



U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

June 3, 2010

The Honorable Patrick J. Leahy
Chairman
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Enclosed please find responses to questions for the record arising from the appearance of Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, before the Committee on September 29, 2009, at a hearing entitled "Body Building Products and Hidden Steroids: Enforcement Barriers." We hope that this information is of assistance to the Committee.

Please do not hesitate to call upon us if we may be of additional assistance. The Office of Management and Budget has advised us that there is no objection to submission of this letter from the perspective of the Administration's program.

Sincerely,

Ronald Weich
Assistant Attorney General

Enclosure

cc: The Honorable Jeff Sessions
Ranking Member

**Responses to Questions for the Record to Joseph Rannazzisi
Deputy Assistant Administrator, Office of Diversion Control
Drug Enforcement Administration
Arising from a Hearing Entitled “Body Building Products and Hidden Steroids:
Enforcement Barriers”
Before the United States Senate Committee on the Judiciary
September 29, 2009**

Questions from Senator Orrin Hatch

1.) What exactly do you need from Congress in order to function more efficiently under the law? How may we help you to keep these dangerous products off the market?

ANSWER:

The Controlled Substances Act (CSA) (Title 21 United States Code) does not contain a provision that would allow the Drug Enforcement Administration (DEA) to “emergency schedule” any of these substances causing the immediate removal of these products from the market. Instead, DEA must complete the Administrative Scheduling process before a substance can be placed in schedule III and ultimately be removed from the market. Currently, chemists are able to create new and potentially harmful substances faster than DEA can identify, test and schedule these substances. Therefore, the new substances will be on the market for a period of time potentially harming the general public. Once scheduled, companies simply abandon them for the next new designer steroid. Additionally, for DEA to schedule any new designer steroid substance, it must establish that the substance is both pharmacologically and chemically similar to testosterone. The challenges in meeting these two criteria can be done, but to do so under the current scientific means is a daunting task. The challenges in meeting this two-pronged hurdle are outlined below:

Challenges to Administrative Scheduling of Anabolic Steroids

In order to pursue the scheduling of an anabolic steroid, criteria must be met as provided by the 2004 Anabolic Steroid Control Act. The two-pronged approach requires that the prohormone or designer steroid be:

- (i) Chemically similar to testosterone; and
- (ii) Pharmacologically similar to testosterone, and not an estrogen, progestin, or corticosteroid, and not DHEA,

to be considered for placement in schedule III of the CSA. The collection of pharmacological information presents challenges that greatly influence the scheduling process from identification of the potential anabolic steroid to initiating the scheduling action. General hurdles to the collection of pharmacological effects similar to testosterone are highlighted below.

- identifying synthetic and pharmacological laboratories
- contracting these services
- conducting the synthetic and pharmacological investigations

First Criterion: Chemical similarity to testosterone

Once a new prohormone or designer steroid has been identified, a structural analysis is conducted to determine similarities to testosterone and other anabolic steroids. This structural evaluation compares the chemical structure of the new steroid to testosterone and other anabolic steroids reported in the scientific literature. Based on established structure activity relationships published in the scientific literature, substitution patterns provide detail as to general class designation (androgen, estrogen, progestin, or corticosteroid) and anticipated effect.

Second Criterion: Pharmacologically similar to testosterone

Due to a lack of information in the scientific literature routinely encountered regarding these new prohormones and designer steroids, DEA is required to initiate pharmacological studies to demonstrate a pharmacological effect similar to testosterone to propose placement in schedule III. To initiate pharmacological testing, the steroid must be synthesized. This process is contracted with the stipulation that the steroid is prepared in high purity and amounts sufficient for testing. Since these evaluations may result in a scheduling action, upon completing synthesis, an independent structural analysis is conducted (by DEA) to ensure study integrity and verify DEA is testing the exact substance to be controlled.

To collect information regarding activity, both the chemical synthesis and pharmacological evaluation are contracted, requiring a bid process for both deliverables.

Chemical Synthesis

A laboratory/organization with expertise in chemical synthesis of steroids must be identified and willing to synthesize the steroid. Some of the general challenges to delivery:

1. **Identification of synthesis laboratory.** The synthetic laboratory will have prior experience in the synthesis of steroids. Many labs are not willing to take on the synthesis due to a lack of experience and/or submit impractical proposals, cost, and time estimates. We have encountered situations where we could not identify a synthetic lab to provide the necessary steroid to put into testing.
2. **Issues critical to process and conducting the chemical synthesis.**
 - a. *Number of synthetic steps to steroid.* The synthetic route required to produce the desired steroid is variable and dependent on the chemical structure of the steroid. The number of synthetic steps and the complexity of those steps vary for each steroid, because no two structures are exactly the same.
 - b. *Reputable source.* A chemical synthesis laboratory must be reputable source, *i.e.* cannot be a gray market source supplying substances to illegitimate operations.
 - c. *Purity.* In addition to preparing the steroid, it must be prepared without impurities.
3. **Steroid delivered.** Steroid of high purity with analytical data is provided.
4. **Structural verification.** Independent verification of structure is required prior to pharmacological testing for study integrity.

Pharmacological Evaluation

A laboratory/organization with expertise in conducting the testing methods required to evaluate the steroid's effects relative to testosterone must be identified. *In vitro* and *in vivo* testing may be conducted by the same laboratory or by different. The amount of time is greatly increased by contracting each assay. Some laboratories possess the capability to conduct all assays while others, particularly academic laboratories, are often limited in their capabilities and can be expected to conduct only one assay.

1. **Identification of testing laboratory.**
2. **Bid Process and testing contracted.** Multiple laboratories may be required to provide all relevant information. The laboratory must have the expertise and availability to undertake the studies.
3. **Study Conduct.** Steroid is delivered to the laboratory for testing. Multiple tests are required to completely evaluate the steroid.
 - a. *In vitro* testing (receptor studies)
 - i. Androgen receptor assay
 - ii. Estrogen receptor assay, subtypes (ER α and ER β)
 - iii. Progestin receptor assay
 - iv. Glucocorticoid receptor assay
 - v. Translocation assay
 - b. *In vivo* testing (animal studies)
 - i. Ventral prostate assay (androgenic)
 - ii. Seminal vesicle assay (androgenic)
 - iii. Levator ani assay (anabolic)
4. **Interpretation of results.** Testosterone-like effects are evaluated based on the data.
5. **Report(s) generated.** Contract laboratory(s) are required to generate a report with testing results. These results may or may not support a scheduling action. May require further testing.

If the steroid meets the criteria for scheduling, a Notice of Proposed Rulemaking is drafted and published. Comments are reviewed and analyzed and if appropriate, a Final Rule is published notifying the public of the scheduling action.

2.) When is the Food and Drug Administration's (FDA) responsibility and when is it the DEA's responsibility to investigate products containing designer steroids or anabolic steroids? Are most of these products truly dietary supplements?

ANSWER:

DEA is responsible for enforcing all provisions of the CSA. The CSA currently lists 59 anabolic steroids as schedule III controlled substances. With a very small number of exemptions, anyone who manufactures, dispenses or distributes a controlled substance must be registered with the DEA to conduct such activities. Consequently, DEA has jurisdiction over the regulation and enforcement of such businesses or individuals. In addition, if a product that is marketed as a dietary supplement contains a substance that meets the statutory definition of an anabolic steroid but that substance is not yet listed as an anabolic steroid, DEA has regulatory authority to initiate rulemaking proceedings to administratively schedule the substance. Further, with respect to those substances that meet the definition of an anabolic

steroid but are not yet on the list of anabolic steroids, it is theoretically possible to obtain criminal conviction of a person who manufactures or distributes such substances. Thus, it is possible that a DEA investigation might provide the evidentiary basis for such a criminal prosecution. However, given the current provisions of the CSA relating to anabolic steroids, obtaining such a conviction can, in many cases, be extremely difficult if not impossible. While DEA defers to the FDA for a precise description of its authorities and responsibilities, it is our understanding that the following general considerations apply. The FDA has authority to investigate all aspects of products marketed as dietary supplements. As to whether or not these products are truly dietary supplements, Director Levy from the FDA described these products in the following manner, "A dietary supplement may not contain an article approved as a new drug or an article authorized for investigation as a new drug for which substantial clinical investigations have been instituted and made public, unless the article was first marketed as a dietary supplement or conventional food. If a product marketed as a dietary supplement is excluded from the dietary supplement category because it contains such an article, then a claim that the product is intended to affect the structure or function of the body causes the product to be a drug. Similarly, if a product marketed as a dietary supplement is not a dietary supplement because it contains no dietary ingredients, a claim that the product is intended to affect the structure or function of the body causes it to be a drug. Synthetic steroids are not dietary ingredients." So, many of the products that claim to be "anabolic" or that are marketed to promote muscle growth may contain "designer steroids" and are, in fact, drugs, created to circumvent the CSA and the Food, Drug and Cosmetic Act.

3.) On July 28th of this year, FDA warned consumers not to take certain body building products because they contained steroids or steroid-like substances. What was DEA's role in this investigation and announcement?

ANSWER:

Prior to the FDA's July 2009 warning regarding bodybuilding products marketed as containing steroids or steroid-like substances, DEA had identified three of the eight steroids named in the FDA warning for placement in schedule III of the CSA. A Notice of Proposed Rulemaking (NPRM), was published in the Federal Register in April 2008. In addition to naming these three steroids in the NPRM, information regarding anabolic effect collected from DEA-sponsored testing was presented as justification for placement in schedule III of the CSA. As of August 2007, 22 products had been identified containing one or more of the anabolic steroids named in the rule, boldione, desoxymethyltestosterone, and 19-nor-4,9(10)-androstadienedione. A similar Internet search was conducted to update the final rule, and in August 2008, 61 products were identified as containing one or more of these anabolic steroids. These products were generally found to be marketed with slight variations in their name. The final rule published on December 4, 2009, makes these three compounds schedule III controlled substances (effective date of January 4, 2010).

4.) I understand that there are three steroids in the final stages of the scheduling process. I imagine there are others in earlier stages. How often has DEA used the simplified administrative scheduling authority granted to it by the 2004 Anabolic Steroid Control Act?

ANSWER:

DEA is involved in an ongoing effort to identify and collect scientific information on purported anabolic steroids that are introduced as new bodybuilding products for their placement in schedule III of the CSA as an anabolic steroid. Data may be obtained from the scientific literature or from DEA-sponsored testing. An anabolic effect similar to that of testosterone is used as justification for placement

in schedule III of the CSA. Unfortunately, for the majority of these new steroids, very limited scientific information exists; therefore, DEA is required to support testing to evaluate the potential anabolic activity of these new steroids. As a matter of scientific integrity, DEA will not pursue placement in schedule III without sound scientific data to support the scheduling of these new steroids.

Since the passage of the 2004 Anabolic Steroid Control Act by Congress, DEA has initiated numerous studies to collect information on anabolic activity. The final rulemaking for three steroids identified in an April 2008 NPRM was published on December 4, 2009, with an effective date of January 4, 2010. Additionally, testing was completed in July 2009 on three additional steroids purported to be anabolic and marketed in numerous products. Two of the three were found to be equally, if not more, active than testosterone in animal models. DEA will propose their placement into schedule III of the CSA. One of the steroids was found to be weakly active and DEA concluded that the overall evidence does not support scheduling at this time. Consistent with the current statutory text, if DEA determines that a particular drug or other substance does not meet the criteria for being considered pharmacologically similar to testosterone, DEA will not pursue administrative scheduling of that drug or substance.

5.) Is it currently legal to manufacture and distribute controlled substances without a DEA registration? What are the penalties associated with such a violation?

ANSWER:

With only a few exceptions, all persons or businesses that manufacture and/or distribute a controlled substance must be registered with DEA. Any person who manufactures or distributes any controlled substance in a manner not authorized by the CSA – including those who manufacture and distribute without a DEA registration – violates 21 U.S.C. 841(a)(1). Other violations of the CSA may also apply depending on the facts of the specific case. As provided in 21 U.S.C. 841(b)(1)(E), a person convicted of violating 21 U.S.C. 841(a)(1) involving an anabolic steroid shall be sentenced to a term of imprisonment of not more than 10 years, a fine not to exceed the greater of that authorized in accordance with the provisions of Title 18, or \$500,000 if the defendant is an individual or \$2,500,000 if the defendant is other than an individual, or both. The Sentencing Guidelines typically play a significant role in the actual sentence imposed. As part of the sentencing process, aggravating or mitigating circumstances may also impact the actual term of the sentence or fine.

The difficulty that DEA is experiencing is that many new designer steroids are substances that are structurally similar to testosterone, but are not yet scheduled since they are new substances. In some instances these new substances are more potent than similar anabolic steroids that are controlled. As explained above in the answer to question 2, while it is theoretically possible to prove the elements of 21 U.S.C. 841(a)(1) with respect to a drug or other substance that meets the definition of an anabolic steroid but is not currently listed as such, obtaining such a conviction is, as a practical matter, often extremely difficult if not impossible. Consequently, with respect to such not-yet-listed anabolic steroids, those unscrupulous persons who knowingly and intentionally manufacture and distribute such substances typically can circumvent the registration requirement with impunity.

6.) *The impression you convey from your testimony is that those who manufacture steroid precursors are innovating and selling products faster than your administrative procedures can keep up, thus allowing products that should be illegal to remain on the market.*

It is my understanding that some in your agency have been considering proposals to deal with this situation. I would be supportive of measures to amend the 2004 Anabolic Steroid Control Act if it can be shown that the law is too burdensome for the agency to respond quickly to marketed substances which clearly should be illegal. To assist the Committee in its consideration of such measures, it would be helpful to have your views on the following questions:

--Since 2004, how many steroid precursor products which were not listed in the law have come to the agency's attention?

ANSWER:

DEA monitors the introduction of new products, bodybuilding discussion forums, and has routine communications with other federal and non-federal agencies to identify new potential anabolic steroids. DEA maintains a list of steroids of interest which currently identifies 21 steroids. Of these 21 steroids, three have been proposed for scheduling upon sponsoring pharmacological studies to collect information regarding testosterone-like effects (NPRM published in 2008), testing has been completed on five additional steroids, and two of the five will be proposed for placement in schedule III in an administrative scheduling action. The remaining steroids will continue to be monitored, to include the scientific literature for new information pertaining to their activity. Currently, 13 steroids are being maintained on a list of steroids of interest that require additional information. DEA routinely reviews the scientific literature for new investigational reports. Independent reports in the scientific literature for identified new agents is rare, therefore, DEA is required to sponsor testing. Thirteen steroids are under review to ascertain potential anabolic activity that is not available in the scientific literature.

--Will you list each product and tell the status of its administrative scheduling?

ANSWER:

A complete list of products containing these steroids would be nearly impossible as new products regularly enter the marketplace. Products are introduced, discontinued, and reintroduced under new names. For example, products purported to contain 19-nor-4,9(10)-androstadienedione, a steroid proposed for placement in schedule III, has been found in the following products: Tren-X, Tren Xtreme, Xtreme Tren, Halo-Tren, and many more. While some of these products have been discontinued, others are still marketed, even after the FDA Warning on bodybuilding products marketed as containing steroids or steroid-like substances.

Since the passage of 2004 Anabolic Steroid Control Act, the DEA has identified and monitored the introduction of new steroids into the supplement market. DEA has evaluated eight new steroids in cellular and animal studies for pharmacological effect similar to testosterone. Three of these steroids have been proposed for placement in schedule III. DEA recently identified and tested two steroids that will be proposed for placement in schedule III. DEA will continue to collect data on the other three steroids and thirteen additional steroids may undergo testing to evaluate pharmacological activity.

The thirteen steroids are as follows:

1. 4-Chloro-17 α -methyl-1,4-androstadiene-3 β ,17 β -diol
2. 4-Chloro-17 α -methyl-andro-4-ene-3,17-diol
3. 4-Androstene-3,11,17-trione
4. 6 α -Methyl-androst-4-ene-3,17-dione

5. Androst-4-ene-3,6,17-trione
6. 2 ϵ ,3 ϵ -Epithio-17 α -methyl-5 α -androstan-17 β -ol
7. 3 β -Hydroxy-5-androstene-7,17-dione (i.e., 7-oxo-dehydroepiandrosterone and 7-oxo-DHEA)
8. 17-Hydroxy-6 α -methyl-ethyletiocholan-3,20-diol
9. 13-Ethyl-3-methoxy-gona-2,5(10)-diene-17-one
10. 4-Chloro-11-keto-17 α -methyl-androst-4-ene-17-ol-3,11-dione
11. 17 α -Methyl-androstan-3-hydroxyimine-17-ol (17 α -methyl-etioallocholan-17 β -ol-3-hydroxyimine)
12. Androstan-3-ol-17-one
13. 17 α -Methyl-androst-1,4-diene-3,17 β -diol

On December 4, 2009, DEA published a final rule placing three steroids (boldione, desoxymethyltestosterone, and 19-nor-4,9(10)-androstadienedione) into schedule III of the CSA (effective date of January 4, 2010).

--Please list the factors, in as much detail as possible; which have contributed to the length of time it has taken to list each product?

ANSWER:

The process describing the administrative scheduling of anabolic steroids as provided by the 2004 anabolic steroid control appears below. Upon controlling the steroid, the corresponding product(s) purported to contain, and those found to contain the steroid but not reported on the label, will be controlled as schedule III products. Schedule III products have the following requirements.

Step-wise detail regarding the administrative scheduling process:

- 1) Multiple sources are utilized to identify the introduction and to monitor new prohormones and designer steroids.
- 2) The chemical structure of the new steroid is compared to testosterone and other known anabolic steroids.
- 3) Scientific literature is thoroughly reviewed for pharmacological information regarding the new steroid.
- 4) Since the majority of new substances found have never undergone scientific evaluation DEA must contract the synthesis of the new steroid.
- 5) The identity and purity of the synthesized steroid is verified by a second source.
- 6) Cell-based studies (*in vitro* analysis) are contracted and conducted.
- 7) Animal studies (*in vivo* analysis) are contracted and conducted.
- 8) Data from testing methodologies is analyzed to assess pharmacological effect similar to testosterone.
- 9) If found to be chemically and pharmacologically similar to testosterone, an administrative scheduling action is initiated.
- 10) Prior to publishing a Notice of Proposed Rulemaking in the *Federal Register*, the rule must be approved by DEA and DOJ. Also, if the rule is identified as significant by the Office of Management and Budget (OMB) under Executive Order 12866, then the rule must be reviewed by OMB prior to publication.
- 11) Public comment period follows publishing of the rule.
- 12) Comment(s) are evaluated and addressed in the final rulemaking.

13) Prior to publishing a final rule in the *Federal Register*, final rulemaking requires DEA and DOJ approval. Also, if the rule is identified as significant under Executive Order 12866, then the rule must be reviewed by OMB prior to publication.

14) Publishing of final rule places substance in schedule III as an anabolic steroid.

7.) I am aware that some in DEA have discussed the possibility of amending the law to allow you to use emergency scheduling authority in order to remove from the market products which are pharmacologically and clinically similar to steroids. If your current authority does not allow such emergency action, it seems a reasonable idea to pursue.

--Why does your current emergency scheduling authority not allow removal of such products from the market?

--What is the status of the proposal on emergency scheduling for steroid similars? When might we expect to see such a proposal from you?

--Will your agency pledge to work with members of the Committee to address any concerns we may have about such a proposal?

ANSWER:

DEA's "emergency scheduling" (or "temporary scheduling") authority to which this question refers is set forth in 21 U.S.C. 811(h). The United States Supreme Court has ruled that this provision of the CSA can only be utilized to control drugs or other substances that meet the criteria for inclusion in schedule I. *Touby v. United States*, 500 U.S. 160, 167 (1991). Because Congress placed all anabolic steroids in schedule III, DEA cannot utilize 21 U.S.C. 811(h) to temporarily schedule a recently emerged anabolic steroid – regardless of the extent of the hazard to the public safety the anabolic steroid may pose. The Department of Justice and the Administration must determine what an appropriate proposal would be to address the emergency scheduling of these substances. DEA is certainly willing to work with members of Congress to address this problem and provide any technical assistance needed in formulating legislation needed to provide DEA with the appropriate authority to emergency schedule these types of products pending any administrative scheduling action.

Questions for Michael Levy, FDA, and Joseph Rannazzisi, DEA, from Senator Orrin Hatch

1.) In a February 21, 2009 FDA Consumer Health Information notice, the FDA stated that since 2004, it has identified several products that claim to be dietary supplements for treating erectile dysfunction and enhancing sexual performance.

Some of these products were found to contain the active ingredient or a substance similar to the active ingredient in Viagra or Levitra. Both Viagra and Levitra were approved by the FDA, went through the premarket drug approval process and, today, may only be sold to consumers with a doctor's prescription.

However, this did not stop unscrupulous companies from marketing these products even though they were in clear violation of the Federal Food, Drug and Cosmetic Act. Similarly, products containing anabolic steroids that are marketed as dietary supplements are adulterated and misbranded. These anabolic steroid products are also in a clear violation of the law. Therefore, requiring the premarket approval of these products will not prevent unscrupulous companies from breaking the law. In my opinion, the better solution is to strengthen the enforcement activities of the FDA and DEA. Mr. Levy and Mr. Rannazzisi do you agree?

ANSWER:

I do not agree for several reasons. First, as a general matter, the fact that certain individuals are willing to engage in blatant violations of a law that is designed to protect the public health and safety does not mean that the law itself should not be modified. To the contrary, such a situation might point to the need to impose additional requirements under the law and/or stricter penalties for those who violate the law. Second, the “designer steroids” encountered on the market today are quite different than the Viagra or Levitra products described above. As I described in my testimony, unscrupulous marketers use existing laws to their advantage. They exploit the requirements under the FDCA to create and sell products that contain drugs similar to testosterone. These are new drugs that, in all likelihood, have never been adequately tested. Some of these new designer steroids are several times more potent than a steroid that is already controlled under the CSA. Products that contain new untested designer steroids have harmed and continue to harm the American public.

There are, however, similarities between the Viagra / Levitra products and the designer steroid products. As you stated above, despite the fact that unscrupulous companies are in “clear violation”, they did not stop marketing these products. Why? In some instances the “companies” that produced and sold the counterfeit Viagra / Levitra products resided outside the United States compounding enforcement efforts. Domestically, however, the answer is quite simple: the risk reward ratio. Under the current legal framework dishonest companies can reap enormous profits from the sale of these products with little or no risk. Even when law enforcement brings to bear all of the existing legal resources, these companies simply stop manufacturing the questionable product, reformulate and market another product. When prosecutions or civil penalties are sought, the outcome is generally minor in comparison to the profits generated from the sale of these dangerous products.

For law enforcement to make a difference it must be able to respond quickly to these newly developed products. When appropriate, DEA must have the ability to immediately restrict the sales of these products or remove them from the marketplace pending any administrative scheduling action. Otherwise these companies will be able to continue operating unabated, always staying one step ahead of any law enforcement action.

2.) In his testimony, Mr. Tygart talks about a product called Superdrol. I have done a little research on this product and am having trouble understanding why it wouldn't be taken off the market through the laws currently on the books? The advertisements I have seen make muscle-building claims and tout it as an anabolic steroid.

ANSWER:

The decision to remove a drug from the marketplace for violation of the FDCA can only be made by the Food and Drug Administration. The DEA does not have any legal authority to remove a dietary supplement from the market for violations of the FDCA.

3.) As I reviewed the testimony of both the DEA and the FDA, both agencies argued that it takes a great deal of time to build a case against a product in order to take it off the market. In other words, the way I interpreted your statements – you are both saying that you cannot just pull a product off the market. But isn't it true that for the vast majority, if not all of these products, they would require an NDI (new dietary

ingredient) notification to FDA? If they are marketing as supplement and haven't filed, FDA can take the product off the market because it is misbranded. If the company has filed an NDI, the FDA may still reject it, as the agency has in over half of all NDI notifications.

ANSWER:

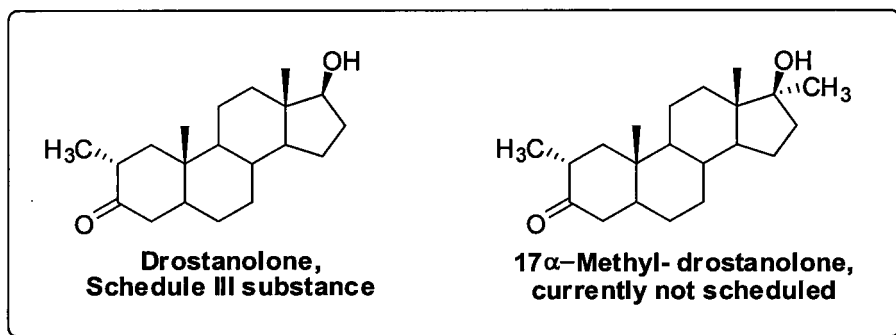
DEA has no authority to remove a product from the market because it contains an NDI. DEA is authorized by the CSA to take action against manufacturers of products that illegally contain controlled substances or that are structurally and pharmacologically similar to testosterone. If a substance, based upon scientific evidence, is found to be structurally and pharmacologically related to testosterone, DEA can utilize its administrative scheduling authority to place the drug in schedule III. However, since these substances are generally introduced into the marketplace with little, if any, scientific data, DEA must sponsor testing to determine pharmacologic similarities.

Questions from Senator Specter

1. Please provide the scheduling status of the anabolic steroid substance contained in the dietary supplement Superdrol and explain why DEA has not scheduled it as a controlled substance on Schedule III.

ANSWER:

The structure of 17 α -methyl-drostanolone (active ingredient in Superdrol) is almost identical to the anabolic steroid drostanolone which is named under the CSA. The two substances differ by the addition of a methyl group to drostanolone to give 17 α -methyl-drostanolone (*figure below*). This modification demonstrates the ingenuity of the chemist intent on circumventing the laws and these occurrences are routine. There are similar examples in the literature where slight structural modifications to anabolic steroids actually enhance the anabolic effect while others decrease it. Typically at the time of producing this potentially new anabolic agent, the chemist is only speculating as to the effect. In comes the unsuspecting user who becomes the guinea pig, providing data on the safety and efficacy of the new substance.



Due to a lack of scientific information related to 17 α -methyl-drostanolone, DEA initiated and sponsored scientific testing to collect pharmacologic data on this steroid. Studies were completed in July 2009 and the steroid was found to be as much as 4-fold more active than testosterone in animal studies.

With studies recently completed, DEA will initiate the administrative scheduling process for this substance. However, as your question suggests, the product Superdrol provides another illustration of the time-consuming hurdles that DEA faces under current law in attempting to schedule a recently emerged designer steroid – and how the unscrupulous individuals who develop and market these products are able to exploit this situation.

2. Please clarify what if any involvement DEA had with regard to the federal search warrant issued in the Bodybuilding .com investigation.

ANSWER:

For clarity, the federal search warrant discussed by Senator Specter during the hearing was not part of a DEA investigation. Nor was a DEA Special Agent the affiant with respect to the search warrant. Instead, this search warrant affidavit was part of a Food and Drug Administration investigation with an FDA Special Agent as the affiant. DEA defers to the FDA for any additional information regarding its investigation or specifics relative to the circumstances surrounding the issuance of the search warrant.

3. You testified DEA has not yet scheduled any new anabolic steroids since the passage of the Anabolic Steroid Control Act of 2004 but that it is close to completing the process to schedule three new anabolic steroids. Please identify those three products and describe how the scheduling process works for these and other similar type substances.

ANSWER:

DEA published a final rule in the Federal Register on December 4, 2009, placing boldione, desoxymethyltestosterone, and 19-nor-4,9(10)-androstadienedione in schedule III of the CSA (effective date of January 4, 2010). (A list of steps has been included as supplemental information to highlight the administrative scheduling process). Upon identification, DEA searched the scientific literature for pharmacologic data related to anabolic effect. Since no literature was found DEA was required to initiate scientific and pharmacological testing to support an administrative scheduling action.

The general steps to control a new steroid are detailed below:

- 1) Multiple sources are utilized to identify and monitor the introduction of new steroids.
- 2) The chemical structure of the new steroid is compared to testosterone and other known anabolic steroids
- 3) Scientific literature is thoroughly reviewed for pharmacological information regarding the new steroid.
- 4) The steroid must be synthesized. DEA must identify a contractor to synthesize the substance. The new steroid must be synthesized with high purity to ensure only the target steroid is being evaluated.
- 5) The identity and the purity of the synthesized steroid is verified by a second source
- 6) Cell-based studies are contracted and conducted
- 7) Animal studies are contracted and conducted
- 8) Both testing paradigms are essential to assessing pharmacological effect similar to testosterone.
- 9) If chemically and pharmacologically similar to testosterone, an administrative scheduling action is initiated.
- 10) Prior to publishing Notice of Proposed Rulemaking in Federal Register, the rule must be approved by DEA, DOJ, and OMB.
- 11). Comment period follows publishing of the rule.
- 12) Comment(s) are evaluated. Proceed with Final Rulemaking as determined from comment(s).

13) Final Rulemaking requires DEA, DOJ, and OMB approval prior to publishing in Federal Register.

4. *As was done in 2004, should Congress immediately amend Section 102 of the Controlled Substances Act to schedule those three new anabolic steroids referenced in question 3 above?*

ANSWER:

While DEA appreciates Congress's concern over these three substances, they were placed into schedule III of the CSA pursuant to the publication of the final rule which was made on December 4, 2009. Though DEA used its administrative scheduling authority to schedule these three substances, there are many more similar substances on the market. It has been DEA's experience that creative chemists simply modify the chemical structure of a substance and DEA must start the process all over. Even under ideal conditions, this process can typically take at least 18-24 months. More typically, the process takes far longer to complete. DEA willingly accepts its role in the rulemaking process and will continue to work to protect the public health and safety within the authority provided to DEA by Congress. At the same time, it is beyond question that when Congress deems it appropriate to legislatively add a substance to the list of anabolic steroids, there is no faster way to achieve the same result. Nonetheless, DEA believes that a complete solution to the problem requires more than merely chasing after each and every new designer steroid; a successful long-term solution would be more all-encompassing.