Testimony of

Richard Kingham
Covington & Burling LLP

before the
Subcommittee on Crime and Drugs
of the
Senate Judiciary Committee
at a
Hearing on Body Building Products and Hidden Steroids: Enforcement Barriers
September 29, 2009

My name is Richard Kingham. I am a partner in the law firm of Covington & Burling LLP. Since joining the firm in 1973, I have concentrated on regulation of foods, drugs, and related products, including controlled substances and dietary supplements. I have taught food and drug law at the University of Virginia School of Law, the Georgetown University Law Center, and universities in the United Kingdom and have served on committees of the Institute of Medicine of the National Academy of Sciences, the National Institutes of Health, and the World Health Organization.

Manufacturers of legitimate dietary supplements share the concerns of Congress and the public with the distribution of body-building products that contain anabolic steroids. The adverse effects of those products are well known, and these substances should not be available for general use. It is important to recognize, however, that the vast majority of dietary supplements are in no way implicated. More than 150 million Americans regularly use legitimate dietary supplements, and those products offer significant health benefits to the people who use them.

There is, moreover, no need to amend existing legislation to deal with anabolic steroids. The Food and Drug Administration and the Drug Enforcement Administration both have ample authority to deal with the problem by making use of existing statutory powers.

Congress has twice amended the Controlled Substances Act to give DEA special power to regulate anabolic steroids. The most recent amendments, enacted in 2004, greatly expanded the list of substances subject to regulation under the statute, including metabolic precursors and salts, esters, and ethers of listed substances. Congress also authorized DEA to add new substances to the relevant schedule without proof of anabolic effect, thus simplifying the burden for administrative scheduling actions. Persons who traffic illegally in scheduled anabolic steroids are liable to severe criminal penalties and other enforcement measures under the Controlled Substances Act.

FDA also has broad powers to prevent distribution of products containing anabolic steroids under existing provisions of the Federal Food, Drug, and Cosmetic Act

(FDCA). Although many of the products currently promoted on the Internet are labeled as "dietary supplements," they are seldom, if ever, in compliance with the dietary supplement provisions of the law. FDA has multiple enforcement tools at its disposal to deal with those products, including provisions under the FDCA relating both to drugs and dietary supplements. Many products, for example, are advertised with claims that fall within the "new drug" provisions of the FDCA, and are for this reason both misbranded and in violation of statutory provisions that require premarket approval of new drugs. Others contain "new dietary ingredients" for which required premarket notifications have not been made to FDA under the dietary supplement provisions of the FDCA. Those products are legally deemed adulterated and are liable to the full range of enforcement measures under the statute, including seizures, injunctions, and criminal prosecution of responsible persons.

The provisions of the FDCA governing premarket submissions for new drugs and new dietary ingredients do not require FDA to prove that a product is unsafe, but only that the required premarket procedures have not been followed. Thus, the burden of proof on the government is minimal, and experience suggests that courts are willing to interpret the provisions of the FDCA liberally to protect the public against unlawful products. For this reason, a warning from FDA, backed up with a credible threat to take formal enforcement action, is usually sufficient to achieve compliance. FDA has in fact issued a number of warning letters to companies that distribute products containing anabolic steroids, and it has the capacity to issue more warning letters and to take formal enforcement actions as needed to protect consumers against these products.

The FDCA also effectively addresses the problem of "designer drugs" that are formulated to circumvent the scheduling provisions of the Controlled Substances Act. Anabolic steroids that are not listed in the relevant schedule will typically be "new" within the meaning of the provisions of the FDCA that require prior approval of new drug applications or submission of new dietary ingredient notifications.

In addition, recent reports suggest that some of the products currently offered on body-building websites are not actually labeled as containing anabolic steroids, even though such substances are detected in laboratory assays. Those ingredients may in fact be surreptitiously added during the manufacturing process of ordinary, otherwise lawful dietary supplements. Such practices are clearly illegal under the FDCA, which prohibits the addition of deleterious substances, imposes requirements for good manufacturing practice that include detailed controls of the ingredients in dietary supplements, and requires label disclosure of ingredients. Quite simply, what's in the bottle must be on the label of a dietary supplement. As with the provisions of the law relating to new drugs and new dietary ingredients, these provisions can be enforced using the full range of sanctions under the FDCA, including seizures, injunctions, and criminal prosecutions.

For these reasons, there is no need to amend existing law to deal with the problem presented by anabolic steroids. FDA and DEA have ample authority under current law.

New statutory requirements for legitimate products could greatly increase the expense of bringing new dietary supplement products to consumers and impose unnecessary

administrative burdens on FDA. Body-building products constitute less than 10 percent of the market for dietary supplements in the United States, and the products that are the subject of this hearing are a tiny fraction of that market segment. It would be a mistake to alter the carefully crafted regulatory framework for all dietary supplements simply to deal with a small number of outlier products that can be effectively controlled under existing statutory provisions.

Richard Kingham
Covington & Burling LLP

1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(202) 662-5268

265 Strand
London WC2R 1BH
020-7067 2000

RKingham@cov.com

Employment

1973 - Present	Covington & Burling LLP, Washington, D.C. and London
1973 - 1981	Associate, Washington office
1981 - 1990	Partner, Washington office Coordinator, Food and Drug Practice Group (1981-1985)
1990 - 2000	Partner, London office
1996 - 2000	Managing Partner, London office
2001 - Present	Partner assigned to Washington and London offices Member of Firm Management Committee (2001-2005) Coordinator, Life Sciences Industry Group (2001-Present) Coordinator, Industry, Regulatory and Legislative Umbrella Group (2005-Present)
2003 - Present	Adjunct Professor, Georgetown University Law Center, Washington, D.C. (regulation of drugs, biologics and medical devices)
1998 - Present	Lecturer, Graduate Program in Pharmaceutical Medicine, Welsh School of Pharmacy, Cardiff University (drug safety regulation and U.S., UK and EU pharmaceutical law)
1977 - 1990	Lecturer, University of Virginia School of Law, Charlottesville, Virginia (seminars in administrative law and food and drug law)
1969 - 1970 & 1964 - 1968	Editorial assistant, *Washington Star*, Washington, D.C.
1968 - 1969	U.S. Army

Professional Qualifications

Member of the District of Columbia Bar and of the bar of the U.S. Supreme Court, the U.S. Courts of Appeals for the Fourth, Fifth, Sixth, Eighth and District of Columbia Circuits, the U.S. District Court for the District of Columbia and the District of Columbia Court of Appeals

Registered Foreign Lawyer in England and Wales

Activities

Current

Business Advisory Council, University of Virginia School of Law
Advisory Board, *Washington Drug Letter*
Member, American Bar Association, Drug Information Association, Food and Drug Law Institute, Food Law Group (UK), Brussels Pharma Law Group

Former

Workshop on Pandemic Influenza, Institute of Medicine, National Academy of Sciences (discussant)
Committee on Acceleration of Biowarfare Countermeasures, Institute of Medicine, National Academy of Sciences (committee member)
World Health Organization CIOMS working group on communication of drug safety information (adviser)
Advisory Board, BNA *World Pharmaceuticals Report*
Advisory Board, *CCH Food and Drug Law Reporter*
National Advisory Allergy and Infectious Diseases Council, National Institutes of Health (council member)
Committee on Issues and Priorities for New Vaccine Development, Institute of Medicine, National Academy of Sciences (committee member)
Committee on Vaccine Supply and Innovation, Institute of Medicine, National Academy of Sciences (adviser)
District of Columbia Department of Human Resources Committee on Alcoholism (committee member)

Professional Listings

Who's Who in American Law
Who's Who in America
Who's Who in the World
Debrett's People of Today
Best Lawyers in America
Washington, D.C., Superlawyers
Washingtonian Magazine annual list of best lawyers in Washington
Chambers Global 2009 (one of three lawyers listed worldwide in Band 1 for Life Sciences Regulatory/Compliance)
Chambers USA 2008 (only lawyer listed in Band 1 nationwide for Life Sciences Regulatory/Compliance, also listed in Band 1 for Healthcare: Pharmaceutical/Medical Products Regulatory in District of Columbia)
Chambers UK (Band 1 for Life Sciences Regulatory/Compliance in London)
Practical Law Company *Life Sciences Cross-Border Handbook* 2008/2009 (leading/highly recommended for Life Sciences Regulatory in U.S., UK and EU)

Education

Juris Doctor, 1973 — University of Virginia

Order of the Coif (top 10 percent of graduating class)
Articles Editor, *Virginia Law Review*
Law Council
Student assistant to Prof. Laurens Rhinelander
Summer associate, Davis Polk & Wardwell, New York
Summer intern, Virginia Governor's Council on the Environment

Bachelor of Arts, 1968 — George Washington University

Trustee Scholar

Richard Kingham is a partner in the law firm of Covington & Burling LLP. Since joining the firm in 1973, he has concentrated on regulation of foods, drugs, and related products, including dietary supplements and controlled substances. He has advised many of the trade associations of industries regulated by the Food and Drug Administration as well as numerous manufacturers of FDA-regulated products. He has taught food and drug law at the University of Virginia, Georgetown University and universities in the United Kingdom and has served on committees of the Institute of Medicine of the National Academy of Sciences, the National Institutes of Health and the World Health Organization.