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REGULATORY STUDIES PROGRAM

Public Interest Comment on
Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements[1]

The Regulatory Studies Program (RSP) of the Mercatus Center at George Mason University is dedicated to advancing knowledge of the impact of regulation on society. As part of its mission, RSP conducts careful and independent analyses employing contemporary economic scholarship to assess rulemaking proposals from the perspective of the public interest. Thus, this comment on the United States Sentencing Commission's Guidelines for United States Courts does not represent the views of any particular affected party or special interest group, but is designed to evaluate the effect of the Agency's proposed guidelines on overall consumer welfare.

I. Introduction

The Food and Drug Administration (FDA) proposes to implement current good manufacturing practice (CGMP) regulations for dietary ingredients and dietary supplements "to promote and protect the public health." Through this proposal, the FDA intends to require firms involved in the production of dietary ingredients and dietary supplements to ensure that such ingredients and supplements are not adulterated or misbranded.

Specifically, the FDA proposal outlines requirements relating to: 1) personnel; 2) physical plant environment; 3) equipment and utensils; 4) production and process controls; 5) holding and distributing; 6) consumer complaints; and 7) records and recordkeeping. These requirements would provide minimum standards for anyone involved in the manufacturing, packaging, or holding of any dietary ingredient or supplement.

The proposal argues that many consumers believe that FDA currently does regulate the manufacturing practices for dietary ingredients and supplements, providing them with

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a false sense of security regarding these products. Of those who do not believe that the FDA regulates in this area, a significant percentage of individuals believes that more government regulation is necessary in the dietary supplements market. In general, a large portion of dietary supplement users do not believe that the products are safe, according to surveys. Further, by providing a common standard for manufacturing practices, FDA claims that the CGMP will provide significant benefits to consumers in terms of reduced adverse outcomes resulting from adulterated supplements, lower search costs resulting from imperfect information about the quality of manufacturing practices, and lower variance in product quality. According to FDA estimates, these expected benefits are twice as large as the costs associated with the proposal.

Unfortunately, the context for FDA involvement in this area involves significant inconsistencies. First, there appears to be a disconnect between what consumers say and what they do. If dietary supplement users really do believe that the products are unsafe, one wonders why they use the products. Further, it is not clear that a government system of certification provides greater benefits than private systems which are already in the process of development. If consumers actually do harbor significant fear about the safety of dietary products, it would appear that there are sufficient private incentives for firms to submit their products for independent analysis and certification. Lastly, the FDA's expressed fears about leaving regulation to state and local officials are unsupported.

II. Statutory Basis for Regulation

The Dietary Supplement Health and Education Act (DSHEA)[2] became law on October 25, 1994. The relevant effect of this law was to amend the Federal Food, Drug, and Cosmetic Act by adding section 402(g). The added section provides that the Secretary of Health and Human Services may prescribe good manufacturing practices for dietary supplements through regulations. According to the FDA, Congress enacted DSHEA "to ensure consumers' access to safe dietary supplements." Under 402(g), a dietary supplement is considered adulterated if "it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations."

FDA modeled the proposed dietary supplement CGMP after the CGMPs currently in place for food products. The CGMP provisions for food relate to a number of practices beyond basic production practices. For example, in addition to prohibiting unsanitary production practices, the food CGMP apply to quality control operations, food handling operations, receiving operations, inspecting operations, packaging operations, processing operations, storing operations, and transporting operations.

In addition to operations treated in food CGMP, dietary supplements raise additional concerns relating to assurances that labeling accurately relates the supplement's identity, purity, quality, strength, and composition.

[2] Pub. L. 103-417.

III. Words vs. Actions

In explaining why the proposed CGMP regulations are needed, FDA cites a 1999 *Prevention* magazine survey whose results were reported in the article "Consumer Use of Dietary Supplements." That poll revealed that "Only 41 percent of the surveyed consumers who use vitamins and minerals think they are very safe and only 50 percent think they are somewhat safe." With respect to herbal products, "only" 24 percent of surveyed users think the products are very safe, and "only" 53 percent think they are somewhat safe.

By inserting the modifier "only" before the survey statistics, FDA highlights that it finds these numbers troubling to the extent that a higher proportion of individuals should be able to view dietary supplement use as safe. However, since these probabilities are conditional on use of the supplements, it begs the question as to why the residual users consume products they apparently view as "unsafe." That is, assuming that the consumers of dietary supplements are rational and that it is irrational to consume unsafe substances, it is possible to infer from their actions that 100 percent of supplement users view these products as sufficiently safe for consumption.

Furthering their justification for the proposed regulations, FDA again cites the *Prevention* survey as documenting that 12 percent of surveyed supplement users have experienced side effects or adverse reactions from the use of dietary supplements. The survey instrument makes no attempt to determine the magnitude of these adverse consequences, and the FDA makes no attempt to compare this number with similar outcomes for similar products that already face FDA mandated CGMPs, such as pharmaceuticals and food. With this contextual information, it is impossible to decide if the 12 percent number is grounds for alarm, despite the fact that the FDA clearly presents it as such.

Lastly, in its justification by survey, the FDA proposal notes that 74 percent of the surveyed consumers believe that "the Government should be more involved in ensuring that these products are safe and do what they claim to do." Again, given that this probability is conditional on actually using dietary supplements, one wonders what motivates such a large majority of survey respondents to seek increased FDA involvement in a product that they already deem safe enough to use.

While the FDA provides this background information as the context for the necessity of FDA involvement in the manufacturing process of dietary supplements, the survey statistics are far from convincing, since they evidence a severe disconnect between what consumers do and what they say they want. Rather than try to examine this puzzle, the FDA proposal simply spins the results to provide pretext for the increase in regulation.

Without further investigation, it would be plausible to attribute the public's clamoring for increased regulation in the dietary supplement market to what economists have

dubbed an "availability cascade."[3] Availability cascades are self-reinforcing mechanisms whereby an expressed belief triggers a chain reaction, giving the perception increasing plausibility through its heightened availability in public discourse, regardless of the existence of data that support or undermine the perception. In the context of dietary supplements, a handful of high profile cases of adverse reactions, such as the February 2003 ephedrine-related death of Baltimore Orioles pitcher Steve Belcher, might provide enough visibility in the public dialogue so as to command disproportionate weight as a data point. In such situations, the high visibility data swamp the effect of the millions of Americans who safely use supplements daily.

While these availability cascades are largely unavoidable, they should give pause to policy makers in relying on public claims of the need for increased government oversight as pretext for more government activity. Ideally, the FDA should present some analysis of how frequently adverse events occur relative to total use if it is going to make a persuasive case for increased involvement.

IV. Independent Certification

Another gap in the FDA's analysis involves its failure to take seriously the opportunity for third party certifications to solve the supposed asymmetric information problems in the dietary supplement market. Despite the fact that, by the FDA's own admission, firms have started introducing supplement certification services, the FDA asserts that such certification will not sufficiently mitigate the information problems consumers face. This assertion is belied by the FDA's own acknowledgement that "well-informed people should be willing to pay for improvements in the quality of information." If such a willingness to pay for information is coupled with consumers' apparent mistrust of the safety of supplements, it is very likely that supplement producers and certification firms alike will recognize a significant profit opportunity to fill this information void. Rather than argue against this possibility seriously, the FDA proposal merely claims that since third party certification has not already induced all manufacturers to adopt "good manufacturing practice models for their products." Because the FDA views third party certification as ineffective, it bases all of its cost benefit analyses on the benchmark of a world without such certification. A rigorous analysis would compare the FDA scheme with a private third party system, favoring whichever regime maximized consumer welfare.

V. Federalism

In discussing why regulation must occur at the federal level, the FDA expresses concerns that state and local regulators will bias their procedures in favor of local producers to the detriment of out of state manufactures and consumers alike. Unfortunately, this concern is already mitigated by the fact that such practices would

[3] See Timur Kuran and Cass Sunstein, "Availability Cascades and Risk Regulation," *Stanford Law Review*, 51(4): 683-768.

surely not pass court scrutiny under the Commerce Clause of the U.S. Constitution.[4] While the FDA is correct in asserting that it has the authority to regulate these markets, its claim that lower level oversight would lead to protectionist activities on the part of state authorities is simply disingenuous in the face of settled case law.

VI. Conclusion and Recommendations

The FDA argues that adoption of CGMP for dietary ingredients and supplements manufacturers is necessary to ensure consumer safety. To provide context for this argument, the FDA relies on survey results suggesting that consumers view these products as unsafe and that they demand an increased role for FDA regulation. Such a foundation is exceedingly weak and begs for hard data making the case for FDA involvement. Further, the FDA virtually ignores the likelihood that third party certification could solve the asymmetric information problems about which the FDA is concerned. This omission limits the value of the FDA cost-benefit analysis supporting federal regulation. Lastly, the FDA uses a red-herring argument about protectionism to discount the possibility of state and local regulation of the manufacturing process for dietary ingredients and supplements.

[4] The seminal case on this point is *Baldwin v. G.A.F. Seelig, Inc.*, 294. U.S. 511 (1935).

Appendix I
RSP Checklist

Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary

Ingredients and Dietary Supplements

Element	Agency Approach	RSP Comments and Grades
1. Has the agency identified a significant market failure?	The Agency assumes that information asymmetry problems and principal-agent problems preclude a market solution. ***Grade: F***	Third party certification has been developed and the agency admits that consumers would be willing to pay for such information.
2. Has the agency identified an appropriate federal role?	The regulation expressly allowed under the Federal Food, Drug, and Cosmetic Act. However, it does not adequately address the possibility of state and local government regulation. ***Grade: B***	Congress explicitly allowed the FDA to regulate the manufacturing processes of firms in the dietary supplements market. Unfortunately, it ignores existing legal safeguards that make its concern about state protectionism moot.
3. Has the agency examined alternative approaches?	The FDA does not adequately discuss the possibility for private certification. ***Grade: F***	See #1 above.

Element	Agency Approach	RSP Comments and Grades
4. Does the agency attempt to maximize net benefits?	The FDA performs its cost benefit analysis on the assumption that private certification is not viable. ***Grade: C***	It is an empirical question whether a public or a private certification system would maximize consumer welfare. The FDA chooses to ignore that question.
5. Does the proposal have a strong scientific or technical basis?	***Grade: N/A***	
6. Are distributional effects clearly understood?	While the FDA recognizes that the proposed regulation will disproportionately affect small manufacturers, it asserts that there is no way to mitigate this effect. ***Grade: C***	It is possible that this disproportionate effect could drive small producers out of the market which could decrease consumer welfare because of supply reductions and decreased innovation.
7. Are individual choices and property impacts understood?	In arguing the need for federal intervention, the FDA relies on survey results suggesting that consumers view dietary supplements as unsafe. The FDA does not recognize that such data are inconsistent with the revealed choices of	If consumers purchase the product, there is a presumption that they evaluate the product as sufficiently safe. The FDA makes no attempt to understand this apparent inconsistency.

	consumers. ***Grade: C***	