

Title: Republic of the Philippines vs. Drugmaker's Laboratories, Inc. and Terramedic, Inc.

Facts:

The case involves the Food and Drug Administration (FDA), formerly known as the Bureau of Food and Drugs (BFAD), and its issuance of Circular Nos. 1 and 8, series of 1997, mandating bioavailability/bioequivalence (BA/BE) testing for the registration of certain pharmaceutical products. This requirement was challenged by Drugmaker's Laboratories, Inc. and Terramedic, Inc. (respondents), who manufacture and trade a pharmaceutical product named Refam, used for treating tuberculosis. Refam was issued a Certificate of Product Registration (CPR) valid until November 15, 2001, without undergoing BA/BE testing due to the absence of local testing facilities at the time. However, when the respondents applied for renewals, they were conditioned on submitting satisfactory BA/BE test results. Failing to provide these, the respondents filed a petition before the Regional Trial Court (RTC) of Muntinlupa City to annul Circular Nos. 1 and 8, s. 1997, arguing the FDA lacks authority under Republic Act No. (RA) 3720, as the power to issue such rules rests with the Department of Health (DOH).

The RTC ruled in favor of the respondents, declaring the circulars null and void and prohibiting the FDA from enforcing them, prompting the FDA to appeal directly to the Supreme Court on a pure question of law.

Issues:

1. Whether or not the FDA may validly issue and implement Circular Nos. 1 and 8, s. 1997.
2. Whether the circulars partake of administrative rules and regulations and thus require compliance with legal standards for issuance.

Court's Decision:

The Supreme Court granted the petition in favor of the FDA, setting aside the RTC's order. It held that the FDA has the authority to issue Circular Nos. 1 and 8, s. 1997, as these circulars do not constitute administrative regulations but are merely meant to administer and supervise the implementation of AO 67, s. 1989. As such, no prior hearing, consultation, and publication are needed for their validity. The Court further recognized the pivotal role of the FDA in ensuring the safety and efficacy of pharmaceutical products available in the market.

Doctrine:

The case reiterates the principle that administrative agencies may exercise quasi-legislative or rule-making powers only when there is a law which delegates these powers to them. Furthermore, administrative regulations classified as legislative rules designed to implement a primary legislation by providing the details thereof must comply with the requirements laid down by the Administrative Code of 1987 on prior notice, hearing, and publication, except where the rule is merely interpretative.

Class Notes:

- Legislative rule: A type of administrative regulation that implements, interprets, or prescribes law or policy, having the force of law.
- Requirement for BA/BE testing: As per AO 67, s. 1989 and Circular Nos. 1 and 8, s. 1997, certain drugs require bioavailability/bioequivalence studies for the Registration of Pharmaceutical Products.
- Administrative Code of 1987: Provides the legal framework for the issuance of administrative rules, including requirements for notice, hearing, and publication.

Historical Background:

RA 3720, known as the "Food, Drug, and Cosmetic Act," was enacted primarily to establish safety, efficacy standards, and quality measures for food, drugs, devices, and cosmetic products. It created the FDA, tasked with the registration and regulation of such products. AO 67, s. 1989, issued by the DOH, outlined the registration rules for pharmaceutical products, introducing the BA/BE testing requirement. The necessity for such testing, and the FDA's (formerly BFAD) authority under amended laws, illustrates the evolving regulatory landscape in response to technological advancements and public health considerations.