

How Supplements are Regulated in the US

written by Mike Roberto | March 14, 2013



The FTC, or Federal Trade Commission – One of the Major Players in Supplement Regulation

When you hear about the government litigating against a supplement company on the news, there are several different agencies that can be (or are) involved. Each agency's role is different, specific, and specialized. Which agency a company is facing off with gives details to the charges. For supplements the two major players are the *FTC* and *FDA*. This article will explain the bureaucracy behind how these groups work.

Nature of the US Government

The US Constitution's fourth article states that the United States shall be ruled by federalism. Federalism is the division of government between different groups: local, state, and federal. In the US, the federal government's powers are limited to only those things stated within the Constitution. Anything outside of the powers expressly stated by the Constitution are state powers.

Of importance to us are the federal constitutional powers to regulate interstate commerce. Interstate commerce is the trade between states. If a product is produced in one state and sold in more places than just that one state, it falls under federal jurisdiction. If a product is produced and sold in only one state, it would be under state jurisdiction.

The Constitution went in effect in 1789, long before the Internet, cars, planes, and other modern technologies. Because of modern technology, interstate commerce occurs much more often than in 1789. The proliferation of interstate commerce forced the federal government to increase in size.

The Creation of Agencies

Federal agencies are legal for the constitution allows the legislative branch to enact laws. If the legislative branch enacted a law that allowed the federal government, the executive branch, to start an agency whose sole purpose is to carry out a certain federal power, the new federal agency would be legal and constitutional. Once the federal agency steps outside of federal powers (for example, into state powers), it would be unconstitutional.

Role of Federal Trade Commission

Originally, the FTC were created for the protection of competition ("The Federal Trade Commission Turns 100" 2010). The 1914 Act created the FTC because the Sherman Antitrust Act failed to properly protect competition as legislature originally intended. The Sherman Antitrust Act's implementation by the judicial system used the "Rule of Reason" which was criticized for being very vague, uncertain, and subjective (Cornell 1987). The 1914 Act, which created the FTC, was an attempt to better protect competition.

It was not until 1938, with the passage of the Wheeler-Lea Act, also called the Federal Trade Commission Act of 1938, that consumer protection was an item of concern for the FTC (Udell 1977). Consumer protection against false advertising is one of the main functions of the FTC today.

Implications of Wheeler-Lea Act

Wheeler-Lea allowed the FTC to have greater regulatory powers. Before Wheeler-Lea, the FTC had powers regulating advertising if the advertisement resulted in an unfair advantage that can hinder competition. After Wheeler-Lea, the FTC had powers to regulate any advertising that was misleading for the purpose of protecting consumers ("The Federal Trade Commission Act of 1938" 1939). The act also removed the necessity for the FTC to prove that consumers were harmed by the advertisement ("The Federal Trade Commission Turns 100" 2010). By removing the necessity of harm, any advertisement that was deemed to be misleading can be penalized even if no one was actually misled or harmed.

The Wheeler-Lea Act allows the FTC to amend misleading advertising by: issuing a cease and desist, restraining the advertisement, and issuing criminal penalties (Handler 1939). Before the act, the FTC only had powers to issue reports and regulate commerce ("The Federal Trade Commission Turns 100" 2010). Although it has the power to issue criminal penalties, the burden of proof for a criminal case, beyond a reasonable doubt, is very hard to prove and therefore such penalties are rare (Cornell 1987).

FTC Improvement Act of 1975

The judicial branch found that the legislative powers of the FTC were far too small given the tasks the FTC must accomplish. The FTC Improvement Act of 1975 expanded the FTC's powers by: expanding the FTC's authority, clarifying the FTC's rulemaking ability, allowing the FTC to have consumer participation,

allowing the FTC to issue fines, and increase the scope of cease and desist orders (Udell and Fischer 1977).

Originally, the FTC was enacted under the constitutional powers of protecting interstate commerce. The 1975 Act expanded the FTC's powers by broadening its scope from anything within interstate commerce to anything within or affecting interstate commerce. This means that the FTC can go after intrastate business if that business has been found to affect interstate commerce (Udell and Fischer 1977). This broadening of scope is fundamental in the present day FTC powers.

Allowing the FTC to have consumer participation, issue fines, and increase cease and desist scopes allows the FTC to have a far greater reach with much faster swiftness. For example, if the FTC issued a fine for company A for a set of behaviors, company B's similar behavior would also be fined as well even if the FTC did not go through the bureaucratic process of showing how company B's behavior is misleading (Udell and Fischer 1977).

Role of Food and Drug Association



The FDA was enacted in 1906 to protect consumers for mislabeled or misbranded foods, drugs, and drinks ("Significant Dates in U.S. Food and Drug Law History" 2013). Supplements are considered an in between category: they are foods that have drug-like properties. With concerns to supplement's the FDA's main purpose is to ensure that supplements are safe for consumption. The FDA does this by testing all supplement ingredients for safety before they reach market ("Dietary Supplements" 2013).

How Government Actions Work

As we have seen, although it was not the FTC's original purpose, the FTC can go after a supplement company if it makes claims that are misleading to consumers. This can include weight loss claims that are misleading, the use of doctor actors who are not physicians, and other deceptive practices. The 1975 Act allows the FTC to make specific industry rules as well.

The FDA's role in supplement regulations is that it ensures that supplements are safe for human consumption. The FDA makes available a list of supplements that have been found to be tainted (see

https://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=tainted_supplements_cder). For the most part, the FDA is concerned with the quality and ingredients of a product whereas the FTC is concerned with the claims being made.

References

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