

THE AUTHORS REPLY: The analysis of CT colonography that Cash cites used a model that was validated in younger adult populations,¹ and the CMS's final decision memo noted that this model had been neither well tested nor previously used.² Furthermore, the memo acknowledged that this analysis combined outcomes from screening for colorectal cancer and abdominal aortic aneurysm. The Preventive Services Task Force recommends performing such screening only once in men who are 65 to 75 years of age and who have a history of smoking; the task force does not recommend such screening in women.³ Thus, less than one sixth of Medicare beneficiaries would be expected to have any benefit. Although the CMS reviewed other data showing that CT colonography is cost-effective only at reimbursement levels that are much lower than current rates,⁴ its decision was based primarily on the inadequacy of the evidence of benefit for this test and not its cost-effectiveness.²

The CMS covers what is "reasonable and necessary."⁵ It would be irresponsible to cover services for which there are no clinical data show-

ing benefits among its beneficiaries, since such services may be associated with harm — from additional unnecessary testing and procedures, anxiety about "incidentalomas," and additional diagnoses of uncertain clinical implications. It is essential that the CMS make decisions on the basis of high-quality clinical trials that reflect the effects on its elderly population.

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Hypersensitivity to Generic Drugs with Soybean Oil

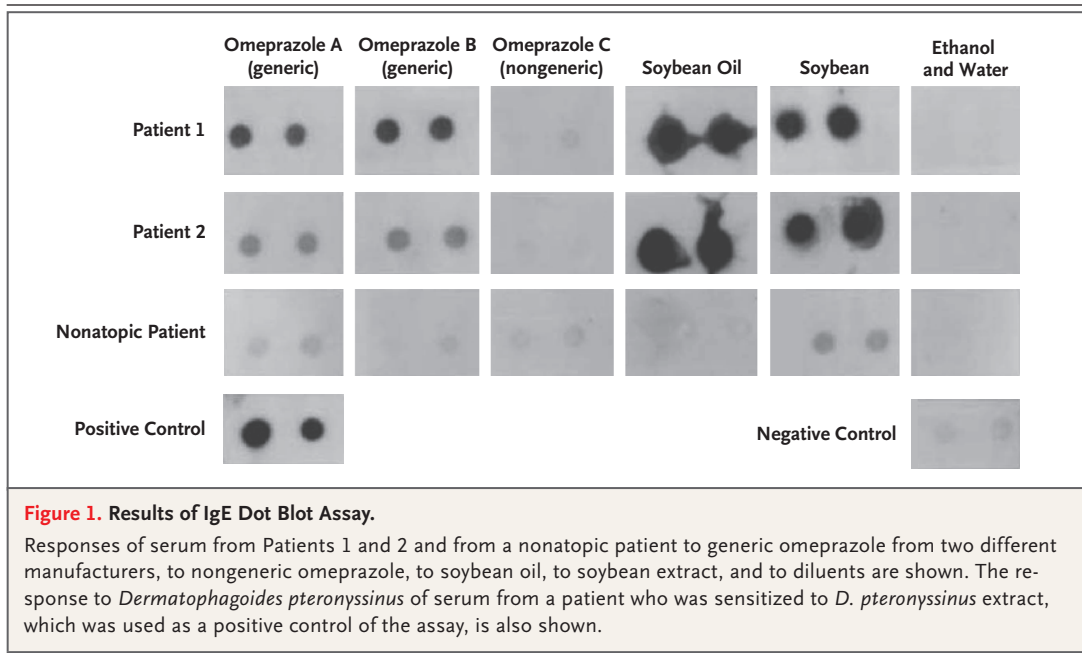
TO THE EDITOR: The use of generic drugs has increased in the European Union in recent years. The main regulatory requirement for these products is that they be bioequivalent to the branded drug. However excipients such as soybean oil can be a cause of hypersensitivity reactions^{1,2}; the protein content of fully refined seed oils should be suspected in the case of allergic reactions.³

We report on two women (58 and 81 years of age) who presented with anaphylaxis a few minutes after ingesting a generic omeprazole capsule.^{4,5} In both women the systolic blood pressure fell to less than 90, and both had sudden onset of difficulty breathing. Both women had previously taken nongeneric omeprazole and had not had a reaction. The generic drug that each of the women took contained approved soybean oil as an excipient. After the women provided written informed consent, skin-prick tests and soybean-specific IgE assays (ImmunoCAP assay, Phadia) were performed. Patient 1 had a wheal diameter of 20 mm after the injection of soybean extract (ALK-Abelló) and a wheal diameter of 14 mm after the injection of the powder contained in a

capsule of generic omeprazole diluted 1:10 in 0.9% saline solution; her soybean-specific IgE level was 9.01 kU per liter. Patient 2 had a wheal diameter of 14 mm after the injection of soybean extract and of 12 mm after the injection of the powder contained in generic omeprazole; her soybean-specific IgE level was 23 kU per liter.

The skin-prick tests for nongeneric omeprazole were negative in the 2 patients and in 10 controls without atopy. The skin-prick tests for generic omeprazole extract were positive in five patients who were sensitized to soybean (wheal diameter, 10 mm).

An IgE dot blot (Bio-Rad) was performed on the powder contained in generic omeprazole capsules from two manufacturers, on the powder in nongeneric omeprazole capsules reconstituted in 20% ethanol and 80% water, on soybean extract, and on soybean oil. The serum from the two patients showed a positive response to the generic omeprazole produced by each of the two manufacturers, to soybean oil, and to soybean extract but a negative reaction to diluent control wells and to nongeneric omeprazole. The serum



from nonatopic controls did not react to any of the products tested (Fig. 1).

Whereas active ingredients are clearly identified in the labels of generic drugs, excipients and additives are frequently defined as “excip. c.s.” A diagnosis of soy allergy should not be overlooked in cases of drug hypersensitivity. We suggest testing for soy in all patients who have hypersensitivity reactions to any drug that may contain soy.

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Dr. Pineda reports being an employee of Diater Laboratories, which specializes in the manufacture of specific immunotherapy with allergens. No other potential conflict of interest relevant to this letter was reported.

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