Might As Well Be Walking Through Quicksand: The Scourge of Unapproved New Drugs Deemed to Be Safe and Effective

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Everyday people take multiple concoctions to treat various medical conditions ranging from the most innocuous to the deadliest. Usually, those drugs are prescribed by a physician after a thorough assessment of the patient’s medical condition. Other times the patient foregoes medical advice and makes up his own medical treatment. In doing so, the patient assumes that the chosen drug is safe and effective to treat his underlying medical condition. But the reality is that the patient might be opening a Pandora’s Box.

The Food, Drug and Cosmetic Act (“FDCA”) defines a drug, among other things, as an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.¹ The FDCA further defines a new drug as one whose composition is “not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof.”²

Prior to introducing, delivering or marketing a new drug in interstate commerce, the drug manufacturer has to file a “New Drug Application” in order to obtain the FDA’s new drug approval.³ The drug manufacturer fulfills this requirement by filing a New Drug Application (“NDA”) with its supporting documentation.⁴ Once this procedure is done, the FDA reviews the same and either approves the NDA, denies the NDA or gives the drug manufacturer notice of an opportunity to have a hearing to determine whether the NDA is approvable or not.⁵ Nevertheless, even if a drug attains a NDA approval, the

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¹ 21 U.S.C. §321(g)(1)(B) (West 2007). Typically, a product’s intended use is determined by its labeling as well as by any other promotional claims made by the seller. See, e.g., Hanson v. Unites States, 417 F.Supp. 30, 35 (D.Minn.), aff’d, 540 F.2d 947 (8th Cir. 1976); U.S. v. Article of Drug Designated B-Complex Cholinos Capsules, 362 F.2d 923, 925-926 (3d Cir. 1966); Nature Foods Centres, Inc. v. United States, 310 F.2d 67, 70 (1st Cir. 1962)
² 21 U.S.C. §321(p)(1) (West 2007). This scientific experts’ recognition is usually referred to as “GRASE” or “generally recognized as safe and effective.”
³ 21 U.S.C. §355(a) (West 2007). Furthermore, an already approved drug might be considered by the FDA as a new drug in certain situations. See, e.g., 21 C.F.R. §310.3(h) (West 2007); United States v. 225 Cartons, More or Less, of an Article or Drug, 871 F.2d 409, 415-20 (3d Cir. 1989); United States v. Articles of Drug, 826 F.2d 564, 566 (7th Cir. 1987).
⁴ The supporting documentation must include “(A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of the drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packaging of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; [and] (F) specimens of the labeling proposed to be used for such drug.” 21 U.S.C. §355(b)(1).
⁵ 21 U.S.C. §355(c) and (d). See, e.g., Warner-Lambert Co. v. Heckler, 787 F.2d 147, 154-156 (3d Cir. 1986); Edison Pharmaceutical Co. v. FDA, 600 F.2d 831 (D.C.Cir. 1979); Smithkline Corp. v. FDA, 587 F.2d 1107 (D.C.Cir. 1978).
FDA’s Secretary can withdraw or suspend the same upon finding of an imminent hazard to the public health. 6

Drug manufacturers expend vast amounts of time and effort in attaining the FDA’s approval of a NDA. With all the research and development involved, it takes a drug manufacturer approximately twelve years and over one billion dollars to develop a new drug. 7 So, it is no wonder that rather than spending all the time and financial resources involved in lawfully developing, manufacturing and seeking FDA’s approval for a new drug, some manufacturers opt to bypass the afore described process and introduce, deliver and market new drugs into interstate commerce without obtaining prior FDA’s approval.

The FDA acknowledges that approximately two percent (2%) of the drugs currently marketed to the general population have not been approved by it as being safe and effective. 8 To address this problem, in June, 2006 the FDA’s Center for Drug Evaluation and Research issued a guidance document entitled “Marketed Unapproved Drugs – Compliance Policy Guide” in order to encourage drug manufacturers to comply with the FDCA’s approval provisions or to remove the unapproved drugs from the market. 9 According to the guide, the FDA will give enforcement priorities to drugs used in health fraud activities and to unapproved drugs with potential side effects. The FDA will also assess those drugs that lack evidence of effectiveness, present challenges to the NDA system, violate the FDCA in any other way, or that have been reformulated to evade FDA’s enforcement actions. 10

Once the FDA identifies an unapproved drug, it can take several enforcement actions against the drug manufacturer. For example, the FDA can request voluntary compliance from the drug manufacturer, initiate injunction proceedings, 11 initiate seizure proceedings, 12 or initiate criminal prosecutions against the manufacturer and/or distributor of the unapproved drug. 13 These enforcement actions are geared towards protecting public health as well as protecting the gullible public from fraudulent claims made by unscrupulous drug manufacturers. That is exactly what happened in Puerto Rico on March 1, 2007 when the federal authorities arrested seven persons, including five physicians, in connection with an unapproved drug marketed and distributed in Puerto Rico by PharmaBlood, Inc. 14

8 Marc Kauffman, Unapproved Drugs Called ‘Threat’, WASH. POST, June 9, 2006, at A10;
10 Id.
13 21 U.S.C. §333
PharmaBlood’s unlawful scheme targeted terminally ill cancer patients by promising them a cure for their cancer by means of a cancer vaccine. Its method consisted of withdrawing the patient’s blood, boiling it, freezing it and then re-injecting it to the patient. PharmaBlood held itself out to cancer patients through advertisements in magazines, newspapers and television.\footnote{Daniel Rivera Vargas, \textit{Alertó al FDA la Publicidad}, \textit{EL NUEVO DIA}, March 3, 2007.} However, in its website, PharmaBlood stated that it also used “an autologous hemoderivative that the FDA considers a new drug not yet approved.”\footnote{See, e.g., Pharmablood, Regulation for the Practice by Physicians of Pharmablood Cancer Vaccination, \textit{available at \url{www.pharmablood.com/PAGE_FDA.htm}} (last viewed Mar. 23, 2007).}

According to the federal authorities, PharmaBlood’s scheme involved fifty cancer patients each of which were charged a sum ranging from $8,000 to $12,900. As in the case of Zenaida Romero,\footnote{Zenaida Romero was a forty-two-year-old cancer patient who opted to forego the recommended chemotherapy after having undergone colon cancer surgery and instead decided to subject herself to PharmaBlood’s cancer vaccine. Her cancer spread to her intestines and she died, leaving three young children behind. \textit{See}, Sandra Morales Blanes, \textit{Infructuosa Búsqueda de Vida}, \textit{EL NUEVO DIA}, Mar. 3, 2007.} most of these patients decided to forego traditional FDA-approved medical treatments lured by the promises made by PharmaBlood and died.

Sadly, this case is not an isolated one but rather a ripple in the unapproved drug milieu. Callous drug manufacturers prey upon vulnerable ailing patients gasping for a breath of fresh air - patients so distraught in their endless quest for hope that they would not hesitate to act against medical advice and expose themselves to “miraculous” new drugs hailed as safe and effective for the treatment and cure of their underlying disease.

The FDCA provides an intricate legal framework to safeguard the health and safety of the general population by approving new drugs scientifically proven to be safe and effective for their intended uses. The FDCA further provides elaborate enforcement provisions aimed at safeguarding public health and protecting the susceptible consumer. But the FDA is constrained by scarce agency resources. It is time for the public to take a leading role in the fight against unapproved new drugs and their devastating effects by forming a partnership with the FDA in order to expose these drugs, bring them to light and have them removed from interstate market. The collective consciousness is wide awake. All that is needed now is the will to do it

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