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PUBLIC CITIZEN'S HEALTH RESEARCH GROUP'S STATEMENT BEFORE THE PHARMACY COMPOUNDING ADVISORY COMMITTEE

by

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The deceptively named Food and Drug Administration Modernization Act (FDAMA) of 1997 adds to the continuing perversion of what was once arguably the world's gold standard for consumer protection to a level reminiscent of the "snake oil" era of the late nineteenth century. The pharmacy compounding provision, along with numerous other aspects of FDAMA, has for the first time since the passage of the Pure Food and Drug Act of 1906 weakened, rather than strengthened, the laws intended to protect consumers. FDAMA, by codifying the FDA's once informal exemption of pharmacist compounded drugs from the requirements for safety and efficacy that manufacturers must provide, has created a dangerous double drug standard in the United States: (1) FDA approved drugs; and (2) drugs compounded by pharmacists.

Drug-induced tragedies compelled Congress in 1962 to amend the Food, Drug and Cosmetic Act (FDCA) to set strict requirements for prescription drug safety and efficacy based on rigorous science and final FDA review of the evidence. This was done for one reason: consumer protection. Contributing to the adoption of these amendments was the recognition of two facts: first, the inability of ordinary physicians using uncontrolled observations and anecdotes to differentiate safe and effective drugs from drugs that were ineffective or even dangerous; and second, that widespread use and acceptance of a drug was proof neither of safety nor efficacy.

The pharmacy compounding industry continues to use the same low standard of analyses used by physicians that led to the passage of the 1962 amendments to the FDCA - uncontrolled observation, and anecdote - as evidence. FDAMA does exempt compounding pharmacists from safety and efficacy standards, but Congress and compounding pharmacists cannot alter the fact that rigorous science is the only known method for providing valid evidence that drug products are safe and effective, and that these products will perform consistently.

Ralph Nader, Founder

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The assertion that compounded drugs fulfill compelling medical needs is an affront to the public's intelligence. There are no compelling medical needs for those compounded drugs that have not been shown to be safe and effective.

The FDA's role in the pharmacy compounding affair has been dismal. The Agency shrank from its legislatively mandated responsibility, consumer safety, in the early 1990s under pressure from the burgeoning compounding industry and pharmacy trade groups, best known for placing political dogma and self-interest before the public's health, and failed to regulate the proliferation of compounded drugs as unapproved new drugs. FDAMA now immunizes pharmacy compounding from FDA regulation and places the public's health in the hands of the state boards of pharmacy.

Public Citizen has no confidence that state boards of pharmacy have either the resources or the expertise to adequately protect the public's health from compounding pharmacists. It is appalling that we were able to fax prescriptions to a pharmacy in Virginia for cyclandelate (Cyclospasmol), a drug, whose marketing approval was revoked in the U.S. in 1997 for lack of efficacy; and for the popular third world "brain tonic", piracetam (Nootropil), a drug that is not approved in the U.S. We were informed that our prescriptions will be sent to us by Federal Express later this week.

Equally appalling was a telephone call we made to a compounding pharmacy in Illinois inquiring about obtaining estradiol pellets for surgical implantation. To the best of our knowledge, numerous New Drug Applications have been submitted and resubmitted for estradiol pellets, none of which the FDA approved presumably for lack of proof of safety and efficacy. The friendly compounding pharmacist told us he makes estradiol pellets "every day" and can "ship them anywhere."

It is clear from the above examples that if the profession of pharmacy and state boards of pharmacy took their societal covenants seriously to protect consumers from derelict practitioners it would not have been possible for Public Citizen to obtain drugs that are unapproved or have been disapproved in the U.S.

Both cyclandelate and piracetam are nominees from the International Academy of Compounding Pharmacists for inclusion on the list of unapproved bulk drug substances that can be used in compounding. Reviewing this list has been chilling, and Public Citizen looks forward with curiosity to what possible kind of evidence that compounding pharmacists will present to support legitimate medical needs for these chemicals. Judging from a number of these nominated chemicals that stimulate, or are precursors to acetylcholine, a "compelling" medical need has been created for brain tonics. There is no justification for placing the public needlessly at risk by allowing the use of any unapproved drug substances in pharmacy compounding.

The FDA must consider, in developing the list of drugs that present demonstrable difficulties for compounding, that a drug is not a bulk chemical, but a final finished dosage form, and that a number of dosage forms are too technologically complicated to be made safely in unregulated facilities not adhering to good manufacturing practice guidelines. These dosage forms include, but should not be limited to:

- **Sterile Products** other than a final product that results from the manipulation of two or more sterile commercially available products according to their FDA approved labeling.

- **Inhalation Solutions** should be sterile and sterile inhalation solutions are available commercially. Sterile solutions cannot be safely made in unregulated facilities.

- **Prolonged, Sustained, or Delayed Release Dosage Forms** that perform consistently cannot be made safely by unregulated compounding pharmacies.

- **Reflavoring of Antibiotics** that according to their FDA approved labeling require reconstitution by a pharmacist at the time of dispensing must not be allowed. This practice may result in the inactivation of the antibiotic and children with infections not being treated.

- **Commercially Available Products** should not be allowed to be copied by compounding pharmacists. This places the public needlessly at risk and is nothing more than stealing.

Compounding pharmacists seeing their survival threatened, allegedly because of managed care and low reimbursements, are misusing their professional status to sell unapproved or disapproved drugs to an unwitting public. Few options are available to protect the public in the present pro-business anti-consumer environment other than providing the public with sufficient objective information to protect themselves from health care providers seeking their own economic survival. The National Roundtable on Health Care Quality, convened by the National Academy of Science's Institute of Medicine, offers the only solution to providing the public with objective information, regulation, when it said: "Regulation is the only mechanism we have to protect the public from egregiously poor providers."

Public Citizen urges that the FDA require in the Pharmacy Compounding regulations that an auxiliary label be attached to all compounded drugs saying:

THIS DRUG HAS NOT BEEN TESTED OR REVIEWED BY THE FOOD AND DRUG ADMINISTRATION FOR SAFETY AND EFFECTIVENESS AND HAS NOT BEEN PRODUCED IN A FACILITY MEETING GOOD MANUFACTURING PRACTICES GUIDELINES.

This simple factual statement will provide consumers with at least some objective information to make an informed decision about accepting or rejecting the risks from pharmacy compounded drugs. Surely, compounding pharmacists must agree with the public's right to objective information about their drugs in order to make informed decisions about their health.

In closing, Public Citizen has communicated to the FDA our concerns regarding consumer representation on the Pharmacy Compounding Advisory Committee. FDAMA requires that one member of this committee be a representative from a consumer organization, and this is not the case. We are concerned that the consumer perspective be adequately represented on this committee for two reasons: first, there is little public awareness that pharmacists can produce, in unregulated facilities, products that have not been shown to be safe and effective; and second, consumers are the only group whose safety is at risk from drugs that are produced and sold by pharmacists that have not been shown to be safe and effective and are produced in unregulated facilities. For these reasons, the FDA's compliance with this statutory requirement regarding the committee's membership is critical.

We hope that this situation can be resolved amicably before any future meetings of the Pharmacy Compounding Advisory Committee.