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HIDING BEHIND AGENCY DISCRETION: THE FOOD AND DRUG ADMINISTRATION'S PERSONAL USE DRUG IMPORTATION POLICY

by Peter S. Reichertz and Melinda S. Friend†

INTRODUCTION

Seatbelts are mandatory, parents are forced to vaccinate their children, and infectious people are quarantined: the law will curtail even the most basic of human rights when the exercise of those rights poses a threat to the public health.¹ Although less obvious, the Food and Drug Administration (FDA or Agency) limits individual freedom in its mission to protect public health.² While most agree that some constraints on individual liberty are justified by FDA's role in serving the public at large, the appropriate balance between the individual and public good is always at issue. Nowhere is the conflict more sharply realized than in FDA's general ban against the importation of unapproved drug therapies, especially when that ban functions to deny terminally ill people access to unapproved, promising drug therapies.³

To ensure that drugs are safe and effective, the FDA generally prohibits the importation of drug products if it has not granted pre-market approval.⁴ FDA's personal use exemption policy partially alleviates individual hardships caused by the general ban on the importation of unap-

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¹ Note that such public health laws are usually state laws, the authority for which is the general state police powers. See *Jacobson v. Massachusetts*, 197 U.S. 11, 24-25 (1905) (upholding stated mandatory smallpox vaccination). In contrast, the federal government does not possess any general police powers. See *id.* at 25.

² In contrast to the general state police powers, the Federal Government's authority to constrain individual rights to serve the public health generally rests on the "commerce clause" of the Constitution, which grants the federal government the power "to regulate commerce . . . among the several States . . ." U.S. CONST. art. I, §8, cl. 3.

³ The Federal Food, Drug, and Cosmetic Act requires a manufacturer to obtain FDA's approval prior to delivering for introduction or introduction of the drug into interstate commerce. See Federal Food, Drug, and Cosmetic Act of 1938 §1, 21 U.S.C. §§ 301, 335(a) (1998).

⁴ See *id.* § 381(a).

proved therapies. The personal use exemption policy permits the importation of small quantities of unapproved drugs for personal use on a case-by-case basis.⁵ Neither codified by statute nor promulgated as a regulation, the guidelines for personal use importation exist only in FDA's Regulatory Procedures Manual.⁶ Consequently, the exemption is almost exclusively implemented by individual FDA personnel from whose decisions there is little meaningful appeal.

Individual FDA personnel do not have complete discretion to allow importation of unapproved therapies for personal use, however; the Agency routinely issues "import alerts" that absolutely prohibit entry of certain drug products.⁷ Import alerts delineate certain drugs, or even whole classes of drugs, that may not be admitted into the country even where FDA personnel might otherwise permit entry under the personal use exemption policy.⁸ The Agency's import alerts are issued as administrative decisions: again, there is little opportunity for public comment or meaningful judicial review.⁹

The odyssey of the AIDS buyers' clubs,¹⁰ which the FDA permitted to import large amounts of unapproved AIDS therapies under the personal use exemption policy, is the most obvious example of FDA's defacto expansion of the policy in response to political pressure. Likewise, FDA's issuance of an import alert for the abortifacient drug RU-486, that denied access to the drug in the United States for all purposes, including cancer research, illustrates the willingness of FDA to contract the scope of its policy in the face of political pressure.¹¹

The lack of legal procedures surrounding the formation and implementation of the personal use exemption policy, including import alerts, leaves it uniquely vulnerable to abuse. The lack of procedural safeguards

⁵ In addition, a FDA regulation permits physicians to request permission to use an unapproved therapy on an emergency basis. See 21 C.F.R. § 312.36 (1998).

⁶ See *FDA Regulatory Procedures Manual, Chapter 9, Subchapter on Coverage of Personal Importations* (visited Feb. 20, 2000) <http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html> [hereinafter *FDA Regulatory Procedures Manual*].

⁷ See U.S. FOOD AND DRUG ADMINISTRATION AND DEPARTMENT OF HEALTH AND HUMAN SERVICES, *IMPORTS*, (visited March 10, 2000) <http://www.fda.gov/ora/import/ora_import_system.html> [hereinafter *IMPORTS*].

⁸ See *id.*

⁹ See *id.*

¹⁰ Acquired Immunodeficiency Syndrome (AIDS) is the name given to a particular set of clinical markers and symptoms caused by infection with the human immunodeficiency virus (HIV). The effects of HIV infection are not uniform, and people infected with HIV may be perfectly healthy or quite sick even without a formal "AIDS" diagnosis. Although the term "AIDS" is used throughout this paper, it should be understood to refer to the entire spectrum of HIV infection.

¹¹ See FOOD & DRUG ADMIN, *Import Alert #66-47* (April 17, 1990) (visited March 10, 2000) <http://www.fda.gov/ora/fiars/ora_import_ia6647.html>. See also *infra* note 117 and accompanying text.

in the formation and implementation of the Agency's policy is particularly troublesome because FDA's denial of access to an unapproved drug may potentially deprive an individual of a lifesaving therapy. Indeed, the importance of FDA's implementation of the policy to various groups has at various times subjected the Agency to intense pressure both to expand and contract the scope of its personal use exemption policy.

Unfortunately, the lack of Agency oversight and judicial review means there is no guarantee that the FDA implements the personal use exemption fairly, or that individual personnel allow importation for personal use in all deserving cases. Moreover, legal precedent established by the RU-486 controversy and during the Laetrile Wars¹² — in which FDA successfully prohibited terminally-ill cancer patients from taking what they believed to be an effective and perhaps lifesaving unapproved drug — make a legal challenge to the personal use exemption policy virtually futile.

Given that the personal use importation exemption governs individuals' access to potentially lifesaving drugs, the Agency has an ethical duty to establish procedural safeguards to ensure the personal use exemption policy is developed and implemented consistently, fairly and effectively. In recognition of the strength of judicial precedent, this Article does not argue that the FDA has a statutory or constitutional mandate to implement the personal use importation policy through notice-and-comment rule making. Indeed, judicial precedent — rightly or wrongly — establishes that there is no constitutional right to have access to a particular drug product. Instead, this Article argues from an ethical and policy perspective, that the FDA should implement a regulation that ensures the right of individuals to import unapproved drug products for personal use in identified circumstances. Even if not legally mandated, there is no bar to implementing the personal use exemption policy through notice-and-comment rule making optimally as a binding, legislative rule.

Part I of this Article begins with an overview of FDA's general ban on the importation of unapproved drug products and the policy reasons for that ban. Part II provides ethical considerations that support the personal use exemption policy as well as practical justification for the policy. Part III provides FDA's current personal use exemption policy that was widely utilized by the AIDS buyers' clubs. However, as discussed in Part IV, an increase of the personal use exemption policy resulted in a proliferation of off-shore companies who claimed their sale of unapproved drugs over the internet to domestic consumers is legal under the personal use exemption policy. Part V provides an analysis of the legal authority underpinning the personal use exemption policy, including im-

¹² See *infra* notes 93-99 and accompanying text.

port alerts, and the administrative and judicial review available to one denied importation under the policy. Part VI of the article explores the legal basis for implementing the personal use importation policy, including import alerts, as a substantive interpretive rule through notice-and-comment rule making procedures. Finally, Part VII concludes that transforming the personal use importation exemption as a substantive rule will have the effect of providing consistent guidelines while simultaneously allowing potentially life-saving treatment for terminally ill patients.

I. FDA'S GENERAL BAN ON THE IMPORTATION OF UNAPPROVED DRUGS

The FDA requires that imported, finished, prescription drugs be approved by the Agency under a New Drug Application (NDA) or Investigational New Drug Exemption (IND).¹³ During its lengthy and exhaustive approval process, the FDA reviews evidence that a drug is safe and effective for its intended use and that it is manufactured in accordance with the Agency's stringent current Good Manufacturing Practices.¹⁴ Compliance with Good Manufacturing Practices imposes rigorous and detailed quality control procedures on the manufacture of drug products.¹⁵ FDA approval of a drug product extends only to the manufacturer awarded approval.¹⁶ The Agency therefore prohibits both imports of drugs that have never been approved for use in the domestic market *and* unapproved foreign-made versions of FDA-approved drugs.

There are several good reasons for prohibiting the import and use of unapproved drugs. First, if the FDA has never approved a drug, the Agency cannot ensure that the drug is either safe or effective for its intended use. Second, the Agency cannot ensure that unapproved versions of approved drugs are of high-quality: not only may unregulated drugs be contaminated, adulterated, or mislabeled, their dose and potency may also be substandard or inconsistent. Finally, the use of unapproved drugs may interfere with the ability to conduct domestic clinical trials for drug therapies seeking FDA approval.¹⁷ This last factor is a particular problem in clinical trials for cancer and AIDS therapies.

¹³ See 21 U.S.C. §§ 355, 381(a)(3) (1998).

¹⁴ 21 C.F.R. §§ 26.1-26.21, app.A-app.E (1999).

¹⁵ See *id.*

¹⁶ See 21 U.S.C. § 381(a) (1998).

¹⁷ The availability of unapproved drugs may decrease demand for participation in clinical trials (i.e., research studies designed to determine the effect of an investigational drug on human study subjects), particularly because in some clinical trials, participants run the risk of receiving a placebo rather than the experimental treatment. See Rebecca Voelker, *Several New Drugs Shift Direction of Treatment and Research for HIV/AIDS*, 275 JAMA 89-90 (1996). For clinical trials dealing with serious illness, participants may be unwilling to risk receiving a placebo and prefer to seek unapproved therapies. In addition, the treatment effect

II. THE NEED FOR A PERSONAL USE EXEMPTION

A. ETHICAL MANDATE TO PERMIT IMPORTATION FOR PERSONAL USE

While the law provides rules by which persons must abide or face the coercive power of the state, ethics seeks to tell people what they 'ought' to do.¹⁸ When access to an unapproved drug therapy may be the only chance for survival for an individual, yet will result in minimal negative effects on the public health, FDA 'ought' to ensure access to the unapproved therapy.

To give a class of things moral status is to ascribe certain rights to all members of that class. The moral rights of a class dictate the ethical boundaries of its treatment, and may give rise to both negative and positive obligations.¹⁹ If we posit a moral right to have access to medical treatment based on a respect for individual life and autonomy, this right creates a duty for society to provide protection for the exercise of that right.²⁰ Conversely, the traditional *ethical* limitation on state action is to refrain from active harm of the individual without cause.²¹ That is, every individual has a claim to justice and autonomy that limits the state's power over that individual.²²

When evaluating the ethics of a government agency action, the question of whether and how an agency acts 'ethically' is often a question of distributive justice — that is, identifying a just principle, by which goods and burdens are distributed between individuals and groups.²³ Under most theories of distributive justice, to be ethical, government action must seek to balance burdens and benefits in order to maximize goods for the greatest number of people. There must also be

of a drug being investigated in a clinical trial may be confused by study subjects' use of unapproved therapies.

¹⁸ Loosely defined, the term 'ethics' refers to rules or values providing a measure by which to evaluate our respective rights and responsibilities. There are numerous sources of ethical guidelines, including religion, philosophy and tradition; obviously, there is not a single accepted established system of ethics.

¹⁹ We would probably all agree, for example, that no living thing 'ought' to be intentionally tortured. This negative right ascribed to all living things may in turn give rise to a positive obligation to stop someone from torturing another. See TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* 59-60 (3d ed. 1989).

²⁰ As John Stuart Mill said, "I have treated the idea of a right as residing in the injured person and violated by the injury . . . To have a right . . . is . . . to have something which society ought to defend me in the possession of." JOHN S. MILL, *UTILITARIANISM* 78-79 (1863).

²¹ See Dan E. Beauchamp, *Community: The Neglected Tradition of Public Health*, in *HASTINGS CENTER REPORT* 28, 31-32 (Dec. 1985).

²² Some argue that the protection of the individual against coercive state regulation is the essence of a just state. See AYN RAND, *MAN'S RIGHTS, CAPITALISM: THE UNKNOWN IDEAL* 320-29 (1967).

²³ See BEAUCHAMP & CHILDRESS, *supra* note 19, at 283.

an appropriate procedure by which the substantive maximization of value is applied correctly to each individual.

For example, a rule that would distribute limited food supplies during famine to households in accordance with the number and ages of each family member would generally maximize the public good. On the other hand, if there were no procedure in place to determine and assure appropriate distribution of the food, the actual distribution might be made according to completely different principle — social status, for example. Without both a substantive principle by which to distribute benefits equitably and a procedure under which such distribution is assured, government action cannot be considered to accord with established ethical norms.²⁴ Moreover, although the government must seek to maximize the public good, its actions are limited by the principles of individual autonomy and beneficence accorded to all moral actors.

As discussed above, FDA's general prohibition on the import of unapproved drug products serves to promote the public health in a variety of ways, including ensuring the safety and efficacy of drug products, providing incentives for the participation in domestic clinical research trials, and protecting the public from those who would profit from ineffective and even unsafe therapies and the desperation of the dying. On the other hand, FDA's general prohibition can present a severe burden to an individual when a promising drug product for a serious or life-threatening condition is available only outside the United States. In such a case, the benefit to the individual or group of individuals is potentially great, while the threat to the public health is relatively small. In addition, careful structuring of a regulation to permit personal use of unapproved drugs under certain conditions could reduce any negative public health consequences. Ethical theory behooves the Agency both to permit an individual access to a promising, unapproved therapy under certain circumstances and to implement procedures by which individuals in appropriate situations could be identified and supported.

B. THE PRACTICAL NEED FOR A PERSONAL USE EXEMPTION

1. *Travelers and Recent Immigrants*

In practical terms, the FDA has long recognized that it has neither the resources nor the mandate to regulate the importation of small amounts of unapproved drugs for personal use by individuals.²⁵ Consider, for example, the number of travelers who begin a course of drug

²⁴ See *id.* at 291.

²⁵ The personal use importation was put in writing as early as 1954, in the form of a directive to the Agency's district offices from FDA's Division of Field Operations. See *RU 486: The Import Ban and its Effects on Medical Research: Hearing Before the Subcomm. on Regulation, Business Opportunities, and Energy, 101st Cong., 2d Sess. 53, 175-77 (1990)*(let-

therapy for an acute condition while abroad and subsequently bring the remaining course of the drug product back with them into the United States. If the particular drug product has never been approved in the United States or is a unapproved, foreign version of a drug product marketed in the United States, importation of the drug is technically illegal.²⁶ In addition to travelers, Americans with recent ties to foreign countries often seek pharmaceutical products that are unavailable domestically or that have non-English labeling.²⁷

Obviously, the FDA must be aware of the importation of a drug product in order to regulate such importation. The Agency requires that all persons importing FDA-regulated products to file an entry notice with the U.S. Customs Service.²⁸ In addition, the Agency works closely with Customs to identify mail and baggage shipments of drug products that might violate FDA laws. Despite FDA's efforts, the amount of imported products regulated by the FDA makes detection of such drugs products very difficult.

2. *Access to Unapproved Therapies to Treat Serious Illnesses*

As the AIDS epidemic unfolded, the FDA came under intense pressure to make potentially valuable unapproved drug products available to critically ill people. In addition to criticizing FDA's drug approval process, AIDS activists fought to gain access to promising new drugs available overseas. Other patient groups, particularly cancer groups, joined with AIDS activists in their push for access to novel therapies for life-threatening conditions only available from foreign sources.²⁹

In 1982, the FDA published a proposed rule reforming the its regulatory process to expand and accelerate access to new drug products.³⁰ As part of its proposal, the FDA suggested that certain individuals would be allowed to import a reasonable quantity of an unapproved drug product for personal use into the United States.³¹ While permitting importation of small amounts of unapproved drug products for private individual

ter from FDA Acting Commissioner to Assistant Secretary of Health)[hereinafter *RU-486 Hearing*].

²⁶ See 21 U.S.C. § 381 (1998).

²⁷ Under the personal use exemption policy, the demand for unapproved foreign drug products by individuals physically located in the United States is often met by importing drugs through the mail. The FDA generally permits individuals to contact willing foreign physicians who then mail the products directly to them. See *FDA Regulatory Procedures Manual*, *supra* note 6.

²⁸ See *IMPORTS*, *supra* note 7.

²⁹ See Elizabeth A. Silverberg, Note, *Looking Beyond Judicial Deference to Agency Discretion: a Fundamental Right of Access to RU 486?*, 59 *BROOK. L. REV.* 1551, 1571 (1994).

³⁰ See *New Drug and Antibiotic Regulations*, 47 *Fed. Reg.* 46,622, 46,642 (1982) (proposed Oct. 19, 1982).

³¹ See *id.*

use purposes, the Agency noted that it would continue to prosecute those seeking to import unapproved products for financial gain.³² The FDA, however, did not include the proposed importation exemption in its final regulations on expediting drug approvals, stating that it found its "policy related to enforcement discretion is better stated in a compliance policy guide."³³

In 1987, the New York-based PWA Health Group formed the first "buyers' club" for the purpose of importing unapproved AIDS drugs into the United States.³⁴ Initially, the group contracted with a domestic company to manufacture AL721. AL721 is a drug that was then available in Israel, and is made from lipids derived from eggs.³⁵ The PWA Health Group characterized AL721 as a food additive and notified both FDA and the media that they would begin to distribute AL721, expecting to publicize the anticipated confrontation with the Agency.³⁶ Instead, the FDA chose to ignore the Club's distribution of AL721.³⁷

One year later in July 1988, the Agency issued a "Pilot Guidance" announcing that, under certain conditions, people with AIDS or cancer would be allowed to import by mail small quantities of unapproved drug products for their personal use under physician supervision.³⁸ FDA Commissioner Young then announced FDA's personal use exemption "Pilot Guidance" at the National Lesbian and Gay Health Conference and AIDS Forum in Boston.³⁹ A concurrent FDA Talk-Paper explicitly noted that people with AIDS had been importing small quantities of dextran sulfate, an unapproved drug product which had long been sold over-the-counter in Japan for use in lowering cholesterol.⁴⁰

The PWA Health Group also began importing and distributing dextran sulfate, its second product, in 1988. FDA's Pilot Guidance along

³² See *id.*

³³ New Drug and Antibiotic Regulations, 50 Fed. Reg. 7452, 7488 (1985)(to be codified at 21 C.F.R. pt. 314.410(a)).

³⁴ See Paula Span, *Pharmacy for the Desperate*, WASH. POST, Apr. 8, 1992, at D1.

³⁵ See *id.* at D2.

³⁶ See Eric Lindemann, Note, *Importing AIDS Drugs: Food and Drug Administration Policy and its Limitations*, 28 G.W.J. INT'L L. & ECON. 133, 154 (1994); See also Span, *supra* note 34.

³⁷ See Span, *supra* note 34, at D2.

³⁸ See *FDA Will Allow Mail Import of Unapproved Drugs*, THE GREEN SHEET (FDA/Weekly Pharmacy Reports), Aug. 1, 1988, at 2-3, available in LEXIS, Market and Industry Library, Medical and Healthcare Folder, Green Sheet-Pharmacy File; *RU-486 Hearing*, *supra* note 25, at 162 (memorandum from FDA/Director, Office of Regional Operations, regarding "Pilot Guidance for Release of Mail Importations").

³⁹ See *FDA Will Allow Mail Import of Unapproved Drugs*, *supra* note 38; *FDA Allowing Individuals to Import by Mail Unapproved Drugs in Personal*, THE GREEN SHEET (FDA/Weekly Pharmacy Reports), Aug. 8, 1988, at 4, available in LEXIS, Market and Industry Library, Medical and Healthcare Folder, Green Sheet-Pharmacy File.

⁴⁰ See *FDA Will Allow Mail Import of Unapproved Drugs*, *supra* note 38, at 3.

with its tolerance of the PWA Health Group's activities resulted in the rapid formation of other buyers' clubs for the importation of AIDS drugs. The buyers' clubs explicitly justified the legality of their activities on FDA's personal use exemption policy.⁴¹

III. THE RESULTING PERSONAL USE EXEMPTION POLICY

A. FDA'S PERSONAL USE EXEMPTION POLICY

On February 1, 1989, the "Pilot Guidance" on personal use importation was formalized as a revision to Chapter 9-71 of FDA's Regulatory Procedures Manual.⁴² As noted in a current U.S. Customs Traveler's Alert, FDA's personal use importation policy simply "represents FDA's current thinking regarding the issues of personal importation and is intended only to provide operating guidance for FDA personnel. The guidance does not create any legally enforceable rights for the public; nor does it operate to bind FDA or the public."⁴³

The Guidance is still in effect and permits importation of unapproved drug products for personal individual use under the following conditions, *not* specifically reserved for people with AIDS or cancer:

SCENARIO 1 — Treatment of non-serious condition

- a) The intended use is appropriately identified; *and*
- b) The use is not for the treatment of a serious condition; *and*
- c) The product is not known to represent a significant health risk.

SCENARIO 2 — Treatment of a serious or life-threatening condition

- a) The intended use is unapproved; *and*
- b) The drug will be used to treat a serious condition for which effective treatment may not be available domestically either through commercial or clinical means; *and*
- c) There is no known commercialization or promotion to persons residing in the United States by those involved in the distribution of the product at issue; *and*
- d) The product is considered not to represent an unreasonable risk; *and*
- e) The individual seeking to import the product affirms in writing that is for the patient's own use (generally not more than a 3 month supply); *and*

⁴¹ See PWA Health Group, Welcome to the People with AIDS Health Group (last modified Oct. 8, 1997) <<http://www.aidsinfonyc.org/pwahg/welcome.htm>>.

⁴² See *FDA Regulatory Procedures Manual*, *supra* note 6.

⁴³ FOOD & DRUG ADMIN, FDA/ORA IMPORT OPERATION TRAVELER'S ALERT, IMPORTATION OF PRESCRIPTION MEDICINES/DRUGS 2 (1997) (visited Feb. 20, 2000) <http://www.fda.gov/ora/import/traveler_alert.htm>.

- f) The individual provides the name and address of the doctor licensed in the United States responsible for his or her treatment with the product *or* provides evidence that the product is for the continuation of a treatment begun in a foreign country.⁴⁴

The personal use exemption policy itself has several provisions whereby the FDA can exert control over the safety of drug products imported under the exemption. First, drugs subject to a FDA import alert are banned from import under the personal use exemption policy.⁴⁵ The FDA will issue an import alert if it has safety concerns regarding a particular drug product or manufacturer.⁴⁶ When it announced its policy, FDA had 40 import alerts in effect covering particular drug products, manufacturers and distributors.⁴⁷ Second, FDA's policy advises agency personnel to permit only importation of drugs that do not represent an unreasonable health risk.⁴⁸ Finally, the Agency requires that the person importing the drug either provide the name and address of the physician under whose supervision the drug will be taken, or provide evidence that the product is for the continuation of a treatment begun in a foreign country.⁴⁹

B. AIDS BUYERS' CLUBS EXPAND THE PERSONAL USE EXEMPTION

The buyers' clubs almost immediately pushed to expand the boundaries of FDA's personal use importation policy after the policy was announced. First, the buyers' clubs imported large quantities of AIDS drugs, far exceeding a three-month supply for any one individual.⁵⁰ Second, arguing that access to drugs meant being able to afford them, many clubs began to import less expensive foreign versions of drugs approved in the United States.⁵¹ The PWA Health Group, for example, had imported fluconazole (a drug to treat fungal infections) for a year prior to

⁴⁴ See *FDA Regulatory Procedures Manual*, *supra* note 6.

⁴⁵ An import alert is issued in the form of an internal FDA memorandum to Agency field agents in district offices and advises the field agents that a particular drug or manufacturer's products should not be admitted under the personal use exemption policy and why. See *IMPORTS* *supra* note 7.

⁴⁶ See *id.*

⁴⁷ See FDA, *Policy on Importing Unapproved AIDS Drugs for Personal Use* (copy on file with author).

⁴⁸ See *FDA Regulatory Procedures Manual*, *supra* note 6.

⁴⁹ See *id.*

⁵⁰ See Span, *supra* note 34, at D1 (noting that in 1991 it is estimated that 5,000 people bought \$1.25 million of products from AIDS Buyers' Clubs).

⁵¹ See *Aerosol Pentamidine Will Be Imported by AIDS Underground Buyers Group at Sharply Lower Prices*, THE BLUE SHEET (FDA/Drug Research Reports), Sept. 27, 1989, at 2-3, available in LEXIS, Market and Industry Library, Medical and Healthcare Folder, Blue Sheet-Health Policy and Research File.

its approval by FDA.⁵² The club then announced that it would not decide whether to stop importing the unapproved version of fluconazole until its U.S. manufacturer, Pfizer, announced the drug's price.⁵³ In addition, numerous buyers' clubs offered pentamidine (to treat a common AIDS-related pneumonia) far below the U.S. drug's cost.⁵⁴ Because the personal exemption policy explicitly requires that the imported drug product be *unapproved* for its intended use in the United States, once the FDA approves the drug in the United States, the buyer's clubs are no longer able to rely on the personal use exemption. Consequently, the buyers' clubs are compelled to pay the higher prices, or else risk prosecution by the FDA.

C. THE FDA'S RESPONSE TO SAFETY CONCERNS UNDER THE EXPANDED POLICY

The FDA was sensitive to safety issues surrounding the reimportation into the United States of drugs that were originally manufactured in the United States and distributed to a foreign market. Because drug products manufactured in the United States are often sold at lower prices in foreign markets, companies were diverting drugs from the foreign market, reimporting them to the United States and selling them at a discount.⁵⁵ The Agency, however, could not regulate the handling or safety of drug products during the time of their export, in other words, there was no guarantee that reimported packages even still contained the drug product as labeled. Because of safety concerns, § 801(d)(1), a part of the Prescription Drug Marketing Act of 1987, banned the reimportation of exported products except when reimportation was by the original manufacturer of the drug.⁵⁶

In-so-far as high U.S. drug prices reflected superior quality and safety, the FDA had every incentive to close off the personal use exemption because of its use as a tool to circumvent the higher costs of domestic drugs. For example, in 1990, Virginia Medicaid sought to import an unapproved foreign version of Sandoz's Clozaril, an antischizophrenic

⁵² See Pfizer Diflucan Approved Jan. 29 for AIDS-related Fungal Infections, IAA Rated Drug Earns FDA Okay in Less Than Year: Shipment to Begin Feb. 16, THE PINK SHEET (FDA/F-D-C Reports), Feb. 5, 1990, at 5-6, available in LEXIS, Market and Industry Library, Medical and Healthcare Folder, Pink Sheet-Pharmaceuticals, Prescriptions and OTC Medications File.

⁵³ See *id.*

⁵⁴ See Delthia Ricks, *AIDS Drug Clubs Offer Hope from Overseas, Buyers' Clubs Are Walking a Thin Legal Line When They Import Unapproved Medication for Desperate Patients*, ORLANDO SENTINEL TRIB., July 12, 1992, at A1.

⁵⁵ See 133 CONG. REC. H3021 (daily ed. May 4, 1987) (statement of Rep. Alexander).

⁵⁶ See Prescription Drug Marketing Act of 1987, § 801(d)(1), 21 U.S.C. § 381(d)(1) (1998).

drug, because the foreign product was less expensive.⁵⁷ The cost of Sandoz's product, however, in part reflected the extensive post-marketing monitoring system that the Agency required Sandoz to maintain as part of its marketing approval. Although the Commonwealth of Virginia proposed to conduct its own monitoring, FDA denied Virginia's request to act as a buyers' club for Clozaril.⁵⁸

The debate over reimportation has recently begun anew. Charging that Americans pay much more for prescription pharmaceuticals than people in other nations, particularly Canada, many have challenged Congress to permit reimportation of approved drugs by wholesalers, distributors and pharmacists. Legislation to allow reimportation has been introduced in both the House and Senate, and the American Medical Association has resolved to support such legislation.⁵⁹ Even Hillary Clinton has gone on record saying that reimportation, at least from Canada, is a good idea as long as safety can be assured.⁶⁰

The FDA, however, has continued to permit the buyers' clubs to operate freely. The activist community vociferously charged that FDA's refusal to allow access to therapies was tantamount to murder; unable to withstand the onslaught, the Agency permitted the buyers' clubs to import unapproved drug products with little interference. In enforcing the personal use exemption policy, the Agency generally tried to draw a clear line between commercial importation of unapproved drugs and importation of potentially lifesaving drugs for nonprofit, humanitarian reasons.⁶¹ The buyers' clubs continued to serve as sources for unapproved therapies until the very safety and quality issues the Agency cites to justify its general ban on unapproved drug products materialized.

In the early 1990's, Hoffman-LaRoche began clinical trials with dideoxycytidine (ddC), a step in seeking FDA-approval of the drug. At the time, ddC was one of the most popular drugs imported by the buyers' clubs.⁶² In what was to be an extremely effective play for market dominance, Hoffman-LaRoche analyzed several samples of ddC from buyers'

⁵⁷ See *Virginia Medicaid Clozaril Importation Proposal troubles FDA, Could be Elicit (sic), THE GREEN SHEET (FDA/Weekly Pharmacy Reports)*, Nov. 26, 1990, at 2, available in LEXIS, Market and Industry Library, Medical and Healthcare Folder, Green Sheet-Pharmacy File

⁵⁸ See *id.*

⁵⁹ See *AMA Delegates Adopt Resolution To Support Allowing Rx Drug Reimportation*, HEALTH NEWS DAILY (FDA/F-D-C Reports), Dec. 9, 1999, at 1, available in LEXIS, Market and Industry Library, Medical and Healthcare Folder, FDC Health News Daily File.

⁶⁰ See Adam Nagourney, *Mrs. Clinton Favors American Access to Cheaper Canadian Medicines*, THE NEW YORK TIMES, Feb. 9, 2000, at B5. Representative Bernie Sanders maintains a collection of press articles surrounding the reimportation effort on the Internet at, (visited March 9, 2000) <<http://bernie.house.gov/legislation/pharmbill/press.asp>>.

⁶¹ See, e.g., FDA News Release P92-3, Jan. 30, 1992 (visited Feb. 20, 2000) <<http://www.fda.gov/bbs/topics/NEWS/NEW00265.html>>.

⁶² See Span, *supra* note 34, at D2.

clubs and found them to be substandard. The FDA subsequently investigated and found that some of the drug sold through the buyers' clubs as ddC did not contain dideoxycytidine at all, and almost none of the other imported ddC met accepted potency or purity standards.⁶³ All but one buyers' club stopped providing imported ddC due to the incontestable, documented quality problems with the unapproved products.⁶⁴ As a result of the ddC quality problems, many in the AIDS community began to reassess the appropriate balance between access to unapproved drugs and government regulation that could ensure quality.⁶⁵

In 1991, the FDA announced a new program to inspect buyers' clubs. In general, the Agency was looking for evidence that the clubs were used for commercial purposes, or that they were engaged in the repackaging and recompounding of drugs, activities which FDA strictly regulates.⁶⁶ The Agency clarified in a Talk Paper that the personal use importation policy did *not* allow the import of drugs approved for use in the United States, and in 1993, the Agency began a program to identify promising AIDS drugs that have not been approved in the United States.⁶⁷

IV. RAMIFICATIONS UNDER THE PERSONAL USE EXEMPTION POLICY

A. THE DECLINE OF THE AIDS BUYERS' CLUBS

In the mid- and late-90's, several developments helped to expand access to drugs for AIDS-related conditions, thus lessening the need for buyers' clubs to act as clearinghouses for inaccessible therapies. First, AIDS activists were successful in forcing the FDA and pharmaceutical companies to expand access to therapies under development in the

⁶³ See *Parallel Track Regs Will Be Expanded to Include Drugs For Serious Illnesses Other Than AIDS Once FDA Is Assured Ongoing Trials Are Not Affected*—Kessler, THE PINK SHEET (FDA/F-D-C Reports), Apr. 13, 1992, at 12-13, available in LEXIS, Market and Industry Library, Medical and Healthcare Folder, Pink Sheet-Pharmaceuticals, Prescriptions and OTC Medications File; *T & G In Brief*, THE PINK SHEET (FDA/F-D-C Reports), Mar. 9, 1992, at T&G-13, 21, available in LEXIS, Market and Industry Library, Medical and Healthcare Folder, Pink Sheet-Pharmaceuticals, Prescriptions and OTC Medications File.

⁶⁴ See Span, *supra* note 34, at D2.

⁶⁵ See *id.*

⁶⁶ See *FDA to Inspect Buyers' Clubs For Unapproved AIDS Drugs to Guard Against Profiteering, Ensure Safety*, THE BLUE SHEET (FDA/Drug Research Reports), Oct. 2, 1991, at 10, available in LEXIS, Market and Industry Library, Medical and Healthcare Folder, Blue Sheet- Health Policy and Research File

⁶⁷ See *Health Care Fraud Penalties to Be Proposed by Rep. Schumer: AIDS Buyers Clubs Cautioned*, THE BLUE SHEET (FDA/Drug Research Reports), June 2, 1993, at 11-12, available in LEXIS, Market and Industry Library, Medical and Healthcare Folder, Blue Sheet-Health Policy and Research File.

United States but not yet approved.⁶⁸ Second, the FDA greatly reduced approval times for drugs, especially AIDS therapies, through its accelerated approval program.⁶⁹ Third, programs such as the AIDS Drug Assistance Program (“ADAP”) helped to ensure economic access to AIDS-related therapies.⁷⁰ Finally, the advent in the United States of the most successful drug treatment to date — protease inhibitors — served to focus demand for AIDS therapies on approved drug products.

Today, many AIDS buyers’ clubs are still alive and well, with seventeen organizations listed on one directory available on the Internet.⁷¹ Most of the buyers’ clubs, however, have discontinued importing unapproved drug products; instead, they generally offer information about and access to pharmaceutical-grade (when available) dietary supplements, which are legally available without a prescription and do not require FDA pre-market approval.⁷² Although at least the PWA Health Group still provides access to some unapproved drug therapies from abroad, the drug-importing function of the buyers’ clubs is no longer as important because most therapies are both financially and physically accessible in the United States, at least for motivated people.⁷³

⁶⁸ See Lois K. Perrin, Note, *The Catch-22 For Persons With AIDS: To Have or Not to Have Easy Access to Experimental Therapies and Early Approval for New Drugs*, 69 S. CAL. L. REV. 105 (Nov. 1995). For example, FDA’s treatment INDs give people without satisfactory alternatives access to investigational (unapproved) new drugs. The expanded access program allows people without other treatment alternatives to receive investigational drugs in conjunction with research studies, even through the person is ineligible for the particular study. See *Active Treatment IND/Expanded Access Programs*, PHARMACEUTICAL APPROVALS MONTHLY (FDA/F-D-C Reports) Jan. 1, 1998, at 19 (copy on file with author).

⁶⁹ See *Drug Approvals Do Not Lag in U.S. Compared to Rest Of World, Com. Kessler Tells FDLI: International Side-by-Side Approval Comparison Shows U.S. Ahead*, THE PINK SHEET (FDA/F-D-C Reports), Dec. 18, 1995, at 9-10, available in LEXIS, Market and Industry Library, Medical and Healthcare Folder, Pink Sheet-Pharmaceuticals, Prescriptions and OTC Medications File. In addition, recent legislation enacted several reforms to expedite approval of important drugs and to expand the information resources about ongoing research with experimental drugs. See *Food and Drug Administration Modernization Act of 1997*, § 506, 21 U.S.C. § 356 (1998).

⁷⁰ ADAP is a state-run program that uses a mix of federal and state funds to provide drugs used to treat HIV and related opportunistic infections to low-income people. Other publicly-funded HIV services include the Ryan White CARE Act of 1996, 42 U.S.C. §§ 201, 300ff-11 (1998), Medicaid, Medicare, and local indigent health care programs. In 1997 total ADAP spending was \$385 million, but despite spending increases, most ADAP programs imposed limits on their services in 1997 because of the growing cost of, and demand for, AIDS-related drugs, especially protease inhibitors. See Press Release, The Kaiser Family Foundation (Jul. 10, 1997) (visited Feb. 20, 2000) <<http://www.kff.org/content/archive/1275/adapr.html>>.

⁷¹ See *ACT UP: Real Treatments for Real People* (last modified June 4, 1999) <<http://www.aidsinfonyc.org/rtrp/buyers.html>>.

⁷² Personal Communication with Mark Neidzolkowsk, Editor, *The PWA Health Group Newsletter* (Feb. 2, 1999).

⁷³ The welcome message on PWA Health Group’s web site provides a glimpse of the struggle between AIDS activists and FDA:

We openly operate the Early Treatment Access Program under the FDA’s Personal Use Importation Guidance, which permits people to bring in a three month’s supply

B. RECENT ISSUES UNDER THE PERSONAL USE EXEMPTION POLICY

Many companies explicitly justify their solicitation of United States consumers to order unapproved products by mail under FDA's personal use importation policy. In 1992, the FDA issued an import alert list of prescription drugs from six foreign mail-order drug firms. The Agency claimed both that the companies were promoting the drugs for unapproved uses and that the drugs were of substandard quality and in some cases counterfeit.⁷⁴ In 1995, a company called Medicine Club International was charged with shipping an unapproved version of Prozac® (fluoxetine) to the United States.⁷⁵ Medicine Club, like other companies, advertised unapproved versions of United States pharmaceuticals at discount prices. Medicine Club's advertisements contained an 800 number and offers to sell the drug in personal use quantities.⁷⁶ Medicine Club International was fined \$500,000, in addition to making a \$339,074 payment for the costs of the investigation.⁷⁷ The company, along with several other companies conducting similar mail-order businesses that were not prosecuted, agreed to establish a \$1 million letter of credit that would be forfeited to the United States if the companies offer unapproved, adulterated or misbranded drugs for sale before the year 2000.⁷⁸

The FDA has also expressed concern with the proliferation of on-line, offshore pharmacies, which have continued to attempt to profit from the personal use exemption policy. For example, in a speech to the American Pharmaceutical Association's annual meeting in March of 1997, a FDA Senior Science Advisor noted that several offshore companies were offering generic versions of drugs with potentially serious side-

of a medication approved elsewhere in the world. It sounds simple, and aside from periodic FDA harassment, it usually is. But it's also important to remember that each time you buy something here at the PWA Health Group, you're performing a political act. Throughout the history of the AIDS crisis in the United States, people with HIV/AIDS have refused to accept the limited wisdom of our government, the medical profession, and the drug companies. We question, we argue, we confront, and, though all of this, we make individual empowered treatment decisions that are right for us. We are proud of this history of struggle and caring, which has been critical to the treatment advances of today, and critical to the place we urgently need to get to a cure.

See PWA Health Group, *supra* note 41. The PWA Health Group continues to import certain therapies that drug companies are unwilling to sponsor for FDA approval for economic reasons.

⁷⁴ See FDA News Release P92-3, Jan. 30, 1992 (visited Feb. 20, 2000) <<http://www.fda.gov/bbs/topics/NEWS/NEW00265.html>>.

⁷⁵ See *Medicine Club pleads guilty to shipping unapproved generic Prozac*, THE PINK SHEET (FDA/F-D-C Reports), Jan. 9, 1995, at T&G-2, available in LEXIS, Market and Industry Library, Medical and Healthcare Folder, Pink Sheet-Pharmaceuticals, Prescriptions and OTC Medications File.

⁷⁶ See *id.*

⁷⁷ See *id.*

⁷⁸ See *id.*

effects due to bioequivalency issues.⁷⁹ In general, these companies offer the drugs for personal use and advise physician supervision. Although the companies may explicitly claim to operate within FDA's personal use exemption, they violate the personal import exemption on several fronts. First, the companies import drug products for commercial gain. Second, most of their products are approved for use in the United States and thus not eligible for the personal use import exemption if they treat a serious condition. Third, the drug products are often adulterated or misbranded. Because these companies are off-shore, it is often very difficult for the FDA to identify the companies and curtail their activities. The Agency has been working to establish cooperative efforts with the countries from which these exporters operate.⁸⁰

In December 1999, The White House announced a new initiative to curtail the illegal sale of prescription drugs over the Internet.⁸¹ Citing the danger to consumers posed by unregulated and illegal Internet pharmacies, and the increasing proliferation of such operations, President Clinton proposed a multi-prongs response, including a \$10 million appropriations in the FY 2001 budget to expand federal enforcement activities against "Fly by Night" Internet pharmacies.⁸² The program has several parts, including bringing Internet pharmacies into compliance with existing pharmacy regulations; strengthening the investigative tools and monetary penalties against illegal Internet pharmacies; and creating a new online program to raise public awareness about illegal Internet drug sales. FDA's Internet site to assist consumers in filling prescriptions safely over the Internet is now up and running.⁸³

V. LEGAL CHALLENGES TO FDA'S PERSONAL USE IMPORTATION POLICY

Because FDA's personal use importation policy is implemented through the exercise of FDA's enforcement discretion, the Agency has little public or judicial accountability for its decisions to permit or prohibit importation of a drug under the policy. Imagine that you are seri-

⁷⁹ See *Internet Generic Phenytoin Sales Are Public Health Concern*, THE GREEN SHEET (FDA/Weekly Pharmacy Reports), Apr. 6, 1998, at 3, available in LEXIS, Market and Industry Library, Medical and Healthcare Folder, Green Sheet-Pharmacy File.

⁸⁰ See *In Home Generic Phenytoin Off-shore Sales of Concern to FDA Because Use of Non-approved Generic May Change Blood Levels of the NTI Drug, Bersein Tells APHA Meeting*, HEALTH NEWS DAILY (FDA/F-D-C Reports), Mar. 26, 1998, at 3, available in LEXIS, Market and Industry Library, Medical and Healthcare Folder, FDC Health News Daily File.

⁸¹ See Office of the Press Secretary, *The Clinton Administration Unveils New Initiative To Protect Consumers Buying Prescription Drug Products Over the Internet* (Dec. 28, 1999) (visited March 6, 2000) <<http://www.fda.gov/oc/buyonline/onlinesalespr.html>>.

⁸² See *id.*

⁸³ See FDA, *Buying Medical Products Online* (visited March 4, 2000) <<http://www.fda.gov/oc/buyonline>>.

ously ill with a rare disease. In consultation with your doctor, who advises you that a drug available only in Germany provides the best treatment, you fly to Germany to obtain a three-month supply. On your return through customs in New York, an agent confiscates the drug, refusing to exercise his enforcement discretion to permit the importation of an unapproved drug product in contravention to the Federal Food, Drug and Cosmetic Act ("FDCA").⁸⁴ Alternatively, the FDA has issued an import alert banning all drug products made by the German manufacturer in question, taking away the agent's enforcement discretion to permit import of the drug for personal use.

You could challenge the agent's denial or the Agency's issuance of an import alert on several fronts, all of which would likely fail. First, you could appeal the denial through FDA's own administrative procedures.⁸⁵ Second, you could bring a legal action against the Agency claiming one or more of the following: (1) the Agency's denial exceeded its statutory or constitutional authority; (2) the Agency's denial was arbitrary and capricious and should thus be overturned under the Administrative Procedure Act (APA);⁸⁶ and (3) the Agency's personal use exemption policy or import alerts are substantive rules that must be promulgated by notice-and-comment rule making under the APA and are therefore void.⁸⁷ As discussed below, administrative law and judicial precedent would virtually ensure the failure of both your administrative appeal to the FDA and of an appeal to the courts.

A. ADMINISTRATIVE APPEAL TO FDA

Having been denied importation of the German drug for personal use, you could contest the refusal at an administrative hearing. By regulation, the Agency must issue a written notice providing the reason for the refusal and the time and place of a hearing at which there is an opportunity to defend the legality of importing the drug.⁸⁸ If the FDA was unsympathetic to your case, however, the fact that you met all the criteria of the personal use exemption policy would be moot. If the drug is unapproved, there is no right to import it, regardless of your compliance with the terms of the personal use importation policy.⁸⁹ Because the FDA

⁸⁴ See Federal Food, Drug, and Cosmetic Act of 1938 §1, 21 U.S.C. §§ 301-397 (1998).

⁸⁵ See *id.* § 334 (1998).

⁸⁶ See 5 U.S.C. § 706(2)(A) (1998).

⁸⁷ See *id.* § 553(b), (c).

⁸⁸ See 21 C.F.R. § 1.94 (1999).

⁸⁹ A court would probably even permit FDA to forgo the hearing unless the importer could show there was a genuine issue regarding the approval status of the drug product. See *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973)(permitting the FDA to deny a statutorily mandated hearing regarding a drug's efficacy unless the manufacturer could show there was a genuine and substantial issue of fact to be presented at the hearing).

itself claims absolute discretion to deny the importation of any unapproved drug, there is no meaningful appeal to the Agency regarding such a denial.

B. FDA'S CONSTITUTIONAL AUTHORITY TO DENY IMPORTATION FOR PERSONAL USE

Failing an administrative appeal, you could challenge FDA's importation denial in the courts, claiming that it violates individual rights protected under the United States Constitution. Intuitively, government action denying an individual access to a potentially lifesaving treatment would seem to violate the constitutional protection of privacy rights and individual autonomy, especially as those rights have been interpreted by the Supreme Court.⁹⁰ Certainly, the person with a terminal illness from whom the FDA confiscates an unapproved drug intended only for personal use must feel that confiscation to be a grave violation of his autonomy and privacy.⁹¹ However, due to well-established judicial precedent described below, an appeal to the courts to overturn FDA's denial of importation for personal use on constitutional grounds has little hope of prevailing.

In litigation spanning twelve years, terminally ill cancer patients seeking to obtain the use of the drug Laetrile,⁹² that many then believed to be an effective cancer treatment, sought to challenge FDA's right to prohibit their use of Laetrile as an unapproved new drug.⁹³ Generally, the cancer patients argued that because they were dying anyway, they had little to lose if Laetrile did not work and should therefore be permitted access to the drug. The FDA categorically responded that it was impossible to know whether a cancer was actually terminal and permitting the use of an unproven therapy could prevent people with cancer

⁹⁰ See, e.g., *Whalen v. Roe*, 429 U.S. 589 (1977); *Planned Parenthood of Central Missouri v. Danforth*, 428 U.S. 52 (1976); *Doe v. Bolton*, 410 U.S. 179 (1973); *Paris Adult Theatre I v. Slaton*, 413 U.S. 49 (1973); *Roe v. Wade*, 410 U.S. 113 (1973); *Eisenstadt v. Baird*, 405 U.S. 437 (1972).

⁹¹ If an Agency decision (not to permit importation of unapproved drugs for personal use) violates the Constitution, it will be reversed under § 706(2)(B) of the APA. See 5 U.S.C. § 706(2)(B) (1998). Moreover, an agency cannot interpret a statute in such a way that the interpretation raises a serious constitutional issue absent a "clear statement" from Congress supporting the interpretation. See *DeBartolo Corp. v. Florida Gulf Coast*, 485 U.S. 568 (1988).

⁹² Laetrile is a compound usually derived from apricot pits that many cancer patients believe to be an effective treatment.

⁹³ See *Rutherford v. United States*, 806 F.2d 1455 (10th Cir. 1986); *Rutherford v. United States*, 616 F.2d 455 (10th Cir. 1980); *Rutherford v. United States*, 582 F.2d 1234 (10th Cir. 1978); *Rutherford v. United States*, 542 F.2d 1137 (10th Cir. 1976); *Rutherford v. United States*, 438 F. Supp. 1287 (W.D. Okla. 1977); *Rutherford v. United States*, 429 F. Supp. 506 (W.D. Okla. 1977); *Rutherford v. United States*, 424 F. Supp. 105 (W.D. Okla. 1977); *Rutherford v. United States*, 399 F. Supp. 1208 (W.D. Okla. 1975).

from seeking treatment with effective, approved therapies. In addition, the FDA cited the dangers of unethical practitioners who provided false hope to the terminally ill for their own financial gain.⁹⁴

In 1977, at the beginning of the Laetrile wars, the United States District Court for the Western District of Oklahoma passionately defended the right of terminally-patients to use Laetrile under the Constitution. The court in *Rutherford v. United States* argued:

The final consequences [of FDA's denial] are ultimately borne by those whose bodies are the battleground on which cancer's war is waged. Many perceive the drug's acquisition as a life and death matter, and are understandably frustrated and enraged over attempts by their own government to deny them the right to decide for themselves questions of such a personal and grave nature. . . . To be insensitive to the very fundamental nature of the civil liberties at issue in this case, and the fact that making the choice, regardless of its correctness, is the sole prerogative of the person whose body is being ravaged, is to display slight understanding of the essence of our free society and its constitutional underpinnings. . . . By denying the right to use a nontoxic substance in connection with one's own personal healthcare, FDA has offended the constitutional right of privacy.⁹⁵

On appeal, however, the 10th Circuit Court of Appeals held that although the choice of whether to have medical treatment or not *is* a privacy right protected by the Constitution, this protection does not extend to the selection of a particular treatment.⁹⁶ Instead, the court found that "the selection of a particular treatment, or at least a medication, is within the area of governmental interest in protecting public health."⁹⁷ The litigation over access to Laetrile thus established FDA's constitutional authority to deny access to unapproved drug products for personal use even in the case of patients with terminal cancer.⁹⁸

⁹⁴ See, e.g., *United States v. Rutherford*, 442 U.S. 544 (1979).

⁹⁵ 438 F. Supp. 1287, 1300-01, (W.D. Okla. 1977).

⁹⁶ See *Rutherford v. United States*, 616 F.2d 455, 457 (10th Cir. 1980), *cert denied*, 449 U.S. 937 (1980). See also *Carnohan v. United States*, 616 F.2d 1120, 1122 (9th Cir. 1980); *Sifre v. Robles*, 917 F. Supp. 133, 137 (D.P.R. 1996); *Jacob v. Curt*, 721 F. Supp. 1536, 1539 (D.R.I. 1989); *Kulsar v. Ambach*, 598 F. Supp. 1124 (W.D.N.Y. 1984); *Gadler v. United States*, 425 F. Supp. 244 (D. Minn. 1977).

⁹⁷ See *Rutherford*, 616 F.2d at 457.

⁹⁸ Laetrile is still subject to FDA Import Alert no. 62-01, (visited March 10, 2000) <http://www.fda.gov/ora/fiars/ora_import_ia6201.html>, and the Agency has threatened enforcement actions against companies attempting to market Laetrile as a dietary supplement. See *FDA warns Florida company it is making 'drug' claims for dietary supplements*, LAETRILE FOOD LABELING & NUTRITION NEWS, Dec. 23, 1998, at 10 (copy on file with author).

C. FDA'S STATUTORY AUTHORITY TO PROHIBIT IMPORTATION FOR PERSONAL USE

Having been denied your appeal on Constitutional grounds, you would be left to argue that the FDA exceeded its statutory authority in prohibiting importation of the unapproved drug for personal use. Under the APA, the initial question for the court would be whether the FDA has the statutory authority to prohibit the importation of unapproved drugs for personal use.⁹⁹ In reviewing FDA's claim of statutory authority, the Court would first inquire whether "Congress has directly spoken to the precise issue at hand."¹⁰⁰

The FDA cites § 801 of the FDCA as requiring the Agency to prohibit the importation of unapproved, new drug products. Section 801 itself, however, simply prohibits the importation of unapproved drugs that *will be introduced into interstate commerce*.¹⁰¹ If personal importation and use of a drug does not constitute an "introduction into interstate commerce," then such importation and use are not a violation of § 801.¹⁰² Outside a courtroom, few would argue that a person who obtains and personally uses an unapproved drug from a foreign source thereby 'introduces' that drug into interstate commerce, even though it satisfies the statutory definition.¹⁰³

The FDA however, interprets § 801 to mandate a general ban on the importation of unapproved, new drug products, even when those products are intended for personal use.¹⁰⁴ In addition, there is judicial precedent that the FDCA's prohibition on the introduction into interstate commerce of unapproved drugs does extend to unapproved drugs imported for personal use. In *Galder v. United States*,¹⁰⁵ the court denied an injunction to a cancer patient seeking to restrain the FDA from prohibiting import of Laetrile for his personal use. The *Galder* court found that the approval requirements for new drugs applied to private

⁹⁹ The APA provides that a court will overturn Agency action when it is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(C) (1998).

¹⁰⁰ *Chevron U.S.A., Inc. v. NRDC*, 467 U.S. 837, 842 (1984).

¹⁰¹ The statute reads that the FDA shall prohibit importation of drugs that it finds are "adulterated, misbranded, or in violation of section 505 . . ." 21 U.S.C. § 381(a)(3) (1998) (emphasis added). Section 505 is the statutory provision requiring the FDA approval of new drug products, and states that "[n]o person shall introduce or deliver for introduction into interstate commerce . . ." an unapproved drug. 21 U.S.C. § 355(a) (1998). The FDCA defines interstate commerce as "commerce between any State or Territory and any place outside thereof . . ." 21 U.S.C. § 321(b) (1998).

¹⁰² See 21 U.S.C. §§ 381(a)(3), 355(a) (1998).

¹⁰³ Although the line of Supreme Court cases interpreting Congressional power under the Commerce Clause of the Constitution would be relevant to an analysis of the phrase "introduction into interstate commerce" in the FDCA, it would not be dispositive.

¹⁰⁴ See *RU-486 Hearing*, *supra* note 25, at 175-77.

¹⁰⁵ 425 F.Supp. 244 (D.Minn. 1977).

persons and that personal transportation of Laetrile from Mexico constituted an introduction into interstate commerce under the FDCA.¹⁰⁶ The court did not consider whether the FDA should permit importation under its personal use policy, and in fact appeared unaware that such a policy existed. The FDA has asserted in other forums however, that the personal use exemption policy has been in effect since the 1950's.¹⁰⁷

If the court, despite precedent, found the FDCA was ambiguous with regard to whether personal use constituted introduction into interstate commerce, its next decision would be whether the Agency's interpretation of ambiguous statutory authority was a permissible construction of the FDCA.¹⁰⁸ Given that FDA's interpretation of § 801 as prohibiting the importation of all unapproved drug products is long standing and well established, a court would almost certainly defer to the Agency's interpretations.¹⁰⁹ Moreover, Congress recently amended the FDCA to explicitly state that a connection with interstate commerce is to be presumed sufficient to give the FDA the authority to enforce the FDCA's drug requirements.¹¹⁰ Because the FDA is well-qualified and charged with the determination of drug safety and efficacy, it is unlikely a court would second guess an Agency determination that all unapproved drugs should be prohibited from importation.¹¹¹

D. FDA'S APPLICATION THE LAW TO THE FACTS IN QUESTION

1. *Enforcement Decision Committed to Agency Discretion*

Having determined that the FDA acts within the bounds of the FDCA and the Constitution in denying importation for personal use generally, you could next argue that the court should review the Agency's

¹⁰⁶ See *id.* at 248.

¹⁰⁷ Although its substance is unknown, some form of the personal use importation was put in writing as early as 1954 as a directive to the Agency's district offices from FDA's Division of Field Operations. See *RU-486 Hearing*, *supra* note 25, at 175-77.

¹⁰⁸ See *Chevron U.S.A., Inc. v. NRDC*, 467 U.S. 837, 843 (1984).

¹⁰⁹ See, e.g., *General Electric Co. v. Gilbert*, 429 U.S. 125 (1976); *NLRB v. Bell Aerospace Co.*, 416 U.S. 267 (1974)(because the agency's decision departed from a long-standing interpretation of its statute, the decision merited little judicial deference).

¹¹⁰ See 21 U.S.C. §379a (1998). Even if a court ruled that the FDA did not have the authority to prohibit the importation of unapproved drug products for personal use as a violation of § 505 of the FDCA, the FDA could simply then reassert its authority on other grounds and reissue such a ruling. The Agency could argue, for example, that because it has no assurance that unapproved drugs are manufactured in accordance with its Good Manufacturing Practices, such products must be presumed to be adulterated. See 21 U.S.C. § 351(a)(2)(b) (1998). Alternatively, because the FDA has not reviewed the indications of directions for use, the Agency could argue that unapproved drug products should be assumed to be misbranded.

¹¹¹ See, e.g., *Lyng v. Payne*, 476 U.S. 926, 939 (1986)(court will defer to the Agency's interpretation of its directive); *United States v. Bacto-Unidisk*, 394 U.S. 784 (1969)(because its overriding purpose is to protect public health, the FDCA must be given a liberal construction in accordance with that purpose).

application of its policy to the particular situation at hand. At this point, a court might refuse to review FDA's implementation of its personal use exemption policy at all, arguing that it was an enforcement decision that was judicially unreviewable.

Under § 701(a)(2) of the APA, courts are prohibited from reviewing agency action that "is committed to agency discretion by law."¹¹² The controlling case is *Heckler v. Chaney*,¹¹³ in which the FDA refused to initiate an enforcement action against a state for the use of an injectable drug for capital punishment although the drug was *not* approved for that use. The Supreme Court held that FDA's decision of whether to initiate an enforcement action was exempt from judicial review as a matter committed to agency discretion under § 701(a)(2).¹¹⁴

Since the inception of the personal use importation exemption policy, the Agency has characterized the policy as an exercise of its discretion *not* to enforce the general prohibition against the importation of unapproved new drugs. Moreover, the FDA argues that import alerts are simply affirmations of the statutory mandate to prohibit importation of unapproved or otherwise violative drug products.¹¹⁵ Although the abuse of discretion doctrine is theoretically difficult, and perhaps generally unworkable,¹¹⁶ it still strongly supports the proposition that, absent a statutory directive, an Agency's exercise of enforcement discretion is generally unreviewable by the courts.

2. *Review of Denial Under Arbitrary and Capricious Standard*

The APA also permits courts to set aside agency action if it is arbitrary or capricious.¹¹⁷ Even if a court were to review the application of the personal use importation policy or the issuance of an import alert to

¹¹² 5 U.S.C. §701(a)(2) (1998). This provision of the APA would seem to be either coextensive and redundant *or* in direct conflict with the APA's grant of judicial authority to set aside agency action that is "an abuse of discretion, or otherwise not in accordance with law . . ." 5 U.S.C. § 706(2)(A)(1998).

¹¹³ 470 U.S. 821, 830-32 (1984). The Supreme Court found that FDA's decision not to enforce certain provisions of the FDCA was not subject to judicial review under § 701(a)(2) of the APA because "if no judicially manageable standards are available for judging how and when an agency should exercise its discretion, then it is impossible to evaluate agency action for 'abuse of discretion.'" *Id.* at 830-32 (referring to 5 U.S.C. § 701(a)(2)(1998)). The Court explained that when an agency decides which violators it will pursue, it considers factors such as its chances of prevailing in the action, its overall regulatory priorities, and competing uses for agency resources, all factors which a court may have particular difficulty and little expertise in reviewing. *Id.*

¹¹⁴ *See id.*

¹¹⁵ *See* Memorandum for the Respondents in Opposition, *Benten v. Kessler*, 505 U.S. 1084 (1992) (No. A-40).

¹¹⁶ *See, e.g.,* Ronald M. Levin, *Understanding Unreviewability in Administrative Law*, 74 MINN. L. REV. 689 (1990).

¹¹⁷ Courts are directed to set aside agency action that is "an abuse of discretion, or otherwise not in accordance with law . . ." 5 U.S.C. § 706(2)(A) (1998).

determine whether the FDA implemented them arbitrarily or capriciously, it is unlikely that the court would overrule a FDA decision (unless the court determined the policy is a substantive rule as discussed below). For example, in a recent declaratory judgement action where the court did review FDA's implementation of the personal use importation policy, the court stated that "[e]ven if an individual complies with [FDA's policy] . . . , the decision whether to permit an individual to import the drugs remains within the discretion of the FDA."¹¹⁸ Given the discretionary nature of the personal use policy's implementation, no denial would be arbitrary or capricious unless FDA's procedure for determining the approval status of a drug was itself challenged.

E. ANALYSIS OF PERSONAL USE POLICY AS A SUBSTANTIVE RULE UNDER THE APA

Alternatively, a court could ask whether the FDA had the authority under the guidelines of the personal use exemption policy to prohibit the importation. In order to frame the legal inquiry in terms of whether the Agency implemented its policy correctly, the court would have to find that the Agency was in fact legally bound by the terms of the policy. Such a finding, however, would be tantamount to classifying the personal use exemption policy as a substantive rule under the APA.¹¹⁹ Again, judicial precedent in this case, in particular the precedent established under the attempt to import RU-486, is contrary to a finding that the personal use importation policy or import alerts are substantive rules. The APA requires that substantive (also known as legislative or formal) rules be formulated through notice-and-comment rulemaking.¹²⁰ In general, substantive rules are like laws in that they serve to determine the rights of a class of people. Unlike informal policy or interpretive rules, substantive rules are binding both on the Agency and the private persons regulated by the rules. In determining whether an agency as complied with the APA's procedural mandates and whether an agency rule is binding, a court must first characterize whether the policy at issue is a substantive rule.

¹¹⁸ *Sifre v. Robles*, 917 F. Supp. 137 (D.P.R. 1996). The court also affirmed the *Rutherford Laetrile* cases as establishing that an individual has no legal right to a particular medical treatment. See *Rutherford v. United States*, 616 F.2d 455, 457 (10th Cir. 1980), *cert. denied*, 449 U.S. 937 (1980).

¹¹⁹ The APA defines rules as "the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or practice." 5 U.S.C. § 551(4) (1998).

¹²⁰ The APA does not define substantive rule, but simply exempts from notice-and comment rule making procedures "interpretive rules, general statements of policy, [and] rules of agency organization, procedure, and practice." 5 U.S.C. § 553(b)(A) (1998).

In *Bellarno Intern. Ltd. v. FDA*, the court overturned an FDA import alert largely banning the reimportation into the United States of a drug originally manufactured in the United States because it was a substantive rule and thus should have been promulgated in accordance with APA notice-and-comment rulemaking procedures.¹²¹ The *Bellarno* court identified four relevant factors in determining that the import alert was a substantive rule: “[t]he binding effect of the pronouncement; the degree of discretion accorded the agency in applying the pronouncement; deference to the agency’s characterization; and the language of the pronouncement itself.”¹²² Logically, the issuance of an import alert, which removes the discretion to permit importation of certain types of drug products regardless of whether the drugs otherwise comply with the FDCA, has the force and effect of a substantive rule.¹²³

If a court decided that the personal use exemption policy itself was a substantive rule, it could then review FDA’s implementation of the policy to determine whether the Agency’s denial was arbitrary and capricious and hold the policy void because it was not implemented by the requisite notice-and-comment rule making procedures.¹²⁴ Although compelling, this line of attack is most likely precluded by the Supreme Court’s review of FDA’s refusal to permit the importation of Mifepristone (RU-486) under the personal use importation policy in accordance with an import alert as described below.

Shortly after FDA issued its 1989 Pilot Guidance for personal use importation, the Agency came under intense Congressional pressure to ensure its policy did not provide American women with access to the abortifacient drug Mifepristone, better known as RU-486.¹²⁵ Unencumbered by procedural requirements or publicity, the FDA moved quickly and in just three weeks issued an import alert banning the importation of RU-486 for personal use on the grounds that the drug was unsafe.¹²⁶ Allegations at the time suggested that in addition to prohibiting the use of

¹²¹ See 678 F.Supp. 410 (E.D.N.Y 1998).

¹²² *Id.* at 413.

¹²³ Section 801(d)(1), a part of the Prescription Drug Marketing Act of 1987, banned the reimportation of exported products except when reimportation was by the original manufacturer of the drug. See Prescription Drug Marketing Act of 1987, 21 U.S.C. § 381(d)(1) (1998).

¹²⁴ The APA exempts form notice-and-comment procedures “interpretive rules, general statements of policy, [and] rules of agency organization, procedure or practice.” 5 U.S.C. § 553 (b)(A), (d)(2)(1998). Substantive or legislative rules, however, must be developed through APA’s notice-and-comment procedures or they are invalid. See, e.g., *Bellarno Intern Ltd., v. FDA*, 678 F. Supp. 410 (E.D.N.Y 1988).

¹²⁵ On May 5, 1989, then FDA Commissioner Frank Young received a letter from eleven anti-abortion activist members of Congress, asking that an import alert be issued for RU-486. Nineteen days later, FDA recommended that RU-486 be placed on the import alert list; the alert was issued on June 6, 1989. See S. 2268, 102d Cong. (1992).

¹²⁶ See FDA Import Alert no. 66-47, (Apr. 17, 1990) (visited Feb. 20, 2000) <http://www.fda.gov/ora/fiars/ora_import_ia6647.html>.

RU-486 as an abortifacient, FDA's import alert also stopped promising research on the drug's use in treating breast and other cancers.¹²⁷

In 1992, a woman named Leona Benten challenged the Agency's right to enforce the import ban in court and sought the immediate use of the RU-486 she had imported to terminate her pregnancy. In order to challenge FDA's import ban, the Abortion Rights Mobilization group flew Ms. Benten to London to obtain RU-486, where she notified the FDA of her intention to return to the United States with the drug for use under the supervision of her physician. She was met at the airport by FDA personnel who seized the drug, and she and the Center for Reproductive Law and Policy filed a complaint in Federal Court in New York for return of the drug and a ruling that FDA's import ban on RU-486 was illegal.¹²⁸ In its initial decision to permit Ms. Benten to use the imported drug, the United States District Court for the Eastern District of New York blasted the lack of notice-and-comment rule making surrounding FDA's issuance of the RU-486 import alert and accused the Agency of banning RU-486 for "political considerations having no place in FDA decisions on health and safety."¹²⁹ In the court's opinion, both the import alert and the personal use exemption policy should have been implemented through notice-and-comment rule making procedures.¹³⁰

On appeal to the Supreme Court, the Eastern District's order returning the RU-486 to Ms. Benten was overturned, and the Agency's right to prohibit the importation of RU-486 was confirmed on July 17, 1992.¹³¹ The Supreme Court held that Ms. Benten did not have a substantial likelihood of succeeding in her argument that the FDA was required to implement its import alert through notice-and-comment rule making procedures.¹³² The Court simply stated this conclusion without discussion, perhaps because the Court was forced to decide the case within a matter of days, as RU-486 can only be safely used as an abortifacient during early pregnancy.¹³³ Despite its lack of explanation, the Supreme Court's decision makes it unlikely that a lower court would again find an FDA import alert to be a substantive rule.

¹²⁷ See *RU486 Hearing*, *supra* note 25.

¹²⁸ See *Supreme Court Upholds FDA Ban on RU-486 Importation; Ban is "Undue Burden" Argues Dissenting Justice*, THE BLUE SHEET (FDA/Drug Research Reports), July 22, 1992, available in LEXIS, Market and Industry Library, Medical and Healthcare Folder, Blue Sheet-Health Policy and Research File

¹²⁹ *Benten v. Kessler*, 799 F. Supp. 281, 285 (E.D.N.Y. 1992).

¹³⁰ See *id.* at 289.

¹³¹ See *Benten v. Kessler*, 505 U.S. 1084 (1992).

¹³² See *id.* at 1085.

¹³³ See *id.*

Upon taking office, President Clinton ordered a review of the Agency's import ban on RU-486.¹³⁴ Although the import ban was not lifted, the United States non-profit group Population Council obtained patent rights to the drugs and filed a new drug application for RU-486 in 1996. The FDA subsequently issued an "approvable letter" to the Population Council for Mifepristone, when used in combination with misoprostol, for termination of early pregnancy.¹³⁵ After the 1996 tentative approval, the Population Council ran into difficulties finding a manufacturer willing bringing the drug to market. In early 1999 however, the Population Council announced it had located a manufacturer for the drug and it was hoped that FDA would give final approval by the end of the year.¹³⁶ On February 18, 2000, the FDA issued another "approvable letter" for Mifepristone when used in combination with misoprostol. Although implying that the early issues blocking final approval of RU-486 had been resolved, the Agency did not comment as to the nature or extent of the remaining issues barring final approval.¹³⁷

However, a court would be even less likely to find that the personal use exemption policy is a substantive rule that should have been implemented through notice-and-comment rule making procedures. Because the FDA has consistently characterized the personal use exemption as a discretionary policy made by individual FDA employees, it cannot easily be characterized as "binding." Unless the Agency ostensibly required its personnel to follow the policy, a court would also be likely to find the personal use exemption to be an interpretive rule exempt from APA-mandated rule making procedures.¹³⁸

¹³⁴ See *Mifepristone (RU-486) Proposed Distribution System is Acceptable, But Abortion Training Process Raises "Serious Concerns," Advisory Committee Concludes*, THE PINK SHEET (FDA/F-D-C Reports), July 29, 1996, at 13-14, available in LEXIS, Market and Industry Library, Medical and Healthcare Folder, Pink Sheet-Pharmaceuticals, Prescriptions and OTC Medications File.

¹³⁵ *FDA Advisory Committee Reviews Mifepristone*, July 19, 1996. (last visited March 4, 2000) <<http://www.fda.gov/bbs/topics/ANSWERS/ANS00748.html>>. The FDA issues "approvable letters" when relatively minor issues necessary for final approval remain unresolved.

¹³⁶ See Marc Kaufman, *Abortion Pill Inches Closer to Production: American Marketer Hopeful that Drug Will Be Available by the End of the Year*, WASH. POST, Mar. 23, 1999, at Z07. In addition, the press reported that fifteen sites nation-wide were participating in a clinical trial of RU-486 sponsored by the Abortion Rights Mobilization (ARM), an advocacy group. See *id.*

¹³⁷ See *FDA Issues Approvable Letter for Mifepristone*, Feb. 18, 2000. (last visited March 4, 2000) <<http://www.fda.gov/bbs/topics/ANSWERS/ANS01005.html>>.

¹³⁸ For example, the United States Court of Appeals for the Fifth Circuit recently held that a FDA Compliance Policy Guide setting forth guidelines on the permissible scope of pharmacy compounding activities was interpretive rule exempt from APA rulemaking procedures. See *Professionals and Patients for Customized Care v. Shalala*, 56 F.3d 592 (5th Cir. 1995).

VI. IMPLEMENTING THE PERSONAL USE EXEMPTION THROUGH SUBSTANTIVE REGULATIONS

FDA's personal use exemption policy is probably best characterized as an interpretive rule that does not require notice-and-comment rule making. The FDA, however, could give binding effect to the personal use importation policy by explicitly promulgating it as a substantive rule through notice-and-comment rule making procedures.¹³⁹ Once the FDA implements a substantive regulation, the Agency and those it regulates are bound by the terms of the rule.¹⁴⁰ That is, the FDA would give up its discretion to deny importation for personal use if an individual met specific criteria established by the rule, while individuals would be on notice that they must meet the rule's criteria in order to import unapproved drugs for personal use. At the administrative hearing of a denial, the question would be whether the particular individual met the criteria under the personal use exemption rule. Judicial review, assuming the court agreed the rule was substantive, would focus on the same question.

If the legislative effect of the policy were challenged in court, the FDA could assert that the FDCA's ban on the import of unapproved drug products for introduction into interstate commerce can be interpreted to permit importation for personal use — the very opposite of the argument FDA has traditionally asserted. Because the FDA would be departing from long-standing precedent, the authority of the policy to bind the Agency and those it governs might be vulnerable in a judicial review.¹⁴¹

The FDA is also free to implement interpretive rules or general policy through notice-and-comment rule making if it so chooses. Congress itself recently charged the FDA with abiding by its guidance documents and ensuring public participation in the formation and implementation of those that are important policy changes, obviously recognizing that much of FDA's guidance can have a substantial impact on substantive rights.¹⁴² At the very least, the FDA could implement its personal use

¹³⁹ A substantive rule must be "rooted in a grant of [quasi-legislative] power by the Congress." *Chrysler Corp. v. Brown* 441 U.S. 281, 301 (1979). Congress has given the FDA the authority to "prescribe regulations of the efficient enforcement of section 381 [governing imports] of this title." 21 U.S.C. § 371(b) (1988).

¹⁴⁰ See *United States v. Nixon*, 418 U.S. 683, 694-95 (1974).

¹⁴¹ See, e.g., *General Electric Co. v. Gilbert*, 429 U.S. 125 (1976); *NLRB v. Bell Aerospace Co.*, 416 U.S. 267 (1974) (because the agency's decision departed from a long-standing interpretation of its statute, the decision merited little judicial deference).

¹⁴² Congress was explicit when it stated:

Although guidance employees of the Food and Drug Administration do not deviate from such guidance without appropriate justification and supervisory concurrence . . . For guidance documents that set forth . . . policy that are of more than a minor nature, complex scientific issues, or highly controversial documents shall not be binding on the Secretary, the Secretary shall ensure that issues, the Secretary shall ensure public participation prior to implementation of guidance documents, unless

importation policy as a guidance document, including import alerts, through notice-and-comment rule making procedures.

VII. CONCLUSION

There are many good reasons for the FDA to implement the personal use exemption, including import alerts, through the APA's notice-and-comment rule making procedures. First, the Agency has not abided by or acted consistently within the bounds of its personal use exemption as it is found in its personnel manual. In the case of the AIDS buyers' clubs, the Agency paid lip-service to the policy, but permitted significantly more unapproved drugs to be imported than the written policy would justify. On the other hand, the FDA appears to have responded to political pressure rather than a public health mandate when it issued its import alert on RU-486. Finally, in all of the controversy over Laetrile, many of those seeking to use Laetrile were not even aware of FDA's personal use importation policy.

Regardless of whether the effect of the Agency's respective decisions was good or bad, FDA's implementation of the personal use exemption certainly does not provide the type of interest-group participation, consistency, fairness and accountability desired in agency action. In contrast, notice-and-comment rule making would bring interested parties into the discussion to develop a personal use importation policy that was flexible and permitted independent review while safeguarding the public health.

Poised as it is at the end of its experience with the widespread importation of unapproved AIDS therapies, the Agency is in an ideal position to turn the wisdom gained by its experience into a regulation that will safeguard both the quality of and access to unapproved drug products. Moreover, if, as is hoped, the need for access to unapproved

AIDS-related therapies continue to diminish, the existence and use of the personal use exemption will become increasingly rare. A formal regulation would at least give those searching for access to an unapproved drug notice that the FDA will allow such access under certain circumstances. A list of the circumstances under which the FDA would permit personal use importation would also provide a court with meaningful standards in a review of FDA's application of the law.

As political and societal values change over time, there is no guarantee that the Agency's current benevolent attitude toward personal use importation will continue, or that the next group seeking access to unap-

the Secretary determines that such prior public participation is not feasible or appropriate.

proved drugs through the exemption will be successful — other groups may not have the political or social clout to ensure FDA's personal use importation policy is implemented (or expanded) for their benefit. At least one person with personal experience of the importation of AIDS-related therapies under the personal use exemption agrees that the potential for abuse of the policy as applied to individuals, or other, less organized groups, necessitates a formal personal use exemption policy.¹⁴³ Another AIDS-activist believes that their movement has changed FDA's stance toward people with life-threatening diseases forever, ensuring access to unapproved products. He fears that implementing a formal policy may lead to a more narrow and restrictive policy.¹⁴⁴ Given the uneven history of the policy's implementation, it is a risk worth taking.

A regulation governing importation for personal use could also set forth guidelines for the issuance of import alerts. Because of the nature of import alerts, the FDA is justifiably reluctant to give up its ability to issue such alerts without procedural impediments. The Agency could reserve the right unilaterally to issue import alerts under its regulation, however, and simply create an administrative procedure requiring the Agency to justify the alert with stated health and safety reasons, publish both the alert and the justification within a designated time-frame, and provide for public comment. Such a regulation would ensure that FDA would at least be forced to detail its rationale for banning certain drugs and to publish the comments of those challenging the propriety of the Agency's ban.

There will always be companies willing to export unapproved drug products to the United States for commercial gain regardless of the legality of their actions. FDA's challenge is to keep abreast of the increasing glut of commercial information available to American consumers, especially over the Internet, in order to protect them from unsafe products. The implementation of a rule governing the personal use exemption policy could serve to put these companies on notice that the FDA will not allow importation under the policy for commercial purposes.

Individual autonomy and self-determination are traditional American values. Nowhere are these rights more fundamental than in an individual's right to control his or her own body. Unless their actions will harm others, it is unconscionable to risk denying people without a future that hope which they can find.

¹⁴³ Personal Communication with Ron Mealy, *Carl Vogel Center* (Feb. 8, 1999).

¹⁴⁴ Personal Communication with Mark Niedzolkowsk, Editor, *The PWA Health Group Newsletter* (Feb. 2, 1999).

