutical and nutritional products previously

reported by Olson and Gallo¹⁴ and Pence and Garrison.¹⁵ In March and April 1998 we mailed 172 surveys to pharmaceutical companies listed in the 1998 *Physicians' Desk Reference*¹⁶ and the 1998 generics supplement to *Pharmacy Times*.¹⁷ Follow-up telephone calls were made to companies that did not respond within a reasonable period. Responses were collected from March 1998 to July 1999.

The first survey item asked if the company had a policy of producing gluten-free products. If the answer was affirmative, the respondent was directed to the second item, which asked if the company guaranteed the gluten free status of its products. If the company did not have a policy, the respondent was directed to item 3, which asked the respondent to identify products that were known to be gluten free. Item 4 asked the respondent to list any company products known to contain gluten or whose gluten status was unknown. Item 5 asked for a listing of any excipients commonly used in the company's products that were potential sources of gluten. The sixth item allowed the respondent to offer explanations of or disclaimers to the information.

Results. Completed surveys were

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received from 38 companies after the initial mailing. Another 26 companies responded in the form of a letter rather than with a completed survey. These letters partially or completely responded to the survey questions. Follow-up telephone calls netted 14 additional written responses and 22 oral responses. Five companies responded by returning an uncompleted survey; each stated that the information being sought was not applicable because the company did not manufacture any product (i.e., the company was a distributor, repackager, etc.). The remainder failed to return the survey or to respond to the telephone call. One survey was returned initially as “addressee unknown.”

Five respondents stated that their company had an established policy of producing gluten-free products, and five stated that they guaranteed the gluten-free status (Table 1). Table 1 also identifies responding companies that did not have a policy or guarantee the gluten-free status of their products but stated that they believed all their products were gluten free. Another group of respondents did not refer to their products as gluten free but stated that they added no ingredients derived from wheat, oats, rye, barley, or spelt (Table 2). They generally claimed that this information was offered so that the celiac disease patient and his or her physician could make a decision about the appropriateness of a product for a patient. In answering survey items 3 and 4, respondents named the specific products that were known to be gluten free (Appendix A) and those known to contain gluten or whose gluten status was unknown (Appendix B). Only one respondent completed item 5, the question that asked for a list of gluten-containing ingredients commonly used in the company's products.

Several disclaimers or explanations were received from respondents who had neither a policy nor a guarantee regarding the gluten status

Table 1.

Companies Indicating Their Products Are Gluten Free^a

Athena Neurosciences (South San Francisco, CA)
Blaine Company (Burlington, KY)
Colgate Oral Pharmaceuticals (Canton, MA)
Dista Products (Indianapolis, IN)
C. B. Fleet Company (Lynchburg, VA) ^{b,c}
Forest Laboratories (St. Louis, MO)
Geneva Pharmaceuticals (Broomfield, CO) ^d
Immunex Corporation (Seattle, WA)
Jacobus Pharmaceutical Company (Princeton, NJ) ^{b,c}
Eli Lilly and Company (Indianapolis, IN)
M.G.I. Pharma (Minnetonka, MN) ^c
Mission Pharmacal Company (San Antonio, TX)
Morton Grove Pharmaceuticals (Morton Grove, IL) ^c
Mutual Pharmaceutical Company (Philadelphia, PA)
Nephron Pharmaceuticals (Orlando, FL) ^b
Novartis Pharmaceuticals Corporation (East Hanover, NJ)
Novopharm USA (Schaumburg, IL) ^c
Pharmaceutical Associates (Conestee, SC)
Procter & Gamble Pharmaceuticals (Mason, OH)
Rhône-Poulenc Rorer Pharmaceuticals (Collegeville, PA)
Roche Pharmaceuticals (Nutley, NJ)
Scandipharm (Birmingham, AL) ^b
Schein Pharmaceutical (Florham Park, NJ) ^e
Tap Pharmaceuticals (Deerfield, IL)
United Research Laboratories (Philadelphia, PA)
Wallace Laboratories (Cranbury, NJ)
Vitaline Corporation (Ashland, OR) ^b

^aUnless otherwise indicated, companies indicated a belief but had no policy or guarantee that their products were gluten free. For such companies, the gluten-free status of any product may change in the future.

^bHas a policy of producing gluten-free products.

^cGuarantees that products are gluten free.

^dApplies only to products manufactured by Geneva Pharmaceuticals.

^eApplies only to products manufactured by Danbury Pharmacal (Danbury, CT).

Table 2.

Companies Indicating They Do Not Add Ingredients Derived from Wheat, Oats, Barley, Rye, or Spelt to Products

Greenstone Ltd. (Portage, MI) ^{a,b}
Hoechst Marion Roussel (Kansas City, MO) ^a
Janssen Pharmaceuticals (Titusville, NJ) ^a
Pharmacia & Upjohn Co. Inc. (Kalamazoo, MI) ^{a,b}
G. D. Searle & Co. (Chicago, IL) ^a
Sidmak Laboratories (East Hanover, NJ) ^a
SmithKline Beecham Pharmaceuticals (Philadelphia, PA) ^{a,b}

^aCompany does not apply the term “gluten free” to products.

^bCompany cannot guarantee that ingredients purchased from other sources are free from minute amounts of gluten contaminants.

of their products. Most commonly, these respondents explained that, although they believed that their products were devoid of gluten, they neither certified the gluten-free status nor tested for gluten in the final products. Several companies also explained that they could not guarantee the gluten-free status of finished products because they were unable to obtain guarantees of gluten-free status from the suppliers of raw materials. Other respondents indicated that, although the starch derivatives

in their products were corn or potato based, they could not exclude the possibility that minute amounts of gluten contaminants from other raw materials at the same locations were present in their inactive ingredients. Commonly, respondents warned that, although their products were gluten free at the time of the survey, their suppliers of raw materials and inactive ingredients could change without notice and that this might affect the gluten status of products. They stressed that information about

gluten content was only as current as the date of correspondence. Lastly, many respondents stated that they were not able to provide a list of gluten-free or gluten-containing products but were able and willing to investigate the gluten content of an individual product in a specific lot for an inquiring health care provider or patient.

Discussion. The information obtained from this survey, although somewhat dated, highlights the challenges in obtaining gluten-free drug and nutritional products. Few companies reported definitively that their products were gluten free. Raw materials obtained from outside sources were the primary reason for this ambiguity.

Gluten, when present in drug and nutritional products, is a component of inactive ingredients added during manufacturing. Inactive ingredients derived from whole grains, grain flour, or grain starch are the most common sources of gluten. Excipients, such as unspecified starch¹⁸⁻²⁰ or pregelatinized starch,^{18,20} dusting powder, flour, and gluten,^{3,21} may be derived from wheat. These inactive ingredients have the highest potential to be sources of gluten in drug and nutritional products. Dextri-Maltose and caramel coloring may be sources of gluten when barley malt is used in manufacturing.^{20,22} Other starch derivatives, such as sodium starch glycolate,^{20,23} dextrin,²⁴ and maltodextrin,²⁰ are processed almost exclusively from potato starch or cornstarch but may rarely be derived from other starches. The botanical source of each of these ingredients must be determined before the product can be considered safe for the celiac disease patient.

Procuring gluten-free products is facilitated when a pharmaceutical company has an established policy of producing only gluten-free products. In such a case, much of the uncertainty about the appropriateness of a product for the celiac disease patient is removed. Only five of the companies surveyed had such a policy, how-

ever. Further complicating the picture is that information is only as current as the date on which it was communicated. Consequently, the patient, the pharmacist, or the physician must contact a manufacturer periodically to be sure that a given product's status has not changed. It is best to refer to the lot number of the product whenever possible.

The claim "new formulation," "new product appearance," or "new manufacturer" on a product label is an important indicator of a potential change in the product's gluten status. Either active ingredients or excipients may have changed. Such claims should alert the health care provider or the patient to contact the manufacturer to determine if the change affected the product's gluten status.

For patients with celiac disease, any medication that enters the gastrointestinal tract, whether it is orally or rectally administered, must be gluten free. The risk of inadvertent gluten ingestion comes not only from limited knowledge about potential gluten-containing excipients but also from failure to disclose excipient sources in package labeling. In our survey, a significant number of respondents were not aware of excipients other than wheat starch that may contain gluten. Currently, a few prescription medications are actually labeled "gluten free" (e.g., prednisone and dexamethasone tablets manufactured by Roxane Laboratories). If this information were included on all gluten-free medications, it would greatly help those with celiac disease avoid gluten intake. A reliable means of identifying and obtaining gluten-free medications and nutritional products is essential to the health of these persons.

Conclusion. Only 5 of 100 pharmaceutical companies that responded to a survey reported having a policy of producing gluten-free products. Many companies believed their products to be gluten free but could not guarantee it.

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Appendix A—Products indicated to be gluten free

Agouron Pharmaceuticals (La Jolla, CA)

Viracept Tablets

American Lecithin Company (Oxford, CT)

PhosChol

Apothecan (Plainsboro, NJ)

Desyrel Tablets

Estrace Tablets

Questran, Questran Light Powder

Trimox Capsules and Suspension

Astra USA (Westborough, MA)

Aquasol A Drops

Aquasol E Drops

Morphine Sulfate Concentrated Oral

Solution 20 mg/mL

Morphine Sulfate Oral Solution 2 mg/mL

Pulmicort Turbuhaler

Rhinocort Nasal Inhaler

Toprol XL Tablets

Xylocaine 5% Flavored Ointment

Athena Neurosciences (South San Francisco, CA)

Atamet Tablets

Atapryl Tablets

Diastat Rectal Gel

Mysoline Tablets

Permax Tablets

Zanaflex Tablets

Bayer Corporation Pharmaceutical Division (West Haven, CT)

Adalat Capsules

Adalat CC Tablets

Baycol Tablets

Biltricide Tablets

Cipro Tablets

Nimotop Capsules

Precose Tablets

Bertek Pharmaceuticals (Morgantown, WV)

Clorpres Tablets

Maxzide Tablets

Maxzide-25 Tablets

Blaine Company (Burlington, KY)

Mag-Ox Tablets

Uro-Mag Tablets

Bristol-Myers Squibb Company (Princeton, NJ)

BuSpar Tablets

Glucophage Tablets

Monopril Tablets

Pravachol Tablets

Serzone Tablets

Eisai (Teaneck, NJ)

Aricept Tablets

Glaxo Wellcome (Research Triangle Park, NC)

Alkeran Tablets

Daraprim Tablets

Imitrex Tablets

Lanoxin Tablets

Purinethol Tablets

Retrovir Capsules

Trandate Tablets

Wellbutrin SR Tablets

Zantac 150 EFFERdose Tablets

Zantac 150 EFFERdose Granules

Zantac 150 GELdose Capsules

Zantac 300 GELdose Capsules

Zantac 75 Tablets

Zantac 150 Tablets

Zantac 300 Tablets

Zyloprim Tablets

Immunex Corporation (Seattle, WA)

Amicar Syrup

Amicar Tablets

Leucovorin Calcium Tablets

Jacobus Pharmaceutical Company (Princeton, NJ)

Dapsone Tablets

Paser Granules

Jones Pharma (St. Louis, MO)

Cytomel Tablets

Levoxyl Tablets

Liqui Char

Tapazole Tablets

McNeil Consumer Products Company (Fort Washington, PA)

Children's Motrin Oral Suspension

Children's Tylenol Chewable Fruit Burst

Flavor Tablets

Children's Tylenol Cold Multi-Symptom

Plus Cough Chewable Tablets

Children's Tylenol Suspension Grape

Flavored Liquid

Extra Strength Tylenol Caplets

Extra Strength Tylenol Liquid

Extra Strength Tylenol PM Gelscaps

Imodium AD Caplets

Infants' Tylenol Cherry Suspension Drops

Lactaid Original Strength Caplets

Lactaid Ultra Caplets

Maximum Strength Tylenol Allergy Sinus

Caplets

Multi-Symptom Tylenol Cold Tablets

Sesame Street Complete Vitamins and

Minerals

Tylenol Extended Relief Caplets

Mead Johnson Nutritionals (Evansville, IN)

Boost

Casec

Choice dm

Choice dm Bar

Comply

Criticare HN

Deliver 2.0

Enfamil

Enfamil AR

Enfamil 22

Enfamil with Iron

Fer-In-Sol

Infalyte

Isocal

Isocal HN

Kindercal

Lactofree

Lipisorb

Magnacal Renal

MCT Oil

Microlipid

Moducal

Natalins Tablets

Next Step Soy Toddler Formula

Next Step Toddler Formula

Nutrament

Nutramigen

Poly-Vi-Flor Drops and Tablets

Poly-Vi-Sol Drops and Tablets

Portagen

Pregestimil

ProSobee

Protain XL

Sustacal Basic

Sustacal Liquid, Pudding, and Powder

Sustacal Plus

Sustacal with Fiber

Sustagen

Temptra Drops

Theragra Tablets

TraumaCal

Tri-Vi-Flor Drops and Tablets

Tri-Vi-Sol Drops

Mikart (Atlanta, GA)

Acetaminophen and Codeine Phosphate

Oral Solution

Butalbital, Acetaminophen, and Caffeine

Tablets

Guaifenesin and Pseudoephedrine

Hydrochloride Tablets

Guaifenesin Tablets

Hydrocodone Bitartrate and Acetaminophen

Elixir

Hydrocodone Bitartrate and Acetaminophen

Tablets

Methazolamide Tablets

MGI Pharma (Minnetonka, MN)

Salagen Tablets

Nephron Pharmaceuticals (Orlando, FL)

Albuterol Sulfate Inhalation Solution

0.083%

Racipinephrine Inhalation Solution 2.25%

Sodium Chloride Inhalation Solution 0.9%

Novopharm USA (Schaumburg, IL)

Acyclovir Capsules 200 mg

Acyclovir Tablets 200, 400, and 800 mg

Albuterol Sulfate Tablets, USP, 2 and 4 mg

Alprazolam Tablets, USP, 0.25, 0.50, 1, and

2 mg

Amoxicillin Capsules, USP, 250 and 500 mg

Amoxicillin for Oral Suspension, USP, 125

and 250 mg/5 mL

Amoxicillin Chewable Tablets, USP, 125 and

250 mg

Atenolol Tablets 50 and 100 mg

Captopril Tablets, USP, 12.5, 25, 50, and

100 mg

Cefaclor Capsules, USP, 250 and 500 mg

Cephalexin Capsules, USP, 250 and 500 mg

Cephalexin for Oral Suspension, USP, 125

and 250 mg/5 mL

Cholestyramine for Oral Suspension, USP,

4 g (regular and light)

Cimetidine Tablets, USP, 200, 300, 400, and

800 mg

Clofibrate Capsules, USP, 500 mg

Clomipramine Hydrochloride Capsules 25,

NOTE Gluten

50, and 75 mg
Diclofenac Sodium Delayed-Release Tablets
75 mg
Flurbiprofen Tablets, USP, 50 and 100 mg
Glipizide Tablets 5 and 10 mg
Glyburide Tablets 1.25, 2.5, and 5 mg
Indapamide Tablets, USP, 1.25 and 2.5 mg
Indomethacin Capsules, USP, 25 and 50 mg
Loperamide Hydrochloride Capsules, USP,
2 mg
Loperamide Hydrochloride Tablets, USP,
2 mg
Metoprolol Tartrate Tablets, USP, 50 and
100 mg
Mexiletine Hydrochloride Capsules 150,
200, and 250 mg
Naproxen Sodium Tablets, USP, 275 and
550 mg
Naproxen Sodium Tablets and Capsules,
USP, 220 mg
Naproxen Tablets, USP, 250, 375, and
500 mg
Nifedipine Capsules, USP, 10 mg
Pindolol Tablets, USP, 5 and 10 mg
Piroxicam Capsules, USP, 10 and 20 mg
Ranitidine Hydrochloride Tablets, USP, 150
and 300 mg
Selegiline Hydrochloride Tablets, USP, 5 mg
Timolol Maleate Tablets, USP, 5, 10, and
20 mg
Tolmetin Sodium Capsules, USP, 400 mg
Ortho McNeil Pharmaceutical (Raritan, NJ)
Floxin Tablets
Haldol Concentrate
Haldol Tablets
Micronor 28 Tablets
Modicon 21 Tablets
Modicon 28 Tablets
Ortho-Cept 21 Tablets
Ortho-Cept 28 Tablets
Ortho-Cyclen 21 Tablets
Ortho-Cyclen 28 Tablets
Ortho-Est 0.625-mg Tablets
Ortho-Est 1.25-mg Tablets
Ortho-Novum 1/35 21 Tablets
Ortho-Novum 1/35 28 Tablets
Ortho-Novum 1/50 21 Tablets
Ortho-Novum 1/50 28 Tablets
Ortho-Novum 7/7/7 21 Tablets
Ortho-Novum 7/7/7 28 Tablets
Ortho-Novum 10/11 21 Tablets
Ortho-Novum 10/11 28 Tablets
Ortho Tri-Cyclen 21 Tablets
Ortho Tri-Cyclen 28 Tablets
Pancrease Capsules
Pancrease MT 4 Capsules
Pancrease MT 10 Capsules
Pancrease MT 16 Capsules
Pancrease MT 20 Capsules
Parafon Forte DSC Caplets
Tolectin DS Capsules
Tolectin 200 Tablets
Tolectin 600 Tablets
Ultram Tablets 50 mg
Vascor Tablets 200, 300, and 400 mg
Parke-Davis (Morris Plains, NJ)
Accupril Tablets
Celontin Kapseals

Cognex Capsules
Dilantin Kapseals and Tablets
Estrostep Tablets
Lipitor Tablets
Loestrin Tablets
Lopid Tablets
Neurontin Capsules
Nitrostat Tablets
Ponstel Capsules
Rezulin Tablets
Zarontin Capsules
Pharmaceutical Formulations (Edison, NJ)
Chlorpheniramine Maleate Tablets
Diphenhydramine Hydrochloride Tablets
DMS Caplets
Ibuprofen Tablets
PolyMedica Pharmaceuticals (Woburn, MA)
Aquachloral Suppositories
AZO Cranberry Capsules
AZO Standard
Belladonna and Opium Suppositories
Cystospaz M Capsules
Cystospaz Tablets
Urised Tablets
**Roberts Pharmaceutical Corporation
(Eatontown, NJ)**
Agrylin Capsules
Cod Liver Oil
Cod Liver Oil Gelcaps
Cod Liver Oil Mint
Colace Capsules
Colace Glycerin Suppositories
Colace Liquid
Colace Microenema
Ethmozine Tablets
Furoxone Liquid
Furoxone Tablets
Mineral Oil
Noroxin Tablets
Pentasa Capsules
Peri-Colace Capsules
Pro-Amatine Tablets
Pro-Banthine Tablets
Saluron Tablets
Salutensin Demi Tablets
Salutensin Tablets
Slow-Mag Tablets
Tigan Capsules
Tigan Suppositories
**Ross Products Division, Abbott Laboratories
(Columbus, OH)**
Alimentum Liquid
Ensure Products
Isomil Formulas
Jevity Products
Similac Formulas
Osmolite Products
Pedialyte Oral Rehydration
Pediasure Formulas
Similac Formulas
Roxane Laboratories (Columbus, OH)
Dexamethasone Tablets
Prednisone Tablets
Shire Richwood (Florence, KY)
Adderall Tablets
Carbatrol Capsules
Solvay Pharmaceuticals (Marietta, GA)
Advanced Formula Zenate Tablets

Cortenema Retention Enema
Creon Delayed-Release Minimicrospheres
Capsules
Dexone Tablets
Duphalac Solution
Estratab Tablets
Estratest Tablets
Hydrocil Instant
Lithobid Tablets
Lithonate Capsules
Lithotabs Tablets
Luvox Tablets
Orasone Tablets
Rowasa Suppositories and Enema
Tap Pharmaceuticals (Deerfield, IL)
Prevacid Capsules
**Upsher-Smith Laboratories (Minneapolis,
MN)**
Bisacodyl Uiserts Suppositories, USP
Hemril HC Suppositories
Klor-Con Tablets
Sorbitol Solution
Watson Laboratories (Corona, CA)
Butalbital, Aspirin, Caffeine, and Codeine
Phosphate Capsules
Clorazepate Dipotassium Tablets
Cyclobenzaprine Tablets
Hydrocodone and Acetaminophen Tablets
(all strengths)
Lorazepam Tablets
Verapamil Tablets
**West-Ward Pharmaceutical Corporation
(Eatontown, NJ)**
Aminophylline Tablets
Butalbital, Acetaminophen, and Caffeine
Tablets
Butalbital, Aspirin, and Caffeine Tablets
Carisoprodol Tablets
Colchicine Tablets
Cortisone Tablets
Dicyclomine Tablets and Capsules
Flurazepam Capsules
Folic Acid Tablets
Hydrocortisone Tablets
Isosorbide Dinitrate Tablets
Prednisone Tablets
Zeneca Pharmaceuticals (Wilmington, DE)
Accolate Tablets
Arimidex Tablets
Casodex Tablets
Nolvadex Tablets
Seroquel Tablets
Sorbitrate Tablets
Sular Tablets
Tenoretic Tablets
Tenormin Tablets
Zestoretic Tablets
Zestril Tablets
Zomig Tablets

**Appendix B—Products indicated
to contain gluten or whose gluten
status is unknown**

Astra USA (Westborough, MA)
Xylocaine 10% Oral Spray
Xylocaine 2% Viscous Solution
Xylocaine 5% Liquid (Flavored)

Glaxo Wellcome (Research Triangle Park, NC)

Leukeran Tablets
Zofran Tablets

Merz Pharmaceuticals (Greensboro, NC)

Anamine Syrup
Anamine TD Capsules
Anatuss DM Tablets and Syrup
Anatuss LA Tablets
Anatuss Tablets and Syrup
Eldercaps
Eldertonic
Glytuss Tablets

Mag-Vita Elixir
Nu-Iron 150 Capsules and Elixir
Nu-Iron Plus Elixir
Nu-Iron V Tablets

Ortho McNeil Pharmaceutical (Raritan, NJ)

Grifulvin V Microsize Suspension and
Tablets
Tylenol with Codeine Elixir
Tylenol with Codeine Tablets No. 2
Tylenol with Codeine Tablets No. 3
Tylenol with Codeine Tablets No. 4
Tylox Capsules

Parke-Davis (Morris Plains, NJ)

Nardil Tablets 15 mg

Schering Laboratories (Kenilworth, NJ)

Normodyne Tablets

Shire Richwood (Florence, KY)

Dextrostat Tablets

Somerset Pharmaceuticals (Tampa, FL)

Eldepryl Capsules

**West-Ward Pharmaceutical Corporation
(Eatontown, NJ)**

Strovite Plus Tablets

Zeneca Pharmaceuticals (Wilmington, DE)

Elavil Tablets