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Date: Fri, 3 May 1996 12:14:34 CST
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Subject: Olestra/FDA

Return-path: <baumgal@lab.med.yale.edu>
From: "Dr. Alex Baumgarten, M.D. Ph.D." <baumgal@lab.med.yale.edu>
Subject: Olestra/FDA
X-Sender: baumgal@lab.med.yale.edu
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Hi: if you were the author of the note in the NEJM re Olestra & the FDA, then please read on. If you weren't, then my apologies for this misaddressed epistle!

The article was right on the target. I have been a panelist for the FDA on a number of issues since 1983. Historically, the FDA used to request various experts to appear before a panel, including international ones, and the panel decision was basically free. In the past few years the situation appears to have changed. As you have indicated, it seems that a decision has been predetermined within the FDA and the purpose and orientation is to ensure the panel follows the party line. Experts are not called, other than that or those put forth by the manufacturer, as they might "confuse" the issue. I think there has been a fundamental change in attitude and orientation suggesting a political need or purpose. Naturally, I have examples, as well as concern over this trend. I also find it somewhat puzzling, except in one partcular context, because on the basis of both direct contact and the public expressions of Dr. Kessler I have come to regard him well. If you or others are interested in discussing this, then by all means let's. Regards, Alex Baumgarten.

Letters 1996

OLESTRA:

Baumgarten to Blackburn