Citizen Petition

The Center for Science in the Public Interest (CSPI) submits this petition under Sections 403(a), 201(n) and 701(a) of the Federal Food, Drug, and Cosmetic Act (FD&CA) to request the Commissioner of Food and Drugs to issue regulations requiring a quantitative disclosure for caffeine-containing products. In addition, CSPI requests that the agency initiate a thorough review of the health effects of caffeine to determine what additional regulatory and educational actions should be taken to protect consumers from adverse effects of caffeine.

I. Introduction

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1 The Center for Science in the Public Interest is a nonprofit organization based in Washington, D.C., that has been working to improve the public’s health through better nutrition and safer food since 1971.
Caffeine has a wide variety of physiological and behavioral effects. Evidence from human studies suggests that caffeine contributes to adverse reproductive outcomes, including reduced fertility, miscarriage, fetal growth retardation, and reduced-birth-weight babies. Based on evidence from animal studies that showed an increased risk of birth defects in rodents fed large amounts of caffeine, in 1981 the Food and Drug Administration (FDA) advised pregnant women to avoid caffeine. The pamphlet states that “Pregnant women should avoid caffeine-containing foods and drugs, if possible, or consume them only sparingly.” The FDA still maintains the 1981 advisory as its official policy on caffeine and pregnancy.

Current food labels do not provide women with the information they need to follow the FDA’s advice to avoid caffeine. Caffeine is present in a variety of foods and beverages, including coffee, tea, colas and other soft drinks, caffeinated water, ice cream, frozen yogurt, and yogurt. Consumers cannot estimate accurately the caffeine content of many of those foods, since many of the products are new and the levels of caffeine vary between brands. Foods with caffeine as an added ingredient, such as soft drinks and caffeinated water, list caffeine in the ingredients list, but they do not provide quantitative information about their caffeine content. Furthermore, the presence of caffeine in foods that naturally contain caffeine, such as coffee and tea, is not indicated on food labels.

In addition to effects on reproduction, caffeine has been shown to adversely affect calcium balance and may contribute to decreased bone density and osteoporosis. Caffeine also

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3 Telephone conversation with Catherine Bailey, FDA, May 12, 1997.
can cause adverse behavioral outcomes, including anxiety and sleeplessness. It is mildly addictive and cessation of consumption may lead to withdrawal symptoms. Those behavioral outcomes and addictiveness have been reported in both children and adults.

Therefore, CSPI requests that the FDA amend its food-labeling regulations to require that caffeine content be listed quantitatively on the labels of foods and beverages that contain caffeine. In addition, the FDA should conduct a thorough review of the health effects of caffeine, including effects on reproduction, behavior, bone-mineral metabolism, blood pressure, and children, to determine what additional regulatory and educational actions should be taken to protect the public from adverse effects of caffeine.

II. Actions Requested

A. The FDA should require disclosure of the caffeine content of foods and beverages

A growing body of evidence suggests that consuming too much caffeine can cause a variety of adverse physiological and behavioral effects. People need information about the caffeine content of food products in order to allow them to regulate their intake. For example, the FDA advises pregnant women to avoid caffeine or consume it only sparingly. Although many women of childbearing age know that they should avoid caffeine or consume it only sparingly during pregnancy, current food labels do not provide women with the information they need to put that advice into practice.

4 See Caffeine and Pregnancy, supra note 2.

5 A small study prepared for CSPI revealed that 78% of women age 18 to 44 are aware that “pregnant women should avoid or consume caffeine only sparingly.” However, the results
should be read narrowly because the study surveyed awareness, not actual behavior. In addition, the survey did not assess knowledge about the presence of caffeine in various types of food. Bruskin-Goldring Research (Edison, N.J.), Omnitel Nutrition Survey conducted May 16-18, 1997.
In addition, the parents of young children might wish to limit their children’s consumption of foods or beverages containing this stimulant to help prevent sleeplessness, anxiety, or addiction to caffeinated products.\(^6\) Adults or teenagers might wish to avoid or limit their caffeine intake because they experience nervousness, irritability, sleeplessness, or rapid heart beat when they consume too much.\(^7\) Others might seek out caffeinated products for their behavioral effects. For example, drivers who wish to stay awake and students studying for exams may occasionally rely on caffeine-containing foods to help them stay alert.

New caffeine-containing products have increased the need for quantitative caffeine labeling. Although many consumers may have experience consuming coffee, regular tea, and cola beverages and may be able to estimate how much they can drink without experiencing behavioral side effects, they may have difficulty estimating their tolerance for newer products such as caffeinated water. The amount of caffeine in food and beverages can vary between brands and can be unpredictable. For example, the caffeine content of blended teas may vary depending on how much black tea they contain. The average eight-ounce cup of pure black tea contains 50 mg of caffeine, a cup of Lipton Soothing Moments blackberry tea has 25 mg of caffeine, and Soothing Moments peppermint tea contains no caffeine. Ben & Jerry’s NO FAT Coffee Fudge frozen yogurt has 85 mg of caffeine per one-cup serving, while Healthy Choice Cappuccino Chocolate Chunk ice cream has only 8 mg of caffeine per serving. In addition, the

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The caffeine content of caffeinated waters varies from 50 to 125 mg per half-liter bottle.

 Furthermore, PepsiCo’s new soft drink, Josta, contains 57% more caffeine than Pepsi-Cola.

 Consumers may be unaware that some products, such as orange sodas, other citrus sodas such as Mountain Dew, coffee yogurt, and coffee ice cream contain appreciable amounts of caffeine. For example, a cup of coffee ice cream or frozen yogurt can have as much caffeine as half a cup of coffee, Sunkist orange soda has more caffeine than Pepsi, or a Dannon coffee yogurt has as much caffeine as a 12-ounce Coca-Cola. Without quantitative caffeine labeling, consumers cannot determine how much caffeine is in the foods they and their children eat.

 Therefore, CSPI urges the FDA to require quantitative caffeine labeling for all foods that contain caffeine, whether added or naturally occurring. The statement, “Contains [number] mg caffeine per serving” should appear prominently on the label. The disclosure statement should be placed adjacent to the ingredient listing because individuals who are interested in food ingredients or have food sensitivities are used to checking the listings for information about ingredients that they wish to limit or avoid. On products (such as pure coffee and tea) that are not required to list ingredients, the statement should be prominently displayed on the label. On all products the caffeine declaration should appear in dark boldface type on a light background and in upper- and lower-case lettering of a type size sufficient to call attention to the declaration.

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8 In June, the American Medical Association adopted a resolution calling on the FDA to ensure that when caffeine is added to a product, the label reflect it in prominent letters, and that the amount of caffeine in the product be written on the label. American Medical Association House of Delegates, Caffeine Drinks, Resolution: 523 (A-97), June 22-26, 1997.
and make it easy to read. The FDA also should encourage retail food-service establishments to
disclose caffeine content on menus, menu boards, coffee cups, or soft-drink containers.

The FDA should determine a threshold level below which quantitative caffeine labeling
would not be required. In determining that level, the FDA should consider the fact that
consumers have varying sensitivity to caffeine and that they may consume caffeine from a
number of different sources each day. A 5 to 10 mg per serving threshold may be appropriate.
Decaffeinated versions of products that ordinarily contain caffeine (coffee, tea, and soft drinks)
should declare either the caffeine content or that they “contain less than X mg of caffeine per
serving,” with X equal to the labeling threshold level.

**B. The FDA should conduct a thorough review of the health effects of caffeine to
determine what additional regulatory and educational actions should be taken to
protect the public from adverse effects of caffeine**

Caffeine is an addictive stimulant.9,10,11,12,13 It is the only drug that is added to or
naturally present in widely consumed foods.14 Because caffeine is consumed by a large

9 J.E. James, Caffeine, health and commercial interest, 89 Addiction 1595-1599 (1994)
[hereinafter James].

10 E.C. Strain, R.R. Griffiths, Caffeine use disorders, in A. Tasman, et al., (eds.) 1
Psychiatry 779-794 (Philadelphia, W.B. Saunders Company 1997) [hereinafter Strain].

11 R.R. Griffiths et al., Low-dose caffeine physical dependence in humans, 255 Journal of
Pharmacology and Experimental Therapeutics 1123-1132 (1990) [hereinafter Griffiths et al.].

12 J.R. Hughes, et al., Indicators of caffeine dependence in a population-based sample, in
Hughes et al.].

13 However, CSPI is not requesting that the caffeine in foods be regulated as a drug.

14 Quinine is also allowed to be added to the food supply, but only in carbonated
proportion of the population, the effects of caffeine on health should be carefully evaluated by
the FDA to determine if further regulatory or educational actions should be taken to inform
consumers about possible adverse health or behavioral outcomes caused by caffeine.

beverages as a flavoring. It is generally found only in tonic water.
For example, the FDA should consider whether a specific label notice about the risks of caffeine to women of childbearing age is warranted given the evidence that caffeine may reduce fertility, cause miscarriage, and reduction in fetal birth weight. All over-the-counter (OTC) drugs, including stimulants in which the active agent is caffeine, bear a label notification for pregnant or nursing women that states, “as with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.”15 It is inconsistent for the FDA to require this information on OTC stimulants and not on the labels of foods that contain similar levels of caffeine. For example, the amount of caffeine in regular strength NoDoz (100 mg per tablet) is similar to the amount in one six-ounce cup of brewed coffee, one half-liter bottle of Krank20 caffeinated water, two eight-ounce cups of tea, a 20-ounce bottle of Mountain Dew, or two eight-ounce cups of Dannon coffee yogurt. Thus, the FDA should investigate how best to notify women about the reproductive effects of caffeine consumption. The agency should rectify the inconsistencies in its policy concerning the information that pregnant and nursing women are given about different products that contain similar amounts of caffeine.

The FDA is also inconsistent in its policy regarding the behavioral effects of caffeine. Vivarin, NoDoz, and similar caffeine-based OTC stimulant drugs are required to carry a label notice that states:

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Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.\textsuperscript{16}

Foods and beverages with similar amounts of caffeine do not provide consumers with that information. The FDA should reconcile this inconsistency between its policy for OTC stimulant drugs and for beverages and foods with similar levels of caffeine. The FDA should give particular consideration to caffeinated, bottled waters, whose marketing often emphasizes their stimulant properties, but of which consumers have no knowledge of the caffeine content relative to soft drinks or other caffeine-containing foods and beverages.17

Similarly, the FDA should reconcile the inconsistencies in its policy for warning parents about the effects of caffeine on children. The FDA requires that OTC stimulant drugs carry the label statement, “Do not give to children under 12 years of age.”18 But it requires no such statement on foods and beverages with similar levels of caffeine that are consumed by and marketed to young children. The FDA should determine whether a notification about children consuming caffeine, similar to that required on OTC drugs, is warranted on foods and beverages containing caffeine.

The FDA also should evaluate the evidence that links caffeine intake to impaired calcium balance. The FDA should determine whether and how it should inform consumers about the modest but potentially important effect of caffeine consumption on bone density and the risk of osteoporosis.

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17 The legality of these products is discussed in section 2(b) of the Statement of Legal Grounds, page 62.

III. Statement of Grounds

A. Statement of Factual Grounds

1. Caffeine content of foods

Caffeine is a natural constituent of coffee, tea, chocolate, and cocoa. In addition, it is added to carbonated soft drinks, such as colas, Dr. Pepper, and citrus sodas (Sunkist orange soda, Surge, and Mountain Dew). Since 1995, a number of companies have begun marketing caffeinated water (e.g., Water Joe, Krank20, Java Water). Most recently, caffeine has been added to fruit-flavored drinks (Mistic Energy Booster) and in fruit juices (Juiced). Table 1 lists the caffeine content of common sources of caffeine in the American diet.

<table>
<thead>
<tr>
<th>Product</th>
<th>Serving Size</th>
<th>Caffeine (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NoDoz, maximum strength; Vivarin</td>
<td>1 tablet</td>
<td>200</td>
</tr>
<tr>
<td>Coffee, brewed</td>
<td>8 ounces</td>
<td>135</td>
</tr>
<tr>
<td>Excedrin</td>
<td>2 tablets</td>
<td>130</td>
</tr>
<tr>
<td>Java Water (caffeinated water)</td>
<td>½ liter (16.9 ounces)</td>
<td>125</td>
</tr>
</tbody>
</table>

19 Sources: National Coffee Association, National Soft Drink Association, Tea Council of the USA, and information provided by food, beverage, and pharmaceutical companies.


21 Beverages sold in 16-ounce or half-liter bottles were counted as one serving because “the whole unit can reasonably be consumed at a single-eating occasion.” 21 C.F.R. § 101.9(2)(i).
<table>
<thead>
<tr>
<th>Drink</th>
<th>Size/Liquid Amount</th>
<th>Caffeine (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Foods International Coffee, Orange Cappuccino</td>
<td>8 ounces</td>
<td>102</td>
</tr>
<tr>
<td>Celestial Seasonings Iced Lemon Ginseng Tea</td>
<td>16 ounces</td>
<td>100</td>
</tr>
<tr>
<td>Krank³0 (caffeinated water)</td>
<td>½ liter (16.9 ounces)</td>
<td>100</td>
</tr>
<tr>
<td>NoDoz, regular strength</td>
<td>1 tablet</td>
<td>100</td>
</tr>
<tr>
<td>Coffee, instant</td>
<td>8 ounces</td>
<td>95</td>
</tr>
<tr>
<td>Aqua blast (caffeinated water)</td>
<td>½ liter (16.9 ounces)</td>
<td>90</td>
</tr>
<tr>
<td>General Foods International Coffee, Cafe Vienna</td>
<td>8 ounces</td>
<td>90</td>
</tr>
<tr>
<td>Ben &amp; Jerry’s No Fat Coffee Fudge frozen yogurt</td>
<td>1 cup</td>
<td>85</td>
</tr>
<tr>
<td>Bigelow Raspberry Royale Tea</td>
<td>8 ounces</td>
<td>83</td>
</tr>
<tr>
<td>Water Joe (caffeinated water)</td>
<td>½ liter (16.9 ounces)</td>
<td>60-70</td>
</tr>
<tr>
<td>Maxwell House Cappuccino, Mocha</td>
<td>8 ounces</td>
<td>60-65</td>
</tr>
<tr>
<td>Anacin</td>
<td>2 tablets</td>
<td>64</td>
</tr>
<tr>
<td>Juiced (caffeinated fruit juice)</td>
<td>10 ounces</td>
<td>60</td>
</tr>
<tr>
<td>Aqua Java (caffeinated water)</td>
<td>½ liter (16.9 ounces)</td>
<td>50-60</td>
</tr>
<tr>
<td>Starbucks coffee ice cream (assorted flavors)</td>
<td>1 cup</td>
<td>40-60</td>
</tr>
<tr>
<td>Häagen-Dazs coffee ice cream</td>
<td>1 cup</td>
<td>58</td>
</tr>
<tr>
<td>Josta (soft drink)</td>
<td>12 ounces</td>
<td>58</td>
</tr>
<tr>
<td>General Foods International Coffee, Swiss Mocha</td>
<td>8 ounces</td>
<td>55</td>
</tr>
<tr>
<td>Mountain Dew</td>
<td>12 ounces</td>
<td>55</td>
</tr>
<tr>
<td>Surge (soft drink)</td>
<td>12 ounces</td>
<td>51</td>
</tr>
<tr>
<td>Tea, leaf or bag</td>
<td>8 ounces</td>
<td>50</td>
</tr>
<tr>
<td>Maxwell House Cappuccino, French Vanilla or Irish Cream</td>
<td>8 ounces</td>
<td>45-50</td>
</tr>
<tr>
<td>Snapple Iced Tea (all varieties)</td>
<td>16 ounces</td>
<td>48</td>
</tr>
<tr>
<td>Diet Coke</td>
<td>12 ounces</td>
<td>47</td>
</tr>
<tr>
<td>Food Item</td>
<td>Serving Size</td>
<td>Calories</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>--------------------</td>
<td>----------</td>
</tr>
<tr>
<td>Coca-Cola</td>
<td>12 ounces</td>
<td>45</td>
</tr>
<tr>
<td>Dannon coffee yogurt</td>
<td>1 cup</td>
<td>45</td>
</tr>
<tr>
<td>Lipton Natural Brew Iced Tea Mix, unsweetened</td>
<td>8 ounces</td>
<td>25-45</td>
</tr>
<tr>
<td>Dr. Pepper (regular or diet)</td>
<td>12 ounces</td>
<td>41</td>
</tr>
<tr>
<td>Häagen-Dazs Coffee Frozen Yogurt, fat-free</td>
<td>1 cup</td>
<td>40</td>
</tr>
<tr>
<td>Sunkist orange soda</td>
<td>12 ounces</td>
<td>40</td>
</tr>
<tr>
<td>Lipton’s Iced Teas (assorted varieties)</td>
<td>16 ounces</td>
<td>18-40</td>
</tr>
<tr>
<td>Pepsi-Cola</td>
<td>12 ounces</td>
<td>37</td>
</tr>
<tr>
<td>Lipton Natural Brew Iced Tea Mix, sweetened</td>
<td>8 ounces</td>
<td>15-35</td>
</tr>
<tr>
<td>Nestea Pure Sweetened Iced Tea</td>
<td>16 ounces</td>
<td>34</td>
</tr>
<tr>
<td>Hershey’s Special Dark chocolate bar</td>
<td>1 bar (1.5 ounces)</td>
<td>31</td>
</tr>
<tr>
<td>Häagen-Dazs Coffee Fudge Ice Cream, low-fat</td>
<td>1 cup</td>
<td>30</td>
</tr>
<tr>
<td>Tea, green</td>
<td>8 ounces</td>
<td>30</td>
</tr>
<tr>
<td>Maxwell House Cappuccino, Amaretto</td>
<td>8 ounces</td>
<td>25-30</td>
</tr>
<tr>
<td>Arizona Iced Teas (assorted varieties)</td>
<td>16 ounces</td>
<td>15-30</td>
</tr>
<tr>
<td>General Foods International Coffee, Viennese Chocolate Cafe</td>
<td>8 ounces</td>
<td>26</td>
</tr>
<tr>
<td>Lipton Soothing Moments Blackberry Tea</td>
<td>8 ounces</td>
<td>25</td>
</tr>
<tr>
<td>Perugina Milk Chocolate Bar with Cappuccino Filling</td>
<td>1/3 bar (1.2 ounces)</td>
<td>24</td>
</tr>
<tr>
<td>Barqs Root Beer</td>
<td>12 ounces</td>
<td>23</td>
</tr>
<tr>
<td>Nestea Pure Lemon Sweetened Iced Tea</td>
<td>16 ounces</td>
<td>22</td>
</tr>
<tr>
<td>Starbucks Frappuccino bar (frozen dessert)</td>
<td>1 bar (2.5 ounces)</td>
<td>15</td>
</tr>
<tr>
<td>Tea, instant</td>
<td>8 ounces</td>
<td>15</td>
</tr>
<tr>
<td>Lipton Natural Brew Iced Tea Mix, diet</td>
<td>8 ounces</td>
<td>10-15</td>
</tr>
<tr>
<td>Hershey bar (milk chocolate)</td>
<td>1 bar (1.5 ounces)</td>
<td>10</td>
</tr>
<tr>
<td>Item</td>
<td>Quantity</td>
<td>Caffeine (mg)</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>----------</td>
<td>--------------</td>
</tr>
<tr>
<td>Healthy Choice Cappuccino Chocolate Chunk or Cappuccino Mocha Fudge Ice Cream</td>
<td>1 cup</td>
<td>8</td>
</tr>
<tr>
<td>Coffee Nips (hard candy)</td>
<td>2 pieces</td>
<td>6</td>
</tr>
<tr>
<td>Maxwell House Cappuccino, decaffeinated</td>
<td>8 ounces</td>
<td>3-6</td>
</tr>
<tr>
<td>Cocoa or hot chocolate</td>
<td>8 ounces</td>
<td>5</td>
</tr>
<tr>
<td>Decaffeinated coffee</td>
<td>8 ounces</td>
<td>5</td>
</tr>
<tr>
<td>Yoplait Cafe Au Lait Yogurt</td>
<td>6 ounces</td>
<td>5</td>
</tr>
<tr>
<td>Lipton Natural Brew Iced Tea Mix (decaffeinated)</td>
<td>8 ounces</td>
<td>&lt; 5</td>
</tr>
<tr>
<td>Dannon Light Cappuccino Yogurt</td>
<td>8 ounces</td>
<td>&lt; 1</td>
</tr>
<tr>
<td>7 UP or Diet 7 UP</td>
<td>12 ounces</td>
<td>0</td>
</tr>
<tr>
<td>Barqs Diet Root Beer</td>
<td>12 ounces</td>
<td>0</td>
</tr>
<tr>
<td>Caffeine-free Coca-Cola or Diet Coke</td>
<td>12 ounces</td>
<td>0</td>
</tr>
<tr>
<td>Caffeine-free Pepsi or Diet Pepsi</td>
<td>12 ounces</td>
<td>0</td>
</tr>
<tr>
<td>Celestial Seasonings Herbal Teas</td>
<td>8 ounces</td>
<td>0</td>
</tr>
<tr>
<td>Celestial Seasonings Herbal Iced Teas (bottled)</td>
<td>16 ounces</td>
<td>0</td>
</tr>
<tr>
<td>Lipton Soothing Moments Peppermint Tea</td>
<td>8 ounces</td>
<td>0</td>
</tr>
<tr>
<td>Minute Maid orange soda</td>
<td>12 ounces</td>
<td>0</td>
</tr>
<tr>
<td>Mug Root Beer</td>
<td>12 ounces</td>
<td>0</td>
</tr>
<tr>
<td>Sprite or Diet Sprite</td>
<td>12 ounces</td>
<td>0</td>
</tr>
<tr>
<td>Stonyfield Farm Cappuccino Yogurt</td>
<td>8 ounces</td>
<td>0</td>
</tr>
</tbody>
</table>

Coffee contains the largest amount of caffeine per serving of all foods and beverages. The average eight-ounce serving\(^{22}\) of ground roasted coffee contains 135 mg of caffeine.\(^{23}\)

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\(^{22}\) Traditionally, the coffee industry and many researchers have used five ounces as the standard serving size for coffee. However, the Nutrition Labeling and Education Act of 1990, defines a serving of coffee as eight fluid ounces and typical coffee mugs are ten ounces and contain eight ounces of fluid. 21 C.F.R. § 101.12(9)(b).
Approximately 14% of all coffee consumed in the U.S. is instant coffee, which has 95 mg of caffeine per eight-ounce serving.\textsuperscript{24}

\textsuperscript{23} See Barone, \emph{supra} note 20.

\textsuperscript{24} National Coffee Association of U.S.A., Inc., \textit{U.S. Coffee Drinking Study} (Winter 1993) [hereinafter \textit{U.S. Coffee Drinking Study}].
The average cup of regular, hot tea contains 50 mg of caffeine per eight-ounce serving for loose leaf or bag tea. Some blended teas, such as Lipton Soothing Moment’s blackberry tea, are packaged and flavored to resemble herbal teas, but contain black tea, and therefore, have about 25 mg of caffeine per serving. Other blended teas, such as Bigelow Raspberry Royale, contain 83 mg of caffeine per eight-ounce serving. Instant tea contains approximately 32 mg of caffeine per eight-ounce serving. Bottled iced teas vary in their caffeine content. Arizona Iced Teas range from 15 to 30 mg of caffeine per 16-ounce bottle, Lipton Iced Teas range from 18 to 40 mg of caffeine per 16-ounce bottle, whereas Snapple Iced Teas contain an average of 48 mg of caffeine per 16-ounce bottle.

Caffeinated soft drinks contain smaller amounts of caffeine per serving than coffee or tea (for example, 45 mg per 12-ounce Coca-Cola and 55 mg per 12-ounce Mountain Dew). However, because they are often consumed in large quantities, soft drinks contribute significant amounts of caffeine to American’s diets.

The newest caffeinated beverages are caffeinated water and juice products. Those products first were marketed in 1995 and now are distributed nationwide. Caffeinated bottled waters such as Water Joe, Krank20, and Java Water contain approximately 30 to 70 mg of caffeine per eight-ounce serving, but are often sold in 16-ounce bottles. Caffeinated orange juice (Juiced) contains 60 mg per ten-ounce bottle.

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26 National Soft Drink Association, Washington, DC.
Caffeine also is a component of cocoa. Thus, hot chocolate and chocolate milk have, on average five mg of caffeine per eight-ounce serving. Chocolate bars such as Hershey’s Milk Chocolate and Hershey’s Special Dark contain 10 mg and 31 mg of caffeine per 1.5 ounce bar, respectively. Perugina Milk Chocolate with Cappuccino Filling contains 24 mg of caffeine per 1.2 ounce serving.

Coffee-flavored ice creams and frozen yogurts often contain caffeine. Ben & Jerry’s Coffee, Coffee BuzzBuzzBuzz Ice Cream and No Fat Coffee Fudge Frozen Yogurt contain 74 and 85 mg of caffeine per cup, respectively. Häagen-Dazs Fat-Free Coffee Frozen Yogurt and Coffee Fudge Low-Fat Ice Cream contain 40 and 30 mg of caffeine per one cup serving, respectively. Starbucks’ line of coffee-flavored ice creams have caffeine contents ranging from 40 to 60 mg per one cup serving. A one-cup serving of Dannon coffee yogurt contains 45 mg of caffeine, about half as much as a cup of instant coffee. In contrast, Yoplait Cafe Au Lait yogurt contains five mg of caffeine per six-ounce cup, and Stonyfield Farms cappuccino yogurt is made from decaffeinated coffee and does not contain an appreciable amount of caffeine.

A number of over-the-counter (OTC) drugs also contain caffeine and are included in Table 1 for comparison. For example, Excedrin, Regular Strength NoDoz, and Maximum Strength NoDoz or Vivarin contain 65, 100, and 200 mg of caffeine respectively, doses similar to those found in beverages.

There is wide-spread availability of low-caffeine or decaffeinated varieties of foods and beverages. Those products provide an alternative for people concerned about caffeine.
2. Caffeine consumption

(a) Caffeine consumption by the general population

Coffee is the leading source of caffeine in the diets of American adults.\(^\text{27}\) Tea is the second biggest contributor to dietary caffeine intake. However, Americans are drinking more carbonated soft drinks than ever before. Annual consumption of non-diet carbonated soft drinks jumped 43% from 1986 to 1994, to an average consumption of approximately eight 12-ounce servings per person per week.\(^\text{28}\) Diet carbonated soft-drink consumption doubled between 1980-84 and 1990-94, reaching 2.3 12-ounce servings per person per week.\(^\text{29}\)

The most popular soft drinks contain caffeine. Coca-Cola, Pepsi-Cola, and Diet Coke were the most popular soft drinks in 1996, capturing 20%, 15%, and 9% of the soft-drink market,

\(^{27}\) See Barone, supra note 20.


\(^{29}\) May-August U.S. Food Consumption, Food Reviews 5-6 (1995).
respectively. Mountain Dew and Dr. Pepper, which also contain caffeine, were the next most popular: each captured 6% of the market.

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30 Beverage World and Beverage Marketing Corporation, The top 10 soft drink review, (March 15, 1997).
The average American adult consumes approximately 3 mg/kg of caffeine daily. That level of consumption translates to 207 mg of caffeine per day for the average woman, weighing 152 pounds (69 kg), and 246 mg for the average adult man weighing 181 pounds (82 kg).

Average-caffeine-consumption data underestimate the intake of caffeine for millions of Americans because the average includes people who do not consume any caffeine-containing products. For example, 48% of Americans do not consume coffee.

Table 2 reports the amount of caffeine consumed by consumers of coffee, tea, or soft drinks according to the U.S. Department of Agriculture (USDA) National Food Consumption Survey (NFCS). The data are expressed as mean caffeine consumption and 90th percentile consumption in mg per kg of body weight. People who did not consume coffee, tea, or soft drinks are not included in the results.

<table>
<thead>
<tr>
<th>Age group (years)</th>
<th>Mean Dose (mg/kg)</th>
<th>90th percentile (mg/kg)</th>
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<tbody>
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31 See Barone, supra note 20.

32 The average American woman weighs 69 kg and the average man weighs 82 kg. Telephone conversation with Robert Kuczmarski, National Center for Health Statistics (April, 1997) [hereinafter Kuczmarski].

33 See U.S. Coffee Drinking Study, supra note 24.

34 Dietary assessment studies underestimate food intake. W. Mertz, J.L. Kelsay, Rationale and design of the Beltsville one-year dietary intake study, 40 suppl. 6 American Journal of Clinical Nutrition 1323-1326 (1984). Thus, actual caffeine intake may be higher.

35 Data are for consumers of any of the three beverages -- coffee, tea, or soft drinks -- and exclude consumers who do not drink one of those beverages. See Barone, supra note 20.
<table>
<thead>
<tr>
<th>Group</th>
<th>Caffeine intakes</th>
<th>Metabolism intakes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-5</td>
<td>1.33</td>
<td>2.79</td>
</tr>
<tr>
<td>6-9</td>
<td>1.10</td>
<td>2.38</td>
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<tr>
<td>10-14</td>
<td>1.08</td>
<td>2.03</td>
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<tr>
<td>15-19</td>
<td>0.98</td>
<td>1.82</td>
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<tr>
<td>20-24</td>
<td>1.79</td>
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<td>8.16</td>
</tr>
<tr>
<td>50-64</td>
<td>3.81</td>
<td>8.11</td>
</tr>
<tr>
<td>65+</td>
<td>3.05</td>
<td>6.69</td>
</tr>
</tbody>
</table>

For women of childbearing age (20 to 49 years), those doses translate to an average daily caffeine intake of 123 to 255 mg for a 69 kg woman. The levels of consumption for the 90th percentile are remarkable. Those doses translate to a daily intake of 275 to 563 mg per day for a 69 kg woman age 20 to 49. The caffeine intake of women of childbearing age is important because the effects of caffeine on reproduction can occur before a woman becomes pregnant or before she knows she is pregnant, and more than half of all pregnancies in the U.S. are unplanned.

(b) Caffeine consumption and metabolism by pregnant women

36 See Kuczmarski supra note 32.

The rate at which caffeine is metabolized varies between individuals. Pregnant women metabolize caffeine at a slower rate than non-pregnant women. Aldridge and colleagues found that the half-life for caffeine increased from an average of 5.3 hours before pregnancy to 18.1 hours in the last two trimesters of pregnancy.\textsuperscript{38} That tripling of the half-life means that a given amount of ingested caffeine results in higher blood levels of caffeine and thus, a higher effective dose of caffeine for both the mother and the fetus. In addition, fetuses and neonates do not have the liver enzymes necessary to metabolize caffeine. As a result, the half-life of caffeine in neonates is about four days.\textsuperscript{39}

Slow caffeine metabolism in pregnant women, fetuses, and newborns leave them particularly vulnerable to caffeine’s effects. Thus, it is especially important that pregnant women have information about the caffeine content of foods. Such information would allow them to reduce their intake of caffeine to help offset changes in caffeine metabolism and decrease the chances of adverse side effects.


According to the 1987-1988 U.S. Department of Agriculture’s Nationwide Food Consumption Survey, the average pregnant woman who consumed coffee, tea, or caffeinated soft drinks consumed 1.47 mg/kg of caffeine from those beverages combined.\textsuperscript{40,41} Those data do not include caffeine from other sources like coffee yogurt (a good source of calcium) or coffee ice cream. Assuming an average pre-pregnancy weight of 152 pounds (69 kg),\textsuperscript{42} that dose translates to an average intake of 101 mg of caffeine per day. The average dose for pregnant women in the 90th percentile of caffeine consumption translates to a daily dose of 230 mg of caffeine. Because the metabolism of caffeine is slower in pregnant women and fetuses than in non-pregnant women, the same dose of caffeine has a greater impact during pregnancy.

\textbf{(c) Caffeine consumption by children}

Children age one to five years who consume coffee, tea, or soft drinks, consume an average of 1.33 mg/kg of caffeine per day, with an average consumption of 2.79 mg/kg for those in the 90th percentile. For children six to 19 years of age, the average daily consumption is approximately 1 mg/kg. Consumption in the 90th percentile ranges from 1.82 to 2.38 mg/kg.

\textsuperscript{40} See Barone, \textit{supra} note 20.

\textsuperscript{41} That average does not include women who do not consume coffee, tea, or caffeinated soft drinks.

\textsuperscript{42} See Kuczmarski, \textit{supra} note 32.
3. Caffeine and health

(a) Caffeine’s effects on reproduction

A large number of epidemiological studies has examined the effects of caffeine on several aspects of reproduction. The epidemiological studies suffer from several limitations such as (a) limited sensitivity due to limited sample size, particularly the limited number of subjects consuming high levels of caffeine; (b) recall bias, which may have influenced the reported level of caffeine intake; (c) the possible presence of confounding factors such as smoking or alcohol consumption which could mask or simulate an effect; and (d) that the measured outcomes are caused by factors in addition to caffeine, thereby increasing background rates in the control group and limiting the sensitivity of some studies. Despite those limitations, the weight of the evidence indicates that caffeine consumption has adverse effects on fertility and fetal development. Clinical intervention trials could more definitively link caffeine to poor reproductive outcome, but such studies would be unethical to perform.

Animal studies support the epidemiologic evidence and have found a clear link between caffeine consumption and poor reproductive outcomes. When a substance is shown to have an adverse effect in animals, researchers must infer the dose at which it might have an effect in humans. When establishing toxicity levels, the FDA generally uses a 100-fold safety factor for substances found to be harmful in animals.43

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43 The FDA has stated that exceptions to a safety factor of 100 may be necessary if potentially sensitive sub-populations are affected, such as children, geriatrics, and individuals with deficiency states and lack of developed enzyme metabolic systems. Center for Food Safety and Applied Nutrition, Food and Drug Administration, Toxicological principles for the safety assessment of direct food additives and color additives used in food, (1993). A safety factor of 1,000 is commonly used in establishing safe levels of exposure for fetuses.
(i) Caffeine’s effect on fertility

Infertility affects approximately 5.3 million men and women in the U.S. It is estimated that 9% of the population in their reproductive years suffers from infertility.\(^44\) Treatment of infertility is often physically and emotionally draining. In addition, it is financially burdensome, because insurance companies rarely cover infertility treatments.

Overall, the epidemiological evidence raises concerns for women trying to conceive. Two prospective studies have examined the effects of caffeine on time to conception. Wilcox et al. studied women who were attempting to get pregnant and did not get pregnant in the first three months. Women who drank more than the equivalent of one cup of coffee per day were half as likely to conceive during a given menstrual cycle.\textsuperscript{45,46} The chance of taking more than 12 months to conceive was 4.7 times greater in women who drank the equivalent of more than one cup of coffee per day compared to those who drank less than one cup of coffee per day.


\textsuperscript{46} Although it is possible that some component other than the caffeine in coffee is causing the adverse health effects, it is likely that caffeine is the active agent. While many of the studies that assessed caffeine’s effects on health and behavior looked at the effects of coffee consumption, the majority included caffeine from other sources including tea and caffeinated sodas. Animal studies using purified caffeine also have found negative health effects.
In the other prospective study of women trying to conceive, caffeine did not increase the
time it took to conceive. However, the authors themselves pointed out that the study lacked the
power to detect small, negative effects. For example, although smoking has been shown to
decrease fertility in a number of other studies, this study was unable to detect an effect of
smoking on time to conception.

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47 E.I.M. Florack, et al., Cigarette smoking, alcohol consumption, and caffeine intake and

48 G. Howe, et al., Effects of age, cigarette smoking, and other factors on fertility:
findings in a large prospective study, 290 British Medical Journal 1697-1700 (1985).

49 D.D. Baird, A.J. Wilcox, Cigarette smoking associated with delayed conception, 253

50 J. Olsen, et al., Tobacco use, alcohol consumption and infertility, 12 International
Four of six retrospective studies showed a link between caffeine consumption and delayed time to conception. The effects of caffeine consumption on impaired fertility were seen at daily caffeine doses as low as 300 to 400 mg (two or three eight-ounce cups of coffee).\textsuperscript{51,52} All six of the studies controlled for smoking. One of the studies revealed an effect of caffeine only in smokers\textsuperscript{53} and a second found a stronger effect in smokers than in nonsmokers.\textsuperscript{54} In contrast, one study found an effect only in the non-smoking women.\textsuperscript{55} In that study, the authors calculated that women who consumed more than 300 mg of caffeine per day had a 17\% lower probability of pregnancy each month than women who drank less than 300 mg. While it is not clear whether an interaction between smoking and caffeine exists, the overall evidence indicates that caffeine has an independent effect on fertility.

Two retrospective studies failed to find a link between caffeine consumption and impaired fertility. However, one study assessed only coffee drinking and not other sources of caffeine.\textsuperscript{56} The authors acknowledged that their results might have differed from previous reports because they might have misclassified caffeine consumption by omitting other caffeinated beverages.

\begin{flushright}
\textsuperscript{51} C.K. Stanton, R.H. Gray, Effects of caffeine consumption on delayed conception, 142 American Journal of Epidemiology 1322-1329 (1995) [hereinafter Stanton].  \\
\textsuperscript{52} M.A. Williams, \textit{et al.}, Coffee and delayed conception (letter), 335 Lancet 1603 (1991).  \\
\textsuperscript{54} F. Bolumar, \textit{et al.}, Caffeine intake and delayed conception: A European multicenter study on infertility and subfecundity, 145 American Journal of Epidemiology 324-34 (1997).  \\
\textsuperscript{55} See Stanton, \textit{supra} note 51.  \\
\textsuperscript{56} E. Alderete, \textit{et al.}, Effect of cigarette smoking and coffee drinking on time to conception, 6 Epidemiology 403-8 (1995).
\end{flushright}
sources. For example, a woman who did not consume coffee might have been classified into the low-caffeine cohort, when in fact she consumed high levels of caffeine from soda or tea.

The other negative study used dietary recall data for caffeine consumption after delivery as the measure of intake while the women were trying to conceive.\textsuperscript{57} Postpartum caffeine consumption might not be an accurate measure of pre-conception consumption levels. It is quite possible that women’s caffeine intake changed over the nine months of pregnancy and after delivery. For example, the estimate could be high because women might have reduced their intake of caffeine while trying to get pregnant, or new mothers might have increased their consumption of caffeine because they were sleep deprived. Conversely, the estimate could be low for women who did not plan their pregnancy. After finding out she was pregnant, a woman might have stopped consuming caffeine during her pregnancy or might have reduced her consumption postpartum because she was nursing.

\textsuperscript{57} M.R. Joesoef, \textit{et al.}, \textit{Are caffeinated beverages risk factors for delayed conception?} 335 Lancet 136-137 (1990) [hereinafter Joesoef, \textit{et al}].
Two studies looked at the relationship between caffeine consumption and specific causes of infertility. One case-control study found an increased risk of infertility due to tubal disease or endometriosis for women who consumed more than 233 mg caffeine per day, an amount found in less than two cups of coffee.\textsuperscript{58} The other study found no association between caffeine consumption and primary infertility.\textsuperscript{59} However, Weinberg and Wilcox raised concerns about the latter study, stating that many women reduce their caffeine intake within the first three months of attempting conception.\textsuperscript{60} They postulated that women who are having fertility problems might reduce their caffeine intake in an attempt to adopt healthier habits, thus masking the effect of higher caffeine intakes that they might have had previously.

Overall, the literature suggests that daily doses of 100 to 300 mg of caffeine increase the time it takes to become pregnant. If, as one study suggests, the risk of taking more than 12 months to conceive is nearly five times higher in women who drink more than 100 mg of caffeine per day, caffeine may contribute significantly to the physical, emotional, and financial burden of infertility in U.S. women.

\textbf{\textit{(ii) Caffeine’s effects on fetal growth}}

\textsuperscript{58} F. Grodstein, \textit{et al.}, Relation of female infertility to consumption of caffeinated beverages, 137 American Journal of Epidemiology 1353-60 (1993).

\textsuperscript{59} See Joesoef, \textit{et al.}, supra note 57.

\textsuperscript{60} C.R. Weinberg, A.J. Wilcox, Caffeine and infertility (letter), 335 Lancet 792 (1990).
Low birth weight is the leading cause of death among infants in the U.S.\textsuperscript{61} Low birth weight increases perinatal, neonatal, and infant morbidity and mortality, as well as development deficits and health problems later in childhood.\textsuperscript{62} In addition to the devastating health consequences of delivering a low-birth-weight infant, a large financial burden is associated with low birth weight. Hospital costs for a low-birth-weight infant can be as high as $26,000 per month.\textsuperscript{63}

A substantial body of evidence shows that caffeine can inhibit fetal growth and thus contribute to reduced birth weight. A reduction in the birth weight of babies leads to more babies being classified as -- and suffering the associated health risk of -- low birth weight.

Seven of ten prospective studies on caffeine consumption and fetal growth found an effect of caffeine, although the results did not achieve statistical significance in all seven of the studies. All ten studies controlled for smoking, which also can cause inhibit fetal growth.

\textsuperscript{61} Low birth weight is defined as a weight at birth of less than 2,500 grams (about 5.5 pounds).

\textsuperscript{62} National Center for Health Statistics, Centers for Disease Control and Prevention, \textit{Health aspects of pregnancy and childbirth: United States, 1982-1988}.

Three of the prospective studies found that consumption of more than 300 mg of caffeine per day lowered birth weight, head circumference, or height.\textsuperscript{64,65,66} One of those studies found that consuming more than 300 mg of caffeine per day increased the likelihood of low birth weight approximately five-fold.\textsuperscript{67} A fourth study found that women who drank more than five cups of coffee per day had a higher incidence of fetuses that were small for gestational age.\textsuperscript{68} A more recent prospective study found that caffeine intake was negatively associated with birth weight, but only in smokers.\textsuperscript{69} That study reported a 1.6\% decrease in birth weight for every 1,000 mg per week (about one cup of brewed coffee per day) increase in caffeine consumption in smokers.

In two of the prospective studies, the decrease in birth weight associated with maternal caffeine intake almost reached statistical significance. The first reported that non-smoking women who drank more than 800 mg of caffeine per day had infants weighing an average of

\begin{footnotesize}
\textsuperscript{64} B. Watkinson, P.A. Fried, \textit{Maternal caffeine use before, during and after pregnancy and effects upon offspring}, 7 Neurobehav Toxicol Teratol 9-17 (1985).


\textsuperscript{67} See Martin, \textit{ supra} note 65.


\end{footnotesize}
187 g (6.6 oz) less than the infants of women who drank 400 mg or less per day (p=0.06).\textsuperscript{70} That study might have failed to demonstrate a statistically significant effect of caffeine on birth weight because the “low dose” group included women who consumed up to 400 mg of caffeine, as well as nonusers of caffeine. In the second study, caffeine consumption greater than 300 mg per day was associated with an average decrease in birth weight of 174 grams (p=0.14).\textsuperscript{71} The authors of that study attributed the failure of the results to reach statistical significance to the fact that the study included few women with high intakes of caffeine.


Two prospective studies failed to find a link between caffeine consumption and fetal growth. The first study included only 18 women who consumed more than 300 mg of caffeine (about 2 cups of brewed coffee) per day.\textsuperscript{72,73} In the second study, consumption of more than 300 mg of caffeine per day during the first and second trimester of pregnancy resulted in a decrease in birth weight of 93 grams and 141 grams, respectively.\textsuperscript{74} However, the effect of caffeine was not significant when adjusted for other risk factors. The authors acknowledged that their study size did not permit them to make definitive conclusions.

\textsuperscript{72} J.L. Mills, \textit{et al.}, Moderate caffeine use and the risk of spontaneous abortion and intrauterine growth retardation, 269 Journal of the American Medical Association 593-597 (1993) [hereinafter Mills \textit{et al.}].

\textsuperscript{73} The study showed no relationship between caffeine ingestion and crown-to-rump length \textit{in utero}. They did observe an effect of caffeine on birth weight. However, that effect was not significant after adjusting for other risk factors including smoking and maternal age.

Three retrospective studies of the effect of caffeine on fetal growth have found that caffeine increased the chances of intrauterine growth retardation or low birth weight. The first study found a dose-response effect of caffeine on intrauterine growth retardation and on birth weight. The second study found that caffeine consumption was related to delivering an infant that was smaller for gestational age than those of non-consumers. The third study revealed a significant reduction in birth weight with an average caffeine intake greater than or equal to 71 mg of caffeine per day, but only for infants born to non-smoking mothers. That study found a statistically significant inverse dose-response relationship between caffeine consumption and birth weight. There was an average decrease in birth weight of 116 grams in the babies of non-smoking women who consumed 7 to 140 mg of caffeine per day, and a 153-gram decrease in birth weight in the babies of women who consumed more than 140 mg of caffeine per day.


In a case-control retrospective study of 131 women, researchers found that caffeine
consumption of greater than 300 mg per day led to a three-fold increase in the risk of delivering
a low-birth-weight baby.\textsuperscript{78} However, that increased risk did not achieve statistical significance,
perhaps because the study was small.

\footnotesize\textsuperscript{78} B.J. Caan, M.K. Goldhaber, \textit{Caffeinated beverages and low birthweight: A case-control
A number of possible mechanisms have been proposed to explain caffeine’s effect on fetal growth. For example, caffeine is a vasoconstrictor that reduces uterine blood flow. Reducing blood flow to the fetus may reduce the supply of nutrients to the fetus and thus impair growth. In pregnant women who were challenged with 200 mg of caffeine at 37.5 weeks gestation, blood flow to the fetus was reduced by 23%. Studies in non-pregnant women demonstrate that caffeine alters nutritional homeostasis and causes calcium loss into the urine. Studies in rats also found that caffeine intake in pregnancy decreases the calcium, magnesium, and zinc content of fetal bones, perhaps inhibiting fetal growth.

Although the literature is inconsistent regarding whether smokers or nonsmokers are at greater risk, the weight of the evidence indicates that maternal caffeine consumption causes a decrease in birth weight.

(iii) Caffeine and miscarriage

Miscarriage can be an emotional and personal tragedy for women and their partners. It occurs in about 15 to 20% of all pregnancies. Most miscarriages occur in the first trimester.

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83 American College of Obstetricians and Gynecologists, Early Pregnancy Loss:
Most often, genetic problems with the embryo are the cause of miscarriage. Other factors, such as the mother’s health status or use of tobacco, alcohol, or other drugs also increase the risk of miscarriage.

Caffeine has been shown to increase the rate of fetal resorption (the equivalent to human miscarriage) in rodents.\textsuperscript{84} Caffeine consumption also is associated with miscarriage and stillbirth in monkeys.\textsuperscript{85}


Epidemiological studies demonstrate an association between caffeine consumption and spontaneous abortion or miscarriage. Two of four prospective studies have found an association between caffeine consumption and spontaneous abortion. The first study found that women who consumed more than 150 mg of caffeine daily, or about nine ounces of brewed coffee per day, were significantly more likely to experience late-first- or second-trimester miscarriages when compared with women who consumed 0 to 150 mg of caffeine per day.\textsuperscript{86} Caffeine consumption of less than 150 mg per day was associated with increased rates of spontaneous abortion only among women who miscarried in their previous pregnancy. The second prospective study found that women who consumed more than three cups of coffee per day during their first month of pregnancy had an almost three-fold greater likelihood of having a miscarriage.\textsuperscript{87}


Two prospective studies failed to link caffeine intake to miscarriage. A small study of 171 women found no relationship between miscarriage and age, pregnancy history, weight, education, prenatal DES exposure, cigarette smoking, use of caffeine, alcohol, or marijuana, cigarette smoking by the father, or other variables.\textsuperscript{88} However, the authors stated that the small size of the study may have limited their ability to detect effects. The other study that found no relationship between caffeine consumption and spontaneous abortion, included only 24 women (\textless 6\%) who consumed more than 300 mg of caffeine per day.\textsuperscript{89} Thus, the study may not have had the power to detect an effect at high caffeine consumption levels.

Four retrospective studies -- two population-based and two case control -- found that caffeine consumption was associated with an increased risk of miscarriage. A population-based, retrospective study that looked at the effects of caffeine, cigarette smoking, and alcohol in pregnant women found an association between coffee consumption and increased risk of miscarriage.\textsuperscript{90} There was a dose-dependent increase in the risk of miscarriage among women whose coffee consumption resulted in daily caffeine intakes of greater than 140 mg. Women in the highest consumption group (consuming greater than 420 mg of caffeine per day) were 15 times more likely to experience a miscarriage than the women with the lowest intake.


\textsuperscript{89} See Mills, \textit{et al.}, supra note 72.

In a study of 56,000 women who either had a baby or miscarried, an increased risk of miscarriage was associated with consumption of greater than five cups of coffee per day.\textsuperscript{91} That effect was statistically significant and dose-dependent. The authors estimated that approximately 2\% of miscarriages could be attributed to coffee drinking.

The first case-control study compared women who had experienced fetal loss to controls with normal pregnancies.\textsuperscript{92} After controlling for stage of pregnancy, age, educational level, smoking, alcohol use, uterine abnormality, and work schedule, there was a dose-dependent increase in risk of fetal loss with increased caffeine consumption during pregnancy and an approximate doubling of the risk for miscarriage among women who consumed more than 321 mg of caffeine per day.

The second retrospective case-control study found a 55\% increased likelihood of consumption of more than 300 mg of caffeine per day in women who had miscarriages compared to controls.\textsuperscript{93} They concluded that heavy caffeine consumption may contribute to 4\% of spontaneous abortions in women not reporting nausea, and 14\% of spontaneous abortions in women reporting nausea. Controlling for nausea is important because nausea is associated with viable pregnancies.\textsuperscript{94,95,96} A woman who does not experience nausea may be more likely to have a miscarriage. In addition, nausea might decrease caffeine intake.\textsuperscript{97} Therefore, women who are

\begin{itemize}
  \item \textsuperscript{92} C. Infante-Rivard, \textit{et al.}, Fetal loss associated with caffeine intake before and during pregnancy, 270 Journal of the American Medical Association 2940-2943 (1993) [hereinafter Infante-Rivard, \textit{et al.}].
  \item \textsuperscript{93} L. Fenster, \textit{et al.}, Caffeine consumption during pregnancy and spontaneous abortion, 2 Epidemiology 168-174 (1991).
  \item \textsuperscript{94} J.M. Brandes, \textit{First trimester nausea and vomiting as related to outcome of pregnancy}, 30 Obstetrics and Gynecology 427-431 (1967).
  \item \textsuperscript{95} D.V.I. Fairweather, \textit{Nausea and vomiting during pregnancy}, 7 Obstetrics and Gynecology Annals 91-105 (1968).
  \item \textsuperscript{96} J.H. Medalie, \textit{Relationship between nausea and/or vomiting in early pregnancy and abortion}, Lancet 117-119 (1957).
\end{itemize}
less nauseous may consume more caffeine and have an increased rate of miscarriage that is independent of caffeine consumption. It is noteworthy that none of the other studies of caffeine consumption and miscarriage took nausea into account.

Overall the evidence indicates that doses of caffeine higher than 150 to 300 mg are associated with an increased risk of miscarriage. The few studies that found no link may have been to small to detect it.

(iv) Caffeine and birth defects

While the link between caffeine consumption and birth defects is not as strong as that for miscarriage, delayed conception, and reduced birth weight, the evidence raises concerns. A case report of three women who gave birth to babies with missing fingers or toes (ectrodactyly) showed that all of the women reported drinking eight or more cups of coffee per day during pregnancy.\textsuperscript{98} That unusual birth defect also occurred in several animal studies.\textsuperscript{99,100}


Two epidemiological studies also linked caffeine consumption to birth defects. A prospective study reported that women who consumed caffeine had a two-fold higher rate of babies with birth defects compared to non-consumers (3.7% in coffee drinkers, 1.7% in non-consumers).\(^\text{101}\) Although that result was not statistically significant, there was a statistically significant increase in the incidence of several specific types of birth defects. The study found a higher incidence of chromosomal abnormalities and congenital multi-anomalies in the offspring of caffeine consumers than in the controls. In addition, the study had limited power to detect effects of higher doses of caffeine. That study of almost 10,000 women included only 53 women who consumed more than five cups of coffee per day. Furthermore the study did not separate consumers of more than five cups of coffee per day from consumers of lower amounts of caffeine to determine if they were at higher risk for birth defects.

A retrospective study of 56,000 women showed an increased likelihood of heart defects among the children of women who drank three or more cups of coffee per day during their pregnancy.\(^\text{102}\) A study on rats in which caffeine was administered to the mothers by injection also found heart defects in the offspring.\(^\text{103}\)

\(^{101}\) Furuhashi, et al., supra note 68.


Three retrospective studies failed to show a link between caffeine consumption and birth defects. Two of those studies included only a small number of women who consumed more than three or four cups of coffee per day. Therefore, they had limited ability to determine whether higher doses of caffeine cause birth defects. In Finland, which leads the world in per capita coffee consumption, a case-control study of infants included more women who drank four or more cups of coffee per day. The study found no increased risk of birth defects with increased caffeine consumption. However, it grouped together several types of birth defects that may or may not be related to caffeine consumption, which may have obscured a link between caffeine and ectrodactyly or heart defects.

Several epidemiological studies may have failed to link caffeine consumption with birth defects because they lacked sufficient power to detect small increases in the rate of birth defects. Because the rate of birth defects is low and the rate of particular birth defects -- for example, ectrodactyly that is caused by caffeine in animals -- are even lower, larger studies may be required to adequately study the effect of caffeine on birth defects.

In 1980, the FDA began advising pregnant women to avoid caffeine-containing foods and drugs. That advice was based largely on animal studies that suggested increased rates of birth defects in rats fed caffeine. In a study by Collins and colleagues, rats were fed caffeine in large, 

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bolus doses, by gavage.\textsuperscript{107} The study reported that one of every five rat pups born to mothers that had been gavage-fed 80 to 125 mg/kg of caffeine while they were pregnant had permanent birth defects, such as ectrodactyly and delayed bone development (ossification). A follow-up study by the same researcher published in 1982 compared the effects of caffeine given by gavage to caffeine administered in drinking water.\textsuperscript{108} That study showed that ectrodactyly was only observed in offspring of the group given caffeine by gavage and not in rats that sipped caffeine in their drinking water. However, the plasma levels of caffeine achieved in the sipping study were only one-tenth that of the level achieved by gavage.


\textsuperscript{108} G.J. Ikeda, \textit{et al.}, Blood levels of caffeine and results of fetal examination after oral administration of caffeine to pregnant rats, 2 Journal of Applied Toxicology 307-314 (1982).
It is not appropriate to dismiss the study in which caffeine was given by gavage. A subsequent study on rats found that administering 100 mg/kg of caffeine as a single daily dose by gavage led to ectrodactyly while giving that same amount of caffeine as a divided dose, four times a day, did not lead to ectrodactyly.\textsuperscript{109} In that study, it was the high blood levels achieved from the bolus dose of 100 mg/kg, and not the method of administration, that caused ectrodactyly in rats.

Criticisms of Collins’ caffeine studies in rats focused on gavage feeding. However, that method of administering potential teratogens is still common practice in animal studies. It is particularly noteworthy that the FDA currently relies on data from gavage studies to determine whether a food additive is teratogenic or toxic.\textsuperscript{110,111} Moreover, while feeding caffeine by gavage may not perfectly simulate the way humans consume caffeine, that method of feeding is probably a better model than is putting caffeine in the rats’ drinking water. Most people do not

\textsuperscript{109} S.E. Smith, \textit{et al.}, Effects of administering caffeine to pregnant rats either as a single daily dose or as divided doses four times a day, \textit{25 Food and Chemical Toxicology} 125-133 (1987).

\textsuperscript{110} T.F.X. Collins, \textit{et al.}, Developmental toxicity of orange B when given to rats by gavage, \textit{12 Toxicology and Industrial Health} 45-57 (1996).

\textsuperscript{111} T.F.X. Collins, \textit{et al.}, Teratogenic potential of FD&C Red No. 3 when given by gavage, \textit{9 Toxicology and Industrial Health} 605-616 (1993).
slowly sip caffeinated beverages throughout the day. For example, half of all coffee is consumed before noon. Much of coffee consumption more closely parallels the administration of caffeine in large, bolus doses rather than sipping caffeine over the course of the day. Therefore, the results of the caffeine gavage studies deserve careful consideration.

(v) Health authorities and leading researchers have warned about caffeine consumption by pregnant women and women trying to conceive

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In its public information about how to have a healthy baby, the March of Dimes suggests that pregnant women avoid caffeine found in tea, coffee, soft drinks, and chocolate.\textsuperscript{113} The March of Dimes states that a pregnant woman should

\ldots cut back or eliminate caffeine from her diet, as some studies suggest that drinking as little as one-and-a-half cups of coffee a day may delay conception and increase the risk of miscarriage.\textsuperscript{114}

A consumer information brochure by the American Dietetic Association entitled, \textit{Caffeine: How little, how much for you and your family?} states that

\ldots sensitivity to caffeine may increase during pregnancy. You may decide to reduce caffeine while you are pregnant or nursing to reduce intake by the baby. Many expectant or nursing mothers limit caffeine consumption to no more than 200 mg per day or eliminate it entirely.\textsuperscript{115}

\textsuperscript{113} The March of Dimes also cosponsors a pamphlet with the International Food Information Council that states a guideline for daily intake of caffeine of 300 mg for pregnant women.


\textsuperscript{115} American Dietetic Association, \textit{Caffeine: How little, how much for you and your family?} Chicago, IL (1988).
Martin and Bracken, researchers at Yale University Medical School, warned that although further work is needed to confirm the effects of caffeine on reproductive outcomes, the FDA warning about the possible risks of caffeine consumption during pregnancy should be continued given the high frequency of caffeine intake in pregnant women.\footnote{116} In 1992, Dlugosz and Bracken wrote,

An earlier review of this literature suggested that caffeine consumption at moderate levels by pregnant women does not adversely affect the fetus. More recent research does not confirm this view, and while there is insufficient evidence to be certain about reproductive effects of caffeine, there is reason for concern.\footnote{117}

Brenda Eskenazi, an epidemiologist at University of California, Berkeley School of Public Health, who has studied the effects of caffeine on miscarriage, growth retardation, and time to conception, wrote in an invited editorial in JAMA in 1993,

In contrast to many other potential reproductive toxicants, caffeine use is under the control of the consumer. Given the widespread consumption of caffeine, any adverse consequences, even if small, would have important public health implications. In 1980, the Food and Drug Administration issued an advisory based largely on animal evidence that stated pregnant women should limit their intake of caffeine to a minimum. After more than a decade of research, this advisory is still appropriate.\footnote{118}

In a study of miscarriage and caffeine intake, Infante-Rivard and colleagues at McGill University concluded that,

\footnote{116} See Martin, \textit{supra} note 65.


... the findings of this study are in agreement with animal data. Since the risk associated with intake of caffeine was substantially elevated, a reasonable recommendation would be to reduce consumption of caffeine [sic] beverages during pregnancy.\textsuperscript{119}

In their study linking caffeine consumption to delayed conception, Stanton and Gray, from the Johns Hopkins School of Hygiene and Public Health, concluded that,

\textsuperscript{119} See Infante-Rivard, et al., supra note 92.
Our findings, along with the findings of Wilcox et al. and Hatch and Bracken, suggest that women who wish to achieve a conception should avoid high levels of caffeine intake.\textsuperscript{120}

(b) Caffeine’s effect on bone-mineral metabolism

Each year in the United States, about 260,000 women experience hip fractures because of osteoporosis.\textsuperscript{121} Over half of those women require help with daily activities for the rest of their lives.\textsuperscript{122} Another 15 to 25\% enter long-term-care institutions as a result of hip fractures. Although many factors -- including low calcium intake, lack of physical activity, and genetic factors -- contribute to osteoporosis, caffeine intake also may play a role.

\textsuperscript{120} See Stanton, supra note 51.

\textsuperscript{121} National Center for Environmental Health, Center for Disease Control and Prevention Osteoporosis Studies, fact sheet (1994).

\textsuperscript{122} Office of Women’s Health, Center for Disease Control and Prevention, Health in Later Years (visited July 15, 1997) <http://www.cdc.gov/od/owh/whily.htm>.
Caffeine’s negative effects on calcium balance are modest. However, the effect over many years of caffeine consumption on bone mineral metabolism should be considered in the context of Americans’ other dietary shortcomings. Americans older than 12 years do not consume enough calcium. In addition, Americans eat a diet high in protein and sodium, which also increases calcium excretion in the urine. Thus, when the effects of caffeine consumption on bone mineral metabolism are put in the context of the overall American diet, its public health significance becomes a concern.

123 A.C. Looker, et al., Calcium Intake in the United States, NIH Consensus Development Conference on Optimal Calcium Intake June 6-8, 1994 [hereinafter Looker et al.].


Four studies looked at the effect of caffeine intake on various components of calcium balance. The first found that caffeine intake impaired calcium absorption, resulting in a negative effect on calcium balance after adjusting for calcium intake, age, and estrogen status.\textsuperscript{126} Two additional studies focused on the effect of caffeine on calcium excretion in the urine. One study demonstrated an increase in calcium excretion one or two hours after caffeine ingestion.\textsuperscript{127} Although the second urinary-excretion study showed that urinary calcium excretion was not significantly higher over a 24-hour period after caffeine consumption, caffeine did have a negative effect on calcium balance.\textsuperscript{128} The authors found that caffeine’s effect on calcium balance was on the input side of the balance equation\textsuperscript{129} and that in order to counteract the effects of caffeine on calcium balance, one would have to consume an extra 53 mg of calcium for each eight-ounce serving of coffee.

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\begin{itemize}
\item While 53 mg of additional calcium may seem low, American women and adolescent girls already consume inadequate levels of calcium. According to data from the National Health and Nutrition Examination Survey (NHANES III), women between 20 and 39 years of age and adolescent girls consumed an average of 765 mg and 810 mg of calcium per day, respectively.\textsuperscript{130}
\end{itemize}
\end{flushright}


\textsuperscript{127} See Massey, \textit{supra} note 81.

\textsuperscript{128} See Barger-Lux, \textit{supra} note 126.

\textsuperscript{129} They found that calcium intake was inversely proportional to caffeine intake. After adjusting for calcium intake, there was a further inverse relationship between caffeine intake and calcium absorption efficiency.

\textsuperscript{130} See Looker \textit{et al.}, \textit{supra} note 123.
National Institutes of Health Consensus Conference.\textsuperscript{131} Data from the USDA’s Nationwide Food Consumption Survey (1987-1988 NFCS) showed that after age 11 the average calcium intake does not reach even 75\% of the Recommended Dietary Allowance (RDA) for calcium for any female age group (the RDA is 800 mg of calcium per day for adult women over 25 years and 1,200 mg for 11 to 24 year old girls and women).\textsuperscript{132}

\begin{footnotesize}
\begin{itemize}
\item[\textsuperscript{131}] National Institutes of Health, \textit{Optimal Calcium Intake}, NIH Consensus Statement, June 6-8, 1994.
\end{itemize}
\end{footnotesize}
One study, which measured fecal calcium excretion in 191 women at multiple time points around the time of menopause, failed to demonstrate an effect of caffeine consumption on calcium loss in feces. However, fecal calcium loss is only one mechanism by which caffeine might affect calcium balance. The failure of investigators to see caffeine-dependent changes in fecal calcium loss only suggests that this particular mechanism is not sensitive to caffeine. The study did not address whether caffeine might have affected overall calcium balance by urinary excretion, absorption, or another mechanism.

In a number of studies, caffeine was associated with decreased bone-mineral density and an increased likelihood of osteoporotic fractures. A USDA prospective study of bone-mineral density showed that in post-menopausal women, daily consumption of caffeine in amounts equal to or greater than that obtained from two or three servings of brewed coffee was associated with decreased bone-mineral density in women with calcium intakes below 800 mg. Since the mean daily calcium intake for women over 30 years is approximately 600 mg, most women who consume more than two or three cups of coffee a day could be causing harm to their bones.

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Three large, well-designed studies found an association between caffeine or coffee intake and problems with bone health. A 1990 report of 3,170 people from the Framingham Study found that consumption of the amount of caffeine contained in 2.5 cups of coffee per day was associated with approximately double the risk of hip fracture.\textsuperscript{136} In addition, a prospective study of 84,484 middle-age U.S. women found that women who consumed more than four cups of coffee per day had a three-fold increased risk of hip fracture.\textsuperscript{137} There was a dose-response relationship between increased coffee consumption and increased risk of hip fractures. A study of 980 older women in Rancho Bernardo, California, found a statistically significant association between lifetime intake of caffeinated coffee and decreasing bone-mineral density of the hip and spine.\textsuperscript{138} However, in women who reported drinking at least one glass of milk per day during most of their adult lives, bone density did not vary with coffee intake, suggesting that increasing


dietary calcium can compensate for the detrimental effects of caffeine. Notwithstanding that finding, older women may not be able to compensate adequately for the loss of calcium associated with caffeine consumption.\textsuperscript{139} Massey hypothesized that the inability of older women to compensate for caffeine consumption may be a result of an inability to increase intestinal reabsorption of calcium, similar to results seen in older rats.

\textsuperscript{139} See Massey, \textit{supra} note 81.
A recent study, funded in part by the National Coffee Association, failed to find an effect of caffeine from zero to eight or more cups of coffee per day on bone density of the hip in 138 healthy postmenopausal women who had not used hormone replacement therapy.\textsuperscript{140} However, the size of the study provided only 80% statistical power for detecting a 4% difference in total-body bone-mineral density between the three caffeine-intake groups. In addition, this study included few participants who consumed high levels of caffeine. The average caffeine consumption of the three groups was 50, 180, and 322 mg.

One small study (122 women) failed to detect a relationship between the rate of bone loss and caffeine, calcium, sodium, or protein intake.\textsuperscript{141} However, the authors concluded that the data did not rule out a possible effect that might be detected with a larger, longer-term study.

Overall, the data show that caffeine has a detrimental effect on calcium balance, bone mineral density, and the risk of fractures. Older women, teenagers, and women who do not consume enough calcium, which unfortunately is the majority of American women, are particularly vulnerable to the bone damage caused by caffeine.

\textbf{(c) Behavioral effects of caffeine}


Caffeine is the most widely consumed psychoactive drug in the world.\textsuperscript{142} It is a stimulant of the central nervous system. It is addictive and can cause physical dependence in regular users.\textsuperscript{143,144,145,146,147} Abrupt cessation of caffeine consumption after a period of sustained use


\textsuperscript{143} See James, supra note 9.

\textsuperscript{144} See Strain, supra note 10.

\textsuperscript{145} See Griffiths, supra note 11.
often causes headache, irritability, sleepiness, and lethargy.\textsuperscript{148,149,150} Withdrawal symptoms can occur after discontinuing a daily caffeine intake of less than 100 mg of caffeine.\textsuperscript{151}

\textsuperscript{146} See Hughes, \textit{supra} note 12.

\textsuperscript{147} Although the consumption of caffeine causes a number of adverse health and behavioral effects, we are not likening addiction to caffeine to addiction to other, more harmful drugs of abuse such as cocaine or heroin. Caffeine intake does not result in cravings for increasing doses of caffeine. Additionally, caffeine dependence is not associated with antisocial behavior like that seen with other drugs of abuse.


\textsuperscript{150} M. van Dusseldorp, M.B. Katan, Headache caused by caffeine withdrawal among moderate coffee drinkers switched from ordinary to decaffeinated coffee: a 12 week double blind trial, 300 British Medical Journal 1558-1559 (1990).

\textsuperscript{151} See Griffiths \textit{et al.}, \textit{supra} note 11.
Caffeine can cause users to experience restlessness, nervousness, insomnia, gastrointestinal disturbances, and cardiac arrhythmia.\textsuperscript{152} In a population-based study of adults, 30\% of caffeine users reported caffeine-induced anxiety in the last year and 39\% reported caffeine-induced insomnia.\textsuperscript{153} In addition, 24\% reported meeting the full criteria for withdrawal as described in the \textit{Diagnostic and Statistical Manual of Mental Disorders} (DSM-IV).

Given the high prevalence of caffeine use and the widespread experiences of behavioral effects among consumers, the FDA should evaluate those effects and determine if any additional regulatory action is warranted to protect consumers from experiencing those effects.

\textbf{(d) Caffeine and children}

Caffeine also has behavioral effects on children. Anxiety and restlessness due to caffeine consumption have been demonstrated in children.\textsuperscript{154} When children age six to 12 years abruptly

\textsuperscript{152} See DSM 4, supra note 7.

\textsuperscript{153} See Hughes, \textit{et al.}, supra note 12.

\textsuperscript{154} See Bernstein, \textit{et al.}, supra note 6.
stopped consuming caffeine, their ability to attend to tasks worsened and they developed headaches. In addition, caffeine use may lead to dependence in children and adolescents.\textsuperscript{155,156}


Consumption of -- and sometimes addiction to -- caffeinated products, such as soft drinks, may contribute to poor diets in children. USDA data show that the average adolescent boy consumes 21 ounces of soda per day, compared to 10 ounces of milk per day.\textsuperscript{157} The average adolescent girl drinks approximately 12 ounces of soda a day, compared to less than eight ounces of milk. Current USDA data also show that children under five years old drink 16\% less milk and 23\% more soft drinks than in the late 1970s.\textsuperscript{158} In another study, teenagers who consumed one or more soft drinks a day consumed one-fifth less calcium than children who did not drink soft drinks.\textsuperscript{159} The author of that study, a nutritionist at the USDA, stated that soft drinks “have the greatest impact on the adequacy of calcium intake” of children and adolescents.\textsuperscript{160}

Researchers have only begun to explore the effects of caffeine on children. The consequences of raising a generation of our nation’s children dependent on a drug that is delivered in food products that often have little or no nutritive value (soft drinks, waters, coffee,


\textsuperscript{158} USDA, What we eat in America--First year results from ongoing survey, Food & Nutrition Research Brief (January 1996).

\textsuperscript{159} P.M. Guenther, Beverages in the diets of American teenagers, 86 Journal of the American Dietetic Association 493-499 (1986).

\textsuperscript{160} Id.
and tea) deserve further consideration by the FDA. The FDA should act on the strength of the current evidence while further studies are conducted.

(e) The need for safety factors in interpretation of the data

When applying the results of scientific studies to regulatory policy, it is important to consider safety factors. For example, the number of subjects in the studies of caffeine’s reproductive effects is small compared to the four million American women who give birth each year\textsuperscript{161} (and the large number of women whose pregnancies end in miscarriage). In addition, the genetic diversity (for example, differences in caffeine metabolism) and lifestyles of those millions of women are greater than that of the test subjects. Also, studies are subject to “noise” in the controls (for example, poor reproductive outcomes can be caused by factors other than caffeine), and are of limited power to identify caffeine-related problems that occur at low rates. For those reasons, if an adverse health effect is identified in an animal or human study, safety factors are normally applied to ensure that a recommended level of consumption would protect the vast majority of consumers.

Studies on the effects of caffeine have found adverse effects produced by a range of exposures. For instance, epidemiological studies found that daily maternal intakes of caffeine of 71 to 500 mg decreased birth weight, 150 to 420 mg increased the rate of miscarriage, and 100 to 400 mg increased the time it took to conceive. Applying a ten-fold safety factor to the highest no-

observed-effect level would mean that women who are pregnant should not consume coffee, but probably could safely consume decaffeinated coffee.

We recognize that there are still some unanswered questions about some of caffeine’s effects. However, the lack of complete consistency in data and absolute proof of a cause-and-effect relationship is customary for most problems that health authorities and regulatory agencies must address. According to Brenda Eskenazi, from the School of Public Health at the University of California at Berkeley,

The weight of the evidence indicates that high levels of caffeine intake (> 300 mg/day) during pregnancy are potentially harmful. But are the data sufficient to conclude that lower levels are safe? We cannot conclude that lower levels are safe, given that studies have conflicting results and exposure assessment is problematic. Also, some sensitive end points have not been adequately studied.162

The same logic would apply to effects of caffeine other than on reproduction.

Given the overall strength of the data, it would be irresponsible for the FDA not to provide consumers, especially women of child-bearing age, with the most health-protective advice and the information they need to put that advice into practice. Thus, the FDA should require disclosure of caffeine content on food labels. Then, it should review the evidence regarding all of caffeine’s health effects and, considering relative safety factors, determine what further educational or regulatory actions it should implement.

B. Statement of Legal Grounds

162 See Eskenazi, supra note 118.
1. The administrative record supports requiring disclosure of caffeine content

On November 15, 1979, after years of meetings between the FDA and CSPI on the subject of warning labels for caffeine-containing products, CSPI filed a Citizen Petition requesting (1) warning labels on coffee and tea to alert consumers to the risks of birth defects and other reproductive problems and (2) the initiation of an educational campaign to inform pregnant women about the risks posed by caffeine consumption. On April 25, 1980, CSPI received a letter from the FDA that was tantamount to a denial of its petition. Therefore, on June 27, 1980, CSPI brought a lawsuit against the agency to compel it to consider whether labels warning against the potentially harmful effects of caffeine were warranted on coffee and tea products.

Following the filing of CSPI’s lawsuit, the FDA issued a proposal on October 21, 1980, to (1) repeal the GRAS status for caffeine, (2) declare that no prior sanction exists for the use of caffeine as an added food ingredient, (3) restrict the use of caffeine as an added food ingredient to current uses and levels, and (4) require that the presence of caffeine as an added ingredient be reflected on the product label in the ingredient declaration. The FDA proposed to permit the continued use of added caffeine under an interim food additive regulation pending studies on “potential fetotoxic and teratogenic properties of caffeine, the comparative metabolism and pharmacokinetic handling of caffeine in humans and experimental animals, the potential behavioral effects of caffeine, and the potential carcinogenicity of caffeine.”

On October 21, 1980, the FDA also published a proposed rule to amend the standard of identity for soda water to recognize that caffeine is no longer required as a characterizing

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ingredient for “cola” and “pepper” type soda water beverages. Instead, the FDA proposed that naturally occurring and added caffeine continue to be allowed as optional ingredients in cola and pepper beverages. Part of the rationale for this proposal was that companies had begun marketing caffeine-free cola products which could not be marketed legally under a standard of identity that required caffeine as a characterizing ingredient.

In response to the FDA’s publication of the proposed rules relating to caffeine, CSPI voluntarily dismissed its suit without prejudice on November 21, 1980. CSPI had hoped that the caffeine rulemaking would resolve the safety questions. Instead, however, more questions have been raised, and the caffeine proposals were never finalized.

Although the FDA initially believed that caffeine was not the subject of a “prior sanction” that would insulate it from regulation as a food additive under the 1958 Food Additive Amendments, in May of 1987 -- following the receipt of comments from industry -- the agency changed its mind and proposed the codification of a prior sanction for caffeine added to nonalcoholic carbonated beverages. The proposed codification stated that caffeine “may be used as a component of nonalcoholic carbonated beverages. The total caffeine content in the finished beverage shall not exceed 0.02 percent by weight.” The FDA stated that “this prior sanction is consistent with the current uses of caffeine permitted by the GRAS regulation (21 C.F.R. 182.1180) and by the food standard for soda water (21 C.F.R. 165.175).” The FDA cautioned that “because no prior sanction was asserted for uses of caffeine in foods other than nonalcoholic carbonated beverages, this proposal does not address the other uses.” It promised to address “at

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164 52 Fed. Reg. 18,923, 18,925 (May 20, 1987).
some future date” the remaining uses of caffeine and comments received in response to the October 21, 1980 proposal.165

165 Id. at 18,925.
In 1989, the FDA issued a final rule revoking the standard of identity for soda water and the proposed revisions to that standard regarding cola and pepper products, concluding that “some provisions of the standard are being adequately dealt with by other regulations, while other provisions are no longer necessary.” The FDA only briefly mentioned the pending proposal to codify a prior sanction for added caffeine, stating that “with the repeal of the standard of identity for soda water, manufacturers will be free to produce any cola or pepper beverage without added caffeine, irrespective of agency action regarding the prior sanction of caffeine.”\footnote{54 Fed. Reg. 398, 399 (Jan. 6, 1989).} Significantly, the agency did not refer to the fact that one year earlier, when it issued the \textit{Final Monograph for Stimulant Drug Products for Over-the-Counter Use}, it required a number of warning statements to appear on products containing caffeine as an active ingredient. Two of the warnings are particularly relevant to this petition:

- The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.\footnote{53 Fed. Reg. 6100, 6105 (Feb. 29, 1988).}

- “Do not give to children under 12 years of age.”\footnote{\textit{Id.}}
Surprisingly, on October 25, 1996, the FDA officially denied CSPI’s 1979 Citizen Petition without prejudice to a future filing on the grounds that: (1) in the time that has elapsed since the filing of the petition in 1979, significant scientific developments may have affected issues raised in the petition; (2) the FDA has expended significant resources educating the public regarding health risks during pregnancy; (3) the FDA has published health information on caffeine consumption for the public at large; and (4) the FDA has budgetary constraints.\textsuperscript{169} The action on the petition after almost 17 years indicates that the FDA has embarked on some laudable housecleaning. The FDA should not, however, conclude that the denial of the petition resolves the matter. Indeed, as the scientific portion of this petition demonstrates, many studies have been conducted since the original petition was filed and provide a wealth of new information. The old and new research indicates the need for the agency, at a minimum, to (a) adopt a quantitative disclosure requirement for added and naturally-occurring caffeine, (b) conduct a thorough review of the scientific evidence on the health and behavioral effects of caffeine, and (c) determine and implement the appropriate regulatory and educational approaches that should be taken to address them.

2. The FDA has the authority to require disclosure of caffeine content on food labels

Under the Federal Food, Drug, and Cosmetic Act’s misbranding provisions, a food is “misbranded” if its label is “false or misleading in any particular.”\textsuperscript{170} Congress further provided

\begin{enumerate}
\item Letter from Ronald G. Chesemore, Associate Commissioner for Regulatory Affairs, FDA, to Dr. Michael Jacobson, Executive Director, CSPI (Oct. 25, 1996).
\item FD&CA § 403(a), 21 U.S.C. § 343(a).
\end{enumerate}
that in determining whether a product is misbranded because of misleading labeling, it is necessary to evaluate whether the label “fails to reveal facts material in the light of . . . representations [made] or material with respect to consequences which may result from the use of the article. . .”\textsuperscript{171} Under its general authority, the FDA has “authority to promulgate regulations for the efficient enforcement of this Act . . . ”\textsuperscript{172} Thus, Congress has given the FDA explicit authority to require that manufacturers provide key additional information beyond what is already required to appear on product labels if the additional information is necessary to prevent consumers from being misled.\textsuperscript{173} As this petition demonstrates, the amount of caffeine in foods and beverages is a material fact for health-conscious consumers, and the disclosure of the caffeine content in a serving of a product is required to prevent consumer deception.

(a) The FDA has the authority to mandate “special labeling” requirements

\textsuperscript{171} FD& CA § 201(n), 21 U.S.C. § 32l(n).

\textsuperscript{172} FD&CA § 701, 21 U.S.C. § 371.

In carrying out its mandate to prevent misbranding, the FDA may require “special labeling” for food “where information is necessary to ensure that consumers are aware of special health risks associated with consumption of a particular product.”\textsuperscript{174} Thus, although the FDA does not consider “protein products intended for use in weight reduction . . . inherently unsafe,” it requires such products to carry a warning statement that provides in pertinent part that “very-low-calorie, protein diets may cause serious illness or death.”\textsuperscript{175} The label further warns “Not for use by infants, children, or pregnant or nursing women.”\textsuperscript{176}

Similarly, the FDA requires products containing Olestra to state:

\textbf{This Product Contains Olestra.} Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E, and K have been added.\textsuperscript{177}

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\begin{itemize}
  \item \textsuperscript{174} 61 Fed. Reg. 3117, 3160 (Jan. 30, 1996) (Final rule permitting use of Olestra).
  \item \textsuperscript{175} \textit{Id.} at 3160. The FDA’s authority to issue such warnings was upheld in \textit{Council for Responsible Nutrition v. Goyan}, No. 80-1124 (D.D.C. Aug. 1, 1980), \textit{reprinted in} Food, Drug Cosm. L. Rep. (CCH) ¶ 38,057.
  \item \textsuperscript{176} 21 C.F.R. § 101.17(d)(1).
  \item \textsuperscript{177} 61 Fed. Reg. at 3159-60.
\end{itemize}
Recently, the FDA has used its authority to require warning statements on the labels of iron-containing products including both dietary supplements (which are considered foods) and drugs. The warning statements are required to help prevent accidental overdoses of iron-containing products by children.178

The FDA has required that a variety of specific information about particular ingredients be disclosed to alert consumers who may have special dietary concerns:

• Diet soft drinks containing both saccharin and sugar must state: “Contains ___mg saccharin (or saccharin salt, as the case may be) per ounce, a nonnutritive sweetener.”\textsuperscript{179}

• The FDA requires that when the term “sodium caseinate” is used in a product labeled non-dairy, the term must be followed by the words “milk derivative.”\textsuperscript{180}

• Combinations of nutritive and nonnutritive sweeteners in diet beverages must bear the statement: “Contains sugar(s); not for use by diabetics without advice of a physician.”\textsuperscript{181}

• To avoid confusion by diabetics, beverages containing sorbitol, mannitol, or other hexitol must state: “Contains carbohydrates, not for use by diabetics without advice of a physician.”\textsuperscript{182}

• Products containing the artificial sweetener aspartame must state: “PHENYLKETONURICS: CONTAINS PHENYLALANINE.”\textsuperscript{183}

• Sulfite levels exceeding a threshold of ten parts per million must be declared on food labels.\textsuperscript{184}

\textsuperscript{179} 21 C.F.R. § 100.130(d)(2).

\textsuperscript{180} 61 Fed. Reg. at 3160, citing 21 C.F.R. § 101.4(d).

\textsuperscript{181} 21 C.F.R. § 100.130(d)(3).

\textsuperscript{182} 21 C.F.R. § 100.130(d)(4).

\textsuperscript{183} 21 C.F.R. §§ 172.804(e)(2), 201.21.

\textsuperscript{184} 21 C.F.R. § 101.100(a)(4).
• Any food whose reasonably foreseeable consumption may result in a daily ingestion of 50 grams of sorbitol or 20 grams of mannitol must state: “Excess consumption may have a laxative effect.”\textsuperscript{185}

• Products containing artificial flavoring, coloring, and chemical preservatives must identify ingredients as such.\textsuperscript{186}

Recently, the FDA issued an advance notice of proposed rulemaking on the declaration of free glutamate in food to protect glutamate-intolerant consumers from adverse reactions. Among the alternatives on which the FDA has sought public comment is a quantitative statement of the amount of free glutamate in a serving of food.\textsuperscript{187}

The courts have upheld the FDA’s authority to impose far more extensive labeling requirements than the simple content disclosure requirement requested in this petition. For example, in \textit{Council for Responsible Nutrition v. Goyan}\textsuperscript{188} and \textit{National Nutritional Foods Association v. Novitch},\textsuperscript{189} two district courts upheld the FDA’s authority to require labels on low-

\textsuperscript{185} 21 C.F.R. §§ 184.1835(e), 180.25(e).

\textsuperscript{186} 21 C.F.R. § 101.22(c).


\textsuperscript{188} No. 80-1124 (D.D.C. Aug. 1, 1980), \textit{reprinted in} Food, Drug Cosm. L. Rep. (CCH) ¶ 38,057.

calorie protein products to make consumers aware of the health risks associated with use of those products. The rationale applied by the courts in those cases supports an FDA decision to require quantitative disclosure for caffeine.

Similarly, in Cosmetic, Toiletry and Fragrance Association, Inc., v. Schmidt, the court upheld the FDA’s authority under sections 201(n) and 701(a) of the FD&CAct to require warnings on labels of all food, drug, and cosmetic products sold in aerosol cans. The warnings tell consumers to avoid puncturing or incinerating the cans and to avoid storing them above 120 degrees Fahrenheit.

More recently, a district court declared Kellogg’s ready-to-eat cereal, Heartwise, misbranded under the Texas Food, Drug and Cosmetic Act because the label failed to warn consumers about potential allergic reactions from the psyllium contained in the product. Significant, the Texas statute parallels the federal law in that failure to reveal material facts about the consequences which may result from using a product constitutes misbranding.

If the FDA has the authority to require such label statements, the agency surely has the authority to require quantitative disclosures in appropriate cases such as the one presented by the presence of caffeine in food products.

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191 21 C.F.R. § 101.17.


193 Id. at 1384.
(b) Disclosure of caffeine content is analogous to the FDA’s common and usual name percentage disclosure requirements for characterizing ingredients

Although CSPI is not seeking to have the percentage of caffeine disclosed on product labels, the FDA regulations governing the declaration of the percent of a characterizing ingredient in the common or usual name of food are analogous to the type of regulation being sought by this petition.

Relying upon its authority to prevent consumers from being misled by omissions of material fact, the FDA has promulgated a general regulation requiring that manufacturers of nonstandardized foods disclose the percentage of characterizing ingredients where:

the proportion of such ingredient(s) . . . has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) . . . is present in an amount greater than is actually the case.194

Under this general policy, the FDA has promulgated labeling regulations for specific products. For example, the FDA regulations require the labels of seafood cocktails to specify the percent of each seafood ingredient present in the product as part of the product’s common or usual name.195 The FDA’s authority to require the disclosure of the percent of each type of

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195 21 C.F.R. § 102.54.
seafood in a product was upheld by the U.S. District Court for the District of Columbia. In upholding the regulation, the district court noted:

that the record support for this regulation indicates the materiality of the percentage of characterizing ingredient in this particular product. Virtually all of the consumer response heartily supported the general principle proposed, and several consumers indicated express approval of disclosure of percentage of ingredients for seafood cocktails as a necessary device for comparative food shopping. [footnote omitted] In light of the materiality of the information required to be disclosed by this regulation, the Court is not persuaded that the Commissioner has exceeded his statutory authority in requiring that the label of seafood cocktail reveal the percentage of seafood ingredients therein.\textsuperscript{197}

Similarly, when Congress passed the Nutrition Labeling and Education Act (NLEA) in 1990 -- reflecting its belief that consumers should be given essential information so that they may make appropriate choices -- it included a provision requiring products purporting to contain juice to declare the percentage of juice in the product.\textsuperscript{198} The FDA later enacted implementing regulations to ensure that consumers would not be misled about the amount of juice in a product.\textsuperscript{199}

In the matter at issue in this petition, requiring the disclosure of caffeine content is similar to requiring the percentage ingredient declaration for seafood, juice, and other characterizing ingredients. While in some cases, the amount of caffeine in a food does not affect the economic value or appearance of a food, caffeine’s stimulant and other health effects have a significant effect on the character of the food and certainly affect consumer acceptance. Percentage ingredient declarations and milligram disclosure statements express similar information about key components. Both serve the same purposes: preventing consumer deception caused by the failure to disclose material facts and furthering the consumer’s ability to engage in meaningful

\textsuperscript{197} \textit{Id.} at 554.


\textsuperscript{199} 21 C.F.R. § 101.30.
comparative food shopping. We are not asking for percentage labeling for products containing caffeine because milligram disclosure is a more appropriate and meaningful requirement for such products.

CSPI’s request for a quantitative disclosure of caffeine on product labels will enable consumers to determine and manage their caffeine intake. On the basis of caffeine-content information, consumers might choose products higher or lower in caffeine. For example, they might choose a coffee ice cream low in caffeine rather than one that is high in caffeine before bed. Or they might choose a bottled, caffeinated water with more caffeine while making a long drive. Quantitative labeling is particularly important for brands of coffee, tea, soft drinks, coffee ice cream, coffee yogurt and other products that contain varying levels of caffeine. Such a label requirement would, therefore, further Congress’ aims and would continue the progress that the FDA has already made to provide consumers with important information about foods to prevent consumer confusion, guide consumer choices, and promote consumer health.

Although technically it is unclear whether added caffeine in nonalcoholic carbonated beverages is GRAS or prior sanctioned, for purposes of this petition, it makes little difference because the prior sanction is consistent with the uses of caffeine permitted by the GRAS

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200 Even though the proposed prior sanction regulation has not been finalized, under the FDA procedural rules, it is considered to be a binding advisory opinion, and the agency may not “recommend legal action against a person or product with respect to an action taken in conformity with an advisory opinion which has not been amended or revoked.” 21 C.F.R.§ 10.85(d)(I) and (e). However, the status of the advisory opinion regulation itself is uncertain because the proposal has not yet been finalized. On October 15, 1992, the FDA proposed to amend the regulations governing advisory opinions. Significantly, under the proposal, advisory opinions would no longer be binding on the agency. 57 Fed. Reg. 47,314 (Oct. 15, 1992).
regulation. And, under either classification, the FDA is not precluded from enacting regulations requiring the quantitative disclosure of caffeine.

As the FDA stated in its Federal Register notice announcing its conclusion that caffeine is prior sanctioned, such status does not exclude caffeine from the FD&C A’s safety requirements:

Section 181.5(b) (21 C.F.R. 181.5(b)) states that ‘the existence of a prior sanction exempts the sanctioned use(s) from the food additive provisions of the Act but not from other adulteration or misbranding provisions of the Act.’ Furthermore, under § 181.1(b), (21 C.F.R. 181.1(b)) the agency may modify or prohibit a prior-sanctioned use of an ingredient ‘based on scientific data or information that show that use of a prior-sanctioned food ingredient may be injurious to health, and thus in violation of section 402 of the Act.’

In that same Federal Register notice, the FDA also stated that prior-sanctioned ingredients may properly be subject to warning labels under appropriate circumstances.

Thus, under section 403(a) of the act (21 U.S.C. 343(a)), the agency could require warning labels on caffeine-containing nonalcoholic carbonated beverages if it determines that such products present a potential health hazard to consumers. Although the FDA does not believe that a requirement for such a warning label is warranted at this time, such a requirement can be proposed at any time the available data indicate a need for such action.

As the latest review of the scientific literature and facts demonstrate, the requirement for quantitative disclosure labels for caffeine is warranted at this time. Although quantitative disclosure does not constitute a “warning label,” the FDA’s declaration of authority to require warning labels surely would encompass this less drastic means of conveying information to consumers.

By the same reasoning, even if caffeine is still considered to be GRAS under 21 C.F.R.

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201 52 Fed. Reg. 18,923, 18,925 (May 20, 1987).

202 Id. at 18,925.
§ 182.1180, a GRAS designation does not exempt caffeine from the adulteration and misbranding provisions of the Act. As in the case of prior sanctions, GRAS status simply exempts a substance from regulation as a food additive.\footnote{See FD&CA § 201(s), 21 U.S.C. § 321(s), 52 Fed. Reg. at 18,925.}
Significantly, the prior-sanctioned status of added caffeine in nonalcoholic carbonated beverages has no effect on products with naturally-occurring caffeine, which is not regulated as a food additive or on caffeine added to products that are not nonalcoholic carbonated beverages.\(^{204}\)

The emergence of caffeinated water and juice products underscores the need for FDA action. At a minimum, the FDA must ensure that such products adequately disclose their caffeine content. Caffeine is arguably the characterizing ingredient in such products whose very names boast of the products’ stimulant property. The products include caffeinated waters such as Aqua Blast and Krank:0 and caffeinated juices such as Energy Booster and Juiced.\(^{205}\) As such, the quantity of caffeine present should be declared to prevent the products from being misbranded.

\(^{204}\) See id., 45 Fed. Reg. at 69,818; 52 Fed. Reg. at 18,925, and discussion at note 164 and accompanying text, supra. New bottled water products and juice beverages containing added amounts of caffeine are being marketed despite the fact that only carbonated beverages with caffeine are either prior-sanctioned or GRAS. The new products are adulterated under sections 402(a)(2)(C) and 409 of the FD&CA because they contain unapproved food additives. As the FDA stated in its proposal to codify the prior sanction for caffeine in nonalcoholic carbonated beverages, “no prior sanction was asserted for uses of caffeine in foods other than nonalcoholic carbonated beverages.” 52 Fed. Reg. at 18,925. Therefore, caffeinated waters and juices are specifically excluded from the scope of the prior sanction proposal or the GRAS regulation which is consistent with that proposal, and appear to be marketed illegally.

\(^{205}\) CSPI recently filed a citizen petition requesting that the agency take action to prevent
3. The FDA should encourage food-service establishments to disclose caffeine content

the unapproved use of the term “energy” on the labels of food packages.
The FDA has increasingly focused on the entire food market: what is being sold on the grocery shelves in processed and unprocessed forms, as well as what is being served in restaurants. When the agency issued mandatory regulations governing the nutritional labeling of packaged food products, it also adopted guidelines for the voluntary nutrition labeling of raw fruit, vegetables, and fish. It left the door open for mandatory regulation in the event it determined that substantial compliance was not being achieved.\textsuperscript{206} Among the provisions in the guidelines relevant to this petition are recommendations for displaying nutrition information at the point of purchase by a variety of means. These measures include: posting a sign, or making the information readily available in brochure, notebook, or leaflet form in close proximity to the foods.\textsuperscript{207}

Recently, regulations went into effect applying a modified version of the FDA’s nutrient-content and health-claim regulations to restaurants that make claims on menus. Significantly, the regulations provide that restaurants may supply this information in a variety of ways, including the signs, brochures, notebooks, and leaflets enumerated in 21 C.F.R. § 101.45, discussed above.\textsuperscript{208}

The FDA should encourage restaurants and other food-service entities that sell ready-to-consume caffeinated products, e.g., coffee shops, convenience stores, fast-food restaurants, etc.,

\textsuperscript{206} 21 C.F.R. § 101.42.

\textsuperscript{207} 21 C.F.R. § 101.45.

\textsuperscript{208} 61 Fed. Reg. 40, 320, 40,332 (Aug. 2, 1996). The regulations were issued in response to a court order in \textit{Public Citizen v. Shalala}, 932 F. Supp. 13 (D.D.C. 1996). The court determined that Congress intended the NLEA to apply to restaurant menus and that the FDA had no discretion to exempt restaurants from the law’s requirements. CSPI joined Public Citizen in bringing this lawsuit.
to inform consumers of the amount of caffeine in a product before they purchase it. Caffeine content could be disclosed on menus, menu boards, cups, or in poster or brochure formats in a manner that is readily available and obvious to consumers.

4. The failure to issue consistent regulations for substances present in both food and drugs is arbitrary and capricious

The FDA has long recognized the need to harmonize labeling regulations for foods and drugs when the same substance appears in both types of products. For example, it has issued consistent food and drug regulations for aspartame,209 Yellow Dye No. 5,210 sodium labeling,211 and iron.212 A regulation requiring the declaration on OTC drug labels of the quantity of calcium, magnesium, and potassium has also been proposed to complement existing food regulations requiring such labeling.213 Most recently, inspired by the success it has experienced in standardizing food labels pursuant to the NLEA, the FDA has embarked on a rulemaking proceeding to standardize the labels for OTC drugs.214 As the FDA stated in the preamble to the

209 21 C.F.R. §§172.804(e)(2), 201.21(b). It is interesting to note that the OTC regulation requires disclosure of the mg of phenylalanine per dosage unit.

210 21 C.F.R. §§ 74.705, 74.1705.


212 62 Fed. Reg. 2218, 2849-50 (Jan. 15 1997) (Final Rule on Iron Containing Supplements and Drugs: Label Warning Statements and Unit-Dose Packaging Requirements) (to be codified at 21 C.F.R. §§ 101.17(e) and 310.518(c)). The same warning must appear on both dietary supplements, which are regulated as foods, and drugs.


proposed OTC drug rule on the disclosure of calcium, magnesium and potassium: “Consumers need to consider their intake from foods, dietary supplements, and drugs.”\footnote{61 Fed. Reg. at 17809.}
It is, therefore, necessary and appropriate for the FDA to enact regulations for caffeine in foods that are consistent with its OTC stimulant regulations. In the OTC stimulant monograph, the directions for use require a quantitative disclosure of the number of mg of caffeine in each pill. 216 No such requirement exists for the caffeine content in food. The monograph also requires a warning that the products are not to be used by children under 12. 217 Again, no such warning is required for food products with the potential to supply comparable amounts of caffeine. CSPI is not requesting that the label disclosure on food be identical to that for over-the-counter stimulants. At this time, we are requesting simply that any food containing more than a threshold level of caffeine bear a quantitative disclosure statement to allow consumers to choose products on the basis of caffeine content. Such a quantitative disclosure would parallel that for diet soft drinks containing both saccharin and sugar 218 and would complement the OTC warnings for stimulants.

216 21 C.F.R. § 340.50(d).
217 Id. at § 340.50(c)(3).
218 21 C.F.R. § 100.130(d)(2).
The inclusion of a quantitative disclosure requirement also would increase the effectiveness of the caffeine warning already required on OTC stimulant products urging consumers to limit the use of other caffeine-containing products, including foods or beverages, while taking the OTC stimulant. Under the current labeling scheme, limiting caffeine intake while taking the OTC stimulant can be difficult, because consumers are not informed of the caffeine content of foods and beverages. For example, a student taking the recommended dose of NoDoz might not realize that consuming a dish (1 cup) of coffee ice cream could lead to the same side effects as drinking a Pepsi. Similarly, parents of children under 12 have no way of knowing if their children are consuming more than the 100 mg of caffeine they would get in an OTC stimulant unless they receive quantitative content information on foods and beverages.

Whether caffeine is in a dish of coffee ice cream or in a pill, consumers should receive comparable quantitative information. To deprive consumers of this information for foods would be arbitrary and capricious. As the Supreme Court has stated:

> The agency must examine the relevant data and articulate a satisfactory explanation for its action including a ‘rational connection between the facts found and the choice made.’ In reviewing that explanation, we must ‘consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.’ Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter

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219 Id. at § 340.50(c)(l).

to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. The reviewing court should not attempt to make up for such deficiencies; we may not supply a reasoned basis for the agency’s action that the agency itself has not given.\textsuperscript{221}

\footnotesize{\textsuperscript{221} Id. at 43.}
The FDA has not articulated a “satisfactory explanation” for its disparate treatment of caffeine in OTC drugs and foods, although it has had ample time to do so. The Tentative Final Orders for OTC Nighttime Sleep-Aid and Stimulant Products, which recommended the warnings cited in this petition, were issued on June 13, 1978.\textsuperscript{222} CSPI’s initial citizen petition requesting regulatory action on caffeine, which was filed on November 15, 1979, was not denied until Oct. 25, 1996, long after the OTC stimulant monograph was finalized.\textsuperscript{223} Despite the passage of 17 years, the FDA has offered no “rational connection” between the facts found by the agency in the OTC stimulant monograph and the decision made with respect to the disclosure of caffeine in food products. Given the fact that the FDA routinely issues equivalent regulations for food and drug products, and given the fact that the FDA considered that it had enough evidence on the effects of caffeine to require dose information and warnings on over-the-counter-stimulant products, any decision not to require at least a quantitative disclosure of caffeine would be “counter to the evidence” and “implausible” and hence arbitrary and capricious.

Indeed the courts have determined that agency actions are arbitrary and capricious when an agency has inexplicably taken inconsistent positions. In \textit{Contractors Transport v. U.S.},\textsuperscript{224} the ICC’s decision denying an application for a certificate of convenience and necessity was vacated and the case remanded for reconsideration where applicants, under substantially similar conditions, received markedly different treatment, and the ICC did not state a basis for its uneven

\textsuperscript{222} 43 Fed. Reg. 25,554, 25,602 (June 13, 1978).

\textsuperscript{223} \textit{Stimulant Drug Products for Over-the-Counter Human Use; Final Monograph}, 53 Fed. Reg. 6100 (Feb. 28, 1988).

\textsuperscript{224} 537 F.2d 1160 (4th Cir. 1976).
disposition of the two applications. The court stated that “patently inconsistent application of agency standards to similar situations lacks rationality and is arbitrary. . . . A reviewing court is powerless to supply an explanation for apparent inconsistencies in an agency’s decisions.”225

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225 *Id.* at 1162.
Similarly, in *Bush-Quayle ‘92 Primary Committee, Inc. v. Federal Election Commission*, the U.S. Court of Appeals for the District of Columbia Circuit determined that the Election Commission had applied inconsistent standards regarding the repayment of federal matching funds to expenditures made during the Reagan and Bush administrations. The court remanded that case to the Commission to permit it to justify its decision. In reaching its decision, the court stated:

> While here the agency’s vice was not complete inattention to its prior policies, its discussion is so perplexing as to sow doubt whether this is a process of reasoned policy making, with a change in direction put in effect for a navigational objective, or the confusion of an agency that is rudderless and adrift.

The failure by the FDA to mandate the quantitative disclosure of the caffeine content in food and beverage products amounts to disparate treatment for caffeine contained in drugs versus caffeine contained in other products. The caffeine content of a cup of coffee is not required to be disclosed, but the caffeine content of a product such as NoDoz, which contains as much caffeine as a six-ounce cup of coffee, must be disclosed. Such treatment defies rational explanation.

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226 104 F.3d 448 (D.C. Cir. 1997).

227 *Id.* at 454.
Moreover, when an agency fails to follow its own regulations, that “constitutes arbitrary and capricious conduct.” In Simmons v. Block, the Eleventh Circuit struck down the award of a contract when the Farmers Home Administration did not follow its own rules for the acceptance of bids on property. In the case of caffeine, arguably the FDA has not followed its own policy when it required manufacturers of OTC stimulants to warn consumers to limit their intake of caffeine from other products, but failed to require manufacturers to disclose the caffeine content of the very foods and beverages to which the agency refers in the OTC stimulant rule. As a result, consumers are not provided with the information necessary to limit their caffeine intake.

IV. Environmental Impact

The action requested is subject to a categorical exclusion under 21 C.F.R. § 25.24(a)(11) and does not require the preparation of an environmental assessment.

V. Economic Impact

No statement of the economic impact of a quantitative labeling rule is required at this time. However, any costs incurred by a quantitative labeling requirement would be offset, in whole or in part, by the savings gained by the possible health benefits. Measuring caffeine content is inexpensive (and already done by many companies whose products contain caffeine).  

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228 782 F.2d 1545, 1549 (11th Cir. 1986).

229 We contacted 32 companies about the caffeine content of their products. Of those companies, 27 provided information about caffeine content.
The cost of adding the information to labels would be modest. Moreover, only a small fraction of food manufacturers would be required to include caffeine content on product labels.

VI. Conclusion

The FDA should ensure that women and other consumers can regulate their caffeine consumption by requiring quantitative labeling of caffeine. The evidence strongly suggests that the FDA should continue to advise women to avoid caffeine during pregnancy and should extend that advice to women trying to conceive. In addition, the FDA should conduct a thorough review of the other health and behavioral effects of caffeine and take appropriate action to inform consumers and protect the public’s health.

The undersigned certify that, to the best of their knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

Respectfully submitted,

Patricia B. Lieberman, Ph.D.
Science Policy Fellow

Margo G. Wootan, D.Sc.
Senior Scientist

Ilene Ringel Heller, Esq.
Senior Staff Attorney

Center for Science in the Public Interest
1875 Connecticut Avenue, N.W.
Suite 300
Washington, D.C.  20009-5728
(202) 332-9110, ext. 342